Standing on the shoulders of giants? A study of scientists’ engagement with patent information

Anna Louise Hescott

A thesis submitted in partial fulfilment of the requirements of Sheffield University for the Degree of Doctor of Philosophy

University of Sheffield

School of Law

April 2014

This thesis is dedicated to my family – my unwavering cheerleaders

Abstract

The patent system is regularly justified on a ‘social contract’ model. This is based, in part, on the concept that the system diffuses information which informs future innovation. The patenting of basic biological materials, particularly when ensuing from research undertaken in universities, is the subject of extensive debate. However, there has been limited study of the scientists involved and of the diffusion of information through the patent system. This thesis attempts to address this gap in knowledge by investigating the engagement of academic biological and stem cell scientists working in the United Kingdom (UK) with patent information. The context in which these scientists work is examined by tracing the multifactorial international and national drivers that have contributed to the increased patenting of biological research in universities. These include: funding conditions requiring the protection of intellectual property; funding models promoting public-private partnerships; guidelines for the management of intellectual property in universities; and the expansion of patentable subject matter to include basic biological materials. The empirical study investigates the extent to which scientific knowledge is diffused through the patent system in the case of biological and stem cell science in the UK. These fields have been pinpointed as ‘great hopes’ for the future both in terms of therapeutic applications and economic return. The results of an empirical study (a survey of 120 academic biological scientists together with interviews with, and structured observations of, 16 stem cell scientists) indicate that the diffusion of scientific information through the patent system is limited. A number of barriers are identified including scientists’ limited awareness of patents; patchy knowledge of the mechanics of the patent system; problems inherent in patent databases; and scientists’ perceptions of patent information. Viewed within the context provided, these findings lead to a number of assumptions central to science- and patent-policy to be questioned, particularly that the patent system disseminates information which ‘teaches’ downstream innovators.

Acknowledgements

I begin by thanking the participants in my study, many of whom remain anonymous to me so cannot be thanked personally.  I am grateful for their willingness to share their time and experiences with me and hope to have done them justice.

I am indebted to my supervisors, Professor Aurora Plomer and Professor David Hornby, for their belief both in this project and in myself. David’s knowledge, insight and experience of the context of which I write have been invaluable, particularly in the early stages of the research. Aurora’s passion for understanding the complex has driven me to think outside the box and her enthusiasm for research inspires me. I am particularly thankful for her ability to understand what I mean before I fully do and for guiding me to understand too. I am grateful to them both for their encouragement and interest, especially when I have struggled to untangle my muddled thoughts and put them on a page. I hope this thesis reflects their efforts as well as my own.

Thank you to all of those involved in supporting my progress in the School of Law, particularly Sarah for her kindness and seemingly eternal willingness to help, Mark and Matthew for their constructive comments and all others who have helped along the way. I would also like to take this opportunity to acknowledge my biology Professor’s, Neil Hunter and David Rice, to whom I am grateful for instilling in me their passion for science and desire for knowledge. Recognition is also due to the University of Sheffield and the School of Law for providing funding for this project from the beginning and to the Modern Law Review for the scholarship which helped me through to the end.

This thesis benefitted greatly from some ‘real life’ experience of the patent system. I am grateful for the summer school at the WIPO Academy which opened my eyes to the vast world of IP and to the EPO Academy for hosting me as an intern. I thank all of my colleagues at the EPO, particularly Anna, Christos, Dianna, Justin and Nigel, for versing me in joys of working in an international office. During my time in Munich I had an excellent academic home thanks to the Max Planck IIC and its incredible library where I was able to discuss IP with my old friends Martin and Alina; I look forward to watching where your IP obsessions take you both.

Without the friends I have made in the PGR room, this experience would have been a far lonelier one. I am especially grateful to Baxter for her sunny disposition, Carlos for ALWAYS smiling, Jen for her warmth, Sara for sharing my love of tea and gossip and Scarlett for never failing to make me giggle. In the last few months, I have been particularly thankful for the boundless support from Ali, Claudia and Keir – your stints as my library buddies/listeners/deliverers of tea and dinner will not be forgotten … repayments are available in kind. I am also thankful for the company and compassion of all of my other PGR colleagues, past and present. For all the non-work friends that have stuck by me despite my inability to talk about anything other than my thesis for the last few months (at least) … thank you! Special thanks to Alice, Amy, Claire, Claudia, Emma, Julie, Lizzie and Vicky for keeping me connected to the outside world and providing ‘carrots’ to get me to the end – you are all truly wonderful. Thanks also to the Belgians, Graces, Knights, Claire, Jen, Heather, Dannev, the medics, the OB girls and my friends from home for providing a variety of tempting opportunities to take time out … I promise to start saying yes more often.

To my darling Matthew – who forms part of my past and is the centre of our future – your work ethic and passion for your subject are breathtaking and have helped me to cling on to my own. I am grateful for your knowledge of this process, your interest in my work and your ever-insightful advice. Of far greater importance, I am thankful to you for holding our home together, for your forbearance, for your ability to always make me smile and for your constant belief in me when I have struggled to believe in myself.

Without the support of my family, well, I wouldn’t be writing acknowledgements – there would be no thesis. My sister who continually inspires me to ‘keep at it’ which, together with her constant support, has pushed me through the tough times … I think we deserve that holiday now! My Grandpa, Potato Bob, has helped both this thesis and I in so many ways.  His belief in lifelong learning is inspirational, and without his critical eye and thought-provoking suggestions ‘from the sidelines’ this thesis would be far less polished. Thank you for your time, patience and interest. My Grandmothers are simply wonderful and provide solid foundations for the rest of us. Thank you both for your unconditional love and warmth … and to Grandma Margaret for the home-cooked meals filled with both.  Thank you also to my Uncle Ken and the Meredith clan for providing much needed support of various kinds throughout my studies. I am extremely grateful to the Connollys, Bacons and Jacksons for providing me with welcoming homes away from home. Daniel, Samuel and Thomas, it has been such a pleasure watching you grow up over the last 9 years – I’m glad to have stayed in Sheffield so long if only for that.

Above all, I am grateful to my parents. Without their continual support, belief and encouragement during the dark days, their willingness to proof read at short notice and the insurance that ends met, I would never have made it this far. I am indebted to the resolve (Mum) and methodical approach (Dad) which they have instilled in me; a combination which has proved invaluable throughout this experience. I cannot explain all of the ways in which they have helped me so I simply thank them both, for everything.

Of course, any errors or omissions remain my own.

**Table of contents**

[Abstract i](#_Toc386403408)

[Acknowledgements ii](#_Toc386403409)

[Table of contents iv](#_Toc386403410)

[Table of legislation and guidelines x](#_Toc386403411)

[Table of cases xiv](#_Toc386403412)

[List of figures and tables xv](#_Toc386403413)

[List of abbreviations xviii](#_Toc386403414)

[Chapter](#_Toc386403415) 1

[The engagement of academic biological and stem cell scientists with the patent system and patent information: an introduction](#_Toc386403416)

[1.1 Introduction 1](#_Toc386403417)

[1.2 Why patents and patent information? 3](#_Toc386403418)

[1.3 Why biological and stem cell science? 7](#_Toc386403419)

[1.4 Why universities? 13](#_Toc386403420)

[1.5 Why the UK? 15](#_Toc386403421)

[1.6 The research questions, methodological approach and scope of the thesis 16](#_Toc386403422)

[1.7 Original contribution 20](#_Toc386403423)

[1.8 The Thesis Roadmap 21](#_Toc386403424)

[Chapter 2](#_Toc386403429)

[Science funding and science policies: an international historical context](#_Toc386403430)

[2.1 Introduction 25](#_Toc386403431)

[2.2 A history of science funding and science policy in the US 26](#_Toc386403432)

[2.2.1 The beginnings of university patenting in the US 27](#_Toc386403433)

[2.2.2 The effect of WWII on the role of US universities 27](#_Toc386403434)

[2.2.3 The Bayh-Dole Act (1980) 29](#_Toc386403435)

[2.2.4 Additional factors in the 1980s and 1990s contributing to the growth in university patenting in the US 30](#_Toc386403436)

[2.2.5 Perceptions of the ‘post- Bayh-Dole’ period 31](#_Toc386403437)

[2.2.6 US Conclusions 33](#_Toc386403438)

[2.3 A history of science funding and science policy in the EU 34](#_Toc386403439)

[2.3.1 EU treaties relating to science and technology 34](#_Toc386403440)

[2.3.2 The Framework Programmes 36](#_Toc386403441)

[2.3.3 The early framework programmes: funding of agriculture and high technology 37](#_Toc386403442)

[2.3.4 Expanding funding to other areas of R&D: the Fourth and Fifth Framework Programmes 38](#_Toc386403443)

[2.3.5 The knowledge based economy, basic research and the European Research Area 39](#_Toc386403444)

[2.3.6 Controversy over the funding of stem cell research in the Sixth Framework Programme 40](#_Toc386403445)

[2.3.7 Supporting basic research and public-private partnerships: the Sixth and Seventh Framework Programmes and the European Research Council 42](#_Toc386403446)

[2.3.8 Europe 2020 and the Innovation Union 45](#_Toc386403447)

[2.3.9 Horizon 2020 46](#_Toc386403448)

[2.3.10 IP management under the Framework Programmes 48](#_Toc386403449)

[2.3.11 EU conclusions 49](#_Toc386403450)

[2.4 Conclusions 50](#_Toc386403451)

[Chapter 3](#_Toc386403452)

[Science funding and science policies: the UK historical context](#_Toc386403453)

[3.1 Introduction 51](#_Toc386403454)

[3.1.1 The Haldane Report (1918) 52](#_Toc386403455)

[3.2 British research policy following WWII – capturing the results of R&D 53](#_Toc386403456)

[3.2.1 The National Research Development Corporation 53](#_Toc386403457)

[3.2.2 The Science and Technology Act (1965) 54](#_Toc386403458)

[3.2.3 The Rothschild Report (1971): a turning point for science funding 55](#_Toc386403459)

[3.3 The 1980s – University ownership of IP, systematic assessment of research and the dawn of university spin-out companies 57](#_Toc386403460)

[3.3.1 The British Technology Group 58](#_Toc386403461)

[3.4 The 1990s – improving economic competitiveness 60](#_Toc386403462)

[3.4.1 A new Office and a Science Cabinet Minister 60](#_Toc386403463)

[3.4.2 Realising Our Potential (1993) 60](#_Toc386403464)

[3.4.3 ‘Competitiveness’, the Higher Education Innovation Fund (HEIF) and the Public Sector Research Exploitation Fund (PSREF) 61](#_Toc386403465)

[3.5 The 2000s – uniting innovation, business, science and education policy within the structure of government 64](#_Toc386403466)

[3.5.1 The Lambert Review (2003) 64](#_Toc386403467)

[3.5.2 The Science and Innovation Framework 2004-2014 65](#_Toc386403468)

[3.5.3 The Warry Report (2006) 66](#_Toc386403469)

[3.5.4 The Sainsbury Review and Innovation Nation (2007) 68](#_Toc386403470)

[3.5.5 Restructuring government departments (2007-2009) – the creation of BIS 69](#_Toc386403471)

[3.5.6 The Wellings Report (2008) 70](#_Toc386403472)

[3.5.7 Intellectual asset management for universities (2011) 71](#_Toc386403473)

[3.5.8 Strategy for UK Life Sciences and the Innovation and Research Strategy for Growth (2011) 72](#_Toc386403474)

[3.5.9 The Wilson Review (2012) 73](#_Toc386403475)

[3.5.10 The Witty Review (2013) 75](#_Toc386403476)

[3.6 Shaping research through quality assessment 76](#_Toc386403477)

[3.6.1 The Research Selectivity Exercise (1986) 77](#_Toc386403478)

[3.6.2 The Research Excellence Framework (2014) 78](#_Toc386403479)

[3.7 Conclusions 79](#_Toc386403480)

[Chapter 4](#_Toc386403481)

[Funding of stem cell science research in the UK](#_Toc386403482)

[4.1 Introduction 81](#_Toc386403483)

[4.2 Recent national stem cell research policy 81](#_Toc386403484)

[4.2.1 The UK Stem Cell Initiative (2005) 82](#_Toc386403485)

[4.2.2 Technology and Innovation Futures (2010) 84](#_Toc386403486)

[4.2.3 Taking Stock of Regenerative Medicine (2011) 85](#_Toc386403487)

[4.2.4 Strategy for UK Life Sciences (2011) 86](#_Toc386403488)

[4.2.5 Strategy for UK Regenerative Medicine (2012) 86](#_Toc386403489)

[4.2.6 The House of Lords Regenerative Medicine Report and Parliamentary Office of Science and Technology Report on Stem Cell Research (2013) 87](#_Toc386403490)

[4.3 Major funders of stem cell research in the UK and their IP Policies 94](#_Toc386403491)

[4.3.1 Funding through the EU FPs 95](#_Toc386403492)

[4.3.2 UK public funding 96](#_Toc386403493)

[4.3.3 Third sector and private not-for-profit funding 98](#_Toc386403494)

[4.3.4 Private for profit funding 100](#_Toc386403495)

[4.4 Concerns surrounding the increased commercialisation of university research 101](#_Toc386403496)

[4.4.1 The ways in which patents may affect the institution of academic science 103](#_Toc386403497)

[4.4.2 Patents and the traditional norms of science 104](#_Toc386403498)

[4.4.3 Openness tensions 106](#_Toc386403499)

[4.4.4 Changing expectations of academic researchers 110](#_Toc386403500)

[4.4.5 Metrics, ‘impact’ and collaboration 111](#_Toc386403501)

[4.5 Conclusions 113](#_Toc386403502)

[Chapter 5](#_Toc386403503)

[Patent policy and the extension of patentable subject matter](#_Toc386403504)

[5.1 Introduction 115](#_Toc386403505)

[5.2 Modern patent rights 115](#_Toc386403506)

[5.2.1 When can a patent be granted? 116](#_Toc386403507)

[5.3 The rationale of the patent system today 118](#_Toc386403508)

[5.3.1 ‘Social contract’ and the patent system 120](#_Toc386403509)

[5.3.2 Disclosure and diffusion of patent information 122](#_Toc386403510)

[5.4 The expansion of patentable subject matter to basic biological materials 123](#_Toc386403511)

[5.4.1 Patenting ‘life’: Diamond v Chakrabarty 123](#_Toc386403512)

[5.4.2 Gene patents and the Myriad case 124](#_Toc386403513)

[5.4.3 Embryonic stem cell patents in the US and Europe 129](#_Toc386403514)

[5.5 The systematics of the patent system: from ‘bricks-and-mortar’ to intangible inventions 135](#_Toc386403515)

[5.5.1 Patent quality and the external ‘expert’ review of patent examination 137](#_Toc386403516)

[5.5.2 The informing role of patent information and the patent information infrastructure 140](#_Toc386403517)

[5.5.3 Publication and dissemination of patent data 141](#_Toc386403518)

[5.5.4 Stem cell scientists’ patent awareness 142](#_Toc386403519)

[5.6 Conclusions 143](#_Toc386403520)

[Chapter 6](#_Toc386403521)

[Empirical research methodology](#_Toc386403522)

[6.1 Introduction 145](#_Toc386403523)

[6.2 Mixed methods research 146](#_Toc386403524)

[6.2.1 The advantages and disadvantages of mixed methods research 148](#_Toc386403525)

[6.2.2 The mixed method model 149](#_Toc386403526)

[6.2.3 Sampling in mixed methods research 153](#_Toc386403527)

[6.2.4 Accessing and recruiting participants 156](#_Toc386403528)

[6.3 The survey 156](#_Toc386403529)

[6.3.1 The self-completion questionnaire 157](#_Toc386403530)

[6.3.2 Response rates 157](#_Toc386403531)

[6.3.3 Questionnaire design 159](#_Toc386403532)

[6.3.4 Analysis 160](#_Toc386403533)

[6.4 The interviews and structured observations 161](#_Toc386403534)

[6.4.1 The interviews 161](#_Toc386403535)

[6.4.2 Semi-structured interviewing 162](#_Toc386403536)

[6.4.3 Interview data analysis 163](#_Toc386403537)

[6.4.4 The structured observation – searching for papers and patents 165](#_Toc386403538)

[6.4.5 Reliability in structured observation 166](#_Toc386403539)

[6.4.6 Validity and structured observation 167](#_Toc386403540)

[6.4.7 The design of the structured observation 168](#_Toc386403541)

[6.4.8 Analysis of the structured observation data 170](#_Toc386403542)

[6.5 Research training and ethics 170](#_Toc386403543)

[6.5.1 Protection from harm 171](#_Toc386403544)

[6.5.2 Privacy 171](#_Toc386403545)

[6.5.3 Informed consent/avoidance of deception 172](#_Toc386403546)

[6.6 Conclusions 173](#_Toc386403547)

[Chapter 7](#_Toc386403548)

[Survey results](#_Toc386403549)

[7.1 Introduction 175](#_Toc386403550)

[7.1.1 Sample characteristics 176](#_Toc386403551)

[7.1.2 Hypotheses 176](#_Toc386403552)

[7.2 Engagement with patent information and the patent information infrastructure 177](#_Toc386403553)

[7.2.1 Have you seen a patent document? 178](#_Toc386403554)

[7.2.2 Have you ever been part of a patent application? 179](#_Toc386403555)

[7.2.3 Do patents exist in your field of research? 180](#_Toc386403556)

[7.2.4 Do you work with patented materials (other than standard laboratory equipment)? 181](#_Toc386403557)

[7.2.5 Use of Patent Databases 182](#_Toc386403558)

[7.2.6 Experiences of using patent databases 184](#_Toc386403559)

[7.3 Patent knowledge 184](#_Toc386403560)

[7.3.1 First-to-file system 185](#_Toc386403561)

[7.3.2 The difference between patent applications and granted patents 186](#_Toc386403562)

[7.3.3 Third party observations 187](#_Toc386403563)

[7.3.4 Research exemption 188](#_Toc386403564)

[7.4 Scientific cultures and perceptions of patent information 189](#_Toc386403565)

[7.4.1 The scientific value of patent information 189](#_Toc386403566)

[7.4.2 Additional comments from participants 190](#_Toc386403567)

[7.5 Analysis of the survey results 191](#_Toc386403568)

[7.5.1 Scientists’ engagement with patent information 191](#_Toc386403569)

[7.5.2 Technical patent knowledge 194](#_Toc386403570)

[7.5.3 Scientific cultures and perceptions of patent information 196](#_Toc386403571)

[7.6 Conclusions 197](#_Toc386403572)

[Chapter 8](#_Toc386403573)

[Findings of the interviews and structured observations](#_Toc386403574)

[8.1 Introduction 199](#_Toc386403575)

[8.1.1 Sample characteristics and hypotheses 199](#_Toc386403576)

[8.2 Engagement with patent information and the patent information infrastructure 200](#_Toc386403577)

[8.2.1 Do patents exist in your field of research? 200](#_Toc386403578)

[8.2.2 Have you ever seen a patent document? 202](#_Toc386403579)

[8.2.3 Have you seen a patent document other than your own? 203](#_Toc386403580)

[8.2.4 UKNSCN patent digests 204](#_Toc386403581)

[8.2.5 Do you work with patented materials? 207](#_Toc386403582)

[8.2.6 Levels of patent database use 208](#_Toc386403583)

[8.2.7 The search task 209](#_Toc386403584)

[8.2.8 Experiences of patent databases 211](#_Toc386403585)

[8.2.9 Search strategies, keywords and the titles of patent documents 213](#_Toc386403586)

[8.2.10 The language and structure of patent information 216](#_Toc386403587)

[8.2.11 The sufficiency of disclosure 217](#_Toc386403588)

[8.3 Patent knowledge 219](#_Toc386403589)

[8.3.1 The patentability requirements 219](#_Toc386403590)

[8.3.2 The difference between A and B specification patent documents 220](#_Toc386403591)

[8.3.3 The territoriality of patents 221](#_Toc386403592)

[8.3.4 Third party observations 222](#_Toc386403593)

[8.3.5 Have you received ever any training about patents? 223](#_Toc386403594)

[8.4 Scientific cultures and perceptions of patent information 226](#_Toc386403595)

[8.4.1 The ‘scientific’ value of patent information 226](#_Toc386403596)

[8.4.2 The perception that patents delay traditional dissemination of knowledge and limit openness 227](#_Toc386403597)

[8.4.3 Concerns about patenting basic and publicly funded science 232](#_Toc386403598)

[8.4.4 The perception that patents are used for things other than information source 234](#_Toc386403599)

[8.4.5 Scientists’ ‘buffer’ their engagement with patents 235](#_Toc386403600)

[8.5 Conclusions 236](#_Toc386403601)

[Chapter 9](#_Toc386403602)

[Discussion](#_Toc386403603)

[9.1 Introduction 239](#_Toc386403604)

[9.2 Implications for the patent system 240](#_Toc386403605)

[9.2.1 Assumptions of the patent system 241](#_Toc386403606)

[9.2.2 Is the patent system informing downstream innovation? 241](#_Toc386403607)

[9.2.3 Is the patent system granting patents for inventions that advance the state of the art? 243](#_Toc386403608)

[9.2.4 Are scientists able to contribute to the system as inventors? 245](#_Toc386403609)

[9.2.5 On-going questions of the patent system 245](#_Toc386403610)

[9.3 Implications for science policy 247](#_Toc386403611)

[9.3.1 Science policy assumptions 247](#_Toc386403612)

[9.3.2 Are patents being applied for when they can be? 247](#_Toc386403613)

[9.3.3 Is duplicative science being undertaken? 248](#_Toc386403614)

[9.3.4 Are scientists infringing on patents? 249](#_Toc386403615)

[9.3.5 Is the increasing patenting of university-based research having undesired consequences on the practice of academic science? 249](#_Toc386403616)

[9.3.6 Perceptions of changes driven by increased focus on patenting university research 250](#_Toc386403617)

[9.3.7 Concerns about anticommons effects 252](#_Toc386403618)

[9.3.8 Are increased patents over university science driving a closure of the scientific domain? 252](#_Toc386403619)

[9.3.9 Are science- and patent- policies driving information feudalism? 253](#_Toc386403620)

[9.3.10 Emerging science policy questions 254](#_Toc386403621)

[9.4 Ways of improving the dissemination of scientific knowledge through the patent system 255](#_Toc386403622)

[9.4.1 Rebalancing power in the patent system to support the social contract 256](#_Toc386403623)

[9.4.2 Improving patent education 257](#_Toc386403624)

[9.4.3 Strengthening disclosure 259](#_Toc386403625)

[9.4.4 Reduce patent information complexities 263](#_Toc386403626)

[9.4.5 Reducing gaming of the system 268](#_Toc386403627)

[9.4.6 Improving the dissemination of technical information in patent documents 271](#_Toc386403628)

[9.5 Conclusion 277](#_Toc386403629)

[Chapter 10](#_Toc386403630)

[Conclusions](#_Toc386403631)

[10.1 Answering the research questions 279](#_Toc386403632)

[10.2 Limitations of the study and recommendations for future research 282](#_Toc386403633)

[10.3 Concluding thoughts 283](#_Toc386403634)

[Appendix 1: The surveys 287](#_Toc386403635)

[Appendix 2: Designing the questions 294](#_Toc386403636)

[Appendix 3: Tables and figures 299](#_Toc386403637)

[Appendix 4: Additional comments from the surveys 313](#_Toc386403638)

[Appendix 5: Interview schedule 315](#_Toc386403639)

[Appendix 6: The observation schedule 317](#_Toc386403640)

[Appendix 7: Consent for interviews and tasks 319](#_Toc386403641)

[Appendix 8: Tables of observations 320](#_Toc386403642)

[Bibliography 328](#_Toc386403643)

Table of legislation and guidelines

#### European Community/Union documents

Council Decision 90/221/Euratom, EEC of 23 April 1990 concerning the framework programme of Community activities in the field of research and technological development (1990 to 1994) [1990] OJ L117

Council Decision 87/516/Euratom, EEC of 28 September 1987 concerning the framework programme for Community activities in the field of research and technological development (1987 to 1991) [1987] OJ L302

Council Decision of the European Communities of 1 January 1973 adjusting the documents concerning the accession of the new Member States to the European Communities [1973] OJ L2/1

Council Resolution 4/8/83 of 25 July 1983 on framework programmes for Community research, development and demonstration activities and a first framework programme 1984 to 1987 [1983] OJ C208/26/1

Decision No 182/199/EC of the European Parliament and of the Council of 22 December 1998 concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002) [1999] OJ L26

Decision No 1110/94/EC of the European Parliament and of the Council of 26 April 1994 concerning the fourth framework programme of the European Community activities in the field of research and technological development and demonstration (1994 to 1998) [1994] OJ L126

Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) [2002] OJ L232

Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013) [2006] OJ L310/15

Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities [2006] OJ L412

Directive 94/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (1998)

European Commission (2004) Work programme for the specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area' Priority 1: Life Sciences, Genomics and Biotechnology for Health. Commission Decision C(2004)2002

European Commission (2011) Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) COM(2011) 809

European Commission Communication (2000) 'Towards a European research area' COM(2000) 6

European Commission Communication (2004) 'Europe and Basic Research' COM(2004) 9

European Commission Communication (2008) 'A European Economic Recovery Plan' COM(2008) 800

European Commission Communication (2009) 'On the progress made under the Seventh European Framework Programme for Research' COM(2009) 209

European Commission Communication (2010) 'EUROPE 2020 A strategy for smart, sustainable and inclusive growth' COM(2010) 2020

European Commission Communication (2011) 'Horizon 2020 – The Framework Programme for Research and Innovation' COM(2011) 808

European Commission Communication (2012) 'A Reinforced European Research Area Partnership for Excellence and Growth' COM(2012) 392

European Commission Decision (2008) 2008/37/EC of 14 December 2007 setting up the ‘European Research Council Executive Agency’ for the management of the specific Community programme ‘Ideas’ in the field of frontier research in application of Council Regulation (EC) No 58/2003 OJ L9/15

European Commission Recomendation (2008) on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations C(2008)1329

European Council (2000) Presidency Conclusions, Lisbon European Council, 23-24 March 2000 (No. 100/1/00)

European Council (2002) Council Decision 2002/834/EC adopting a specific programme for research, technological development and demonstration. 'Integrating and strengthening the European Research Area' (2002-06) OJ L294

European Council (2002) Presidency Conclusions, Barcelona European Council, 15 and 16 March 2002 (SN 100/1/02 REV 1)

European Council (2003) Presidency Conclusions, Brussels European Council, 20 and 21 March 2003 (8410/03 Polgen 29)

European Council Regulation (EC) (2008) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines OJ L30/38

European Parliament Resolution Investing in research: an action plan for Europe COM(2003) 226 – 2003/2148(INI)

Regulation (EC) 294/2008 of the European Parliament and of the Council of 11 March 2008 establishing the European Institute of Innovation and Technology [2008] OJ L97/1

Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC

Single European Act [signed 1986, entered into force 1987] OJ 169

Treaty establishing the European Atomic Energy Community [signed 1957, entered into force 1958]

Treaty establishing the European Coal and Steel Community [signed 1951, entered into force 1952, expired 23 July 2002]

Treaty establishing the European Economic Community [signed 1957, entered into force 1958]

Treaty on the European Union [signed 1992, entered into force 1993] OJ C 191

Treaty on the Functioning of the European Union [signed 2007, entered into force 2009] OJ C306

#### International

Convention on the Grant of European Patents, signed in Munich, Germany, 5 October 1973 as amended (14th Edition, August 2010)

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakech Agreement Establishing the World Trade Organisation, signed in Marrakech, Morocco, 15 April 1994

Patent Cooperation Treaty, signed in Washington DC, United States of America, 19 June 1970

#### United Kingdom

British Technology Group Act 1991 Ch 66

Development of Inventions Act 1948

Development of Inventions Act 1967

Human Fertilisation and Embryology Act 1990 Ch 37

Human Fertilisation and Embryology (Research Purposes) Regulations 2001

Science and Technology Act 1965

The Patents Regulations 2000 (SI 2000 No.2037)

UK Patents Act 1977 (as amended) An unofficial consolidation produced by Patents Legal Section 1 October 2013

#### United States

U.S. Code Title 35-Patents

Senate Report No. 96-480 (1979) University and Small Business Patent Procedures Act Report of the Committee on the Judiciary United States Senate

Patent and Trademark Amendments Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015-28 (codified at 35 U.S.C.A §§ 200-212 (2001))

Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311-2320 (codified as amended at 15 U.S.C. §§ 3701-3714 (1994))

California Stem Cell Research and Cures Act Proposition 71 2004

Table of cases

***CJEU***

*Brüstle v Greenpeace* [2012] C-34/10 1 CMLR 41

#### EPO

*G2/06 Wisconsin Alumni Research Fund* [2009] OJ EPO 306

*Technion Research and Development Foundation, Ltd.* [2014] (T 2221/10)

#### United Kingdom

*Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd.* [2004] UKHL 46

*International Stem Cell Corporation v Comptroller General of Patents* [2013] EWHC 807

#### United States

*Diamond v Chakrabarty* [1980] 447 US 303

*Association for Molecular Pathology et al. v Myriad Genetics, Inc. et al.* [2013] 569 US 12-398

List of figures and tables

**Figures**

Figure 6.1: Diagrammatical representation of the empirical process used

Figure 7.1: Bar graph showing the proportional representations of the responses of the total population and the subpopulations to the question ‘Have you ever seen a patent document?’

Figure 7.2: Bar graph showing the proportional representations of the responses of the total population and the subpopulations to the question ‘Have you ever been part of a patent application?’

Figure 7.3: Pie chart showing the responses of the total population to the question ‘Do patents exist in your field of research?’

Figure 7.4: Pie chart showing the total population’s responses to the question ‘Do you work with patented materials (other than standard laboratory equipment)?’

Figure 7.5: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the question ‘Have you used a patent database in the last five years?*’*

Figure 7.6: Pie chart showing the results to the question ‘Which patent database did you visit most recently?*’*

Figure 7.7: Pie chart showing the results to the question ‘What happened when you used this patent database?’

Figure 7.8: Bar chart showing the proportional representations of the responses of the total population and subpopulations to the statement ‘I only need to think about patenting my research when I am certain it will have a profitable application’

Figure 7.9: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘I know the difference between an A and B specification patent document’

Figure 7.10: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘The only chance for scientists to question a patent is after it has been granted’

Figure 7.11: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘Even if a patent exists on a material I am using, I cannot be sued because I am carrying out research’

Figure 7.12: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘Patents do not provide a useful source of knowledge’

Figure 7.13: Pie charts showing the proportional representations of the total population to the question ‘Which of the following best describes your main employment?’

Figure 7.14: Pie chart showing the proportional representations of students, respondents with PhDs and those falling outside these categories (‘other’) within the total population

**Tables (all available in Appendix 3)**

Table 1: Survey responses to the question ‘Which of the following best describes your main employment?’

Table 2: Survey responses to the question ‘Please indicate which of the following best describes your scientific role’

Table 3: Survey responses to the question ‘Which of the following best describes your primary area of research?’

Table 4: Survey responses of the total population and subpopulations to the question: ‘Have you ever seen a patent document?’ and chi-squared test results for paired subpopulations

Table 5: Survey responses of the total population and subpopulations to the question: ‘Have you ever been part of a patent application?’ and chi-squared test results for paired subpopulations

Table 6: Survey responses of the total population and subpopulations to the question: ‘Do patents exist in your field of research?’ and chi-squared test results for paired subpopulations

Table 7: Survey responses of the total population and subpopulations to the question: ‘Do you work with patented materials (other than standard laboratory equipment)?’

Table 8: Survey responses of the total population and subpopulations to the questions: ‘In the last 5 years, have you visited an online patent database? If you have, please indicate which database you visited most recently’ and chi-squared test results for paired subpopulations

Table 9: Survey responses to the question: ‘What happened when you used this patent database?’

Table 10: Survey responses of the total population and subpopulations to the statement: ‘I only need to think about patenting my research when I am certain it will have a profitable application’ and chi-squared test results for paired subpopulations

Table 10: Survey responses of the total population and subpopulations to the statement: ‘I only need to think about patenting my research when I am certain it will have a profitable application’ and chi-squared test results for paired subpopulations

Table 12: Survey responses of the total population and subpopulations to the statement: ‘The only chance for scientists to question a patent is after it has been granted’ and chi-squared test results for paired subpopulations

Table 13: Survey responses of the total population and subpopulations to the statement: ‘Even if a patent exists on a material I am using, I cannot be sued because I am carrying out research’ and chi-squared test results for paired subpopulations

Table 14: Survey responses of the total population and subpopulations to the statement: ‘Patents do not provide a useful source of knowledge’ and chi-squared test results for paired subpopulations

Table 15: Survey responses of the total population and subpopulations to the statement: ‘Pre-existing academic literature can affect the outcome of a patent application’ and chi-squared test results for paired subpopulations

List of abbreviations

|  |  |
| --- | --- |
| BBSRC | Biotechnology and Biological Sciences Research Council |
| BERR | Department of Business, Enterprise and Regulatory Reform |
| BIS | Department for Business, Innovation and Skills |
| BTG | British Technology Group |
| CAFC | Court of Appeals of the Federal Circuit |
| CIPA | Chartered Institute of Patent Attorneys |
| CIRM | California Institute for Regenerative Medicine |
| CJEU | Court of Justice of the European Union |
| DIUS | Department for Innovation, Universities and Skills |
| DoH | Department of Health |
| EBA | Enlarged Board of Appeal (of the EPO) |
| EC | European Commission |
| ECJ | European Court of Justice |
| ECMC | European Commission Model Contract |
| EIT | European Institute of Innovation and Technology |
| EP | European Patent |
| EPC | European Patent Convention |
| EPO | European Patent Office |
| EPSRC | Engineering and Physical Sciences Research Council |
| ERA | European Research Area |
| ERC | European Research Council |
| ERCEG | European Research Council Expert Group |
| ESC | Embryonic Stem Cell |
| ETP | European Technology Platform |
| EU | European Union |
| FP | Framework Programme |
| GDP | Gross Domestic Product |
| HE | Higher Education |
| HEFCE | Higher Education Funding Council for England |
| HEIF | Higher Education Innovation Fund |
| hESC | Human Embryonic Stem Cell |
| IMI | Innovative Medicines Initiative |
| IP | Intellectual Property |
| IPAN | Intellectual Property Awareness Network |
| IPReg | Intellectual Property Regulation Board |
| IPRs | Intellectual Property Rights |
| iPSCs | Induced pluripotent stem cells |
| JTI | Joint Technology Initiative |
| KT | Knowledge Transfer |
| MP | Member of Parliament |
| MRC | Medical Research Council |
| NESTA | National Endowment for Science, Technology and the Arts |
| NHS | National Health Service |
| NIH | National Institute of Health |
| NRDC | National Research Development Corporation |
| NUS | National Union of Students |
| OA | Open Access |
| OECD | Organisation for Economic Cooperation and Development |
| OST | Office of Science and Technology |
| PCT | Patent Cooperation Treaty |
| PHOSITA | Person having ordinary skill in the art |
| PI | Principal Investigator |
| PSREF | Public Sector Research Exploitation Fund |
| R&D | Research and Development |
| RAE | Research Assessment Exercise |
| RCUK | Research Councils UK |
| REF | Research Excellence Framework |
| RSE | Research Selectivity Exercise |
| SC4SM | Stem Cells for Safer Medicines |
| SEA | Single European Act |
| SME | Small and Medium Enterprise |
| TEEC | Treaty Establishing the Economic Community |
| TFEU | Treaty on the Functioning of the European Union |
| TRIPS | The Agreement on Trade Related Aspects of Intellectual Property Rights |
| TSB | Technology Strategy Board |
| TTO | Technology Transfer Office |
| UK | United Kingdom |
| UKIPO | UK Intellectual Property Office |
| UKNSCN | UK National Stem Cell Network |
| UKRIF | UK Research Partnership Investment Fund |
| UKSCF | UK Stem Cell Foundation |
| UKSCI | UK Stem Cell Initiative |
| US | United States of America |
| USPTO | United States Patent and Trademark Office |
| WARF | Wisconsin Alumni Research Fund |
| WIPO | World Intellectual Property Office |
| WWI | World War One |
| WWII | World War Two |

Chapter 1

The engagement of academic biological and stem cell scientists with the patent system and patent information: an introduction

## Introduction

Over the course of the last century, major discoveries in biology have brought with them huge potential in answering fundamental questions about life and realising the hopes aligned with scientific study including. These events include the discovery of DNA; the development of genetic cloning; mapping the human genome and the discovery of stem cells. Many such discoveries have been made in universities, often funded, in part at least, by public money. Patents, a form of intellectual property right, are now routinely granted over ‘inventions’ which are the results of research and development (R&D) ensuing from these discoveries. Historically, patents were granted over ‘bricks-and-mortar’ inventions, classically machines, or more recently in the biomedical field, end-products such as pharmaceutical preparations.[[1]](#footnote-1) Following the expansion of patentable subject matter, patents now often cover basic ‘upstream’ science many steps removed from final products, such as cell lines in the case of stem cell science.[[2]](#footnote-2) Coupled with the evolution of related science policy[[3]](#footnote-3) encouraging patenting in universities, this has meant that the number of university patents has grown massively in recent decades.[[4]](#footnote-4)

There are a wide variety of questions raised by the patenting of: upstream research; university-based and publicly funded research; and biological materials, particularly in relation to stem cells. These include how patents affect downstream innovation and the availability of research tools to downstream researchers;[[5]](#footnote-5) whether upstream patents create anticommons;[[6]](#footnote-6) how patenting affects the research environment, norms and incentives of academic science;[[7]](#footnote-7) whether patents should be granted over certain types of science[[8]](#footnote-8) and the role of the patent system in disseminating technical information.[[9]](#footnote-9) A number of theoretical and empirical studies have attempted to shed light on these issues.[[10]](#footnote-10) This project connects with the questions from a different angle. It considers how academic scientists engage with the patent system, specifically through patent information, and the barriers to such engagement. The thesis provides an insight into the key factors that contribute to these perceptions by examining the context in which the scientist’s work. The study gathers a novel empirical dataset of the use of patent information by biological and stem cell scientists and examines what these findings mean in the wider context of science- and patent- policy. This is an important study because whilst there is a wealth of literature relating to various aspects of patenting and universities, few studies consider a key actor in the process: the academic scientists on which this thesis centres.

This chapter sets out the social, political and economic context of the research; the research questions of the thesis and the methodological approach employed; the scope and limitations of the work; the contribution of the thesis and concludes with a roadmap of the thesis.

## Why patents and patent information?

Scientific progress is a cumulative endeavour – previous work informs subsequent research, allowing scientists to build on the efforts of others.[[11]](#footnote-11) The dissemination of new knowledge is central to this process: if new knowledge is not available to downstream researchers, it cannot be used to inform downstream research. Knowledge dissemination is particularly crucial in the early stages of emerging research which is many steps removed from an end-product, as is the case in biological and stem cell science undertaken in universities – the foci of this research. In academia, the dissemination of new knowledge has traditionally been achieved through journal publications, conference presentations and teaching. As a result of changes in patent law and research funding and policy (discussed in Chapters 2-4), knowledge from academic research is now potentially captured by, and disseminated through, the patent system.[[12]](#footnote-12)

In today’s ‘knowledge based economy’[[13]](#footnote-13) it is unsurprising that an economic rationale for the patent system is so prominent in debate surrounding the system, not least because the legal policy has an economic rationale that clearly links knowledge with economics.[[14]](#footnote-14) The basis of this rationale is that in order to achieve the desired goal of economic growth, the patent system is required to incentivise both innovation and knowledge transfer.[[15]](#footnote-15) This is based on two main assumptions: 1) the grant of exclusive patent rights provides an incentive for socially and economically desirable levels of invention and innovation; and 2) the system incentivises disclosure of information which may otherwise be kept secret.[[16]](#footnote-16) In this way, patents can be viewed as a ‘social contract’: society grants inventors exclusive rights over their inventions in return for disclosure of information.[[17]](#footnote-17) Consequently, disclosure is often reported as being the *quid pro quo* of the patent system.[[18]](#footnote-18) Disclosure, it is claimed, encourages the transfer of knowledge, which informs and provides incentives for ‘downstream innovation’[[19]](#footnote-19) allowing inventors to build on the work of others.[[20]](#footnote-20) To facilitate this, patent laws require that patent information must be publicly released in a timely manner and with sufficient detail to enable someone ‘skilled in the art’ to practise the patented invention.[[21]](#footnote-21) These legal requirements aim to offset the potential social cost of providing monopoly rights by encouraging the release of information into the public domain, information which otherwise may be kept secret and therefore unavailable to wider society.

Reliance on the legal requirements of publication and disclosure may not be sufficient to realise the diffusion of knowledge at the centre of the economic rationale for patents. Commentators have argued that these requirements allow patent documents to contain precisely sufficient information to obtain a patent right (i.e. enough information to satisfy the patent offices’ interpretation of the legal requirement of disclosure) but not the information which is required to achieve the claimed societal benefit of the system.[[22]](#footnote-22) Moreover, it has been argued that the patent system is ‘gamed’ by patent lawyers, with information disclosed in patents purposely incomplete, confusing and difficult to find (i.e. by using obtuse titles and keywords), leaving the patentee with a broad patent and society with minimal information gain – skewing the patent bargain.[[23]](#footnote-23) Whether the information needed for the invention “to be performed by a person skilled in the art”[[24]](#footnote-24) is made publicly available through patents in a meaningful and accessible manner raises questions about ‘disclosure’ and the modalities of ‘publication’. This is particularly important from the perspective of the economic rationale for the patent system. Drahos proposes that to fully realise the knowledge transfer aim of the system’s economic rationale, diffusion of information is key.[[25]](#footnote-25) Building on Drahos’ work, this thesis considers whether the diffusion of biological and stem cell science through the patent system is effective and what barriers exist to such diffusion.

In his extensive work investigating the global governance of the patent system, Drahos offers a useful framework from which to investigate the real-life workings of the patent system. He indicates that:

“Patent systems in their present form represent deep concentrations of power and dominance in which networks of big businesses, patent attorneys and patent offices cooperate to produce an insider governance of the system.”[[26]](#footnote-26)

In his interviews with patent offices, Drahos found that the social value of the patent system was viewed as an ideal, trumped by the client-based model driven by the current governance of the system.[[27]](#footnote-27) It is this governance which is, he argues, undermining the patent social contract, yet maintaining it as a cover to sustain public support for the patent system. Thus, without the informative role of patents, the supposedly public system may be exposed as a system aimed at creating benefit for a few powerful groups. These groups are keen to publicise the importance of this teaching role but are not currently supporting the social diffusion necessary to support the social contract. They are also the groups which have been shown to direct the future of the system.[[28]](#footnote-28) As such, Drahos notes:

“The basic problem of the patent system can be simply stated. Standard-setting and administration of the system is dominated by a globally integrated private governance network. This network has made the patent social contract largely meaningless. More rule-based reform of the system will simply see this private governance network continue to bend the process of rule-making to its own ends.”[[29]](#footnote-29)

According to Drahos, reclaiming of the patent social contract may be achieved through the ‘separation of powers’ principle by exposing the power imbalances in the system and the formation of an active ‘outsider’ governance network.[[30]](#footnote-30) This network could be made up of lots of small interested parties, so-called ‘outsiders’, including government departments (aka public funders of science), “science researchers who still subscribe to public good values” and “university administrators who still have some sense of the public-good mission of universities”.[[31]](#footnote-31) He continues that creating this outsider network will not be simple: the lack of public transparency in the patent system means outsiders are unaware of the extent of the power of the insiders,[[32]](#footnote-32) knowledge which might drive them to act collectively. Further he argues that an exposure of the powers at play might help create a political environment where politicians have the incentives to aid in the reclaiming the social contract.[[33]](#footnote-33) It is within this framework that the findings of the thesis will be considered and a number of recommendations will be made.

## Why biological and stem cell science?

Progress in the biological sciences continues to unveil information about life, bringing with it the potential to tackle some of the major problems facing humanity today. As a result, established fields of biology have been reshaped in recent decades and a number of new fields have ‘emerged’. These ‘emerging biotechnologies’ share three characteristics: uncertainty, ambiguity and ‘transformative potential’.[[34]](#footnote-34) They are also surrounded by promise and expectations which perpetually develop, shaping the futures of the fields and the work of scientific researchers.[[35]](#footnote-35) This is certainly the case in the emerging field of stem cell science.[[36]](#footnote-36) Since the discovery of stem cells in the 1960s, the field has been surrounded by high expectations and has come to be heralded as a ‘great hope’ for both healthcare and economies. However, the field continues to be surrounded with ambiguity and uncertainty and, despite huge growth in the field,[[37]](#footnote-37) the reported potentials largely remain far from fruition. The science still remains at an early stage with relatively few products on the horizon.[[38]](#footnote-38) Accordingly, a lot of research in the area is still ‘basic’ and undertaken in universities, funded in part by public money.[[39]](#footnote-39) At present, the field is considered too risky for big pharmaceutical companies to get intensively involved in in-house R&D; therefore, there has been a perceived need to provide incentives for public-private partnerships in order to harness private funding.[[40]](#footnote-40)

Stem cells are a special type of cell with two key characteristics which distinguish them from other cells in an organism: 1) they can self-renew, dividing indefinitely in culture whilst maintaining their undifferentiated state; and 2) they can give rise to specialised, differentiated cells.[[41]](#footnote-41) It is these properties that have given rise to the wide-ranging hopes and expectations of the field deriving from the potential applications of the science for drug screening, disease modelling and direct medical treatments.[[42]](#footnote-42) Estimations of these potentials include a global market of cell-based therapies reaching $8.5 billion in the next decade[[43]](#footnote-43) and media headlines regularly include terms such as ‘cure’, ‘treatment’, ‘transplant’ and ‘breakthrough’.[[44]](#footnote-44)The potential therapeutics relate to a wide variety of diseases for which there are, as yet, very limited or no treatments. Such diseases include neurological disorders, sight loss, diabetes, stroke and spinal cord injury.[[45]](#footnote-45) However, it is likely that many of these potentials are quite far from being realised; the science remains at a very early stage. Concern has been raised about the effects of these expectations on the scientists themselves and the potential risks associated if these ‘promises’ are not fulfilled.[[46]](#footnote-46) It is unsurprising, therefore, that the field has been the subject of attention of scientists, academics, the public and policy makers, the latter of which has increasingly aimed at encouraging and supporting the translation of basic science to evidential products and therapies.[[47]](#footnote-47)

The UK has a strong history in stem cell research, with three Nobel Prize winners in the field.[[48]](#footnote-48) Stem cell science and, more recently, the associated field of regenerative medicine remain high on the national political agenda, attracting considerable interest from policy-makers and science funders.[[49]](#footnote-49) Since the Human Fertilisation and Embryology Act was passed in 1990, allowing limited licensed, regulated research to take place using human embryos,[[50]](#footnote-50) the fields have grown massively in the UK. In 2005, the Government pledged, through the UK Stem Cell Initiative, to increase investment in stem cell research to between £41 and £104 million per annum over the next 10 years.[[51]](#footnote-51) From then on, the problems involved in supporting translation from research to product have been the subject of a number of reports and funding initiatives. For example, in 2010 regenerative medicine and stem cell science were pinpointed by BIS as a ‘Growth opportunity for the 2020s’.[[52]](#footnote-52) In 2011, a Cell Therapy Catapult was launched by the Government to operate with funding from public and private bodies, to “focus on the development and commercialisation of cell therapies and advanced therapeutics”.[[53]](#footnote-53) In 2012, regenerative medicine was identified as one of eight key technologies for the future[[54]](#footnote-54) and the House of Lords Science and Technology Select Committee initiated an inquiry on regenerative medicine.[[55]](#footnote-55) The Committee reported in 2013 highlighting a number of challenges that continue to surround the field, with particular concerns about the UK’s current ability to support the translation and commercial exploitation of the science.[[56]](#footnote-56)

Patents for products and processes relating to stem cells have been applied for since the late 1980s, with a huge growth in applications in the 1990’s and early 2000’s,[[57]](#footnote-57) many covering science far upstream of any likely products (evidenced by the huge number of patents and the dearth of commercially available therapeutics). As a result, the global stem cell patent landscape is complex, with many hundreds of patents granted internationally to date.[[58]](#footnote-58) Concerns have been raised about the potential of these patents to cause an anticommons effect particularly given the emerging and ‘broadly enabling’ nature of stem cells and the challenges involved in inventing around such a technology.[[59]](#footnote-59)

Together with relatively relaxed regulation of the research and significant funding in the area, the UK Intellectual Property Office’s (UKIPO) liberal view on stem cell patenting in the 2000’s meant that the number of patents in the stem cell field in the UK grew significantly since the first application was filed in 1989.[[60]](#footnote-60) It is also notable that universities have been unusually active in their patenting activity in this field. In comparison with other patent-rich technological areas, a far higher proportion of the top applicants for patents in the UK were universities (almost half[[61]](#footnote-61)) and 42% of granted patents were assigned to universities, compared to 46% assigned to the corporate sector[[62]](#footnote-62) (similar to the situation in the US[[63]](#footnote-63)).

While the numbers of stem cell patents have increased in recent decades, the future of patenting in some sectors of the field is uncertain following a number of key patent cases (e.g. Brüstle v Greenpeace and the (ongoing) cases surrounding the WARF patents[[64]](#footnote-64)). Notwithstanding this, many of the processes involved in and results of stem cell research have been, indeed still (likely) are, patentable.[[65]](#footnote-65) However, concerns about the ensuing ambiguity and uncertainty continue to be raised by many including stem cell researchers themselves.[[66]](#footnote-66) Such concerns are likely to affect the scientists at the centre of this study.

Despite the growth in patenting of stem cell science and aligned concerns in the academic literature about the potential problems relating to the complex patent landscape, in 2008 at the inaugural meeting of the UK National Stem Cell Network (UKNSCN), it became apparent that UK stem cell scientists were unaware of foundational embryonic stem cell patents which had been granted two years earlier.[[67]](#footnote-67) Given this apparent lack of awareness and a dearth of empirical data regarding stem cell scientists in the UK, there was a clear need to garner information about the engagement of these scientists with patent data paving the way for this project. Analysis of this data gathered helps to inform of the legal and technical barriers to public access to patent information and engagement with the patent system.

Few empirical studies centre on stem cell scientists, but one is particularly relevant to this thesis. A study by Caulfield and others showed that whilst Canadian stem cell researchers perceive patents to have had a negative effect on their research, this has rarely been observed in practice. [[68]](#footnote-68) When questioned about their motivations for pursuing research careers the scientists noted that “the development of inventions or a patenting record were rated moderately important or not important at all”. However, the majority of principal investigators (PIs) “considered the role of patents in facilitating research translation to be important or very important” and roughly half “felt that way regarding the role of patents in relation to the receipt of research grants.”[[69]](#footnote-69) Of particular relevance here is that more than half of the PIs questioned were aware of patent controversies in their field, and that a similar proportion of the PIs disagreed with claims that patent information facilitated information sharing or allowed researchers to identify and use the inventions of others. In turn this led the investigators to report a “lack of enthusiasm for [disclosure] a conventional benefit associated with patents, and warrants future investigation.”[[70]](#footnote-70) It is of particular interest given that the majority of respondents “agreed that patents benefit society by facilitating knowledge translation, investment and the production of useful technologies and products.”[[71]](#footnote-71)Why do stem cell scientists lack enthusiasm for ‘disclosure’ through the patent system when they recognise the benefits patents can afford? This study aims to uncover potential reasons behind these apparent inconsistencies.

## Why universities?

The importance of research in today’s knowledge based economy has been widely recognised, not least in the UK.[[72]](#footnote-72) Universities are major undertakers of R&D in the UK performing 27% of all R&D, approximately two-thirds of which is publicly funded.[[73]](#footnote-73) This research is highly valued and deeply embedded in the UK economy; knowledge exchange between Higher Education Institutions (HEIs) and public, private and third sectors is currently valued at £3.431 billion per annum.[[74]](#footnote-74) It is therefore unsurprising that it is claimed that the potential role of this research in economic growth, and more recently in economic recovery, is significant:

“Just as castles provided the source of strength for medieval towns, and factories provided prosperity in the industrial age, universities are the source of strength in the knowledge-based economy of the twenty-first century.”[[75]](#footnote-75)

Following the financial crisis of 2008, attention turned to sectors outside of banking to support the economy. Science has been cited as a potentially significant source of economic growth and as a result, there are high expectations from scientific R&D:

“Faced with such [economic] uncertainties, the UK must build on its existing strengths. This country has a proud track record of achievements in science and engineering.”[[76]](#footnote-76)

Universities are conventionally viewed as having two missions: teaching and research. Accordingly, the majority of knowledge exchange from universities has traditionally taken place through teaching and publication in peer reviewed journals and conference presentations, with the UK having a particularly strong publication record.[[77]](#footnote-77) However, within the UK’s modern knowledge based economy, university research is expected to deliver on another mission: knowledge exchange for wealth creation.[[78]](#footnote-78) Not only are universities expected to produce knowledge, they are now increasingly expected to make money from it. As a consequence, universities have progressively been called to provide justification for their funding, showing that this investment is ‘paying off’, particularly where public money is involved:

“Public funding for research and knowledge exchange will focus even more strongly on excellence and on maximising the benefits for the economy and society.… The public would expect us to maximise the benefits of excellent research they pay for.”[[79]](#footnote-79)

This has driven a number of factors aiming at ‘maximising’ the benefits of research in the UK, particularly in the case of public funds. These are discussed at length in the following chapters, but here it is sufficient to say that they have contributed to an increased trend to seek patents over the results of university research.[[80]](#footnote-80)

An assumption within policies that have advocated the patenting of research in universities is that traditional academic practices are inefficient in facilitating translation from research to product and realising the economic potential of research. Further, these policies assume that patenting improves translation of research to product and the capture of economic return. As will be discussed in the subsequent chapters, these assumptions entails several points: 1) that the patenting of early stage research in universities encourages more innovation and translation than traditional scientific practices; 2) that such patents ‘pay-off’ economically; 3) that patents are being granted over ‘inventions’ which advance the state of the art; and 4) that the patent system makes information publicly available which can ‘teach’ others, supporting scientific progress through knowledge dissemination. Points 3 and 4, which are also central to the rationale of the patent system, presume that scientists can and do engage with patent information in order to either assess it or learn from and build upon it. This thesis investigates whether, and to what extent, this holds true of academic biological scientists, particularly stem cell scientists, working in UK.

## Why the UK?

The decision to focus on the UK was made for several reasons in addition to the national science policy focus on biological and stem cell science previously described. Patent law, research funding and higher education/university policy varies between countries and, while shaped by international contexts, are largely defined by national governments.[[81]](#footnote-81) It was therefore important to limit the study to a group of scientists working in a particular jurisdiction. With regard to the study of stem cell science, this was particularly pertinent: it has been argued that stem cell research “represents a patchwork of patchworks” with countries having taken different approaches to various aspects involved including legal permissibility, regulation, funding, patenting and commercialisation of the research.[[82]](#footnote-82) Therefore, in order to draw reliable conclusions about the field, it was important to investigate the specific situation in the UK. Finally, there is a relative wealth of studies relating to patents, universities and basic science in the United States (US), which is regularly drawn upon throughout the thesis, but little exists regarding the specific case of the UK. This thesis aims to help address this dearth.

Notwithstanding the focus on the UK, this thesis draws upon international examples throughout. An international element is important due to the global nature of the science and the influence of major competitor economies on policy in related areas in the UK. This is particularly noted in the case of the US and European Union (EU). In the latter, there is considerable influence of its institutions on R&D in the Member States. The international dimension is most notably demonstrated between Chapters 2 and 3 in which the historical drivers of increased patenting in universities both internationally and in the UK respectively are discussed. In addition, a number of the patent cases, discussed with regard to the expansion of patentable subject matter, were heard at US and EU courts and patent offices. The results of these cases have influenced the practice and policy of the UKIPO and European Patent Office (EPO) thus shaping the context in which UK scientists work.

## The research questions, methodological approach and scope of the thesis

This thesis investigates the engagement of academic biological scientists’, particularly stem cell scientists’, working in the UK with the patent system and patent information. The project involves a multi-method approach relying on both desk-based and empirical research, the presentation of which is clustered into 4 parts. To approach the overarching aims of the thesis, a number of sub-questions are addressed in different sections before being drawn together for discussion.

Parts 1 and 2 describe the context in which the scientists at the centre of the empirical study work. This is done in part through chronological analysis of legal and policy developments internationally, nationally, and in the specific case of stem cell science in the UK. The question may be raised: why is it necessary to detail these histories? A lot has been written about the commercialisation of academic research but this is sometimes taken as a starting point for discussion, without considering the history of how and why this has happened. A historical overview is essential to understand the evolution of policies which direct innovation systems.[[83]](#footnote-83) This thesis attempts to include such a history in ongoing debates. Within the specific context of the empirical study of this thesis, it is important to understand the history of the environment in which the participants work in order to interpret their perceptions of patent information and to allow for an informed discussion of the implication of the results on policy relating to research funding, university IP management and the patent system.

**Part 1** asks‘what is the context in which UK academic biological and stem cell scientists’ work?’ This is broken down into two parts:

1. Chapters 2 and 3 retrace the evolution of patenting of biological science in universities, considering a variety of multifactorial drivers involved
2. Chapter 4 sets out the policy and funding of stem cell science in the UK

**Part 2** (Chapter 5) considers patent policy, the extension of patentable subject matter to cover the building blocks of modern science and how the patent system copes with such patents.

**Part 3** (Chapters 6-8) describes the empirical study of the thesis which focused on the following questions:

1. Are scientists aware of the patent landscape within which they work?
2. What do scientists know about patents and patent information?
3. How do scientists use, perceive and value patents and patent information?
4. How do scientists search for patent information and what are the barriers they experience when doing so?

**Part 4** (Chapters 9 and 10) considers the implications of the findings of the earlier parts for both science- and patent- policy and presents a number of potential remedies before providing the conclusions of the thesis.

As the various research questions indicate, the overall research is interdisciplinary drawing on aspects of economics, history, law, public policy, science and the sociology of science. These mixtures were required in order to understand the context in which the scientists studied work and how these affect their perceptions and experiences; a study missing any of the disciplines previously mentioned would be unable to provide an overview of the situation studied. This interdisciplinary approach means that the thesis draws upon a large range of primary and secondary sources, concepts and theories as well as deriving a novel dataset through the empirical study.

In selecting the research questions, a number of choices have been made defining the scope of the thesis and thereby limiting the majority of the discussion to patents and patent information; universities; biological and stem cell science; and the UK. As a result, this study inevitably has a restricted scope and a number of limitations. Those limitations relating to the empirical methodology, such as the sampling used and the restrictions of the methods, are discussed in Chapter 6. There are also a number of restrictions in the scope of the topics covered in the thesis, discussed below.

For the purpose of discussion in this thesis, it is proposed that scientists can play three key roles in the patent system; they can act as inventors, follow-on users of information, and/or regulators. Scientists can play two key roles as users of the patent system: they can be patent information producers (inventors) or patent information users (follow-on users). These two roles are not mutually exclusive. A scientist may be a follow-on user, and subsequently act as an inventor, or *vice versa*, and at times the two roles may be concurrent. Scientists can also take on a further, third role in the patent system: a ‘regulating’ function. In this role, scientists may provide ‘observations’ on patent applications in the form of third party observations, or file oppositions post-grant, giving them a role of ‘quality control’ within the system. This thesis, given its focus on patent information and the dissemination of scientific information through the patent system, is largely interested in scientists as follow-on users. However, many of the findings from both phases of the study are also pertinent to the other roles of scientists and are highlighted as such in the presentation of the results and subsequent discussion.

Inseparable from the focus on universities, the study is concerned with academic scientists rather than scientists working in industry. The decision is in part pragmatic; it was not practicable within one thesis to discuss both groups and carry out a comparative empirical study. In addition, there are clear differences between university scientists and scientists working in industry with regard to patent practices. The contexts in which the two groups work are markedly different in terms of incentive structures, funding pressures, autonomy, etc. More pertinently, scientists working in industry are supported by a wide variety of staff including full-time patent attorneys whose roles include ensuring scientists have freedom to operate; supporting them in protecting any patentable position; and making them aware of any patent information not available in academic literature. This level of support does not exist within UK universities.[[84]](#footnote-84) Therefore, the experiences and perceptions of both groups with regard to patenting are likely to be disparate and could not be captured within the scope of this thesis. Further, the use of patent information in UK businesses has been investigated[[85]](#footnote-85) but a comparable study has not been carried out within the university environment.

This thesis confines its discussion to the biological sciences, more particularly stem cell science. Whilst there are other sectors where patenting of basic science in universities is also the subject of ongoing debate (such as nanotechnology), the precise context of each field involves distinct and unique challenges, problems and issues which are likely to affect researchers in different ways. For instance, the ongoing discussion on the patenting of nanotechnology is quite different from that of stem cell science.[[86]](#footnote-86) For these reasons, to help ensure homogeneity it was necessary to limit the empirical study to a small group of scientists similar in terms of educational background, experience, funding pressures, etc., in order to gather comparable findings from which to draw reliable conclusions.

Much of the academic, legal and public discussion surrounding the practice and patenting of stem cell science has focused on the ethical issues involved. Extensive discussion of the ethics of patenting biological materials is beyond the scope of the thesis: the research questions are not associated with whether biological/stem cell inventions *ought* to be patentable or not on ethical grounds. Rather, they focus on how the growth of patenting in these fields has occurred; how scientists perceive the effects of patenting in the field on their research; and the availability of scientific information through the patent system. However, such ethical discussion continues to influence the undertaking of the research and the patentability of the products of biological research, particularly in the case of stem cell research.[[87]](#footnote-87) Further, it is borne in mind that scientist’s perceptions of these wider ethical debates may impact upon their views of the patent system and patent information. Therefore, while the ethical issues involved are not discussed extensively, the thesis is mindful of their influence on the participants and the context in which they work.

Finally, the development of patent case law in the fields of biological and stem cell science is not discussed at length. Although it considers major patent cases in different parts (particularly with regard to the expansion of patentable subject matter), it does not provide an in-depth legal analysis of the cases. This thesis draws upon such analysis[[88]](#footnote-88) where appropriate but is largely concerned with scientists’ use of patent information and the barriers to such use. Thus, the effects of some of the major patent cases in the field on the scientists are considered and their influence on the empirical results is borne in mind when considering the study’s findings.

## Original contribution

While a number of studies have been undertaken in a variety of related areas, none have conducted a comprehensive review of the variety of factors which have driven the increased patenting in universities alongside an empirical study of academic biological and stem cell scientists’ engagement with and perceptions of patents and patent information. This thesis therefore offers an original contribution, particularly through the generation of empirical data. Further, the empirical mixed-methodology employed is unique given the use of a structured observation. Existing studies tend to rely on either surveys or interviews to investigate various aspects of the patenting of science, none actively observe patent searching. In addition, a novel analysis of the patenting of university-based research is offered through combination of multifactorial drivers: the international science policy context; the national science policy context; evolving patent policy; and the particular drivers of patenting stem cell science in the UK.

## The Thesis Roadmap

### Part 1 – Science funding policies

The first part of the thesis, Chapters 2-4, retraces the science policy and funding context in which the scientists at the centre of the empirical study work. Science policy and funding has become increasingly focused on maximising translation of basic research to commercial product and capturing the economic return from this process in order to make research ‘pay-off’ and support wider economic goals. It will be shown that as a result of these policies, scientists are operating in a context wherein their sources of research funding come with various strings attached.Chapter 2 considers the international context, focusing on the US and the EU. Chapter 3 centres on the evolution of UK science policy, and Chapter 4 details the specifics of stem cell science policy and funding in the UK showing that there has been a major policy focus on the field, resulting in large public and private investment in the research in the UK and a number of notable public-private partnerships. These chapters will show that basic science has been regularly pinpointed by policymakers as the type of science that should be part of translational and wider commercial initiatives, often involving collaboration with the private sector. As a result, the funding of basic research comes with a number of terms and conditions attached, aimed at supporting this. Scientists are increasingly required to consider the potential commercial applications of their basic research; they are often expected to work with the private sector; and they are to pursue the acquisition of patents where possible. Given the upstream patenting of research in emerging fields such as stem cell science and the long translational process required to achieve the commercial products central to the aims of science policy, it is important to consider whether these policies facilitate the translation of research to product – a process which requires the dissemination of information.

### Part 2 – Patent policy

Part 2, Chapter 5, focuses on the legal backdrop to the study: the patent system. This chapter begins by considering how a patent is defined in law, noting the standard patentability requirements (novelty, inventive step and industrial application) and the legal requirements of disclosure and publication. It then continues to consider a popular justification of the patent system (the ‘social contract’ rationale) and extension of the system to new arenas through the expansion of patentable subject matter to cover basic biological materials. This has happened in parallel with the development the science policy detailed in Part 1 and has contributed to the increase in university patenting activity in recent decades. The extension of patentable subject matter is discussed with particular focus on a number of landmark patents and patent cases (namely Diamond v Chakrabarty, the Myriad patents, the WARF patents and Brüstle v Greenpeace). These examples highlight some of the tensions at play in the field which are then considered more thoroughly together with questions about the ability of the patents system to cope with such patents and disseminate scientific information.

### Part 3 – Scientists’ engagement with the patent system

Chapter 6 sets out the methodology employed in the empirical study considering the specifics of each of the methods used; the limitations of the model; how the data were analysed; and some of the practical challenges encountered. A sequential-explanatory model was used whereby a survey of 120 biological scientists was followed by interviews with, and structured observations of, 16 senior stem cell scientists. Chapters 7 and 8 present the data gathered from the fieldwork, outlining the analytical themes that emerged. Chapter 7 details the findings of the survey, highlighting the points which were to be further investigated during the interviews and structured observations, the results of which are presented in Chapter 8. The findings of the study indicate that there are a number of barriers limiting the engagement of biological scientists with the patent system and patent information including attitudinal barriers, technical/knowledge barriers and problems inherent in the patent information infrastructure.

### Part 4 – Discussion and conclusions

Chapter 9 provides a discussion of the findings, situating the empirical data within the context presented in Parts 1 and 2. This discussion indicates that the empirical findings are not abstract but rather ensue from the science- and patent- policy context in which academic stem cell scientists’ work. The discussion also relates the findings to a number of on-going debates including access to knowledge (particularly open access to research publications); the assumptions within justifications of the patent system; the transparency and governance of the patent system; the assumptions behind policies which have driven the patenting of university research; and the effect of patenting on the academy and academic scientists. The chapter presents the implications of the findings on these debates for both science- and patent- policy. A number problematic areas are identified together with a range of potential solutions which may help to overcome the barriers identified which currently limit scientists’ engagement with patent information. The final chapter, Chapter 10, pulls together the findings of earlier chapters, reflects on the study and provides suggestions for future research.

Chapter 2

Science funding and science policies: an international historical context

## Introduction

The number of patents filed by universities has grown markedly since the Second World War (WWII), and particularly since the 1980s.[[89]](#footnote-89) This increase was first noted in the US, then subsequently across Europe, the UK, and has become an almost global phenomenon.[[90]](#footnote-90) When discussing this increase, many commentators focus on a limited account centring their debates on the Bayh-Dole Act in the US. This and the following chapters take a broader historical view, reviewing a variety of sources which indicate that a much wider and more complex set of issues have contributed to the increase in patenting by universities. These multifactorial drivers will be split into those relating to science policy and funding (presented in Chapters 2-4) and patent policy (discussed in Chapter 5).

The factors relating to science funding and science policy will be examined in 3 regions: the US and then the EU in this, the international chapter; and the UK in Chapter 3, the national chapter, and Chapter 4, the stem cell chapter. These areas have been chosen because they demonstrate that the drive to commercialise university research has been driven by different initiatives at different times dependent on regional circumstances. As Grimaldi and othersevidence, the science policies developed reflect the specific historical, legal and organisational characters of the regional public research systems.[[91]](#footnote-91) It is worth noting that while the cases presented are examples of developed regions, economically emerging countries have also developed related policies in recent years; the spread of a drive to commercialise publicly funded research has not been bound by stage of economic development.[[92]](#footnote-92)

In terms of content of this chapter, it is evident that there is a greater emphasis on the EU. While the US is important from a historical point of view, instigating the global trend of attempting to increase the commercialisation of publicly funded research, more focus is paid to the EU because of the direct influence that EU policy and funding has on science in the UK as a Member State of the EU.

## A history of science funding and science policy in the US

Some of the key developments in the move towards the commercialisation and patenting of publicly funded research first took place in the US. As a result, the US has often been used as a bench mark for comparison and as a model to increase the commercialisation of publicly funded research in other regions. In the US, the increasing drive to commercialise the results of publicly funded research followed reports, many after WWII, which noted that this research wasn’t paying off: huge investments were being made in research which rarely progressed to the market and had little apparent direct economic output.[[93]](#footnote-93) The majority of commentary on the US focuses on the Bayh-Dole Act of 1980, but it is evident that universities were involved in commercialisation and patenting long before this. Further, as Mowery and Sampat indicate and as the following discussion shows, it is not only legal developments, such as the Bayh-Dole Act, but also a variety of other factors that have contributed to the increase in the patenting of US university research.[[94]](#footnote-94) As such, they note: “Bayh-Dole is properly viewed as initiating the latest, rather than the first, phase in the history of US university patenting.” [[95]](#footnote-95) The subsequent historical review will therefore look further into the past and take a wide variety of issues and initiatives into account to map the increasing focus on university patenting in the US.

### The beginnings of university patenting in the US

The first US university patents were granted in the early twentieth century[[96]](#footnote-96) with the first wave of such patents following the end of WWI.[[97]](#footnote-97) By 1930, research collaboration between US universities and industry was common and patents were sometimes granted over inventions created during this research.[[98]](#footnote-98) One such invention developed and patented in a university led to the creation of the Wisconsin Alumni Research Foundation (WARF) in 1925.[[99]](#footnote-99) As will be discussed in section 5.4.3, WARF have played a significant part in the story of stem cell patenting. Notwithstanding these few isolated cases, university patenting was not widespread across the US at this time. Only some of the leading research universities had patent policies prior to WWII, several of which actively discouraged patenting.[[100]](#footnote-100)

### The effect of WWII on the role of US universities

WWII changed the role of US universities as research performers. Following the war, the share of industry funding greatly declined while the budgets of universities expanded with the US government investing “unprecedented levels of federal funding on research and development”: the number of university patents subsequently increased.[[101]](#footnote-101) Mowery and Sampat point to two main motives for increased university patenting following the surge in federal funding of research in the years following WWII: 1) more research meant more patentable inventions were likely to be developed; and 2) many federal sponsors required formal patent policies to be adopted at this time.[[102]](#footnote-102) These conditions varied from sponsor to sponsor, but by 1950 most US universities had adopted formal patenting policies.[[103]](#footnote-103)

Notwithstanding these requirements, some universities patented only if it was in the ‘public interest’, others discouraged medical patenting and few universities managed their own patents, preferring to outsource their patent management to organisations such as the WARF (in the case of the University of Wisconsin) or the Research Corporation.[[104]](#footnote-104) By 1970, the Research Corporation managed the patents for over 200 institutions, but realising that it was running at a loss worked with its clients to develop the ability of universities to manage the start of the technology transfer process.[[105]](#footnote-105) This, combined with the growth of the field of molecular biology and the increasing number of ‘inventions’ in this field;[[106]](#footnote-106) the concurrent reduction in federal funding for R&D; and increases in the cost of research meant that by the mid-1970s most US universities were developing offices to manage their own patents in an attempt to find another income stream to support their research.[[107]](#footnote-107) As a result, federal funders were inundated with requests to provide universities with the exclusive rights over the IP but the funders still lacked coherent policy on this point, instead working on a case-by-case basis leading to widespread confusion and uncertainty.[[108]](#footnote-108)

By the late 1970’s, following the increasing numbers of requests from universities wanting to manage their own patents, the Senate Report on the University and Small Business Patent Procedures Act (which led to the adoption of the Bayh-Dole Act) noted that the bureaucracy surrounding the commercialisation of federally funded research was extremely complicated with 24 different patent policies in use by federal agencies.[[109]](#footnote-109) The patent policies, while numerous, all shared one common aspect: the patents from research undertaken using federal funds were automatically the property of the Federal Funding Agencies.[[110]](#footnote-110) The report further noted that the Federal Funding Agencies had a poor record of making the patents and inventions available to private businesses for development and commercialisation: of the 28000 patents owned by government, only 4% had been licensed.[[111]](#footnote-111) Between the ‘passive’ patent policy of Federal Funding Agencies and the ‘red tape’ involved, few companies were willing to invest in developing federally funded inventions and these inventions rarely made it to market.[[112]](#footnote-112) In addition, it was noted that universities and non-profit organisations were much more efficient in delivering products to market than the Federal Funding Agencies, with the report noting that universities “have been able to successfully license 33 percent of their patent portfolios.”[[113]](#footnote-113) The report stated concerns about international competitiveness and the concurrent desire to increase the production of new products.[[114]](#footnote-114) These concerns led to the passing of the Bayh-Dole Act in 1980, causing what Eisenberg terms “a sea change in US government policy toward intellectual property rights in the results of government-sponsored research”.[[115]](#footnote-115)

### The Bayh-Dole Act (1980)[[116]](#footnote-116)

The Patent Rights in Inventions Made with Federal Assistance Act, more commonly known as the ‘Bayh-Dole Act’, was enacted by the United States Congress on December 12 1980.[[117]](#footnote-117) Congress stated its intention to encourage maximum use of publicly funded research by private organisations in the text of the Act:

“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and non-profit organizations to ensure that inventions made by non-profit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non use or unreasonable use of inventions; and to minimize the costs of administering policies in this area.”[[118]](#footnote-118)

The legislation was enacted on the view that patents were needed to encourage the private investment needed to develop inventions into products.[[119]](#footnote-119) To achieve this, taking into account the assertions of the earlier Senate Report, the Bayh-Dole Act enabled small businesses and non-profit organisations (including universities) to patent their inventions and permitted them to hold the title for the patent, rather than it being held automatically by the relevant Federal Funding Agency[[120]](#footnote-120) (while allowing the agency to have non-exclusive access to the invention[[121]](#footnote-121)). In addition, these patents could be licensed to the private sector on an exclusive (or non-exclusive) basis.[[122]](#footnote-122) In this way, the Act aimed to increase the number of inventions based on research funded with public money in universities to be brought to the market and made available to the public by private firms. As a result, Lee notes that after the Act, from the perspective of universities, “patents were seen as a necessary conduit for transferring federally funded technologies to the private sector for commercialisation”.[[123]](#footnote-123)

### Additional factors in the 1980s and 1990s contributing to the growth in university patenting in the US

“The 1980s were a time of great concern about U.S. “competitiveness,” as well as a general movement to shrink government and make it more efficient and responsive.”[[124]](#footnote-124)

As Jaffe and Lerner highlight in the above quote, the 1980s brought dramatic changes in the US driven by concerns about international competitiveness: the Bayh-Dole Act was not the only legal development which influenced the growth of university patenting at this time.[[125]](#footnote-125) Another was the Supreme Court’s decision in Diamond v Chakrabarty in 1980 which expanded patentable subject matter (see section 5.4.1 for further discussion). Yet another was the introduction of the Court of Appeals of the Federal Circuit (CAFC) in 1982. The CAFC was a “strong champion of patent holder rights”; the decisions of the court encouraged patent applications by extending and increasing the rights of patent holders.[[126]](#footnote-126) This took place in three main ways: the court decisions supported the extension of patentable subject matter; it became easier to gain a patent; and the court made it easier to enforce granted patents.[[127]](#footnote-127)

Jaffe and Lerner point to a further development in the US in the 1990s which made it easier to obtain a patent: the US Patent and Trademark Office (USPTO) moved from being a tax-funded agency to one funded by fees, meaning that the office was motivated to grant patents in order to be self-sufficient.[[128]](#footnote-128) They argue that the creation of the CAFC and the changes in USPTO administration distorted the balance between parties involved in the patent system, favouring patent holders over the concept of social benefit as per the patent social contract, and that this problem is “especially extreme in technologies that are believed to be key to current economic development, including electronics, software, and biotechnology.”[[129]](#footnote-129)

### Perceptions of the ‘post- Bayh-Dole’ period

Since the passing of the Bayh-Dole Act the number of patents granted to universities and the number of licenses over these patents has risen sharply; the number of university-industry collaborations dramatically increased; and there has been an increase in the number of university spin-out companies.[[130]](#footnote-130) In these ways, the Act has been perceived as a success in terms of its original aims. However, a number of concerns have been raised regarding these increases. For example, there are concerns about the effects of patenting early stage technologies on the undertaking of downstream research (see discussion in sections 5.4 and 5.5) and the effects on the provision and pricing of products, particularly in the healthcare field.[[131]](#footnote-131) Further, even against the claims regarding the increase in the number of university patents, it is naïve to claim the situation is exclusively positive. For example, there is evidence indicating that few university-owned IPRs create substantial income, if any at all.[[132]](#footnote-132) In addition, it has been argued that the ‘quality’ of patents from US universities declined after the Bayh-Dole Act.[[133]](#footnote-133)

Despite the mixed reviews, the Bayh-Dole Act has often been viewed as a positive example of how countries can encourage universities to successfully commercialise their research. In an attempt to emulate the apparent ‘successes’ of the US in this arena many countries have created their own versions of the Bayh-Dole Act.[[134]](#footnote-134) However, such comparisons are problematic. As the historical analysis has shown, a number of factors and initiatives have played a part including the increasing importance of biotechnology in innovation.[[135]](#footnote-135) In this way, a number of scholars have argued that it is not possible to assign the apparent successes of the US experience to the Bayh-Dole Act alone[[136]](#footnote-136) and also that the data used to attribute success to the Act lacks transparency.[[137]](#footnote-137) As argued in a recent report by the OECD, an additional problem for comparison between the successes of knowledge commercialisation policies in different regions is the limited comparable data available. This may put an unjust focus on patent data which is relatively easy to gather and compare.[[138]](#footnote-138)Accordingly, those wishing to learn from the US must recognise the fact that much of the patenting activity that appears to have grown in the wake of the Bayh-Dole Act is the result of multifactorial drivers, not the Bayh-Dole Act alone, and the US model cannot be easily mapped or compared with other policies. Consequently Pavvitt argues that the US model should: “be used only very sparingly. Consult local practising scientists and users beforehand”*.*[[139]](#footnote-139)

### US Conclusions

It has shown that the growth in patenting in US universities since WWII has been the product of a number of factors and a complex history. The developments have included not only the Bayh-Dole Act but also the emergence of the field of biotechnology and patenting in the field following the Diamond v Chakrabarty decision; policies aimed at strengthening IP rights through the CAFC; and the changing model of the USPTO.

The US experience, while distinctive, is not unique in its aims. As mentioned at the beginning of this chapter, the increasing drive to patent and commercialise publicly funded research has spread becoming an almost global trend. The following section will trace the parallel developments in the EU, before Chapter 3 turns to the specific case of the UK.

## A history of science funding and science policy in the EU[[140]](#footnote-140)

Like in the US, where funding for research can come directly from Federal and State budgets, there are two main sources of public funding for research within Member States of the EU: national public funding (which will be examined specifically in the case of the UK in Chapter 3) and central funding from the EU. As such, both sources of funding shape the environment in which UK academic scientists, the subjects of the study, work. The following sections discuss the evolution of EU science policy and funding of science. First, the parts of the EU treaties regarding R&D will be examined. Then, the policies relating to EU funding and the major funding programmes of the EU will be discussed, noting the fluctuating emphasis on basic and applied research and the growing focus on public-private partnerships and IP.

### EU treaties relating to science and technology

Concerted policies to fund research contributing to set economic and social objectives began in the Founding Treaties of the 1950’s.[[141]](#footnote-141) These Treaties created the European Communities and aimed to increase economic cooperation between states. To help achieve this aim, coordinated, collaborative research policies were adopted. For example, the Common Agricultural Policy was adopted through the Treaty Establishing the Economic Community of 1957.[[142]](#footnote-142) Subsequent Treaties built on this collaborative approach to research policy.

Article 130 of the Single European Act (SEA) (1986) identified strengthening the scientific and technological base as a community objective.[[143]](#footnote-143) This was to be achieved by supporting both public and private entities to undertake R&D and encouraging collaboration between these institutions “to exploit the Community’s internal market potential to the full”[[144]](#footnote-144). In addition, the SEA specifically set as an objective of the Community the “stimulation of the training and mobility of researchers in the community”[[145]](#footnote-145) and set out an intention for further frameworks of funding[[146]](#footnote-146) which “may be adapted or supplemented, as the situation changes”.[[147]](#footnote-147) The latter allowed policy to determine and support research priorities in the short term in response to the evolving policy in between funding rounds.

The Treaty of the European Union (1992), commonly known as the Maastricht Treaty, allowed almost any area of science and technology ‘deemed necessary’ to promote competitiveness to be funded:

“The Community shall have the objective of strengthening the scientific and technological bases of Community industry and encouraging it to become more competitive at international level, ***while promoting all the research activities deemed necessary by virtue of other Chapters of this Treaty***.”[[148]](#footnote-148)

(Emphasis added to text not present in the equivalent article of the SEA)

This inclusion meant that funding would no longer be limited to agriculture, ‘industry’ and applied technology (as per the earlier treaties): subsequent funding could support a wider range of fields and institutions, reflective of the developing needs of promoting the community within the global economy.

The most recent treaty, the Treaty on the Functioning of the European Union (TFEU) (2007), also known as the Lisbon Treaty, covers R&D under Articles 179-190 and provides terms for regular Framework Programmes under Articles 182-186. Article 179 is an evolution of Article 130 of the Treaty of the European Union above:

“The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties.”[[149]](#footnote-149)

Until the Lisbon Treaty, the language relating to research policy within the Treaties focused largely on promoting industrial, applied R&D. The broadening of this to ‘including in its industry’ expanded the remit of support to include basic scientific research.

### The Framework Programmes

Based on the developing principles contained in the treaties, the public funding of research in the EU has been shaped by policies detailed in the Framework Programmes (FPs). Since being launched in 1983 (preceding the SEA, Maastricht and Lisbon Treaties), the FPs have been the major central funding initiatives of the EU. Each FP runs for a number of years with seven programmes completed to date (FP1-7) and an eighth, Horizon 2020, launched in 2014. Since their inception, the overall aims of FPs have remained largely the same as defined in the resolution for the first programme:

“Community action can be justified where it presents advantages (added value) in the short, medium or long term from the point of view of efficiency and financing or from the scientific and technical point of view as compared with national activities.”[[150]](#footnote-150)

Each FP has funded a range of activities which have supported projects in small and medium-sized enterprises, research centres and universities[[151]](#footnote-151) but as will be shown, the agendas of the FPs have evolved in four significant ways:

1. Extension of funding from applied science and technology to include earmarked funds in support of basic science;
2. Intensification of policies promoting public-private-partnerships;
3. Increasing focus on IP and
4. Substantial increases in funding[[152]](#footnote-152)

These developments are subsequently discussed through a historical overview of the programmes.

### The early framework programmes: funding of agriculture and high technology

The adoption of the first Programme, FP1, was announced in a Council Resolution in 1983 with the aim of defining a community-wide strategy for science and technology.[[153]](#footnote-153) The potential benefits of multinational cooperation to promote efficiency and competitiveness of research efforts were noted at this time, particularly in relation to industry and agriculture (in line with the Founding Treaties). [[154]](#footnote-154)The Second Framework Programme, FP2, was launched in 1987.[[155]](#footnote-155) In line with the SEA’s aim to “strengthen the scientific and technological basis of European industry” the technical objectives of FP2 focused on industrial modernisation and funding highly technological sectors of Community industry such as information technology.[[156]](#footnote-156) In 1990, the Third Framework Programme (FP3) was announced.[[157]](#footnote-157) The objectives of FP3 were largely akin to those of FP2,[[158]](#footnote-158) again focusing on highly technological industries. However, in addition FP3 included funding for a non-technical aspect of R&D: the “management of intellectual resources: … human capital and mobility”[[159]](#footnote-159) to “make optimum use of their [Member States] scientific and technical infrastructure, paving the way for a genuinely European scientific and technical community.”[[160]](#footnote-160) This was to be achieved through increased training and mobility of research staff and building networks: “introducing a European dimension into the training of scientific research and technological development staff”[[161]](#footnote-161) – again in line with the SEA.[[162]](#footnote-162) This reflected a growing an interest in expanding the remit of funding to cover more than industrial, applied R&D, an interest which grew during the subsequent FPs.

### Expanding funding to other areas of R&D: the Fourth and Fifth Framework Programmes

The Fourth Framework Programme, FP4, was announced in 1994 and was the first FP following the adoption of the Maastricht Treaty in 1992. In line with Maastricht, which aimed to promote all research ‘deemed necessary’, FP4 covered a wider range of activities than previous programmes. For example, in addition to high technology industries (similar to those in FP2 and FP3), FP4 also covered activities including transport and socio-economic research[[163]](#footnote-163) and ‘demonstration projects’, the aim of which was “to prove the technical viability of a new technology”[[164]](#footnote-164). The latter type of activity allowed more scope for supporting basic scientific research than previous programmes. The Fifth Framework Programme, FP5, announced in 1998, [[165]](#footnote-165) largely built on the objectives of FP4, supporting a wide range of R&D.

### The knowledge based economy, basic research and the European Research Area

In January 2000, noting that Europe was lagging behind its competitor, notably the US and Japan (particularly in terms of investment in research as a percentage of gross domestic product (GDP)), the European Commission proposed the creation of a European Research Area (ERA)[[166]](#footnote-166). Within the proposal for the ERA, the Commission noted the importance of science in the future of the EU and argued that research funding needed to change or “Europe might not successfully achieve the transition to a knowledge-based economy.”[[167]](#footnote-167)

The ERA was proposed as an attempt to combat the fragmentation between research efforts of Member States. This was explicitly mentioned in relation to the public funding of research[[168]](#footnote-168) and the importance of funding basic research was noted:

“Basic research is now carried out in various institutional frameworks: universities, research institutes, companies and consortia of each. In some cases it can be translated fairly rapidly into concrete applications. This has been the case, for example, with breakthroughs in molecular biology and immunology in the field of health. It can also give rise to unexpected applications years later in fields somewhat removed from the ones they started out in … Europe would be quite wrong to reduce its investment in this area.”[[169]](#footnote-169)

The Lisbon Strategy, the result of the Lisbon European Council of March 2000 which endorsed the creation of the ERA, set the objective of making the EU:

"[T]he most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion"[[170]](#footnote-170)

In 2002, the Barcelona Europe Council stated that the EU was still lagging behind its competitors in terms of R&D efforts. To combat this, and help achieve the goals of the Lisbon Strategy, the Barcelona Council aimed to increase spending on R&D from 1.9% to 3% of GDP by 2010, with two-thirds of the increase expected to come from the private sector.[[171]](#footnote-171) As part of these efforts, measures to increase private investment in R&D were to be put into place including the earmarking of specific funds for public-private partnerships.[[172]](#footnote-172)

One such measure was the creation of the European Institute of Innovation and Technology (EIT) which was launched in 2008[[173]](#footnote-173) to:

“[C]ontribute to sustainable European economic growth and competitiveness by reinforcing the innovation capacity of the Member States and the Community.”[[174]](#footnote-174)

To achieve this, the EIT aimed to physically bring together previously fragmented research and higher education systems in ‘knowledge ecosystems’ to support the translation of research results into commercial opportunities. The EIT became operational in 2010 and, while it does not directly fund research projects, it funds the establishment of Knowledge and Innovation Communities (KICs): long-term collaborations between HEIs, research organisations (public or private), businesses and other stakeholders.[[175]](#footnote-175)

### Controversy over the funding of stem cell research in the Sixth Framework Programme

Whilst FP4 and FP5 did not exclude research involving embryos, the position regarding the funding of embryonic stem cell research under the programmes was unclear.[[176]](#footnote-176) Notwithstanding this, projects involving stem cell research were funded during these programmes.[[177]](#footnote-177) In the run up to launch of the Sixth Framework Programme (FP6), the funding of research involving embryonic stem cells, particularly hESCs, was the subject of considerable controversy.[[178]](#footnote-178) In the adoption of FP6 in 2002, it was determined that research projects involving the use of supernumerary human embryos and hESCs could be financed subject to ethical and regulatory review.[[179]](#footnote-179) Further, the following could not be financed:

“Research activity aimed at human cloning for reproductive purposes, research activity invented to modify the genetic heritage of human beings … [and] research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement”[[180]](#footnote-180)

Debate continued, but, in 2004, the third call for proposals for projects to be funded under FP6 Priority 1: Life Sciences, Genomics and Biotechnology for Health included a variety of projects explicitly involving the use of embryos and hESCs.[[181]](#footnote-181) It has been estimated that during FP6, €500 million funded 151 such projects.[[182]](#footnote-182) 77 of these included participants from the UK, of which 16 were co-ordinated by UK researchers and include ESTOOLS and EuroStemCell each of which each received approximately €12 million under FP6.[[183]](#footnote-183)

### Supporting basic research and public-private partnerships: the Sixth and Seventh Framework Programmes and the European Research Council

FP6 was announced in 2002 to “contribute to the creation of the European Research Area and to innovation.”[[184]](#footnote-184) In line with the ERA proposals, it was stated that the FP6 would support:

“[T]he full spectrum from basic to applied research, to the development of scientific and technical excellence and to the coordination of European research.”[[185]](#footnote-185)

While the priorities of the programme were similar to previous FPs, the language used was markedly different, including terms such as ‘knowledge economy’,[[186]](#footnote-186) ‘European Research Area’,[[187]](#footnote-187) ‘translational’ research[[188]](#footnote-188) and ‘innovation’[[189]](#footnote-189) in line with terms of the Lisbon Strategy. The same terms were also used in the documents regarding FP7, which was announced in 2006.[[190]](#footnote-190) Following from the aim of FP6 to support a ‘spectrum’ of research, a number of changes took place under FP7. These included structured programmes for public-private partnerships[[191]](#footnote-191) and specific funding for investigator-driven basic research.

In line with the aims of the Lisbon Strategy to increase private investment in research in the EU, and the subsequent creation of the EIT, there have been a series of public-private-partnerships under FP6 and FP7: European Technology Platforms[[192]](#footnote-192) (ETPs), Public-Private Partnerships[[193]](#footnote-193) (PPPs) and Joint Technology Initiatives[[194]](#footnote-194) (JTIs). Each programme has aimed to encourage interaction between public and private actors but only PPPs and JTIs merge public and private funding sources. These types of earmarked funds encourage institutions, such as universities, to undertake user-driven research in order to secure research funds.

JTIs were first introduced in 2008 under FP7 and are set up under Article 187 TFEU.[[195]](#footnote-195) JTIs are long term public-private partnerships which follow from the ETPs of FP6, but unlike ETPs, JTIs can be funded by Framework funding.[[196]](#footnote-196) One JTI established under FP7 is the Innovative Medicines Initiative (IMI) (under FP6 this was the ETP on Innovative Medicines). The IMI is a partnership between the EU, through FP7 funding, and the pharmaceutical industry, through the European Federation of Pharmaceutical Industries and Associations. Both parties contribute €1 billion, making it Europe’s largest public-private partnership.[[197]](#footnote-197) IMI promotes collaborations between industry and academia to encourage pharmaceutical R&D in Europe.[[198]](#footnote-198)

The growth of public-private partnerships demonstrates a move towards encouraging increased collaboration between universities and businesses, the perceived importance of which was explicitly stated in a Commission Communication in 2009:

“The 7th Framework Programme is adapting to help the EU meet its goals of creating a low carbon, knowledge-based society. It seeks to increase its leverage effect on public and private R&D investment and to diversify its instruments in order to maximise European added value. FP7 remains a crucial instrument to promote scientific excellence and technological development, responding to EU policy priorities and the needs of industry and society. The current adverse economic context underlines its importance even more. FP7 contributes to sustained research efforts, both private and public, as exemplified in the public private partnership initiatives”[[199]](#footnote-199)

In addition to the increased focus on public-private partnerships in recent FPs, specific funding has been assigned for basic research at the European level heightening interest in the economic returns of university-based research. Following the broadening of EU funding of research under the Lisbon Treaty to specifically include projects outside of industry and efforts to create an ERA,[[200]](#footnote-200) the European Research Council (ERC) was launched in 2007 to administer funding for basic research.[[201]](#footnote-201) This launch followed several years of growing support in the EU organs for increasing basic research funding.[[202]](#footnote-202) The ERC began under the FP7 ‘Ideas’ programme with a budget of €7.5 billion (15% of the total FP7 budget).[[203]](#footnote-203) The ERC supports ‘frontier research’[[204]](#footnote-204) through an investigator-driven, competitive funding structure to encourage …

“… researchers to identify new opportunities and directions for research, rather than being led by priorities set by politicians. This approach ensures that funds are channelled into new and promising areas of research with a greater degree of flexibility.”[[205]](#footnote-205)

### Europe 2020 and the Innovation Union

In response to the global financial crisis of 2008 and the end of the Lisbon Strategy, the European Commission released a communication in 2010 entitled “Europe 2020: A strategy for smart, sustainable and inclusive growth”[[206]](#footnote-206). This defined targets for the next decade and provided strategies to achieve them. In the document, the Commission proposed a target investment in R&D of 3% of EU GDP by 2020[[207]](#footnote-207) – the same aim as the Lisbon Council asserted to have achieved by 2010[[208]](#footnote-208) – noting that Europe was still investing a lower proportion of GDP than the US and Japan, particularly with regard to private investment.[[209]](#footnote-209) As in the Lisbon Agenda, the importance of increasing private investment was noted:

“Europe needs to focus on the impact and composition of research spending and to improve the conditions for private sector R&D in the EU”.[[210]](#footnote-210)

The Europe 2020 document also proposed a flagship initiative called ‘Innovation Union’, the aim of which was …

“… to re-focus R&D and innovation policy on the challenges facing our society, such as climate change, energy and resource efficiency, health and demographic change. Every link should be strengthened in the innovation chain, from 'blue sky' research to commercialisation.”[[211]](#footnote-211)

To achieve this ‘Innovation Union’, the Commission proposed a number of actions to improve research and innovation performance, many aimed at harnessing private investment in R&D. These actions included to: complete the ERA; improve conditions for business to innovate; introduce ‘European Innovation Partnerships’ (public-private partnerships) including ‘building the bio-economy by 2020’; improve EU instruments which support innovation (including the Framework Programmes); and promote collaboration between education, business, research and innovation (e.g. through the EIT, PPPs, JTIs and ETPs).[[212]](#footnote-212)

### Horizon 2020

The latest FP ‘Horizon 2020’ launched in 2014. Horizon 2020 is the first FP to follow the TFEU and the financial crisis. Accordingly, it is unsurprising that the programme differs from its predecessors. In its planning, the European Commission detailed how Horizon 2020 would be a ‘break from the past’, combining for the first time existing strategies for framework funding, the Competitiveness and Innovation Framework Programme[[213]](#footnote-213) and EIT activities.[[214]](#footnote-214) In addition, the Commission stated that the programme would have ‘key novelties’ including that its architecture will be simpler than previous programmes and new models of funding would be announced, with less ‘red tape’ and “the integration of research and innovation by providing seamless and coherent funding from idea to market”.[[215]](#footnote-215)

In December 2013, Horizon 2020 was established in a European Parliament and Council Regulation.[[216]](#footnote-216) The Regulation details the context for the programme, including the perceived importance of investing in research and innovation following the financial crisis[[217]](#footnote-217) and, in line with Article 179 of the TFEU, the Regulation provides that the programme will aim to “strengthen its scientific and technological base”.[[218]](#footnote-218) The objectives are also complementary to other policies:

“The general objective of Horizon 2020 is to contribute to building a society and an economy based on knowledge and innovation across the Union by leveraging additional research, development and innovation funding and by contributing to attaining research and development targets, including the target of 3 % of GDP for research and development across the Union by 2020. It shall thereby support the implementation of the Europe 2020 strategy and other Union policies, as well as the achievement and functioning of the European Research Area (ERA).”[[219]](#footnote-219)

Horizon 2020 will focus on three priorities: 1. Excellent science; 2. Industrial leadership and 3. Societal challenges.[[220]](#footnote-220) The first of these, Excellent Science …

“… aims to reinforce and extend the excellence of the Union's science base and to consolidate the ERA in order to make the Union's research and innovation system more competitive on a global scale.”[[221]](#footnote-221)

To achieve this, the programme will support bottom-up activities including the funding of ‘frontier’ research through the ERC, and funding collaborative research in ‘future and emerging technologies’ to establish new fields of research and innovation.[[222]](#footnote-222) The ‘Industrial leadership’ priority “aims to speed up development of the technologies and innovations that will underpin tomorrow’s business” by providing support for R&D in specific areas including biotechnology and improving access to ‘risk finance’ to help overcome the deficit in venture capital funding following the financial crisis.[[223]](#footnote-223) The final priority, ‘Societal challenges’ indicates that funding will be ‘focused’ on specific objectives, including health and well-being.[[224]](#footnote-224) A number of funding models will be used to support these priorities including a wide variety of public-private partnerships.[[225]](#footnote-225)

### IP management under the Framework Programmes

As mentioned in the introduction to the EU section of this chapter, there has been an increased focus on IP arising from research funded through the FPs since their inception. There has been some unified guidance about the management of IPRs created in projects funded by the FPs since the first European Commission Model Contract (ECMC) was introduced during FP2 in 1988.[[226]](#footnote-226) Since then, this has expanded and evolved into increasingly detailed, lengthy guidance on the management of IPRs. Under FP7 the guide regarding IPRs is 50 pages long,[[227]](#footnote-227) twice that of the equivalent FP6 guide.[[228]](#footnote-228) In addition, support for those involved in the creation and management of IP under the FPs has also increased. In 1998, the Commission, noting the relevance of IP to research, set up an Intellectual Property Rights Helpdesk to assist researchers funded under the FPs on IP-related issues.[[229]](#footnote-229)

In addition to the specific guidance for research undertaken with framework funding, clarification has been issued for the wider research community of the EU. The European Commission issued a recommendation in 2008 ‘on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations’[[230]](#footnote-230) as part of its effort to create the ‘fifth freedom’: the free circulation of knowledge. The document stated:

“An effort should be made to better convert knowledge into socio-economic benefits. Therefore, public research organisations need to disseminate and to more effectively exploit publicly-funded research results with a view to translating them into new products and services.”[[231]](#footnote-231)

Additionally, Member States were recommended to …

“Encourage public research organisations to establish and publicise policies and procedures for the management of intellectual property … [and] support the development of knowledge transfer capacity and skills in public research organisations, as well as measure to raise the awareness and skills of students – in particular in the area of science and technology – regarding intellectual property, knowledge transfer and entrepreneurship”[[232]](#footnote-232)

The Recommendation continued to provide principles for IP policies in publicly funded organisations which include to:

“Raise awarenessand basic skills regarding intellectual property and knowledge transfer through training actions for students as well as research staff, and ensure that the staff responsible for the management of IP/KT [knowledge transfer] have the required skills and receive adequate training.”[[233]](#footnote-233)

While uptake of these recommendations are voluntary, they are indicative of the growing perceived need to support the exploitation of the products of publicly funded research and a top-down pressure to develop bottom-up policies to achieve this including institutional guidelines and education of both IP managers and scientists themselves.

### EU conclusions

This section has shown that EU science policy predates the institution of the Union. Articles regarding R&D have been preserved in all major treaties since the Founding Treaties. These articles have evolved to include an increasing range of research areas, developing beyond agriculture and industry to support the funding of basic research. In addition, there has been a persistent emphasis on maximising the benefits of being a Union – of increasing collaboration amongst Member States to improve the Union’s position within a competitive global climate. This emphasis has been renewed in recent years with the aim of creating the ERA. The agendas of the FPs have evolved to reflect these legal developments and policies. This has been driven by increasing calls for supporting public-private partnerships and the development of increasingly detailed guidance on the management of IP arising from FP-funded projects. As a result, institutions and researchers in EU Member States are increasingly expected to pursue commercial efforts, including patenting.

## Conclusions

A review of the historical evolution of the funding of science in both the US and the EU has been made.  It has been shown that in both regions multi-faceted, multi-level and multi-actor drivers led to the adoption of a variety of legal instruments and policies aimed at enhancing the commercialisation of basic research in universities and the development of patenting policies in these institutions. This chapter has provided an international background which contextualises the study. As well as the EU’s clear influence on the UK (and funding of a significant number of stem cell research projects undertaken in the UK), the US is a major competitor of the UK in terms of scientific R&D. The histories provided will be shown to have shaped the basis of modern science policy in the UK, as discussed in the subsequent chapter.

Chapter 3

Science funding and science policies: the UK historical context

## Introduction

In parallel with those developments described regarding the US and the EU, national science policy in the UK has become increasingly focused on encouraging the commercialisation and patenting of basic research undertaken in universities. This chapter will show that, as in the international cases, this has been driven by a variety of factors. These include: changes in government structures and departments; the reorganisation of the research funding councils and their missions; an intensification of policies calling for increased interaction between universities and the private sector; changing conditions of public funding; the developing assessments of research ‘quality’ and an increased focus on protecting and managing IP in universities. Together, these have driven an expectation that publicly funded research in the UK will provide a (relatively short term) return on investment, pushing universities to incorporate this into their overall management and research practice. This has altered the perceived role of research, universities and researchers:

“The role of universities and academics is widely seen to be changing. With governments and other players investing significant sums in research and tertiary education, this brings great implications for the redesign of research and development institutions. Universities often argued by scientists themselves to be institutions that should primarily be aimed at hosting free enquiry and the pursuit of knowledge, or spaces of reflection, have increasingly been looked to as some of the main sources of innovation and inputs into wealth creation – they are now ‘places of expectation’”[[234]](#footnote-234)

As with the previous one, this chapter will trace chronologically the changes in UK science policy and funding alongside the drivers for change, clustering together some of the changes into themes for ease of discussion. For example, the changes in government structure in the period 2007-2009 are dealt with together as are the developing accountability measures for funding from the higher education research councils.

### The Haldane Report (1918)

The origins of modern science policy in the UK can be traced to the Haldane Report of 1918.[[235]](#footnote-235) The Haldane Report followed WWI, during which national research funding had been focused very heavily on the war effort, directed at developing applications for use in the war. Lord Haldane’s report suggested that the government’s strategic departmental funding (e.g. funding for defence) be made distinct from ‘general’ research, separating the administration of non-strategic scientific research from the executive functions of the government.[[236]](#footnote-236) This general research was to be funded and administered through advisory councils (known today as the research councils), overseen by a Minister but at an arm’s length from the government. Scientists were to define the role of science and shape future research by determining what research should be funded, including considering the economic aspects of research.[[237]](#footnote-237)

This separation of funding administration became known as the ‘Haldane Principle’ and was a central pillar of the Labour Government’s science policy in the 1960s.[[238]](#footnote-238) While there is no clear definition of the principle, the term is used to describe the notion highlighted in the Haldane Report that decisions about the spending of research funds should be made by researchers rather than politicians: science as autonomous from politics and public policy.[[239]](#footnote-239)

## British research policy following WWII – capturing the results of R&D

Britain invested heavily in R&D during WWII, particularly through the Defence Research Establishments.[[240]](#footnote-240) As in WWI, wartime research efforts were concentrated on specific objectives, accelerating the application of research results. The post-war question was how this could be maintained.[[241]](#footnote-241)

### The National Research Development Corporation

As in the US, in the aftermath of WWII, concerns were raised in the UK that large amounts of money were being spent on R&D with little evident application or financial return. One result of this was the establishment of the National Research Development Corporation (NRDC).

Although government departments were active in applying the results of research undertaken ‘in house’ after WWII, it was not clear how other publicly funded research was to be utilised.[[242]](#footnote-242) This prompted a number of formal discussions in 1947 between the Treasury, Board of Trade, and the Department of Scientific and Industrial Research, resulting in the creation of the National Research Trust Committee.[[243]](#footnote-243) The debates between these groups focused on the concept that public-funding support for the exploitation of inventions was justifiable if it contributed to national social and economic goals.[[244]](#footnote-244) In 1947, the Committee recommended that an organisation be set up to control inventions created through public funds and promote their commercial application.[[245]](#footnote-245) The resultant organisation, the NRDC, was established in 1948 by the Board of Trade through the Development of Inventions Act (1948).[[246]](#footnote-246) The NRDC’s functions were to commercialise innovations from publicly funded research undertaken in government research centres and universities by securing patents and licensing them to industry “where the public interest so requires".[[247]](#footnote-247) With post-war Britain working hard to remain competitive in the global economy, this ‘public interest’ was largely interpreted to mean national economic interest.[[248]](#footnote-248) In 1950, the NRDC was given first right of refusal to IP resulting from publicly funded research resulting in an effective monopoly of control of this IP.[[249]](#footnote-249) This marked a move towards the centralised control of IP from publicly funded research to support national economic policy. This can be seen as a parallel to the automatic ownership of IP by Federal Funding Agencies in the US from the 1950s-1970s (see section 2.2.2), paving the way for a story mirroring that of the pre-Bayh-Dole Act period in the US.

### The Science and Technology Act (1965)

As previously mentioned the ‘Haldane Principle’ became a pillar of science policy in the 1960s. The Principle was central to the Science and Technology Act (1965), passed under a Labour administration. This Act established the research councils and remains the main statute governing the councils today.[[250]](#footnote-250) The research councils were to be the administrators of general research (i.e. non-strategic) funding and policy, working under the relevant Secretaries of State.[[251]](#footnote-251) Under this Act, the Secretaries of State were (and remain) able to shape the work of the councils and influence their spending by highlighting priorities in line with contemporary national policy.[[252]](#footnote-252) Whilst the administration of general research funding fell outside of central government departments, instead under the control of researchers, the strategic priorities for science and technology remained under government control.

The Act in part recovered the autonomy of research from politics and public policy following WWII where research funds were focused on supporting specific national war efforts, much like the aims of the Haldane Report following WWI. However, there was a slight but significant difference from the vein of the Haldane Report in the Act: while the research councils were able to administer the funding they received from government on the basis of peer review, thereby allowing researchers some decision-making power regarding the spending of public funding, the government determined funding priorities allowing it to effectively ‘earmark’ funds in line with contemporaneous national policy.

### The Rothschild Report (1971): a turning point for science funding

The Rothschild Report of 1971, commissioned by the Conservative Government in which Margaret Thatcher was the Minister in charge of the science budget, began a shift in science funding away from the Haldane Principle. The Green Paper report, entitled ‘Organisation and Management of government R&D’ stated: “The concepts of scientific independence used in the Haldane Report are not relevant to contemporary discussion of government research.”[[253]](#footnote-253) Rothschild argued that scientists could not be trusted with decisions of national science policy and that applied science should be carried out on a ‘customer-contractor’ basis with basic research aimed at supporting clear applied potential:

“[It is] also sometimes said, in justification of basic research, that chance observations made during such work, and their subsequent study may be just as important as those made during applied research and development. While there is some truth in this contention, the country’s needs are not so trivial as to be left to the mercies of a form of scientific roulette”[[254]](#footnote-254) … “However distinguished, intelligent and practical scientists may be, they cannot be so well qualified to decide what the needs of the nation are, and their priorities, as those responsible for assuring that those needs are met. This is why applied R & D must have a customer."**[[255]](#footnote-255)**

In the case of publicly funded research, the government, through its departments was to be this customer and the research councils were to be the contractors. Shergold and Grant note that the report essentially required that money previously awarded to the research councils (to be spent as they saw fit) now had to be won as contracts from government departments who determined the aims of the research.[[256]](#footnote-256) The Report reoriented science funding toward applied research and redefined the role and autonomy of the research councils. The model also brought with it greater scrutiny of the work of scientist’s by their funders, with scientists having to increasingly justify their demands on public resources.

The Report was widely debated, with the Government receiving over 400 documents about the report and a related debate took place in the House of Lords.[[257]](#footnote-257) Richard Jones writes that the suggestions of the report “were strongly resisted by the Royal Society and many senior scientists as amounting to an unwarranted infringement of the autonomy of science by politicians”[[258]](#footnote-258). He also points to the fact that Margaret Thatcher’s commercial experience of science left her “particularly resistant” to ideas that science should have special status outside of the market, that “her adoption of the principle that science, too, could be marketised, should not be a surprise.”[[259]](#footnote-259) Despite discontent among the scientific community, in 1972 a White Paper[[260]](#footnote-260) was published emphasising the arguments in the Rothschild Report for adopting the ‘customer-contractor principle’ in government funded R&D. Thus, the model set out in the Rothschild Report was employed by the Conservative Government led by Margaret Thatcher and used to effect the ‘marketisation’ of science.[[261]](#footnote-261)

## The 1980s – University ownership of IP, systematic assessment of research and the dawn of university spin-out companies

The Rothschild Report set out a framework which promoted an increased use of research contracting between the public and private sectors. In his analysis of Thatcher’s science policy, Jon Agar argues that the Rothschild Report was not only the basis of the marketisation of science but also contributed to her attempts to marketise other areas.[[262]](#footnote-262) The concept was based on the 3E’s: economy, efficiency and effectiveness.[[263]](#footnote-263)

The reduction of public-budgets for science through the 1980s meant that money had to come from somewhere if national R&D was to continue at the same level. [[264]](#footnote-264) The answer was to be the private sector. In order to encourage private sector investment in R&D a similar story to that of the US in the 1970s played out.[[265]](#footnote-265) During the 1980s, in addition to the developing national marketisation of science, the management of university patents changed drastically; research funded with public money faced increased scrutiny though formal assessment; and universities were encouraged to start launching businesses based on their research. Despite the reduction in public funds for R&D, the political influence over the undertaking of publicly funded research was greater than ever by the end of the 1980’s. Following the Science and Technology Select Committee’s report onCivil R&D in 1989, it is claimed that the government:

“… placed strategic priorities for research under the consideration of Ministers and the PM during the public expenditure round; set up the Science and Technology Assessment Office within the Cabinet Office and established clear objectives for expenditure and developed systematic criteria for assessing and managing research; and asked research bodies to consider the national benefits of their work, including the economic impact and commercial exploitation of their work.”[[266]](#footnote-266)

### The British Technology Group

The policy of marketising science, which began with the Rothschild Report creating a framework favouring an increased role for industry in science, was further facilitated by the merging of NRDC with the National Enterprise Board (set up in 1975 to support technological initiatives[[267]](#footnote-267)), forming the British Technology Group (BTG) in 1981.[[268]](#footnote-268)

In line with the aims of the NRDC, BTG was tasked to promote the development and application of new technology and retained the monopoly over patents from publicly funded research, previously held by the NRDC.[[269]](#footnote-269) However, in 1985, in the footsteps of the Bayh-Dole Act of 1980 in the US, the monopoly was ended to incentivise universities and individual researchers to play more of a proactive role in patenting and exploiting their inventions. Because the original monopoly held by the NRDC over patents was provided through a Treasury Circular, a non-statutory mechanism, it was possible to rescind the monopoly from BTG without parliamentary consultation or legislative change. Sir Keith Joseph, the then Secretary of State for Education and Science, announced to the House of Commons:

“The government's overall aims in the new arrangements are to increase the exploitation of research funded by the councils, for the maximum benefit of the United Kingdom economy; to strengthen and improve exploitation, through freer competition between exploiting agencies in the public and private sectors and in other ways; therefore, to place responsibility and initiative for exploitation as fully as possible on researchers, their institutions and the councils, consistent with their legal responsibilities; and to increase the incentive for researchers and their establishments by enabling them and the work that they do to benefit from increased exploitation.”[[270]](#footnote-270)

Under these new arrangements, the IPRs created from publicly funded research were no longer automatically assigned to BTG: they could be owned by researchers and universities, providing they could assure the research councils they could manage the related rights.[[271]](#footnote-271) In addition, researchers and universities were actively ‘incentivised’ to exploit their research by promising them benefits from such activities. This prompted the creation of technology transfer offices (TTOs) within some universities and ‘spin-out’ companies began to appear. [[272]](#footnote-272) The first spin-out company from a UK university was Oxford Molecular Ltd, founded in 1989[[273]](#footnote-273) and the number of such companies has grown ever since.[[274]](#footnote-274)

Despite this attempt to encourage universities to manage their own IP, by 1991 few universities had opted to use the opportunity to manage their own patents with many opting to continue to use BTG[[275]](#footnote-275) (just like in the US with the Research Corporation pre-Bayh-Dole). The move to rescind BTG’s monopoly in 1985 had not been as successful as hoped in encouraging universities to manage their own IP and it was decided that further developments were needed to achieve this aim. One approach was the privatisation of BTG. During a debate in the House of Lords in 1991 it was argued that BTG should “take its place in the private sector where we think it belongs” as it was using a successful commercial approach which was being limited because it was a public sector company.[[276]](#footnote-276) Further, it was no longer fulfilling its “primary task of translating new research ideas into commercial products”.[[277]](#footnote-277) Consequently, the British Technology Group Act was enacted in 1991; BTG became a company whose sole shareholder was the Treasury.[[278]](#footnote-278) The following year BTG was privatised following a management buyout from Government and in 1995 it was floated on the stock market.[[279]](#footnote-279) With BTG privatised, more UK universities opted to develop TTOs to manage their IP ‘in house’ (as in the US after the Bayh-Dole Act) and since then, universities have become increasingly pro-active in commercialising their research.[[280]](#footnote-280)

## The 1990s – improving economic competitiveness

The national science policy of the 1990s was part of the wider national and EU developments of the time aimed at increasing international competitiveness.[[281]](#footnote-281) In this decade, structural changes within government brought science and technology policy to the fore of public policy. In addition, through the development of specific funds, there was a continued encouragement of public-private partnerships and commercialisation of research in universities.

### A new Office and a Science Cabinet Minister

Following the general election of 1992, a Cabinet minister was appointed for the first time to oversee the government’s handling of science and technology policy and the Office of Science and Technology (OST) was established.[[282]](#footnote-282) The OST held responsibility for the UK’s science budget and the development of science policy. Over the following years the volume of science policy documents increased, with the release of a number of White Papers and the commission of several reviews of science and technology policy, often focusing on the contribution of research to the UK economy and international competitiveness.

### Realising Our Potential (1993)

In 1993, the government set out its intentions to improve the UK’s competitiveness through its science and technology base in the White Paper ‘Realising Our Potential’ reflecting “the widely perceived contrast between our [the UK’s] excellence in science and technology and our relative weakness in exploiting them to economic advantage”.[[283]](#footnote-283) The paper included a number of commitments including:

“[E]suring the efficiency and effectiveness of government-funded research” and “[D]eveloping stronger partnerships with the science and engineering communities, industry and the research charities”[[284]](#footnote-284)

The paper maintained the role of the private sector in developing products but noted that the current model was inadequate: there was a need to join up the private and public research sectors. Richard Jones argues that the paper:

“… set out an argument for government funding of science based on the classical notion of market failure – the failure of private-sector inventors to be able fully to capture the benefits of scientific advances.” [[285]](#footnote-285)

This apparent failure led to calls in the paper to encourage public-private collaboration and the research councils were asked to reduce barriers in the innovation process, encouraging a supply and demand model between the public and private sectors[[286]](#footnote-286); developing the principles of the Rothschild Report and increasing privatisation.[[287]](#footnote-287) Accordingly, Ben Martin argues this paper required the research councils to “ensure that the research they funded was more closely related to the needs of ‘users’ in industry and elsewhere.”[[288]](#footnote-288) This led a move toward greater collaboration between universities and industry and an increased scrutiny of the application potential of research.

### ‘Competitiveness’, the Higher Education Innovation Fund (HEIF) and the Public Sector Research Exploitation Fund (PSREF)

Despite the significant political change that followed 18 consecutive years of Conservative administrations, there was no major change in science policy on the election of a Labour Government in 1997.[[289]](#footnote-289) The 1993 Realising Our Potential White Paper was followed in 1998 by the ‘Competitiveness’ White Paper that made further commitments to improve the economic competitiveness of the UK through increased investment in research. The paper contained commitments to: “vigorously promote the commercialisation of university research – including new incentives for researchers to work with business…”[[290]](#footnote-290) and earmarked funds to support public-private partnerships. These ‘incentives’ included the creation of HEFCE’s ‘Higher Education Research Reach Out to Business and the Community’ fund in 1999 which led to the creation of the Higher Education Innovation Funding (HEIF) in 2001. The HEIF continues today with an annual budget of £150 million.[[291]](#footnote-291) The HEIF is publicly funded and is intended to incentivise knowledge exchange activities between the private sector and HEIs. Funding from the HEIF is awarded competitively, particularly rewarding the generation of income from research results.[[292]](#footnote-292) The fund can be viewed as a measure to incentivise the commercialisation of research in universities by financially supporting and rewarding such activities.

HEIs were not the only types of PROs targeted for reform following the 1998 Competitiveness White paper: all publicly funded research was under scrutiny. The government also commissioned a report to investigate the commercialisation in ‘public sector research establishments’ (PSREs[[293]](#footnote-293)) and make recommendations to increase successful commercialisation of research undertaken in these institutions.[[294]](#footnote-294) The resultant Baker Report (entitled “Creating Knowledge Creating Wealth: Realising the economic potential of public sector research establishments”[[295]](#footnote-295)) was released in 1999 and stated that:

“PSREs generate large bodies of knowledge predominately at the taxpayer’s expense, and there is a moral and economic imperative to ensure not only the advancement of knowledge but, where possible, the exploitation of that knowledge for the benefit of the nation.”[[296]](#footnote-296)

The Report argued that although PRSEs had economic potential, there were barriers to funding and implementing commercialisation and knowledge transfer activities, particularly noting the existence of a ‘development gap’ (often referred to as the ‘valley of death’) whereby early stage research was not being developed through to commercialisation due to lack of funding.[[297]](#footnote-297) The government’s response to the Baker Report announced the establishment of a fund, the Public Sector Research Exploitation Fund which was launched in 2001[[298]](#footnote-298) “to enable public sector research establishments to develop their capacity to exploit their science and technology potential”.[[299]](#footnote-299) In addition the Report noted that:

“[T]echnology transfer is most effectively pursued in those PSREs which see it as an explicit part of their mission and culture, and where it is enthusiastically led by senior management, and supported by the sponsor department or Research Council.”[[300]](#footnote-300)

This quote captures the concept which emerged in the removal of BTGs monopoly over patents in 1985 and developed in subsequent policy: that publicly funded research efforts should include technology transfer and IP management in their mission and that research councils should also encourage this.

## The 2000s – uniting innovation, business, science and education policy within the structure of government

Labour’s science policy in the 2000s attempted to unite innovation, business, science, and education policy. This was achieved by changing the structure and administration of government departments overseeing these issues, continuing to encourage public-private partnerships and further incentivising commercialisation in universities.

### The Lambert Review (2003)

Five years after the Competitiveness Report (1998) and the subsequent Baker Report (1999), the Treasury commissioned the Lambert Review of Business-University Collaboration. This Review aimed to investigate the existing knowledge transfer between universities and industry, and to consider how business-university interactions could be improved to better support the British economy:

“The context for the review was a sense that the UK performs well in terms of the academic quality of its science and technology base, but is not as good at commercialising the knowledge generated in its universities as some other countries – notably the USA.”[[301]](#footnote-301)

The Report concluded that while there is “much good collaborative work underway already, there is more to be done”[[302]](#footnote-302) and issued a number of recommendations to help improve the observed situation. The topics of IP and technology transfer featured heavily in the report and 6 recommendations were made in these areas.[[303]](#footnote-303) Of particular interest to this thesis, the reported stated there was …

“… a lack of clarity over the ownership of IP in research collaborations. This makes negotiations longer and more expensive than otherwise would be the case, and it sometimes prevents deals from being completed. The Review expresses concern that universities may be setting too high a price on their IP. Public funding for basic research, and for the development of technology transfer offices, is intended to benefit the economy as a whole rather than to create significant new sources of revenue for the universities. Even the most successful US universities tend to generate only small amounts of money from their third stream activities, and most acknowledge that their reason for engaging in technology transfer is to serve the public good.”[[304]](#footnote-304)

The value of university IP and its role in the innovation chain was challenged for the first time since the beginnings of the targeted promotion of developing and managing IPRs in universities.

### The Science and Innovation Framework 2004-2014

The basis of the last decade of public spending on science and technology was set out in Labour’s ‘Science and Innovation Framework 2004-2014’.[[305]](#footnote-305) In line with previous policy, the Framework documented a perceived need for the UK to support science R&D to in order produce economic impact and remain competitive in the developing global economy. Richard Jones suggests that the Framework is based on the same concepts as the 1993 White Paper, namely the market failure of the private sector to capture the benefits of scientific advances and to deliver innovation but, he argues, the Framework recognised the changing models of innovation toward ‘open innovation’ and private-public collaboration.[[306]](#footnote-306) In this way, the Framework is a progression of earlier policies which aimed at increasing private investment, intensifying calls for investment but recognising the particular value of collaboration between the private and public sectors. The Framework called for higher commercialisation of publicly funded research and more engagement and collaboration between public, private and non-profit organisations.[[307]](#footnote-307) To achieve its aims, the Framework proposed to increase investment in R&D by £1 billion during the review period[[308]](#footnote-308) and to increase the proportion of GDP spent on R&D from 1.9% to 2.5%[[309]](#footnote-309) (in line with the EU Lisbon Strategy). As a result, there was an increase in the funding of university science, reorienting research funding from applied to basic science, but also a reshaping of what basic research was: it was expected to function as the precursor for pre-determined applied research with clear economic potential rather than ‘curiosity driven research’.[[310]](#footnote-310)

The 2004 Framework also contained the Government’s response to the earlier Lambert Review.[[311]](#footnote-311) The response agreed with the findings of the Review and set out plans to address its recommendations. Several measures were confirmed in the Framework in response to the Lambert recommendations, including an increase in the HEIF to £110 million a year by 2007-8 to “further build the capacity in the university sector for knowledge transfer”.[[312]](#footnote-312) The Framework noted the continued perceived importance of university-business collaboration in realising the potential of the research base in the UK:

“Over the next ten years, it is critical that the levels of business engagement with the science base increase, to realise fully the economic potential of the outputs of our science base … the government will continue to put in place resources to encourage scientists and engineers to turn basic and strategic research into successful new products and services, and to engage more fully with business.”[[313]](#footnote-313)

Subsequently, the Lambert Working Group on IP was formed to clarify the issues surrounding the IP involved in university-business collaborations as identified in the Lambert Review. In 2008, the Group (working under the UK Intellectual Property Office (UKIPO)) produced model agreements for managing IP resulting from university-business collaborations.[[314]](#footnote-314)

### The Warry Report (2006)

Following the 2004 Framework which called for increased economic impact of publicly funded research, the Director General of Science and Innovation commissioned a report by Peter Warry, the then Chair of the Particle Physics and Astronomy Research Council, in 2006.[[315]](#footnote-315) The report, entitled ‘Increasing the economic output of the Research Councils’, issued the following recommendations:

* “Chairs of Research Councils should ensure that economic impact is given a high profile in Council strategy.”[[316]](#footnote-316)
* “The Research Councils should influence the behaviour of universities, research institutes and Funding Councils in ways that will increase the economic impact of Research Council funding.”[[317]](#footnote-317)
* “RCUK should engage Government, business and the public services in a wide-ranging dialogue to develop overarching, economically relevant ‘research missions.’ These missions should address major strategic challenges for the UK.”[[318]](#footnote-318)
* “Research Councils should make strenuous efforts to demonstrate more clearly the impact they already achieve from their investments.”[[319]](#footnote-319)

While these are not necessarily new principles (they are in line with the reshaping of the Research Councils following the Rothschild Report in the 1970s) it is worth noting that they are intensifications of earlier principles driving public-private collaboration and reflect a drive to influence the culture of universities and researchers. Following the report, Research Councils UK (RCUK) published an action plan entitled ‘Increasing the Economic Impact of the Research Councils’[[320]](#footnote-320) which indicated the councils would focus on building public-private partnerships through specific programmes and developing measures to assess economic potential of funding applications and funded programmes. This has been enforced through the requirement of funding applicants to specify the potential ‘impact’ of their research in their applications (see section 3.6 for more details).

### The Sainsbury Review and Innovation Nation (2007)

The agenda of the 2004-2014 Framework was reinforced by the Sainsbury Review of Science and Innovation: ‘A Race to the Top: A Review of government’s Science and Innovation Policies’. The Review suggested that in order to continue to compete strongly in the global economy, the UK needed to focus on higher-level skills and a strong science and research base.[[321]](#footnote-321) In line with this, the Review recommended that “the government continues to fund increases in basic science in line with the Ten Year Science and Innovation Framework 2004-2014”[[322]](#footnote-322) and called for “more effective ways to exploit our investment in research”[[323]](#footnote-323) in line with the Warry Report. Part of the recommendations for the latter involved increasing the role of the Technology Strategy Board (TSB) in overseeing the Research Councils, and supporting industry in gaining access to R&D funds,[[324]](#footnote-324) further intensifying the drive toward public-private collaborations. Other recommendations of the review included improving knowledge transfer from, and commercialisation of, research undertaken in universities.[[325]](#footnote-325)

Following the Sainsbury Review, the government issued a White Paper entitled ‘Innovation Nation’.[[326]](#footnote-326) The paper adopted many of the points raised by the Review, suggesting a range of initiatives to help businesses collaborate with universities to develop research into products (e.g. aiming to double the number of Knowledge Transfer Partnerships[[327]](#footnote-327) and provide ‘innovation vouchers’ for businesses to work with ‘knowledge based institutions’[[328]](#footnote-328)). These initiatives were addition incentives for developing public-private partnerships.

### Restructuring government departments (2007-2009) – the creation of BIS

As previously noted, in the early 1990s the Office for Science and Technology was created along with a cabinet post for a science minister, indicating science and technology issues were high on the political agenda. Thereafter, changes in the structure and roles of government departments have reflected the move towards incentivising university-business collaboration and the commercialisation of research results. Public policy responsibilities for four related areas (business, innovation, science and universities) have become increasingly adjoined. Under the Labour leadership of Gordon Brown, there were two key times of change in structure relating to these priorities. In 2007 the Department of Education and Skills was split into the Department for Children, Schools and Families and the Department for Innovation, Universities and Skills (DIUS), with DIUS assuming responsibility for universities. At the same time the Department of Trade and Industry (responsible for business, innovation and science) was devolved, passing its responsibilities for innovation and science to DIUS and its business responsibilities to the newly formed Department of Business, Enterprise and Regulatory Reform (BERR). This meant the DIUS covered universities, innovation and science. In 2009, DIUS and BERR merged to form the Department for Business, Innovation and Skills (BIS). For the first time, business, innovation, science and universities became the responsibilities of a single government department: BIS. BIS cites its priorities as:

**“1. Knowledge and Innovation** Promote excellent universities and research and increased business innovation

**2. Skills** Build an internationally competitive skills base and promote more opportunities for individuals in realising their potential

**3. Enterprise** Boost enterprise and make this the decade of the entrepreneur; and rebalance the economy across sectors and across regions

**4. Trade and investment** Stimulate exports and inward investment

**5. Markets** Create a positive business environment; and protect and empower consumers”[[329]](#footnote-329)

BIS oversees the work of a number of organisations including the UKIPO, RCUK (and consequently the individual research councils), HEFCE and the TSB, administering policies relating to business, higher education, innovation, IP, research funding and science. It is evident that public policy viewed this combination of business, innovation, science and universities within one department as essential to achieving the aim of “supporting sustained growth and higher skills across the economy”.[[330]](#footnote-330)

### The Wellings Report (2008)

Following the Sainsbury Review and the Innovation Nation White Paper, the Labour Government commissioned a report to investigate the role of intellectual property in Higher Education.[[331]](#footnote-331) The report (entitled ‘Intellectual Property and Research Benefits’) was delivered by Professor Wellings (Vice Chancellor of Lancaster University) in 2008. Commercialisation metrics cited in the report indicate that there had been a …

“… very rapid change in research commercialisation activity in universities in the UK, suggesting that the various government and funding council policies encouraging greater levels of commercialisation have begun to take effect.”[[332]](#footnote-332)

The metrics cited in the report to support the claim that commercialisation had increased included an increase in the number of licensing ‘full time equivalents’ per institution from 2.4 in 2001 to 4.8 in 2004, an increase in invention disclosures per US$100 million research expenditure from 31 in 2001 to 45 in 2005.[[333]](#footnote-333) Despite this seemingly positive picture in terms of earlier policy objectives, the Wellings Report noted that the UK was continuing to underperform in relation to its major competitors as reported in the Lambert Review five years earlier:

“[I]t is clear that UK institutions have a poor level of patenting and a weak income derived from licenses, options, assignments relative to the other economies [namely Australia, Canada and USA].”[[334]](#footnote-334)

The Wellings Report noted a number of barriers to university-business interactions – one being “an over-emphasis on IP when universities and businesses work together on collaborative research projects”.[[335]](#footnote-335) The same problem had been noted in the earlier Lambert Report. Wellings also noted that the role of IP was sector dependent, and that:

“[T]he Life Sciences and Pharmaceutical sectors frequently need strong IP protection to justify further staged investment and to secure returns on any products successful placed in the market.”[[336]](#footnote-336)

This indicates that IP issues are particularly pertinent in the life sciences (as discussed further in Chapters 4 and 5).

### Intellectual asset management for universities (2011)

Alongside the increasing pressure for universities to commercialise their research, guidelines were produced by the UKIPO to assist universities in managing their IP. The UKIPO responded to the recommendations of the Lambert Review, the resultant work of the Lambert Working Group on IP, the Wellings Report and the European Commission’s 2008 recommendation on managing university IP (see section 2.3.10). In 2011, the UKIPO published a strategy guide entitled ‘Intellectual asset management for universities’. The guidelines have received praise for their “more flexible, bespoke approach to IP management”[[337]](#footnote-337) akin to the recommendations of the 1999 Baker Report, encouraging institutions to develop individual strategies for IP management. The guide aims to “help senior university managers set strategies to optimise the benefits from the intellectual assets created by their staff and students”[[338]](#footnote-338) and claimed:

“Many universities are now fully aware of how to commercialise the IP arising from their research base. However, there is now a much broader appreciation that impact extends beyond the simple commercialisation of patents. Universities now need to be able to create an overall strategy for managing their IP in line with their mission.”[[339]](#footnote-339)

This statement indicates that the UKIPO considered many universities to be ‘fully aware’ of how to exploit their IP and that the real problem was how to balance this exploitation with their aims, in line with the earlier Lambert Review and the Wellings Reports. Whilst patents were being sought by universities, a number of points of uncertainty about their management and role in the innovation process remained.

### Strategy for UK Life Sciences and the Innovation and Research Strategy for Growth (2011)

This thesis focuses specifically on biological science. In recent years, policy has paid particular attention to the potential value of this science in supporting the economy and considering how this can be realised (this is further discussed in Chapter 4 with regard to stem cell science funding and policy). For example, in 2011 BIS released its ‘Strategy for UK Life Sciences’ through its Office of Life Sciences. The strategy focused on encouraging companies to undertake R&D in the UK by trying to reduce barriers to commercialisation; simplifying market regulation; and encouraging investment in R&D. Through this strategy BIS committed to invest £310million to “support the discovery, development and commercialisation of research”.[[340]](#footnote-340) Part of this commitment involved the formation of the £180 million “Biomedical Catalyst Fund”.[[341]](#footnote-341) The fund, operated by the MRC and the TSB, aims to encourage private investment in the translation and commercialisation of research from academia and SMEs. Once again, this demonstrates a move toward encouraging public-private partnerships.

At the end of 2011, BIS issued a White Paper entitled ‘Innovation and Research Strategy for Growth’.[[342]](#footnote-342) In this document, the newly elected Coalition government asserted its commitment to continue Labour’s efforts to increase the commercialisation of publicly funded research by fostering collaboration between business and universities and improving the environment for commercialising research.[[343]](#footnote-343) Steps to achieve this include the provision of funds to create ‘Catapult’ centres[[344]](#footnote-344) – one of which focuses on cell therapy[[345]](#footnote-345) – physically situating researchers and businesses together; improving the incentives for business to collaborate with universities through changes in tax credits; introducing voucher style incentives for SMEs; and increasing investment in the Small Business Research Initiative.[[346]](#footnote-346)

### The Wilson Review (2012)

A 2011 White Paper entitled “Higher Education: Students at the Heart of the System” reiterated the perceived importance of business-university collaborations[[347]](#footnote-347) and accordingly a report into such collaborations was commissioned. The report (‘A Review of Business–University Collaboration’) by Professor Sir Tim Wilson highlighted the role of universities in supporting the national economy following the 2008 financial crisis.[[348]](#footnote-348)

The report detailed a dramatic increase in the number of business university collaborations since the Lambert review[[349]](#footnote-349) but it was also noted that the UK continued to underperform on these metrics in relation to its main competitors:

“[I]n the broader aspects of economic growth, the global reputation of UK universities remains underexploited. Just as the first decade of this century has demonstrated the immense benefits of business–university collaboration, the second decade should build on those achievements to attain world‐class status and see the global reputation of the UK university sector being utilised as a stimulus for both indigenous economic growth and inward investment.”[[350]](#footnote-350)

The report’s recommendations covered a wide variety of topics, pointing to the complexity of business-university collaboration and a need to ‘join up’ policy in supporting such collaboration.[[351]](#footnote-351)These recommendations were endorsed in the response to the review from BIS resulting in commitments to “improve incentives rewarding researchers for the economic impact of their research … [and] further incentivising universities … to increase interactions with businesses”.[[352]](#footnote-352)

These recommendations have been built into the BIS Business Plan 2012-2015 which demonstrates the continuing focus of strengthening public-private partnerships to support the UK’s economy. As with earlier policies, funds have been earmarked to achieve this with BIS committing to:

“Provide £100 million capital funding for universities to leverage in private or charity co-investment in significant long-term partnerships … Enable greater private investment in research and aid the commercialisation of technology and research through the creation of centres of scientific and technological excellence and stronger links between universities and industries … [for example] iii. Construction and establishment of the Francis Crick Institute through a unique partnership between the Medical Research Council, Cancer Research UK, Wellcome Trust and three of London’s top universities (UCL, ICL, KCL).”[[353]](#footnote-353)

The £100 million capital funding was a result of an announcement in the 2012 budget;[[354]](#footnote-354) in line with the aim to turn the UK into the “technology hub of Europe”[[355]](#footnote-355), the Chancellor committed to support fund entitled the UK Research Partnership Investment Fund (UKRIF). The aims of the UKRIF are to:

“a. Enhance the research facilities of HEIs undertaking world-leading research.

b. Encourage strategic partnerships between HEIs and other organisations active in research.

c. Stimulate additional investment in HE research.

d. Strengthen the contribution of the research base to economic growth.

The fund will support large-scale projects that can leverage substantial co-investment from private sources building on the research excellence in the higher education sector.”[[356]](#footnote-356)

This ‘co-investment’, is the key change in the UKRIF in comparison to the HEIF. Rather than partnerships whereby the private sector may effectively contract research to be undertaken in universities supported by public funds, under the UKRIF the projects are co-funded with public and private funds. The provision of funding is such that the projects must secure at least twice the funding from private sources as is allocated from the UKRIF.

A further incentive for private investment in the commercialisation of research is through tax incentives, including the introduction of the ‘Patent Box’. This measure, also announced in the 2012 Budget, was to be phased in from 2013 and by 2017 will reduce corporation tax to 10% on profits earned from patents.[[357]](#footnote-357) The Strategy for UK Life Sciences argued this measure is particularly beneficial to the life sciences industry.[[358]](#footnote-358)

### The Witty Review (2013)

The role of universities in facilitating economic growth has been reiterated in the most recent Government review of universities – ‘The Witty Review’:

“Universities should assume an explicit responsibility for facilitating economic growth, and all universities should have stronger incentives to embrace this “enhanced Third Mission” – from working together to develop and commercialise technologies which can win in international markets to partnering with innovative local Small and Medium Enterprises (SMEs). An annual report should set out universities’ Third Mission work, together with actions the Government should take to better facilitate it.”[[359]](#footnote-359)

Within the review, universities were repeatedly called to work with industry, harnessing private funds within a model called ‘Arrow Projects’:

“The UK’s research strength is a great national asset which we should work hard to maintain and develop. It can be the foundation for building a lead in the critical research-led technologies and sectors of the future. Universities where world class research is taking place should lead collaborative efforts to develop technologies offering the UK comparative advantage in international markets, and to realise the associated economic benefits. These collaborations are termed “Arrow Projects” – combining an arrow tip of leading research with an arrowhead of associated economic activity … They would bring together leading researchers, industrial and supply chain partners and key economic players such as LEPs, wherever they might be located.”[[360]](#footnote-360)

Within these projects, the role of basic research is emphasised alongside the perceived importance of supporting translation and collaboration between universities and business.

The Government’s response to the Review committed to “making a long term commitment to supporting universities in a third mission to deliver economic growth”:

“Universities contribute to economic and social development. The Government encourages Universities wherever appropriate to make contributing to economic growth a key third mission, alongside teaching and research.”[[361]](#footnote-361)

While the Government response to the Review did not commit the £1 billion recommended by Witty for the ‘Arrow Projects’,[[362]](#footnote-362) it did accept the reviews conclusion that “more can be done to simplify the funding landscape for businesses and researchers” and committed to improve the connectedness of funding streams “that enable accelerated commercialisation of key technologies”.[[363]](#footnote-363)

## Shaping research through quality assessment

As has been mentioned throughout this chapter, researchers and universities have increasingly been called to justify their funding in line with the developing criteria of funders. In the case of public funding, this is dependent on the type of funding involved. With research council funding, funding applications must now detail their ‘pathways to impact’, evidencing foresight of potential applications, and applications are assessed against these measures.[[364]](#footnote-364) Third-stream funding (such as funding through the HEIF and UKRIF) is awarded dependent on criteria developed to assess the ability to deliver ‘knowledge exchange’ between private and public partners.[[365]](#footnote-365) The other main form of public funding, direct funding through the Higher Education Funding Councils, is dependent on a number of factors assessing the quality of research. The most version of this review – the Research Excellence Framework (2014) – has its origins in the 1980s when regular reviews of university research began. Ever since, the factors used in these reviews have become increasingly complex.

### The Research Selectivity Exercise (1986)

To provide accountability for public funding decisions and ensure the 3E’s were being met, formal methods to evaluate public spending were devised during the 1980s. In the case of publicly funded research undertaken in universities, to the discontent of the academic community,[[366]](#footnote-366) this resulted in the ‘Research Selectivity Exercise’ (RSE).[[367]](#footnote-367) The University Grant Committee (a predecessor of the modern higher education funding councils) undertook the first review in 1986 and successive exercises have taken place periodically ever since. The results of the RSE determined what proportion of the total public spending on universities each institution would receive. This effectively meant that direct funding for universities was now dependent on criteria set out, and measured, by the government. By adjusting the types of criteria involved, and the value placed on each criterion, policy has been able to provide incentives for universities to undertake research in a manner aligned with the national policies of the time (as per the changes to the Research Council funding allocations in the 1970s following the Rothschild report).

The RSE came under criticism for not being sufficiently rigorous, leading to a more intensive review in the shape of the Research Assessment Exercise (RAE) in 1989. [[368]](#footnote-368) This increase in rigour through intense peer review was developed over successive reviews, diminishing criticism about the quality of the reviews but increasing the workload in both the funding councils and universities, reaching an estimated cost of £100 million for the 2006 RAE.[[369]](#footnote-369) Martin and Guena show that while the early RAEs brought some improvements, they entailed costs which increased over subsequent reviews resulting in diminishing returns.[[370]](#footnote-370) Thus, while the early RAEs were welcomed for being more rigorous, they quickly became extremely costly. In 2006, the Treasury proposed that the reviews should be based on metrics including funding received from the research councils.[[371]](#footnote-371) Martin notes that this was met with “fierce opposition from academics loathed to see the disappearance of peer review from the assessment process”.[[372]](#footnote-372) The result, the Research Excellence Framework (REF) was to be a mix of the two: peer review and quantitative bibliometrics.

### The Research Excellence Framework (2014)

As previously noted, reviews of the quality of research in HEIs have become increasingly complicated and quantitative. The latest review, the Research Excellence Framework (REF), is to be completed in 2014 and aims to:

“… produce assessment outcomes for each submission made by institutions. The funding bodies intend to use the assessment outcomes to inform the selective allocation of their research funding to HEIs, with affect from 2015-16. The assessment provides accountability for public investment in research and produces evidence of the benefits of this investment. The assessment outcomes provide benchmarking information and establish reputational yardsticks.”[[373]](#footnote-373)

These are in line with the aims of the original RSE, but the process of the review and the metrics used have evolved in line with policy.[[374]](#footnote-374) Policy based on a linear model of basic research to innovation, aimed at increasing commercialisation in HEIs, has been reflected in the quantitative bibliometrics used in the 2014 REF. For example, for the first time the assessment criteria include quantitative measures of the ‘impact’ of funded research, in line with the recommendations of the Warry Report and subsequent RCUK action plan. ‘Impact’ now accounts for 20% of the REF score[[375]](#footnote-375) and one tangible measure of this impact is patents.[[376]](#footnote-376) This is another way in which universities and researchers and now encouraged to patent their research: their future funding depends on it.

## Conclusions

National policies and measures aimed at increasing the commercialisation of basic research in universities have intensified in recent decades. The measures described in this chapter have included the reorganisation and reorientation of public research funding (e.g. through the explicit requirements for the Research Councils to consider the economic potential of the research it funds); changes in the terms and conditions of funding (e.g. through ‘pathways to impact’ and the REF); the development of specific funds to encourage public-private partnerships (i.e. the HEIF and UKRIF); and an increasing focus on protecting and managing IP in universities.

The changes described in this chapter have not only affected applied science (as was the case in the direct contracting of defence research in the Wars), but also basic, upstream science. This basic science has become a major focus of science policy in recent years, with life sciences regularly being pinpointed as a ‘great hope’ for the future. As a result of the histories detailed, researchers and universities are increasingly expected to engage in research which involves collaboration with industry and the commercialisation of their research to support the ‘Third Mission’ of universities. While these policies have relatively long histories, uncertainty remains and is likely to affect researchers in a way that is not fully understood. The Lambert Review, the Wellings Report and the UKIPO Intellectual Asset Management guidelines all highlighted that while there is a continuing promotion of securing and manging patents in universities, the role of patents in commercialisation and the translation of research remains uncertain and may hinder the creation and maintenance of public-private partnerships and the undertaking of downstream research. Further, while there are guidelines regarding the management of IPRs arising from publicly funded research, these are not compulsory; the sharing of the IP, as well as profits from future applications, resultant from public-private partnerships is unclear and may cause problems in the future. Consequently, scientists are at the centre of the implementation and effects of these complex policies. Their perceptions and experiences of related issues deserves investigation, hence the empirical study of this thesis.

Chapter 4

Funding of stem cell science research in the UK

## Introduction

As mentioned in the introduction to this thesis, stem cell science has been chosen as the main subject of study because of the particular national focus on; large investments in; and high expectations of the field. This chapter examines the evolving landscape and funding of stem cell science in the UK, particularly stem cell research undertaken in universities, thus describing the working environment of the scientists at the centre of the empirical study. First, a number of policy documents are chronologically reviewed to understand the particularities and expectations of the field, showing that stem cell science has repeatedly been highlighted as a field of great scientific, therapeutic and economic potential. Next an overview of the funding of the field is offered with a review of the IP policies of the major funders in the UK. The final part of the chapter provides an account of some of the concerns surrounding the increasing drive to commercialise university research, focusing on issues which are likely to impact on scientists themselves.

## Recent national stem cell research policy

Over the last decade, stem cell research has been strategically prioritised, marking the field as a major hope for the future of British science.[[377]](#footnote-377) As will be shown, the related policy has increasingly centred on translational and commercial aspects with continuity on these issues between successive governments, irrespective of political persuasion. This emphasis mirrors the developing focus of general science policy on the commercial aspects of scientific research, as described in the previous chapters.

### The UK Stem Cell Initiative (2005)

Following the establishment of the California Institute for Regenerative Medicine (CIRM) in 2004,[[378]](#footnote-378) Chancellor Gordon Brown announced the launch of a UK Stem Cell Initiative (UKSCI) in the 2005 Budget. The aim of this was to “formulate a ten-year vision for UK stem cell research, creating a platform for coordinated public and private funding of research.”[[379]](#footnote-379) Later that year the Department of Health issued the UKSCI Report & Recommendations.[[380]](#footnote-380) When analysing the status of UK stem cell research at that time, the report identified a number of weaknesses impacting upon the UK’s competitiveness in this area, a concern of general science policy of the time:

* “Gaps in UK funding for translational research
* Unknown business model & return on investment
* Lack of involvement by big pharmaceutical companies
* Lack of venture capital investment
* Lack of regulatory clarity for clinical use of stem cell therapies
* Lack of central co-ordinated strategy leading to “cottage industry” approach
* Smaller science base than US
* History of innovations being lost to the US for commercialisation phase
* Lack of clarity on Intellectual Property and Licensing Issues”[[381]](#footnote-381)

To address these issues, the report proposed a 10-year programme based upon a series of recommendations for the UK to:

“… consolidate its current position of strength in stem cell research and mature, over the next decade, into one of the global leaders in stem cell therapy and technology”.[[382]](#footnote-382)

The programme was expected to cost between £41M and £104M per annum, a significantly greater public investment than the pre-existing £30M per annum.[[383]](#footnote-383) The report outlined plans not only to increase public funding but also encourage private funding in stem cell research and build specific public-private partnerships. In particular, the report recommended:

* “The UK government should establish a public-private partnership to develop predictive toxicology tools from stem cell lines.”[[384]](#footnote-384)
* “Research Councils and private sector funding bodies should support the development of stem cell therapy production units at UK Centres of Excellence in stem cell research.”[[385]](#footnote-385)
* “The government and Research Councils should strengthen the levels of funding for basic stem cell research over the next decade.”[[386]](#footnote-386)
* “The government should provide funding for clinical and translational stem cell research over the next decade at a level matching that raised by the UK Stem Cell Foundation (UKSCF), up to a maximum of £10M per annum, and administer it via UKSCF / Medical Research Council collaboration.”[[387]](#footnote-387)

The UKSCI was an explicit encouragement from the government of public-private collaboration in stem cell research, in line with general science policy of the time (see, for example, the Science and Innovation Framework 2004-2014, section 3.5.2). One example of a public-private collaboration resulting from the UKSCI is Stem Cells for Safer Medicines (SC4SM). SC4SM, which still operates today, was set up as a consortium funded by government departments (BIS and the TSB), the MRC and BBSRC and the private sector.[[388]](#footnote-388)

The report also indicated that several ‘Centres of Excellence’ should be identified and supported with core funding to focus primarily on stem cell research.[[389]](#footnote-389) To date, a number of these Centres have been created, including the MRC Scottish Centre for Regenerative Medicine at Edinburgh University (opened in 2008) and The Wellcome Trust-Medical Research Council Cambridge Stem Cell Institute (opened in 2012). The latter is an example of a long term public-private partnership, combining 30 research teams with a clear intention to focus on the translation of basic research: scientists, technology specialists and doctors work together to develop therapeutic products. This “unrivalled opportunity for industry collaboration” was summed up in the remarks of Professor Austin Smith (the head of the centre):

“The Wellcome Trust-MRC Cambridge Stem Cell Institute will be an invigorating environment for cross-fertilisation between fundamental and translational researchers. Our aim is to close the knowledge gap and drive stem cell research forward towards clinical applications. The world-class facilities will attract the best international talent from the fields of stem cell biology and regenerative medicine to pursue this goal.”[[390]](#footnote-390)

The development of these centres shows a specific focus on supporting translational research in the fields, bringing together experts in fundamental, translational and clinical research from industry and academia.

### Technology and Innovation Futures (2010)

In 2010, BIS released a document entitled ‘Technology and Innovation Futures: UK Growth Opportunities for the 2020s’.[[391]](#footnote-391) The document highlighted “a range of developments which have the potential over the next 20 years to support sustained economic growth in the UK.”[[392]](#footnote-392) Developments in regenerative medicine, particularly in stem cell science, were cited as a key hope in advancing the UK life sciences sector:

“Regenerative medicine could be a driver for growth for the [pharmaceutical] sector if translational research, regulatory and financial challenges can be overcome. Stem cells have the greatest potential in the field of regenerative medicine, and could see widespread application by the early-mid 2020s.”[[393]](#footnote-393)

The report noted, however, that while the field showed great promise (both in terms of therapeutic and economic potential) this would not materialise in the immediate future and would require significant support in the short-term with efforts to overcome “translational research, regulatory and financial challenges”.[[394]](#footnote-394) Addressing these challenges has been the subject of subsequent policy.

### Taking Stock of Regenerative Medicine (2011)

In 2011, BIS and DoH released a report entitled ‘Taking Stock of Regenerative Medicine in the United Kingdom’.[[395]](#footnote-395) As part of this review, BIS commissioned a bibliometric analysis of regenerative medicine. The analysis showed that the field was “highly active and competitive” with the UK producing world-class research, strong in terms of both the number of peer reviewed papers and citations (with the citation impact in this field being greater than that of the general science base). [[396]](#footnote-396)

Additionally, the ‘Taking Stock’ report announced a number of measures that aimed at increasing the competitiveness of the UK in this field[[397]](#footnote-397) and overcoming the “steep technological, regulatory and strategic barriers to realising regenerative medicine’s significant potential”.[[398]](#footnote-398) The Government was to take action to: better co-ordinate public investment and leverage funding from private sources; ensure the regulatory framework was facilitating and was supported by a strong intellectual property regime; provide greater clarity and help to get these highly innovative products to patients; and support the sector in the long-term.[[399]](#footnote-399) The report noted that:

“Regenerative medicine has seen significant public funding over the last 10 years, and is beginning to receive modest, but increasing, investment from pharmaceutical companies, and private equity. However, as is often the case with emerging technologies, regenerative medicine has predominantly been funded from public and third sector (charity) sources to date. For example, the third sector invested approximately £38 million in regenerative medicine research between 2005-2009 and the public sector has invested over £200 million in the field since 2003”[[400]](#footnote-400)

The strategy since has been to promote private investment and public-private collaboration in the field (in line with wider national science policy as described in Chapter 3).

### Strategy for UK Life Sciences (2011)

Published a few months after the ‘Taking Stock’ report, the Strategy for UK Life Sciences committed to create a £180 million ‘Biomedical Catalyst Fund’.[[401]](#footnote-401) The fund, administered by the MRC and the TSB, supports translational research from concept to commercialisation, and aims to harness private investment in the translation and commercialisation of research from academia and SMEs. The strategy also announced plans for a Cell Therapy Technology and Innovation Centre (now known as the Cell Therapy Catapult).[[402]](#footnote-402) The Centre was to receive £10 million per year over 5 years from the TSB to drive research through to translation, ready for entrance to phase III clinical trials. The Catapult hopes to leverage at least £10 million per year from other grant funders and another £10 million per year from industry contracts.[[403]](#footnote-403) The report also noted that the MRC, EPSRC and BBSRC would ring-fence £25 million for a fund, the UK Regenerative Medicine Platform, to help identify promising research to be taken into the Catapult.[[404]](#footnote-404)

### Strategy for UK Regenerative Medicine (2012)

In 2012, in a speech to the Royal Society about growth and economics of science, George Osborne (Chancellor of the Exchequer), cited regenerative medicine as one of “eight future technologies where we believe we can be the best - where we already have an edge, but we could be world-leading.”[[405]](#footnote-405) One week later, the research councils and the TSB published a ‘Strategy for UK Regenerative Medicine’. The review: “identified eight key UK strategic objectives that will need to be addressed if the UK is to make the most of its current position.”[[406]](#footnote-406) These objectives were: investment in underpinning research; studying efficacy and safety of therapeutics; product development; clinical delivery and evaluation; innovation and value systems; remaining alert to international developments; focus (identifying areas meriting concerted investment); and promoting interdisciplinary collaboration.[[407]](#footnote-407)

### The House of Lords Regenerative Medicine Report and Parliamentary Office of Science and Technology Report on Stem Cell Research (2013)

A Parliamentary Office of Science and Technology (POST) Report on Stem Cell Research was published in March 2013.[[408]](#footnote-408) This report detailed the scientific background, regulatory and ethical framework, scientific advances and clinical developments in the field to date. Further, the report highlighted a number of challenges facing the field including regulatory uncertainty and barriers to commercialisation including concerns about funding models and the patentability of stem cell research.[[409]](#footnote-409)

The POST report was used to provide history and scientific background for a House of Lords (HoL) inquiry on Regenerative Medicine.[[410]](#footnote-410) This inquiry was not the result of a particular driver: regenerative medicine was viewed collectively by the committee as a very important developing topic, attracting considerable Member interest and therefore made it through the Committee’s inquiry selection processes.[[411]](#footnote-411) The aim of the inquiry was to …

“[C]onsider whether the UK is in a position to support the translation of knowledge from world-leading research in the field of regenerative medicine to treatments, and to benefit from the associated commercial opportunities.”[[412]](#footnote-412)

The inquiry took evidence from a wide variety of stakeholders including: academic research scientists; industry; representatives of government departments; regulators; patient interest groups; healthcare providers; and patent lawyers.[[413]](#footnote-413) The Committee issued its report in July 2013 which stated:

“Regenerative medicine has the potential to save lives and to help support the UK economy. The UK has a great potential resource in the NHS which could make it an attractive place for investment. But the UK is currently underprepared to realise the full potential of regenerative medicine. The many words which have been spoken about regenerative medicine must translate into action, and quickly. We must not miss out on this opportunity to lead the world in this work.”[[414]](#footnote-414)

The report sets out very plainly that, in the eyes of the Lords at least, regenerative medicine holds great promise both in terms of health and the economy:

“[I]t has enormous potential to treat and cure diseases. It could also improve the quality of peoples’ lives and generate significant economic benefits for the UK.”[[415]](#footnote-415)

However, the report expressed concerns about the UK’s ability to deliver. In particular, it argued there is a need for prompt development from research to product for the potential economic and therapeutic benefits to be realised. A number of barriers to research translation in the field were identified: uncertainty amongst investors;[[416]](#footnote-416) a complex regulatory environment;[[417]](#footnote-417) an unattractive environment to conduct clinical trials;[[418]](#footnote-418) and problems relating to the scale-up,[[419]](#footnote-419) manufacturing[[420]](#footnote-420) and delivery[[421]](#footnote-421) of potential products. Bearing these issues in mind, the Lords made a number of recommendations that: “if acted upon, would facilitate the translation of scientific knowledge into clinical practice and encourage its commercial exploitation”.[[422]](#footnote-422) Again, this highlighted the perceived dual importance of potential health and economic benefits.

Of particular interest to this thesis is the report’s emphasis on commercialisation, an entire chapter of the report devoted to the subject. Within this, two sections are of particular relevance and are discussed subsequently: ‘business models, venture capital and the funding gap’; and ‘intellectual property’.

#### Business models, venture capital and the funding gap

The financing of research and translation was a major concern to both industry-representatives and basic scientists responding to the HoL inquiry.[[423]](#footnote-423) As few products have made it to market, there are currently no clear business models for cell-based therapies, something which had been noted in earlier studies about the commercialisation of regenerative medicine.[[424]](#footnote-424) Accordingly, it was noted in the report that attracting funding from venture capitalists and large companies was difficult. Given the associated risks relating to the immaturity of the field, investors were choosing to invest in other sectors with clear paths to return on investment over regenerative medicine.[[425]](#footnote-425)

With the money not coming willingly from private sources, the public sector had attempted to enhance investment in the field through specific public and public-private funding initiatives (for example through the Regenerative Medicine Platform and the Cell Therapy Catapult) and incentives for private investment. However, these initiatives were met with mixed opinions. For instance, Regener8 (a strategic alliance between university researchers and an innovation centre funded by the UK research councils to promote international private/public partnerships) submitted that there simply was not enough money available to support the UK’s attempts to maintain its competitive position.[[426]](#footnote-426) While it was argued that the Cell Therapy Catapult provided a significant attempt at bridging the ‘valley of death’,[[427]](#footnote-427) its ability to fund progress was “limited by its budget”[[428]](#footnote-428). The NHS Blood and Transplant Service took a different view, arguing that:

“[T]he challenge is not the availability of money, especially with the recent creation of the BioMedical Catalyst, Cell Therapy Catapult and Regen Med Platform, but confusion as to which fund/scheme/organisation researchers should approach.”[[429]](#footnote-429)

Whilst welcoming the Catapult, the CEO of Intercytex was worried that the Catapult was overly concerned with meeting quantitative Government targets and was at risk of ‘soaking up’ “all future Government funding or at worst become ‘state sponsored competition’ to SMEs struggling to develop their own products or services”.[[430]](#footnote-430)

The report called for the work of the Catapult to be refocused to support ‘high growth potential projects’:

“Whilst it is right for the Cell Therapy Catapult to share its expertise, as it establishes itself, it must first focus on developing investable propositions and building connections (including with investors)”[[431]](#footnote-431)… “we are concerned that it [the Cell Therapy Catapult] is seeking to achieve too much too quickly, given the level of funding. We recommend that the TSB and the Cell Therapy Catapult prioritise its activities to enable the Cell Therapy Catapult to focus on taking high growth potential projects through clinical trial to be phase III trial ready and developing links with the regenerative medicine community.”[[432]](#footnote-432)

In order to improve commercial viability and encourage private interest and investment in the field, the report identified submissions from stakeholders to take such concerns into account when making decisions about public funding of the field:

“The Association of the British Pharmaceutical Industry (ABPI) recommended that early dialogue with industry on manufacturing, scalability, transportation and delivery solutions and considerations of “commercial viability” should be funding criteria for translation and applied research.”[[433]](#footnote-433)

This highlights a pressure from the private sector for public funding to focus on applied research with clear potential commercial application. Additionally, another recommendation indicated that translational funding should be a priority, with calls to draw money from other areas:

“At the very least, investment should be made in facilities to support the scale-up of treatments in mid to late stage clinical development. Money for this, and other recommendations, should be found by the reprioritisation of budgets and innovative funding methods”[[434]](#footnote-434)

Further, the report called for the researchers to be encouraged and supported to consider commercial issues during early-stage research.[[435]](#footnote-435) The report incorporated this view in one recommendation:

“We recommend that the phase II disease teams of the TSB regenerative medicine platform, and other regenerative medicine funding programmes, specifically require researchers to involve manufacturing and scale-up experts in their development process to ensure that translational work is scalable and therefore deliverable to a large number of patients”[[436]](#footnote-436)

Such a ‘specific requirement’ would pressurise basic scientists to factor commercial potential into the planning and undertaking of their work.

#### Intellectual property

The discussion on commercialisation in the report also included a section on intellectual property, noting respondents’ mixed views on the topic. The majority of respondents viewed patentability as crucial, particularly in securing investment;[[437]](#footnote-437) developing spin-out companies; and securing research collaborations.[[438]](#footnote-438) Investors were apprehensive that: “in the absence of a patented ‘product’ there was no obvious business model beyond that of essentially offering an expert service, which they considered harder to commercialise”.[[439]](#footnote-439) Trevor Cook, partner with Bird and Bird, noted in his written evidence for the report:

“[I]t can be seen that the patent system plays a vital role in the commercial development of regenerative medicine because in the absence of suitable patent protection for a particular regenerative technology, or the realistic prospect of it (because much early stage funding occurs long before any patents that have been applied for are actually granted), the private sector support that is necessary for the commercial development of that technology will not be forthcoming.”[[440]](#footnote-440)

However, the role and importance of patents in the field was disputed by some. For example, Professor Chris Mason, a scientist at University College London (UCL), argued that the importance of patents has been overstated; that patents are potentially unnecessary given that the complexity of delivering products in this field effectively protects value and investment.[[441]](#footnote-441) Similarly, Pfizer (the industrial sponsor of a large project at UCL, as further discussed in section 4.3.4) argued that the significance of patenting was greater in traditional, pharmaceutical-type small molecule products than more complex cell-based therapies where know-how could be highly valuable.[[442]](#footnote-442)

The review also noted a number of concerns about the ruling in Brüstle v Greenpeace (discussed further in section 5.4.3): that the ruling had resulted in a lack of clarity and uncertainty about what can and cannot be patented in the field, possibly deterring potential investors[[443]](#footnote-443) and leaving researchers wondering if “they should abandon work in this field in Europe”.[[444]](#footnote-444) However, Julian Hitchcock and Alex Denoon (both from the law firm Lawford Davies and Denoon) argued that this view was based on a misunderstanding: that concerns that the case began “the end for European or British embryonic stem cell research” was a “fallacy”.[[445]](#footnote-445) The head of the UKIPO commented “most areas of regenerative medicines are patentable”.[[446]](#footnote-446) Notwithstanding these counterarguments, researchers and commentators remain concerned about the implications of the ruling and are uncertain about its effect.[[447]](#footnote-447)

The report also detailed how universities were often limited in their ability to deal with patenting issues (as previously stated in the Lambert and Wellings Reviews as discussed in Chapter 3):

“[I]n many cases, universities were ill-equipped to deal with the commercial aspects inherent within the patenting framework, and to support applications and patents over the timeframes required… This suggested a lack of shrewdness when it comes to patenting in universities”[[448]](#footnote-448)

Further, academics reported that they needed more support in filing for patents.[[449]](#footnote-449) In a similar vein, Aiden Courtney, CEO of Roslin Cells, remarked how innovators were currently expected to act in areas where they have little experience:

“[T]he challenge we have in cell therapy is that ... most of the people coming into developing cell therapy are likely to be either academics trying to start a company or new companies who are probably going through that regulatory process for the first time, and it is very difficult for them to find someone to give them the guidance to take them through the regime”[[450]](#footnote-450)

These responses reinforce the observation in the report that universities and innovators needed additional support to patent research in order to help secure the economic potential and the creation of support funding was recommended:

“TSB should set-up a time-limited support fund for regenerative medicine patents … open to university researchers who wish to pursue patents beyond the first stage, so that potential income from regenerative medicine products is not lost. Such a fund would help foster this fledgling industry and be a helpful tool until university patent offices are better placed to deal with the potential value of these products.” [[451]](#footnote-451)

***The Government response to the inquiry***

In October 2013, the Government released its response to the HoL report.[[452]](#footnote-452) The Government reiterated its commitment to the field “given its huge opportunities for technological advance and the economic benefits we believe it can bring to the UK economy.”[[453]](#footnote-453) While somewhat evasive in its responses to many of the recommendations of the report, regularly noting “the TSB and Research Councils will respond further” a number of commitments were made including the creation of a Regenerative Medicine Expert Group[[454]](#footnote-454) and streamlining of regulatory information through the Health Research Authority to better support researchers.[[455]](#footnote-455) Regarding the problems relating to intellectual property highlighted in the HoL report, the Government did not commit to creating additional support for researchers as recommended in the HoL report, noting:

“The TSB currently offers funding that can include the cost of patenting. Projects awarded funding through their collaborative R&D competitions can claim for costs associated with new patents generated within the project. The TSB will respond further to this recommendation.”[[456]](#footnote-456)

This response focuses on funding the costs of patenting; missing the more general points made in the HoL report that researchers, universities and investors are uncertain about the patenting of stem cell science and have insufficient support in this area.

## Major funders of stem cell research in the UK and their IP Policies

There are a number of funding streams involved in the funding of stem cell science in the UK: the EU FPs; public funding through the research councils, government departments and special government initiatives; private funds and third sector bodies. Each of these will be considered in turn, alongside the terms and conditions regarding the IP of the funded project, although it is noted that many projects utilise a variety of these funding streams.[[457]](#footnote-457) While the majority of the information presented could equally apply to the majority of science funding, this section will identify particular examples in the field of stem cell science.

Each IP policy puts an onus on the host institution and accordingly researchers themselves: at a minimum, they are required to consider IP-related issues, and, at most, they are expected to actively seek out, protect and manage all potential IPRs. It will be shown that in all cases except private funding, the funding agreements pass ownership of IP to the host organisation(s), which is then expected to protect and manage the IP where possible. If the organisation does not protect and manage the IP in a way which is deemed acceptable to the funding body, the funder can claim ownership of the IP and manage it accordingly. Further, it will be shown that in the case of the EU FPs and public funding, any profits made from IP remain with the funded institutions. However, where funding comes from the third sector, at least in the case of the main third sector funder of stem cell science, the Wellcome Trust, a proportion of any profit must be returned to the funder. In the case of private funding, the IP agreement between the funder and the host institution is not clear. However, it is likely that the host organisation will have to devote time and resources to reach agreements regarding IP when negotiating private funding.

### Funding through the EU FPs

Research involving stem cells, and more particularly the patenting of products of this research, has attracted widespread ethical and political debate. Such debate has been rife within the EU, effecting the provision of funding through the FPs for research involving stem cells.[[458]](#footnote-458) Notwithstanding this, the number of programmes relating to stem cell science has grown during recent frameworks.[[459]](#footnote-459) Under FP6, over €500 million was invested in projects using stem cells (almost 3% of the total FP6 budget of €17.88 billion).[[460]](#footnote-460) Of the 151 projects funded, 77 included participants from the UK, of which 16 were co-ordinated by UK researchers and include ESTOOLS and EuroStemCell each of which each received approximately €12 million.[[461]](#footnote-461) Whilst data detailing the exact investment in the UK is not available (given that each project involves multiple partners), it is clear that the UK is a major player in terms of securing EU level funding for research involving stem cells.

As discussed in section 2.3.10, a sizeable literature of IP guidance has developed for research funded under the FPs. The grant conditions detail that generated ‘foreground’,[[462]](#footnote-462) including IP, is the property of the creator(s).[[463]](#footnote-463) If multiple parties are involved they should establish a formal agreement regarding the ownership of any resultant IP prior to commencement of the project.[[464]](#footnote-464) Within the funding agreements, IP can be transferred if the new assignees take on the obligations defined in the conditions of funding.[[465]](#footnote-465) These obligations include: ensuring the foreground is used[[466]](#footnote-466), providing for the protection of IP through attempting to secure IPRs[[467]](#footnote-467) and acknowledging the funding source in patent applications.[[468]](#footnote-468) If the IP may be used in a commercial application through IPRs and the owner does not protect or transfer it, the EU may assume ownership of the foreground.[[469]](#footnote-469) Whilst these guidelines indicate that IP must be protected where appropriate, ownership of the IP in funded consortia must be determined between the members themselves and so is likely to differ between projects.

### UK public funding

As was established in section 4.2, the UK government has repeatedly highlighted regenerative medicine and stem cell science as research priorities. Accordingly, large investments of public money have been made in these areas. The majority of such public funding is invested in basic research.[[470]](#footnote-470) In addition to funding a large number of individual projects, there have also been a number of more specific initiatives including the development of a new site for the UK Stem Cell Bank.[[471]](#footnote-471) In line with public policy, public funds have been increasingly earmarked for translational research.[[472]](#footnote-472) There have been several such initiatives in recent years, including the Regenerative Medicine Platform (£20 million to be invested through the first call for project proposals, administered in 2013[[473]](#footnote-473)) and the Cell Therapy Catapult (£10 million per year for five years). In addition to these larger initiatives, the research councils invested over £77 million in regenerative medicine in 2012.[[474]](#footnote-474)

In line with general science policy, the RCUK IP guidelines indicate the councils “positively encourage the exploitation of the results of the research they support, as a contribution to enhanced quality of life, sustainability and competitiveness of the UK.”[[475]](#footnote-475) The terms and conditions of the grants indicate that ownership and responsibility for securing IP rights, generally, lies with the grantee.[[476]](#footnote-476) In exceptional circumstances ownership may be held by either the funding council or passed to a third party if this is deemed to be of “national benefit”.[[477]](#footnote-477) If the research is funded in collaboration with other parties, the organisations receiving RCUK funding must arrange formal agreements regarding ownership of IP in line with the council’s terms and conditions before the research begins.[[478]](#footnote-478) In addition, the guidelines indicate that the grantee organisation is responsible for ensuring that there should be “suitable recognition and reward to researchers” involved and that individuals associated with the research understand the arrangements for exploitation.[[479]](#footnote-479) Other government bodies which fund stem cell research (e.g. the TSB) include similar criteria in their funding conditions. As with RCUK funding, all IP is the property and responsibility of the funded consortia who must agree how to manage resultant IPRs.[[480]](#footnote-480)

### Third sector and private not-for-profit funding

A number of charities and private ‘not-for-profit’ organisations have provided funding for research involving stem cells including the British Heart Foundation; Cancer Research UK; the UK Stem Cell Foundation; and the Wellcome Trust. Data from the Association of Medical Research Charities indicates:

“Investment by the third sector in regenerative medicine has been growing in the last five years: over £51 million was invested in regenerative medicine between 2005 and 2010, and average annual investment increased from £6 million in the period 2005-08 to £13 million in 2009.”[[481]](#footnote-481)

The Wellcome Trust has spent £40 million on basic stem cell research in the last five years[[482]](#footnote-482) making it the largest single third sector investor in stem cell research. As such, the Wellcome Trust’s IP policy is considered as an example of third sector IP policy. The Trust “supports the appropriate protection and use of intellectual property rights (IPR) to maximise healthcare benefit and to enable fundamental biomedical research to flourish”.[[483]](#footnote-483) It notes this is within its “obligation [as a charity] to ensure that useful results from the research that it funds are applied for the public good.”[[484]](#footnote-484)

The Trust’s rules on IP from funded projects are similar to those of RCUK, requiring grantees to take responsibility to identify, protect, manage and exploit arising IP and make specific arrangements when entering into collaboration with additional institutions or funders.[[485]](#footnote-485) As with RCUK, these responsibilities may be taken on by the Trust if deemed necessary.[[486]](#footnote-486) However, they contain an additional requirement. The grantee organisation must:

“… consider whether the protection, management and exploitation of such Trust-funded IP is an appropriate means of achieving the public benefit.”[[487]](#footnote-487)

It is notable that this criterion is absent from the RCUK terms and conditions which detail that organisations should:

“… make every reasonable effort to ensure that the intellectual assets obtained in the course of the research, whether protected by intellectual property rights or not, are used to the benefit of society and the economy”[[488]](#footnote-488)

Unlike the Wellcome Trust conditions, the RCUK terms do not call for organisations to consider if protecting and exploiting IP is an ‘appropriate’ means of achieving this. Further, the Trust requires that the institution requests consent before commercialising IP and accepts “standard revenue- and equity- terms”.[[489]](#footnote-489) These terms detail that the Trust will receive up to 40% of net income and 40% equity shares.[[490]](#footnote-490) These requirements highlight that the Wellcome Trust maintains a vested interest in the research it funds and entail additional work (beyond that attached to RCUK and EU FP funding) on the part of the university and accordingly academic scientists themselves.

### Private for profit funding

In 2010, there were 26 regenerative medicine companies registered in the UK, a relatively high number in comparison to other EU Member States.[[491]](#footnote-491) It has been estimated that:

“[R]egenerative medicine, and regenerative-medicine related, companies contribute around £150 million of production and £80 million gross value added to the UK economy, that is around one percent of current production figures for UK pharmaceutical manufacturing and around 10% of the global cell therapy market”.[[492]](#footnote-492)

Some universities have collaborated with private companies to research in this area. For example, in 2009, UCL announced it had “entered into a collaboration with the biopharmaceutical group Pfizer … to advance development of stem cell-based therapies for age-related macular degeneration”.[[493]](#footnote-493) This collaborative arrangement was extended in 2011.[[494]](#footnote-494)

While it is clear that private companies do sponsor as well as undertake stem cell research,[[495]](#footnote-495) it is not clear how much is spent by private companies on R&D in this field. Details have been released about the specific investments of some companies, [[496]](#footnote-496) but general, sector-wide numbers for investment in R&D in stem cell research are not available.

The terms and conditions attached to public-private partnerships are not always clear. What is clear is that, prior to starting the project, a formal agreement should developed regarding the sharing of IP in any partnership that is funded with finance from RCUK, the TSB, or the EU FPs. Beyond this, it is difficult to generalise about the IP agreements in public-private partnerships; the content of such agreements are not public and are likely to vary. For example, one agreement could see all IP and related profits handed to the private entity, whilst another may provide for the equal division of such IP and profits between the private funder and the host organisation.

Considering the partnership project between UCL and Pfizer, because the exact terms of the agreement are not public, it is not clear what the arrangements are regarding the ownership and benefit-sharing terms of any IP arising from the research. However, the collaboration agreement states that Pfizer holds the option to “commercialise any resulting product.”[[497]](#footnote-497) It implies, therefore, that Pfizer has first rights refusal to license IP. Further, a press release stated that:

“Pfizer will provide funding to UCL to enable research into the development of stem cell-based therapies for AMD [acute macular degeneration] as well as other retinal diseases. Pfizer will also contribute expertise in the design and execution of clinical studies, interaction with global regulators, and in product manufacturing techniques.”[[498]](#footnote-498)

This indicates that in addition to funding R&D, Pfizer will be active in both the planning and commercial aspects of the research.

While it is difficult because of confidentiality to make generalisations regarding the IP policies of private funding of university research, it is reasonable to assume that the university will have to devote time and resources to negotiating, and monitoring adherence to, the terms for the management of any IP and IPRs arising from the project. Further, the economic returns to each partner in public-private funded project will vary depending on the terms of the IP agreements.

## Concerns surrounding the increased commercialisation of university research

Together with Chapters 2 and 3, this chapter has shown that there has been a promotion of the commercialisation of basic research in universities, not least in the fields of biological and stem cell science. This has been the subject of criticism for a variety of reasons, some of which may influence scientists’ perceptions of patents and patent information.

As mentioned previously, in line with pressures to commercialise their work, universities and academic researchers have had to adapt to survive and thrive, adapting their norms to the developing funding environment:

“Recent changes within science policy, and also the greater economic and social expectations that are being placed on science, are having significant consequences for scientific personnel and research and development institutions.” [[499]](#footnote-499)

There are many ways in which such change is occurring:

“Universities have been and are changing their strategies, organisational structures and competencies, in order to respond to these new external demands and the associated pressure for enhanced professional internal management practices … In short, as the role of universities in economic growth and innovation has been increasingly emphasised, so too have pressures on them been raised.”[[500]](#footnote-500)

Further, Martin and Hughes note that the impact of research cannot be measured solely in the abstract (i.e. in terms of quantitative measures); the effect on researchers of pushing an impact agenda must also be considered:

“The impact of publicly funded research depends not only on understanding transitional pathways, but also involves examining the ways that scientists are motivated or influenced by problems and areas of research stimulated by interactions through these pathways. Impact involves both the presence and the effectiveness of the mechanisms or pathways by which knowledge is exchanged and connections are made, but also the extent to which the nature of the pathways or connections between the public and private sector domains influences the direction and nature of research in the former.”[[501]](#footnote-501)

This is also supported by empirical data, for example from Owen-Smith and Powell[[502]](#footnote-502) and Tartari, Salter and D’Este[[503]](#footnote-503), which indicate that scientists’ perceptions of costs and benefits in engaging in knowledge transfer and commercialisation activities are crucial to understanding their willingness to engage with these activities.

### The ways in which patents may affect the institution of academic science

According to Robert Merton’s seminal sociological study of science, the goal of science research is “the extension of certified knowledge.”[[504]](#footnote-504) Merton suggested that a set of norms were at play to support these ends, norms based upon the values of the institution of science.[[505]](#footnote-505) The four ‘Mertonian norms’ are:

1. ‘Universalism’ is based on the idea that science is impersonal, that scientific research is not dependent on an individual’s “personal or social attributes”; all scientists can contribute, and build upon, a communal body of knowledge.[[506]](#footnote-506)
2. ‘Communism’ within the context of scientific institutions means that the results of scientific research are “a product of social collaboration and are assigned to the community.”[[507]](#footnote-507) Again, this allows for the existence of a pool of knowledge to which all can contribute to and all can draw from.
3. ‘Disinterestedness’ means that scientists work with the aim of pushing the boundaries of knowledge rather than fulfilling personal motives.[[508]](#footnote-508)
4. ‘Organised-scepticism’ refers to the idea that scientific claims must be subjected to scrutiny before being accepted as fact. This norm is important because empirical fact is “both a methodological and an institutional mandate”.[[509]](#footnote-509)

Whether these norms remain the main drivers of science has been questioned by a number of academics.[[510]](#footnote-510) Whilst the traditional norms are not generally disputed, questions have been raised about whether they continue to represent the undertaking of science today. Of interest to this thesis is the ways in which changing models of funding; the consequent changes in both incentives and institutional structures; and increased patenting impacts upon the traditional norms of science.

### Patents and the traditional norms of science

Eisenberg argues that the patent system is inconsistent with the Mertonian norms of scientific research, particularly in biological fields:

“[T]he patent system threatens the interest of the scientific community in the free use and extension of new discoveries.”[[511]](#footnote-511)

Rai builds on this argument noting that although the traditional norms of science were originally maintained in the field of molecular biology as it moved from a basic to more applied science, the increasing patenting of basic research has eroded traditional norms changing scientific incentive structures, increasing selfishness and contributing to reduced sharing amongst the scientific community.[[512]](#footnote-512) Further, Eisenberg argues that the incentives provided by policies aimed at increasing the commercialisation of academic research must be questioned if universities are to maintain their original mission of undertaking research for social value:

“One might worry about whether the revenue incentives created for research performers by the Bayh-Dole Act are a good thing. Is the lure of patent royalties leading universities and investigators to select research projects that appear likely to yield patent rights? If so, is this quest distracting them from research that is more valuable from a broader social perspective?” … There is a fine line between using patents to motivate universities to cooperate in transferring research discoveries to the private sector for commercial development and using patents to motivate universities to perform research of a character that is likely to yield potential commercial products. The former motivation may change how universities disseminate the results of their research; the latter may change the character of the research itself.”[[513]](#footnote-513)

Although written about the effects of the Bayh-Dole Act in the US, the same applies to wider policy aimed at technology transfer and capturing short-term economic returns from research, such as those seen in modern science policy in the UK. In a similar vein, Kapczynski argues that the differences between private companies and universities must be recognised and preserved if the public value of universities is to be maintained.[[514]](#footnote-514) Radder extends these critiques to argue that a divergence from Mertonian norms is not only problematic from the perspective that it is changing the conduct of science, but also that it is undermining justifications of academic institutions that claim to adhere to these norms:

“[P]atenting the results of academic research does not conform to the specific norms derived from the more general Mertonian values. Put differently, the introduction of academic patenting directs science away from, rather than bringing it closer to, the realization of these values. Since these Mertonian values are at the basis of many of the recently adopted codes of good scientific conduct, they can be expected to find quite general support … Hence, the recent patenting practices of public research institutions stand unjustified … The conclusion is that academic patenting is normatively undesirable … universities should either abolish their patenting practices or denounce their adherence to the Mertonian ethical codes. If they do neither - which is unfortunately the case thus far - their ethos proves to be no more than a superficial ideology that masks their real behavior.”[[515]](#footnote-515)

This raises a related question: should patents be granted over publicly funded research results? Eisenberg argues this question is rooted in four interrelated points:

1. That these patents create a double taxation on society: society pays twice for the invention by paying for the research to be undertaken and then paying to access the invention;
2. That patent incentives should not be necessary to incentivise publicly funded research;
3. That promoting the routine patenting of publicly funded research “calls into question the public goods rationale for public funding of research”; and
4. That providing incentives for patents over publicly funded research may diminish the public domain of research which is essential for future progress.[[516]](#footnote-516)

Such concerns have also been raised by scientists such as James Watson in the Myriad case (as discussed in section 5.4.2). The last point highlighted by Eisenberg (diminishing the public domain of research necessary for future research) has also been raised with regard to the ways in which pressures to commercialise basic research have affected the practice, institutions and incentive structures in universities.

### Openness tensions

Traditionally, academic science has been regarded as an open enterprise, different to that of the private sector with each having a market for scientific knowledge determined by their norms and priorities.[[517]](#footnote-517) This is linked to the traditional Mertonian model, on which Merton writes:

“The institutional conception of science as part of the public domain is linked with the imperative for communication of findings. Secrecy is the antithesis of this norm; full and open communication its enactment. The pressure for diffusion of results is reinforced by the institutional goal of advancing the boundary of knowledge and by the incentive of recognition which is, of course, contingent upon publication.”[[518]](#footnote-518)

Eisenberg notes that “both the norms and the rewards of science promote prompt disclosure of new discoveries through publication”[[519]](#footnote-519). The concept of communism is satisfied by the fact that scientists are rewarded by professional recognition when they publish information encouraging scientists to publish their findings as quickly as possible.[[520]](#footnote-520) This scientific aim of publication also fulfils the Mertonian norms of disinterestedness (publication allows for the scrutiny of scientific research), universalism (anyone can contribute to publication independent of their personal attributes) and organised scepticism (peer review in publication facilitates scrutiny of scientific claims).

Eisenberg explains that whilst there are clear reasons for disclosing research results in line with the traditional norms (such as scientific recognition and credibility and widespread dissemination and use and defeating potential patent claims), there are also strong motivations for withholding results (such as retaining exclusive rights for customers, avoiding disclosure to rivals and preserving patent rights). The latter of these are amplified where IPRs are involved.[[521]](#footnote-521) As a result, the increase in, and drive towards, commercialisation and patenting of publicly funded research has challenged the traditional norms of science, particularly the norm of ‘openness’. The aim of commercialisation is to effectively exploit work and intellectual property, by its very nature, provides restrictive rights, which can be at odds with prompt open dissemination (e.g. delaying publication in order to protect novelty). As has been shown, the changes in the institutional structures and incentives of academic science mean that scientists may be driven to patent prior to publication. Patent rights may limit traditional practices of disclosure.[[522]](#footnote-522) This tension has led to questions being asked about the closing of the public domain of science – or the scientific commons – and also the availability of research findings to other researchers and the wider public.[[523]](#footnote-523) The conflict has also been acknowledged by the UKIPO:

“The vast majority of a university’s output is put directly into the public domain by publication in journals or by free dissemination. The ability of researchers to publish must be preserved, but industrial contracts and IP protection need to be considered, for example by educating researchers on the necessity to file a patent application before publishing, or by allowing industrial partners to request delays in publication in order to accommodate patent filing. IP related activities may generate a small, but welcomed, proportion of a university’s revenue, but can have a wider economic impact by enabling new knowledge to create new jobs and deliver innovation to the economy.”[[524]](#footnote-524)

The Royal Society has argued that at times restricting openness for some time in line with filing for patents may be necessary to support the ‘public interest’:

“[E]ffective commercial exploitation of some publicly funded research is in the public interest and may require limitations on openness”[[525]](#footnote-525)

The tension is likely to be felt by scientists and may influence their perceptions of the patent system and patent information.

#### The parallel open access debate

Patenting is not the only subject where the importance of openness is being called into question; there are a number of related movements. For example, this ‘openness tension’ has been highlighted in the debate about open access (OA) to research publications. OA aims to improve the flow of information, removing barriers to access, use and reuse of information, to encourage transparency, openness and accountability.[[526]](#footnote-526) In 2012, the UK Government made a commitment to dramatically improve free access to publicly funded research publications by 2014.[[527]](#footnote-527) This pledge followed the report of a group commissioned by the UK Minister of State for Universities and Science, David Willetts MP. The group, led by Dame Janet Finch, was charged “with recommending how to develop a model, which would be both effective and sustainable over time, for expanding access to the published findings of research.”[[528]](#footnote-528) The group released its report entitled “Accessibility, sustainability, excellence: how to expand access to research publications” (the Finch report) in July 2012. The report recommended that “the UK should embrace the transition to open access”[[529]](#footnote-529) and a provided a number of proposals on how to achieve this. The report advised that the cost of publication in open access journals should be built into publicly funded research grants.[[530]](#footnote-530) This is not just a national movement. The European Commission has committed that from 2014 “all articles produced with funding from Horizon 2020 will have to be accessible”[[531]](#footnote-531) and intends “60% of European publicly-funded research articles to be available under open access by 2016”.[[532]](#footnote-532)

The OA movement has led to debate about the traditional business model of publishing. Traditionally research results were published in journals to which research institutions, groups and individuals could access the information for a cost, often paying for a license, a subscription or paying on a ‘pay-per-view’ basis. Since the advent of the internet an increasing amount of journal content has become available online, with the majority of journals using digital publishing as a complementary service to their paper versions. Originally, this digital publication was based on the traditional business model of publication, also requiring a licence, subscription or individual payment to access articles. New business models have been adopted by groups such as BioMed Central which publishes over 220 open-access, peer reviewed journals providing articles free at the point of access.[[533]](#footnote-533)

The rationale for open access to scientific journal literature is similar to the knowledge transfer rationale of patents: both aim to improve access to research findings. In the case of open access, the argument is posed particularly in relation to publicly funded research, i.e. as is the focus of this thesis. This is based on the argument that the results of publicly funded work should be freely accessible in the public domain – an argument which the Finch report claims is ‘compelling’ and ‘fundamentally unanswerable’.[[534]](#footnote-534) This further highlights the tensions involved in the commercialisation of publicly funded research. A parallel is therefore drawn between open access to research publications and open access to patent information.

### Changing expectations of academic researchers

Traditionally the career progression of scientists has been largely dependent on the quality and quantity of their academic publications. However, other factors such as ‘impact’ and patents are increasingly part of the equation. This is a move from tradition, altering the role of researchers. Owen-Smith and Powell’s interviews with American academic life scientists showed that patents are increasingly accepted as a legitimate activity in academic science and are sometimes viewed as reaffirmations of the originality of their work and contribute to their scientific renown.[[535]](#footnote-535) This implies a shift from the traditional reward system. Further, Azoulay, Ding and Stuart’s study of almost 4,000 academic life scientists in the US showed that there is a relationship between patenting and career progression with patenting researchers being more productive (35% more research papers) at each career stage than their non-patenting counterparts and suggest that, in recent decades:

“[P]atenting has come to be recognized as a legitimate form of scientific output in the academic life sciences. If this is the case, in future years we may observe that further increases in academic patenting will occur in the early career years as patents come to be viewed as an important means of disseminating research findings and therefore of building a professional reputation.”[[536]](#footnote-536)

The authors conclude that this has led to a change in the academic incentive system that “may be evolving in ways that accommodate deviations from traditional scientific norms of openness”[[537]](#footnote-537). As with the spread of policies aimed increasing the commercialisation of academic research, the increasing acknowledgement of patents and ‘entrepreneurial’ activity as a measure of research quality may spread from the US to the UK. This process appears to have begun with the inclusion of patents in REF metrics. This forces researchers to further consider patenting, not only to secure funding but also to demonstrate the impact of their research – both potentially important factors in career progression.

The effect of these policies on researchers has also been investigated from a psychological perspective. Qualitative data of US academics indicates that the rise of policies promoting ‘academic entrepreneurship’ has driven a modification of academics’ ‘role identities’ resulting in a “hybrid role identity that comprises a focal academic self and a secondary commercial persona”.[[538]](#footnote-538) Interestingly, Jain, George and Maltarich highlight two mechanisms which academics use to preserve their traditional role identities: delegating and buffering. These were used by the academics interviewed to avoid association with technology transfer. This research demonstrated that scientists perceive problematic tensions between their ‘traditional’ and ‘commercial’ roles.

### Metrics, ‘impact’ and collaboration

Despite the promotion of the commercialisation of academic research, and while the quantity of patent applications and granted patents from universities has increased, it remains the case that the majority of these institutions make little direct income from their IP.[[539]](#footnote-539) In line with the increase in patent applications and grants, the income to universities from IP increased 88% between 2003-4 and 2011-12 to over £61 million.[[540]](#footnote-540) Likewise, the costs of protecting the IP has increased, rising to more than £31 million in 2011-12,[[541]](#footnote-541) a net gain of around £30 million. While £30 million may seem like a lot, it is less than 1% of the claimed £3.3 billion value of knowledge transfer from universities – the vast majority of knowledge transfer value comes from sources other than income from IP. Further, it is not clear whether these figures include the cost of time spent in developing applications for IPRs. The picture is likely to be similar to the US with few individual universities generating significant net income from their IP.[[542]](#footnote-542)

In addition to the limited income from IP in universities, it has regularly been noted that a focus on protecting IP can, in fact, hamper collaboration with industry and thus the knowledge exchange through these channels.[[543]](#footnote-543) These problems have also been noted specifically in the field of stem cell research. A report by Paul Martin and Emma Rowley on ‘Barriers to the Commercialisation & Utilisation of Regenerative Medicine in the UK’,[[544]](#footnote-544) involving interviews with 54 stakeholders, revealed that one barrier to the commercialisation of research related to confusion surrounding IP rights, particularly ownership of the rights.[[545]](#footnote-545) The report also argued that an increased awareness of the potential benefits of IP for universities had driven an increase in the expectations of financial returns, causing tensions in partnerships:

“[W]here traditionally the acquisition of academic science has been financially attractive, this is becoming less so. Industrial participants reported that they were faced with increasing financial and contractual demands, which altered both the working relationships and financial rewards that they had become accustomed to receiving. Partnerships and the management of intellectual property were seen to be vital components to knowledge acquisition and sharing in relation to driving regenerative medicine forward. However, there were competing tensions: universities were perceived to be making bigger requests for payment in relation to IP rights.”[[546]](#footnote-546)

Further, the drive to commercialise academic research has led to concern amongst the academic research community that the long-term value of publicly funded science supported by traditional models of research dissemination is being neglected in policy decisions in favour of short-term economic ‘impact’.[[547]](#footnote-547) It has been argued that this increased focus on impact, particularly short-term economic impact, will diminish the focus on, and funding of, basic research.[[548]](#footnote-548) Further, Ben Martin and Alan Hughes have argued that the focus on quantitative measures of impact (such as numbers of patents and spin-outs in the REF exercise) may backfire in the future:

“[O]f the various channels or ‘pathways to impact’ through which research in the university base may contribute to innovation, some are more amenable to quantitative assessment of impact, others less so. Over-emphasis by policy-makers on the more readily accessible forms of impact may be counterproductive to research impact in the long term.”[[549]](#footnote-549)

Martin and Hughes also argue that while metrics indicate that the impact of research has increased, this may be due to “increased requirements to report impacts and the incentives to intensify efforts to record and report relevant data … [leading] to an element of ‘inflation’ over time.”[[550]](#footnote-550) Thus, it is possible that the metrics provided may be overestimated – the income from IP may be lower than reported.

## Conclusions

Given the acknowledged potential of stem cell science (and the associated field of regenerative medicine) to improve healthcare and support the UK economy, it is unsurprising that large public and private commitments have been made to support the field. UK stem cell-specific policy has increasingly focused on the translational and commercial aspects of the research in a hope of realising potentials of the field (in line with general national science policy as described in Chapter 3). As a result, public funding models have developed, and specific public funds have been created, which favour the creation of public-private partnerships. This has resulted in an environment where the conditions of funding often require basic scientists to work in translational teams and consider regulatory and commercial issues from a very early stage in the research process. Further, the terms and conditions of basic research funding require IP to be protected where possible. Largely (except in the case of private, for profit funding where details are less clear) these conditions pass management of resultant IP to grantees’ institutions (e.g. universities). This obliges universities and consequently academic researchers to consider these issues throughout the research process. Notwithstanding this expectation, as highlighted in the recent HoL Report on Regenerative Medicine, universities have historically struggled to manage IP and the current models require researchers to work in areas where they have little experience and have indicated they feel they receive insufficient support.

The final section of the chapter presented a number of concerns surrounding the increased focus on the commercialisation and patenting of basic research in universities. It has been suggested that such a focus is incompatible with the traditional norms of science and has changed the role of academic researchers and institutions. Further, concerns have been raised about the effect of patents on the traditionally ‘open’ model of science and the potential downstream effects of this (in line with the arguments posed in the debate regarding ‘open access’ to research publications). These issues may affect the engagement of stem cell scientists with the patent system, as investigated in the empirical study.

Chapter 5

Patent policy and the extension of patentable subject matter

## Introduction

This chapter discusses a variety of aspects relating to the patenting of basic biological research. An introduction is given to patents, explaining the legal requirements of patentability before discussing the ‘social contract’ rationale for the patent system and the aligned requirements of disclosure and publication. Under this rationale, it is assumed that the patent system rewards inventions which fulfil these requirements and that the system disseminates technical information to inform future innovation. Through a brief description of a number of landmark cases, it will then be shown that the notion of patentable subject matter has expanded in recent decades to include upstream basic biological research. These cases include Diamond v Chakrabarty, Association for Molecular Pathology v Myriad Genetics, the ongoing questions surrounding the WARF patents and the case of Brüstle v Greenpeace. Alongside this account, it will be shown that the patents in question have been the subject of considerable controversy, attracting commentaries from a wide variety of groups including eminent scientists. These comments will be used to highlight a number of concerns about upstream patenting which are elaborated upon in the final part of the chapter. This concluding part will consider the ability of the patent system to cope with upstream biological patents, specifically the ability of the system to capture upstream ‘inventions’ and disseminate the related scientific information.

## Modern patent rights

Intellectual property (IP) is a collective term which refers to “any form of original creation that can be bought or sold”.[[551]](#footnote-551) There are a number of forms of IP rights (IPRs), each covering a different type of ‘original creation’ including trademarks, designs, copyrights and, the focus of this thesis, patents. Today, patents are used to protect inventions. A patent provides the patent owner exclusive rights to control the use of a patented invention, preventing others from making, using, importing or selling the invention in the territory where the patent has been granted for up to 20 years.[[552]](#footnote-552) The patent system is governed by national laws and international treaties[[553]](#footnote-553) which are administered by patent offices and specialist courts.

### When can a patent be granted?

Upon fulfilment of patentability[[554]](#footnote-554) criteria defined in national and international legal instruments,[[555]](#footnote-555) the patentee has a right to a standard set of legal entitlements. The corollary is that the issuing patent office must grant a patent when the criteria are met[[556]](#footnote-556) and specialist courts can enforce the patentee’s rights if the patent is infringed.[[557]](#footnote-557) Patent law also provides for the revocation of granted patents when it is found, post-grant, that one or more of the legal criteria have not been fulfilled.[[558]](#footnote-558)

General patentability requirements are present across different national, regional and international legal instruments.[[559]](#footnote-559) These requirements are cross-checked during the examination of patent applications and a patent is only granted if they are found to be fulfilled. Section 1(1) of the UK Patents Act (1977) sets out the main patentability requirements:

“A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say -

(a) the invention is new;

(b) it involves an inventive step;

(c) it is capable of industrial application;

(d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A”[[560]](#footnote-560)

Some things cannot be patented such as discoveries, scientific theories, algorithms and artistic works.[[561]](#footnote-561) In addition, some patent laws contain exclusions regarding inventions: “the commercial exploitation of which would be contrary to public policy or morality.”[[562]](#footnote-562) Following the EU Directive on Biotechnological Inventions (1998), the UK Patents Act was amended in 2000[[563]](#footnote-563) to specifically exclude from patentability:

“the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene; … uses of human embryos for industrial or commercial purposes.”[[564]](#footnote-564)

These exclusions have proved controversial, as further discussed in section 5.4 with regard to the patenting of biological materials and ‘discoveries’.

In addition to these various requirements, patent laws require that a patent application contains a specification[[565]](#footnote-565) that “disclose[s] the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.”[[566]](#footnote-566) Another requirement is that patent applications must be made publicly available within 18 months of the date of filing, and granted patents must be published as soon as possible after the date of grant.[[567]](#footnote-567) These requirements oblige patent applicants to make information about their invention public in return for a monopoly patent right.

Patent claims may be invalidated post-grant if the aforementioned legal criteria have not been met. Accordingly, a patent may be revoked for lack of novelty; lack of inventive step; lack of industrial application; if it is excluded from patentable subject matter (for example if it is found to cover a discovery rather than an invention); or if “the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art”[[568]](#footnote-568). The interpretation and application of these criteria in emerging fields of science have proved to be contentious, as discussed in sections 5.4 and 5.5.

## The rationale of the patent system today

Different justifications have been offered as rationales for the patent system and have fluctuated in popularity during the history of the patent system.[[569]](#footnote-569) These largely focus on four arguments highlighted by Machlup in his seminal 1958 report on the US Patent System: the ‘natural-law’ thesis, the ‘reward-by-monopoly’ thesis, the ‘monopoly-for-incentive’ thesis and the ‘exchange-for-secrets’ thesis.[[570]](#footnote-570) The latter two are often coupled together into a modern economics-based justification, described by Sterckx as a “consequentialist (economic) justification”.[[571]](#footnote-571)Sterckx notes this “is considered by most commentators as the most convincing justification”; it is the most prominent justification in debates about the system and is used to promote extension of the system.[[572]](#footnote-572) Its eminence is not bound by subject: it is provided in arguments by economic, legal and philosophical commentators and policymakers alike.[[573]](#footnote-573)

The ‘consequentialist’ justification considers the costs and benefits to innovators and society. In order to optimise patent policy within this justification, there needs to be a maximisation of societal benefit at minimal societal cost. The approach …

“… does not see patents as a ‘natural right’ the inventor should have, but as a policy instrument which should be adapted by government in the interests of society. Patents aim at supplementing market forces, which do not lead on their own to the socially desirable level of innovation. The benefits of the patent system reflect its mission – to encourage invention and diffusion of technology; and its costs reflect its modus operandi, which is to restrict the use of inventions.”[[574]](#footnote-574)

The justification acknowledges the centrality of the patentability requirements and the potential value of disclosure in achieving the anticipated economic benefits of the system. Under this model, patents are argued to encourage and facilitate innovation. This is based on two main assumptions: 1) the grant of exclusive patent rights provides an incentive for socially and economically desirable levels of invention and innovation; and 2) the system requires disclosure of information and knowledge on which innovators may build which may otherwise be kept secret. More explicitly, the rationale details that in order to achieve economic growth, the patent system is required to incentivise innovation and knowledge transfer through the grant of monopoly rights. In this way, patents can be viewed as a form of social contract: society grants inventors exclusive rights over their inventions in return for disclosure of information on which other innovators may build.[[575]](#footnote-575)

Guellec and van Pottelsberghe, two former chief economists of the EPO, consider the patent system from such an economic perspective: “… the aim of the patent system is economic in nature: it is to foster innovation and growth”.[[576]](#footnote-576) This growth is facilitated by disclosure through the patent system:

“It is one aim of the patent system to make disclosure a preferred option to the inventor. Disclosure facilitates follow up inventions … As Werner von Siemens, a vocal advocate of patents in the late nineteenth century, once said: ‘Because by patenting each new thought is carried into the world; one hundred minds may take it up, may steer it to completely different paths and make good use of it’” … The major source of new technology is new knowledge, relating to science, technology, business or other … Technical change is accelerated, and less costly, when researchers have access to more knowledge, to more ideas that they could combine, recombine and test.”[[577]](#footnote-577)

In this way, disclosure is claimed to improve the speed and efficiency of invention in society “which is central to economic growth”.[[578]](#footnote-578)

### ‘Social contract’ and the patent system

Within the modern consequentialist justification, patents can be construed as a form of ‘social contract’ in which a patent is offered in return for public disclosure of an innovation. Society forgoes potential loss through the exclusionary rights provided by a patent in return for potential benefits brought about by disclosure of information relating to the innovation:

“Conceived solely in terms of an individual reward for an individual inventive effort, the grant of patent rights has a pleasing simplicity and a certain symmetry. An inventor invents, abandons his secret and is rewarded for doing so. The publication of his secret adds to knowledge, and his reward acts as an incentive for others to invent and be rewarded.”[[579]](#footnote-579)

This ‘social contract’ perspective is not new. As Drahos notes, “the disclosure conception of the patent contract developed well after the establishment of the patent institution and was pre-dated by the social value conception of the patent contract”.[[580]](#footnote-580) Further, Machlup and Penrose detail the use of social contract theory in their account of nineteenth century justifications of the patent system.[[581]](#footnote-581)

The use of this theory in relation to disclosure is relatively recent. Since the inclusion of patent specifications in patent applications and the accompanying disclosure requirement, disclosure has been given weight as an objective of the system.[[582]](#footnote-582) Consequently, disclosure is often reported as being the *quid pro quo* of the patent system;[[583]](#footnote-583) disclosure and publication, it is claimed, encourages knowledge transfer, which informs and provides incentives for downstream innovation[[584]](#footnote-584) allowing inventors to ‘build on the shoulders’ of their predecessors.[[585]](#footnote-585) This ‘social contract’ model, with disclosure as the *quid pro quo* of the system, persists in justifications of the patent system.[[586]](#footnote-586) For example, the case of Kirin-Amgen, Inc. v Hoeschst Marion Roussel Ltd(2004) illustrates the importance of the patent specification in fulfilling the information disclosure function of the patent system. This was expressed in Lord Hoffmann’s concluding remarks in the case:

“An invention is a practical product or process, not information about the natural world. That seems to me to accord with the social contract between the state and the inventor which underlies patent law. The state gives the inventor a monopoly in return for an immediate disclosure of all the information necessary to enable performance of the invention. That disclosure is not only to enable other people to perform the invention after the patent has expired. If that were all, the inventor might as well be allowed to keep it secret during the life of the patent. It is also to enable anyone to make immediate use of the information for any purpose which does not infringe the claims. The specifications of valid and subsisting patents are an important source of information for further research, as is abundantly shown by a reading of the sources cited in the specification for the patent in suit. Of course a patentee may in some cases be able to frame his claim to a product or process so broadly that in practice it will be impossible to use the information he has disclosed, even to develop important improvements, in a way which does not infringe. But it cannot be right to give him a monopoly of the use of the information as such.”[[587]](#footnote-587)

The judgment highlighted the Court’s view of the centrality of the disclosure requirement in the justification of the use of patents and the maintenance of a ‘social contract’ notion in legal practice.

### Disclosure and diffusion of patent information

From the social contract perspective, it is important that the patent system returns on its promise: that patents are only granted upon fulfilment of the legal requirements of patentability and that disclosure is indeed a *quid pro quo* for the grant of the exclusive monopoly. There are a variety of modern critiques of the ‘social contract’ model based on concerns that the balance is skewed; that the system is biased toward the inventor and away from social value, favouring private rather than public concerns.[[588]](#footnote-588) For example, there are concerns that patents of ‘poor quality’ are regularly granted.[[589]](#footnote-589) Whilst there is little empirical evidence regarding how ‘inventive’ patented ‘inventions’ are, the evidence available suggests that the inventive step standard is extremely low.[[590]](#footnote-590) In addition, Drahos argues the traditional social contract justification focuses too heavily on the legalistic acts of disclosure and publication rather than diffusion of information of social value:

“The modern patent social contract justification assumes that disclosure is the essence of the bargain. It is not. What matters is that the patentee must deliver an invention of social value, or something that at least has potential social value. It is then up to society to find ways to realize the social value of the invention. Capturing the full social value of invention information depends critically on policies aimed at the social diffusion of that information, something which the requirement of a mere paper disclosure of the invention is unlikely to achieve … On a social value conception of the patent contract, it is the diffusion of invention information of social value that matters, not the legal ritual of disclosure.”[[591]](#footnote-591)

Building on Drahos’ model, this thesis investigates whether the patent system is supporting the social diffusion of patent information in the fields studied: biological and stem cell science.

## The expansion of patentable subject matter to basic biological materials

Patents were originally awarded for ‘bricks-and-mortar’ inventions but the scope of eligible patent subject matter has expanded dramatically in recent decades. Following a series of landmark cases, patents have been routinely awarded over non-tangibles, often the products of upstream basic research (regularly undertaken in universities) Such intangibles include software sequences, business methods, micro-organisms, genes and methods of developing stem cell lines.

### Patenting ‘life’: Diamond v Chakrabarty

In the US, up until 1980 it was widely held that products of nature were unpatentable.[[592]](#footnote-592) This changed with the US Supreme Court’s decision in the case of Diamond v Chakrabarty. The applicant (Chakrabarty) applied for a patent over a bacterium capable of breaking down crude oil. In the first instance, the USPTO refused the application on the basis that, in line with general understanding of the time, that micro-organisms were ‘products of nature’.[[593]](#footnote-593) The US Supreme Court overturned the USPTO’s decision, holding that the natural version of the bacterium had been transformed by human intervention (an inventive step) so that it was no longer ‘natural’:

“A live, human-made micro-organism is patentable subject matter under §101. Respondent's micro-organism constitutes a "manufacture" or "composition of matter" within that statute.”[[594]](#footnote-594) … “[T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter”[[595]](#footnote-595)

This case paved the way for the extension of patents to other biological materials, provided they fulfilled the standard patentability criteria.

### Gene patents and the Myriad case

From the late 1980s, the USPTO led a policy of patenting isolated genes; a policy which was affirmed in the US courts in the 1990s.[[596]](#footnote-596) This policy spread internationally[[597]](#footnote-597) with the EU Directive on Biotechnological Inventions (1998) specifically stating that isolated elements of the human body “including the sequence or partial sequence of a gene” may be patentable.[[598]](#footnote-598) As a result, the number of patents over genes grew fast, with the number of such patents in the US alone passing 15,000 in 2010.[[599]](#footnote-599) The growth of patents in this field has been the subject of considerable controversy,[[600]](#footnote-600) recently culminating in the US in the landmark ‘Myriad case’.

In the caseAssociation for Molecular Pathology v Myriad Genetics(2013)(the Myriad case), the US Supreme Court invalidated patents on isolated BRCA1 and BRCA2 genes.[[601]](#footnote-601) This unanimous decision was based on the courts view that the claims covered naturally occurring gene sequences, which had simply been isolated but not changed, remaining ‘products of nature’.[[602]](#footnote-602) Thus, the claims did not satisfy U.S.C. 35 §101 which states:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain apatent therefore, subject to the conditions and requirements of this title.”[[603]](#footnote-603)

The Court, however, held that complementary DNA (cDNA) forms of the genes could be patented because they were not a ‘product of nature’.[[604]](#footnote-604) Following the case, in a memo to its staff the USPTO formally revised its long-standing policy regarding gene patents:

“As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not.”[[605]](#footnote-605)

The legal impact of the case is, as yet, uncertain. It has been suggested that in addition to the effect on future patent applications over 8000 US granted patents citing naturally occurring sequences could be overturned following Myriad*.*[[606]](#footnote-606) In addition, the use of §101 rather than §103 (which details the standard patentability criteria) to invalidate the patents has caused concern amongst the legal community that the decision has reopened questions which were thought to have been answered.[[607]](#footnote-607) The case could be relied upon to challenge other patents, and indeed is the basis of an appeal against the WARF patents (as described in the subsequent section).

The Myriad patents and the Supreme Court ruling have drawn commentary not only amongst legal practitioners, academics and policy groups[[608]](#footnote-608) but also attracted debate amongst the wider public.[[609]](#footnote-609) The concerns of scientists are reflected in submissions to the Court from eminent scientists. For example, in his *amicus brief* to the US Supreme Court regarding the case, James Watson (the co-discoverer of DNA and a major figure in the American project to sequence the human genome) highlighted a number of key concerns about the patenting of gene sequences arguing that such patents are ‘unnecessary’ and should not have been granted over basic research intended to inform downstream research:

“[M]uch of what we know about human genes traces back to the Human Genome Project, which was structured as a public works project, intended to benefit everyone by deciphering our genetic code. Our goal was to construct a map of what already existed in nature, namely our genes. Accordingly, I, along with other prominent scientists, expressed the strong opinion that human genes should not be patented. There was simply no need for it. …. It was a mistake by the Patent Office to issue patents on human genes and a mistake by those who filed for those patents … human gene patents are not necessary to encourage scientists to advance our knowledge and develop innovative new medicines or biotechnology inventions. The important innovations needing patent protection are not the human genes themselves but the technologies that use human genes”[[610]](#footnote-610)

The Myriad case also brought up an aspect of moral argument against patenting biological materials. Watson highlighted a view that genes are too ‘special’ to be patented:

“[A] human gene is fundamentally unique – unlike any ordinary “composition of matter.” A gene conveys information – the instructions for life. As a product of nature, a human gene’s primary purpose is to encode the information for creating proteins, enzymes, cells, and all the other components that make us who we are. … Life’s instructions ought not to be controlled by legal monopolies created at the whim of Congress or the courts.”[[611]](#footnote-611)

Thus, there is a sense within at least some parts of the scientific community that there is something precious about naturally-occurring biological entitles, particularly those which carry ‘knowledge’ or ‘instructions’ (as is also the case with stem cells) which means they should be excluded from being patented. While this thesis does not attempt to grapple with the appropriateness of patenting biological entitles *per se*, it is important to note that some scientists are troubled by patents on ‘life’.

Further, Watson highlighted that gene patents could limit downstream innovation:

“The important innovations needing patent protection are not the human genes themselves but the technologies that use human genes. And here, it is important that the human genes can be reasonably accessible so that as many top minds can develop the new technologies based on human genes.”[[612]](#footnote-612) … “A human genome cluttered with no trespassing signs granted by the Patent Office inhibits scientific progress, particularly in the development of useful tests and medicines in areas requiring multiple human genes. The resources devoted to cancer research, neurological diseases, and other areas will be diverted to concerns about whether one can use a particular human gene. For a new assay using hundreds of human genes, the sea of patents and patent applications would create hundreds, if not thousands, of individual obstacles to developing and commercializing the assay.”[[613]](#footnote-613)

These concerns are in line with the anticommons theory proposed by Eisenberg and Heller. Opposite to the ‘tragedy of the commons’ (an overuse of commonly owned resources[[614]](#footnote-614)), the ‘tragedy of the anticommons’ is an underuse of privately owned resources.[[615]](#footnote-615) The tragedy of the anticommons occurs when “multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use” and licensing royalties add to the cost of innovation.[[616]](#footnote-616) Eisenberg and Heller hypothesise that an anticommons has occurred in the case of biomedical research where patents are granted on ‘upstream’ research to multiple private parties.[[617]](#footnote-617) This may provide barriers to future research and the realisation of downstream products.[[618]](#footnote-618) Based on the theory they identify …

“… an unintentional and paradoxical consequence of biomedical privatization: A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development.”[[619]](#footnote-619)

While academic debate about anticommons theory has been extensive, empirical evidence has been inconclusive.[[620]](#footnote-620) However, in line with Watson’s remarks, biological scientists have been reported to believe that “contrary to the current consensus, proliferation of IP protection has a strongly negative effect on research in their disciplines.”[[621]](#footnote-621)

It has been posited that in addition to the problem of a material anticommons, large numbers of upstream patents may also cause a knowledge anticommons. Murray and Stern’s study suggested that, in line with anticommons theory, there was a “statistically significant but modest decline in knowledge accumulation as measured by forward citations” for publications with associated IPRs, as opposed to publications without such rights.[[622]](#footnote-622) In other words, they observed a decline in downstream research where a patent existed on the published research.

Within the scientific community, concerns have been raised about the potential of knowledge anticommons developing in the case of gene patents. This concern is amplified where broad patents are sought over early stage technologies which cannot be ‘invented around’.[[623]](#footnote-623) For example, with regard to gene patents John Sulston and Joseph Stiglitz, both Nobel Prize winners in their respective fields of medicine and Economics, wrote:

“Like basic mathematical theorems, genes are an example of "basic knowledge"—the kind of knowledge that typically cannot and should not be patented. Had Alan Turing's mathematical insights been patented, the development of the modern computer might have been greatly delayed … Patents such as those in this case [Myriad] not only prevent the use of knowledge in ways that would most benefit society, they may even impede scientific progress. Every scientific advance is built on those that came before it. There is still a great deal to learn about our genes, particularly how they contribute to disease. Gene patents inhibit access to the most basic information. … Any marginal social benefits of patenting genes clearly do not measure up to the profound costs of locking down knowledge. If, as a result of the refusal to grant a patent for genes, there is a slight slowdown in private research expenditures, it can and should be made up for by an increase in public expenditures.”[[624]](#footnote-624)

Concerns about knowledge anticommons amplified the ‘openness tensions’ discussed in section 4.4.3, alongside the problems regarding sufficient disclosure and the patent information infrastructure described later in section 5.5.3.

### Embryonic stem cell patents in the US and Europe

Patenting in the field of stem cell science has grown exponentially since patents relating to stem cells were first granted in the 1990s (with applications growing to more than 10,000 in 2007[[625]](#footnote-625)) and patents are being granted on ‘upstream’ research. As a result, the patent landscape is complex[[626]](#footnote-626) giving rise to concerns about potential anticommons effects complicating the translation of research to product.[[627]](#footnote-627) Together with moral debates, these issues have played out alongside some landmark cases in the US and Europe.

#### The WARF patents

In 1998, James Thomson reported, in the journal Science, that his team had developed the first line of human embryonic stem cells (hESCs).[[628]](#footnote-628) Before this publication, three patent applications based on the work were filed at the USPTO, the EPO and in individual European Countries (including the UK).[[629]](#footnote-629) The patents were assigned to Thomson’s sponsor, the Wisconsin Alumni Research Fund (WARF) and have become known as ‘the WARF patents’.

The WARF patents in the US

The three WARF patents were granted in the US by the USPTO (one in 1998, one in 2001 and the last in 2006[[630]](#footnote-630)). In 2006, following WARF’s “aggressive and restrictive policy toward educational and scientific institutions, which slowed distribution of cell lines and cast a shadow over the ability of researchers to advance knowledge”,[[631]](#footnote-631) the Foundation for Taxpayer and Consumer Rights and the Public Patent Foundation, filed a challenge of all three patents with the USPTO. [[632]](#footnote-632) This challenge was based on the argument that the patent claims were overly broad; were ‘anticipated’ by earlier patents; and would have been obvious to a person skilled in the art (given information readily available in the public domain).[[633]](#footnote-633) In 2007, the USPTO’s initial ruling on the challenge was to reject all claims of the three patents holding that the claims were obvious and anticipated by earlier patents.[[634]](#footnote-634) In response, WARF appealed this decision and amended the claims of the patents, narrowing their scope. Consequently, WARF were reissued the three patents in their amended form in 2008.[[635]](#footnote-635) On the back of the Myriadcase in 2013, the Public Patent Foundation has launched a renewed appeal against the WARF patents in the US arguing that these also cover ‘products of nature’ and therefore should not be permissible under §101 U.S.C. 35.[[636]](#footnote-636)

The WARF patents in Europe

While in the US legal controversy over the WARF patents focused on technical aspects, in Europe the related debate centred on the morality of patenting stem cells. In 1998, the EU adopted the Directive on Biotechnological Inventions.[[637]](#footnote-637) Article 5(1) of the Directive prohibits the patenting of “the human body, at the various stages of its formation and development”. Article 5(2) allows patents on an isolated human ‘element’ even if it is identical to that found in nature. Article 6(1) prohibits patents on inventions “where their commercial exploitation would be contrary to *ordre public* or morality” with Article 6(2)(c) explicitly prohibiting patents on “uses of human embryos for industrial or commercial purposes”. The lack of specific mention of the patentability of hESCs in the Directive, together with the specific permissibility of patenting human ‘elements’ and the prohibition of patents contrary to *ordre public,* resulted in a variety of approaches being adopted across the EU.[[638]](#footnote-638)

In 2004, an examining board of the EPO rejected WARFs patent application on the grounds that it was contrary to *ordre public,* stating that practice of the invention necessitated the destruction of embryos.[[639]](#footnote-639) Following an appeal from WARF, the Enlarged Board of Appeal (EBA) of the EPO issued its decision in 2008. The EBA found the patent to be invalid because the claimed product:

“… at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, even if the said method is not part of the claims.”[[640]](#footnote-640)

Such destruction was deemed contrary to morality under Article 53(a) EPC and rule 28(c) of the EPC implementing regulations[[641]](#footnote-641) (which came into being through the implementation of the Directive on Biotechnological Inventions).

While the WARF patents were never granted in the UK, the UKIPO adopted a relatively liberal approach to considering stem cell patents,[[642]](#footnote-642) indicating in 2003:

“[T]he Office is ready to grant patents for inventions involving such cells [human embryonic pluripotent stem cells] provided they satisfy the normal requirements for patentability.”[[643]](#footnote-643)

As a result of the ruling of the Grand Chamber of the Court of Justice of the European Union (CJEU) Brüstle v Greenpeace*,* the UKIPO’s policy on the grant of patents over inventions involving hESCs has had to be revised noting:

“[T]he Office practice will now recognise that where the implementation of an invention requires the use of cells that originate from a process which requires the destruction of a human embryo, the invention is not patentable”[[644]](#footnote-644)

#### Brüstle v Greenpeace[[645]](#footnote-645)

In 1997 Oliver Brüstle filed a patent relating to neural precursor cells.[[646]](#footnote-646) In 2009, following an appeal against the patent from Greenpeace, the German Supreme Court referred the case to the CJEU requesting clarification of the legal definition of “human embryos” with regard to patentability under Article 6(2)(c) of the Directive for Biotechnological Inventions; and clarification of the expression “uses of human embryos for industrial and commercial purposes” within Article 6(1) of the Directive.[[647]](#footnote-647) In October 2011, the Grand Chamber of the CJEU handed down its decision. The Court held that “the concept of ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense”[[648]](#footnote-648). The Court defined the term ‘human embryo’ as including “any human ovum … as soon as fertilised”[[649]](#footnote-649); “a non-fertlised human ovum into which the nucleus from a mature human cell is transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.”[[650]](#footnote-650) The Court ruled:

“Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.”[[651]](#footnote-651)

The Court indicated that the exclusion from patentability covered not only inventions whose production involved the destruction of embryos but also downstream patents which rely on earlier work/materials involving such destruction, irrespective of the point at which this has taken place:

“The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant.”[[652]](#footnote-652)

The ruling was relied upon by opponents of stem cell research in the Horizon 2020 discussions, attempting to exclude funding of research involving hESCs from the programme.[[653]](#footnote-653) Whilst this attempt was not successful (research involving hESCs may be funded under Horizon 2020[[654]](#footnote-654)) the full implications of the ruling are as yet uncertain.[[655]](#footnote-655) Plomer highlights the paradox the ruling has created whereby research which is morally permissible and lawful in many Member States of the EU, and which Member States and the EU have funded with intent of commercialisation where possible, has been rendered unpatentable.[[656]](#footnote-656)

The CJEU’s decision in the Brüstle case has recently been relied upon by a Technical Board of Appeal at the EPO. The Board refused a patent on the basis that:

“Inventions which make use of publicly available human embryonic stem cell lines which were initially derived by a process resulting in the destruction of the human embryos are excluded from patentability under the provisions of Article 53(a) EPC in combination with Rule 28(c) EPC (points (10) to (29))”[[657]](#footnote-657)

The Board decided that the claims of the patent could not be practiced without the destruction of embryos, at the time of filing, and that:

"[A]n invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos. In that case too, the view must be taken that there is use of human embryos within the meaning of Article 6(2)(c) of the Directive. The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant."[[658]](#footnote-658)

Noting a “need for uniformity in harmonised European patent law”,[[659]](#footnote-659) and that “although judgements of the ECJ are not legally binding on the EPO or its boards of appeal, they should be considered as being persuasive”,[[660]](#footnote-660) the Technical Board observed its decision was ‘in line’ with the ruling in the Brüstle case.[[661]](#footnote-661) While this decision somewhat clarifies the reach of the Brüstle ruling with regard to the position of the EPO, the effect of the case on national patent offices and courts is less certain.[[662]](#footnote-662)

Given the ruling in Brüstle and the ensuing uncertainty it is unsurprising that scientists have raised concerns about its effects.[[663]](#footnote-663) A number of eminent stem cell scientists have also commented on their discomfort at the moral implications against their work in the case:

“There was a large concern, certainly among my colleagues, about the tone of and the way that that judgment was delivered. It appeared to imply a sense of immorality and non-ethical standards for working with human ES cells in general. I know that the judgment did not specifically say that, but there was that kind of tone and implication. There was some concern that this was a ripple effect and a thin end of the wedge whereby these sorts of arguments could be used by other people to undermine our ability to work with human embryonic stem cells much more generally, irrespective of the patent issue. So there was a general concern in the community from that point of view.”[[664]](#footnote-664)

These concerns are likely to have an effect on scientists’ perceptions of patents, particularly scientists working in the field (the participants of the empirical study).

## The systematics of the patent system: from ‘bricks-and-mortar’ to intangible inventions

Following the expansion of patentable subject matter to cover intangible inventions questions have been raised about whether the patent system is able to cope:

“The feeling is widespread that the patent system as we know it, despite its impressive achievements, will need significant transformation in order to address the new challenges raised by the knowledge economy. Patents … were designed at a time when the production and dissemination of knowledge were small scale activities compared with tangible, manufacturing activities.”[[665]](#footnote-665)

As the above quote indicates, an important point to be made is that patents were designed long ago for ‘bricks-and-mortar’ inventions, forms of end-products, or ‘downstream innovations’.[[666]](#footnote-666) As has been shown, patents have been granted over basic scientific knowledge in the life sciences, or ‘upstream research’. These patents are often on inventions many steps removed from end-products meaning some of these patents can shape the futures of entire scientific fields.[[667]](#footnote-667) This has raised the question: is the patent system suitable for modern science?

This is not an abstract academic concern; it is a concern of patent offices themselves. The EPO undertook a large-scale project to “rediscover and renew the basic principles underpinning [the EPO] and its inherent purpose”[[668]](#footnote-668) and find out whether the current IP system “can still accommodate and adapt to meet the needs of the twenty-first century’s information society.”[[669]](#footnote-669) The project identified “the five most important driving forces which will create the greatest uncertainty; causing the system to become increasingly complex and unpredictable.”[[670]](#footnote-670) The most relevant here is the ‘Knowledge paradox’: that while it is clear that the volume of knowledge is growing exponentially, the value of the knowledge created is uncertain.[[671]](#footnote-671) This paradox coupled with the speed of technological progress and obsolescence, something that patent law struggles to cope with,[[672]](#footnote-672) results in a ‘clogged’ system. Similar concerns have also been voiced by a number of academic commentators and groups, such as the Nuffield Council on Bioethics in the UK[[673]](#footnote-673) and the Secretary’s Advisory Committee on Genetics, Health, and Society in the US.[[674]](#footnote-674)

Further, Eisenberg has noted that the patent system is essentially ‘one-size-fits all’, yet the role of the system in different fields is dependent on the field itself.[[675]](#footnote-675) With this in mind she questioned:

“Is a patent system developed to establish rights in mechanical inventions of an earlier era up to the task of resolving competing claims to the genome on behalf of the many sequential innovators who elucidate its sequence and function, with due regard to the interests of the scientific community and the broader public?”[[676]](#footnote-676)

This question is difficult to answer, and entails a variety of additional issues, some of which are considered below and are likely to influence scientists’ views on the patent systems.

### Patent quality[[677]](#footnote-677) and the external ‘expert’ review of patent examination

There are widespread concerns that the patent system is granting patents of poor quality.[[678]](#footnote-678) Aligned with this are concerns that the process of patent examination is problematic. This is based on two points: the strains examiners are facing and the ability of examiners to fulfil their job in examining patent applications. On the first point, there is a huge global backlog of patent applications[[679]](#footnote-679) which, together with considerable administrative time constraints, have left patent examiners under great strain and patent examining difficult.[[680]](#footnote-680) Faced with high levels of pending applications, patent examiners are expected to work faster, risking patent quality by potentially “missing relevant prior art or misjudging obviousness”.[[681]](#footnote-681) This means that while there are features in the patent system to discourage the propagation of poor quality patents (i.e. the patent requirements) it appears that these are not fulfilling their goal.[[682]](#footnote-682) On the second point (the ability for patent examiners to fulfil their job examining patents) there is a question of whether patent examiners have sufficient knowledge about technical fields to assess whether a patent application fulfils the requirements of patentability and disclosure.

It is the duty of the patent office to ensure that the legal requirements are upheld during the examination process, that patents are not granted for inventions that fall short on these requirements. This is not a simple task. While the requirements are legal requirements, a level of technical knowledge is needed to determine whether an application meets them. Patent examiners are often tasked with examining patents in fields in which they have not been formally trained. This is particularly true of emerging fields such as stem cell science. As Noveck notes, patent examiners are “not expected to be a master of all areas of innovation”:

“While the examiner may have an undergraduate degree in computer science, she does not necessarily know much about cutting-edge, object-oriented programming languages. She’s not up on the latest advances coming out of Asia. She may not have seen anything like the patent application for bioinformatics modelling of the human genome or the application for a patent on poetry-writing software! … She does not necessarily have a Ph.D. in science, and there is little opportunity on the job for continuing education. As an expert in patent examination, she is not and is not expected to be a master of all areas of innovation.”[[683]](#footnote-683)

Given the foregoing concerns regarding patent examiners’ knowledge, it has been argued that the people best equipped to determine whether a patent application meets the requirements are those working at the forefront of knowledge in the given field,[[684]](#footnote-684) after all, these are the notional persons ‘skilled in the art’ on which the patent requirements are centred.

Patent law provides an opportunity for pre-grant review by ‘outsiders’ to improve patent quality: third party observations.[[685]](#footnote-685) This is a legal opportunity whereby a third party (any person other than the applicant) can comment on a patent application, post-publication but pre-grant. This opportunity is rarely used.[[686]](#footnote-686) Attempts have been made to improve uptake of the third party observation opportunity through programmes such as ‘Peer to Patent’.[[687]](#footnote-687) This programme facilitates the participation of ‘citizen experts’ in the patent examination process by harnessing community involvement to select the 10 most relevant articles of non-patent prior art to pass on to the examiner. This is based on the argument that examiners are effective in searching through patent databases but “resource and time constraints hinder the examiner’s ability to search for non-patent literature.”[[688]](#footnote-688) An evaluation of the US project indicated that a “significant amount” of non-patent literature was submitted by Peer to Patent reviewers, which “could have a profound effect on the examination process”.[[689]](#footnote-689) It was found that in more than 25% of cases, patent examiners did rely upon information from the scheme, and the scheme was generally well received by examiners.[[690]](#footnote-690) Similar results were found in the UK pilot of the scheme,[[691]](#footnote-691) highlighting the potential value of engaging scientists in patent examination.

### The informing role of patent information and the patent information infrastructure

Seymore notes that a patent disclosure which “cannot teach a person having ordinary skill in the art ... how to practice the invention has little substantive value.”[[692]](#footnote-692) It has been suggested that patents do not effectively disseminate sufficient information to enable **a person skilled in the art to ‘practice’ the invention.**[[693]](#footnote-693)From the perspective of the patentee, there is only incentive to disclose as much information as is required to obtain a patent, no more.[[694]](#footnote-694) In fact, there is a disincentive to provide any more information than necessary as to do so reduce the strength of the position of the initial inventor in the market of follow-on inventions.[[695]](#footnote-695) In effect, patent applicants may be able to gain a patent and maintain an element of trade-secrecy over the same information which is at odds with the aims of the patent system.[[696]](#footnote-696) In this way, the patent social contract can be gamed in favour of the patentee. Further, it has been argued that the lack of a working example requirement in patent law may limit disclosure through patent information.[[697]](#footnote-697)

Non-tangible, upstream ‘inventions’ (such as many of the subjects of patents in the stem cell field) present another problem regarding sufficiency of disclosure: in these cases what is enabling?

**“Patenting in areas related to stem cells, especially in terms of claiming proprietary rights to ‘pluripotency’, is opening up new challenges to the drafting of patent specifications in terms of what would be considered as adequate disclosures, allowable and enforceable claims construction, and examination processes in patent offices and further the framing of national policies.”[[698]](#footnote-698)**

In a field where the science being patented is so far from product, in what sense can a patent specification be ‘enabling’ if the end use of the invention is unknown at the time? In such cases, the role of the patent office to determine sufficiency of disclosure is arguably more complicated than in the case of a mechanical, tangible invention.

### Publication and dissemination of patent data

Historically, full records of patent documents were only accessible as hard copies held at certified centres.[[699]](#footnote-699) In the early 1990s, documents were arranged into collections which were available on CDs and by the end of the 1990s there were numerous online free and fee-paying patent databases.[[700]](#footnote-700) These developments have led to a variety of challenges in supporting the public diffusion of patent information.

While published patent applications and all granted patent documents are notionally available through free, public databases, there are a variety of problems associated with these sources. The databases are notoriously difficult to use and are deficient in terms of timeliness and completeness of information regarding both applications and grants.[[701]](#footnote-701) In addition, patent applications should be published 18 months after filing but this is not always the case: “... there are loopholes in the publication laws that allow patent applicants to postpone disclosing their findings.”[[702]](#footnote-702) Further, the classification systems for patents has struggled to keep up with the speed of scientific advance meaning patents in the same field may be filed under different codes.[[703]](#footnote-703) Once the relevant patent document has been found, the information within it must be retrievable. Accessibility is reportedly somewhat limited because many patent documents online are not available in a complete, computer searchable format.[[704]](#footnote-704) Together, these issues mean that even if readers know what information they are looking for, this may be difficult to find and access.

In order for knowledge to be disseminated through patent documents, end-users must be able to find and understand the knowledge of interest to them. Patent documents in their current guise are difficult to understand, particularly to those unfamiliar with reading them (i.e. research scientists). Patent information contains technical and complicated terminology; the language of patent documents is termed ‘patentese’. This ‘patentese’ can prove challenging to even those familiar with patents.[[705]](#footnote-705) It is therefore not surprising that end users are reported to find patent documents difficult to understand.[[706]](#footnote-706)

### Stem cell scientists’ patent awareness

There have been some studies which have indicated that scientists’ awareness and understanding of patents is limited.[[707]](#footnote-707) This has also been highlighted in the field of stem cell science. The existence of foundational stem cell patents on cardiomyocytes in the UK was the subject of a panel discussion at the inaugural meeting of the UK National Stem Cell Science Network (Edinburgh, April 2008).[[708]](#footnote-708) The panel included representatives of the UKIPO and the US company Geron which, at the time, owned several of these patents. In the course of the debate, it became clear that a substantial number of stem cell scientists, including those who had been working within the boundaries of the patents, were not aware of their existence despite the fact that they had been granted 2 years earlier.[[709]](#footnote-709) The patent attorney representing Geron offered reassurances that there were no intentions of initiating infringement proceedings against scientists involved in basic research. Following the meeting, the UKIPO agreed with the UK National Stem Cell Network (UKNSCN) to provide a regular update on stem cell patent applications and grants in the UKNSCN quarterly bulletins as a means to facilitate patent awareness amongst stem cell scientists.[[710]](#footnote-710) The reasons for the poor awareness of patents among stem cell scientists in the UK had not previously been explored. Together with the variety of concerns surrounding the patenting of stem cell science, there was a clear need to garner empirical information about the engagement of stem cell scientists with patent data. The empirical study of this thesis gathered such evidence. Analysis of this data will help inform of the legal and technical barriers to facilitating the translation of research.

## Conclusions

The first part of this chapter described the legal requirements of patentability, namely novelty, inventive step, industrial application, together with disclosure and publication. These requirements are central to the modern ‘social contract’ rationale of the patent system which is based on providing incentives for innovation and facilitating downstream innovation through ‘teaching’. From the perspective offered by Drahos, it is vital that the patent system not only captures true ‘inventions’ but also that patent information is effectively ‘diffused’ so that it can feed into downstream innovation.

It was then shown that the concept of patentable subject matter has developed in recent decades to cover ‘upstream’ biological materials. The Myriad case, the Brüstle case and the potential appeal against the US WARF patents indicate that the expansion is now being questioned. This has cast doubt on the validity of existing patents as well as the future patentability of progress in related biological fields. These instances have also highlighted concerns regarding the effects of these patents on scientific research (such as the potential of anticommons developing). Together with concerns about the connotations of these cases regarding the morality of the research in question, particularly noted following the ruling in the Brüstle case, these issues are likely to affect scientists’ perceptions of the patent system.

The final part of the chapter discussed a number of ongoing questions regarding the patenting of upstream biological materials. The section focused on questions surrounding the ability of the patent system to capture such inventions; meaningfully apply the patentability requirements; and disseminate technical information to the public in an accessible, usable and timely manner. The chapter concluded by highlighting the apparent lack of awareness of foundational patents amongst stem cell scientists, a prompt for the empirical study presented in the following chapters.

Chapter 6

Empirical research methodology

## 6.1 Introduction

In light of the background research provided, the empirical study aimed to answer a number of questions, relating to the overarching aims of the thesis:

1. Are scientists aware of the patent landscape within which they work?
2. What do scientists know about patents and patent information?
3. How do scientists use, perceive and value patents and patent information?
4. How do scientists search for patent information and what are the barriers they experience when doing so?

The empirical study was composed of three parts: an initial, quantitative study and a subsequent set of qualitative interviews during which participants were observed undertaking a ‘task’ which consisted of them searching for academic and patent publications. This chapter discusses the overall methodology of the study and the specifics of each of the methods, before the results are presented in Chapters 7 and 8.

As indicated in the introductory chapter, this study is innovative in its mixed method design. The majority of empirical studies relating to scientists and patenting employ a mono-method approach using either surveys or interviews[[711]](#footnote-711), or have different foci to this. For example, Hall, Oppenheim and Sheen used a combination of methods but their study focused on the use of patent information by SMEs.[[712]](#footnote-712) Lei, Jenuja and Wright conducted a number of ‘follow up’ interviews after their survey but these focused on problems relating to accessing IP-protected materials highlighted by their survey data.[[713]](#footnote-713) Further, this study is not only mixed method, it is also novel in its inclusion of a structured observation of scientists’ engagement with patent information.

## Mixed methods research

While it is important to detail and justify the methodological choices made in the design of any study, Bryman argues there is more need to do so in the case of mixed methods research.[[714]](#footnote-714) He provides 6 criteria which must be considered in the justification of the use of mixed methods models:

1. Each constituent method is appropriately implemented;
2. Transparency of the implementation of the methods;
3. The use of mixed methods needs to be linked to the research questions;
4. Researchers must be explicit about the research design and its appropriateness;
5. A rationale must be provided for the use of mixed methods research; and
6. A focus on the integration of the methods and data must be maintained.

This chapter attempts to cover all of these issues.

The three-method model of the empirical study is an example of a mixed method strategy:

“Mixed method studies are those that combine the qualitative and quantitative approaches into the research methodology of a single study or multiphased study.” [[715]](#footnote-715)

Mixed methods strategies describe not only the approaches used in data collection, but also during analysis.[[716]](#footnote-716) This is true of the study in this thesis: each method produced both quantitative and qualitative data which were analysed using both traditionally quantitative and qualitative analytic techniques (as described in sections 6.3.4 and 6.4.8 respectively).

Mixed methods approaches have grown in popularity since the 1980s following discontent at having to make methodological decisions as to whether to use quantitative *or* qualitative methods.[[717]](#footnote-717) To overcome this problem, mixed methods research combines both types of method; they “are studies that are products of the pragmatist paradigm and that combine the qualitative and quantitative approaches within different phases of the research process.”[[718]](#footnote-718) This pragmatic approach allows methods of traditionally disparate epistemologies (and therefore traditionally conceptually incompatible approaches) to be combined by prioritising the research question over the philosophical standpoint of the methods, maintaining that “scientific enquiry is not “formalistic” and that researchers may be both objective and subjective in epistemological orientation over the course of studying a research question”:[[719]](#footnote-719)

“[P]ragmatists consider the research question to be more important than either the method they use or the worldview that is supposed to underlie the method. Most good researchers prefer addressing their research question with any methodological tool available, using the pragmatist credo of “what works”… For most researchers committed to the thorough study of a research problem, method is secondary to the research question itself, and the underlying worldview hardly enters the picture, except in the most abstract sense.”[[720]](#footnote-720)

In this way, mixed-methodologists recognise the strengths in both qualitative and quantitative research and promote the application of both deductive and inductive logic to undertake their studies.[[721]](#footnote-721) This allows for both descriptive and confirmatory questions to be used within one study.[[722]](#footnote-722) As such, the analytic strategy used in this research was flexible, moving between analysis of quantitative and qualitative data and different data sources to elaborate on, explain, and understand the findings. This is the basis of Chapter 9 which draws upon the dataset as a whole to consider the findings in relation to the background presented in Chapters 2-5 alongside the results detailed in Chapters 7 and 8.

While mixed method approaches are not limited by epistemological position, as Tashakkori and Teddlie note these approaches are not ignorant of the role that values play in the research process:

“Pragmatists believe that values play a large role in conducting research and in drawing conclusions from their studies, and they see no reason to be particularly concerned about that influence … pragmatists decide what they want to research, guided by their personal value systems; that is, they study what they think is important to study. They then study the topic in a way that is congruent with their value system, including variables and units of analysis that they feel are the most appropriate for finding an answer to their research question. They also conduct their studies in anticipation of results that are congruent with their value system.”[[723]](#footnote-723)

It is therefore to be borne in mind that the questions posed, the research strategy used and the conclusions drawn from the data are likely to be shaped by my own experiences of science and the academy and my values. For example, I believe that scientific research is extremely important, particularly where that research may result in life-changing therapeutics and must therefore be supported in ways that promote these ends. This is in line with the ontological approach of pragmatism: that reality is external and explanations are chosen to describe this reality in line with the values of the researcher.[[724]](#footnote-724) I believe that the subject of study is of value therefore I study it in a way that seems sensible to me, conscious these are decisions that I have made am are likely to result in findings reflecting my worldview. Accordingly, my findings may not reflect what another researcher may have found if studying the area; the approach is subjective and the findings must be read as such.

### The advantages and disadvantages of mixed methods research

Mixed methods studies are undertaken for a variety of reasons.[[725]](#footnote-725) Creswell argues that the use of a mixed method strategy enhances the strength of a study to be greater than that of mono-method approaches.[[726]](#footnote-726) In this case, a mixture of methods were employed to develop a research agenda (i.e. identifying points from the preceding survey to investigate in the interviews and observed search task); expand the scope of the project (i.e. starting with ‘small’ research questions in the quantitative survey and expanding them through the qualitative study and structured observation); to explain the results identified in the survey through the interviews and search task to help to understand the results generated during the survey in more depth. In addition, the mixture of methods allowed triangulation of the findings, connecting results from a variety of data sources and methods, increasing their validity.[[727]](#footnote-727) These benefits of using a mixed method approach allow stronger inferences to be drawn from the data than in the case of mono-methods approaches thereby increasing their validity.

Mixed methods studies have some limitations. The combination of approaches often requires more time and resources than mono-method approaches; the researcher must learn to undertake both qualitative and quantitative research and analysis; and the combined interpretation of results of different methods is more complicated than interpreting the findings of a single method.[[728]](#footnote-728) These limitations are overcome, in part at least, through efforts of the researcher to learn how to employ different methods; invest the time and resources required to undertake the methods; and a willingness to work through complex data in order to analyse, triangulate and interpret results from different methods. Notwithstanding the potential disadvantages associated with mixed methods research the advantages outweigh concerns about the limitations. Further, I believe the research questions necessitated a mixed methods approach and, in line with the pragmatic approach of mixed methods, the research strategy employed was dictated by my view of how the research questions could best be answered.

### The mixed method model

In mixed methods approaches, the constituent methods can be combined in a variety of ways. The taxonomy of potential strategies includes parallel/simultaneous studies; equivalent status designs; dominant-less dominant studies; and sequential studies.[[729]](#footnote-729) The strategy used depends on the timing and order of the methods, the weighting given to each method, and the way in which the data is interpreted.[[730]](#footnote-730) A diagram is provided subsequently to demonstrate the empirical process used.



The approach used in this thesis was, in essence, a two-phased sequential explanatory strategy[[731]](#footnote-731) meaning it initially employed a largely quantitative survey, the results of which were analysed and then probed during a second, largely qualitative phase (the interviews and structured observations). Within sequential explanatory models, sequential analysis allows the findings of one method to form the starting point for the analysis of the second method:[[732]](#footnote-732) themes were identified during the survey and investigated further during the interview and observation phase. Given this specific, distinct informing role of the survey within the model, and the clear distinction between the two phases, the results of the survey are presented separately from the interviews and observations. This separation was also made in Hall, Oppenheim and Sheen*’*s study of the barriers to the use of patent information in SMEs where the results of the survey component of their study were presented in one paper, and the results of their interviews presented in another.[[733]](#footnote-733)

There are two additional facets to the strategy employed. The quantitative survey was undertaken in two parts: first some surveys were distributed in person (stage 1) and preliminary analysis was undertaken (stage 2) allowing the survey instrument to be developed (stage 3) before a subsequent larger scale version of the survey was administered online (stage 4). The data from both sets of surveys were then analysed using parallel mixed analysis[[734]](#footnote-734) to combine the resultant qualitative and quantitative data (stage 5). The second phase of the study involved the concurrent use of two methods: a set of interviews and a structured observation element. These were developed (in stage 6) following the analysis of the surveys, before being administered (stage 7) and analysed in parallel (stage 8). Following the initial sequential analysis of the two separate phases, parallel mixed analysis was undertaken (stage 9). During this integrative stage, the findings of the different methods were drawn together to make inferences, with comparison between the primary analyses of the two phases to provide triangulation of findings, thereby improving the validity of the analysis.

### Sampling in mixed methods research

The participants in phase 1, the survey, were not the same participants as in phase 2, the interview and structured observation phase. Further, the sample sizes are clearly disparate: 120 in phase 1 and 16 in phase 2. As is explained in the following quote, this difference is a methodological possibility in sequential designs:

“In a sequential design, the issue arises as to whether the same or different participants need to be selected for the two phases of the project. Further, the question arises as to whether the number of participants will be the same or different for the two phases. On the issue of sample size, the sizes of the quantitative and qualitative samples may be unequal given the nature of quantitative research to generalize to a population whereas the qualitative sample is to provide an in-depth understanding of a small group of individuals. Further, since the two samples are not being directly compared as in concurrent designs, the sample sizes in a sequential design do not need to be of equal sizes.”[[735]](#footnote-735)

In the second concurrent phase, the interview and structured observation were undertaken together and therefore the same participants took part in both methods.

As with many methodological choices, the decision to use different samples in the two phases was also determined, in part, by practicalities. While the thesis comments largely on stem cell scientists, access to a large enough survey group of stem cell scientists to draw statistically reliable results was not possible given the conditions of the ethical approval and access points available for this thesis. The decision was therefore made to administer the survey to a wider variety of ‘biological’ rather than ‘stem cell’ scientists (although many of the respondents stated that they were stem cell scientists). This allowed comparisons to be made between the two groups because stem cell scientists are not distinct from biological scientists; they are a microcosm of this group. Given the particular focus of the thesis on stem cell scientists, it was essential that those interviewed identified themselves as stem cell scientists. It was possible to access a large enough population of this group to draw valid results from.

Deciding on the sampling of a population is a necessity in almost all empirical research – it is rare that all members of a population are consulted.[[736]](#footnote-736) When considering which sampling techniques to use it is necessary to bear in mind what generalisations you wish to be able to make from the data collected. In both phases, representative samples[[737]](#footnote-737) were sought with the aim of being able to make informed inferences about two much larger populations:

1. UK stem cell scientists (in the interviews and survey)
2. UK university-based scientists working in biology related disciplines (in the survey)

In order to gain representative samples, bias must be kept to a minimum. To do this, all members of microcosmic populations of the above groups were contacted in the survey. In the case of UK stem cell scientists, all UK-based delegates of the UK National Stem Cell Network conference were contacted. For a representative sample of the population ‘UK university based scientists working in all biology related disciplines’, a link was sent to all e-mail addresses in University of Sheffield e-mail lists associated with biology. Approaching all members of these two microcosmic populations gives a potential sample size of 100% of the populations.

The second phase of the study was a concurrent-mixed model; the interviews and structured observations were undertaken together, with the same sample being used for each method. To achieve a representative sample for this phase, a database was compiled of potential interviewees by searching UK university webpages for staff undertaking stem cell science. These people were contacted via email and were asked to pass on the information about the study to others who fitted the profile of senior stem cell scientists. This allowed for snowball sampling through 6 access points. This sampling approach heralded meetings with 16 senior stem cell scientists from 6 different institutions.[[738]](#footnote-738)

The sampling technique was also a form of convenience sampling;[[739]](#footnote-739) the groups were specifically chosen because they were accessible. Convenience sampling holds the problem that such samples are not always representative of a larger population. This was considered when deciding the populations to generalise to. For example, both ‘larger’ populations are only based on people working in the UKbecause all of the participants were based within the UK. However, the convenience of, for the survey, only contacting researchers from the University of Sheffield and attendants of the UKNSCN must be borne in mind when drawing generalisations from the results. In the interviews, the sample was part convenience: 2 of the access points were initiated through contacts of my supervisors. The other 4 points arose from my email call for participants.

During the analysis of the results, it must be remembered that the samples may not directly represent the populations aforementioned. For example, the scientists attending the UKNSCN may be elite members of the UK stem cell scientist population; their attendance at this conference is indicative that they are research active and highly interested in dissemination of research. Further, the people who responded to my interview call may have a stronger interest in patent-issues than those who did not. Another important consideration is the variance within the sample. With the survey, the UKNSCN sample is likely to be homogenous in that they are all related to stem cell science, the main desirable attribute in choosing this group, making the variation amongst the population quite low in relation to their field. However, it may be a fairly heterogeneous population when considering their role (e.g. PhD student versus principal investigators). Therefore, there was a large variance in the roles of respondents, which may affect the answers given. This is taken into account in the analysis of results. With the University of Sheffield sample, homogeneity comes from having the same, but variance was likely to be seen between sub-disciplines of biology and participants’ professional roles. In the interviews, there was limited variance in roles (all were senior stem cell scientists, either working as post-doctoral scientists or principal investigators) but there was heterogeneity in that the group came from 6 different institutions. All of these issues concerned with sampling were considered in the analysis when making generalisations to the wider populations.

### Accessing and recruiting participants

With regard to the issue of accessing and recruiting scientists to participate in the study, I was in a somewhat advantaged position when I began this research thanks to my educational biography, and the network of my supervisors. These factors afforded me a range of contacts to support my access to the participants (as aforementioned, 2 of the interview access points relied upon my supervisors’ networks). My educational biography also provided me with a certain basic knowledge of the issues at play in this project. While I am not a practising natural scientist myself, I have a natural science background and know many ‘bench’ scientists. In short, science and scientists are not alien to me: I understand the language and context in which these people work including the nature of the science itself and some of the pressures and constraints involved. When conducting the empirical research I could also make use of my own scientific background to think critically about what I was told and reflect on that during and after the fieldwork, something a researcher without my background may have lacked.

## The survey

Phase 1, the survey, was based on a self-completion questionnaire,[[740]](#footnote-740) a copy of which can be reviewed in Appendix 1. The survey intended to ascertain data relating to scientists awareness of patents; their knowledge about the mechanics of the patent system; and their use and perceptions of patent information.

The survey was first distributed at the UK National Stem Cell Network (UKNSCN) Conference in York (March 2011) where 38 responses were received. Following initial analysis of these responses, the questionnaire was modified and set up as an internet questionnaire, using Survey Monkey as a platform website. A link to this was sent to all UK-based UKNSCN delegates (in May 2011) and e-mail addresses in University of Sheffield e-mail lists associated with biology (in June 2011). 82 questionnaires were completed online, giving a total survey sample size of 120.

### The self-completion questionnaire

All participants were asked to complete the survey themselves because it made the survey quicker to administer; removes interviewer effects;[[741]](#footnote-741) there was no variability between the ways and order in which questions are asked; and (in the case of the online questionnaires) respondents could choose when and where to complete the questionnaire.

The choice to administer a self-completion questionnaire also had disadvantages. For example, when compared with interviews, during self-completion questionnaires respondents cannot be prompted when struggling to answer questions, no elaboration of answers can be sought, few respondents are likely to complete open answer questions, the questionnaire can be read as a whole which may affect respondents answers because the questions are not perceived as independent from each other, it is difficult to ask lots of questions because respondents are likely to get bored and quit the questionnaire (potentially reducing the response rate) and self-completion questionnaires are renowned for having low response rates.

### Response rates

The level of completion of a social research method is known as the ‘response rate’.[[742]](#footnote-742) The response rate associated with self-completion questionnaires (particularly those administered online) is often low in comparison to questionnaires completed face-to-face, sometimes with the help of an administrator.[[743]](#footnote-743) The level of response during the face-to-face distribution of questionnaires at the UKNSCN was close to 100%. A link to the online questionnaire was sent out, via e-mail, to attendees of the UKNSCN and later, to specific lists at the University of Sheffield.[[744]](#footnote-744) The e-mail was sent to 251 UKNSCN attendees in May 2011. 10 online responses were received from UKNSCN delegates 9 of which were completes sets of answers, giving a completion rate of 90%.[[745]](#footnote-745) Combining this with the 100% completion rate during the personal distribution of questionnaires at the conference gives a completion rate of UKNSCN attendees of 98%.[[746]](#footnote-746) The online response rate was approximately 3.6%[[747]](#footnote-747) of the whole UKNSCN population. Combining this with the 38 responses received at the conference gives a response rate of 18.7%[[748]](#footnote-748) for the UKNSCN population.[[749]](#footnote-749)

The survey link was sent to University of Sheffield lists (4154 e-mail addresses) in June 2011. 106 responses were received, 82 of which were complete responses. This gives a completion rate of 77.4%[[750]](#footnote-750) and a response rate of 1.97%.[[751]](#footnote-751) Overall, given a population of (4154+251=) 4405, the response rate was 2.72%[[752]](#footnote-752) with a completion rate of 83.8%.[[753]](#footnote-753)

Clearly, the response and completion rates of the personally distributed and the online questionnaires were markedly disparate. This is likely to be due to a lower inducement in the case of online questionnaires: it is easier to decline beginning, or completing, a questionnaire online than face-to-face.[[754]](#footnote-754) There are some ways of improving response rates, such as monetary incentives and reminders. However, these were not deemed appropriate in this case and had not been included in the ethics approval process.

The main problem caused by low response rates is that it is almost impossible to prove that those who did not respond hold the same opinions as those who did. Consequentially, this provides an inevitable form of bias, which makes it difficult to generalise the findings to a larger population. Non-response is a source of error whereby some members of the sample do not participate.[[755]](#footnote-755) Non-response must be considered when analysing the results of empirical research because it cannot be certain that non-respondents hold the same opinions as those who take part. For example, it could be claimed that the respondents in this case hold stronger opinions about patents than non-respondents because they took the time to complete the survey.[[756]](#footnote-756) Therefore, those people who participated in the survey (and indeed in the interviews) may hold particularly strong opinions of patenting and patent information. Therefore, whilst the data gathered may not be entirely generalisable to the broader populations, it provides an important insight into scientists’ perceptions of patent information. Further, the role of the surveys in gathering data to help develop the interview schedule did not necessitate a high response rate.

### Questionnaire design

The overall design of the questionnaire was shaped by the survey instrument used in the 2009 study by Lei, Jenuja and Wright regarding agricultural biologists’ perceptions of the effects of patents on the availability of research tools.[[757]](#footnote-757) Their questionnaire combined a variety of question types (including open and closed questions and Likert scales) and question topics (including attitudinal indicators, professional characteristics questions). The questionnaire used in this thesis (provided in Appendix 1) also used a variety of question types and focused on 6 main themes; formal knowledge, attitudes to patents, awareness of patents, finding and understanding patent information, professional characteristics and finally a space was offered for respondents to offer any further information concerning patents. The questions were based on the primary empirical questions (see section 6.1) which arose from the background research presented in Chapters 2-5. For example, to help answer the general question ‘what do scientists know about patents and patent information?’ the participants were asked specific questions about such knowledge including: do you agree or disagree with the following statement: pre-existing academic literature can affect the outcome of a patent application?

Visually, the paper-based questionnaire was designed to fit onto two pages, including all of the information relating to participation and contact details. Further, the expected response time was kept to between 5 and 10 minutes so that length did not deter respondents. Efforts were also made to give the questionnaire an attractive and simple layout: questions were written in bold and boxes were provided for all of the answers. Closed questions were presented with vertical answers in cases where the answers were long but in the question where a Likert scale was used, the answers were presented horizontally, with the statements vertically. Again, this was done to make the questionnaire as simple as possible for respondents to look at, understand and complete. Additionally, clear instructions were given about how to respond to the different types of question. Some of the pertinent issues regarding the design of the questionnaire and its constituent questions are discussed further in Appendix 2.

### Analysis

As described in section 6.2.2, initial analysis of the survey helped to develop the subsequent interview schedule and inform the design of the search task. The quantitative data from the surveys were statistically analysed using the software package SPSS. This was done by first coding the answers (assigning them numerical values) and inputting the resultant numerical data into SPSS before statistical tests were carried out. Due to the nature of the survey phase of informing the design of the subsequent interviews and structured observations, the statistical analyses undertaken were relatively simplistic. In the presentation of results, the findings often refer to as frequencies or percentages. Pearson’s Chi-squared tests were used to assess whether there were statistically significant differences in the responses between independent groups or subpopulations (e.g. those who have seen a patent versus those who have not seen a patent) to some questions. More information about the results of these tests is available in the relevant tables in Appendix 3. The qualitative data arising from the open questions (available in Appendix 4) was interpreted alongside the quantitative data and is fed into the relevant sections of the results. These qualitative portions helped greatly in designing the interview schedule as they highlighted some perceptions that the quantitative data were not able to capture.

## The interviews and structured observations

For the second phase of the study, a qualitative interview schedule was developed focusing on themes arising from the survey and a structured observation of a search task was designed to empirically observe scientists’ searching behaviours and their analysis and interpretation of patent information. The methods are described and discussed in detail below. As with the first phase, once this design stage had taken place, ethical approval was sought and gained before the fieldwork took place.

These methods were used to delve into all of the questions posed in the empirical study (questions a-d in section 6.1). The structured observation was the major method which was used to gather data relating to how scientists search for patent information.

### The interviews

16 interviews took place between November 2011 and March 2012. These were semi-structured and took place on a 1:1, face-to-face basis, totalling over 15 hours. The interviews were conducted in the workplaces of the participants: in lab spaces, offices or university cafes. This choice was made for two key reasons. First, it was easier to recruit participants for approximately one hour of their time than to ask them to spend time travelling to meet with me. Secondly, to question scientists about issues relating to their work, it made sense to speak with them in the spaces they inhabit during their working lives.

### Semi-structured interviewing

Semi-structured interviewing was used because it allows the researcher to adapt the questioning according to the answers of the interviewees and to probe points of interest, while ensuring particular topics are covered. The term ‘semi-structured interview’:

“… covers a wide range of instances. It typically refers to a context in which the interviewer has a series of questions that are in the general form of an interview schedule but it able to vary the sequence of questions … the interviewer usually has some latitude to ask further questions in response to what are seen as significant replies.”[[758]](#footnote-758)

As part of the mixed method approach of the study, these interviews allowed issues raised by the survey to be probed. The topics covered during the interviews included scientists’ perceptions of patents and patent information; the effect of patenting on the scientific environment; knowledge of the patent landscape of the stem cell field and knowledge of particular patents; previous experiences of searching for patents and interpreting patent information; and the differences between academic and patent publications/databases.

In semi-structured interviews, it is common for an interview schedule to be designed and used during the interviews (see Appendix 5). In this case, an interview schedule was also used to ensure that particular points arising from the survey phase were probed further. The interview schedule was designed around these points, trying to ensure that questions and topics flowed reasonably well, but bearing in mind that the ordering of questions may vary in response to early questions in line with the flexible nature of semi-structured interviewing. As with the survey, issues such as question design, the use of probing and following questions, comprehensible language and avoiding leading questions were all incorporated into the design of the interview schedule and continued to be considered during the interviews themselves. For example, many of the questions were purposely phrased in an open manner, inviting the participants to share their own view and experiences. Indeed, this opportunity was regularly taken up, with the conversation rolling into unanticipated territories. On several occasions participants spoke of their own experiences and in terms of sums of money made or lost in patent-related dealings and provided names of people involved (including patent attorneys, TTO staff, colleagues and peers). The fact these scientists talked of their own, often fraught, experiences of patenting are indicative of the rapport developed with the interviewees. Therefore, the data gathered is likely to be reflective of their honest views.

In a further effort to prepare for the interviews, a pilot interview and structured observation were conducted to help ensure that the methods and questions were suitable to yield answers to the questions being asked. Following transcription of the pilot interview, I realised that I had been quite rushed during the pilot due to nerves (and an associated fear of silence), not allowing space for reflection and elaboration of answers from the interviewee, or the preparation of suitable probing questions from myself. This reflection led me to approach the other interviews with a less hurried manner in order to get the most from each interview.

### Interview data analysis

The interviews were recorded using a digital recording device and transcribed before analysis using the computer-assisted qualitative data analysis software NVivo. The analysis began during the fieldwork: throughout the interviews and transcription, I noted particular points of note, themes and patterns. These built not only on the themes arising from the results of the survey, but also from unexpected points of the interviews. As Bryman describes, and following the interviews I can confirm: “One of the main difficulties with qualitative research is that it very rapidly generates a large, cumbersome database.”[[759]](#footnote-759) There are a variety of analytical approaches which can help to make sense of such data. In this case I employed the NVivo software package to code[[760]](#footnote-760) the transcriptions, which were then analysed using thematic analysis.

Braun and Clark define thematic analysis as:

“… a method for identifying, analysing, and reporting patterns (themes) within data. It minimally organises and describes your data set in (rich) detail.”[[761]](#footnote-761)

In this way, thematic analysis provides a way of understanding data and noticing both narrow and broad themes[[762]](#footnote-762) within the data which can then be investigated across the dataset. In this study, there were 53 narrow codes, which were compiled into ~10 narrow themes, which together gave rise to a few broad themes. For example, one code ‘dates (of filing, publication or grant)’ was part of the narrow theme ‘language in patent information’ which fell under the broad theme of ‘understanding patent information’. During this study, thematic analysis began during data collection (for example, noticing patterns during the interviews) and did not end until the reporting of the data was completed. In this way, Braun and Clark note: “Analysis involves a constant moving back and forward between the entire data set, the coded extracts of data that you are analysing, and the analysis of the data that you are producing.”[[763]](#footnote-763)

Given the homogeny between the interviewees (they were all post-docs or principal investigators (PIs) working in academic institutions in the UK) and the relatively narrow scope of the research questions (i.e. investigating how they perceive and engage with the patent system and patent information), theoretical saturation[[764]](#footnote-764) was reached relatively quickly. After 10 interviews, ~85% of the final 53 thematic codes had been generated, indicating that the same topics were being covered by the participants.[[765]](#footnote-765) The additional codes which were not covered by the first 10 interviews were either smaller codes which were then included in other codes (such the codes ‘keywords’ and ‘titles’ were included into ‘language’), or were the results of somewhat off-topic reflexive questioning, such as specific comments about particular databases or the alternatives to patenting research. This apparent theoretical saturation indicates that the topics covered are likely to represent the majority of topics which would have been covered if more members of the population had been questioned, thus improving the validity of making generalisations from the findings to the general population.

### The structured observation – searching for papers and patents

Following the interviews, participants were invited to take part in a search task in the form of a structured observation. [[766]](#footnote-766) This involved the participants searching for a scientific paper and then for a related patent document. The aim of this was to garner information about scientist’s strategies to find and assimilate different types of information, and the obstacles they encountered trying to do so. This method was the main approach to collecting evidence for the question: ‘how do scientists search for patent information and what are the barriers they experience when doing so?’ While this was touched upon in the questionnaires and during the interviews, an observed search task was the best way to gather empirical evidence about scientists’ ‘experience’. This method also helped gather data regarding the other questions of the study.

Structured observations allow the researcher to systematically observe behaviours, rather than learning about them second hand through interviewing or surveying where respondent’s perceptions of their behaviour may be inaccurate.[[767]](#footnote-767) Participants are observed under predetermined conditions and against criteria defined in an observation schedule[[768]](#footnote-768) (see Appendix 6). In this study, there was an additional facet to the structured observation: participants continued to be interviewed during the observation. This was done so that participants could be questioned about their observed behaviours and choices during searching and their experiences of using different databases and search options thus adding depth of understanding to the data gathered. In this way, Bryman argues that accompanying structured observation with other methods can be more effective in probing behaviours than using structured observation alone.[[769]](#footnote-769) Further, McCall argues that, in comparison to interviews and surveys, structured observation:

“… provides (a) more reliable information about events; (b) greater precision regarding their timing, duration, and frequency; (c) greater accuracy in the time ordering of variables”[[770]](#footnote-770)

In these ways, structured observations offered an attractive method to study scientists’ behaviours and practices.

There are a number of problematic issues regarding reliability and validity of structured observations which had to be considered. These are discussed in the following sections. In addition to these broader concerns, criticisms have been raised about the usefulness of the data collected from structured observations. These include that the information gathered in structured observation can be somewhat flat, lacking explanation of reasoning behind behaviours; that the data can be fragmented and therefore difficult to compare between participants and build a bigger picture from.[[771]](#footnote-771) In this study, these criticisms were opposed by using a mixed method approach and the continuation of the interviews during the structured observations generating points for triangulation of the results to improve the reliability and validity of the inferences made from the findings.

### Reliability in structured observation

The key issue with reliability in the case of structured observations is consistency between observations.[[772]](#footnote-772) In some studies, there may be concerns of inter-observer consistency if there is more than one observer involved. This was not the case in this study therefore the concern here is intra-observer consistency: whether each participant was studied in the same way and whether the observer affected the observation in the same way between participants. To counteract this concern, two efforts were taken. First, an observation schedule with designed with a clear focus for the search task and predefined questions and points of observation. Secondly, the observations were recorded both visually and verbally, allowing comparative coding to take place after the observations, helping to allay concerns that the participants may not have been observed in the same way.

### Validity and structured observation

In structured observations it is important to consider measurement validity: whether a measure is actually measuring what it intends to. Bryman notes the validity of a measure entails two points: “whether the measure reflects the concept it has been designed to measure … and error that arises from the implementation of the measure in the research process.”[[773]](#footnote-773) The first of these is assumed, based on the design of the observation schedule (as described in section 6.4.7) and coding of the data (as described in section 6.4.8). The latter issue, the concern of error in measurement includes concerns about the administration of the observation schedule: was it always administered in the same way? In this study, all participants were offered the same information; asked to undertake the same search task; and a standard set of questions were asked making the data collected comparable. Concerns also include whether there is a reactive effect amongst the observed negating their natural behaviours. This is a complicated issue regarding what is known as the ‘reactive measurement effect’:[[774]](#footnote-774) do people change their behaviour when being observed? The likely answer in this case is yes and no. I do not believe that the participants are likely to have changed their behaviour when looking for the academic paper: this is a practice they are familiar with, and probably confident in undertaking, making them relatively comfortable being observed undertaking this practice. On the other hand, I believe their behaviour will have changed from their unobserved state in searching for the patent because they were forced to change their behaviour, not because they may behave differently when not being observed. By this, I mean that participants are likely to display a reactive behaviour because (as the survey had implied) the majority of the participants were unlikely to have previously searched for patents or used patent databases, therefore they are unlikely to have an unobserved behaviour for this practice. In order to combat concerns about the potential reactive effect on the validity of the data, all participants were observed in similar conditions; all were given the same starting information and the same equipment; and each was observed using the same observation schedule.

### The design of the structured observation

As previously mentioned, there are no (known) published examples of similar structured observations where scientists are asked to look for patent information. There are some information-retrieval studies tasks in which data specialists have been asked to search dummy databases for information in order to determine how the data can be better mined.[[775]](#footnote-775) Other studies have surveyed patent information user’s experiences of database searching, but have not observed such searching *in situ*.[[776]](#footnote-776)

The observation aimed to elucidate how scientists search for, and attempt to understand, patent information and the problems they have in doing so. It was therefore important to design a task which would achieve this aim. For reasons discussed further below, it was necessary to record the undertaking of the task. This was done by taping an audio of the task to capture the verbal exchanges with the participants and using screen capture technology to create a video of the searches.

The search task consisted of two sub-tasks: first, participants were asked to search for a landmark paper in their field. The purpose of asking them to look for the academic paper first was three-fold: first, it allowed them to become comfortable with the situation at hand (i.e. being recorded); secondly, it meant they could be directed to search for a patent without giving them information they would not otherwise have had (such as a confirmation of the inventor, assignee or any bibliographic data (such as document numbers or dates)); and thirdly, it gave them a point of reference with which they could compare the information in the patent. Once the participants completed the search, they were provided with a paper copy of the paper for reference.

The participants were then asked to search for a patent relating to the academic paper. For this, they were provided with a basic follow on instruction such as: ‘can you show me how you would look for a patent relating to that paper?’ Unlike when searching for the papers, many of the participants required further instruction to find the patent. For example, some of the participants did not think that there was such a patent. They were told that there was and that I wanted them to try and search for it. Others required encouragement when they seemed like they might give up on the search. One participant looked flummoxed after approximately 10 minutes of using Google. I suggested they might like to use a patent database, after which they searched ‘patent database’ in Google. While it can therefore not be claimed that each of the participants had the exact same instructions throughout the search task, it would not have been possible to conduct the task without some feeder instructions. Many of the participants would have given up long before they began using a patent database, and given the often limited time I had with the participants, time would have run out and I would have been unable to complete the follow up questions. Therefore, if they were unable to find the patents using a patent database, they were allowed to conclude that part of the task if they indicated they wanted to do so.

The participants were then all given copies of the patent documents and were asked a number of questions about their perceptions of the information within these documents. It is important to note that due to the fact that patents evolve throughout their lifetime from application to grant (to potential lapse/revocation) with regard to content and legal status, the task was somewhat time limited. By this, it is meant that it was important to ensure that participants were facing the same search constraints and information in order to ensure validity and comparison between participants. In order to achieve this, several measures were taken: the structured observations were all undertaken within 2 months of each other (limiting the potential for the information to change); I continued to monitor the patents in question throughout this period (during which I did not notice any of the information pertinent to the search task changed); and when participants were asked to interpret the information within the patent documents, the participants were provided with identical paper copies of the documents which I had printed before the first task took place.

### Analysis of the structured observation data

The notes, transcripts of the audio recordings and the screen capture videos of each observation were compiled before thematic coding and analysis took place. The observations garnered both qualitative and quantitative data, meaning the analysis of the data from this method was an example of a parallel mixed analysis adding to the mixed methods approach of the study.

The quantitative data included how long it took each participant to find the paper, and subsequently the patent, how many participants used particular databases. This data was analysed using basic statistics including frequencies and averages. The qualitative data gathered during the search task included the scientists’ perceptions of patent databases; their search strategies; and their interpretations of patent documents. This data was largely the result of the narrative account of the observations, prompted by the ongoing interview questions. This data was analysed using thematic analysis (as described in section 6.4.3).

## Research training and ethics

Prior to the commencement of the study, research training in research ethics; qualitative and quantitative methods; and data analysis were undertaken to develop the skills required to conduct the empirical research. In addition, ethical approval for the empirical portion of the research was required before the research could be undertaken. This was granted from the School of Law upon proof that a number of ethical issues had been considered and accounted for. These issues largely surrounded the key principles of ethical research highlighted by Bryman: privacy, informed consent, protection from harm and avoidance of deception.[[777]](#footnote-777) These are also central to policy guidelines on good research conduct.[[778]](#footnote-778) Each of these issues, and their relevance to the various methods adopted in the empirical study are discussed below.

### Protection from harm

In any research, it is important to protect all participants from harm where possible. Therefore, in research design, efforts must be made to anticipate and avoid consequences of the research that may be predicted as being potentially harmful. A number of measures were taken to protect the participants from harm (personal or reputational). While the data collected was not expected to be sensitive, participants may have been concerned about how they would be represented in the write-up of the research. They were therefore assured that data would be anonymised. For example, all findings are reported in a gender-neutral manner. Participation in the study was entirely voluntary. Participants were informed (on both the information sheet and the consent form) that they could withdraw at any point during data collection but that their “right to withdraw does not extend to the withdrawal of already published findings or in a way that compromises anonymised data sets.” In order to protect both the participants and myself from other potential harms, all of the face-to-face elements were conducted on university premises during normal working hours. My supervisors were informed of when these interviews were due to take place and were contacted before and after each session.

### Privacy

It is important to protect participant’s privacy not only because an assurance of privacy was included in the scientists’ consent to participate, but also because privacy should be respected where possible and appropriate. Further, there is nothing to gain in the presentation of the results in this study by identifying the participants beyond indicating that they belong to the populations of interest here: for example, they are not publicly-appointed people. In this case it is of far greater importance that the participants remained anonymous than that they could be identified. It was both possible and appropriate in this case, therefore participants’ privacy was protected as far as possible.

Participants’ privacy was protected by ensuring that the data collected was confidential and that the recorded data was not easily identifiable. In order to support the anonymity of the recorded information, no personal identifiers (such as names and locations of the participants) were recorded during the interviews and structured observations of the search task. Data protection measures were put in place to ensure the confidentiality of personal data. Throughout the project I maintained control of all the data collected. All electronic data were stored on a password protected computer and individual files were password protected. All paper records were stored in a locked drawer in the School of Law when not in my personal possession. Finally, in the presentation and discussion of the results, the data has been anonymised by removing any other potential identifiers (such as the names of the participants’ spin-out companies or university TTOs).

### Informed consent/avoidance of deception

It is important to gain informed consent and to avoid deception because these principles supports the avoidance of harm and should therefore be maintained where possible. The principles indicate that participants must have adequate information regarding the purpose of the project, benefits, risks, timescale, sponsors, etc., to decide whether they wish to be involved

This research was undertaken overtly: all participants were aware they were being studied and knew who they were being studied by. Therefore, it was possible to gain informed consent (unlike the case sometimes where research is undertaken covertly). This was achieved by providing participants with a clear statement of the research including work contact details for myself and my supervisors in case they had any further questions. In the case of the surveys the information was provided at the beginning of the survey (see Appendix 1) and the interviewees who participated in face-to-face interviews were provided with an information sheet before the interview began (see Appendix 7). All participants were given the opportunity to ask any questions they might have about the research before deciding whether to take part. Written consent forms were collected for the interviews after ensuring that the participant had all the information they wanted beforehand. This included consent to record the interviews and structured observation elements. Respondents to the survey were informed in the information sheet that taking part in the survey was taken as consent for the use of the information provided in an anonymised form.

In order to avoid deception I was always clear and honest with the participants when they questioned the nature of the research and my motivations/methods. The only instances when I was not entirely explicit were to maintain the privacy and anonymity of other participants. For example, some respondents asked me who else had taken part and this information was not given. I would argue this was not deceptive as such, just not overt, and was vital to maintaining the other principles behind the research.

## Conclusions

This chapter has discussed the mixed method approach used in the empirical study and the specifics of each constituent method. It was shown that a mixed method approach was used to gather a variety of sources of both quantitative and qualitative data. The particular type of approach used in this study is a sequential explanatory model, allowing the results of the first phase to inform the design of the second phase. The first phase consisted of a largely quantitative survey, administered in two parts to a total of 120 biological scientists. Following initial analysis of the survey results, interview and structured observation schedules were developed and administered to 16 senior stem cell scientists. As the two phases were distinct in time, sample size and sample composition, the findings of each phase are presented separately in the following two chapters, with comparison between the results of both phases where appropriate (i.e. where similar questions were asked in both phases, and where one result may influence another). It was explained that there were a number limitations of the methodology and therefore of the generalisations that can be made from the data to the larger population. However, due to the purposive representative sampling and thematic saturation, the results are likely to be indicative of the general populations. These issues are borne in mind in the presentation of the findings and in the discussion of the implications of the study in Chapter 9.

Chapter 7

Survey results

## 7.1 Introduction

This chapter presents and analyses the results of the survey, highlighting findings of particular interest and those which were to be probed further in the interviews. As was discussed in Chapter 6, the main aim of the survey was to gather initial data to be probed further in the second empirical phase. Due to the sequential explanatory model of the study, the survey was used to help generate an interview schedule and support in the design of the structured observation. Owing to this scoping nature, brevity is favoured in this chapter; the main role of this data was to highlight areas for subsequent study and provide data triangulation points for the analysis of the second phase of the study. The presentation of the interview and task results in the subsequent chapter draws and builds upon the survey findings. Thus, to minimise repetition, this chapter contains little discussion of the findings beyond their presentation and role in identifying points to be further investigated in the second phase. Further, when consulting the survey in Appendix 1, it may be noted that answers to all of the questions posed are not discussed. Those results omitted from this discussion were not illuminating in the context of the research questions or in determining the content of the interviews.[[779]](#footnote-779)

The findings are structured around the following topics or themes which arose from the results:

* Engagement with patent information and the patent information infrastructure
* Patent knowledge
* Scientific cultures and perceptions of patent information

Within the discussion, percentages are reported to 3 significant figures and p-values are reported to 3 decimal places. Tables of the data are available in Appendix 3.

### Sample characteristics

All of the 120 survey respondents were biological scientists, the majority of whom indicated that they work in university laboratories funded partially with public funds in addition to an industrial/private/charity grant. 87% of the sample worked within universities, with 92% funded, at least partially, with public money.[[780]](#footnote-780) This indicates that the findings of this survey are mainly indicative of academic scientists funded in part by public money.

Some of the questions asked in the survey allowed the total population to be broken down into a number of subpopulations. Interesting similarities and differences between the groups will be highlighted in relation to specific questions. These subpopulations are as follows: respondents holding PhDs and those without PhDs;[[781]](#footnote-781) stem cell scientists and scientists working in other fields;[[782]](#footnote-782) participants who have seen a patent document and those who have not;[[783]](#footnote-783) and participants who have been part of a patent application and those who have not. [[784]](#footnote-784)

### Hypotheses

Whilst the survey was largely exploratory, there were some expectations of what the results might show. In accordance with the discovery at the UKNSCN inaugural meeting in 2008 that scientists were unaware of the existence of foundational patents in their field, it was expected that scientists would have a limited awareness of and engagement with patent information. Further, as observed in other studies, the exact level of knowledge, awareness and engagement was expected to be different amongst different groups of the population.[[785]](#footnote-785)

It was expected that with regard to awareness of, engagement with and understanding of patent information those who hold PhDs would have reported higher levels than those who do not; those who have seen a patent document were expected to report higher levels than those who have not;[[786]](#footnote-786) participants who have been part of a patent application would demonstrate higher levels than those who have not;[[787]](#footnote-787) and stem cell scientists would report higher levels than scientists in other fields. These hypotheses are commented on throughout the presentation of results where appropriate.

## Engagement with patent information and the patent information infrastructure

For scientists to participate in the patent system in any of the three roles discussed on page 18, engagement with patent information is assumed. To broadly assess the respondents’ ‘engagement’ with patent information, a number of questions were asked relating to any previous experience they had with viewing patent documents (including using patent databases), being part of patent applications and their awareness of patents which may be related to their work.

### Have you seen a patent document?

As shown in Figure 7.1, when asked, almost half (48.8%) of those surveyed had not seen a patent document.[[788]](#footnote-788) Predictably, 100% of those who had been part of a patent application had seen a patent, compared with only 26% of those who had not (p=0.000). Approximately 75% of PIs and post-docs had seen a patent document, whereas the same proportion of the student population had notseen a patent document (p =0.000).

##### Figure 7.1: Bar graph showing the proportional representations of the responses of the total population and the subpopulations to the question ‘Have you ever seen a patent document?’[[789]](#footnote-789)

This finding, while interesting does not explain why almost half of the survey participants had not seen a patent document. Some of the other results of this survey give some indication of why this may be the case (for example, the limited use of patent databases) but a fuller explanation for this finding was sought during the interviews.

### Have you ever been part of a patent application?

As shown in Figure 7.2, almost one-third (32.4%) of the sample reported that they had been part of a patent application.[[790]](#footnote-790) As expected, the results indicated that while approximately 60% of the group holding PhDs had been part of a patent application, none of the student group had been part of an application (p=0.000).[[791]](#footnote-791) 64.9% of respondents who had seen a patent document had also been part of an application (100% of whom held PhDs). Conversely, and predictably, none of the respondents who had not seen a patent document had been part of a patent application (64.9% versus 0%, p=0.000).

##### Figure 7.2: Bar graph showing the proportional representations of the responses of the total population and the subpopulations to the question ‘Have you ever been part of a patent application?’

### Do patents exist in your field of research?

When asked: ‘Do patents exist in your field of research?’ the majority of the group indicated that they were aware that patents existed in their field of research but a notable proportion either did not know or thought they did not. As can be seen in Figure 7.3, 82.5% of the total population indicated that they thought patents existed in their field of research, 14.2% were ‘not sure’ and 3.3% thought patents do not exist in their field of research.[[792]](#footnote-792) This variance amongst the population may be contributed to by other findings including that half of respondents had never seen a patent document and, as later described, 60% of those surveyed had not used a patent database in the last 5 years. Interestingly, in line with the hypotheses, 91% of stem cell scientists indicated that they thought patents existed in their field of research, compared with 78.3% of non-stem cell scientists.

##### Figure 7.3: Pie chart showing the responses of the total population to the question ‘Do patents exist in your field of research?’

### Do you work with patented materials (other than standard laboratory equipment)?

While 82.5% of participants indicated that patents existed in their field, Figure 7.4 shows that the respondents were largely split as to whether they worked with patented materials, with a small tendency towards thinking they did. 37.5% of the total population thought they did work with patented materials, 28.3% were not sure and 34.2% thought they did not.[[793]](#footnote-793) While it cannot be known from the data gathered whether the respondents did or did not work with patented materials, it is interesting to note that approximately one-third were unsure indicating that these scientists had either not tried to investigate this, or they had tried and had been unable to find out.

##### Figure 7.4: Pie chart showing the total population’s responses to the question ‘Do you work with patented materials (other than standard laboratory equipment)?’

In line with the trends observed when respondents were asked whether patents existed in their field, more of the stem cell scientists (48.6%) thought that they worked with patented materials than those working in other fields (32.5%); more of the group holding PhDs (45.8%) thought that they worked with patented materials than those without PhDs (23.4%); 58.3% of those who had been part of a patent application thought that they worked with patented materials compared with only 22% of those who had not; and more of those who had seen a patent document thought that they worked with patented materials (54.8%) than those who had not (15%).

### Use of Patent Databases

Patent databases are the most direct route for scientists to access patent databases themselves. Therefore, respondents were asked about their use and experiences of these databases. Figure 7.5 shows that less than 40% of the total population had used a patent database in the last five years.[[794]](#footnote-794)

##### Figure 7.5: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the question ‘Have you used a patent database in the last five years?*’*

The biggest difference observed between the subpopulations was that 71.4% of those who had seen a patent document had visited an online database, compared with none of those who had not seen one. This difference was expected; if participants have not seen a patent document it is unlikely that they have ever accessed an online database. Interestingly, almost 30% of the subpopulation who had seen a patent document had not used an online database. Further, in accordance with the hypotheses, 20% of those who had not been part of a patent application had used an online database. This is less than a third of the proportion of those who had been part of a patent application and had used an online database (20.0% versus 70.8%, p=0.000). The proportion of the principal investigator and post-doc subpopulation that had used a database represents more than twice that of the student group (55.2% versus 23.4%, p=0.001) indicating that students are far less likely to use patent databases than their senior counterparts.

All of the respondents who had used an online patent database in the last 5 years had used public databases. As Figure 7.6 shows, the EPO-hosted ‘espacenet’ database accounted for 36.2% of database use; 34.0% used Google Patent Search; 12.8% used Free Patents Online, 6.4% used the WIPO-hosted Patentscope and 10.6% of users had used ‘other’ databases (these were all named in the spaces provided as public databases).

##### Figure 7.6: Pie chart showing the results to the question ‘Which patent database did you visit most recently?*’*

### Experiences of using patent databases

Figure 7.7 shows that, of those who had used an online patent database in the last 5 years, 60.0% said they had ‘found and understood the information they had been looking for’; 33.3% had found but not understood all of the information; 4.4% had not been looking for a specific document; and 2.2% did not find the information they wanted.[[795]](#footnote-795)

##### Figure 7.7: Pie chart showing the results to the question ‘What happened when you used this patent database?’

## Patent knowledge

The dissemination of knowledge through the patent system assumes that end-users have the basic knowledge needed to engage with, and learn from, patent information. Further, when participating in the patent system as inventors or regulators, scientists also require knowledge of the system. The following section details the results of questions posed to investigate levels of such knowledge.

### First-to-file system

Under the UK Patents Act, the priority date for a patent application is the date of filing.[[796]](#footnote-796) This is known as ‘first-to-file’ system whereby the right to a patent grant lies with the first person to apply for patent protection over an invention, regardless of the date of invention. This means that if an inventor were to wait until they were certain the invention would have a profitable application, someone else may file for a patent on the invention before them. As a result, the true inventor may lose the right to hold a patent for their work. It is important to investigate whether scientists are aware of this because if they are not, if they are waiting for a profitable application to become apparent, they may lose out on holding the rights to their intellectual work and delay engagement with patent information. The participants were presented with the statement: ‘I only need to think about patenting my research when I am certain it will have a profitable application’. While (as can been seen in Figure 7.8) the majority of respondents disagreed (74.8%) with this statement, a significant proportion agreed (25.2%), with similar results seen across all subpopulations.[[797]](#footnote-797)

##### Figure 7.8: Bar chart showing the proportional representations of the responses of the total population and subpopulations to the statement ‘I only need to think about patenting my research when I am certain it will have a profitable application’

### The difference between patent applications and granted patents

When patent applications are published, they are known as ‘A’ specifications. When an application has been granted the document issued is a ‘B’ specification.[[798]](#footnote-798) Thus, the difference between an A and a B specification patent document is critical. As Figure 7.9 shows, 97.5% of participants disagreed with the statement ‘I know the difference between an A and B specification patent document’,[[799]](#footnote-799) with a high proportion of these participants indicating that they ‘strongly disagreed’ with the statement.[[800]](#footnote-800) This is a striking statistic.

##### Figure 7.9: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘I know the difference between an A and B specification patent document’

### Third party observations

As described in section 5.5.1, patent law provides an opportunity through which third parties can comment on the patentability of a patent application: third party observations.[[801]](#footnote-801) When presented with the false statement ‘The only chance for scientists to question a patent is after it has been granted’ 59.5% of the total population correctly disagreed[[802]](#footnote-802) (see Figure 7.10).

##### Figure 7.10: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘The only chance for scientists to question a patent is after it has been granted’

While more stem cell scientists (68.8%) appeared to know that scientists could question a patent pre-grant than scientists in other fields (55.6%), all of the other subpopulations showed different results than expected. There was a statistically significant variation between the student group and the group holding PhDs, with 74.4% and 52.5% (p=0.025) disagreeing respectively. Additionally, a statistically significantly smaller proportion of those who had seen a patent document disagreed than those who had not seen a patent (43.9% versus 67.5%, p=0.033). Similarly, fewer participants who had been part of a patent application (45.8%) disagreed than those who had not been part of one (64.0%).

### Research exemption

Under UK patent law there are uses which do not constitute infringement of a patent. These uses are detailed in Section 60(5) of the UK Patent Act 1977. The scope of the exemptions, particularly the research exemption in Section 60(5)(b) (“it is done for experimental purposes relating to the subject-matter of the invention”[[803]](#footnote-803)) is generally thought to be uncertain.[[804]](#footnote-804) In 2008, the UKIPO carried out a consultation “to seek evidence on the effect of the patent research exemption as allowed under Section 60(5) of the Patent Act 1977 and to identify the extent of stakeholder concerns on this aspect of patent law.”[[805]](#footnote-805) 32 of the 35 respondents to this consultation thought there was need to clarify the research exemption[[806]](#footnote-806) indicating that the legal scope of the research exemption is not clear.

As Figure 7.11 shows, approximately 25% of all respondents agreed with the statement ‘Even if a patent exists on a material I am using, I cannot be sued because I am carrying out research’.[[807]](#footnote-807)

##### Figure 7.11: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘Even if a patent exists on a material I am using, I cannot be sued because I am carrying out research’

## Scientific cultures and perceptions of patent information

As discussed in section 4.4, there are a number of debates surrounding the patent system which relate to the effect of patents on the institution of science. Therefore, questions were posed to assess scientists’ perceptions of these issues.

### The scientific value of patent information

The ‘scientific’ value of patent data was called into question by the fact that almost one-third of the respondents stated that they did not think patents provided a useful source of knowledge (31.9%)[[808]](#footnote-808) (see Figure 7.12).

##### Figure 7.12: Bar graph showing the proportional representations of the responses of the total population and subpopulations to the statement ‘Patents do not provide a useful source of knowledge’

Almost 75% of those who had seen a patent and almost 80% of those who had been part of a patent application thought patents provide a useful source of knowledge, higher than their counterparts (62.5% and 64% respectively). This indicates that those who have engaged with patent information consider it to be more valuable than those who have not.

### Additional comments from participants

At the end of the survey, the participants were invited to make any further comments about patents and/or their own experiences with patents (available in full in Appendix 4). A few topics were commented upon several times and therefore contributed to the basis of the interview topics. A number of the comments relate to the perceived disparity between the rules of the patent system and the traditional ethos of publicly funded science:[[809]](#footnote-809)

“[T]he concept of claiming ideas which are, more often than not, built on a lot of publicly funded research/education seems daft. Research should be done to achieve technology that raises standards of living for everyone, not just the rich.”

“[T]he expectation that Universities should mimic the patenting strategies of large corporations like pharmaceutical companies is basically wrong. That's asking Universities to play in a field where they will always be the weakest player. I also found that my institution's policy that academics should conduct all their research in a manner that preserves the potential for patent is toxic to basic research … I would not waste any thoughts on the patentability of my research unless a potential economic benefit of it became very obvious. Instead I am concentrating on doing my research according to traditional (not for profit) tradition, e.g. discussing my results freely with peers even outside of my institution and using my unpublished data as example in classes. On a more fundamental level, I do not agree that academics or universities should patent their discoveries. In my opinion there is something fundamentally flawed in the expectation that universities are expected to make significant financial income from patenting their research products?”

Regarding awareness of patents, one respondent wrote:

“I tend to be aware of background research and commercially [available] products in my field and sometimes am aware of patents but don't undertake patent searches myself … I rely on the University research Office to establish patentability of my research. I simply fill in a [specific] form and take it from there.”

One of the participants who had attempted to engage with patent information wrote of the reasons they had chosen to do so, and a problem they encountered:

“As a research scientist I solely use patents to find out about research that has been carried out that is relevant to my area of work. I often find it very difficult to locate the information of interest to me within the patent.”

Another respondent (an academic stem cell science PI, who had previously used a patent database) wrote “It would be good if academic scientists were taught the most effective way to access and use patent databases”. This participant had used an online database but indicated they also were unable to find the information they were looking for.

One respondent claimed that “as is the case in academic publishing, patents can often report false or selectively presented data”. This may contribute to the perceived limited value of patent data evidenced by this survey. Additionally, another respondent stated that they held patent information in a lower stead than traditional forms of knowledge transfer; that current practices to preserve the potential to patent are “toxic to basic research”; and that patenting can interfere with optimising the societal benefit of academic research.

## Analysis of the survey results

The findings indicate that the respondents to the survey had limited engagement with patent information and highlighted a number of barriers which may contribute to this.With regard to the hypotheses offered, notable differences were observed between the subpopulations. The results of many questions reflected the hypotheses: those with higher levels of education, previous experience as part of a patent application, engagement with patent information and stem cell scientists fared ‘better’ than their counterparts. In line with these findings, the participants of the second phase of the study (senior academic stem cell scientists) were expected to have a higher knowledge, awareness and engagement with patent information.[[810]](#footnote-810)

### Scientists’ engagement with patent information

All of the roles that scientists can play in the patent system assume engagement with patent information. Without such engagement, inventors may misjudge their patentable position; regulators may not know of applications which they could offer useful comment on and downstream innovators may miss information which could help inform their R&D efforts. The findings indicate that the survey respondents had limited engagement with patent information, leading their participation in the patent system to be questioned. Almost half of the respondents had never seen a patent document before and are unlikely to directly engage with patent information. This result is lower than that of a study of nanotechnologists where it was found 64% had read a patent.[[811]](#footnote-811) This suggests that discipline may be a factor affecting likelihood to look at patent documents. However, this is likely to only be at a broad level (e.g. biology- versus physics- related fields) because similar proportions of groups identified by different biological research areas were found to have seen a patent document in this survey. While 82.5% of the participants of this survey indicated that they knew that patents exist in their field this does not indicate whether they are aware of particular patents or if they are just aware of patenting in their field at a general level. The extent of patent awareness was examined during the interviews.

Despite the majority of respondents indicating that they thought patents exist in their field, the group were largely split as to whether they were working within patents with one-third unsure indicating that they were unsure on this point. This is concerning when considering each role of scientists in the patent system. As inventors, if they are unsure of whether they are working within patents, scientists may misjudge their patentable position. As regulators, they may miss patents on which they may be able to offer a third party observation on patentability. As follow on innovators, scientists may be at risk of infringement if their work falls outside the scope of the legal research exemption.[[812]](#footnote-812) This uncertainty was probed in the interviews: are scientists aware of particular patents that they work with? Given the split as to whether the respondents thought they used patented materials when most of the scientists knew that patents existed in their field, what affects this opinion? Have they carried out searches to find out?

Fewer than 40% of respondents had used patent databases meaning 60% are unlikely to be engaging directly with patent information, if at all. Almost 30% of the subpopulation who had seen a patent document had not used an online database. This is a similar proportion to those who have been part of a patent application, where 28.2% had not used an online database. The question is therefore raised: where have these participants seen a patent document if not when using an online database? The answer is likely to be that these participants have been shown patent documents by others (i.e. their patent attorneys of university TTO staff) and it is possible that they have only seen their own patent documents and those of related patents. This suggests that even though all of the subpopulation who had been part of a patent application indicated they had seen a patent document, 30% of this group may not to have seen other patents relating to research other than their own.[[813]](#footnote-813) This is in line with the model of academic role perceptions proposed by Jain, George and Maltarich(detailed in section 4.4.4)which indicated that scientists ‘buffer’ their engagement with the patent system through others in order to maintain their ‘academic’ persona and avoid association with their ‘entrepreneurial’ role.[[814]](#footnote-814) Scientists’ perceptions of this tension were investigated further in the second phase. The proportions of the population (and the subpopulations) that had used a patent database are, on the whole, very similar to the numbers who indicated they knew that they worked with patented materials. For example, 45.9% of stem cell scientists thought they worked with patented materials and 48.6% of this group had used an online database. This may indicate a link between online database use and awareness of one’s use of patented materials. This is logical and indicative of the importance of database use to learn about the state of the patent landscape of a field.

Knowing that all of the respondents who had used patent databases before had used public databases challenges the result that more than 90% thought they had found the information they had been looking for and that 60% thought they had understood all of the information. As discussed in section 5.5.3, public databases are notoriously untimely and incomplete.[[815]](#footnote-815) Further, patents have territorial validity only and databases vary in their territorial scope (an international patent filed in several countries may only have been granted in some countries and the claims granted can vary from country to country). At the time of the study, Google Patent Search only searched US patents[[816]](#footnote-816) and whilst espacenet can be used to search for filings under the Patent Cooperation Treaty (PCT)[[817]](#footnote-817), at the EPO through the EPC and national filings, this presupposes the technical knowledge to do so and to interpret the search results accordingly.

### Technical patent knowledge

To participate in the patent system as inventors, follow-on users or quality regulators, it is assumed scientists have the basic knowledge required to do so. The findings of previous study indicate that a lack of basic knowledge of patents may be a barrier to engagement with, and effective use of, patent information.[[818]](#footnote-818) The results of this survey highlighted that scientists’ technical patent knowledge is somewhat limited and may therefore constrain knowledge diffusion through the patent system and scientists’ general ability to participate in the patent system. The second phase of the study, the interviews and observations, further examined scientists’ technical knowledge of the patent system.

Regardless of whether a patent is proven to have economic value or not, the point at which knowledge is gained and presented to a patent office is critical in securing patent protection. Therefore, if one waits for a profitable application to become clear, this may result in a patent file date which is too late to secure a patent right. The finding that 25% of respondents thought they only needed to think about patenting their research when certain that it would have a profitable application means that they are at risk from foregoing the opportunity to hold a right over their intellectual efforts. In addition, waiting for a profitable application may prevent end-users from engaging with patent literature until they are ready to file for a patent. Leaving engagement to this late point may mean that scientists are not aware of information on which they could provide third party observations or which could inform their innovative efforts.

All but two respondents were unaware of the difference between A and B specification patent document. While, to a patent specialist, the difference is obvious and of clear importance, given the results obtained in this survey it is not known to scientists. If the difference is not known or understood, the reader of a patent document may not be aware of its legal status. As a result, scientists could divert their research to ‘invent around’ a patent which has not been granted. Alternatively, failure to appreciate the difference in the status of the claims means that scientists working at the forefront of knowledge, ideally placed to comment on ‘prior art’ and the novelty of a patent application, may not use the opportunity to make third party observations about patent applications because they believe the patent has already been granted. The lack of understanding about the difference between A and B specifications may also mean that opportunities offered by initiatives such as the UKNSCN’s publication of stem cell patent digests are not fully exploited.[[819]](#footnote-819) These issues were investigated in more detail in the interviews.

Given that 97.5% of participants did not know the difference between an A and a B specification patent document, it is unlikely that the 93% of database usershad found the information that they were looking for, as they believed, and even less likely that 60% of them had understood all of the information they encountered. This implies that the respondents believed they had the tools to understand the information they encountered which has been demonstrated not to be true. To further assess this disparity, the interview participants were questioned about their understanding of patent information.

As described in section 5.5.1, there are formal mechanisms for third parties to question claims in a patent application prior to grant. However, evidence from the US and UK indicates that this opportunity is rarely used.[[820]](#footnote-820) Peer scientists are the most likely to be aware of prior art in their field, particularly through scholarly publications. If scientists are not aware of the opportunity to present observations pre-grant, relevant prior art may be missed by in the examination process. Approximately 40% of the group surveyed were unaware that they could question a patent pre-grant. This is particularly striking when combined with the finding that almost all participants were aware that prior art could affect a patent application.[[821]](#footnote-821) These results compound the finding that 97.5% of those surveyed were not aware of the difference between a patent application and a grant document, and may therefore assume that a patent application has been granted and that there is no longer a chance of questioning it pre-grant.

The finding that 25% of respondents thought they could not be sued if they are carrying out research is in line with the findings of Lei, Jenuja and Wright which they attributed to the philosophy provided to them: ““If I do my research and don’t make money, even if I broke the law, nothing would happen to me. I am just doing research for the public.””[[822]](#footnote-822) As previously stated, the extent of the legal research exemption remains unclear. Whether, and why, scientists believe they may or may not be infringing other people’s patents if they are carrying out basic research was further probed in the interviews.

### Scientific cultures and perceptions of patent information

Some of the findings of the survey indicate that scientists’ perceptions of the patent system and patent information may influence their engagement with patent information. Almost one-third of participants stated that they thought patents were not a useful source of knowledge. This perception may lead scientists to disregard, or avoid using, patent information thereby scientists’ engagement with the patent system. The value scientists ascribe to patent information was probed in the second phase of the study.

The ‘further comments’ from participants indicated that a number of topics which were not really investigated in the survey may affect scientists’ engagement with the patent system and patent information. The comments largely focused on the misfit between academic scientific cultures and intellectual property; the ‘toxic’ effect of patents on the research environment; barriers to accessing and understanding patent information; and concerns about the quality of data in patent documents. These issues were further investigated in the interviews.

## Conclusions

The results of this survey are consistent with the findings of previous studies of different groups of end-users’ engagement with the patent system in showing that the engagement of publicly funded biological scientists with patent information is limited.[[823]](#footnote-823) Further, the results point to a number of barriers which are curtailing such engagement. The results show that scientists have a limited awareness of patents, low levels of patent database use and restricted basic knowledge about patents and indicated that a number of scientists questioned the value of patent information and the effect of patents on scientific cultures. These findings potentially limit the dissemination of knowledge at the centre of the ‘social contract’ rationale for the patent system, and the participants’ ability to contribute to the patent system as inventors and regulators through the third party observation system. The roots of the limitations observed in the survey phase were further investigated in the second phase of the study, the findings of which is presented in the next chapter.

Chapter 8

Findings of the interviews and structured observations

## Introduction

Building on the findings of the survey, this chapter presents the results of the second phase of the empirical study: the interviews and structured observations. This phase included some of the same ‘closed’ questions asked in the survey, but a large proportion of the questions were ‘open’, based on the findings of the surveys. The interviewees’ answers were then probed depending on their responses, in line with the semi-structured nature of the interview schedule. As a result, the findings sometimes draw on the survey results and are structured around the same themes but with a greater variety and depth of topics covered. Finally, the data from the interviews and observations are often indistinct in their presentation, due to the concurrent nature of this phase of the study. Where the data relates specifically to the structured observations (for example section 8.2.7 on the use of patent databases during the search task) this is highlighted.

### Sample characteristics and hypotheses

Between November 2011 and March 2012, 16 senior stem cell scientists (7 group leaders and 9 post-doctoral researchers) were interviewed from 6 different institutions. All of the interviewees had received funding from public sources (e.g. the UK Research Councils), and some had also received funding from private and third-sector entities. In the survey, this group displayed higher than average awareness of, engagement with, and knowledge of the patent system and patent information. Therefore, the participants in this second phase were expected to perform relatively highly and, while they are expected to be reflective of the wider community of academic stem cell scientists in the UK, the results are likely to be reflective of an elite group of the wider population of academic biological scientists. As a result, this wider population is expected to have a lower engagement with, awareness and understanding of patent information than that demonstrated by the interviewed group.

## Engagement with patent information and the patent information infrastructure

As in the survey, the participants’ level of engagement with patent information was investigated by asking questions regarding their awareness of the patent landscape surrounding their work and their previous use of patent information. The interviews probed the reasoning behind the limited engagement with patent information reported in the surveys. Through the structured observations, the participants were actively observing searching for and engaging with patent information.

### Do patents exist in your field of research?

The question asked in the survey: ‘do patents exist in your field of research?’ was also posed to the interviewees to gauge their basic awareness of patents potentially relating to their work. Being both part of the PI and post-doc group (91.5% of whom thought patents existed in their field) and stem cell group (91% of this group agreed), it was unsurprising that all of those interviewed thought patents exist in their field. Whilst this finding indicates a high level of awareness of patents existing in their field, it is superficial. The depth of awareness could not be deduced from this finding and was therefore probed further.

Upon further questioning, it was found that the level of awareness of patents varied greatly among the group. For example, one participant said “I am sure they probably do, yes, there probably is some”. Others were able to name particular inventors and specific patents. The interviewees were then asked how they knew patents exist in their field. Nine of the participants indicated they knew because they either held patents or had previously applied for patents. The reasoning behind the other seven interviewees’ awareness was less clear at first, but was found to include that patents had been mentioned at meetings or in conversations with colleagues.

Many of the participants indicated that their awareness was a result, in part at least, of the public debate about patenting stem cells:

“[O]bviously the patenting of stem cells is quite a public discussion” (Interviewee 8)

“I guess patents are more in the public domain now, I mean with the issues with Oliver Brüstle in Europe, it is hard to ignore” (Interviewee 7)

This is in line with a Canadian study which evidenced that many stem cell scientists were aware of ‘patent controversies’ in this field.[[824]](#footnote-824)

When asked about their awareness of specific patents, fourteen of the interviewees said that they knew of the existence of particular patents in their field. Upon investigation, it was apparent this awareness varied greatly among this group with some comments including “I think there are a couple on media products” whilst others were aware of the existence of specific patents and specific inventors, particularly famous patents and inventors such as the WARF patents and James Thomson or Oliver Brüstle. In addition, some participants indicated they knew of specific patents because they ‘affected’ their own work or knew of the patents of particular competitors. These points are discussed below.

#### Awareness due to relation to own work

Some of the interviewees said they were aware of particular patents relating to their own work. However, upon probing further, this awareness was not always because they had actively sought to find out if such patents existed. For example, one had come across a particular patent when researching for a grant application, but was previously unaware that the technology involved had been patented:

“I was looking at a particular technology which I thought was available and not in any way protected and then during a basic search I found a patent that I wasn’t aware of and I sort of looked at it and thought ‘how on earth did they manage to patent that?’” (Interviewee 7)

Others had specifically searched for patents when pursuing developing a commercial strategy, for example when launching spin out companies, which might affect their own freedom to operate:

“I have seen a few others, I mean I have tried, when we have been looking at sort of freedom to operate issues, we have looked for what has been protected but I have not looked at too many of them actually.” (Interviewee 15)

#### Knowledge of competitor’s patents

A few participants knew of particular competitors with patents providing comments including:

“Yes, particular patents and a particular author that I know has already patented something and so of course then I would look at other things that they would have done.” (Interviewee 12)

“I have looked up particular names … as in Thomson J. … and big Californian names.” (Interviewee 1)

Two interviewees said that they became aware of competitor’s patents in the context of being part of a company, for example one said:

“[W]e definitely looked at the WARF patents … that was very much in the context of setting up our company and trying to work out the relationship with what we could do academically, what we could do commercially and what we could transfer academically to the company.” (Interviewee 3)

But the participant took the view that:

“Ultimately that is going to be the CEO and the business development guys’ jobs. I mean I will keep in touch with the literature and they will probably be keeping more in touch with the patent landscape.” (Interviewee 3)

This is an example of scientists ‘buffering’ their engagement with patent information (further discussed in section 8.4.5).

Another interviewee commented that they had previously looked at patents to gauge what competitors might be working on, and planning on working on, in the future:

“Obviously you want to see what prior art there is and things like that … you can gain quite a lot from patents that you wouldn’t otherwise gain from a paper … It is different because you get a sort of feel for what people are really trying to work on, the downstream steps, because they often put in claims specific to this.” (Interviewee 1)

This, whilst awareness of the general existence of patents in their field was high amongst the interviewees, their knowledge of particular patents varied greatly.

### Have you ever seen a patent document?

A basic measure of a scientist’s engagement with patent information is whether they have seen a patent document. The survey results showed that less than half (48.8%) of those asked had previously seen a patent document, with 75% of the PI and post-doc population having seen a patent document. A higher proportion of those interviewed said that they had seen a patent document before (87.5%, all of whom were PIs or post-docs). The two interviewees who had not seen a patent document were post-docs and indicated the reason they had not seen a patent was because they thought they did not need to:

“*Anna(A): Have you ever seen a patent document?*

Interviewee (I): No.

*A: That’s fine. Have you ever considered trying to look at patents?*

I: It is not something that has ever come up for me; I’ve never had a reason to.

*A: Do you think that you work within a patent?*

I: No.

*A: Have you ever checked?*

I: No – I am working in a university so it wouldn’t be a problem.” (Interviewee 5)

This perception is discussed further in section 8.2.5.

### Have you seen a patent document other than your own?

Combining a couple of findings of the survey, it was inferred that approximately 30% of those surveyed who had seen a patent document were likely to have only seen their own.[[825]](#footnote-825) Similarly, it was found that 6 of the 14 (42.8%) interviewees who reported having seen patent documents may have only seen their own. This finding is similar to Ouellette’s finding that 36% of nanotechnologists had only seen their own patent document.[[826]](#footnote-826) One interviewee who holds two patents was not even sure they had seen the final documents of their own patents:

“I have certainly seen everything that went into the patents so I am hesitating slightly, would I have had to sign one as an inventor? … I am not sure if I have seen a patent document or just seen a complete version of what went into the patent, I am not sure about that.” (Interviewee 16)

Of the eight interviewees who claimed to have seen a patent document other than their own, one reported they had come across a patent document ‘in passing’ but had not studied it. Another was unsure of why they had looked for a patent:

“I had a really quick flick through one once, I don’t even remember why but it just went on and on and on and I quickly got bored and that was it.” (Interviewee 11)

The other six gave specific reasons for having seen the patents of others. One had acted as a consultant to lawyers:

“I am very much aware of a lot of the patents in my field … I have been used as a consultant by patent lawyers to go through information on claims.” (Interviewee 4)

Another was trying to write their own patent so had looked at others to learn about the art of writing patents:

“Yes. I regularly go onto the European Patent Office and use their website to look for patents mainly because I’m writing some patents at the moment … I have looked at how, when it has gone to a patent attorney … just how they wrote it from our papers, just sort of mimicking what they have done. Now whether that is good or not, I am not sure.” (Interviewee 1)

Therefore, even when the participants reported having seen patent documents other than their own, this was rarely to use them as a source of scientific information. Only two of the interviewees had consulted the patents of others which related specifically to their own work with one reporting:

“[S]ometimes I have heard about a researcher who has patented something and I am interested in that product then I will look for that” (Interviewee 2)

The other said:

“I used to work on [a technology] and I think there is a lot of patents on there and very little in the literature so because it is such a small field I think I just happened upon a patent because I was searching and searching for any information that I could find on them.” (Interviewee 8)

### UKNSCN patent digests

One effort made within the stem cell community to improve scientists awareness of patents in the field was the production of stem cell patent digests. As mentioned in section 5.5.4, following the 2008 inaugural conference of the UKNSCN, at which a panel discussion revealed a lack of awareness amongst scientists of foundational patents on hESCs granted by the UKIPO, the UKNSCN commissioned the UKIPO to produce digests of stem cell patents (both applications and grants) for its members. The digests were brought to the attention of network members in emails, and made available on the networks webpage, from which the following extract was taken:

“UKNSCN produces these digests in partnership with the UK's Intellectual Property Office (IPO), who include their search strategy as an annex to each digest. … [The service] is provided at cost to the Network.”[[827]](#footnote-827)

In April 2011, the RCUK published a report entitled ‘RCUK Review of the UK National Stem Cell Network’. The report contained information from a survey in which network members were questioned about their experience of the network. [[828]](#footnote-828) One question on the survey asked: “Please indicate if you have used any of the following UKNSCN services over the past two years.” These ‘services’ included the patent digests. 49% indicated they had not used them, 10% did not answer the question and 41% of respondents indicated they had looked at the patent digests. When asked of their perceptions of the digests, of the 41% that had used the digests, 26% found the service ‘very useful’, 41% ‘fairly useful’, 17% ‘not very useful’, 2% ‘not useful at all’ and 15% answered ‘don’t know’.[[829]](#footnote-829)

During the interviews, participants were asked whether they were UKNSCN members and whether they were aware that the network produced patent digests. While all but one interviewee had been members of the UKNSCN, only 7 of these were aware of the patent digests and just 3 had ever opened the document. Of those who had consulted the digests one said:

“That would have been one of my current things for awareness … I may have skimmed one or two but not much.” (Interviewee 16)

Another indicated that they did open the digests and claimed they could pick out the patents of relevance to them but that the usefulness of the digests was limited:

“I don’t think they are sufficiently detailed … You then have to look them up, so it is a sort of screen of what people are doing but you would have to look at each patent after that.” (Interviewee 1)

Those who were aware of the existence of the digests but had not looked at the digests claimed they had not done so for a couple of reasons. Several reasoned that they did not need to engage with the digests because they had applied for patents themselves previously with one commenting:

“I had sort of been through it by that point and so as I said I learnt a lot on the job so I didn’t think that would tell me much more than I already knew.” (Interviewee 15)

This comment revealed a misunderstanding of what the patent digests had been intended for. They were not an educational resource about patents in general; they were intended to highlight new patent applications and grants of particular interest to stem cell scientists.

Another reason provided by the participants for not engaging with the digests was that they were part of a deluge of information which they did not value enough to consult:

“I get them all the time but I never read them. … The problem with all of those things, frankly, is that you get deluged with so much information you tend to say ‘I will look at it if I really want to’. So I get monthly things from the UK Stem Cell Network but I get a lot of emails from a lot of places. If I looked at them all I could spend the whole week doing that instead of actually doing any real work, so the net result is, in fact it is true with a lot of things that people should be aware of, that you are in danger of just drowning everyone in information.” (Interviewee 3)

Another commented:

“I just don’t open all of the stuff that comes out … I wouldn’t read it even if I was aware … I just don’t think it is of value to me.” (Interviewee 4)

One participant indicated that they knew that the emails from the UKNSCN included information regarding patents but wasn’t specifically aware of the digests or what they were for:

“I receive the news and sometimes I think they tell about patents … I think maybe I have seen something about it but I didn’t know it was something they were already doing more seriously.” (Interviewee 2)

These findings are reflective of the RCUK report findings. Whilst almost half of the interviewees were aware of the digests, a small proportion used the service and few had found the service ‘useful’.

### Do you work with patented materials?

This question was asked during the interviews to further probe the participants’ awareness of patents in their field. One participant who described their lab as ‘commercially savvy’ was aware of a patent affecting their work and that the director of their group had obtained a licence from the patent owner to ensure they were able to continue with their research without concern of infringement:

“*A:* *Do you know if you are working within a patent?*

I: Yes I am, but I don’t really care. It doesn’t affect what I do.

*A: Why do you say that?*

I: Well, we have a licence to use it so it is okay.” (Interviewee 12)

Another spoke of potential confusion about the legal relevance of patents caused by territoriality (further discussed in section 8.3.3):

“Yes and no, because it differs between the USA and Europe, things like that. I sort of have an idea but that might not be absolutely precise.” (Interviewee 1)

Several participants indicated they were no longer sure, following the Brüstle case:

“I am not completely up to date … we work with human embryonic cells primarily and last year there was this big sort of discussion in the European Union and well, sort of everything, not only the cells and the research on embryonic stem cells but anything, any proof of concept that is coming out of embryonic cell research apparently cannot be patented and that was going to be challenged but I have lost track of whether that has been successful or not so I don’t know the state of affairs as of today.” (Interviewee 14)

One participant who had their own patents and reported they had seen a number of patent documents was asked if they knew the patent landscape surrounding their work reporting “No, absolutely not” but was not concerned about this. They said they did not need to know because they “wouldn’t be doing anything commercial”. This sentiment was echoed by many of the other participants:

“I mean no [I am not working with a patent] … well some things could be affected by that WARF patent still and their applications. There are probably other things for stuff that we do for which there are a lot of patents around but I haven’t really, frankly bothered to think about them much. … I mean there are significant patents … but on the whole it doesn’t bother me because it is essentially basic research that we do.” (Interviewee 3)

“We are pure researchers, we are basic researchers, we are not going to commercialise what we find, we are going to be doing basic nuts and bolts so I am led to believe that we could carry on regardless [of patents] to some extent. If we did things in the right way we could pursue it, and then … if we found something useful, to go back to the patent holders and say that we have done basic research and be quite humble about it and ask if it was anything they might like to take forward.” (Interviewee 7)

“The presence of a patent wouldn’t necessarily stop me doing work because most of it wouldn’t develop to anything commercial.” (Interviewee 1)

“[W]e wouldn’t be doing anything commercial so that [infringement] wouldn’t arise” (Interviewee 16)

These comments indicate a widespread belief amongst the participants that undertaking ‘basic’ research does not constitute infringement, at least not until the point it develops into ‘something commercial’. This is in line with the findings of other studies.[[830]](#footnote-830) As section 7.3.4 discussed, the research exemption, in UK law at least, remains uncertain and thus these scientists’ lack of concern may be unfounded. Further, the perception that patents ‘don’t matter’ until a research becomes ‘commercial’ indicates that these scientists are unlikely to look at patents, particularly at a point where it may inform their research.

### Levels of patent database use

The survey showed that 55.2% of PIs and post-docs had used patent databases before. Similarly, half of the interviewees had used databases before but many of these were hazy about their experiences with most indicating that they rarely visited the databases. One group leader said: “I must have” with another saying: “I have tried to I think but not very hard” and one post-doc commented: “yes, but don’t ask me which one”. As with the survey, those interviewees who had indicated they had used patent databases had all used public databases. Their experiences of these databases were probed during the interviews and further questions were asked during the structured observations (as discussed in sections 8.2.7-8.2.11).

Those who had not used a database but had applied for patents previously indicated that they ‘pass on those things’ to someone else, once again ‘buffering’ and ‘delegating’ their engagement with patent information (as discussed in section 8.4.5). This is in line with the hypothesis proposed in section 7.5.1 following the finding that almost 30% of those who had seen a patent and been part of a patent application had not used a patent database: these people are likely to have been shown patent documents by others (i.e. their patent attorney).

There were other reasons that participants had not used patent databases including a lack of awareness of their existence (for example saying “I don’t know if there is any kind of search engine for patents”) and the perception that they had not needed to use them:

“I know that they [patent databases] exist. Occasionally when I am google searching particular techniques or approaches I will find a database or at least a page in a database that will have the discovery on there. But I haven’t been to a patent database to search for one; I just know that they are out there to use should I want to.” (Interviewee 7)

### The search task

As described in section 6.4.4, participants were asked to undertake a task to search for an academic paper and a related patent whilst being observed (a detailed account of the observations of the searches is provided in Appendix 8). Following the search task, participants were given paper copies of the paper and the US and European Patent (EP) applications and grants. They were then questioned about their understanding and perceptions of the documents.

The paper at the centre of the task was on ground breaking research from Shinya Yamanaka (the joint winner of the 2012 Nobel Prize for Physiology of Medicine) and was published in Cell in August 2006. This paper was the first to describe the generation of iPS cells.[[831]](#footnote-831) A patent application on the work described in this paper was filed in 2005.[[832]](#footnote-832) The gravity of this patent has since been highlighted. For example, the initial public offering of Cellular Dynamics, founded by James Thomson, in the US, highlighted a non-exclusive license agreement concerning the ‘Yamanaka patent estate’ including:

*“*39 U.S. and foreign patents and patent applications expiring between 2026 and 2029 the most significant of which so far is U.S. Patent No. 8,048,999, which covers the Yamanaka set of reprogramming factors.”[[833]](#footnote-833)

This ‘999 patent is the US version of the patent which the participants were asked to search for. Of the Cellular Dynamics licensing, one prominent stem cell scientist, Paul Knoepfler, noted:

“I find it very interesting that this licensing was deemed necessary. Other labs developing iPS cell-related technologies should take heed that even Thomson’s company decided it had to get licensing from Yamanaka although Thomson has been an innovator on iPS cells too.”[[834]](#footnote-834)

Thus, these patents are highlight significant in the stem cell field.

When prompted to search for the paper, the participants found it quickly and easily.[[835]](#footnote-835) The time taken to find the paper ranged from 20 seconds to 5 minutes 35 seconds, with a mean average of 2 minutes. While this timing data is clearly problematic in that the search conditions were not uniform, it is useful in comparing the relative ease of searching for differing information. None of the interviewees struggled to find the paper, but some were slowed down by the speed of their computers and others by their strategies of using databases. For example, one of the participants organised all of the results by date rather than relevance to their search, possibly assuming the paper was more recent than it was, meaning they had to consider a number of results before finding the correct paper. Another used a word in their search which did not appear in the title of the paper and therefore had to carry out a second search, thus slowing down their search.

Once they had found the paper, the participants were asked to look for the first patent relating to the paper. Some indicated they did not think there were any patents relating to iPS cells:

“As far as I know he never applied for one; there is no patent covering iPS cells …I’m sure there are some downstream but this first one, I thought he never patented it” (Interviewee 14)

They were told that there was and were asked to search for it. Some thought there would be information in the paper highlighting a patent if there was one but could not find any such information.

All of the participants began with searches in general search engines such as Google or Bing using terms such as ‘patent’ ‘Yamanaka’ and ‘iPS cells’. The time taken to find the patent ranged from 3 minutes 30 seconds to 17 minutes, with some guidance along the way (for example, pointing them towards searching for patent databases following unsuccessful searches in google). Two participants stopped searching after 10 minutes, having made little progress in attempting to find the patent, becoming frustrated and asking to conclude the search. The mean average time taken to find the patent by the other 14 interviewees was 10 minutes and 40 seconds, over five times the average time it took them to find the paper. On average, it took each participants 9 times longer to find the patent than it took them to find the paper (range: 2.12-21 times longer) (see Appendix 8).

### Experiences of patent databases

In general, during the search task the interviewees struggled to use patent databases. They were uncertain of how best to carry out searches and were unsure about their findings. When using these databases, the participants generally used the ‘simple’ search options, rather than ‘advanced’ searches. This approach meant that far more patent documents were picked up than, for example, when providing a specific inventors name in the correct search text box in an advanced search. As a result, the participants received hundreds of patent documents in response to their searches. Many of these were completely unrelated to what they were looking for. For example, one participant looked at one patent on an invention regarding a mechanical screw and commented: “He is good but he can’t be that good that he is applying for patents on that.”

The experiences of patent databases observed during the task were not exceptional. Those who had previously used patent databases indicated that they had found the databases problematic on these occasions as well. For example, one said that they ‘regularly’ used patent databases but was unsure as to whether they were able to find what they were searching for when they did, yet questioned the ability of professionals to undertake a superior search:

“I was able to find patents relating to what I wanted to do but what I wasn’t sure of was whether I was missing a load of patents because I wasn’t doing a complete proper search and I am never quite sure because the patent lawyers wanted a lot of money to do a search and actually I never found that they came up with many different to what I could do in a few seconds.” (Interviewee 1)

One participant indicated that although they had previously tried to use a patent database they had struggled to understand how to use it and had therefore been unable to find the information that they were looking for:

“I think it is complicated … I went on a patent database but I couldn’t figure out how it was working really, so that’s why I couldn’t really find the information.” (Interviewee 2)

Some of the interviewees commented on the particular databases which they had previously used. One participant had tried to use the USPTO’s database. When asked about this experience they said:

“I have tried, but I cannot use it, I have given up on it, I really struggled. At least the European one is fairly straight forward, but I have to remember what I do each time. It’s easier if you are looking for a specific patent but I am not sure about the results when I am looking at a topic.” (Interviewee 1)

The EPO’s patent database, espacenet, was also perceived to be problematic. Several interviewees said they had used espacenet. When asked why they favoured this over other databases one interviewee remarked: “It’s just easy to use”. Another who ‘regularly’ visits espacenet said they found the experience to be:

“Not too bad, but as I said there are problems … I think the problem is we are spoilt now, we can find information about anything, you expect to be able to find it and it is not quite that easy with this.” (Interviewee 9)

Accordingly, another interviewee commented on the limitations of espacenet:

“I mean it’s problematic, it’s not Google and it’s a bit difficult to understand why it is not because if all of this information is being coded correctly when you put full-text searches in and things like that, authors names and stuff, it is surprising how difficult it can be to get some patents out … It doesn’t seem to be very tolerant of case sensitivity or anything so the search engine is not very good. You would think if you just put in a few things in the free text search that it should be able to pull the thing out but it is amazing, well what it seems to do is it seems to pull out everything, it doesn’t seem very selective either … it seems to pull out all sorts of rubbish and buried somewhere in there, not at the top, will be the patent you want often, like about 3 pages in you will eventually find it.” (Interviewee 10)

This is in line with the problems the participants faced when using the patent databases (with regard to a lack of tolerance to searching for ‘factors’ rather than the term ‘factor’ as described in the following section).

What the participants were not aware of was that the publicly-available tools and databases they were using are not guaranteed to be accurate. For example, the EPO admits on its own website that the data within it is suboptimal:

“The EPO does not accept any responsibility for the accuracy of data and information originating from other authorities than the EPO; in particular, the EPO does not guarantee that they are complete, up-to-date or fit for specific purposes.”[[836]](#footnote-836)

“Although we take the utmost care to ensure error-free entries, we cannot guarantee that the data is either up to date or correct. You should not therefore base important decisions solely on this data. Instead, you can use it to help you make up your mind whether you need to consult a patent professional or check with the relevant patent-granting authority first.”[[837]](#footnote-837)

WIPO gives similar disclaimers.[[838]](#footnote-838)

### Search strategies, keywords and the titles of patent documents

During the searches the titles of patent documents were found to be problematic. One participant tried to use the title of the paper to find the patent copying the title into a search engine and added ‘patent Japan’ commenting: “A lot of the time I would just do that but I suppose that is dependent on it having the same title as the paper.” When that search did not bring up the patent they said: “It is just some of them, like all the Geron ones pull up when you do Google searches.” When asked if they regularly used titles of their own papers to name the related patents they said: “I tend to just because then if someone wants the information it is much easier to find.”

During the task, participants were asked to comment on the title of the patent with all being surprised about the title for a number of reasons. Many of the participants said the title of the patent was surprisingly vague:

“I: I would just think it was a patent on iPS cells but nothing more than that. Is that really all it is?

*A: Yes, that’s the title.*

I: Wow, that’s vague.” (Interviewee 12)

Others noted that the title of the patent did not reflect the related academic paper:

“The trouble is, the title of the patent may not be anything to do with the paper.” (Interviewee 1)

“I would have expected something with iPS, but the name is not expected, but then iPS is only because of that title [points at paper] that everyone now calls them iPS cells, that is the scientific name. Now presumably, the patent is not on the cell, it is on the process, and the process involves factors that reprogram the nucleus down to the developmental lineages so it is a totally plausible name but perhaps not what I would have looked for if I was searching for a title.” (Interviewee 4)

This highlighted another problem – that scientific language changes and patent information may not keep up with this:

“I: Things are renamed so it’s easy to miss them with a keyword search.

*A: Have you found that before?*

I: Yes, you find different things when you search with different words which scientifically mean the same thing.” (Interviewee 9)

Others commented on the potential value from the perspective of a patent holder of having vague or misleading titles for patents:

“[T]hey certainly would have a heading as obtuse as possible wouldn’t they so it wouldn’t be immediately obvious what it might be useful for.” (Interviewee 16)

*“*It depends which patent attorney you go to. Different ones have different strategies but they deliberately make them hard to guess. One of ours in something like ‘pluripotent stem cells’ which tells you bloody nothing about what the patent is about, so, you know, if you put that title in it would bring that up but it would also bring up a load of other stuff I suspect.” (Interviewee 10)

Further, lots of the interviewees commented on the misleading language used in the title. The title of the patent suggests that it covers a single ‘factor’ but the claims describe multiple ‘factors’, as does the paper and its’ title ‘Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors’. This peculiarity was commented on by many of the interviewees:

“I: Well, it is not just one factor though is it? That is the thing that I find a bit strange, is that something wrong with the English there?

*A: Possibly …*

I: Yes, because you would have Nuclear Reprogramming Cocktail or something like that but as it is written it definitely sounds wrong, probably a language thing … I think they should have got the title right.” (Interviewee 15)

“I: I might have [looked at the patent] because I am interested in nuclear reprogramming but I wouldn’t in any way have anticipated it was about any of the standard ways of getting iPS cells because it is four factors or more, 3 minimum.

*A: Yes, and I suppose factor indicates it being just one.*

I: Exactly.” (Interviewee 16)

“That is very interesting, so that is making it a single factor … I find it odd that they have used ‘factor’, when you look at it is more than one … Hmm, this is really annoying me because it is not a single factor and that is not being described properly.” (Interviewee 9)

“I wouldn’t expect it to just be one factor because there are four on the paper so that is quite surprising that there is one … I think it should have an s on the end.” (Interviewee 11)

“They are talking about factors, they are not talking about one factor so I only read the first few claims but they are claiming directly obviously Oct4, Sox2, c-myc, Klf4. Well, that is factors. As it happened you can just do with one, but that is not what they are claiming so they should have said factors there if you are going to be absolutely correct about it.” (Interviewee 10)

This may be a sign of gaming (see discussion in section 9.4.5): purposively making patents difficult to find in patent databases, which do not cope well with variations in syntax during searches.

The search tasks, therefore, highlighted that scientists have problems finding and accessing patent information. It must be remembered that these were problems that they encountered even when they were looking for specific patents (knowing the inventor and a rough date for the patent). Further, they were supported and being told when they had found the right information. They are even less likely to have found patents of interest to them if they were doing a general search alone.

### The language and structure of patent information

Upon inspection of the patent documents during the structured observations, some of the participants commented on the repetitive nature of the information and the problems this caused in comprehending the information that they encountered:

“I think it would be very very difficult to read because at every stage you have to be going back all the time.” (Interviewee 6)

“It feels repetitive which is just making it really complicated for me to understand, it is definitely not something I could skim read … it feels like gibberish at this point when they are referring back and referring back.” (Interviewee 11)

All of the participants indicated that a significant barrier to understanding the information was the language used in the documents which was noted to be particularly complex, limiting the perceived value of the information in the patent document, particularly in comparison with the related paper:

“I think they are a very hard source of information to understand … it wouldn’t be my first point of call to go to a patent and read that information, I would hopefully read maybe a paper if they had published to just get the summary because it is so pernickety and the language is very hard … It is ridiculous. I mean I understand why it has to be like that because it has to be specific but they make me lose the will to live, they are so hard to read.” (Interviewee 12)

“This is really overcomplicated, a paper should be clear and that [points at paper] was clear whereas this [points at patent document] isn’t … it is stuff like ‘as a more preferred embodiment’ ‘provided the aforementioned factor’, it is like argh! What aforementioned factor? You flick up again, oh aforementioned factor here, so where is this, what factor? Why can’t they just say what factor it is? You know, why can’t they just say it is klf or something? I totally understand [the paper] … I would have to probably give up a whole afternoon which I wouldn’t do when I could read a paper in half an hour and I would be better informed I think.” (Interviewee 11)

“It’s horrendous, I find that the claims are odd, there are no verbs.” (Interviewee 6)

“I don’t think it is accessible language at all. It is not accessible in that it is rather like, you just don’t know the rules of the game so you don’t know how to interpret it … it is like it has been written in a different language almost, that is the problem is that you don’t quite understand why it is taking 5 claims to describe what would essentially be written in one line in a paper because of all the general claims and all of the generalising and stuff like that … I think that is the problem whereas if you think about research papers, they are deliberately, well some people seem incapable of doing this, but they are deliberately written to be readable. So if you think about a research paper it is describing quite technical things which are very very specialised, but if they are written correctly anybody should be able to read it.” (Interviewee 10)

In addition, several participants commented that the graphs and pictures were of far worse quality than one would expect in an academic paper, compounding the problems regarding language. For example, one participant noted:

“Well the thing I would do as well is, as a scientist, I would take this and I would try and read some of the claims and think ‘well I can’t read that’ so then I would think ‘I’ll have a look at the figures because the figures will tell me loads’ and they are like this, absolutely useless, you can’t even see anything and you can’t read it, you would never get away with that in a journal, they don’t tell you anything.” (Interviewee 12)

The problematic language and perceived poor quality of the supporting figures in patent documents could lead to a misunderstanding of information and is likely to contribute to scientists’ perceptions of the value of patent information (discussed further in section 8.4.1).

### The sufficiency of disclosure

A patent application must disclose sufficient information for the invention to enable “a person skilled in the art” to practise the invention if it is to be granted and subsequently this information must be published. Disclosure, as described in Chapter 5, is often described as the *quid pro quo* of the patent system. The requirement of disclosure is described in Section 14(3) of the UK Patents Act which provides:

“The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.”[[839]](#footnote-839)

During the interviews and tasks, the participants were questioned as to whether they thought patent documents contained enough information to perform the invention (i.e. fulfilling the disclosure requirements). The comments were mixed with a few believing that, given time to comprehend the information in patents, they might be able to reproduce the invention. Many others believed the information was insufficient to practise the invention and that the language problems could not be overcome:

“*A: Could you attempt what it claims?*

I: Absolutely not. I would have no hope. I wouldn’t know where to start to be honest not without the paper at least.” (Interviewee 12)

Correspondingly, one interviewee commented that the value of patent information is limited by the level of disclosure and that this may be caused, in part, by examiners having limited knowledge of the advancing science:

“There is always something left out because obviously people can go and read that [patent documents] … they don’t want to give all of their secrets away. So you will get some bits out of it but it is limited … you could reproduce it to a certain level but there are fine details that are missing. For example, it will say something like “Fibroblast growth factor was used between x and y” rather than telling you exactly what it is … there are a lot of ranges in there … I think people are quite selective with what they put in … I suppose it’s hard to get people who have a good enough background to know what’s been done before. Perhaps the wool has been pulled over their eyes.” (Interviewee 9)

One participant reported a particular instance where patent information had held insufficient information for the claimed invention to be carried out, believing that the information was withheld to maintain a competitive advantage:

“I have an example in mind where it was distinctly not a useful piece of information, it was, there is a commercial media that we use a lot … which is patented, and the company won’t tell you what’s in it so you go to the patent and look at it. The problem is what the patent does is say it could contain this, or it could contain that, or it could be this or it could be that, and so actually you end up thinking ‘it hasn’t really told me anything.’” (Interviewee 3)

Others also questioned the ability of patent documents to disseminate scientific information:

“I don’t think it is accessible language at all … I get the impression that that is not the primary objective of them, they are just meant to be read by lawyers and judges and not normal people …. Are patents really written for the general public or are they written for the profession, do you know what I mean? It is one thing to say ‘you have written this, it is deliberately confusing and the average person on the street can’t understand that’ to saying to somebody who would normally read it, so a judge, a barrister, a solicitor, a patent attorney, patent examiner, if they can understand it, if that is the group you want to participate, I think you have to decide: which is it? Or should you have two sets of documents which we do for certain things actually, and research things, when you write some grants now, I think most of them now, you have to write a synopsis which is for the general public. They are only about a page but we have to write something which is completely intelligible even though the rest of it tries to be but it would still have technical language in terms of art. Wouldn’t one thing just to be to have something like that? ‘This is a patent about a hoover which is super-duper because it creates cyclonal ...’ I don’t know. And then you would have both things. … I think that if you want a monopoly, all of the information should be out there and understandable to lay people, that is the *quid pro quo*, then it’s all open, you’re protected so what are you worried about? … if we give them a monopoly they should give us all of the information in a way we can read it, simple.” (Interviewee 10)

While it is clear that participants knew that some information needed to be disclosed, they were uncertain about the level and quality of information required with many commenting that insufficient information was given in documents and all found the information inaccessible due to problems with the language. This is likely to affect scientists’ perceptions of the value of patent information and therefore the likelihood they will engage with it.

## Patent knowledge

The dissemination of scientific knowledge through the patent system assumes that users have the basic knowledge necessary to understand patent information. The quantitative survey showed scientists had a low level of basic knowledge regarding patents (see 7.3). The interviews probed participants’ knowledge of patent mechanics further.

### The patentability requirements

Under UK patent law:

“A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say - (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application”[[840]](#footnote-840)

The interviewees were asked what they thought the patent requirements were. A standard reply was:

“I think it has to be novel and there are some other criteria as well but I don’t know quite what they are.” (Interviewee 8)

Interviewees who hold patents themselves gave more sophisticated answers including:

“It has to be completely novel, no prior art, something that you wouldn’t have conceived with the knowledge that you had to date, so it is not like just reengineering something and then filing.” (Interviewee 15)

Many interviewees were aware that inventions must be novel but were hazy about this meaning a lack of prior art and none commented on the need for an industrial application. Only three of the interviewees commented on the requirement for a patentable invention to show an inventive step with one saying:

“There has to be an inventive step … there has to be an improvement over prior art.” (Interviewee 14)

And another alluded to the concept of an inventive step but did not use the term:

“It has to be not common sense, not that any intelligible person could infer the application or implications from what is published.” (Interviewee 4)

Several interviewees expected that ‘scientific’ standards were patent requirements such as proof-of-working and reproducibility. For example, one said “I presume there is a requirement for a significant amount of data to back it up” while another said “it must show reproducibility.” As one participant who had applied for a number of patents noted, this is not the case, there is no working requirement in patent law:

“Those two initial, as I said, were speculative patents and at that time I realised that you don’t need to have done anything to write a patent and also that the standard of proof is far from that for a scientific paper … What is absolutely evident … and is also relevant to this recent European Court of Justice ruling [in the Brüstle case], is that there is a question: are these patents any use of not? Well, clearly they are in setting up a company, you go off to a venture capitalist and they want to know what patent protection you’ve got, kind of irrespective, I think, of whether they are ‘real’. … We had an idea at the time for something else … which was pretty new at the time so we wrote another speculative patent … and then having done that we invented a lot of other things …we probably wrote about another dozen patents on ideas we had, most of which we had little or no evidence for, then of course you have a year to try and gather data for it … it is a strange concept.” (Interviewee 3)

### The difference between A and B specification patent documents

Following the search, the participants were given a copy of the EP and US applications and grants. They were asked whether the patent documents referred to applications or grants. Some guessed, but many commented that they ‘wouldn’t have a clue’. As discussed in section 7.3.2, the difference between A and B specification patent documents is an important one: it indicates whether the document refers to a patent application (an A specification) or a granted patent (a B specification). The survey results revealed that 97.5% of those asked did not know the difference between an A and B specification patent document and accordingly none of the interviewees did either. One participant hazarded a guess that it was to do with an update of the claims. When the difference was explained, several interviewees were shocked they didn’t know the difference and the majority were pleased to now know the distinction with one saying: “Wow, that’s amazing, I had no idea it was so simple, this is really helpful for me.”

### The territoriality of patents

Patents are territorial in nature: a patent granted by the UKIPO is only valid in the UK; a patent granted by the USPTO is only valid in the US.[[841]](#footnote-841) Some international treaties allow a single application to be filed for multiple jurisdictions at once, the PCT and the EPC being the most relevant of these to inventors in the UK. The legal situation is particularly complicated in Europe because applicants can apply for both national patents (through national offices (e.g. the UKIPO in the UK)) and/or European patents under the EPC (filed with the EPO) through these offices directly or using the PCT route through WIPO.[[842]](#footnote-842) In addition, the ‘origin’ and legal routing of the patent application (whether it be through WIPO, the EPO or national routes) has important practical implications for database users, because the modalities of the searches are dictated by the routing of the application: searchers may potentially miss a national patent which has been filed originally as an international application. Therefore, it is important to understand the territoriality of patents in order to find and understand patent information and its impact.

When questioned, many of the interviewees were not aware that patent rights are territorial. For example, when asked where the US and EP patents covered, one said “I wouldn’t have the first clue” while another (incorrectly) commented “Once they are patented in one place they cover everywhere, right?” Others, mainly those who themselves held patents, had some idea that patents were territorial but were still uncertain, with comments including:

“I know there are UK patents and there are also European ones and I think there are, they are separate from, the worldwide ones. In our field there are big Japanese groups so I suppose Japanese ones and also the US but I don’t really know.” (Interviewee 13)

Some interviewees knew that there were some multinational filing systems but were uncertain of the details:

“I do know there are regions a little bit like CD and DVD regions, the world is carved up into sort of the US, Europe, Asia and other markets and that these markets are different territories … if you have coverage in one that doesn’t necessarily mean that you have coverage in another and that to get universal, or worldwide protection, it is a much more involved process of going through all the territories, I’m not sure how many there are.” (Interviewee 7)

Once participants had found, or were given, the patent documents (one EP and one US) they were asked whether they had ‘been applied for here’ (i.e. in the UK, but this terminology was avoided to further test the participants understanding of the information). All participants were able to determine that the UK territory is not covered by the US patent but the situation concerning the EP patent was less well understood. On the front page of the EP patent application document it indicates the application has designated the UK; this can be seen by the letters ‘GB’ under the heading ‘Designated Contracting States’. While three participants assumed that EP patents cover the UK, with comments such as “If it is European then yes”, others were less sure: “Presumably” and “I think so” and “I’m never quite sure about that one actually … I’ve looked at all that information before and not been sure.” Several thought that the EP document did not, either because they thought the UK was not included in the EP patent application, or they were looking for ‘UK’, not ‘GB’:

“I can’t see us there, UK.” (Interviewee 9)

### Third party observations

The participants were asked if they thought they could question a patent before it was granted. None knew of the specific opportunity to file third party observations, and many remarked that they would not use it even if they did, they would simply disregard the information if they thought that the patent did not fulfil the patentability requirements:

“*A: Do you know anything about whether you can question a patent at any point if you doubted it?*

I: I think that if I saw something like that I would just disregard it rather than wanting to actually file something against it.” (Interviewee 13)

Others indicated they wouldn’t use the opportunity because they wouldn’t read patent applications:

“If you read those circulars [such as emails about the UKNSCN digests] then maybe you could say ‘I knew that and it was obvious’ … but I wouldn’t read it because I couldn’t care … Most scientists would say ‘I will wait till the paper comes out.’” (Interviewee 4)

Notwithstanding this, several participants said they thought such observations would be useful in facilitating expert review in the examination process:

“I do think that needs to be done because scientists will know more than the examiner about the field and what has already been done. Yes, for somebody related to that field I think that could be really useful.” (Interviewee 12)

“I actually do think that you should have the opportunity to do it because it is like peer review” (Interviewee 15)

### Have you received ever any training about patents?

As the previous sections have shown, the participants’ understanding of patent information was hampered, in part at least, by their limited knowledge of patent technicalities. This may be contributed to by the dearth of formal education available to academic scientists regarding patent-related issues, particularly with regard to using patents as an information source. Training is available on an ad-hoc basic in different institutions but it is not formally built into the academic syllabus or ongoing professional education of scientists (discussed in section 9.4.2). Given this, it is unsurprising that, when questioned, it was apparent that none of the interviewees had ever received formal training about patent information or patent specifics (other than from a commercial perspective, i.e. to avoid publishing anything they might want to apply for a patent on until they have filed an application).

When asked whether they had ever received any training about patents, those who had previous experience of patenting commented that they felt they had learnt ‘on the job’.

“No training no, just what I’ve picked up.” (Interviewee 1)

“I do hold two patents so I have been led through the processes by University lawyers, and [funding council] lawyers." (Interviewee 4)

“Some of the work that we did … was commercially funded and we would have been instructed in things like confidentiality and so on including a little bit of background about patents.” (Interviewee 16)

In addition to their own practical experiences, some of those who had previously applied for patents indicated that general talks had led them to seek out more information about patents themselves:

“No [formal training], not other than me going to lectures and things where people have mentioned WIPO, espacenet and things like that, and then I have gone on to look at what they are.” (Interviewee 9)

One participant was aware of some training available to them, but had not participated in such training:

“I haven’t been to them but there have been some training sessions organised by the Scottish Stem Cell Network once or twice a year and they get Marks and Clarks and DLA Piper, the lawyers to come along and tell people about the ins and outs of patenting so there is that resource.” (Interviewee 15)

Some had attended courses where patents had been mentioned but were not the focus of the sessions:

“[Patenting] has come up on the fringes of some training courses I have been on. I have been on sort of courses on funding and of course, patents come into elements of that” (Interviewee 7)

“No official training but workshops and I heard about it in seminars and conferences … I have been to a workshop on commercialisation of science but not on searching, well, they did talk about how to research on a patent database but I did not do it myself.” (Interviewee 2)

Many participants were not aware of any training particularly about patents that was available to them:

“Not that I have come across at uni no, you get alerts for different training sessions and I haven’t seen anything to do with patents at all, certainly not recently.” (Interviewee 11)

And another said:

“Not specifically about patents I mean I know that the University as a whole is quite big on the intellectual property side of things but I don’t know an awful lot about patents myself.” (Interviewee 13)

A perceived need to improve knowledge about and understanding of patent information is highlighted by the following extract where one group leader observed that awareness is superficial and that people are less aware of many basic issues to do with patenting:

“I think there is enough information around now that people tend to know about the whole issue of IP and it being important and its possibilities. Probably what people aren’t so aware of are some of the issues around actually getting a patent, what you can and cannot do, the dangers of releasing information ahead of time, things that you need to do to secure your position with regards to IP, those are things that people are possibly less aware of.” (Interviewee 3)

Indeed, many of the interviewees remarked on the need for more training, particularly following the interview and task with a number of the interviewees indicating that they had found the process enlightening. For example, one group leader said:

“I think it has been very useful for me too, actually learning more about this system. It is not one of my strengths but I do think it is very important … you are not going to be able to spin it out unless you can protect your IP.” (Interviewee 15)

Another commented:

“I think it would be good to have more training to sort of understand more closely what might be more relevant to patent, not what is more relevant … I suppose what a claim is, really what a claim is sometimes I am never quite sure. It is quite confusing.” (Interviewee 1)

The uptake of formal training may be limited due to the attitude of some interviewees, that IP training is not a priority for them because they don’t view their research as patentable. For example, one participant remarked:

“I suppose from my point of view I am not expecting, personally, to be developing or filing any patents so I haven’t really explored that area.” (Interviewee 13)

In addition, in line with comments regarding the UKNSCN patent digests in section 8.2.4, uptake of training could be limited by the relevance of the training:

“… if it [training] was something that was specifically related yes, like you, then that would keep my interest but if it was coming from a much broader basis I think I would be less likely to attend, it has to be really relevant.” (Interviewee 6)

One participant, who was also a lecturer, indicated they thought it would be worthwhile to go further than general patent education and include training about finding patent information into undergraduate courses:

“We have different modules about ethics and protecting ideas and all that but certainly we are not teaching that, using patent information, patent databases for places of scientific information… I teach a module which is basically retrieval of information and when you just said that I thought ‘I should include that in the module’ because I never really, I know that it is there but because we don’t tend to use it, and it should be taught.” (Interviewee 14)

These results show that whilst some of the participants had received training about commercialisation, none had received any specific formal training regarding the mechanics of the patent system and patent information.

## Scientific cultures and perceptions of patent information

In addition to the aforementioned perception held by many of the participants that because they worked with basic science they did not need to think about patents, a number of other cultural factors may contribute to their limited engagement with patent information, particularly as a source of scientific information.

### The ‘scientific’ value of patent information

Almost one-third of those questioned in the survey did not think patents provided a useful source of knowledge. While from this it may be assumed that two-thirds think that patents can provide a useful source of knowledge, it was not clear what this knowledge was expected to be useful for. During the interviews, participants were asked if they thought patents could be a useful source of information or knowledge and why.

As many of the previous findings have shown, there are a number of reasons that scientists may question the value of patent information: many do not regularly engage with the information directly; they find it difficult to access and understand; many think that patents should be based on scientific norms (such as proof of concept) and, upon inspection, did not think that patent documents effectively disclosed sufficient information about the invention for them to ‘practice’ it. Accordingly, few participants passed positive comment on the value of patent information with the majority questioning of its scientific value. The following is an example of this:

“*A: Do you think that patents could be a useful source of information or knowledge to you?*

I: In what respect?

*A: As an information source.*

I: But they don’t really tell you much, do they? That is why you patent something so that everything is hidden, that is what I understood.” (Interviewee 5)

Another commented further that their perceived limited value of patent information was due to the incompleteness of the information in patents:

“*A:* *Do you think that patents are a useful source of knowledge?*

I: They can be, again, the detail that you have in them, there is always something left out because obviously people can go and read that, and people are worried, they don’t want to give all of their secrets away. So you will get some bits out of it but it’s limited.” (Interviewee 14)

In addition several participants were suspicious of the quality of the scientific information in patents with comments including:

“The bottom line is most patents really aren’t worth the paper they are printed on … you know that with a peer reviewed journal someone else has looked at the science so I mean yes, a patent might be able to give you some ideas but I wouldn’t trust it.” (Interviewee 9)

“When I look at what is in a patent, I have at the back of my mind that it has not been peer reviewed or something could not have been verified – that is not the same with a paper [in an academic journal].” (Interviewee 2)

“It is not like a full paper where you see all the evidence that it really does work and that, really, the conclusion is important. I think a patent can sometimes be more an idea with some back-up but it is not necessarily the whole thing.” (Interviewee 14)

These latter comments highlighted a perceived lack of ‘proof of concept’ data and a lack of peer review in the patent examination process (caused in part, perhaps, by the lack of awareness of the opportunity to file third party observations).

### The perception that patents delay traditional dissemination of knowledge and limit openness

The novelty requirement of patent law provides that “an invention shall be taken to be as new if it does not form part of the state of the art”.[[843]](#footnote-843) Consequently, if inventors want to secure a patent, they cannot publicly talk of or publish information regarding their invention until they have filed a patent application on it. 95% of those surveyed were aware that pre-existing academic literature can undermine a patent application, and all of those interviewed were aware of this too.

The interviewees all commented that they felt that the increase in patenting of stem cell science had contributed to a change in the culture of the field, alongside more general concerns about talking about science before it has been published. The vast majority of participants viewed this change as being negative:

“People are much more guarded, which is a shame.” (Interviewee 15)

“I have almost stopped going to … [some large] meetings now because the level of secrecy: people will only talk about things once they are published. Science has been materially changed, the conduct, by the unwillingness to talk about stuff until it has been secured. And it is partly securing patents but it is even more securing publication and impact, and that is not your brief but it is at least as corrupting of open progress of science as is patents.” (Interviewee 4)

One interesting observation on the effect of this increased ‘secrecy’ was provided by one interviewee; that it may obscure practices which require openness, such as overseeing clinical trials:

“There is an interesting ethical dimension too in terms of, particularly with things like stem cell science and gene therapy, things that are controversial, we have evolved a principle of being open and transparent and part of the transparency is that you have the full details of what we are doing, they are open for public inspection but it is contingent upon them having the patent. There has been, I have heard it said quite explicitly in a possible consequence in the light of the European [Brüstle] ruling, is the alternative for companies is to continue but to bottle up, and everything comes under commercial confidentiality, and then you have a big concern from an ethical position of can the ethical committee properly appraise and assess something. And that comes up, you are probably aware I suppose, I am a member of [a committee] and we have been involved in [overseeing a] stem cell trial … these issues of whether all of the data is available and all of these issues, and openness of the data and access to the data which they claimed is fundamentally dependent on a sort of confidence of confidentiality.” (Interviewee 4)

The novelty requirement can cause a lag in the presentation and publication of information through traditional mediums of dissemination which was noted by many of the interviewees:

“Yes, I often think the science in … [journals] is older than I would expect.” (Interviewee 9)

And another offered an example of this:

“You know that that is not something that has just been done. You know that has probably been at least two years in the making if not longer. For example, my boss with his patent, I have been working with him for four years and it has only just been published, he filed it maybe a year before I started and it has only just been published, so it takes a long time.” (Interviewee 12)

With scientists career progression and recognition based, in significant part at least, on the quality and rate of publication, many interviewees were frustrated with this lag with one participant saying:

“It is definitely frustrating because you can’t talk freely about the things about you want to do and engage people in the way that you would normally do in a research field.” (Interviewee 13)

Another spoke of the effect of the delay in publication on the field:

“Everyone is so secretive now and you never hear anything new unless it is published or patented and by then it’s old anyway.” (Interviewee 9)

Several of the interviewees indicated that this observed change in culture had developed over their careers:

“Yes, absolutely, first in the States but more and more here now too. It is very different to what it was in the ‘80s when I was a young scientist. Yes, it changes meetings ... I used to spend all of my time at the poster sessions because that is where the new ideas are coming through and you could just wander down and talk to the people “Where is this coming from and what is it doing next? What are the problems?” You know, it is just talking about it, and now all you get is stuff that is in press, and the next stages, “What is coming next?” are “I’m not allowed to talk about.” (Interviewee 4)

“I have become quite a cynic about [patents] in our field because you go to so many meetings where people can’t tell you anything real about what they are doing because they are patenting and it has almost become people’s goal rather than the advancement of science and dissemination to colleagues. And I know for a fact that some people will hold back information in papers because they are thinking about having it patented and they don’t want anybody else to know.” (Interviewee 8)

Another agreed and noted that this is likely to be due to the huge expense of R&D in the field and the perceived need to protect investment in the field:

“Yes, over my career completely. When I started patents, as I said, were rarely heard of and if you were going to file a patent it is because you are trying to do something that is, you are having an invention or that type of thing, or you were after money. And I think now it is more understood that it is not really the money, and you are not going to make money out of it, it is just part of a process if you are going to take your contribution to the later stages with things like clinical trials. So it is money but it is money, not like personal gain, but being able to get support in order to be able to take that to the next stage and if you are doing translational medicine then you need to take the private sector on board. You need a lot of money and the way to do it is to be able to, for them to know that the system, the ideas are protected. So I think that has changed a lot, especially in the last 10 years.” (Interviewee 14)

This was echoed by a post-doc who commented on the particular economic potential of stem cell therapies:

“The potential for it to be exploited commercially is huge because you know, they can form any cell in the body and you know you can make anything out of them. So, people are interested and I think compared to perhaps other fields, a lot more commercially aware that that could mean something that they could exploit commercially. So yes, definitely, there is a big difference, meetings are very secretive.” (Interviewee 12)

The post-doc interviewees were particularly worried about delaying publication because of the need for a proven track record of recent publications in grant applications:

“The priority for me is publication and the dissemination of information so I wouldn’t be likely to patent anything.” (Interviewee 8)

Another indicated they thought that …

“If you start messing around with IP, it’s expected that you drop into a publication black hole” (Interviewee 7)

However, it was not only post-docs vying for a strong early career publication portfolio who were concerned about the delay in publication required to protect one’s potential to secure a patent. Several group leaders went so far as to say that they would not delay publication in order to attempt to patent. One indicated that they had foregone potential patenting opportunities because they could not afford to wait to talk about their work:

“It is incredibly frustrating, and the reason why I say that is I could have pursued the filing of another patent on the thing I am trying to do now and the reason that I didn’t is that I couldn’t afford to have that in the way when I was going to meetings and talks … it was more important to be able to talk to people and get feedback.” (Interviewee 14)

Another said they would not delay publication to patent, but that this was a luxury afforded by seniority:

“I don’t play that game and I am secure enough in my position not to have to play that game. … When it is delayed longer than is necessary in getting into the public domain that is where I draw the line.” (Interviewee 4)

One misunderstanding shared by several interviewees, which could lead to longer lags than necessary, was that one must wait for a patent application to be published before publishing elsewhere. During the task, several interviewees indicated that they were not aware that publication of the invention elsewhere can occur before publication of the patent application.

“I: Hmm, but I don’t see how the publication date [of the patent] relates [to the paper], it isn’t 2006.

*A: Well, it is that one, the publication date is later than the filing date; it is the filing date that matters for that.*

I: So even though it is published after the published paper that is okay?

*A: Yes, because it is after the date of filing.*

Okay. I would have thought they had to wait for the patent to be published.” (Interviewee 6)

This is untrue: patent law provides that a patent application need only be *filed* in the territory in question before publication elsewhere, not published.[[844]](#footnote-844) Accordingly, one group leader observed that, if handled carefully, the publication lag could be minimised by filing for a patent as soon as possible and attempting to publish immediately:

“People who are being very effective at working in a very rapidly moving area actually manage this quite well I think don’t they, so that, hmm, what will happen, you protect it as soon as you can … before you then publish probably, the really well known labs I suspect would. I suspect people in competitive areas are quite keen to publish so it probably wouldn’t have a huge delaying effect because publication is so important. It is certainly there but I am not sure that it would delay things very much from the big labs anyway, the ones which really work well.” (Interviewee 16)

A couple of group leaders commented that after experiencing long delays during previous attempts to patent they had altered their practice to work in this way:

“What I am trying to do is to look for things at a very early stage when it is just a very early preliminary data and start the process [to file a patent] there so that when I get into it I can publish perhaps not as a paper because that can take a lot longer but to take it to a conference for example, then all of that stuff will be clear and out of the way and we will be able to talk freely.” (Interviewee 1)

One group leader indicated that they had possibly lost out on potential patents previously due to prior publication and would now file something ‘initial’ before publishing but only if they thought the effort was ‘worthwhile’:

“*A: So, you have sort of alluded to the issue of publication prior to filing a patent; have you found that to be a limitation?*

I: No, it is possible that we have sort of scuppered ourselves before putting in a patent because we haven’t really thought about it at the time. Um, I mean it could be an issue but because I’m less interested in worrying about trying to patent anything unless I really knew than before. In those days we were kind of thinking about it we were thinking of anything and everything that could possibly happen so I’ve come to a kind of feeling now that most of it is kind of pointless … getting papers out is most important … But I mean, I don’t think there is a big issue there because it is not very difficult to file a patent, I mean you can file the initial thing very quickly and so it actually shouldn’t be too onerous to do it.

*A: So if you had any concern you would just put in a patent application then publish as soon as possible?*

I: Yes, I mean it costs a few hundred quid but you can almost get away with putting a draft of your paper in the initial thing because you can alter it later.” (Interviewee 3)

One interviewee described their lab as “commercially savvy” and commented on the difference between this and a purely academic approach to research:

“Yes, absolutely, 100% [I think there is a time lag in academic publications] and it is very frustrating. The problem with going down the if you like, commercial exploitation of your research versus an academic research route is that for an academic it is all about publications in good journals and you know, being able to disseminate your results, you know, via you know doing a talk or something like that. Whereas when you are working on this sort of stuff, you can’t obviously be your own prior art essentially, so you know, I can’t talk about things and you know I haven’t been able to publish as quickly or readily as I perhaps would have done if it were purely research-based.” (Interviewee 12)

### Concerns about patenting basic and publicly funded science

In addition to concerns about the increased secrecy in the field and delays in publication, some participants spoke of a discomfort in the proprietary aspect of patents infiltrating basic, publicly funded research and the way this was shaping the future of the field. For example:

“The fact that research funding for developing [treatments for degenerative diseases] goes to other compounds that have patent protection rather than the biologically most effective compounds. You know, it is a corrupting process … in pursuing the goal driven by the biology.” (Interviewee 4)

Such comments are in line with the critiques discussed in section 4.4 regarding the perceived problems of patenting university and basic research.

In line with the Royal Society’s view that sometimes such limitations were necessary to support the ‘public interest’[[845]](#footnote-845), some of the scientists reasoned that this may be acceptable in some circumstances:

“[I]n some ways it will limit the development of the science but in other ways we have to be pragmatic and you know, if this if funded by public money or via a company, we still have to get as much out of it as possible and if there is any profit there, certainly from public funded money, it should be fed back into the appropriate pot that feeds back into that funding.” (Interviewee 15)

“I feel that the ownership of something is hard to get my head around, you know, how you can own a biological process because I find it hard to get my head around that whole concept, but at the same time, I think it also, for the technology to progress, I think it is necessary to have some way of making money out of it and show that once we understand something we don’t have to keep rehashing the wheel, we can build on it.” (Interviewee 11)

Others remarked on the increased acceptance and expectance of commercialisation activities:

“What I think I have seen is an acceptance of commercial development. 20 years ago people used to say ‘I’m not going to commercialise my research – that is disgusting’ and now it is the other way round; why haven’ you commercialised it? Why haven’t you taken it up?” (Interviewee 1)

“I think it is changing … before patents were seen as a very mercenary thing, you were selling your soul to the devil because you were trying to profit from your research, whereas now it is becoming more that it is a necessary thing to do.” (Interviewee 14)

Some of the participants also passed comment on concerns about patenting science far upstream of products. For example, two noted the potential problems regarding ‘anticommons’ and the potential effect of upstream patents on science downstream:

“I think in biology, another thing that is commented on is there are so many patents that cross, you would have to have so much cross-licensing that it is debatable whether they are in fact enforceable, whether any one person could enforce a patent without a good deal of other people, there is so much interference basically from other patents.” (Interviewee 10)

“[I]t is a patent minefield of too many people claiming a slice of the action, way way way in advance of therapies, and so if we were wanting to take, if and when the biology is at the stage that we could take a human ES cell and reliably and reproducibly differentiate it to a specific phenotype for clinical application, then taking that to a clinical trial would be a mine field for our lawyers.” (Interviewee 4)

Others remarked on the problem of patenting something far upstream from a product, in a fast moving field, without knowing the potential uses of the invention:

“This patent was granted maybe six years ago and we are still trying to learn about the system so it will take about another 10 years until it is ready to have an application so by that time I don’t know, I don’t think it will be very relevant”

“I also wonder how relevant this is now because it has only just been accepted in 2011 and the original paper was published in 2006, I mean the whole field has really come on since then where they are not using retroviruses for example, they are not even using genes they are just using small molecules and stuff like that so I wonder even how relevant this is now.” (Interviewee 14)

### The perception that patents are used for things other than information source

Patents can fulfil a number of different roles: they can prevent others using your invention; they can be licensed to make money; they are increasingly used as a quantitative measure of research quality/impact (for example through the REF) and they can be useful in securing capital for future research. These are the benefits of patenting as advocated in science policy and consequently by universities to their researchers. The interviews showed that scientists are highly aware of the uses of patents as advocated by policy. This was made evident during the interviews when asked about the potential use of patents, no participants commented on the informative value of patent information but rather noted the potential for patents to secure funding, private partnerships, personal financial reward, for founding spin-out companies and the potential of patent information to monitor competitors or consider one’s own ability to patent:

“[I]t’s another route for investment into the research, and also maybe personal money” (Interviewee 1)

“[T]hey provide security for getting money invested into new areas” (Interviewee 16)

“[I]f you want to attract private funding to support your research, to take into a clinical trial, you may need to get a patent” (Interviewee 14)

In the promotion of these varied roles of patents and patent information through policy and institutional practices, patents may be overlooked until scientists’ believe their work is becoming ‘commercial’ and the role of patents in disseminating information may be imperceptible.

### Scientists’ ‘buffer’ their engagement with patents

In line with the perception that patents are useful for things others than knowledge dissemination (and the model proposed by Jain, George and Maltarich whereby scientists have a hybrid role perception, preferring to align themselves with their traditional academic self rather than their entrepreneurial self[[846]](#footnote-846)) the findings of the interviews indicate that the participants often ‘buffer’ their engagement with the patent system:

“I couldn’t tell you, it was all handled by the lawyers” (Interviewee 4)

“The company handled it” (Interviewee 14)

“Ultimately that is going to be the CEO [of the spin out] and the business development guys’ jobs” (Interviewee 3)

This ‘buffering’ was not always felt to be a smooth process. Several of the participants indicated that they felt uncomfortable with the pressure to commercialise their work from their employers and questioned the abilities of those involved:

“They [the commercialisation team] guided me through it [applying for a patent]. It seemed quite labour intensive, not only expensive but also quite a lot of paperwork.” (Interviewee 14)

“They [the commercialisation team] are useless here.” (Interviewee 9)

“We have recurrent brow-beating from the employer that commercialisation of intellectual property should be one of the priorities of our research … At the end of the day, I am not somebody who directs my life or my lab to maximise those returns, as much as my employer would like me to do so.” (Interviewee 3)

“A lot of that [industrial engagement and commercialisation] is managed by people in the school [of biology] has one full time officer who is actually quite good, we have a senior academic at the management level who is much more of a plonker, worthy but not very effective in research so he gets involved in this, but the chap who is sort of the middle level administrative manager is pretty good. The university people I find more divorced from reality and they are just pursuing the money rather than the science.” (Interviewee 4)

This participant later continued:

“Being a senior academic I have my own views on what is right and what is wrong and not all the regulations are, well I work round them … I’m sure I’m not alone in that. You know, we academics talk about how to get around the universities policies.” (Interviewee 4)

## Conclusions

It was shown that, in line with the findings of the survey, the vast majority of the interview participants did not regularly engage with patent information, particularly not at an early stage in the research process or to use the information as a source of scientific knowledge. Many of the participants were uncertain of the patent landscape surrounding their work and none were previously aware of the foundational patent at the centre of the search task. Further, the scientists’ limited engagement may be attributed to a number of barriers evidenced in the survey and the interviews. The structured observation evidenced that even when the scientists did attempt to engage with patent information, they had problems finding and accessing the information due to problems inherent in public patent databases. These problems include practical difficulties; limited functionality; built-in constraints on search tools and language; and general user-unfriendliness of the patent databases compared to general search engines. When faced with patent information in the structured observations, scientists questioned the value of patent information due to the language used, the structure of the documents, the perceived lack of peer review and the sufficiency of disclosure. Their limited understanding of the particulars of patent law and patent documentation may also hamper their comprehension of patent information. Further, on the whole, the participants thought that they receive sufficient information through traditional means of knowledge dissemination, sources which they trust more. The barriers also related to cultural factors such as the perception that the scientists were doing ‘basic’ science so they thought that patents didn’t affect them; they thought patents were useful for ‘other things’ rather than as sources of information; many perceived that the increased patenting of basic science in universities had a negative effect on the scientific commons, their institutions and their professional roles and some participants questioned the patenting of upstream research.

As mentioned at the beginning of this chapter, the interview participants were elite members of a field where science policy pushes them to commercialise and patent their research and there have been a number of high profile legal cases surrounding patents in the field. This group (PIs and post-docs working in the field of stem cell science) showed higher engagement with, awareness and knowledge of patent information than other groups in the survey. Although the sample sizes involved were relatively small, it is possible to suggest that the findings of the interviews are likely to be reflective of a ‘high performing’ group within the wider population of academic biological scientists; the rest of this population are likely to have lower levels of engagement, awareness and understanding of patent information.

In summation, the findings of the second phase of the study build upon those of the survey, again highlighting that academic stem cell scientists’ engagement with the patent system is limited. By investigating the barriers to engagement initially exposed in the survey further, it was apparent that these barriers are significant and are likely to affect all three roles which scientists can participate in the patent system: as inventors, follow-on innovators and regulators. These findings have a number of implications when viewed within the context of the science- and patent-policy detailed in Parts 1 and 2 of the thesis. These implications are discussed in the subsequent chapter alongside ways of potentially improving the dissemination of scientific knowledge through the patent system.

Chapter 9

Discussion

## 9.1 Introduction

The previous two chapters have detailed the findings of the empirical study and considered the reasoning behind them. This chapter discusses the significance of a number of key findings including that:

1. The vast majority of the participants did not regularly access patent information. In particular, even when they did access patent information, this was rarely done at a stage early enough to inform their research;
2. Many of the scientists questioned the value of patent information as a source of technical information, particularly in comparison to academic publications;
3. The majority of those interviewed were unaware of the existence of the foundational patent at the centre of the search task;
4. During the search task, all of the scientists struggled to find and access patent information;
5. In each of the methods utilised, the bulk of participants had problems understanding patent information due to the use of technical specialist language embedded in patent documents and patent databases;
6. Many of the scientists questioned were uncertain of the legal requirements of the patent system; and
7. The scientists were largely unaware of their potential role as evaluators of patents.

These findings indicate that there are a number of barriers to scientists playing their roles within the patent system: as inventors; evaluators (through third party observations); downstream innovators; and as potential infringers of patents. These barriers relate to the ways within which scientists perceive patents to have changed their working cultures and the institutions in which they work, contributing to a limited interest in patent information; problems relating to the patent information infrastructure; and scientists’ limited knowledge of patent specifics.

When situated within the context presented in the first two parts of the thesis, these findings have a number of implications. This chapter begins by discussing these in two sections: how the results relate to the patent system; and how they relate to science policy. The contributions of the findings to ongoing debates surrounding the patenting of upstream, university-based science are borne in mind. The second part of the chapter considers a number of potential ways of improving the dissemination of knowledge through the patent system in light of the findings of the study.

It must be borne in mind throughout this discussion that the findings are based on the views of a relatively small sample. Thus, it is difficult to make generalisations about the wider populations from which the samples were drawn. Notwithstanding this, the fact that thematic saturation was reached during the interviews within a modest sample indicates that the findings are likely to be representative of scientists with a similar occupational profile to those interviewed. Therefore, while the following discussion based on the conclusions drawn from a limited sample, there is cause to believe that these are at least somewhat representative of the wider populations of academic biological and stem cell scientists working in the UK.

## Implications for the patent system

“The patent social contract justification recognizes the cumulative nature of innovation. … Keeping inventions secret means that inventors have less information and tools with which to solve problems … the patent system currently does a very poor job of making information available to downstream inventors. A lot of information does not make it into patent specifications and the information that does is crafted in patent drafting language that is often of little use to scientific experts. Sometimes finding patents in the first place may be difficult.”[[847]](#footnote-847)

As Drahos notes in the above quotation, there are a number of problems inherent in the patent system that are currently preventing it from working as claimed within the social contract justification. The findings of this study have empirically evidenced these issues and scientists’ perceptions of them. Therefore, the results have a number of implications for the patent system, at least when viewed from the dominant rationale of the system. This section deals with the various implications in turn and considers the range of questions that they raise.

### Assumptions of the patent system

Before considering what the findings imply about the current working of the patent system, some basics must be revisited. As Chapter 5 showed, the dominant ‘social contract’ rationale for the patent system provides that it encourages technological progress by incentivising and rewarding invention; and that it facilitates downstream innovation through the public disclosure of information. There are a number of legal requirements embedded within the patent system to support these aims: novelty, inventive step, industrial applicability, disclosure and publication. It is assumed that, through these requirements, patents are granted over inventions which advance the state of the art and that the patent system informs downstream innovation through the public dissemination of technical information. The following sections deals with these points, considering what the findings of the study indicate about each.

### Is the patent system informing downstream innovation?

It is generally assumed that the patent system informs downstream innovation by disseminating technical information. The release of information is said to be the *quid pro quo* of the grant of exclusive patent monopoly rights. The assumption is particularly relevant to fields where patents are being granted many steps removed from an end product, such as in the case of stem cell science. In these cases, downstream innovation can be shaped by the availability of information regarding upstream research.

The release of information through the patent system is supported by the legal requirements of disclosure and publication and the supposed public availability of patent information following publication. The assumption entails a number of points: 1) that the patent system encourages public disclosure of information that may otherwise be kept secret; 2) that the information disclosed is ‘sufficient’ for a person skilled in the art to practise the invention; 3) that innovators can find and do read patent information at a point at which it can inform their research; and 4) that the information can be understood by a technical audience (e.g. scientists). The first point has been questioned by a number of scholars.[[848]](#footnote-848) The findings of this study call into question the latter three points, and thus the assumption that the patent system is informing downstream innovation, at least in the case studied.

The findings of this study indicate that there is limited engagement with patent information by scientists, particularly in the early stages of research. This limits the potential value of patent information in informing downstream innovation. At present, the system is not facilitating this engagement due to a number of barriers that were uncovered in the study. Biological and stem cell scientists question the value of patent information as a source of technical information. They also struggle to find, access, and understand patent information even when they try to. Further, the value of the information in patents was questioned on the grounds of sufficiency. Several of those interviewed noted they would struggle to practise the invention with the information within the patent document. In essence, the system assumes that the barriers experienced by the scientists to meaningfully engage with patent information do not exist and/or overestimates the ability of the supposed users of the system to overcome them.

The question may be raised: does it matter if the system is not normally informing innovation in the stem cell field? It may be argued that is it not a problem, that downstream innovation is adequately informed through other mediums rendering this function of the patent system superfluous to the information needs of academic scientists. This was shown to be an assumption of those surveyed who assumed that all of the technical information which was publicly available that they could benefit from was available through traditional academic sources (e.g. peer reviewed journal publications). This is a potentially problematic assumption on three points: 1) not all research institutions use traditional academic channels of knowledge dissemination; 2) journal publications are not freely available to everyone; and 3) patent law has different requirements than traditional sources of scientific information. The latter point means that even if a journal article has been published on the same concept as a (published) patent application/grant the information within each source may be different.

The finding that the patent system is not regularly informing downstream research raises a number of questions: are scientists ‘missing out’ on potential teachings by not engaging with patent information at an early stage in the research process? Are they at an increased risk of infringing the patents of others due to a lack of engagement with patent information? Are they able to make an assessment as to whether their research is patentable? Are they able to assess the patent applications of others? What can be done to improve the dissemination of knowledge through the patent system? These are important questions not only in terms of the justification of the patent system, but also assumptions about the way the system works as used in the promotion of increased patenting in the academic sphere.

### Is the patent system granting patents for inventions that advance the state of the art?

In addition to the assumption that the patent system incentivises and facilitates the dissemination of technical knowledge, another assumption of the system is that patents are granted over inventions that advance the state of the art. While the study did not set out to investigate this assumption specifically, it did highlight a particular issue that leads it to be questioned. The assumption is built into the patent system through the legal requirement of novelty and inventive step. It is presumed that only applications that fulfil these requirements are granted; only inventions that advance the state of the art are worthy of a monopoly right. Ensuring that these legal requirements are upheld during the examination process, that patents are not granted for inventions that fall short on these requirements, is the duty of the patent office. This is not a simple task. While the requirements are legal requirements, a level of technical knowledge is needed to determine whether an application meets them. As it was described in Chapter 5, patent examiners are often tasked with examining patents in fields in which they have not been formally trained. This is particularly true of emerging fields such as stem cell science. Questions have been raised about whether patent examiners have sufficient technical knowledge of these fields to enable them to determine whether an application meets the necessary requirements.[[849]](#footnote-849) It has been argued that the people best equipped to determine whether a patent application meets the requirements are those working at the forefront of knowledge in the given field[[850]](#footnote-850) (stem cell scientists in the case studied), after all, these are the notional ‘person[s] skilled in the art’ on which the patent requirements are based.

There is a legal procedure for such pre-grant review: third party observations. [[851]](#footnote-851) These observations are likely to be a much simpler and cheaper mode of improving the quality of patent stock than undertaking post-grant litigation.[[852]](#footnote-852) Despite this, the opportunity to file third party observations is rarely used.[[853]](#footnote-853) This is of little surprise given the findings of the study. There are several steps that must be fulfilled in order for an outsider to provide a third party observation (when, for example where the outsider has an indication that the ‘invention’ has been published elsewhere prior to the date of filing):

1. They must know that there is, in patent law, a window of opportunity in which to file a third party observation on an application;
2. They must be aware of the existence of the patent application in question;
3. They must be able to find the patent application;
4. They must be able to understand the various technical and legal terms in the patent application; and
5. They must know how to file an observation.

As the results showed, the scientists studied were largely unaware that they could file third party observations; they struggled to find and understand patent information; and many were uncertain of the legal requirements of the patent system. All of these points challenge the ability of the scientists to contribute third party observations. While the presence of a third party observation system recognises the possible value of external review, it cannot be assumed that this is playing any meaningful role in the examination process. This raises the question: are patents being granted in cases where they shouldn’t be because the third party observation procedure is not being used? Are patents being granted over inventions that are not inventive, novel or do not publicly disclose sufficient information? Together with indications that this may be the case,[[854]](#footnote-854) these are important questions given the assumption that the patent system rewards inventions that advance the state of the art and release information into the public domain.

Another finding that questions the assumption that the patent system is granting patents that advance the technical state of the art is that many of those questioned noted differences between legal and scientific standards regarding ‘disclosure’ and ‘invention’. Further, the requirements of patent law and academic publications are different – patent law does not require proof of concept or any results, unlike academic publications. The disjunction of legal and scientific understandings of the concept of ‘invention’ has been raised by scientists and in the courts in the field of stem cell science.[[855]](#footnote-855)

### Are scientists able to contribute to the system as inventors?

While this thesis did not set out specifically to investigate scientists as inventors, the results do relate to their ability to fulfil this role. For example, if scientists are uncertain of the legal requirements of the patent system, are they prejudicing their own applications by publicly disclosing their invention before filing? Are they not filing applications for inventions that fulfil the legal patentability requirements? Are they aware of where the existing patent gaps are in their field? These are particular problems in the eyes of science funders and policy makers and are discussed further in section 9.3.

### On-going questions of the patent system

The implications of the findings contribute to concerns that the patent system is not working as assumed in the fields investigated, that these assumptions are simply ‘rhetoric’ used to promote the patent system rather than a representation of reality. This raises a number of questions: if, as this study indicates, the patent system is not working as it is advocated to be, can the system be justified on the basis that it promotes innovation and the dissemination of knowledge? Are patents being granted over inventions which advance the state of the art sufficiently to be worthy of a monopoly right (i.e. are the novelty and inventive step standards too low)? Is the patent system striking a balance between private rights and societal benefit?

The findings also support arguments that the patenting of basic science is problematic. Such arguments are currently being raised in the courts, for example in the Myriad case and with the WARF patents, highlighting the disconnection between the norms and notions of the patent system and basic science. Questions are raised such as: are patents being granted on truly novel scientific ‘inventions’, or just claims which fulfil the legal requirements of the system? Is the patent system appropriate in the case of basic, emerging science? Should patentable subject matter have been extended to cover science so far removed from products? Are these types of patents creating a barrier to future research? Are patents the best way to exploit science for society? These are also important questions in the context of the arguments for the public funding of research.

Further, given that the findings have also resulted in the questioning of some assumptions of the patent system, it is important to consider the other assumptions of the system. For example, is the patent system the best way to encourage invention in emerging fields of science? Do patents encourage investment in early stage research? Do patents pay off economically? While the study at hand cannot inform answers to these complex questions, they are important to questions to consider given the findings and the context provided. It may be argued that it doesn’t matter if scientists are not using patent information to inform downstream innovation; that they are not contributing to the system through third party observations; or that they are potentially falling short on their assumed role as inventors, provided that the system is returning on the more explicit economic aims of the system. At present however, questions in this area remain unanswered.

## Implications for science policy

As Part 1 of this thesis detailed, the commercialisation of university-based research has become a central pillar of science policy with a significant focus on securing patents. However, as the previous section detailed, the findings of the study indicate that the patent system is not working as assumed in the fields of biological and stem cell science. Despite the policy-based pressures and incentives for academic scientists to patent their research, the study has highlighted that there are a number of barriers preventing them from meaningfully understanding and engaging with the system in any of their three supposed roles: as inventors, downstream innovators and regulators. This section considers what this means from a science policy perspective, and the questions that are raised by the results.

### Science policy assumptions

Part 1 of the thesis showed that the promotion of patenting of university-based research is built on the presumption that traditional academic practices are insufficient to facilitate ‘desirable’ levels of translation and economic return. This entails several points: 1) that the patenting of early stage research in universities encourages more innovation and translation than traditional scientific practices; 2) that such patents ‘payoff’ economically; 3) that patents are being granted over inventions, advancing the state of the art; and 4) that patents supply information which can ‘teach’ other scientists, supporting scientific progress through knowledge dissemination. The final two points, also central to the aims of the patent system, presume scientists can engage with patent information in order to either assess it, or learn from and build upon it. As has been discussed in the previous section, the results indicate these assumptions are questionable in the case studied. The following sections consider what this means in the context of the aims of the science policy set out in Part 1.

### Are patents being applied for when they can be?

Science policy aimed at promoting patenting and the increased capture of the economic potential of research assumes that patents are being applied for when they can be and that they are not being applied for when the ‘invention’ is not patentable. This presupposes that inventors are aware of the legal requirements of patentability. However, the results of the study indicate this assumption may be unfounded; it was shown that many of the scientists questioned were uncertain of the requirements. In addition, given the finding that the scientists rarely engaged with patent information, particularly at an early stage in their research, they are unlikely to know if their ‘invention’ has already been patented until they attempt to patent. These findings imply that scientists may risk prejudicing a potentially patentable application by publically disclosing the invention (undermining the novelty of the invention), or oppositely they may believe they have a patentable invention when they do not.

### Is duplicative science being undertaken?

In addition to its teaching function, patent information can also play a number of other functions in the research process. One such function is signalling what research has already been done, thereby helping to reduce potential duplications of effort. The EPO estimates the cost of duplicate research to be €20 billion a year in Europe alone, citing this as a key reason to engage with patent information.[[856]](#footnote-856) Duplication of effort is of particular concerns to funders. A central principle of research funding is that the research being funded can contribute new knowledge, that it is original. During funding applications, applicants (and peer reviewers of these applications) are expected to check that the research for which funding is being sought has not already been undertaken. The concern here, arising from the findings of the study, is that if scientists are not engaging with patent information at an early stage in the research process, they may be missing information that indicates that the research they are planning has already been done. This problem intensifies when considered in the context of policies aimed at increasing the economic return of research through the patenting of research results. If the research has already been done, and patented, but a secondary version of the research has been undertaken when the patent literature was not checked, not only has there been a duplication of effort but also the secondary research may not be patented.

### Are scientists infringing on patents?

This is a difficult question to answer, especially given the lack of clarity regarding the research exemption in patent law. However, it is reasonable to hypothesise that, given the limited awareness of foundational patents and limited engagement with patent information, scientists may be unknowingly working within the scope of the claims of patents (as was found to be the case in the stem cell field in 2008, see section 5.5.4). Further, there was an evident lack of concern amongst scientists regarding infringement. Many of those studied believed there would not be a problem because they were carrying out basic research: 75% of those surveyed thought they could not be sued if they infringed patents. This may be due to widely held attitude explained succinctly by one interviewee: “We are working on the basic biology and I don’t pay attention to the patents”. Therefore, while the research exemption remains unclear, and scientists continue to be unaware of patents potentially affecting their work, it is not possible to dismiss concerns that these scientists may be infringing the patent rights of others.

### Is the increasing patenting of university-based research having undesired consequences on the practice of academic science?

As Part 1 described, research and funding policy has developed to encourage commercialisation of research in universities. While some have argued that the rise of an entrepreneurial approach to academia is necessary,[[857]](#footnote-857) many others have noted the negative consequences of this approach.[[858]](#footnote-858) As discussed in section 4.4, concerns have been raised that the long-term public value of science, supported by traditional models of research dissemination, is being neglected in policy decision making in favour of short-term economic ‘impact’.[[859]](#footnote-859) Independent of an opinion on the policies introduced, it is clear universities and researchers have had to adapt to survive and thrive within policies aimed at supporting commercialisation of university-based research.[[860]](#footnote-860) More generally, it has been argued that a focus on commercialisation in universities has negated the other missions of universities and the traditional norms of academic science.[[861]](#footnote-861) It is difficult to reconcile maximising revenue with the traditional teaching and research aims of universities and as such, policies aimed at increasing commercialisation in universities may limit the value of universities as social institutions. As highlighted in section 4.4.2, Eisenberg has noted four policy flaws of a system which “pervasively promotes patenting federally-sponsored inventions”[[862]](#footnote-862) limiting the aim to support the development and availability of new inventions to society:

1. The policies create a double taxation on society: society pays twice for the invention by paying for the research to be undertaken and then paying to access the invention;
2. Patent incentives should not be necessary to incentivise publicly funded research to be undertaken;
3. Promoting the routine patenting of publicly funded research “calls into question the public goods rationale for public funding of research”; and
4. Providing incentives for patents over publicly funded research may diminish the public domain of research which is essential for future progress.

The following sections indicate that these flaws are perceived negatively by researchers, and may help to explain their evident limited engagement with the patent system.

### Perceptions of changes driven by increased focus on patenting university research

One factor running through the findings relating to scientists’ apparent low interest in patent information was a perception that patents are not part of the traditional model of science. More notable here is that patents are not part of the standard means of knowledge transfer of teaching, conference presentations and academic publications. This perception was based on two related points. First, that policy has generally forced a divergence from the traditional norms of science, altering the research environment in universities, the institutions themselves and the role of academic researchers. Secondly, that the traditional norms of science do not fit well with patent rights. The study evidenced that these issues were sensed by scientists as having a negative effect on the research environment and their traditional role as academic researchers. As described in 4.4.4, it has been suggested that this change to scientists’ role perceptions is something scientists find problematic, preferring to align themselves with the academic portion of their hybrid personas rather than the entrepreneurial part.[[863]](#footnote-863) This is likely to contribute to scientists’ apparent low interest in engaging with the patent system and patent information and why they ‘buffer’ such engagement through third parties, such as staff in TTOs and patent attorneys.

One way in which institutional structures have changed to facilitate the patenting of academic research is the increase in the number of commercialisation teams/TTOs in universities. Before 1990, only 34 had formally begun commercialisation with few having specific teams, now all universities in the UK have a commercialisation team/dedicated TTOs.[[864]](#footnote-864) These teams vary widely in size and structure and it has been suggested that their effectiveness in developing and exploiting IPRs is determined in part by the quality of their relationship with researchers.[[865]](#footnote-865) Therefore, it can be assumed that TTOs and commercialisation teams in universities will attempt to build relationships with researchers, forcing the researchers to acknowledge the apparent increasing importance of patenting their research: the entrepreneurial part of their role identity. Under the hybrid role identity model described by Jain, George and Maltarich,[[866]](#footnote-866) this is likely to be something researchers are uncomfortable with. In line with this theory, the study showed that researchers perceived the drive to patent and engage with TTOs as having a negative effect on their role, adding a layer of complication to the jobs of researchers and a move away from their traditionally self-directed academic role. This may contribute to a lack of interest in using the patent system.

In addition, policies aimed at impact and economic returns have also changed the incentive structure of academic science. Traditionally the career progression of academic scientists was largely dependent on quality and quantity of academic publications. However, as described in section 3.6, factors such as ‘impact’ and patents are increasingly part of the equation due to their importance in modern funding policies, driven by developing science policy. This move from tradition augments the role of the researcher forcing them to identify with their entrepreneurial role identity. The results of the study showed that scientists negatively perceived the ways in which patents were changing their incentive structure, which may contribute to scientists’ lack of interest in patent information.

### Concerns about anticommons effects

While the empirical methods used cannot evidence whether an anticommons is occurring or not in the stem cell field, it is notable that concerns were raised about the effect of upstream patenting on the translation to a therapeutic product in line with anticommons theory. Such concerns, if reflective of the presence of an anticommons, highlight a potential problem that may be on the horizon given that patents have been granted in large numbers over upstream technologies;[[867]](#footnote-867) the realisation of therapeutic product may be severely hampered by the complex patent landscape in the field.

### Are increased patents over university science driving a closure of the scientific domain?

Concerns were raised by the majority of those interviewed that patents limit the open availability of scientific knowledge. While at odds with the patent systems aim of diffusing technical knowledge, these concerns arose from the perception that patenting can delay or even negate dissemination through traditional means such as academic publications and conference presentations with an increased ‘secrecy’ noted in recent years. Further, the information in patents may not be enabling. Additionally, the 18 month delay in the publication of patent applications means that, if the information is not published elsewhere, there is an inevitable delay in contributing the information to the public domain. This may limit the open domain of science (a concern discussed in 4.4.3) and support the theory of knowledge anticommons: that patents over knowledge limit the likelihood that future researchers use the patented knowledge in downstream research.[[868]](#footnote-868) Further, the findings of this study indicate that the decline in knowledge accumulation may be greater than measured in the study by Murray and Stern because patenting can delay or even negate publication; onward citation (the data used in that study) cannot measure this effect. Taking this into account, it may be hypothesised that the knowledge anticommons is greater than reported in Murray and Sterns study which highlighted a “statistically significant but modest decline in knowledge accumulation as measured by forward citations”.[[869]](#footnote-869) Whether or not it is the case that patents do contribute to a closing of the scientific domain, the scientists studied seemed to perceive that this was the case.

### Are science- and patent- policies driving information feudalism?

The problems described above regarding the perceived negative effect of pro-patent policies on universities, research practice, scientific norms and the closing of the scientific domain, indicate that the existence of patent rights in academia may limit knowledge dissemination. This potentially compromises the economic aims of the enduring science policy which is, in part at least, based on encouraging translation and downstream innovation reliant on efficient knowledge dissemination. This indicates a risk of frustrating the long term potential of the knowledge economy; an economy which globalised nations have become reliant upon. This finding supports Drahos and Braithwaite’s theory of information feudalism:

“Information feudalism is a regime of intellectual property rights that is not economically efficient, and does not get the balance right between rewarding innovation and diffusing it. Like feudalism, it rewards guilds instead of inventive individual citizens. It makes democratic citizens trespassers on knowledge that should be the common heritage of humankind, their educational birthright. Ironically, information feudalism, by dismantling the publicness of knowledge, will eventually rob the knowledge economy of much of its productivity.”[[870]](#footnote-870)

The theory of information feudalism is based on the concept that developments in intellectual property regimes in recent decades have widened global inequalities by increasing the privatisation of knowledge.[[871]](#footnote-871) One such development that Drahos and Braithwaite point to is the impact of IPRs on university research which they argue is causing an “undersupply of public knowledge goods”.[[872]](#footnote-872) They argue that this is resultant of a reduction in traditional knowledge dissemination in favour of IPR restricted knowledge and a change in research priorities caused by the increased presence of IPRs in universities. [[873]](#footnote-873) The results of the study indicate both of these consequences are occurring, potentially leading to the reduction of public knowledge goods, and supporting the theory of information feudalism.

### Emerging science policy questions

The findings indicate that some of the assumptions behind policies that have driven patenting at universities may be flawed, at least in the case studied. This raises a number of questions about the policies: if they are not fulfilling the assumptions studied, what are they doing? Are they fulfilling their more explicit economic aims, e.g. the encouragement of investment and short term economic returns to institutions potentially undermining the long term value of research? Are academic scientists and universities able to return on the aims of the policies? Have the policies achieved anything other than the creation of a pro-IP culture in universities? Are patents a purely quantitative measure of this culture or can they be used as a qualitative measure for future funding decisions, as per the assumption of their inclusion in the REF? Should universities rethink their IP strategies?

These issues raise a fundamental question about a major assumption of modern science policies: does patenting encourage and support translation of basic research better than traditional model of basic science in universities and commercial development in private companies? Are these policies creating more harm than good to scientific progress in the long-term? Are these policies directing scientific research toward economically promising research, rather than scientifically and socially desirable research? These questions are central to considerations about the role of publicly funded research and the aims of science policy.

## Ways of improving the dissemination of scientific knowledge through the patent system

As the study showed, there are a number of barriers to scientists engaging with patent information in a way that can inform their downstream research and highlighted concerns that the patent system is not necessarily granting patents over ‘inventions’ and releasing enabling patent information. The study also demonstrated the limitations and constraints faced by scientists to input into the patent system (i.e. through third party observations and filing patents). These findings are particularly concerning given that they largely represent the field of stem cell science where patents are being granted over upstream research and expectations of the field are high. This led to the questioning of a number of the assumptions of the patent system which has been shown to be a problem not only for the legal underpinnings of the system, but also for the science policies which have driven use of the system in universities.

The following sections offer a number of suggestions that could potentially improve the dissemination of technical knowledge to scientists through the patent system. These potential ‘remedies’ are grouped into three parts: 1) improving patent education for scientists; 2) improving disclosure; and 3) improving dissemination. As Drahos argues:

“On a social value conception of the patent contract, it is the diffusion of invention information of social value that matters, not the legal ritual of disclosure.”[[874]](#footnote-874)

The remedies discussed are based on this premise.

It is worth noting that in line with the findings of this study, many commentators have emphasised the importance of aligning scientific and legal norms to improve perceptions of and engagement with the patent system.[[875]](#footnote-875) The following remedies therefore generally focus on achieving this by improving openness and supporting adherence to the traditional Mertonian norms of science. Further, it must be borne in mind that these remedies are theoretical suggestions. Whilst the potential downsides with regard to other aims of the patent system are mentioned, the key aim of knowledge dissemination is taken to supersede other concerns. Therefore, ‘cost-benefit’-type analyses may need to be undertaken prior to implementation of the proposals.

### Rebalancing power in the patent system to support the social contract

Drahos states:

“The basic problem of the patent system can be simply stated. Standard-setting and administration of the system is dominated by a globally integrated private governance network. This network has made the patent social contract largely meaningless. More rule-based reform of the system will simply see this private governance network continue to bend the process of rule-making to its own ends.”[[876]](#footnote-876)

From this perspective, reclaiming the patent social contract requires a ‘separation of powers’[[877]](#footnote-877) and the formation and utilisation of an ‘outsider’ governance network to overcome the problems resultant of the current power of the private ‘insider’ network (patent offices, big businesses, patent attorneys, private database producers, etc.). [[878]](#footnote-878) To drive the creation of an active outsider network, transparency in the system needs to be increased to help expose the power of the insiders to gain political momentum to help rebalance power in the patent system.[[879]](#footnote-879)

Whilst remedies based on ‘rule-making’ (i.e. changing patent laws and policies of patent offices) are potentially helpful in improving the dissemination of knowledge through the patent system, these may be shaped by the powerful ‘insider’ network thus limiting their potential benefits. Therefore, remedies led by the notional outsider network may be more successful in achieving the aims of improved diffusion of valuable information in patent documents. The OA to research publications movement, driven by such ‘outsiders’, has resulted in the situation where transparency is being improved through active requirements from research funders to make information publicly available. The same could happen with the patent system with improved transparency of the system fuelling a separation of power. Many of the suggested remedies discussed subsequently therefore aim at utilising the existing powers of ‘outsiders’ including research funders, universities and researchers themselves to change the current working of the system. For example, in the case of university and/or publicly funded research, improvements could be led by public funders, institutions and researchers themselves. Ouellette argues that because university inventions are likely to be publicly disclosed anyway (as opposed to the results of research undertaken in private institutions), universities should lead the way “in writing patent specifications that are clear and technically useful; university patents should contain at least as much information as corresponding papers.”[[880]](#footnote-880) This could be done through ‘encouragement’ or by changing requirements of funding, as has been the case in the OA agenda following the Finch Report. These measures may not only enhance the technical value of the information itself, they could also improve scientist’s access to and comprehension of patent information.

### Improving patent education

Compared with their counterparts working in the private sector, patent education is particularly pertinent in the case of university researchers. Private companies often employ patent attorneys to liaise directly with researchers. Whilst universities do have TTOs, these are often limited in their resources and capabilities.[[881]](#footnote-881)

Despite the increasing number of patents on publicly funded research and a long history of policies aimed at encouraging this trend, relevant training is inconsistent and often insufficient in publicly funded institutions.[[882]](#footnote-882) This has recently been evidenced amongst students in the UK. In October 2012 the National Union of Students (NUS) together with the Intellectual Property Awareness Network (IPAN) and UKIPO published the findings of a quantitative survey of 2,000 students in the UK. The survey was designed upon the assumption posited by the UKIPO that, in line with policies aimed at increasing commercialisation of research to drive economic growth:

“An awareness and understanding of IP developed in education is key to achieving an IP savvy workforce which can use IP to deliver growth for the UK”[[883]](#footnote-883)

Only 12% of respondents were taught about patents (most of these were students studying law, business and engineering courses). The findings led the report to conclude that …

“The inconsistency of IP teaching is indicated by the fact that most students possess an unrealistic understanding of their current level of IP knowledge. Despite expressing high levels of confidence in performing IP tasks and an awareness of the need to protect their IP rights, few students showed an understanding of the basic practicalities involved in dealing with the scenarios posed. Similarly, it is clear from their responses that students have very limited awareness of the appropriate procedures.”[[884]](#footnote-884)

The study in this thesis also highlighted these problems. Whilst some scientists were aware of/had participated in training mentioning patents, this was almost solely aimed at improving scientists’ ability to participate in the system as inventors, not as users of patent information consumers. Further, the training that they had received did not focus on educating scientists about the potential value of patent information or how to access and interpret it. Such education may help in tackling the barriers relating to of accessing and understanding patent information.

In addition, the apparent lack of education may lead scientists to overestimate their understanding of patent information, as highlighted in the NUS, IPAN, UKIPO study of students. It may also hamper their ability to access patent data. Given the observation that scientists struggled to understand the user interface and search pathways of the databases during the search task, scientists may benefit from some training regarding how to use the patent databases. This may improve their ability to find and access patent information. However, the extent of training must suit its purpose. It is unrealistic to claim that scientists should have a high level of knowledge of the specifics of patent law or the working of the patent system, as is currently required to find and understand patent information. More realistic training may involve education aimed at providing scientists with a basic level of knowledge about the requirements of patentability and how to search for, and interpret, patent information. This could be achieved through an online teaching portal, incorporated into the on-going career development training for academic scientists. Further, the study evidenced a number of deeper issues at play which are limiting the disclosure of technically valuable patent information. These cannot be solved by improving education and involve a number of changes to the current working of the patent system.

### Strengthening disclosure

It has been widely argued that the legal system is not demanding sufficient disclosure in patent applications (i.e. that patents are being granted without releasing the notional standard of information into the public domain) and therefore that there is a need to strengthen the interpretation of the legal requirement of disclosure.[[885]](#footnote-885) The results of this study support this argument. When scientists were faced with patent documents, they did not think they could reproduce the invention (as per the disclosure requirement), some intimating they believed this was a conscious decision of the patentee. This challenges the notion that patents are ‘enabling’.

#### Raising the bar in patent offices and patent courts

A number of proposals have been put forward to strengthen the legal requirement of disclosure. Ouellette argues that patent offices and courts should notionally ‘raise the bar’ by routinely requiring enabling disclosure in return for a patent, negating the need for information users to undertake ‘undue experimentation’.[[886]](#footnote-886) This was highlighted in the study when scientists complained that the patent documents they had seen gave vague information about the quantities and timings needed to practise an invention. When comparing the information in patents with that in academic papers, it was noted the scientists studied that the information in patents was not as prescriptive as the methods given in papers. Reducing this disparity may improve scientists’ perceptions of patent information and according may increase their use of it.

#### The inclusion of a working example

The disclosure requirement could also be improved by requiring a working example of the invention in a patent application. Seymore argues that the teaching function of patents would greatly benefit such an inclusion in patent law.[[887]](#footnote-887) He suggests that requiring a working example would raise the standard of disclosure; simplify the consideration of the sufficiency of disclosure; yield more robust patents; and bridge the disconnection between science and patent law helping make patents a more competitive source of technical knowledge. This disconnect was commented on by a number of those studied, who remarked they preferred academic journal publication because this information contained proof of concept through experimental results. A working example requirement may be problematic in the case of patenting early stage research given that a tangible product may be unknown. However, in the case of patents on or referring to biological matter (e.g. stem cell lines), there is a requirement in the UK that a sample of the material be deposited at a registered bank (e.g. the UK Stem Cell Bank[[888]](#footnote-888)) at the point of filing if it is not readily publicly available. This aims to bypass concerns about disclosure.[[889]](#footnote-889) However, this does not overcome concerns about the lack of proof of concept. The inclusion of experimental results would therefore bring patents more in line with academic papers and may help allay some of the concerns which may contribute to a low perceived value of patent information.

#### Increasing peer review of patent information

Other remedies involve utilising end-users (e.g. scientists) to improve disclosure through the system pre- and post-grant. Pre-grant, the disclosure requirement could be assessed by PHOSITAs (‘person having ordinary skill in the art’: the US term analogous with the notional ‘person skilled in the art’ in UK patent law[[890]](#footnote-890)), through peer review. The findings indicate that one of the reasons scientists do not value patent information as a source of technical information is that they are not peer reviewed.

The process of peer review of research is qualitative: peers assess whether research is worthy of publication/funding/presentation, dependent on the quality of the research. As a result, it is expected that research published in academic journals is trustworthy and is of scientific value. The peer review process is enshrined in the practice of academic scientific research: it has a long history and is a trusted form of assessing knowledge prior to dissemination. Peer review supports the traditional norms of science as set out by Merton: it allows contribution by anyone, based on merit not background (universalism); it releases information into the scientific commons (communalism); it support the benefit of scientific enterprise without personal gain (disinterestedness); and it facilitates critical scrutiny of scientific claims (organised scepticism).

As has been discussed, the current use of the third party observation system as a form of peer review is very low, and the barriers to engagement with patent information are limiting its use. The potential remedy here therefore is employing other methods to increase scientists’ engagement with patent information, alongside improving the visibility of the third-party observation system. One way in which this problem has been approached is the Peer to Patent system.[[891]](#footnote-891) The system attempts to increase the uptake of the third party observation system by highlighting applications to potential peer reviewers, something which was believed to be achieved in pilot studies of the project.[[892]](#footnote-892) Another method of increasing peer review has been proposed by Ouellette who suggests that patent offices could actively utilise PHOSITA peer reviewers by sending patents out for review to nominated experts, as per the process used in peer review of journal articles.[[893]](#footnote-893) This option, while more administratively time consuming, may overcome concerns that were raised regarding the Peer to Patent system (which was based on self-nominated experts) that the information provided was not always very relevant or helpful.[[894]](#footnote-894) Both methods may increase the use of the third party observation system would potentially increase the perceived value of patent information by better aligning the system with academic traditional norms. Further, an increased use of the system in this way would increase engagement with patent information and knowledge dissemination through the system, at least to the reviewers.

At the post-grant stage, Fromer argues that it should be easier to question sufficiency of disclosure post-grant and to facilitate improved disclosure at this stage through annotation of the original granted document.[[895]](#footnote-895) This could be done in response to questions from patent information users, by “establishing an obligation that patentees respond if a PHOSITA asks a good-faith question about reproducibility.”[[896]](#footnote-896) Again, both of these options would bring the patent system more in line with scientific norms, potentially helping to raise scientists’ interest in using the system as a source of technical information.

### Reduce patent information complexities

Another way of improving the sufficiency of patent disclosures is to refocus the requirement of the technical audience of the information. Janis and Holbrook argue that the requirement is now aimed at satisfying a legal requirement and, therefore, a legal audience. [[897]](#footnote-897) They suggest a refocusing of patent law on the notion of the PHOSITA, ensuring that a realistic technical user is considered as the end user of the system during the examination procedure.[[898]](#footnote-898) With regard to the disclosure requirement, a refocus on the PHOSITA would theoretically improve the comprehensibility of patent information for scientists by targeting the information at a more realistic version of the notional person working in the field in question, rather than a legal professional.

Refocusing the requirement on the PHOSITA could be approached by reducing the complexities of patent information. Patent information can be difficult for scientists to comprehend because of the technical and legal layers built into patent documents: patent information is a complex form of information. This was highlighted in this study with many interviewees complaining about the obtuse and confusing language in which patent documents are written. This complexity is resultant of the dual purpose of patent information: it must detail a legal right and provide a source of information. As such, patent information spans both legal and technical concepts, inevitably resulting in complexity.

While a level of complexity is necessary to support the dual role of patent information, it has been argued that patent information is excessively complicated for those ‘skilled in the art’ to understand,[[899]](#footnote-899) frustrating the potential ‘teaching’ role of the information. The findings of the study support this argument. This excessive complication is based on two points: 1) the idiosyncrasies of patent information (such as the language within and the structure of patent documents); and 2) ‘gaming’ of the patent system through patent information (for example, by giving patent documents obtuse titles to mask the information from database searchers). The results of the study indicated both of these issues limit scientists’ use of patent information.

#### Reducing the complexities of language and structure

Patents are written in ‘patentese’, a term used to describe the legal jargon in which patents are written. The use of such language is necessary to achieve the legal aims of the patent: to mark the boundaries of protection. The study showed that a result of this is that the informative aspect is superseded by the legal aim; scientists struggle to comprehend patentese. The complicated language and perceived poor quality figures in patent documents could lead to a misunderstanding of information and is likely to contribute to the limited perceived value of patent information. For example, if a scientist misinterprets the information in a patent document not only may they misunderstand the patent and its legal boundaries, but they may also rely on the misunderstood information in planning future research.

It has been argued that patentese is further complicated by the practices of patent lawyers.[[900]](#footnote-900) Patent applications are normally written by patent attorneys whose aim is to get their client (the inventor) the widest possible legal protection which can stand up to litigation if necessary. To advance this aim, patent attorneys may use purposely ambiguous language which may be defended in court as meaning a number of different things, depending on the argument presented, or cover a wider scope of invention than can be foreseen by the inventor. In this way, the system can be gamed. The use of ambiguous language compounds the confusion caused by patentese further limiting the informative aspect of patents. At the point of examination, patent examiners must determine whether a patent passes the patentability requirements. The disclosure requirement details that “[t]he specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.”[[901]](#footnote-901) This leaves subjective decisions for the examiner: is the information posed ‘clear enough’ and what is the ‘person skilled in the art’? Patent examiners have a vested interest in granting patents where possible: it is self-serving for them to do so, both in terms of ease of approach and financial incentives.[[902]](#footnote-902) This gives applicants and their representatives an advantage in patent negotiations. As Drahos argues:

“Patent attorneys and examiners participate in a dance in which both are highly familiar with the technical steps, and both know that if the steps are followed there is a good chance that the dance will lead to the grant of a patent.”[[903]](#footnote-903)

This ‘dance’ allows patent attorneys to play their game, to release as little information as possible, in complicated language, while gaining as broad a patent as possible for their client.

With regard to the problem of patentese, it could be argued that patent law could require that patents are written in a more accessible language. However, in addition to the ‘dance’ described above which potentially limits major simplifications to the language used, there is a legal necessity to use the legal jargon of patentese: to demarcate the boundaries of the patent right. Patent documents are structured differently to traditional academic sources, a factor which may also limit scientists’ comprehension of patent information.[[904]](#footnote-904) Fromer offers a way of overcoming both of these problems. She argues that disclosure would be better supported by a document consisting of two completely separate ‘layers’: a technical layer and a legal layer.[[905]](#footnote-905) Each would address different sets of readers (legal and technical audiences), signalling information relevant to each group and tailoring the information to the needs of the audience thus allowing “each respective layer’s goals to be maximised.”[[906]](#footnote-906) The technical layer could follow the traditional structure of academic publications, written in scientific language. The legal layer could follow the current structure, written in patentese. This approach would limit the ability to game the system, but would require extra work on the part of patent attorneys and examiners.

In addition to these legally-driven changes, the outsider network could mobilise itself by actively encouraging or requiring through funding terms and conditions that patents from publicly funded research are written clearly, perhaps by attaching an additional abstract written in scientific terms. Attention may need to be paid, from the patentee’s position, that this abstract did not disclose anything that was not within the legal portion of the document. While a potentially challenging task, it is most likely achievable; such additional abstracts are already offered as a service by value-added databases, written by scientific specialists.[[907]](#footnote-907)

#### Reducing the use of vague titles

In addition to using ambiguous language throughout the patent document, patent lawyers may give patents purposely ambiguous titles to make patents more difficult to find. If patents are difficult to find, the patentee skews the patent bargain, gaining a patent right without disclosing information in an easy to find way. In this way, the patent system can be gamed. This is made possible because patent law does not define a requirement that the title fits the invention. Further, multiple patents may share the same title making it difficult to determine which patent is most relevant without reading through them all. On top of these problems, public patent databases are limited in their syntax searching: even if you know the title of the patent, it is not always easy to find it. Comparing this with academic publications, the opposite is true. There is nothing to gain by making papers difficult to find. The easier a paper is to find, the more accessible it is to the academic community, availing the information to be built upon to further the scientific endeavour. There are gains to be made by individual researchers for making their publications as visible as possible.[[908]](#footnote-908)

Whether or not it was intended, the title of the patent used in the structured observation is an example of how lawyers can use deficiencies in patent databases to advance their efforts to hide their clients’ patents. While it cannot be determined with the data gathered that this was intentionally done, it does highlight the potential to game the current databases by using deficiencies within them to obscure information. Better aligning the titles with the scientific content of the patent might help scientists to find and interpret patent information. To overcome the potential to game the system using titles two things need to be done: 1) patent databases need to improve, particularly in their handling of syntax; and 2) patent titles need to accurately describe the invention involved. The former point is dealt with elsewhere (in section 9.4.6) as part of a long list of potential improvements that could be made to public patent databases. In order to address the second point, the ability to game the system by using deceptive titles needs to be reduced. While there is nothing explicit in UK patent law regarding the features of a patent title, the UKIPO’s manual of patent practice (which explains the practice of the Office within the Patents Act) contains a number of references to the title of the invention.[[909]](#footnote-909) Noting the significance of the title to finding a patent, the manual notes that:

“[Titles] are used by patent searchers and to be of assistance in this connection a title should not only adequately indicate the subject of the invention but should also avoid the use of words which might convey different meanings to persons interested in different arts.”[[910]](#footnote-910)

Further, the examination process includes checking for “the presence of a suitable title”.[[911]](#footnote-911) While this indicates the importance of ensuring a title is accurate and descriptive, other rules limit such descriptiveness. One rule requires that a title is given which does not disclose the invention, given that it is published prior to publication of the application in full.[[912]](#footnote-912) Further, the title “must be short”,[[913]](#footnote-913) a condition which may limit its explanatory potential. Examiners are therefore required to find a subjective balance ensuring a title is ‘suitable’ and ‘indicates the subject of invention’ without giving away the essence of the invention, and this must be done in less than 158 characters.[[914]](#footnote-914) These requirements allow for gaming of the system. A patent attorney can enter a title that may be deemed ‘suitable’ and ‘indicates the subject of invention’, but this may still conceal the patent from patent searchers. Provided the title passes the examiner, the patent bargain is skewed: patentees can hold a patent while concealing the information to be released into society. Therefore, to overcome the potential to game the system using titles, examiners must be encouraged to strictly adhere to the rule of checking for “the presence of a suitable title” and a secondary, more explanatory title could be required and indexed in patent databases following publication of the application in full.

### Reducing gaming of the system

As the results highlighted, there are currently a number of ways in which the system can be gamed to cause imbalance in the patent bargain. This was shown to contribute to barriers regarding accessing and understanding patent information. To overcome this problem, the opportunity and desire to game the system must be reduced. In order to reduce gaming of the system two things can potentially be done: 1) the opportunity to game the system can be reduced (as discussed in the subsequent sections on language and titles); and 2) gaming can be discouraged.

In order to discourage gaming of the patent system, a number of different regulatory approaches may be taken involving a variety of stakeholders. These approaches intend to encourage compliance with the aims of the patent system and patent law as discussed throughout the thesis, focusing particularly on supporting disclosure of invention information through the patent system. A number of these approaches are presented below and are dealt with from the least to most punitive. This is in line with the responsive regulation model ‘enforcement pyramid’ put forward by Ayres and Braithwaite.[[915]](#footnote-915) The regulatory approaches within the pyramid should compliment each other, driving compliance the same desired behaviours. Within this hierarchical model, cooperative, persuasive approaches are found at the bottom of the pyramid and more punitive actions are found higher up the pyramid and are taken only when the lower level approaches have not achieved compliance. Accordingly, when compliance is not achieved with cooperative forms of regulation, the regulator may choose to use ‘somewhat punitive’ actions “only reluctantly and only when dialogue fails, and then escalate to even more punitive approaches only when the more modest forms of punishment fail”[[916]](#footnote-916). This approach also means that regulatees (in this case patent attorneys) willing to comply with the more cooperative measures are rewarded with lesser punishments than those who do not comply at that stage. Braithwaite argues that this approach support compliance and helps avoid game playing through by: 1) making it beneficial for regulatees to be compliant (i.e. avoiding harsher punishment by complying) and 2) making the use of punitive actions higher up the pyramid justifiable: “By resorting to more dominating, less respectful forms of social control only when more dialogic forms have been tried first, coercive control comes to be seen as more legitimate”.[[917]](#footnote-917)

***The development of codes of professional conduct and ongoing training and development of patent attorneys***

Currently, patent attorneys are regulated through membership of the Chartered Institute of Patent Attorneys (CIPA):

“All members of the institute agree to abide by the Institute’s Charter, Bye-Laws and Rules. These hold that all members are of good repute, maintain a high standard of rectitude and professional conduct and promote well-founded public confidence in the patent, design and trade mark systems.”[[918]](#footnote-918)

Within this framework, following the Legal Services Act 2007, the CIPA established an independent regulatory board, the Intellectual Property Regulation Board (IPReg). IPReg is responsible for the regulation of patent and trade mark attorneys in the UK, setting the qualification requirements for these professions, handling complaints and setting and maintaining codes of conduct.

Codes of conduct are developed based on the common values and norms within a professional group, highlighting expectations and encouraging individuals to take responsibility for their actions. While a useful tool to promote compliance, there are a number of problems potential problems to relying on guidance within codes of conduct. Such principle-based guidance provides uncertainty, unpredictability and is challenging to enforce. These problems were highlighted in Drahos’ study of patent offices which found that the UKIPO had tried to reduce the gaming of the system by patent attorneys by using a voluntary code of practice, but that this had seemingly had little effect.[[919]](#footnote-919) Further, the existing IPReg code of conduct focuses on the legal procedures involved in drafting, filing and prosecuting patent applications with little reference to the wider role of the patent system, i.e. the potential benefits of disclosure. On the other hand, a benefit of this type of regulation is that can be continually reviewed and quickly developed in response to changing requirements. Given concerns about the gaming of the system and limited disclosure through the system, the code of conduct could therefore be developed to encourage the profession to internalise a norm of full disclosure by highlighting the societal value of disclosure and encouraging behaviours that support disclosure. Also low in the regulatory pyramid, complementary to the developed code of conduct, the standards of patent attorney training and development regulated by IPReg could be modified to ensure that both qualifying education and ongoing training and development provide positive reinforcement of the importance of disclosure though the patent system. Once again, this approach could be monitored and developed as required in the future.

***Punishing gaming***

Moving further up the regulatory pyramid, the regulatory methods become more punitive. As previously discussed, under the responsive regulation pyramid model, these should only be employed when lower regulatory measures do not achieve the desired compliance. In this case, a regulator could only turn to more punitive measures when the developed code of conduct and continuing training and development programmes have not achieved the desired compliance.

Drahos argues that the costs of gaming call for regulation of gaming practices through an independent regulator (e.g. IPReg) equipped with punitive powers.**[[920]](#footnote-920)** These powers could escalate from written warnings highlighting non-compliance and setting out further potential punishments, to fines, to temporary- or permanent-deregistration. Under this model, following written warning and a fine, initial deregistration could be time limited, with attorneys re-registered after a period of time and after further training to reinforce the importance of disclosure, or deregistration could be permanent. In accordance with the regulatory pyramid model, permanent deregistration should only occur after repeated non-compliance following previous short-term deregistration. While these punitive regulatory approaches provide prescriptive requirements, clarity and certainty, they involve high compliance costs and should only be employed after regulatory approaches lower in the pyramid have been trialled.

### Improving the dissemination of technical information in patent documents

There are a number of ways in which patent information could be better disseminated amongst the scientific community and made more accessible. These approaches are often aligned with measures advocated in the OA to research results movement, as discussed below.

#### Link patent data to scientific literature

The findings of the interviews indicated that scientists prefer to engage with academic publications rather than patent documents for a number of reasons, one being that publications are a trusted source of technical information and a source with which they feel familiar. In line with Fromer and Ouellette, it is therefore argued that “Increasing mixing of the scientific and patent literature would go a long way toward increasing scientists’ engagement with patents.”[[921]](#footnote-921) There are a number of ways in which this could be achieved, which are already modelled in private patent databases as ‘value-added’ services.

One attempt based on linking patent information to other sources of information was attempted by the UKNSCN through the patent digests, which the study showed had not been regularly used by the scientists it was aimed at supporting. This lack of uptake had been based, in part at least, on a misconception of the role of the digests and a disinterest in consulting information outside of academic literature. Increasing a direct linkage between academic publications and patent information through citation and the incorporation of patent documents in general database search results could improve the uptake of patent information.

There have been several studies based on how often scientific literature is cited in patent applications[[922]](#footnote-922) but there are few studies of the opposite: the citation of patent documents in scientific literature. This may be due to the rarity of the occurrence. One small scale study found that no articles published in Science and Nature in a given month cited patents.[[923]](#footnote-923) In a much larger study, Glänzel and Meyer found that 1.7% of articles considered cited patents.[[924]](#footnote-924) They also found that the majority (~70%) of those papers citing patents were chemistry-related, indicating that citation is field dependent.[[925]](#footnote-925) A more recent study by Lebovitz found that almost one-third of biomedical research articles were associated with patent applications but disclosure of the applications through these articles only occurred in 12.5% of these cases.[[926]](#footnote-926) He argued that increasing the visibility of patent applications in scientific literature would provide notice of potential rights in the area and therefore the potential restrictions on use of the work, helping prevent infringement and improve the uptake of patent information by scientists.[[927]](#footnote-927) The citing of patent documents in scientific literature could help build scientist’s awareness of patents, particularly by highlighting patents of relevance to a reader, which was shown in the study to be a limiting factor in the uptake of knowledge available through the patent system. By utilising a trusted source of technical information, this may also increase the perceived value of patent information. Further, for patents still at the application stage, such citation may facilitate the uptake of the third party observation system.

One way of achieving increased linkage between scientific and patent literature would be to require authors to include information about any associated patent applications and/or granted patents in academic papers as a condition of publication, as is the case with declaring financial interests. This could be a requirement enforced by publishers, funders and/or universities. Another way of improving visibility of patents to peer scientists would be to require patent applicants/scientists to list patents (pending or granted) on their webpages, alongside their paper citations. In addition, in line with the OA to research results movement, a copy of the patent application could be added to an OA repository at the point of filing and linked to related papers by the inventor. Another way of increasing visibility is the incorporation of patent documentation in general search engines, such as Google and Google Scholar, and specific science search engines such as PubMed (the database most commonly used by participants in the study’s search task).

#### Improve public patent databases

All of the participants of the study who indicated that they had previously used a patent database, and all of those who used patent databases during the structured observation, used public, free to use databases. As highlighted in section 5.5.3, these databases are reportedly problematic in terms of timeliness, completeness and usability. The results of this study highlighted these problems. All of the patent search task participants struggled to use the patent databases they encountered effectively. It is not only scientists who have problems using the databases; problems have been reported by other groups too including SMEs and expert users.[[928]](#footnote-928)

Free access to patent information is essential to supporting the knowledge dissemination at the heart of the aim of the patent system and the knowledge dissemination that underpins science policy. Drahos argues that in addition to the legal requirement of publication, patent offices are duty-bound by their position as ‘society’s agent’ to support the diffusion of patent information and optimize transparency within the system (in addition to their more obvious role of examining patent applications).[[929]](#footnote-929) Policy makers also advocate this dual role of the patent office. For example, the president of the EPO, Benoit Battistelli, can be regularly quoted as saying these two roles are equally important.[[930]](#footnote-930)

Many patent offices maintain databases, free at the point of use and accessible over the internet.[[931]](#footnote-931) What they don’t do, at present, is make patent information easy for non-patent professionals to find and access. The free public databases are notoriously difficult to use, as evidenced in this study, and are deficient in terms of timeliness and completeness of information regarding both applications and grants.[[932]](#footnote-932) In parallel with concerns driving the movement for OA to research publications, access to patent information is partly limited by cost. Just as with academic journals, there is a multitude of ‘value-added’, private databases for patent information. These databases are run on a business model whereby they create sufficient ‘value’ to be able to charge users fees by enhancing the utility of the databases (in comparison with free public databases).[[933]](#footnote-933) The mere presence of a market for fee-paying databases highlights that there are problems with free to use databases, and therefore free access to patent information. Drahos argues that this difference creates a system with private transparency: the system is transparent if you are willing and able to pay.[[934]](#footnote-934) This creates a cost barrier to patent information in the same way knowledge dissemination through research publications has been limited by pay-walls to accessing academic journals. From an OA perspective, this is unacceptable, particularly in the case of the private transparency of information arising from publicly funded work: it should be freely accessible in the public domain.[[935]](#footnote-935) Similarly, the private transparency in the system undermines the rationale of public information dissemination as the *quid pro quo* of an exclusive patent monopoly right.

Without public transparency, patent information users may make decisions based on unfounded assumptions, which could not only limit the dissemination of knowledge through the patent system, but may also increase the risk of infringement; litigation; duplication of efforts; and unnecessary redirections of research efforts. The results of the study support these concerns. These problems to end-users of information can be linked to positive outcomes for powerful players in the governance of the patent system. Hence, Drahos argues that private transparency is intentionally maintained.[[936]](#footnote-936) The private transparency in the patent system has resulted in the development of a big business. Commercial providers of patent databases, patent lawyers, and patent information specialists command large fees to overcome the problems inherent in free public databases. As Drahos details, commercial providers have organised themselves into powerful groups that have worked to maintain the divide between the utility of public and private databases.[[937]](#footnote-937) Such providers have argued that this division is reasonable based on the claim that “information cannot be free” and that patent offices should “concentrate on providing the raw data, and maybe stay with rudimentary public sites.”[[938]](#footnote-938) This argument, opposite to that behind OA movements, is based on business concerns. Improving public, free, access to patent information would damage the commercial patent information industry, a distasteful concept to those who profit from it. It is no coincidence that these are the groups reported to be powerful members of the insider network steering the evolution of patent systems.[[939]](#footnote-939)

Calls for public database improvement have been heeded, to an extent, by some patent offices. For example, in June 2011, the UKIPO launched ‘Ipsum’, an ‘Online Patent Information and Document Inspection Service’, aimed at improving the timeliness and availability of patent information.[[940]](#footnote-940) The EPO has also improved its free information sources, building a European Patent Register (for legal status searching), teamed up with Google to provide patent translation and has worked on making the interface more user-friendly and improving its user support.[[941]](#footnote-941) Another attempt at improving the public transparency of the patent system has come from Google. In 2006, Google launched Google Patents, initially covering only patent applications and grants from the USPTO but, as of August 2012[[942]](#footnote-942) (after the study), it also includes patents filed through the EPC and PCT.[[943]](#footnote-943) Further, Google Scholar now, as a default setting, automatically includes patents in search queries. However, the global nature of Google may lead one to believe they cover patents filed in all patent offices and it is not made clear that this is not the case unless one specifically searches the help pages. While the efforts to improve the public transparency of the system are to be applauded, as this study has shown, there is more to be done. At a minimum, patent databases should be upfront about their shortcomings – they must plainly detail what is and what is not available through their system.

If public transparency is to be achieved in the patent system, public patent databases need to be significantly improved both behind the scenes and in their user-interfaces. One benefit of having a successful cluster of private databases is that they provide real-world examples of the types of improvements that could be made. Simmons described the ‘ideal patent information system’ as having …

“... universal coverage of all patents from all countries, with immediate updating. It would provide maximum recall with minimum false drop. Chemical structures would be searchable from specific and generic queries, with retrieval of all records with any amount of overlap between the query structure and the structures disclosed in the patent. Mechanical and electrical drawings would be searchable. All inventive concepts would be indexed for retrieval, and all prior art disclosed in the patent would be retrievable and distinguishable from the technology claimed as new. Search strategy building would be intuitive. There would be easy access to the original documents.”[[944]](#footnote-944)

Thus, there are many changes that can be made. Behind the scenes: data must be coded and indexed in a user-friendly manner; data must be uploaded promptly; any missing data should be filled in; data must be maintained; and the data should be updated as soon as appropriate when legal developments occur (such as notification of grant). The utility of public databases could also be improved by developing more user-friendly interfaces, containing information aimed at the basic user (i.e. scientists) and assuming very limited prior understanding of the patent system or patent databases. Guellec and van Pottelsberghe point out that the search tools and databases used by examiners could be made available to the public.[[945]](#footnote-945) Further, Drahos argues that at the very least patent offices should create subject-specific databases, which would allow scientists to more easily find patents of relevance to them.[[946]](#footnote-946)

To achieve these improvements, patent offices will have to increase their spending on database management, reducing their profit, and risk damaging the income of patent attorneys and the commercial database business. The costs associated with improving the databases could be built into the management of the patent system to achieve a balance between public and private benefits, a notion the system is premised upon. Concerns that this may damage the commercial database industry may be allayed if a margin for payment can be maintained, whilst ensuring the potential to disseminate knowledge to innovators is preserved. Private databases could develop additional sophisticated value-added tools (such as patent landscaping), which they could charge for, without harming the potential for basic knowledge dissemination. In this way, private database providers would be working for their income, rather than packaging something that should be freely available to the public.

## Conclusion

The first part of the chapter showed that the results indicate that the present situation raises a variety of questions about the fundamental aims of the patent system and science policies which have driven the increased patenting of basic research in universities. These concerns deserve further investigation if such policies are to be maintained and if the patent system is to continue to be justified, in part at least, on its function of disseminating knowledge.

The second part of the chapter showed that there are many ways in which the dissemination of knowledge through the patent system could be improved by tackling the factors which were shown to be limiting scientists’ engagement with patent information. Many of these remedies focused on better aligning science- and patent- policy with the traditional norms of science. Further, a number of remedies aimed at embedding patent literature within sources of traditional dissemination. Some of the remedies are relatively simple (for example, linking patent applications to scientific literature) and could be led by ‘outsiders’ such as funders, universities and researchers, potentially influenced through shaping science policy (as has been the case in the OA to research results movement). Other remedies (such as those requiring legal change) are more complex, particularly when viewed within Drahos’ theory of insider governance. Therefore, these ‘rule based’ remedies may be difficult to implement whilst maintaining the aim of improving knowledge dissemination without being shaped by the insider network. While interesting, without (currently unavailable) additional data about the costs and benefits of these proposals, all of the potential remedies remain speculative suggestions. If an aim of the patent system is to disseminate technical information, it is important that these options are investigated further and that at least some are implemented. As discussed throughout this thesis, this is particularly important in the case of patenting early stage research, especially when viewed in addition to concerns about the effects of such patenting on university research.

Chapter 10

Conclusions

## 10.1 Answering the research questions

This study sought to investigate the engagement of academic biological scientists, particularly stem cell scientists, working in the UK with the patent system and patent information. Through a multi-method approach a complex picture has emerged indicating that a wide variety of factors contribute to the empirically evidenced limited engagement of these scientists with the patent system and patent information. The thesis contributes to important debates questioning the role of the patent system within the academy and builds on existing evidence to suggest that the patent system is not working as advocated. By including the views and experiences of the scientists at the centre of the research alongside a historical analysis of the policy drivers of the current situation, the research adds a novel contextualisation to the associated debates.

In Part 1 of the thesis (Chapters 2-4) it was shown that the scientists at the centre of the empirical study work within a complex environment, shaped by the evolution of science policies and the funding of scientific research at both the international and national level which have led to an increase of patenting of biological science in universities. By retracing the evolution of science policies in the US and the EU, Chapter 2 showed that multifactorial drivers led to policies which increasingly promoted commercialisation and patenting of research in often as a requirement of research funding. Chapter 3 undertook a similar historical analysis of the situation in the UK. It was shown that, shaped by international trends, national science and funding policies have become increasingly focused on the encouragement of commercialisation of university research. This has been enacted by changes in funding requirements; the increased expectation to develop public-private partnerships and the ring-fencing of budgets for such initiatives; and rising calls for researchers to patent their research where possible externally, from funders, and internally, from universities themselves. The specific focus of stem cell science was examined in Chapter 4, where it was shown that there has been a particular national focus on the field, and an increasing focus on reaping the economic and therapeutic potential of the science. As a result, stem cell scientists undertaking basic, ‘upstream’, research are expected to work within an environment where their funding comes with strings attached and they are expected to patent basic research far removed from a therapeutic product or application despite having limited support to do so.

Part 2 (Chapter 5) centred on patent policy, the dissemination function of the patent system and the extension of patentable subject matter to cover upstream biological research. It was shown that this expansion has been contentious for a number of reasons and that there are a wide range of concerns about the effect of upstream patenting on downstream innovation in biological fields. These issues continue to play out in the courts and academic debate with concerns often raised by scientists themselves. The context provided in Parts 1 and 2 highlighted concerns about the effects of the increasing commercialisation of academic science and the role of the patent system in informing downstream innovation. Given the limited empirical data available to investigate these concerns, particularly data relating to academic biological and stem cell scientists, an empirical study was undertaken and presented in Part 3 (Chapters 6-8).

The empirical survey of academic biological and stem cell scientists working in the UK which was conducted to investigate some questions arising from the first two parts of the thesis:

1. Are scientists aware of the patent landscape within which they work?
2. What do scientists know about patents and patent information?
3. How do scientists use, perceive and value patents and patent information?
4. How do scientists search for patent information and what are the barriers they experience when doing so?

Chapter 6 set out the methodology used – a sequential explanatory mixed method approach incorporating surveys, interviews and structured observations. Chapter 7 presented the findings of a survey of 120 biological scientists. The results showed that the engagement of the group with patent information was limited, and pointed to a series of barriers to this engagement. These barriers included limited awareness of patent landscapes, patchy patent knowledge and negative perceptions of the effect of patents on scientific culture. These findings were then used to develop interview and structured observation schedules for the second phase of the study. The results of the interviews and structured observations were then presented in Chapter 8. The findings built upon, and helped to explain, the results of the survey. It was found that the scientist’s awareness of the patent landscape in which they work was superficial and few ‘regularly’ engaged with patent information (particularly early in the research process). Through the structured observations it was shown that when the participants were asked to search for a foundational patent on iPS cells they encountered significant hurdles due in part to functional limitations in public patent databases. When the participants studied the patent documents, they generally struggled to understand them due to the technical, ‘patentese’ language in which the scientific claims to innovation are expressed together with concerns that the scientific information was not sufficiently disclosing. This led them to question the scientific value of the information detailed in the patent document as a source of scientific knowledge. In addition, the interviews revealed that many scientists had negative perceptions of patents due to the ways in which they perceive patents as changing their traditional academic role and ‘closing’ the traditionally ‘open’ scientific commons. In summary, the findings showed that UK biological and stem cell scientists have limited engagement with patent information for a variety of reasons including not only the tensions between the increasing pressure on academics to commercialise ‘basic’ research and traditional science cultures but the technical barriers erected by the patent system itself to make patent information accessible and understandable to those it is intended to ‘teach’.

The final part of the thesis (Chapter 9 and this concluding chapter) completes the research. Chapter 9 discussed the implications of the findings on patent policy, before examining the implications for science policy. It was found that the present situation raises critical questions about the central aims of the patent system and science policies that have driven an increased patenting of upstream biological research. The second part of the chapter considers a range of options to improve access to and dissemination of scientific ‘innovations’ through the patent system. The options reviewed include improving patent education for academic scientists; raising the bar in patent examination and in the review of patents in legal cases and centring the patentability requirements on the notion of ‘person skilled in the art’; increasing peer review; reducing the use of technical ‘patentese’ language; reducing opportunities to game the system; linking patent information to traditional scientific literature and, critically, improving the functionality, timeliness and accuracy of patent databases. Building on Drahos’ theory of insider governance in the patent system, it is expected that these suggestions may be opposed by the powerful insiders of the system, showing a great need to mobilise an ‘outsider network’ to encourage a change to the current situation and in order to improve transparency of the patent system through access to and dissemination of patents on stem cell science and ‘innovations’.

## Limitations of the study and recommendations for future research

While the research conducted in this thesis offers some original insights on scientist’s perceptions of the patent system and the barriers they encounter when seeking to access the system, the study has a number of limitations based on its focus and methodology. First, the decisions made in narrowing the research questions mean that the conclusions can only be read in this context. While investigations of other fields of science with similar characteristics may yield the same conclusions, it is only by studying these fields that this can be known. In addition, it is not clear if the same conclusions would be drawn in other jurisdictions or in researching institutions other than universities. By empirically studying only one group involved in the research process, it may be the case that the different views of other scientists are missed. Secondly, the approach taken brings a number of limitations. For example, a methodology including greater emphasis on case law analysis and/or the ethical debates surrounding the patenting of stem cell science may have offered different conclusions, particularly if the empirical portion of the study had not been included. Finally, if the sample sizes in the empirical study were larger, it would be possible to be more confident about their generalisability to the wider populations. Thus, it could be useful to scale up the size of the study.

These limitations lead to some suggestions for future research. Such research could include a comparative study with other emerging fields, such as nanotechnology; a comparative study with stem cell scientists in different jurisdictions; an expanded study to consider other actors involved, such as staff working in university TTOs and patent attorneys; or the inclusion of different methods such as ethnography to help more fully understand the effect of patents on academic culture. Evidence from these further studies could be used together with the findings of this thesis to help underpin evidence-based policies to support the future of science in universities.

## Concluding thoughts

Whilst the immediate impact of the findings of the empirical study may have at first seemed limited, when discussed within the wider context of science and patent policy the findings point to some critical concerns. These concerns are amplified when considering the fields of study – biological and stem cell science – and the aligned economic and therapeutic expectations of the research involved. If these expectations are to be achieved, the science must be supported, from the point of basic research to the delivery of product. Given the existing dearth of date to understand how to best do this, the findings of this thesis echo the call made by others for further research to be undertaken to produce a sound basis for science policy, particularly in the stem cell field where much is at stake.[[947]](#footnote-947) However, even with more evidence, as Eisenberg wrote almost 20 years ago:

“Retreating from the policy may be difficult at this stage. Research performers have adjusted to the incentives created by current policy. When government policy creates and distributes new property rights, it is inevitable that someone will protest if those rights are later taken away.”[[948]](#footnote-948)

According to Drahos’ account of the powers at play in the ‘global governance of knowledge’, it is only through increased transparency in the patent system and the mobilisation of the outsider network that the system can be evaluated and forced to change. Therefore, it is concerning that there have been movements from the insider network to decrease transparency by extending legal provision to limit disclosure in patent documents. In 2012, following a request from Congress, the USPTO issued a request for comments on the “Feasibility of Placing Economically Significant Patents Under a Secrecy Order and the Need to Review Criteria in Determining Secrecy Orders Related to National Security”. The document questioned “whether the United States should identify and bar from publication and issuance certain patent applications as detrimental to the nation’s economic security”.[[949]](#footnote-949) This would involve extending the current legal provision to put an application under a secrecy order which might be “detrimental to national security”[[950]](#footnote-950) for “such period as the national interest requires” to include applications with may be detrimental to ‘national economic security’. The document also details that “proposed legislation would instruct the [USPTO] to publish only an abstract of the application” at 18 months rather than a full application. The piece continues to note there are a number of ways to ‘assist’ secrecy until the issuance of a patent including; requesting that an application is not published until a patent is issued, use of a secrecy order, or requesting a ‘prioritized examination’ to speed up examination.[[951]](#footnote-951) The majority of comments received were highly controversial of the proposals, voicing concerns of the interpretation of the term ‘national economic interest’ and the uncertainty that could ensue from having increased numbers of ‘submarine patents’.[[952]](#footnote-952) While it is not clear what will come of this proposal, from the perspective of the patent social contract model it is troubling that such a proposal has been made in the first place. If disclosure is to remain an aim of the patent system, it is important that a network of outsiders mobilize themselves to prevent these changes and actively work to improve the diffusion of knowledge through the system. This is particularly important if patents are to continue to be used to ‘protect’ the results of publicly funded, basic science undertaken in universities.

Appendix 1: The surveys

**1 Initial Questionnaire**

This research is being undertaken by Anna Hescott, Doctoral candidate from the School of Law, University of Sheffield as part of her PhD. If you have any questions or comments about this research, please contact her directly at [a.hescott@shef.ac.uk](mailto:a.hescott@shef.ac.uk)

By filling out this questionnaire you are consenting to use of the data provided in an anonymised manner. Participation is entirely voluntary.

Thank you in advance for your time.

1. Please indicate your level of agreement by marking the appropriate response: Strongly agree (SA), Agree (A), Disagree (D) or Strongly disagree (SD)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Statement | SA | A | D | SD |
| Pre-existing academic literature can affect the outcome of a patent application |  |  |  |  |
| Patents do not provide a useful source of knowledge |  |  |  |  |
| The only chance for scientists to question a patent is after it has been granted |  |  |  |  |
| Even if a patent exists on a material I am using, I cannot be sued because I am carrying out research |  |  |  |  |
| It is my responsibility to keep up to date with patents in my field |  |  |  |  |
| If I am not aware of a patent I can infringe it |  |  |  |  |
| Patents are only granted to privately funded scientists |  |  |  |  |
| I only need to think about patenting my research when I am certain it will have a profitable application |  |  |  |  |

1. Do patents exist in your field of research?

Yes No I am not sure

1. Do you work with patented materials (other than standard laboratory equipment)?

Yes No I am not sure

1. In the last 5 years, have you visited an online patent database? If no, continue to question 6. If yes, indicate which patent database you visited most recently:

espacenet (hosted by the European Patent Organisation)

Google patent search

Delphion

PATENTSCOPE (hosted by the World Intellectual Property Organisation)

Free patents online

Other (please specify) ………………………………………

1. What happened when you used this patent database?

I found what I was looking for and understood the information

I found what I was looking for but was not sure what all of the information meant

I did not find the information I was looking for

I was not looking a specific document

Other (what happened?) ……………………………………

1. Please indicate which of the following best describes your scientific role:

Masters student

PhD student

Technician

Post-doctoral researcher

Principle investigator

Other (please specify) ………………

1. Which of the following best describes your primary area of research:

Stem cell science

Biomedical science

Molecular biology

Genetics

Biochemistry

Other (please specify) ………………………

1. Which of the following best describes your main employment?

Solely publicly funded university laboratory

University laboratory funded partially with public funds in addition to an industrial/private grant

Industrial/privately funded laboratory

Charity funded laboratory

Other (please specify) ………………………………….

If you have any more information about your experiences with the patent system please write this overleaf or e-mail Anna Hescott directly at [a.hescott@shef.ac.uk](mailto:a.hescott@shef.ac.uk).

Thank you for taking the time to complete this questionnaire. Please write your contact details on the next sheet if you are willing to be contacted to take part in future, related, research. Participation is entirely voluntary and participants may refuse to take part in the future.

**NOTE:** Contact details will not be used in conjunction with the data provided on this questionnaire

1. **Online survey**

Page 1: Introduction

You are being invited to take part in a research project investigating the interaction of scientists with the patent system. Prior interaction with patents is not necessary; anyone can complete the survey.

This is a student research project being undertaken in pursuit of a PhD at the University of Sheffield. This project aims to examine the ways in which scientists interact with the patent system, and their understanding of patent information.  
The survey will take 5-10 minutes to complete. You will be asked about your knowledge of patenting and your interaction with patent databases. At the end of the survey, you will be asked for your occupational characteristics. No personal identifiers will be used.

Participation

It is up to you to decide whether or not to take part. If you do start the survey and decide not to finish it, you are free to withdraw from the research at any time

Confidentiality

All the information collected about you during the course of the research will be kept strictly confidential. All data collected will be anonymised i.e. you will not be identifiable in the report of this investigation.

Research Results and Publication

The results of the research will be published as a PhD thesis when completed. Anonymised data collected may be used in future, related research undertaken by the researcher and may be published. You will not be identified in any publications.

Ethics

This project has received ethical approval from the University of Sheffield, School of Law Ethics Review Board.

Complaints

If you have any complaints about this research, or wish to raise any concerns you should contact my PhD supervisor, Professor Aurora Plomer at the School of Law, University of Sheffield, Bartolomé House, Winter Street, Sheffield, S3 7ND, or e-mail: [a.plomer@sheffield.ac.uk](mailto:a.plomer@sheffield.ac.uk)

Further Information

Please contact me at the following address if you would like more information about this research: a.hescott@sheffield.ac.uk

Page 2:

1. Are you part of the University of Sheffield?

Yes

No

Page 3: Awareness of patents

1. Please indicate your level of agreement by marking the appropriate response: Strongly agree (SA), Agree (A), Disagree (D) or Strongly disagree (SD)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Statement | SA | A | D | SD |
| Pre-existing academic literature can affect the outcome of a patent application |  |  |  |  |
| Patents do not provide a useful source of knowledge |  |  |  |  |
| The only chance for scientists to question a patent is after it has been granted |  |  |  |  |
| Even if a patent exists on a material I am using, I cannot be sued because I am carrying out research |  |  |  |  |
| I know the difference between an A and a B specification patent document |  |  |  |  |
| It is my responsibility to keep up to date with patents in my field |  |  |  |  |
| If I am not aware of a patent I can infringe it |  |  |  |  |
| Patents are only granted to privately funded scientists |  |  |  |  |
| I only need to think about patenting my research when I am certain it will have a profitable application |  |  |  |  |

Page 4: Interaction with patents

1. Do patents exist in your field of research?

Yes

No

I am not sure

1. Do you work with patented materials (other than standard laboratory equipment)?

Yes

No

I am not sure

1. Have you ever seen a patent document?

Yes

No

1. Have you ever been part of a patent application?

Yes

No

Page 5: Online patent databases

1. In the last 5 years, have you visited an online patent database? If you have, please indicate which database you visited most recently. **[[953]](#footnote-953)**

I have not visited an online patent database in the last 5 years

espacenet (hosted by the European Patent Organisation)

Google patent search

Delphion

Derwent

PATENTSCOPE (hosted by the World Intellectual Property Organisation)

Free patents online

Other (please specify)

Page 6:

1. What happened when you used this patent database?

I found what I was looking for and understood the information

I found what I was looking for but was not sure what all of the information meant

I did not find the information I was looking for

I was not looking for a specific document

Other (please specify)

Page 7: Occupational characteristics

1. Please indicate which of the following best describes your scientific role

Masters student

PhD student

Technician

Post-doctoral researcher

Principal investigator

Other (please specify)

1. Which of the following best describes your primary area of research?

Stem cell science

Biomedical science

Molecular biology

Biochemistry

Structural biology

Genetics

Microbiology

Genomics

Physiology

Evolutionary biology

Medicine

Other (please specify)

1. Which of the following best describes your main employment?

Solely publicly funded University research laboratory

University research laboratory funded partially with public funds in addition to an industrial/private/ charity grant

Industrial/privately funded laboratory

Charity funded laboratory

Other (please specify)

Page 8:

[Thanks you for taking the time to complete this survey. If you have any further comments on patents please enter them in the box below.  
If you are willing to be contacted to take part in related future research, please fill in your contact details below. Participation is entirely voluntary and participants may refuse to take part at any point in the future.  
NOTE: Contact details provided will not be used in conjunction with the data provided in this questionnaire](http://www.surveymonkey.net/MySurvey_EditPage.aspx?sm=6d2VQZJtyvMrodMy6a%2bKNJDmL5bdtL%2fxsWFVpmGmDW%2fUKJbBbWXY0NlLi%2fYF9R%2bW&TB_iframe=true&height=450&width=650)

1. Comments on patents:
2. Contact details:

Appendix 2: Designing the questions

1. Self-completion questionnaires

In a self-completion questionnaire respondents, axiomatically, fill out the questionnaire themselves. Participants were asked to complete the survey themselves because it this made the survey quicker to administer, self-completion removes interviewer effects (where characteristics of the survey administrator may affect the answers given), there is no variability between the ways and order in which questions are asked and (in the case of the online questionnaires) respondents can choose when and where to complete the questionnaire. The choice to administer a self-completion questionnaire also had disadvantages. For example, when compared with interviews or investigator-administered questionnaires, during self-completion questionnaires respondents cannot be prompted when struggling to answer questions; no elaboration of answers can be sought; few respondents are likely to complete open answer questions; the questionnaire can be read as a whole which may affect respondents answers because the questions are not perceived as independent from each other, it is difficult to ask lots of questions because respondents are likely to get bored and quit the questionnaire (potentially reducing the response rate) and self-completion questionnaires are renowned for having low response rates.[[954]](#footnote-954) Attempts were made to reduce some of the problems associated with self-completion questionnaires. For example, to overcome the problem of questionnaires being read as a whole, respondents could see the whole questionnaire at once with the paper-based questionnaires at the UKNSCN but the online questionnaire limited the rate at which participants could progress through the questionnaire, showing them few questions at a time to help avoid an effect of other questions on a questions answer. Additionally, some of the questionnaires were administered face-to-face which increased the response rate

1. Question order

The questions were ordered from most challenging to answer through to easiest to answer: i.e. questions that participants were least likely to know the answers and would therefore have to think hardest about were posed first, and questions that they definitely knew the answer to (e.g. their field of expertise and their professional role) were left until last. This was done in order to try and get the best information from the questionnaire. If the most difficult questions were left till the end, it is possible the attention of the participant may be less than at the start thus potentially reducing the reliability of the results. In addition, questions about professional characteristics were placed at the end of the survey so that participants were not immediately presented with questions of apparently little relevance to the research being carried out.

The ordering of questions may affect responses if a previous question has an effect on respondents. Therefore, attitudinal questions were presented first, in order to ensure that answers were provided that had not been influenced by previous questions. Unfortunately, it is difficult to be certain that there is no question order effect but as the questions were always presented in the same order this should help to ensure any question order effect was uniform across all respondents.

1. ‘Closed’ questions

The majority of the questions were presented in a ‘closed’ form. This is to say that the respondent had to choose from a set of fixed options from which they had to choose an answer. Advantages of using these types of questions over ‘open’ questions include that the questionnaire is easier and quicker for participants to complete, the answers are easier to process, answers are comparable and the meaning of the question may be clarified by offering fixed answers. Disadvantages of ‘closed’ questions include a loss of spontaneity in answers. To try and avoid this having a negative effect on results an ‘other (please specify)’ response was offered for many of the questions. This gave participants the opportunity to provide a response which did not fit into the fixed answers offered and clarify what they meant by this. This option was not used often, indicating that the fixed answers were sufficient to include the majority of responses.

1. ‘Open’ questions

Two open questions were present at the end of the online questionnaire, and the same information was invited in the paper-based questionnaire. These were: “Comments on patents” and “Contact information” where a space was provided below for an answer to be written. Open questions were used in these cases because they allow respondents to answer however they wish (which is particularly necessary for the ‘contact information’ section). In the case of “comments on patents” and open question was used to allow for unusual (and often unexpected) responses. These open questions require more effort on the participant’s part than closed questions, which is likely to explain why few responses were received, alongside the fact that answers were not required to these questions.

1. Likert scales

A Likert scale was used in question 1. The scale provided offered 4 options for response to statements: strongly agree (SA), agree (A), disagree (D) and strongly disagree (SD). This meant that the answers provided were balanced, giving two supporting answers and two opposing answers. It is necessary to give a balanced set of options to closed questions so that the answers are not loaded towards a positive or negative selection, potentially influencing responses. Two positive options and two negative options were provided in order to allow more textured results to be obtained giving a richer dataset. If the answers offered were just ‘agree’ and ‘disagree’, the results could only be presented and analysed in a binary form. The use of 4 options means that the results can be analysed in a multifaceted way: either by considering all four answers separately or reducing the options to a binary form by grouping SA with A SD with D.

Often Likert scales are made of an odd number of options, including a ‘don’t know’ or ‘I have no opinion’ option. The lack of such an option is a controversial subject in questionnaire design. The main argument for including this is that not having one potentially forces respondents to indicate having an opinion that is not one they actually hold. [[955]](#footnote-955) On the other hand, presenting a ‘don’t know’ or ‘no opinion’ option in response to attitudinal indicators can be associated with participants not providing an opinion when they have one, or selecting ‘don’t know’ because this is easier than considering another answer.[[956]](#footnote-956) Studies (such as that carried out by Krosnick and others in 2002[[957]](#footnote-957)) have shown that having a ‘don’t know’ option reduces the likelihood of those holding an opinion expressing it. The study by Krosnick and othersfound that not having a no-opinion option did not reduce the quality of the data, and, in fact, reduces the risk of obtaining inaccurate results.[[958]](#footnote-958) Additionally, the study suggested that the likelihood of choosing a ‘no opinion’ answer was increased where participants “devoted little effort to the reporting process”[[959]](#footnote-959) and when respondents were answering secretly instead of orally to a question.[[960]](#footnote-960) Answers to this questionnaire were offered under anonymity. It was therefore decided that, in order to obtain considered answers, a ‘don’t know’ or ‘no opinion’ option would not be included in the optional responses to the attitudinal indicators, forcing participants to determine and disclose their true opinions.

In addition to the aforementioned issues concerning offering a ‘no opinion’ or ‘don’t know options, when investigating attitudes by asking whether participants agree or disagree with statements ‘don’t know’ is not always necessary, and is sometimes inappropriate. For example, given the statement; ‘I know the difference between an A and a B specification patent application’ if a respondent does not know the difference, they should answer ‘disagree’. A ‘don’t know’ response would indicate that they did not know whether they knew of the difference provided in the statement. This would not be a factual response. It was, however, borne in mind that this strategy is not appropriate for all types of questions, for example questions where an answer is quantifiable ‘don’t know’ is often necessary. For example, in the question ‘Do you work with patented materials?’ respondents may know whether they do or not (answering yes or no respectively) but they may truthfully be unaware of whether they do. In this case a ‘don’t know’ option was necessary and, therefore, offered.

1. Question phrasing

Some of the questions were phrased with the statement providing the truth, others contained false statements. This was done to encourage participants to read the question carefully and consider their responses, rather than repeatedly responding with the same answer.

1. Single answers

All of the closed questions required a single answer (this was forced on the online questionnaire). Accordingly, questions were phrased in a way that single answers were appropriate. For example the options ‘**primary** area of research’ and ‘**main** employment’ were offered rather that ‘research area’ and ‘employment’ more generally. This was done in order to ensure that the most relevant and considered answer was chosen. Where the options provided in the closed questions may not have covered all of the possible answers (for example in the question “Which of the following best describes your primary area of research?), an “other (please specify)” option was offered. This allowed respondents to provide an accurate answer even if it was not presented to them as an option in the response section.

1. Forcing answers

In the paper-based questionnaire, some respondents did not complete all of the answers, reducing the completeness of the overall dataset. It was therefore decided to force answers in the case of the online questionnaire where an answer to almost every question was required (except for where the logic step permitted a question to be missed and in the open questions as previously discussed). This was done in order to obtain complete datasets for each participant, allowing for a richer dataset and more comparable data between respondents.

The completion rate in the online questionnaire was approximately 75%. A contributing factor to this is likely to be the forcing of answers. Had participants been able to only answer questions they wanted to, the completion rate may have been higher: they would have only completed the questions they wanted to. However, some questions may have had far higher responses than others, potentially skewing overall impressions taken from the results.

1. Timeframes

In the question regarding whether participants had used an online database a timeframe for this use was offered: “In the last 5 years, have you visited an online patent databases? … If yes, please indicate the patent database you visited most recently.” A timeframe was used for two reasons; offering a timeframe reduces the risk of memory problems and ambiguity whereby respondents may not remember if they have used an online patent database longer than 5 years ago and secondly, because few online patent databases have been running for longer than 5 years. The initial question actually covered two questions: whether the participant had used an online patent database in the last 5 years (options being yes, or no) and if yes, which database they had used most recently. At this point, a logic step was added to avoid asking about too many matters in one question. If the respondent answered yes, they were subsequently asked about their experience during their last database usage. If they answered no, they were directed to skip this secondary question, and move onto the next.

Appendix 3: Tables and figures

Notes on tables and figures:

All results are reported to 3 significant figures (except in the case of significance values which are, as is customary, presented to 3 decimal places and in the figures where only whole numbers are presented).

In tables 4-8 and 10-16 the frequencies are presented followed by the valid percent in brackets (e.g. 5 (20.0) denotes a frequency of 5 and 20.0%).

Pearson’s chi-squared tests were carried out to assess whether there were significant differences between independent groups (subpopulations) (e.g. those with PhDs versus students) responses to some of the questions. The results of these tests are shown at the bottom of the relevant tables (4-8 and 10-16).

Terms used in tables and figures:

A = Agree

Chi2 = chi-squared

D = Disagree

f = frequency

N/A = not applicable (this term has been used where the numbers in the cells included in the Chi2 equation were too small for a reliable chi-value to be obtained in order to provide a valid significance (p) value)

Not part = respondents who have not been part of a patent application

Not seen = respondents who had not seen a patent document

Other = respondents belonging to other fields than stem cell science

Part = respondents who have been part of a patent application

PhD = respondents holding PhDs (as determined by them being post-doctoral researchers or principal investigators)

SA = strongly agree

SD = strongly disagree

Seen = respondents who indicated they had seen a patent document

Significance = statistical significance of chi-squared value

Stem = stem cell scientists

Students = Masters or PhD students

Total = total population

## 

Figure 7.13: Pie charts showing the proportional representations of the total population to the question ‘Which of the following best describes your main employment?’

1. The group were split into ‘University’ workers (consisting of the groups Solely publicly funded University research laboratory, University research laboratory funded partially with public funds in addition to an industrial/private/ charity grant and Non lab academics) and non-university respondents (the remaining groups make up this portion)

b) The population is split into those supported partially by public funds (Solely publicly funded University research laboratory, University research laboratory funded partially with public funds in addition to an industrial/private/ charity grant, Non lab academic and Government funded laboratory) and those who are supported solely by private funds (Industrial/privately funded laboratory and Charity funded laboratory )

Table 1: Survey responses to the question ‘Which of the following best describes your main employment?’

|  |  |  |
| --- | --- | --- |
| Which of the following best describes your main employment? | Total population | |
| f | % |
| Solely publicly funded University research laboratory | 25 | 20.8 |
| University research laboratory funded partially with public funds in addition to an industrial/private/ charity grant | 69 | 57.5 |
| Industrial/privately funded laboratory | 4 | 3.33 |
| Charity funded laboratory | 5 | 4.17 |
| Other | 1 | 0.83 |
| Non lab academic | 10 | 8.33 |
| Business | 4 | 3.33 |
| Government funded laboratory | 2 | 1.67 |
| Total | 120 | 100 |

Table 2: Survey responses to the question ‘Please indicate which of the following best describes your scientific role’

|  |  |  |
| --- | --- | --- |
| Please indicate which of the following best describes your scientific role | Total population | |
| f | % |
| Masters student | 5 | 4.17 |
| PhD student | 42 | 35.0 |
| Technician | 8 | 6.67 |
| Post-doctoral researcher | 25 | 20.8 |
| Principal investigator | 34 | 28.3 |
| Business | 5 | 4.17 |
| Other | 1 | 0.83 |
| Total | 120 | 100 |

Table 3: Survey responses to the question ‘Which of the following best describes your primary area of research?’

|  |  |  |
| --- | --- | --- |
| Which of the following best describes your primary area of research? | Total population | |
| f | % |
| Stem cell science | 37 | 30.8 |
| Biomedical science | 20 | 16.7 |
| Molecular biology | 2 | 1.67 |
| Genetics | 3 | 2.50 |
| Biochemistry | 10 | 8.33 |
| Other | 22 | 18.3 |
| Structural biology | 4 | 3.33 |
| Microbiology | 5 | 4.17 |
| Physiology | 2 | 1.67 |
| Evolutionary biology | 1 | 0.83 |
| Medicine | 14 | 11.7 |
| Total | 120 | 100 |

Table 4: Survey responses of the total population and subpopulations to the question: ‘Have you ever seen a patent document?’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Have you ever seen a patent document? | | Stem | Other | PhD | Students | Part | Not part | Total |
| Valid | Yes | 6 (60.0) | 36 (50.0) | 32 (74.4) | 8 (25.0) | 24 (100) | 13 (26.0) | 42 (51.2) |
| No | 4 (40.0) | 36 (50.0) | 11 (25.6) | 24 (75.0) |  | 37 (74.0) | 40 (48.8) |
| Total | 10 | 72 | 43 | 32 | 24 | 50 | 82 |
| Missing | | 27 | 11 | 16 | 10 |  |  | 38 |
| Total | | 37 | 83 | 59 | 42 | 24 | 50 | 120 |
| Chi2 value | | 0.351 (1 cell <5, 25%, min 4.88) | | 18.0 | | 35.5 | |  |
| Significance | | N/A | | 0.000 | | 0.000 | |

Table 5: The responses of the total population and subpopulations to the question: ‘Have you ever been part of a patent application?’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Have you ever been part of a patent application? | | Stem | Other | PhD | Students | Seen | Not seen | Total |
| Valid | Yes | 2 (50.0) | 22 (31.4) | 23 (59.0) |  | 24 (64.9) |  | 24 (32.4) |
| No | 2 (50.0) | 48 (68.6) | 16 (41.0) | 23 (100) | 13 (35.1) | 37 (100) | 50 (67.6) |
| Total | 4 | 70 | 39 | 23 | 37 | 37 | 74 |
| Missing | | 33 | 13 | 20 | 19 | 5 | 3 | 46 |
| Total | | 37 | 83 | 59 | 42 | 42 | 40 | 120 |
| Chi2 value | | 0.596 (2 cells <5, 50%, min 1.3) | | 25.8 | | 35.5 | |  |
| Significance | | N/A | | 0.000 | | 0.000 | |

Table 6: Survey responses of the total population and subpopulations to the question: ‘Do patents exist in your field of research?’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Do patents exist in your field of research? | Stem | Others | PhD | Students | Seen | Not seen | Part | Not part | Total |
| Yes | 34 (91.9) | 65 (78.3) | 54 (91.5) | 34 (72.3) | 40 (95.2) | 25 (62.5) | 24 (100) | 34 (68.0) | 99 (82.5) |
| No |  | 4 (4.82) | 1 (1.70) | 3 (6.38) | 1 (2.38) | 3 (7.50) |  | 4 (8.00) | 4 (3.33) |
| Not sure | 3 (8.10) | 14 (16.9) | 4 (6.77) | 10 (21.3) | 1 (2.38) | 12 (30.0) |  | 12 (24.0) | 17 (14.2) |
| Total | 37 (100) | 83 (100) | 59 (100) | 47 (100) | 42 (100) | 40 (100) | 24 (100) | 50 (100) | 120 (100) |

**Table 7: Survey responses of the total population and subpopulations to the question: ‘Do you work with patented materials (other than standard laboratory equipment)?’**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Do you work with patented materials (other than standard laboratory equipment)? | Stem | Others | PhD | Students | Seen | Not seen | Part | Not Part | Total |
| Yes | 18 (48.6) | 27 (32.5) | 27 (45.8) | 11 (23.4) | 23 (54.8) | 25 (62.5) | 14 (58.3) | 11 (22.0) | 45 (37.5) |
| No | 10 (27.1) | 31 (37.3) | 21 (35.6) | 17 (36.2) | 13 (31.0) | 18 (45.0) | 8 (33.3) | 21 (42.0) | 41 (34.2) |
| Not sure | 9 (24.3) | 25 (30.1) | 11 (18.6) | 19 (40.4) | 6 (14.3) | 16 (40.0) | 2 (8.33) | 18 (36.0) | 34 (28.3) |
| Total | 37 | 83 (100) | 59 (100) | 47 (100) | 42 (100) | 40 (100) | 24 | 50 (100) | 120 (100) |

Table 8: Survey responses of the total population and subpopulations to the questions: ‘In the last 5 years, have you visited an online patent database? If you have, please indicate which database you visited most recently’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| In the last 5 years, have you visited an online patent database? If you have, please indicate which database you visited most recently | | Stem | Others | PhD | Students | Seen | Not seen | Part | Not Part | Total |
| Yes | espacenet | 7 | 10 | 9 | 5 | 9 |  | 4 | 4 | 17 |
| Google patent search | 5 | 11 | 10 | 5 | 9 |  | 4 | 5 | 16 |
| PATENTSCOPE |  | 3 | 3 |  | 3 |  | 3 |  | 3 |
| Free patents online | 3 | 3 |  | 1 | 5 |  | 3 |  | 6 |
| Other | 2 | 3 | 5 |  | 4 |  | 3 | 1 | 5 |
| Total | 17 (45.9) | 30 (36.1) | 32 (54.2) | 11 (23.4) | 30 (71.4) |  | 17 (70.8) | 10 (20.0) | 47 (39.2) |
| No | | 20 (54.1) | 53 (63.9) | 27 (45.8) | 36 (76.6) | 12 (28.6) | 40 (100.0) | 7 (29.2) | 40 (80.0) | 73 (60.8) |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 1.03 | | 10.3 | | 41.3 | | 18.0 | |  |
| Significance | | 0.310 | | 0.001 | | 0.000 | | 0.000 | |

Table 9: Survey responses to the question: ‘What happened when you used this patent database?’

|  |  |  |
| --- | --- | --- |
| What happened when you used this patent database? | Total population | |
| f | % |
| I found what I was looking for and understood the information | 27 | 60.0 |
| I found what I was looking for but was not sure what all of the information meant | 15 | 33.3 |
| I did not find the information I was looking for | 1 | 2.2 |
| I was not looking for a specific document | 2 | 4.4 |
| Total | 45 | 100 |

Table 10: Survey responses of the total population and subpopulations to the statement: ‘I only need to think about patenting my research when I am certain it will have a profitable application’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| I only need to think about patenting my research when .etc. | | Stem | Other | PhD | Students | Seen | Not seen | Part | Not part | Total |
| Valid | SD | 7 (19.4) | 18 (21.7) | 15 (25.9) | 4 (8.51) | 9 (21.4) | 6 (15.0) | 8 (33.3) | 7 (14.0) | 25 (21.0) |
|  | D | 21 (58.3) | 43 (51.8) | 28 (48.3) | 31 (66.0) | 22 (52.4) | 24 (60.0) | 10 (41.7) | 29 (58.0) | 64 (53.8) |
|  | A | 6 (16.7) | 20 (24.1) | 11 (19.0) | 12 (25.0) | 10 (23.8) | 9 (22.5) | 5 (20.8) | 13 (26.0) | 26 (21.8) |
|  | SA | 2 (5.56) | 2 (2.40) | 4 (6.90) |  | 1 (2.38) | 1 (2.50) | 1 (4.17) | 1 (2.00) | 4 (3.36) |
|  | Total | 36 (100) | 83 (100) | 58 (100) | 47 (100) | 42 (100) | 40 (100) | 24 (100) | 50 (100) | 119 (100) |
| Missing | | 1 |  | 1 |  |  |  |  |  | 1 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2  value | | 1.633 (2 cells < 5, 25%, min 1.21) | | 9.517 (2 cells < 5, 25%, min 1.79) | | 0.691 (2 cells < 5, 25%, min 0.98) | | 4.271 (3 cells < 5, 37.5%, min 0.65) | |  |
| Significance | | N/A | | N/A | | N/A | | N/A | |
|  |  |  |  |  |  |  |  |  |  |  |
| Valid | D | 28 (77.8) | 61 (73.5) | 43 (74.1) | 35 (74.5) | 31 (73.8) | 30 (75.0) | 18 (75.0) | 36 (72.0) | 89 (74.8) |
|  | A | 8 (22.2) | 22 (26.5) | 15 (25.9) | 12 (25.5) | 11 (26.2) | 10 (25.0) | 6 (25.0) | 14 (28.0) | 30 (25.2) |
|  | Total | 36 (100) | 83 (100) | 58 (100) | 47 (100) | 42 (100) | 40 (100) | 24 (100) | 50 (100) | 119 (100) |
| Missing | | 1 |  | 1 |  |  |  |  |  | 1 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 0.244 | | 0.001 | | 0.015 | | 0.074 | |  |
| Significance | | 0.621 | | 0.969 | | 0.902 | | 0.786 | |

Table 11: Survey responses of the total population and subpopulations to the statement: ‘I know the difference between an A and a B specification patent document’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| I know the difference … | | Stem | Other | PhD | Students | Seen | Not seen | Part | Not part | Total |
| Valid | SD | 8 (80.0) | 54 (76.1) | 32 (74.4) | 27 (87.1) | 29 (70.7) | 33 (82.5) | 16 (66.7) | 41 (82.0) | 62 (76.5) |
| D | 2 (20.0) | 15 (21.1) | 10 (23.3) | 3 (9.67) | 10 (24.4) | 7 (17.5) | 7 (29.2) | 8 (16.0) | 17 (21.0) |
| A |  | 1 (1.41) |  | 1 (3.22) | 1 (2.43) |  |  | 1 (2.00) | 1 (1.23) |
| SA |  | 1 (1.41) | 1 (2.32) |  | 1 (2.43) |  | 1 (4.17) |  | 1 (1.23) |
| Total | 10 | 71 | 43 | 31 | 41 | 40 | 24 | 50 | 81 |
| Missing | | 27 | 12 | 16 | 16 | 1 |  |  |  | 39 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 0.305 (5 cells <5, 62.5%, min 0.12) | | 4.362 (4 cells<5, 50%, min 0.42) | | 2.776 (4 cells<5, 50%, min 0.49) | | 4.445 (5 cells <5, 62.5%, min 0.32) | |  |
| Significance | | N/A | | N/A | | N/A | | N/A | |
|  | |  | |  | |  | |  | |  |
| Valid | D | 10 (100) | 69 (97.2) | 42 (97.7) | 25 (96.8) | 39 (95.1) | 40 (100) | 23 (95.8) | 49 (98.0) | 79 (97.5) |
| A |  | 2 (2.8) | 1 (2.3) | 1 (3.2) | 2 (4.9) |  | 1 (4.2) | 1 (2.0) | 2 (2.5) |
| Total | 10 | 71 | 43 | 31 | 41 | 40 | 24 | 50 | 81 |
| Missing | | 27 | 12 | 16 | 16 | 1 |  |  |  | 39 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 0.056 (2 cells<5, 50%, min 0.025) | | 0.056 (2 cells<5, 50%, min 0.84) | | 2.001 (2 cells<5, 50%, min 0.99) | | 0.289 (2 cells<5, 50%, min 0.65) | |  |
| Significance | | N/A | | N/A | | N/A | | N/A | |

Table 12: Survey responses of the total population and subpopulations to the statement: ‘The only chance for scientists to question a patent is after it has been granted’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The only chance for scientists to … | | Stem | Other | PhD | Students | Seen | Not seen | Part | Not part | Total |
| Valid | SD | 9 (25.7) | 6 (7.41) | 10 (16.9) | 3 (6.98) | 7 (17.1) | 1 (2.50) | 6 (25.0) | 1 (2.00) | 15 (12.9) |
| D | 15 (42.9) | 39 (48.1) | 21 (35.6) | 29 (67.4) | 11 (26.8) | 26 (65.0) | 5 (20.8) | 31 (62.0) | 54 (46.6) |
| A | 10 (28.6) | 31 (38.3) | 24 (40.7) | 10 (23.3) | 19 (46.3) | 13 (32.5) | 12 (50.0) | 16 (32.0) | 41 (35.3) |
| SA | 1 (2.86) | 5 (6.17) | 4 (6.80) | 1 (2.32) | 4 (9.76) |  | 1 (4.17) | 2 (4.00) | 6 (5.17) |
| Total | 35 (100) | 81 (100) | 59 (100) | 43 (100) | 41 (100) | 40 (100) | 24 (100) | 50 (100) | 116 (100) |
| Missing | | 2 | 2 |  | 4 | 1 |  |  |  | 4 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 7.651 (3 cells < 5, 37.5%, min 1.81) | | 10.359 (2 cells < 5, 25%, min 2.11) | | 15.696 (4 cells<5, 50%, min 1.98) | | 16.107 (4 cells<5, 50%, min 0.97) | |  |
| Significance | | N/A | | N/A | | N/A | | N/A | |
|  |  |  |  |  |  |  |  |  |  |  |
| Valid | D | 24 (68.6) | 45 (55.6) | 31 (52.5) | 25 (74.4) | 18 (43.9) | 27 (67.5) | 11 (45.8) | 32 (64.0) | 69 (59.5) |
| A | 11 (31.4) | 36 (44.4) | 28 (47.5) | 11 (25.6) | 23 (56.1) | 13 (32.5) | 13 (54.2) | 18 (36.0) | 47 (40.5) |
| Total | 35 (100) | 81 (100) | 59 (100) | 43 (100) | 41 (100) | 40 (100) | 24 (100) | 50 (100) | 116 (100) |
| Missing | | 2 | 2 |  | 4 | 1 |  |  |  | 4 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 1.718 | | 5.04 | | 4.556 | | 2.199 | |  |
| Significance | | 0.19 | | 0.025 | | 0.033 | | 0.138 | |

Table 13: Survey responses of the total population and subpopulations to the statement: ‘Even if a patent exists on a material I am using, I cannot be sued because I am carrying out research’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Even if a patent exists on a material I am using… | | Stem | Other | | PhD | Students | Seen | Not seen | Part | | Not part | Total |
| Valid | SD | 8(22.9) | 13 (15.7) | | 9 (15.5) | 7 (14.9) | 9 (21.4) | 6 (15.0) | 5 (20.8) | | 9 (18.0) | 21 (17.8) |
| D | 17 (48.6) | 51 (61.4) | | 34 (58.6) | 29 (61.7) | 20 (47.6) | 25 (62.5) | 12 (50.0) | | 31 (62.0) | 68 (57.6) |
| A | 9 (25.7) | 13 (15.7) | | 9 (15.5) | 10 (21.3) | 7 (19.5) | 7 (16.7) | 3 (12.5) | | 9 (18.0) | 22 (18.6) |
| SA | 1 (2.86) | 6 (7.23) | | 6 (10.3) | 1 (2.13) | 6 (14.3) |  | 4 (16.7) | | 1 (2.00) | 7 (5.93) |
| Total | 35 | 83 | | 58 | 47 | 42 | 40 | 24 | | 50 | 118 |
| Missing | | 2 |  | | 1 |  |  |  |  | |  | 2 |
| Total | | 37 | 83 | | 59 | 47 | 42 | 40 | 24 | | 50 | 120 |
| Chi2  value | | 3.551 (2 cells <5, 25%, min 2.08) | | | 3.153 (2 cells < 5, 25%, min 3.13) | | 7.361 (2 cells<5, 25%, min 2.93) | | 5.936 (4 cells <5, 50%, min 1.62) | | |  |
| Significance | | N/A | | | N/A | | N/A | | N/A | | |
|  | |  | |  | | |  | | |  | |  |
| Valid | D | 25 (74.1) | 64 (77.1) | | 43 (74.1) | 25 (76.6) | 29 (69.0) | 31 (77.5) | 17 (70.8) | | 40 (80.0) | 89 (75.4) |
| A | 10 (25.9) | 19 (22.9) | | 15 (25.9) | 11 (23.4) | 13 (31.0) | 9 (22.5) | 7 (29.2) | | 10 (20.0) | 29 (24.6) |
| Total | 35 | 83 | | 58 | 47 | 42 | 40 | 24 | | 50 | 118 |
| Missing | | 2 |  | | 1 |  |  |  |  | |  | 2 |
| Total | | 37 | 83 | | 59 | 47 | 42 | 40 | 24 | | 50 | 120 |
| Chi2 value | | 0.428 | | | 0.084 | | 0.746 | | 0.770 | | |  |
| Significance | | 0.513 | | | 0.772 | | 0.388 | | 0.380 | | |

Table 14: Survey responses of the total population and subpopulations to the statement: ‘Patents do not provide a useful source of knowledge’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patents do not provide a … | | Stem | Other | PhD | Students | Seen | Not seen | Part | Not part | Total |
| Valid | SD | 7 (18.9) | 14 (17.1) | 14 (23.7) | 2(4.35) | 12(29.3) | 2 (5.00) | 10 (41.7) | 4 (8.00) | 21 (17.6) |
| D | 19 (51.4) | 41 (50.0) | 23 (39.0) | 31 (67.4) | 18 (43.9) | 23 (57.5) | 9 (37.5) | 28 (56.0) | 60 (50.4) |
| A | 10 (27.0) | 19 (23.2) | 15 (25.4) | 11 (23.9) | 6 (14.6) | 13 (32.5) | 4 (16.7) | 13 (26.0) | 29 (24.4) |
| SA | 1 (2.70) | 8 (9.76) | 7 (11.9) | 2 (4.35) | 5 (12.2) | 2 (5.00) | 1 (4.17) | 5 (10.0) | 9 (7.56) |
| Total | 37 | 82 | 59 | 46 | 41 | 40 | 24 | 50 | 119 |
| Missing | |  | 1 |  | 1 | 1 |  |  |  | 1 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 1.891 (1 cell <5, 12.5%, min 2.80) | | 12.155 (1 cell <5, 12.5%, min 3.94) | | 11.607 (2 cells<5, 25.0%, min 3.46) | | 12.121 (3 cells<5, 37.5, min 1.95) | |  |
| Significance | | N/A | | N/A | | N/A | | N/A | |
|  | |  | |  | |  | |  | |  |
| Valid | D | 26 (70.3) | 55 (67.1) | 37 (62.7) | 33 (71.7) | 30 (73.2) | 25 (62.5) | 19 (79.2) | 32 (64.0) | 81 (68.1) |
| A | 11 (29.7) | 27 (32.9) | 22 (37.3) | 13 (28.3) | 11 (26.8) | 15 (27.5) | 5 (20.8) | 18 (36.0) | 38 (31.9) |
| Total | 37 | 82 | 59 | 46 | 41 | 40 | 24 | 50 | 119 |
| Missing | |  | 1 |  | 1 | 1 |  |  |  | 1 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 0.120 | | 0.948 | | 1.06 | | 1.74 | |  |
| Significance | | 0.729 | | 0.330 | | 0.304 | | 0.187 | |

Table 15: Survey responses of the total population and subpopulations to the statement: ‘Pre-existing academic literature can affect the outcome of a patent application’ and chi-squared test results for paired subpopulations

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pre-existing … | | Stem | Other | PhD | Students | Seen | Not seen | Part | Not part | Total |
| Valid | SD |  | 1 (1.22) | 1 (1.72) |  |  | 1 (2.50) |  | 1 (2.00) | 1 (0.85) |
| D | 1 (2.86) | 4 (4.87) |  | 3 (6.67) |  | 3 (7.50) |  | 3 (6.00) | 5 (4.27) |
| A | 14 (40.0) | 34 (41.5) | 18 (31.0) | 22 (48.9) | 7 (17.1) | 22 (55.0) | 3 (12.5) | 25 (50.0) | 48 (40.0) |
| SA | 20 (57.1) | 43 (52.4) | 39 (67.2) | 20 (44.4) | 34 (82.9) | 14 (35.0) | 21 (87.5) | 21 (42.0) | 63 (52.5) |
| Total | 35 | 82 | 58 | 45 | 41 | 40 | 24 | 50 | 117 |
| Missing | | 2 | 1 | 1 | 2 | 1 | 0 | 0 | 0 | 3 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 0.775 (4 cells <5, 50%, min 0.30) | | 9.022 (4 cells <5, 50%, min 0.44) | | 20.083 (4 cells <5, 50%, min 0.49) | | 13.862 (4 cells <5, 50%, min 0.32) | |  |
| Significance | | N/A | | N/A | | N/A | | N/A | |
| Valid | D | 1 (2.86) | 5 (6.10) | 1(1.72) | 3(6.67) |  | 4(10.0) |  | 4(8.00) | 6 (5.13) |
| A | 34 (97.1) | 77 (93.9) | 57 (98.3) | 42 (93.3) | 41 (100) | 36(90.0) | 24(100) | 46(92.0) | 111 (94.9) |
| Total | 35 | 82 | 58 | 45 | 41 | 40 | 24 | 50 | 117 |
| Missing | | 2 | 1 | 1 | 2 | 1 | 0 | 0 | 0 | 3 |
| Total | | 37 | 83 | 59 | 47 | 42 | 40 | 24 | 50 | 120 |
| Chi2 value | | 0.529 (2 cells,5, 50%, min 1.79) | | 1.658 (2 cells<5, 50%, min 1.75) | | 4.318 (2 cells<5, 50%, min1.98) | | 2.030(2 cells<5, 50%, min 1.30) | |  |
| Significance | | 0.467 | | 0.198 | | 0.038 | | 0.154 | |

Appendix 4: Additional comments from the surveys

Respondent 47 (publicly funded, bioinformatics postdoctoral researcher, has used online database):

“I write software the patenting of which is possible in the USA but not in Europe. Our main journals in the field have come out strongly against software patenting … and insist that software published in it is made available under an appropriate license such as the GPL (GNU Public License). … In 2003/4 we patented a method for medical diagnostics … but could not patent the visualisation I co-developed. Personally I was happy with that: the 'technical effect' of the gene signature we developed is protected and the visualisation a means-to-an-end.”

Respondent 48 (publicly and privately funded biomaterials principal investigator, has not used online database):

“I rely on the University research Office to establish patentability of my research. I simply fill in a [special] form and take it from there. I tend to be aware of background research and commercially products in my field and sometimes am aware of patents but don't undertake patent searches myself.”

Respondent 56 (biochemistry, publicly funded PhD student, has used online database):

“IP is viewed by some as a means to protect investment that goes into research. This is all well and good but unfortunately shafts the poorer people of the world. When a huge agrocompany like Monsanto can sue a farmer because Monsanto seed drifted into his farm from a neighbouring farm, we have a problem. When people can't make life saving drugs cheap and affordable for everyone because one group is hogging the patent, we have a problem. Although I know relatively little about IP law, the concept of claiming ideas which are, more often than not, built on a lot of publicly funded research/education seems daft. Research should be done to achieve technology that raises standards of living for everyone, not just the rich.”

Respondent 76 (publicly and privately funded medicine principal investigator, has used online database):

“I think that as is the case in academic publishing, patents can often report false or selectively presented data.”

Respondent 101 (publicly and privately funded molecular biology principal investigator, has used online database):

“Several years ago, I was involved in one patent application, and I also willingly carried out my research in the manner recommended by KT office (i.e. lab book signing, confidentiality etc.). Through that experience, I discovered that this was all a waste of time and effort because my institution does not have the financial resources or legal workforce to file many patents, and only makes a real effort in the very rare cases where there would be high likelihood of short-term commercial benefits. I do not believe this is because my institution is poorly managed, simply that this is the best that could have been expected of a University. This experience convinced me that the expectation that Universities should mimic the patenting strategies of large corporations like pharmaceutical companies is basically wrong. That's asking Universities to play in a field where they will always be the weakest player. I also found that my institution's policy that academics should conduct all their research in a manner that preserves the potential for patent is toxic to basic research. So, nowadays, I go through the motions of complying with the requirements of lab book signing etc., but I would not waste any thoughts on the patentability of my research unless a potential economic benefit of it became very obvious. Instead I am concentrating on doing my research according to traditional (not for profit) tradition, e.g. discussing my results freely with peers even outside of my institution and using my unpublished data as example in classes. On a more fundamental level, I do not agree that academics or universities should patent their discoveries. In my opinion there is something fundamentally flawed in the expectation that universities are expected to make significant financial income from patenting their research products. My view of how academic's research can best contribute to society is best illustrated by Jonas Salks's attitude to suggestions that he should have patented his anti-polio vaccine.”

Respondent 111 (publicly and privately funded stem cell science principal investigator, has used online database):

“It would be good if academic scientists were taught the most effective way to access and use patent databases”

Respondent 117 (publicly and privately funded Biochemistry PhD student, has used online database):

“As a research scientist I solely use patents to find out about research that has been carried out that is relevant to my area of work. I often find it very difficult to locate the information of interest to me within the patent.”

Appendix 5: Interview schedule

1. Training

* Have you received any training about patents?
* Have you received any training about patent information or patent databases?

1. Awareness
   * Do patents exist in your field?
   * No/not sure
     + Why?
   * Yes
     + How did you find out? Have you carried out a patent search?
     + Are you aware of particular patents in your field?
     + Are you working within a patent?

* Have you seen a patent?
  + Yes
    - Where? Under what circumstances?
  + No
    - Why not?
* What could be done to improve awareness? What do you think are the barriers to awareness?

1. Basic knowledge

* What do you think are the requirements of an invention for it to be subject of a patent grant?
* Are you aware that the UKNSCN provides stem cell patent digests?
* What could be done to improve levels of basic knowledge?

1. Scientific value of patent information

* Do you consider patents to be a useful source of knowledge? Why do you hold this belief?
* What information contained in patents (e.g. scope of claims, legal information, signalling of competitors work) do you consider to be most/least valuable?
* Survey comments also included the belief that patents are toxic to basic research; does this opinion limit scientists’ value of patent information?

1. Legal/scientific disparities

* Ask about opinion of language in patents vs. language in papers and structure of documents
* Do these issues contribute to your opinion of patent information?

1. Finding and understanding

* Have you used a patent database before?
  + No
    - Why not?
    - What do you think you would find?
  + Yes
    - Why?
    - Which one? Why this one?
    - What did you expect to find?
    - Did this match your experience?
    - How did you assess if you found the information you were looking for?
* Ask about what they think about titles of patents

1. Further comments

Appendix 6: The observation schedule

In order to construct a suitable observation schedule, a few things needed to be considered:

1. The focus of the observations: who and what is to be observed. In this study, the focus was UK university-based senior stem cell scientists and their practices and perceptions of searching for academic papers and patents in their field.
2. Categories: what observations are being looked for? The categories in this case included the length of time to find the paper and patent; the search strategies employed and the databases used; scientists’ perceptions of searching for papers and patents and the databases they encountered; scientists’ understanding of the patent documents they saw. These were all prompted and probed using interview questions such as ‘what do you think of this database?’ and ‘where do you think this patent applies to territorially?’
3. Observing behaviour: how were the observations to be recorded? There are a number of different ways of observing behaviour in structured observation involving different ways in which the observer monitors: for example, is everything being recorded or just the behaviour at given time points? In this case focal sampling was used where a participant is observed and the observer records behaviour of interest to the schedule.[[961]](#footnote-961) The observations were recorded in terms of the incidents of the behaviours and particular practices which formed part of the task and also the participants’ perceptions of different aspects of the task. In order to allow all of this data to be collected and analysed, both visual and audio recordings were recorded using screen capture software and a digital recording device. In addition, notes were taken of any particularities of the observations in order for these to be taken into account during the analysis (for example, one participants internet crashed during the observation). These various recordings of the observations allowed coding and analysis to be undertaking following the observations meaning that I was not rushed into making inferences about behaviours.

The following observations schedule was developed, and as with the interviews was administered in a semi-structured manner allowing for further guidance and reflexive questioning of the participants.

|  |  |  |
| --- | --- | --- |
| Task | Question(s) | Observation categories |
| Search for academic paper | Can you show me how you would search for the landmark paper from Shinya Yamanaka? | Visual observation of search strategy.  Question answers  During analysis: how long did it take the participant to find the paper? |
| Why have you chosen to search like that? |
| Search for patent and evaluation of patent information | Can you show me how you would search for the related patent? | Visual observation of strategy.  Question answers  During analysis: how long did it take the participant to find the patent? |
| Why have you begun your search like that? |
| Have you ever used this database before? |
| How do you find the database compares with academic literature databases? |
| What do you think of the search interface of the database? |
| Can you show me how you might find out if the patent has been granted? |
| Can you show me how you might find out where the patent has been applied for? And what are the different paths of applying for patents? |
| Can you show me how you might find out where the patent has been granted? |
| Do you know what this A and this B mean? |

Appendix 7: Consent for interviews and tasks

This research is being undertaken by Anna Hescott, Doctoral candidate from the School of Law, University of Sheffield as part of her PhD. If you have any questions or comments about this research, please contact her directly at [a.hescott@shef.ac.uk](mailto:a.hescott@shef.ac.uk) or alternatively, Professor Aurora Plomer, the lead supervisor of this project. She can be contacted at Bartolomé House, Winter Street, Sheffield, S3 7ND, or at [a.plomer@shef.ac.uk](mailto:a.plomer@shef.ac.uk)

Data collected will be anonymised, and used in a race-, gender- and rank-neutral manner – no names, place of employment or other identifying details will be used in the presentation of this research.

Participation is voluntary. You have the right to refuse to participate in this research at this point, and can withdraw from the research at any point without having to give a reason. (Note: this right to withdraw does not extend to the withdrawal of already published findings or in a way that compromises anonymised data sets).

Please tick this box to confirm that you have read the information sheet and have had the chance to ask any questions you have about the research

Please tick this box if you consent to the use of an audio recording device during this interview

Please tick this box if you consent to the use of a computer screen capture programme to be used during the task

Please tick this box if you wish to be sent a summary of the research findings

By signing below, you are consenting to the use of data provided in an anonymised form.

Name (block capitals)

Signature

Appendix 8: Tables of observations

Searches for the academic paper

|  |  |  |  |
| --- | --- | --- | --- |
| Participant number | Time taken to find paper (seconds) | Search process | Notes |
| 1 | 45 | Google search with authors name; chose result referring to the journal of publication; paper found |  |
| 2 | 250 | Google search for pubmed; visit PubMed site; PubMed simple search using name of author and keywords; asked for date; found paper |  |
| 3 | 135 | Google search for PubMed; visit PubMed site; PubMed simple search for author and year of publication; found paper |  |
| 4 | 35 | Google search for PubMed; PubMed simple search for author and keyword; select last page; found right paper |  |
| 5 | 80 | Google search for PubMed; PubMed simple search for author, year and keyword; selects right paper |  |
| 6 | 335 | Google search for PubMed; PubMed simple search for author and keyword; looks through each page; right paper found on last page |  |
| 7 | 190 | Tab 1: open PubMed; Tab 2: open google, google search for author; Tab1: PubMed simple search author and keyword; Tab 2: select authors academic homepage, scroll down to references; Tab 1: last page of PubMed search, select correct paper | Unusual approach using multiple tabs |
| 8 | 110 | Google search for PubMed; PubMed simple search for author and ‘stem cell’; selects correct paper |  |
| 9 | 45 | Google search for PubMed; PubMed simple search author and keywords; go to last page, select correct paper |  |
| 10 | 190 | [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov); select PubMed; simple search author with first initial, year and keyword; correct paper not in results; new search first author with first initial, second author and keyword; correct paper not in results; new search with first and second authors, selects correct paper | Problem using keyword which is commonly used to refer to the paper but wasn’t in the original paper |
| 11 | 35 | PubMed; simple search: author and keyword; select correct paper |  |
| 12 | 180 | PubMed; simple search; author and keyword; goes through each page; selects correct paper on last page |  |
| 13 | 90 | PubMed; simple search; author and stem; sort by publication date; select last page; select correct paper |  |
| 14 | 35 | Google search for nlm; go to [www.nlm.nih.gov](http://www.nlm.nih.gov); click ‘search biomedical literature’; PubMed search author and keyword; go to last page; select correct paper |  |
| 15 | 140 | [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov); select PubMed; simple search first and second author and year of publication; select correct paper |  |
| 16 | 20 | [www.cell.com](http://www.cell.com); search author, keyword and year of publication; go to last page; select correct paper |  |

**Patent searching**

|  |  |  |  |
| --- | --- | --- | --- |
| Participant number | Time taken to find patent (seconds) | Search process | Notes |
| 1 | 625 | Google search: surname, first initial, keyword patent; unsuccessful search; google search: European Patent Office; select ‘searching for patents’; clicked ‘open espacenet at the EPO’; smart search: surname and first initial; 93 results; quick search: search terms box: change type of research to persons or organisations: surname and first initial; 93 results; select advanced search: key words in title search: keywords in title and surname in applicant; 21 results; select wrong patent (too late) “I don’t know if that is the original one or not”; back, select another wrong patent (too late) “no, that’s not the one – I assume that it is before this but I cannot find it, I suppose it might not be iPS, so I could go back to search again and just put stem cell in or something.”; new advanced search: keywords in title: stem, applicant: surname and first initial; 1 result, unrelated; back: applicant: surname and first initial; 12 results (none relevant); “The trouble is, the title of the patent may not be anything to do with the paper”; 3 more searches with different keywords; finally found after dismissing patents which with priority dates too late (“It’s obviously before this”) | Had previous experience of using EPO search. Used inventors name in applicant field. Knew some results were irrelevant by dates. |
| 2 | 530 | Studies paper “I don’t know if it written on the paper”; google search: patent, surname and first initial and keywords; selects result referring to stem cell schools and stem cell intellectual property; google search: patent number, first initial, surname and keywords; select Wikipedia stem cell page; “I cannot find anything” – “you might like to look in a patent database”; google search: patent database; select google patents: search: surname and stem cells; too many results; search: surname key words stem cells; selects patent and reads abstract; “I guess this on maybe … is it this one?” – “No” – “No, it’s a bit late maybe”; back; “This one?” – “Yes” | Thought patent might be referred to on the paper. Randomly picked results – did not know which one was the original patent. |
| 3 | 600 | “I’m not too sure how to do that but okay, I would probably um … I don’t’ know. I would probably hunt, oh, I don’t know really … I really don’t know off the top of my head, I would probably hunt around the patent offices or something like that but I just don’t know. I give up” | [Screen capture did not work but participant used google and espacenet, gave up after 10 minutes] |
| 4 | 600 | “I wouldn’t have a clue where to even begin. What I would do is go to google and put in patent record”; google: patent record; selects link for USPTO – selects patents tab, back to home page, patents; “It’s not obvious is it?”; selects search for patents; selects accessing published applications link, selects link to [www.uspto.gov/patft/index](http://www.uspto.gov/patft/index)); “It’s just pure serendipity which link you go down.”; selects quick search: surname, and keywords; no search results; removes keywords; approx. 11000 results; add second author surname; 845 results; add year of paper; 277 results; add keywords; 4 results “I would think it is that one” – selects patent with later priority date than paper publication date; “No … okay it is that one there” – selects correct patent | Selected wrong patent – priority date too late. |
| 5 | 570 | Bing search: author, year, patent stem cells; select result updating about the patent landscape “is this it?” – No; Bing search: author, year, patent; search referred to different patent holder with same surname; Bing search: author first and surname, year, patent: found later patents; “I can’t think what else I could put in” – recommended to visit a patent database; Bing search: author first and surname, year, patent database; selected page relating to Canadian patent; “is that it?” – “Yes - you have found a related Canadian patent” | Didn’t think there was a related patent, wrongly thought they had found the patent – just found a blog related to it, searched based on year of publication of the paper |
| 6 | 1105 | “I know it must be from before the paper. I am going to look through the paper to see if there is anything about it in there … there is nothing at the end, nothing in the discussion”; google search: surname stem cell patent; looks at a few pages; “Hmm, nothing there I don’t think.”; clicks through to stem cell school homepage; “This isn’t the right sort of information. Hmm, epo.org, is that related to patents?”; back to search results; “I should have just done that [clicked on news page]”; back to search results “I’ll try that epo page”; select epo.org; select patent register; “I’ll do a quick search, oh, I don’t know any of the information it is asking for”; directed to espacenet page; quick search: full text – surname key words and stem cells’ “He’s probably got about a billion.. Hmm, which one, do we know which year it was, 2006 the paper, so before then”; 27 results; browses titles; “I’m going to presume it is one of these because they are related to the same thing as the paper I think.” | Used news page. Didn’t know epo.org related to patents. Had expected both authors of the paper to be on patent. Expected title to use plural version of word which it uses in the singular form. |
| 7 | 1020 | Tab 1: google search ‘author patent keyword’; select Nature News Blog page; opens 3 tabs from links from blog; Tab 3: iPS cell-related patent portfolio; selects first, and correct, patent title (4 minutes); instructed to find full document; google search using reference number from previous result and ‘full patent’; found US patent family (6 minutes) but didn’t select first patent. Participant asked to find if it affects ‘us here’; google patent search for UK Patent Office Search; select [www.ipo.gov.uk](http://www.ipo.gov.uk); search: author; select first result: patent for a pen; use reference number from earlier search; too many results; search: keywords and author first and surname; select “Inventions involving human embryonic stem cells” ([www.ipo.gov.uk/p-pn-stemcells-20090203.htm](http://www.ipo.gov.uk/p-pn-stemcells-20090203.htm)); participant stuck, told to try espacenet; google search for espacenet; select gb portal (wwww.gb.espacenet.com); quick search (words in title or abstract) keywords and author first and surname; no results; visit epo home; smart search; key words and author first and surname; select NZ patent referring to correct patent | Again, used multiple tabs. Found patent citation quickly but couldn’t find correct full patent document, instructed to use espacenet, GB version didn’t yield results – even found a patent for a pen – had to use main EPO page. |
| 8 | 210 | Google search: patent database; select [www.ip.thomson.reuters.com](http://www.ip.thomson.reuters.com); back; select [www.google.com/patents](http://www.google.com/patents); search surname keywords stem cells; 1090 results’ selects correct patent; “is this the one?” “Yes” “I was just going by the date. Because the paper is from 2006 so I thought it must be just before.” | Knew they were looking for patent filed before paper published. |
| 9 | 860 | “Okay, I would look at the back pages [of the paper] because you might get some things written down in here.”; looks through paper; “I’m not seeing any information in here telling me there is anything I need to go and look at … so then what I would probably do is go to espacenet”; google search: espacenet; select GB espacenet home page; quick search, worldwide, persons – both authors; 671 results; “That second one looks good, not exactly it I don’t think … but we also have this one here … which is nearer to the date [of the paper] so I need to find out really about some of these other numbers (points at territory and classification numbers) there are quite a few aren’t there? … okay, so what I would probably need to do is just narrow that down so I can do an advanced search”; advanced search: keywords in title, person – first author; “He has got loads of different ones there … So this is 2009, I should expect to see one earlier. That one should be the original one then. Actually, it could one of those two, the factors are the ones for this paper though. … Those ones are virtually the same really aren’t they, what is the difference between that and that? (2 US patent applications with same title, same priority date but different application numbers and different publication dates) … I wonder what the differences are, I could probably go and look at them now … I would like to see the whole thing so I would go to the original document”; looked through them; not correct patents; “That actually isn’t the patent relating to the paper, it is a later one”; goes back to search results “It’s not on here is it?”; “No.”; told to search for title; used plural of word in title; no results; told to use singular; found patent. | Expected some information about the patent to be in the paper. Had previously used espacenet. Encountered problems because they used keywords not included in the original patent but commonly used to refer to the invention now. Later encountered problems because they used a plural of one word in title, but the patent title contained the word as in its singular form and hence the patent was not found using the search |
| 10 | 535 | Studies paper “Let’s just see if there is anything in here, I am just checking to see if there’s any reference to a patent or anything in here … there is nothing in here, well there probably might well be, but I’m not sure.”; google search: EPO patent; select link to espacenet; select ‘open espacenet at the EPO’; search surname and key word; 0 results; “I might try the advanced one … so let’s have a look here what we can search on. This is where you get confused because would he be an inventor, or would he be an applicant? You would hope he would be an inventor. I couldn’t tell anything about dates, you know, you are never going to guess that from even publication”; advanced search: inventor – surname, and keyword in title or abstract; 6 result; “That looks fairly promising, there are a couple at 200x, I don’t know which one it is, I would have to read them”; “Right, we have got several US ones but they are a nightmare to read because they deal with some stupid format where you need another piece of software to actually read them, they don’t always do PDFs … It is a slightly strange way of doing it as well, you know you think ‘why can’t you just have the whole thing?’”; select one patent, scans, back, selects another, scans, “I would have to read this a bit to see. Okay, so it looks like it is a variation,.., there are two with the same priority … selects JP related patent “This is what I wanted, but that is still the 2011 one isn’t it, I want the equivalent of this one which they are referring to from 2005” | Uncertain whether to use author in inventor or applicant search. Complained it wasn’t simple to find full documents. |
| 11 | 620 | “This is the sort of thing that would take bloody ages I think”; google search: author surname, keyword, patent; selects news page; “I think this is the code of it … so if I just pick one, this is him but I don’t know if he has got more than one; searches several wrong numbers through google, looks through several): “is that the one?” – “No” … “Hmm, this one is earlier [than the paper] so they must be the original ones I’m guessing from the original paper because they were put in before it was published so I’m guessing that, I’ll just try another one. So I’m a bit stuck now”; searches another number from news piece; clicks through to espacenet link; “Is that it? That number?”; “Yes” | Knew it needed to be an earlier filing date than the paper publication. Helped by science journalism piece. |
| 12 | 255 | Google search: author surname patent; selects news piece; back; selects WIPO page; finds WIPO listing of correct patent |  |
| 13 | 880 | Studies paper; google search: patent database country X patent office; selects first result; go to patents page; back to google results; selects ‘how to search foreign patents in english’; select industrial property digital library; select FI/F-term search; search 2nd author surname and stem cell; 0 results; search 2nd author surname; 0 results; “I don’t know what is wrong with it”; directed to espacenet; quick search: 2nd author surname; over 100,000 results’ search words in title or abstract: 2nd author surname and key word and stem cell; 0 results; search words in title or abstract: 2nd author surname and stem cell; 0 results; search: stem cell and keyword; 510 results; back adds persons or organisations: 1st and 2nd author surnames and city of work; 10 results; “I don’t know if any of these are right” “It is on there”, selects at random, looks through; selects one; “I think this one is relevant”, priority date too late; “It is not quite the right one”, back; selects correct one “Is it this one?” – “Yes” |  |
| 14 | 735 | “So now if you could try and find a patent relating to that”; “As far as I know, he never applied for one; there is no patent covering [that type of cell]”; “There are.” …”I’m sure there are some downstream but this first one, I thought he never patented it”; “Well there is something relating to that paper”; Google search: keyword surname IP patent; select investment news story; back; select university announcement; back; new search: keyword, surname, IP patent WIPO; browses results; selects news story; back; select free patents online result “This one is September 2011 … I’m afraid I’m stuck”; google: wipo; select wipo.int; search: surname keywords stem cells; no results; search: surname keyword; no results; search: surname; 1 irrelevant result; back to WIPO homepage, selects patents tab, select patentscope; search surname; selects inventor, select university; select IP services; “This is not helping me, I don’t think it is narrowing the search. And also I am quite impatient, instead of going through all of the instructions on what to do I just start with a gut feeling. Um, okay, I’m stuck”; directed to espacenet; quick search: words in the title or abstract – surname; 12 results: “He is good but he can’t be that good that he applying for patents on that [non-related patents]”; back; news search keywords; 16 results; “This is weird because with that I think we have the right type of patents here so it should be here but I don’t think it is”; advanced search: inventor – surname, keywords in title: keywords; 0 results; back; search different keywords and authors surname; 1 result: select related patent | Didn’t think patents had been applied for covering the type of cells in question. Struggled to find any relevant results through WIPO. Directed to espacenet. Used keyword used commonly to refer to invention but was not in patent so did not yield relevant results. |
| 15 | 410 | Google search: title of paper plus patent plus authors country of birth and work; unsuccessful search; search for international patent office; select [www.wipo.int](http://www.wipo.int); search in box on homepage: keywords; unsuccessful search; home, link to patents, select patentscope; new tab: google search: search author surname, keyword and patent; found blog relating to US patent: asked to find full text; copied reference number to google search; found US patent document |  |
| 16 | 600 | Bing search: surname, patent, keywords; selects Nature commentary piece; bing: patents, Japan; selects Japanese patent office; selects patent link; site search: surname; “No English results. That is no good is it? He is probably the X equivalent of Smith.”; search author name and keywords; “This could take a long time … how many minutes until I can give in? … “I wouldn’t’ usually give in this easily but I think I will have to”; directed to espacenet; advanced search: inventor: surname; “Oh right, I don’t think all of these can be his”; internet slowed; switched to paper task. |  |

Bibliography

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakech Agreement Establishing the World Trade Organisation, signed in Marrakech, Morocco, 15 April 1994

*Association for Molecular Pathology et al. v Myriad Genetics, Inc. et al.* [2013] 569 US 12-398

British Technology Group Act 1991 Ch 66

*Brüstle v Greenpeace* [2012] C-34/10 1 CMLR 41

California Stem Cell Research and Cures Act Proposition 71 2004

‘The case: Myriad at the Supreme Court (Fitzpatrick Cella Haper & Scinto LLP)’ (2013) <<http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Myriad-fischer-rothman-carlin.pdf>> accessed 13 April 2014

‘Cellular Dynamics International IPO (as filed with the Securities and Exchange Commission on June 3, 2013. Registration No. 333)’ (2013) <<http://www.sec.gov/Archives/edgar/data/1482080/000148208013000014/cdi-sx1publicfiling12013.htm>> accessed 05 April 2014

Convention on the Grant of European Patents (European Patent Convention) signed in Munich, Germany, 5 October 1973 as amended (14th Edition, August 2010)

Council Decision 90/221/Euratom, EEC of 23 April 1990 concerning the framework programme of Community activities in the field of research and technological development (1990 to 1994) [1990] OJ L117

Council Decision 87/516/Euratom, EEC of 28 September 1987 concerning the framework programme for Community activities in the field of research and technological development (1987 to 1991) [1987] OJ L302

Council Decision of the European Communities of 1 January 1973 adjusting the documents concerning the accession of the new Member States to the European Communities [1973] OJ L2/1

Council Resolution 4/8/83 of 25 July 1983 on framework programmes for Community research, development and demonstration activities and a first framework programme 1984 to 1987 [1983] OJ C208/26/1

Decision No 182/199/EC of the European Parliament and of the Council of 22 December 1998 concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002) [1999] OJ L26

Decision No 1110/94/EC of the European Parliament and of the Council of 26 April 1994 concerning the fourth framework programme of the European Community activities in the field of research and technological development and demonstration (1994 to 1998) [1994] OJ L126

Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) [2002] OJ L232

Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013) [2006] OJ L310/15

Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities [2006] OJ L412

Development of Inventions Act 1948

Development of Inventions Act 1967

*Diamond v Chakrabarty* [1980] 447 US 303

Directive 94/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (1998)

European Commission (2004) Work programme for the specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area' Priority 1: Life Sciences, Genomics and Biotechnology for Health. Commission Decision C(2004)2002

European Commission (2011) Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) COM(2011) 809

European Commission Communication (2000) 'Towards a European research area' COM(2000) 6

European Commission Communication (2004) 'Europe and Basic Research' COM(2004) 9

European Commission Communication (2008) 'A European Economic Recovery Plan' COM(2008) 800

European Commission Communication (2009) 'On the progress made under the Seventh European Framework Programme for Research' COM(2009) 209

European Commission Communication (2010) 'EUROPE 2020 A strategy for smart, sustainable and inclusive growth' COM(2010) 2020

European Commission Communication (2011) 'Horizon 2020 – The Framework Programme for Research and Innovation' COM(2011) 808

European Commission Communication (2012) 'A Reinforced European Research Area Partnership for Excellence and Growth' COM(2012) 392

European Commission Decision (2008) 2008/37/EC of 14 December 2007 setting up the ‘European Research Council Executive Agency’ for the management of the specific Community programme ‘Ideas’ in the field of frontier research in application of Council Regulation (EC) No 58/2003 OJ L9/15

European Commission Recomendation (2008) on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations C(2008)1329

European Council (2000) Presidency Conclusions, Lisbon European Council, 23-24 March 2000 (No. 100/1/00)

European Council (2002) Council Decision 2002/834/EC adopting a specific programme for research, technological development and demonstration. 'Integrating and strengthening the European Research Area' (2002-06) OJ L294

European Council (2002) Presidency Conclusions, Barcelona European Council, 15 and 16 March 2002 (SN 100/1/02 REV 1)

European Council (2003) Presidency Conclusions, Brussels European Council, 20 and 21 March 2003 (8410/03 Polgen 29)

European Council Regulation (EC) (2008) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines OJ L30/38

European Parliament Resolution Investing in research: an action plan for Europe COM(2003) 226 – 2003/2148(INI)

*G2/06 Wisconsin Alumni Research Fund* [2009] OJ EPO 306

HC Deb 1985, vol 79, col 97-100

HL Deb 1991, vol 529, cc436-63

Human Fertilisation and Embryology (Research Purposes) Regulations 2001

Human Fertilisation and Embryology Act 1990 Ch 37

*International Stem Cell Corporation v Comptroller General of Patents [2013] EWHC 807*

*Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd.* [2004] UKHL 46

‘The NRDC role in technology transfer’ (1983) Electronics & Power 121

Patent and Trademark Amendments Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015-28 (codified at 35 U.S.C.A §§ 200-212 (2001))

Patent Cooperation Treaty, 1970, signed in Washington DC, United States of America, 19 June 1970

The Patents Regulations 2000 (SI 2000 No.2037)

‘Peer to patent’ <<http://www.peertopatent.org/>> accessed 13 April 2014

‘Regenerative Medicine Expert Group’ <https://[www.gov.uk/government/policy-advisory-groups/regenerative-medicine-expert-group](http://www.gov.uk/government/policy-advisory-groups/regenerative-medicine-expert-group)> accessed 10 April 2014

Regulation (EC) 294/2008 of the European Parliament and of the Council of 11 March 2008 establishing the European Institute of Innovation and Technology [2008] OJ L97/1

Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC

‘Request for *ex parte* reexamination patent number 5, 843, 780 Primate Embryonic Stem Cells’ (2006) <<http://www.pubpat.org/assets/files/warfstemcell/780Request.pdf>> accessed 13 April 2014

Science and Technology Act 1965

Senate Report No. 96-480 (1979) University and Small Business Patent Procedures Act Report of the Committee on the Judiciary United States Senate

Single European Act [signed 1986, entered into force 1987] OJ 169

Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311-2320 (codified as amended at 15 U.S.C. §§ 3701-3714 (1994))

*Technion Research and Development Foundation, Ltd. [2014] T 2221/10*

Treaty establishing the European Atomic Energy Community [signed 1957, entered into force 1958]

Treaty establishing the European Coal and Steel Community [signed 1951, entered into force 1952, expired 23 July 2002]

Treaty establishing the European Economic Community [signed 1957, entered into force 1958]

Treaty on the European Union [signed 1992, entered into force 1993] OJ C 191

Treaty on the Functioning of the European Union [signed 2007, entered into force 2009] OJ C306

U.S. Code Title 35-Patents

‘UCL-Pfizer to develop pioneering stem cell sight therapies’ (2009) <<http://www.ucl.ac.uk/news/news-articles/0904/09042301>> accessed 07 April 2014

‘UCL and Pfizer Announce Extension to Collaboration To Advance Development Of Stem Cell-Based Therapies’ (2011) <<http://www.ucl.ac.uk/ioo/news110225.php>> accessed 11 April 2014

‘Wellcome Trust and MRC invest in world-class Stem Cell Institute at Cambridge (August 2012)’ (2012) <<http://www.cam.ac.uk/research/news/wellcome-trust-and-mrc-invest-in-world-class-stem-cell-institute-at-cambridge/>> accessed 23 April 2014

Academy of Medical Sciences, *A new pathway for the regulation and governance of health research* (Sciences AoM 2011)

Adams J, ‘History of the patent system’ in Takenaka T (ed), *Patent Law and Theory A Handbook of Contemporary Research* (Edward Elgar 2008)

Agar J, ‘Thatcher, Scientist’ Notes and Records of the Royal Society <<http://rsnr.royalsocietypublishing.org/content/early/2011/05/13/rsnr.2010.0096.abstract>> accessed May 25, 2011

Agrawal A and Henderson R, ‘Putting Patents in Context: Exploring Knowledge Transfer from MIT’ (2002) 48 Management Science 44

Andrews PW and Gokhale PJ, ‘From teratomas to embryonic stem cells: discovering pluripotency’ (2011) 12 Nature Reviews Molecular Cell Biology

Ayres I and Braithwaite J, *Responsive Regulation: Transcending the Deregulation Debate* (OUP 1992)

Azoulay P, Ding W and Stuart T, ‘The determinants of faculty patenting behavior: Demographics or opportunities?’ (2007) 63 J Econ Behavior & Organization 599

Baker J, *Creating Knowledge Creating Wealth: Realising the economic potential of public sector research establishments* (Treasury H 1999)

Bard BJA, ‘The National Research Development Corporation’ (1955) 71 Aslib Proceedings 84

Battistelli B, ‘The future of the European patent system - current developments and trends. Speech by Mr Benoît Battistelli President of the European Patent Office to the ASEAN Member States-EPO Heads of Intellectual Property Offices Conference ’ (2011) <<http://www.epo.org/news-issues/press/speeches/20121109.html>> accessed 2 April 2014

BBSRC, ‘UK Regenerative Medicine Platform’ (2012) <<http://www.bbsrc.ac.uk/web/FILES/PreviousAwards/uk-regenerative-medicine-platform-bgrd.pdf>> accessed 10 April 2014

Bently L and Sherman B, *Intellectual Property* (3rd edn, OUP 2009)

Bergman K and Graff GD, ‘The global stem cell patent landscape: implications for efficient technology transfer and commercial development’ (2007) 25 Nature Biotechnology 419

Bessen J and Meurer MJ, *Patent failure: How judges, bureaucrats and lawyers put innovators at risk* (Princeton UP 2008)

Bhattacharya A, ‘Science funding: Duel to the death’ (2012) 488 Nature 20

Björk B-C and others, ‘Open Access to the Scientific Journal Literature’ (2010) 5 PLoS One 1

Boehm K and Silberston A, *The British patent system* (CUP 1967)

Bok D, ‘The Benefits and Costs of Commercialization of the Academy’ in Stein DG (ed), *Buying in or selling out? The Commercialization of the American Research University* (Rutgers UP 2004)

Braithwaite J, ‘On speaking softly and carrying big sticks: Neglected dimensions of a republican separation of powers’ (1997) 47 UTLJ 305

–––, *Restorative Justice and Responsive Regulation* (OUP 2002)

Branstetter L and Ogura Y, ‘Is Academic Science Driving a Surge in Industrial Innovation? Evidence from Patent Citations NBER Working Paper 11561 (2005)’ <<http://repository.cmu.edu/sds/48>> accessed 10 April 2014

Braun V and Clarke V, ‘Using thematic analysis in psychology’ (2006) 3 Qualitative research in psychology 77

Bruneel J and others, *The search for talent and technology: Examining the Attitudes of EPSRC Industrial Collaborators towards Universities* (Advanced Institute of Management Research 2009)

Brüstle O, *Neural precursor cells, method for the production and use thereof in neural defect therapy (PCT/DE1998/003817)* (1999)

–––, *Neural precursor cells, method for the production and use thereof in neural therapy (DE1997156864)* (1997)

Bryman A, ‘June 1989 and beyond: Julia Brannen’s contribution to mixed methods research’ (2014) Int J Social Research Methodology 1

–––, *Social Research Methods* (OUP 2012)

BTG, ‘History’ <<http://www.btgplc.com/about-us/history>> accessed 23 April 2014

Busquin P, ‘Introduction at 'Ethical aspects of stem cell repositories and stem cell databases' conference in Brussels’ <<http://archive.eurostemcell.org/Documents/Ethics/Philipe_Busquin.pdf>>

California Institute of Regenerative Medicine, ‘Summary of CIRM rounds of funding’ (2012) <<http://www.cirm.ca.gov/our-funding/where-our-funding-goes/funding-rounds/summary-cirm-rounds-funding>> accessed 05/01/13

Campbell KH and others, ‘Sheep cloned by nuclear transfer from a cultured cell line’ (1996) 380 Nature 64

Caulfield T, ‘Stem cell patents and social controversy: A speculative view from Canada’ (2006) 7 Med L Int 219

–––, ‘Stem Cell Research and Economic Promises’ (2010) 38 JL Med & Ethics 303

Caulfield T, Bubela T and Murdoch C, ‘Myriad and the mass media: the covering of a gene patent controversy’ (2007) 9 Genetics in Medicine 850

Caulfield T and others, ‘Patents, commercialization and the Canadian stem cell research community’ (2008) 3 Regenerative Medicine 483

Caulfield T and others, ‘International stem cell environments: a world of difference’ (2009) Nature Reports Stem Cells

Cell Therapy Catapult, ‘Budget unveils £55m large-scale Cell Therapy Manufacturing Centre for the UK’ (2014) <https://ct.catapult.org.uk/news-page/-/asset\_publisher/tDqW3YjSO45r/content/budget-unveils-%C2%A355m-large-scale-cell-therapy-manufacturing-centre-for-the-uk> accessed 10 April 2014

Centre for Patent Innovations at New York Law School, ‘Peer to Patent First Anniversary Report’ (*New York Law School*, 2008) <<http://dotank.nyls.edu/communitypatent/P2Panniversaryreport.pdf>> accessed 23 April 2014

–––, ‘Peer to Patent Second Anniversary Report’ (2009) <<http://dotank.nyls.edu/communitypatent/CPI_P2P_YearTwo_lo.pdf>> accessed 23 April 2014

CIPA, ‘Code of Conduct and Discipline’ <<http://www.cipa.org.uk/pages/Conduct_discipline>> accessed 20/08/2014

CMS Legal, ‘International Patent Litigation Guide’ (2013) <<http://www.cmslegal.com/patentswithoutborders/Documents/CMS%20International%20Patent%20Litigation%20Guide%202013.PDF>> accessed 23 April 2014

Converse JM and Presser S, *Survey questions: Handcrafting the standardized questionnaire*, vol 63 (Sage 1986)

Cook-Deegan R, *The gene wars: science, politics, and the human genome* (W. W. Norton & Company Ltd 1994)

Cook T, ‘Stem Cell Patenting in the European Union’ (2012) 17 JIPR 73

Cookson C and Jack A, ‘Pfizer to build £41m UK stem cell centre (Financial Times, 13 November 2008)’ (2008) <<http://www.ft.com/cms/s/0/9f12390e-b1b7-11dd-b97a-0000779fd18c.html>> accessed 23 April 2014

Cookson C and Jack A, ‘US Supreme Court rules that only synthetic genes are patentable (Financial Times, 13 June 2013)’ (2013) <<http://www.ft.com/cms/s/0/bde7853c-d43a-11e2-a464-00144feab7de.html>> accessed 23 April 2014

Creswell J, Clark VP and Garrett A, ‘Methodological Issues in Conducting Mixed Methods Research Designs ’ in Bergman MM (ed), *Advances in mixed methods research: Theories and applications* (Sage 2008)

Creswell JW, *Research design: Qualitative and quantitative approaches* (Sage 1995)

Creswell JW, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (3rd edn, Sage 2009)

Dame Janet Finch, *Accessibility, sustainability, excellence: how to expand access to research publications: Report of the Working Group on Expanding Access to Published Research Findings* (Research Innovation Network 2012)

Darrow JJ, ‘Neglected Dimension of Patent Law's PHOSITA Standard’ (2009) 23 Harv JL & Tech 227

Davies DS, ‘The Early History of the Patent Specification’ (1934) 50 LQR 86

Denzin N, *The Research Act* (2nd edn, McGraw-Hill 1987)

Department for Business Innovation & Skills, ‘About BIS’ <<http://www.bis.gov.uk/about>> accessed 23 April 2014

–––, ‘Business Plan 2012-2015 ’ (2012) <<http://www.bis.gov.uk/assets/biscore/corporate/docs/b/12-p58-bis-2012-business-plan.pdf>> accessed 23 April 2014

–––, *Following up the Wilson review of business-university collaboration: next steps for universities, business and government* (BIS 2012)

–––, *The Government's Response to Sir Andrew Witty's Review of Universities and Growth* (BIS 2014)

–––, *Higher Education: Students at the Heart of the System (White Paper, Cm 8122, 2011)*

–––, *Innovation and Research Strategy for Growth (White Paper, Cm 8239, 2011)*

–––, ‘Letter to Dame Janet Finch on the Government Response to the Finch Group Report: “Accessibility, sustainability, excellence: how to expand access to research publications”’ (2012) <<http://www.bis.gov.uk/assets/biscore/science/docs/l/12-975-letter-government-response-to-finch-report-research-publications.pdf>> accessed 23 April 2014

–––, ‘Public Sector Research Exploitation Fund’ <<http://www.bis.gov.uk/policies/science/knowledge-transfer/psre>> accessed 23 April 2014

–––, ‘Strategy for UK Life Sciences’ (2011) <<http://www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences>> accessed 23 April 2014

Department for Business Innovation & Skills and Department of Health, *Taking Stock of Regenerative Medicine in the United Kingdom* (BIS 2011)

Department for Innovation Universities & Skills, *Innovation Nation (White Paper, Cm 7345, 2008)*

Department of Commerce and US Patent and Trademark Office, *Notice of Request for Comments on the Feasibility of Placing Economically Significant Patents Under a Secrecy Order and the Need to Review Criteria Used in Determining Secrecy Orders Related to National Security (Federal Register, 77:77, 23662-23665)* (2012)

Department of Health and others, *Science and innovation investment framework 2004-2014: next steps* (HMSO 2006)

Department of Trade and Industry, *Our Competitive Future: Building the Knowledge Driven Economy (White Paper, Cm 4176, 1998)*

Devlin A, ‘The misunderstood function of disclosure in patent law’ (2010) 23 Harv JL & Tech 401

Dobbs ER, ‘The Organisation and Control of Scientific Research by the United Kingdom Government’ (1972) 1 Higher Education 345

Drahos P, *The Global Governance of Knowledge* (CUP 2010)

–––, *A Philosophy of Intellectual Property* (Dartmouth Publishing Group 1996)

Drahos P and Braithwaite J, *Information Feudalism* (Earthscan Publications Ltd 2002)

Dulken Sv (ed) *Introduction to Patents Information* (4th edn, The British Library 2002)

Dutfield G, *Intellectual Property Rights and the Life Sciences Industries Past, Present and Future* (2nd edn, World Scientific 2009)

Economic and Social Research Council, *Science in the economy and the economics of science* (ESRC 2007)

Eisenberg R, ‘Genomics in the public domain: strategy and policy’ (2000) 1 Nature Reviews Genetics 70

–––, ‘How Can You Patent Genes?’ (2002) 2 Am J Bioethics 3

–––, ‘Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA’ (2004) 19 Berkeley Tech LJ 885

–––, ‘Patenting the human genome’ (1990) 39 Emory LJ 721

–––, ‘Proprietory Rights and the Norms of Science in Biotechnology Research’ (1987) 97 Yale LJ 177

–––, ‘Public Research and Private Development: Patents and Technology Transfer in Government-Sponsered Research’ (1996) 82 Virginia L Rev 1663

–––, ‘Re-examining the role of patents in appropriating the value of DNA sequences’ (2000) 49 Emory LJ 783

–––, ‘Structure and function in gene patenting ’ (1997) 15 Nature Genetics 125

Emmerich C, ‘Comparing first level patent data with value-added patent information: A case study in the pharmaceutical field’ (2009) 31 World Patent Information 117

Enrico Deiaco, Hughes A and McKelvey M, ‘Universities as strategic actors in the knowledge economy’ (2012) 36 Camb J Econ 525

EPO, ‘Business use of patent information’ <<http://www.epo.org/searching/essentials/business.html>> accessed 09 April 2014

–––, ‘Espacenet Quick help’ <<http://worldwide.espacenet.com/help;jsessionid=AD7A4B3001A9E254D861D581D3B2D6EB.espacenet_levelx_prod_2?quickHelpPage=inpadoclegalstatus.5&locale=en_EP&method=handleQuickHelp#q3>> accessed 05 April 2014

–––, ‘INPADOC legal status’ <<http://worldwide.espacenet.com/help?topic=legalstatusqh&locale=en_EP&method=handleHelpTopic>> accessed 05 April 2014

–––, *Scenarios for the future: how might IP regimes evolve by 2025? What global legitimacy might such regimes have?* (European Patent Office 2007)

Etzkowitz H, ‘The evolution of the entrepreneurial university’ (2004) 1 Int J Tech & Globalisation 64

Etzkowitz H and Leydesdorff L, ‘The dynamics of innovation: from National Systems and "Mode 2" to a Triple Helix of university-industry-government relations’ (2000) 29 Research Policy 109

–––, ‘The Future Location of Research and Technology Transfer’ (1999) 24 J Tech Transfer 111

Etzkowitz H and others, ‘The future of the university and the university of the future: evolution of ivory tower to entrepreneurial paradigm’ (2000) 29 Research Policy 313

European Commission, ‘Development of Community research - commitments 1984-2013’ <<http://ec.europa.eu/research/fp7/pdf/fp-1984-2013_en.pdf#view=fit&pagemode=none>> accessed 20 April 2014

–––, ‘Guide to Intellectual Property Rights provisions for FP6 projects. Version 2’ <<http://ec.europa.eu/research/fp6/model-contract/pdf/fp6-iprguidelines_en.pdf>> accessed 23 April 2014

–––, ‘Guide to Intellectual Property Rules for FP7 Projects. Version 3’ <<http://ec.europa.eu/research/participants/portal/ShowDoc/Extensions+Repository/General+Documentation/Guidance+documents+for+FP7/Intellectual+property+rules/ipr_en.pdf;efp7_SESSION_ID=CqW8Q2QC4XFzJ2Z93DfxCGL7n3ZMHqwX8y2v7kKCtp5vQy924G3P!-1607111007>> accessed 23 April 2014

–––, *Press Release 'Scientific data: open access to research results will boost Europe's innovation capacity' (IP/12/790)* (2012)

European Commission Directorate General for Research Life Sciences Genomics and Biotechnologies for Health, *Stem Cells: European research projects involving stem cells in the 6th Framework Programme* (European Commission 2008)

European Research Council, ‘Glossary: Frontier Research ’ <<http://erc.europa.eu/glossary/term/267>> accessed 23 April 2014

–––, ‘Mission’ <<http://erc.europa.eu/about-erc/mission>> accessed 23 April 2014

EuroStemCell, ‘European Court bans stem cell patents’ (2011) <<http://www.eurostemcell.org/story/european-court-bans-stem-cell-patents>> accessed 23 April 2014

EuroStemCell, Institute for Integrated Cell-Material Sciences and Elsevier, *Stem Cell Research: Trends and Perspectives on the Evolving International Landscape* (Elsevier 2013)

Feldman MP, Colaianni A and Liu CK, ‘Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program’ Intellectual property management in health and agricultural innovation: a handbook of best practices, Volumes 1 and 2 <<http://www.iphandbook.org/handbook/ch17/p22/>>

Feldman R and Furth D, ‘The Intellectual Property Landscape for iPS Cells’ (2010) 3 Stan JL Science & Policy 16

Fromer JC, ‘Patent Disclosure’ (2009) 94 Iowa L Rev 539

Fujii A, Iwayama M and Kando N, ‘Overview of the patent retrieval task at the NTCIR-6 workshop’ (2007) Proceedings of the Sixth NTCIR Workshop Meeting 359

Ganguli P, Khanna R and Prickril B, ‘Defining the Future: Emerging Issues in Biotechnology, Intellectual Property Rights and Technology Transfer’ in Ganguli P, Khanna R and Prickril B (eds), *Technology Transfer in Biotechnology: A Global Perspective* (Wiley 2009)

Geuna A, ‘The Changing Rationale for European University Research Funding: Are There Negative Unintended Consequences?’ (2001) 35 J Econ Issues 607

Geuna A and Martin BR, ‘University research evaluation and funding: an international comparison’ (2003) 41 Minerva 277

Geuna A and Nesta LJ, ‘University patenting and its effects on academic research: The emerging European evidence’ (2006) 35 Research Policy 790

Gibbons M and others, *The new production of knowledge: The dynamics of science and research in contemporary societies* (Sage 1994)

Gitter DM, ‘International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption’ (2001) 76 NYUL Rev 1623

Glänzel W and Meyer M, ‘Patents cited in the scientific literature: An exploratory study of 'reverse' citation relations’ (2003) 58 Scientometrics 415

Google, ‘About google patents’ <<http://www.google.com/googlepatents/about.html>> accessed 29 September 2011

Government Office for Science and Department for Business Innovation & Skills, *Technology and Innovation Futures: UK Growth Opportunities for the 2020s* (BIS 2010)

Gowers A, *Gowers Review of Intellectual Property* (HMSO 2006)

Graff GD and others, ‘Not quite a myriad of gene patents’ (2013) 31 Nature Biotechnology 404

Grata G, ‘The Innovate/SMEs programme and the IPR Helpdesk: Director, Innovation/SMEs programme, introduces the IPR-Helpdesk ’ <<ftp://ftp.cordis.europa.eu/pub/focus/docs/supplement_ipr99_en.pdf> > accessed 23 April 2014

Grimaldi R and others, ‘30 years after Bayh–Dole: Reassessing academic entrepreneurship’ (2011) 40 Research Policy 1045

Guellec D and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System - IP Policy for Innovation and Competition* (OUP 2007)

Guest G, Bunce A and Johnson L, ‘How many interviews are enough? An experiment with data saturation and variability’ (2006) 18 Field Methods 59

Gurry F, ‘The Disclosure of Technology in the Patent System, speech at the Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate’ (2011) <<http://www.wipo.int/about-wipo/en/dgo/speeches/dg_who_wipo_wto_med_11.html>> accessed 14 April 2014

Haigh GE and others, ‘NRDC and the Environment for Innovation’ (1971) 232 Nature 527

Hall M, Oppenheim C and Sheen M, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I: Questionnaire survey’ (1999) 25 J Info Science 335

–––, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part II: Results of in-depth interviews’ (2000) 26 J Info Science 87

Hamilton A, Madison J and Jay J, *The federalist papers* (OUP 2008)

Harmon SH, Laurie G and Courtney A, ‘Dignity, plurality and patentability: the unfinished story of Brustle v Greenpeace’ (2013) 38 E L Rev 92

HEFCE, *Higher Education – Business and Community Interaction Survey: 2011-12* (HEFCE 2013)

–––, ‘Higher Education Innovation Funding 2011-12 to 2014-15. Policy, final allocations and request for institutional strategies (2011/16)’ (2011) <<http://www.hefce.ac.uk/media/hefce1/pubs/hefce/2011/1116/11_16.pdf>> accessed 23 April 2014

–––, ‘Special initiative Invitation to apply for funds UK Research Partnership Investment Fund 2012-2015 (2012/12)’ (2012) <<http://www.hefce.ac.uk/media/hefce/content/pubs/2012/201212/UKRPIF%20final%2011%20May%202012.pdf>> accessed 23 April 2014

Heller MA and Eisenberg RS, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ (1998) 280 Science 698

Henderson R, Jaffe AB and Trajtenberg M, ‘Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965–1988’ (1998) 80 Rev Econ & Statistics 119

Hill MW, ‘Access in Britain to patent documents and information’ (1981) 3 World Patent Information 9

HM Government, *Government Response to the House of Lords Science and Technology Committee Inquiry into Regenerative Medicine (Cm 8713, 2013)*

HM Revenue & Customs, ‘ERSM100030 - University Spin-outs: What is a spin-out company?’ <<http://www.hmrc.gov.uk/manuals/ersmmanual/ersm100030.htm>> accessed 23 April 2014

HM Treasury, *Budget 2005 (HC372)* (2005)

–––, *Budget 2012 (HC1853)* (2012)

–––, *Lambert Review of Business-University Collaboration: Summary of Consultation Responses and Emerging Issues* (HMSO 2003)

–––, *Treasury Circular 5/50* (1950)

HM Treasury, Department of Trade and Industry and Department for Education and Skills, *Science and Innovation Investment Framework 2004-2014* (HMSO 2004)

Holbrook TR, ‘Possession in Patent Law’ (2006) 59 Southern Methodist University Law Review 123

Holden C, ‘Prominent Researchers Join the Attack on Stem Cell Patents’ (2007) 317 Science 187

House of Commons Innovation Universities Science and Skills Committee, *Putting science and engineering at the heart of government policy: eighth report of session 2008-09, Vol. 1: Report, together with formal minutes*, vol 168 (The Stationary Office 2009)

House of Lords Science and Technology Committee, *Regenerative medicine* (Office TS 2013)

House of Lords Science and Technology Select Committee, *Regenerative Medicine: Oral and Written evidence* (2013)

House of Lords Select Committee on Stem Cell Research, *Stem Cell Research HL 83(i)* (HMSO 2002)

Hughes A, ‘Open innovation, the Haldane Principle and the new production of knowledge: science policy and university-industry links in the UK after the financial crisis’ Centre for Business Research, University of Cambridge Working Paper No 425 (2011) <<http://www.cbr.cam.ac.uk/pdf/WP425.pdf>> accessed 23 April 2014

Hughes A and Kitson M, ‘Pathways to impact and the strategic role of universities: new evidence on the breadth and depth of university knowledge exchange in the UK and the factors constraining its development’ (2012) 36 Cambridge journal of economics 723

Hughes A and Martin B, ‘Enhancing Impact: The value of public sector R&D’ <<http://www.cbr.cam.ac.uk/pdf/Impact%20Report%20-%20webversion.pdf>> accessed 23 April 2014

Innovative Medicines Initiative, ‘Mission’ <<http://www.imi.europa.eu/content/mission> > accessed 23 April 2014

Intellectual Property Awareness Network, UK Intellectual Property Office and National Union of Students, *Student attitudes towards intellectual property* (NUS 2012)

IPReg, (2014) <<http://ipreg.org.uk/wp-content/files/2014/04/IPO-Code-of-Practice.pdf> > accessed 20/08/2014

Jaffe AB and Lerner J, *Innovation and Its Discontents - How our broken patent system is endangering innovation and progress, and what to do about it* (3rd edn, Princeton UP 2007)

Jain S, George G and Maltarich M, ‘Academics or entrepreneurs? Investigating role identity modification of university scientists involved in commercialization activity’ (2009) 38 Research Policy 922

Janis MD and Holbrook TR, ‘Patent Law's Audience’ (2012) 97 Minn L Rev

Jasanoff S, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton UP 2005)

Joho H, Azzopardi LA and Vanderbauwhede W, ‘A survey of patent users: an analysis of tasks, behavior, search functionality and system requirements’ (2010) Proceedings of the third symposium on information interaction in context 13

Jones R, ‘SPERI Paper No.6 - The UK's Innovation Deficit & How to Repair it’ <<http://speri.dept.shef.ac.uk/wp-content/uploads/2013/10/SPERI-Paper-No.6-The-UKs-Innovation-Deficit-and-How-to-Repair-it-PDF-1131KB.pdf>> accessed 10 April 2014

Kabler K, ‘Burdens of Section 101 following Myriad (Fenwick & West LLP)’ (2013) <<http://www.fenwick.com/FenwickDocuments/Burdens_of_Section_101.pdf>> accessed 13 April 2014

Kapczynski A, ‘Addressing Global Health Inequalities: An Open Licensing Approach for University Innovations’ (2005) 20 Berkeley Tech LJ 1031

Keith S, ‘Inventions, patents and commercial development from governmentally financed research in Great Britain: the origins of the National Research Development Corporation’ (1981) 19 Minerva 92

Kieff SF, ‘Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science-A Response to Rai and Eisenberg’ (2000) Volume 95 Northwestern University School of Law Law and Economics Papers

Kitch E, ‘The Nature and Function of the Patent System’ (1977) 20 J L & Econ 265

Knoepfler P, ‘Treasure Trove Cellular Dynamics IPO filing: big money, iPS cell IP rights, and trade secrets’ (2013) <<http://www.ipscell.com/tag/ips-cell-patents/>> accessed 05 April 2014

Konski AF and Spielthenner DJ, ‘Stem cell patents: a landscape analysis’ (2009) 27 Nature Biotechnology 722

Krimsky S, ‘The Profit of Scientific Discovery and Its Normative Implications’ (1999) 75 Chi-Kent L Rev 15

Krosnick JA and others, ‘The Impact of "No Opinion" Response Options on Data Quality: Non-Attitude Reduction or an Invitation to Satisfice?’ (2002) 66 The Public Opinion Quarterly 371

Lagemaat WG, ‘Patent archives – the silent threat’ (2005) 27 World Patent Information 27

Lambert R, *Lambert Review of Business-University Collaboration* (HMSO 2003)

Lander ES, *Brief for amicus curiae Eric S. Lander in support of neither party, Myriad, 133 S. Ct. 2107 (No. 12-398)* (2013)

Laurie G, ‘Patenting Stem Cells of Human Origin’ (2004) 26 EIPR

Lebovitz RM, ‘The Duty to Disclose Patent Rights’ (2007) 6 Nw J Tech & Intell Prop 36

Lee P, ‘Patents and the university’ (2013) 63 Duke LJ

Lei Z, Jenuja R and Wright BD, ‘Patents versus patenting: implications of intellectual property protection for biological research’ (2009) 27 Nature Biotechnology 36

Lemley MA, ‘Patenting Nanotechnology’ (2005) 58 Stan L Rev 601

–––, ‘Rational Ignorance at the Patent Office’ (2001) 95 Nw UL Rev

Lord Rothschild, *A Framework for Government Research and Development (Cmnd 5046, 1972)*

Lord Sainsbury of Turville, *The Race to the Top - A Review of Government’s Science and Innovation Policies* (HMSO 2007)

Lords Select Committee, ‘Inquiry launch: Regenerative Medicine ’ (2012) <<http://www.parliament.uk/business/committees/committees-a-z/lords-select/science-and-technology-committee/news/regenerative-medicine-inquiry-launch/> > accessed 23 April 2014

Loring JF and Campbell C, ‘Intellectual Property and Human Embryonic Stem Cell Research’ (2006) 311 Science 1716

Macdonald S, ‘Exploring the Hidden Costs of Patents’ in Drahos P and Mayne R (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan 2002)

Machlup F, *An Economic Review of the Patent System* (Office USGP 1958)

Machlup F and Penrose E, ‘The Patent Controversy in the Nineteenth Century’ (1950) 10 J Econ History 1

MacLeod C, *Inventing the industrial revolution: The English patent system, 1660-1800* (CUP 2002)

Martin BR, ‘The Research Excellence Framework and the ‘impact agenda’: are we creating a Frankenstein monster?’ (2011) 20 Research Evaluation 247

Martin P and Bateson P, *Measuring behaviour* (CUP 1986)

McCall GJ, ‘Systematic field observation’ (1984) Annual Review of Sociology 263

McDonald-Maier L, ‘esp@cenet: Survey reveals new information about users’ (2009) 31 World Patent Information, 142

McKusick VL, ‘A Study of Patent Policies in Educational Institutions, Giving Specific Attention to the Massachussetts Institute of Technology’ (1948) 245 J Franklin Institute 193

McLachlan G and Whitehead TP, *Five Years After: A Review of Health Care Research Management After Rothschild: Including an Essay by Thomas P. Whitehead* (OUP 1978)

McVeigh K, ‘US supreme court rules human genes cannot be patented (The Guardian, 13 June 2013)’ (2013) <<http://www.theguardian.com/law/2013/jun/13/supreme-court-genes-patent-dna>> accessed 23 April 2014

Meara JP, ‘Just Who is the Person Having Ordinary Skill in the Art-Patent Law's Mysterious Personage’ (2002) 77 Wash L Rev 267

Merton R, *The sociology of science: theoretical and empirical investigations* (The University of Chicago Press 1973)

Meyer M, ‘Does science push technology? Patents citing scientific literature’ (2000) 29 Research Policy 409

Mills AE and Tereskerz PM, ‘Empirical analysis of major stem cell patent cases: the role of universities’ (2010) 28 Nature Biotechnology 325

Ministry of Reconstruction, *Report on the machinery of Government (Cd 9230, 1918)*

Ministry of Science Technology and Innovation (Denmark), ‘The European Research Council: A Cornerstone in the European Research Area. Report from an expert group ’ (2003) <<http://erc.europa.eu/sites/default/files/content/ERCexpertgroupfinalreport.pdf>> accessed 23 April 2014

Moir HV, *Patent Policy and Innovation: Do Legal Rules Deliver Effective Economic Outcomes?* (mcEdward Elgar 2013)

Moran N, ‘European court bans embryonic stem cell patents’ (2011) 29 Nature Biotechnology 1057

Mowery D and others, ‘The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980 ’ (2001) 30 Research Policy 99

Mowery DC and Sampat BN, ‘University Patents and Patent Policy Debates in the USA, 1925-1980’ (2001) 10 Industrial and Corporate Change 781

MRC, ‘About us: Our origins’ <<http://www.mrc.ac.uk/About/History/index.htm>> accessed 05 April 2014

–––, ‘Wellcome Trust and MRC invest £13m to create a new national stem cell resource’ (2012) <<http://www.mrc.ac.uk/Newspublications/News/MRC008920>> accessed 23 April 2014

MRC and others, *A Strategy for UK Regenerative Medicine* (MRC 2012)

Murray F, ‘The Stem-Cell Market - Patents and the Pursuit of Scientific Progress’ (2007) 356 New Eng J Med 2341

Murray F and Stern S, ‘Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis’ (2007) 63 J Econ Behavior & Organization 648

Narin F, Hamilton KS and Olivastro D, ‘The increasing linkage between US technology and public science’ (1997) 26 Research Policy 317

National Endowment for Science TatA, *(2009) The Connected University Driving Recovery and Growth in the UK Economy (TCU/23)* (NESTA)

National Institute for Biological Standards and Control, (UK Stem Cell Bank: Patent Depositary Service ) <<http://www.nibsc.org/uk_stem_cell_bank/patent_depositary.aspx>> accessed 07 April 2014

National Institutes of Health, ‘Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)’ (2012) <<http://report.nih.gov/categorical_spending.aspx>> accessed 15 April 2014

–––, ‘Stem cell glossary’ <<http://stemcells.nih.gov/info/pages/glossary.aspx>> accessed 23 April 2014

Newton D, ‘A survey of users of the new British Library Patent Information Centre’ (2000) 22 World Patent Information 317

NHS Choices, ‘Hope and hype: An analysis of stem cells in the media’ (2011) <<http://www.nhs.uk/news/2011/11November/Documents/hope_and_hype_1.0.pdf> > accessed 23 April 2014

Nielen M, Vries Sd and Geijsen N, ‘European stem cell research in legal shackles’ (2013) 32 EMBO 3107

Noveck B, ‘"Peer to Patent": Collective Intelligence, Open Review and Patent Reform’ (2006) 20 Harv JL & Tech 123

–––, *Wiki Government: How technology can make government better, democracy stronger, and citizens more powerful* (Brookings 2009)

Nuffield Council on Bioethics, *Emerging biotechnologies: technology, choice and the public good* (Bioethics NCo 2013)

–––, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council on Bioethics 2002)

OECD, *Commercialising Public Research: New Trends and Strategies* (OECD 2013)

–––, *Innovation and Growth - rationale for an innovation strategy* (OECD 2007)

–––, ‘OECD Glossary of Statistical Terms’ <<http://stats.oecd.org/glossary/detail.asp?ID=6864>> accessed 23 April 2014

–––, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003)

Office for National Statistics, *UK Gross Domestic Expenditure on Research and Development, 2012* (ONS 2014)

Office of Science and Technology, *The Government’s Response to the Baker Report: “Creating Knowlege, Creating Wealth:” Realising the economic potential of Public Sector Research Establishments* (HMSO 2000)

–––, *Realising our Potential: A Strategy for Science, Engineering and Technology (White Paper, Cm 2250, 1993)*

Orwant J, ‘Improving Google Patents with European Patent Office patents and the Prior Art Finder’ (2012) <<http://googleresearch.blogspot.co.uk/2012/08/improving-google-patents-with-european.html>> accessed 02 April 2014

Osborne G, *Speech by the Chancellor of the Exchequer, Rt Hon George Osborne MP, to the Royal Society (9th November)* (2012)

Ouellette LL, ‘Do Patents Disclose Useful Information?’ (2012) 25 Harv JL & Tech 531

Owen-Smith J and Powell WW, ‘Careers and contradictions: faculty responses to the transformation of knowledge and its uses in the life sciences’ in Vallas S (ed), *The Transformation of Work (Research in the Sociology of Work, Volume 10)* (Emerald Group Publishing Ltd 2001)

Parliamentary Office of Science and Technology, *Stem Cell Research* (POST 2013)

PatCom, ‘Mission Statement’ <<http://www.patcom.org/>> accessed 02 April 2014

Pavitt K, ‘Public policies to support basic research: What can the rest of the world learn from US theory and practice?(And what they should not learn)’ (2001) 10 Industrial and Corporate Change 761

Peer-to-Patent, ‘Peer to Patent’ <<http://www.peertopatent.org/>> accessed 23 April 2014

Pfizer, ‘Pfizer's Stem Cell Research Policy’ <<http://www.pfizer.com/research/research_clinical_trials/stem_cell_research>> accessed 11 April 2014

Plomer A, ‘After Brustle: EU accession to the ECHR and the future of European patent law’ (2012) 2 Queen Mary Journal of Intellectual Property 110

–––, ‘Beyond the HFE Act 1990: the regulation of stem cell research in the UK’ (2002) 10 MLR 132

–––, ‘EU Ban on Stem Cell Patents: Intended and Unintended Consequences’ (2011) <<http://eutopialaw.com/2011/11/04/eu-law-and-the-human-embryo-the-consequences-of-brustle-v-greenpeace/#more-644>> accessed 11 April 2014

–––, ‘Horizon 2020: EU funding of hESC research in the balance’ (2012) <<http://eutopialaw.com/2012/10/24/horizon-2020-eu-funding-of-hesc-research-in-the-balance/>> accessed 11 April 2014

Plomer A and others, *Stem Cell Patents: European Patent Law and Ethics Report (FP6 ‘Life sciences, genomics and biotechnology for health. Project number SSA LSSB-CT-2004-005251)* (Nottingham Uo 2006)

Plomer A, Taymor KS and Scott CT, ‘Challenges to Human Embryonic Stem Cell Patents’ (2008) 2 Cell Stem Cell 13

Plomer A and Torremans P (eds), *Embryonic Stem Cell Patents European Law and Ethics* (OUP 2009)

Plomer A and Tsarapatsanis D, ‘The Asymmetry of Human Dignity as a Fundamental Value and Constitutional Right in Europe’ in Zaccardi G (ed), *Global Community Yearbook of International Law and Jurisprudence 2012 edition* (OUP 2012)

Porter G and others, ‘The patentability of human embryonic stem cells in Europe’ (2006) 24 Nature Biotechnology 653

Public and Corporate Economic Consultants, *Strengthening the Contribution of English Higher Education Institutions to the Innovation System: Knowledge Exchange and HEIF Funding. A report for HEFCE* (PACEC 2012)

Public Patent Foundation, *Opening Brief of Appellant in Consumer Watchdog v WARF* (2013)

–––, ‘WARF Stem Cell Patents’ <<http://www.pubpat.org/warfstemcell.htm>> accessed 13 April 2014

Radder H, ‘A Deflationary, Neo-Mertonian Critique of Academic Patenting’ in Suárez M, Dorato M and Rédei M (eds), *EPSA Epistemology and Methodology of Science* (Springer 2010)

Rai AK, ‘Regulating Scientific Research: Intellectual Property Rights and the Norms of Science’ (1999) 94 Nw UL Rev 77

Rai AK and Cook-Deegan R, ‘Moving beyond “isolated” gene patents’ (2013) 341 Science

Rai AK and Sampat BN, ‘Accountability in patenting of federally funded research’ (2012) 30 Nature Biotechnology 953

RCUK, ‘Impact Policies: Intellectual Property’ <<http://www.rcuk.ac.uk/ke/policies/>> accessed 11 April 2014

–––, ‘Increasing the economic impact of the Research Councils’ (2007) <<http://www.rcuk.ac.uk/RCUK-prod/assets/documents/publications/ktactionplan.pdf>> accessed 23 April 2014

–––, ‘Pathways to Impact’ <<http://www.rcuk.ac.uk/ke/impacts/>> accessed 10 April 2014

–––, ‘RCUK Policy and Guidelines on Governance of Good Research Conduct’ (2013) <<http://www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf>> accessed 07 April 2014

–––, ‘RCUK Review of the UK National Stem Cell Network (UKNSCN) Annex A full - survey results ’ <<http://www.bbsrc.ac.uk/web/FILES/Reviews/rcuk-review-of-uknscn-annex-a-survey-results-2011.pdf>> accessed 05 April 2014

–––, ‘Terms and Conditions of Grants ’ (2013) <<http://www.rcuk.ac.uk/RCUK-prod/assets/documents/documents/tcfec.pdf>> accessed 10 April 2014

REF2014, ‘FAQs: Research Outputs (REF2)’ <<http://www.ref.ac.uk/faq/researchoutputsref2/>> accessed 07 April 2014

–––, ‘REF 01.2011 Decisions on assessing research impact’ (2011) <<http://www.ref.ac.uk/media/ref/content/pub/decisionsonassessingresearchimpact/01_11.pdf>>

–––, ‘REF 2014 Citation data’ <<http://www.ref.ac.uk/subguide/citationdata/>> accessed 07 April 2014

–––, ‘Research Excellence Framework’ <<http://www.ref.ac.uk/>> accessed 23 April 2014

Reneuron, ‘About us’ <<http://www.reneuron.com/about-reneuron>> accessed 11 April 2014

Research Council Economic Impact Group, ‘Increasing the economic impact of Research Councils: Advice to the Director General of Science and Innovation, Department of Trade and Industry (06/1678)’ (2006) <<http://www.bis.gov.uk/files/file32802.pdf>> accessed 23 April 2014

Resnik DB, ‘The commercialization of human stem cells: ethical and policy issues’ (2002) 10 Health Care Analysis 127

Resnik DB, *The Price of Truth: How Money Affects the Norms of Science* (OUP 2007)

Rhodes RA, ‘The hollowing out of the state: The changing nature of the public service in Britain’ (1994) 65 The Political Quarterly 138

Richards G, *University Intellectual Property: A Source of Finance and Impact* (Harriman House Ltd 2012)

Roin B, ‘Note: The Disclosure Function of the Patent System (Or Lack Thereof)’ (2005) 118 Harv L Rev 2007

Rosenberg N and Nelson RR, ‘American universities and technical advance in industry’ (1994) 23 Research Policy 323

Rowley E and Martin P, *Barriers to the Commercialisation & Utilisation of Regenerative Medicine in the UK* (Nottingham Uo 2009)

Royal Society, *Keeping science open: the effects of intellectual property policy on the conduct of science* (Society R 2003)

–––, *Science as an open enterprise: The Boundaries of Openness* (Society R 2012)

–––, *The Scientific Century - securing our future prosperity (RS policy document 02/10)* (Society R 2010)

Salter B, ‘Transnational governance and cultural politics: the case of human embryonic stem cells and the European Union's Sixth Framework Programme ’ <<http://www.york.ac.uk/res/iht/projects/l218252005/SalterTransnationalGovernance.pdf>> accessed 16 April 2014

Sastry T and Bekhradnia B, *Using metrics to allocate research funds: A short evaluation of alternatives to the Research Assessment Exercise* (Institute HEP 2006)

Scotchmer S, ‘Standing on the shoulders of giants: cumulative research and the patent law’ (1991) J Econ Perspectives 29

Scotchmer S and Green J, ‘Novelty and Disclosure in Patent Law’ (1990) 21 RJE 131

Scott CT, ‘Stem cells: new frontiers of ethics, law, and policy’ (2008) 24 Neurosurgery Focus 1

Secretary's Advisory Committee on Genetics HaS, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (USA DoHHS 2010)

Sevilla C and others, ‘Impact of gene patents on the cost-effective delivery of care: the case of BRCA1 genetic testing’ (2003) 19 Int J Tech Assessment in Health Care 287

Seymore SB, ‘The Teaching Function of Patents’ (2010) 85 Notre Dame L Rev 621

Shergold M and Grant J, ‘Freedom and need: The evolution of public strategy for biomedical and health research in England’ (2008) 6 Health Research Policy and Systems

Siegal DS and Phan PH, *Analyzing the Effectiveness of University Technology Transfer: Implications for Entrepreneurship Education* (Emerald Group Publishing Ltd 2005)

Simmons ES, ‘Patent databases and Gresham’s law’ (2006) 28 World Patent Information 291

Simon BM, Murdoch CE and Scott CT, ‘Pluripotent patents make prime time: an analysis of the emerging landscape’ (2010) 28 Nature Biotechnology 557

Sir Andrew Witty, *Encouraging a British Invention Revolution: Sir Andrew Witty's Review of Universities and Growth (BIS/13/1241)* (BIS 2013)

Smith A, ‘'No' to ban on stem-cell patents’ (2011) 472 Nature Correspondence

Soetendorp R, ‘'Food for engineers': intellectual property education for innovators’ (2004) 18 Industry and Higher Education 363

Soetendorp R and others, ‘Engineering enterprise through intellectual property education-pedagogic approaches’ (2005) 4 WSEAS Transactions on Advances in Engineering Education 359

Stem Cells for Safer Medicines, ‘Funding partners’ <<http://sc4sm.org/funding-partners/>> accessed 10 April 2014

Sterckx S, ‘The Ethics of Patenting - Uneasy Justifications’ in Drahos P (ed), *Death of Patents* (Lawtext Publishing Ltd 2005)

Stiglitz J and Sulston J, ‘The Case Against Gene Patents (The Wall Street Journal, 16 April 2010)’ (2010) <<http://online.wsj.com/news/articles/SB10001424052702303348504575183982493601368>> accessed 23 April 2014

Takahashi K and Yamanaka S, ‘Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors’ (2006) 126 Cell 663

Tang P, *Exploiting University Intellectual Property in the UK. A report prepared for the UKIPO* (Institute IP 2008)

Tartari V, Salter A and D’Este P, ‘Crossing the Rubicon: exploring the factors that shape academics’ perceptions of the barriers to working with industry’ (2012) 36 Camb J Econ 655

Tashakkori A and Teddlie C, *Mixed methodology: Combining qualitative and quantitative approaches*, vol 46 (Sage 1998)

Teddlie C and Tashakkori A, *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioral sciences* (Sage 2009)

Thambisetty S, ‘The Evolution of Sufficiency in Common Law’ LSE Legal Studies Working Paper No 6/2013 <<http://eprints.lse.ac.uk/48995/1/WPS2013-06_Thambisetty.pdf>> accessed 23 April 2014

Thomson J, *Primate Embryonic Stem Cells (US 5,843,780 )* (WARF 1998)

–––, *Primate Embryonic Stem Cells (US 6, 200, 806)* (WARF 2001)

–––, *Primate Embryonic Stem Cells (US 7, 029, 913)* (WARF 2006)

Thomson JA and others, ‘Embryonic Stem Cell Lines Derived from Human Blastocysts’ (1998) 282 Science 1145

Thomson Reuters, ‘A bibliometric analysis of regenerative medicine’ (2011) <https://[www.gov.uk/government/uploads/system/uploads/attachment\_data/file/32435/11-1059-bibliometric-analysis-of-regenerative-medicine.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32435/11-1059-bibliometric-analysis-of-regenerative-medicine.pdf)> accessed 23 April 2014

Thursby JG and Thursby MC, ‘University Licensing and the Bayh-Dole Act’ (2003) 301 Science 1052

Thursby MC, *Introducing Technology Entrepreneurship to Graduate Education: An Integrative Approach* (Emerald Group Publishing Ltd 2005)

TSB, ‘About the Cell Therapy Catapult’ <https://ctcatapult.innovateuk.org/documents/2156401/2232869/About-the-Cell-Therapy-Catapult.pdf> accessed 23 April 2014

–––, ‘Guide to Technology Strategy Board Collaborative Research and Development Competitions ’ (2011) <https://connect.innovateuk.org/documents/2998699/3675995/TSB+Funding+Guide.pdf/7c241ed9-a20c-4b20-adfe-42c8c9253bd3> accessed 11 April 2014

Tseng Y-H, Lin C-J and Lin Y-I, ‘Text mining techniques for patent analysis’ (2007) 43 Information Processing & Management 1216

UK Patents Act 1977 (as amended) An unofficial consolidation produced by Patents Legal Section 1 October 2013

UK Stem Cell Initiative, ‘Report & Recommendations’ (2005) <<http://www.dh.gov.uk/ab/UKSCI/DH_098510>> accessed 23 April 2014

UKIPO, ‘Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office ’ <<http://www.ipo.gov.uk/biotech.pdf>> accessed 07 April 2014

–––, ‘Intellectual Asset Management for Universities’ (2011) <<http://www.ipo.gov.uk/ipasset-management.pdf>> accessed 23 April 2014

–––, ‘Inventions involving human embryonic stem cells’ (2003) <<http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells.htm>> accessed 05 April 2014

–––, ‘Inventions involving human embryonic stem cells’ (2012) <<http://www.ipo.gov.uk/p-pn-stemcells-20120517.htm>> accessed 16 April 2014

–––, ‘Manual of Patent Practice’ (2013) <<http://www.ipo.gov.uk/downloads/practice-manual.pdf>> accessed 07 April 2014

–––, ‘Model Research Collaboration Agreements’ <<http://www.ipo.gov.uk/whyuse/research/lambert/lambert-mrc.htm>> accessed 23 April 2014

–––, ‘New online patent inspection service launched’ (2011) <<http://www.ipo.gov.uk/press-release-20111006.htm>> accessed 07 October 2011

–––, ‘‘Patent Publication Enquiry’’ <<http://www.ipo.gov.uk/patent/p-find/p-find-publication.htm>> accessed 23 April 2014

–––, *The Patent Research Exception Consultation: Summary of Responses* (UKIPO 2008)

–––, *The Patent Research Exception: A Consultation* (UKIPO 2008)

–––, ‘Patentability of human embryonic stem cells’ <<http://www.ipo.gov.uk/pro-types/pro-patent/p-policy/p-policy-biotech/p-policy-biotech-stemcell.htm>> accessed 05 April 2014

–––, ‘Peer to patent pilot’ (2012) <<http://www.ipo.gov.uk/p2p-report.pdf>> accessed 07 April 2014

–––, *Stem Cells: UKNSCN patent watch landscape* (UKIPO 2012)

–––, ‘Why use IP?’ <<http://www.ipo.gov.uk/whyuse.htm> > accessed 05 April 2014

UKNSCN, ‘'Patent Digests'’ <<http://www.uknscn.org/downloads/patent_digests.html>> accessed 09 November 2011

USPTO, ‘Economic Security SO’ <[http://www.uspto.gov/ip/global/patents/esso/index.jsp#](http://www.uspto.gov/ip/global/patents/esso/index.jsp) > accessed 02 April 2014

–––, ‘Memorandum: Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc.’ (2013) <<http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf>> accessed 10 April 2014

Valdivia WD, ‘University Start-Ups: Critical for Improving Technology Transfer’ Center for Technology Innovation at Brookings <<http://www.brookings.edu/~/media/research/files/papers/2013/11/start%20ups%20tech%20transfer%20valdivia/valdivia_tech%20transfer_v29_no%20embargo.pdf>> accessed 10 April 2014

Visser PS and others, ‘Mail surveys for election forecasting? An evaluation of the Columbus Dispatch poll’ (1996) 60 Public Opinion Quarterly 181

Vrtovec KT and Scott CT, ‘The European Court of Justice Ruling in Brüstle v. Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe’ (2011) 9 Cell Stem Cell 502

Walsh JP, Arora A and Cohen WM, ‘Working Through the Patent Problem’ (2003) 299 Science 1021

Walsh JP, Cohen WM and Cho C, ‘Where excludability matters: Material versus intellectual property in academic biomedical research’ (2007) 36 Research Policy 1184

Watson JD, *Brief of James D. Watson, Ph.D. as amicus curiae in support of neither party, Myriad, 133 S. Ct. 2107 (No. 12-398)* (2012)

Weaver DF and Barden C, ‘Don't overlook the rigorously reviewed novel work in patents’ (2009) 461 Nature 340

Webb E and others, *Unobtrusive Measures: Non-reactive Research in the Social Sciences* (Rand McNally 1966)

Wellcome Trust, ‘Conditions under which a grant is awarded’ <<http://www.wellcome.ac.uk/stellent/groups/corporatesite/@sf_central_grants_admin/documents/web_document/wtx026668.pdf>> accessed 10 April 2014

–––, ‘Policy on intellectual property and patenting ’ <<http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002762.htm>> accessed 10 April 2014

–––, ‘Wellcome Trust-funded intellectual property: exploitation consent and standard revenue/equity-sharing agreement (CRSA/12/2009)’ <<http://www.wellcome.ac.uk/stellent/groups/corporatesite/@technology_transfer/documents/web_document/wtd003534.doc> > accessed 11 April 2014

Wellings P, *Intellectual property and research benefits* (BIS 2008)

Wilson T, *A Review of Business-University Collaboration* (BIS 2012)

WIPO, ‘Offices for which PCT national phase information is available in PATENTSCOPE Search Service’ <<http://patentscope.wipo.int/search/en/nationalphase.jsf>> accessed 05 April 2014

–––, ‘PATENTSCOPE Content of the Database’ <<http://www.wipo.int/patentscope/search/en/content.jsf> > accessed 05 April 2014

Yamanaka S, *Nuclear Reprogramming Factor (EP 1 970 446)* (2011)

Zarzeczny A and others, ‘iPS Cells: Mapping the Policy Issues’ (2009) 139 Cell 1032

**Anonymous sources**

‘The case: Myriad at the Supreme Court (Fitzpatrick Cella Haper & Scinto LLP)’ (2013) <<http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Myriad-fischer-rothman-carlin.pdf>> accessed 13 April 2014

‘Cellular Dynamics International IPO (as filed with the Securities and Exchange Commission on June 3, 2013. Registration No. 333)’ (2013) <<http://www.sec.gov/Archives/edgar/data/1482080/000148208013000014/cdi-sx1publicfiling12013.htm>> accessed 05 April 2014

‘Peer to patent’ <<http://www.peertopatent.org/>> accessed 13 April 2014

‘Regenerative Medicine Expert Group’ <https://[www.gov.uk/government/policy-advisory-groups/regenerative-medicine-expert-group](http://www.gov.uk/government/policy-advisory-groups/regenerative-medicine-expert-group)> accessed 10 April 2014

‘Request for *ex parte* reexamination patent number 5, 843, 780 Primate Embryonic Stem Cells’ (2006) <<http://www.pubpat.org/assets/files/warfstemcell/780Request.pdf>> accessed 13 April 2014

‘UCL-Pfizer to develop pioneering stem cell sight therapies’ (2009) <<http://www.ucl.ac.uk/news/news-articles/0904/09042301>> accessed 07 April 2014

‘UCL and Pfizer Announce Extension to Collaboration To Advance Development Of Stem Cell-Based Therapies’ (2011) <<http://www.ucl.ac.uk/ioo/news110225.php>> accessed 11 April 2014

‘Wellcome Trust and MRC invest in world-class Stem Cell Institute at Cambridge (August 2012)’ (2012) <<http://www.cam.ac.uk/research/news/wellcome-trust-and-mrc-invest-in-world-class-stem-cell-institute-at-cambridge/>> accessed 23 April 2014

1. For an extensive history of the co-evolution of the patent system and the life sciences see Graham Dutfield, *Intellectual Property Rights and the Life Sciences Industries Past, Present and Future* (2nd edn, World Scientific 2009) [↑](#footnote-ref-1)
2. Eisenberg discusses this with regard to gene patents in Rebecca Eisenberg, ‘How Can You Patent Genes?’ (2002) 2 Am J Bioethics 3, 3. The same can be said of many modern biological inventions, including those relating to stem cell science, for example, James Thomson’s ‘WARF’ patents (James Thomson, *Primate Embryonic Stem Cells (US 5,843,780 )* (WARF 1998), James Thomson, *Primate Embryonic Stem Cells (US 6, 200, 806)* (WARF 2001) and James Thomson, *Primate Embryonic Stem Cells (US 7, 029, 913)* (WARF 2006)) [↑](#footnote-ref-2)
3. In this thesis, the term ‘science policy’ is used to discuss policy for science; policies which shape the undertaking of scientific research. This discussion focuses largely on policies relating to the funding of research. [↑](#footnote-ref-3)
4. See data in OECD, *Commercialising Public Research: New Trends and Strategies* (OECD 2013) 33 [↑](#footnote-ref-4)
5. See, for example, Zhen Lei, Rakhi Jenuja and Brian D. Wright, ‘Patents versus patenting: implications of intellectual property protection for biological research’ (2009) 27 Nature Biotechnology 36 [↑](#footnote-ref-5)
6. Michael A. Heller and Rebecca S. Eisenberg, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ (1998) 280 Science 698 [↑](#footnote-ref-6)
7. Hans Radder, ‘A Deflationary, Neo-Mertonian Critique of Academic Patenting’ in Mauricio Suárez, Mauro Dorato and Miklós Rédei (eds), *EPSA Epistemology and Methodology of Science* (Springer 2010), Lee Branstetter and Yoshiaki Ogura, ‘Is Academic Science Driving a Surge in Industrial Innovation? Evidence from Patent Citations NBER Working Paper 11561 (2005)’ <http://repository.cmu.edu/sds/48> accessed 10 April 2014), Ajay Agrawal and Rebecca Henderson, ‘Putting Patents in Context: Exploring Knowledge Transfer from MIT’ (2002) 48 Management Science 44 [↑](#footnote-ref-7)
8. For example, Eisenberg, ‘How Can You Patent Genes?’ [↑](#footnote-ref-8)
9. Benjamin Roin, ‘Note: The Disclosure Function of the Patent System (Or Lack Thereof)’ (2005) 118 Harv L Rev 2007, Jeanne C. Fromer, ‘Patent Disclosure’ (2009) 94 Iowa L Rev 539 and Lisa Larrimore Ouellette, ‘Do Patents Disclose Useful Information?’ (2012) 25 Harv JL & Tech 531 [↑](#footnote-ref-9)
10. See notes 5-9 above [↑](#footnote-ref-10)
11. See discussion in Suzanne Scotchmer, ‘Standing on the shoulders of giants: cumulative research and the patent law’ (1991) J Econ Perspectives 29 [↑](#footnote-ref-11)
12. On the history of these changes see, for example, Henry Etzkowitz and others, ‘The future of the university and the university of the future: evolution of ivory tower to entrepreneurial paradigm’ (2000) 29 Research Policy 313 and Aldo Geuna and Lionel JJ Nesta, ‘University patenting and its effects on academic research: The emerging European evidence’ (2006) 35 Research Policy 790 [↑](#footnote-ref-12)
13. ““The knowledge based economy” is an expression coined to describe trends in advanced economies towards greater dependence on knowledge, information and high skill levels, and the increasing need for ready access to all of these by the business and public sectors” OECD, ‘OECD Glossary of Statistical Terms’ <http://stats.oecd.org/glossary/detail.asp?ID=6864> accessed 23 April 2014 [↑](#footnote-ref-13)
14. The eminence of this rationale is not bound by subject: it is provided in commentaries by economic, legal and philosophical commentators alike as well as policy makers. See, for example, Dominique Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System - IP Policy for Innovation and Competition* (OUP 2007), Adam B. Jaffe and Josh Lerner, *Innovation and Its Discontents - How our broken patent system is endangering innovation and progress, and what to do about it* (3rd edn, Princeton UP 2007)), Fritz Machlup, *An Economic Review of the Patent System* (United States Government Printing Office 1958), Francis Gurry, ‘The Disclosure of Technology in the Patent System, speech at the Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate’ (2011) <http://www.wipo.int/about-wipo/en/dgo/speeches/dg\_who\_wipo\_wto\_med\_11.html> accessed 14 April 2014 and ‘The future of the European patent system - current developments and trends. Speech by Mr Benoît Battistelli President of the European Patent Office to the ASEAN Member States-EPO Heads of Intellectual Property Offices Conference ’ (2011) <http://www.epo.org/news-issues/press/speeches/20121109.html> accessed 2 April 2014). [↑](#footnote-ref-14)
15. It is argued that patents are required to supplement free market forces “which do not lead on their own to the socially desirable level of innovation.” Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System* 3 [↑](#footnote-ref-15)
16. For discussion on this second point see Timothy R. Holbrook, ‘Possession in Patent Law’ (2006) 59 Southern Methodist University Law Review 123 and Roin, ‘The Disclosure Function of the Patent System ’ [↑](#footnote-ref-16)
17. A brief discussion of the history of this disclosure justification is provided in Lionel Bently and Brad Sherman, *Intellectual Property* (3rd edn, OUP 2009) 339. For further discussion see Sivaramjani Thambisetty, ‘The Evolution of Sufficiency in Common Law’ LSE Legal Studies Working Paper No 6/2013 <http://eprints.lse.ac.uk/48995/1/WPS2013-06\_Thambisetty.pdf> accessed 23 April 2014, John Adams, ‘History of the patent system’ in Toshiko Takenaka (ed), *Patent Law and Theory A Handbook of Contemporary Research* (Edward Elgar 2008) and Christine MacLeod, *Inventing the industrial revolution: The English patent system, 1660-1800* (CUP 2002) 41-50. [↑](#footnote-ref-17)
18. For further discussion on the role of disclosure through the patent system see, for example, Edmund Kitch, ‘The Nature and Function of the Patent System’ (1977) 20 J L & Econ 265 D Seaborne Davies, ‘The Early History of the Patent Specification’ (1934) 50 LQR 86, Fromer, ‘Patent Disclosure’, Alan Devlin, ‘The misunderstood function of disclosure in patent law’ (2010) 23 Harv JL & Tech 401, Sean B. Seymore, ‘The Teaching Function of Patents’ (2010) 85 Notre Dame L Rev 621 and Roin, ‘The Disclosure Function of the Patent System ’ [↑](#footnote-ref-18)
19. In his seminal article, Machlup argued that “inventive activity must precede the patent, whereas innovative activity may follow it.” (Machlup, *An Economic Review of the Patent System*  56) The terms ‘downstream innovation’ (modified from ‘downstream product development’) and ‘upstream research’ are taken from Heller and Eisenberg, ‘Can Patents Deter Innovation? ’In this way, patenting is the middle-point: events that happen prior to a patent are ‘upstream’ and subsequent events are ‘downstream’. [↑](#footnote-ref-19)
20. This cumulative function of invention has been highlighted in high technology/fast-moving fields such as biotechnology and stem cell science (Jaffe and Lerner, *Innovation and Its Discontents*  64 and Scotchmer, ‘Standing on the shoulders of giants’ 29). [↑](#footnote-ref-20)
21. UK Patents Act 1977 (as amended) An unofficial consolidation produced by Patents Legal Section 1 October 2013 s. 16(1) and s. 14(3) [↑](#footnote-ref-21)
22. See, for example, Stuart Macdonald, ‘Exploring the Hidden Costs of Patents’ in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan 2002) 15, Peter Drahos, *The Global Governance of Knowledge* (CUP 2010) 311, Fromer, ‘Patent Disclosure’ and Seymore, ‘The Teaching Function of Patents’ [↑](#footnote-ref-22)
23. See Devlin, ‘The misunderstood function of disclosure in patent law’ 403, Roin, ‘The Disclosure Function of the Patent System ’ 2025-26 and Drahos, *The Global Governance of Knowledge* 298 [↑](#footnote-ref-23)
24. UK Patents Act s. 14 (3) [↑](#footnote-ref-24)
25. Drahos, *The Global Governance of Knowledge* 31-32 [↑](#footnote-ref-25)
26. Ibid 288 [↑](#footnote-ref-26)
27. Ibid 303 [↑](#footnote-ref-27)
28. See discussions in Dutfield, *Intellectual Property Rights and the Life Sciences Industries* Ch 3 and Drahos, *The Global Governance of Knowledge* Ch 11 [↑](#footnote-ref-28)
29. Drahos, *The Global Governance of Knowledge* 290 [↑](#footnote-ref-29)
30. Ibid 293 [↑](#footnote-ref-30)
31. Ibid 291 [↑](#footnote-ref-31)
32. Ibid 291 [↑](#footnote-ref-32)
33. Ibid 292 and 312 [↑](#footnote-ref-33)
34. Nuffield Council on Bioethics, *Emerging biotechnologies: technology, choice and the public good* (Nuffield Council on Bioethics 2013) xix [↑](#footnote-ref-34)
35. Ibid para 9-11 and 38 [↑](#footnote-ref-35)
36. The emerging nature of the field aligns with the fact that key strides in the field were, and continue to be, made by scientists working in universities, including the isolation of mouse embryonic stem cells (ESCs) in 1981, the isolation of human ESCs (hESCs) in 1998 and the reprogramming of ESCs to make induced pluripotent stem cells (iPSCs) in 2006 (a poster showing the major breakthroughs in the field is available in Peter W. Andrews and Paul J. Gokhale, ‘From teratomas to embryonic stem cells: discovering pluripotency’ (2011) 12 Nature Reviews Molecular Cell Biology). [↑](#footnote-ref-36)
37. The proportion of publications has grown from 0.4% (of global total) in 1996, to 1% in 2012, with an annual growth rate of 7% (compared with 2.9% in all fields) between 2008 and 2012. EuroStemCell, Institute for Integrated Cell-Material Sciences and Elsevier, *Stem Cell Research: Trends and Perspectives on the Evolving International Landscape* (Elsevier 2013) 5 [↑](#footnote-ref-37)
38. House of Lords Science and Technology Committee, *Regenerative medicine* (The Stationary Office 2013) paras 9-18 [↑](#footnote-ref-38)
39. In the UK 79% of funding for regenerative medicine funds basic research (ibid 29) [↑](#footnote-ref-39)
40. See discussion in ibid Ch 5 [↑](#footnote-ref-40)
41. For a glossary of stem cell terms see National Institutes of Health, ‘Stem cell glossary’ <http://stemcells.nih.gov/info/pages/glossary.aspx> accessed 23 April 2014 There are a variety of types of stem cells, categorised by their ability to give rise to other types of cell. Totipotent cells are capable of giving rise to all types of differentiated cells in an organism, with the potential to develop into an entire organism (these cells include the fertilised egg (the zygotes) and the first few cells arising from the division of the zygote). Pluripotent cells can differentiate into all tissues of an organism but are not capable of giving rise to a whole organism (these include cells of the inner cell mass of a blastocyst: embryonic stem cells). Multipotent cells can develop into multiple, yet limited, numbers of cell types (for example, there are multipotent blood cells which can develop into a variety of differentiated blood cells such as monocytes and lymphocytes). For a long time, it was thought that this process was linear: totipotent cells became pluripotent cells which in turn became multipotent, unipotent and then finally differentiated. Ground breaking work showed that it was possible to reverse this process, either by removing the nucleus of an adult cell and placing it into a denucleated egg which can then develop into a variety of cell types (this is the basis of somatic cell nuclear transfer, used to create Dolly the sheep, see Keith HS Campbell and others, ‘Sheep cloned by nuclear transfer from a cultured cell line’ (1996) 380 Nature 64 ibid) or by reprogramming cells using genetic factors to increase their potency (such as in the case in creating induced pluripotent stem cells, where an adult cell is ‘reprogrammed’ to act like a pluripotent stem cell, see for example Kazutoshi Takahashi and Shinya Yamanaka, ‘Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors’ (2006) 126 Cell 663). [↑](#footnote-ref-41)
42. See discussion in Timothy Caulfield, ‘Stem Cell Research and Economic Promises’ (2010) 38 JL Med & Ethics 303 [↑](#footnote-ref-42)
43. Government Office for Science and Department for Business Innovation & Skills, *Technology and Innovation Futures: UK Growth Opportunities for the 2020s* (BIS 2010) 18 [↑](#footnote-ref-43)
44. NHS Choices, ‘Hope and hype: An analysis of stem cells in the media’ (2011) <http://www.nhs.uk/news/2011/11November/Documents/hope\_and\_hype\_1.0.pdf > accessed 23 April 2014 [↑](#footnote-ref-44)
45. House of Lords Science and Technology Committee, *Regenerative medicine* paras 9-22 [↑](#footnote-ref-45)
46. See Timothy Caulfield, ‘Stem cell patents and social controversy: A speculative view from Canada’ (2006) 7 Med L Int 219. This concern is also raised with regard to other biological fields (see discussion in Nuffield Council on Bioethics, *Emerging biotechnologies: technology, choice and the public good* Ch 2). [↑](#footnote-ref-46)
47. See Chapter 4 [↑](#footnote-ref-47)
48. Professor Sir Martin Evans FRS (2007), Professor Sir Robert Edwards FRS (2010) and Professor Sir John Gurdon FRS (2012). See discussion in House of Lords Science and Technology Committee, *Regenerative medicine* para 31 [↑](#footnote-ref-48)
49. See, for example, UK Stem Cell Initiative, ‘Report & Recommendations’ (2005) <http://www.dh.gov.uk/ab/UKSCI/DH\_098510> accessed 23 April 2014, Government Office for Science and Department for Business Innovation & Skills, *Technology and Innovation Futures*, MRC and others, *A Strategy for UK Regenerative Medicine* (MRC 2012) and House of Lords Science and Technology Committee, *Regenerative medicine* [↑](#footnote-ref-49)
50. Human Fertilisation and Embryology Act 1990 Ch 37 s. 11(1)(c) and sch. 2 s. 3(1). The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 extended the purposes for which embryo research could be licensed. For further discussion see Aurora Plomer, ‘Beyond the HFE Act 1990: the regulation of stem cell research in the UK’ (2002) 10 MLR 132 [↑](#footnote-ref-50)
51. UK Stem Cell Initiative, ‘Report & Recommendations’ [↑](#footnote-ref-51)
52. Government Office for Science and Department for Business Innovation & Skills, *Technology and Innovation Futures* paras 2.1(5) and 2.1(6) [↑](#footnote-ref-52)
53. Department for Business Innovation & Skills, ‘Strategy for UK Life Sciences’ (2011) <http://www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences> accessed 23 April 2014, 10 [↑](#footnote-ref-53)
54. George Osborne, *Speech by the Chancellor of the Exchequer, Rt Hon George Osborne MP, to the Royal Society (9th November)* (2012) [↑](#footnote-ref-54)
55. Lords Select Committee, ‘Inquiry launch: Regenerative Medicine ’ (2012) <http://www.parliament.uk/business/committees/committees-a-z/lords-select/science-and-technology-committee/news/regenerative-medicine-inquiry-launch/ > accessed 23 April 2014 [↑](#footnote-ref-55)
56. House of Lords Science and Technology Committee, *Regenerative medicine* [↑](#footnote-ref-56)
57. Karl Bergman and Gregory D. Graff, ‘The global stem cell patent landscape: implications for efficient technology transfer and commercial development’ (2007) 25 Nature Biotechnology 419 [↑](#footnote-ref-57)
58. Ibid [↑](#footnote-ref-58)
59. Ibid See also Antoinette F Konski and Doris JF Spielthenner, ‘Stem cell patents: a landscape analysis’ (2009) 27 Nature Biotechnology 722 and Robin Feldman and Deborah Furth, ‘The Intellectual Property Landscape for iPS Cells’ (2010) 3 Stan JL Science & Policy 16 [↑](#footnote-ref-59)
60. UKIPO, *Stem Cells: UKNSCN patent watch landscape* (UKIPO 2012) 5-6 [↑](#footnote-ref-60)
61. Ibid 9 [↑](#footnote-ref-61)
62. Ibid 14 [↑](#footnote-ref-62)
63. These findings mirror Bergman and Graff’s study of US patents which showed that patenting in the stem cell field has grown since the late 1980s, with increasing levels of growth, and that 44% of granted stem cell patents in the US were assigned to public sector institutions, compared to only 3% of the USPTO patent grants for all technologies between 1986 and 2005. A general increase in the number of patent publications involving stem cell technology was seen since the late 1980s through the PCT, the USPTO and in Europe. Bergman and Graff, ‘The global stem cell patent landscape’ 420 [↑](#footnote-ref-63)
64. See discussion in 5.4.3 [↑](#footnote-ref-64)
65. Shawn HE Harmon, Graeme Laurie and Aidan Courtney, ‘Dignity, plurality and patentability: the unfinished story of Brustle v Greenpeace’ (2013) 38 E L Rev 92 [↑](#footnote-ref-65)
66. See discussion in section 4.2.6 and 5.4.3 [↑](#footnote-ref-66)
67. See discussion in section 5.5.4. Further, around the same time, a US programme ‘Peer to Patent’ highlighted the potential importance of experts (e.g. academic scientists) in assisting pre-grant examination of patents (see 5.5.1). [↑](#footnote-ref-67)
68. Timothy Caulfield and others, ‘Patents, commercialization and the Canadian stem cell research community’ (2008) 3 Regenerative Medicine 483 [↑](#footnote-ref-68)
69. Ibid 485 [↑](#footnote-ref-69)
70. Ibid 486 [↑](#footnote-ref-70)
71. Ibid 485 [↑](#footnote-ref-71)
72. See, for example, Tim Wilson, *A Review of Business-University Collaboration* (BIS 2012) and Lord Sainsbury of Turville, *The Race to the Top - A Review of Government’s Science and Innovation Policies* (HMSO 2007). For a global overview see OECD, *Innovation and Growth - rationale for an innovation strategy* (OECD). [↑](#footnote-ref-72)
73. In 2012, £7.211 billion was spent on R&D in the higher education sector in the UK. Approximately two-thirds of this comes from the government (roughly split between the Higher Education Funding Councils and the Research Councils, and ~6% coming directly from government departments), 15% comes from overseas funding (including the EU FPs), 14% comes from private non-profit bodies, 4% comes from HEIs themselves and 4% comes from business enterprise (Office for National Statistics, *UK Gross Domestic Expenditure on Research and Development, 2012* (ONS 2014), data available at <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-335613>). See also *The Scientific Century - securing our future prosperity (RS policy document 02/10)* (Royal Society 2010) 16-17 [↑](#footnote-ref-73)
74. Data from HEFCE shows that Higher Education Institutions are deeply embedded in KBE, valuing the knowledge exchange between HEIs and public, private and third sectors at £3,431 million in 2010/2011 – a 45% increase in real terms since 2003-4 (HEFCE, *Higher Education – Business and Community Interaction Survey: 2011-12* (HEFCE 2013) 4). [↑](#footnote-ref-74)
75. Lord Dearing 2002 as cited in Wilson, *The Wilson Review* preface [↑](#footnote-ref-75)
76. Royal Society, *The Scientific Century*  4 [↑](#footnote-ref-76)
77. Ibid 9 [↑](#footnote-ref-77)
78. This is often referred to as the ‘third mission’ of universities but has also discussed in terms of concepts such as ‘mode 2’, the ‘triple helix approach’ and the ‘engaged university’ which all take an activity- and goal-oriented view of public research. See, for example, Etzkowitz and others, ‘The future of the university and the university of the future’, Henry Etzkowitz and Loet Leydesdorff, ‘The Future Location of Research and Technology Transfer’ (1999) 24 J Tech Transfer 111 and Henry Etzkowitz and Loet Leydesdorff, ‘The dynamics of innovation: from National Systems and "Mode 2" to a Triple Helix of university-industry-government relations’ (2000) 29 Research Policy 109 [↑](#footnote-ref-78)
79. UKIPO, ‘Intellectual Asset Management for Universities’ (2011) <http://www.ipo.gov.uk/ipasset-management.pdf> accessed 23 April 2014, 8 [↑](#footnote-ref-79)
80. There has been a steady increase in patent applications and grants awarded to universities in recent years (from 1310 applications and 460 grants in 2003-04 to 2270 applications and 830 grants in 2011-12). The UK Universities cumulative stock of active patents rose to 16,654 by 2011-12, a 10% increase on the previous year. HEFCE, *Higher Education – Business and Community Interaction Survey: 2011-12*  [↑](#footnote-ref-80)
81. For example, patent law in the UK is shaped by EU legislation such as the Directive 94/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (1998) which led to changes in the UK Patents Act in 2000 (The Patents Regulations 2000 (SI 2000 No.2037). The relevant amendments can be found at UK Patents Act s. 76A and Schedule A2). Further, research funding in the UK is contributed to and therefore shaped by the EU Framework Programmes (as discussed in Chapters 2-4). [↑](#footnote-ref-81)
82. Timothy Caulfield and others, ‘International stem cell environments: a world of difference’ (2009) Nature Reports Stem Cells [↑](#footnote-ref-82)
83. “National and sectoral technology policies are mediated by intermediate institutions, be these firms, governmental entities, or other structures. Understanding the operation and evolution of national innovation systems therefore requires an analysis of the ways in which policies within these institutions develop, as well as an analysis of the interaction between national or sectoral policies and these institutions.” David C. Mowery and Bhaven N. Sampat, ‘University Patents and Patent Policy Debates in the USA, 1925-1980’ (2001) 10 Industrial and Corporate Change 781, 781 [↑](#footnote-ref-83)
84. It is suggested that TTOs in most universities are small and have limited capacity and ‘high-level expertise’. Paul Wellings, *Intellectual property and research benefits* (BIS 2008) 11 [↑](#footnote-ref-84)
85. Matthew Hall, Charles Oppenheim and Margaret Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I: Questionnaire survey’ (1999) 25 J Info Science 335 and Matthew Hall, Charles Oppenheim and Margaret Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part II: Results of in-depth interviews’ (2000) 26 J Info Science 87 [↑](#footnote-ref-85)
86. Although Lemley points to concerns regarding patenting upstream research (such as anticommons and thickets) in the field of nanotechnology which are common to the many emerging technologies, including stem cell science, the nature of the science is markedly different (see Mark A. Lemley, ‘Patenting Nanotechnology’ (2005) 58 Stan L Rev 601). [↑](#footnote-ref-86)
87. For example, Graeme Laurie, ‘Patenting Stem Cells of Human Origin’ (2004) 26 EIPR, David B Resnik, ‘The commercialization of human stem cells: ethical and policy issues’ (2002) 10 Health Care Analysis 127, the collection in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents European Law and Ethics* (OUP 2009), Aurora Plomer and Dimitrios Tsarapatsanis, ‘The Asymmetry of Human Dignity as a Fundamental Value and Constitutional Right in Europe’ in Giuliana Zaccardi (ed), *Global Community Yearbook of International Law and Jurisprudence 2012 edition* (OUP 2012) and Harmon, Laurie and Courtney, ‘Dignity, plurality and patentability’. Also see discussion in section 5.4.3. [↑](#footnote-ref-87)
88. See, for example, the collection of essays in Plomer and Torremans, *Embryonic Stem Cell Patents European Law and Ethics*, Christopher Thomas Scott, ‘Stem cells: new frontiers of ethics, law, and policy’ (2008) 24 Neurosurgery Focus 1 and Harmon, Laurie and Courtney, ‘Dignity, plurality and patentability’ [↑](#footnote-ref-88)
89. See data in OECD, *Commercialising Public Research* 33 [↑](#footnote-ref-89)
90. Etzkowitz and others, ‘The future of the university and the university of the future’ [↑](#footnote-ref-90)
91. Rosa Grimaldi and others, ‘30 years after Bayh–Dole: Reassessing academic entrepreneurship’ (2011) 40 Research Policy 1045 [↑](#footnote-ref-91)
92. OECD, *Commercialising Public Research* 56 [↑](#footnote-ref-92)
93. See the historical information provided in Senate Report No. 96-480 (1979) University and Small Business Patent Procedures Act Report of the Committee on the Judiciary United States Senate [↑](#footnote-ref-93)
94. Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ 811 [↑](#footnote-ref-94)
95. Ibid 799 [↑](#footnote-ref-95)
96. See discussion in Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA, 1925-1980 and Nathan Rosenberg and Richard R Nelson, ‘American universities and technical advance in industry’ (1994) 23 Research Policy 323 [↑](#footnote-ref-96)
97. Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ 783 [↑](#footnote-ref-97)
98. Ibid 787 [↑](#footnote-ref-98)
99. In 1924, whilst working at The University of Wisconsin, Dr Harry Steenbock patented a method of increasing the levels of vitamin D in food. However, the university “was not interested in managing these patents, and Steenbock convinced several alumni to create the Wisconsin Alumni Research Foundation (WARF)” ibid 788 [↑](#footnote-ref-99)
100. V. L. McKusick, ‘A Study of Patent Policies in Educational Institutions, Giving Specific Attention to the Massachussetts Institute of Technology’ (1948) 245 J Franklin Institute 193 as cited in Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ [↑](#footnote-ref-100)
101. Rebecca Eisenberg, ‘Public Research and Private Development: Patents and Technology Transfer in Government-Sponsered Research’ (1996) 82 Virginia L Rev 1663, 1671 [↑](#footnote-ref-101)
102. Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ 789-90 [↑](#footnote-ref-102)
103. McKusick, ‘A Study of Patent Policies in Educational Institutions’ as cited in Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ [↑](#footnote-ref-103)
104. Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ 791 [↑](#footnote-ref-104)
105. Ibid 793-94 [↑](#footnote-ref-105)
106. David Mowery and others, ‘The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980 ’ (2001) 30 Research Policy 99 100 [↑](#footnote-ref-106)
107. Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ 793-94 [↑](#footnote-ref-107)
108. Ibid 795 [↑](#footnote-ref-108)
109. S.REP.NO. 96-480 2 [↑](#footnote-ref-109)
110. Ibid 2 [↑](#footnote-ref-110)
111. Ibid 2 [↑](#footnote-ref-111)
112. Ibid 19 [↑](#footnote-ref-112)
113. Ibid 2 [↑](#footnote-ref-113)
114. Ibid 1 [↑](#footnote-ref-114)
115. Eisenberg, ‘Public Research and Private Development’ 1663 [↑](#footnote-ref-115)
116. The Bayh-Dole Act was not the only move of the US Government to improve the transfer of federally funded research. In the same year, the Stevenson-Wydler Act called for federal laboratories to actively pursue technology transfer activities. (Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311-2320 (codified as amended at 15 U.S.C. §§ 3701-3714 (1994))) [↑](#footnote-ref-116)
117. Patent and Trademark Amendments Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015-28 (codified at 35 U.S.C.A §§ 200-212 (2001)) [↑](#footnote-ref-117)
118. Ibid § 200 [↑](#footnote-ref-118)
119. Eisenberg, ‘Public Research and Private Development’ 1669 [↑](#footnote-ref-119)
120. Bayh-Dole Act (1980) §202 [↑](#footnote-ref-120)
121. Ibid §202(c)(4) [↑](#footnote-ref-121)
122. Ibid §202 and §203 [↑](#footnote-ref-122)
123. Peter Lee, ‘Patents and the university’ (2013) 63 Duke LJ 32 [↑](#footnote-ref-123)
124. Jaffe and Lerner, *Innovation and Its Discontents*  4 [↑](#footnote-ref-124)
125. Ibid 4. See also Mowery and others, ‘The growth of patenting and licensing by U.S. universities’ 100 [↑](#footnote-ref-125)
126. Mowery and others, ‘The growth of patenting and licensing by U.S. universities’ 103 [↑](#footnote-ref-126)
127. Jaffe and Lerner, *Innovation and Its Discontents*  10 [↑](#footnote-ref-127)
128. Ibid 11 [↑](#footnote-ref-128)
129. Ibid 3 [↑](#footnote-ref-129)
130. See data in OECD, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003) and OECD, *Commercialising Public Research*. See also discussion in Mowery and others, ‘The growth of patenting and licensing by U.S. universities’. [↑](#footnote-ref-130)
131. “Health and Society Secretary's Advisory Committee on Genetics, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (Department of Health & Human Services USA 2010) 89 and Christine Sevilla and others, ‘Impact of gene patents on the cost-effective delivery of care: the case of BRCA1 genetic testing’ (2003) 19 Int J Tech Assessment in Health Care 287 [↑](#footnote-ref-131)
132. Valdivia shows that in the US, “In 2012 … the top 5% of earners (8 universities) took 50% of the total licensing income of the university system; and the top 10% (16 universities) took nearly three-quarters of the system’s income.” (at 6) and over the past 20 years, 87% of university TTOs did not even break even (at 9). Walter D. Valdivia, ‘University Start-Ups: Critical for Improving Technology Transfer’ Center for Technology Innovation at Brookings <http://www.brookings.edu/~/media/research/files/papers/2013/11/start%20ups%20tech%20transfer%20valdivia/valdivia\_tech%20transfer\_v29\_no%20embargo.pdf> accessed 10 April 2014 [↑](#footnote-ref-132)
133. Rebecca Henderson, Adam B. Jaffe and Manuel Trajtenberg, ‘Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965–1988’ (1998) 80 Rev Econ & Statistics 119 [↑](#footnote-ref-133)
134. OECD, *Commercialising Public Research* 56 [↑](#footnote-ref-134)
135. Mowery and others, ‘The growth of patenting and licensing by U.S. universities’ 116. The distinctive case of biotechnological research was also evidenced by Branstetter and Ogura in their study of the relationship between academic science and industrial innovation. They found that USA patents citing academic literature “increased very rapidly from the mid 1980s through the late 1990s” and revealed this was largely to citations in the “bio-nexus” indicating a strong concentration of academic-industrial relationships in bioscience related areas. (Branstetter and Ogura, ‘Is Academic Science Driving a Surge in Industrial Innovation?’) [↑](#footnote-ref-135)
136. See, for example, Mowery and Sampat, ‘University Patents and Patent Policy Debates in the USA’ 812, Mowery and others, ‘The growth of patenting and licensing by U.S. universities’, Arti K Rai and Bhavan N Sampat, ‘Accountability in patenting of federally funded research’ (2012) 30 Nature Biotechnology 953 and Jerry G. Thursby and Marie C. Thursby, ‘University Licensing and the Bayh-Dole Act’ (2003) 301 Science 1052 [↑](#footnote-ref-136)
137. Rai and Sampat, ‘Accountability in patenting of federally funded research’ 955-56 [↑](#footnote-ref-137)
138. OECD, *Commercialising Public Research* 26 [↑](#footnote-ref-138)
139. Keith Pavitt, ‘Public policies to support basic research: What can the rest of the world learn from US theory and practice?(And what they should not learn)’ (2001) 10 Industrial and Corporate Change 761, 775 [↑](#footnote-ref-139)
140. These laws and policies have a history that predates the institution of the Union and have changed markedly over time alongside the development of the institution itself: what began as an economic union has evolved into an institution which covers a huge variety of policy areas, including R&D. It is noted that the meaning of the term ‘European Union’ has evolved over time but for, simplification, the term is used throughout this section. The European Union as it is known today has only existed since the Lisbon Treaty (which entered into force in 2009). Prior to that, the European Union was originally established in 1992 by the Maastricht Treaty and absorbed the European Communities – the ECSC, EURATOM and the EEC – as one of its three pillars. The European Communities were established in the 1950s by treaties commonly referred to as the founding treaties. The founding treaties were originally signed by 6 states: Belgium, Germany, France, Luxemburg, Italy and the Netherlands. In 1973, the enlargement of the Communities began with the ascension of the UK, Ireland and Denmark (Council Decision of the European Communities of 1 January 1973 adjusting the documents concerning the accession of the new Member States to the European Communities [1973] OJ L2/1 ibid [↑](#footnote-ref-140)
141. These Treaties are: The Treaty establishing the European Coal and Steel Community (Treaty establishing the European Coal and Steel Community [signed 1951, entered into force 1952, expired 23 July 2002]); The Treaty establishing the European Atomic Energy Community (Treaty establishing the European Atomic Energy Community [signed 1957, entered into force 1958]) and The Treaty Establishing the European Community (Treaty establishing the European Economic Community [signed 1957, entered into force 1958]) [↑](#footnote-ref-141)
142. Objectives of the Common Agricultural Policy were set out in Article 39 and 41 of the TEEC (EEC Treaty) [↑](#footnote-ref-142)
143. Single European Act [signed 1986, entered into force 1987] OJ 169 Article 130 [↑](#footnote-ref-143)
144. Ibid Article 130f [↑](#footnote-ref-144)
145. Ibid Article 130g(d) [↑](#footnote-ref-145)
146. Ibid Article 130i-q [↑](#footnote-ref-146)
147. Ibid Article 130i [↑](#footnote-ref-147)
148. Treaty on the European Union [signed 1992, entered into force 1993] OJ C 191 Article 130f (1) [↑](#footnote-ref-148)
149. Treaty on the Functioning of the European Union [signed 2007, entered into force 2009] OJ C306 Article 179 [↑](#footnote-ref-149)
150. Council Resolution 4/8/83 of 25 July 1983 on framework programmes for Community research, development and demonstration activities and a first framework programme 1984 to 1987 [1983] OJ C208/26/1 Annex II Selection Criteria [↑](#footnote-ref-150)
151. See, for example, Council Decision 87/516/Euratom, EEC of 28 September 1987 concerning the framework programme for Community activities in the field of research and technological development (1987 to 1991) [1987] OJ L302 , 1 [↑](#footnote-ref-151)
152. Based on current prices, €0.593 billion was invested in 1984 under FP1, rising steadily to €11.114 billion in 2013 through FP7 (European Commission, ‘Development of Community research - commitments 1984-2013’ <http://ec.europa.eu/research/fp7/pdf/fp-1984-2013\_en.pdf#view=fit&pagemode=none> accessed 20 April 2014) [↑](#footnote-ref-152)
153. Council Resolution on first framework programme (1983) Annex II Selection criteria [↑](#footnote-ref-153)
154. Ibid Articles 1 and 2 [↑](#footnote-ref-154)
155. Council Decision second framework programme [↑](#footnote-ref-155)
156. Ibid Article 1.2 [↑](#footnote-ref-156)
157. Council Decision 90/221/Euratom, EEC of 23 April 1990 concerning the framework programme of Community activities in the field of research and technological development (1990 to 1994) [1990] OJ L117 [↑](#footnote-ref-157)
158. Ibid Annex II The Activities [↑](#footnote-ref-158)
159. Ibid Article 2. 2 [↑](#footnote-ref-159)
160. Ibid Annex 2 III s. 6 [↑](#footnote-ref-160)
161. Ibid Annex II The Activities [↑](#footnote-ref-161)
162. SEA Article 130g(d) [↑](#footnote-ref-162)
163. Decision No 1110/94/EC of the European Parliament and of the Council of 26 April 1994 concerning the fourth framework programme of the European Community activities in the field of research and technological development and demonstration (1994 to 1998) [1994] OJ L126 Annex 1 page 4 [↑](#footnote-ref-163)
164. Ibid Annex III Scientific and technical objectives [↑](#footnote-ref-164)
165. Decision No 182/199/EC of the European Parliament and of the Council of 22 December 1998 concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002) [1999] OJ L26 [↑](#footnote-ref-165)
166. ERA proposed in European Commission Communication (2000) 'Towards a European research area' COM(2000) 6 [↑](#footnote-ref-166)
167. Ibid 4 [↑](#footnote-ref-167)
168. Ibid 9 [↑](#footnote-ref-168)
169. Ibid 6 [↑](#footnote-ref-169)
170. European Council (2000) Presidency Conclusions, Lisbon European Council, 23-24 March 2000 (No. 100/1/00) [↑](#footnote-ref-170)
171. European Council (2002) Presidency Conclusions, Barcelona European Council, 15 and 16 March 2002 (SN 100/1/02 REV 1) para 47 [↑](#footnote-ref-171)
172. Ibid para 27 [↑](#footnote-ref-172)
173. Regulation (EC) 294/2008 of the European Parliament and of the Council of 11 March 2008 establishing the European Institute of Innovation and Technology [2008] OJ L97/1 [↑](#footnote-ref-173)
174. Ibid Article 3 Objective [↑](#footnote-ref-174)
175. Ibid Article 2 Definitions [↑](#footnote-ref-175)
176. Phillippe Busquin, ‘Introduction at 'Ethical aspects of stem cell repositories and stem cell databases' conference in Brussels’ <http://archive.eurostemcell.org/Documents/Ethics/Philipe\_Busquin.pdf> [↑](#footnote-ref-176)
177. Ibid. Busquin notes that 50 programmes involving stem cell research were funded under FP5, 90% of which used adult stem cells and only one project involved hESCs. [↑](#footnote-ref-177)
178. See extensive discussion of these events in Brian Salter, ‘Transnational governance and cultural politics: the case of human embryonic stem cells and the European Union's Sixth Framework Programme ’ <http://www.york.ac.uk/res/iht/projects/l218252005/SalterTransnationalGovernance.pdf> accessed 16 April 2014 [↑](#footnote-ref-178)
179. European Council (2002) Council Decision 2002/834/EC adopting a specific programme for research, technological development and demonstration. 'Integrating and strengthening the European Research Area' (2002-06) OJ L294 Article 6(3) [↑](#footnote-ref-179)
180. Ibid 8 [↑](#footnote-ref-180)
181. European Commission (2004) Work programme for the specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area' Priority 1: Life Sciences, Genomics and Biotechnology for Health. Commission Decision C(2004)2002 [↑](#footnote-ref-181)
182. European Commission Directorate General for Research Life Sciences Genomics and Biotechnologies for Health, *Stem Cells: European research projects involving stem cells in the 6th Framework Programme* (European Commission 2008) [↑](#footnote-ref-182)
183. Ibid [↑](#footnote-ref-183)
184. Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) [2002] OJ L232 Article 1 3 [↑](#footnote-ref-184)
185. Ibid 2 [↑](#footnote-ref-185)
186. Ibid 1 [↑](#footnote-ref-186)
187. This term is evident throughout the text and within the title: “Decision … concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation” ibid [↑](#footnote-ref-187)
188. Ibid 7 [↑](#footnote-ref-188)
189. Ibid Again, the term innovation is used throughout the text and in the title: “contributing to the creation of the European Research Area and to innovation” [↑](#footnote-ref-189)
190. Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities [2006] OJ L412 [↑](#footnote-ref-190)
191. European Commission (2011) Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) COM(2011) 809 Article 2 Definitions (d): “’public-private partnership’ means a partnership where private sector partners, the Union and, where appropriate, other partners, commit to jointly support the development and implementation of a research and innovation programme or activities” [↑](#footnote-ref-191)
192. In March 2003, the European Council launched plans for series of public-private partnerships labelled European Technology Platforms (ETPs) to encourage communication between European research and innovation efforts (European Council (2003) Presidency Conclusions, Brussels European Council, 20 and 21 March 2003 (8410/03 Polgen 29) 14). The ETPs began during FP6 and continue to function today. While associated with the Framework Programmes, ETPs are not funded by the programmes: they are forums for communication to create strategic research agendas agreed amongst public and private actors but do not fund research. [↑](#footnote-ref-192)
193. Three specific PPPs launched in 2009 following the European Economic Recovery Plan (European Commission Communication (2008) 'A European Economic Recovery Plan' COM(2008) 800 15-16) to focus on specific industrial sectors to support employment and encourage competitiveness to aid economic recovery. Like the JTIs, the PPPs are co-funded by private and public sources. [↑](#footnote-ref-193)
194. European Council Regulation (EC) (2008) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines OJ L30/38 [↑](#footnote-ref-194)
195. “The Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes” Lisbon Treaty Article 187 [↑](#footnote-ref-195)
196. Regulation for Joint Technology Initiative on Innovative Medicine (2008) 1 [↑](#footnote-ref-196)
197. ‘Mission’ <http://www.imi.europa.eu/content/mission > accessed 23 April 2014 [↑](#footnote-ref-197)
198. Ibid [↑](#footnote-ref-198)
199. European Commission Communication (2009) 'On the progress made under the Seventh European Framework Programme for Research' COM(2009) 209 10 [↑](#footnote-ref-199)
200. The development of the ERA was proposed in Towards a European Research Area (2000) [↑](#footnote-ref-200)
201. European Commission Decision (2008) 2008/37/EC of 14 December 2007 setting up the ‘European Research Council Executive Agency’ for the management of the specific Community programme ‘Ideas’ in the field of frontier research in application of Council Regulation (EC) No 58/2003 OJ L9/15 [↑](#footnote-ref-201)
202. The European Research Council Expert Group (ERCEG) was set up in 2002 (European Research Council, ‘Mission’ <http://erc.europa.eu/about-erc/mission> accessed 23 April 2014). In 2003, the ERCEG issued a report calling for a competitive European fund for basic research to help decrease the gap in the research performance of Europe and its competitors (‘The European Research Council: A Cornerstone in the European Research Area. Report from an expert group ’ (2003) <http://erc.europa.eu/sites/default/files/content/ERCexpertgroupfinalreport.pdf> accessed 23 April 2014). At the end of 2003, the European Parliament issued a Resolution committing to set up a European Research Council (European Parliament Resolution Investing in research: an action plan for Europe COM(2003) 226 – 2003/2148(INI). In 2004, the European Commission issued a communication on ‘Europe and Basic Research’ which noted the “general value of increasing knowledge and the importance of basic research for economic and social development” and formally endorsed support for basic research funding at a European level (European Commission Communication (2004) 'Europe and Basic Research' COM(2004) 9 ). In the creation of the ERC was proposed in the ‘Ideas’ programme of FP7 (Decision seventh framework programme 21). [↑](#footnote-ref-202)
203. Decision setting up the European Research Council Executive Agency (2008) [↑](#footnote-ref-203)
204. “The term 'frontier research' reflects a new understanding of basic research. On one hand it denotes that basic research in science and technology is of critical importance to economic and social welfare, and on the other that research at and beyond the frontiers of understanding is an intrinsically risky venture, progressing on new and most exiting research areas and is characterized by an absence of disciplinary boundaries.” European Research Council, ‘Glossary: Frontier Research ’ <http://erc.europa.eu/glossary/term/267> accessed 23 April 2014 [↑](#footnote-ref-204)
205. European Research Council, ‘Mission’ [↑](#footnote-ref-205)
206. European Commission Communication (2010) 'EUROPE 2020 A strategy for smart, sustainable and inclusive growth' COM(2010) 2020 [↑](#footnote-ref-206)
207. Ibid 5 [↑](#footnote-ref-207)
208. Barcelone European Council Presidency Conclusions (2002) para 47 [↑](#footnote-ref-208)
209. Europe 2020 (2010) 12: “R&D spending in Europe is below 2%, compared to 2.6% in the USA and 3.4% in Japan, mainly as a result of lower levels of private investment.” [↑](#footnote-ref-209)
210. Ibid 12 [↑](#footnote-ref-210)
211. Ibid 12 [↑](#footnote-ref-211)
212. Ibid 12-13 [↑](#footnote-ref-212)
213. Following the aim of the Lisbon Strategy to improve the climate for SMEs the Competitiveness and Innovation Framework Programme was established to support innovation activities, mainly within SMEs. The programme aimed to complement the activities of FP7, initially running from 2007-2013. Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013) [2006] OJ L310/15 [↑](#footnote-ref-213)
214. European Commission Communication (2011) 'Horizon 2020 – The Framework Programme for Research and Innovation' COM(2011) 808 2 [↑](#footnote-ref-214)
215. Ibid 4 [↑](#footnote-ref-215)
216. Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC [↑](#footnote-ref-216)
217. Ibid 162 [↑](#footnote-ref-217)
218. Ibid Article 1 [↑](#footnote-ref-218)
219. Ibid Article 5 [↑](#footnote-ref-219)
220. Ibid Article 5 [↑](#footnote-ref-220)
221. Ibid 123 [↑](#footnote-ref-221)
222. Ibid 123 [↑](#footnote-ref-222)
223. Ibid 123 [↑](#footnote-ref-223)
224. Ibid 124 [↑](#footnote-ref-224)
225. Ibid Articles 23-25. There will also be a number of public-public partnerships to develop collaborations between national and regional programmes (Article 26), in accordance with Article 185 TFEU. [↑](#footnote-ref-225)
226. Council Decision second framework programme [↑](#footnote-ref-226)
227. European Commission, ‘Guide to Intellectual Property Rules for FP7 Projects. Version 3’ <http://ec.europa.eu/research/participants/portal/ShowDoc/Extensions+Repository/General+Documentation/Guidance+documents+for+FP7/Intellectual+property+rules/ipr\_en.pdf;efp7\_SESSION\_ID=CqW8Q2QC4XFzJ2Z93DfxCGL7n3ZMHqwX8y2v7kKCtp5vQy924G3P!-1607111007> accessed 23 April 2014 [↑](#footnote-ref-227)
228. European Commission, ‘Guide to Intellectual Property Rights provisions for FP6 projects. Version 2’ <http://ec.europa.eu/research/fp6/model-contract/pdf/fp6-iprguidelines\_en.pdf> accessed 23 April 2014 [↑](#footnote-ref-228)
229. ‘The Innovate/SMEs programme and the IPR Helpdesk: Director, Innovation/SMEs programme, introduces the IPR-Helpdesk ’ <ftp://ftp.cordis.europa.eu/pub/focus/docs/supplement\_ipr99\_en.pdf > accessed 23 April 2014 [↑](#footnote-ref-229)
230. European Commission Recomendation (2008) on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations C(2008)1329 [↑](#footnote-ref-230)
231. Ibid [↑](#footnote-ref-231)
232. Ibid [↑](#footnote-ref-232)
233. Ibid Annex 1, 1.6 [↑](#footnote-ref-233)
234. Economic and Social Research Council, *Science in the economy and the economics of science* (ESRC 2007) 39 [↑](#footnote-ref-234)
235. Ministry of Reconstruction, *Report on the machinery of Government (Cd 9230, 1918)* [↑](#footnote-ref-235)
236. ST Keith, ‘Inventions, patents and commercial development from governmentally financed research in Great Britain: the origins of the National Research Development Corporation’ (1981) 19 Minerva 92, 97 [↑](#footnote-ref-236)
237. “Although the operations of the Medical Research Committee [MRC] are within the province of the Minister responsible for Health Insurance…the Minister relies…upon the MRC to select the objects upon which they will spend their income, and to frame schemes for the efficient and economical performance of their work.” Ministry of Reconstruction, *Haldane Report* paras 34-39 [↑](#footnote-ref-237)
238. HC Deb 9 December 1964, vol 703 cols 1553-1686, as cited in House of Commons Innovation Universities Science and Skills Committee, *Putting science and engineering at the heart of government policy: eighth report of session 2008-09, Vol. 1: Report, together with formal minutes*, vol 168 (The Stationary Office 2009) [↑](#footnote-ref-238)
239. Ibid 138-41 [↑](#footnote-ref-239)
240. Keith, ‘Inventions, patents and commercial development from governmentally financed research in Great Britain’ 116 [↑](#footnote-ref-240)
241. See discussion in G. E. Haigh and others, ‘NRDC and the Environment for Innovation’ (1971) 232 Nature 527, 528 [↑](#footnote-ref-241)
242. Ibid 528 [↑](#footnote-ref-242)
243. For further information about the exact nature and content of these discussions see Keith, ‘Inventions, patents and commercial development from governmentally financed research in Great Britain’ [↑](#footnote-ref-243)
244. Ibid 115 [↑](#footnote-ref-244)
245. Ibid 113 [↑](#footnote-ref-245)
246. Development of Inventions Act 1948 [↑](#footnote-ref-246)
247. Development of Inventions Act 1967 and B.J.A. Bard, ‘The National Research Development Corporation’ (1955) 71 Aslib Proceedings 84, 84-87 [↑](#footnote-ref-247)
248. President of the Board of Trade 1948, as cited in Keith, ‘Inventions, patents and commercial development from governmentally financed research in Great Britain’ 116 [↑](#footnote-ref-248)
249. HM Treasury, *Treasury Circular 5/50* (1950) as cited in ‘The NRDC role in technology transfer’ (1983) Electronics & Power 121 [↑](#footnote-ref-249)
250. Although the MRC had been in existence since 1911, in some form, it only became a Research Council under Royal Charter through this Act (see MRC, ‘About us: Our origins’ <http://www.mrc.ac.uk/About/History/index.htm> accessed 05 April 2014) [↑](#footnote-ref-250)
251. Science and Technology Act 1965 [↑](#footnote-ref-251)
252. Ibid Article 2(1) [↑](#footnote-ref-252)
253. Rothschild report as cited in House of Commons Innovation Universities Science and Skills Committee, *Putting science and engineering at the heart of government policy* [↑](#footnote-ref-253)
254. Rothschild report as cited in Gordon McLachlan and Thomas Patterson Whitehead, *Five Years After: A Review of Health Care Research Management After Rothschild: Including an Essay by Thomas P. Whitehead* (OUP 1978) 25 [↑](#footnote-ref-254)
255. Rothschild report as cited in E. Roland Dobbs, ‘The Organisation and Control of Scientific Research by the United Kingdom Government’ (1972) 1 Higher Education 345, 351 [↑](#footnote-ref-255)
256. Miriam Shergold and Jonathon Grant, ‘Freedom and need: The evolution of public strategy for biomedical and health research in England’ (2008) 6 Health Research Policy and Systems 4 [↑](#footnote-ref-256)
257. McLachlan and Whitehead, *Five Years After: A Review of Health Care Research Management After Rothschild: Including an Essay by Thomas P. Whitehead* 33 [↑](#footnote-ref-257)
258. Richard Jones, ‘SPERI Paper No.6 - The UK's Innovation Deficit & How to Repair it’ <http://speri.dept.shef.ac.uk/wp-content/uploads/2013/10/SPERI-Paper-No.6-The-UKs-Innovation-Deficit-and-How-to-Repair-it-PDF-1131KB.pdf> accessed 10 April 2014 16 [↑](#footnote-ref-258)
259. Ibid 16 [↑](#footnote-ref-259)
260. *A Framework for Government Research and Development (Cmnd 5046, 1972)* [↑](#footnote-ref-260)
261. See discussion of this marketization in Jon Agar, ‘Thatcher, Scientist’ Notes and Records of the Royal Society <http://rsnr.royalsocietypublishing.org/content/early/2011/05/13/rsnr.2010.0096.abstract> accessed May 25, 20114ibi [↑](#footnote-ref-261)
262. Ibid [↑](#footnote-ref-262)
263. Rod AW Rhodes, ‘The hollowing out of the state: The changing nature of the public service in Britain’ (1994) 65 The Political Quarterly 138, 144 [↑](#footnote-ref-263)
264. Jones, ‘The UK's Innovation Deficit and How to Repair it’ 3 [↑](#footnote-ref-264)
265. As described in sections 2.2.1-2.2.3, following reducing federal funding for science in the US the Research Corporation was set up and universities began to manage their own IP, culminating in the Bayh Dole Act in 1980. [↑](#footnote-ref-265)
266. House of Commons Innovation Universities Science and Skills Committee, *Putting science and engineering at the heart of government policy* 41 [↑](#footnote-ref-266)
267. Keith, ‘Inventions, patents and commercial development from governmentally financed research in Great Britain’ 121 [↑](#footnote-ref-267)
268. BTG, ‘History’ <http://www.btgplc.com/about-us/history> accessed 23 April 2014 [↑](#footnote-ref-268)
269. With the merger, BTG held the rights to first refusal over the IP from government-funded research (, ‘The NRDC role in technology transfer’) [↑](#footnote-ref-269)
270. HC Deb 1985, vol 79, col 97-100 [↑](#footnote-ref-270)
271. Ibid [↑](#footnote-ref-271)
272. The term spin-out company is used in this thesis in line with the definition provided by HMRC: “Universities and other Research Institutions (RIs) which own Intellectual Property (IP) often develop that IP further through companies created in association with the researcher from the institution who worked on the project. These companies are commonly referred to as spin-out or spin-off companies.” (HM Revenue & Customs, ‘ERSM100030 - University Spin-outs: What is a spin-out company?’ <http://www.hmrc.gov.uk/manuals/ersmmanual/ersm100030.htm> accessed 23 April 2014) [↑](#footnote-ref-272)
273. Graham Richards, *University Intellectual Property: A Source of Finance and Impact* (Harriman House Ltd 2012) 17 [↑](#footnote-ref-273)
274. 191 new companies were established in 2011-12 and over 998 spin-out companies were active in the UK at this time. (HEFCE, *Higher Education – Business and Community Interaction Survey: 2011-12*  21) [↑](#footnote-ref-274)
275. HL Deb 1991, vol 529, cc436-63, cc 436 [↑](#footnote-ref-275)
276. Ibid cc 436 [↑](#footnote-ref-276)
277. Ibid cc 436 [↑](#footnote-ref-277)
278. British Technology Group Act 1991 Ch 66 [↑](#footnote-ref-278)
279. BTG, ‘British Technology Group 'History'’ [↑](#footnote-ref-279)
280. Wellings, *The Wellings Report* 11. Before 1990, only 34 universities had formally begun commercialisation with few having specific teams, now all universities in the UK have a commercialisation team/dedicated TTOs. [↑](#footnote-ref-280)
281. *Realising our Potential: A Strategy for Science, Engineering and Technology (White Paper, Cm 2250, 1993)*  para 1.10 [↑](#footnote-ref-281)
282. Ibid para 1.10 [↑](#footnote-ref-282)
283. Ibid para 1.13 [↑](#footnote-ref-283)
284. Ibid para 8.2 [↑](#footnote-ref-284)
285. Jones, ‘The UK's Innovation Deficit and How to Repair it’ 13 [↑](#footnote-ref-285)
286. , *Realising our Potential: A Strategy for Science, Engineering and Technology (White Paper, Cm 2250, 1993)*  para 3.23 [↑](#footnote-ref-286)
287. Ibid para 1.18(9) [↑](#footnote-ref-287)
288. Ben R Martin, ‘The Research Excellence Framework and the ‘impact agenda’: are we creating a Frankenstein monster?’ (2011) 20 Research Evaluation 247. See also Jones, ‘The UK's Innovation Deficit and How to Repair it’ 13 [↑](#footnote-ref-288)
289. Jones, ‘The UK's Innovation Deficit and How to Repair it’ 13 [↑](#footnote-ref-289)
290. Department of Trade and Industry, *Our Competitive Future: Building the Knowledge Driven Economy (White Paper, Cm 4176, 1998)* Executive Summary [↑](#footnote-ref-290)
291. HEFCE, ‘Higher Education Innovation Funding 2011-12 to 2014-15. Policy, final allocations and request for institutional strategies (2011/16)’ (2011) <http://www.hefce.ac.uk/media/hefce1/pubs/hefce/2011/1116/11\_16.pdf> accessed 23 April 2014 2-3 [↑](#footnote-ref-291)
292. Public and Corporate Economic Consultants, *Strengthening the Contribution of English Higher Education Institutions to the Innovation System: Knowledge Exchange and HEIF Funding. A report for HEFCE* (PACEC 2012) para 1.32 [↑](#footnote-ref-292)
293. PRSEs are defined in the report as “a diverse collection of public bodies carrying out research in pursuit of various government objectives” John Baker, *Creating Knowledge Creating Wealth: Realising the economic potential of public sector research establishments* (HM Treasury 1999) para 1.2. Appendix 1 of the report provides a list of PRSEs, examples of which are the Central Science Laboratory, the Laboratory of Molecular Biology and the Health and Safety Laboratory. [↑](#footnote-ref-293)
294. Ibid section 1.1 [↑](#footnote-ref-294)
295. Ibid [↑](#footnote-ref-295)
296. Ibid section 1.4 [↑](#footnote-ref-296)
297. Ibid 5.19. [↑](#footnote-ref-297)
298. Office of Science and Technology, *The Government’s Response to the Baker Report: “Creating Knowlege, Creating Wealth:” Realising the economic potential of Public Sector Research Establishments* (HMSO 2000) para 41 [↑](#footnote-ref-298)
299. Department for Business Innovation & Skills, ‘Public Sector Research Exploitation Fund’ <http://www.bis.gov.uk/policies/science/knowledge-transfer/psre> accessed 23 April 2014 [↑](#footnote-ref-299)
300. Baker, *Creating Knowledge Creating Wealth* s.1.15 [↑](#footnote-ref-300)
301. HM Treasury, *Lambert Review of Business-University Collaboration: Summary of Consultation Responses and Emerging Issues* (HMSO 2003) s.1.1 [↑](#footnote-ref-301)
302. *Lambert Review of Business-University Collaboration* (HMSO 2003) 2 [↑](#footnote-ref-302)
303. Ibid Ch 4 [↑](#footnote-ref-303)
304. Ibid 4 [↑](#footnote-ref-304)
305. HM Treasury, Department of Trade and Industry and Department for Education and Skills, *Science and Innovation Investment Framework 2004-2014* (HMSO 2004) [↑](#footnote-ref-305)
306. Jones, ‘The UK's Innovation Deficit and How to Repair it’ 13 [↑](#footnote-ref-306)
307. HM Treasury, Department of Trade and Industry and Department for Education and Skills, *Science and Innovation Investment Framework 2004-2014* 1 [↑](#footnote-ref-307)
308. Ibid 1 [↑](#footnote-ref-308)
309. Ibid 7 [↑](#footnote-ref-309)
310. Jones, ‘The UK's Innovation Deficit and How to Repair it’ 13 [↑](#footnote-ref-310)
311. HM Treasury, *The Lambert Review* Annex C [↑](#footnote-ref-311)
312. HM Treasury, Department of Trade and Industry and Department for Education and Skills, *Science and Innovation Investment Framework 2004-2014* 74 [↑](#footnote-ref-312)
313. Ibid 75 [↑](#footnote-ref-313)
314. UKIPO, ‘Model Research Collaboration Agreements’ <http://www.ipo.gov.uk/whyuse/research/lambert/lambert-mrc.htm> accessed 23 April 2014 [↑](#footnote-ref-314)
315. ‘Increasing the economic impact of Research Councils: Advice to the Director General of Science and Innovation, Department of Trade and Industry (06/1678)’ (2006) <http://www.bis.gov.uk/files/file32802.pdf> accessed 23 April 2014 [↑](#footnote-ref-315)
316. Ibid 3 [↑](#footnote-ref-316)
317. Ibid 3 [↑](#footnote-ref-317)
318. Ibid 4 [↑](#footnote-ref-318)
319. Ibid 5 [↑](#footnote-ref-319)
320. On the back of the Warry Report, RCUK developed an action plan to increase the economic effectiveness of the research they funded by: funding and undertaking knowledge transfer activities, building strategic partnerships with the private sector, funding specific collaborative programmes, developing measures to consider economic potential in funding applications, etc. (see RCUK, ‘Increasing the economic impact of the Research Councils’ (2007) <http://www.rcuk.ac.uk/RCUK-prod/assets/documents/publications/ktactionplan.pdf> accessed 23 April 2014). [↑](#footnote-ref-320)
321. Lord Sainsbury of Turville, *The Sainsbury Review* 1-2 [↑](#footnote-ref-321)
322. Ibid 34 [↑](#footnote-ref-322)
323. Ibid 3 [↑](#footnote-ref-323)
324. Ibid 5 [↑](#footnote-ref-324)
325. For example, Recommendation 4.2 “HEIF4 funding should be entirely on the basis of a formula, and the formula should be constructed so that the money is allocated on the basis of a competition and now goes largely to business-facing universities.” and Recommendation 4.8: “The government should continue to support PRSE commercialisation.” Ibid [↑](#footnote-ref-325)
326. Department for Innovation Universities & Skills, *Innovation Nation (White Paper, Cm 7345, 2008)* [↑](#footnote-ref-326)
327. Ibid 35 [↑](#footnote-ref-327)
328. Ibid 5 [↑](#footnote-ref-328)
329. Department for Business Innovation & Skills, ‘Business Plan 2012-2015 ’ (2012) <http://www.bis.gov.uk/assets/biscore/corporate/docs/b/12-p58-bis-2012-business-plan.pdf> accessed 23 April 2014 [↑](#footnote-ref-329)
330. Department for Business Innovation & Skills, ‘About BIS’ <http://www.bis.gov.uk/about> accessed 23 April 2014 [↑](#footnote-ref-330)
331. Wellings, *The Wellings Report* Appendix 1, Letter from The Rt Hon John Denham MP, Secretary of State for Innovation, Universities and Skills [↑](#footnote-ref-331)
332. Ibid 10 [↑](#footnote-ref-332)
333. Data from Australia as cited in ibid 22 [↑](#footnote-ref-333)
334. Ibid 10 [↑](#footnote-ref-334)
335. Ibid 4 [↑](#footnote-ref-335)
336. Ibid 4 [↑](#footnote-ref-336)
337. Royal Society, *Science as an open enterprise: The Boundaries of Openness* (Royal Society 2012) 47 [↑](#footnote-ref-337)
338. UKIPO, ‘Intellectual Asset Management for Universities’ 4 [↑](#footnote-ref-338)
339. Ibid 2 [↑](#footnote-ref-339)
340. Department for Business Innovation & Skills, ‘Strategy for UK Life Sciences’ 9 [↑](#footnote-ref-340)
341. Ibid 26 [↑](#footnote-ref-341)
342. Department for Business Innovation & Skills, *Innovation and Research Strategy for Growth (White Paper, Cm 8239, 2011)* [↑](#footnote-ref-342)
343. Ibid 1 [↑](#footnote-ref-343)
344. Ibid 26 “A Catapult is a physical centre where the very best of the UK's businesses, scientists and engineers work side by side on late-stage research and development - transforming “high potential” ideas into new products and services to generate economic growth.” [↑](#footnote-ref-344)
345. TSB, ‘About the Cell Therapy Catapult’ <https://ctcatapult.innovateuk.org/documents/2156401/2232869/About-the-Cell-Therapy-Catapult.pdf> accessed 23 April 2014 In the 2014 Budget, £55 million was allocated to develop a Cell Therapy Manufacturing Centre to be managed by the Cell Therapy Catapult. Cell Therapy Catapult, ‘Budget unveils £55m large-scale Cell Therapy Manufacturing Centre for the UK’ (2014) <https://ct.catapult.org.uk/news-page/-/asset\_publisher/tDqW3YjSO45r/content/budget-unveils-%C2%A355m-large-scale-cell-therapy-manufacturing-centre-for-the-uk> accessed 10 April 2014 [↑](#footnote-ref-345)
346. Department for Business Innovation & Skills, *Innovation and Research Strategy for Growth*  1-2 [↑](#footnote-ref-346)
347. Department for Business Innovation & Skills, *Higher Education: Students at the Heart of the System (White Paper, Cm 8122, 2011)* 39 [↑](#footnote-ref-347)
348. Wilson, *The Wilson Review* 13. This point has been raised by others for example, Technology and the Arts National Endowment for Science, *(2009) The Connected University Driving Recovery and Growth in the UK Economy (TCU/23)* (NESTA) 4 and Alan Hughes, ‘Open innovation, the Haldane Principle and the new production of knowledge: science policy and university-industry links in the UK after the financial crisis’ Centre for Business Research, University of Cambridge Working Paper No 425 (2011) <http://www.cbr.cam.ac.uk/pdf/WP425.pdf> accessed 23 April 2014 1 [↑](#footnote-ref-348)
349. Wilson, *The Wilson Review* 1 [↑](#footnote-ref-349)
350. Ibid 82 [↑](#footnote-ref-350)
351. Ibid 2 [↑](#footnote-ref-351)
352. *Following up the Wilson review of business-university collaboration: next steps for universities, business and government* (BIS) 23 [↑](#footnote-ref-352)
353. Department for Business Innovation & Skills, ‘Business Plan 2012-2015 ’ 5 [↑](#footnote-ref-353)
354. HM Treasury, *Budget 2012 (HC1853)* 41 [↑](#footnote-ref-354)
355. Ibid para 1.224 [↑](#footnote-ref-355)
356. HEFCE, ‘Special initiative Invitation to apply for funds UK Research Partnership Investment Fund 2012-2015 (2012/12)’ <http://www.hefce.ac.uk/media/hefce/content/pubs/2012/201212/UKRPIF%20final%2011%20May%202012.pdf> accessed 23 April 2014 [↑](#footnote-ref-356)
357. HM Treasury, *Budget 2012 (HC1853)* para 2.98 [↑](#footnote-ref-357)
358. Department for Business Innovation & Skills, ‘Strategy for UK Life Sciences’ 25 [↑](#footnote-ref-358)
359. *Encouraging a British Invention Revolution: Sir Andrew Witty's Review of Universities and Growth (BIS/13/1241)* (BIS 2013) 6 [↑](#footnote-ref-359)
360. Ibid [↑](#footnote-ref-360)
361. Department for Business Innovation & Skills, *The Government's Response to Sir Andrew Witty's Review of Universities and Growth* (BIS 2014) 4 [↑](#footnote-ref-361)
362. As recommended in , *The Witty Review* 8 [↑](#footnote-ref-362)
363. Department for Business Innovation & Skills, *The Government's Response to Sir Andrew Witty's Review* 17 [↑](#footnote-ref-363)
364. RCUK, ‘Pathways to Impact’ <http://www.rcuk.ac.uk/ke/impacts/> accessed 10 April 2014 [↑](#footnote-ref-364)
365. HEFCE, ‘Higher Education Innovation Funding 2011-12 to 2014-15’ 5 [↑](#footnote-ref-365)
366. Martin, ‘The Research Excellence Framework and the ‘impact agenda’’ 249 [↑](#footnote-ref-366)
367. For a discussion of the origins and development of these reviews, see ibid [↑](#footnote-ref-367)
368. Ibid 249 [↑](#footnote-ref-368)
369. Tom Sastry and Bahram Bekhradnia, *Using metrics to allocate research funds: A short evaluation of alternatives to the Research Assessment Exercise* (Higher Education Policy Institute 2006) 12 [↑](#footnote-ref-369)
370. Aldo Geuna and Ben R Martin, ‘University research evaluation and funding: an international comparison’ (2003) 41 Minerva 277 303 [↑](#footnote-ref-370)
371. Department of Health and others, *Science and innovation investment framework 2004-2014: next steps* (HMSO 2006) 3 [↑](#footnote-ref-371)
372. Martin, ‘The Research Excellence Framework and the ‘impact agenda’’ 249 [↑](#footnote-ref-372)
373. ‘Research Excellence Framework’ <http://www.ref.ac.uk/> accessed 23 April 2014 [↑](#footnote-ref-373)
374. See discussion in Martin, ‘The Research Excellence Framework and the ‘impact agenda’’ 247 and Alan Hughes and Ben Martin, ‘Enhancing Impact: The value of public sector R&D’ <http://www.cbr.cam.ac.uk/pdf/Impact%20Report%20-%20webversion.pdf> accessed 23 April 2014 5-6 [↑](#footnote-ref-374)
375. REF2014, ‘REF 01.2011 Decisions on assessing research impact’ (2011) <http://www.ref.ac.uk/media/ref/content/pub/decisionsonassessingresearchimpact/01\_11.pdf> 6 [↑](#footnote-ref-375)
376. ‘FAQs: Research Outputs (REF2)’ <http://www.ref.ac.uk/faq/researchoutputsref2/> accessed 07 April 2014 [↑](#footnote-ref-376)
377. It is not claimed that stem cell research has not taken place in the UK before this, rather that policy developments in the field which have brought it to the fore of science policy have occurred largely in the last 10 years. In the UK, research using human embryos has been regulated since the passing of the Human Fertilisation and Embryology Act of 1990, allowing limited, licensed research to take place. The grounds for research using human embryos was extended in 2001, allowing licenses to be issued for research “increasing knowledge about the development of embryos” and “serious disease” and “enabling any such knowledge to be applied in developing treatments for serious disease” Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s. 2(2). See discussion of these developments in Plomer, ‘Beyond the HFE Act 1990’. In 2002, the House of Lords Stem Cell Research Committee reported making a number of recommendations to Government on interpreting the 2001 regulations, supporting continuing research on both adult and embryonic stem cells to maximise the potential of the field (House of Lords Select Committee on Stem Cell Research, *Stem Cell Research HL 83(i)* (HMSO 2002)). [↑](#footnote-ref-377)
378. In 2004, the California Stem Cell Research and Cures Act (also known as Proposition 71) was enacted (California Stem Cell Research and Cures Act Proposition 71 2004). The Act created the California Institute for Regenerative Medicine (CIRM) with a budget of $3 billion (s. 125291.30). By the end of 2012, CIRM had invested almost $1.7 bil lion (California Institute of Regenerative Medicine, ‘Summary of CIRM rounds of funding’ (2012) <http://www.cirm.ca.gov/our-funding/where-our-funding-goes/funding-rounds/summary-cirm-rounds-funding> accessed 05/01/13). There has also been significant federal funding of stem cell science: the National Institutes of Health (NIH) invests approximately $1.2 billion in stem cell research each year (National Institutes of Health, ‘Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)’ <http://report.nih.gov/categorical\_spending.aspx> accessed 15 April 2014). [↑](#footnote-ref-378)
379. HM Treasury, *Budget 2005 (HC372)* para 3.70 [↑](#footnote-ref-379)
380. UK Stem Cell Initiative, ‘Report & Recommendations’ [↑](#footnote-ref-380)
381. Ibid [↑](#footnote-ref-381)
382. Ibid 5 [↑](#footnote-ref-382)
383. Ibid 9 [↑](#footnote-ref-383)
384. Ibid Recommendation 1 [↑](#footnote-ref-384)
385. Ibid Recommendation 4 [↑](#footnote-ref-385)
386. Ibid Recommendation 5 [↑](#footnote-ref-386)
387. Ibid Recommendation 6 [↑](#footnote-ref-387)
388. Stem Cells for Safer Medicines, ‘Funding partners’ <http://sc4sm.org/funding-partners/> accessed 10 April 2014 [↑](#footnote-ref-388)
389. UK Stem Cell Initiative, ‘Report & Recommendations’ 8 [↑](#footnote-ref-389)
390. ‘Wellcome Trust and MRC invest in world-class Stem Cell Institute at Cambridge (August 2012)’ (2012) <http://www.cam.ac.uk/research/news/wellcome-trust-and-mrc-invest-in-world-class-stem-cell-institute-at-cambridge/> accessed 23 April 2014 [↑](#footnote-ref-390)
391. Government Office for Science and Department for Business Innovation & Skills, *Technology and Innovation Futures* [↑](#footnote-ref-391)
392. Ibid 2 [↑](#footnote-ref-392)
393. Ibid 18 [↑](#footnote-ref-393)
394. Ibid 18 [↑](#footnote-ref-394)
395. Department for Business Innovation & Skills and Department of Health, *Taking Stock of Regenerative Medicine in the United Kingdom* (BIS 2011) [↑](#footnote-ref-395)
396. Thomson Reuters, ‘A bibliometric analysis of regenerative medicine’ (2011) <https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/32435/11-1059-bibliometric-analysis-of-regenerative-medicine.pdf> accessed 23 April 2014 [↑](#footnote-ref-396)
397. Department for Business Innovation & Skills and Department of Health, *Taking Stock of Regenerative Medicine* 2 [↑](#footnote-ref-397)
398. Ibid 3 [↑](#footnote-ref-398)
399. Ibid 5 [↑](#footnote-ref-399)
400. Ibid 22 [↑](#footnote-ref-400)
401. Department for Business Innovation & Skills, ‘Strategy for UK Life Sciences’ 26 [↑](#footnote-ref-401)
402. Ibid 10 [↑](#footnote-ref-402)
403. TSB, ‘About the Cell Therapy Catapult’ [↑](#footnote-ref-403)
404. Department for Business Innovation & Skills, ‘Strategy for UK Life Sciences’ 11 [↑](#footnote-ref-404)
405. , *Speech by the Chancellor of the Exchequer, Rt Hon George Osborne MP, to the Royal Society (9th November)*  [↑](#footnote-ref-405)
406. MRC and others, *A Strategy for UK Regenerative Medicine* 2 [↑](#footnote-ref-406)
407. Ibid 2-3 [↑](#footnote-ref-407)
408. Parliamentary Office of Science and Technology, *Stem Cell Research* (POST 2013) [↑](#footnote-ref-408)
409. Ibid Ch 6 [↑](#footnote-ref-409)
410. Lords Select Committee, ‘Inquiry launch: Regenerative Medicine ’ [↑](#footnote-ref-410)
411. Personal communication with the Committee on 3 March 2014 [↑](#footnote-ref-411)
412. ‘Inquiry launch: Regenerative Medicine ’ [↑](#footnote-ref-412)
413. The full list of respondents is available in House of Lords Science and Technology Committee, *Regenerative medicine* Appendix 2 [↑](#footnote-ref-413)
414. Ibid 71 [↑](#footnote-ref-414)
415. Ibid 5. It is notable that while many other reports concerned with the commercialisation of science have focused on economic return largely in terms of boosting UK competiveness through profit, this report also notes the potential for savings in terms of providing healthcare products for chronic and degenerative diseases (at 16). [↑](#footnote-ref-415)
416. Ibid 35 [↑](#footnote-ref-416)
417. Ibid 35 and 37 [↑](#footnote-ref-417)
418. Ibid 43-44. This had also been identified in the POST report (Parliamentary Office of Science and Technology, *Stem Cell Research*) and in a report by the Academy of Medical Sciences (Academy of Medical Sciences, *A new pathway for the regulation and governance of health research* (Academy of Medical Sciences 2011)). [↑](#footnote-ref-418)
419. House of Lords Science and Technology Committee, *Regenerative medicine* 49-50 [↑](#footnote-ref-419)
420. Ibid 51 [↑](#footnote-ref-420)
421. Ibid 54-55 [↑](#footnote-ref-421)
422. Ibid 5 [↑](#footnote-ref-422)
423. Ibid 56 [↑](#footnote-ref-423)
424. Ibid 56 This had also been mentioned in previous reports such as the UK Stem Cell Initiative, ‘Report & Recommendations’ and independent reports such as Emma Rowley and Paul Martin, *Barriers to the Commercialisation & Utilisation of Regenerative Medicine in the UK* (University of Nottingham 2009) [↑](#footnote-ref-424)
425. House of Lords Science and Technology Committee, *Regenerative medicine* 56 [↑](#footnote-ref-425)
426. Regener8 as cited in ibid 58 [↑](#footnote-ref-426)
427. Cell Therapy Catapult in ibid 57 [↑](#footnote-ref-427)
428. Ibid 57 [↑](#footnote-ref-428)
429. Ibid 59 [↑](#footnote-ref-429)
430. CEO Intercytex in ibid 58 [↑](#footnote-ref-430)
431. Ibid 60 [↑](#footnote-ref-431)
432. Ibid 51 [↑](#footnote-ref-432)
433. Ibid 51 [↑](#footnote-ref-433)
434. Ibid 52 [↑](#footnote-ref-434)
435. Ibid 51 [↑](#footnote-ref-435)
436. Ibid 52 [↑](#footnote-ref-436)
437. See, for example, Alliance for Regenerative Medicine in ibid 61 [↑](#footnote-ref-437)
438. Ibid 61 [↑](#footnote-ref-438)
439. Ibid 61 [↑](#footnote-ref-439)
440. House of Lords Science and Technology Select Committee, *Regenerative Medicine: Oral and Written evidence* (2013) 181 [↑](#footnote-ref-440)
441. Ibid 61 [↑](#footnote-ref-441)
442. House of Lords Science and Technology Committee, *Regenerative medicine* 62 [↑](#footnote-ref-442)
443. GE Healthcare and RCUK in ibid 63 [↑](#footnote-ref-443)
444. Ibid 63 [↑](#footnote-ref-444)
445. Julian Hitchcock and Alex Denoon in ibid 63 [↑](#footnote-ref-445)
446. Sean Dennehey in ibid 63 [↑](#footnote-ref-446)
447. See Aurora Plomer, ‘EU Ban on Stem Cell Patents: Intended and Unintended Consequences’ (2011) <http://eutopialaw.com/2011/11/04/eu-law-and-the-human-embryo-the-consequences-of-brustle-v-greenpeace/#more-644> accessed 11 April 2014 and Myrthe Nielen, Sybe de Vries and Niels Geijsen, ‘European stem cell research in legal shackles’ (2013) 32 EMBO 3107. Harmon, Laurie and Courtney have called for ‘more measured responses’, indicating that the effects of the ruling may not be as far reaching as first thought (Harmon, Laurie and Courtney, ‘Dignity, plurality and patentability’). [↑](#footnote-ref-447)
448. House of Lords Science and Technology Committee, *Regenerative medicine* 63 [↑](#footnote-ref-448)
449. Ibid 63 [↑](#footnote-ref-449)
450. Aiden Courtney in ibid 39 [↑](#footnote-ref-450)
451. Ibid 64 [↑](#footnote-ref-451)
452. HM Government, *Government Response to the House of Lords Science and Technology Committee Inquiry into Regenerative Medicine (Cm 8713, 2013)* [↑](#footnote-ref-452)
453. Ibid 1 Additional funding to support commercialisation in the field was announced the 2014 Budget in the form of a £55 million investment to create a ‘Cell Therapy Manufacturing Centre’ in the UK to be run by the Cell Therapy Catapult. Cell Therapy Catapult, ‘Budget unveils £55m large-scale Cell Therapy Manufacturing Centre for the UK’ [↑](#footnote-ref-453)
454. , *Government Response to the House of Lords Science and Technology Committee Inquiry into Regenerative Medicine* 10. This group has now been set up, see ‘Regenerative Medicine Expert Group’ <https://www.gov.uk/government/policy-advisory-groups/regenerative-medicine-expert-group> accessed 10 April 2014 [↑](#footnote-ref-454)
455. , *Government Response to the House of Lords Science and Technology Committee Inquiry into Regenerative Medicine* 4 [↑](#footnote-ref-455)
456. Ibid 13 [↑](#footnote-ref-456)
457. For example, the Human induced Pluripotent Stem Cell Initiative (HIPSCI) was funded by both the MRC and Wellcome Trust. ‘Wellcome Trust and MRC invest £13m to create a new national stem cell resource’ (2012) <http://www.mrc.ac.uk/Newspublications/News/MRC008920> accessed 23 April 2014 [↑](#footnote-ref-457)
458. See section 2.3.6. Funding for projects involving human embryonic stem cells was explicitly allowed, in restricted cases, under FP6. For a discussion of the history of this controversy in the run up to FP6 see Salter, ‘Transnational governance and cultural politics’ [↑](#footnote-ref-458)
459. Using the Cordis database, a search was carried out to assess how many projects had involved stem cells during each framework programme (advanced search, projects, search all fields: “stem cells”, programme type: first programme through to seventh programme). 151 such projects were funded in FP6 and 315 were funded in FP7. [↑](#footnote-ref-459)
460. European Commission Directorate General for Research Life Sciences Genomics and Biotechnologies for Health, *Stem Cells: European research projects involving stem cells in the 6th Framework Programme* [↑](#footnote-ref-460)
461. Ibid [↑](#footnote-ref-461)
462. ““Foreground” means the results, including information, materials and knowledge, generated in a given project, whether or not they can be protected. It includes intellectual property rights” European Commission, ‘Guide to Intellectual Property Rules for FP7 Projects. Version 3’ 5 [↑](#footnote-ref-462)
463. Ibid 27 [↑](#footnote-ref-463)
464. Ibid 27-28 [↑](#footnote-ref-464)
465. Ibid 28 [↑](#footnote-ref-465)
466. Ibid 30 [↑](#footnote-ref-466)
467. Ibid 29 [↑](#footnote-ref-467)
468. Ibid 30 [↑](#footnote-ref-468)
469. Ibid 30 [↑](#footnote-ref-469)
470. 79% of public funding in regenerative medicine funded basic/early preclinical research in 2010. House of Lords Science and Technology Committee, *Regenerative medicine* 29 [↑](#footnote-ref-470)
471. In 2002, the research councils requested additional funding from the Government for stem cell research. £40M was awarded and supported “a broad range of stem cell research grants, and provided support for capacity building, public engagement and essential infrastructure such as the UK Stem Cell Bank.” (<http://www.rcuk.ac.uk/research/xrcprogrammes/prevprogs/Pages/StemCells.aspx>) [↑](#footnote-ref-471)
472. For example, in 2008-9 TSB, in partnership with MRC, BBSRC and EPSRC, funded projects through the Regenerative Medicines Programme (£21.5 million) with the aim “of ensuring that UK businesses could achieve a commercially competitive edge with global impact by underpinning and enabling the best regenerative medicine businesses in the UK to flourish” House of Lords Science and Technology Committee, *Regenerative medicine* 30 [↑](#footnote-ref-472)
473. BBSRC, ‘UK Regenerative Medicine Platform’ (2012) <http://www.bbsrc.ac.uk/web/FILES/PreviousAwards/uk-regenerative-medicine-platform-bgrd.pdf> accessed 10 April 2014, 1 [↑](#footnote-ref-473)
474. House of Lords Science and Technology Committee, *Regenerative medicine* 28 [↑](#footnote-ref-474)
475. RCUK, ‘Impact Policies: Intellectual Property’ <http://www.rcuk.ac.uk/ke/policies/> accessed 11 April 2014 [↑](#footnote-ref-475)
476. RCUK, ‘Terms and Conditions of Grants ’ (2013) <http://www.rcuk.ac.uk/RCUK-prod/assets/documents/documents/tcfec.pdf> accessed 10 April 2014 21 [↑](#footnote-ref-476)
477. Ibid 21 [↑](#footnote-ref-477)
478. Ibid 21 [↑](#footnote-ref-478)
479. Ibid 21 [↑](#footnote-ref-479)
480. TSB, ‘Guide to Technology Strategy Board Collaborative Research and Development Competitions ’ (2011) <https://connect.innovateuk.org/documents/2998699/3675995/TSB+Funding+Guide.pdf/7c241ed9-a20c-4b20-adfe-42c8c9253bd3> accessed 11 April 2014, 22 [↑](#footnote-ref-480)
481. Data reported in House of Lords Science and Technology Committee, *Regenerative medicine* 33 and 64 [↑](#footnote-ref-481)
482. House of Lords Science and Technology Select Committee, *Regenerative Medicine: Oral and Written evidence*  774 [↑](#footnote-ref-482)
483. Wellcome Trust, ‘Policy on intellectual property and patenting ’ <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002762.htm> accessed 10 April 2014 [↑](#footnote-ref-483)
484. Ibid [↑](#footnote-ref-484)
485. Wellcome Trust, ‘Conditions under which a grant is awarded’ <http://www.wellcome.ac.uk/stellent/groups/corporatesite/@sf\_central\_grants\_admin/documents/web\_document/wtx026668.pdf> accessed 10 April 2014 7(i) [↑](#footnote-ref-485)
486. Ibid 7(iii) [↑](#footnote-ref-486)
487. Ibid 7(ii) [↑](#footnote-ref-487)
488. RCUK, ‘Terms and Conditions of Grants ’ 21 [↑](#footnote-ref-488)
489. Wellcome Trust, ‘Conditions under which a grant is awarded’ 5 [↑](#footnote-ref-489)
490. Wellcome Trust, ‘Wellcome Trust-funded intellectual property: exploitation consent and standard revenue/equity-sharing agreement (CRSA/12/2009)’ <http://www.wellcome.ac.uk/stellent/groups/corporatesite/@technology\_transfer/documents/web\_document/wtd003534.doc > accessed 11 April 2014 3.3(d) and 3.4(a) [↑](#footnote-ref-490)
491. Only Germany was higher with 29 companies, REMEDiE in House of Lords Science and Technology Committee, *Regenerative medicine* 23 [↑](#footnote-ref-491)
492. UK Regenerative Medicine Community in ibid 24 [↑](#footnote-ref-492)
493. ‘UCL-Pfizer to develop pioneering stem cell sight therapies’ (2009) <http://www.ucl.ac.uk/news/news-articles/0904/09042301> accessed 07 April 2014 [↑](#footnote-ref-493)
494. ‘UCL and Pfizer Announce Extension to Collaboration To Advance Development Of Stem Cell-Based Therapies’ (2011) <http://www.ucl.ac.uk/ioo/news110225.php> accessed 11 April 2014 [↑](#footnote-ref-494)
495. See, for example, Pfizer, ‘Pfizer's Stem Cell Research Policy’ <http://www.pfizer.com/research/research\_clinical\_trials/stem\_cell\_research> accessed 11 April 2014 and Reneuron, ‘About us’ <http://www.reneuron.com/about-reneuron> accessed 11 April 2014 [↑](#footnote-ref-495)
496. For example, in 2008, it was announced that Pfizer was investing £41 million in a centre to house research into regenerative medicine, including stem cell based work.Clive Cookson and Andrew Jack, ‘Pfizer to build £41m UK stem cell centre (Financial Times, 13 November 2008)’ (2008) <http://www.ft.com/cms/s/0/9f12390e-b1b7-11dd-b97a-0000779fd18c.html> accessed 23 April 2014 [↑](#footnote-ref-496)
497. ‘UCL-Pfizer to develop pioneering stem cell sight therapies’ [↑](#footnote-ref-497)
498. Ibid [↑](#footnote-ref-498)
499. Economic and Social Research Council, *Science in the economy and the economics of science* 8 [↑](#footnote-ref-499)
500. Enrico Deiaco, Alan Hughes and Maureen McKelvey, ‘Universities as strategic actors in the knowledge economy’ (2012) 36 Camb J Econ 525 [↑](#footnote-ref-500)
501. Hughes and Martin, ‘Enhancing Impact: The value of public sector R&D’ 13 [↑](#footnote-ref-501)
502. Jason Owen-Smith and Walter W. Powell, ‘Careers and contradictions: faculty responses to the transformation of knowledge and its uses in the life sciences’ in Steven Vallas (ed), *The Transformation of Work (Research in the Sociology of Work, Volume 10)* (Emerald Group Publishing Ltd 2001) [↑](#footnote-ref-502)
503. Valentina Tartari, Ammon Salter and Pablo D’Este, ‘Crossing the Rubicon: exploring the factors that shape academics’ perceptions of the barriers to working with industry’ (2012) 36 Camb J Econ 655 671 [↑](#footnote-ref-503)
504. Robert Merton, *The sociology of science: theoretical and empirical investigations* (The University of Chicago Press 1973) 270 [↑](#footnote-ref-504)
505. “[The norms are] expressed in the form of prescriptions, proscriptions, preferences and permissions. They are legitimized in terms of institutional values.” Ibid 269 [↑](#footnote-ref-505)
506. Ibid 270-73 [↑](#footnote-ref-506)
507. Ibid 273-75 [↑](#footnote-ref-507)
508. Ibid 275-77 [↑](#footnote-ref-508)
509. Ibid 277-78 [↑](#footnote-ref-509)
510. For example, Resnik suggests an expanded set of norms are at play in the undertaking of modern science, based on the work of Merton but attempting to account for the changes that the institutions of science has faced since Merton’s work of the 1970s. Resnik includes the following ethical principles in his model: honesty; carefulness; objectivity; openness; freedom; credit; respect for intellectual property; respect for colleagues and students; respect for research subjects; competence; confidentiality; legality; social responsibility; and stewardship of resources(David B. Resnik, *The Price of Truth: How Money Affects the Norms of Science* (OUP 2007) Ch 2). See also Scott F Kieff, ‘Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science-A Response to Rai and Eisenberg’ (2000) Volume 95 Northwestern University School of Law Law and Economics Papers [↑](#footnote-ref-510)
511. Rebecca Eisenberg, ‘Proprietory Rights and the Norms of Science in Biotechnology Research’ (1987) 97 Yale LJ 177 [↑](#footnote-ref-511)
512. Arti K. Rai, ‘Regulating Scientific Research: Intellectual Property Rights and the Norms of Science’ (1999) 94 Nw UL Rev 77, 93-100 [↑](#footnote-ref-512)
513. Eisenberg, ‘Public Research and Private Development’ [↑](#footnote-ref-513)
514. Amy Kapczynski, ‘Addressing Global Health Inequalities: An Open Licensing Approach for University Innovations’ (2005) 20 Berkeley Tech LJ 1031, 1085-86 [↑](#footnote-ref-514)
515. Radder, ‘A Deflationary, Neo-Mertonian Critique of Academic Patenting’ 229 [↑](#footnote-ref-515)
516. Eisenberg, ‘Public Research and Private Development’ 1667 [↑](#footnote-ref-516)
517. Fiona Murray, ‘The Stem-Cell Market - Patents and the Pursuit of Scientific Progress’ (2007) 356 New Eng J Med 2341, 2341-42 [↑](#footnote-ref-517)
518. Merton, *The sociology of science* 274 [↑](#footnote-ref-518)
519. Eisenberg, ‘Proprietory Rights and the Norms of Science in Biotechnology Research’ 184 [↑](#footnote-ref-519)
520. Merton, *The sociology of science* 286 [↑](#footnote-ref-520)
521. Rebecca Eisenberg, ‘Genomics in the public domain: strategy and policy’ (2000) 1 Nature Reviews Genetics 70 [↑](#footnote-ref-521)
522. Rebecca Eisenberg, ‘Patenting the human genome’ (1990) 39 Emory LJ 721, 744 [↑](#footnote-ref-522)
523. See discussions in Heller and Eisenberg, ‘Can Patents Deter Innovation? ’ and Fiona Murray and Scott Stern, ‘Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis’ (2007) 63 J Econ Behavior & Organization 648 [↑](#footnote-ref-523)
524. UKIPO, ‘Intellectual Asset Management for Universities’ 2 [↑](#footnote-ref-524)
525. Royal Society, *Science as an open enterprise* 44 [↑](#footnote-ref-525)
526. Dame Janet Finch, *Accessibility, sustainability, excellence: how to expand access to research publications: Report of the Working Group on Expanding Access to Published Research Findings* (Research Innovation Network 2012) 5 [↑](#footnote-ref-526)
527. Department for Business Innovation & Skills, ‘Letter to Dame Janet Finch on the Government Response to the Finch Group Report: “Accessibility, sustainability, excellence: how to expand access to research publications”’ (2012) <http://www.bis.gov.uk/assets/biscore/science/docs/l/12-975-letter-government-response-to-finch-report-research-publications.pdf> accessed 23 April 2014 [↑](#footnote-ref-527)
528. Dame Janet Finch, *The Finch Report* 2 [↑](#footnote-ref-528)
529. Ibid 7 [↑](#footnote-ref-529)
530. Ibid 7 [↑](#footnote-ref-530)
531. European Commission, *Press Release 'Scientific data: open access to research results will boost Europe's innovation capacity' (IP/12/790)* (2012) 1 accompanying European Commission Communication (2012) 'A Reinforced European Research Area Partnership for Excellence and Growth' COM(2012) 392 [↑](#footnote-ref-531)
532. European Commission, *Press Release 'Scientific data: open access to research results will boost Europe's innovation capacity' (IP/12/790)* 1 accompanying A Reinforced European Research Area Partnership for Excellence and Growth (2012) [↑](#footnote-ref-532)
533. Bo-Christer Björk and others, ‘Open Access to the Scientific Journal Literature’ (2010) 5 PLoS One 1, 1 [↑](#footnote-ref-533)
534. Dame Janet Finch, *The Finch Report* 5 [↑](#footnote-ref-534)
535. Owen-Smith and Powell, ‘Careers and contradictions’ [↑](#footnote-ref-535)
536. Pierre Azoulay, Waverley Ding and Toby Stuart, ‘The determinants of faculty patenting behavior: Demographics or opportunities?’ (2007) 63 J Econ Behavior & Organization 599, 614-15 [↑](#footnote-ref-536)
537. Ibid 623 [↑](#footnote-ref-537)
538. Sanjay Jain, Gerard George and Mark Maltarich, ‘Academics or entrepreneurs? Investigating role identity modification of university scientists involved in commercialization activity’ (2009) 38 Research Policy 922, 922 [↑](#footnote-ref-538)
539. Lambert, *The Lambert Review*  para 4.33. This has been evidenced recently in the US using data which showed 87% of university TTO’s did not recoup their costs through IP licensing revenues (Valdivia, ‘University Start-Ups’ 9). [↑](#footnote-ref-539)
540. HEFCE, *Higher Education – Business and Community Interaction Survey: 2011-12*  [↑](#footnote-ref-540)
541. Ibid [↑](#footnote-ref-541)
542. Valdivia, ‘University Start-Ups’ [↑](#footnote-ref-542)
543. See for example, Lambert, *The Lambert Review*  para 4.10-4.11, Wellings, *The Wellings Report*, Johan Bruneel and others, *The search for talent and technology: Examining the Attitudes of EPSRC Industrial Collaborators towards Universities* (Advanced Institute of Management Research 2009), Alan Hughes and Michael Kitson, ‘Pathways to impact and the strategic role of universities: new evidence on the breadth and depth of university knowledge exchange in the UK and the factors constraining its development’ (2012) 36 Cambridge journal of economics 723 and Rowley and Martin, *Barriers to the Commercialisation & Utilisation of Regenerative Medicine in the UK* [↑](#footnote-ref-543)
544. Rowley and Martin, *Barriers to the Commercialisation & Utilisation of Regenerative Medicine in the UK* [↑](#footnote-ref-544)
545. Ibid 21. This was also noted more generally in Lambert, *The Lambert Review*  para 4.13-4.18 [↑](#footnote-ref-545)
546. Rowley and Martin, *Barriers to the Commercialisation & Utilisation of Regenerative Medicine in the UK* 67 [↑](#footnote-ref-546)
547. Royal Society, *Science as an open enterprise* 47 and Ananyo Bhattacharya, ‘Science funding: Duel to the death’ (2012) 488 Nature 20. More generally, see discussions in Hughes and Martin, ‘Enhancing Impact: The value of public sector R&D’ and Aldo Geuna, ‘The Changing Rationale for European University Research Funding: Are There Negative Unintended Consequences?’ (2001) 35 J Econ Issues 607 [↑](#footnote-ref-547)
548. Royal Society, *The Scientific Century*  [↑](#footnote-ref-548)
549. Hughes and Martin, ‘Enhancing Impact: The value of public sector R&D’ 76 [↑](#footnote-ref-549)
550. Ibid 40 [↑](#footnote-ref-550)
551. UKIPO, ‘Why use IP?’ <http://www.ipo.gov.uk/whyuse.htm > accessed 05 April 2014 [↑](#footnote-ref-551)
552. Patent rights be infringed under any of the conditions of the meaning of infringement as provided in UK Patents Act s. 60. The territoriality of patents is noted in the meaning of infringement in the use of the phrase “in the United Kingdom” in s. 60(1), indicating that infringement can only occur (under the UK Patents Act) within the UK. The term of a patent is detailed in s. 25 – the 20 year period begins with the date of filing (s. 25(1)). However, a patent may cease to have effect before the end of this 20 year period if the appropriate renewal fees are not paid (s. 25(3)). [↑](#footnote-ref-552)
553. For example, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakech Agreement Establishing the World Trade Organisation, signed in Marrakech, Morocco, 15 April 1994, Convention on the Grant of European Patents (European Patent Convention) signed in Munich, Germany, 5 October 1973 as amended (14th Edition, August 2010) and UK Patents Act [↑](#footnote-ref-553)
554. The term ‘patentability’ covers the substantive conditions that must be met for a patent to be held valid [↑](#footnote-ref-554)
555. For example, The TRIPS Agreement , EPC and UK Patents Act [↑](#footnote-ref-555)
556. UK Patents Act s. 18 [↑](#footnote-ref-556)
557. Ibid s. 60 and s. 61 [↑](#footnote-ref-557)
558. Ibid s. 72 [↑](#footnote-ref-558)
559. See, for example, ibid s. 1, EPC Article 52, The TRIPS Agreement Article 27 [↑](#footnote-ref-559)
560. UK Patents Act s. 1(1) [↑](#footnote-ref-560)
561. Ibid s. 1(2) [↑](#footnote-ref-561)
562. Ibid s. 1(3) [↑](#footnote-ref-562)
563. The Patents Regulations 2000 (SI 2000 No.2037) The relevant amendments can be found at UK Patents Act s. 76A and Schedule A2 [↑](#footnote-ref-563)
564. UK Patents Act s. 76A(3) [↑](#footnote-ref-564)
565. Ibid s. 14(2) [↑](#footnote-ref-565)
566. Ibid s. 14(3) and further s. 14(5) provides that the specification must contain claims which shall “(a) define the matter for which the applicant seeks protection; (b) be clear and concise”. A similar requirement is also present in The TRIPS Agreement Article 29(1) and EPC Article 83. [↑](#footnote-ref-566)
567. UK patent law provides that a patent application must be made public, usually within 18 months from the filing date (s. 16 (1)) and that a patent grant is published as soon as possible after grant (s. 24(1)) UK Patents Act. This also applies under the EPC (Article 93) and PCT (Article 21, for applications). [↑](#footnote-ref-567)
568. Ibid s. 72(1) [↑](#footnote-ref-568)
569. For example, see Machlup, *An Economic Review of the Patent System*  3 regarding the spread of the patent system in the 17th and 18th centuries and the justifications involved. For an extensive discussion of the different philosophical justifications for intellectual property rights see Peter Drahos, *A Philosophy of Intellectual Property* (Dartmouth Publishing Group 1996). [↑](#footnote-ref-569)
570. Machlup, *An Economic Review of the Patent System*  21 [↑](#footnote-ref-570)
571. Sigrid Sterckx, ‘The Ethics of Patenting - Uneasy Justifications’ in Peter Drahos (ed), *Death of Patents* (Lawtext Publishing Ltd 2005) 193 [↑](#footnote-ref-571)
572. Ibid 193 [↑](#footnote-ref-572)
573. See for example Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System*, Jaffe and Lerner, *Innovation and Its Discontents* ), Machlup, *An Economic Review of the Patent System* . In addition, leading policymakers have spoken of the economic rationale. See for example, the EPO’s President Battistelli's speech “a patent system is not a goal in itself, it is an economic tool to promote innovation. This is why, for example, I consider that, for a patent office, the wide dissemination of the technological information contained in patent applications is as important as its role in granting patent protection.” Battistelli, ‘The future of the European patent system - current developments and trends. Speech by Mr Benoît Battistelli President of the European Patent Office’ [↑](#footnote-ref-573)
574. Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System* 3 [↑](#footnote-ref-574)
575. See discussion in Drahos, *The Global Governance of Knowledge* 27-32 [↑](#footnote-ref-575)
576. Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System* 3 [↑](#footnote-ref-576)
577. Ibid 75 [↑](#footnote-ref-577)
578. Ibid 48-49 [↑](#footnote-ref-578)
579. Klaus Boehm and Aubrey Silberston, *The British patent system* (CUP 1967) 1 [↑](#footnote-ref-579)
580. Drahos, *The Global Governance of Knowledge* 31 [↑](#footnote-ref-580)
581. Fritz Machlup and Edith Penrose, ‘The Patent Controversy in the Nineteenth Century’ (1950) 10 J Econ History 1, 26 [↑](#footnote-ref-581)
582. Moir notes that “Because the objective of patent policy is not specified in the legislation, but the disclosure conditionality is, disclosure is often given weight in legal circles as the objective of the system … Some therefore argue that patents lead to higher economic growth, not by inducing more invention, but because of information disclosure. While this theory is strongly held in legal circles, it has not generally been well regarded by economics and has not been empirically tested…” Hazel VJ Moir, *Patent Policy and Innovation: Do Legal Rules Deliver Effective Economic Outcomes?* (mcEdward Elgar 2013) ibid 39 [↑](#footnote-ref-582)
583. For further discussion on the role of disclosure in patent law see, for example, Kitch, ‘The Nature and Function of the Patent System’, Fromer, ‘Patent Disclosure’, Devlin, ‘The misunderstood function of disclosure in patent law’, Seymore, ‘The Teaching Function of Patents’ and Roin, ‘The Disclosure Function of the Patent System ’ [↑](#footnote-ref-583)
584. In his seminal article Machlup argued that “inventive activity must precede the patent, whereas innovative activity may follow it.” (Machlup, *An Economic Review of the Patent System*  56.) The terms ‘downstream innovation’ (modified from ‘downstream product development’) and ‘upstream research’ are taken from Heller and Eisenberg, ‘Can Patents Deter Innovation? ’. In this way, invention is the middle-point: events that happen prior to a patent are ‘upstream’ and subsequent events are ‘downstream’. [↑](#footnote-ref-584)
585. The rationale recognises the cumulative nature of invention: inventors benefit from the earlier work of others and information released about their inventions through the patent system. This cumulative function of invention is particularly true in high technology/fast-moving fields such as biotechnology and stem cell science (Jaffe and Lerner, *Innovation and Its Discontents*  64). [↑](#footnote-ref-585)
586. On the perceived importance of disclosure from the perspectives of key policy makers see Battistelli, ‘The future of the European patent system - current developments and trends. Speech by Mr Benoît Battistelli President of the European Patent Office’ and Gurry, ‘The Disclosure of Technology in the Patent System’. For a discussion of the use of this justification in the US see Holbrook, ‘Possession in Patent Law’. [↑](#footnote-ref-586)
587. *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd.* [2004] UKHL 46, 77 [↑](#footnote-ref-587)
588. Drahos, *The Global Governance of Knowledge* 31-32 [↑](#footnote-ref-588)
589. See, for example, discussion in James Bessen and Michael J. Meurer, *Patent failure: How judges, bureaucrats and lawyers put innovators at risk* (Princeton UP 2008), Beth Noveck, *Wiki Government: How technology can make government better, democracy stronger, and citizens more powerful* (Brookings 2009) and further discussion in section 5.5.1. [↑](#footnote-ref-589)
590. In her in-depth study of business methods patents in Australia, Moir determined “the quantum of inventiveness required for a patent is abysmally low.” She notes that the concept of inventiveness is problematic: “inventiveness is not a discrete variable but rather covers a continuum from none to radically inventive. The issue for a balanced patent policy is where along this continuum to draw the line – at what point will there generally be sufficient benefit to the nation to merit the monopoly grant?” Moir, *Patent Policy and Innovation* 50 [↑](#footnote-ref-590)
591. Drahos, *The Global Governance of Knowledge* 31-32 [↑](#footnote-ref-591)
592. For an extensive discussion of the history of the biotechnology industry and patenting see Dutfield, *Intellectual Property Rights and the Life Sciences Industries*. Dutfield highlights that while some patents had been granted over microorganisms in the 18th and 19th century, including Pasteur’s patent over a yeast culture patent, since the 1880s, the product of nature doctrine had “apparently disallowed the patenting of any further life forms.” (at 196) [↑](#footnote-ref-592)
593. *Diamond v Chakrabarty* [1980] 447 US 303, 306 [↑](#footnote-ref-593)
594. Ibid 303 [↑](#footnote-ref-594)
595. Ibid 310 [↑](#footnote-ref-595)
596. See discussion in Donna M Gitter, ‘International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption’ (2001) 76 NYUL Rev 1623 and Robert Cook-Deegan, *The gene wars: science, politics, and the human genome* (W. W. Norton & Company Ltd 1994) Ch 19 [↑](#footnote-ref-596)
597. See Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council on Bioethics 2002) Ch 3 and Appendix 2 and Cook-Deegan, *The gene wars* 330 [↑](#footnote-ref-597)
598. Directive on Biotechnological Inventions Article 5(2) [↑](#footnote-ref-598)
599. Graff and others identified “15, 359 patents containing at least one simple composition-of-matter claim to an isolated nucleic acid molecule that most closely fits the definition of “gene” patent as challenged in the Myriad case” Gregory D Graff and others, ‘Not quite a myriad of gene patents’ (2013) 31 Nature Biotechnology 404, 407 [↑](#footnote-ref-599)
600. See, for example, Cook-Deegan, *The gene wars*, Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton UP 2005) Ch 8, Dutfield, *Intellectual Property Rights and the Life Sciences Industries* Ch 8, Nuffield Council on Bioethics, *The Ethics of Patenting DNA* and Secretary's Advisory Committee on Genetics, *The SACGHS on Gene Patents* [↑](#footnote-ref-600)
601. *Association for Molecular Pathology et al. v Myriad Genetics, Inc. et al.* [2013] 569 US 12-398 [↑](#footnote-ref-601)
602. Ibid 12 [↑](#footnote-ref-602)
603. U.S. Code Title 35-Patents §101 [↑](#footnote-ref-603)
604. *Association for Molecular Pathology et al. v Myriad Genetics, Inc. et al.*16-17 [↑](#footnote-ref-604)
605. USPTO, ‘Memorandum: Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc.’ (2013) <http://www.uspto.gov/patents/law/exam/myriad\_20130613.pdf> accessed 10 April 2014 [↑](#footnote-ref-605)
606. Graff and others, ‘Not quite a myriad of gene patents’ [↑](#footnote-ref-606)
607. Trevor Cook explains that the Biotechnology Directive was thought to have resolved the question of whether genes were patentable in the EU. (Trevor Cook, ‘Stem Cell Patenting in the European Union’ (2012) 17 JIPR 73). On the ongoing questions raised by the case in the US see Kevin Kabler, ‘Burdens of Section 101 following Myriad (Fenwick & West LLP)’ (2013) <http://www.fenwick.com/FenwickDocuments/Burdens\_of\_Section\_101.pdf> accessed 13 April 2014 and ‘The case: Myriad at the Supreme Court (Fitzpatrick Cella Haper & Scinto LLP)’ (2013) <http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Myriad-fischer-rothman-carlin.pdf> accessed 13 April 2014. [↑](#footnote-ref-607)
608. See for example, Secretary's Advisory Committee on Genetics, *The SACGHS on Gene Patents*, Sevilla and others, ‘Impact of gene patents on the cost-effective delivery of care’, Timothy Caulfield, Tania Bubela and CJ Murdoch, ‘Myriad and the mass media: the covering of a gene patent controversy’ (2007) 9 Genetics in Medicine 850 and Arti K Rai and Robert Cook-Deegan, ‘Moving beyond “isolated” gene patents’ (2013) 341 Science [↑](#footnote-ref-608)
609. The high cost of the BRCA tests became highly publicised following Angelina Jolie’s decision to undergo a double mastectomy after she tested positive for BRCA1. The later press coverage of the Myriad case was extensive, often using Jolie as an example in discussion. See, for example, Karen McVeigh, ‘US supreme court rules human genes cannot be patented (The Guardian, 13 June 2013)’ (2013) <http://www.theguardian.com/law/2013/jun/13/supreme-court-genes-patent-dna> accessed 23 April 2014 and Clive Cookson and Andew Jack, ‘US Supreme Court rules that only synthetic genes are patentable (Financial Times, 13 June 2013)’ (2013) <http://www.ft.com/cms/s/0/bde7853c-d43a-11e2-a464-00144feab7de.html> accessed 23 April 2014. [↑](#footnote-ref-609)
610. James D. Watson, *Brief of James D. Watson, Ph.D. as amicus curiae in support of neither party, Myriad, 133 S. Ct. 2107 (No. 12-398)* (2012) 3-4 [↑](#footnote-ref-610)
611. Ibid 3 [↑](#footnote-ref-611)
612. Ibid 4 [↑](#footnote-ref-612)
613. Ibid 19. Eric Lander highlighted similar concerns that patents can ‘wall off’ fields of study where the invention cannot be circumvented, creating ‘insurmountable barriers’ to research and innovation (Eric S. Lander, *Brief for amicus curiae Eric S. Lander in support of neither party, Myriad, 133 S. Ct. 2107 (No. 12-398)* (2013) 22-26) [↑](#footnote-ref-613)
614. “Thirty years ago in Science, Garrett Hardin introduced the metaphor “tragedy of the commons” to help explain overpopulation, air pollution, and species extinction. People often overuse resources they own in common because they have no incentive to conserve.” Heller and Eisenberg, ‘Can Patents Deter Innovation? ’ 698 [↑](#footnote-ref-614)
615. They theorise that such a tragedy occurs when “multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use … Once an anticommons emerges, collecting rights into usable private property is often brutal and slow.” Ibid 698 [↑](#footnote-ref-615)
616. Ibid 699 [↑](#footnote-ref-616)
617. Ibid 698 [↑](#footnote-ref-617)
618. Ibid 701 [↑](#footnote-ref-618)
619. Ibid 698 [↑](#footnote-ref-619)
620. Murray and Stern, ‘Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge?’, John P Walsh, Wesley M Cohen and Charlene Cho, ‘Where excludability matters: Material versus intellectual property in academic biomedical research’ (2007) 36 Research Policy 1184. There have been studies that indicate that if there is an anticommons effect, academic scientists do not perceive this as a problem due to an attitude that working solutions could be found to overcome these issues which, together with a lack of awareness of the patent landscape in which they work means scientists may intentionally or unintentionally infringe existing patents. For example, John P. Walsh, Ashish Arora and Wesley M. Cohen, ‘Working Through the Patent Problem’ (2003) 299 Science 1021 reported working solutions from the scientists ranging from licensing to intentional infringement, with a belief that intentional infringement came under the concept of “research exemption”. See also Lei, Jenuja and Wright, ‘Patents versus patenting’ [↑](#footnote-ref-620)
621. Lei, Jenuja and Wright, ‘Patents versus patenting’ 36 [↑](#footnote-ref-621)
622. Murray and Stern, ‘Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge?’ 683 [↑](#footnote-ref-622)
623. This concern has also been raised in relation to stem cell patents (see Ann E Mills and Patti M Tereskerz, ‘Empirical analysis of major stem cell patent cases: the role of universities’ (2010) 28 Nature Biotechnology 325, 326). [↑](#footnote-ref-623)
624. Joseph Stiglitz and John Sulston, ‘The Case Against Gene Patents (The Wall Street Journal, 16 April 2010)’ (2010) <http://online.wsj.com/news/articles/SB10001424052702303348504575183982493601368> accessed 23 April 2014 [↑](#footnote-ref-624)
625. Bergman and Graff, ‘The global stem cell patent landscape’ 6 [↑](#footnote-ref-625)
626. Ibid, Konski and Spielthenner, ‘Stem cell patents: a landscape analysis’, Brenda M Simon, Charles E Murdoch and Christopher T Scott, ‘Pluripotent patents make prime time: an analysis of the emerging landscape’ (2010) 28 Nature Biotechnology 557 and Feldman and Furth, ‘The Intellectual Property Landscape for iPS Cells’ [↑](#footnote-ref-626)
627. Bergman and Graff, ‘The global stem cell patent landscape’, Jeanne F. Loring and Cathryn Campbell, ‘Intellectual Property and Human Embryonic Stem Cell Research’ (2006) 311 Science 1716, Amy Zarzeczny and others, ‘iPS Cells: Mapping the Policy Issues’ (2009) 139 Cell 1032 1035 and Mills and Tereskerz, ‘Empirical analysis of major stem cell patent cases’ [↑](#footnote-ref-627)
628. James A. Thomson and others, ‘Embryonic Stem Cell Lines Derived from Human Blastocysts’ (1998) 282 Science 1145 [↑](#footnote-ref-628)
629. See discussion in Aurora Plomer, Kenneth S. Taymor and Christopher Thomas Scott, ‘Challenges to Human Embryonic Stem Cell Patents’ (2008) 2 Cell Stem Cell 13 [↑](#footnote-ref-629)
630. Thomson, *Primate Embryonic Stem Cells (US 5,843,780 )*, Thomson, *Primate Embryonic Stem Cells (US 6, 200, 806)* and Thomson, *Primate Embryonic Stem Cells (US 7, 029, 913)* [↑](#footnote-ref-630)
631. Plomer, Taymor and Scott, ‘Challenges to Human Embryonic Stem Cell Patents’ [↑](#footnote-ref-631)
632. ‘Request for *ex parte* reexamination patent number 5, 843, 780 Primate Embryonic Stem Cells’ (2006) <http://www.pubpat.org/assets/files/warfstemcell/780Request.pdf> accessed 13 April 2014 (similar requests were filed for the other two patents – US 6, 200, 806 and US 7,029, 913) [↑](#footnote-ref-632)
633. Ibid 17 These concerns were also raised by scientists themselves (see Constance Holden, ‘Prominent Researchers Join the Attack on Stem Cell Patents’ (2007) 317 Science 187) [↑](#footnote-ref-633)
634. Public Patent Foundation, ‘WARF Stem Cell Patents’ <http://www.pubpat.org/warfstemcell.htm> accessed 13 April 2014 [↑](#footnote-ref-634)
635. Ibid [↑](#footnote-ref-635)
636. “WARF did not create or alter the properties inherent in stem cells any more than Myriad created or altered the genetic information encoded in the DNA it claimed”. Public Patent Foundation, *Opening Brief of Appellant in Consumer Watchdog v WARF* (2013) 15 [↑](#footnote-ref-636)
637. “effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology” Directive on Biotechnological Inventions para 3 [↑](#footnote-ref-637)
638. Aurora Plomer and others, *Stem Cell Patents: European Patent Law and Ethics Report (FP6 ‘Life sciences, genomics and biotechnology for health. Project number SSA LSSB-CT-2004-005251)* (University of Nottingham 2006) and Gerard Porter and others, ‘The patentability of human embryonic stem cells in Europe’ (2006) 24 Nature Biotechnology 653 [↑](#footnote-ref-638)
639. Wisconsin Alumni Research Foundation (2004) Hematopoietic differentiation of human embryonic stem cells Application No. 00 957 842.8, November 18, 2004 as cited in Plomer, Taymor and Scott, ‘Challenges to Human Embryonic Stem Cell Patents’ [↑](#footnote-ref-639)
640. *G2/06 Wisconsin Alumni Research Fund* [2009] OJ EPO 306 Order 2 Question 2 [↑](#footnote-ref-640)
641. Ibid para 15-31 [↑](#footnote-ref-641)
642. Porter and others, ‘The patentability of human embryonic stem cells in Europe’ [↑](#footnote-ref-642)
643. UKIPO, ‘Inventions involving human embryonic stem cells’ (2003) <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells.htm> accessed 05 April 2014. This position was maintained following the EPO’s 2008 decision in WARF (see UKIPO, ‘Patentability of human embryonic stem cells’ <http://www.ipo.gov.uk/pro-types/pro-patent/p-policy/p-policy-biotech/p-policy-biotech-stemcell.htm> accessed 05 April 2014[)](http://www.ipo.gov.uk/pro-types/pro-patent/p-policy/p-policy-biotech/p-policy-biotech-stemcell.htm) [↑](#footnote-ref-643)
644. UKIPO, ‘Inventions involving human embryonic stem cells’ (2012) <http://www.ipo.gov.uk/p-pn-stemcells-20120517.htm> accessed 16 April 2014 [↑](#footnote-ref-644)
645. For extensive discussions of the case see Harmon, Laurie and Courtney, ‘Dignity, plurality and patentability’ and Aurora Plomer, ‘After Brustle: EU accession to the ECHR and the future of European patent law’ (2012) 2 Queen Mary Journal of Intellectual Property 110 [↑](#footnote-ref-645)
646. The patent was first filed at the German patent office (Oliver Brüstle, *Neural precursor cells, method for the production and use thereof in neural therapy (DE1997156864)* (1997)) then through the PCT, designating the EPO Oliver Brüstle, *Neural precursor cells, method for the production and use thereof in neural defect therapy (PCT/DE1998/003817)* (1999) [↑](#footnote-ref-646)
647. *Brüstle v Greenpeace* [2012] C-34/10 1 CMLR 41 para 23 [↑](#footnote-ref-647)
648. Ibid para 34 [↑](#footnote-ref-648)
649. Ibid para 35 [↑](#footnote-ref-649)
650. Ibid para 36 [↑](#footnote-ref-650)
651. Ibid operative part 3 [↑](#footnote-ref-651)
652. Ibid para 49 [↑](#footnote-ref-652)
653. The ruling became the basis of a legal challenge from some MEPs to prevent the funding of research using hESCs under Horizon 2020. For a discussion of this challenge see Aurora Plomer, ‘Horizon 2020: EU funding of hESC research in the balance’ (2012) <http://eutopialaw.com/2012/10/24/horizon-2020-eu-funding-of-hesc-research-in-the-balance/> accessed 11 April 2014 [↑](#footnote-ref-653)
654. Regulation Horizon 2020 Article 19.4 [↑](#footnote-ref-654)
655. Plomer, ‘EU Ban on Stem Cell Patents’, Cook, ‘Stem Cell Patenting in the European Union’, Nielen, Vries and Geijsen, ‘European stem cell research in legal shackles’ and Katja Triller Vrtovec and Christopher Thomas Scott, ‘The European Court of Justice Ruling in Brüstle v. Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe’ (2011) 9 Cell Stem Cell 502. Harmon, Laurie and Courtney have called for ‘more measured responses’, indicating that implications of the ruling may not be as far reaching as first thought (Harmon, Laurie and Courtney, ‘Dignity, plurality and patentability’ 101-102). [↑](#footnote-ref-655)
656. Plomer, ‘EU Ban on Stem Cell Patents’ [↑](#footnote-ref-656)
657. *Technion Research and Development Foundation, Ltd. [2014] T 2221/10*  Headnote [↑](#footnote-ref-657)
658. Ibid para 37 [↑](#footnote-ref-658)
659. Ibid para 37 [↑](#footnote-ref-659)
660. Ibid para 39 [↑](#footnote-ref-660)
661. Ibid para 44 [↑](#footnote-ref-661)
662. Following the CJEU decision in Brüstle, the German Federal Court of Justice overturned the German Federal Patent Court’s ruling in part, upholding the patent in an amended form, including the provision that “no human embryonic stem cells are used during the generation of which embryos are destroyed.” (see discussion inNielen, Vries and Geijsen, ‘European stem cell research in legal shackles’). The UK High Court has since made a reference to the CJEU for a preliminary ruling to clarify the term ‘human embryos’ in the Directive on Biotechnological Inventions asking “Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term “human embryos” in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions?” (*International Stem Cell Corporation v Comptroller General of Patents [2013] EWHC 807*  para 59) [↑](#footnote-ref-662)
663. Nuala Moran, ‘European court bans embryonic stem cell patents’ (2011) 29 Nature Biotechnology 1057, Austin Smith, ‘'No' to ban on stem-cell patents’ (2011) 472 Nature Correspondence and Nielen, Vries and Geijsen, ‘European stem cell research in legal shackles’ [↑](#footnote-ref-663)
664. Peter Andrews in House of Lords Science and Technology Select Committee, *Regenerative Medicine: Oral and Written evidence*  352-53. See also EuroStemCell, ‘European Court bans stem cell patents’ (2011) <http://www.eurostemcell.org/story/european-court-bans-stem-cell-patents> accessed 23 April 2014 [↑](#footnote-ref-664)
665. Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System* 2 [↑](#footnote-ref-665)
666. The terms ‘downstream innovation’ (modified from ‘downstream product development’) and ‘upstream research’ are taken from the seminal article Heller and Eisenberg, ‘Can Patents Deter Innovation? ’ In this way, invention is the middle-point. Events that happen prior to invention are ‘upstream’ and subsequent events are ‘downstream’. [↑](#footnote-ref-666)
667. One such example is the Stanford ‘Cohen-Boyer’ patents relating to recombinant DNA techniques (see discussion in Maryann P. Feldman, Alessandra Colaianni and Connie Kang Liu, ‘Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program’ Intellectual property management in health and agricultural innovation: a handbook of best practices, Volumes 1 and 2 <http://www.iphandbook.org/handbook/ch17/p22/> ). The WARF patents are reported to have shaped the stem cell field (see Bergman and Graff, ‘The global stem cell patent landscape’ and Konski and Spielthenner, ‘Stem cell patents: a landscape analysis’). [↑](#footnote-ref-667)
668. EPO, *Scenarios for the future: how might IP regimes evolve by 2025? What global legitimacy might such regimes have?* (European Patent Office 2007) 1 [↑](#footnote-ref-668)
669. Ibid 1 [↑](#footnote-ref-669)
670. Ibid 3 [↑](#footnote-ref-670)
671. Ibid 3 [↑](#footnote-ref-671)
672. Rebecca Eisenberg, ‘Re-examining the role of patents in appropriating the value of DNA sequences’ (2000) 49 Emory LJ 783, 783-800 [↑](#footnote-ref-672)
673. In the Nuffield Council on Bioethics discussion paper ‘The ethics of patenting DNA’ it was noted patents on DNA “may hamper innovation” (at 53) and could “have a deleterious effect of the development and use of [diagnostic tests based on DNA sequences]” (at page 53). Further, that “broad patents in this area could also restrict other forms of research” (at page 51). In addition, in terms of patenting naturally-occurring nature of DNA, it was argued that patents may confer “too great a monopoly in the light of the contribution and inventiveness of their product” (at page 53). Nuffield Council on Bioethics, *The Ethics of Patenting DNA* [↑](#footnote-ref-673)
674. Secretary's Advisory Committee on Genetics, *The SACGHS on Gene Patents* [↑](#footnote-ref-674)
675. Rebecca Eisenberg, ‘Structure and function in gene patenting ’ (1997) 15 Nature Genetics 125 [↑](#footnote-ref-675)
676. Eisenberg, ‘Re-examining the role of patents in appropriating the value of DNA sequences’ 783 [↑](#footnote-ref-676)
677. The Gower review defines patent quality as referring “to how well the patent was prepared and examined and how well the patent meets patentability requirements. Patent quality is different from technical merit and patent value.” Andrew Gowers, *Gowers Review of Intellectual Property* (HMSO 2006) para 5.20 [↑](#footnote-ref-677)
678. See for example ibid para 3.18 and 5.20-5.32, Mark A. Lemley, ‘Rational Ignorance at the Patent Office’ (2001) 95 Nw UL Rev and Noveck, *Wiki Government*. Concerns have also been raised about the threat of low patent quality on the future patent system (EPO, *Scenarios for the future* 8). [↑](#footnote-ref-678)
679. It has been estimated that there are 10 million unexamined applications globally. EPO, *Scenarios for the future* 20 [↑](#footnote-ref-679)
680. At the USPTO, examiners have “just fifteen to twenty hours to research the patent application and write up her findings.” Noveck, *Wiki Government* 5 [↑](#footnote-ref-680)
681. EPO, *Scenarios for the future* 17 [↑](#footnote-ref-681)
682. Bessen and Meurer, *Patent failure* 11 [↑](#footnote-ref-682)
683. Noveck, *Wiki Government* 4 [↑](#footnote-ref-683)
684. See discussion in Beth Noveck, ‘"Peer to Patent": Collective Intelligence, Open Review and Patent Reform’ (2006) 20 Harv JL & Tech 123 [↑](#footnote-ref-684)
685. UK Patents Act s. 21(1) [↑](#footnote-ref-685)
686. It has been suggested than approximately 1 in 200 applications have third-party observations filed against them (Gowers, *The Gowers Review* para 5.25). [↑](#footnote-ref-686)
687. . For a discussion of the history of the project see Noveck, *Wiki Government* [↑](#footnote-ref-687)
688. ‘Peer to Patent Second Anniversary Report’ (2009) <http://dotank.nyls.edu/communitypatent/CPI\_P2P\_YearTwo\_lo.pdf> accessed 23 April 2014 23 [↑](#footnote-ref-688)
689. Ibid 24 [↑](#footnote-ref-689)
690. Ibid 5. Peer-to-Patent contributed prior art was relied upon by the USPTO in more than 25% of the applications involved in the project. Further, 69% of examiners thought that a program like Peer-to-Patent would be useful if incorporated into regular office practice and 67% of examiners believe Peer-to-Patent would be useful in doing their job. [↑](#footnote-ref-690)
691. UKIPO, ‘Peer to patent pilot’ (2012) <http://www.ipo.gov.uk/p2p-report.pdf> accessed 07 April 2014 [↑](#footnote-ref-691)
692. Seymore, ‘The Teaching Function of Patents’ 625-26 [↑](#footnote-ref-692)
693. See for example, Fromer, ‘Patent Disclosure’, Ouellette, ‘Do Patents Disclose Useful Information?’, Seymore, ‘The Teaching Function of Patents’ and Roin, ‘The Disclosure Function of the Patent System ’ [↑](#footnote-ref-693)
694. Fromer, ‘Patent Disclosure’ 553 [↑](#footnote-ref-694)
695. Ibid 553 and Suzanne Scotchmer and Jeremy Green, ‘Novelty and Disclosure in Patent Law’ (1990) 21 RJE 131, 144-5 [↑](#footnote-ref-695)
696. Roin, ‘The Disclosure Function of the Patent System ’ 2024 [↑](#footnote-ref-696)
697. Seymore, ‘The Teaching Function of Patents’ 654-56 [↑](#footnote-ref-697)
698. Prabuddha Ganguli, Rita Khanna and Ben Prickril, ‘Defining the Future: Emerging Issues in Biotechnology, Intellectual Property Rights and Technology Transfer’ in Prabuddha Ganguli, Rita Khanna and Ben Prickril (eds), *Technology Transfer in Biotechnology: A Global Perspective* (Wiley 2009) 5 [↑](#footnote-ref-698)
699. Under the Patent Amendment Act of 1852 the Patent Office held all of the UK’s patents in a patent library. In 1981 more centres were certified to hold patent documents. Michael W. Hill, ‘Access in Britain to patent documents and information’ (1981) 3 World Patent Information 9, 9 [↑](#footnote-ref-699)
700. Stephen van Dulken (ed) *Introduction to Patents Information* (4th edn, The British Library 2002) 93 [↑](#footnote-ref-700)
701. For a general introduction to patent databases see: ibid Ch 9. For more in depth commentaries, see Christiane Emmerich, ‘Comparing first level patent data with value-added patent information: A case study in the pharmaceutical field’ (2009) 31 World Patent Information 117 and in Willem Geert Lagemaat, ‘Patent archives – the silent threat’ (2005) 27 World Patent Information 27, 28. These papers highlight particular problems with public databases regarding database utility, gaps in patent offices digital datasets and data coverage. [↑](#footnote-ref-701)
702. Roin, ‘The Disclosure Function of the Patent System ’ 2024 [↑](#footnote-ref-702)
703. Fromer, ‘Patent Disclosure’ 585 [↑](#footnote-ref-703)
704. Lagemaat, ‘Patent archives – the silent threat’ [↑](#footnote-ref-704)
705. Seymore, ‘The Teaching Function of Patents’ 626 [↑](#footnote-ref-705)
706. See discussion in Roin, ‘The Disclosure Function of the Patent System ’ 2025 [↑](#footnote-ref-706)
707. Lei, Jenuja and Wright, ‘Patents versus patenting’ and Ouellette, ‘Do Patents Disclose Useful Information?’ [↑](#footnote-ref-707)
708. These patents were brought to the attention of UK stem cell scientists by Aurora Plomer in a presentation at the inaugural meeting 2008 (‘IP rights and stem cells’ – at the invitation of the *UK National Stem Cell Network*, Inaugural Conference – Edinburgh, 9th-11th April 2008) [↑](#footnote-ref-708)
709. See discussion in Aurora Plomer ‘Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions Ch 7 in Plomer and Torremans, *Embryonic Stem Cell Patents European Law and Ethics* 198 [↑](#footnote-ref-709)
710. Ibid 198 [↑](#footnote-ref-710)
711. For example, Ouellette, ‘Do Patents Disclose Useful Information?’ used a survey whilst Owen-Smith and Powell, ‘Careers and contradictions’ and Agrawal and Henderson, ‘Putting Patents in Context’ used interviews [↑](#footnote-ref-711)
712. Presented separately in two articles: Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’ and Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part II’ [↑](#footnote-ref-712)
713. Lei, Jenuja and Wright, ‘Patents versus patenting’ [↑](#footnote-ref-713)
714. Alan Bryman, ‘June 1989 and beyond: Julia Brannen’s contribution to mixed methods research’ (2014) Int J Social Research Methodology 1 [↑](#footnote-ref-714)
715. Abbas Tashakkori and Charles Teddlie, *Mixed methodology: Combining qualitative and quantitative approaches*, vol 46 (Sage 1998) 17-18 [↑](#footnote-ref-715)
716. “the term mixed methods typically refers to both data collection techniques and analyses given that the type of data collected is so intertwined with the type of analysis used.” Ibid 43 [↑](#footnote-ref-716)
717. Ibid 3-5 [↑](#footnote-ref-717)
718. Ibid 19 [↑](#footnote-ref-718)
719. Ibid 25 [↑](#footnote-ref-719)
720. Ibid 21 [↑](#footnote-ref-720)
721. Ibid 24-25 [↑](#footnote-ref-721)
722. Charles Teddlie and Abbas Tashakkori, *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioral sciences* (Sage 2009) 33 [↑](#footnote-ref-722)
723. Tashakkori and Teddlie, *Mixed methodology* 26-27 [↑](#footnote-ref-723)
724. Ibid 23 [↑](#footnote-ref-724)
725. These reasons include triangulation, completeness, explanation of results from one method using another, explaining unexpected results, identifying samples for secondary methods, etc. For further information, see Alan Bryman, *Social Research Methods* (OUP 2012) 628-50 [↑](#footnote-ref-725)
726. John W. Creswell, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (3rd edn, Sage 2009) 4 [↑](#footnote-ref-726)
727. Webb and others described the value of triangulation in improving the validity of a study: “Once a proposition has been confirmed by two or more independent measurement processes, the uncertainty of its interpretation is greatly reduced. The most persuasive evidence comes through a triangulation of measurement processes” (Eugene Webb and others, *Unobtrusive Measures: Non-reactive Research in the Social Sciences* (Rand McNally 1966)). Denzin described four types of triangulation: data triangulation, investigator triangulation, theory triangulation and methodological triangulation. In this study, there is both data and methodological triangulation. Both qualitative and quantitative methods are used and a variety of data types are obtained to study the same phenomena and by comparing and contrasting the data, uncertainty about the findings can be reduced thus increasing their validity (Norman Denzin, *The Research Act* (2nd edn, McGraw-Hill 1987)) (both sources are used as cited in Teddlie and Tashakkori, *Foundations of mixed methods research* 75) [↑](#footnote-ref-727)
728. Bryman, *Social Research Methods* 649-50 [↑](#footnote-ref-728)
729. John W Creswell, *Research design: Qualitative and quantitative approaches* (Sage 1995) as cited in Tashakkori and Teddlie, *Mixed methodology* 18 [↑](#footnote-ref-729)
730. For a taxonomy of the variety of models available for mixed methods research see page Creswell, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* 206-17 [↑](#footnote-ref-730)
731. Ibid 211 “The sequential explanatory strategy is a popular strategy for mixed methods design … It is characterized by the collection and analysis of quantitative data in a first phase of research followed by the collection and analysis of qualitative data in a second phase that builds on the results of the initial quantitative results.” [↑](#footnote-ref-731)
732. Tashakkori and Teddlie, *Mixed methodology* 12 [↑](#footnote-ref-732)
733. Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’ and Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part II’. Conversely, in the study by Lei, Jenuja and Wright, the data are presented together, but with a major emphasis on the dominant quantitative survey data and less reference to the ‘follow-up interviews (‘case studies’ of the interviews are available as supplementary material to the article) (Lei, Jenuja and Wright, ‘Patents versus patenting’). Given the space to do so in this thesis (as opposed rather than the more limited space in a paper) both the qualitative and quantitative data are presented in detail. [↑](#footnote-ref-733)
734. Tashakkori and Teddlie, *Mixed methodology* 128 “Also known as triangulation of data sources, parallel mixed analysis of QUAL and QUAN data is probably the most widely used data analysis strategy … While the obtained QUAN data are analyzed through statistical procedures, the interview and observational data are (or can be) analysed through content analysis.” [↑](#footnote-ref-734)
735. John Creswell, Vicki Plano Clark and Amanda Garrett, ‘Methodological Issues in Conducting Mixed Methods Research Designs ’ in Manfred Max Bergman (ed), *Advances in mixed methods research: Theories and applications* (Sage 2008) 76 [↑](#footnote-ref-735)
736. Population is defined as the “universe of units from which a sample is to be selected” Bryman, *Social Research Methods* 714 [↑](#footnote-ref-736)
737. A sample is defined as the “segment of the population that is selected for investigation. It is the subset of the population.” A representative sample is defined as “a sample which reflects the population accurately so that it is a microcosm of the population” both ibid 715 [↑](#footnote-ref-737)
738. Senior scientists (all holding PhDs – i.e. post-docs or PIs) were interviewed because a statistically larger proportion of those with PhDs had seen patent documents, been part of patent applications and used patent databases than those without PhDs and many of the questions in the interviews focused on engagement with patent data. [↑](#footnote-ref-738)
739. Bryman defines a convenience sample as a “sample that is selected because of its availability to the researcher.” Bryman, *Social Research Methods* 710 [↑](#footnote-ref-739)
740. For a discussion on the choice to use a self-administered questionnaire, as opposed to an investigator-administered questionnaire, see Appendix 2.1. [↑](#footnote-ref-740)
741. This is where characteristics of the survey administrator may affect the answers given [↑](#footnote-ref-741)
742. A response rate can be calculated using the following equation: (Number of completed surveys/Total sample size) x 100%

     Another interesting thing to consider is the completion rate which tells us how many usable surveys were received from the respondents who began the survey. This can be found be using the formula: Number of completed surveys/(Total sample-((uncompleted surveys + uncommunicative sample members)) x 100% [↑](#footnote-ref-742)
743. Bryman, *Social Research Methods* 235 [↑](#footnote-ref-743)
744. E-mails were only sent to those scientists working in the UK (251 attendees). An e-mail link was also sent to 4154 addresses at the University of Sheffield. These were all postgraduates (taught and research), academics (teaching and research, clinical researchers, clinical teaching) and technical staff (technicians and experiment officers). The e-mail lists used were those covering the aforementioned individuals in biology related departments. [↑](#footnote-ref-744)
745. (Usable questionnaires/ (total sample – unsuitable or un-contactable members of the sample)) x 100% = (9/(251-241)) x 100% = 90% [↑](#footnote-ref-745)
746. Assuming no double responses: ((9 + 38) /( 251- 203)) x 100% = 97.9% (3 s.f.) [↑](#footnote-ref-746)
747. (Usable questionnaires/ total sample) x 100 % = (9/251) x 100% = 3.59% (3 s.f.) [↑](#footnote-ref-747)
748. Assuming no double responses: (47/251) x 100% = 18.7% (3 s.f.) [↑](#footnote-ref-748)
749. This is higher than the 15.9% response rate reported by Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’ 338; similar to the 20% response rate reported by Ouellette, ‘Do Patents Disclose Useful Information?’ 554; and a little lower than that of Lei, Jenuja and Wright, ‘Patents versus patenting’ 36 who reported a 25% response rate [↑](#footnote-ref-749)
750. (Usable questionnaires/ (total sample – unsuitable or un-contactable members of the sample)) x 100% = (82/(4154-4048)) x 100% = 77.4% (3 s.f.) [↑](#footnote-ref-750)
751. (Usable questionnaires/ total sample) x 100 % = (82/4154) x 100% = 1.97% (3s.f.) [↑](#footnote-ref-751)
752. 120/4405 x 100% = 2.72% [↑](#footnote-ref-752)
753. 82+9+38/106+10+28 x 100% = 129/154 x 100% = 83.8% (3s.f.) [↑](#footnote-ref-753)
754. Bryman, *Social Research Methods* 674-77 [↑](#footnote-ref-754)
755. Bryman defines non-response as a “source of non-sampling error that occurs whenever some members of a sample refuse to cooperate, cannot be contacted, or for some reason cannot supply the required data.” Ibid 713 [↑](#footnote-ref-755)
756. The work of Visser, Krosnick, Marquette and Curtin supports this view. They found that surveys with lower response rates produced more generalisable results than surveys with higher response rates; that methods of encouraging greater response (e.g. persistence in contacting people for their responses) did not necessarily pay off in being able to make better generalisations of the general population. Through the analysis of 15 years of political polls, the study showed that the estimates from a mail survey with a 20% response rate were more accurately aligned with election results than a telephone survey with a 60% response rate. Penny S Visser and others, ‘Mail surveys for election forecasting? An evaluation of the Columbus Dispatch poll’ (1996) 60 Public Opinion Quarterly 181 [↑](#footnote-ref-756)
757. 23/10/2009 Zhen Lei provided the original survey instrument (in a personal email) used to generate the data used in the publication: Lei, Jenuja and Wright, ‘Patents versus patenting’ [↑](#footnote-ref-757)
758. Bryman, *Social Research Methods* 212 [↑](#footnote-ref-758)
759. Ibid 565 [↑](#footnote-ref-759)
760. This involves grouping passages of text on a particular topic and can be done electronically using specialist software. For further discussion of coding see ibid 575-78 [↑](#footnote-ref-760)
761. Virginia Braun and Victoria Clarke, ‘Using thematic analysis in psychology’ (2006) 3 Qualitative research in psychology 77 80 [↑](#footnote-ref-761)
762. “A theme captures something important about the data in relation to the research question, and represents some level of patterned response or meaning within the data set.” Ibid 83 [↑](#footnote-ref-762)
763. There are 6 steps in thematic analysis: 1) familiarising yourself with your data; 2) generating initial codes; 3) searching for themes; 4) reviewing themes; 5) defining and naming themes; and 6) producing the report. Ibid 85 [↑](#footnote-ref-763)
764. This term ‘theoretical saturation’ is used to describe the point at which no new thematic codes are generated: the interview transcripts simply build on the data already gathered. For further information about different types of saturation in data gathering and analysis see Bryman, *Social Research Methods* 426. [↑](#footnote-ref-764)
765. This is similar to the study by Guest, Bunce and Johnson which found that after 12 interview scripts had been coded (from a sample of 30 interviews with “a relatively homogeneous population” in a study with “fairly narrow objectives”), 92% of the codes had been generated. Greg Guest, Arwen Bunce and Laura Johnson, ‘How many interviews are enough? An experiment with data saturation and variability’ (2006) 18 Field Methods 59, 74 [↑](#footnote-ref-765)
766. For an extended discussion of structured observations see Ch 12 in Bryman, *Social Research Methods* [↑](#footnote-ref-766)
767. Ibid 270 [↑](#footnote-ref-767)
768. Ibid 272 [↑](#footnote-ref-768)
769. Ibid 284 [↑](#footnote-ref-769)
770. George J McCall, ‘Systematic field observation’ (1984) Annual Review of Sociology 263 277 as cited in Bryman, *Social Research Methods* 279 [↑](#footnote-ref-770)
771. Bryman, *Social Research Methods* 284 [↑](#footnote-ref-771)
772. Ibid 279 [↑](#footnote-ref-772)
773. Ibid 280 [↑](#footnote-ref-773)
774. Webb and others, *Non-reactive Research in the Social Sciences* 13 as cited in Bryman, *Social Research Methods* 281 “the research subject’s knowledge that he is participating in a scholarly search may confound the investigator’s data”. Webb and others detailed four types of this effect: the guinea pig effect (where a participant wants to be observed behaving in a positive way which will create a good impression rather than their natural state); role selection (whereby participants take on assumed roles); measurement as a change agent (the effect of the researchers physical presence on the observation); and response sets (where a respondent purposely reacts inappropriately or at odds to their normal behaviour as a reaction to being observed). In this case, the participants may have been affected by the guinea pig effect and the physical presence of the observer. [↑](#footnote-ref-774)
775. See, for example, Atsushi Fujii, Makoto Iwayama and Noriko Kando, ‘Overview of the patent retrieval task at the NTCIR-6 workshop’ (2007) Proceedings of the Sixth NTCIR Workshop Meeting 359 and Yuen-Hsien Tseng, Chi-Jen Lin and Yu- I. Lin, ‘Text mining techniques for patent analysis’ (2007) 43 Information Processing & Management 1216 [↑](#footnote-ref-775)
776. Hideo Joho, Leif A Azzopardi and Wim Vanderbauwhede, ‘A survey of patent users: an analysis of tasks, behavior, search functionality and system requirements’ (2010) Proceedings of the third symposium on information interaction in context 13, L. McDonald-Maier, ‘esp@cenet: Survey reveals new information about users’ (2009) 31 World Patent Information, 142 and David Newton, ‘A survey of users of the new British Library Patent Information Centre’ (2000) 22 World Patent Information 317. These studies show that the majority of searchers are patent specialists and the general results indicate that respondents wanted improvements in patent databases (in terms of search speed, full-text searching and clearer user-interfaces). [↑](#footnote-ref-776)
777. Bryman, *Social Research Methods* 135 [↑](#footnote-ref-777)
778. See, for example, ‘RCUK Policy and Guidelines on Governance of Good Research Conduct’ (2013) <http://www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf> accessed 07 April 2014 [↑](#footnote-ref-778)
779. This is done to provide the best presentation of the data in the context of the research questions posed. (“Whichever approach you take, remember not to include all your results. You should present and discuss only those findings that relate to your research questions. This requirement may mean a rather painful process of leaving out many findings, but it is necessary, so that the thread of your argument is not lost” Bryman, *Social Research Methods* 689) [↑](#footnote-ref-779)
780. Appendix 4 table 1 [↑](#footnote-ref-780)
781. The group holding PhDs are indicated by the respondents being post-docs (25) or PIs (34) (59, 49.1% of the 120 people asked). The group without PhDs are comprised of MA (5) and PhD students (42) (47, 39.2% together). See table 2. Caulfield and others used a similar distinction, grouping ‘network PIs’ and comparing them with trainees “to isolate and determine the impressions of PIs, as they were the subset of the entire sample group most likely to be involved in research commercialization activities.” Caulfield and others, ‘Patents, commercialization and the Canadian stem cell research community’ 485 [↑](#footnote-ref-781)
782. See table 3. This distinction was made to assess whether stem cell scientists performed differently to scientists from other fields. 37 respondents (30.8%) were stem cell scientists. 83 respondents (69.2%) indicated they worked in other fields. See table 3. [↑](#footnote-ref-782)
783. See table 4. 42 (51.2%) had seen a patent document, 40 (48.8%) had not. [↑](#footnote-ref-783)
784. See table 5. 24 (32.4%) had been part of a patent application and 50 (67.6%) had not. [↑](#footnote-ref-784)
785. See for example, Caulfield and others, ‘Patents, commercialization and the Canadian stem cell research community’, Lei, Jenuja and Wright, ‘Patents versus patenting’, Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’ and Ouellette, ‘Do Patents Disclose Useful Information?’ [↑](#footnote-ref-785)
786. Following from the finding by Hall, Oppenheim and Sheen that companies who have experience with patent protection had higher engagement with, and awareness of patent information. Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’ [↑](#footnote-ref-786)
787. Ibid [↑](#footnote-ref-787)
788. See table 4 [↑](#footnote-ref-788)
789. Terms used in the figures: Not part = respondents who have not been part of a patent application; Not seen = respondents who had not seen a patent document; Other = respondents belonging to other fields than stem cell science; Part = respondents who have been part of a patent application; PhD = respondents holding PhDs (as determined by them being post-doctoral researchers or principal investigators); Seen = respondents who indicated they had seen a patent document; Stem = stem cell scientists; Students = Masters or PhD students; Total = total population [↑](#footnote-ref-789)
790. This is very similar to the level amongst agricultural biologists reported by Lei, Jenuja and Wright where 34% of their sample had “obtained or applied for patents” (Lei, Jenuja and Wright, ‘Patents versus patenting’ 37). [↑](#footnote-ref-790)
791. See table 5. This is similar to the result obtained by Agrawal and Henderson who noted that 56% of professors had been an inventor on a patent Agrawal and Henderson, ‘Putting Patents in Context’ 49) [↑](#footnote-ref-791)
792. See table 6 [↑](#footnote-ref-792)
793. See table 7 [↑](#footnote-ref-793)
794. See table 8. This is similar to the findings of previous studies e.g. “Slightly over half the patentees/licensees in our sample conducted patent searches” Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’ 342 [↑](#footnote-ref-794)
795. Table 9 [↑](#footnote-ref-795)
796. UK Patents Act s. 5(1) [↑](#footnote-ref-796)
797. See table 10 [↑](#footnote-ref-797)
798. UKIPO, ‘‘Patent Publication Enquiry’’ <http://www.ipo.gov.uk/patent/p-find/p-find-publication.htm> accessed 23 April 2014 [↑](#footnote-ref-798)
799. See table 11. [↑](#footnote-ref-799)
800. 62 of 81 (76.5%) of respondents questioned [↑](#footnote-ref-800)
801. UK Patents Act s. 21 [↑](#footnote-ref-801)
802. Table 12 [↑](#footnote-ref-802)
803. UK Patents Act s. 60(5)(b) [↑](#footnote-ref-803)
804. See for example, Gowers, *The Gowers Review* 45-46, Nuffield Council on Bioethics, *The Ethics of Patenting DNA* 9 and Royal Society, *Keeping science open: the effects of intellectual property policy on the conduct of science* (Royal Society 2003) para 3.23 [↑](#footnote-ref-804)
805. UKIPO, *The Patent Research Exception: A Consultation* (UKIPO 2008) 3 [↑](#footnote-ref-805)
806. UKIPO, *The Patent Research Exception Consultation: Summary of Responses* (UKIPO 2008) 2 [↑](#footnote-ref-806)
807. See table 13 [↑](#footnote-ref-807)
808. Table 14 [↑](#footnote-ref-808)
809. Full text in Appendix 4 [↑](#footnote-ref-809)
810. It is interesting to note that in response to almost all of the questions, either all of the groups expected to fare better either did or they all did not, except for in the case of stem cell scientists versus scientists in other fields (i.e. either those who had been part of a patent application, those who had seen a patent document and those with PhDs all fared well or they all did not). This indicates that these splits are significant and that each had a similar effect. However, even when the results for all of the other subpopulations did not fit the hypotheses stem cell scientists often still fared better than scientists in other fields, particularly regarding basic knowledge of patenting. [↑](#footnote-ref-810)
811. Ouellette, ‘Do Patents Disclose Useful Information?’ [↑](#footnote-ref-811)
812. As described in section 7.3.4, the legal scope of the research exemption is reportedly unclear. [↑](#footnote-ref-812)
813. This is in line with Ouellette’s finding where 36% of US nanotechnologists had not seen a patent other than their own. Ouellette, ‘Do Patents Disclose Useful Information?’ 31 [↑](#footnote-ref-813)
814. Jain, George and Maltarich, ‘Academics or entrepreneurs? ’ [↑](#footnote-ref-814)
815. See, for example, Emmerich, ‘Comparing first level patent data with value-added patent information’ and Lagemaat, ‘Patent archives – the silent threat’ [↑](#footnote-ref-815)
816. ‘About google patents’ <http://www.google.com/googlepatents/about.html> accessed 29 September 2011 [↑](#footnote-ref-816)
817. The Patent Cooperation Treaty (PCT) provides a procedure for patent applications to be filed in multiple contracting states through the World Intellectual Property Organisation (Patent Cooperation Treaty, 1970, signed in Washington DC, United States of America, 19 June 1970) [↑](#footnote-ref-817)
818. Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’, Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part II’ and Ouellette, ‘Do Patents Disclose Useful Information?’ [↑](#footnote-ref-818)
819. At a cost to the network, the UKNSCN, in partnership with the UKIPO, provided regular two-monthly patent digests from November 2008-October 2011, which were available on their webpage (this initiative is further discussed in sections 5.5.4 and 8.2.4). Each of these digests contained details of the recent patent applications and grants. While these two types of document are presented separately, as ‘PUBLISHED “A” SPECS’ and ‘GRANTED “B” SPECS’ respectively, there was nothing that explicitly mentioned that the ‘PUBLISHED “A” SPECS’ are applications, not grants. [↑](#footnote-ref-819)
820. “The USPTO received one third-party prior art submission for every 500 applications published in 2007.” Centre for Patent Innovations at New York Law School, ‘Peer to Patent First Anniversary Report’ (*New York Law School*, 2008) <http://dotank.nyls.edu/communitypatent/P2Panniversaryreport.pdf> accessed 23 April 2014 6. See also Gowers, *The Gowers Review* 83 indicating only 0.5% of applications have third party observations filed against them. [↑](#footnote-ref-820)
821. 111 of 117 (94.9%) agreed with the statement “Pre-existing academic literature can affect the outcome of a patent application” See table 15. [↑](#footnote-ref-821)
822. Lei, Jenuja and Wright, ‘Patents versus patenting’ 37 [↑](#footnote-ref-822)
823. See, for example, Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part I’, Hall, Oppenheim and Sheen, ‘Barriers to the use of patent information in UK small and medium-sized enterprises. Part II’ and Lei, Jenuja and Wright, ‘Patents versus patenting’ [↑](#footnote-ref-823)
824. Caulfield and others, ‘Patents, commercialization and the Canadian stem cell research community’ 485 [↑](#footnote-ref-824)
825. See section 7.5.1. These respondents had seen a patent document but not used a patent database. This suggests that they had been shown a patent document by someone else, e.g. a patent attorney, and it is probably that they have only seen their own patent and other documents relating to this. [↑](#footnote-ref-825)
826. Ouellette, ‘Do Patents Disclose Useful Information?’ 589 [↑](#footnote-ref-826)
827. A total of 19 digests were provided, one every two-months, between November 2008 and the closing of the network in October 2011 (UKNSCN, ‘'Patent Digests'’ <http://www.uknscn.org/downloads/patent\_digests.html> accessed 09 November 2011) [↑](#footnote-ref-827)
828. ‘RCUK Review of the UK National Stem Cell Network (UKNSCN) Annex A full - survey results ’ <http://www.bbsrc.ac.uk/web/FILES/Reviews/rcuk-review-of-uknscn-annex-a-survey-results-2011.pdf> accessed 05 April 2014 [↑](#footnote-ref-828)
829. Ibid 4 [↑](#footnote-ref-829)
830. Lei, Jenuja and Wright, ‘Patents versus patenting’ 37 [↑](#footnote-ref-830)
831. Takahashi and Yamanaka, ‘Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors’ [↑](#footnote-ref-831)
832. A patent application was filed at the Japanese Patent Office on 13 December 2005 (JP20050359537), acting as a priority document for a PCT filing for a patent titled ‘Nuclear Reprogramming Factor’ on 06 December 2006 (International Application number: PCT.JP206/324881 (international publication number: WO 2—7/069666), see Shinya Yamanaka, *Nuclear Reprogramming Factor (EP 1 970 446)* (2011)). [↑](#footnote-ref-832)
833. ‘Cellular Dynamics International IPO (as filed with the Securities and Exchange Commission on June 3, 2013. Registration No. 333)’ (2013) <http://www.sec.gov/Archives/edgar/data/1482080/000148208013000014/cdi-sx1publicfiling12013.htm> accessed 05 April 2014. See also Zarzeczny and others, ‘iPS Cells: Mapping the Policy Issues’ 1034 [↑](#footnote-ref-833)
834. Paul Knoepfler, ‘Treasure Trove Cellular Dynamics IPO filing: big money, iPS cell IP rights, and trade secrets’ (2013) <http://www.ipscell.com/tag/ips-cell-patents/> accessed 05 April 2014 [↑](#footnote-ref-834)
835. 1 participant used Google to search, entering the authors name and title of the paper, another went directly to the homepage of the journal in which the paper featured, and the other 14 used PubMed to search. A table of these observations can be viewed in Appendix 8. [↑](#footnote-ref-835)
836. EPO, ‘INPADOC legal status’ <http://worldwide.espacenet.com/help?topic=legalstatusqh&locale=en\_EP&method=handleHelpTopic> accessed 05 April 2014 [↑](#footnote-ref-836)
837. EPO, ‘Espacenet Quick help’ <http://worldwide.espacenet.com/help;jsessionid=AD7A4B3001A9E254D861D581D3B2D6EB.espacenet\_levelx\_prod\_2?quickHelpPage=inpadoclegalstatus.5&locale=en\_EP&method=handleQuickHelp#q3> accessed 05 April 2014 [↑](#footnote-ref-837)
838. “WIPO bears no responsibility for the content of PCT international applications and related documents.” ‘PATENTSCOPE Content of the Database’ <http://www.wipo.int/patentscope/search/en/content.jsf > accessed 05 April 2014 and “… absence of information for a given office does not necessarily indicate a non-entry in that office.” ‘Offices for which PCT national phase information is available in PATENTSCOPE Search Service’ <http://patentscope.wipo.int/search/en/nationalphase.jsf> accessed 05 April 2014 [↑](#footnote-ref-838)
839. UK Patents Act s. 14(3) [↑](#footnote-ref-839)
840. Ibid s. 1(1) [↑](#footnote-ref-840)
841. Bently and Sherman, *Intellectual Property* 5 [↑](#footnote-ref-841)
842. The Patent Cooperation Treaty (PCT) provides a procedure for patent applications to be filed in multiple contracting states through the World Intellectual Property Organisation (Patent Cooperation Treaty, 1970, signed in Washington DC, United States of America, 19 June 1970) [↑](#footnote-ref-842)
843. UK Patents Act s. 2(1) [↑](#footnote-ref-843)
844. Under the UK Patents Act, the date of priority is the date of filing (s. 5(1)) and the standard of novelty is measured against the state of the art publicly available before this time (s. 2(2)). [↑](#footnote-ref-844)
845. “… effective commercial exploitation of some publicly funded research is in the public interest and may require limitations on openness…” Royal Society, *Science as an open enterprise* 44 [↑](#footnote-ref-845)
846. Jain, George and Maltarich, ‘Academics or entrepreneurs? ’ [↑](#footnote-ref-846)
847. Drahos, *The Global Governance of Knowledge* 298 [↑](#footnote-ref-847)
848. See for example, Roin, ‘The Disclosure Function of the Patent System ’, Fromer, ‘Patent Disclosure’, Devlin, ‘The misunderstood function of disclosure in patent law’ and Holbrook, ‘Possession in Patent Law’ [↑](#footnote-ref-848)
849. See Noveck, *Wiki Government*and Centre for Patent Innovations at New York Law School, ‘Peer to Patent First Anniversary Report’ [↑](#footnote-ref-849)
850. Noveck, ‘"Peer to Patent"’ [↑](#footnote-ref-850)
851. See UK Patents Act s.21 and EPC Article 93 [↑](#footnote-ref-851)
852. It is estimated that patent litigation in the Patents Court costs, on average, £50,000-£500,000 with appeals costing £100,000-£200,000 (CMS Legal, ‘International Patent Litigation Guide’ (2013) <http://www.cmslegal.com/patentswithoutborders/Documents/CMS%20International%20Patent%20Litigation%20Guide%202013.PDF> accessed 23 April 2014 98). It is free to file a third party observation, although fees would have to be paid for legal support if required. [↑](#footnote-ref-852)
853. Third party observations are filed on approximately 1 in 200 patents in the UK. Gowers, *The Gowers Review* para 5.25 [↑](#footnote-ref-853)
854. See results of a study of the inventiveness of business method patents in Moir, *Patent Policy and Innovation*. See more generally discussion in Bessen and Meurer, *Patent failure* and Noveck, *Wiki Government* and Fromer, ‘Patent Disclosure’ [↑](#footnote-ref-854)
855. See discussion in section 5.4.3 [↑](#footnote-ref-855)
856. EPO, ‘Business use of patent information’ <http://www.epo.org/searching/essentials/business.html> accessed 09 April 2014 [↑](#footnote-ref-856)
857. See for example Henry Etzkowitz, ‘The evolution of the entrepreneurial university’ (2004) 1 Int J Tech & Globalisation 64 and Michael Gibbons and others, *The new production of knowledge: The dynamics of science and research in contemporary societies* (Sage 1994) [↑](#footnote-ref-857)
858. See for example Derek Bok, ‘The Benefits and Costs of Commercialization of the Academy’ in Donald G Stein (ed), *Buying in or selling out? The Commercialization of the American Research University* (Rutgers UP 2004), Sheldon Krimsky, ‘The Profit of Scientific Discovery and Its Normative Implications’ (1999) 75 Chi-Kent L Rev 15 and Resnik, *The Price of Truth* [↑](#footnote-ref-858)
859. See for example, Royal Society, *Science as an open enterprise*, 47 and discussion in Hughes and Martin, ‘Enhancing Impact: The value of public sector R&D’ [↑](#footnote-ref-859)
860. Economic and Social Research Council, *Science in the economy and the economics of science*, 8 [↑](#footnote-ref-860)
861. See, for example, Merton, *The sociology of science* 275, Radder, ‘A Deflationary, Neo-Mertonian Critique of Academic Patenting’, Eisenberg, ‘Proprietory Rights and the Norms of Science in Biotechnology Research’ and Rai, ‘Regulating Scientific Research’ [↑](#footnote-ref-861)
862. Eisenberg, ‘Public Research and Private Development’ 1666-1667 [↑](#footnote-ref-862)
863. See section 4.4.2 and Jain, George and Maltarich, ‘Academics or entrepreneurs? ’ [↑](#footnote-ref-863)
864. Wellings, *The Wellings Report* 11 [↑](#footnote-ref-864)
865. P Tang, *Exploiting University Intellectual Property in the UK. A report prepared for the UKIPO* (Intellectual Property Institute 2008) as cited in Wellings, *The Wellings Report* [↑](#footnote-ref-865)
866. Jain, George and Maltarich, ‘Academics or entrepreneurs? ’ [↑](#footnote-ref-866)
867. Bergman and Graff, ‘The global stem cell patent landscape’, Konski and Spielthenner, ‘Stem cell patents: a landscape analysis’ and Feldman and Furth, ‘The Intellectual Property Landscape for iPS Cells’ [↑](#footnote-ref-867)
868. Murray and Stern, ‘Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge?’ [↑](#footnote-ref-868)
869. Ibid 683 [↑](#footnote-ref-869)
870. Information Feudalism Peter Drahos and John Braithwaite, *Information Feudalism* (Earthscan Publications Ltd 2002) 219 [↑](#footnote-ref-870)
871. Drahos and Braithwaite point to a number of developments including: the power plays in the ‘knowledge game’; the creation and adoption of TRIPs; the impact of patents over biological knowledge; and the impact of copyright on the internet. Ibid 17 [↑](#footnote-ref-871)
872. Ibid 218 [↑](#footnote-ref-872)
873. ibid 218 [↑](#footnote-ref-873)
874. Drahos, *The Global Governance of Knowledge* 32 [↑](#footnote-ref-874)
875. See, for example, Ouellette, ‘Do Patents Disclose Useful Information?’, Seymore, ‘The Teaching Function of Patents’, Fromer, ‘Patent Disclosure’and Mark D. Janis and Timothy R. Holbrook, ‘Patent Law's Audience’ (2012) 97 Minn L Rev [↑](#footnote-ref-875)
876. Drahos, *The Global Governance of Knowledge* 290 [↑](#footnote-ref-876)
877. Ibid 293. For more information about this theory see John Braithwaite, ‘On speaking softly and carrying big sticks: Neglected dimensions of a republican separation of powers’ (1997) 47 UTLJ 305 and Alexander Hamilton, James Madison and John Jay, *The federalist papers* (OUP 2008) as cited in Drahos, *The Global Governance of Knowledge* [↑](#footnote-ref-877)
878. Drahos, *The Global Governance of Knowledge* 288-91 [↑](#footnote-ref-878)
879. Ibid 291-92 [↑](#footnote-ref-879)
880. Ouellette, ‘Do Patents Disclose Useful Information?’ 585 [↑](#footnote-ref-880)
881. Tang, *Exploiting University Intellectual Property in the UK* [↑](#footnote-ref-881)
882. On the limited IP education available in universities the UK, see discussions in Ruth Soetendorp, ‘'Food for engineers': intellectual property education for innovators’ (2004) 18 Industry and Higher Education 363, Ruth Soetendorp and others, ‘Engineering enterprise through intellectual property education-pedagogic approaches’ (2005) 4 WSEAS Transactions on Advances in Engineering Education 359 and Intellectual Property Awareness Network, UK Intellectual Property Office and National Union of Students, *Student attitudes towards intellectual property* (NUS 2012). With regard to IP education in the US see Donald S. Siegal and Phillip H. Phan, *Analyzing the Effectiveness of University Technology Transfer: Implications for Entrepreneurship Education* (Emerald Group Publishing Ltd 2005) and Marie C. Thursby, *Introducing Technology Entrepreneurship to Graduate Education: An Integrative Approach* (Emerald Group Publishing Ltd 2005). [↑](#footnote-ref-882)
883. Sean Dennehy, Acting Chief Executive of the UKIPO in Intellectual Property Awareness Network, UK Intellectual Property Office and National Union of Students, *Student attitudes towards intellectual property* 6 [↑](#footnote-ref-883)
884. Ibid 39 [↑](#footnote-ref-884)
885. See, for example, Fromer, ‘Patent Disclosure’, Roin, ‘The Disclosure Function of the Patent System ’, Seymore, ‘The Teaching Function of Patents’ and Ouellette, ‘Do Patents Disclose Useful Information?’ [↑](#footnote-ref-885)
886. Ouellette, ‘Do Patents Disclose Useful Information?’ 574 [↑](#footnote-ref-886)
887. Seymore, ‘The Teaching Function of Patents’ [↑](#footnote-ref-887)
888. National Institute for Biological Standards and Control, (UK Stem Cell Bank: Patent Depositary Service ) <http://www.nibsc.org/uk\_stem\_cell\_bank/patent\_depositary.aspx> accessed 07 April 2014 [↑](#footnote-ref-888)
889. UKIPO, ‘Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office ’ <http://www.ipo.gov.uk/biotech.pdf> accessed 07 April 2014 para 121 [↑](#footnote-ref-889)
890. In UK Patent Law, the PHOSITA is known as ‘person skilled in the art’ (for example, UK Patents Act s. 3 and s. 14(3)) The notion of a PHOSITA in patent law has been addressed by several commentators. See, for example, Jonathan J Darrow, ‘Neglected Dimension of Patent Law's PHOSITA Standard’ (2009) 23 Harv JL & Tech 227, Rebecca Eisenberg, ‘Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA’ (2004) 19 Berkeley Tech LJ 885 and Joseph P Meara, ‘Just Who is the Person Having Ordinary Skill in the Art-Patent Law's Mysterious Personage’ (2002) 77 Wash L Rev 267 [↑](#footnote-ref-890)
891. Peer-to-Patent, ‘Peer to Patent’ <http://www.peertopatent.org/> accessed 23 April 2014 See further discussion in 5.5.1. [↑](#footnote-ref-891)
892. See Centre for Patent Innovations at New York Law School, ‘Peer to Patent First Anniversary Report’ and UKIPO, ‘Peer to patent pilot’ [↑](#footnote-ref-892)
893. Ouellette, ‘Do Patents Disclose Useful Information?’ 576-78 [↑](#footnote-ref-893)
894. UKIPO, ‘Peer to patent pilot’ 17 [↑](#footnote-ref-894)
895. Fromer, ‘Patent Disclosure’ 591-92 [↑](#footnote-ref-895)
896. Ouellette, ‘Do Patents Disclose Useful Information?’ 579-80 [↑](#footnote-ref-896)
897. Janis and Holbrook, ‘Patent Law's Audience’ [↑](#footnote-ref-897)
898. Ibid 74-75 [↑](#footnote-ref-898)
899. See, for example, Fromer, ‘Patent Disclosure’ and Drahos, *The Global Governance of Knowledge* 304-10 [↑](#footnote-ref-899)
900. See, for example, Fromer, ‘Patent Disclosure’ and Drahos, *The Global Governance of Knowledge* 304-10 [↑](#footnote-ref-900)
901. UK Patents Act s. 14(3) [↑](#footnote-ref-901)
902. Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System* 218 [↑](#footnote-ref-902)
903. Drahos, *The Global Governance of Knowledge* 309 [↑](#footnote-ref-903)
904. Scientific publications consist of technical information and generally follow the traditional IMRAD structure: introduction, methods, results, analysis and discussion. Patent documents have a three part structure: a cover page with bibliographic information (e.g. filing date, patent number, title, inventors name); a specification describing the invention (this includes the background, summary, description and drawings relating to the invention) and the claims defining the scope of the patent right. [↑](#footnote-ref-904)
905. Fromer, ‘Patent Disclosure’ 563-64 [↑](#footnote-ref-905)
906. Ibid 586 [↑](#footnote-ref-906)
907. For example, the Chemical Abstracts Service and Delphion databases offer rewritten abstracts. [↑](#footnote-ref-907)
908. If a paper is visible (and the information within it is useful) follow-on users of the information may cite the paper in their own publications. In this way, the citation rate of a paper creates a marker of its perceived quality by the academic community; the more a paper is cited, the more ‘impact’ it has. In addition, as an accepted measure of impact, citation data is likely to be taken into account in career progression decisions and is, indeed, used in grading research outputs in the REF exercise (‘REF 2014 Citation data’ <http://www.ref.ac.uk/subguide/citationdata/> accessed 07 April 2014). [↑](#footnote-ref-908)
909. UKIPO, ‘Manual of Patent Practice’ (2013) <http://www.ipo.gov.uk/downloads/practice-manual.pdf> accessed 07 April 2014 [↑](#footnote-ref-909)
910. Ibid para 14.51 [↑](#footnote-ref-910)
911. Ibid para 14.49 [↑](#footnote-ref-911)
912. Ibid para 14.04.10 [↑](#footnote-ref-912)
913. Ibid para 14.49 [↑](#footnote-ref-913)
914. Ibid para 14.49 [↑](#footnote-ref-914)
915. Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (OUP 1992) [↑](#footnote-ref-915)
916. John Braithwaite, *Restorative Justice and Responsive Regulation* (OUP 2002) 30 [↑](#footnote-ref-916)
917. Ibid 33 [↑](#footnote-ref-917)
918. CIPA, ‘Code of Conduct and Discipline’ <http://www.cipa.org.uk/pages/Conduct\_discipline> accessed 20/08/2014 [↑](#footnote-ref-918)
919. Drahos, *The Global Governance of Knowledge* 309 [↑](#footnote-ref-919)
920. Ibid 311 [↑](#footnote-ref-920)
921. Ouellette, ‘Do Patents Disclose Useful Information?’, 587 and also generally in Fromer, ‘Patent Disclosure’ [↑](#footnote-ref-921)
922. See, for example, Branstetter and Ogura, ‘Is Academic Science Driving a Surge in Industrial Innovation?’, Martin Meyer, ‘Does science push technology? Patents citing scientific literature’ (2000) 29 Research Policy 409, Francis Narin, Kimberly S Hamilton and Dominic Olivastro, ‘The increasing linkage between US technology and public science’ (1997) 26 Research Policy 317 and Agrawal and Henderson, ‘Putting Patents in Context’ [↑](#footnote-ref-922)
923. Donald F. Weaver and Christopher Barden, ‘Don't overlook the rigorously reviewed novel work in patents’ (2009) 461 Nature 340 [↑](#footnote-ref-923)
924. Wolfgang Glänzel and Martin Meyer, ‘Patents cited in the scientific literature: An exploratory study of 'reverse' citation relations’ (2003) 58 Scientometrics 415, 418 [↑](#footnote-ref-924)
925. Ibid 419 [↑](#footnote-ref-925)
926. Richard M Lebovitz, ‘The Duty to Disclose Patent Rights’ (2007) 6 Nw J Tech & Intell Prop 36, 38 [↑](#footnote-ref-926)
927. Ibid [↑](#footnote-ref-927)
928. See Joho, Azzopardi and Vanderbauwhede, ‘A survey of patent users’ [↑](#footnote-ref-928)
929. Drahos, *The Global Governance of Knowledge* 34 and 299-300 [↑](#footnote-ref-929)
930. See, for example, ‘The future of the European patent system - current developments and trends. Speech by Mr Benoît Battistelli President of the European Patent Office’. See also Gurry, ‘The Disclosure of Technology in the Patent System’ [↑](#footnote-ref-930)
931. For example, IPSUM at the UKIPO, espacenet at the EPO and Patentscope at WIPO [↑](#footnote-ref-931)
932. See Emmerich, ‘Comparing first level patent data with value-added patent information’ and Lagemaat, ‘Patent archives – the silent threat’ [↑](#footnote-ref-932)
933. In addition to improved functionality, many of the databases also offer additional features such as tracking tools, citation monitors, patent landscape mapping and abstracts written for non-legal professionals. [↑](#footnote-ref-933)
934. Drahos, *The Global Governance of Knowledge* 35 [↑](#footnote-ref-934)
935. In line with the arguments regarding open access to academic publications, see Dame Janet Finch, *The Finch Report* 5 [↑](#footnote-ref-935)
936. Drahos, *The Global Governance of Knowledge* Ch 11 [↑](#footnote-ref-936)
937. Ibid 300-01 [↑](#footnote-ref-937)
938. ‘Mission Statement’ <http://www.patcom.org/> accessed 02 April 2014 [↑](#footnote-ref-938)
939. Drahos, *The Global Governance of Knowledge* [↑](#footnote-ref-939)
940. UKIPO, ‘New online patent inspection service launched’ (2011) <http://www.ipo.gov.uk/press-release-20111006.htm> accessed 07 October 2011 [↑](#footnote-ref-940)
941. Personal communication with the Director of espacenet. [↑](#footnote-ref-941)
942. Jon Orwant, ‘Improving Google Patents with European Patent Office patents and the Prior Art Finder’ (2012) <http://googleresearch.blogspot.co.uk/2012/08/improving-google-patents-with-european.html> accessed 02 April 2014 [↑](#footnote-ref-942)
943. ‘About google patents’ [↑](#footnote-ref-943)
944. Edlyn S Simmons, ‘Patent databases and Gresham’s law’ (2006) 28 World Patent Information 291 293 [↑](#footnote-ref-944)
945. Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System* 219 [↑](#footnote-ref-945)
946. Drahos, *The Global Governance of Knowledge* 302-03 [↑](#footnote-ref-946)
947. Caulfield, ‘Stem Cell Research and Economic Promises’ 309 [↑](#footnote-ref-947)
948. Eisenberg, ‘Public Research and Private Development’ 1727 [↑](#footnote-ref-948)
949. “In this context, the Subcommittee describes “economic security” as ensuring that the United States receives the first benefits of innovations conceived within this country, so as to promote domestic development, future innovation and continued economic expansion.” *Notice of Request for Comments on the Feasibility of Placing Economically Significant Patents Under a Secrecy Order and the Need to Review Criteria Used in Determining Secrecy Orders Related to National Security (Federal Register, 77:77, 23662-23665)* (2012) 23663 [↑](#footnote-ref-949)
950. 35 U.S.C. 181 or UK Patents Act s. 22 [↑](#footnote-ref-950)
951. *Notice of Request for Comments on the Feasibility of Placing Economically Significant Patents Under a Secrecy Order and the Need to Review Criteria Used in Determining Secrecy Orders Related to National Security (Federal Register, 77:77, 23662-23665)* 23664 [↑](#footnote-ref-951)
952. The comments are available at ‘Economic Security SO’ <http://www.uspto.gov/ip/global/patents/esso/index.jsp# > accessed 02 April 2014 [↑](#footnote-ref-952)
953. There was a logic step added in this question: if the respondent answered ‘I have not visited an online patent database in the last 5 years’ they continued to question 9 on page 7. If the respondent gave any other answer to this question they were directed to question 8 on page 6 where they were asked details of their last use of an online patent database. [↑](#footnote-ref-953)
954. Bryman, *Social Research Methods* 235 [↑](#footnote-ref-954)
955. Jean M Converse and Stanley Presser, *Survey questions: Handcrafting the standardized questionnaire*, vol 63 (Sage 1986) 35-36 as cited in Jon A. Krosnick and others, ‘The Impact of "No Opinion" Response Options on Data Quality: Non-Attitude Reduction or an Invitation to Satisfice?’ (2002) 66 The Public Opinion Quarterly 371 [↑](#footnote-ref-955)
956. Krosnick and others, ‘The Impact of "No Opinion" Response Options on Data Quality’ 371 [↑](#footnote-ref-956)
957. Ibid [↑](#footnote-ref-957)
958. Ibid 371 [↑](#footnote-ref-958)
959. Ibid 371 [↑](#footnote-ref-959)
960. Ibid 399-400 [↑](#footnote-ref-960)
961. Paul Martin and Patrick Bateson, *Measuring behaviour* (CUP 1986) as cited in Bryman, *Social Research Methods* 279 [↑](#footnote-ref-961)