Distal Horizons

An investigation of the justifiable downstream limits to the positive protection of traditional knowledge associated with genetic resources within drug discovery

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September 2015

Abstract

International initiatives, such as the Nagoya Protocol to the United Nations Convention on Biological Diversity (the Protocol), have created (or are creating) “access and benefit sharing” rights which seek to ensure that genetic resources and traditional knowledge associated with such genetic resources (“TKAGR”) cannot be used without the consent of rights holders. These initiatives (including the Protocol) are unclear on how far non-consensual “use” extends to man-made downstream derivatives of the products of genetic expression. It also gives no guidance as to the degree to which control over TKAGR should extend throughout the drug discovery process. This work demonstrates how such TKAGR entering into a drug discovery process will be diluted with other information, used as an inspiration for further research, or for the development of research tools which may, in turn, lead to further discoveries and highlights how useful drugs may be very distal from the original inspiration provided by the TKAGR. This work also examines the causal link between an original piece of TKAGR and remote “downstream” uses of that information within drug discovery. It identifies “serendipitous” discoveries of unexpected second uses as a potential point at which the causation *in law* link to distal use may potentially be broken. This thesis examines the high level normative justifications for these rights, and in particular uses consequentialist/utilitarian, contribution/desert claims and distributive justice (Rawlsian *maximin)* claims to test their justifiable scope.

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Acknowledgements

I would like to thank Professor Stuart Bell and Professor Caroline Hunter, as Heads of Department, for their permission to study at York Law School and for their words of unstinting encouragement throughout.

I am extremely grateful to my advisors, Professor Simon Halliday and Professor T.T. Arvind, for their advice, passion, fascinating debates at the coffee shop of the Royal York Hotel, and for the freedom to pursue my ideas.

My thanks also go to Salwa Eweis and Louise Prendergast for their administrative and technical assistance.

My deepest thanks go to my wife, Elinor, and boys, Alasdair and Arthur, for their love, support and (above all) patience.

Author's Declaration

I confirm that all the work included in this thesis is my own and is not the result of any collaboration. Neither has any of this work been submitted for examination at this, or any other institution, for another award.

Peter Stuart Harrison

Chapter 1

Introduction

“The heedless exploitation of nature and the careless use of resources already threaten our inheritors with a world physically and spiritually impoverished”

Declaration of the 14th Biennial Wilderness Conference (1975)

“Knowledge itself is power”

Francis Bacon, *Meditationes Sacrae* (1597)

1.1 Overview of the aim and scope of this work

The aim of this work is to examine the balance between respect for the justifications of rights holders and the liberty of the broader world in relation to a new-born, or at least newly evolving, intellectual property right. Its aim is to determine where, if at all, any justifiable limit can be drawn to the downstream scope of positive rights of indigenous peoples to traditional knowledge associated with genetic resources when that knowledge is used within the search for new pharmaceutically-active compounds (or new uses for such compounds) within drug discovery research.

Such positive rights have been created (or are in the course of being created) as part of an international drive to preserve biodiversity and indigenous culture by creating control over access to, and utilisation of, genetic resources and the traditional knowledge which is associated with such resources.

The concept of controlling the use of genetic resources may initially appear to be relatively straightforward. Taking a plant cutting, propagating it, and growing it indisputably looks like the accessing and using of that plant. However, examination of the concept of a genetic resource rapidly reveals that, with the advent of biotechnological tools for manipulating the genome, any assumption of simplicity is misplaced – and we are led to question whether "genetic information" such as a nucleotide sequence (or even the natural epigenetic modification of a genome) can be considered a genetic resource. Yet further complexities are encountered when considering whether the biochemical products of genetic expression such as enzyme proteins and the products of enzymatic reactions (or even man-made chemical derivatives thereof) are to be included within the subject matter to be controlled.

Such problems of definition are further amplified when we come to consider "traditional knowledge associated with genetic resources". This type of knowledge can take many forms and be held in many ways – of particular interest in the present study is knowledge of how a particular genetic resource can be used to influence a human disease state. However, due to the inherent malleability, mixability and easily reproduced nature of information, such traditional knowledge is perhaps harder even to define and delimit than "genetic resources". This is particularly true when one looks at the fate such knowledge within the process of drug discovery. Unfortunately, the provisions of the extant (and proposed) international instruments relating to the protection of genetic resources and associated traditional knowledge are unclear with regard to this downstream scope.

Stimulated by these uncertainties, the core of this work is the examination of the justifiable downstream scope of a positive right in traditional knowledge associated with genetic resources in the light of a substantial empirical examination of the drug discovery process. This empirical examination highlights how any piece of information (including traditional knowledge) entering into a drug discovery process is subject to significant mixing with other information leading to its dilution/attenuation. Such a piece of information may serve as the inspiration for further discoveries (alone, or mixed in with other information) and those discoveries may themselves serve as further stimulus for new research directions, or be used as part of more iterative development work. However it is used, the information will enter into a series of complex and overlapping discovery pathways, including "dead-ends" and feedback loops. In many cases any useful downstream discovery will (though always causally linked *in fact* to the original information) appear particularly distal or remote from the information which served as the original stimulus to the work.

This complex epistemic dilution throws up a significant challenge: should we consider *any* downstream use (for example the development of a new drug) as constituting the use of the original inspiring piece of traditional knowledge, no matter how greatly that information has been diluted.

The question is an important one – the efficient and non-wasteful exploitation behaviour and investment decisions of all parties affected by a right rely upon an informed and reliable appreciation of a right's scope.

There is, of course, one potentially simple answer to this problem of epistemic dilution – why do we not just say that *all* downstream uses which are caused *in fact* by the original inspiration provided by the traditional knowledge constitute use of that original knowledge? Such an approach would certainly save us looking into the complex causal continuum between inspiration and outcome to determine a point at which to limit the right to control downstream use. However, the problem with such a simplistic approach is that it ignores the interests of immediately affected third parties, in particular, and of the broader world in general. As will be discussed in this work, determination of a justifiable *legal* scope of a right requires a determination of causation *in law*, as opposed to a mere determination of causation *in fact*. That justifiable scope is dependent upon the reason(s) for the existence of the right – reasoning which must balance competing interests.

Established intellectual property law does not commonly consider such questions of scope as ones of causation as such, instead relying on judgments of imitativeness and non-imitativeness. Inherent within such considerations of imitativeness is the concept of conflicting "contribution" - intellectual property rights do not exist *in vacuo* in that one always has to consider conflicting claims between those seeking to assert the right and those properly seeking to avoid it.

In the present case, what a simple causation *in fact* test arguably ignores is a recognition of the contribution made by those pharmaceutical researchers who are developing (or have developed) the new information in which the original inspiration is being "diluted". This conflict between the contributions of the indigenous peoples who have discovered the traditional knowledge which has inspired the work and those downstream researchers who have built upon that inspiration is at the heart of the current work.

Looking at the question of downstream scope through the lens of competing contributions we might argue that the scope should end where the accretion of downstream contributions somehow “outweighs” the contribution made by the indigenous “originators”. However, we are still presented with the question of where such a “tipping point” of competing contributions should be arrived upon.

Comparing conflicting contributions is inherently difficult – it is not easy to “measure” a single contribution, nor summate a number of contributions. Indeed, the current work shows that when you empirically examine the drug discovery process you find that there are few easily determined points at which one might obviously argue that such a tipping point has been reached and that chain of causation *in law* could be broken. Perhaps what we require is some sense of a “step change” in the nature of the competing contributions. Of course, we do not have necessarily to reinvent the wheel here. We might ask whether any guidance can be taken from other intellectual property rights that have been forced to wrestle with questions of scope within the field of drug discovery. Naturally, the field of patent law is the most obvious choice.

It should be stressed at the outset that the subject matter of established patent law is a distinctly different creature from that of envisaged positive rights in traditional knowledge associated with genetic resources. Accordingly, direct comparison between patent law and control over traditional knowledge is potentially misleading, and needs to be treated with caution. However, patent law and the processes of drug discovery have had a long interaction, particularly with regard to questions of “downstream” scope. Provided that the distinct differences of patent law are borne in mind, the history of this interaction may act as a source of putative concepts to be considered in the context of the scope of traditional knowledge in the present problem.

One of the chief aspects of the interaction between patent law and drug development has been the recurrent question of whether a claim to one therapeutic use of a drug should extend the discovery of a second therapeutic (or other) use.

With such questions in mind (and in the light of this work’s empirical analysis of the flow of information through the topography of drug discovery processes) the current work posits that “serendipitous” discoveries of a new use of the subject of the traditional knowledge (what might be termed within patent law as the uncovering of an unexpected “second use”) might act as a putative point at which one might consider there to be a break in the causation *in law* link between the original stimulus and the useful outcome. Crucially, this is a point at which the competing contributions between the indigenous peoples on the one hand, and pharmaceutical researchers on the other, is brought to a head. Here, one is forced to ask why the indigenous "discovery" of one therapeutic use should prevent third party exploitation of a second, entirely unforeseen, use. As will be seen in this work, this is a question which takes us to the heart of what contribution *means* in this context.

As already stressed, although an understanding of existing types of intellectual property right may act as a source of inspiration for our thinking, the different nature of traditional knowledge means that the guidance found in those other rights can take us only so far. As such, in addressing normative problems in this area we are pushed back to first principles – we need to ask: What are the underlying philosophical reasons for the existence of these rights? As will be seen, such justifications fall into two camps – those justifications based upon consequentialist goals and deontological justifications based on concepts of duty. Both are considered in depth in this work. Accordingly, this work looks to apply the philosophical "tool-box" of reasons for the existence of property rights in intangible concepts to the question of competing claims in relation to serendipitously discovered new uses and attempts to arrive at a synthesis of the results obtained from the application of each justification.

The reader should be warned from the outset that this is not an area in which it is easy to arrive at definitive conclusions. Indeed, the author identifies the key contributions of this work to be the recognition and analysis of a number of significant complexities and difficulties which should inform the investigations of future workers in this field. These complexities and difficulties are both empirical and theoretical. They are as follows:

1) The complexity of the passage of traditional knowledge associated with genetic resources through the topology of the drug discovery process and the difficulty of identifying clear points within the movement of such information at which limits of control may be investigated;

2) The complexity of the epistemic dilution of the idea held within a piece of traditional knowledge associated with genetic resource through the drug discovery process and the complexity of competing contributions which sit upon the back of the entanglement of information within that discovery process;

3) The difficulty in the application of contribution-based reward justifications for the control of information in the light of a complicated plurality of types and sources of competing contributions and to specific examples of contribution and of competing contributions;

4) The complexity in determining the true nature of serendipity, and second uses in the light of the nature of traditional knowledge; and

5) The potential complexities wrought by the existence of a right to control information which has no temporal limitation.

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The remainder of this chapter is intended to give further introductory background to the problem considered in this work, to outline the analytical approaches taken to address that problem, and to provide a guide to the structure of this work.

1.2 Claims of misappropriation of traditional knowledge associated with genetic resources

Many compounds that have pharmacological effects in humans are derived from eukaryotic organisms (such as plants, animals, fungi) and bacteria. In some cases these compounds have been honed by hundreds of millions of years of evolution to have exquisite selectivity and potency in biological systems – indeed, some of these compounds are amongst the most toxic substances know. [1] In some organisms (particularly plants and fungi), they are used for defence against predators, whereas in predator organisms they are more often used as tools in the hunt for prey. In yet others

[1] For example the LD_{50} dose in humans of botulinum toxin from the bacterium *Clostridium botulinum* (the "botox" of botox cosmetic treatments) has been estimated to be 1.3–2.1 ng/kg by intravenous or intramuscular injection and 10–13 ng/kg when inhaled. Stephen S Arnon, R Schechter, TV Inglesby, DA Henderson, JG Bartlett, MS Ascher, E Eitzen , AD Fine, J Hauer , M Layton, S Lillibridge, MT Osterholm, T O'Toole, G Parker, TM Perl, PK Russell, DL Swerdlow, and K Tonat, "Botulinum Toxin as a Biological Weapon: Medical and Public Health Management"(2001) 285 (8) Journal of the American Medical Association 1059

they are used in the drive to reproduce.[2] In some cases the biological effect produced by evolution has been harnessed by man to provide beneficial therapeutic effects and many currently approved drugs have their origin in plants and fungi [3, 4] or animal venoms. [5]

Often the Western understanding that a particular organism contained a compound of potential therapeutic benefit arose out of the knowledge of folk-healers or traditional medicine systems.[6,7,8,9] In many historical cases, those Western ethnobotanists and scientists accessing and using traditional knowledge have treated this knowledge as a non-rivalrous and non-excludable "public good" and have treated the originators of this knowledge to be undeserving of recognition or reward for its subsequent use and similarly undeserving of any degree of control over the use of the information.[10]

More lately, the interface between indigenous knowledge and Western pharmacology has become an area of high emotions, polemics and political activism.[11, 12, 13, 14, 15, 16, 17]

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[2] Gadi VP Reddy and Angel Guerrero, "Interactions of insect pheromones and plant semiochemicals" (2004) 9(5) Trends in Plant Science 253

[3] Paul A Cox, "The ethnobotanical approach to drug discovery: strengths and limitations" in Derek J Chadwick and Joan Marsh (eds), *Ethnobotany and the Search for New Drugs* (John Wiley & Sons 1994) (Ciba Foundation Symp 185) 25, 27

[4] Norman R Farnsworth, "The role of ethnopharmacology in drug development" in *Bioactive compounds from Plants* (John Wiley & Sons 1994) (Ciba Foundation Symp 154) 2

[5] Glenn F King (ed), *Venoms to Drugs: Venom as a Source for the Development of Human Therapeutics* (Royal Society of Chemistry, Abingdon, 2014)

[6] Londa Schiebinger, *Plants and Empire, Colonial Bioprospecting in the Atlantic World* (Harvard University Press 2004)

[7] Bill Laws, *Fifty Plants that Changed the Course of History* (David & Charles 2010)

[8] Michael J Balick and Paul A Cox, *Plants, People, and Culture: The Science of Ethnobotany* (Scientific American Library 1997)

[9] CM Cotton, *Ethnobotany: Principles and Applications* (John Wiley & Sons, Chichester, 1996), 234

[10] Philip Schuler, "Biopiracy and Commercialization of Ethnobotanical Knowledge" in J Michael Finger & Philip Schuler (eds) *Poor People's Knowledge* (World Bank and OUP 2004)

[11] Graham Dutfield, *Intellectual Property Rights, Biogenetic Resources and Traditional Knowledge* (Earthscan Publications, London and Sterling, VA 2004)

[12] Mary Riley (ed), *Indigenous Intellectual Property Rights, Legal Obstacles and Innovative Solutions* (Altamira Press 2004)

[13] Daniel Wüger, "Prevention of Misappropriation of Intangible Cultural Heritage through Intellectual Property Laws" in J Michael Finger & Philip Schuler (eds) *Poor People's Knowledge* (World Bank and OUP 2004)

Shiva[18] uses the term biopiracy to include *all* aspects of the control by Western commercial interests of biological resources and biodiversity [19] However, it is generally more common for biopiracy to be used to describe a narrower set of circumstances, namely the particular situation where a genetic resource (and information relating to that genetic resource) obtained from indigenous peoples is used scientifically, or commercially, without their consent and/or without those indigenous peoples having received any benefit from the "downstream" use of said genetic resources and/or the related information.[20, 21]

This history of claimed misappropriation eventually led to a movement to secure legal mechanisms by which indigenous peoples would gain control over genetic resources and traditional knowledge such that misappropriation could no longer occur.[22] However, as will be discussed further in this work, the particular nature of traditional knowledge is such that its protection is not easily achieved through the use of what might be termed "established" intellectual property rights (such as copyright, patents, utility models, trade secrets, trade marks, plant variety protection, or geographical indications), or through the law of confidence.[23] Attempts to protect traditional

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[14] Chidi Oguamanam, *International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity, and Traditional Medicine* (University of Toronto Press, Toronto ON 2006)

[15] Graham Dutfield, "Protecting the Rights of Indigenous Peoples: Can Prior Informed Consent Help?" in Rachel Wynberg, Doris Schroeder and Roger Chenells (eds) *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case* (Springer, Dordrecht 2009) 53

[16] SS Latha, "Biopiracy and protection of traditional medicine in India" (2009) 31(9) EIPR 465

[17] Daniel F Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates* (Earthscan Publications London and Stirling, VA 2012)

[18] Vandana Shiva, *Biopiracy: the Plunder of Nature and Knowledge* (South End Press, New York, NY & Boston, MA 1997)

[19] Shiva (n 18), 3

[20] Dutfield "Protecting the Rights of Indigenous Peoples" (n 15), 55

[21] Robinson (n 17), 14

[22] Rosemary J Coombe, "The Recognition of Indigenous Peoples' and Community Traditional Knowledge in International Law" (2002) 14 St Thomas L Rev 275

[23] Dutfield *Intellectual Property Rights, Biogenetic Resources and Traditional Knowledge* (n 11), 101

knowledge relating to genetic resources, (and traditional knowledge and cultural expression more widely) have therefore focused on the creation of a set of *sui generis* rights which, independent of currently-established intellectual property rights, would ensure that such genetic resources and related knowledge could only be controlled by those originally holding the information.

The drive to prevent "misappropriation" of genetic resources and related traditional knowledge has taken place, with differing rates of progress, in a number of international fora. The key fora are:

a) The World Trade Organisation ("WTO");
b) The United Nations ("UN"); and
c) The World Intellectual Property Organisation ("WIPO")

The nature of the rights established under the current (and proposed) international solutions to countering misappropriation of genetic resources and traditional knowledge are set out in Chapter 2 of this work and a "family tree" of these approaches is set in Figure 2.1 of that chapter.

Most developed amongst these international approaches is the October 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity (the "Protocol") which will be discussed in depth in Chapter 2.

1.3 The problem of downstream use

1.3.1 The dilution of knowledge within drug discovery

The development "trails" within drug development are often long and complicated, and the original contribution from biological source or traditional knowledge is often overestimated. [24]

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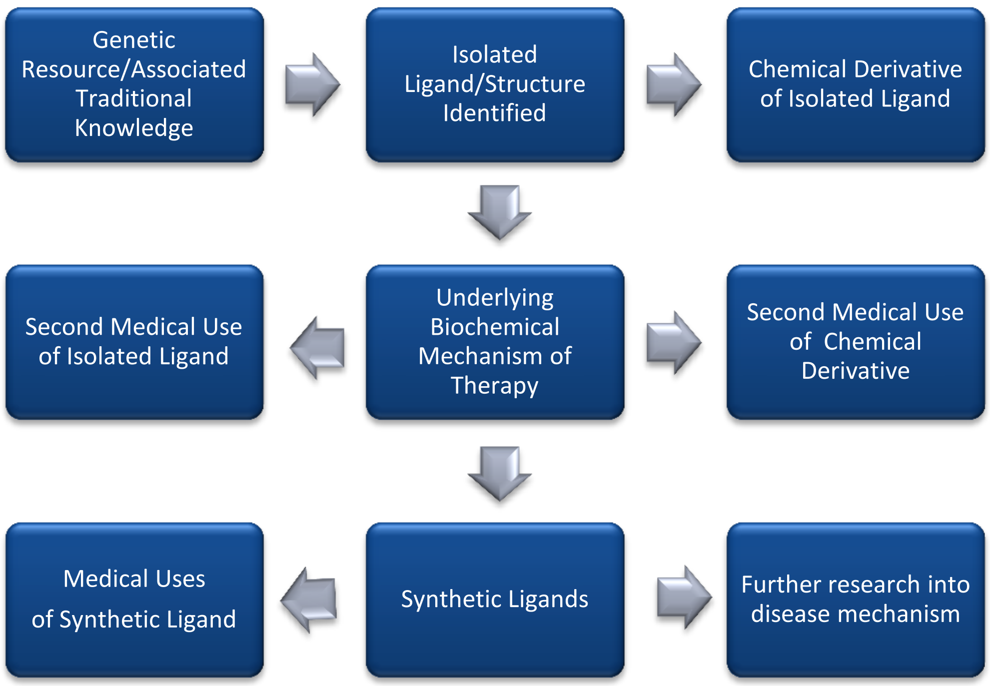
[24] Graham Dutfield, "A critical analysis of the debate on traditional knowledge, drug discovery and patent-based biopiracy" (2011) 33(4) EIPR 238

A piece of traditional knowledge can take many such routes within the drug discovery process – there are many pathways and feedback loops, the original information may be admixed to a greater body of existing information regarding the clinical problem, and there may be further admixture to the original information of discoveries derived from it and subsequent admixture to other "parallel" information which is not derived from it. In such a way, the original information is "diluted" or "attenuated". Here we immediately see the conflict between the original contribution of the indigenous peoples and contribution provided by those performing the research which lies at the heart of the current work – the dilution of knowledge throughout the drug discovery process is arguably accompanied by a concomitant dilution in contribution.

Chapter 4 of this work will look at the topography of the drug discovery research process in greater depth. However, for introductory purposes, Figure 1.1 shows a much-simplified schematic showing some of the potential steps that a genetic resource/piece of traditional knowledge may take within a drug discovery process.

Figure 1.1 Simplified schematic of path taken by a piece of traditional knowledge within the drug discovery process.



For simplicity, this flow diagram suggests that the steps are fairly linear. However, the "real life" drug discovery trail for a particular drug or family of drugs will rarely show such linearity. It is, of course, entirely possible that the scientific (and commercial) benefits of using a particular piece of original knowledge may be relatively "proximal" to that original knowledge and the history of the science of pharmacology is full of the use of relatively simple plant extracts or compounds directly purified from such extracts to give a therapeutic benefit.[25]

However, the extraction and testing a biochemical constituent of a genetic resource is, within modern drug discovery, far more usually merely the *beginning*, rather than the end, of a process of finding a safe and efficacious drug. [26, 27]

Evolution through natural selection can be improved upon in the search for a better drug, but such work has the additional advantage for those sponsoring the work of generating intellectual property "space" relative to their competitors' efforts. Indeed, much research into chemical derivatives is also undertaken in the search for so-called "me-too" (or, perhaps less pejoratively, "follow-on") compounds which allow a competitor to enter a market without infringement of earlier patents covering the field (but which can also yield truly enhanced pharmacological chemical entities).[28] Such modification of compounds is but one element of the drug discovery process. The finding of a new pharmacologically active compound within a genetic resource may uncover an as yet unknown biological mechanism within humans (or at least previously unknown ways of affecting known systems) which can give rise to further lines of research, both in terms of new chemical entities and new therapeutic benefits.

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[25] One can see this where particular endogenous toxins are simply extracted and used. One example is the use of the puffer fish toxin, tetrodotoxin as a research tool. CH Lee and PC Ruben, "Interaction between voltage-gated sodium channels and the neurotoxin, tetrodotoxin" (2008) 2(6) Channels (Austin) 407

[26] DG Grahame-Smith and JK Aronson, *Oxford Textbook of Clinical Pharmacology and Drug Therapy* (Oxford University Press, Oxford 1992), 3

[27] John Hall, "The drug development process" in Ignazio Di Giovanna and Gareth Hayes (eds) *Principles of Clinical Research* (Wrightson Biomedical Publishing, Petersfield UK 2001) 1

[28] Aidan Hollis "Me-too Drugs: Is there a problem?" (2004) http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf (Accessed September 2015)

Given the pharmaceutical industry's striving not only to improve on an original, but to seek out clear intellectual property space, it is highly likely that the scientific (and commercial) benefits of using a piece of original traditional knowledge related to a genetic resource will be significantly distal to a complex process of mixing and dilution of the original information.

1.3.2 Where *should* the right end?

The core purpose of the Protocol is to provide a set of *binding* mechanisms for implementing the access and fair and equitable benefits sharing ("ABS") objectives of the CBD. As will be discussed in Chapter 2, it does this by creating what are essentially rights of veto over certain genetic resources and over specific traditional knowledge which relates to those genetic resources. However, when one looks at the real-world complexity of drug discovery research and the provisions of the Protocol we see a potential problem.

It might be argued that much of the rhetoric in the argument for creating positive rights in traditional knowledge seems to take an uncomplicated view of the role of traditional knowledge in pharmaceutical discovery/development and tends, in particular, not to mention the more "distal" and "remote" research activities. It also tends to assume that all downstream uses of a piece of traditional knowledge relating to a genetic resource, or another piece of traditional knowledge which relates to a therapeutic solution, are derived in a simple, linear, fashion from the original piece of knowledge. As we have seen, this is not necessarily the case.

As will be seen in detail in Chapter 2 of this work, the way in which certain articles of the Protocol came to be drafted (and certain definitions came to be defined and incorporated into those articles) would appear to leave a degree of uncertainty over the scope of protection offered by the Protocol in relation to the *downstream* use of biochemical constituents of genetic resources.[29]

These uncertainties stimulated the author to ask the following question (which is the core of the current work):

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[29] As yet, the rights created by the proposed WIPO treaty are undetermined.

> Given the potential dilution of the original traditional knowledge associated with a genetic resource, is it justifiable to allow the "owner" of the original knowledge to possess an absolute veto on all downstream activity or are other solutions more supportable?

Or reframed:

i) Does a broad, apparently unending, scope of veto on use constitute fair/justifiable protection for the holders of traditional knowledge regarding the therapeutic efficacy of genetic resources, even where the "non-consensual" use, is extremely distal to the original knowledge?; and

ii) If such a scope is unfair/unjustifiable, can we gain any certainty as to where the scope *should* end (which may be interpreted as an activity *not* constituting access/use)?

Although the question was stimulated by the uncertainty of the Protocol in this regard, (and may inform our understanding of the correct interpretation of the Protocol), it is a more fundamental normative question whose solution (if there is one) is more broadly applicable to the protection which *should* be afforded to indigenous peoples, whichever method of creating positive rights is promulgated within a jurisdiction (and indeed whatever solution is arrived at by WIPO or the WTO).

It should be immediately noted that the key focus of this work is deliberately upon the right to *veto* downstream use, as opposed to a right merely to share in the fruits of a third party's existing, or intended, commercial exploitation. A right to veto is a significantly stronger right than a mere right to share benefits of exploitation in that it allows the right holder to choose whether the subject matter is exploited, how it is exploited, by whom and on what terms. A right to share in proceeds of exploitation which is not supported with a right to veto is a lesser right. Accordingly, questions of the justification and scope of the stronger veto rights fall first to consideration. As will be seen, however, the appropriateness of a mere compensation model relative to downstream vetoes and questions of determination of compensation based upon "contribution" are dealt with within the context of proposed policy options (see Chapter 5).

1.4 How should we seek to address this problem of "scope"?

Although the downstream use question set out above is relatively simple to formulate, it is one which is harder to answer.

The current work addresses the overall question by essentially asking two related, and intertwined, questions:

a) How can one delineate the boundary of a right to control traditional knowledge? and

b) What are the philosophical justifications for a veto right in traditional knowledge associated with genetic resources?

The work adopts two parallel analytical approaches to these questions:

a) analogical reasoning which:

i) treats the involvement of a piece of traditional knowledge associated with a genetic resource within the a drug discovery process as a flow of information (a chain of causation) during which the original concept becomes diluted through the contribution of others; and (alongside that approach);

ii) seeks to determine what justifiable parallels (if any) can be drawn with relevant existing categories of intellectual property rights, particularly in relation to the identification of putative boundaries and the handling of competing contributions;

and

b) the application of a "tool-box" of philosophical justifications for property in intangible concepts to putative boundaries to the right.

Each of these questions, and analytical approaches, will be dealt with in turn.

1.4.1 Boundary/"crux" point delineation

As will be dealt with in more detail in Chapter 3, trying to create exclusivity in an intangible (such as knowledge) is inherently wrought with problems. Ideas are by their nature non-exclusionary and non-rivalrous and exclusivity in ideas can be only be created through the imposition of what Bentham styled the "head of law". [30] If one is (through a positive legal mechanism) to carve-out or delineate an area which is to be excluded from the use of others, one needs to be able with reasonable certainty to identify the point at which third-party use is to be prevented. However, whereas the "core" of an idea may seem easy to articulate, problems begin to arise when one seeks to determine the "edges" of a concept (edges which are crucial to delineating an exclusionary boundary).

The uncertainty of such delineation is related to the nature of the type of information that one seeks to protect. Problems of delineation of both "backward-looking" (subsistence) and "forward-looking" (infringement) boundaries are (as will be discussed in Chapter 3) arguably more acute in relation to "raw" ideas, than when dealing with (relatively) more concrete *expressions* of such ideas. Traditional knowledge which tells us of the therapeutic benefit of a particular genetic resource is, arguably, information in its "rawest" form.

In the current problem, the issues concerning boundary delineation are compounded by the complexity of the mechanisms by which a piece of traditional knowledge can be used within the field of drug discovery. It is this mix of the inherent breadth of the nature of traditional knowledge, teamed with the plurality and complexity of potential downstream uses, which makes the determination of justifiable limits to positive rights to control its use a thorny problem.

Thorny as it may be, if we are to get anywhere with finding a justifiable limit we need to identify some putative boundaries which can be taken on for further analysis. As will be discussed below, this work uses two approaches to seek such putative boundaries. The first is to identify parallels with concepts of breaks in chains of causation and to

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[30] Jeremy Bentham *Manual of Political Economy* (1839) reprinted in W Stark (ed) *Jeremy Bentham's Economic Writings* (George Allen & Unwin, London 1952), 263

apply such concepts, where applicable, by analogy. The second seeks to identify potentially relevant concepts which have been used by within the analysis of other intellectual property rights and to apply such concepts, where applicable, by analogy. It should be immediately noted that both approaches are used in parallel and inform one another.

1.4.2 Philosophical justifications for a veto right

Attempts to delineate the putative edges of a right are crucial precursors to questions of scope and without such examination one is in danger of dealing merely in broad generic terms. However, such enquiries cannot, of themselves, answer the question of what is a *justifiable* limit to a particular right to exclude others from an activity. A determination of such justifiable limits can, by definition, only come from the application of the *philosophical* grounds for excluding others from an activity to a particular situation.

As will be further discussed in Chapter 3, there is a rich body of higher-level philosophical principles (consequentialist, deontological, and those not so easily categorised) which have been used to for excluding third party use of what might be called "intellectual products" and thereby justifying the existence of intellectual property rights in the light of opposing justifications for the preservation of a "commons of ideas". The present study will seek to identify and summarise these justifications and apply them to the question of the proper scope of positive protection over uses of traditional knowledge associated with genetic resources. However, simple rehearsal of the underlying opposing justifications is likely to provide only broad generic principles as to the limit of these rights. Where one is faced with a continuum or "grey-scale" of putative "infringements" (i.e. non-consensual uses), such a broad examination is unlikely, of itself, to provide more focussed guidance as to whether certain forms of distal activity should constitute non-consensual use.

The power and usefulness of a philosophical position within a legal context comes from the ability to apply it to "real world" situations. Indeed, for Underkuffler:

> "the adoption of a theoretical dimension – means nothing without knowing to *what* this theory is to be applied" [31] [emphasis from original]

In the present case the "what" to which we are seeking to apply a theoretical dimension – *i.e.* our philosophical "tool kit" -is the putative boundary delineation to the right identified through analogical reasoning.

1.4.3 Analogical Reasoning: Causation, dilution and the topography of the drug discovery process.

Intellectual property rights are often analogised as creating exclusivity "over" a "field" of activity. The mental image conjured up is perhaps one of a 2D "area", or perhaps even a 3D "space". Such images can help us visualise a problem and they certainly assist in the drawing of 2- or 3-dimensional Euler diagrams. In this analogy, questions of scope are visualised as the determination of the (sometimes fuzzy) "edges" of the area or space. However, analogies are simply that, and we need always to be aware of their limitations. What is used as a mental aid should not circumscribe our ways of thinking.

An outstanding feature of the present case is the sense of a "flow" of information (traditional knowledge) through a series of pathways where one piece of knowledge stimulates a further downstream use. It is the nature of that information at any point in the pathway (and the use to which it is put) which provides the path-dependency with the original inspiring knowledge. In such a case, perhaps a more productive analogy is with a causal chain rather than with an excluded "area" with "edges". It is to this type of analogical reasoning that we will now turn.

We are concerned in this work with the question of whether a particular use is consensual or not. This would appear, on the face of it, to have a relatively straight-forward binary outcome - consent is either granted or consent is not granted. In fact, the granting of consent, or otherwise, has many complexities – does the person giving (or denying) consent have the authority to grant/deny it? Is the consent (or denial) clear? Is the consent/denial contingent upon something else? These complexities are important

[31] Laura S Underkuffler, *The Idea of Property: It's Meaning and Power* (Oxford University Press, Oxford 2005), 21

(and given the way traditional knowledge may be held by indigenous groups could be particularly problematic in relation the granting of consent to use of such knowledge). There is, however, a further question – is the consent properly *required*? In our present case we can ask: is the downstream use of a piece of knowledge within a drug discovery programme such that consent is required?

Our first approach may be to say that this question has a simple answer based upon a simple causation analysis: Did the use in question *in fact* derive from the original piece of information? If so, consent is required.

If we look (broadly) at the application of a causation *in fact* (or *sine qua non*) test to the situation in which a new drug has been developed on the basis of a piece of traditional knowledge associated with a genetic resource, we would find that *but for* the original piece of traditional knowledge one would never have arrived at the final drug in the way in which it was arrived at. Of course, one may have eventually arrived at that drug by other (path-independent) means (for example through random screening), but possibly less simply, quickly, or cheaply as by the path-dependent means. However, the path-independent means does not concern us in this respect – it is, by definition, not dependent *in fact* upon the original information.

Now if causation in fact *alone* is sufficient to create liability, we might successfully argue that *any* downstream use, no matter how distal or remote (and no matter how changed, diluted and widely dissipated the original "inspiration" has become) can be subject to a veto from the original holder of the information.

Within the philosophy of scientific discovery there is a long tradition of recognition that new discoveries are based upon the work of those which have gone before. Newton's quote that:

> "If I have seen further it is by standing on the sholders [sic] of Giants"[32]

[32] Letter from Newton to Hooke (5 February 1676) HW Turnbull, JF Scott, AR Hall (eds) *The Correspondence of Isaac Newton Volume I* (1959 Cambridge University Press, Cambridge), 416

has become famous,[33] but was clearly derived (somewhat ironically, and perhaps deliberately) from the earlier statement "*nanos gigantum humeris insidentes"* (dwarves on the shoulders of giants) attributed of Bernard of Chartres.[34]

Although Hanson[35] acknowledges that all scientific discoveries have to be causally dependent *in fact* upon the work that has gone before, he stresses that such causality is merely backward looking once a discovery has been made - if one is *within* a chain of discovery it does not, of itself, render the last step in the discovery trite or obvious, nor take us unerringly to the final conclusion *before* that discovery is made.

Is a strict causation *in fact* test correct in our present instance? Such "but for" tests for causation give only a stark binary outcomes, lack subtlety and could be taken to absurd extremes - there is a *sine qua non* link between a wrong turning taken by Leopold Lojka in Sarajevo on 28 June 1914 and the detonation of a nuclear device over Nagasaki 31 years and 42 days later - the latter event would have not have happened but for the former.[36]

Other problems with a *sine qua non* test arise where one considers that causal chains are not only long, but that one event will be the "result" of the interaction of a large variety of distinct efferent events or preconditions – a particular situation is often the outcome of multiple equilibria of causes. Following a Baconian[37] empirical approach, much scientific experimentation will seek to control as many efferent factors as possible so as to isolate the causative factor of interest. However, such control is impossible where performing an *ex post facto* analysis of the historic causes of an event. In addition,

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[33] So famous as to appear on the edge of the British two pound coin.

[34] "Bernard of Chartres used to compare us to [puny] dwarfs perched on the shoulders of giants. He pointed out that we see more and farther than our predecessors, not because we have keener vision or greater height, but because we are lifted up and borne aloft on their gigantic stature." John (of Salisbury, Bishop of Chartres) *The Metalogicon: A Twelfth-century Defense of the Verbal and Logical Arts of the Trivium* (California University Press, 1955), 167

[35] Norman Russell Hanson, *Patterns of Discovery, An Inquiry into the Conceptual Foundations of Science* (Cambridge University Press, Cambridge 1965), 50

[36] Hanson (n 35) cites the popular saying "For the want of a nail a shoe was lost; for the want of a horse a rider was lost; for the want of a rider the battalion was lost; for the want of a battalion a battle was lost; for the want of a victory a kingdom was lost – all for the want of a nail."

[37] Francis Bacon, *Novum Organum Scientiarum* (1620)

multiple efferent events cause particular problems where there is duplicative causation (two efferent factors each of which was sufficient alone to cause an event) or pre-emptive causation (when an intervening factor brings forward an event which would have happened anyway due to a prior, but delayed-action, cause).

The limitations of "but for" tests in relation to determination of legal responsibility has given rise to much serious scholarship[38] Simply put, a "pure" *sine qua non* test encounters extreme difficulty when applied to legal problems. Hart and Honoré [39] argue the merits of a bifurcated analysis in which an initial causation *in fact* test is subject to a second stage (causation *in law*) analysis which examines whether there is any reason which precludes treating a cause as a cause (or an intervening event as an intervening event) for policy purposes.

There are parallels in our present problem with the problems of remoteness seen in other torts. There is a rich tradition within the law more generally of using ideas of causation to examine remoteness and, although much of the focus of that analysis has been in relation to the law of negligence, it is certainly not limited to that tort.[40] However, the vast majority of the examination relates to the remoteness of *loss* whereas the remoteness in the current problem might be better described as remoteness of "gain" or advantage.

Although Hart and Honoré acknowledge that causation may be applied to questions of gain[41] they use the example of gains leading to reduction in a claimant's loss, rather than the enrichment of the defendant. However, remoteness of "gain" has been examined within the context of the assessment of the quantum of an account of profits where the contribution that the infringement made to overall enrichment of the infringer

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[38] For example see HLA Hart and Tony Honoré, *Causation in the Law* (OUP 1985); Richard W Wright "Causation in Tort Law" (1985) 73 Cal L Rev 1735; Michael S Moore *Causation and Responsibility, An Essay in Law, Morals and Metaphysics* (Oxford University Press, Oxford 2009); Richard Goldberg *Perspectives on Causation* (Hart Publishing, Oxford and Portland, Oregon 2011)

[39] HLA Hart and Tony Honoré, *Causation in the Law* (Oxford University Press, Oxford 1985), 110

[40] Hart (n 39), 84

[41] Hart (n 39), 86

is called to be determined.[42, 43, 44, 45] There is, however, no reason to limit our analytical "tool box" to causation principles considered within issues of apportionment alone.

If there *is* to be a difference in outcome between a strict causation *in fact* analysis and causation *in law* analysis on a particular set of facts, that difference must reflect the justifications which underpin the right which the putative claimant is seeking to assert.

As stated above, the problem is that justifications will often take the form of very broad principles and without *specific* examples of "remoteness" with which to test those principles the guidance they supply may seem very abstract and hard to apply. Accordingly, a useful causation *in law* analysis requires an understanding of the appropriate types of "intervening event" which could break a chain of causation *in law*.

As stated above, in our present problem, the pharmaceutical development process is complex. Accordingly, determination of potential "chain breaking" types of interventions (or combinations of interventions) requires an empirical understanding of the processes by which drugs are discovered.

The present work will (in Chapter 4) therefore seek to understand the topography of pharmaceutical discovery and development process from the perspective of the journey of a piece of traditional knowledge through that process. It will seek to identify whether there are points in that process which, due to a notable feature in the nature of the mixing of the information at that point, may arguably stand in the way of a chain of causation *in law*. For consistency of terminology these putative "chain breaking" interventions in causation in law will be termed "crux points" in the drug discovery process.

In parallel, and where necessary (and as discussed below), caveated guidance will be sought from approaches that have been taken within patent law when it has looked at the scope of patent rights within the drug discovery process.

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[42] See for example *Celanese International Corp v BP Chemicals Ltd* [1999] RPC 203

[43] Alexander J Stack, A Scott Davidson & Stephen R Cole, "Accounting of Profits Calculations in Intellectual Property Cases in Canada" 17(2) CIPR 405

[44] Lionel Bentley, "Accounting for Profits Gained by Infringement of Copyright: When does it end?" (1991) EIPR 5, 10-11

[45] *Imperial Oil Limited* et al *v Lubrizol Corporation* et al (1996) 71 CPR (3d) 26, 30 (Canadian FCA)

1.4.4 Analogical reasoning: Guidance from established intellectual property rights

Questions of "distal"/"remote" use are not alien to the field of intellectual property and the approaches used in examining the problem of remoteness/distality in other intellectual property rights may be assistance. However, before we can "read across" from the experience gained with more established intellectual property rights, or seek to apply other intellectual property approaches by analogy, we need to recognise how the subject matter of a positive right in traditional knowledge is similar to (and different from) that of those established rights.

Traditional knowledge (being information) is fundamentally similar to the subject matter of a patent (ideas). However the trans-generational nature of traditional knowledge and the historical nature of its discovery render it inappropriate for patent protection.

Patents (and other *registered* intellectual property rights) create so-called "monopoly" rights which can be enforced against a third party, even where ideas developed by the infringing third party have not originated from the patentee.[46] The infringer may have generated the idea entirely independently of, and without any knowledge of, the patent and yet still infringe.[47] Patents allow what Attas[48] calls a "*path-independent extension of the right in the idea*". Patent claim interpretation, even the purposive interpretation required under the European Patent Convention[49] and English law,[50] is inherently

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[46] The use of "monopoly" in this context is to distinguish these types of rights from rights which restrict copying alone, there remains debate over whether such monopolies should be considered as true monopolies in an economic sense. See RE Meiners & RJ Staaf, "Patents, Copyrights, and Trademarks: Property or Monopoly?"(1990) 13 Harv J L & Pub Pol'y 911, 916-917 and John F Duffy, "Intellectual Property as Natural Monopoly: Toward a General Theory of Partial Property Rights" (2004) (http://www.utexas.edu/law/magazine/wp/wp-content/uploads/centers/clbe/duffy_intellectual_property_natural_monopoly.pdf) (Accessed February 2015)

[47] Although the infringer's knowledge of the patent may in some cases go to the damages recoverable by the patentee. See for example United States Code, Chapter 35 §284. Provisions can also exist for "secret prior user" defences; see for example Section 64 UK Patents Act 1977 (as amended).

[48] Daniel Attas, "Lockean Justifications of Intellectual Property" in Axel Gosseries, Alain Marciano and Alain Strowel (eds), *Intellectual Property and Theories of Justice* (Palgrave Macmillan 2008) 29, 47

[49] Article 69, European Patent Convention 1973 (as revised by the Act revising the EPC of 29 November 2000) and The Protocol on the Interpretation of Article 69, 1973, (as revised by the Act revising the EPC of 29 November 2000)

dependent on path-dependent infringement and any guidance that can be taken from patent law needs to be very carefully considered with this fundamental difference in mind.

In contrast, the Protocol positive rights in traditional knowledge (and current WIPO proposals) envisage that the idea informing the infringing use will have originated from the protected traditional knowledge. The extension of the right in the mis-used information is "path-dependent". Of course it cannot really be otherwise; use of entirely independently-arrived upon information cannot ever be a *misuse* of the traditional information. In this respect, at least, positive rights in traditional knowledge arguably more closely resemble a copyright, or a right in confidential information, both of which require a path-dependent infringement/breach of right. Despite this passing similarity, crucially copyright laws are not usually perceived as protecting ideas *as such*.[51]

Equitable rights to prevent a breach of confidence (or to be compensated for such a breach) do allow for the protection of information *as such*, but differ significantly from Protocol/WIPO-proposed positive rights in traditional knowledge in that they require an *inequitable* breach of confidence on the part of the defendant.[52] Crucially, this requirement is absent in respect of the Protocol positive rights (within Article 7 and Article 5(5); and WIPO-proposed positive rights).[53]

In any event, although there may exist some situations in which traditional knowledge is held by a narrow group of individuals who are bound by a mutual obligation of confidence (and where disclosure to a third party could be said to be in breach of such an obligation), there will be other (perhaps many other) situations in which the relevant information is held more broadly within an indigenous group (or groups) and/or has long been passed to third parties. Here the information could never possess the requisite quality of confidence for the application of an equitable right based on breach of confidence. It should be noted that limitation of protection to only that information

[50] *Kirin-Amgen Inc v Hoechst Marion Roussel Limited* [2004] UKHL 46

[51] See for example*: Baigent and another v Random House Group Ltd* [2007] All ER (D) 456

[52] See for example: *Coco v A N Clark (Engineers) Ltd* [1969] RPC 41

[53] See Chapter 2

which could be argued to be "confidential" would severely curtail the quantity of indigenous knowledge that could ever be eligible for protection and would place considerable evidential burdens upon those seeking to control its dissemination.

Given these fundamental differences, it is argued in this work that no *direct* guidance can be taken from these existing intellectual property rights.

However, notwithstanding, the identified differences between the subject matter for patent protection and traditional knowledge associated with genetic resources, there is a long history of interface between patent law and the drug discovery process – notably in relation to competing contribution. Provided that the differences are appreciated, the considerations of patent law with respect to questions of scope within drug discovery may serve as a source of analogous concepts for consideration when examining downstream limits to the right to control traditional knowledge.

1.4.5 Application of high level justifications to determined "crux points"

Both analogical approaches discussed above are, of course, merely tools for locating putative boundary delimitations to test against high-level philosophical justifications for control over intangibles.

It should be immediately noted that the aim of the study is *not* to reconcile the fundamental differences between the conflicting high-level justifications. The author seeks to be deliberately agnostic as to the merits of the competing philosophies at the highest level (for example the overarching validity of utilitarianism *versus* deontological justifications). The aim is to apply the justifications as "tools" for determining the correct scope of the veto rights in traditional knowledge associated with genetic resources. In doing so, the validity of the justification as applied to the subject matter will be critically examined on a case by case basis. However, it is intended that application of the key (and indeed radically different) high-level justifications will illuminate different facets of the putative veto right.

Whilst acknowledging the significant differences in approach between the diverse philosophical positions, the work will seek to arrive at a synthesis of the outcomes obtained from the application of each high-level justification.

1.5 Overview of the structure of this work

The first exercise within this work (set out in Chapter 2) is to determine what the provisions of the Protocol appear to say in respect of the scope of a positive right in traditional knowledge associated with a genetic resource. As will be seen, the outcome of that analysis is that the downstream scope of such a right within the Protocol is unclear. As has been discussed above, the determination of what the Protocol says in this regard should not, of itself, impact on the outcome of the justificatory analysis based on first principles. However, notwithstanding that, an examination of the provisions of the Protocol is highly instructive as it serves to introduce some key concepts of downstream use that will be engaged with later in this work. Crucial here is the disconnect between the concept of a genetic resource *per se* and that of traditional knowledge *associated with* that genetic resource.

Before the high level justifications for rights in traditional knowledge can be brought to bear upon putative boundary limitations (the "crux points" discussed above) we must establish broadly what theoretical arguments have been used to justify the protection of knowledge and how such arguments can be applied more particularly to the protection of traditional knowledge associated with genetic resources. This is achieved in Chapter 3 of this work.

As discussed above if we look to treat the involvement of traditional knowledge associated with a genetic resource with the drug discovery process as a flow of information and a process of dilution of the original contribution, we need to understand the types of flows of information we might see – we need a sense of the topography of the drug discovery process. Accordingly, an empirical study of this process is set out in Chapter 4 of this work.

Within that study (and reflecting on analogies with patent law) the serendipitous discovery of second medical and other uses is identified as a potential point at which there is an arguable step change in the dilution of the original contribution. As a result, the empirical study is further focussed upon four case studies from the history of drug discovery in which "serendipitous" discoveries were made:

a) The identification of an anti-coagulant effect of acetylsalicylic acid (aspirin) a downstream derivative of the original compound (salicin) found in the genetic resource;

b) The identification of a local anaesthetic effect of cocaine (a compound directly found in the genetic resource but known to have psychoactive effects);

c) The discovery of the dye mauveine whilst attempting to synthesise quinine; and

d) The discovery of anti-tumour effects of the vinca alkaloids (directly found in the genetic resource but believed to have anti-diabetes effects).

Having identified serendipitous discoveries as a putative step change in contribution dilution, it is at this point that the two parallel streams of the study come together. In Chapter 5 the key philosophical justifications for veto rights in traditional knowledge associated genetic resources identified in Chapter 3 are applied to the serendipitously discovery "crux point" identified in Chapter 4.

It was anticipated that each high-level justification could provide a variety of different answers to the question of scope in relation to the identified crux point. Accordingly the next step in the study (in Chapter 6) is to determine to what extent (if at all) the answers provided through the application of high-level justifications to the identified crux point can be synthesised/reconciled.

Part of this analysis brings us to the question of what a "serendipitous" discovery actually is and how one can be defined in practice. There is particular focus (within the latter part of Chapter 6) on what a serendipitous discovery means where the "second" therapeutic use is in fact derived from a common physiological process as is the first use. The finding of that, and the other analyses, are brought together and summarised in the Conclusion in Chapter 7.

Chapter 2

Analysis of the *sui generis* anti-misappropriation rights within the Nagoya Protocol

Benignius leges interpraetandae sunt, quo voluntas earum conservetur

"Laws should be interpreted in a liberal sense so that their intention may be preserved."

Digest of Justinian I, iii, xviii (529 CE)

Attributed to Marcus Tullius Cicero (106-43 BCE)

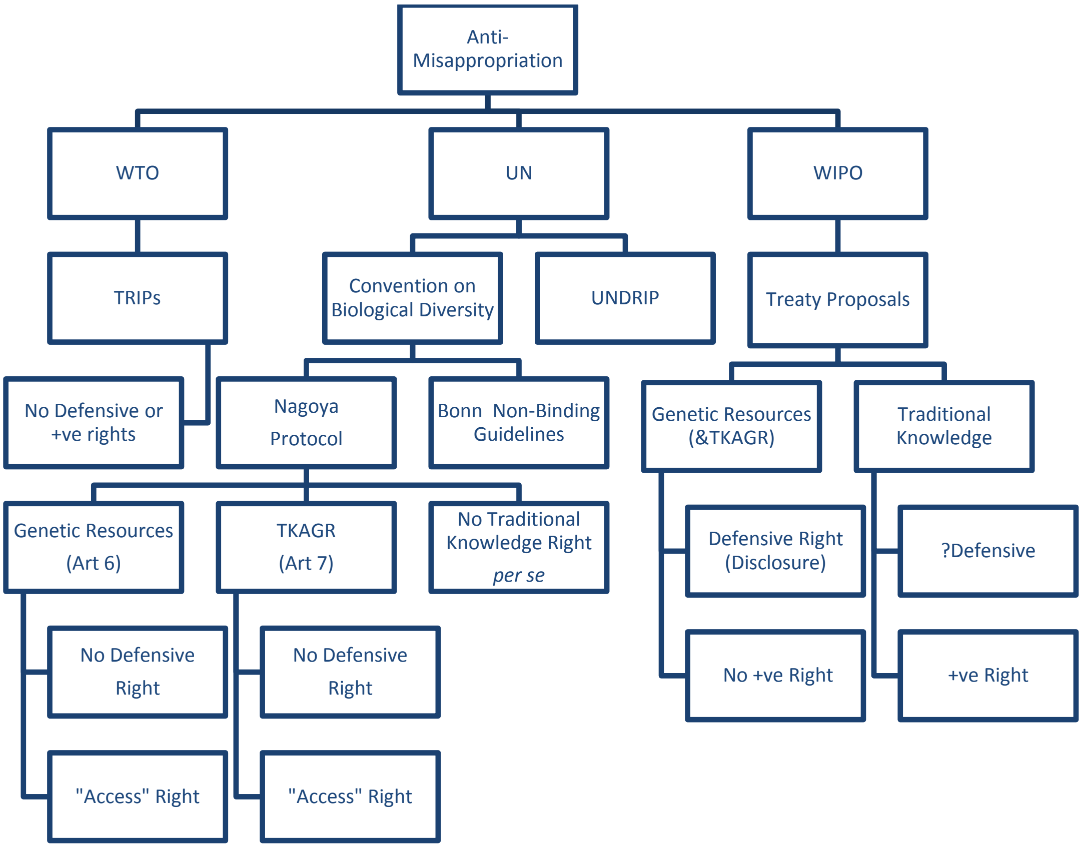
2.1 Introduction

As explained in Chapter 1 of this work, the question of whether (in the light of the potential dilution of the original traditional knowledge related to a genetic resource within the drug discovery process) it is justifiable to allow the "owner" of the original knowledge to possess an absolute veto on all downstream activity was originally stimulated by the uncertainty of the Protocol in this regard. It was also explained that the answer to this normative question of competing contributions between indigenous peoples and pharmaceutical researchers could only lie in the application of high-level philosophical doctrines to the problem, notwithstanding the actual provisions of the Protocol (or indeed of any future WIPO or WTO treaty in this regard).

The aim of the current chapter is, therefore, to explore those provisions of the Protocol which create *sui generis* rights in traditional knowledge associated with genetic resources (and the related provisions relating to the protection of genetic resources alone) and determine whether the veto rights apparently set out in the Protocol can be interpreted as extending to *all* path-dependent downstream uses arising out of such original traditional knowledge.

Before this analysis is undertaken this chapter will introduce the key international approaches taken to address claims misappropriation of genetic resources and related traditional knowledge with a particular focus on the Protocol.

<u>Figure 2.1 "Family Tree" of international approaches to anti-misappropriation rights.</u>



Key: TKAGR: Traditional Knowledge Associated Genetic Resources

UNDRIP: UN Declaration on the Rights of Indigenous Peoples

2.2 International "solutions" to claims of misappropriation

As alluded to in the introductory chapter, the drive to address claims of misappropriation of genetic resources and related traditional knowledge has taken place, with differing rates of progress, in a number of international fora. The key fora are:

d) The World Trade Organisation ("WTO");

e) The United Nations ("UN"); and

f) The World Intellectual Property Organisation ("WIPO");

These international tracks are summarised in Figure 2.1 as a "family tree" of international approaches to anti-misappropriation rights.[54]

2.2.1 The WTO Route

The "early" (pre-2012) history of progress within the WTO has been described in some detail by Kiene[55] and it is not the intention of this work to revisit the developments under the WTO in any detail. Negotiation has centred on redrafting of Article 27.3(b) of The Trade Related Aspects of Intellectual Property Agreement ("TRIPs"). Article 27.3(b) TRIPs allows signatory countries to exclude from patentability:

> "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes".

Of course, this provision also allows other signatories to allow patents for such processes.

At the time of signature the whole concept of patenting life forms was (and still is)[56] controversial, and a requirement that the provisions of the subparagraph be reviewed was built in to the subparagraph from the outset.[57] Of course, if one were seeking to ensure that the protection of traditional knowledge was incorporated into TRIPs this review provision could be seen as an opening. Indeed the interface between Art 27.3(b) and the 1993 United Nations Convention on Biological Diversity ("CBD") (see below)

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[54] In addition to these international approaches, there is a broad raft of anti-misappropriation legislation promulgated by individual jurisdictions. Much of that has followed (or is likely to follow) the routes taken by the multilateral routes under the CBD or WIPO and it is the aim of this work to focus on the broader multilateral approaches and the broader principles supporting positive rights to control over traditional knowledge rather than to take a jurisdiction by jurisdiction approach.

[55] Tobias Kiene, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field. An Intercultural Problem on the International Agenda* (Waxmann, Münster 2012), 191

[56] M Hussain, "Patenting of Life Forms: Reflections on Some Legal and Ethical Issues" (2014) 4(2) IUP Law Review 7

[57] "The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement" TRIPS Article 27.3(b)

was identified in Paragraph 19 of the 2001 Doha Declaration[58] and it was agreed that the work of the TRIPs Council should consider the protection of traditional knowledge and folklore in the review of TRIPs. Many WTO members in the global South consider that the discouragement of "biopiracy" should be a key part of any new TRIPs provision. However, the majority of current proposals [59] concern a "defensive" protection through a requirement that patentees disclose the origin of traditional knowledge/genetic resources in their application, rather than development of a positive right. It would be fair to say that progress on amendment to 27.3(b) within the WTO as it relates, not only to prevention of misappropriation of traditional knowledge and genetic resources, but also to the question of patenting of life forms has been glacial.[60]

The momentum in the development of *positive* anti-misappropriation rights has been more effectively taken forward within the ambit of the United Nations (and to a lesser extent) within WIPO.

2.2.2 The United Nations Route

The United Nations has addressed the question of rights in traditional knowledge through two distinct tracks. In September 2007 the General Assembly on the United Nations adopted the UN Declaration of the Rights of Indigenous Peoples ("UNDRIP").[61]

Although UNDRIP broadly addresses the rights of indigenous people, there are three articles (11, 24 and 31) of specific relevance to the question of traditional knowledge (and related genetic resources):

Article 11 states:

> "Indigenous peoples have the right to practise and revitalize their cultural traditions and customs. This includes the right to maintain, protect and develop

[58] http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (Accessed September 2015)

[59] http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm (Accessed September 2015)

[60] (n 59)

[61] http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf (Accessed September 2015)

the past, present and future manifestations of their cultures, such as archaeological and historical sites, artefacts, designs, ceremonies, technologies and visual and performing arts and literature."

"States shall provide redress through effective mechanisms, which **may include restitution**, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs." [emphasis added]

Article 24 states:

"Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals..."

Article 31 states:

"Indigenous peoples have the right to maintain, **control**, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, **control**, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions." [emphasis added]

"In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights."

Additionally, Article 38 provides that States shall take appropriate measures, including legislation, to achieve the ends of UNDRIP. However, although it is a legally binding declaration, UNDRIP gives no specific detail on how these broad ends should be achieved.

In contrast, substantial advances have been made through the United Nations' environmental mechanism. On June 5 1992 the United Nations CBD was opened for signature. It came into force on 29 December 1993, having been ratified by 194 members of the United Nations.[62] The CBD is, first and foremost, a convention which looks to protect the biodiversity of the planet,[63] ensuring sustainable use and fair and equitable sharing of the exploitation of biodiversity. Towards that final end, Article 8(j) of the CBD requires that each contracting party shall "as far as possible and as appropriate":

> "Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices" [64]

In 2002, the sixth CBD Conference of Parties agreed a set of guidelines (the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization"[65] – hereafter the Bonn Guidelines) with the aim of providing guidance to legislators in implementing Article 8(j) of the CBD. The Bonn Guidelines were entirely voluntary [66] and expressly did not seek to amend parties' obligations under the CBD[67] or further create or assign rights.[68] However, the sixth CBD Conference of Parties did explain that it considered these guidelines:

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[62] http://www.cbd.int/information/parties.shtml (A notable omission is the United States of America which signed the convention in June 1993 but has so far failed to ratify; the only signatory to do so.)

[63] Kiene (n 55),198

[64] http://www.cbd.int/convention/articles/default.shtml?a=cbd-08 (Accessed September 2015)

[65] CBD COP Decision VI/24, http://www.cbd.int/decision/cop/default.shtml?id=7198 (Accessed September 2015)

[66] CBD COP Decision VI/24 Annex I(7)

[67] CBD COP Decision VI/24 Annex I(2)

[68] CBD COP Decision VI/24 Annex I(5) & I(6)

> "are a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing".[69]

This "evolutionary" progress reached a landmark with the adoption in October 2010 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity (the "Protocol"). As at September 2015, the Protocol has 92 signatories, 65 of which have ratified the Protocol.[70] The Protocol came into force on 12 October 2014.[71,72]

The key aim of the Protocol is to provide a set of *binding* mechanisms for implementing the access and fair and equitable benefits sharing ("ABS") objectives of the CBD. However, the Protocol is its deliberately limited scope. It (and the Bonn Guidelines before it) originates from the CBD and accordingly its absolute focus is on the misappropriation of *genetic* resources, and the misuse of traditional knowledge which is related to a particular genetic resource, rather than attempting to create a broader positive right in traditional knowledge *per se*. As we will see, the protection of traditional knowledge more broadly has been taken up within the agenda of WIPO.

Broadly speaking, the Protocol looks to apply two obligations (*access* subject only to prior informed consent and *use* subject to benefit sharing) to the users of two separate, but closely related, resources (genetic resources and traditional knowledge associated with genetic resources). The key operative provisions are summarised in Table 1.1.

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[69] CBD COP Decision VI/24 Paragraph 6

[70] https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml (Accessed September 2015)

[71] http://www.cbd.int/doc/press/2014/pr-2014-10-12--protocol-en.pdf (Accessed September 2015)

[72] Tim Roberts "Regulation: A new form of intellectual property?" (2014) 43(3) CIPA Journal 150

Table 2.1 Key elements of the Nagoya Protocol articles giving rise to positive rights

Article	"Right holder"	Subject matter	Controlled activity	Condition
5(1)	Party	genetic resources	utilization (including "subsequent applications and commercialization")	fair and equitable sharing upon mutually agreed terms
5(2)	indigenous and local communities	genetic resources	utilization	fair and equitable sharing based on mutually agreed terms
5(5)	indigenous and local communities	traditional knowledge associated with genetic resources	utilization	fair and equitable sharing upon mutually agreed terms
6(1)	Party	genetic resources	access for utilization	prior informed consent
6(2)	"indigenous and local communities"	genetic resources	access	prior informed consent or "approval and involvement"
7	"indigenous and local communities"	TKAGR	access	prior informed consent or "approval and involvement" and establishment of mutually agreed terms

In relation to access to genetic resources Article 6(1) states:

> "In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party."

And Article 6(2) states:

> "In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources."

In relation to the sharing of benefits arising out of use of genetic resources Article 5(1) states:

> "In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms."

And Article 5(2) states:

> "Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms."

With regard to "access" to traditional knowledge associated with genetic resources Article 7 states:

> "In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established."

With regard to sharing the benefits arising out of the use of traditional knowledge associated Article 5(5) states:

> "Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms."

Neither Article 6 nor 7 is drafted in what one might consider to be a "classic" way to create a positive intellectual property right. However, the key element to any positive intellectual property right is that certain identified activities are prohibited without the *consent* of the right holder (or put another way the right holder has a right to veto certain activities of third-parties) and it is (usually[73]) for the right holder alone to determine under what circumstances the consent will be given (or the veto on use will be lifted). Taking that approach, Article 6(1) by requiring prior informed consent from a Party (meaning here a nation state) clearly creates a positive (veto) right over that access.

However, the position of Articles 6(2) and Article 7, relating to indigenous peoples rather than nation state Parties, is somewhat less clear. Article 6(2) *either* requires prior informed consent from indigenous and local communities holding the knowledge *or* "approval and involvement" from those indigenous and local communities which have the "established right to grant access to such resources". Article 7 *either* requires prior informed consent from indigenous and local communities holding the knowledge *or* "approval and involvement" from those indigenous and local communities with, in either case, a further requirement that "mutually agreed terms" should be established.

In neither Article 6(2), nor Article 7, is it clear how, if at all, such "approval and involvement" is materially different from "prior informed consent". Morgera *et al.*[74]

[73] Such rights can be subject in some cases to compulsory licensing regimes.

[74] Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unravelling the Protocol: A Commentary on the Protocol on Access and Benefit Sharing to the Convention on Biological Diversity* (Brill/Nijhoff, Leiden 2014), 152 and 175

suggest that whereas the term "approval and involvement" is derived from Article 8(j) of the CBD, the "prior informed consent" language seen in both articles is derived instead from Article 11 of UNDRIP. They further suggest that the use of "approval and involvement" as an alternative to "prior informed consent" may reflect the reluctance of some parties to fully endorse within the Protocol a human rights (*i.e.* UNDRIP) standard of indigenous control over resources. They further suggest that such reluctance may stem from governmental sensitivities regarding the grant of rights to indigenous communities and that the alternative "consent" versus "approval" language provides for flexibility in implementation. Savaresi [75] also identifies the different sources of language, but suggests that (if a difference does in effect exist) Parties' overriding obligations to respect the primacy of human rights law should, in any event, seek to follow the UNDRIP-derived approach.[76]

Whilst acknowledging the different origins of each phrase, it seems difficult to realistically argue that the operative effect of "consent" should be any different from "approval" considering the overall context of the Protocol. [77,78] This is particularly true of Article 7 where both "approval" and "consent" are both allied to a further requirement that access should be subject to "mutually agreed terms".

Whatever degree of consent is required, we need also to understand the nature of the activity which is subject to that control. In both Articles 6(2) and 7 this activity is the *accessing* of the subject matter of the right. The question of whether this "access" means a first-time physical apprehension, continued physical apprehension, first-time conceptual apprehension or continued conceptual apprehension is moot, and will be dealt with in detail further in this chapter.

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[75] Annalisa Savaresi, "The International Human Rights Law Implications of the Protocol" in Elisa Morgera, Matthias Buck, and Elsa Tsioumani (eds) *The 2010 Protocol on Access and Benefit-sharing in Perspective: Implications for International Law and Implementation Challenges* (Martinus Nijhoff Publishers, Leiden 2012) 53, 70

[76] It is worth noting here that it is questionable whether UNDRIP does in fact provide support for an injunctive remedy rather than merely compensatory relief (see Chapter 3 of the current work).

[77] Morgera *Unravelling the Protocol* (n 74), 153

[78] Gurdial Singh Nijar, *The Protocol on ABS: An Analysis* (CEBLAW Kuala Lumpar 2011), 26

Assuming that Articles 6(2) and 7 *do* create a positive veto right, we see that broadly they work in tandem to control access to a genetic resource and to the traditional knowledge which will give that genetic resource value or enhanced value. We should note, however, that both contain a (different) qualification. In Article 6(2) control (approval or consent) is limited to those indigenous and local communities which "have the established right to grant access to such resources". The Article 7 right is significantly less qualified, requiring merely that relevant traditional knowledge is "held" by indigenous and local communities.

Articles 5(1), 5(2) and 5(5) of the Protocol are perhaps less clear in creating positive (veto) rights. They require that the benefits arising out of *use* should be shared in a "fair and equitable" way and that such sharing should be on "mutually agreed terms". A requirement for "fair and equitable" sharing arguably does not, of itself, create an unambiguous *veto* right – one might imagine that a third party user of a resource may simply continue to use the resource without hindrance, provided that a "fair and equitable" share is provided to the right holder. One might further imagine that this fair and equitable share could be determined *ex post facto* by a binding determination (whether by a court, tribunal, binding mediator or arbitrator). In many ways, such an approach would mirror the compulsory licensing regimes seen in numerous intellectual property systems.[79] Crucially, however, such an approach would not, of itself, allow for an *absolute* veto on use.

However, the requirement that benefit sharing is on *mutually agreed terms* is difficult to interpret in the light of the "fair and equitable" requirement. What if the mutual agreement is not on "fair and equitable" terms, is the agreement rescindable/voidable? Who is to say what is fair and equitable? More importantly, with regard to consent, it would on the face of the language in Article 5 appear that, even if the terms of the potential agreement are perfectly "fair and equitable", the party having the right to impose sharing (indigenous people or Party as appropriate) must have a right to refuse to agree – if this were not the case it could not be a truly free, *mutual* agreement. If this is correct, the right to refuse to agree (even on what would appear to an external

[79] See for example Sections 48, 48A, 48B, 49 and 50 UK Patents Act 1977 (as amended).

observer to be objectively fair terms) should be seen as a right to refuse consent (that is a veto right) similar to that (more clearly and expressly) set out in Articles 6(2) and 7.

We need to note that Article 5(2) – dealing with control over genetic resources- contains a similar qualification as is seen in Article 6(2), in that its provisions only apply to

> "genetic resources that are held by indigenous and local communities in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources".

Mirroring the position seen with Article 7, Article 5(5) – dealing with traditional knowledge relating to genetic resources – is much less qualified requiring only that the knowledge is "held" by the relevant indigenous or local community.

2.2.3 The WIPO Routes

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("GRTKF") is currently working on text-based negotiations to establish an international legal instrument which will seek to protect of traditional knowledge, traditional cultural expressions and genetic resources.[80] Although there may eventually be a single treaty document, traditional knowledge, traditional cultural expressions and genetic resources are being treated as three separate negotiating strands, each with their own GRTKF sub-committee. Compared to the advancement of the Protocol under the CBD, historic progress has been slow - the current draft documents within each stream contain many (often contradictory) proposals which reflect the (often contradictory) aims of the negotiating parties.[81,82,83] The current rate of progress under WIPO continues to be sluggish; indeed

[80] http://www.wipo.int/tk/en/igc/ (Accessed September 2015)

[81] WIPO/GRTKF/IC/28/5 http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=276361 (Accessed September 2015)

[82] WIPO/GRTKF/IC/28/6 http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=276220 (Accessed September 2015)

[83] WIPO/GRTKF/IC/28/4 http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=276319 (Accessed September 2015)

the 2014 WIPO General Assembly failed to come to a decision on the 2015 work program of the IGC.[84]

The current WIPO drafts do not create a formal mechanism for enforcing the positive rights in genetic resources *per se*, such as those created under the CBD. The focus of the current working papers on genetic resources considered by the GRTKF committee are focussed on *defensive* rights only – predominantly a requirement for disclosure of origin of genetic resources and associated traditional knowledge in patent applications.[85]

In contrast to this relatively conservative approach, the GRTKF has taken two distinct strands in relation to traditional knowledge:

a) A *Positive Right* -The development of a *sui generis* right in traditional knowledge;

and

b) A *Defensive Right* - Requirement that the grant of any other intellectual property rights involving traditional knowledge should require mandatory disclosure of traditional knowledge holders and the country of origin, as well as evidence of compliance with prior informed consent and benefit-sharing requirements.[86]

In contrast to the Protocol, what is proposed here is a positive right in traditional knowledge *in general*, not just in traditional knowledge associated with genetic resources (although, of course, there is no reason why such knowledge will not be caught in the broader right). The current GRTKF drafts contain a wide number of potential options. However, all current draft options give the holders of traditional knowledge a veto over third party use of that traditional knowledge.[87]

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[84] (n 80)

[85] WIPO/GRTKF/IC/28/4 (n 83)

[86] WIPO/GRTKF/IC/28/5 (n 81)

[87] WIPO/GRTKF/IC/28/5 (n 81)

2.3 The positive protection provisions of the Protocol

As has been discussed in above, Articles 5, 6 and 7 of the Protocol purport to create rights to control access to, and utilization of, genetic resources and particular traditional knowledge associated with a genetic resource. The subject matter, controlled activity and conditions for use were summarised in Table 2.1

As can be seen in that table, the condition being placed upon the "controlled activity" varies according to the controlled activity being regulated. Where the controlled activity is "access" to the relevant subject matter the condition is prior informed consent (or "approval and involvement"). Where the controlled activity is "utilization" of the relevant subject matter, the condition is "fair and equitable sharing based on mutually agreed terms". Article 6(1) is different in this regard in that the controlled activity is "access for utilization" and under Article 5(1) the benefits arising out of "subsequent applications and commercialization" are to be subject to fair and equitable sharing based on mutually agreed terms.

However, as we will see, the particular provisions in relation to the scope of protection given to "traditional knowledge associated with genetic resources" cannot be read in isolation from the broader provisions of the Protocol. Clearly our first point for understanding the scope of these provisions of the Protocol is to understand what is meant by the key terms "access", "genetic resources" and "utilization".

2.4 What does "access" to a genetic resource mean?

Notwithstanding the importance of the term, access is not defined within the CBD or the Protocol.

In relation to a *physical* resource, it is clear that accessing that resource means taking *physical* possession of the resource. An ethnobiologist being given plant samples by a group of indigenous peoples (or a government department) is clearly "accessing" those samples. However, is a geneticist who is later given that plant by the ethnobiologist (and goes on to extract DNA from it) equally "accessing" that material?

"Access" could conceivably mean the first-time physical apprehension of a physical resource or the *continued* physical apprehension of a physical resource. Whether access refers to the first accessing or to a continued/ongoing access is important. If it is the latter one could see access as extending beyond mere *physical* access within the jurisdiction in which the genetic resources are held, to a broader concept of *legal* access. This being a permission for the continued holding of a genetic resources that would be otherwise be prohibited.[88] The debate on this point is far from settled and has been the subject of some polemic debate. [89, 90]

Although, one dictionary definition of the verb "access":

> "the action of going or coming to or into, coming into the presence of or into contact with"[91]

gives a strong emphasis on the first movement toward something, it is certainly not inconceivable to see the word within the context of the Protocol as meaning a *series* of different "accessings", with each accessing occurring each time something new is done to the resource.

Tvedt and Fauchald[92] report that during the negotiation of the Protocol there were "considerable divergences" regarding the meaning of "access to genetic resources" and the legal definition of when such access would actually be said to occur. The view of many "user" countries was that genetic resources are accessed when a biological sample crosses a national boundary. The view of "provider" countries was that access occurs when biological material is *used* – regardless of whether it crosses a national boundary. Tvedt and Fauchald state that:

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[88] Pierre Du Plessis, "Disclosure of origin of biological resources and potential effects of the Protocol" (2011) 40(5) CIPA Journal 331

[89] Tim Roberts, "CBD and Nagoya – a rejoinder" (2011) 40(6) CIPA Journal 403

[90] Pierre Du Plessis, "CBD and Nagoya " (2011) 40(7) CIPA Journal 466

[91] The Compact Oxford English Dictionary (Oxford University Press, Oxford 1979), 52

[92] MW Tvedt, and OK Fauchald, "Implementing the Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway" (2011) 14(5) JWIP 383

> "Between these views, there is a gap in practical effects for the implementation of ABS. To establish a functional system for implementing the [Protocol], countries will need to agree on when access happens." [93]

In their document "Access and Benefit Sharing, Introduction and Context (July 2010)"[94](published before the completion of the negotiation of the Protocol) the UK Department for the Environment Food and Rural Affairs succinctly summed up the view of those inclined to a broader interpretation of "access":

> "Acquisition of genetic resources means the act of actually physically obtaining the material. It does not imply permission to use it. By contrast, "access to genetic resources" means the permission to physically obtain and **subsequently to use** the genetic resources. This implies a positive and physical action to the genetic resources, going beyond, for instance, simply observing them (*e.g.* the passive, aesthetic, pleasure derived from looking at cut flowers or ecotourists visiting rainforests). [emphasis added]

We have to recognise that if this broader interpretation of access, encompassing subsequent activity, is not correct then the requirement for consent/approval for degree of control provided by the rights holders would arguably be restricted solely to the *very first* occasion upon which the subject matter of the rights in question were acquired. At first sight this may seem unduly limited. However, one has to appreciate that the Protocol does, within Article 5, contain other provisions ensuring that the "utilization" of the resource is subject to mutually agreed terms (which as previously argued creates its own veto). This narrow interpretation is arguably also consistent with the overriding objective of the Protocol set out at Article 1:

> "The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, **including by** appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by

[93] Tvedt and Fauchald (n 92), 385

[94] www.defra.gov.uk/environment/natural/biodiversity/internationally/access-genetic-resources (accessed September 2015)

appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components." [emphasis added]

Indeed, if anything, Article 1 could be said to envisage "access" as something of a narrower subset of broader "utilization" rather than being required to be co-terminous with it.

However, even if we do take a broader interpretation - wherein Article 6 envisages a positive right controlling some sort of *ongoing* legal access - we are left with the question: what is it access to? Does it relate only to use of genetic material containing DNA, the DNA alone, or does it envisage something yet further, such as "access" to other chemical compounds found in organism - for example a plant-derived, therapeutically-active ligand? To address that question we need to look to the meaning of "genetic resources"

2.5 The meaning of "genetic resources"

The concept of "genetic resources" is clearly at the heart of the Protocol. It is the subject matter which is "utilized", "accessed" and "accessed for utilization". Given the importance of the term, the definition provided within the Protocol is surprisingly brief. Indeed, the definition of "genetic resources" is taken in its entirety from the definition provided in Article 2 of the CBD. Correa[95] reports that during negotiation of the CBD there was little discussion of the meaning of "genetic resources" and due to time pressures a "lowest common denominator" definition, legally ambiguous, but acceptable to the majority, was decided upon. That definition is as follows:

> "Genetic resources" means genetic material of actual or potential value."

where:

> "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity."[96]

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[95] Carlos M Correa "Implications for BioTrade of the Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization" (2012) paper prepared for the BioTrade Initiative on UNCTAD (UNCTAD/DITC/TED/2011/9)

[96] CBD Article 2

The first point to note is that the definition of "genetic resources" is not coterminous with that of "genetic material" but is "genetic material of actual or potential value". It is not entirely clear what this limitation to actual or potential value achieves. One might ask what is meant by "value" and further ask: "actual or potential value" to whom? However one answers these questions, it is arguable that the definition is flexible enough to provide for changes in what constitutes actual or potential value as science and technology develop.[97]

The term "functional units of heredity" is not defined in either the Protocol or the CBD itself. However, on the face of it a functional unit of heredity would seem to refer to a gene; the Merrion Webster dictionary[98] defines a gene as:

> "a specific sequence of nucleotides in DNA or RNA that is located usually on a chromosome and that is the **functional unit of inheritance** controlling the transmission and expression of one or more traits by specifying the structure of a particular polypeptide and especially a protein or controlling the function of other genetic material" [emphasis added]

In its very narrowest sense, "material of plant, animal, microbial or other origin containing functional units of heredity" could refer solely to DNA[99] extracted from the cells of an organism (this being the a part of the original organism which contains functional hereditary units) whether that DNA encodes for the entire genome of the organism, or encodes for only a sub-set of genes of interest.

However, one might argue that the term "material" could more broadly refer to an entire organism (or any part of an organism) which contains "functional units of heredity". If this were the case "genetic material" of an organism would include any element of the

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[97] Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva and Frederic Perron-Welch (with Natasha Ali and China Williams) *IUCN Explanatory Guide to the Protocol on Access and Benefit-sharing*. (IUCN Environmental Policy and Law Paper No.83, 2012) , 64 (https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the__protocol.pdf) (Accessed September 2015)

[98] "Gene" in Merriam-Webster.com. http://www.merriam-webster.com/dictionary/gene (Accessed September 2015).

[99] Deoxyribosenucleic acid

organism which would enable it to be propagated – which in a plant would include either a cutting or a seed or a spore. Such a definition of “genetic material” would also appear to be broad enough to encompass those (unusual) eukaryotic cells such as platelets (thrombocytes) and mature red blood cells (erythrocytes) which although they lack nuclear DNA, possess (as do all eukaryotic cells)[100] mitochondrial DNA (clearly a functional unit of heredity, if only of the mitochondrion itself).

Although not expressly clear on which interpretation of “genetic material” is correct, the CBD does, somewhat confusingly, provide a separate definition of "Biological resources" which:

> “includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.”[101]

This separate definition of “biological resource” which includes “genetic resources” within a broader definition, alongside separate mention of “organisms or parts thereof” would seem to suggest that the narrower (DNA-only) interpretation of “genetic resources” is correct. There otherwise seems little additional work for a broader (part of organism) definition of “genetic material” to do (other than to distinguish parts of organisms which do not contain units of heredity such as structural proteins, although this is a small subset of part of organisms).

This narrow interpretation is supported by Correa[102] who notes that it is consistent with the prevailing thinking in the in the early 90’s (when the CBD was agreed) that manipulation of large or small sections of DNA would be the crucial element in exploitation of genetic resources.

What is the impact of a narrower (DNA-only) interpretation of “genetic resources”? One can immediately see that any “use” of DNA alone will be radically different to use of a “part of an organism containing units of heredity”.

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[100] Francisco J Iborra, Hiroshi Kimura and Peter R Cook, “The functional organization of mitochondrial genomes in human cells” (2004) 2 BMC Biology 9

[101] CBD Article 2

[102] Correa (n 95)

2.6 Products of genetic expression

Genes (the CBD's "functional units of heredity") are the way in which an organism encodes the instructions for making the molecules which make up the structural components of cell and tissues, and the molecules which regulate and catalyse reactions within the cells. For all (non-viral) organisms, when a particular gene is expressed the relevant portion of DNA within a chromosome is "transcripted" into a strand of messenger RNA[103] ("mRNA") in which the sequence of base pairs in the DNA is reflected in the sequence of base pairs in the mRNA. That strand of mRNA itself serves as a template for the synthesis of a polypeptide chain in which the order of the amino acids making up that chain is itself determined by the sequence of nucleic acid bases within the mRNA. In this way the nucleic acid base sequence in the mRNA is "translated" into the amino acid sequence. That polypeptide chain is subjected to post-translational modification which "folds" the chain into a functional protein. Where this protein is an enzyme it will (subject to regulatory messages) catalyse the conversion of other biochemicals within the cell.[104] In this way the (non-DNA) biochemical components of an organism are an *expression* of the genetic material of the cell, even if they are not *themselves* functional units of heredity.

The question of whether "non-DNA" biological components of an organism fall within the scope of "genetic resources" for the purpose of the Protocol is an important one. If they did not, potentially important substances found within an organism – including the biologically-active ligands which have biological effects in other organisms (such as prokaryotic and eukaryotic toxins) would arguably be excluded from the access and benefit sharing provisions of the Protocol.

If one takes a narrow interpretation of "genetic resources" to include only the DNA of an organism then one might argue that "use" of that DNA will, of necessity, include only those techniques in which that piece of DNA itself is manipulated. These might include taking the entire genome of an organism (that could be expressed in its entirety

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[103] Ribosenucleic acid

[104] See Christopher K Mathews, KE van Holde and Kevin G Ahern *Biochemistry* (Benjamin Cummins, San Francisco, 2000), 875-1110

through nuclear transfer cloning) or a sub-set of genes of interest which can be spliced into the genome of another organism. Such a sub-set of genes could be used to provide the recipient (genetically modified) plant, animal, fungus or microorganism with a beneficial advantage (*e.g.* drought, pest, or herbicide resistance) or to stimulate the recipient organism to synthesise a particular molecule (which molecule itself may be used to provide a therapeutic benefit). Although these are undoubtedly powerful and commercially important techniques, they do not include "use" which takes a product of genetic expression (such as a protein or a metabolite produced through enzyme catalysis) as a starting point.

The fear that such products of genetic expression would be excluded from the access and benefit sharing provisions of the Protocol was a major driving force for the negotiators for the "provider" countries at the negotiations of what would become the Protocol. [105,106,107,108] Aubertin & Filoche[109] report that provider country negotiators argued that:

> "the creation of wealth (and thus of benefits which may be shared) does not take place as result of the use of DNA, or the genes themselves, but (in 89% of cases according to the megadiverse group of countries) as a result of research and development regarding biochemical components (which include not only natural molecules, but also synthetic products which copy a natural molecule, medicines and so on)."

and that:

> "a Protocol dealing only with the use of genetic resources in the strict sense of the term, and not derivatives, would therefore be meaningless".

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[105] EC Kamau, B Fedder, and G Winter, "The Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" (2010) 6(3) Law, Environment and Development Journal 246, 251

[106] Correa (n 95), 14

[107] Morgera *Unravelling the Protocol* (n 74), 66

[108] Greiber (n 97), 63

[109] Catherine Aubertin and Geoffroy Filoche "The Protocol on the use of genetic resources : one embodiment of an endless discussion" (2011) 2(1) Sustentabilidade em Debate – Brasília 51

Correa[110] reports that the result of the negotiation was the addition to the Protocol of the concepts of "utilization", "biotechnology" and "derivative" which were not present in the CBD and states that it was "*the common understanding among all Parties was that the definition of "Utilization of genetic resources" held the key to determining whether the scope covered derivatives or not".*

Greiber *et al.* also report that:

> "Late in the protocol negotiations, it became clear that many of the contentious technical issues could be solved if there were a clear understanding of the concept of utilization. ...the Parties included Subparagraph (c) defining the term "utilization of genetic resources". This definition helps to provide legal certainty through specific indicators that make a clear test for determining when the Nagoya Protocol governs a particular activity and when it triggers the obligation to share benefits." [111]

It is to the definition of "utilization of genetic resources" that we must now turn. As will be seen, some of the confidence in the clarity of the definition shown in the last quote is optimistic.

2.6 What does "utilization of genetic resources" mean?

Throughout the Protocol genetic resources is used in tandem with the term "utilization". Article 3 of the Protocol which deals with scope adds little and merely states:

> "This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge".[112]

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[110] Correa (n 95), 14

[111] Greiber (n 97), 63

[112] Article 3 of the Protocol

Article 5(1) refers to the sharing of benefits “arising from the utilization of genetic resources as well as subsequent applications and commercialization”, Article 5(2) refers to benefits arising from the “utilization of genetic resources” and Article 6(1) refers to access to genetic resources for their “utilization”. So what does “utilization” mean here?

The relevant definitions are provided in Article 2 of the Protocol:

> (b) “Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;
>
> (d) “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
>
> (e) “Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Our starting point for analysis is the term “research and development on the genetic and/or biochemical composition of genetic resources”.

Research and development on the “genetic composition of genetic resources” would seem relatively clear – meaning analysis of the DNA sequences found within the particular genetic resource. What, though, does research and development on the *biochemical* composition of genetic resources mean?

As we have seen above, the definition of “genetic resources”/“genetic material” in the Protocol (via Article 2 of the CBD) is rather scant. As is also highlighted above, the “material...containing functional units of heredity” within the definition of “genetic resources” can possibly be interpreted in two ways:

a) functional units of heredity alone; or

b) more broadly as “material” of the organism in question which contains “functional units of heredity”.

If one assumes for the moment that the first (functional units of heredity alone) interpretation is correct, this leaves us with a difficult question over the meaning of research and development on the *biochemical* composition of genetic material/resources. If we reasonably assume that "genetic composition" means the nucleotide sequence within a strand of DNA, then we are left looking for *other* biochemical elements of the DNA strand(s) which may be the subject for investigation.

Within eukaryotic organisms nuclear DNA is wrapped around structural proteins called histones to form a composite material with DNA (which is called chromatin). These structures (together with non-histone chromosomal proteins) are used to assist the organised coiling of DNA within a chromosome, protecting it, ensuring it fits within the nucleus and regulating gene expression.[113] Modification of histones, together with DNA-methylation, are mechanisms for bringing about long-lasting heritable (so-called "epigenetic") changes to the way in which the genome of an organism is expressed which are separate from modification of the nucleotide sequence.[114] Studies of chromatin structure and epigenetics would arguably meet the narrow definition of non-nucleotide sequence research on units of heredity. However, (although they are important areas for study in their own right) in the light of broader concerns over the scope of "utilization of genetic resources", it would seem perverse to give research and development on the biochemical composition of genetic resources such a narrow interpretation.[115]

In contrast, if we interpret "genetic material" to not be limited to DNA with or without histones (the functional units of heredity), but more broadly include that "material of plant, animal, microbial or other origin" which contains the "functional units of heredity" (that is *any* part of an organism which contains genetic material), it would logically follow that research and development on the *biochemical* composition of genetic resources would appear to mean research on the biochemical composition of

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[113] Mathews (n 104), 1075

[114] Adrian Bird, "Perceptions of epigenetics" (2007) 447 Nature 396

[115] This approach is consistent with the rule of interpretation set out in Article 31(1) of the 1969 Vienna Convention on the Law of Treaties namely: "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".

such “material of plant, animal, microbial or other origin containing functional units of heredity”. Since the DNA nucleotide sequence element of the resource would appear to be dealt with by the first part (genetic composition) of the definition, the reference to “biochemical composition” could arguably mean all those *other* biochemical elements present in the material, created through genetic expression. This interpretation seems by far the more realistic - even though the narrow interpretation of “genetic resources” (as is discussed above) would seem to be the correct one when looking at the CBD alone.

Examining the meaning of research and development on genetic resources, Correa follows a similar line of reasoning:

> “...Interestingly, this definition [of utilization] alludes to research and development on the ‘biochemical composition’ of genetic resources, that is, the arrangement of the chemistry of the compounds of living tissues and the processes in a living organism, and not to research and development on biochemical compounds as such. It may be understood, however, that any study of a ‘biochemical composition’ may include that of the individual components.” [116]

Such a broad interpretation is supported by the Report of the Meeting of the Group of Legal and Technical Experts (“GLTE”) on Concepts, Terms, Working Definitions and Sectoral Approaches.[117] Kamau *et al.*[118] state:

> “The Protocol does not contain a list of kinds of R&D as was envisaged in prior deliberation. [119,120] Those lists can however still be used as indications. The one resulting from the Group of Legal and Technical Experts on Concepts, Terms,

[116] Correa (n 95), 14

[117] Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UN Doc UNEP/CBD/WG-ABS/7/2 (12 December 2008) https://www.cbd.int/doc/meetings/abs/abswg-07/official/abswg-07-02-en.pdf (Accessed September 2015)

[118] Kamau (n 105), 251

[119] Access and Benefit Sharing, COP decision IX/12 (UNEP/CBD/COP/DEC/IX/12 (2008) Section B of Annex II and WG-ABS official document 7/2

[120] UNEP/CBD/WG-ABS/7/2 (n 117)

> Working Definitions and Sectoral Approaches contained a non-exhaustive list consisting of the following activities:
>
> - Genetic modification
> - Biosynthesis (use of genetic material as a 'factory' to produce organic compounds)
> - Breeding and selection
> - Propagation and cultivation of the genetic resource in the form received
> - Conservation
> - Characterisation and evaluation
> - Sequencing genes or genomes
> - Production of compounds naturally occurring in genetic material (extraction of metabolites, synthesis of DNA segments and production of copies)
>
> It is of high importance that R&D on the biochemical composition of the genetic resource is covered. This means that, for instance, drugs based on the extraction of chemicals from biological resources are subject to benefit sharing."

Kamau *et al*. go on to state that:

> "The provider states were successful concerning the extension of benefit sharing to benefits from biochemical compounds resulting from genetic expression or metabolism of biological or genetic resources. Biochemicals that do not contain hereditary traits clearly do not fall under the term 'genetic resource'; they are hence not subject to sovereign rights of provider states and, more specifically, to the PIC requirement. They can however – and were now indeed – be captured by the term 'utilisation of genetic resources'. This term triggers benefit-sharing duties."[121]

[121] Kamau (n 105), 251

The list set out in the GLTE Report is instructive. Although most are equally consistent with a DNA-only interpretation of "genetic resources" the suggestion of "Propagation and cultivation of the genetic resource in the form received" is clearly more consistent with a broader "part of organism" interpretation, as this would include propagation of seeds, spores or cuttings of plants.

2.8 The Meaning of "Biotechnology" and "Derivatives"

As stated above, in the light of the context of the Protocol, a reading of "conduct research and development on the biochemical composition of genetic resources" to include non-DNA biochemicals appears to be the interpretation which avoids outcomes which seem counter to the overall spirit of the Protocol.

However, Morgera *et al.*[122] suggest that "biochemical composition of genetic resources" in Article 2(c) does not in fact clarify the object of the utilisation "self-evidently" but go on to state that the combined reading of Article 2(c) with the other "new" definitions provided in the Protocol "in particular that of derivatives" leads to the conclusion that utilization of genetic resources includes research on the products of genetic expression.

The current work argues just the contrary, in that the definition of "Derivatives" falls far short of providing clarity. (Although as will be explained, since that lack of clarity is found in a non-limiting example it arguably does not actually serve to effectively limit the scope of the definition of "utilization of genetic resources".)

If one performs a simple "de-nesting" of the nested definitions found within "utilization of genetic resources" one arrives at the following:

> "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of [any technological application that uses biological systems, living organisms, or [naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic

[122] Morgera, *Unravelling the Protocol* (n 74), 65

resources, (even if they do not contain functional units of heredity)] thereof, to make or modify products or processes for specific use]].”

(NB. The square brackets show the nesting of the definitions)

The complexity, and lack of clarity, is obvious.

“Biotechnology” is provided as a (non-limiting) example of one of the means *by which* to conduct research and development on the genetic and/or biochemical composition genetic resources; that is it is described as a mechanism or *tool*. The general understanding of biotechnology is broad and such technology has a long history. Dutfield [123] identifies three “generations” of biotechnology:

a) traditional technologies such as brewing and bread making (in which yeasts are used to effect chemical transformations);

b) microbial fermentation (including tissue culture and modern plant and animal breeding); and

c) technologies dependent upon the transference of DNA from one organism to another to develop transgenic organisms.

Peters takes a similar broad approach, again highlighting the genesis of biotechnology in prehistoric plant and animal breeding, in the use of yeast in bread making and brewing and the use of bacteria to make yoghurts and cheeses. She distils the meaning as follows:

> “In its purest form, the term “biotechnology” refers to the use of living organisms or their products to enhance human health or the human environment” [124]

Notwithstanding the different means used, one of the recurring similarities of all types of biotechnology is the production of a final “product” whether that be a disease-

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[123] Dutfield, *Intellectual Property, Genetic Resources and Traditional Knowledge* (n 11), 14

[124] Pamela Peters, *Biotechnology A Guide to Genetic Engineering* (Wm C Brown Publishers, Dubuque, IA ,1995), xi

resistant crop, a monoclonal antibody, an antibiotic or a stilton cheese. This focus on products is, of course, reflected in the definition originally provided in the CBD:

> "A technological application that uses biological systems, living organisms, or derivatives thereof, to **make or modify products or processes** for specific use" [emphasis added] [125]

If we assume, for the moment, that the original CBD definition of genetic material intended to capture DNA alone, we can see that the definition of "Biotechnology" was entirely consistent with that narrow interpretation. It would be consistent the use of transgenic whole organisms ("living organisms") whose genome has been modified by the insertion of particular genes to manufacture a particular proteins (or downstream products from those proteins where those proteins are enzymes). It would certainly include (but not be limited to) the application of "*In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles."[126]

However, if we assume that "genetic material" should be read as (also) meaning "parts of organisms which contain functional units of heredity" then in terms of "conducting research and development on the *genetic* composition" such an interpretation would be consistent with techniques which do not specifically seek to move DNA through *in vitro* nucleic acid techniques, but which attempt the "Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection."[127] Such techniques could include the production of monoclonal antibodies through the creation of hybridoma cell lines made by fusing B-lymphocytes with a myeloma cell line.[128,129,130]

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[125] Nagoya Protocol Article 2

[126] Article 3(i) (a), Cartagena Protocol on Biosafety to the Convention on Biological Diversity

[127] Article 3(i) (b), Cartagena Protocol (n 126)

[128] César Milstein, "The hybridoma revolution: an offshoot of basic research" (1999) 21 (11) *BioEssays* 966

[129] Ivan Roitt, *Essential Immunology* (Blackwell Science, Oxford 1997), 121

[130] Huw Davies *Introductory Immunobiology* (Chapman & Hall, London, 1997) 161

In both the examples above, one might argue that the "Biotechnology" is being used to exploit the *genetic* composition of the "genetic resource" rather than being part of the research and development on the (non-chromatin) *biochemical* composition of the "genetic resource".

If this is correct, how then might these "biotechnology" applications be used in the research and development of the *biochemical* of the genetic resource? As we have seen, the understanding of biotechnology extends beyond what the Cartagena Protocol on Biosafety to the Convention on Biological Diversity calls "Modern Biotechnology"[131] (essentially *in vitro* nucleic acid techniques and cell fusion techniques) and the definition within the CBD is certainly not so limited.[132] Such research into the biochemical composition of genetic resource would certainly include the use of cell and tissue cultures using *unmodified* organisms to assist in the making of greater amount of the substance in question.

In practice, however, there is no split in the use of biotechnology techniques as between *genetic* and *biochemical* composition - *all* biotechnology techniques are available for research on the (non-DNA) biochemical composition of a resource, notably the use of genetically modified bacteria or eukaryotic cell lines to produce sufficient quantity of a substance for analysis and study. One might imagine here the production of human interferon through the use of transgenic bacteria.[133]

To conclude, the un-amended definition of "Biotechnology" in the CBD is entirely consistent with a broad interpretation of "genetic resources" to mean "parts of an organism containing functional units of heredity" and "biochemical composition of genetic resource" to include the non-DNA products of genetic expression. It is, however, equally consistent with a narrower chromatin-only interpretation of "genetic

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[131] Article 3(i) Cartagena Protocol on Biosafety (n126)

[132] Indeed the presence of a narrower definition for "Modern Biotechnology" within the Cartagena Protocol on Biosafety to the Convention on Biological Diversity supports a broader interpretation for "biotechnology" within the CBD and Protocol.

[133] Dieter Riesenberg, Klaus Menzel, Volkmar Schulz, Klaus Schumann, Gerhard Veith, Georg Zuber and Wolfgang A Knorre, "High cell density fermentation of recombinant *Escherichia coli* expressing human interferon alpha 1" (1990) 34(1) Appl Microbiol Biotechnol 77

resource" or a chromatin-only interpretation of "research and development on the biochemical composition of the genetic resource".

2.8.1 Does the new definition of "Derivative" assist?

As we have seen the Protocol introduces a definition of "Derivative":

> "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."[134]

In itself, the definition of "Derivative" is clear. Had it been inserted as an expansion of the definition of "genetic material" at Article 2 of the CBD it would have unambiguously expanded the that term to include any protein (such as an enzyme) produced through genetic expression or any naturally occurring compound produced through enzyme catalysed metabolism within the organism in question. This is not, however, how the phrase is used[135] - indeed it is not used as a capitalised defined term *anywhere* within the Protocol. Instead it is arguably used as what appears to be a clarificatory example of the term "Biotechnology".

As we will see, the way in which "Derivative" entered into the Protocol is complex. However, if we understand the mention of "derivatives" within the Article 2 CBD (and Article 2 Protocol) definition of Biotechnology as being a reference to "Derivative" as a defined term within Article 2(e) of the Protocol, then its effect is (arguably) to amend the definition of Biochemistry to the following:

> "any technological application that uses biological systems, living organisms, or [naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, (even if they do not contain functional units of heredity)] thereof, to make or modify products or processes for specific use]"

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[134] Nagoya Protocol Article 2(e)

[135] It is interesting to note that "derivatives" may have been used in this way in the indicative list of typical mutually agreed terms set out at Paragraph 44(i) of the (non-binding) Bonn Guidelines: "Provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products." (COP 6 Decision VI/24 "Bonn Guidelines" Part D Paragraph 44(i)). However, even here it is not really evident what is meant by a "derivative" of a genetic resource in this context.

There are a number of ways in which one can read this substitution and none is entirely satisfactory. If one pays heed to the "thereof" then it seems to refer to the use an application which uses naturally occurring biochemical compounds from biological systems or living organisms to make or modify products or processes for specific use. If one treats the "thereof" as being vestigial (having been left behind during rushed negotiation) it seems to refer to the use of an application which uses naturally occurring biochemical compounds to make or modify products or processes for specific use.

In both cases, what seems to be described is the use of a "naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources" within a technical application used in research upon genetic resources. This interpretation is somewhat confused - as we saw above, the underlying constant of Biotechnology is that it is a *process* for producing product and this requirement is still present within the definition. However, putting that requirement to one side for the moment, we crucially need to recognise that the application of a "naturally occurring biochemical compound" is a description of the *actor* upon a *subject*, rather than a description of the subject itself.

If this was the intention of the negotiators of the Protocol then the definition of "Derivative", and where it is inserted works relatively clearly. There are, indeed, very many such "naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources" which are used in the conduct of research upon the "genetic and/or biochemical composition of genetic resources". There does not appear to be a requirement that the genetic resources from which the tool is taken has to be the same genetic resource upon which the tool is being used. As such, the definition would include the use of DNA probes taken from other organisms, dyes and stains derived from plants, animals, fungi and microbes, inhibitors of intracellular metabolism, and ligands at intracellular or extracellular receptors. Nor is there, of course, any restriction on using a tool obtained from one organism ("genetic resource") upon the biochemical composition of the same genetic resource – one might imagine here the use of tetrodotoxin obtained from the puffer fish to examine voltage-gated sodium channels in the same species of puffer fish.[136]

[136] Lee (n 25)

Although the definition of "derivative" clearly works in this (limited) way, it hardly seems a necessary clarification, given that the use of such compounds have long been a mainstay of biological research techniques.[137] In addition, such an explanation hardly seems "in character" given the other, rather sparse, definitions provided within the CBD and Protocol. We also have the remaining problem that the application using the "naturally occurring biochemical compound" should directly produce a product (*á la* a Biotechnology application) which is clearly not the case with all biological research tools. So why is this expanded definition of "Derivative" found where it is?

Morgera *et al.*[138] report that developing nations sought during the negotiation of the Protocol to ensure that the Protocol included specific reference to derivatives, arguing that this is where the main interest of modern biological research lies. In contrast, some developed nations sought to ensure that the provisions of the Protocol merely applied to functional units of heredity (i.e. DNA).[139] Morgera *et al.* further state that as a result of this impasse, the term "derivative" did not find its way into the operative terms of the Protocol but it was understood that by way of compromise[140] the term "utilization of genetic resources" would include the "notion" of derivatives.

As we have seen, the word "derivative" was already present in the existing (1992) CBD definition of "Biotechnology", namely:

> "any technological application that uses biological systems, living organisms, or **derivatives** thereof, to make or modify products or processes for specific use" [emphasis added].

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[137] See Chapter 4

[138] Morgera, *Unravelling the Protocol* (n 74), 66

[139] Matthias Buck and Claire Hamilton, "The Protocol on Access to Genetic Resources and Benefit-sharing Arising from their Utilisation to the Convention on Biological Diversity" Review of European Community and International Environmental Law (2011) 47, 56

[140] Ryo Kosaka, *The Negotiating History of the Protocol on ABS: Japanese Perspective* (2012) http://www.ipaj.org/english_journal/pdf/9-1_Kohsaka.pdf (Accessed September 2015)

What appears to be referred to here is derivatives of biological systems or living organisms (which have most likely been created through modification of the genetic material within them), rather than to the biochemicals produced through translation of genes into proteins. Notwithstanding that (very) distinctly different use, the presence of the word "derivative" at that position appears to have acted as an easily negotiated route for insertion of the new definition of "Derivative" without having to negotiate a new definition of "Biotechnology". Of course, taking that route has actually left us with the rather limited effect of "Derivative" as a non-limiting example of a tool to be used on genetic resources (and a strange hangover requirement to directly produce a product or process as would be the case with a Biotechnology application). The result is certainly difficult to untangle. Morgera *et al.* [141] understandably refer to this approach as "puzzling". However, they then go on to state that the relevance of the definition of "Derivative" to the interpretation of "utilization of genetic resources" can be argued on two grounds:

a) ""utilization" **implicitly** refers also to research and development through the application of biotechnology **on** derivatives" [emphasis added]; and

b) "The definition of "utilization" makes reference to the "biochemical composition of genetic resources" which arguably relates to the reference to compounds in the definition of "derivatives" as it is only the latter that provides the necessary elements to circumscribe this otherwise vague concept".[142]

With regard to point b) Morgera *et al.* appear to suggest that the term "biochemical composition of genetic resources" is unclear. As discussed above, this author believes one can interpret that term clearly when one broadly interprets "genetic material" to include the cells of an organism which contain "functional units of heredity". However, even assuming uncertainty in this regard, given that "Derivative" is used as an example of a tool ("Biotechnology") used to act *upon* the subject of "biochemical composition of genetic resources" it is hard to see how one can easily use the reference to "biochemical

[141] Morgera, *Unravelling the Protocol* (n 74), 66

[142] Morgera, *Unravelling the Protocol* (n 74), 67

compound" in the definition of Derivative to guide us as to the overall meaning of "biochemical composition of genetic resources".

This use of "derivative" as somehow clarificatory of, or integrated within, "genetic resources", notwithstanding rules of interpretation is prevalent. Vogel *et al.*[143] are highly critical of this approach:

> "Despite the introduction of 'derivative' in Article 2 (e), 'derivative' is not incorporated into Article 3 which defines the scope. Nevertheless, many delegates and scholars are not disheartened. They have inferred 'derivative' in the phrase 'utilisation of such sources'. Unfortunately for the advocates, such an inference is not obvious and would morph 'utilisation of such sources' into a "panchrestron", Garrett Hardin's neologism for something that signifies everything and therefore means nothing"[144]

Morgera *et al.*'s point a) is (at first sight, at least) stronger. They suggest that if your understanding of "biotechnology" is a narrow one, meaning merely the use of organisms to make products following manipulation of their genetic material, then such an understanding would not be entirely consistent with research on the products of genetic expression found within a genetic resource. They suggest that expanding the meaning of biotechnology to include the use of "Derivatives" (as newly defined) is consistent with "biotechnology" meaning a broader range of activities and, in particular, including research on the products of genetic expression found in a genetic resource.

At first blush, this may seem a reasonable interpretation. Indeed, as we have seen the original definition of "Biotechnology" in Article 2 of the CBD (without the expansion of the term "derivative") appears to refer only to the use of biological systems or living organisms (which have most likely been created through modification of the genetic material within them) *to make products*. However, although that interpretation is certainly consistent with a narrower understanding of biotechnology, as was discussed

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[143] Joseph Henry Vogel, Nora Álvarez-Berríos, Norberto Quiñones-Vilches, Jeiger L Medina-Muñiz, Dionisio Pérez-Montes, Arelis I Arocho-Montes, Nicole Val-Merniz, Ricardo Fuentes-Ramírez, Gabriel Marrero-Girona, Emmanuel Valcárcel Mercado and Julio Santiago-Ríos, "The Economics of Information, Studiously Ignored in the Protocol on Access to GeneticResources and Benefit Sharing" (2011) 7/1 Law, Environment and Development Journal 52

[144]Garrett Hardin, 'Meaninglessness of the Word Protoplasm' (1956) 82/3 Scientific Monthly 112

above, the use of those "narrow" techniques are still entirely consistent with a broad interpretation of "genetic resources" and a broad interpretation of "research and development on the genetic or biochemical composition".

In addition, the inclusion of the new definition of "Derivatives" within the definition of "Biotechnology" is consistent with a broad understanding of the term biotechnology and with research on the products of genetic expression found within the cells of a genetic resource. However, if this were the aim of the inclusion of a specific definition of "Derivative" term, it seems a relatively imprecise way of achieving the end, and we are still left with the problem of reconciling the need for the application to directly produce or modify a product or process.

Although concluding that the operative effect of the new definition of "derivative" is to further clarify that research and development on "naturally occurring biochemical compounds resulting from genetic expression or cellular metabolism and not containing DNA" can fall within "utilization of genetic resources", Morgera *et al.* are (unsurprisingly) concerned that "the unfortunate drafting may raise doubts in interpreters and as a consequence lead to variations in national legislation implementing the Protocol". [145]

To conclude this section, we might broadly conclude that the new definition of "Derivative" though in itself clear is poorly placed within the definitions provided within the CBD and the Protocol. As part of the definition of "genetic material" or "genetic resource" it would have provided welcome clarification. As part of the definition of "Biotechnology" (which is itself merely a non-limiting example of research and development) perhaps all we can really say with regard to the use of the term "Derivative" is that it is at least not-inconsistent with the definition of "biochemical composition of genetic resources" including naturally occurring products of genetic expression. As we will see, however, its presence has caused significant confusion.

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[145] Morgera, *Unravelling the Protocol* (n 74), 68

2.9 "Isolated" derivatives

Morgera *et al.* raise the problem of what they refer to as an "isolated derivative", that is a derivative "acquired and utilised without physical access to genetic resources, such as those isolated from their natural environment and available *ex situ.*"[146] Although they argue that such compounds fall within the scope of "utilization of genetic resources" they are concerned that there may be variations in national legislation implementing this aspect of the Protocol.

This author sees no realistic difficulty in interpreting "research and development on the genetic and/or biochemical composition of genetic resources" as encompassing work on such an isolated derivative. The mere fact that a naturally occurring compound has been isolated from its genetic resource source makes it no less a constituent part of biochemical composition and *in vitro* (or indeed *in silico*) study of it no less study of the biochemical composition of genetic resource source. Correa is in agreement:

> " ... A 'biochemical compound' is any chemical compound naturally occurring in living organisms. It may be used without separation from the biological resource to which it belongs (e.g. dried plants) or isolated and even synthesized. Currently available techniques allow researchers to precisely detect, isolate and structurally characterize bioactive natural compounds. 'Naturally occurring' may be interpreted in this context as meaning that a biochemical compound is the result of processes at the cellular level, unaltered by human intervention, that have taken place *in vivo* or *in vitro*. This would include, hence, compounds obtained at laboratories or production facilities."[147]

In contrast Greiber *et al.* state:

> "The definition of "utilization" however, refers to research and development on the biochemical composition of genetic resources. This linkage between biochemical compounds and genetic resources has led to some different

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[146] Morgera, *Unravelling the Protocol* (n 74), 68

[147] Correa (n 95) 14

interpretations, especially as to whether biochemicals must be accessed simultaneously with access to genetic resources. Therefore, there is no consensus on the situation of "isolated derivatives" (e.g., an extract from a plant stored in a lab) that have not been accessed simultaneously with the genetic resources." [148]

Some of this confusion would appear to derive from an unnecessary conflation of the idea of "access" with that of "utilisation".

2.10 The problem of "Chemical Derivatives"

The analysis provided above would appear to strongly suggest that research and development on the naturally occurring biochemical compounds resulting from genetic expression or cellular metabolism of a genetic resource falls within the scope of "utilization of genetic resources" for the purposes of the benefit sharing provisions of Article 5 of the Protocol.

However, as is shown in Figure 1.1 (and discussed in detail in Chapter 3) the identification and isolation of such a compound (though often of great importance) is often merely the beginning of a research and development trail aimed at the production of chemicals, which though based upon the original compound, are chemically modified such as to enhance their biological efficacy and bioavailability and reduce their side-effect profile relative to the original compound. Within the field of biochemistry such compounds are referred to as chemical derivatives (or more simply derivatives) of the original biochemical.[149]

One might suggest that in the light of the long-standing use of the term "derivative" within the field of biochemistry that the use of the term "derivative" within the Protocol is unfortunate and potentially confusing.[150] Notwithstanding this potential confusion, we need to be absolutely clear; the reference to "Derivative" within the Protocol is *not* a

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[148] Greiber (n 97), 67

[149] Derivative : "a chemical substance related structurally to another substance and theoretically derivable from it" (http://www.merriam-webster.com/dictionary/derivative) (Accessed September 2015)

[150] Though as we can see, it was perhaps originally used for an entirely different purpose within the CBD.

reference to man-made chemical derivatives, but (as we have seen) has a very specific given meaning in the Protocol, being:

> "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."[151]

By definition then, the meaning of the phrase "naturally occurring" excludes any man-made, non-naturally chemical derivatives. However, we should not be confused into believing that this limitation could assist us in the broader question of whether chemical derivatives fall within the scope of Article 5. The operative effect of the term "Derivative" has been examined above, and as this term is used within Article 2 of the Protocol (as a non-limiting example of "Biochemistry") it would not operate to extend the scope of the meaning of research and development on genetic resources. Crucially, however, neither would its limited scope (of itself) operate to limit the scope of meaning of research and development on genetic resources to research and development upon naturally occurring compounds alone.[152]

The answer to this question of interpretation (if there is one) has to lie in the definition of "utilization of genetic resources" and particularly the phrase "research and development on the biochemical composition of genetic resources".

Assuming "biochemical composition of genetic resources" to mean the products of genetic expression, we can be reasonably confident that the following broad classes of substances created by the metabolism of a genetic resource would fall within the provisions of Article 5:

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[151] Nagoya Protocol, Article 2(e)

[152] Although the operative effect of the definition of Derivative does not assist us in this regard, we can at least note that if the broad aim of introducing the term "Derivative" had been (as Morgera *et al.* (n 74) suggest) to ensure that compounds naturally produced within a cell by genetic expression were caught within the access and benefit sharing provisions of the Protocol the concept of derivative would not include a chemical derivative.

a) a naturally occurring RNA strand produced directly from the transcription of the DNA of the organism;

b) a naturally occurring protein produced from the transcription/translation of the DNA of the organism;

c) glycosylated protein (such as a functional enzyme) produced from the metabolism of the protein produced in (b) above; and

d) biochemical compound ("X") whose synthesis was catalysed by the enzyme in (c) above.

However, a chemical derivative of the biochemical "X" above is not a member of the set of endogenous compounds which are naturally produced within a cell by genetic expression – it would not be part of the "biochemical composition" of the genetic resource.

Could, however, the production of a chemical derivative of "X" (called hereafter "X-A") be considered to be part of the "research and development" on X. As we see in more detail in Chapter 4 of this work, the use of chemical derivatives of an endogenous biochemical can be used to enhance our understanding of the interaction between X and the intra- or extra-cellular target through which X has a biological effect. Is this sufficient to constitute research on the *original* substance?

Correa states:

> "There is no universally accepted definition of 'research and development'. The concept, as used for statistical purposes, includes basic and applied research as well as 'experimental development' understood as 'systematic work, drawing on existing knowledge gained from research and/or practical experience, that is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed'. The ordinary meaning of the concept seems to more broadly encompass **improvements on existing products**.

> This set of definitions seems to leave little doubt that the Protocol does cover the utilization of genetic resources as such, as well as of their 'derivatives', understood as the biochemical compounds present in such resources." [emphasis added][153]

In support, Correa cites this statement made by the Union for Ethical BioTrade*:*

> "[T]he Protocol now clearly encompasses research and development to identify new bioactive compounds and natural ingredients for food, supplement and cosmetics products…Research on the properties of extracts and molecules from plants, for example, and their development and commercialization as ingredients in pharmaceuticals, cosmetics or nutraceuticals would thus now be distinctly subject [to] access and benefit sharing requirements." [154]

However, Correa is less certain that chemical derivatives "downstream" of the original biochemical compounds originating in an organism would be covered within the definition of "utilization of genetic resources". He states:

> "It has been argued that developing countries failed to achieve the inclusion of derivatives in the Protocol. In accordance with one commentator,
>
> > "developing countries were keen to ensure that biochemical derivatives of genetic resources were included in the scope, since these are used commercially as much as genetic resources (e.g. for screening medically active compounds to develop new drugs). In the end, derivatives were not included in the scope, but they were defined as biochemicals, which at least provides the basis for further negotiation.[155]"

[153] Correa (n 95)

[154] Union for Ethical Biotrade (UEBT), *Protocol on Access and Benefit Sharing Technical Brief* (2010)

[155] Krystyna Swiderska "What happened at Nagoya?" (2010) (www.iied.org) (Accessed March 2015)

> This interpretation, however, seems to be based on a concept of 'derivatives' broader than that adopted by the Protocol. In fact, the definition of 'derivative' in the Protocol is narrow, as it only encompasses 'a naturally occurring biochemical compound'. 'Derivative' is often understood more broadly as including products based on or elaborated with such biochemical compounds...
>
> ...This means that while the benefit sharing obligations under the Protocol clearly apply in relation to naturally occurring biochemical compounds, **the extent to which it would apply to downstream products derived, in turn, from such compounds is less clear.** However, the benefit sharing obligation could apply in cases where a product (e.g. for cosmetic use) contains biochemical compounds, to the extent that those compounds add value to the product." [emphasis added][156]

Aubertin & Filoche[157] are in agreement with Correa that "research and development" on biochemicals produced within the genetic resource falls within the definition of "utilization of the genetic resource". However, with regard to downstream derivatives they appear somewhat more certain than Correa and state (at page 59):

> "...the issue of derivatives was also sidelined [in the final text]. Derivatives are defined in Article 2e as "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity." However, no further mention is made of them. This definition was probably kept for political reasons, but it can be assumed that it will have little effect, since the Protocol contains no obligations in this respect. By presenting derivatives as nothing more than a biochemical compound from a living organism, **claims relating to synthetic molecules with a structure similar to a natural substance fall outside the scope of the Protocol**. **It would therefore appear that a natural molecule which has been synthesized and altered does not fall within the scope of the Protocol, even if it was "inspired" by nature."** [emphasis added]

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[156] Correa (n 95)

[157] Aubertin (n 109)

As discussed above, the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches[158] arrived at a non-exhaustive list of "typical uses" of genetic resources. Amongst that long list there was one use that could arguably be construed as encompassing a chemical derivative namely:

> "Use of genetic material as a "factory" to produce organic compounds, such as: Active compounds for pharmaceutical production"

However, since the list of organic compounds to be manufactured concludes with "Other naturally occurring compounds" it would appear that the active compounds envisaged are *naturally occurring* rather than man-made derivatives. Overall the uses are entirely focussed on work on naturally occurring substances. A similar approach is taken in respect of a discussion on the meaning of "derivatives". Although an opportunity was there for the drafters of the Protocol to specifically identify *chemical* derivatives of the biochemical composition of genetic resources the opportunity was not taken.

Overall, one has to conclude that the question of whether "utilization" includes work on human-made chemical derivatives of naturally occurring biochemicals remains entirely unclear.

2.11 Genetic "Information"

The discussion above demonstrates that there remain significant uncertainties over what constitutes "research and development" on "genetic resources". However, one clear constant in the discussion on "utilisation" set out above is that the research is done upon DNA or biochemicals which have physically originated *from the genetic resource itself*. What if, however, the subject for research and development did not *physically* originate from the genetic resource itself but was independently synthesised using information gained from the original genetic resource? Such a situation could arise where one had synthesised DNA on the basis of the nucleotide structure ("synthetic DNA") or synthesised an exact chemical copy of the endogenous biochemical found within the genetic resource ("a biomimetic").

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[158] UNEP/CBD/WG-ABS/7/2 (n 117)

Extending control over genetic information could radically change the scope and nature of access and benefit sharing provisions of the Protocol, and each of these two situations will be dealt with in turn. Having addressed these situations we will examine whether using the concepts of "genetic information" gives further guidance in relation to the scope of Article 6 and Article 5(1) and (2) of the Protocol in relation to manmade chemical derivatives of the products of genetic expression.

2.11.1 Genetic Information 1: Is synthetic DNA covered within the definition of "genetic resources"?

Until relatively recently, the most common technique for generating DNA strands was to generate so-called complementary DNA ("cDNA"). Here DNA is synthesized from a messenger RNA (mRNA) template obtained from a cell. The mRNA template is itself generated by transcription from DNA genes of the original organism. As such there is an arguable chain of causation from the *original* genetic material to the cDNA, via the mRNA template. The cDNA thus generated is most often used for gene cloning or probes.[159]

Another technique used alongside cDNA is polymerase chain reaction ("PCR"). PCR allows the amplification of a small DNA template called a DNA oligonucleotide or DNA primer. The template has, to date, been obtained from an organism and there is, again, an arguable chain of causation from the original organism to the DNA created by PCR.[160]

However, new technology allows a DNA strand to be created *de novo* – without the need for a primer or template. Oligonucleotide strands are built from a digital database of the required base pair sequences and annealed together to make longer DNA strands. Once generated, these synthetic DNA molecules can work like those created from a

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[159] Ernst-Ludwig Winnaker, *From Genes to Clones, Introduction to Gene Technology* (VCH, Weinheim Germany, and New York, NY, 1987), 32

[160] RK Saiki, DH Gelfand, S Stoffel, SJ Scharf, R Higuchi, GT Horn, KB Mullis, and HA Erlich "Primer-directed enzymatic amplification of DNA with a thermostable DNA polymerase" (1988) 239 (4839) Science 487

template and can be used in gene cloning or even in the generation of synthetic genomes.[161]

Although this technology may enable to production of *de novo* human-designed genes which do not appear in nature, much work will focus on the synthesis of (or adaptations of) known genes that currently exist in nature. However, to synthetically replicate a naturally-occurring functional DNA strand or gene, knowledge of the nucleotide sequence of that DNA strand or gene will be required. That nucleotide sequence will have been generated by research on the original organism. Certainly without the information on the base pair sequence of the original DNA the synthetic copy would be very unlikely to replicate the specific functionality of the original.

Can use of a naturally originating nucleotide sequence from a genetic database be considered to be "accessing" or "utilising" genetic material even if there is no physical access to genetic material?

2.11.1.1 "Accessing"

It is worth looking again at the definition of genetic resources at Article 2 of CBD (and Art 2 of the Protocol) namely that: "Genetic resources" means *genetic material of actual or potential value*, where "Genetic material" *means any material of plant, animal, microbial or other origin containing functional units of heredity*. Clearly synthetic DNA contains functional units of heredity (indeed self-replicating organisms containing synthetic DNA have been produced[162]). However, is it of plant, animal, microbial or other *origin*?

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[161] HG Khorana, KL Agarwal, H Büchi, MH Caruthers, NK Gupta, K Klbppe, A Kumar , E Ohtsuka, UL RajBhandary, JH van de Sande, V Sgaramella, T Tebao, H Weber, and T Yamada, "Studies on polynucleotides. 103. Total synthesis of the structural gene for an alanine transfer ribonucleic acid from yeast" (1972) 72 (2) J Mol Biol 209

[162] Daniel G Gibson, John I Glass, Carole Lartigue, Vladimir N Noskov, Ray-Yuan Chuang, Mikkel A Algire, Gwynedd A Benders, Michael G Montague, Li Ma, Monzia M Moodie, Chuck Merryman, Sanjay Vashee, Radha Krishnakumar, Nacyra Assad-Garcia, Cynthia Andrews-Pfannkoch, Evgeniya A Denisova, Lei Young, Zhi-Qing Qi, Thomas H Segall-Shapiro, Christopher H Calvey, Prashanth P Parmar, Clyde A Hutchison III, Hamilton O Smith, and J Craig Venter,"Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome" (2010) 329 (5987) Science 52

The Oxford English Dictionary defines “origin” as meaning:

> “1. The act of fact of arising or springing from something; derivation; rise; beginning of existence in reference to its source or cause.
>
> 2. That from which anything arises, springs or is derived.” [163]

Arguably *the beginning of existence* of a copy synthetic strand of DNA *in reference to its source or cause* is the original genetic sequence - in the sense that “but for” the existence of the original-naturally occurring genetic sequence the synthetic copy in that form could not exist. However, although the information originates from the original organism does the *material* originate from that organism? This is far from clear.

Du Plessis (a negotiator at the Nagoya summit on behalf of Namibia)[164] has stated that:

> “DNA sequences are information, written in chemicals and that using such information without PIC and benefit sharing is tantamount to theft a, in the same way that copying CDs would be.”

However, Du Plessis gives no explanation as to how the wording of the Protocol achieves this aim. Morgera *et al.* [165] address the question of access to/utilization of genetic information as part of a broader concern for the impact of “bioinformatics” on the Protocol. They conclude that the Protocol is unclear with regard to the question of whether genetic information falls within the definition of “Genetic Resources” and indeed that the Protocol was conceived without consideration of bioinformatics, but that this is an area which needs to be determined if the Protocol is not to become obsolete within “a few years’ time.” Focussing further on the definition of “Genetic Resources” they paraphrase Tvedt and Shei’s argument[166] that:

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[163] The Compact Oxford English Dictionary (Oxford University Press, Oxford 1979)

[164] Du Plessis (n 88)

[165] Elisa Morgera, *Unravelling the Protocol* (n 74), 70

[166] Morten Walløe Tvedt and Peter Johan Schei “The Term 'Genetic Resources': Flexible and Dynamic while Providing Legal Certainty?” in S Oberthür and GK Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Protocol* (Routledge , London/New York, 2014) ,18

"functional" [units of heredity] could refer to both the genetic structure *per se* and to the information encapsulated in the DNA sequence that can be screened and transferred electronically and become functional in a new digital form. In that light, it has been argued that the biological *origin* rather than the biological *form* of the information matters for falling under the definition of the utilisation of genetic resources."

This focus on *functionality* may appear at first sight to be a reasonable purposive interpretation of the definition of genetic materials. It is, of course, the functionality of the "functional units of heredity" which gives purpose and potential value to the genetic component of genetic material. If such a purposive approach were not taken, it would allow a party to reproduce the functionality of a naturally-occurring gene by producing a synthetic DNA copy of it and thereby take the benefit/functionality of that gene whilst avoiding the access provisions of the Protocol. However, in considering this question of functionality we need to be careful of oversimplification – only a small fraction (1.5% in humans) of eukaryotic DNA directly codes for proteins (in the form of "exons"),[167] the remainder takes the form of intragenic DNA ("introns") (non-coding DNA which sits within a gene) and intergenic DNA, non-coding DNA which sits between genes. Although sometimes given the name "junk DNA", it is increasingly clear that non-coding DNA (in combination with histones) plays a role in chromosome structure, gene expression, and epigenetic heredity.[168]

Some intergenic DNA codes for RNA which is not translated into proteins, but has a structural role (e.g. ribosomal RNA) or regulatory function (miniRNA) within the cell. Other non-coding DNA contains "pseudo-genes" – fossil genes which have lost their ability to be expressed or non-expressed viral genes, telomeres (which protect against chromosomal degradation during cell division) and "conserved" non-coding sequences which show a high degree of evolutionary conservation and may be involved in gene

[167] Tyra G Wolfsberg, Johanna McEntyre and Gregory D Schuler "Guide to the draft human genome" (2001) 409 Nature 824, 824

[168] Elizabeth Pennisi, "Genomics. ENCODE project writes eulogy for junk DNA" (2012) 337 (6099) Science 1159, 1161

regulation.[169] The ENCODE consortium have recently reported that “The vast majority (80.4%) of the human genome participates in at least one biochemical RNA and/or chromatin associated event in at least one cell type”,[170] although with further research this figure may go higher.

In the light of this, limiting the definition of “functional units of heredity” merely to expressed genes (entrons) seems overly narrow. However, bringing non-coding DNA within the ambit of the access/utilisation requirements of the Protocol may present its own, significant, difficulties. For example, in relation to highly conserved non-coding sequences, these sequences may have been preserved across aeons and taxonomic groupings – just because the original sequence was determined from a sample taken from a *liana* from a megadiverse nation, does not mean that the same sequence could not have been equally determined from a yeast, a mouse, or an elephant. We need to ask: In what way is the code from the *liana* unique or special such that a right to control access is justifiable?

The same (difficult) question can also be raised in relation to those *expressed* portions of DNA which are wholly or closely conserved - “75% of our expressed genetic make-up is the same as a pumpkin - 57% the same as a cabbage”.[171] Why should a particular nation (or indigenous group) have a right to control “access” to a nucleotide sequence which has been determined from an organism (say a *liana*) which was found within a certain nation state (say Ecuador) when it could have as easily been determined from a yeast in Burton-on-Trent?

If the nucleotide sequence is entirely conserved across taxonomic groups then what would happen if the “accessor” of the nucleotide sequence argued in their defence that the sequence information actually used by them had originated not from the Ecuadorian *liana* but from the defendant’s independent determination from the genome of the

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[169] The ENCODE Project Consortium; Ian Dunham et al. “An Integrated Encyclopedia of DNA Elements in the Human Genome” (2012) 489 (7414) Nature 57

[170] Dunham (n 169)

[171] Gillian K Ferguson, *The Human Genome: Poems On The Book Of Life* http://www.thehumangenome.co.uk/THE_HUMAN_GENOME/Primer.html (Accessed September 2015)

Burtonian yeast? In this case would control over the sequence reside in the party which controls the resource from which the nucleotide sequence information was *first* determined – akin to a path-independent monopoly right to the sequence? Or is there an *originality* requirement (akin to copyright) where independent (non-path dependent) determination of the sequence constitutes a defence to "infringement"? It would seem extraordinary within the overall context if the Protocol had created the first path-independent right, so the latter path independent approach appears more feasible. However with "copy-rights" there is often a continuum of complexity and a middle ground - what if the defendant (although truly independently sequencing the nucleotide sequence) had been in some way directed toward that gene by an understanding of functionality of sequence by work done on the *liana*? What if the nucleotide sequence were not entirely conserved across species – how similar would the "copied" sequence need to be considered an "accessing" of the original sequence, or would it in some way rely upon Tvedt and Shei's "functionality" and how does one determine or compare such "functionalities"?

Although this is something of an extreme (though plausible) example, in practice claims over a right to control access are more likely to focus on a situation where the nucleotide sequence (or sequences) encodes for something which is distinctive to the organism from which the sequence was determined. One might imagine here that our Ecuadorian *liana* contains entrons which encode for an enzyme which catalyses the synthesis of a compound which is found to have anti-cancer properties. Where those entrons are *only* to be found in that particular species of *liana*, then unique control to access may arguably be more easily justified. Of course, it may be that the sequences encoding for the production of that particular anti-cancer compound are found within a genus of *liana* (or that a family of very closely related compounds is found in that family). We might ask, does control over access extend to the entirety of the genus or to the entirety of the class of compounds? What degree of distinctiveness over other sequences and compounds is required?

All these questions very much highlight the problem which arises when rights over access are decoupled from a *physical* causal link to a genetic entity (such as an actual organism) and attached (only) to an *informational* causal link. It is clear that the Protocol contains no guidance as to how these questions should be answered and appeals to concepts of "functionality" raise as more questions and uncertainties than they answer. As will be seen below, this problem of loss of a physical causal link also applies in relation to synthetic biomimetics.

No doubt as studies on the regulatory and other roles of non-coding DNA proceed, it may be that the interaction between non-coding regions of DNA and coding DNA (and with histones) becomes better understood. These findings may then be argued to be an important part of the information concerning the functionality of the "functional units of heredity" and subject to access requirements. Again some of the interactions may be found to be common across taxonomic groups and the question of why such generic interplays should be controlled will arise. The same problem will likely arise in relation to findings in epigenetics.

Again, where the interaction between non-coding DNA and coding-DNA is unique to a species, unique control to access over that interaction may be more easily justified. One should note here that the genetic control over the degree to which a particular gene or set of genes is expressed can be a crucial aspect of an organism. One example is the *cinchona* tree. Different strains of *cinchona* produce different quantities of quinine (and related alkaloids) a fact which has been responsible for significant examples of industrial espionage, geopolitics, and military strategy. [172, 173]

2.11.1.2 "Utilization"

Beyond the question of "access", the synthetic DNA "problem" also gives rise to questions concerning benefit sharing under Article 5 of the Protocol.

As we have seen above, the definition of "utilization of genetic resources" at Article 2 of the Protocol means to conduct research and development on the genetic and/or biochemical *composition* of genetic resources. So does the use of a nucleotide sequence determined from an endogenous gene to generate a synthetic DNA strand constitute "research" on the *composition* of original genetic resource and so pull that strand of synthetic DNA within the benefit-sharing provisions of Articles 5 regardless of the *physical* origin of the DNA molecule(s)? We saw in relation to the question of

[172] Balick & Cox (n 8), 28

[173] Enrique Raviña, *The Evolution of Drug Discovery: From Traditional Medicines to Modern Drugs* (Wiley-VCH, Weinheim, Germany, 2011)129

"accessing" a genetic resource that making the leap from considering the resource to be an *informational* resource (rather than merely a *physical* resource) required an appeal to the purpose of the access requirements, something which could be assisted by reference to the "functionality" of the functional unit of heredity.[174, 175] One might sensibly argue that such interpretative strategies are not required where one is looking at research and development upon a genetic resources – research and development is inherently more about *information* than is the concept of access. However, although we may not have the question of what functionalities are required (and how we compare competing functionalities) we still have the significant questions over entitlement, "originality" and "substantive copying" with regard to sequences which are conserved across taxonomic groups – all concepts to which the Protocol gives no guidance.

As with the question of access, it is again difficult to limit this definition of "research" to that (entronic) DNA which is expressed as a protein alone without taking account of intragenic and extragenic non-coding DNA and epigenetics.

2.11.2 Genetic Information 2: Are "biomimetics" covered within the definition of "utilization of genetic resources"?

Let us assume that a compound of potential interest ("X") has been isolated from the Ecuadorian *liana* discussed above. As has been discussed in detail above, it is likely that "utilization of a genetic resource" would encompass research and development on compound X (if not, perhaps, a downstream chemical derivative of compound X). Part of that research would almost certainly be to characterise the chemical structure of that compound through analytical chemistry. Once the structure of X is characterised it can be set out in a structural formula.

That information could be taken by a synthetic chemist whose task is to perform a *de novo* synthesis of X. If that task is successful, the synthetic chemist would have created

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[174] Peter Johan Schei and Morten Walløe Tvedt " 'Genetic Resources' in the CBD: The Wording, the Past, the Present and the Future" Fridtjof Nansen Institute Report 4/2010 (http://www.fni.no/doc&pdf/FNI-R0410.pdf) (Accessed September 2015)

[175] Tvedt and Schei (n 166),18

a compound – termed here X^S - which though an *exact* copy ("biomimetic") of X was not *physically* derived from the Ecuadorian *liana* - the only connection between X^S and X which is physically derived from the Ecuadorian *liana* (termed here X^O) is a link of *information* – the knowledge of the structure of X, which knowledge has been derived from study of the genetic resource.

If we take the approach of those which believe that the term "Derivative" expands the meaning of "genetic resource", we might ask whether biomimetics are actually *"a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources"*? Clearly, in one narrow sense they are not, in that they have not *physically* been produced by the genetic expression or metabolism of the particular organism in question. However, where X^S is (as is entirely possible) chemically indistinguishable from X^O, one might argue that it has still *resulted* (in a broader causal sense) from genetic expression or metabolism of biological or genetic resources; our knowledge of its structure would not exist *but for* the genetic expression or metabolism of biological or genetic resources.

If one places no importance on the term "Derivative" (other than merely to serve to define the tool by which the research and development is conducted) then one is forced back to looking at the definition of "utilization" more broadly. As has been argued above, utilization is likely to encompass research on the products of genetic expression or metabolism in any event. One might argue that where there is no physical difference between X^S and X^O there is no practical difference in performing research upon X^S as on X^O. Also as above, it was the knowledge of the structure of X^O that allowed us to synthesise X^S in the first place. Excluding X^S from control would seem here like a relatively easy way to avoid the provisions of the Protocol, given that the compound differs only in that it was made in a laboratory "*de novo*", as opposed to being extracted from the organism.

However, just as was the case for synthetic DNA, we encounter a dilemma. Where one severs the direct *physical* causal link between the genetic resource and X^O, the causal route to X^S has to pass through an indirect *information* stage. In the case of synthetic DNA we looked at the position where a conserved entronic gene sequence found in an Ecuadorian *liana* could have equally been found in our Burton-on-Trent yeast. What if we apply that example to the product (our compound X) of the gene sequence? Here X^O can be as equally found in the *liana* as in the yeast.[176] In this sense there is nothing special about the genetic resources of the *liana* - other than that X was discovered in the liana first.

A control over utilisation of the information concerning the structure X - such that control could be exercised over the use of X^S would here be based upon "firstness"– again not a concept apparently envisaged (or legislated for) within Articles 6 and 5(1) and (2) of the Protocol.

2.12 Genetic expression and downstream derivatives

Does the concept of "genetic information" discussed above give us any further guidance in relation to the question of whether the scope of Article 6 and Article 5(1) and (2) of the Protocol encompasses manmade chemical derivatives of the products of genetic expression?

If a genetic resource (which can incorporate the products of expression of the genes within the resource) can be interpreted not only as a *physical* resource but as an *informational* resource, might one argue that if the informational causal chain can extend to the reproduction of nucleotide sequences, (or to the reproduction of biomimetic copies (X^S of X^O)) it could also extend to an X-A downstream chemical derivative of or X^O (or X^S)?

As we saw above, it is unclear on a doctrinal analysis of the Protocol whether it clearly covers downstream chemical derivatives. As with our biomimetic, once one moves into an informational (rather than physical) causal chain the potential causal reach becomes greater. One might very successfully argue that it was the knowledge of the existence of compound X (found within the Ecuadorian *liana*) which led to the synthesis of X-A (or indeed of X-B or any other combination). However, allocating a right to control

[176] This would be true for a small molecule. For proteins, even where the primary peptide sequence is identical, there is likely to be a difference in the post-translational modification/glycosylation of the protein as between the *liana* and the yeast.

downstream use of *information* where that compound could have equally been found expressed by the genome of an organism in a different taxonomic group comes to rely on an idea of firstness and "copying". These are certainly difficult concepts to deal with in relation to a genetic resource *per se* – in a sense the right in information only comes into existence once the scientific information (nucleotide sequence or biochemical structure) has been "harvested" by someone from the genetic resource – it is difficult to envisage how such a right in the information can exist in the genetic resource in an inchoate form *before* such discovery.

Although reliance upon an informational causal link is problematic with regard to genetic resources *per se* (and was perhaps not fully envisaged by the formulators of the Protocol), the move from a physical causal link to an *informational* causal link is the key element of the protections given in Articles 7 and 5(5) of the Protocol. It is possible therefore that the scope of protection offered by these provisions will be more flexible than the protections offered by Article 6 and 5(1) and (2), (and quite clearly some informational link was entirely intended by the formulators of the Protocol) and it is to these positive protections that we will now turn.

2.13 The right to control "access" to traditional knowledge associated with genetic resources under Article 7

As we have seen, Article 7 of the Protocol requires "*the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established*" before traditional knowledge associated with a genetic resource can be "accessed". As with the access right under Article 6, it is difficult to see this requirement for prior consent/approval as creating anything other than a positive right, although the right is not formulated as one might a classical intellectual property right. Again, however, we are left with the question of what "access" means in this context. The Protocol itself gives us no guidance.

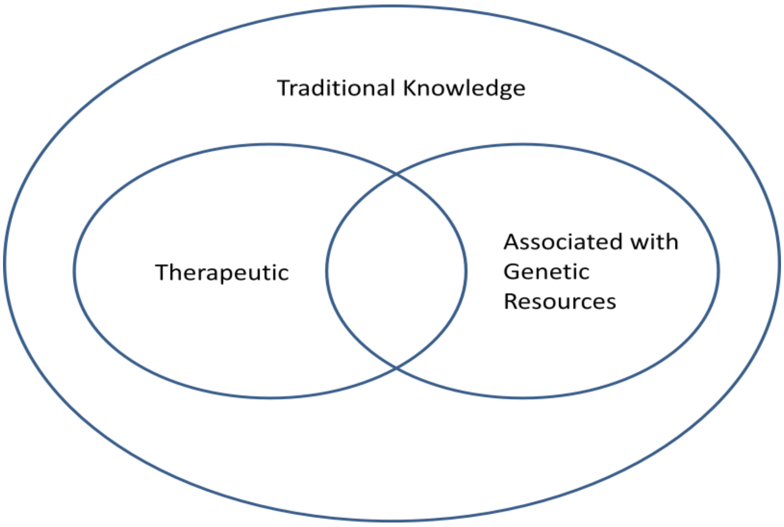
When we examined the meaning of "access" as it relates to genetic resources *per se* we saw that access could mean merely the first physical access of the resource or, as was argued by the provider countries, a broader concept of ongoing "access" wherein new permissions were required for new "accessings" of the resource. Similar arguments can apply in relation to the Article 7 right although taking into account the markedly different subject matter.

Traditional knowledge can be very broadly defined. In relation to potentially useful genetic resources it is perhaps best described as the knowledge (however held, whosoever held by, and however widely) that tells us that any type of genetic resource may be useful and the ways it can used and prepared to give that usefulness. Of course, the usefulness of a genetic resource (and the information associated with it) may not relate to a therapeutic benefit - one might imagine here a plant that has particular drought-, pest- or disease- resistance. Similarly there is an entire body of traditional knowledge which is *not* limited to useful organisms. Within this body is sub-set of traditional knowledge with relates to therapeutic benefits (or purported benefits) which are *not* linked to genetic resources (these might include therapies related to variants of acupuncture or cupping or body modification (such as tattoos), or variants of body manipulations such as reflexology, osteopathy and chiropractic). There will also be traditional knowledge which relates to neither therapeutic benefits nor genetic resource *per se* – this will include traditional cultural expression and other knowledge such as presence of mineral and water resources, animal migration and climate patterns The relationship between these types of traditional knowledge is summarised in the Euler diagram in Figure 2.2.

Of course, it is the intersection between the sub-sets of therapeutic traditional knowledge and traditional knowledge associated with genetic resources which is likely to be that of most interest to those seeking to develop “novel” pharmaceutical ligands. However, we need to note that the very nature of traditional knowledge held within indigenous groups means that these many of these sub-sets are, in practice, artificial and would likely not correspond to how the indigenous peoples, themselves, perceive such knowledge. The knowledge may have unclear edges and overlaps within a particular customary activity – for example where a plant (or mixture of plants) is used to induce euphoria/hallucination within a broader ceremonial activity.[177]

[177] For example see the use of *ayawasca* by the indigenous peoples of the Amazonian Basin. Don Jose Campos, *Shaman and Ayahuasca - Journeys To Sacred Realms* (Divine Arts, San Francisco 2011)

<u>Figure 2.2 Euler diagram showing relationships between types of traditional knowledge.</u>



Notwithstanding these classifications, crucially (and obviously) traditional knowledge is not a *physical* resource but an *informational* one and this changes the very nature of how it can be accessed. Access in the form of mere physical acquisition cannot apply - although traditional knowledge can be recorded in physical form, is certainly not limited to it. The "acquisition" here is instead conceptual and the acquiring of the concept could certainly be argued to be access to the information. However, does this mean that it is only the *first* acquisition of the concept from the holders of the information which is the "accessing" event? One might imagine here that an ethnobiologist obtains the first disclosure from a particular indigenous group in Ecuador of the anti-tumour effects of ground-up *liana* seeds. It is hard to argue that such an event is other than an "accessing" for the purpose of Article 7. However, what about the case where our ethnobiologist publishes her findings and a third-party uses them to find the appropriate *liana* for anti-cancer research purposes – is the initial reading the accessing or the acting upon that reading to source the liana?

Given the overall purpose of the Protocol (and the access provisions of Article 6) it would seem perverse to limit access to the very *first* accessing event - a "one-off" event, a single dipping into the "well" of indigenous information, after which all further use of the information is permitted. Indeed, given the overall context of the Protocol, it would seem more consistent that each new user should require consent to access and that for each user continued “access” to a piece of traditional knowledge relating to a genetic resource requires *continual* ongoing consent from the holders of the traditional knowledge for use of the knowledge. If this were not the case the provisions of Article 7 would be limited and easily evaded.

However, where one creates a requirement for ongoing consent to “access” in relation to something as intangible as an idea, the potential is there for the scope of control to be very broad indeed. Does the reference to prior informed consent here mean that that consent must encompass the all continued usage of (alternatively put as continued “access” to) the information and that *any* new use of the information, howsoever remote, requires permission?

When examining the meaning of “access” as it applied to “genetic resources” under Article 6 we saw that (provided there was physical causal link between the source of the subject matter being controlled and access) the scope of control was relatively easily determined (subject to questions over chemical derivatives). However, we also saw that with extension of control into synthetic DNA and biomimetics there was a decoupling from physical causation to an *informational* causal link which was dependent upon detailed knowledge of a particular nucleotide sequence or chemical structure. We also saw that where the physical causal link became decoupled we came to rely more on questions of “firstness” and “discovery” or “originality” to identify the party who should have control.

At this point we need to be clear that the Protocol has no requirement that the indigenous peoples have to have any understanding of the biological mechanism by which the organism to which they are referring has its effect. Indeed, any such requirement would render the provisions of Article 7 essentially useless. One might imagine a situation in which an indigenous people mistakenly believed a therapeutic benefit was derived from a fruit, whereas in fact the effect was created by a mould growing within the fruit of which they were unaware. It is hard to imagine that such a mistaken belief would render the indigenous group’s Article 7 right of control over the information as in some way invalidated by this error. However, as we shall see later in this work (see Chapter 5) there may be an impact on the scope of control where the “errors” are of a different nature.

In relation to a right to control access under Article 7 there appears to be no requirement that a piece of traditional knowledge should be connected to a *specific* physical sample of genetic resource – indeed such a requirement would be overly restrictive, and would (again) clearly lead to the Article 7 right being easily evaded.

Article 7 also contains no express requirement for the information to be used in any particular way. There is no requirement within Article 7 (unlike Article 6(1)) that the genetic resource to which a piece of traditional knowledge is associated should simultaneously be "utilised" as seems to be the case Article 6 (1). If this were the case then one successfully might argue that the scope of Article 7 would be curtailed by the definition of "utilisation of genetic resources" (whatever that actually means).

However, in the absence of such an express link there seems little basis to assume that Article 7 is so restricted. Therefore, traditional knowledge associated with a genetic resource can realistically only mean information which relates to the characteristics and properties of a "genetic resource" more generally. Genetic resource here, of course, means material of plant, animal, microbial or other origin containing functional units of heredity which is of actual or potential value. Presumably, *any* information relating to a particular plant, animal, microbe or other organism (presumably also covering fungi) containing functional units of heredity will be covered.

2.14 The right to benefit-sharing under Article 5(5)

Article 5(5) of the Protocol states that:

> "Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms."

As discussed in relation to the sharing of benefits under Articles 5(1) and (2), although the requirement for fair and equitable sharing of benefits does not, of itself, create a right to control use, the requirement that such sharing should be on mutually agreed terms arguably creates such right.

The key term in relation to understanding the scope of such a right is clearly "utilization of traditional knowledge associated with genetic resources". Unlike utilization of genetic resources, this term is not expressly defined within the Protocol or the CBD. As with "access" to traditional knowledge associated with genetic resources under Article 7, it is clear that such use does not have to relate to a specific *physical* sample of a genetic resource.

Morgera *et al.* [178] suggest that "utilization of traditional knowledge associated with genetic resources" needs to be understood "by combining different elements of the Protocol" and that the term can be "interpreted along similar lines to the definition of utilization of genetic resources".

However, as we have seen in the analysis above, the meaning of "utilization of genetic resources" (and also "access to genetic resources") is far from clear, particularly where the purported causal link is *informational* rather than physical. We should also note that although there is no doubt that the provisions of Article 7 and Article 5(5) should work together with Article 6 and Article 5(1) and (2) where appropriate, the meaning of "utilization of traditional knowledge associated with genetic resources" does not seem to be expressly linked to, or restricted by, the definition of "utilization of genetic resources" nor is there are requirement that "utilization of genetic resources" should occur alongside the "utilization of traditional knowledge associated with genetic resources" (although there will, of course, be many occasions when both will happen concurrently).

What Morgera *et al.* actually go on to imply is something distinctly different from (and broader than) "utilisation of genetic resources", suggesting that the traditional knowledge should:

> "serve as lead information for the utilisation of genetic resources, it can be understood as hinging on the same intent (research and development) as genetic resources." [179]

Here Morgera *et al.* reflect the view of the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(J) and Related Provisions of the Convention on Biological Diversity who state that:

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[178] Morgera, *Unravelling the Protocol* (n 74), 74

[179] Morgera, *Unravelling the Protocol* (n 74), 74

> "In essence, traditional knowledge that sparks the process or provides the lead to the properties of a genetic resource although it may not be reflected in the end-product remains associated to that product." [180]

And those of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing who state:

> "...traditional knowledge often provides the lead to genetic resources with potential properties, even if the traditional knowledge does not match the end product. Thus it should nevertheless be covered by the International Regime. Although the traditional knowledge used for the final product may not match the body of traditional knowledge, traditional knowledge adds value to genetic resources by providing a massive increase of efficiency in identifying genetic resources with potential properties. Traditional knowledge can therefore be considered as an indicator of the potential properties of a genetic resource. At the same time, it was noted by some that traditional knowledge does not always provide useful leads to genetic resources."[181]

The work of these UNEP[182] expert groups was not incorporated as clarification into the operative provisions of the Protocol. However, what they seem to envisage is something which is decidedly broader than utilisation of genetic resources *per se*. If this position was incorporated into our understanding of the Article 5(5) right, it would allow the right to encompass a situation where a piece of traditional knowledge serves as a "lead" (or inspiration) to research workers to investigate the properties of the genetic resource to which the traditional knowledge relates – essentially giving a reason to look at this particular resource in a particular way, rather than others. The position

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[180] Report of the Sixth Meeting of the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(J) and Related Provisions of the Convention on Biological Diversity, Conference of the Parties to the Convention on Biological Diversity Tenth Meeting Nagoya, Japan, 18-29 October 2010, 36 https://www.cbd.int/doc/meetings/cop/cop-10/official/cop-10-02-en.pdf (Accessed September 2015)

[181] Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing Montreal 9-15 November 2009 (UNEP/CBD/WG-ABS/8/2), 8 http://www.cbd.int/doc/meetings/abs/abswg-08/official/abswg-08-02-en.pdf (Accessed September 2015)

[182] United Nations Environmental Program

also acknowledges that the information could attach itself to a downstream product that did not necessarily "match" or "reflect" the original traditional knowledge. This broader understanding of "utilisation of traditional knowledge associated with genetic resources" would appear to be consistent with the overall context of the Protocol and of Article 8(j) of the CBD. However we cannot determine from these positions whether the scope of Article 5(5) should extend to all downstream products, in all circumstances.

2.15 Scope of Article 5(5) and Article 7: Conclusion

What seems to be missing from the "positive" rights in relation to "traditional knowledge associated with genetic resources" under the Protocol is any principle or guidance for determining a balance which combines fair protection for the traditional knowledge/genetic resources rights holders with a reasonable degree of legal certainty for third parties. Where such knowledge serves as a research "lead" for further development, the Protocol itself gives no clear guidance as to how far that knowledge can have a "reach through effect" into new scientific discoveries or at what stage would a researcher be considered free of the traditional knowledge right.

2.16 Further conclusions – types of information

Beyond the determination of the scope of the provisions of the Protocol, a more fundamental point which is highlighted by this analysis is the disconnect between the concept of a genetic resource *per se* and that of traditional knowledge *associated with* that genetic resource.

This disconnect might appear relatively obvious on initial examination if one equates a genetic resource only with its physical embodiment. However, when examining the meaning of "genetic resource" we see that there is an argument that it extends beyond the mere *physical* embodiment of the resource to include a concept of genetic *information* which incorporates DNA sequences and even epigenetic code. If such genetic information is excluded from being considered a "genetic resource" there would be substantial scope for evading a positive right to control the use of the genetic resource.[183] It is also argued in this chapter that a biochemical produced by the expression of the genome of a genetic resource should also be considered a component of a genetic resource (although the coverage of downstream chemical derivatives of such a component is less clear).

What is clear however is that, although traditional knowledge *associated with* a genetic resource is a species of information, it is of an unrelated type to the informational component of a genetic resource. Traditional knowledge *associated with* a genetic resource (though it may serve as a gateway to their study) is not related to DNA or epigenetics. Accordingly, arguments which are applied to extend the definition of a genetic resource cannot properly be used to extend the definition of traditional knowledge associated with a genetic resource. Equally, however, the definition of a genetic resource does not delimit the meaning or scope of traditional knowledge associated with a genetic resource and, in principle, the downstream scope of a right to control such traditional knowledge cannot be curtailed by considerations which would apply in relation to genetic "information". In this respect the traditional knowledge associated with a genetic resource is a broader (and far less proscribed) concept than the informational component within the genetic resource.

[183] Although, it is also noted that this could create some strange anomalies where a gene sequence is conserved across a wide range of taxonomic groups some of which might be as easily accessed from countries other than the biodiverse global South.

Chapter 3

The justification for positive rights in traditional knowledge associated with genetic resources

"Because the rule of law exists, and above all because it encourages and protects acts of innovation ... we in the modern world expect that tomorrow will be better than today. Our view of the universe is essentially optimistic because of the marriage between law and innovation. Law gives the individual the confidence to explore, to risk, to adventure into the unknown, in the knowledge that he as an inventor, will be protected by society."

James Burke, *The Day the Universe Changed* (1985)

"Central to the ideology of IPRs is the fallacy that people are creative only if they can make profits and guarantee them through IPR protection."

Vandana Shiva, *Biopiracy -The Plunder of Nature and Knowledge* (1997)

3.1 Introduction

As was stated in Chapter 1, to understand the justifiable scope of a positive right to traditional knowledge associated with genetic resources we need to examine the theoretical underpinnings for the existence of rights to control the use of ideas (and their expression) in general, and then apply those theories to the case for the existence of a positive right in traditional knowledge associated with genetic resources in particular. This chapter will follow that approach.

The first step, however, is to identify the special difficulties which the protection of intangible concepts present as these problems very much underlie the ways in which the theoretical underpinnings are brought into practical effect.

3.2 The “problem” of intangibles

The power and value an intellectual property right resides in its ability to limit the freedom of those who do not own the right to engage in certain activities. The degree to which it does this, and the exact activities which are curtailed, will depend on the exact nature of the right. However, at their heart all intellectual property rights confront a problem: they are an attempt through positive law, and the enforcement of that positive law, to create exclusivity in intangible goods which would otherwise be inherently difficult to control. [184]

A purely tangible object is (usually) relatively easily defined –its physical limits circumscribe the boundary of the thing itself. Similarly, use of a purely tangible object is rivalrous (or subtractable) [185, 186] – use by one person cannot help but deprive others of that particular use of the object (or subtract that use from the use of others). Its use can also (in theory, if not necessarily always in practice, and often subject to considerable cost) be excluded through physical possession or physical control of access. As such, exclusivity in that tangible thing is relatively easily achieved. However, this is not the case for ideas, or for the varied ways in which an idea may be expressed.

The field of epistemology - what an idea *is* or how we can classify, or be certain of, knowledge has been the subject of philosophical discourse for millennia.[187] For present purposes, however, we need to acknowledge that knowledge and ideas, and their expression, are at heart merely information. In distinct contrast to tangible objects, the use of information is non-rivalrous – my use of a piece of information cannot deprive another (or indeed many millions of others) from identical use of that information.

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[184] Christopher May, *The Political Economy of Intellectual Property Rights* (Edward Elgar Cheltenham 2010), Volume 1, x

[185] Charlotte Hess and Elinor Ostrom, “Introduction” in Charlotte Hess and Elinor Ostrom (eds) *Understanding Knowledge as a Commons: From Theory to Practice*. (The MIT Press, Cambridge, Massachusetts 2007) 3, 9

[186] Vincent Ostrom and Elinor Ostrom, “Public Goods and Public Choices” in ES Saras (ed) Alternatives for Delivering Public Services: Toward Improved Performance (Westview Press, Boulder, CO 1977)

[187] James Garvey & Jeremy Stangroom, “The Story of Philosophy: A History of Western Thought” (Quercus, London 2012), 179

Similarly, in contrast to tangible objects, information is physically unexcludable - it is easily copied, disseminated, adapted, mixed with other information and the mixed information can be further copied, disseminated, adapted and mixed, *ad infinitum*. [188]

However you seek to classify it, whether as an idea, an instruction, a concept, an algorithm, a behaviour, or a meme,[189] once the intellectual product of a mind is first conveyed out of the mind of its author its ready amenability to imitation and adaptation allows it take on a "life of its own", entirely independent of its author. In the absence of a legal mechanism to constrain downstream use by others, the original author cannot but lose control over their intellectual product. As was (more poetically) stated by Jefferson:

> "If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me..." [190]

However, the problems with controlling the use of intellectual products do not end with the non-rivalrous and non-excludable nature of their use. Unlike a purely tangible object, there is also the significant problem of *defining* an intangible. If I am seeking to assert control over information through a legal mechanism, my first task is to understand *what* the information is – that is *how* the intangible is defined. Given the inherent malleability and adaptability of information, it is important that I understand the "boundaries" of what is to be protected. However, the boundaries I need to consider are "multi-dimensional". The first, and perhaps most obvious dimension, relates to my understanding of the point at which the initial information has become so changed, or is so different, that it no longer represents, or is a part of, that which was originally

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[188] Hess (n 185)

[189] Susan Blackmore, "The Meme Machine" (Oxford University Press, Oxford 1999), 4

[190] Thomas Jefferson, Letter to Isaac McPherson, 13 August 1813, 13 Writings 333 (http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html, (Accessed September 2015)

conceived. Attas has referred to this as the problem of "individuation"[191] of ideas which he divides into three areas:

> a) the problem of distinguishing between an idea in its first expression and the many secondary expressions it might stimulate;
>
> b) the problem of distinguishing between a general and more abstract idea and the specific details that are required to put it into practice; and
>
> c) the problem of extension of protection of an idea to cover the same idea which has been independently conceived.

We might for current purposes call these the "forward-looking" boundaries of the intangible.

The second dimension relates to my understanding the boundaries between what I have conceived (and seek to protect) and the field of the ideas/information of others which have gone before me. Attas has called this the problem of "origination"[192] and identifies the difficulty of considering a newly minted concept as being in some way separate from the multitude of previously existing concepts which have acted as the back drop and or stimulation for the concept under consideration. Gibson uses the term "origination" to describe the process of identifying and individuating the creator of a work, the origin of a work and the "presumption of a finite, concluded and indeed lifeless material form". [193] For current purposes we might call these the "backward-looking" boundaries of the intangible.

It is worth noting here that Gibson coins a useful term within this context. As we will see, philosophical justifications for the existence of rights to control ideas often require some degree of "contribution" by the author in the form of originality, inventiveness

[191] Attas (n 48), 49

[192] Attas (n 48), 41

[193] Johanna Gibson, *Community Resources: Intellectual Property, International Trade and Protection of Traditional Knowledge* (Ashgate, Farnham Surrey 2005), 81

and/or novelty – that is a sense in which the subject matter of protection is not imitative of something else. Gibson describes this state as "in-imitativeness".[194]

From an epistemological stand-point, we can see the very close links between individuation and origination. Indeed, all forms of established intellectual property right have grappled, and continue to grapple, with both boundary dimensions. Determination of the forward-looking (individuation) boundaries is most commonly couched in the language of infringement – does a third party use of the protected intangible fall within the scope of the protected intangible? In contrast, the backward-looking (origination) boundaries are most commonly encountered when looking at questions of validity or subsistence – is the intellectual product sufficiently different from the intellectual products that have gone before to warrant protection? In most cases there will be a complex interplay between both boundary dimensions. When defendants argue that their (allegedly infringing) use of a purportedly protected intellectual product is a mere repetition of that which was understood before the conception of the asserted intellectual product, putative rights holders can find themselves navigating with difficulty between the Scylla of asserted validity and Charybdis of asserted infringement.[195]

Given the inherent nature of information, both types of boundaries are rarely distinct. With regard to the backward-looking boundary there will very likely be a continuum between that which went before and that which is sought to be protected, and with regard to the forward-looking boundary, a continuum between that which is sought to be protected and that which is adapted by others from that information. The question of where to draw a definitional line within these continua goes to the very heart of the existence of the right in the intangible.

Sometimes a party seeking exclusive use of information will seek to define a piece of information by reference to a tangible product which is created out of that information. This may seem to give a reassuring foothold, but it is in some cases erroneous and care must be taken – although the tangible product may be *one* embodiment of a broader

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[194] Gibson (n 193), 81

[195] See for example the so-called "Gillette defence" run in *Gillette Safety Razor Co v Anglo-American Trading Co* (1913) 30 RPC 465

piece of information, it may not represent the entirety of the information, or indeed all the potential embodiments which could flow from the information.

That said, the degrees of uncertainty along the forward-looking and backward-looking dimensions will vary as between the types of intellectual product to be protected - the protection of “pure” ideas *per se* being subject to the greatest degree of uncertainty and the protection of the more concrete expressions of an idea being subject to less uncertainty. The narrower the embodiment of the idea then, by definition, the less uncertainty will surround its definition in both dimensions. Accordingly, where a party chooses only to protect a narrow embodiment of an idea, they will likely encounter fewer problems with asserting validity and infringement. The choice between the certainty (and potential lesser commercial reward) provided by asserting a narrow embodiment and the potentially greater commercial gains (but increased uncertainty) through assertion of a broader embodiment is a perennial difficulty for intellectual property owners (and, indeed, their advisors).

However, why should we be concerned if the boundaries of that which I am seeking to assert control over are indefinable? What mischief comes from my “woolly” boundaries?

Of course, my control over a piece of information inherently requires others to curtail their utilisation of that information. If I assume, as a general point, that it is correct that I should only prevent others from an activity with some justification, then it would seem right that the boundary of my control should only extend to that which is supported by that justification (whatever that justification may be). Any control that extends beyond this is, by definition, unjustifiable.

Any such analysis is, of course, based on an assumption that it is in some sense improper to place limitations on others, but is otherwise focussed upon the argument of the person asserting the right. We need to be aware that such assertions of right are rarely made into a justificatory “vacuum”. Hohfeld[196,197] highlighted the correlative

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[196] Wesley Newcomb Hohfeld, “Some Fundamental Legal Conceptions as Applied in Judicial Reasoning” (1913) 23 Yale Law Journal 16, 30

[197] Wesley Newcomb Hohfeld, “Fundamental Legal Conceptions as Applied in Judicial Reasoning” (1917) Faculty Scholarship Series, Paper 4378

nature of rights versus duties – granting a right to one has the correlative effect of imposing duties upon other. Following such an Hofeldian approach, Waldron[198] states that:

> "Since legal duties are hard things for people to have - since they constrain conduct and in that sense limit freedom - we should expect the realm of duties to be the testing ground for claims of right. The realm of duties - the propositions about duty that a given claim of right entails - is where we should expect the problems with the right (if there are any) to surface."

Whether one sees questions of what duties should be borne by others as some sort of background into which rights are asserted, or as direct opposing arguments for the existence of a right, or whether one perceives the imposition of a right as in some way curtailing inherent rights of others, the question of the justification for the existence or scope of a right might be considered as a "justificatory equation". Such an equation would pit the justification(s) for the existence of the right on one side of the equation against justification(s) for the non-existence of the right on the other side of the equation. However, this is not in any way a "zero sum" arithmetic equation. We need to immediately note that the scope of a particular right may be supported by more than one (and potentially many) justifications. Further, not all such justifications may be of equal validity or merit and differing justifications may give rise to differing justifiable limits. Altogether, it is unlikely that the "set" of scopes supported by these varied justifications will be co-terminous. Similarly, it could be unlikely that the opposing justifications would create a co-terminous set of counter-scopes, or indeed that each counter-argument would be fully aligned with each "pro" argument.

However, as will be seen, problems of non-alignment are usually addressed by the narrower, specific, arguments for the existence of a right being countered by broader, general counter-arguments based upon inherent individual liberty.[199]

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[198] Jeremy Waldron, "From Authors to Copiers: Individual Rights and Social Values in Intellectual Property" (1993) 68 Chicago Kent L R 841, 842

[199] Hugh Breakey, "User's Rights and the Public Domain" in *Intellectual Liberty – Natural Rights and Intellectual Property* (Ashgate Law, Ethics and Governance Series, Farnham, Surrey 2012), 75

3.3 The "problem" of knowledge

Assuming for the moment that control should be limited by justification, is there an argument that the position is particularly acute in respect of the control of knowledge? Is knowledge in some way *special*? There is a long tradition that a restriction on the use of ideas *per se* cannot be justified at all, a tradition in part captured in the medieval, rhyming aphorism:

> *Scientia donum Dei est,*
>
> *Unde vendi non potest.*

(knowledge is a gift from God and should not be sold) [200, 201] and developed in the writings of Kant, Fichte and Hegel (as will be discussed later in this chapter). Notwithstanding this thinking, it is not an overstatement to say that the transfer and adaptation of information has been, and continues to be, at the very heart of the development of human civilisation - indeed one might ask what *is* human civilization without knowledge? For Bronowski:

> "Man is distinguished from other animals by his imaginative gifts. He makes plans, inventions, new discoveries, by putting different talents together; and his discoveries become more subtle and more penetrating, as he learns to combine his talents in more complex and intimate ways."[202]

In the light of this it might be argued, at the very least, that the freedom to use information is not one to be interfered with lightly. Accordingly, a restriction of the right of others to use knowledge might, at the very least, be seen to be one where:

> a) a particularly high justificatory threshold is required, and
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> b) there is a need to be particularly cognisant of not improperly restricting the action of third parties.

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[200] Gaines Post, Kimon Giocarinis and Richard Kay, "The Medieval Heritage of a Humanistic Ideal: Scientia donum Dei est, unde bendi non potest" (1995) 11 Traditio 195, 197

[201] Lewis Hyde, *Common as Air: Revolution, Art and Ownership* (Union Books, London 2010), 20

[202] Jacob Bronowski, *The Ascent of Man* (Book Club Associates, London 1977), 20

Here the inherent uncertainty in defining the boundaries of a piece of information adds a further layer of concern. Such uncertainties (combined with the inherent imperfections in any legal mechanism) may give us a high (perhaps unavoidable) probability that any mechanism which grants rights of control over information will result in some third parties being improperly prevented from doing that which they would otherwise be free to do. Is this risk a price too high to pay? That question cannot be addressed within this work, but certainly an appreciation of the danger caused by the inherent uncertainty of the boundaries to information must be carefully considered when looking at the "justificatory equation" for imposing any control over information.

Notwithstanding any such justificatory equation, it would seem reasonable that the formulators of intellectual property rights (and those tasked with making them work) should, in any event, be particularly sensitive to the balance of conflicting interests between the justifications for granting protection to an intellectual product and the right of the broader world to work freely, and ensure that a careful framework of rules (and guidance for their interpretation) is in place so as to reduce the danger of improper curtailment of third party activity.

Indeed, support for a clear framework of rules also derives from a closely related source. Bingham[203] identified a requirement that "*law is accessible, and so far as possible, clear and predictable*" as one of his principles underpinning the rule of law. Indeed, the importance of clarity and predictability in law has a long history [204, 205] and has been cited by senior appellate courts in a variety of jurisdictions.[206, 207] Whatever the justification for controlling the use of intellectual products, it is hard to envisage why the principle of clarity and predictability in law (and in its application) should not apply to understanding the limitations to the scope of an intellectual property right.

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[203] Tom Bingham, *The Rule of Law* (Penguin Law 2011) 37

[204] *Hamilton v Mendes* (1761) 2 Burr 1198, 1214

[205] *Vallejo v Mendes* (1774) 1 Cowp 143, 153

[206] *Black Clawson International Ltd v Papierwerke Waldhof-Aschaffenburg AG* [1975] AC 591, 638

[207] *Sunday Times v United Kingdom* (1979) 2 EHRR 245, 271

Accordingly, ensuring that any intellectual property right framework provides a mechanism for determining with a reasonable degree of certainty what is (and what is not) protected or permitted, is not only of immense practical significance to those seeking to operate the law, but is an element in securing the proper rule of law. Of course, the inherent uncertainties of defining information do not make providing such a "reasonable degree" of certainty easy. However, these inherent uncertainties might be argued to place a heavy burden on the formulators and adjudicators of intellectual property laws to give due care to questions of scope of protection.

3.4 High level justifications for the protection of knowledge

The key high level philosophical justifications for the existence of intellectual property rights protecting knowledge (or its expression) are most commonly divided into *consequentialist* claims or *deontological* approaches.[208, 209, 210, 211]

Within the first group of justifications positive law is created in an attempt to meet a perceived societal need or collection of such needs. As is the case with any consequentialist approach, the most contentious question is how we choose (and justify) the consequences that should be sought. In relation to the existence of intellectual property rights, the most commonly expressed consequentialist goal is a desire to incentivise artistic, social and technological development (though this essentially utilitarian motivation is often presented as a desire to achieve positive "economic" outcomes).[212, 213] This is a justification which has been particularly applied to the protection of inventions through a patent system.[214, 215, 216]

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[208] Peter Drahos, "A Philosophy of Intellectual Property" (Dartmouth Publishing, Aldershot, Brookfield, USA, Singapore, Sydney, 1996)

[209] Graham Dutfield & Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar, Cheltenham 2008), 47

[210] Estelle Derclaye, "Patent law's role in the protection of the environment - re-assessing patent law and its justifications in the 21st century" (2009) 40(3) IIC 249

[211] A Moore, (2011) Stanford Encyclopedia of Philosophy (http://plato.staford.edu/enties/intellectual-property) (Accessed September 2015)

[212] Mark A Lemley, "Ex Ante versus Ex Post Justifications for Intellectual Property" (2004) 71(1) University of Chicago Law Review 129

The deontological approaches are based on natural rights, human rights or other matters of "duty". The natural rights justifications essentially fall into two mains camps:

i) "labour-desert" based on the concept that we own ourselves and by mixing our labour with the world we gain ownership in that we have mixed our labour with; and

ii) rights based on freedom of personality and the extension of individual personality.

It should be stressed, however, that although all intellectual property rights have the key similarity in that they seek (to varying degrees) to exclude third parties from engaging in certain "intellectual" or commercial activities, the range of subject matter covered by intellectual property rights is so broad that certain of the philosophical justifications for "intellectual property" often seem to sit more comfortably for some rights than for others.

Advocating a pluralistic approach to the justification of intellectual property, Resnik highlights that different rights require different balances of "competing moral values in the light of the particular facts and circumstances".[217] Mr Justice Laddie (of the High Court of England & Wales), in a more Orwellian vein, put it thus:

> "it seems to me to be strongly arguable that not all intellectual property rights are equal. Some are more equal than others. It is convenient and conventional to treat copyright, designs, topography rights, moral rights, confidential information,

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[213] Seana Valentine Shiffrin, "The Incentives Argument for Intellectual Property Protection" in in Axel Gosseries, Alain Marciano and Alain Strowel (eds) *Intellectual Property and Theories of Justice* (Palgrave Macmillan, New York 2008) 29

[214] Fritz Machlup & Edith Penrose, "The patent controversy in the nineteenth century" (1950) 10(1) Journal of Economic History 1

[215] Vincenzo Denicolo and Luigi Alberto Franzoni, "The contract theory of patents" (2003) 23 International Review of Law and Economics 365

[216] Matthew Fisher, "Classical economics and philosophy of the patent system" (2005) 1 IPQ 5

[217] David B Resnik, "A Pluralistic Account of Intellectual Property" (2003) 46(4) Journal of Business Ethics 319, 319

patents and trade marks as a group. But there are substantial differences between them..."[218]

Accordingly, we will find in the present analysis that not all the philosophical justifications that have been provided to justify the existence of intellectual property will necessarily comfortably justify the control of traditional knowledge associated with genetic resources (indeed some, arguably do not support it at all), whereas with others the struggle is not so great.

However, before we engage in this exercise we need firstly to address whether the application of what could be argued to be essentially "Western" intellectual concepts of property, and of the self, are appropriate to the protection of something (traditional knowledge) which is are radically different in nature from the usual subject matter of Western intellectual property law. As we will see some of the problems with the application of Western philosophical approaches arise from the way in which traditional knowledge is "developed" (that is in an *ad hoc* way across generations) and held within indigenous groups. These are, however problems, that can be dealt with on a case-by-case basis and do not (of themselves) necessarily undermine the entire process of bringing an "alien" Western philosophy to bear upon this subject matter.[219]

A greater criticism is that in many cases the ways in which traditional knowledge is conceived and respected by indigenous peoples are not founded upon Western notions of self and (particularly) of property. [220], [221], [222], [223]Notwithstanding this, we have to

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[218] Laddie J in *Philips Electronics NV v Ingman Limited, The Video Duplicating Company Limited* [1999] FSR 112, 134

[219] Although they may of course create difficulties in bringing traditional knowledge within the framework of existing intellectual property rights.

[220] Joseph Githaiga, "Intellectual Property Law and the Protection of Indigenous Folklore and Knowledge" (1998) 5(2) E Law: Murdoch University Electronic Journal of Law para.18 (http://www.murdoch.edu.au/elaw/issues/v5n2/githaiga52.html*)* [Accessed September 2015]

[221] Johanna Gibson "Community and the Exhaustion of Culture. Creative Territories in Creative Cultural Expressions" in Fiona Macmillan and Kathy Bowrey (eds) *New Directions in Copyright Law Volume 3* (Edward Elgar Publishing, Cheltenham 2006), 21

[222] Gibson (n 193), 82

consider that the positive rights to control genetic resources (and traditional knowledge associated with genetic resources) established within the Protocol (or to be created in any other Western mechanism such as the WTO or WIPO) are a function of *positive law* created within a Western legal philosophical framework. Accordingly, there is an argument for saying (whether or not such an approach is appropriate or otherwise to the subject matter) that such rights need to be assessed on essentially Western philosophical terms. This work will assume this to be the case, and will use Western philosophical approaches where assessing situations in which those rights will be interacting, and conflicting, with third-party intellectual property rights (and concepts of freedom) whose justifications are themselves rooted within the Western tradition.

In any event, critics of the protection of traditional knowledge (perhaps at some time hence a pharmaceutical company seeking to avoid a veto over downstream use) are likely to root their arguments in the Western philosophical tradition and such criticisms are likely most properly countered using the same philosophical paradigm.

We will see that there are some philosophical approaches, notably restorative justice and communitarianism which, though clearly Western concepts, are less commonly used to justify intellectual property rights *per se*, but may have a particular role in the justification of rights to control traditional knowledge associated with genetic resources.

Although generally not one of the "usual" key justifications for intellectual property, ideas based on the concept of communitarianism – that communities are entitled to rights based on their being a distinct community, have been used as a justification for rights in traditional knowledge.[224] More recently, Munzer has used ideas of restorative/corrective justice to justify rights in traditional knowledge.[225] Accordingly,

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[223] Andreas Rahmatian, "Neo-colonial aspects of global intellectual property protection" (2009) 12(1) Journal of World Intellectual Property 40

[224] Gibson (n 193)

[225] Stephen R Munzer, "Corrective justice and intellectual property rights in traditional knowledge" in Annabelle Lever (ed) *New Frontiers in the Philosophy of Intellectual Property* (Cambridge University Press, Cambridge, 2012), 58

these justifications will be examined alongside the more "traditional" deontological and consequentialist justifications.

Although ideas of distributive justice have long played a significant part in the debate concerning the ownership of property, they have only more recently being applied to questions of the rightness of control over ideas – most commonly to examine the imposition of Western intellectual property regimes in the Global South. [226, 227, 228] This work will also therefore look to consider the extent to which distributive justice, particularly a Rawlsian *maximin* analysis, can be applied to the question of scope of positive rights in traditional knowledge associated with genetic resources.

In summary, the key justifications examined in this work are:

a) Deontological justifications:

i) Lockean desert-based justification for property
ii) Kantian authorial personality
iii) Fichtean right based on personality
iv) Hegelian right based on personality

b) Consequentialist (including utilitarian) justifications:

i) The incentive to innovate
ii) The incentive to commercialise
iii) The incentive to preserve
iv) Preservation of global health

c) Distributive justice

[226] Margaret Chon, "Intellectual Property from Below: Copyright and Capability for Education" (2007) 40 UC Davis L Rev 803

[227] Keith Aoki, "Distributive Justice and Intellectual Property: Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)" (2007) 40 UC Davis L Rev 717

[228] Anupam Chander and Madhavi Sunder, "Is Nozick Kicking Rawls's Ass? Intellectual Property and Social Justice" (2007) 40 UC Davis L Review 563

d) Communitarian justifications

e) Restorative/corrective Justice

3.5 Deontological Justifications

3.5.1 Lockean desert-based justifications

3.5.1.1 Locke's theory of property

John Locke's *An Essay on Concerning the True Original, Extent, and End of Civil Government* was published in 1689[229] (the so-called "Second Treatise" of Locke's *Two Treatise of Government*). This was in Britain, and elsewhere, a period during which the absolute power of monarchs was the subject of fierce debate, to (and beyond) the point of revolution. Locke's views on absolute monarchs, the origins of a sovereign's authority and the need for separation of powers informed much of the thinking of revolutionary political philosophers and lawyers thereafter, including those involved in drafting the United States Declaration of Independence and Constitution.[230]

A key element of Locke's thesis, the justification for the ownership of property in private hands, is found at Chapter V (entitled "Of Property") of the *Second Treatise*[231]. For Ferguson there is an argument that Locke's theories on property set the course for the foundation of a widely distributed private property rights and broad-based democracy in the British colonies in North America, Australia, New Zealand and the United States.[232] Locke's theory of property has also become an important element in the academic analysis of the justification for intellectual property rights. Locke's thesis can be summed up as follows:

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[229] Although there is argument over the date of the composition of the work. See Peter Laslett, *Locke, Two Treatise of Government* (Cambridge University Press, Cambridge 1988), 45

[230] AC Grayling, *Towards the Light, The Story of the Struggles for Liberty and Rights That Made the Modern West* (Bloomsbury, London 2007), 114

[231] Laslett (n229), 285

[232] Niall Ferguson, *Civilization, The West and the Rest* (Allen Lane, London 2011), 107

a) At some point in an indeterminate past (but at least before the advent of a monetary economy) mankind existed in a "State of Nature" governed by the "Law of Nature";

b) Within that State of Nature the World and all therein had been granted by God to Mankind to be held in common. This combined holding of the resources of the world is referred to as "the Common";

c) Within this State of Nature the number of humans inhabiting the planet is small in comparison to the essentially inexhaustible resources of the Common. The Common can provide for all;

d) To be useful to humans the resources of the Common need to be harvested in some way, whether it be foraging, hunting or fishing;

e) Every man has property in his own person, similarly the labour of his body and the work of his hands belong to that person;

f) When a person removes a resource from the Common he mixes his *labour* with it. That person owns his *labour* and by mixing it with the resource he joins to the resource something which is his own which makes the resource part of his own property.

g) In so doing the resource is removed from the Common for the exclusive use of that person.[233]

h) In applying labour to a resource such as to remove a resource from the common a "*property"* is *"begun*" in the resource.

i) At the time of removal of the resource from the common there is no requirement that there be any consent from the other commoners (essentially the broader community) for the "property" to begin;

[233] Laslett, (n 229), 288 (Locke Chapter V Paragraph 28.)

j) For a "property" to begin, however, there is a requirement that there is "*enough, and as good left in the common for others*". This has come to be known as the "enough and as good" proviso;

k) The removal of the resource cannot be to an extent that would result in the spoiling of unused resource.[234] This has come to be termed the "waste" exception or "non-waste" requirement.

l) These principles apply not only to fruit, game and other resources, but to the land itself. The improvement of untamed land to enhance the resources that can be created on it will begin a property in that parcel of land. This accumulation of a right in land is subject to the same exceptions as other resources. If the land is unused it returns to the common and may be appropriated by another who will work and improve the land.[235]

m) It is the application of labour which gives value to something whether it be food, resources or land. The greater the application of labour to a thing or land the greater the value developed in that thing or land.

n) Where a man harvests more than he can make use of without the harvest decaying, but uses the excess to barter for something else that he needs, or does not perish (such as precious metals or diamonds), that would not fall foul of Locke's waste exception. This is beginning of a monetary economy. Locke states:

> "And *thus came in the use of Money*, some lasting thing that Men might keep without spoiling, and by mutual consent Men would take in exchange for the truly useful, but perishable Supports of Life." [236]

o) The use of money uncouples the amount of land that a person may properly own without breaching the waste exception. Where a man can accumulate wealth through accumulation of non-perishables (such as gold, silver or diamonds) then he can

[234] Laslett (n 229), 290 (Locke Chapter V, Paragraph 31)

[235] Laslett (n 229), 294 (Locke Chapter V, Paragraph 36)

[236] Laslett (n 229), 300 (Locke Chapter V, Paragraph 46)

accumulate more land than can immediately support his family without "wasting" the Common.

p) Such non-perishables are not of themselves of value, as they do not of themselves contribute to feeding, clothing and transporting a man. Their value arrives only from the consent of the community. [237]

q) As societies developed, the initial ownership of property under the Law of Nature, created through the application of labour, became recognised through tacit acceptance of the community and eventually formalised through positive laws of an organised government.

It should be stressed that within Locke's thesis the tacit acceptance of the value of imperishable metals or money (and which allows the development of unequal holdings without breaching the waste exception) remains separate from the tacit acknowledgement of holdings in land.

If Locke's theory is to be accepted as correct, *in toto*, then it has a major implication which was identified by Locke himself. Where peoples are considered *not* to be mixing their labour with the land, then the land itself and the natural produce which it creates remain part of the Common. If such land is in the Common then it is free to be brought into private ownership by the application of labour to it. Even where labour *is* being applied to the land, in the absence of a monetary economy the waste exception would apply such that any holding could only be justified if it were small enough to support a family without causing waste to the Common. Locke refers a number of times to the uncolonised portions of the Americas as an example of a continuation of the State of Nature where the land and its resources remain in the Common. Of course, at the time of Locke's writing (1689) the east coast of North America was progressively being developed by English and French colonies which were converting the native forest to farm land.[238, 239, 240]

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[237] Laslett (n 229), 302 (Locke Chapter V, Paragraph 50)

[238] Lawrence James, *The Rise and Fall of the British Empire* (Abacus, London 1995), 3

Writers such as Shiva[241] consider Locke's theories on property to be part of the philosophical underpinning to Western ideas justifying the exploitation of "vacant" land, a way of thinking which she describes as legitimising colonial exploitation within the British Empire and the United States and as a justification for the dispossession of indigenous peoples across the globe. Locke was in fact involved with drafting the constitution of one British colony (Carolina) and it would seem at least likely that a philosophy which would provide direct legitimisation for the British colonists' expropriation of land from indigenous hunter-gatherer peoples was within his contemplation.

Locke's theory of property has formed the basis of a libertarian, Neo-Lockean school of thought. Perhaps foremost amongst these "Neo-Lockeans" is Robert Nozick who argues that justice in property holdings relies upon a just *initial* acquisition of the property from the Common and a just chain of transfers thereafter.[242] Where a transfer in the chain is in some way improper Nozick allows for a "rectification" of title – what Radin calls a theory of "corrective justice".[243]

3.5.1.2 The Lockean Justification for Intellectual Property

The Lockean theory that one can gain property over the Common through the application of one's labour, has been applied to the creation of an exclusive property right in ideas – ideas that were (until they were conceived of) in a "Common" of yet to be had ideas. By analogy with Locke's theory of property over tangible goods, here it is the application of labour (that is the work done in conceiving the idea) that is sufficient to wrest the idea out of the "Lockean Common" and into private ownership. This

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[239] Don Gillmor and Pierre Turgeon, *Canada, A People's History* (Vol 1) (McClelland & Stewart, Toronto 2000), 76

[240] Niall Ferguson, *Empire* (Penguin, London 2003), 55

[241] Shiva (n 18), 3

[242] Robert Nozick, *Anarchy, State and Utopia* (Basic Books, New York 1974), 175

[243] Margaret J Radin, *Reinterpreting Property* (University of Chicago Press, Chicago 1993), 106

concept has been looked at considerable length by Hughes [244] who considers the Lockean justification in many ways more appropriate for intangible ideas than for tangible property. Hughes believes that the propertizing of ideas under the Lockean model can be justified if three propositions can be met. These propositions are:

a) The production of ideas requires a person's **labour**;

b) These ideas are appropriated from a Lockean Common which is itself not significantly devalued by the ideas removal from it (in compliance with the "**enough and as good**" proviso); and

The ideas can be made property without breaching the **non-waste condition**.

Hughes states that Locke's theory of property can be interpreted in two ways:

i) Society rewards labour with property on *instrumental* grounds. Society *must* give a reward or no-one will provide their labour ; or

ii) On a normative basis, labour *should* be rewarded with property.

3.5.1.3 Labour - Avoidance

Taking the first point, Hughes states that in the Lockean model a person's handiwork becomes their property because the work of an individual's hands and "the energy, consciousness, and control that fuel their labour" is their own. Hughes asks the question whether the act of conceiving ideas can indeed be referred to a "labour" in the Lockean sense. Labour is most often thought of as physical "sweat of the brow" activity. Hughes suggests that many might suppose that the work of producing ideas is preferable to manual labour. However, Hughes suggests that even if this is correct in some cases even those working on developing ideas may in fact prefer to be doing something less onerous - creation being for most people less fun than recreation. Hughes states:

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[244] Justin Hughes, "The Philosophy of Intellectual Property" (1988) 77 Geo LJ 287

> "Although "idea work" is often exhilarating and wonderful, it is something we generally have to discipline ourselves to do, like forcing oneself to till the fields or work on assembly lines."[245]

Hughes refers to this as the "avoidance" view of labour. He suggests that there are two distinct strands to this avoidance approach: a normative proposition of Locke's labour theory (the very unpleasantness of labour justifies a reward) and an instrumental argument (that no one would perform labour without reward – a position itself based on a utilitarian foundation that the product of labour generally enhances the public good). Hughes argues that although the instrumental argument is often provided as proof of the normative position, and both can coexist, neither in fact requires acceptance of the other to be valid.

Hughes suggests[246] that Locke had the utilitarian position in mind when he stated that "*he who appropriates land to himself by his labour, does not lessen but increase the common stock of mankind*"[247]. Hughes feels that the instrumental argument has dominated case law and judicial announcements and where the normative "labour deserves reward" position has emerged, it is as an adjunct to the instrumental position.

Hughes believes that the wide acceptance of the instrumental argument - that developing ideas is sufficiently unattractive that it needs to be encouraged by the reward of an intellectual property right, supports the argument that the work done in creating ideas is sufficient to meet the Lockean labour requirement.[248]

3.5.1.4 "Labour-desert" or "value added" theory

Hughes also examines the "value-added" or "labour desert" interpretation of Locke's labour justification. This approach is not based on the unpleasantness of labour – indeed Hughes states that this understanding of property does not, in fact, require an understanding of the concept of labour *per se*. Hughes comments that labour *per se*, no

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[245] Hughes (n 244), 302

[246] Hughes (n 244), 299

[247] Laslett (n 229), 294 (Locke Chapter V, Paragraph 37)

[248] Hughes (n 244), 304

matter how arduous, could potentially create nothing of value to broader society, or something which was only of value to the labourer himself. What is important in the value added approach is that the labour expended produces something *of value* to society – something beyond what morality requires the individual to produce. Hughes comments that judicial or legislative statements that fuse the normative and instrumental elements of the labour avoidance justification are probably based, unknowingly, on the value-added theory. Hughes goes on to say that although the value-added theory is often thought to be an instrumentalist approach – inventors/creators will be incentivised to add value to the Common provided they have some personal gain, there is a normative proposition that such inventors/creators *should* be rewarded if they have enhanced the commonweal, even if personal gain was not what actually incentivised them to enhance the Common.

3.5.1.5 The "enough and as good" requirement

In Locke's theory during the early days of the Common it is essentially inexhaustible. The acquisition of a part of the Common through the application of labour by one family does not in practice remove part of the Common from anyone else, so there is no moral reason why the first labourer should not acquire property over the subject of his labour – his acquisition is *non-competitive*.

In relation to tangible property the period during which a labourer could truly acquire property in the Common in a non-competitive manner would be short lived – the Common would not have "enough and as good" for very long.

By propertizing an idea out of the Common of potential ideas is the inventor/creator exhausting that Common? Once propertized that particular idea is now outwith that Common, but is there an inexhaustible supply of "enough and as good" ideas remaining in the Common? Hughes suggests that the idea of the effectively inexhaustible Common applies more properly to intangibles than to tangible property. Indeed other than in extraordinary circumstances (and even then only for a very short time) the concept of the inexhaustible Common can *only* apply to the Common in ideas.

3.5.1.6 The "permanent common"

Notwithstanding this "inexhaustibility", if one does allow propertization of the ideas Common are there certain ideas which should never become propertized?

Hughes believes that the prevention of private propertization of certain central ideas allows intellectual property law avoid the inequitable control of core resources that can be present in physical property systems. He states:

> "Even in a vast wilderness, an individual should not be permitted to claim certain physical goods as property because their extraction will not leave "as good and as many" for the remaining individuals. The "New World" prior to its colonization may have been as close to a Lockean common as human history records, yet it is easy to make a list of things which the society could not allow to be appropriated as private property: the Amazon, St. Lawrence and Ohio Rivers, the Cumberland Pass, or the St. George's Bank fisheries."[249]

Hughes considers that there are two broad classes of idea that should not be subject to propertization these are his "everyday ideas" and "extraordinary ideas" which he mentioned in his overview of what constitutes an intellectual property right. In respect of everyday ideas (such as washing the car, taking the dog for a walk) allowing for their propertization would breach the "enough and as good" proviso since they are so fundamental to everyday existence that their removal from the Common would unavoidably deplete the Common. In respect of "extraordinary" ideas Hughes sees these as falling into two categories: those which are important because they reveal fundamental information about the functioning of the universe (such as mathematical concepts and algorithms and scientific discoveries) and those which, although initially amenable to property ownership, become with time and use increasingly important to the functioning of society and accordingly become "depropertized" – akin perhaps to the genericisation of trade marks.

Hughes sees the spectrum of protectable ideas as sitting between the two extremes of common and extraordinary ideas. However, he identifies that ideas related to the two

[249] Hughes (n 244), 320

extremes can be protectable. Car washing *per se* is unprotectable, a new car washer can be. Integral calculus *per se* is unprotectable whereas a new notation to express it can be.

3.5.1.7 The non-waste condition

As mentioned above the aspect of Locke's theory of property which has the most logical difficulty is the non-waste condition and the allowance for enhanced land holding through the acquisition of non-perishable metals and jewels. Hughes believes that many intellectual property systems no not embody, or require, a non-waste condition. The core component to his argument is that ideas do not "spoil" in the way that natural produce may. He argues that although some may say that ideas are perishable (in that stories become old, literature styles become outdated, technologies become obsolescent) there is in fact no *real* deterioration in the idea and the loss is only seen against the social background and may (dependent on trends in fashion or technology developments) be reversible. [250]

Hughes does not believe that the lack of requirement for a non-waste condition is fatal to the application of the Lockean theory of property to intellectual property (particularly given the rapidity with which Locke moves away from the non-waste condition with the advent of imperishable assets/ monetary economy). Indeed, as was mentioned earlier, Hughes believes that the "enough and as good" requirement probably only holds true for the concept of a Common of ideas and:

> "That may mean that Locke's unique theoretical edifice finds it firmest bedrock in the common of ideas"[251]

Although in conclusion Hughes believes that elements of a Lockean argument to justify intellectual property are powerful he does not believe that a pure Lockean solution is complete. As he states:

> "Those who try to apply Locke to all modern property end up multiplying distinctions like pre-Copernican astronomers calculating celestial orbits with their

[250] Hughes (n 244), 328

[251] Hughes (n 244), 329

Ptolemaic epicycles. At some point it becomes easier to reorient one's universe." [252]

3.5.1.8 Post-Hughes Analysis

Attas[253] takes a substantially less charitable approach to the Lockean justification than Hughes. Attas particularly tackles the question of Locke's positive method of private appropriation. Locke provides in the "mixing" of a labourer's own labour with the Common a "mechanism" by which a previously commonly-owned aspect of the Common comes into the private ownership of the labourer. Attas highlights Nozick's [254] point that even if labour can be "owned" in any real sense why should its mixing with the Common allow ownership in an aspect of the common rather than *vice versa*?

Attas also quotes Shiffrin who argues against a Lockean basis for intellectual property on the grounds that something which originates in our own mind (though "owned" whilst an idea in our own heads), cannot be used to control others once it has been dissipated into the public domain.[255]

Attas' principle focus is, however, on what he terms the "problem of origination".

If Locke's positive method of private appropriation, whereby an individual acquires a *prima facie* exclusive claim to previously commonly held resources, is to operate one has to be able to identify with certainty the ideas which are to be appropriated. Attas argues that any ideas can be either discoveries, inventions or artistic creations. However, regardless of its type, no idea is created in a vacuum. All ideas arise out of the societal background of their time. New discoveries rely upon previous discoveries, new inventions incorporate previous technology, and artistic creations whether musical, dramatic or in the visual arts incorporate styles, patterns and concepts from previous

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[252] Hughes (n 244), 330

[253] Attas (n 48), 29

[254] Nozick (n 242)

[255] Seana Valentine Shiffrin, "Lockean Arguments for Private Intellectual Property" in Stephen R Munzer (ed) *New Essays in the Legal and Political Theory of Property* (Cambridge University Press, Cambridge 2001) 165

work. One cannot with any absolute certainty determine the "origination" of the idea from that which went before. Attas argues that within a formalised intellectual property system one can develop mechanisms by which one can determine (for the sake of a particular right) where the old ideas stop and where new ideas begin. However, for Attas this approach is one of *convention* not one of *natural* law.

Attas also looks at Locke's third proviso the negative requirement that others' interests would not be harmed by appropriation (whether through the enough and as good requirement or the non-waste requirement). Attas' key argument under the head of "non-harm to others" is in relation to what he describes as the "individuation" of ideas. The problem relates to defining the boundaries of what you seek to individuate. Attas acknowledges that there can be difficulties in defining the boundaries of a tangible object. Attas quotes Nozick's question:

> "If a private astronaut clears a place on Mars, has he mixed his labor with (so that he comes to own) the whole planet, the whole uninhabited universe or just a particular plot?" [256]

However, part of the problem can be addressed by the fact labour is purposive and this defines the extent of the object laboured upon. For Attas, however, many discoveries and inventions are merely serendipitous and such chance discoveries cannot be defined by the purpose of the inventor. Attas' view is that defining the boundary of an idea is more difficult than for tangible property and can be "baffling". [257]

Attas also briefly looks at questions of imitation, parody and inspiration and the question of where an idea ends. He is also concerned about the difference between a general abstract idea and the specific details that are required to put the general idea into practice and the question of whether such specifics are caught within the general.

However, difficult as these questions are, most troubling for Attas is the question of whether ownership of an idea should extend to ownership of an *identical* idea even where such an idea is arrived at independently by a third party (as is the case with

[256] Nozick (n 242), 174

[257] Attas (n 48), 47

patents) what Attas calls a "path-independent extension of the right in the idea", or should allow for free ownership of an independently conceived idea provided there is no copying nexus back to the original idea (as is arguably the case with copyright), what Attas terms – "a path-dependent extension of the right in the idea".

Attas accepts that positive law can handle these types of problems making "*reasoned and principled justifications for intellectual property in some cases and rejecting it in others*"[258] . As with the problem of origination, his argument is that the uncertainty leads one to conventional approaches based upon a consequentialist analysis, rather than a Lockean *natural* law justification.

For Attas, the difficulty with regard to certainty and being able to draw a *natural* line, is enhanced by the "squeeze" between certainty in origination and certainty in individuation. He states that for clear origination you need to reject background and contributory influences. For clear individuation you have may need to include offshoots and derivatives of the ideas. The two positions are in Attas' view contradictory (a little like the classic *Gillette* squeeze [259] in UK patent law between patent validity and claim scope mentioned above). Atta states:

> "The dual problems of origination and individuation pose a thorny problem even for a conventionalist account. For it appears that the more we are willing to recognise the owner as the originator of the idea, brushing aside inputs of preceding ideas, the less we are able consistently to recognise offshoots of the idea as within it. That is to say, the narrower we individuate the intellectual product. For we cannot have it both ways: that the idea owes nothing to its predecessors yet its successors are wholly indebted to it."[260]

The problems of origination and individuation are significant difficulties for the practical application of the Lockean account (as will be seen below when we seek to use it in the determination of the justifiable scope of positive rights in traditional knowledge

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[258] Attas (n 48), 52

[259] *Gillette Safety Razor Co v Anglo-American Trading Co Ltd* [1913] 30 RPR 465

[260] Attas (n 48), 53

associated with genetic resources). Although Dutfield & Suthersanen are sensitive to these problems (stating that Locke's theory of property might be considered as being "too basic and outdated" at its core) they highlight that it does at least serve to identify the inherent conflict which sits at the heart of an intellectual property right. They state that:

> "since the beginning there have been two competing stakeholders: the labourer (inventor, author, investor, entrepreneur) and the "commons" (which can be other labourers or competitors within the market or societal welfare sector such as health or education).
>
> Hence, Locke's theory is useful in urging us to consider the need for the existence and maintenance of a "public domain" (as opposed to several private domains) or an intellectual commons (as opposed to intellectual property)." [261]

3.5.1.9 The Lockean model as applied to Traditional Knowledge

How might one apply a purely Lockean model to traditional knowledge associated with a genetic resource? We might look in the first place to the following scenario: an indigenous group uncover (through serendipity or deliberate and iterative "trial and error" or a combination of both) a useful characteristic of a particular plant. Such information may have been determined within one generation or added to by serendipity/trial and error over a series of generations. As Hughes would apply Locke's model, it is the application of "labour" the process of discovering the information (which previously resided in the idea Common) which would entitle the group to claim rights to control the information.

Although they approach the question in relation to the creation of artistic works, Munzer & Raustiala [262] have provided perhaps a systematic (and an almost consistently negative) analysis of justifications of intellectual property to the question of traditional knowledge. They examine the justification of an intellectual property right in traditional

[261] Dutfield & Suthersanen (n 209), 55

[262] Stephen R Munzer and Kal Raustiala, "The uneasy case for intellectual property rights in traditional knowledge" (2009) 29 Cardozo Arts & Entertainment Law Journal 39

knowledge under the Lockean principle of desert based on labour. They have no conceptual objection to a traditional knowledge right residing in a *group* – for them it is open to groups to obtain rights based on a joint contribution. However, they identify a problem with a right in traditional knowledge: the original "investigators/creators" are "*by definition*" dead. They question whether (even if such originators were entitled to rights commensurate with their labour) it is correct that the originator's "desert" should extend to their distant descendants or unrelated inhabitants of a region who have subsequently come to know of the knowledge. Surprisingly, they do not seek to apply (or criticise) Nozick's neo-Lockean entitlement theory approach[263] that where property has been justly acquired (appropriated from the Common) in the past (and where subsequent transfers are just) then the claim of title to the property *in the present* can be justified.

At this point Munzer & Raustiala also consider that where the indigenous group have endeavoured to keep a piece of traditional knowledge secret that the group should have a right to control access to that information and bring an action for misappropriation for a breach of confidentiality but give no real reason why or indeed how such reasoning fits into an analysis of a Lockean justification for rights in traditional knowledge.

Munzer & Raustiala examine the Lockean justification further under the concept of "firstness". They state that firstness, (being the first to make, obtain or occupy the property) does not, of itself, provide a strong general or specific justification for property rights but does provide a particular justification where "*disputes over desert or incentives prove very difficult or costly on other grounds*".[264]

Munzer & Raustiala briefly examine the Lockean case for intellectual property. Munzer & Raustiala conclude (without any strong justification) that provided one looks at the Lockean Common of future ideas as one which is an "open-access common" rather than one in which the idea resources are owned in common, then a firstness argument may have merit.

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[263] Nozick (n 242), 151

[264] Munzer & Raustiala (n 262), 62

Notwithstanding this, Munzer & Raustiala's principal difficulty with the firstness argument is similar to that raised by them in relation to labour desert. Even *if* firstness matters, the current holders of the traditional knowledge were *not* in fact the first to make the discovery (or to individualise the idea out the Common to use the Lockean analogy) and Munzer & Raustiala do not see why the descendants should be entitled to a right which may be justified only to their remote ancestors. Again, surprisingly, they do not seek to apply or criticise Nozick's just entitlement approach.

Munzer & Raustiala imagine a situation in which traditional knowledge rights are asserted in a centuries old traditional dance and look at the incremental changes in that dance with time. Their analysis is as follows:

i) Perhaps the "originators" of the dance in fact borrowed elements from other long lost dances of their ancestors or from other groups. We cannot know;

ii) Looking at incremental changes may give separate "layered" rights to the individual increments, but not to the *entirety* of the dance; and

iii) Enquiries into firstness would likely be very fact specific and in fact entirely indeterminate in the absence of written records.

Can such an argument be flawed because it is actually a trans-temporal "group" which has progressively developed the dance and it is this "group" which can lay claim to the traditional rights rather than the membership of that group from time to time? Whist Munzer & Raustiala accept that such a claim may weaken their "remote descendant" critique (but do not say why), they revert back to the argument that firstness does not, in any case, provide a justification for specific or particular intellectual property rights. They also add that the trans- temporal group claim requires an *indefinite duration* of the right in the dance to allow the bundle of rights in the dance to develop and amalgamate. However, they believe this is counter to the need to balance private property rights against the public interest (which has driven the development of limited durations for intellectual property rights) but give no philosophical rationale for why traditional knowledge should, or should not, be time limited.

Munzer & Raustiala's concern about the difficulty in identifying the source of the traditional knowledge right seems to echo Attas' broader concern about the problem of origination (and the problem of individuation). However, is their problem actually a sub-category of Attas' broader philosophical concern? Munzer & Raustiala's concern appears predominantly to be in relation to the practical *evidential* problems envisaged in finding the source of the information – there is an argument that their concern would be met if substantial written evidence were for whatever reason available.

Although they do not mention it, Munzer & Raustiala's observation of the potential complexity seen in determining the origin and scope of a particular piece of knowledge does seem to provide further evidence in support of Attas' argument that it is hard to see a *natural law* justification for intellectual property rights in general.

It would also suggest that Attas' reasoning can comfortably be extended to a traditional knowledge right (which Attas himself did not address) and may suggest that traditional knowledge (particularly where the information is of a trans-generational and/or of an inseparably amalgamated nature) is an area in which the problems of origination and individuation can be particularly difficult – not unlike questions of jointly originated artistic works.

3.5.2 Personality-based Justifications for Intellectual Property

Broadly speaking there are three related arguments under this head. The first is Kant's limited, but interesting, arguments against pirated books based on "authorial personality". The second is based on Fichte's ideas of rights based on personality. The third is based on Hegel's broad metaphysical system. Each will be dealt with in turn.

3.5.3 The Kantian Justification

3.5.3.1 Kant on property ownership

As we have seen, the Lockean-desert account for intellectual property rights relies upon an extension of Locke's original views relating to the first ownership of a piece of tangible property (land or the produce of land) into claims to ownership over a portion of the supposed *terra nullius* of "as yet to be had ideas". This account is grounded in Locke's key principle of self-ownership, a self-ownership which serves as the fount of ownership of things extrinsic to the self.

Kant's justification of ownership of property, though similarly deontological, is founded on a radically different basis – namely the individual's *innate* right to freedom. For Kant, the right to ownership of property in things is *not* an inherent natural law right, but is merely derivative upon a person's inherent right to control his affairs.[265, 266, 267] Accordingly, in his *Metaphysics of Morals* of 1797, Kant defines property in this way:

> "...that is rightfully mine...with which I am so connected that another's use of it without my consent would wrong me." [268]

The most direct way in which a person can be connected with something is by *physical* possession, what Kant describes as "sensible" possession. However, if free beings are to be able to realize their inherent freedom by using objects for their freely chosen purposes one cannot require that they retain physical possession of them at all times. So for Kant:

> "...something external would be mine only if I may assume that I would be wronged by another even though I am not in possession of it." [269]

- mere physical possession is not, of itself, sufficient to create ownership of an object. The possession required to give effect to individual freedom is "intelligible possession" where the owner is deprived by the action of a third party on the owner's property even if the property is spatially separate from the owner and even if the owner is unaware of the actions of the third party.

Of course, having intelligible possession of a particular object requires all other free beings to respect that possession and refrain from using that object. The unilateral declaration of intelligible possession would impact on the freedom of others and

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[265] Paul Guyer, *Kant on Freedom, Law and Happiness* (Cambridge University Press, Cambridge UK, 2000), 236

[266] Allen D Rosen, *Kant's Theory of Justice* (Cornell University Press, Ithaca, New York, 1993), 19

[267] Allen W Wood, *Kantian Ethics* (Cambridge University Press, Cambridge UK, 2008), 197

[268] Immanuel Kant, The Metaphysics of Morals (1797) 6.245 (in Mary J Gregor (translator & ed) *Immanuel Kant, Practical Philosophy* (Cambridge University Press, Cambridge UK, 1996), 401

[269] Gregor (n 268)

interfere with the universality of the right to freedom. However, universality can be maintained if all free beings agree to respect other's claims to intelligible possession. The mutual obligation to respect property rights can only exist within a society – a civil condition - which provides a mechanism to acknowledge and police such ownership and to determine competing claims. Indeed, for Kant, the creation of a condition in which the property is respected and protected is one of the reasons why free individuals are obligated to work towards the achievement of a civil state.

So far the theory addresses how existing claims to ownership are respected. How, though, are initial claims to ownership treated? In Chapter 2 of the *Metaphysics of Morals*[270] Kant describes a stepwise process by which an object comes into the ownership of an individual through original acquisition. It is a process consistent with his categorisation of sensible and intelligible possession:

i) *Apprehension* of an object which belongs to no one (otherwise it would conflict with another's freedom in accordance with universal laws). This apprehension is taking possession of the object in space and time – *possessio phaenomenon*; followed by

ii) *Giving a sign (declaratio)* of your possession of this object and of your intention to exclude everyone else from it; followed by

iii) *Appropriation (appropriatio)* – as the act of the general will of the community giving an external law through which everyone is bound to agree with your choice of acquisition.[271]

Empirical possession requires priority in time relative to anyone else who seeks possession of it and originality requires a unilateral choice to acquire.

Under this principle where one has a *terra nullius* of land the individual is free to seek to acquire land. However, this initial acquisition – what Kant refers to as "taking control" or *occupatio* - gives rise only to a "provisional" ownership which requires confirmation by the consent of others. Obtaining provisional ownership requires that the

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[270] Gregor (n 268), 411

[271] Gregor (n 268), 411

acquirer give a signal to the world at large that a claim is being made – be it a "keep out" sign or a fence. Crucially, however, the provisional acquirer has to have the *physical* capacity to keep control of the land against others. The turning of provisional ownership into a finalised ownership requires broad consensus that you own the property – indeed it is only once all have consented to your ownership that it becomes truly valid. To reach this stage requires "negotiation" with others supervised and policed by those in authority within society. Kant is unclear as to the exact process for resolving conflict over disputed claims, but is clear that the parties have a duty to arrive at settlements which tend to secure a fully civil condition for society. Alongside this, property claims in general grow more finalised as society advances to a fully civil condition.[272]

3.5.3.2 Kant and Intellectual Property

Can this philosophy of ownership be extended to ownership over intangibles such as ideas? There is a glaring problem. The key to Kant's *occupatio* phase of acquisition is that the prospective owner must have the wherewithal to *physically* defend his acquisition against all comers. As mentioned at the beginning of this chapter tangible objects whether it be land (or the fruit of that land) are rivalrous and physically excludable. Intangible things, such as ideas, are just the opposite – in the absence of a formal mechanism securing protection - they are non-rivalrous and non-excludable. No physical mechanism of acquisition or defence is possible.

As we have seen Locke's natural right theory is arguably amenable to a logical leap into the realm of the *terra nullius* of "as yet to be had" ideas – it does not rely on physical defence of the acquired property. In contrast, the extension of Kant's *occupatio* into this sphere is significantly more problematic. Kant himself states that:

> "Original acquisition of an external object of choice is called taking control of it (*occupatio*), and only corporeal things (substances) can be acquired originally"[273]

[272] Marcus Verhaegh, "Kant and Property Rights" (2004) 18(3) Journal of Libertarian Studies 11, 12

[273] Gregor (n 268), 412

Indeed, there is further evidence that Kant would never have intended such an extension of his account for the acquisition of property into the realm of intangibles.[274] In 1785, Kant published his essay *Of the injustice of Counterfeiting Books* in which he proposed a *sui generis* right of "authorial" personality. According to Pievatolo,[275] Kant saw this authorial right as a *ius personale* (a right to compel others to do things) rather than an invention of a new *ius reale* (right in property). In doing so, Kant saw himself as following the Roman law tradition in which only tangible objects – *res quae tangi possunt* – are amenable to ownership.

As Dutfield and Suthersanen highlight, [276] at the time of Kant's writing *Of the injustice of Counterfeiting Books,* the Holy Roman Empire [277] was a complex mosaic of independent states. With no consistent overarching law controlling the printing and selling of books the situation was rife for trade across the Empire in pirated books. Kant was seeking a justifiable mechanism for preventing this piratic trade. Kant divided a book into three theoretical elements:

i) a mere physical commodity – bound pages with writing on;

ii) as a means for conveying thoughts; and

iii) as a "speech"

In relation to i) when the purchaser purchases a book she purchases *that* book and owns *that* object and may dispose of it as she wishes. However, save for lighting fires and propping up tables, that book has little value without the input of the author. In relation to ii) reprinting of books cannot prevent the original author from conceiving her thoughts – ideas cannot be stolen as they are not property. [278] Accordingly neither

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[274] Maria Chiara Pievatolo, Freedom, ownership and copyright: why does Kant reject the concept of intellectual property? (2010) http://ssrn.com/abstract=1540095 (Accessed September 2015)

[275] Pievatolo (n 274)

[276] Dutfield & Suthersanen (n 209), 56

[277] Famously stated by Voltaire to be "neither holy, nor Roman, nor an empire". François-Marie Arouet (Voltaire), *Essai sur l'histoire générale et sur les mœurs et l'esprit des nations* (1756) Chapter 70

[278] Pievatolo (n 274), 3

element i) nor element ii) will give a right to prevent reprinting of books. Indeed, as *ius reale* can only apply to things and not to ideas, the purchaser of a book may reproduce the work for themselves as they are merely doing something with their private property.

To find a justification for preventing commercial reprinting Kant has to invoke a separate, *ius personale*, mechanism. Accordingly, Kant sees a book as a "speech" or an "action" by the author – an *opera* – which in 1785 could only be conveyed to a wider audience through the medium of the book. As Dutfield & Suthersanen put it:

> "To Kant, the author retains the opera or speech. It is not a commodity to be sold and bought. The book as opus is merely the mute instrument which holds the book as opera." [279]

Why should this focus on the concept of a book as speech matter? Pievatolo puts it thus:

> "To speak in the name of another without his authorization is like engaging in a relationship with another without his consent. As personal rights, according to Kant, concern relations among free beings, they can arise only from expressed agreements. Hence the unauthorised printer is like the unauthorized spokesperson, who produces a relation to the author with the public without being entitled to do it." [280]

Clearly Kant in some respects anticipates the ideas of modern copyright in that there is a concept of a right in the work which sits separately from the vessel in which the work resides (be it a book, magnetic tape or digital format). However, his idea of *opera* in a work is not, as we have seen, a *property* right. It is arguably a good deal closer to the concept of a moral right in a work, but it is more than a right to attribution or a right to prevent derogative treatment. Neither, however, does it include a right to prevent creation of derivative works (perhaps as it cannot interfere with the creation of ideas). Kant's concept of *opera* is narrow and does not extend to other art forms.[281] In many

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[279] Dutfield & Suthersanen (n 209),57

[280] Pievatolo (n 274), 3

[281] Pievatolo (n 274), 4

respects Kant's thinking in relation to the rights of the publisher bears a closer similarity to the concept of unfair competition than to copyright *per se*.

For Pievatolo, Kant's deliberately narrow approach to controlling piracy is consistent with his overall philosophy. She concludes her paper [282] by stating that Kant sticks to the Roman Law tradition (that *ius reale* cannot apply to intangibles) not because of conservatism, but because of Enlightenment - liberty of speech is an important part of the innate right of freedom and cannot be suppressed without suppressing freedom itself.

3.5.3.3 Kant and traditional knowledge

To what extent can Kant's ideas on the protection of property, and his limited right to authorial personality, assist with the question of the justification for a right to veto use of traditional knowledge associated with genetic resources?

Kant's theory of acquisition of property expressly excludes ownership in intangibles - an exclusion which is consistent with his concept of a narrow scope of protection offered by a right to authorial personality. Any attempt at application of Kant's account for property to the present question requires us to go back to first principles. Traditional knowledge, even traditional knowledge associated with genetic resources, and even knowledge with the most practical of applications, remains a body of intangible *ideas.* According to Kant there can be no ownership in ideas.

We might seek to suggest that indigenous peoples have through the use of secrecy, social structure and of taboos, sought to exclude third parties from appropriating a particular piece of knowledge and in so doing placed a clear *declaratio* to the world that the information was theirs and that they thereby sought to derive "provisional" ownership over the information. However, since no *possessio phaenomenon* is possible in respect of an intangible, any attempt to seek such provisional ownership must fail.

Notwithstanding this failure, can we seek to apply Kant's concept of "authorial personality" to the question? Authorial personality as described in *On the injustice of Counterfeiting Books* is, as we have seen, deliberately limited. It will not create any sort

[282] Pievatolo (n 274), 7

of property in ideas. However, it does argue that anyone who seeks to act as a "spokesperson" for an author will require their consent to do so. In *On the injustice of Counterfeiting Books* it is the reprinting of a book – the "retelling" as it were of the *opera* inherent in the original book (without the consent of the author) that is amoral, since it creates a relationship between the author and the publisher without the author's consent.

Can we say that a group of indigenous peoples are in a sense an author? The Kantian authorial personality account is strongly reliant on the innate freedom of *the individual*. No matter how close knit, it might be difficult to describe a group of indigenous people as a single individual. Of course, the closer knit, and less dispersed the group, the closer they may approximate to an individual. However, there will be a continuum of closeness of relationships across varying indigenous groups and it is impossible to say with any certainty what the requisite "closeness" to create an authorial identity should be.

Even if, for the sake of argument, we assume that a close knit indigenous group *can* have the requisite authorial personality, does unauthorised use of the information created by the group within a pharmaceutical research process constitute an unauthorised "retelling" of the *opera* - the "speech" of the indigenous group in the information? It is hard to say whether a piece of information can be considered a "speech" as such. On the one hand, Kant does not provide us with a *de minimis* definition below which the subject matter of a book is in some way unworthy of being a speech. On the other hand, it is hard to envisage that the oral divulgement of a piece of information by one or more members of an indigenous group to (say) an ethnobotanist, constitutes authorial "speech" in the way that Kant envisaged.

Assuming, again for the sake of argument, that misuse of a piece of information does constitute unauthorised "retelling" of the speech within the information, we need to remind ourselves that the mischief which Kant sought address relied upon the presence of two (or more) competing publishers, one authorised, the other not. We need also to note that Kant's proposed solution was that the unauthorised publisher would pay damages to the authorised publisher. Kant does not propose any form of *injunction* preventing the unauthorised publisher from publishing (enforceable by the author or the rightful publisher). Such an approach would seem consistent with Kant's view that property rights (giving the right to *exclusive* use) cannot exist in intangibles. His solution, though compensating the rightful publisher, still allows the ideas within the work to continue to be disseminated.

Following Kant's approach "authorial personality" approach closely (and for the moment accepting the many assumptions made above), it might appear that if the indigenous group were to give consent to one pharmaceutical company to utilise a piece of traditional knowledge associated with genetic resources, the group would not have a power of *veto* over unauthorised use by a second pharmaceutical company, but the authorised user may have a right of *compensation* from the unauthorised user.

Do we, though, need these competing "publishers" for Kant's approach to apply? Is there some broader principle within Kant's approach which will allow us to examine misuse in the absence of an authorised "publisher"/user? As discussed above, Kant's theoretical basis for the right to authorial personality relies upon the innate freedom of the individual to enter into relationships only with consent and the "relationship" with the unauthorised publisher is created by the unauthorised publisher without the author's consent. Kant himself makes a "universal observation"[283] which includes reference to the relationship between the author and his editor. He states:

> "...the editor transacts his business of editor not merely in his own name, but in the name of another (namely the author) and without consent cannot transact [it] at all."[284]

This highlights the importance which is seen throughout the essay on the "name" of the author (which is of course closely linked to the personality of the author). Later in his universal observation, Kant clearly expresses that works of art may be imitated and are to be seen as distinct from the written word as they are not the "speech" of a named author:

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[283] Immanuel Kant "Of the injustice of counterfeiting books" (1785) http://staffweb.hkbu.edu.hk/ppp/fne/essay3.html , 7 (Accessed September 2015)

[284] Kant (n 283)

> "But the writing of another is the speech of a person (opera); and whoever publishes it can speak to the public only in the name of this other, and say nothing more of himself than that the author makes the following speech to the public through him."[285]

Crucially Kant allows the production of derivative works as they are no longer the speech of the original author:

> "When one in the meantime alters (abridges or augments or retouches) the book of another, so that it would now be wrong even to give it out under the name of the author of the original; then the retouching in the proper name of the publisher is no counterfeit, and therefore not prohibited. For here another author transacts through his editor another business than the first, and consequently seizes this in his business with the public not a bit; he represents not that author, as speaking through him, but another. Likewise, the translation into another language cannot be held to be a counterfeit; for it is not the same speech of the author, though the thoughts may be exactly the same."

The right envisaged by Kant therefore seems to sit more closely to a right to protect of goodwill and reputation than one which controls *ideas*. As is stated above, it is in many ways a form of unfair competition provision in favour of *named* authors.

Can we apply this general principle to our indigenous group holding traditional knowledge associated with genetic resources? Even assuming a sufficient degree of closeness such that the group can be considered an "author", the information they hold seems much closer to mere information than to Kant's "speech". Downstream use of traditional knowledge associated with genetic resources is very likely to be divorced from the "name" of the indigenous group and in any event much will be akin to the derivative works which according to Kant's account are free to use.

To conclude, attempting to "shoehorn" the Kantian concept of authorial personality into service as a justification for protecting traditional knowledge associated with genetic resources is fraught with difficulties. In fact, the clearest message that we get from

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[285] Kant (n 283)

Kant's theory of property, which is consistent with his concept for authorial personality, is that ideas cannot ever be prevented from being used. Even Kant's remedy for breach of authorial personality was *compensatory* rather than a right to veto use. Kant's approach therefore appears to militate against any right veto on the non-consensual use of traditional knowledge associated with genetic resources.

3.5.4 The Fichtean Justification

3.5.4 .1 Fichte and Intellectual Property

Johan Gottlieb Fichte outlines his justification for the protection of intellectual property in his essay *The Illegality of the Unauthorised Reprinting of Books,* published in 1793 [286] (eight years after the publishing of Kant's *Of the injustice of Counterfeiting Books*). Fichte's philosophy broadly follows that of Kant, in being based on the inherent freedom of the individual. However, in looking at the protection of authors he arrives at a somewhat different outcome. [287, 288] As we have seen, Kant's justification for preventing the unauthorised reprinting of books is based on the relationship between the author and the public (and publishers), and the concept that a book incorporates the "speech" of the author. Unlike Kant, who rejects outright the idea, Fichte accepts that there can be some ownership of intangibles. For Fichte a book consists of the physical, tangible elements (paper, bindings &c.) with which a purchaser of the book can do as she likes, and separate "non-physical" elements.

These non-tangible elements can be divided into the following:

i) the ideas in the book (the "material" or "content"); and

ii) the expression of the ideas (the "form").

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[286] Graham Mayeda "Commentary of Fichte's "The Illegality of the Unauthorised Reprinting of Books: An Essay on Intellectual Property During the Age of the Enlightenment" (2008) University of Ottawa Law & Technology Journal 141, 171

[287] Mayeda (n 286), 171

[288] Pievatolo (n 274), 4

In relation to the ideas in a book, Fichte believed that once ideas are published by an author they are placed into the public domain. Mayeda[289] gives two reasons why Fichte believed this should be the case:

a) the acquisition of ideas entails no interference with the thoughts or physical person of the author; and

b) in producing a work for public consumption, the author must have wished to communicate the ideas and share them with others.

In marked contrast with this position in relation to ideas, Mayeda goes on to explain that in Fichte's account;

> "The right to appropriate and use the form in which the ideas are expressed is not transferred to the purchaser. The form of expression is a creation of the author; it is a unique expression of her personality. It follows that any use or appropriation of form entails a violation of the personality of the author."[290]

This marked divide in the treatment of an idea *per se* and the form in which the idea is expressed would appear to foreshadow modern copyright law.

3.5.4 .2 Fichte and traditional knowledge

Can we apply Fichte's concept of protection of expression to an indigenous group holding traditional knowledge associated with traditional knowledge? Again we have got a significant problem (as we had with Kant's approach) in apportioning a personality to a group. However, even assuming a sufficient degree of closeness such that the group can be considered an "author" for these purposes, we must stress that the traditional knowledge held by the group is much closer to being an idea *per se* than to an expression of that idea.

As we have seen, Fichte does not have an objection to the protection of ideas based on any inherent difficulty with "owning" an intangible (as was the case with Kant) - his

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[289] Mayeda (n 286), 151

[290] Mayeda (n 286), 152

exclusion of ideas *per se* is, to some degree, based on the intention of the author to share her ideas with the world. In relation to traditional knowledge held by an indigenous group, the question of whether they are seeking/have sought to share such knowledge will depend on the circumstances in which the information is divulged. However, the difficulty with the protection of ideas *per se* within Fichte's account is inherent within the way he sees authors connecting with ideas – it is the way in which ideas and their connections are communicated to others through words and mental images – how there are *expressed* - which are unique to the author and which give rise to the personality right.

To the extent that the traditional information is held in some form which embodies a group *expression* of the idea, that expression could fall within the ambit of Fichte's right based on personality. However, any downstream use of the information within drug discovery is very unlikely to be using any particular "form" in which the information is originally held. Any form will likely to have been jettisoned early within the passage of the traditional knowledge through the research process and downstream use will likely be use of pure information, e.g. "plant A is useful for treating disease X". It is difficult to see how such pure information could be the subject of Fichte's right protection *expression*. Accordingly Fichte's approach (as did Kant's) militates against any right of veto over the non-consensual use of traditional knowledge associated with genetic resources.

3.5.5 The Hegelian Justification

3.5.5.1 The Hegelian Justification for Property

Hegel's Elements of the Philosophy of Right (*Grundlinien der Philosophie des Rechts*) was published in Berlin in 1821. This includes his discussion of the role of and justification for property rights.

Hegel's broader philosophy has attracted substantial criticism. Warburton summarises many views thus:

> "That question "What does it mean?" is one that readers of Hegel's work ask themselves a lot. His writing is fiendishly difficult, partly because, like Kant's, it

is mostly expressed in very abstract language and often used terms that he has himself invented. No one, perhaps not even Hegel, has understood all of it."[291]

and

> "...Hegel irritated many philosophers. Some philosophers even treated his work as an example of the risk of using terms imprecisely. Bertrand Russell came to despise it, and A.J. Ayer declared that most of Hegel's sentences expressed nothing at all. For Ayer, Hegel's writing was no more informative than nonsense verse and considerably less appealing."[292]

However, Russell states that:

> "Even if (as I myself believe) almost all Hegel's doctrines are false, he still retains an importance which is not merely historical, as the best representative of a certain kind of philosophy which, in others, is less coherent and less comprehensive." [293]

Hughes [294] states that Hegel's justification for property are rooted in his general philosophy – the individual's will is at the core of an individual's existence and is constantly seeking actuality (*Wirklichkeit*) and effectiveness in the world. Personality is related to the will's struggle to actualise itself, and a person must translate his freedom into an external sphere in order to exist as an "Idea". Dutfield & Suthersanen summarise the property theory thus:

> "Hegel declared that property is the initial and final embodiment of freedom and individuality. Indeed, to fail to have a sphere of property in one's own life is to

[291] Nigel Warburton, *A Little History of Philosophy* (Yale University Press, New Haven and London 2011),126

[292] Warburton (n 291), 127

[293] Bertrand Russell, *History of Western Philosophy* (Routledge Classics, London and New York 2004), 667

[294] Hughes (n 244), 331

> fail to attain self-conscious knowledge of oneself as a free person. To achieve a personality, and to be a person, an individual must control his external and internal environment and control his resources. Once again, control (as well as actualisation of one's will) is best achieved by a set of property rights."[295]

For Hughes[296] assertion of the self alone is not sufficient to create a property right, any claim to property must be acknowledged and approved. Through such acceptance, the will's possession of an object (through "occupation" or "embodiment") becomes property. Hughes believes that although Hegel seems to support a "first possession" or labour theory, this is not what Hegel means by "occupation". Although the will can only occupy something which is a virgin object (or something which has been abandoned) this first occupation is, in itself, insufficient. A property right is only retained so long as the will in some way manifests itself in the object; The will must continue to *want* the object and is required to *continually reaffirm* this desire. Accordingly, the property right can be lost through a failure to reaffirm, or by active withdrawal. Hughes states that although application of "labour" to an object may denote occupation it is not a necessary prerequisite – one may equally manifest will in a natural object to which one has become *emotionally* attached. Hughes further states that *use* of an object is not a requirement for occupation. He also states that marking or imposing a form on an object or keeping the object in close spatio-temporal proximity to an individual can all be helpful indicia of the individual's will, but again these are not *requirements* for occupation. Similarly abandonment of an object depends on the will's desire to possess an object, and does not require external indicia.

3.5.5.2 The Hegelian Justification for Intellectual Property

The application of Locke's property theory to the field of intellectual property requires something of a theoretical stretch with the imagining of a "Common" of putative ideas and the acquisition of parts of that Common through the application of labour. Although Hegel's concept of property is perhaps not as intuitively easy to grasp as Locke's, its application to the realm of intellectual property (particularly in artistic works) arguably

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[295] Dutfield & Suthersanen (n 209), 58

[296] Hughes (n 244), 334

requires something less of an intellectual stretch. In fact, as Hughes states[297] for Hegel intellectual property does not need to be justified by analogy to physical property and indeed, for Hughes, the analogy to *physical* property distorts the Hegelian relation between personality, mental traits and the will.

Hegel identifies that people may be hesitant to call intellectual attainments which are created by the mind "things". However, in Paragraph 68 of his *Elements of the Philosophy of Right*, Hegel outlines *why* intellectual property rights should exist. The paragraph is instructive, particularly in the way in which it appreciates the non-rivalrous nature of intangible intellectual products:

> "The distinctive quality of intellectual production may, by virtue of the way in which it is expressed, be immediately transformed into the external quality of a thing, which may then in turn be produced by others. In acquiring it, the new owner may thus appropriate the thoughts which it communicates or the technical invention which it embodies, and it is this possibility which at times (as with literary works) constitutes the sole purpose of such things and their value as acquisitions; in addition, the new owner at the same time comes into possession of the *universal ways and means* of so expressing himself and of producing a multiplicity of such things." [298]

Hegel notes that the creation of such proprietorship is not "without utility":

> "The purely negative, but most basic, means of furthering the sciences and arts is to protect those who work in them against *theft* and to provide them, with security for their property, just as the earliest and most important means of furthering commerce and industry was to protect them against highway robbery." [299]

The Hegelian justification for property and intellectual property rights has been subject to criticism. Firstly, we have to appreciate that Hegel was seeking to develop an entire

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[297] Hughes (n 244), 333

[298] Allen W Wood (ed) and HB Nisbet (translator), *G W F Hegel, Elements of the Philosophy of Right* (Cambridge University Press, Cambridge 2003), 98

[299] Wood & Nisbet (n 298), 99

(and distinct) metaphysical system and one arguably needs to be careful not to use elements of his philosophy in a "pick-and-mix" manner outwith the context of his metaphysic system of the self. Indeed, Harris states that:

> "Some Hegelian apologists regard it as an impertinence to seek to quarry justice reasons at all from Hegel's writings. Hegel's aim was to reveal the working out of World Spirit through the march of history. Steps in this process should only be analysed from within his metaphysical structure." [300]

However, even assuming that Hegel's overall metaphysical system is not flawed, and that elements are not taken out of context, commentators have identified particular difficulties *within* the Hegelian property theory as it specifically applies to intellectual property. There are two key points: the question of alienation of the self and the question of what type subject matter is actually covered by Hegel's concept of intellectual property.

Alienation

Whereas Hegel believes that one can alienate most "real" property when one no longer wishes to occupy it, one of the basic tenets that underlie his philosophy is that one cannot alienate (or surrender) any universal element of one's self. Hughes,[301] Moore, [302] and Dutfield & Suthersanen[303] identify Hegel's concern in relation to whether this inalienability can be applied to intellectual products: does the giving away (or selling) of an item which embodies the expression of an idea act as an alienation of the ownership of that expression?

For Dutfield & Suthersanen,[304] the "crux" of Hegel's justification for intellectual property is given in Paragraph 69 of his *Elements of the Philosophy of Right*:

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[300] James W Harris, *Property and Justice* (Oxford University Press, Oxford 1996), 232

[301] Hughes (n 244), 320

[302] Moore (n 211), 8

[303] Dutfield & Suthersanen (n 209), 58

[304] Dutfield & Suthersanen (n 209), 59

> "Since the person who acquires such a product[305] possesses its entire use and value if he owns a *single* copy of it, he is the complete and free owner of it as an individual item. But the author of the book or the inventor of the technical device remains the owner of the *universal* ways and means of reproducing such products and things, for he has not immediately alienated these universal ways and means as such but may reserve them for himself as his distinctive mode of expression."[306]

Here Hegel identifies one of the crucial characteristics of most intellectual property (with the exception perhaps of *droit de suite* or artists' resale rights) namely that the right exists separately from a *particular* thing incorporating the right. Here also perhaps can be seen the beginning of the doctrine of exhaustion of rights (or first sale doctrine), namely that in selling a particular item incorporating the right the owner of the right can only control the initial sale, but not subsequent sales.

Subject Matter

What type of intangible intellectual product is the subject matter of Hegel' extension of the personality? We saw above that neither Fichte, nor Kant, gave justifications for the control of information as information *per se*. Paragraph 68 of Hegel's *Elements of the Philosophy of Right* (set out above) appears to have a focus on the "expression" of an individual as the basis for the existence of the right.

As Hughes highlights there exists a spectrum of intellectual products that demonstrate varying degrees of personality of the author of the work: from (at one end) works of art which arguably contain a substantial embodiment of the author's personality, through to (at the other) end computer programs, chip topography masks, client lists and industrial patents.[307]

Hughes posits that the higher the degree of technical constraint within an object or problem, the less opportunity there is for personal expression. Generally speaking an

[305] This is a product embodying an expression of the author of a thing.

[306] Wood & Nisbet (n 298), 99

[307] Hughes (n 244), 344

artist is constrained only by her materials and her opportunity for expression is accordingly very large. Hughes believes that at some point the technical constraints will become so large that any meaningful expression of the personality is impossible. He stresses, however, that even creation of a highly technical intellectual product may still provide some limited mode of expression of the personality of the creator – there may be many ways to achieve a similar technical end but the creator can choose between them, and in doing so expresses her personality. In addition, a creator may become known for a particular solution, even if that solution style is acknowledged only within a small coterie.

Hughes points out that this analysis refers only to *one* variety of expression, namely one in which the intellectual work becomes the *conduit* for the expression personality. He points out that another potential Hegelian property claim exists where the creator claims the property in order to *create* (rather than *express*) a particular persona. Hughes believes such a claim has limits – one cannot simply seek to be associated with a thing without there being some *internal* connection. He points out that it is true that certain inventors become associated with their inventions (Hughes refers to Doppler, Edison and Bell but there are, of course, many others). However, those relationships arise in time as a result of the invention, not necessarily due to an *initial* assertion of personality.

Although his writing is far from clear, Hegel himself seems to give guidance (within Paragraph 69) that his concept of property in intangible concepts should extend only to the control of ideas which are embodied in a particularly *form*. He accepts that those who are made aware of an idea may themselves be entitled to rights where that idea is put into a new form:

> "Besides, the destiny of a product of the intellect is to be apprehended by other individuals and appropriated by their representational thinking, memory, thought, etc. Hence the mode of expression whereby these individuals in turn make what they have learned ... into an alienable thing will always tend to have some

> distinctive *form*, so that they can regard the resources which flow from it as their property, and may assert their right to reproduce it."[308]

Although the point is by no means clear, it would appear that Hegel's concept of intellectual property (though covering the physical embodiment of technical concepts) follows the thinking of Fichte and Kant in not extending to the protection of ideas *per se*.

3.5.5.3 Hegel and traditional knowledge

How can we apply Hegel's justification for intellectual property to an indigenous group holding traditional knowledge associated with genetic resources?

Munzer & Raustiala do not formally address a Hegelian personality-based justifications for a right in traditional knowledge. However, they do approach the issue under the head "Moral Right of the Community".[309]

They consider the question of whether a "moral right" of an indigenous community in relation to a piece of traditional knowledge should give rise to an intellectual property right in that knowledge. They state that the concept of moral right (or rights) as arising in the civil law tradition and point to the French *droit moral* and German *Urheberpersönlichkeitsrecht* ("originator's personality right") as examples. They state that although the rationale for such rights is disputed, most often its basis is said to be the idea of personality or personhood developed by Kant, Fichte and Hegel. They also highlight that these rights, which include a right of attribution and a right to prevent derogatory treatment of a work, are essentially non-economic in nature.

Munzer & Raustiala believe that for such moral rights to apply to an indigenous group one would have to envisage that that group acted together as an "author" since it is the personality (or personhood) of the author which is central to the idea of a moral right. They accordingly ask:

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[308] Wood & Nisbet (n 298),100

[309] Munzer & Raustiala (n 262), 68

> "In what sense if any could a community have a "personality"? In what sense if any could one ascribe "personhood" to a community? Stereotypes are to be resisted, in part because they subsume all members of a group under one image. We do not say that these questions lack a non-stereotypical answers. However, we fail to see a clear path to satisfactory answers."[310]

They ask whether the moral right of the community may potentially form the basis of a *sui generis* right of *indefinite* duration because:

a) citing Tsosie[311], as indigenous peoples face a special threat to their culture they should have a right to control "*who can tell their stories and who can use their designs and symbols*"; and

b) since the *actual* creator and the *moment* of creation (or fixation) of the traditional knowledge cannot be determined no other form of intellectual property could be available.

Munzer & Raustiala argue against such a justification. The moral right argument is strongest for them if one can assume that the indigenous people who are claiming the right approximate as closely as possible to a single "personality", for example they lived in a tight-knit group in one location and their language, culture and practices remain virtually constant. Although they accept that this may exceptionally be the case, they argue that in the great majority of situations this situation is disrupted by migration of individuals (in and out), intermarriage of individuals from other linguistic/cultural groups, and the adoption of external cultural ideas and practices, a process they describe as cultural "hybridization" or "blending". Whilst stating that such hybridisation is in general a "good thing" they note that it provides a problem for a traditional knowledge based on group personality:

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[310] Munzer & Raustiala (n 262), 71

[311] R Tsosie, "Reclaiming Native Stories: An Essay on Cultural Appropriation and Cultural Rights" (2002) 34 Ariz St LJ 299, 310

> "across the span of history, every cultural group has possessed [traditional knowledge]...This raises the question why indigenous people's [traditional knowledge] ought to receive protection that other group's knowledge lacks".[312]

They further argue that although it might be logically consistent to extend indefinite, group-related protection to all folklore (wherever it may be found) this would be disproportionate. Munzer & Raustiala believe that a proportionate response, based on moral right, would be:

a) *divulgation* the right to make an item of their traditional knowledge known to the world and in this respect "public" but to retain the power to keep that item from being used in any way by others – and therefore out of the public domain in a different respect; and

b) *attribution*: the right to prevent attribution of the knowledge to any other group.

Given Munzer & Raustiala's general opposition to a *sui generis* positive right in traditional knowledge, on other grounds, this does appear to be a major concession. In fact, their "divulgation" right looks very close to a positive right in all but name. It is strange that they support this because, by their own argument, there remain significant problems to attributing a Hegelian (or Kantian, or Fichtean) personality to an indigenous group both in terms of the containment of its membership and in temporal aspects (when is the personality meant to exist – when the traditional knowledge was developed or evolved or "fixed" by contact with the West?).

Although, the closer knit the body holding the knowledge arguably the stronger a personality basis for an intellectual property right in such knowledge, we need to note that (as Oguamanam[313] stresses) the ways in which such knowledge is held is in no way uniform. Oguamanam cites Drahos who states:

> "Indigenous peoples have perhaps evolved more complex structures for access and use of knowledge than western communities...Some knowledge may be open

[312] Munzer & Raustiala (n 262), 72

[313] Chidi Oguamanam, *International Law and Indigenous Knowledge* (University of Toronto Press, Toronto 2006), 158

> to all (including non-indigenous people) to use...some knowledge may be open to all clan members to use...while other knowledge may only be available to the initiated...and some individuals may be given temporary appropriation rights over some knowledge."[314]

Oguamanam also points to the work of Gupta [315] who highlights that fact that contribution of indigenous community members to innovation and conservation will not be equal.

The problem in apportioning a personality to a group is clearly difficult. However, even if we can assume within a particular situation that there is a sufficient degree of closeness such that the group can be considered an "author" for the purposes of justifying a Hegelian (or Kantian or Fichtean) personality right there is a greater problem.

As was identified above, traditional knowledge associated with genetic resources is much closer to being information *per se*. There seems no reason then to suggest that Hegel's justification should not encounter the same difficulties as seen with the application of Fichte's justification. If the basis for a right is based upon expression of an idea, that justification will fail to support a justification for a right in information *per se*. Accordingly, for this author, Hegel's approach (as did Kant's and Fichte's) militates against any right of veto on the non-consensual use of traditional knowledge associated with genetic resources where such knowledge is an *idea* rather than the expression of an idea.

Although he does not address the philosophies of Kant, Fichte or Hegel, it is interesting to note that Taubman[316] envisages that traditional communities can have a "collective" personality. For Taubman:

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[314] Peter Drahos, "Indigenous Knowledge and Duties of Intellectual Property Owners" (1997) 11 IPJ 179, 186

[315] A Gupta, "Getting Creative People, Individuals and Communities Their Due: Framework for Operationalizing Articles 8(j) and 10(c)" (1996) Paper submitted to the Secretariat of the Convention on Biological Diversity, 120

[316] Antony Taubman, "Is there a right of collective personality?" [2006] EIPR 485

> "The right of personality includes the entitlement to choose what face is presented to the public, unless the public interest trumps private interests; it is a right not to have a public personality imposed upon one, but to retain control over one's public identity. In a parallel manner, indigenous communities claim control over their collective cultural persona as a form of self determination. ...protection of a community's collectively held [traditional knowledge] and [traditional cultural expressions] does not mean simply closing off links with other cultural communities or the commercial domain, but about choosing what aspects of the collective identity may be used and disseminated beyond the community, and on what terms—including the recognition of customary law constraints on the use of elements of a community's cultural identity."[317]

For Milius, however, there are some difficulties with this account:

> "One of the conceptual problems with such a move is that the essence of distinctive characters is their identifiable variable for personhood, and combining a large number of them into a collectivity really does not alter the separateness of their individual autonomy associated with their individual personhoods. This means that the whole cannot be considered the sum of its parts in the gaze of the law, but really as various collective superseding qualities of the whole (in this case having to do with traditional values and customs) which generally prevail over individual noise in the mix."[318]

To the extent that Taubman's collective persona applies to the protection of cultural *expression* there very are clear echoes of the thinking of Kant, Fichte and Hegel in relation to the protection of the persona. However, Taubman also sees indigenous collective personality as encompassing not only the way in which a collective persona, or its outward expression, is represented but to the control of traditional knowledge *per se*:

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[317] Taubman (n 316), 490

[318] Djims Milius, "Justifying intellectual property in traditional knowledge" [2009] IPQ 184, 196

> "There are external and internal aspects to the sense of violation that arises when traditional personality is appropriated. External exploitation of [traditional knowledge] and [traditional cultural expressions] is seen as misappropriation—a taking, theft or even conversion—of cultural or intellectual property; but it is also sensed as intrusion on the community itself."[319]

The question of whether "information" as such should be properly considered to be part of the collective external persona of an indigenous group remains moot and will vary from group to group. There are of course strong echoes here of the "utility through control" discussed later in this Chapter. There are also strong echoes of Gibson's communitarian justification discussed below (in which a right to control traditional knowledge arises out of the right of a community to manage its affairs). Indeed, if Taubman's collective personality can encompass information *per se* it might perhaps be more properly treated as a part of a communitarian or a utility through control justification rather than being seen as within the "rights based on personality" philosophy of Kant/Fichte or Hegel. Indeed such a treatment also addresses Milius's concern with regard to the difficulty of pooling individual identities.

3.6 Human Rights Justifications

3.6.1 Human Rights Justifications for Intellectual Property in General

The two major heads set out above, Locke/ labour-desert and rights based in personality constitute by far the major deontological justifications for general intellectual property rights, at least in terms of analysis and commentary. However, the question of the justification for intellectual property within the context of developments in international human rights law also needs to be considered.

Dutfield & Suthersanen[320] consider three main international human rights documents which touch upon intellectual property rights to be:

a) The Universal Declaration of Human Rights ("UDHR") 1948;

[319] Taubman (n 316), 487

[320] Dutfield & Suthersanen (n 209), 215

b) The International Covenant on Economic, Social and Cultural Rights ("ICESCR") 1966; and

c) The International Covenant on Civil and Political Rights ("ICCPR") 1966.

Article 27 of the UDHR states that:

> "(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
>
> (2) Everyone has the right to the protection of the **moral and material interests resulting from any scientific, literary or artistic production of which he is the author**."[emphasis added]

This is supported by rights to property ownership in Articles 17:

> *"(1) Everyone has the right to own property alone as well as in association with others.*
>
> *(2) No one shall be arbitrarily deprived of his property."*

And rights protecting reputation under Article 12:

> *"No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks."*

The UDHR is not a legally binding document, but its provisions were put into legally binding form through the ICESCR and ICCPR. As is stated by Dutfield & Suthersanen[321], the ICCPR fails to provide a positive basis for intellectual property rights although moral rights are indirectly protected through Article 17 of the ICCPR which essentially repeats the wording of Article 12 UDHR.

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[321] Dutfield & Suthersanen (n 209), 217

Articles 19(2) and (3) ICCPR provide an indirect acknowledgement of intellectual property rights in relation to a proviso to the right to a freedom of expression stating:

> 2. Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice.
>
> 3. The exercise of the rights provided for in paragraph 2 of this article carries with it special duties and responsibilities. It may therefore be subject to certain restrictions, but these shall only be such as are provided by law and are necessary:
>
> > (a) For **respect of the rights or reputations of others**;
> >
> > (b) For the protection of national security or of public order (ordre public), or of public health or morals. [emphasis added].

Arguably, however, the strongest reference to intellectual property rights comes from Article 15 of the ICESCR which follows the provisions of Article 27 UDHR. Article 15 states that:

> “1. The States Parties to the present Covenant recognize the right of everyone:
>
> (a) to take part in cultural life;
>
> (6) to enjoy the benefits of scientific progress and its applications;
>
> (c) to benefit from the protection of the moral and material interests resulting from any **scientific, literary or artistic production of which he is the author**.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
>
> 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields.” [emphasis added]

In the view of Dutfield & Suthersanen[322] Article 15 identifies a requirement to balance on the one hand the right to access scientific and cultural good with on the other the right of authors and inventors to be protected without identifying the legal means by which this balance should be achieved. Arguably then the right for authors and inventors to have some form of balanced protection is a human right. This would not, however, necessarily seem to be the case.

In November 2005, the UN Committee on Economic, Social and Cultural Right issued its General Comment No. 17 (2005) in relation to Article 15, Paragraph 1 (c), of the ICESCR (the “General Comment”). This is a somewhat confusing text. It essentially states that whereas human rights are fundamental, as they are inherent to the human person as such:

> “intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole” [323]

This is, of course, essentially a restatement of a consequentialist, incentivisation of creativity, position. It also states that in contrast to human rights:

> “intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, often with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even

[322] Dutfield & Suthersanen (n 209), 218

[323] UN Committee on Economic, Social and Cultural Right General Comment No. 17 (2005), Para 1

forfeited, human rights are timeless expressions of fundamental entitlements of the human person." [324]

It thereby concludes that:

> "Whereas the human right to benefit from the protection of the moral and material interests resulting from one's scientific, literary and artistic productions safeguards the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living, intellectual property regimes primarily protect business and corporate interests and investments. Moreover, the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements. It is therefore important not to equate intellectual property rights with the human right recognized in article 15, paragraph 1 (c)."[325]

The general Comment goes on to give normative guidance to states in terms of giving effect to Article 15(10(c). For Dutfield & Suthersanen[326] it is clear that the concern of the Committee was that intellectual property rights had become too closely associated with large corporate entities, rather than individual authors/creators. So there is in the General Comment support for the moral interests element of the human right (more akin perhaps to a Kantian/Fichtean authorial personality). The treatment of the "material" interests is less clear, but seems to relate to a right for the author to obtain an adequate standard of living:

> "Unlike other human rights, the material interests of authors are not directly linked to the personality of the creator, but contribute to the enjoyment of the right to an adequate standard of living (Art. 11, para. 1).

[324] Comment No 17 (n 323), Para 2

[325] Comment No 17 (n 323), Para 2 to 3

[326] Dutfield & Suthersanen (n 209), 219

The term of protection of material interests under article 15, paragraph 1 (c), need not extend over the entire lifespan of an author. Rather, the purpose of enabling authors to enjoy an adequate standard of living can also be achieved through one-time payments or by vesting an author, for a limited period of time, with the exclusive right to exploit his scientific, literary or artistic production." [327]

It would be fair to conclude that the position of intellectual property rights as human rights, (with the exception of moral rights for authors to ensure attribution and prevent derogative treatment) is far from clear.

Dutfield & Suthersanen point to the Solemn Declaration adopted at the Centenary Assembly of the Berne Union as the only intellectual property treaty that makes reference to human rights when it states:

"...that copyright is based on human rights and justice, as creators of beauty, entertainment and learning, deserve that their rights in their creation be recognized and effectively protected both in their own country and in all other countries of the world." [328]

There are perhaps in this phrase clearer echoes of Hegelian personal "recognition" and Lockean reward than to human rights *per se*. In any event, as Dutfield & Suthersanen point out, the status of the Solemn Declaration is legally ambiguous. Dutfield & Suthersanen go on to put forward the counter argument that classic intellectual property rights (again with the exception of moral rights for authors to ensure attribution and prevent derogative treatment) cannot be human rights as they run counter to the social and ethical aims of human rights law. Whereas human rights laws do advocate some type of "reasonable" reward, that reward can be delivered in alternative ways than simply giving the author/inventor monopolistic rights to prevent copying/exploitation. Dutfield & Suthersanen point to indigenous peoples' rights in ancestral knowledge (presumably to benefit sharing) as an example of such an alternative approach.

[327] Comment No 17 (n 323), Paragraph 15 to 16

[328] Dutfield & Suthersanen (n 209), 221

3.6.2 Human Rights and Intellectual Property Rights in Traditional Knowledge

In September 2007 the General Assembly on the United Nations adopted the UN Declaration of the Rights of Indigenous Peoples ("UNDRIP"). Although this Declaration broadly addresses the rights of indigenous people, there are three articles (11, 24 and 31) of specific relevance to the question of traditional knowledge (and related genetic resources):

Article 11

> "Indigenous peoples have the right to practise and revitalize their cultural traditions and customs. This includes the right to maintain, protect and develop the past, present and future manifestations of their cultures, such as archaeological and historical sites, artefacts, designs, ceremonies, technologies and visual and performing arts and literature."
>
> "States shall provide redress through effective mechanisms, which **may include restitution**, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs." [emphasis added]

Article 24

> "Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals..."

Article 31

> "Indigenous peoples have the right to maintain, **control**, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, **control**,

> protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions." [emphasis added]
>
> "In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights."

Article 38 also provides that States shall take appropriate measures, including legislation, to achieve the ends of UNDRIP. However, UNDRIP gives no specific detail on how these broad ends should be achieved.

Whereas Article 15(1)(c) ICESCR (in the light of the interpretation provided by the General Comment) would seem to exclude intellectual property rights as being a basic human right, Article 11 and Article 31 arguably go further in establishing some right to control traditional knowledge *per se* and intellectual property in that traditional knowledge (in Article 31). However, the nature of that "control" within Article 31 is unclear: it certainly does not *expressly* extend to an absolute veto over third party non-consensual use (and with it injunctive relief).

Somewhat more clarity is provided by Article 11, which establishes that there should be "effective" redress which "may include restitution". What does "restitution" mean in this context?

In relation to tangible property (including land) one would imagine that "restitution" reasonably means the restoration of property misappropriated without free, informed prior consent. However, in relation to intangible property such a return cannot be affected. One then has to ask whether in such circumstances compensation in lieu of restitution could constitute "effective redress". Crucially, UNDRIP itself makes no express mention (anywhere) of whether the right to "free, informed prior consent" also gives rise to a right to veto future, or ongoing, third party use. However, working from first principles, if UNDRIP entitles me (as a minimum) to restitution of misappropriated tangible property that restitution would, by virtue of the rivalrous nature of the use of tangible property) of necessity prevent use of that property by the misappropriator. In the light of this, it would seem strange that the appropriate redress in relation to intangible property would not similarly prevent use of that property by third parties – *i.e.* a veto.

Given the import placed upon preservation and revitalisation of indigenous culture within UNDRIP one has to ask why intangible property should be disadvantaged relative to tangible property simply by dint of the non-rivalrous nature of its use.

However, this rather simplistic analysis is complicated by the fact that Article 28 of UNDRIP (which relates to the misappropriation without free, prior and informed consent of indigenous lands, territories and resources) has specific reference to the award of "just, fair and equitable compensation" when restitution is not possible. This compensation should "take the form of lands, territories and resources equal in quality, size and legal status or of monetary compensation or other appropriate redress".[329] One might ask: If monetary compensation is appropriate address for misappropriation of real property, why should that not be suitable redress for intangible property? We might also ask how much we should read into the absence of compensation wording within Article 11.

Although not specifically focussing on Article 11, Sargent [330] has recently highlighted the difficulties and uncertainties which have been created by the lack of clear language within UNDRIP with regard to free, prior and informed consent and the creation of veto rights. She points to the work of the International Law Association Rights of Indigenous Peoples Committee (2006 - 2012)[331] which concludes that UNDRIP create some veto rights in relation to some Articles but not in relation to others. However, in relation to Articles 10, 11, 28 and 29 the ILA committee conclude that:

> "such a [veto] right seems to exist with respect to measures of relocation of indigenous peoples from their lands or territories, measures resulting in the taking of indigenous peoples' cultural, intellectual, religious and spiritual property or

[329] UNDRIP Article 28(1)

[330] Sarah Sargent, "What's in a name? The contested meaning of free, prior and informed consent in international financial law & Indigenous rights" in Valentina Vadi and Bruno de Witte (eds) *Culture and International Economic Law* (Routledge, Oxford 2015) 87, 96

[331] International Law Association, Rights of Indigenous Peoples Committee (2006 - 2012) Sofia Conference (2012) Final Report (http://www.ila-hq.org/en/committees/index.cfm/cid/1024) (Accessed September 2015)

lands, territories and resources, as well as measures of storage or disposal of hazardous materials in the lands or territories of indigenous peoples."[332]

However, no reasoning is given for this position is given. The view that UNDRIP creates veto rights is not universal. The permanent mission of Canada to the United Nations has stated that Canada does not interpret free, prior and informed consent as providing indigenous peoples with a veto[333] Sargent concludes that the ILA Final Report gives no "detailed clarity on when FPIC is required to be used, or what it means-consult, consent or more – in any given situation."[334]

Broadly speaking then, we cannot be clear whether UNDRIP envisages a veto right to prevent third party misappropriation of traditional knowledge or a right to compensation for misuse.

As Savaresi[335] highlights, UNDRIP is not legally binding upon the members of the UN. Of course many UN members are signatories of the Protocol and UNDRIP is expressly "noted" in the preamble to the Protocol and Article 4(3) of the Protocol expressly states that it should "*be implemented in a mutually supportive manner with other international instruments relevant*" to the Protocol.

However, as has been noted by Morgera *et al.*[336] if UNDRIP is limited to providing compensatory relief this would appear to have been exceeded by the access and benefit sharing requirements of the Protocol.

3.7 Consequentialist Justifications for Intellectual Property

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[332] Sofia Conference Report (n 331), 7

[333] http://www.canadainternational.gc.ca/prmny-mponu/canada_un-canada_onu/statements-declarations/other-autres/2014-09-22_wcipd-padd.aspx?lang=engV (Accessed September 2015)

[334] Sargent (n 330), 98

[335] Savaresi (n 75), 66

[336] Morgera, *Unravelling the Protocol* (n 74), 119

The consequentialist justifications for intellectual property tend to be those most commonly expressed by intellectual property practitioners, judges and politicians and in the preambles to intellectual property legislation, whilst (for Merges):

> "often intoning one of a few stock passages penned in a spare moment by Thomas Jefferson" [337, 338]

Such justifications for intellectual property generally start from the broadly utilitarian perspective that intellectual creativity and innovation *per se*, and the betterment of society though the resultant enhanced intellectual and economic wealth that arises from these activities and their commercialisation, are things which enhance the "greater happiness of society". This enhancement is to be achieved through the adoption of policies which encourage and support the creation of intellectual products. Moore[339] sums up the theory in the following terms:

i) society in general ought to attain an optimum of social utility;
ii) as part of this aim, society should seek to optimise the amount of intellectual works being produced;
iii) a necessary condition for promoting the creation of valuable intellectual works is granting limited rights of ownership to authors and inventors;
iv) without certain guarantees as to the control of production of copies, authors and inventors might not engage in producing intellectual works;
v) although the success of such policies cannot be ensured' failure is inevitable if those who incur no investment costs can seize and reproduce the intellectual effort of others; and therefore
vi) adoption of systems of protection (such as copyright, patent, and trade secret) yields an optimal production of intellectual production, and a corresponding optimal amount of social utility.

Shiffrin states that the consequentialist justification argument:

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[337] Robert P Merges, *Justifying Intellectual Property* (Harvard University Press, Cambridge, MA 2011),4

[338] Intonation to which the current author is equally guilty (see n190).

[339] Moore (n 211), 10

> "contends that intellectual property protections must be given to creators in order to give them the incentive to create their work...In theory that incentive operates to stimulate creation of some work by promising the power to prevent other similar works from being produced or distributed." [340]

In fact, the consequentialist argument could be said to rely on two related, but distinct, incentives: the incentive to innovate and the incentive to commercialise.

Such incentives-based approaches are closely linked to economic approaches to the analysis of intellectual property. Broadly speaking these approaches seek to determine conditions in which markets operate at optimal efficiency.[341]

3.7.1 Criticisms of Incentives-based Justifications for Intellectual Property

The criticisms of the incentives-based justifications are wide ranging and the commentary here will be kept deliberately brief to allow focus on how this justification relates to the protection of traditional knowledge.

The first key criticism is that market efficiency approaches are based upon a too simplistic notion that the efficiency of the market is the principal desirable outcome of set of positive laws. Even where one takes a purely Benthamite approach, that is assuming that the enhancement of the *total* utility of a society is key (without reference to the distribution of social utility within that society), the utilitarian support for the desire to achieve an efficient market is based upon a simplistic "efficient economy leads to more and better goods leads to more general happiness" causal chain. As will be discussed below, even this approach takes little account of any Millian "quality" of utility concerns.[342] Where one rejects a total utility approach and places importance on problems of distribution, and demands of personal liberty, such a simplistic equation becomes still less viable.[343, 344]

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[340] Shiffrin (n 255), 94

[341] See Dutfield & Suthersanen (n 209), 49 for a brief overview.

[342] Amartya Sen, The Idea of Justice (Penguin Books, London 2010) 311

[343] Sen (n 342), 310

The second key criticism is that we cannot actually tell that providing intellectual property rights *does actually* serve to incentivise innovation. Moore[345] suggests that empirical questions about the costs and benefits of intellectual property in encouraging innovation and its commercialisation are difficult to determine and have not been conclusive. Shriffrin[346] expresses further concerns that one cannot actually know whether the works incented under the law are superior in some respect (perhaps quantity or quality) to those that have been deterred by the law.

Other commentators [347,348, 349, 350, 351] have gone further in their criticism, arguing that a proliferation of intellectual property rights creates a tragedy of the "anti-commons" which has the effect of stifling the very innovation and commercialisation that it was intended (under the consequentialist account) to be incentivised.

Within this criticism is the argument that inventors will invent in any case, even in the absence of incentives. Shiffrin[352] points out that many authors/inventors will be driven to create works (even in the absence of any formal incentivisation through intellectual property rights) through a desire to develop, *inter alia*, their art, reputation and for the general good of society. She argues that to justify a "strong" intellectual property regime the incentives argument must advance beyond what she calls:

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[344] Amartya Sen, "The possibility of social choice" (1999) 89 American Economic Review 178

[345] Moore, (n 211)

[346] Shiffrin (n 255), 94

[347] MA Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) 111 Harv L Rev 621

[348] MA Heller & R Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698

[349] Dan L Burk & Mark A Lemley, "Policy Levers in Patent Law" (2003) 89 Va L Rev 1575

[350] Mark A Lemley, 'Property, Intellectual Property, and Free Riding' (2005) 83 Tex L Rev 1031

[351] Samantha Leung, "The commons and anticommons in intellectual property" (2010) 16 UCL Jurisprudence Review 16

[352] Shiffrin (n 255),94

"the modest claim that creators need the funding available from intellectual property rights to recoup creation and labour costs; and that given the ability of competitors to make cheap copies, the funds creators need may exceed what would be available through unprotected release of their products and creations on the market. "[353]

[353] Shiffrin (n 255), 96

3.7.2 Consequentialist Arguments for a Positive Right in Traditional Knowledge

3.7.2.1 The "Incentive to Innovate" Argument

For Munzer & Raustiala [354] indigenous people may require a right to prevent others from using the traditional knowledge without providing compensation, but for Munzer & Raustiala this (and presumably any stronger right) cannot be defended on the basis of an incentive to innovate since no incentive in the form of intellectual property rights was required for *extant* traditional knowledge to be developed:

> "The innovation has already occurred: at most we might use incentives to justify possible incremental improvements to existing [traditional knowledge]" [355]

Such a criticism relies on a very static view of the development of traditional knowledge. In contrast Dutfield & Suthersanen [356] suggest that such ongoing innovation in traditional knowledge is a live and ongoing process. Indeed Mazzocchi refers to this ongoing evolution of traditional knowledge as "traditional science". [357]

However, Munzer & Raustiala add that the more an indigenous group looks to innovate some piece of shared knowledge, the less "traditional" that knowledge appears. If a group (or an individual) do develop some new aspect of the traditional knowledge such information would, they argue, be justified protection on the basis of innovation, and indeed, such a development may well be the valid subject matter of an existing, "classical" form of intellectual property. For them, however, that new innovation should not form the basis for a *sui generis* right in traditional knowledge.

3.7.2.2 The "Incentive to Commercialise" Argument

Munzer & Raustiala contrast the incentive to commercialise from that to innovate. For them this incentive to commercialise justification is not subject to the "innovation has

[354] Munzer & Raustiala (n 262), 329

[355] Munzer & Raustiala (n 262), 329

[356] Dutfield & Suthersanen (n 209), 73

[357] Fulvio Mazzocchi, "Western science and traditional knowledge: Despite their variations, different forms of knowledge can learn from each other" (2006) 7(5) EMBO Rep 463

already happened" criticism that they directed at the incentive to innovate ground. Any incentive to commercialise is directed at taking an existing piece of traditional knowledge and encouraging its commercial exploitation with the aim of bringing the information to a wider market and stimulating investment. Munzer & Raustiala believe that this "consequentialist argument has some force" but point out the following limitations:

i) It is not a justification for protection of traditional knowledge that the indigenous group seek to retain within their group for example sacred knowledge;

ii) "any plausible extent of legal protection will not include indefinite duration" (although no reason is given for this); and

iii) "unless the extent of legal protection is exquisitely calibrated, and unless indigenous peoples know the extent of that protection- each of which is difficult to secure- they may well under-invest or over-invest in commercializing their [traditional knowledge]".[358]

Munzer & Raustiala point out that any such over-investment would be problematic for indigenous peoples as it would lead them to spend resource that they do not have. For example they may become embroiled in unsuccessful enforcement activities which could lead "rent-dissipation" of the value of the intellectual asset (once it was realised that the key element of the asset was free to use). They may also become involved in "rent-seeking" activities such as lobbying government for preferential treatment.

3.7.2.3 Other Utilitarian and Quasi-Utilitarian Approaches - "Stability"

Munzer & Raustiala point to a utilitarian justification for property rights based on a desire to ensure "*stability, security of expectations and the smooth functioning of society and the economy*"[359] and examine whether such this utilitarian model provides a justification for intellectual property right in indigenous traditional knowledge. They

[358] Munzer & Raustiala (n 262), 74

[359] Munzer & Raustiala (n 262), 66

cite the WIPO *Composite Study on the Protection of Traditional Knowledge*[360] as an example of such an argument. The composite study states:

> "a clear, transparent and effective system of TK protection increases legal security and predictability to the benefit not only of TK holders, but also of society as a whole, including firms and research institutions who are potential partners of TK holders. These benefits go beyond the promotion of innovation as such, given the argument that IP forms of protection of TK are unnecessary since the innovation will have taken place without IP protection." [361]

Munzer & Raustiala agree that stability and certainty are desirable as a general aim, but state that having such a desire does not, of itself, inform how one particularly achieves that aim through the formulation of positive laws. They state (somewhat mischievously in this author's view) that certainty could equally be arrived at through an announcement that no rights existed in traditional knowledge. Although that may well be correct, such a position would, of course, completely ignore any other justification for the existence of such rights.

Under this head (though it could perhaps more properly be discussed under the "Incentive to Commercialise" head) Munzer & Raustiala further cite the Composite Study where it states:

> "A third potential rationale for IP protection of TK concerns economic development and poverty alleviation: if the communities so wished, the formalization and recording of traditional communities' intangible assets would transform them into capital, thus facilitating the establishment of commercial ventures within traditional communities. Many traditional communities that live in apparent poverty are actually rich in knowledge — but their knowledge, not being the subject of formal property titles, is prone to commercial misappropriation by others. Furthermore, once recognized through titles, TK

[360] WIPO Intergovernmental Committee on Intellectual Property & Genetic Resources, Traditional Knowledge and Folklore, Composite Study on the Protection of Traditional Knowledge WIPO/GRTKF/IC/5/8 (2003)

[361] WIPO/GRTKF/IC/5/8 (n 360), 14, para 35

> could be used as collateral security for giving traditional communities facilitated access to credit." [362]

As stated above, Munzer & Raustiala have some sympathy with a utilitarian justification for a right in traditional knowledge based on an incentive to commercialise, but highlight that the traditional knowledge as capital argument relies on "*sanguine, perhaps heroic, empirical assumptions about which IP right will turn out to be valuable*" [363] and highlight that a great deal of intellectual property is, in fact, worth very little.

3.7.2.4 Preservation of culture

Although they do not it put as such, Munzer & Raustiala's "stability" head may actually be pointing to a further, broader, utilitarian argument for a positive right in traditional knowledge namely preventing an *impoverishment* of Mills' "greater happiness".

Dutfield & Suthersanen [364] and Dutfield [365] in looking at traditional knowledge as an emerging right, propose that a positive traditional knowledge right would improve the lives of the traditional knowledge holders and communities. They point to the fact that many examples of traditional activity are in decline, and many modes of traditional cultural expression are being lost. [366] One might argue that from a utilitarian prospective an incentive not to *lose* is equivalent to an incentive to *gain*. An incentive to "commercialise" and make a financial gain from existing traditional knowledge could potentially serve as an incentive to retain knowledge and cultural forms that would otherwise not be valued and would potentially be lost in wake of the spread of "Western" cultural and scientific norms and a market economy.

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[362] WIPO/GRTKF/IC/5/8 (n360), paragraph 35

[363] Munzer & Raustiala (n 262), 68

[364] Dutfield & Suthersanen (n 209), 329

[365] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (n 11), 97

[366] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (n 11), 97

Dutfield [367] and Dutfield & Suthersanen [368] also point to a potential benefit to the national economies in which a particular piece of traditional knowledge originates as consequentialist justification for providing a positive right to traditional knowledge. As has been discussed in the introduction to this work (and will be further discussed in Chapter 4) the contribution of traditional knowledge to pharmaceutical (and food) products can be high. Without positive rights this value would not be captured and would not enter into the (usually poor) originator economy. They highlight, however, that the economic potential of traditional knowledge should not be over-estimated as much will have no commercial application at all.

3.7.2.5 Preservation of the Environment

Closely linked to the preservation of indigenous culture, Dutfield [369] additionally points to conservation of the environment from which traditional knowledge originates as a further consequentialist justification for providing a positive right to traditional knowledge.

Some traditional knowledge directly relates to methodologies of agricultural or forest management. For example, much of what has been considered "virgin" rain forest has been actively managed by indigenous peoples over generations including clearance, plant selection and planting of "forest gardens". [370] If plants and the traditional knowledge associated with them are perceived as having potential commercial value then the incentive to preserve them and the environment in which they are found may be enhanced, particularly in the face of external infrastructure development, mining, logging and ranching pressures.

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[367] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (n 11), 98

[368] Dutfield & Suthersanen (n 209), 329

[369] Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (n11), 99

[370] KF Wiersum, "Forest gardens as an 'intermediate' land-use system in the nature-culture continuum: Characteristics and future potential" (2004) 1 Advances in Agroforestry 123

3.7.2.6 Exploring "preservation through valorisation"

This "preservation through valorisation" approach to the maintenance of indigenous culture and of the natural environment by giving value to traditional knowledge, (and to the genetic resources to which that traditional knowledge relates) requires examination in terms of:

a) what utilitarian goals are served by the policy;

b) how the positive laws create the desired value; and

c) whether that value serves to meet the utilitarian goals identified.

As we will see, this analysis eventually brings us to a potential "utilitarian paradox" at the interface between the preservation of the biodiverse environment and Western market economy at which the traditional rights justification operates.

3.7.2.7 What utilitarian goals are served by the policy?

The basis of a rule-utilitarian justification is that as a result of a particular policy (or positive legal rule) the overall utility of a society is enhanced.[371, 372] However, it has long been a matter for debate amongst utilitarians as to how one might actually seek to determine whether that policy has had the desired effect of enhancing overall the utility of a society.[373] Can one really perform a *felicific calculus* (or calculation of happiness) of an entire society? Can one examine with any certainty whether a particular policy has had an impact on that *calculus*?

Given the complexity of a modern (and even a pre-modern) society, the analysis of the impact of policy is, of necessity, more commonly focussed on the effect on the perceived mischief to which the policy is directed (and the spill over effects into related

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[371] RB Brandt, *Ethical Theory* (Prentice-Hall, Englewood Cliffs, NJ 1959);

[372] RB Brandt, "Toward a Credible Form of Utilitarianism" in H-N Castañeda and G Nakhnikian (eds), *Morality and the Language of Conduct* (Wayne State University Press, Detroit 1963) 107

[373] James Garvey and Jeremy Strangroom, *The Story of Philosophy: A History of Western Thought* (Quercus, London 2012), 286

areas), rather than looking at the *global* utility within a society. However, even if one *were* somehow able to quantify the global happiness of a society, we need to ask whether it is really the "amount" of happiness in society that is important, or whether the *quality* of happiness is also important.

The question of what *types* of happiness should inform a model for living life, and whether we are obligated to do more than pursue pleasure for its own sake, has a very long history, and formed a key part of the (Stoical and other) criticism of the philosophy of Epicurus [374, 375]and part of the search for the definition of an objective well-being within a *eudaimonic* life. [376, 377] The question of difference in *quality* of social utility was rapidly identified by utilitarians and Bentham's broad definition of happiness [378] was challenged by Mill who held that "higher" forms of happiness, arising from intellectual achievements, gave greater utility than "baser" forms. Mill famously stated:

> "It is better to be a human being dissatisfied than a pig satisfied; better to be Socrates dissatisfied than a fool satisfied. And if the fool, or the pig, are of a different opinion, it is because they only know their own side of the question. The party to the comparison knows both sides." [379]

Progressive as Mill was for his time, this approach does reflect something of a high-Victorian view of culture, and of the world. However, even if one does not follow such a strict Millian approach, the idea that there are differing qualities of happiness/utility does not seem unreasonable, and is certainly reflected in our own experience of life. However, in looking at such questions of quality of utility one is immediately confronted by substantial problems of subjectivity. We all have our own personal

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[374] Garvey & Strangroom (n 373), 128

[375] Russell (n 293), 231

[376] Alasdair MacIntyre, *A Short History of Ethics: A history of moral philosophy from the Homeric Age to the twentieth century* (Routledge Classics, Oxford 2002), 77

[377] Noel Stewart, *Ethics: An Introduction to Moral Philosophy* (Polity Press, Cambridge 2009), 61

[378] Jeremy Bentham, *The Principles of Morals and Legislation* (1789) 1

[379] John Stuart Mill, *Utilitarianism, Liberty & Representative Government* (JM Dent and Sons, London & Toronto 1910), 9

interests, values and concerns: one women's happiness cannot simply be another's (although Harris has argued that there are some *fundamental* things which all (non-pathological) humans perceive as important to happiness and contribute to what should universally be accepted as a good life [380] an approach which follows Rawls' [381] and Honderich's [382] view that one can specify the "primary goods" which are necessary pre-conditions for wellbeing).

Even if one could advance beyond this problem of subjectivity, how might you even arrive at an *objective* calculation of any difference in utility? As Blackburn states:

> "...although we might judge that this year's holiday was better than last year's, we are not apt to think it makes sense to say it was twice as good, or that it generated half as many units of utility as (say) a lifetime's consumption of chocolate." [383]

Accordingly, when engaging in any utilitarian analysis we need to acknowledge throughout the problems posed by quantity, quality, subjectivity and lack of objective calculation.

Perhaps the simplest utilitarian account for preservation of traditional knowledge is that the existence of such knowledge provides a social utility *in itself* in that it is part of the "patrimony of mankind". Although Mill argued that high Western art (say Michelangelo's painting of the vault of the Sistine Chapel or a Bach violin *concerto*) generated significant utility, he accepted that utility could be found in the appreciation of a broad range of achievements:

> "A cultivated mind – I do not mean a philosopher, but any mind to which the fountains of knowledge have been opened, and which has been taught in any tolerable degree, to exercise its faculties – finds sources of inexhaustible interest

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[380] Sam Harris, *The Moral Landscape: How Science can Determine Human Values* (Black Swan, London 2010), 28

[381] John Rawls, *A Theory of Justice* (Oxford University Press, Oxford 1972), 78

[382] Ted Honderich, "The Question of Well-being and the Principle of Equality" (1981) xc Mind 481

[383] Simon Blackburn, *Oxford Dictionary of Philosophy* (Oxford University Press, Oxford 1996) 388

> in all that surrounds it; in the objects of nature, the achievements of art, the imaginations of poetry, the incidents of history, **the ways of mankind, past and present**, and their prospects in the future." [384] [emphasis added].

Whether Mill's concept of human achievement would have, in fact, extended to traditional knowledge *per se* (rather than the utility generated by the Western scholarly examination of it) is unclear, but it would in the current century seem perverse not to extend a Millian utility to the art, forms of living, and knowledge of indigenous peoples (even where that knowledge cannot be readily defined as "artistic" according to Western mores).

To this contribution to the utility of all mankind might also be added a more particular sense of "happiness" which arises where a society of indigenous peoples are free to live a life which allows them to feel spiritually fulfilled by following their traditional religious beliefs and customary norms. This narrower utilitarian goal is naturally specific to a smaller group that that of all mankind. Of course, where one is pursuing a "greatest happiness for the greatest number" rule-utilitarianism, one will encounter difficulties in promoting a specific utility for one group in conflict with a broader utility for a greater number. One is possibly left here attempting to balance the "narrow" enhanced social utility of an indigenous group "living in peace" to enjoy their traditional knowledge against a potential enhanced utility of a broader society brought about through (say) infrastructure development leading to rainforest destruction. Such conflicts are not easily resolved but do highlight the importance of determining the set of utilities that are intended to be produced (or at least incentivised) by one's proposed positive law.

The discussion above focuses of the quality of happiness. This debate can be taken further into the question of whether "happiness" alone is a sufficient determinant for governing consequentialist policy. There is a long and rich history in philosophy in assessing whether the true determinant of utility should be the broader "well-being" of individuals. [385] The question extends further into what determines what constitutes well-

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[384] Mill (n 379), 15

[385] Patricia Walsh, "Well-being" in Ted Honderich (ed) *The Oxford Companion to Philosophy* (Oxford University Press, Oxford 1995), 908

being – for example an idea of objective eudaimonic human flourishing[386] or a more subjective test?

One might consider that "wellbeing" is a less subjective marker than mere "happiness" and that this relative objectivity could allow one to reduce well-being or welfare into something which is empirically measureable and amenable to the arithmetic balancing of summed welfare measures.

Recently Derclaye and Taylor [387] have suggested that the rule-utilitarian justification for intellectual property has been misapplied by the Chicago "law and economics" school such that an enhancement in societal wealth (as evinced by such economic markers as Gross Domestic Product) acts as the sole proxy for greater societal well-being - a flawed process which serves to ignore wider concepts of human well-being. They suggest [388] that other "markers" for human well-being should be applied when looking to justify intellectual property rights:

a) Marker 1—Happiness – or more accurately "positive affect";

b) Marker 2—Health - including all aspects of physical health: not only freedom from disease and injury, but also adequate nutrition. It would also include mental health;

c) Marker 3—Life-satisfaction - a complementary notion to happiness: the two are combined in the construct of "subjective well-being";

d) Marker 4—Success in realising central life goals/values - the extent to which a person succeeds in securing the things they most care about, whether these be goals to which they aspire or aspects of their lives that matter to them;

[386] CCW Taylor, "Eudaimonia" in Ted Honderich (ed) *The Oxford Companion to Philosophy* (Oxford University Press, Oxford 1995), 252

[387] Estelle Derclaye and Tim Taylor, "Happy IP: replacing the law and economics justification for intellectual property rights with a well-being approach" (2015) 37(4) EIPR 197

[388] Estelle Derclaye and Tim Taylor, "Happy IP: aligning intellectual property rights with well-being" (2015) 2015(1) IPQ 1

e) Marker 5—Supportive personal relationships including marriage, relationships with family members, friendships and even relationships with others such as neighbours and work colleagues, insofar as these can be regarded as supportive;

f) Marker 6—Personal development - the development, improvement and exercise of various mental and physical aspects of our natures as human being, including the development of intellectual skills and the acquiring of knowledge, typically through education;

g) Marker 7—Leisure -the opportunity to spend time relaxing and to pursue interests and activities beyond those required by work, or by the need to secure the essentials for human existence;

h) Marker 8—Adequate income/resources - sufficient resources to enable certain other markers of well-being, such as good health (which implies adequate nutrition) and achievement of personal goals, to be secured. Those resources, in most societies, will typically be in the form of income or wealth but need not necessarily be so in all circumstances;

i) Marker 9—Rewarding employment – predominantly as an enabler of other markers (provided that the employment relationship is not abusive). [389]

Derclaye and Taylor conclude when applying their "well-being" test to broadly rule-utilitarian justifications for intellectual property rights that:

a) from a creator's and inventor's perspective, "*the current intellectual property laws (based on the proxy of income) are generally adequate*" and:

b) from a user's perspective such laws "*are also in the main adequate*".

They note, however, that "some adjustments are necessary". And highlight that:

> "Under a well-being perspective, there are a great number of intellectual achievements which should not be protected and certainly those contrary to *ordre*

[389] Derclaye &Taylor (n 388), 2

> *public* and morality would fall in this category. We leave the question whether more achievements could fall in this category for another paper." [390]

If we apply Derclaye and Taylor's "well-being" markers to the indigenous sphere, we can see that what is described above as the "narrower" utility of allowing indigenous peoples to feel spiritually fulfilled by following their traditional religious beliefs and customary norms would seem to particularly echo with Derclaye and Taylor's Marker 1 (happiness), Marker 3 (life-satisfaction/"subjective well-being") and Marker 4 (success in realising central life goals/values). Although Derclaye and Taylor do not specifically highlight indigenous communities within their description of Marker 5 (supportive personal relationships), it seems likely that within a close indigenous community this marker would be a strong element in an individual's well being. It is also likely that this marker of well-being would be particularly enhanced through the ability of the individuals within a group to follow their traditional religious beliefs and customary norms.

However, even such broader markers of "well-being" remain anthropocentric. A further, and distinctly separate, utilitarian account is that the preservation of a biodiverse environment is a "utility" in itself. Singer [391] divides the potential utility of preservation of the environment into two values: *intrinsic* value based upon the value of the thing itself, and *instrumental* value based upon the thing's ability to contribute to other utilitarian ends. It is of course possible that a single thing may have overlapping intrinsic and instrumentalist values to varying degrees. However, is important to appreciate from where the contributions to overall utility are made – particularly where one is seeking to influence that utility through positive law. For Singer the intrinsic value of the preserving the environment can itself take two forms.[392]

The first of these is that we as humans (today and in the future) are culturally and/or spiritually enriched by the act of living within in a biodiverse environment (and hence our happiness is enhanced). This enrichment is again a highly subjective appreciation,

[390] Derclaye &Taylor (n 388), 13

[391] Peter Singer, *Practical Ethics* (Cambridge University Press, Cambridge 1999), 274

[392] Singer (n 391), 276

both as between persons and between cultures. For example modern Western concepts of the aesthetics of nature have arguably been shaped by romantic, "Burkean" concepts. [393] As with the utility found in enjoyment of traditional knowledge *per se*, one might also posit that indigenous peoples gain a specific utility in the enjoyment of their ancestral environment (although as we will see that may be subject to conflicting Western-orientated utilities).

The second intrinsic value is based on the view that we should extend our view of utility to encompass not only *human* "happiness" but a broader, non-anthropocentric, concept of *environmental* well-being (sometimes referred to as "deep ecology"). [394, 395, 396, 397]

Outwith these broader (somewhat Millian) concepts, there is a more practical (and perhaps more Benthamite) aspect – a biodiverse landscape has *instrumental* value to humans in supporting their other endeavours and even the quality of their existence. In some cases this may be through a moderating effect on local (or even global) climate, soil and watercourse protection. In others, it may be through the provision of plant species which can be used for food, fibres, or as the basis for drug discovery and of genetic materials which may form the basis for the development of disease-, pest- or drought-resistance. Indeed, this role as a store of genetic resources may also be seen as an "insurance policy" against future uncertainty, which would again provide a social utility in itself. As Atkins puts it:

> "One anthropocentric but important concern about the extinction of species is that it wipes our sources of intricate molecules that have taken millions of years to emerge." [398]

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[393] See Dale Jamieson, *Ethics and the Environment* (Cambridge University Press, Cambridge 2008), 158

[394] Aldo Leopold, *A Sand County Almanac* (Oxford University Press, New York 1949)

[395] Arne Naess, "The Shallow and the Deep, Long Range Ecology Movements: A Summary" (1973) 16 Inquiry 95

[396] William Devall and George Sessions, *Deep Ecology: Living as if Nature Mattered* (Gibbs M Smith, Inc, Salt Lake City 1985)

[397] Peter Singer, *Animal Liberation* (Harper Collins, New York 2002)

[398] Peter Atkins, *What is chemistry?* (Oxford University Press, Oxford 2013), 13

The degree of “usefulness” (or instrumental value) of a particular biodiverse landscape will depend on the landscape in question, and will also vary according to whom the landscape is being useful. Global climate effects, and acting as a genetic bank, will be useful to a larger population of people, although the effect may seem remote. In contrast, local climate effects will be more immediately useful to a narrower group of people who actually live within, or next to, the affected landscape.

We need to note that although such intrinsic and instrumental utilitarian benefits arising out of the preservation of a biodiverse environment would arguably be greater within an environment which is in something approaching a “pristine” state, often this supposedly pristine state is illusory and is in fact the product of long interaction between people and nature. For example, much of what has been considered “virgin” rain forest has been actively managed by indigenous peoples over generations including selective clearance, plant selection and planting of “forest gardens.” [399] Notwithstanding this, indigenously managed forests preserve a significant body of indigenous flora [400] and are likely always to be a greater contributor to the environmental side of our utilitarian “equation” than would be the entirely cleared alternative.

To summarise, we have a number of utilitarian goals which may be served by creating value in traditional therapeutic associated with genetic resources:

1) Spiritual/cultural (“Millian”/intrinsic):

    a) Traditional knowledge is part of the “patrimony of mankind” and provides utility its own right;

    b) The spiritual fulfilment of indigenous peoples by following traditional religious beliefs and customary norms;

    c) Humans broadly (and indigenous peoples more specifically) are culturally and/or spiritually enriched by existing in a biodiverse environment; and

[399] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (n 11), 99

[400] Wiersum (n 370)

d) Utility encompasses not only *human* "happiness" (anthropocentric utilitarianism) but a broader non-anthropocentric concept of the well-being of the environment *itself*.

2) Practical ("Benthamite"/instrumental):

a) Biodiversity itself provides utility through its support of other human endeavours (through a moderating effect on local (or even global) climate, soil and watercourse protection or the provision of plant species which can be used for food, fibres, or as the basis for drug discovery and of genetic materials which may form the basis for the development of disease-, pest- or drought-resistance); and

b) An "insurance policy" against future uncertainty (the environment acting as a store of potential treatments of plant and animal diseases, pesticides and drought-resistance).

To the extent that any of these utilities do not conflict, might there be an argument for conflating these fractionated utilities into a single pooled environmental/cultural utility? As early as 1988 the Declaration of Belem (agreed at the First International Congress of Ethnobiology in Belém, Brazil) [401] stated that there was an "*inextricable link between cultural and biological diversity"*.[402] One might envisage that there is little potential conflict within the class of Millian/intrinsic utilities described above and within the class of Benthamite/instrumental utilities. Generally speaking there may also seem little scope for conflict between the two classes: third party instrumental "enjoyment" of traditional knowledge *per se* is unlikely to conflict with the intrinsic utilities described save (importantly) with an intrinsic "utility through control" of traditional knowledge (which is described below).

401 Darrell A Posey and Graham Dutfield, *Beyond Intellectual Property: Toward Traditional Resources Rights for Indigenous Peoples and Local Communities: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities* (International Development Research Centre, Ottawa 1996), 7

[402] 1988 Declaration of Belém, Preamble

Given this potential conflict, and the likelihood that positive rights/valorisation will affect each utility to varying degrees, each utility will examined separately in the following analysis (although the potentially close interaction between the preservation of the environmental and of traditional knowledge utilities will continue to be acknowledged).

3.7.2.8 The Achievement of utilitarian goals through valorisation

How then does creating value in traditional knowledge associated with genetic resources achieve the utilitarian goals of preservation of the biodiverse environment or of traditional knowledge *per se* (or a conflation of the two)? How is this value created in the first place?

It is crucial to note that the preservation of the environment (and of culture) relies on the *behaviour* of relevant actors responding to economic factors (including conflicting values), whether they be the indigenous peoples themselves, or those external agents responsible for making business or planning decisions. However, although some economic theories can apply an objective value to a commodity, it has long been recognised within economics that for most individual economic actors the determination of value (which will drive behaviour) is subjective [403] - and this subjective value is derived from individual's *perception* of the importance of an item. This perceived value[404] of an asset is the function of many factors. These will include desirability (based in part on the amount of money that may be made from the asset), ease of resale, and, crucially, rarity/accessibility: Taylor states:

> "Valuation is always directed toward a definite quantity of a particular good or service. Choices and decisions are not concerned with the whole supply of a certain good or service. This marginal orientation was lacking in the classical economists' groping with the so-called paradox of value. They were unable to resolve the intriguing question of why diamonds had a higher price per unit than

[403] Thomas C Taylor, *An Introduction to Austrian Economics* (Ludwig von Mises Institute, Auburn Alabama 1980) Chapter 4 (http://mises.org/austecon/chap4.asp) (Accessed September 2015)

[404] At least in respect of monetary value - we should note here that people can value an object in other, non –monetary, ways.

> water when everyone knew that water was more useful and valuable than diamonds. Only through the principle of diminishing marginal utility could this conceptual dilemma be eliminated. Each additional unit of a particular good is devoted to a use that is less important and urgent than the use to which the preceding unit was applied." [405]

If you were dying of thirst in a desert you would clearly value water over a diamond. Perception based on situation and *relative position* is important.

However, when looking at availability of an asset we need to recognise that since intangible property is (as was discussed at the beginning of this chapter) both non-rivalrous and non-excludable, exclusivity can only be created through the imposition of positive law.

The "classic" intellectual property argument for creating value runs as follows: a requirement on third parties that they require prior consent from the rights holder before they can use information creates an (artificial) scarcity in the information which enhances its commercial value. In the absence of a right to control there may be value to third parties in the subject matter but since free-riders will be free to use the subject matter as they wish, value will not attach to the information in the hands of its originators. However, if we acknowledge that subjective perception is crucial in creating value need to understand that value is a more complex concept than merely creating artificial scarcity in something. Such a model only works where there is some actual or potential use for the information – control over the use of something inherently useless is highly unlikely to create any value. In addition the terms of exclusivity established by positive law - such as certainty of definition and ease of enforcement - become paramount in determining the subjective value of the right.

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[405] Taylor (n 403)

3.7.2.9 Preservation of the environment

There are many economic threats to biodiverse environments including logging, mining, the clearing of forest for animal pasture, infrastructure projects and the growth of urban areas, many of which will be driven by *immediate* profit motives and economic concerns.

One may be sceptical of the ability of enhanced value of genetic resources and traditional knowledge associated with them to successfully counter such immediate economic drivers. One might imagine scenarios where there is a significant disconnection between the value of genetic resources and traditional knowledge on the one hand, and preservation of the biodiverse environment on the other. Taking (an extreme) example, profiting from Western use of genetic resources and traditional knowledge associated with that knowledge could conceivably occur in the absence of the environment from which it originated - perhaps the genetic resource has already been collected (and could be propagated elsewhere) and/or the relevant knowledge (whether nucleotide sequence, biochemical structure or traditional knowledge) has already been already "collected" and preserved – thereby leaving the land upon which the genetic resource originated free for other uses to generate monetary profit. This admittedly extreme case, highlights that the linkage between genetic resource/traditional knowledge value in general and the preservation of the environment is in good part based on the *promise* of as yet unknown (and yet potentially valuable) genetic resource/traditional knowledge combinations.

Unfortunately, much of the promise of genetic resources "in the bush" is just that – a promise. Some genetic benefits may be entirely unknown, others may be directed through indigenous knowledge, however full realisation of their true value to Western science/commerce may appear a relatively distant probability compared to the near certainty of the return to be made from, say, clear-cutting a forest to create animal pasture to produce hamburger meat. Even taking account of this probability of failure, Western economics and accountancy practice additionally places significantly greater value to profit made today versus profit made tomorrow – simply because of the cumulative effect of a rate of return on money invested today. [406]

Notwithstanding this scepticism in overall efficacy, the perception amongst all the concerned actors of *some* value in genetic resources and in traditional knowledge associated with those resources (created through the existence of a right to control use) must be better than *no* perceived value whatsoever (created through the absence of a right to control use).

3.7.2.10 Preservation of traditional knowledge for its own sake

Outwith the preservation of the biodiverse environment, we identified a separate utilitarian justification for a positive right in traditional knowledge in the preservation of traditional knowledge for its own sake (either as part of the "patrimony of mankind" or as part of the spiritual life of a specific indigenous people).

Here one might see the valorisation of traditional knowledge as having a more direct effect on preservation in a world where traditional knowledge is threatened by the encroachment of Western values. Where traditional knowledge (including that associated with genetic resources) can become a source of actual (or potential) wealth one could expect the creation of an economic drive which would act towards the preservation of the source of that wealth in the face of competing cultural pressures. Again, there is an irony that one is using a Western market economic mechanism to counter a problem essentially caused by Western market economy.

Again, we need here to recognise that information *can* exist away from the environment in which it was created even more easily than can a genetic resource. Let us imagine that a huge ethnobotanical survey (akin to an emergency archaeological dig) could achieve the end of collecting all the relevant indigenous information in an area before it was lost. Might that not, in itself, serve the utilitarian goal of preserving part of the "patrimony of mankind" more easily than creating a body of rights which will hopefully have their eventual effects through value created by market-economic forces?

[406] Singer (n 391), 270

It is here perhaps that taking a somewhat reductionist utilitarian approach might lead us astray. Our imaginary survey, even if it could in some way entirely reliably capture all the appropriate information, would preserve only one facet of the information. Information about genetic resources, no matter how accurate, becomes of mere historical interest in the absence of the genetic resource to which it is related. Of course, our imaginary survey could potentially be extended to encompass the collection of *all* genetic material related to the traditional information. Would this again serve to fulfil our "patrimony of mankind" utilitarian goal without reliance on positive rights? In a purely reductionist sense the answer may be "yes", but again reductionism leads us astray. Few people would say that watching animals in a zoo is as spiritually satisfying as seeing them in the wild. Similarly, knowing that genetic material is safely preserved in the Royal Botanic Gardens Millennium Seed Bank [407] or the Svalbard Global Seed Vault [408] (and is thereby fulfilling a crucial instrumentalist utility), is arguably not as spiritually satisfying as knowing that the plants are growing "in the wild".

Realistically it makes sense to in this instance to conflate the "patrimony of mankind" and "preservation of biodiverse environment" utilitarian goals, rather than treat them as separate entities – both elements arguably enhance the other (particularly within traditionally managed environments). We can see that our imaginary "perfect" ethnobotanical survey is not a substitute for a rights mechanism which aims to preserve both elements.

Notwithstanding its (intrinsic if not instrumentalist) utilitarian "failure", our imaginary ethnobotanical survey is in any case just that – in reality no survey can be wholly truly comprehensive. No doubt some captured information and genetic resource is better in an emergency situation that no information/genes at all, but it cannot be a substitute for the preservation of information and genetic resource *in situ* in a social environment in which information and genes will be preserved.

[407] http://www.kew.org/science-conservation/collections/millennium-seed-bank (Accessed September 2015)

[408] https://www.regjeringen.no/en/topics/food-fisheries-and-agriculture/agriculture/svalbard-global-seed-vault/id462220/ (Accessed September 2015)

We have, however, identified above an additional utilitarian goal: that traditional knowledge is preserved for its own sake *as part of the spiritual life of indigenous peoples*. Clearly here the reductionist approach taken, and criticised, above in relation to preservation of the "patrimony" of mankind" is even less sustainable. The spiritual life of the indigenous peoples is closely linked to the biodiverse environment, and to the use of genetic resources *within* their social, customary and religious context. It makes even less sense to talk here of "data bases" and "gene banks" than it did above – the preservation of information here is still more closely linked to the utilitarian goal of preservation of the biodiverse environment. It is also here that arguably a Western market economy mechanism seems at its most alien.

3.7.2.10 Utility through "control"

It is at this point that we should identify that the requirement that prior informed consent is required before a third party may use traditional knowledge associated with traditional knowledge might not only have its utilitarian benefit through valorisation of the information. Such a requirement may also go *directly* to the "well-being" of indigenous peoples (notably Derclaye and Taylor's Marker 4 -success in realising central life goals/values and Marker 5 -supportive personal relationships).

The requirement for prior informed consent needs to encompass the right to say "no" or it is not true consent. This right to exclusively consent to the use of information may, of itself, go to spiritual fulfilment of indigenous peoples – for example if their traditional religious beliefs and/or customary norms direct that sacred or special information should be maintained within the indigenous group. Milius [409] describes it thus:

> "the power to maintain control over one's traditional knowledge might confer a very real and cultural/spiritual sense of independence and self-reliance where that knowledge is used to the benefit of the community. Even where the knowledge is held by a small circle of practitioners, those who belong to that community at large and who benefit from the particular [traditional knowledge] through membership may also feel the real sense of autonomy that group self-reliance

[409] Milius (n 318), 198

> brings, and in not having to depend on outsiders for their technological knowledge and expertise."

Although this may be an entirely justifiable basis for having a right to control access, its applicability will be case-dependant rather than the broader applicability which applies to the valorisation of traditional knowledge. We need also note that, the "utility through control" goal is reliant, in the long term at least, on the broader preservation of the culture and environment which supports the appropriate traditional religious beliefs and/or customary norms. We also need to note that the absolute exercise of a veto over use of traditional knowledge in achievement of a "utility through control" goal may in certain cases play against the creation of value in that knowledge which might otherwise be achieved through consensual commercial exploitation.

3.7.2.11 A utilitarian paradox?

On first examination the preservation of a biodiverse environment, and traditional knowledge *per se*, (for all the reasons set out above) would seem to an unarguable "good". However, the actual utilitarian landscape is more complex than can be captured in such a simplistic approach.

A Western market-economy, profit-motivated, ethos (at least in those cases where it treats biodiverse landscapes as an expendable, and limitless, resource for exploitation) is arguably at odds with many of the pro-biodiversity principles previously outlined. Much of the threat to biodiverse environments, the genetic resources within them, and the traditional knowledge relating to them, comes from an increasing "Westernisation" of the human societies which live on and/or exploit the land on which the biodiverse environment in question is found. In a society where the importance of Western consumer items/services increases, it is conceivable that things previously considered to be part of the "wealth" of the pre-Westernisation society may lose value and consequently be lost. It is certainly possible that in a diminution of the value of the "old ways", therapeutic knowledge (particularly that held by a relatively small group of people), cultural expression and language is liable to be lost. Dutfield [410] cites the 1997 IUCN Inter-Commission Task Force on Indigenous Peoples which states that:

> "cultures are dying out faster than the peoples associated with them. It has been estimated that half the world's languages – the storehouses of people's intellectual heritages and the framework for their unique understandings of life – will disappear within a century"[411]

However, if we are to acknowledge that human happiness comes in many forms, we need consider that in many respects the Western market economy could, of itself, be said to bring an amount, if a different *type*, of social utility to the overall utilitarian calculus.

It has been argued that pre-Western indigenous existence was arguably always closer to the ideas of Hobbes [412] than to Rousseau [413, 414] (or indeed Marx [415]). Ferguson has described the life of the hunter-gatherer in Hobbesian terms, emphasising the violent and competitive nature of that life, and asserts that in many cases where hunter-gatherers encounter Western-"comforts" they relatively rapidly abandon their previous life. [416]

This is undoubtedly an oversimplification. The history of the interface between Western society and indigenous peoples is beyond the scope of the present work, but we must acknowledge that the bringing of indigenous peoples within, or close to, the ambit of Western society has been heavily influenced throughout history by war, disease, slavery, forced- and unforced- religious conversions, and government policy (whether

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[410] Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (n11), 97

[411] IUCN Inter-Commission Task Force on Indigenous Peoples (1997), 60

[412] Thomas Hobbes, *Leviathan* (First Published 1651; JM Dent & Sons, London 1940), 63 (Chapter XIII)

[413] Jean-Jacques Rousseau, *Discourse on the Origin and Basis of Inequality Among Men* (First Published 1755)

[414] Niall Ferguson, *The ascent of money: A financial history of the world* (Allen Lane, London 2008),18

[415] Garvey & Strangroom (n 373), 247

[416] Niall Ferguson, *The ascent of money: A financial history of the world* (Allen Lane London 2008), 18

deliberately hostile, indifferent or guided by a misplaced paternalistic/pastoral concern) including change in environmental use, inward migration, and forced resettlement. Much of this is not by any means confined to the depths of history – Allen [417] reports on the efforts of the government of Indonesia to discourage the activities of the *kerei* medicine men of the animist Mentawai peoples living off the coast of Sumatra.

Even if not deliberately seeking to destroy indigenous society, the approach of many Western governments (and of some governments in the global South) has often been to discount the utility provided by indigenous ways of life, at the expense of the utility provided by a Western-style economy. Indeed, as has been touched upon above, Western-style economic theory is predicated on the value of economic development *today* over long-term values such preservation of something (whether traditional knowledge or the environment) for the future (even where an allocation of value could be made). Singer suggests that application of an accountancy "discount rate" to future goods means that:

> "values gained one hundred years hence rank very low in comparison with values gained today; and values gained one thousand years in the future scarcely count at all" [418]

However, although the "advantages" of Western development (whether it be the availability of consumer goods or the advent of Western surgery and medicine) can be very poorly distributed within developing economies, they do add an element social utility which cannot be easily excluded from our felicific calculus for the affected community. The impact of Ferguson's Western "comforts" cannot be easily ignored. Here we might look at the move by the Inuit of Arctic Canada from a self-sustaining, self-reliant (though highly precarious [419]), hunter-gatherer communities to one reliant on the cash-economy. This occurred, in part, through the abandonment of reliance on dog-sled teams following the introduction of the snow-mobile or "metal-dog". Snow-

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[417] Benedict Allen, "*Last of the Medicine Men*" (BBC Worldwide, London 2000), 13

[418] Singer (n 391), 270

[419] Richard Harrington (Edmund Carpenter (ed)), "*Padlei Diary, 1950: An account of the Padleimiut Eskimo in the Keewatin District west of Hudson Bay during the early months of 1950*" (Rock Foundation, New York 2000)

mobiles are faster, more powerful, and far more convenient than a dog team.[420] However, whereas a dog-team can run on meat obtained from hunting and fishing, snow-mobiles run on petroleum products and require new mechanical parts - inevitably bringing their users into the cash economy. However, even here we need to acknowledge that this abandonment was a process actively encouraged by the Canadian government (and supported by other government policies including the settlement of the previously nomadic Inuit into fixed towns and villages).[421, 422]

So when we look to the utilitarian landscape surrounding the preservation of the environment we see a complex picture: on one hand we can argue that there is a social utility (both instrumental and intrinsic) to be gained from the preservation of the biodiverse environment *per se*, preservation of traditional knowledge *per se* and indigenous ways of life for their own sake; on the other hand we might argue that the growth of Western market economy (which appears to threaten the existence of the biodiverse environment and forms of indigenous society) provides its own species and quantity of utility.

The question of how one might assesses the quantity, and quality, of these competing contributions to the overall calculation of total social utility (and indeed whether the two sides of the utilitarian calculation actually conflict one another in all circumstances) is again beyond the scope of this study. However, we need to acknowledge the irony which sits at the heart of the approach of giving commercial value to traditional knowledge as a way of protecting the biodiverse environment - the "incentivisation through valorisation" approach seeks to operate through an effect *within* the Western market economic framework, rather than operating within the framework of traditional indigenous ways of living.

There has been substantial criticism of this use of Western market economy-based approach - along the lines that such Western methods are unsuited to the protection of

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[420] The author is the possessor of a dogsled proficiency certificate.

[421] James Houston, "Fifty Years of Thinking it Over" in Maria von Finckenstein (ed) *Celebrating Inuit Art 1948-1970* (Key Porter Books, Toronto, Ontario 1999) 36

[422] Sonja Lührmann, "Arctic" in Christian F Feest (ed) *The Cultures of Native North Americans* (Könemann, Cologne 2000) 30, 44

something so alien from the market economy as traditional knowledge.[423] However, in contrast to this position, we might argue that since the threat to traditional knowledge arises *out of* Western market economic forces, an approach which affects those forces is a pragmatic solution which addresses a broader utilitarian aim. Indeed one might say that the valorisation approach addresses *both* sides of the "environment versus market-economy" utilitarian conflict identified above.

3.8 Unjust Enrichment, Misappropriation and Restitution

Munzer & Raustiala define these concepts in the following way:

i) *Unjust Enrichment* is A's receipt of an economic benefit to B's detriment such that A's retaining it without paying B would be unfair;

ii) *Misappropriation* is an improper or dishonest form of unjust enrichment, as distinct from cases where A receives an economic benefit innocently or is unaware of the detriment to B; and

iii) *Restitution* is, broadly, a basis for A's liability to B because of unjust enrichment and, narrowly, the payment A should make to B to remove the injustice.[424]

Munzer & Raustiala again cite the WIPO Composite Study as giving an example of an unjust enrichment argument where it states:

> "The fourth rationale for IP-related protection of TK concerns international trade relations, ... One general argument for international cooperation on IP protection has been that its absence in foreign countries leads to an unfair advantage for local manufacturers, since they do not need to compensate the IP right holder, or to contribute to the costs of research and development. Other factors being equal, foreign IP right owners will be in disadvantage vis-à-vis their local imitators, and therefore the lack of IP protection amounts to non-tariff barriers to trade. Just as this applies to the pharmaceutical, software and entertainment industries, it would

[423] Gibson (n 193), 73

[424] Gibson (n 193), 75

> apply to IP-related TK and the commercial interests of traditional communities that make use of their TK in their economic life, especially when they are seeking to trade beyond their community. Similar considerations apply when TK holders see their interests not in direct commercial terms, but in terms of restraining other people's unacceptable commercial practices involving their TK, such as misleading or deceptive behavior." [425]

Munzer & Raustiala refer to this as a "quasi-utilitarian" argument which is potentially plausible but which is not supported by empirical evidence. However, they perceive the argument to be chiefly referring to unjust enrichment of *insiders*, entities within the country in which the traditional knowledge originates. Although this may be correct in part, the key thrust of the argument is actually this: that in the absence of positive protection, traditional knowledge suffers the same disadvantages as befall those subject matters (for which there *are* internationally established intellectual rights) where the machinery for enforcing those rights are not in place or are in practice ineffectual. Essentially the argument is: if you think it is unfair when "Western" rights are not respected, is it not similarly unfair for traditional knowledge to (perpetually) suffer the same fate? This is certainly a call to fairness and equal treatment, but it is not perhaps entirely the same call to fairness (or is at least a species of that call) upon which an equitable right of restitution would be based.

Munzer & Raustiala simplify the scenario and argument to be as follows:

i) An indigenous people have a right to their traditional knowledge;

ii) If not protected, outsiders using that traditional knowledge will obtain unjust enrichment to the detriment of the indigenous people; and

iii) It is unfair to retain full benefit from the improper use without making a restitutionary payment to the indigenous people. [426]

[425] WIPO/GRTKF/IC/5/8 (n 360), 15, para 38

[426] Munzer & Raustiala (n 262), 76

Munzer & Raustiala highlight that determining the quantum of such a royalty is difficult. However, that practical difficulty is not the basis of their opposition to this argument. They state that even if something is *morally* appropriate that is not the same as what is, or should be, *legally* appropriate. This, of course, goes to the very heart of whether there is a rationale for a positive intellectual property right in traditional knowledge. They point to the fact that in some circumstances the balance of other values (such as competition) means that innovators are sometimes not rewarded and point to some examples of situations where this happens. Their examples [427] assume that all traditional knowledge is in the form of broad ideas of the type that would not be protectable *per se* under copyright law. They do not address the question of what should happen when a piece of traditional knowledge is narrower in scope and applicability, such as a specific therapeutic use for a plant extract.

3.9 Distributive Justice

According to Spinoza "*Justice consists in the habitual rendering to every man his lawful due*".[428] But as, Comte-Sponville [429] highlights, we are left with the question as to what this lawful due may be – what *is* my own? – what *should* it be? These two approaches highlight the core interaction between distributive and corrective (commutative) justice. The first establishes how property *should* be distributed, the second how that distribution should be properly maintained in the interactions between people. Gordley [430] asserts that within Aristotle's *Nicomachean Ethics* a higher concept of human welfare underlies the requirement for both distributive and corrective justice. For each person to live in a manner in which their human potentialities are realised "society must distribute resources fairly and, having done so, it must maintain the distribution". Because of this requirement for the preservation of fair distribution, corrective justice ensures that a person who gains at another's expense must compensate

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[427] Munzer & Raustiala (n 262), 78

[428] Baruch Spinoza, *A Theologico-Political Treatise*, in *The Chief Works* Vol 1 (Dover Publications, New York 1951) 208

[429] Andre Compte-Sponville, *A Short Treatise on the Great Virtues* (Vintage, London 2003), 74

[430] James Gordley, "Tort Law in the Aristotelian Tradition" in David G Owen (ed) *Philosophical Foundations of Tort Law* (Oxford University Press, Oxford 1995) 131, 157

the loser. For Gordley, this Aristotelian account "*underlies the law of property, unjust enrichment and tort*" – and it is this account which has informed most all Western debate on this issues from Aquinas, and the Scholastic rediscovery of the works of Aristotle onwards. [431, 432]

The interface between these two forms of justice is at the heart of questions of control of property: I should have mechanisms to control property – including compensation for my loss of property - but only to the extent that my right to that property can be supported by a distributive justification – that is a justification as to why I, in particular, should have property in a certain thing rather than someone else. In this sense deontological arguments for the existence of intellectual property rights *are* distributive justice arguments.

As we have seen above the "natural rights" justification for ownership of property, and by extension intellectual property, is based on the idea that a person has unalienable rights which cannot be surrendered within the social contract. Both Locke and Hegel's view of property was essentially dependent on an idea of the person – for Locke the inalienable ownership of the self is what allows for ownership of land and goods (subject to his provisos) once a person's labour has been mixed with the material world. For Hegel the self is inalienable, and where intellectual products are created which are the extension of the self, these are similarly inalienable.

However, a core feature of the natural rights argument for the existence of an intellectual property rights is that they should only be owned by the person who is *deserving* of the right. Indeed, in relation to the Lockean labour-desert theory this is a rather circular statement, as it is the desert itself arising from the mixing of labour – essentially the self – with something external to the self - which gives rise the right. Accordingly, subject to the provisos, the "property" acquired is coterminous with the desert. Taking the Lockean analogy further, intellectual property rights should be seen from the perspective of an exception to a general freedom to use of the "intellectual

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[431] Richard Tuck, *Natural Rights Theories ,Their origin and development* (Cambridge University Press, Cambridge 1979)

[432] Richard W Wright, "Right, Justice and Tort Law" in David G Owen (ed) *Philosophical Foundations of Tort Law* (Oxford University Press, Oxford 1995) 159, 166

commons".[433] Accordingly, asserting ownership over that part of the intellectual commons which you cannot justly claim is improperly removing information from that commons.

In terms of Kantian/Hegelian personality right justifications it is the creation of something which is an extension of the personality which gives originates the right – the contribution by the personality is key. The corollary of this is that where in individual has not created something/made a contribution there can be no justifiable ownership and/or moral right to control use.

Both Lockean-desert and personality right justifications meet an immediate *inherent* counter-argument that there can be no natural right to the ownership of information or alternatively takes the form that the information commons cannot ever be enclosed.

What arises is a tension between a natural right to know[434] and rights to intellectual liberty[435] on the one hand, and a right to property in that which I have created on the other. This can either be seen as a limited ownership exception to a broader right to intellectual freedom – a "fencing off" of a commons - or as a set of limitations upon the conditions in which a natural right can spring into existence from a "vacuum"– though the result is essentially the same. However, wherever one starts the argument, the crucial factor at the centre of the tension is the concept of *contribution*. Whether reflecting the deontological justifications (or not), the idea that the protection afforded by the right can only extend to the contribution made by the potential right holder is the bedrock of formal intellectual property laws.[436] This focus upon contribution is, of course, a core element of the consequentialist incentivisation argument for intellectual

[433] Jonathan Trerise, "Liberty and the Rejection of Strong Intellectual Property Rights" in Axel Gosseries, Alain Marciano and Alain Strowel (eds) *Intellectual Property and Theories of Justice* (Palgrave Macmillan, Basingstoke 2010) 122

[434] Aristotle, *Metaphysics* Book I, 980a 21

[435] Breakey (n199), 75

[436] See for example Articles 84, 85, 123(2) and 123(3) of the Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000

property – the putative creators of intellectual products are incentivised to create such products by the provision of a "reward" for their efforts.

A focus on rewarding contribution is arguably a key element to Gordley's [437] fair distribution of society's resources. However, the ability to "contribute" is often tied up with the resources that the contributor already possesses – particularly in the field of technological developments. What if that initial distribution of resources is unfair – is it fair to continue to maintain an unfair *status quo ante* by offering yet further reward? It is here that we need to look to broader questions of distributive justice.

Rawls [438] uses a *maximum minimorum* ("maximin") gain and loss analysis as an heuristic tool to demonstrate why it is that a person in Rawls's "original position" would seek a society in which social and economic inequalities are to be to the greatest benefit of the least advantaged members of society – essentially where extremes of inequality of wealth are minimised (the "difference principle").

The maximin analysis used by Rawls is set out in Table 3.1

Table 3.1 Rawls's maximin analysis. (values in 00's of dollars)

	Circumstances		
Decisions	**C_1**	**C_2**	**C3**
d_1	-7	8	12
d_2	-8	7	14
d_3	5	6	8

As Rawls notes, this table is not a game of strategy – there is no one to play "against". Instead Rawls has the person in the original position facing a number of potential outcomes: circumstances C_1 through to C_3. The person in the original position, sitting as she is behind the "veil of ignorance" cannot know in which of these circumstances she will find herself. She can, however, through her decision (d_x) as to the ordering of

[437] Gordley (n 430), 157

[438] Rawls, *A Theory of Justice* (n 381), 153

society, select a set of outcomes which in which the worst outcome is better than the worst outcomes of all the other strategies. In Rawls's table the set of options which provides this "maximisation of the minimum" is decision $d_{3.}$ Although d_2 would provide a greater potential upside ($1400) for some, it also provides the greatest downside (namely a debt of $800) for others.

Rawls uses the maximin analysis as a starting point for arriving at his argument that the social contract should be built on the principle of liberty, namely that each person is to have an equal right to the most extensive total system of equal basis liberties compatible with a similar system of liberty for all, paraphrased as "*people must be allowed the freedom to pursue the kind of life they would wish to lead provided it does not directly or indirectly harm another*". [439]

In addition, in following the maximin approach the person in the original position has to evaluate any institutional framework as if she *was sure* that she would become the most disadvantaged member of a particular society. This leads Rawls to his "difference principle". This asserts that although such inequalities cannot be avoided, social and economic inequalities should be organised such as to give the greatest benefit of the *least advantaged* members of a society. Thus any evaluation of any possible institutional framework must start by identifying with the interests of the worst-off individual in society. [440]

It is crucial to note that Rawls is not requiring the sweeping away of all inequalities where such inequalities can be justified on other grounds, provided that such inequalities provide conditions in which the *absolute* (rather than *relative*) condition of the least advantaged in society (C_1 in the table above) is enhanced (the minimum is maximised). In its purist form, the incentivisation/consequentialist argument for intellectual property could meet this requirement. If the provision of a reward for inventive efforts directly leads to a broader total enrichment of the entirety of society such that the situation of C_1 is improved over the situation without such incentivisation

[439] Peter Vardy and Paul Grosch, *The Puzzle of Ethics* (Fount London, 1999), 139

[440] John C Harsanyi, "Can the Maximin Principle Serve as a Basis for Morality? A Critique of John Rawls's Theory" (1975) 69(2)The American Political Science Review 594, 596

then such a policy is not contrary *per se* to the principles of Rawlsian distributive justice. Significant questions, of course, remain as to whether such a policy *in fact* enhances the total wealth of society or whether the wealth so created is so unevenly distributed that C_1 sees no benefit or so little benefit as to be essentially unappreciable.

At first blush one might argue that the creation of *sui generis* rights in genetic resources and traditional knowledge associated with genetic resources is a policy which avoids the "trickle down" problems of a broad incentivisation policy, and adheres to the difference principle by moving directly to enhancing the situation of a group of disadvantaged individuals within global society - namely indigenous peoples within the global South. However, we need to immediately note that the difference principle does not, of itself, *create* a deontological or consequentialist right - it is a principle to be adhered to in the *application* of other rights, justifications and policy approaches if one is seeking to ensure distributive justice. If we are following a Rawlsian approach, we need first to seek fundamental justifications for excluding non-consensual use of traditional knowledge associated with genetic resources and then seek to ensure that the application of justification serves to maximise the minimum situation for our most disadvantaged person "C_1".

OseiTutu[441] looks at the justification for a positive intellectual property right in traditional knowledge and asks the question whether protecting traditional knowledge through a *sui generis* intangible right would create a more equitable regime from a distributive justice perspective. She states that for many the *sui generis* right is a deontological one based on upon Locke's labour desert theory. However, she believes that such rights can result in an imbalanced intellectual property system which allows the intellectual property right to take priority over competing interests and fears for the required "retraction" of the public domain to create an exclusive right. She states:

[441] JJ OseiTutu, "A *sui generis* regime for traditional knowledge: The cultural divide in Intellectual Property Law" (2011) 15 Marquette Intellectual Property Law Review 147

> "If a *sui generis* traditional knowledge right is to be created, the broader social good served by protecting traditional knowledge as a new form of intellectual property right should be very clearly articulated"[442]

OseiTutu also suggests that an indefinite, monopoly right for traditional knowledge would:

> "offend the principle of balance between the interests of the right holder and the public." [443]

She concludes that:

> "If the goal of access to affordable knowledge and information is a worthy one, then an assessment of traditional knowledge from a distributive justice perspective leads to the conclusion that a *sui generis* intangible property right in traditional knowledge may not be the most appropriate response to the problems of bio-piracy and misappropriation. The corollary to this position is that the international community should be mindful of the need to balance rights and obligations in the development of international intellectual property law and policy." [444]

However, OseiTutu gives no specific guidance as to how achieve such a balance in relation to the scope of a *sui generis* traditional knowledge right.

3.11 Restorative/corrective justice ("reparations")

Munzer [445] has recently proposed a justification for rights in traditional knowledge based upon "corrective justice". He proposes six conditions precedent for such a corrective right. The first four he considers "background" conditions. These are:

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[442] OseiTutu (n 441), 190

[443] OseiTutu (n 441), 193

[444] OseiTutu (n 441), 213

[445] Munzer (n 225)

1) Some wrongs must have been committed against an indigenous group, some or all of its members, their successors, or both;

2) The wrongdoers, or their successors, are identifiable as a group, individual members of a group, some other entity, or some combination of these;

3) The wrongs unjustifiably caused harm to an indigenous people, or some of its members; and

4) Those harmed are identifiable as an indigenous group, or as individual members, of an indigenous group, or both.

Once such injustices have been established, one would then need to consider whether:

5) No excuse is available such that the wrongdoers or their successors lack a moral duty to rectify their wrongs and undo the harm caused; and

6) Granting intellectual property rights in traditional knowledge in principle would be an effective and reasonably efficient means of compensating or restoring justice to the indigenous people or its members who have been harmed.

It is important to note that what is envisaged here is that once a sufficient present (or historic) indefensible wrong can be proved then a right to protect traditional knowledge will be granted where that provides "effective and reasonably efficient" restorative justice. There is no requirement for any *specific* link between the type of wrong and the remedy, nor it would seem, a clear link between the magnitude of the wrong and the remedy (other than that the "reasonable" efficiency does not have to be economically optimal only not "seriously inefficient"). [446]

Munzer himself immediately recognises that the corrective justice of which he speaks is not what most would understand as an Aristotelian commutative justice, in which a *specific* wrongdoer directly corrects a *specific* wrong which that wrongdoer has wrought upon a *specific* wronged individual. For Munzer, such an Aristotelian approach is

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[446] Munzer (n 225), 62

inappropriate as it is "*too rigid to deal with wrongs done by many sorts of wrongdoers to many sorts of victims*". [447] He states further:

> "in typical situations involving indigenous groups, harmed over many generations in many different ways by many different individuals, outsiders of various sorts, corporations and nation starts, it would be Procrustean to try to make the remedy due to indigenous groups exactly equal to the gains of wrong doers under an idealized correlatively-structured system of corrective justice. Given the remedial constraints thrown up by these complicated situations, one must make room for some constraints of efficiency. If this is rough corrective justice, so be it." [448]

Of course, what Munzer denigrates as "Procrustean" logic and an "idealized correlatively-structured system of corrective justice", namely that legal remedy should match the wrong committed and that one should have certainty in the application of the law against one, is thought by others to be a core principle of the rule of law. [449]

Notwithstanding obvious evidential problems, [450] crucial questions remain as to the *degree* of wrong required to support a claim. A key facet in Munzer's scheme is that there no requirement for a clear linkage between the precondition for acquiring a right and the right given but we are not told what threshold of wrong needs to be met in the first place. Does a combination of smaller wrongdoings have an additive affect and if so how should this affect be determined? Crucially (and closely linked) we are not told upon what basis Munzer's defence of a "lack a moral duty to rectify their wrongs and undo the harm caused" is to be determined. Is this to be judged against an absolute standard of whether the wrongdoer should have reasonably believed they were acting inequitably? If so, in relation to historic abuses, is that standard to be determined as at the time of commission of the wrongful act or by today's standards?

[447] Munzer (n 225), 62

[448] Munzer (n 225), 62

[449] Bingham (n 203), 37

[450] For example the delineation of where one indigenous group ends and another begins and acquiring evidence of historic injustice against a specific indigenous group.

Assuming that past wrongs of any sort do provide a justification for the creation of a *sui generis* right in traditional knowledge, what *type* of right is to be considered to be appropriate correction? Munzer divides corrective justice into compensatory justice (equivalent to money damages at law) and restorative justice (equivalent to injunctive relief, restitution and other relief in equity). However, he also sees corrective justice as incorporating "reparations" for (predominantly past) wrongs and sees corrective reparations as either compensatory or restorative, or both. It is this concept of "reparation" which is at the centre of Munzer's justification for protection of traditional knowledge. Accordingly, there seems no reason why such protection *could not* in principle include the grant of an absolute veto (through injunctive relief) alongside the award of compensation. Crucially, however, Munzer avoids answering the question as to which intellectual property rights in traditional knowledge should be given to indigenous peoples in a particular circumstance. He also avoids advocating a set of appropriate intellectual property rules. His thrust is that effective compensatory and/or restorative elements in relation to misuse of traditional knowledge should form part of an appropriate suite of reparations for past wrongs (which may also include land grant, healthcare, education and monetary damages) determined on a case by case basis.

This type of "what seems right at the time" *smörgåsbord* of remedies approach has the undoubted benefit of flexibility, but fails to address the question of third party certainty. In addition, the "past wrongs deserve some type of reparation" justification may benefit from philosophical simplicity, but is so loose as to provide little concrete basis determining the correct balance between the compensatory and/or restorative elements of the "reparation" on a case by case basis. Most cases will require determination between competing equities. Under Munzer's reparation justification, a defendant may find themselves essentially burdened with the inequities of entirely unrelated third parties whose actions were unrelated to the case in question and which occurred in distant history. One might imagine here a defendant party who were entirely happy to pay compensation for a misappropriation, but maintained that their use was so distal to the original information that injunctive relief was inappropriate. Under the reparation justification the (perhaps significant) historic abuses of unrelated others could here go into the balance of equities. Even if this were the case, we have no sense as to how inequities should be weighted as between the current defendant and third party wrongdoers on one axis, as between current misappropriation and historic wrongs on another axis and as between gravity of wrongs on yet another axis. Of course, such uncertainties make the translation of Munzer's reparation justification to a set of generally applicable principles for broader application exceptionally difficult.

3.12 A communitarian approach

In her monograph *Community Resources*, Gibson [451] proposes a communitarian basis for positive sui *generis* rights of control over traditional knowledge. The philosophical grounds for the creation of such rights are communitarian and as such are not grounded in the utilitarianism/consequentialism, individual natural rights (Lockean or Hegelian/Kantian personality right), corrective justice, nor Rawlsian distributive justice. Gibson states that:

> "Fundamentally, the concept of community resources recognises obligations to cultural diversity and dignity through the acknowledgement of, and respect for, traditional and Indigenous communities. According to the model of community resources, communities are entitled to manage their resources in observance of customary laws, values, and traditional practices." [452]

A claim to community is the basis of the right, but Gibson is highly sensitive to the origination/individuation problems inherent in such claim and in the identification of resources under that claim. According she sets out the following requirements for a claim:

1) Assertion of community by community – self-recognition will trigger a presumption in favour of community;

2) Assertion of resources by community – recognition of community and claim by that community to the knowledge in question will trigger a presumption that the knowledge is traditional;

3) Rebuttal of presumption by competing claim – assertion of community and of resources may be rebutted by the parties seeking commercialisation of or access to knowledge (on the grounds set out below); and

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[451] Gibson (n 193)

[452] Gibson (n 193), 287

4) Proportionality – the application of equitable principles to determine validity of the claim (whether to community or to traditional knowledge). [453]

In applying a principle of proportionality Gibson states:

> "In other words, the process **[that is the rebuttable claim to community and rebuttable presumption to traditional knowledge]** will involve a balancing of interests according to equitable principles of international law. It is not claimed here that equity is the source of the law, but that equitable principles necessarily inform the decision as to competing interests." [454]

What type of right is envisaged here – a right to compensation or a right to veto non-consensual use, or both? Although she does not expressly outline these options, Gibson considers a requirement for free and prior informed consent before traditional knowledge can be used by others to be "fundamental" to her model and an essential element of legitimate use or appropriation. This is, of course, consistent with a right to control resources arising out of a claim to community. She states:

> "Communities must be entitled to consent to the use of their knowledge as appropriate and under conditions to be determined by the communities and in accordance with their customary laws."

This absolute right to control would appear to point to a right of veto backed by injunctive relief. However, such a right is not absolute. Gibson highlights the fact that there may be problems identifying those entitled to grant consent in particular circumstances. In such a situation Gibson's believes:

> "The application of free and prior informed consent within the present model would impose a duty upon those seeking to use what they ought reasonably to

[453] Gibson (n 193), 287

[454] Gibson (n 193), 288

believe to be a traditional knowledge or natural/genetic resources, to make reasonable efforts to ascertain and contact the relevant community." [455]

Where such reasonable efforts have been made and an indigenous community subsequently become aware of a misappropriation and enforce their rights, Gibson sees there being no damages payable to the community although there may be benefit sharing and return of assets "where appropriate".

3.13 Conclusions

We have seen that a number of the philosophical justifications which are ordinarily used to support the existence of classical intellectual property rights have been raised in support of positive rights in traditional knowledge. However, the translation of those justifications into this area highlights some of the inherent problems with certain of those justifications. In addition, the distinctive nature of traditional knowledge means that many of those justifications are stretched. Certainly, none of the justifications are infallible: each approach has problems in its application in certain circumstances. One cannot be purist in applying deontological justifications and neither is the consequentialist account without its difficulties (particularly in relation to assuredly achieving its set goals).

There would appear to be significant problems with a Lockean, labour desert-based justification for a monopolistic intellectual property right in traditional knowledge associated with genetic resources. We have seen that Attas strongly argues against the existence of a natural law justification for intellectual property, based on the problems of certainty surrounding the "origination" and "individuation" of the subject matter (and the "squeeze" between the two). The *origin* of traditional knowledge is, by its very nature, difficult to determine. Even in the (unlikely) presence of concrete evidence surrounding its creation, the trans-generational and iterative (and ongoing) nature of the creation of traditional knowledge may make it particularly sensitive to Attas' criticism. There are also problems as to why such rights should exist *now* whereas the "inventions"/ "discoveries" incorporated within the knowledge may have made by (sometimes very distant) ancestors and questions as to why any such right should have

[455] Gibson (n 193), 290

an indeterminate duration. However, as has been stressed by Dutfield & Suthersanen, even though the labour-desert account has difficulty in giving particular answers to specific questions, it does remind us to examine a right in terms of the balance between the desert of an originator and the liberty of the rest of the world.

From a right based in personality perspective, a key criticism is that it is difficult to imagine a personality right sitting comfortably with a potentially diverse group of indigenous peoples, particularly within a trans-generational (and potentially multi-site) setting. Chief amongst the problems with this account, however, is that Kantian authorial personality and Fichtean/Hegelian personality rights do not support the control of knowledge *per se*.

The "classic" consequentialist justification for intellectual property rights is that through providing a reward to creators they incentivise the creation of new "products" of intellectual endeavour and further incentivise the commercialisation of such products. The exact application of such a justification to a right in traditional knowledge associated with genetic resources is problematic – much of the subject matter of the right will be have been already been created so, simply put, its creation cannot be incentivised. In contrast, one can potentially see how providing incentives to create commercial value in indigenous knowledge would accord with the utilitarian aim, not of creating new knowledge, but of preventing the *loss* of existing knowledge (not only from the relevant indigenous group themselves, but from mankind more broadly). If one can also argue that creating value in such knowledge also provides an incentive to maintain the cultural and ecological environment in which the knowledge resides then the utilitarian justification will be further strengthened.

To this utilitarian account may be added a separate and particular "utility" that comes from indigenous peoples controlling their own knowledge in accordance with their customary practices.

Gibson has advanced a separate but related communitarian justification which arises out of a claim to community and assures that an identified community should be able to control their own information under conditions to be determined by the communities and in accordance with their customary laws. This is, however, a right that may be tempered by concepts of equity where competing interests are to be evaluated.

In his review with Raustiala, Munzer generally found the usual philosophical justifications for intellectual property rights to be wanting when applied to the protection of traditional knowledge. He has more recently advanced the grant of rights to control traditional knowledge as part of a package of broader "reparations" for past wrongs committed upon a traditional group. The current work has identified:

a) the difficulty in translating the "case by case" basis of such a doctrine to broader principles for general applicability; and

b) the problems associated with determining how inequities should be weighted as between the current defendant and third party wrongdoers, as between current misappropriation and historic wrongs and as between gravity of wrongs; and any sense of third party certainty.

To the extent that underlying philosophical justifications for such rights in traditional knowledge associated with genetic resources can be determined, the question of whether the allocation of property which arises out of following those justifications gives rise to a fair distribution of property across society still remains.

Although supportive of human creativity and flourishing, established human rights do not create an express right to intellectual property. The position in respect of indigenous peoples has been advanced somewhat by UNDRIP. Article 11 UNDRIP enshrines a right to practise and revitalize indigenous cultural traditions and custom. However, it does not set a minimum standard in terms of the way in which indigenous people's cultural, intellectual, religious and spiritual property taken "without their free, prior and informed consent or in violation of their laws, traditions and customs provides" will be protected other than that there should be "effective" redress which "may include restitution". Clearly, all rights supported by other justifications should at least be compliant with the rights envisaged under UNDRIP.

To conclude then, although there are uncertainties as to the philosophical support for positive rights in traditional knowledge associated with genetic resources, the above analysis provides a road map of the approaches (and difficulties) which must be considered in the remainder of this work.

Chapter 4

The landscape of drug discovery

"Everything is poisonous, nothing is poisonous, it is all a matter of dose."

Claude Bernard *Pathologie expérimentale* (1872),72

4.1 Introduction

It was argued in Chapter 1 of this work that if we are to gain insight into the limits of a positive right in traditional knowledge associated with genetic resources within the field of drug discovery, we need first to understand the process by which drug candidates are discovered, and the ways in which such traditional knowledge has entered (and continues to enter) the discovery process together with the ways in which it has been (and is) used within that process. It is the aim of this chapter, therefore, to explore the topography of the drug discovery process and understand the flow of information within it.

Much of the modern drug discovery process is reliant on an understanding of *why* it is that chemical agents have the biological effect that they do. The first part of this chapter will introduce some of the fundamental concepts which underlie the action of drugs and why plant, animal and microbially-derived active substances (products of genetic expression) have had a major role in drug discovery. The chapter will then look at the non-linear and highly iterative nature of drug discovery (and briefly why it is different from drug *development*) and at the processes that might be involved in taking traditional knowledge associated with genetic resources associated with traditional resources through to a fully-characterised drug. Having done this, the chapter will then seek to determine whether there are any points in the described drug discovery process which could be identified as the "crux points" discussed in Chapter 1 – that is points in the drug discovery process where the nature of the movement of information is such as may give rise to break in a causation in law analysis of the scope of positive rights in tradition knowledge associated with genetic resources.

4.2 The pharmacological background

The majority of therapeutic and psychoactive drugs work through action a biologically active compound (a "ligand") at a protein receptor site present on, or within, a cell. The receptor sites are present on/in the cell as part of the body's internal signalling mechanism. Biological signals are often mediated through small endogenous ligands (whether neurotransmitters, hormones, parahormones, trophins, or other signals) which interact with their specific target protein receptor to cause a downstream biochemical response. These ligands "bind" to the receptor causing a conformational change in the structure of the receptor protein. It is this structural change which elicits the downstream biochemical effect, in many cases mediated through switching an enzyme on or off, or opening or closing an ion channel through a membrane. [456, 457]

To minimise the chances that that the individual signalling systems interfere, the receptor sites and ligands in one system often show a high degree of intersystem specificity. This has been (rather simplistically) termed the "lock and key" hypothesis [458]. Although the analogy serves for present purposes, it is worth noting that the inter-molecular interaction between the ligand and receptor is in reality more subtle. In particular, just because a ligand binds to a receptor does not necessarily mean that the receptor will be activated. Different parts of the ligand molecule may be considered as carrying more of a "binding" functionality, whereas other parts may be considered as carrying more of an "activation" functionality. Again this is a simplification, and in many cases the functionalities of parts of the ligand molecule are not clear-cut, or are mixed.

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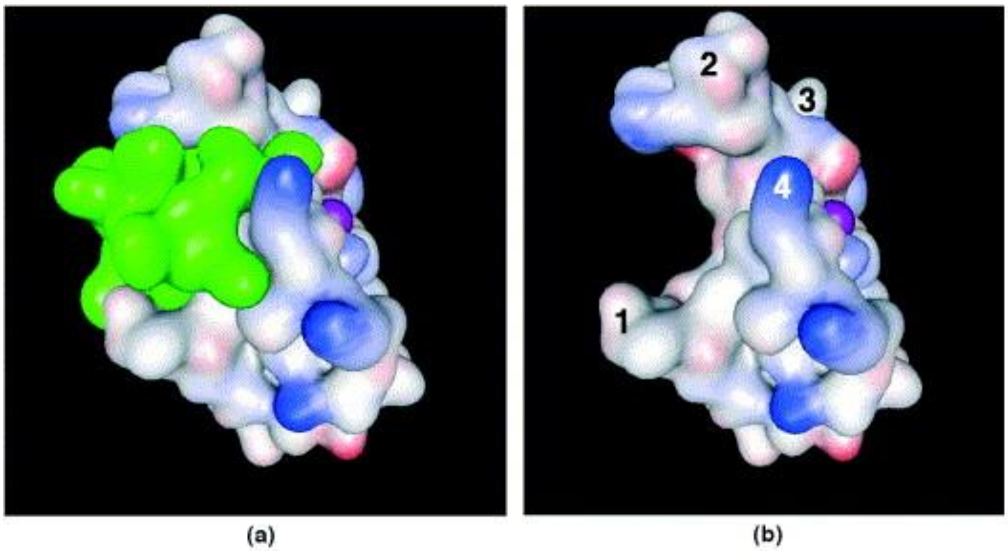
[456] Elliott M Ross and Alfred Goodman Gilman, "Pharmacodynamics": Mechanisms of Drug Action and the relationship between Drug Concentration and Effect Alfred" in Goodman Gilman, Louis S Goodman, Theodore W Rall & Ferid Murad (eds) *Goodman & Gilman's The Pharmacological Basis of Therapeutics* (Macmillan Publishing Company, New York, Toronto and London, 1985) 35

[457] Rick Ng, *Drugs, From Discovery to Approval* (John Wiley & Sons, New Jersey 2004), 15

[458] Matthews (n104), 369

It is important to appreciate that the molecular "key" of the ligand has a 3-D structure and will interact with the 3-D "lock" (perhaps better described as a 3D "pocket") of the receptor. In many cases the 3-D structure will "mirror" the 3D shape of the pocket but other factors are important, particularly the interaction between the electrostatic charge of regions of the pocket and key, or the hydrophilic/hydrophobic interactions between regions of the pocket and key. A 3-D representation between a ligand (α-bungarotoxin) from a snake (krait) venom and a peptide portion of the acetylcholine receptor (present at the neuromuscular junction) gives a flavour of the 3-D nature of this interaction and is set out at Figure 4.1.



<u>Figure 4.1(from Harel *et al.*)</u> Three-dimensional surface drawing of the structure of α-BTX/Hap2 complex, determined by X-ray diffraction. Colour of the α-BTX corresponds to the electrostatic charge, with blue positive and red negative. (a) α-BTX/Hap2 complex; Hap2 is shown in green. (b) α-BTX with Hap2 removed. [459]

[459] The figure is reprinted from, M Harel, R Kasher, A Nicolas, JM Guss, M Balass, M Fridkin, AB Smit, K Brejc, TK Sixma, E Katchalski-Katzir, JL Sussman, and S Fuchs, "The binding site of acetylcholine receptor as visualized in the X-ray structure of a complex between α-bungarotoxin and a mimotope peptide" (2001) 32 Neuron 265 (Copyright (2001) Elsevier Science).

Relatively small changes in the chemical structure of the ligand can diminish the potency of the ligand at the receptor – analogous to altering the shape of the "key". However, some small chemical changes can enhance the potency of the ligand or maintain/enhance its binding capability, but restrict the degree to which the ligand activates the receptor. A compound which activates a receptor is called an *agonist* and one that which prevents agonists from reaching the "lock" (but without activating the receptor themselves) are called *antagonists*. So-called *inverse* agonists bind to the receptor but elicit an opposite biological effect than would an agonist. [460]

The same endogenous ligand may have different effects in different parts of the body. These differing effects are usually mediated through sub-types within the same receptor "family". Although these receptors all show affinity for the same endogenous ligand, they can be distinguished by differing affinities for (often biologically-derived) exogenous ligands. A classic example is that of the endogenous ligand acetylcholine, the first neurotransmitter to be identified (by Dale and Löwi) [461]. Acetylcholine has effects across the body through a variety of signalling systems which are summarised in Table 4.1.

For brevity, the present description of pharmacologically active agents is limited to those which have actions at "classic" receptors. Whilst this is true for many such agents, it should be noted that many other drugs act through actions as biochemical precursors (enzyme substrates), enzyme substrates which prevent enzyme activity (sometimes termed "anti-metabolites"), other enzyme inhibitors, ion channel blockers or uptake inhibitors or through a direct action on cell membranes or gene expression. However, for the present purposes many of the points raised about ligand-target specificity and the drug discovery research process remain as true for these agents as for "classic" receptor ligands.

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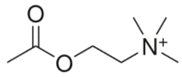
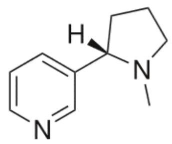
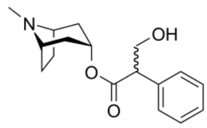
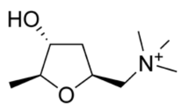
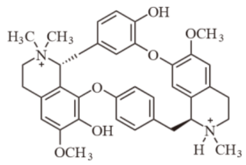
[460] Originally styled "contragonists". DJ Nutt, PJ Cowen, and HJ Little, "Unusual interactions of benzodiazepine receptor antagonists" (1982) 295 (5848) Nature 436

[461] Leonard A Stephens, *Explorers of the Brain* (The Scientific Book Club, London 1973), 152

Table 4.1 Sub-types of acetylcholine receptors [462, 463]

System	Receptor Subtype	Endogenous Agonist	Exogenous Agonist	Exogenous Antagonist
Central Nervous System	Nicotinic	Acetylcholine[464] 	Nicotine[465] (obtained from tobacco plant *Nicotiana tabacum* and other members of the nightshade family) 	Atropine[466] (obtained from Deadly Nightshade, *Atropa belladonna*) 
Motor Neurons (Neuromuscular Junction)	Nicotinic	Acetylcholine	Nicotine	Atropine
Autonomic Nervous System	Muscarinic	Acetylcholine	Muscarine[467] (obtained from the mushroom *Amanita muscaria*) 	Tubocurarine[468] (obtained from the South American climbing vine *Chondrodendron tomentosum*) 

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[462] HP Rang and MM Dale, *Pharmacology* (Churchill Livingstone, Edinburgh, 1987), 113

[463] Structures taken from Wikipedia and reproduced under Wikipedia commons licence.

[464] Maryadele J O'Neil (Senior Ed), *The Merck Index, An Encyclopedia of Chemicals Drugs, and Biologicals* (Merck & Co Inc Whitehouse Station, New Jersey, 2001), 17

[465] O'Neil (n 464), 1169

[466] O'Neil (n 464), 151

[467] O'Neil (n 464), 1129

[468] O'Neil (n 464), 1746

4.2.1 Therapeutic agents from living organisms

The basis of much modern pharmacology has been the determination of classes of endogenous ligands, their receptor sites and downstream actions followed by the development of drugs to mimic the action of the endogenous agonist (or act as antagonists or inverse agonists) at specific target sites.

Throughout the course of evolution of life on Earth, biological organisms have often found an evolutionary advantage in producing compounds which have binding effects at receptors meant for endogenous signalling ligands in other organisms. [469] These compounds are, in most cases, not exact copies of the endogenous ligand, but have different structures which allow a remarkable specificity and potency at the receptor sites (better in many cases than the endogenous ligand). Many compounds have evolved as toxins or venoms used in animals for hunting or defence, or used in plants to discourage their being eaten (or to elicit a biological response in the animal which is in some other way advantageous to the plant). [470]

Throughout human history the discovery of the biological effects of mostly plant, and some animal, toxins on humans led to the development of the first therapeutic (and psychoactive) drugs. Often these were used in the form of plant or animal extracts.

The ancient Greek word *pharmakon* can mean both “drug” and “poison”, a mix of meanings which underlies the interplay between the toxic effects of some plant- and animal-derived ligands and their therapeutic benefits. [471] The formal, informal or trial and error “study” of plant and animal “poisons” often led to the development of folk remedies, or more formalised herbal and traditional medicine systems.

It was the later systematic investigation of the biological effects of many of the biologically-derived exogenous ligands that gave the first (Western-scientific) insight into the workings of the body’s internal signalling mechanisms. As was the case for the

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[469] Linda Fellows and Anthony Scofield, “Chemical Diversity in Plants” in Timothy Swanson (ed), *Intellectual Property and Biodiversity Conservation: an Interdisciplinary Analysis of the Values of Medicinal Plants* (Cambridge University Press 1995) 19

[470] Fellows & Schofield (n 469)

[471] Jacques Derrida, “Plato’s Pharmacy” in *Dissemination* (Barbara Johnson (trans)) (University of Chicago Press, Chicago IL 1981), 70

acetylcholine receptor seen in Table 4.1, many biological receptor sites were discovered, (and classified) by using plant-derived drugs. In some cases this was before the existence, or nature of, the endogenous ligand was itself understood.

Although as stated some cases the plant-, or animal-, derived ligands are exquisitely specific for, or potent at, the endogenous target receptor, in other cases the plant-, or animal-, derived ligands are unspecific (causing undesired side-effects) and/or lack desired potency. In both cases there may be a therapeutic requirement to modify the performance of the ligand at the receptor.

It is the task of the medicinal chemist to engineer changes to the plant/animal-derived ligand (or the endogenous ligand) to create the desired specificity/potency profile. In the past this was often done by getting a “feel” for what changes to the structure of the ligand would cause certain changes. This was often founded upon a data-base of existing ligands and their known binding at, and downstream effects mediated through, the receptor site. As mentioned, the interaction between the ligand and receptor relies on a complex interplay between the 3-D shape, electrostatic charge and hydrophobic/hydrophilic character of the ligand molecule. Accordingly, understanding how changes to chemical structure of a ligand impact upon these elements is not trivial. However, increased understanding of the structure of the receptors (through genomic, proteomic and glyconomic studies) gives researchers a better understanding of the structure of the “lock” and how various aspects of the ligand “key” interact. This has led to a further rationalisation of the design of modified ligands. [472]

Most endogenous ligands are, in general, relatively small chemical compounds relative to the size of the protein receptor site to which they bind. Many plant-, animal- or microbe-derived ligands or the chemically modified versions of these (or endogenous) ligands developed by medicinal chemists are similarly small and there relatively few places on the molecule to make chemical changes. In addition, the “key” part of the ligand molecule which interacts with the “lock” needs to have a very particular 3D conformation and electrostatic/hydrophobic character and relatively few departures

[472] Ansgar Schuffenhauer, Nathan Brown, Paul Selzer, Peter Ertl, and Edgar Jacoby, “Relationships between Molecular Complexity, Biological Activity, and Structural Diversity” (2006) 46 J Chem Inf Model 525

from this template will retain the desired activity. These limitations have meant that the developers of pharmaceuticals have found little in the way of protectable intellectual property "space" around the ligands.

In the past two decades, in an attempt to find clear intellectual property space, the pharmaceutical industry initiated lead compound identification based on testing "random" combinatorial chemistry libraries. In this approach randomly-generated compounds were tested in very large numbers against known receptor targets using an automatic testing methodology termed "fast-throughput screening". The idea was that by testing a large "galaxy" of compounds many unpredicted, and unpredictable (and hopefully therefore patent-protectable) "hits" would be discovered and form the basis for new pharmaceutical development. To the disappointment of drug companies (and their investors) very few therapeutically useful (and commercially successful) agents have been identified using this methodology. [473] Part of the explanation for this comparative lack of success is that the vast majority of the compounds randomly produced by combinatorial chemistry lacked the structural complexity that is seen in many biologically-active compounds or were not sufficiently "drug-like".

Effective pharmaceutical drugs, and biologically-derived toxins, are required to be "bioavailable". This means that they can be absorbed by the body and distributed within the body to the desired target without being excreted or metabolised before they can reach that target. Broadly speaking the bioavailability of a compound can be predicted from its structure (what is now called "Lipinski's Rule of Five" [474]). However, very many of the randomly generated compounds developed by combinatorial chemistry lacked these chemical characteristics, were not bioavailable, and so were essentially useless as a therapeutic drug "lead" - no matter how effectively they bound, activated or blocked the receptor.

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[473] T Kodatek, "The rise, fall and reinvention of combinatorial chemistry" (2011) 47(35) Chem Commun (Camb) 9757

[474] CA Lipinski; F Lombardo; BW Dominy and PJ Feeney, "Experimental and computational approaches to estimate solubility and permeability in drug discovery and development settings" (2001) 46 Adv Drug Del Rev 3

4.2.2 "Bioprospecting"

The relative failure of random combinatorial chemistry/fast-throughput screening approach has led to something of a return to so-called "rational" pharmacology. The advances in genomics, proteomics and glyconomics (which allow researchers to better understand biological target structure) mentioned above are now increasingly being allied to the search for biologically active compounds from flora, fauna and microflora (so called "bioprospecting") to find "novel" ligands for those sites.

It is possible for a microorganism-, plant- or animal- derived ligand to mimic the 3D "key" of an endogenous ligand by recreating a similar 3D structure through a different chemical structure than that used by the endogenous ligand. Although that 3D structure may itself be broadly predictable, the way in which the biologically-derived ligand reproduces that structure need not be so predictable. Herein lies the potential strength of "bioprospecting" as a research tool to find "new" therapeutic approaches. Approaches that may also give researchers some intellectual property distance from their competitors.

By far the greatest reservoir of biodiversity of the planet (and alongside it a reservoir of biological "toxins") exists in the tropics, particularly (but not exclusively) in the equatorial rain forests. However, a tropical rainforest will harbour many thousands of plant species and many of those species may have many separate strains. Random testing of plant species is possible and has had some success. During the early- to mid-1960's random testing of plant samples conducted by the US Cancer Chemotherapy National Service Center resulted in the isolation of the anti-cancer drug taxol from the Pacific Yew *Taxus brevifolia.* [475] However such random testing tends to give little return on investment. [476]

How then could a pharmaceutical researcher looking for new ligands from these environments narrow the search? One approach, *phylogenetic surveying*, is to seek out other species of a genus which is already known to yield bioactive or therapeutic agents,

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[475] MH Wani, H Taylor, MP Wall, P Coggon and A McPhail,, "Plant antitumor agents. VI. The isolation and structure of taxol, a novel antileukemic and antitumor agent from *Taxus brevifolia*" (1971) 93 (9) J Am Chem Soc 2325

[476] Balick & Cox (n 8), 37

remove samples, purify extracts and test them. A further approach, *ecological surveying*, is to examine plants which occur in similar ecological niches, or have similar phenotypic characteristics, to plants which are known to yield bioactive or therapeutic agents. However, a further approach, (sometimes referred to as *ethnobotanical surveying*) is to rely upon the knowledge of the indigenous peoples who have lived with and used the biological resource, and who have developed, perhaps over generations, an understanding of the therapeutic or psychoactive effects of the biological resource. [477]

There are a great many examples of the success of the ethnobotanical approach. [478, 479] Cox [480] lists 50 drugs which have been derived from ethnobotanical leads, but suggest that this is an underestimate and cites Farnsworth's estimate [481] of such drugs being closer to 88. Although impressive, raw numbers do not perhaps give an impression of the importance that these drugs have played in the development of Western medicine (and for that matter in Western recreational drug use). Cox's list of 50 includes the well-used drugs set out in Table 4.2. [482]

[477] See by way of recent example ethnopharmacological studies on desert teak. Mahendra Jaina, Rakhee Kapadiac, Ravirajsinh Navalsinh Jadejad, Menaka Chanu Thounaojamd, Ranjitsinh Vijaysinh Devkard, and Shri Hari Mishrab "Traditional uses, phytochemistry and pharmacology of *Tecomella undulate* – A review" (2012) 2(3) Asian Pacific Journal of Tropical Biomedicine S1918

[478] Schiebinger (n 6)

[479] Laws (n 7)

[480] Cox (n 3), 27

[481] Farnsworth (n 4)

[482] Not all of the drugs named by Cox and Farnsworth arise from *indigenous* ethnobotanical leads. Some have arisen from Western folk knowledge.

Table 4.2 Some major ethnobotanically-derived medicines (after Cox [483])

Drug	Therapeutic use
aspirin	analgesic, anti-inflammatory
atropine	pupil dilator
cocaine	anaesthetic
codeine	CNS stimulant
dicoumarol	antithrombotic
digoxin	cardiotonic
digitoxin	cardiotonic
ephedrine	bronchodilator
hyoscamine	antispasmodic
morphine	analgesic
physostigmine	glaucoma therapy
pseudoephedrine	decongestant
quinine	antimalarial
reserpine	antihypertensive
scopolamine	anti-motion sickness
tubocurarine	muscle relaxant
tetrahydrocannabinol	antiemetic
theophylline	diuretic
vinblastine	cancer therapy
vincristine	cancer therapy

Within the Western pharmaceutical tradition the science of studying drugs arising from natural (including plant) sources is known as “pharmacognosy”. This is a science which touches on many other areas of study most notably phytochemistry (the study of plant-derived chemicals) and “ethnobotany”. Phytochemistry is, of course, a broader area of study that looking merely at therapeutic ligands. Similarly “ethnobotany”, a term originating in 1896 with American botanist John W. Harshberger, [484] takes in many areas beyond therapeutic plants but can be broadly defined as the study of the

[483] Cox (n 3), 27

[484] John W Harshberger, “The Purposes of Ethnobotany” (1896) 21 Botanical Gazette 146

interaction between indigenous peoples and plants.[485] Ethnobotany is by its nature an interdisciplinary field. Balick and Cox suggest that the ideal ethnobotanist is a:

> "combination anthropologist, archaeologist, botanist, chemist, psychologist, ecologist, explorer, folklorist, pharmacologist, and diplomat".[486]

Notwithstanding the success of the ethnobotanical approach, Balick and Cox suggest that there has been a degree of prejudice in the Western medical community against it. They argue that this may be the result of cultural prejudice during the Western colonial period when Western medicine was:

> "taken as a prime exemplar of the constructive and beneficial effects of European rule" and "one of its indisputable claims to legitimacy".[487]

They suggest, however, that the use of plants as a source of candidate molecules has (re)gained favour due to a) the awareness of the loss of biodiversity, b) the use of fast-throughput screening to screen plant-derived candidates, and c) a growing appreciation of the sophistication of indigenous knowledge systems. In previous work Balick[488] has highlighted the rapid erosion of ethnobotanical knowledge which is, as he puts it, caught between the loss of species and habitat on the one hand and loss of cultural legacy of experience on the other. As already mentioned, the relative failure of the random screening of combinatorial chemistry libraries will also have had an influence on the new focus on plant-derived candidates.

Of course, not all research leads provided by indigenous traditional knowledge will progress in a linear pattern to a marketed drug. In some cases the therapeutically active ligand will be new to science and will be used in a new drug in a purified but unchanged form. In some cases the plant will be found to contain already known ligands. In others the plant may be screened for a therapeutic indication which is different from the

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[485] Cotton (n 9), 1

[486] Balick & Cox (n 8), 7

[487] Balick & Cox (n 8), 36

[488] Jennie Wood Sheldon and Michael J Balick, "Ethnobotany and the search for balance between use and conservation" in Timothy Swanson (ed), *Intellectual Property and Biodiversity Conservation: an Interdisciplinary Analysis of the Values of Medicinal Plants* (Cambridge University Press 1995) 45, 52

indication suggested by the folk use of the plant. [489] Balick and Cox suggest that a plant which is bioactive in one respect may serve as a better candidate for other types of bioactivity that those which show less bioactivity and point to supporting evidence from within the Samoan ethnopharmacopoeia.[490, 491]

4.2.3 Potential drug discovery pathways

As set out above, there is a long tradition of indigenous knowledge and Western folklore providing the starting point for pharmaceutical development. However, in the modern era therapies very rarely take the form of a simple plant extract but are more commonly in the form of pure ligand (or ligands) contained within an inert excipient. This section looks at the potential pathways by which traditional knowledge can be incorporated into a "modern" pharmaceutical.

The present discussion will assume that a "new" (to pharmaceutical science) therapeutic use for a "new" (to pharmaceutical science) genetic resource has been revealed to a pharmaceutical research team. What are the potential ways in which the research lead provided by this information will inform pharmaceutical development? A (by no means comprehensive) overview of the potential pathways by which a piece of genetic material or associated piece of traditional knowledge could find their way through the drug discovery process was summarised in Figure 1.1 (in Chapter 1).

It is important to recognise that the progression of steps set out in the figure is not necessarily linear, nor in series. Many steps will be performed in parallel. In addition many steps will require a series of iterative "feedback loops". Very often advances in one limb of the research process will inform others, as will previously understanding from the literature or the research team's existing "know-how". Initial testing methodologies and extraction techniques may be supplanted by radically different techniques depending on parallel developments.

The "research team" is described here as one entity. However, it should be noted that the skill sets required for this work are unlikely to be found within a single team. These

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[489] Balick & Cox (n 8), 33
[490] Balick & Cox (n 8), 39

[491] PA Cox, LR Sperry, M Tuominen and L Bohlin, "Pharmacological activity of the Samoan ethnopharmacopoeia" (1989) 43 Economic Botany 487

skills will range from chemical analysis, classic *in vitro* and *in vivo* pharmacology, molecular biology, medicinal chemistry, computer (or so-called "*in silico*" [492, 493]) modelling, and chemical synthesis, to clinical trials. Only within the largest pharmaceutical company would all these skills be found within one organisation. Even if that were the case, it is common for elements of the research effort to be contracted out to other commercial laboratories or to university-based researchers. It is possible for some of the work to be conducted within a public domain environment and here research teams might follow leads set by other groups that have been communicated at conferences and in research publications. Naturally there is a possibility of a mix of these approaches, but where the lead has originated from within a commercial organisation concerns over commercial competitors may limit the degree of disclosure until full patent protection has been achieved.

Possible steps in the process are as follows:

a) Isolation of active constituent(s) from plant material. Extraction techniques may depend on the suspected chemical nature of the active constituent (which may be informed by information on known ligands at receptors suspected of producing the therapeutic effects)

b) *In vitro* testing of the active constituent against a known *in vitro* model. The choice of model may be dependent upon the purported therapeutic benefit of active constituent:

c) *In vivo* testing of the active constituent against known animal models;

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[492] Nathan Brown, In Silico *Medicinal Chemistry: Computational Methods to Support Drug Design* (Royal Society of Chemistry, Abingdon 2015)

[493] Alan GE Wilson (ed), *New Horizons in Predictive Toxicology: Current Status and Application* (Royal Society of Chemistry, Abingdon 2011)

d) Determination of the chemical structure of active structure (using a variety of chemical analytical tools);[494]

e) Determination of the receptor site. This may be a known receptor site, a previously unknown sub-type of known receptor family, or a previously unknown receptor family;

f) If it is a new sub-type (or new family) of receptor the active constituent may be used as a tool to determine distribution of the receptor protein in the body using immuno- or radioligand-histochemistry and similar techniques;[495]

g) If it is a new sub-type or new family of receptor, determination of the protein structure of receptor site. This will include gaining an understanding of shape of the "pocket" of the receptor and the linkage to a downstream biological process (*e.g.* an enzyme or ion channel);

h) If it is a new sub-type or new family of receptor, comparison with genomic libraries to determine the genes coding for the receptor. If the genes coding for the receptor can be identified, this may lead to studies to determine the distribution and control of gene expression for this receptor across the body;[496]

i) If it is a new sub-type or new family of receptor, there will likely be studies of post-translational modification of the protein. There will also likely be studies of the receptor "life-cycle" and systems for up- and down-regulation of the receptor;

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[494] CSJ Walpole, "The Role of Chemistry in the Drug Discovery Process" in HP Rang (ed) *Drug Discovery and Development: Technology in Transition* (Churchill Livingston Elsevier, Edinburgh 2006) 121

[495] HP Rang, "Pharmacology: its role in drug discovery" in HP Rang (ed) *Drug Discovery and Development: Technology in Transition* (Churchill Livingston Elsevier, Edinburgh 2006) 163

[496] H LeVine and HP Rang, "The role of genomics and bioinformatics" in HP Rang (ed) *Drug Discovery and Development: Technology in Transition* (Churchill Livingston Elsevier, Edinburgh 2006) 77

j) Determination of endogenous ligand. If a previously unknown signalling system, this may lead to an entirely new understanding of a disease process and development of a novel class of therapeutic interventions and the development of new *in vivo* animal models. This may also lead to an understanding of an entirely new family of receptors, the metabolic processes for producing the endogenous ligand and how the receptors are controlled and how the endogenous ligand is inactivated and/or re-cycled;

k) Preparation of simple chemical derivatives of the active component (this will include input from the receptor structure studies);

l) The "new" receptor site may also be used as a target in fast-throughput screening against known pharmaceutically active ligands or against a library of ligands produced by combinatorial chemistry to uncover previously unexpected agonist ligands at the site;[497]

m) An understanding of the genes coding for the receptor may lead to an understanding of changes to receptor density/expression in disease states and may lead to development of gene therapy to address problems;

n) Genes coding for the enzyme producing the endogenous active can be spliced into micro-organisms (recombinant DNA) to produce the enzyme/endogenous active; and

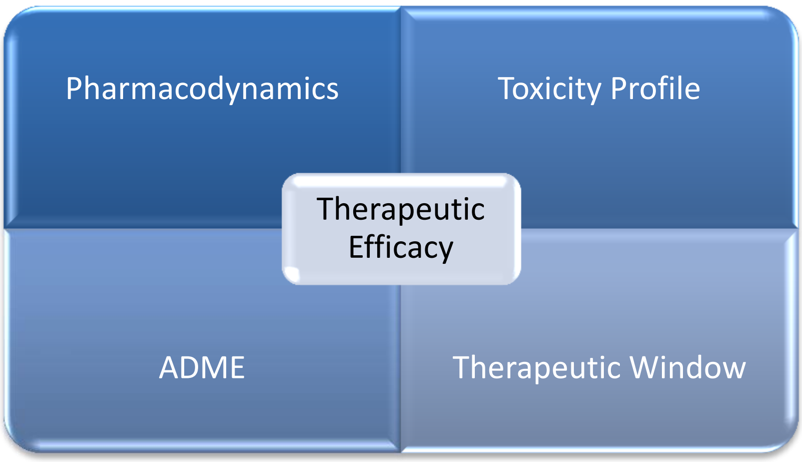
o) An understanding of the gene sequence coding for the receptor, or the enzyme making the endogenous ligand, may allow for the *de novo* synthetic production of the gene (using DNA synthesis technology) and could eventually be used in the development of artificial organisms.

[497] K Stoeckli and H Haag, "High Throughput Screening" in HP Rang (ed) *Drug Discovery and Development: Technology in Transition* (Churchill Livingston Elsevier, Edinburgh 2006) 99

In some cases the biological effect mediated by the ligand may not be what is therapeutically desired. It may be that the therapeutic effect is mediated through interaction with one sub-type of receptor whereas a second effect, a "side-effect" is mediated through interaction with another. It may be that at doses higher than those that at which the ligand has its beneficial effect there may be other biological effects of the ligand at different receptors or in entirely different biochemical systems. The difference between the dose at which a ligand has its beneficial effect and the dose at which it demonstrates deleterious side-effects is termed the "therapeutic window" for the ligand. Some drugs, such as many antibiotics, have a relatively large therapeutic window whereas anti-cancer drugs have a very narrow (or essentially no) therapeutic window and were it not for the grave effects of the disease the side-effects would not ordinarily be tolerated.

Chemical modification of an exogenous ligand may change the activation/binding characteristics and could also potentially change an agonist into an antagonist (or *vice versa*) or an inverse agonist (or a "partial" agonist). Any such change would affect the therapeutic benefit to be derived, the side effect profile and with it the therapeutic window. The interplay with the receptor itself (termed "pharmacodynamics") cannot be looked at in isolation. Chemical changes will also impact on the bioavailability (the adsorption, distribution, metabolism and excretion or "ADME" [498]) of the ligand.

<u>Figure 4.2 Schematic diagram of the factors influencing therapeutic efficacy</u>



[498] Studies which combine ADME investigations with toxicity studies are termed "ADMET" trials. The study of the time course and nature of adsorption, distribution, metabolism and excretion of a drug is termed *pharmacokinetics.*

A schematic diagram of the key factors influencing therapeutic efficacy is set out in Figure 4.2.

Knowledge of the structure of the new receptor protein may lead to synthesis of entirely novel agonist or antagonists at that receptor which may find use in the original therapeutic indication, or as will be seen, in second or further indications or in further research into the biological mechanism.[499]

4.2.4 "Biomimetics"

In some circumstances the genetic resource from which the ligand is purified can be difficult to obtain in reliable quantities or the ligand itself may be difficult to extract from the genetic resource. In these cases it may be cost-effective to make the ligand through synthesis in the laboratory. However, this may not always be straight-forward. Some biologically-derived compounds have complex structures which are difficult to replicate using "non-biological" synthetic pathways. In addition many biologically-derived ligands can exist in two (or another multiple of two) "optical" isomers. This means that the compound can exist either as a "right-handed" isomer or as a mirror-image "left-handed" isomer. Although they will share the same atoms their structures are different. In many cases one optical isomer can be biologically active whereas the other isomer is ineffective. For example, all of the amino acids used by all life on earth are L- isomers; D-isomers of amino acids cannot be used in biological processes. In contrast, all the sugars used by all the life on earth are D-isomers, the L-form being unused.

Where compounds are made by enzymatic processes the vast majority of the resultant compound will exist as one optical isomer only. Where a compound is made by other (non-enzymatic) chemical pathways the synthetic pathway is ordinarily blind to optical isomerism and a near 50:50 ratio of each isomer (a so-called "racemic mixture") will be produced. In some cases the racemic mixture will be "deracemated" (separated out) by researchers (perhaps using affinity chromatography) to leave only the effective isomer.

It is important to note that the desired end product of the synthetic pathway is an exact copy the biologically-derived ligand. These compounds are termed "biomimetics". A

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[499] David C Blakemore, Paul M Doyle, and Yvette M Fobian (eds), *Synthetic Methods in Drug Discovery* (Royal Society of Chemistry, Abingdon 2015)

fully deracemated biomimetic would be chemically and biologically indistinguishable from the original ligand of which it was a copy.

However, it should also be noted that where a copy of a *protein* is made by splicing the gene coding for the protein into a cell, the protein produced may *not* be an exact copy of the original. This is because after proteins are synthesised they undergo a process by which sugar groups are attached to the protein. This is called glycosylation (more prevalent in eukaryotic cells). The pattern of glycosylation (and other so-called post-translation modification) will change depending on the type of host-cell. Although the biological effect of the resultant copy may be equivalent to that of the original protein, the protein cannot be described as an *exact* copy and therefore the term “biosimilar” (sometimes “follow-on biologic”) will be more appropriate.[500]

Using an entirely synthetic approach to making a ligand may open up new synthetic possibilities for making “derivatives” which are not reliant upon using the biologically-derived ligand as a starting point. Of course, these new ligands may themselves serve as a tool for further investigation of the underlying disease mechanisms.

4.2.5 Drug development

Much of the discussion set out above deals with what is properly considered drug “discovery”. We additionally need to briefly consider the related field of drug “development”.

Given the integrated and iterative nature of research the divide between discovery and development can be somewhat unclear. A clearer divide is perhaps between clinical and pre-clinical work, although again there is substantial communication and iterative work between the two areas during the course of the development of a drug.

Much of drug “discovery” relates to the identification (through pre-clinical work) of a candidate for clinical trials. Many drugs which form the basis of the modern pharmacopoeia (or their predecessors) were tested on humans or launched onto the

[500] European Medicines Agency, Committee For Medicinal Products for Human Use, Guideline on Similar Biological Medicinal Products (CHMP/437/04) (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003517.pdf) (Accessed September 2015)

market with little (or no) regulatory supervision and many tragic mistakes were made along the way.

Accordingly, in the modern era before a drug can be marketed in a territory it requires "marketing approval" from the appropriate medicines regulatory authority for that territory.

The process by which that approval is granted is exceptionally highly regulated and a candidate drug is required to pass a number of distinct hurdles before it can pass on to the next stage of the process. Although each regulatory authority will have its own criteria for granting approval, there are substantial commonalities (commonly following US Food and Drug Administration ("FDA") and/or European practice) and initiatives towards consistent approaches (particularly harmonisation within the EU under EU Regulations and the practice of the European Medicines Agency, "EMA").

For the purposes of this work I will refer to drug "discovery" as pre-clinical research which leads to the identification of a potentially useful ligands and "development" as both the pre-clinical and clinical research process required to obtain medicines regulatory agency marketing approval.

A brief description of the phases of drug development is set out in Table 4.3. As will be seen the pre-clinical phase of drug development deals predominantly with assessment of the toxicology profile of the candidate molecule.

Requiring competitors to engage in a full reproduction of the drug development process before they can sell an identical product is perceived to be both wasteful of animal and human testing, and to present a very high barrier to entry for competitor products with a resultant elevated price payable by health systems. Accordingly, in a number of systems generics companies are permitted to obtain marketing authorisation for drugs on the back of the regulatory data set provided by the originator company, provided that they can be demonstrate that the drug being marketed is the same as that for which authorisation has been granted (a so-called "abridged" procedure). However, given the cost of assembling a data set, and to provide an incentive to innovate, originator companies are commonly provided with a period of data and marketing exclusivity during which only they (or their licensees) can rely on the data set. This data exclusivity is an important, and valuable, quasi-intellectual property right.

Although the grant of a marketing authorisation will allow a drug to be marketed for a particular therapeutic indication, there is in many territories a further hurdle to the widespread use of the drug. This is a requirement to pass a "health technology assessment" to determine whether, in a particular territory, the public authority funding healthcare can justify funding the use of the drug or other therapy (on usually a cost-effectiveness basis).

Table 4.3 Phases of Drug Development [501, 502, 503]

Development Phase	Nature
Pre-Clinical Testing	Data gathered on genotoxicity, toxicity, oncogenicity, reproductive toxicology.
Phase I	First in man study. Assessment of tolerability, pharmacokinetics and pharmacodynamics in (usually) healthy volunteers.
Phase II	First study in patients with the disease to be treated. Assessment of tolerability, pharmacokinetics and pharmacodynamics in patients. Assessment of optimum dose and side effect profile.
Phase III	Assessment of outcomes in patients approximating to the "real-life" population of patients. Forms a significant part of the data portfolio used to gain regulatory approval.
Phase IIIB	Phase III style studies which are not intended to form part of the regulatory dossier but which will provide further evidence to persuade practitioners to use the drug – including evidence of cost-benefit, quality of life advantages.
Phase IV	Post-marketing surveillance. Phase III studies cannot hope to cover all real-life situations and Phase IV surveillance allows for an ongoing assessment of safety and efficacy.

501 John Hall, "The drug development process" in Ignazio Di Giovanna and Gareth Hayes (eds), *Principles of Clinical Research* (Wrightson Biomedical Publishing 2001), 1

502 David R Hutchinson, *How Drugs are Developed, A Practical Guide to Clinical Research* (Brook Medical Publications 1997), 2

503 I Hägglöf and Å Holmgreen, "Regulatory Affairs" in HP Rang (ed) *Drug Discovery and Development: Technology in Transition* (Churchill Livingston Elsevier, Edinburgh 2006) 281

4.2.6 Drug discovery, a linear path?

As has been described in the earlier parts of this Chapter, there are many paths that can be taken by a pharmaceutical research team involved in drug discovery.

The external perception of drug research is often of a linear process by which a solution is inevitably arrived at. This is however rarely the case - the drug discovery process is often iterative and there are many parallel steams. Often there are dead-ends where the hoped for result, whatever it may be, is not arrived at. Often important discoveries are made but they are not taken up. This may be the result of the researcher being outside of the scientific "mainstream", publishing in a less well read language or in an inappropriate, or obscure, journal. The process can be influenced by personalities, scientific fashion and by commercial concerns. As will be seen, serendipitous discoveries, particularly observations of side-effects of existing drugs can play an important role. Any sense of linearity may be the result of "hindsight", an inherent "outcome reporting bias" amongst research teams themselves (and the editors of scientific journals) against the publication of negative rather than positive results [504, 505] or the desire by the media (and drug marketers) to present a coherent and easily accessible story of development. Such reporting both in scientific journals and the media may give the impression of a certain inevitability to the research outcome which is not apparent to those working in the field at the time. However, as a compound enters the drug development stages the process, driven by medicines regulatory requirements, becomes (as is seen above) somewhat more linear and proscribed (though still beset by uncertainty).

Kubinyi's diagrammatic representation of the "drug design cycle"[506] divides into two parts. Part one (reproduced in Figure 4.3) deals with lead *structure* identification; this is a chemical whose structure shows promise as the basis for further examination. As can be seen, this process may take its "inspirations" from a wide variety of sources

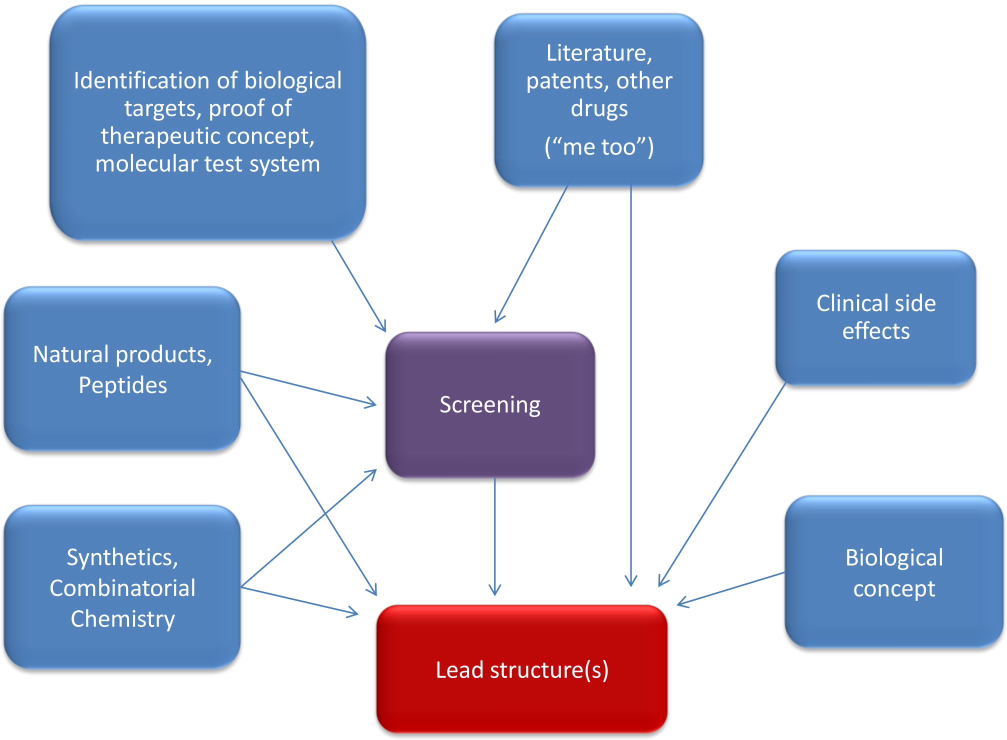
[504] Kerry Dwan , Douglas G Altman, Juan A Arnaiz, Jill Bloom, An-Wen Chan, Eugenia Cronin, Evelyne Decullier, Philippa J Easterbrook, Erik Von Elm, Carrol Gamble, Davina Ghersi, John P A Ioannidis, John Simes, and Paula R Williamson, "Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias" (2008) 3(8) PLoS ONE e3081

[505] Ben Goldacre, *Bad Science* (Harper Perennial 2009), 224

[506] Hugo Kubinyi in Raviña (n 173), 463

including literature and patent searching, reviews of endogenous and exogenous natural ligands (including from bioprospecting), reviews of synthetically produced ligands, and the understanding of biological processes underlying the pathological condition. Key to the process is screening of the candidate molecule against an *in vivo* animal model or an *in vitro* molecular target (and very likely both).

Figure 4.3 Drug Design Cycle: Lead structure identification (after Kubinyi) [507]



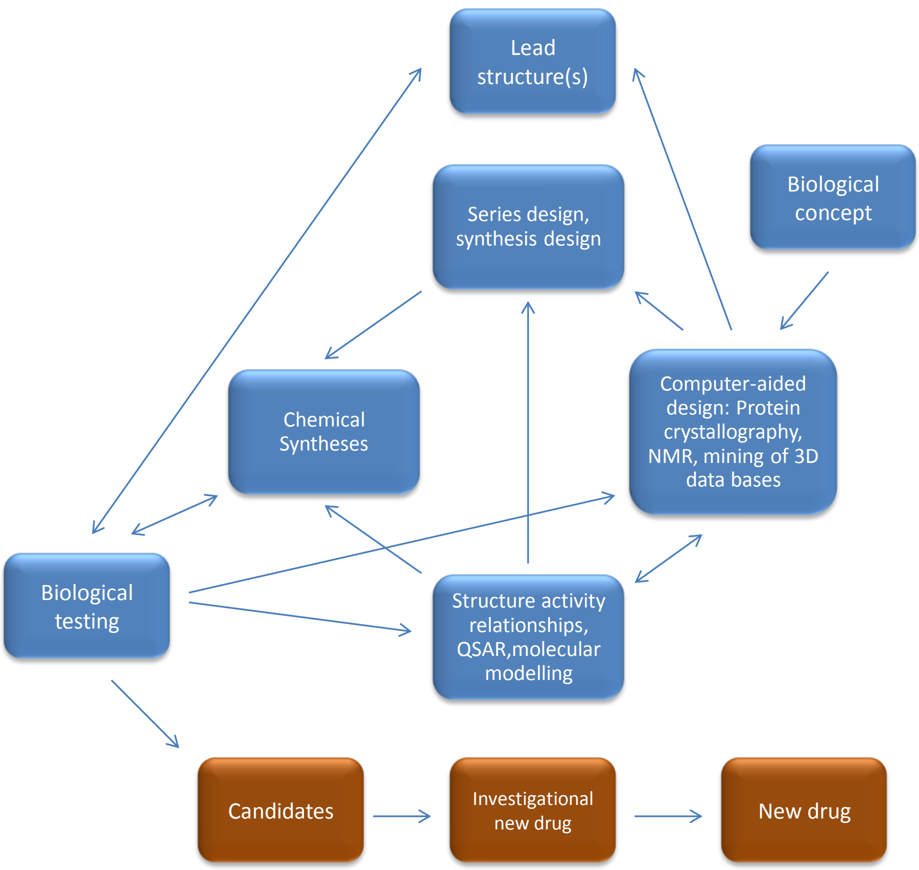
Once a lead structure is identified it is entered into a process of "lead structure optimisation" (part two of Kubinyi's design cycle; reproduced here in Figure 4.4) in the hope of finding a compound which is a drug "candidate".

As can be seen this lead structure optimisation is again a highly iterative process involving a large number of feedback loops between design of a new derivative, design of a new synthetic pathway to produce that derivative, actual chemical synthesis and the

[507] Kubinyi (n 506)

biological testing of the new derivatives. A drug candidate is required to be a good deal more than a biologically active substance which has the desired effect at a particular receptor site – it must have the desired clinical efficacy and additionally meet appropriate absorption, distribution, metabolism, excretion and toxicology (side-effect profile) requirements in both *in vitro* tests and animal/human *in vivo* testing. Much of the final work on taking a candidate to final marketed drug is done within clinical trials work (the somewhat more linear process shown at the bottom of Figure 4.4).

Figure 4.4 Drug Design Cycle: Lead structure optimization (after Kubinyi) [508]



Key: QSAR: Quantitative structure–activity relationship models[509, 510]

[508] Kubinyi (n 506)

Although separation into these two phases in the diagrams is helpful to our understanding of the overall processes, lead structure identification and optimisation are in fact closely linked together with feedback loops between the two, particularly in the development of biological testing mechanisms.

4.3 Looking for crux points – the flow of information and the "dilution" of contribution

The description given above (including the schematics in Figures 4.3 and 4.4) highlights the extreme degree of mixing of ideas and concepts in the drug discovery process. Very many separate inspirations will be mixed together stimulating the collection of data which will itself be fed back into the cycle. As has been stressed, the overall process of moving from a piece of traditional knowledge associated with genetic resources to a lead compound or new marketed drug (or indeed any downstream point on the way to these outcomes) involves significant mixing of information such as to cause a "dilution" of the original inspiration into a body of other information.

Notwithstanding this dilution effect, it is clear that if we apply a pure *sine qua non* causation test, *all* such downstream use flowing from the original inspiration will be caused in fact by the information within the original inspiration. However, as has been discussed in Chapter 1 of this work, the appropriate test for any situation in which one is seeking to determine a legal liability is not one of causation *in fact*, but one of causation *in law*.

Although we can seek to "describe" dilution of information in that we can (in a particular circumstance) seek to locate the disparate sources of information, determine how those pieces of information have come together and have created an outcome, it is harder to measure what we might term the degree or "amount" of dilution of a piece of information. To do so requires an understanding of what one means by "amount" – the test cannot be merely quantitative: Some pieces of information are clearly more

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[509] C Nantasenamat, C Isarankura-Na-Ayudhya, T Naenna, and V Prachayasittikul, "A practical overview of quantitative structure-activity relationship" (2009) 8 Experimental and Clinical Sciences Journal 74

[510] Mark Cronin and Judith Madden (eds), In Silico *Toxicology: Principles and Applications* (Royal Society of Chemistry, Abingdon 2010)

“important” that other pieces of information and retain their importance, even where they have been quantitatively “swamped” by other data. However, deciding what is meant by “important” is an evaluative judgement based one’s frame of reference (which may, in part, relate to what one is seeking to achieve with the information).

If we now imagine that alongside the mixing and dilution of information we see a mixing and dilution of “contribution” we see a parallel problem. If we imagine that contribution is connected with information then, as we follow the passage of information through the system, we can see concomitant flows of “contribution”. As with information *per se* we can describe the sources of contribution, how they have come together and the eventual outcome. However, as with the concept of importance measuring the “dilution” of contribution cannot be a quantitative exercise but is based upon an evaluative determination of what one means by contribution. One might simplistically say that contribution should be “based upon” or “linked to” importance, but this merely takes us back to what one means by importance and indeed it may be difficult to divorce one’s definition of “important” from that of contribution.

One might argue then, that what we see when we look at the passage of a piece of traditional knowledge associated with genetic resource through the drug discovery process is a “morass” of competing contributions sitting on the back of an entanglement of information. There clearly is some form of epistemic dilution going on but how can we hope to measure it or categorise it?

When one examines the topography of drug development, we see that much of drug discovery efforts could be described as sequential [511] and accumulative. Here the work performed by pharmaceutical researchers follows on from (or merely adds to) the core epistemic elements provided by the traditional knowledge. There is a substantial increase in the volume of additional knowledge, but no matter how much the original traditional knowledge is diluted in terms of volume, the underlying nature of the contribution made by the traditional knowledge to the downstream product remains unchanged.

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[511] Where each successive development builds in an essential way on its predecessor. See James Bessen and Eric Maskin, “Sequential innovation, patents, and imitation” (2009) 40(4) RAND Journal of Economics 611

Perhaps if we are to find a putative "crux point" we need to determine a third party downstream contribution which affects a "step change" in the *nature* of the downstream product when compared to the original contribution. On examination we find there appear few obvious such points.

It is here that the author turns to the long interface between patent law and the drug discovery process for inspiration. As has been stated in Chapter 1, any parallels between patent law and putative positive rights in traditional knowledge need to be treated very carefully, and it must be stressed that direct analogies with patent law are to be avoided. However, patent law has (as will be discussed further in the analysis in Chapter 6) particularly had to wrestle with the question of whether newly discovered uses for an old thing should be awarded separate patent protection. [512] This has come to a notable head in addressing the question of whether a second therapeutic use of a known substance which is already known to have a therapeutic benefit should be patentable.[513, 514]

This is an area where there to be a distinct clash of conflicting contributions (and an arguable "step change" in the *nature* of the downstream product when compared to the original contribution). Accordingly, the current work has taken that problem as an inspiration in the identification of the following putative "crux point" in the drug development process, namely where an unexpected ("serendipitous") discovery of a new use for a particular genetic resource (or the compounds found in a particular genetic resource or their chemical derivatives) is made on the back of the original piece of traditional knowledge associated with a genetic resource.

Having identified such discoveries as a putative crux point, the determination of whether that point can be justified as a point at which the chain of causation *in law* is broken can only (as is discussed in Chapter 1) be determined by the application of high level philosophical principles which take into account the reasons for the existence of

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[512] See *Mobil Friction Reducing Additive G 2/88* (OJEPO 4/90) and *Bayer G 6/88* (OJEPO 4/90)

[513] "Legal Advice from the Swiss Federal Intellectual Property Office (FIPO), dated 30 May 1984" [1984] OJ EPO 581

[514] Eisai (Second medical indication) G 5/83 [1984] OJEPO 64

the right in the first place. That analysis is taken forward in the next Chapter. However, before moving on to that analysis, this Chapter will conclude by looking more closely at the nature and history of serendipitous discoveries within the drug discovery process.

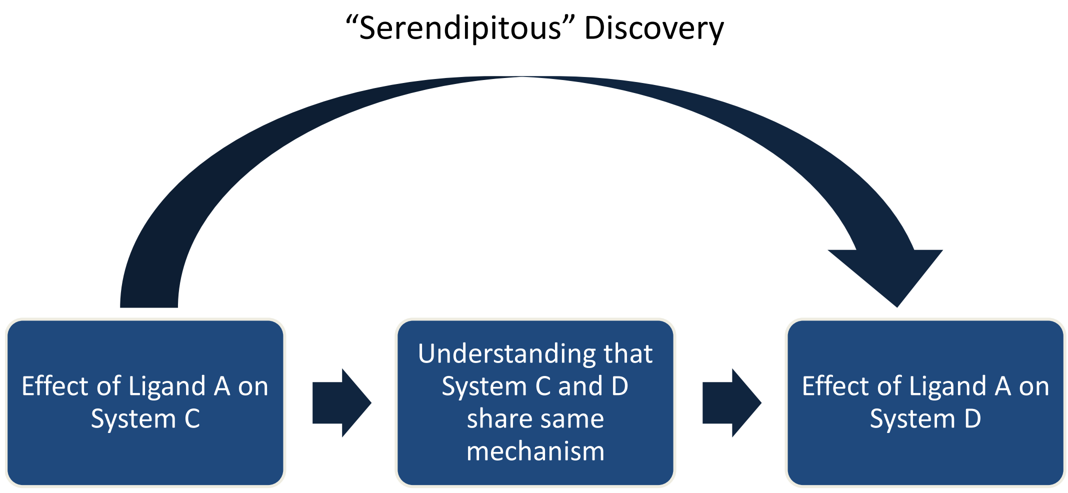
4.4 The nature of "serendipitous" discoveries of new uses

Let as assume that our plant-derived ligand has been isolated, purified, and chemically characterised. As has been stated, such ligands may have effects on more than one area of the body, so leading to undesirable side effects. However, sometimes the "side effects" are in some way desirable and here the ligand may become a candidate for providing a second therapeutic benefit to an apparently unrelated set of symptoms. This is often referred to as a "second medical use" of the compound. However, such second uses need not be limited to medicine or, indeed, even to biology. The distinctive element in such a step from one part of the research process to the next is that there has been an entirely non-obvious, or unexpected, revelation of a new feature (use) of the "thing" (for example ligand) obtained from the genetic resource.

It is crucial to point out immediately that not all steps to a new use will be appear quite so momentous. The more one understands about the underlying biological target of a ligand, the more that the second use may seem obvious. Figure 4.5 shows this in schematic form. By way of example, when one combines our current knowledge of the inhibitory effect of acetylsalicylic acid (aspirin) on the activity of cyclooxygenase enzymes with our current understanding that the prostaglandins and thromboxanes synthesised by cyclooxygenase enzymes have a role both in the mediation of in the inflammatory response in injured tissue *and* in the regulation of blood platelet adherence, the "discovery" that aspirin not only serves as an anti-inflammatory but as a cardio- and stroke-protective agent may seem trite. However, this understanding of the underlying biochemical connection was not at all the situation when the anti-coagulant benefits of aspirin were originally uncovered by Craven (see case study below).

Of course, what happens in practice (and what happened in the case of aspirin –again see case study below) is that the discovery of an unexpected second therapeutic benefit will initiate research into the biological processes which may underlie the two apparently different benefits.

Figure 4.5 Schematic of the nature of serendipitous discoveries in biology



For the purposes of the current work, a "serendipitous discovery" of a second use will be taken to mean one in which the second use is truly unexpected in the light of the current understanding of the underlying biology when the discovery of the second use is made. It is accepted that with our increasing understanding of the ways in which ligands mediate their effects, such serendipitous discoveries are likely to be much less common than was the case in the past. However, we cannot assume that we have reached an "end of history"[515] with regard to our understanding of biological processes and new genetic resource-derived ligands are still leading us to as yet unknown biological targets. By way of example we may look to the discovery of the mechanistic target of rapamycin ("mTOR"). [516] This is a protein involved in mammalian intracellular

515 Francis Fukuyama, "The End of History?" The National Interest (Summer 1989) https://ps321.community.uaf.edu/files/2012/10/Fukuyama-End-of-history-article.pdf (Accessed September 2015)

516 Eric J Brown, Mark W Albers, Tae Bum Shin, Kazuo Ichikawa, Curtis T Keith, William S Lane & Stuart L Schreiber "A mammalian protein targeted by G1-arresting rapamycin–receptor complex" (1994) 369 Nature 756

regulation which was only uncovered through research on the immunosuppressant effect of the macrocyclic antibiotic, rapamycin. Rapamycin was itself found in the *Streptomyces hygroscopicus* bacterium which was in turn found in prospected soil samples found on the Pacific island of Rapa Nui (Easter Island).[517] There surely yet remain many unknown biological mechanisms that may reveal unexpected routes to clinical therapy. For example, (and as mentioned in Chapter 2) relatively recent developments in epigenetics have overturned scientific dogma in relation to the control of expression of the genome. [518]

4.5 Case Studies of Serendipitous Discoveries of Second Uses within Drug Discovery

4.5.1 Introduction

The question posed in relation to serendipitous discoveries of second uses is far from theoretical. Such serendipitously discovered uses have been major contributors to the development of medical (and other) science. Table 4.4 summarises some examples of compounds arising out of research performed on plant-derived drugs and some serendipitously-discovered second uses of plant-derived drugs (or their derivatives) derived from research on those compounds.

Sometimes such discoveries have been in relation to the initial plant-derived compound – the discovery of the anaesthetic effect of cocaine represents an example of this. Occasionally the serendipitously-discovered second use relates to a chemical derivative of the initial plant-derived compound, such as the cardio-protective effect of acetyl salicylic acid (aspirin).

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[517] Claude Vézina, Alicia Kudelski, and SN Sehgal, "Rapamycin (AY-22, 989), a new antifungal antibiotic i) Taxonomy of the producing streptomycete and isolation of the active principle" (1975) 28(10) The Journal of Antibiotics 721

[518] Bird (n 114)

<u>Table 4.4 Examples of serendipitously-discovered second uses of plant-derived drugs</u>[519]

Compound initiating trail	**Plant**	**Compounds arising from research trails**	**Original therapeutic benefit**	**Serendipitously discovered second use or new compound**
Salicin	*Salix alba* (willow) *Spirea ulmaria* (meadow sweet)	aspirin mefanamic acid flufenamic acid diclofenac celecoxib refecoxib	Antipyretic	Reduced blood clotting (aspirin)
Cocaine	*Erythoxylum coca* (coca)	β-eucaine orthocaine benzocaine bupivicaine lignocaine procaine	Mild CNS stimulant	Local anaesthetic (cocaine)
Morphine	*Papaver somniforum* (opium poppy)	codeine diacetylmorphine (“Heroin”) oxycodone hydrocodone metopon dextromethorphan etorphine buprenorphine pethidine methadone dextromoramide piritamide fentanyl remifentanil	Pain relief	Haloperidol (anti-psychotic)
Quinine	*Cinchona spp.* (quina quina)	pamaquin mepacrine sontoquine chloroquine primaquine antipyrine	Anti-malarial	Mauveine dye Antipyrine
Vinblastine Vincristine	*Catharanthus roseus* (Madagascar or rosy periwinkle)	vindesine vinorelbine	Anti-diabetic	Anti-tumour effect

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519 Table compiled from a review of case studies provided in Walter Sneader, *Drug Discovery: the evolution of modern medicines* (John Wiley & Sons, Chichester, England, 1985), Walter Sneader, *Drug Discovery, A History* (John Wiley & Sons, Chichester, England, 2005), and Raviña (n173)

Chemical work related to a plant-derived compound can sometimes uncover previously unthought-of compounds with unthought-of uses – Perkin's discovery of mauveine dye whilst tying to synthesise quinine is a truly startling (and world-changing) example of this. In the case of the Madagascar (or rosy) periwinkle an unsuspected (anti-tumour) effect of compounds found in the plant (vincristine and vinblastine) was discovered even though the anti-diabetes research trail stimulated by traditional knowledge relating to the plant was unsuccessful.

The remainder of this Chapter is devoted to abbreviated case studies of four of these examples, both by way of illustration and as examples for further analysis within Chapter 6.

4.5.2 Salicin – fever and cardiovascular effects

The development of naturally-derived salicin into aspirin has been called:

> "the beginning of medicinal chemistry as a science, the optimization of a drug through alternating biological testing and chemical modification." [520]

The discovery of aspirin is also interesting as it was essentially discovered through two parallel research streams, each looking at different, and unrelated, plants.

An eighteenth century Oxfordshire clergyman, the Reverend Edward Stone, identified the anti-rheumatism and anti-fever effects of the bark of the white willow or *Salix alba*. He was led to study this tree by the bitter taste of its bark (similar to that of the anti-febrile bark of the South American *chinona* tree) and by that fact that the tree grew in damp conditions which were thought to give rise to fevers. This latter "lead" came out of Stone's application of the "Doctrine of Signatures", a long-standing concept in which physical or habitat characteristics of a plant which were considered to be "similar" to a particular disease or symptom were thought to be "pointing the way" to a cure for that disease or symptom. Although he recorded the effects of willow bark

[520] Georg Albers-Schönberg, "The pharmaceutical discovery process" in Timothy Swanson (ed) *Intellectual Property Rights and Biodiversity Conservation: An interdisciplinary analysis of the values of medicinal plants* (Cambridge University Press 1995) 68

extract in a letter to the Royal Society of 1763.[521] Stone did not personally take his discovery any further. [522] Although Stone appears to have been unaware of the, fact, infusions of Willow bark had in fact long been used against fever in European herbal folklore. Willow brew was used by Hippocrates for pain in childbirth and Pliny and Galen both suggested it be use against inflammation. [523]

Following Stone's communication to the Royal Society, willow bark extract was used as a cheaper substitute for cinchona bark. In 1826 Brugnatelli and Fontana determined the active substance in willow bark to be salicin, a compound which was isolated by Leroux in 1829.

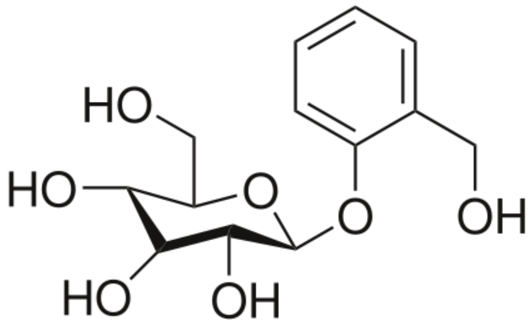

Figure 4.6 Structural formula of salicin [524]

In 1838, Italian chemist Raffaele Piria working in Italy developed an acid derivative of salicin which showed enhanced anti-fever efficacy. He named this derivative salicylic acid. The pharmacological effect of willow bark is mediated through salicylic acid, the metabolite of the compound salicin which is found in the bark. In 1830 Johann Pagenstecher working in Switzerland (independently of the work of Stone) determined that an extract of the meadowsweet flower (*Spirea ulmaria*) would have anti-fever

[521] Edward Stone, "An Account of the Success of the Bark of the Willow in the Cure of Agues" (1763) 53 Philosophical Transactions 195

[522] Peter Fairley, *The Conquest of Pain* (Michael Joseph, London, 1978), 125

[523] Raviña (n 173), 24

[524] By Harbin. Public Domain. (https://commons.wikimedia.org/wiki/File:Salicin.svg) (Accessed September 2015)

effects.[525] Again meadowsweet was known within European herbal medicine for its pain reducing properties. In 1835 Karl Jakob Löwig (working in Berlin) read of the work of Pagenstecher and determined that the active constituent was an acid which he named *spirsäure* from the Linnean name for the meadowsweet plant. This was the same salicylic acid which had been produced by Pirea. [526, 527]

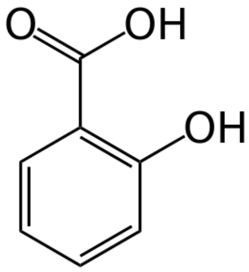

Figure 4.7 Structural formula of salicylic acid [528]

Salicylic acid was found to be effective against pain and inflammation. However, due (in part) to its acidity, salicylic acid can cause severe irritation to the gastric mucosa causing extreme gastric pain. This was a great limitation to its use and eventually German chemists Felix Hoffmann and Arthur Eichengrün, working for Bayer AG, developed an acetyl derivative of salicylic acid, sodium acetylsalicylate, which avoided many of the gastric complications of the original substance. [529, 530]

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[525] Raviña (n 173), 24

[526] Walter Sneader, *Drug Discovery: the evolution of modern medicines* (John Wiley & Sons, Chichester, England, 1985), 82

[527] Walter Sneader, *Drug Discovery, A History* (John Wiley & Sons, Chichester, England, 2005), 359

[528] By Benjah-bmm27. Public Domain. (https://commons.wikimedia.org/wiki/File:Salicylic-acid-skeletal.svg) (Accessed June 2015)

[529] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 82

[530] Sneader, *Drug Discovery, A History* (n 527), 359

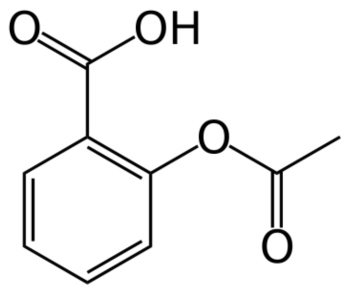

Figure 4.8 Structural formula of acetylsalicylic acid (aspirin) [531]

Looking for a name for the new drug, Bayer developed the trade name "Aspirin" from its German name *acetylspirsäure.* When the history of the development of Aspirin was written in 1933, Eichengrün's significant role in the development of Aspirin was excluded due to his Jewish background. His role in testing sodium acetylsalicylate on himself and then arranging for clinical trials after Bayer's pharmacologists had initially rejected the compound, was replaced by a story that Hoffmann had tested the new drug on his poorly father. [532] Aspirin became for many years (until the advent of the other non-steroidal anti-inflammatory drugs, paracetamol and ibuprofen, in the late 50's and early 60's) one of the first lines of treatment of inflammation.

Based upon anecdotal observations of bleeding in patients taking aspirin, cardiologist Paul Gibson proposed (in a 1948 letter to The Lancet) that salicylates may have a role in treating coronary heart disease [533] and followed this up in 1949 with publication a small-scale study demonstrating a benefit in angina patients. [534] This lead was not taken up.

In the late 1940's California family physician Lawrence Craven made an observation that during tonsillectomies and tooth extractions patients who had been used aspirin gum pain relief required longer for their bleeding to stop. Without any understanding of

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[531] By Benjah-bmm27. Public Domain. (https://commons.wikimedia.org/wiki/File:Aspirin-skeletal.svg) (Accessed June 2015)

[532] Walter Sneader, "The discovery of aspirin: a reappraisal" (2000) 321 Br Med J 1591

[533] Paul C Gibson, "Salicylic acid for coronary thrombosis?" (1948) 1 Lancet 965

[534] Paul C Gibson, "Aspirin in the treatment of vascular diseases" (1949) 2 Lancet 1172

the underlying biochemical mechanism, Craven hypothesized aspirin was prolonging clotting time and that this effect may be beneficial in preventing coronary heart disease. In an uncontrolled study of 400 patients over two years Craven gave “preventative” aspirin to patients between 40 and 65. He published his results in a one page letter to a local medical journal.[535] This work was followed up with a further uncontrolled study in 8000 patients published in the Mississippi Valley Medical Journal. [536, 537] Craven’s work received little immediate recognition, perhaps due to the uncontrolled nature of his trial and the relative obscurity of its publication. However, the concept of using aspirin to prevent cardiovascular disease gained more credibility when Weiss and Aledort [538] working in New York demonstrated that aspirin had an effect of platelet aggregation. This stimulated a series of randomized controlled trials in patients [539, 540] which successfully demonstrated the cardio-protective effects of aspirin. The effect of low-dose of aspirin as a prophylaxis against stroke and heart attacks is perhaps one of the classic examples of a serendipitous “second medical use”.

Following the Nobel Prize-winning work of a team led by John Vane [541, 542] it is now understood that aspirin has its anti-inflammatory effect through the irreversible inhibition of one of the enzymes (cyclooxygenase) responsible for the synthesis of

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[535] Lawrence L Craven, “Acetylsalicylic acid, possible preventive of coronary thrombosis” (1950) 4(2) Ann West Med Surg 95

[536] Lawrence L Craven, “Experiences with aspirin (acetylsalicylic acid) in the nonspecific prophylaxis of coronary thrombosis” (1953) 75 Miss Valley Med J 38

[537] Lawrence L Craven “Prevention of coronary and cerebral thrombosis” (1956) 78 Miss Valley Med J 213

[538] Harvey J Weiss, and Louis M Aledort, “Impaired Platelet/Connective-Tissue Reaction in Man After Aspirin Ingestion” (1967) 290 The Lancet 495

[539] PC Elwood, AL Cochrane, ML Burr, PM Sweetnam, G Williams, E Welsby, SJ Hughes, and R Renton, “A Randomized Controlled Trial of Acetyl Salicylic Acid in the Secondary Prevention of Mortality from Myocardial Infarction” (1974) 1 Br Med J 436

[540] Paul M Ridker, Mary Cushman, Meir J Stampfer, Russell P Tracy, and Charles H Hennekens, “Inflammation, Aspirin, and the Risk of Cardiovascular Disease in Apparently Healthy Men” (1979) 336 N Engl J Med 973

[541] John R Vane “Inhibition of prostaglandin synthesis as a mechanism of action of Aspirin-like drugs” (1971) 231(25) Nature: New Biology 232

[542] SH Ferreira, Salvador Moncada, and John R Vane "Indomethacin and aspirin abolish prostaglandin release from the spleen" (1971) 231(25) Nature: New Biology 237

prostaglandins and thomboxanes (inflammatory mediators which are in part responsible for the body's inflammation response). It is now also understood that as well as being inflammatory mediators, prostaglandins and thomboxanes both play a role in the platelet aggregation seen in blood clotting [543] which explains aspirin's previously surprising effects on the two systems.

4.5.3 Cocaine – psychoactivity and anaesthetic effect

Erythoxylum coca and *Erythoxylum novogranatense* are shrubs which grow of the Amazonian slopes of the Andes of Peru, Ecuador and Bolivia. The chewing of coca leaves has long been practised by the indigenous peoples and is an integral part of native culture which continues to the present day.

The practice was reported in Pedro Cieza de Leon's *Crónica del Perú* of 1565 [544] and by Nicholas Monardes in his *Historia medicinal de Indias occidentales* in 1569. [545] Archaeological evidence suggests that *Erythoxylum coca* was brought under cultivation in the eastern Andes by 5000 BCE. [546] Pre-Columbian Andean ceramic figurines have been found which look to have a plug in their cheek, and small ceramic containers which may be associated with coca chewing and dating from 3000 BCE have been found in coastal Ecuador. [547] The chewing of coca leaves was well established under the Inca empire, but was limited to nobles, priests and the *chasquis* couriers. [548] The chewing of coca leaves has a mild euphoric effect which in the Andes is used to counteract the effects of altitude. [549, 550]

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[543] H Tohgi, S Konno, K Tamura, B Kimura and K Kawano, "Effects of low-to-high doses of aspirin on platelet aggregability and metabolites of thromboxane A2 and prostacyclin" (1992) 23(10) Stroke 1400

[544] Raviña (n 173), 29

[545] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 49

[546] Balick & Cox (n 8), 169

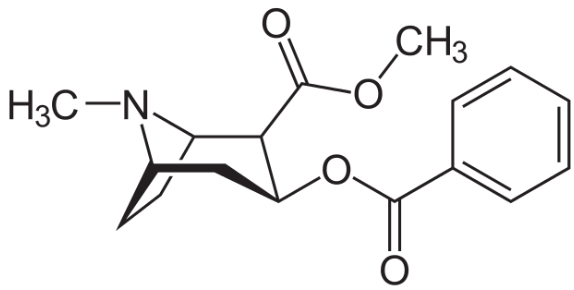
[547] Balick & Cox (n 8), 169

[548] Laws (n 7), 72

[549] John Mitchell Watt, "Magic and Witchcraft in Relation to Plants and Folk Medicine" in Tony Swain (ed) *Plants in the Development of Modern Medicine* (Harvard University Press, Cambridge, Massachusetts 1972) 68, 85

After the Spanish conquest of the Andes, Spanish missionaries attempted to restrict the use of coca but Spanish slave owners (and later slave owners in the United States) encouraged its use amongst slaves as a way of enhancing productivity. [551] In the 1880's Coca leaf became a major component of various "tonics" (famously including Coca-Cola [552]) and untested medicines.

In 1855 Friedrich Gaedchke extracted an active alkaloid from coca leaves and in 1860 Albert Niemann (at the University of Gottingen) isolated pure crystals of this alkaloid from the coca leaf which he named "cocaine". During this work Niemann had tasted his crystal and found that it made his tongue insensitive to pain but did not act on this finding. [553]



<u>Figure 4.9 Structural formula of cocaine</u> [554]

In the mid- to late- 19th century cocaine and coca leaf extract were seen as being nothing more than a mild stimulant, much like caffeine found in tea and coffee, and the risk of addiction was unsuspected. In the 1880's Sigmund Freud began investigating how the indigenous peoples of the Andes used coca leaves to stave off exhaustion. According to

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550 WJ Bishop, "Some early literature on addiction with special reference to tobacco" (1949) 46 Brit J Addiction 49

551 Laws (n 7), 72

552 Laws (n 7), 73

553 Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 49

554 By NeuroTIKER. Public Domain. (https://en.wikipedia.org/wiki/File:Kokain_-_Cocaine.svg) (Accessed June 2015)

DuQuesne and Reeves, [555] Freud initially saw cocaine as something of a panacea, and invited many of his friends to try it. However, whilst using cocaine as part of a treatment for morphine addiction in a friend, the development of cocaine addiction in that friend led to Freud's rejection of drug therapy for psychiatric disorders. [556]

In 1882 Carl Koller, an ophthalmologist working in Vienna, began searching for a way in which to conduct eye surgery on patients whilst they were awake. In 1884 Koller's friend Freud invited Koller to work on the stimulant effects of the cocaine alkaloid. During this work Freud told Koller that he and others had found that cocaine produced a numbing effect on the tongue when taken orally. Koller was still working in parallel on his search for an ophthalmic anaesthetic, and on hearing of cocaine's numbing effects immediately began to test a cocaine solution in the eye of a frog. He moved on to testing it on his own eye and that of his colleague with great success. Within months of Koller's paper on the anaesthetic effects of cocaine being delivered at a conference in Heidelberg, cocaine was being used as a local anaesthetic for eye surgery and ear, nose and throat surgery. [557, 558, 559] This local anaesthetic effect of cocaine acted as the stimulant for a broad range of derivatives which have created very effective local anaesthetic agents including benzocaine,[560, 561] procaine,[562] Novocaine (an injected local anaesthetic for dental surgery),[563, 564] lignocaine (or lidocaine),[565, 566] mepivacaine, ropivacaine and bupivacaine (used for continuous epidural anaesthesia in childbirth). [567]

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[555] Terence DuQuesne and Julian Reeves, *A Handbook of Psychoactive Medicines* (Quartet Books, London, Melbourne and New York, 1982), 65

[556] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 49

[557] Raviña (n 173),30

[558] Sneader, *Drug Discovery, A History* (n 527), 98

[559] Carl Koller, "History of cocaine as a local anaesthetic" (1941) 117 J Am Med Ass 1284

[560] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 53

[561] Raviña (n 173), 31

[562] Raviña (n 173), 31

[563] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 55

[564] Raviña (n 173), 31

[565] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526),56

These compounds are now understood to have their effect through a prevention and conduction of a nerve impulse in the nerve cell membrane. The seminal (and Nobel Prize-winning) work on the conduction of the nerve impulse was done by Alan Hodgkin and Andrew Huxley in 1952 [568, 569] and the understanding of the effect of local anaesthetics one the nerve action potential was only understood in the 1970's and early 1980's.[570, 571] However, since this work came later than the discovery of most local anaesthetics, that knowledge was unknown to the majority of those involved in the history of the development of local anaesthesia and cocaine derivatives. Those workers were reliant only on a structure-function correlation gained through the amassed data from trial and error studies (some of which correlations would not be widely disseminated as much of the work was undertaken within the commercial laboratories of pharmaceutical companies).

4.5.4 Quinine and mauveine

Malaria has historically been, and still is, one of the most lethal and debilitating diseases. It is now known to be caused by a microorganisms of the genus Plasmodium (particularly in humans, *P. falciparum* and *P. vivax*, while *P. ovale*, and *P. malariae*) which are transmitted by mosquitoes of the genus *Anopheles*. These microorganisms

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[566] Raviña (n 173), 32

[567] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 57

[568] Alan L Hodgkin and Andrew F Huxley, "A quantitative description of membrane current and its application to conduction and excitation in nerve" (1952) 117(4) J Physiol 500

[569] Roy Porter (ed), *The Hutchinson Dictionary of Scientific Biography* (Helicon, Oxford 1994), 336

[570] Bertil Hille, "Local anaesthetics: hydrophilic and hydrophobic pathways for the drug receptor interaction" (1977) 69 J Gen Physiol 497

[571] Alfred Goodman Gilman, Louis S Goodman, Theodore W Rall & Ferid Murad *Goodman & Gilman's The Pharmacological Basis of Therapeutics* (Macmillan Publishing Company, New York, Toronto and London, 1985), 303

mature and reproduce in the liver and blood cells (at different stages of their life cycle) causing cell damage and fever. [572]

Before any understanding of the cause of the disease or of its mode of transmission, it was called in English the ague fever and believed to be transmitted by "bad air" (*mal aria* in Italian) found near swamps and stagnant water (of course, in reality, the breeding ground of the *Anopheles* mosquito). [573]

The beginnings of the Western understanding of the bark from which quinine is obtained is surrounded by uncertainty. On one account, it begins with the posting of Don Luis Gerónimo Fernández de Cabrera de Bobadilla Cerda y Mendoza, Count of Chinchón, as Viceroy of Peru. According to a report by Sebastiano Bado (published in 1663) in 1638, in Lima, Chinchón's wife, the Countess of Chinchón, was critically ill with malaria and his physician suggested that they use the bark of the *quina quina* tree as a treatment this having long been used by indigenous peoples of Andes for relieving fever. [574, 575] After Chinchón's wife recovered from the fever Bado attributes her as bringing the bark of the *quina quina* tree back to Spain. Although the report of Bado has since been put into doubt, [576] Linnaeus, believing the story, named the genus of *quina quina* tree, *Cinchona*, after the Countess (though in the process misspelling her name). [577]

However, in 1633 the Augustinian monk, Antonio de la Calancha, recorded the properties of the *quina quina* tree in his *The Chronicle of St. Augustine*. It appears that the Spanish missionaries had been informed of the properties of the bark of the *quina quina* by the indigenous peoples of the "Land of Loxa" (now Ecuador). The Jesuits

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[572] WHO World Malaria Report http://www.who.int/malaria/publications/world_malaria_report_2012/wmr2012_no_profiles.pdf (Accessed April 2015)

[573] Laws (n 7), 42

[574] Laws (n 7), 42

[575] Jane Achan, Ambrose O Talisuna, Annette Erhart, Adoke Yeka, James K Tibenderana, Frederick N Baliraine, Philip J Rosenthal, and Umberto D'Alessandro, "Quinine, an old anti-malarial drug in a modern world: role in the treatment of malaria" (2011) 10 Malar J 144

[576] Raviña (n 173), 126

[577] Balick & Cox (n 8), 28

began to use the *quina quina* bark for the prophylaxis and treatment of malaria. Cardinal Johannes de Lugo, Superior General of the Jesuit Order in Rome, who had family connections with Seville (the monopoly trading port with Peru) asked for the so-called "Peruvian Bark" to be sent to the (malaria-troubled) Vatican in 1645. In 1655 it was used during the Papal convocation and successfully prevented deaths from malaria amongst the cardinals. In protestant Europe the *quina quina* bark powder became known as "Jesuit Powder" and although the powder reached England by 1654, Oliver Cromwell died of malaria in 1658 having refused to be "Jesuited" by its administration. [578, 579]

European science in the late-18th century was looking to isolate specific chemical substances from plant extracts. With its clear advantages as an anti-malarial, the *quina quina* bark was a key focus of this effort. In 1820 Joseph Pelletier and Joseph Caventou isolated an alkaloid compound which they called quinine from the bark of the yellow *Cinchona*. [580, 581] Since an infusion of *quina quina* bark was unpleasant to taste and varied widely in concentration of active constituent, purified quinine had great advantages in terms of patient compliance and control of side-effects over the bark. However, quinine itself could not be synthesised and its only source remained purification of *quina quina* bark. Demand for the bark led to substantial supply problems and denudation of the native *Cinchona* species in the Andes. In an early attempt to control genetic resources, the governments of Bolivia, Ecuador, Peru and Colombia prohibited the export of *Cinchona* seeds and plants. However, through botanical espionage the European imperial powers developed their own *Cinchona* plantations, the most successful being of alkaloid-rich strains of *Cinchona* planted in the Dutch East Indies. [582, 583] Balick and Cox state that:

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[578] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 9

[579] Balick & Cox (n 8), 27

[580] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 9 and 13

[581] Raviña (n 173), 128

[582] Balick & Cox (n 8), 28

[583] Raviña (n 173), 129

> "By 1930 the Dutch plantations in Java produced 22 million pounds of bark, yielding 97 percent of the world's quinine."[584]

Difficulties in obtaining the *quina quina* bark led to a drive to make artificial quinine and the effort to produce quinine through a synthetic route had begun in earnest by the mid-nineteenth century. However, the task was problematic and in 1853 Louis Pasteur had to report his failure to determine the structure of quinine.

In early 1856, the 18 year old William Henry Perkin was working as the student and assistant of August Wilhelm von Hofmann at the Royal College of Chemistry in London (now Imperial College) on a project to synthesize quinine. Hofmann sought to make the quinine alkaloid by the oxidisation of aniline with potassium dichromate. Whilst Hofmann was away in Germany during the Royal College's Easter vacation, Perkin performed one such experiment at the laboratory he had set up in his home in Stepney, London. Reacting toluidine (4-methylphenylamine) with chromic acid, Perkin was left with a dark sludge which suggested to him that the reaction had been a failure - probably due to contaminants in the reagents. He repeated the experiment using aniline (phenylamine) and again produced a dark residue. [585] On washing the sludge from the glassware with ethanol he noticed a vibrant purple colour. Considering this finding not to be a part of the quinine project set by Hofmann, Perkin began independent work on investigating the purple compound. Working with Pullars dye works in Perth, Scotland, to find a suitable mordant, Perkin found his purple compound (which he named aniline purple, but which eventually became known as mauveine) to be an effective colour-fast dye of silk and applied for a patent for it in mid-1856. [586] Up to that date, a strong, colour-fast, purple dye, Tyrian purple, could only be obtained from sea snails of the family *Muricidae*, but this was expensive and difficult to obtain (a reason why purple had come to be controlled by, and became symbolic of, Roman emperors). [587] Despite Hofmann's contrary advice, Perkin and his father built a factory in Greenford,

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[584] Balick & Cox (n 8), 29

[585] Porter (n 569), 545

[586] S Garfield, *Mauve: How one man invented a colour which changed the world* (Faber & Faber, London, 2000)

[587] CJ Cooksey, "Tyrian purple: 6,6'-Dibromoindigo and Related Compounds" (2001) 6 Molecules 736

Middlesex (opened in 1859) to commercially (and very successfully) exploit the aniline purple dye. [588] Interestingly (and perhaps not surprisingly), Hofmann was at this time embarking on his own development of violet dyes (which he patented in 1863). [589]

Silk dyed with Perkin's mauveine dye became popularized by Queen Victoria and the Empress Eugénie of France. Although the structure of Perkin's mauve dye was only elucidated in 1994, [590] Perkin's use of aniline as a starting point for the manufacture of vibrant, colour-fast dyes was very rapidly taken up from the mid-19th century onwards. [591] Atkins states:

> "Thus he laid the foundation of all his and much of Britain's national wealth".[592]

Sneader describes Perkin's discovery as:

> "the single greatest stimulus for the development of organic chemistry" [593]

The discovery led to the development, particularly in Germany, of major dye manufacturers such as BASF (originally the Badische Anilin- und Soda-Fabrik company), [594] Bayer, and Höchst. [595]

The first systemically used antibiotic drug, the sulphonamide Prontosil, was developed from an analine dye within the laboratories of Bayer AG. [596] This stimulated further

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[588] Porter (n 569), 545

[589] Porter (n 569), 340

[590] O Meth-Cohn and M Smith, "What did W H Perkin actually make when he oxidised aniline to obtain mauveine?" (1994) 1 J Chem Soc Perkin 5

[591] R Brightman, "Perkin and the Dyestuffs Industry in Britain"(1956) 177 Nature 80

[592] Atkins (n 398),88

[593] Sneader, *Drug Discovery, A History* (n 527), 125

[594] Werner Abelshauser, Wolfgang von Hippel, Jeffrey Allan Johnson, and Raymond G Stokes, *German Industry and Global Enterprise. BASF: The History of a Company* (Cambridge University Press, Cambridge UK 2004)

[595] Anthony S Travis, "Perkin's Mauve: Ancestor of the Organic Chemical Industry" (1990) 31(1) Technology and Culture 51

[596] H Otten, "Domagk and the development of the sulphonamides" (1986) 17(6) *Journal of Antimicrobial Chemotherapy* 689

development of antibiotic drugs based on dyes, and many dye companies became, in turn, major players in drug discovery. [597] In the light of all this, Perkin's mauve has been called (perhaps without undue hyperbole) *"the colour which changed the world"*. [598]

The structure of quinine was eventually determined by Paul Rabe in 1918 [599] and in 1944 Robert Woodward and William Doering published details of a *de novo* route for quinine synthesis. [600] Since then there have been many improvements of the method for synthesis, but extraction from *Cinchona* bark remains more economically viable. [601]

Quinine also served as the initiator of another research trail when Ludwig Knorr, at the University of Erlangen, in 1887 and whilst seeking to make a quinoline derivative made an antipyretic and analgesic called antipyrine. Antipyrine became the basis of a family of pyrazole drugs which were very widely used in pain relief. [602]

4.5.5 The vinca alkaloids – anti-tumour effects

The Madagascar or rosy periwinkle **(***Catharanthus roseus* previously categorised as *Vinca rosea*) is a plant which, though originally indigenous to Madagascar, has long been cultivated as an ornamental species across the tropics and sub-tropics. [603] Working at the University of Western Ontario in 1949, endocrinologist Ralph Noble sought to examine the effect of extracts of the rosy periwinkle on rat blood glucose. Noble was

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[597] Ernst Bäumler *In search of the magic bullet: Great adventures in modern drug research* (Thames and Hudson, London 1965), 15

[598] S Garfield, *Mauve: How one man invented a colour which changed the world* (Faber & Faber, London 2000)

[599] P Rabe and K Kindler, "Uber die partielle Synthese des Chinins. Zur Kenntnis der China-Alkaloide XIX" (1918) 51 Ber Dtsch Chem Ges 466

[600] RB Woodward and WE Doering, "The Total Synthesis of Quinine" (1944) 66(5) J Am Chem Soc 849

[601] Raviña (n 173),129

[602] Raviña (n 173), 26

[603] M van Bergen and W Snoeijer, "*Catharanthus* G.Don. The Madagascar Periwinkle and Related Species" (1996) 96 (3) Wageningen Agricultural University Papers 1

inspired to begin this work after he had heard of the folk use in the Caribbean of the rosy periwinkle in the treatment of diabetes. Noble received samples of the plant from Jamaica, and prepared an extract. Neither oral nor injected administration of that extract affected blood glucose levels. However, when injecting the animals with extract, Noble found that the rats seemed to suffer from an enhanced level of infection. Investigating this further, Noble found that, after an initial enhancement, treated rats showed greatly reduced leucocyte levels which seemed to be the result of damage to the bone marrow of the animals.

Given that similar effects were seen with current anti-tumour drugs, Noble wondered whether the extract might contain an anti-cancer agent. Working with organic chemist, Charles Beer, Noble isolated an active alkaloid, vincristine (originally named vincaleukoblastine) from the periwinkle extract which was found to have an inhibitory effect on transplanted tumours. This work was reported at the New York Academy of Sciences meeting in 1958. [604]

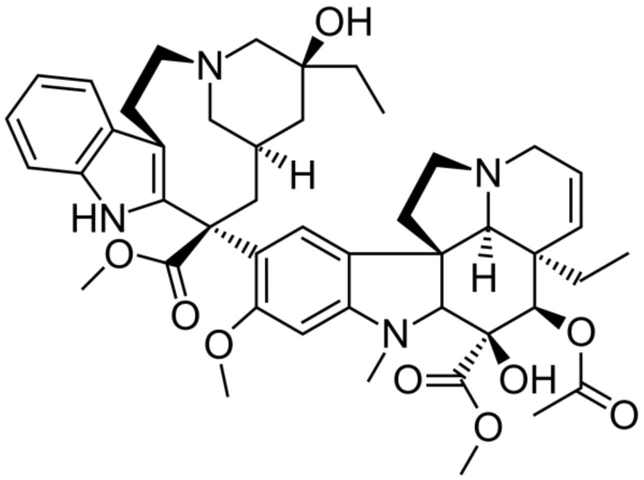


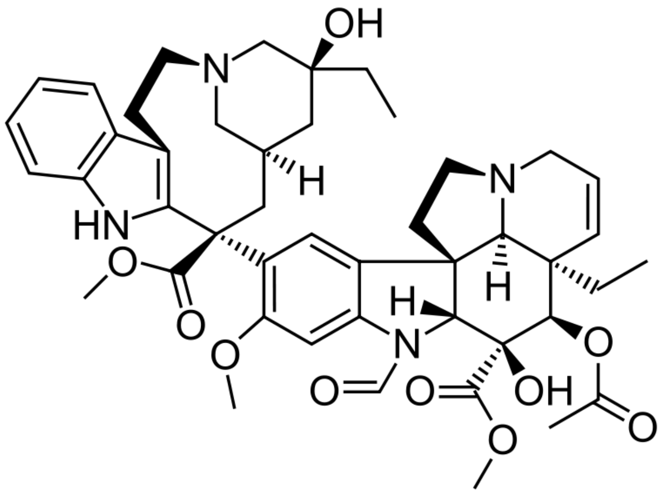
Figure 4.10 Structural formula of vinblastine [605]

At that meeting Gordon Svoboda from Eli Lilly & Co announced to Noble and Beer that a team at Eli Lilly (stimulated by reports of folk use of rosy periwinkle against diabetes - but this time in the Philippines) had similarly found that extract of the plant (obtained

[604] RL Noble, CT Beer and JH Cutts, "Role of chance observations in chemotherapy" (1958) 76 Ann NY Acad Sci 882

[605] By Fvasconcellos. Public Domain. (https://commons.wikimedia.org/wiki/File:Vinblastine.svg) (Accessed June 2015)

from within the USA) showed no antidiabetic efficacy. However, Eli Lilly had a general pharmacological screening program and an extract from the plant was put through that and a beneficial effect was observed when it used against transplanted acute lymphocyte leukaemia in mice. [606, 607, 608, 609] This work led to the use of vinblastine against lung and breast cancer. [610]



<u>Figure 4.11 Structural formula of vincristine</u> [611]

Synthetic chemistry and screening studies at the Institut de Chimie des Substances Naturelles at Gif-sur-Yvette, Paris, have since led to the development of two semi-synthetic analogues of the naturally occurring vinca alkaloids – vindesine and vinorelbine which have anti-tumour activity [612, 613]

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[606] Sneader, *Drug Discovery: the evolution of modern medicines* (n 526), 356

[607] Sneader, *Drug Discovery, A History* (n 527), 102

[608] Dutfield "Protecting the Rights of Indigenous Peoples" (n 15), 63

[609] Raviña (n 173),157

[610] N Neuss, M Gorman, and GH Svoboda, "Vinca alkaloids. III. 1. Characterisation of leurosine and vincaleukoblastine, new alkaloids from *Vinca rosea* Linn" (1959) 81 J Am Chem Soc 4754

[611] By <u>Fvasconcellos</u>. Public Domain. (https://commons.wikimedia.org/wiki/File:Vincristine.svg) (Accessed June 2015)

[612] Sneader, *Drug Discovery, A History* (n 527), 103
[613] Raviña (n 173), 158

The vinca alkaloids are believed to have their anti-tumour effects by having an effect on disruption of cell division through an effect on the tubulin microtubules within the mitotic spindles which are which are used to separate eukaryotic chromosomes during cell mitosis. [614, 615, 616]

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[614] L Wilson, K Anderson, and K Creswell, "On the Mechanism of Action of Vinblastine" (1974) 63 J Cell Biol 373a

[615] Richard H Himes, Roderick N Kersey, Irene Heller-Bettinger, and Fred E Samson "Action of the Vinca Alkaloids Vincristine, Vinblastine, and Desacetyl Vinblastine Amide on Microtubules *in Vitro*" (1976) 36 Cancer Res 3798

[616] Mary Ann Jordan and Leslie Wilson, "Microtubules as a target for anticancer drugs" (2004) 4 Nature Reviews Cancer 253

Chapter 5

Application of Philosophical Justifications for Intellectual Property to the Serendipitous Discovery of Second Uses

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“What is luck”, he said, “but the ability to exploit accidents?”

Jeanette Winterson, *The Passion* 1987

“Obey the Biblical injunction: Seek and ye shall find.

But seek not to find that for which ye seek.”

Michael Lipschutz (Cosmochemist) [617]

5.1 Introduction

The analysis of the topography of drug discovery set out in Chapter 4 supported the claim that that (notwithstanding significant admixture with other information), there always remains a causation *in fact* thread by which even the most remote downstream uses of a piece of traditional knowledge associated with genetic resources can be said to have taken some advantage of the original “inspiration”. The analysis also showed that the majority of the causal chains which run from the “inspiration” provided by a piece of traditional knowledge to a marketed drug appear to show no special features which might give rise to a break in the a chain of causation *in law*, the progression commonly resembles a smooth continuum involving sequential and accumulative contributions.

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[617] In David E Fisher, “Putting the Idle to Work” in Jeremy Webb (ed) *Nothing: Surprising Insights Everywhere from Zero to Oblivion* (The Experiment LLC, New York 2014) 183, 190

That analysis did, however, (with inspiration from problems encountered in patent law) identify "serendipitous" discoveries of second uses for the resource as a point at which the third party downstream contribution may arguably change the nature of the downstream product relative the original indigenous contribution and that such serendipitous discoveries may act as a putative "crux point" at which the key high level justifications for a right in traditional knowledge may be brought to bear.

It is the aim of this chapter to perform that analysis.

5.2 Policy options

To assist with a consistent analysis across each philosophical justification (and in coming to a synthesis of the approaches in the Chapter 6) this work will examine to what extent (if at all) the findings from each analysis comply with five potential policy options in relation to the legal treatment of a serendipitous discovery of a second use based on a piece of traditional knowledge associated with genetic resources.

In the Rawlsian *maximin* analysis set out later in this chapter, the person in Rawls' "original position" is asked to choose between these five policy options or (as they are termed there) "decisions". For consistency, this "decision" terminology (and their numbering) is used throughout the entire study.

These decisions are as follows:

- in decision $\mathbf{d_1}$ it is decided there should be no veto right to traditional knowledge associated with genetic resources *at all*;
- in decision $\mathbf{d_2}$ it is decided that there should be a veto right to traditional knowledge associated with genetic resources which extends to all and anything which is derived *in fact* from the original piece of traditional knowledge, without limitation;
- in decision $\mathbf{d_3}$ it is decided that although there should be an access right to traditional knowledge associated with genetic resources it is also decided that any such access right should not extend to preventing the use of a product arising out of a truly serendipitous discovery (even where such discovery would

not *in fact* have been made without the lead provided by the traditional knowledge associated with the genetic resource);

- in decision $\mathbf{d_4}$ it is decided that although there should be an access right to traditional knowledge associated with genetic resources it is also decided that any such access right should not extend to preventing the use of a product arising out of a truly serendipitous discovery (even where such discovery would not in fact have been made without the lead provided by the traditional knowledge associated with the genetic resource). However, any such use is subject to a compensatory mechanism based on an apportionment determined by an assessment of relative contributions; and

- In decision $\mathbf{d_5}$ it is decided that, although there should be an access right to traditional knowledge associated with genetic resources, it is also decided that any such access right should not extend to preventing any downstream use of a product. However, any such use is subject to a compensatory mechanism based on an apportionment determined by an assessment of relative contributions.

5.3 Deontological Justifications

5.3.1The application of Lockean labour-desert theory

5.3.1.1 Initial considerations: Ownership and temporal scope

As was stated in Chapter 3, there are some difficult questions to be addressed in relation to the application of either labour-desert or personality right approaches to ownership of traditional knowledge associated with genetic resources, not least due to the lack of certainty of subject matter for the right. The question of ownership is especially acute in light of the trans-generational evolution of traditional knowledge associated with genetic resources over a long course of time, with potentially multiple authors and influences.

Similarly, the forward looking individuation and backward looking origination and in-imitativeness boundaries of any right cannot help but touch on questions of *temporal* scope. Backward looking boundaries need to be examined at the time the protected innovation is made or (more likely for a right in traditional knowledge) when the claim to the "innovation" is made. Forward looking boundaries need to be assessed at the time the claim is asserted against another or when a third party is seeking to individuate a follow-on concept from an inspiration.

Under Articles 7 and 5 of the Protocol the rights in traditional knowledge associated with genetic resources are not time limited (and neither is the restriction on use of genetic resources under Articles 6 and 5). Current WIPO proposals for positive rights in traditional knowledge [618] similarly do not envisage a time limitation. This may appear on the face of it highly unusual – the majority of intellectual property rights are time limited [619] and this time limitation is considered by Hughes [620] to part of the "social bargain" between the grant of rights to innovators and the preservation of the right of others to innovate.

It is interesting to note that when one examines those time limited rights one realises that there is often, and of necessity often has to be, a close link between a temporal limitation and *certainty* of the originator. For example, Article 7(1) of the Berne Convention [621] requires that signatory states should have a minimum term of copyright protection of the life of the author and fifty years after his death. Similarly, Article 7*bis* of that Convention requires that an identical minimum term of protection shall also apply in the case of a work of joint authorship, provided that the terms measured from the death of the author shall be calculated from the death of the last surviving author.

As was stated above, the question of "authorship" is acute in light of the trans-generational evolution of traditional knowledge associated with genetic resources. There is likely to be no single or identifiable "author" upon which to hang a start point for the time limitation of the right. This lack of an identifiable author is problematic from a

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[618] WIPO/GRTKF/IC/28

[619] Those which are not time limited include registered trade marks, rights in passing off and unfair competition (all of which are fundamentally orientated toward the protection of trading goodwill) and the right to prevent the inequitable disclosure of confidential information.

[620] Hughes (n 244), 296

[621] Berne Convention for the Protection of Literary and Artistic Works of 1886 (as last amended on September 28, 1979), http://www.wipo.int/treaties/en/text.jsp?file_id=283698#P127_22000
(Accessed September 2015)

pure natural rights perspective. As we have seen much of the classical natural rights account, whether Lockean-desert or based on personality rights, relies on the extension of the inalienable freedom of the individual and in our present case that "individual" is either lost to history or (more likely) consists of a number of separate individuals (all similarly lost to history) who have developed the knowledge over time.

However, if we are to accept that there is a natural rights justification for a positive right in traditional knowledge associated with genetic resources, we may have to similarly accept that there can be no temporal limitation on the positive right. It is, in fact, difficult to see how such a right could function with such a limitation. Such a lack of temporal limitation is entirely consistent with looking at the positive right as a right of the *entire* indigenous community. As Gibson argues:

> "...Indigenous and traditional interests in medicinal and agricultural knowledge, cultural expressions, stories, dance, and so on, are integral to continuing Indigenous and traditional cultures. That significance and relationship to the community exists in perpetuity." [622]

As a heuristic tool, the current work will seek to limit the number of variables in the overall problem and assume in the Lockean and personality right analyses undertaken below that the *inherent* problems of ownership are resolved. Similarly, with regard to the analyses set out below it has been assumed, again as a heuristic tool, that all positive rights to control the use of traditional knowledge associated with genetic resources are *without* temporal limitation.

5.3.1.2 The importance of "contribution"

Let us assume that an indigenous group tell a bioprospector that "plant A is good for treating ailment X". From a Lockean perspective there is an argument that the group has a justifiable claim over that which they have contributed, namely that plant A is good for treating ailment X. However, does that *specific* basis allow the indigenous group to *also* have a justifiable claim to general "therapeutic usefulness" which would cover not only the treatment of ailment "X" or creation of effect "B" (which was their specific

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[622] Gibson (n 193), 121

“contribution”) but also to the treatment of ailment “Y”, or even ailment “Z”, or is their supportable claim limited only to that which was their *original* contribution? The difference is potentially crucial.

There is a unifying factor which is entirely central to a Lockean/labour-desert-based account of the propertization of intangibles. That is that the right to control the use of information is inextricably linked to the *contribution* being made by the individual seeking to claim a right over the information. Contribution here is akin to the “mixing of labour” with the commons in Locke’s original account; it is the conception of an idea which pulls that idea out of the commons of “yet to be had ideas” and into the ownership of the author of the idea. Without contribution it is impossible to see why there should be any “reward” or indeed to whom one would give it. However, although there can be no reward without contribution, we are left asking what *degree* of contribution is required for there to be a reward? Here then we see the term “contribution” needing to encompass elements of Gibson’s “in-imitativeness”, a sense that desert is based on achieving a “worthy” level of originality and non-obviousness from what has gone before. We must also examine the contribution of others who are using the first idea as an inspiration: at what point does their contribution outweigh the contribution of the originators and achieve a sufficient level of in-imitativeness such that their development is “worthy”:

a) of its own protection; and

b) to break free of the original idea?

Within a consequentialist account, where one is seeking to affect a particular outcome though imposition of a particular positive law, one can envisage how one might look to set appropriate thresholds of in-imitativeness. Although it would undoubtedly be extremely difficult in practice, within this approach there is, in theory, a way of “titrating” your threshold such as to give the effect (or balance of effects) you wish to achieve. One might think here of ongoing debates and case law surrounding the setting of an inventive step requirement within patent law, but there are, of course, very many more examples.

In contrast, the setting of a threshold for in-imitativeness within a Lockean account is harder, perhaps even impossible. How does one know what *degree* of contribution should deserve reward? This, of course, echoes Attas' "uncertainty of origination/individuation" attack on the entire natural rights justification for intellectual property. [623] Although we can immediately acknowledge these potential difficulties, is there anything that a Lockean analysis can bring to the current problem?

As stated above, within the natural rights account we can, at the very least, say that without *any* contribution *at all* there can be no reward. To what extent can we take this very basic proposition to investigate competing claims to contribution? We need to know what "claims" are being asserted before we can make judgment upon them.

To do so we would have to identify, and deconstruct, the "building blocks" of the concepts in play - what will be referred to here as the epistemological "elements" of a putative contribution. In the present case, the crucial question is to ask: What epistemological elements have been contributed by the indigenous holders of the information which could give rise to a right to control? What type of "claim" is being made by the indigenous group? How would this claim compare with that made by a third party discoverer of a serendipitous discovery of a second use?

Once the epistemological elements have been identified, we will then need to determine from whom they have originated. Given the potential complexity of meaning of the term "contribution" within the Lockean account, within the analysis set out below "contribution" will be used in what is its most basic way – the test applied will be the mere *independence* of contribution of an epistemological element from third party contributions of other elements.

Let us consider the following two scenarios:

a) The "North versus South Scenario" in which, with respect to the same plant "A", we find that a group of indigenous peoples (the "North" group) have identified only that it can treat ailment "X", whereas another group of indigenous people (the "South" group) have identified that it can treat ailment "Y" (but do not know of the effect on "X"); and

[623] Attas (n 48), 53

b) The “North versus West Scenario” (seen at the end of Chapter 4) in which Western pharmaceutical company “West” know, on the basis of the traditional knowledge divulged by Group North that plant “A” is useful for the treatment of ailment “X” and begin working on plant A and extract the previously unknown pharmaceutically active compound, “Red”, from it. Red is found to have an even more potent effect on ailment “X” than plant “A”. However, during the testing of Red in animals an *entirely unexpected* biological response is noted which leads to the investigation of Red as a treatment for ailment “Y”. Red becomes a successful (and profitable) drug for the treatment of “Y”.

The knowledge of North and South can arguably be divided into two epistemological elements:

a) Knowledge of very existence of plant “A” and
b) Knowledge therapeutic effect of Plant “A”:

    i) in the case of North that it treats ailment “X”; and
    ii) in the case of South that it treats ailment “Y”.

The knowledge of West arguably consists of three epistemological elements:

a) Knowledge of existence of plant “A” (knowledge obtained from North);
b) Knowledge that Plant “A” treats ailment “X” (knowledge obtained from North)
c) Knowledge that Plant “A” treats ailment “Y” (knowledge discovered by West)

Assuming, as a heuristic tool, that a right to control information is dependent upon the *independent* contribution of the putative right holder, what would that give us in relation to each epistemological element?

In the North versus South scenario, *both* North *and* South have found that Plant A is therapeutically valuable. North understand that A can treat X (but not Y) whereas South understand that A can treat Y (but not X). In each case, their understanding is contingent upon understanding that plant A exists and is therapeutically valuable (which has been independently determined by both North and South). However, in both cases the scope of their understanding of the *whole* range of therapeutic effect is partially compromised. If their rights are *exactly* coterminous with their independent contribution then arguably North can control the use of A for treatment of X (but not Y) and South can control the use of A for treatment of Y (but not X).

In the West versus North scenario, *only* North have independently found that Plant A is therapeutically valuable (what will be described as the broad "claim"). North understand that A can treat X (but not Y), whereas West understand that A can treat Y (and X). For both North and West, their narrow understanding is contingent upon the understanding that plant A exists *and* is therapeutically valuable (the broad "claim"). However, in marked contrast to the North versus South scenario, West's broader understanding has not been *independently* determined by West, but by North. If North's rights are coterminous with their *independent* contribution, then North should control West's use of A for treatment of X.

If West's rights are coterminous with their *independent* contribution, then West have in fact made no *entirely* independent contribution – their understanding of the effect of A on Y is contingent upon the broad knowledge (the existence and therapeutic usefulness of A) determined by North.

However, North have not *independently* contributed the understanding that A can treat Y - the understanding of the effect of A on Y has been determined by West (even though West's understanding is contingent upon knowledge determined by North).

The concept of rights being coterminous with independent contribution would seem to reasonably solve the North versus South conundrum. However, applied to West versus North it leaves us in a state of limbo – although it obviously supports North's control over the use of plant A to treat X, in relation to plant A treating disease Y, West have not independently arrived at an understanding that A treats Y. However, importantly, *neither has North*. They have at most made only a *part contribution*. So on an "independently-arrived at" test, North cannot assert control ownership over the use of A for Y as they have not contributed the "beneficial effect on Y" element.

Clearly, using this test gives a very limited outcome: one would only have a right to control over *all* those epistemological elements you have *independently* conceived (or discovered). No broader claims that encompass other narrower epistemological elements would be ever be permitted, but neither would any new narrow claims be awarded. So if we are going to allow any future claims such a strict test cannot apply.

However, going back to Attas' criticism above, although one can perhaps make such a system work, the doing of this (for example by setting thresholds for in-imitativeness) is a question of the imposition of positive law, not of *natural* law.

5.3.1.3 Types of claim

If we are to permit North to have a claim over West's later use of plant A for treatment of Y, we need to consider how such a claim would be structured. Such a broader claim might be considered to operate in two ways:

a) as an "inchoate" claim; or

b) as an "inherent" claim

5.3.1.4 An "inchoate" claim

Here we are saying that within North's original discovery there are in fact *two* claims. One is the narrow claim to the use of plant A for treatment of X. The other is an inchoate claim to "use of plant A for other therapeutic purposes which will incorporate use of plant A for other therapeutic indications". The validity of this inchoate claim is dependent upon North's narrower discovery of "the use of plant A for treatment of X" – this has to be the case as without the support of the narrower claim there can be no claim at all. This inchoate claim is in some way "made whole" at some future date when a further discovery is made in relation to plant A.

Is such an inchoate claim which catches later developments "as and when" they arise consistent with a Lockean account of propertization of ideas? Looking at the problem by way of analogy to Locke's "inclosure" of common land, one could imagine that the claimant is inclosing one small area (based upon the narrow contribution) from the commons. The claimant is also inclosing a larger area which corresponds to the larger (though partial) claim. This area may not be so developed as the narrower one – perhaps only services and drainage have been put in - but nothing has yet been built. The question remains, however, if I come to build a house on the serviced and drained land, does the original claimant have an *absolute* right to bar me from building, or only a right to charge me for the provision of services and drainage. If so, how much can he charge? One might argue that the charge should be in line with their part contribution, but how is *that* to be determined? Again the Lockean natural rights approach *per se* desperately struggles to address questions of degree. However, although a justification for an absolute bar to downstream use cannot be ruled out, we can see that the idea of a partial inchoate claim, justified by a partial contribution and warranting a partial degree of compensation is not inherently *inconsistent* with the Lockean account for rights in intellectual property.

5.3.1.5 An "inherent" claim

Within an indigenous context, when a plant (or an extract from it) is administered to a patient it is possible that the active compound (or compounds) found within the plant will (dependent on dose) have *all* their pharmacological effects to a greater or lesser degree. However, only *some* of these effects, the more obvious ones, may be recognised by the indigenous users of the plant. Let us suppose that West's "serendipitously discovered" second medical effect was *in fact* present throughout the use by North, but remained unrecognised. Can, North, the indigenous originators of the "first" medical use say that any serendipitously discovered second medical effect was *inherently* disclosed within the first administration, and that this was part of their "contribution". If so, might that, of itself, support a claim to broad ownership that the plant was simply "therapeutically" or (still more broadly) "biologically" useful?

Questions relating to inherency have exercised patent law for decades. [624] The crucial question has been whether the discovery of a new technical effect in relation to a previously known compound should form the basis for a patent to that new technical effect, even where that technical effect was *inherently* present in the previous use of the compound, but not recognised.

Generally speaking, case law in EPC signatory states and the EPO (notably the approach of the Enlarged Board of Appeal of the European Patent Office in *Mobil Friction Reducing Additive G 2/88* [625] and *Bayer G 6/88* [626]) and in the US [627] supports

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[624] Lionel Bentley and Brad Sherman, *Intellectual Property Law* (Oxford University Press, Oxford 2014), 548

[625] OJEPO 4/90

[626] OJEPO 4/90

[627] Dan L Burk and Mark A Lemley, "Inherency" (2005) 47(2) William and Mary Law Review 371

the proposition that disclosure of a product for a narrower use does not prevent a patent for a later-discovered use, even if the later discovered effect was inherently present in the first use. The crucial factor to be considered is whether previous disclosures, or patents relating to the compound, have made the "hidden" effect available to the public. If so, a patent for the second effect will be invalid for lack of novelty. Mere prior use (in which the hidden effect is not recognised) is insufficient to invalidate such a second patent. [628]

The case of *Merrell Dow Pharmaceuticals* [629, 630] before the United Kingdom House of Lords, examined the related question of whether a previously unknown mechanism for achieving a known effect was patentable. Here Merrell Dow had discovered that their anti-histamine drug, terfenadine, actually mediated its effect through a carboxylic-acid metabolite of terfenadine (fexofenadine, produced in the liver of humans), not through terfenadine itself as had been previously believed. They sought to patent the acid metabolite. The court held that the original terfenadine patent disclosed how to use terfenadine, notwithstanding that the mechanism by which this was achieved was unknown.

This approach is consistent with the approach taken in *Mobil*; the crucial difference between this situation in *Merrell Dow* and that in *Mobil* is that in *Merrell Dow* the claims in both patents were directed to the same end –the antihistamine effect- rather than to a hidden second effect. In *Mobil* the claims in the patent in suit were directed to an entirely different use (friction reduction) as opposed to anti-rust effects.

Within EPC signatory states, the patentability of products for therapeutic use can appear somewhat byzantine. Article 54(4) EPC ensures that one can have a patent to a therapeutic or diagnostic use of a known substance or composition provided that such

[628] It is worth noting in passing here that it was, of course, the "new use for a known thing" cases such as *Mobil* and *Bayer* which served as an inspiration in Chapter 4 for the selection of serendipitous discoveries of new uses as a putative crux point for further examination.

[629] *Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd & Penn Pharmaceuticals Ltd* [1996] RPC 76

[630] Helen Cline, "The House of Lords Decision in Merrell Dow Pharmaceuticals –v- Norton Limited & Penn Pharmaceuticals" (1995) 14 Biotechnology Law Report 956

use of the known substance is not already known. In practice this means that the first discoverer of the "first medical use" of a compound is entitled to a broad protection for the compound. For example S4A(3) UK Patents Act 1977 states:

> "In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art."

UKIPO Manual of Patent Practice states:

> "Section 4A(3) has the effect that a known substance or composition may be patented for use in a method of treatment by surgery or therapy or a method of diagnosis practised on the human or animal body, provided that its use in any such method is new ("first medical use"). That is to say, if a known substance or composition not previously used in surgery, therapy or diagnosis is found to be useful in treating, say a human disease, or to obtain a specific "therapeutic" effect (e.g. analgesic or antibiotic), a patent for the substance or composition for use in therapy (unspecified) may be obtained, i.e. **the claim need not be limited to the specific therapeutic effect**; additional claims directed towards more than one specific therapeutic effect may be allowed in the same patent application, provided of course that they are supported by the description." [emphasis added]

So called "second medical use" claims under EPC patent law are also permitted, but have received special legislative treatment. This treatment has been driven in very large part by the impact of the exclusion (for public policy reasons) of methods of medical treatment, surgery and diagnosis from patentability. [631] The potential problem was that where a second therapeutic effect was identified for a known chemical compound (all else in the invention being the same as that which went before) any novelty would reside only in a method of treatment, which is specifically excluded under EPC Article 53(c). This problem exercised many patent offices, and courts, (and led to some

[631] EPC Article 53(c). See also Section 4A(1) UK Patents Act 1977

interesting legal fictions)[632, 633] but was eventually dealt with by way of a specific legislative allowance [634, 635, 636] (although the effect of claims permitted by such allowance remains the subject of recent litigation). [637, 638]

Any second (or subsequent) medical use patent (narrowed by "use") serves its commercial purpose either by extending patent protection for the first patentee or by allowing a second patentee to have rights (although those rights will be subject to the first, broader, patent during its monopoly period).

5.3.1.6 Inchoate claims versus inherent claims

Whilst the "inchoate" claim envisaged above may seem to be achieving a similar end to the inherent claim by increasing scope of protection, when we look closely we see that both claims are achieving that end in distinctly different ways.

Returning to our Lockean commons analogy, rather than the inchoate claim based on part contribution (services and drains) situation seen above, in the inherent claim situation our Lockean builder is essentially saying: "I have built some houses over here (which I am claiming) but in doing so I have inadvertently built some other (invisible) houses over there, of which you (and I) were until now unaware, but which will stop you from building your identical (to the invisible houses) houses on that land".

If such an approach *was* acceptable within a Lockean model, one might envisage that it would be less amenable to a "payment for services provided solution" and more

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[632] "Legal Advice from the Swiss Federal Intellectual Property Office (FIPO), dated 30 May 1984" [1984] OJEPO 581

[633] Eisai (Second medical indication) G 5/83 [1984] OJEPO 64

[634] UKIPO Practice Notice: Patents Act 1977-Second Medical Use Claims (http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-medical.htm) (Accessed September 2015)

[635] Eddy D Ventose, "Patent Protection for Second and Further Medical Uses Under the European Patent Convention" (2009) 6(1) SCRIPTed 57 (http://www.law.ed.ac.uk/ahrc/script-ed/vol6-1/ventose.asp) (Accessed September 2015)

[636] S4A(4) UK Patents Act 1977

[637] *Warner-Lambert Company LLC v Actavis Group Ptc EHF & Oths* [2015] EWCA Civ 556

[638] Luke Kempton and Alisa Carter, "Bitter Pill to Swallow" (2015) 44(6) CIPA Journal 38

consistent with creating an absolute bar. However, it seems this approach has significantly greater problems than mere questions of degree. It is hard to see that an invisible house of which no one (not even the builder) knows can be a contribution deserving of reward.

There are, as is stressed elsewhere, significant problems in reading across from posited patent law to a natural rights account, However, looking at European patent law's approach to inherency, we can perhaps say that the approach taken in *Mobil* and *Bayer* is broadly consistent with the natural rights account for property rights set out above. In *Mobil* the friction reducing effect of the compound (which had originally been used as a rust inhibitor) had been unknown, and the "discovery" of this new effect was deemed to provide adequate novelty to warrant a new patent. The new understanding was a "contribution" and was rewarded with *separate* protection.

In marked contrast, the provisions of European patent law which allow broad claims to therapeutic use in relation to *first medical use claims* appear to be inconsistent with Lockean natural rights account in that the allowable claim seems broader than underlying contribution.

5.3.1.7 "Fundamental" elements

We have established above that if North *are* to have control over use of A to treat disease Y they need to have a justifiable claim to the "broader" understanding of the general "therapeutic usefulness" of A. Might they argue that the understanding that A exists, and is therapeutically valuable, is in some way a *fundamental* piece of information in the calculation which "trumps" other (newly determined) epistemological elements? What would such a "fundamental" epistemological element look like?

One approach might be to argue that: a) an epistemological element is *fundamental* to the drug discovery process if further developments would not have happened (or not happened in the way they did) without that element, and b) all developments dependent on that *fundamental* epistemological element are subject to control. Applying this definition of fundamental to the North versus West scenario, the knowledge of the existence and therapeutic usefulness of plant A was undeniably fundamental to West's discovery (in that it would not have been arrived at but for North's knowledge) and accordingly the new use should be subject to control by North.

This is, of course, an entirely circular argument – the definition of "fundamental" is defined here by what arises out of it – if the distal discovery does not arise out of the initial information, then the original information is not fundamental in relation to the discovery. It is also, merely, a causation *in fact* test: all distal use would be subject to control – notwithstanding that the originator(s) of the original information could never have ever anticipated that distal use.

The advocate of a total veto over all downstream use (our decision d_2) might argue that this definition of "fundamental" is correct. However, what we are missing in the Lockean account is a reason to say why should be so – an answer to the question: why is the fundamental element *so* fundamental that the contribution of others, no matter how significant, cannot be recognised? Again a natural rights account runs into difficult problems with determining degree.

Setting any definition of *fundamental* can clearly be done through positive law. It is, however, in reality the same as setting thresholds for individuation and in-imitativeness of a follow-on right and this brings us directly back to the problem of setting the limits on the "inchoate" partial claim discussed above.

5.3.1.8 "Too-broad" claims and "insufficient" epistemological elements

An alternative approach to our problem may be to analyse what would constitute "too broad" a claim. Let us consider the two following scenarios:

a) North, thinking to make claims to various plants in their environment, and knowing that plant A is without effect, fraudulently claim that plant A treats X (when it does not). Whilst investigating the claim pharmaceutical company "East" uncover the fact that plant A treats Y.

b) North, thinking to make claims to various plants in their environment, merely make a broad claim that plant A is therapeutically beneficial, but refuse to disclose in what way. In fact they do not know whether it is effective, they merely make the assertion as part of a "land grab" for rights in knowledge.

> Following up this broad "lead" pharmaceutical company "Down" uncover that plant A does, in fact, successfully treat disease Y.

In both cases East's and Down's discoveries have only been arrived at following North's assertion of a therapeutic benefit of plant A. Although it seems intuitively wrong for North to be able properly assert a right to control over East's and Down's use of Plant A, why is this so?

North's claims in North versus East and North versus Down are fraudulent. Can such fraudulent behaviour give rise to a Lockean natural right? Aquinas' *Secunda Secundæ* of his *Summa Theologiæ* examines certain virtues and vices in detail. [639, 640] At Question 77 of *Secunda Secundæ* Aquinas turns his attention to the concept of fraud committed in the course of buying and selling. [641] He concludes that:

> "Ambrose says (De Offic. iii, 11): "It is manifestly a rule of justice that a good man should not depart from the truth, nor inflict an unjust injury on anyone, nor have any connection with fraud."
>
> A threefold fault may be found pertaining to the thing which is sold. One, in respect of the thing's substance: and if the seller be aware of a fault in the thing he is selling, he is guilty of a fraudulent sale, so that the sale is rendered unlawful. Hence we find it written against certain people (Isaiah 1:22), "Thy silver is turned into dross, thy wine is mingled with water": because that which is mixed is defective in its substance." [642]

Although North's fraudulent claim is not based upon fraud within trading *per se*, we can perhaps extrapolate from Aquinas' thinking that taking fraudulent advantage is not permitted within a natural rights account for property. Indeed, Locke himself is keen to

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[639] Frederick Copleston, *Thomas Aquinas* (Search Press, London 1976), 12

[640] Brian Davies, *Aquinas* (Continuum, London and New York 2002), 4

[641] Marcus Lefébure, *St Thomas Aquinas: Summa Theologiæ* (Blackfriars, London 1975) Vol 38 Injustice (2a 2æ, 63-79), 213

[642] Fathers of the English Dominican Province, *Summa Theologiæ of St Thomas Aquinas* (Second and Revised Edition, 1920) (2a 2æ, Q77)
http://www.newadvent.org/summa/3077.htm (Accessed September 2015)

stress that an initial acquisition of property in the natural state can occur only where such acquisition does not disadvantage the wider community – acquisition can happen only where there remains “enough and as good” in the commons for others. It is hard to see how a fraudulent acquisition could sit within this community framework.

There is, however, a further reason why such claims lack a Lockean basis. As discussed above the key to the Lockean/labour-desert thesis is that a man may properly acquire that which is his desert and no more. Taking a pure desert approach to rights in the claimed traditional knowledge in both scenarios, North have not actually made any genuine contribution *at the time the claim is made*. The claim to therapeutic usefulness is not supported by any specific example – it is essentially insufficient to be worthy of “reward”.

As far as North actually know, plant A has no therapeutic benefit. Taking a parallel from patent law the claim to therapeutic usefulness might be said to extend beyond the scope of the actual invention. [643] Although, in each case a genuine contribution is eventually arrived at (by East, and Down respectively), this could not have been known, or even suspected, before those discoveries were made.

However, let us look at one further scenario:

North mistakenly (but honestly) believe that plant A treats X when it fact it does not. The effect that North have observed is in fact caused by a mould growing on the plant although this is unknown. Following up this mistaken “lead” pharmaceutical company “Up” uncover that plant A successfully treats disease Y, an effect which was unknown by North.

Here, there has been no fraud committed – the error is genuine. When we apply a desert basis to justify a right to control of downstream use we find ourselves in a position where the Lockean analogy becomes somewhat stretched. Although North have not *actually* made the contribution they think they have, they have arguably made *a* contribution - we know that, in their hands at least, plant A is effective against X. Is this

[643] See for example the enablement requirement under Chapter 35 United States Code 112 and the requirement for disclosure of the invention under EPC Article 83 and requirement for claims to be supported by the specification under EPC Article 84.

mistaken contribution sufficient to justify protection? Arguably it (and other permutations of mistaken contribution) are no different from a true understanding that "A treats X" so perhaps should be treated no differently. Such an analysis does not, however, assist us any further in answering the question as to whether the broader claim to "therapeutic usefulness" is justifiable.

5.3.1.9 Conclusions from a Lockean perspective

The underlying principle of the Lockean justification for intellectual property can be distilled into the statement that the justifiable scope of protection given by a right has to be coterminous with the contribution of the person claiming that right. However, what that account struggles to tell us what *contribution* actually means, both the contribution of the right holder and the competing contribution of a third party who has developed a follow-on concept from (or made a discovery from) the original idea.

The analysis conducted above would seem to suggest both that:

a) the idea of an "inherent claim", in which the unrecognised presence of the second use within the first indigenous use provides the basis for a claim over the second use once it is made, seems more difficult to support from a Lockean perspective; and

b) there is no inherent conflict with the Lockean justification where one envisages a partial inchoate claim based upon a partial contribution and giving rise to a partial degree of control.

However, what this entire analysis *really* demonstrates is the inherent difficulties the Lockean account faces in relation to origination and individuation. We see that setting levels of in-imitativeness (particularly in relation to follow-on works) are absolutely crucial in terms of establishing scope, but can realistically only be done through the imposition of *positive* law and not in some way "divined" from natural rights.

No matter how we attempt to analyse things in terms of "inchoate" and "inherent" claims, the complete uncertainty surrounding both the meaning of "contribution" and ways to compare competing contributions under the Lockean justification means we cannot entirely exclude that a *partial* contribution will warrant an *absolute* right to veto the downstream use arising out of the serendipitous discovery. One might suspect that for this to happen the initial partial contribution would need to be considered so "fundamental" as to trump all other subsequent third-party contributions. However, under this account we simply have no certainty that an understanding as to the existence of a plant with a particular therapeutic effect is appropriately *fundamental* so to supersede all other subsequent contributions such that they are deemed unworthy of reward, or indeed otherwise. We are in the dark.

However, where we have conflicting partial contributions what we can say is that it not inconsistent with a Lockean account to dispense with an *absolute* veto and in its place provide permission for the user of the serendipitous (or indeed lesser) discovery to use their discovery subject to an acknowledgement of the partial contribution made by the holder of the traditional knowledge (perhaps based on compulsory licensing, apportionment of reward/compensatory damages).

So applying the analysis set out above to our policy options d_1 to d_5 we find that the Lockean justification does not appear to support decision d_1 (no veto/compensation at all).

We find that neither d_4 (limited veto with compensation), nor d_5 (no veto but compensation) are inconsistent with the Lockean account. However, given the problem of defining contribution, the account can give us no concrete guidance as to which of those approaches is more justified. With regard to decision d_2, again all we can really say with any confidence is that the total veto of *all* downstream is not inconsistent with the Lockean model.

Looking at the question of which approach is more justifiable as between d_3 and d_4, we might intuitively say that the provision of compensation commensurate with degree of contribution would appear more fundamentally consistent with a Lockean account than not providing any compensation at all. We should note, however, that since the Lockean approach cannot give us any absolute guidance as to the definition of contribution, it might be difficult to say that a situation in which the degree of contribution was so minimal as not to warrant compensation was inconsistent with a Lockean justification.

Perhaps all we can realistically say is that d_4 (limited veto with compensation) seems to be closer "in spirit" to Locke's account of propertization than does d_3 (limited veto without compensation).

These outcomes are summarised in Table 5.1. Up arrows signify support for the decision. Down arrows signify lack of support for the decision. Queries denote where no clear answer can be drawn.

<u>Table 5.1 Application of Lockean justification to potential policy options</u>

Decision	**Lockean labour-desert**
decision $\mathbf{d_1}$: (no veto, no compensation)	↓↓↓
decision $\mathbf{d_2}$: (total veto)	↑ (Not inconsistent)
decision $\mathbf{d_3}$: (limited veto)	↑ (Not inconsistent)
decision $\mathbf{d_4}$: (limited veto + compensation)	↑ (Not inconsistent)
decision $\mathbf{d_5}$: (no veto, but compensation)	↑ (Not inconsistent)

5.3.2 Rights based on personality

Although the justification of the right differed somewhat between them, Fichte and Hegel argued that a right should exist that protects how ideas are *expressed*. Kant developed a concept that authorial personality should be respected. Crucially, however, none of these thinkers proposed that ideas *per se* should attract such protection. Indeed Kant *expressly* excluded such protection and the exclusion is inherent in Hegel's and Fichte's justifications for protection.

In Chapter 3, we saw the difficulty that arose in applying rights based upon personality to a situation in which the subject matter for protection had likely been created by multiple, unknown and undocumented "authors" across an intergenerational time frame.

Even assuming a sufficient degree of closeness such that a relevant indigenous group can be considered an "author" for these purposes, the traditional knowledge associated with genetic resources held by that group is most likely properly defined as information *per se* rather than as an expression of information. Accordingly, Hegel's, Kant's and Fichte's justification of protection of *expression* alone militates against *any* right of veto of the non-consensual use of traditional knowledge associated with genetic resources. However, if sufficient authorial "closeness" can be imputed then there is an argument that such a group would be at least be entitled to a right of attribution.

Looking at our potential policy options these justifications support decision d_1 (no veto). The strength of the prohibition against protection of ideas applies equally to all decisions (d_2, d_3, d_4 and d_5) in which some type of veto or compensation is permitted. These outcomes are summarised in Table 5.2. Up arrows signify support for the decision. Down arrows signify lack of support for the decision. Queries denote where no clear answer can be drawn. The weighting of support shown is to be considered *within* a justification, there is no attempt to represent weighting as between justifications.

Table 5.2 Application of personality rights theories to potential policy options

Decision	Kantian	Fichtean	Hegelian
decision $\mathbf{d}_{1:}$ (no veto)	↑↑↑	↑↑↑	↑↑↑
decision $\mathbf{d}_{2:}$ (total veto)	↓↓↓	↓↓↓	↓↓↓
decision $\mathbf{d}_{3:}$ (limited veto)	↓↓↓	↓↓↓	↓↓↓
decision $\mathbf{d}_{4:}$ (limited veto + compensation)	↓↓↓	↓ ↓↓	↓↓↓
decision $\mathbf{d}_{5:}$ (no veto, but compensation)	↓↓↓	↓ ↓↓	↓↓↓

5.4 Utilitarian goals and the scope of the positive right in traditional knowledge associated with genetic resources

Chapter 3 of this work outlined a number of utilitarian goals which might potentially be served by the existence of positive right in traditional knowledge associated with genetic resources. These were broadly:

a) preservation of a biodiverse environment;

b) preservation of traditional knowledge for its own sake (broader patrimony of mankind); and

c) "utility through control" – a specific utility for an indigenous group derived through the knowledge that they are controlling their own patrimony according to traditional laws and cultural norms.

5.4.1 The valorisation model

It was posited in Chapter 3 that the first two identified utilitarian goals outlined above would be achieved, in the main, by influencing the behaviour of relevant actors through the creation of "value" in the information contained within traditional knowledge associated with genetic resources. This value would, in turn, be created through an artificial scarcity in the information achieved through the imposition of positive law limiting use of the information. Here control over information would allow for the results of commercial exploitation to be directed to the rights holders (or indeed to also licensees under those rights, for example a pharmaceutical company, who would derive a commercial advantage over their competitors).

However, it was acknowledged that:

a) a "valorisation" model only works where there is some actual or potential use for the information – control over the use of something inherently useless is highly unlikely to create any value;

b) value is a more complex concept than merely creating artificial scarcity in something;

c) subjective perception is crucial in creating value;

d) the terms of exclusivity established by positive law - such as certainty of definition and ease of enforcement - become paramount in determining the subjective value of the right.

Given this final point, in particular, it seems reasonable (at first examination) to suggest that the scope of a positive right in traditional knowledge associated with genetic resources cannot help but be an important element in determining the degree of perception of value of such a right and thereafter the effect on the chosen utilitarian goals.

However, we need to recognise that in this valorisation mechanism we are presented with a potentially tenuous causal link between the imposition of rights of control over traditional knowledge associated with genetic resources and the achievement of utilitarian goals. That overall link relies on certain actors perceiving sufficient value in traditional knowledge associated with genetic resources such that it drives their behaviour towards actions which will promote (or at least support) the utilitarian ends. Any stimulus for preservation of the environment also faced significant challenges in the light of massive financial drives to "utilise" the environment in destructive ways. So going from positive right to environmental/traditional knowledge preservation involves many major causation leaps, each leap not without difficulty.

This creates a number of problems in examining the desirable scope of the positive right:

Firstly, we cannot be certain that the relevant actors' behaviour will in every case actually serve to save a biodiverse environment and/or traditional knowledge *per se* (or indeed some conflation of the two).

Secondly, given such causal complexity, it is surely unlikely that we could deduce any sort of clear linear correlation between perceived value and utilitarian benefit along the lines that "increase in value *x* gives enhancement in utilitarian effect *y*" and "reduction in *z* value gives reduction in utilitarian effect *w*". Still further it is difficult with any certainty to say what is the minimal scope of protection that would give rise to the requisite increase in value required to affect the desired utilitarian benefits or confirm:

a) that the perceived value of traditional knowledge associated with genetic resources is maximally optimised by giving it the broadest possible scope to a positive right; or

b) that the broadest possible scope to a positive right in traditional knowledge associated with genetic resources is required to give effect to the utilitarian goals of the positive right.

However, notwithstanding these uncertainties it seems broadly reasonable to suggest that the utilitarian goals are probably best served by ensuring that the highest possible number, and type, of actors perceive *genuine* value in genetic resources and traditional knowledge.

The factors feeding into a person's perception of value are numerous. Such perception is, by definition, subjective and will vary from one individual to another, and from one cultural group to another. Notwithstanding this, it seems difficult to argue other than that the perception of value will be weakened if it becomes clear that the rights can be easily be by-passed. However, would a right holder realistically expect that the right in traditional knowledge would extend to extremely remote downstream uses and to what degree would excluding such extremely remote uses diminish the perception of value?

We might intuitively surmise that permitting *proximate* uses to escape would have a more significant effect on perceived value that permitting *remote* uses to escape. However, as we are dealing with perception, there is a substantial subjective element at work here and much could be based upon the existing hopes, and prior expectations, of the right holder. If I am told (erroneously) that my right will cover everything and I subsequently find this not to be the case, the faith and value I place on my right may be more impacted than if I am initially given a realistic view of the power of my right. Similarly, one might expect that the right holder's consideration of what she considers to be a "fair" scope of protection will similarly impact on perception of value - although it is perhaps difficult to divorce a sense of what an individual will consider to be "fair" from her initial expectations.

In other fields of activity significant perceived value is given to rights which do not cover "everything". Newcomers to the field of intellectual property – especially those who believe they have some or other "rights", are often initially disappointed to realise just how curtailed those rights are - whether it be due to the inherent limitations of the appropriate rights themselves, their statutory exclusions or, especially, by the competing rights of others. Many people will, however, readily accept that there has to be a balance between the rights allocated to the right holder and the rights which remain with the "intellectual commons". Acknowledgement of this balance does not necessarily diminish the perceived value in that which they own.

At this point the staunch (and single-minded) advocate of consequentialist justifications might simply ask why are we worried about minimum scope in any event? Why do we not simply give the policy its best chances of success by creating a positive right with the broadest possible scope?

The first point to note here is that we should not immediately assume that the above uncertainties are inherently fatal to the underlying utilitarian justification(s) for positive protection. Rule utilitarian justifications for legal policy do not ordinarily rely on a clear linear correlation between policy “cause” and desired “effect”; their aim is toward creating a social and/or economic environment which will *generally* serve to encourage the achievement of the goal of the policy. Why then, is more scope of protection not automatically better?

The critics of rule utilitarianism are many. Hart [644] (among others, including Rawls [645]) attacks utilitarianism on the basis that it treats humans as a means to an end rather than as ends in themselves, highlighting that utilitarianism:

> a) treats humans as having no value as persons in themselves but merely as experiencers of pleasure;
>
> b) treats the pleasure of one individual as being replaceable by the greater happiness of the community; and
>
> c) looks to the enhancement of the overall happiness of society without concern for the distribution of that wealth.

Comte-Sponville[646] supports the second criticism by putting forward a Kantian view that it can never be right to condemn an innocent individual for the maximisation of the collective wellbeing.

To all these criticisms can be added the difficulty of calculating *total* happiness (or well-being) of society, the difficulty of assessing what is meant by happiness/well-being, how “true” happiness can be separated from “conditioned” happiness, and the difficulty in determining that future “pleasures” are indeed result of present policies. [647]

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[644] HLA Hart, “Between Utility and Rights” in *Essays in Jurisprudence and Philosophy* (Clarendon Press, Oxford 1983) 198, 200

[645] John Rawls, *A Theory of Justice* (Harvard University Press, Cambridge MA 1971, Revised Edition Belknap Press 1999), 160

[646] Compte-Sponville (n 429), 62

[647] JJC Smart and Bernard Williams, *Utilitarianism For and Against* (Cambridge University Press, Cambridge 1973), 82

If we assume that rule utilitarianism is a broadly valid philosophy, might the criticism that individuals are disadvantaged for the maximisation of the collective wellbeing be met in part by implementing an approach that only the minimum positive laws required to achieve the utilitarian aim be put in place, but no more? If we seek to adopt this "balanced" approach in the current problem we would indeed look to find the minimal scope of protection that would give us our desired utilitarian outcomes. However, as we have seen the uncertainty of a causal connection between value and effect in this case militates against our easily determining such a minimal scope.

How, then, does one then go about "squaring the circle"? Perhaps one approach is to look to achieve a balance between a utilitarian "push" in the direction of ever broader scope and a deontological push in the other direction. At this point the advocate of natural rights might argue that that the logical train set out in the valorisation model is overly complex and we might find that the application of Ockham's *lex parsimoniae* [648] pushes us further toward a direct examination of a (much more direct) deontological account for positive rights in traditional knowledge associated with genetic resources than a (tortuous) utilitarian one. However, as we have seen the natural rights account fails to give us much clear guidance in terms of justifiable limits to scope.

The validity of synthesised analyses will be discussed in the next chapter, but it might be noted here that if the deontological argument for rights in traditional knowledge associated with genetic resources can be found to be at least *not inconsistent* with achieving utilitarian aims, then this will assist in our reaching a synthesised approached which may (partially) satisfy advocates for both rule utilitarianism *and* deontological approaches.

5.4.2 "Utility through control"

As was identified in Chapter 3, there is arguably a separate utilitarian goal – a utility gained through the control of information feeding into the spiritual life an indigenous

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[648] William of Ockham's *Numquam ponenda est pluralitas sine necessitate* [Plurality must never be posited without necessity], 'Sentences of Peter Lombard' (*Quaestiones et decisiones in quattuor libros Sententiarum Petri Lombardi* (ed. Lugd., 1495), i, dist. 27, qu. 2, K).

group – which is *directly* served by giving control over access to traditional knowledge associated with genetic resources. Such a goal does not rely on a process of valorisation and accordingly does not rely upon a potentially tortuous and/or causally tenuous route between positive law and utilitarian goal. The creation of control inherently delivers the narrow utility.

In this situation the greater degree of control is broadly likely to deliver a greater degree of "utility", but again the degree to which it does so will depend on the cultural norms of the relevant indigenous peoples. To what extent would those indigenous groups believe that their traditional knowledge is being improperly used by truly distal uses? Again this will depend on the group in question and the use. It is, however, difficult to immediately accommodate the idea of monetary compensation for downstream use (as in option d_4) within this account. It seems likely that true control envisaged within this account means the ability to definitively bring non-consensual use to a stop, rather than a right to an award of compensation.

5.4.3 Conflict between utilitarian goals – global health

We have seen in the discussion above that the inherent uncertainties seen in the valorisation model create significant problems in reliably achieving the stated utilitarian goal of preservation of the biodiverse environment and/or traditional knowledge *per se* (or a conflation of the two). That discussion assumed, however, that the attempt to achieve such ends was consistent with a *broader* utilitarian account.

There is, however, a potential problem with such an assumption and it is this. If we are seeking an enhancement in the *greater* utility of the *greatest* number, might not that broad utility be better served in the present case by allowing those with the better skill and financial resources untrammelled access to traditional knowledge associated with genetic resources? If a pharmaceutical company (with those skills and resources) can take a take a piece of traditional knowledge associated with genetic resources and develop it into a product which successfully removes or alleviates a disease state (or its symptoms) in a broad population of people that would otherwise not have access to that drug, is that not a greater utility for the greater number of persons than its use being restricted to a small band of indigenous peoples – notwithstanding that the pharmaceutical company will be compensated for its own investment?

In contrast, providing a *total* veto on downstream use would mean that the development of a therapy which could benefit all of humanity (or a large part of it) could potentially be prevented by the decision of a small group of indigenous people. Here the existence of the veto right, which is supposed to bring about one set of utilitarian goals (preservation of the environment and traditional knowledge *per se*) through the creation of value in the traditional knowledge associated with genetic resources, arguably directly counters another type of utility (that of wider human health).

In addition, as we have seen the causal link between the imposition of veto rights, the valorisation of traditional knowledge associated with genetic resources and the preservation of the environment and indigenous lifestyles is reliant on an uncertain idea of "perception of value" in traditional knowledge. In marked contrast, the causal link between a piece of traditional knowledge serving as stimulus for drug development drug and the final product is arguably more concrete. One might therefore argue that the potential, but definite, "negative" impact of the veto rights on the felicific calculus of humanity (through inhibiting drug development) is likely to outweigh any "positive" utilitarian impact the veto rights may elicit.

When we look to creating "utility through control" we, of course, see what is perhaps the most *direct* link between the creation of a positive right and a utilitarian goal. However, such a goal is still subject to the same overall criticism of utilitarianism and the problems raised with regard to competing utilities. Is the happiness of a small group of indigenous peoples more important than wider human health?

Milius touches upon the question thus (but takes the discussion no further):

> "Should one give consideration to the value of utility, it might be more instrumentally productive that, for instance, [traditional knowledge] about medicinal properties of a specific plant held by its custodians be "shared" with a powerful pharmaceutical company that intends to develop a drug out of that knowledge. This is of course assuming that the principle of utility favours doing good for, or reaching, the greatest number possible. Alternatively, it is true that holding this knowledge secret within the community might also be useful to its members, or other groups (or perhaps also particular individuals) judged to qualify by the community. In terms of numbers however, the principle of utility

might suggest the [traditional knowledge] be readily and most efficiently transferred to the company."[649]

This crucial balance will be returned to below.

5.4.4 Conclusion and Policy proposals

How do these arguments apply to our policy proposals d_1, d_2, d_3, d_4 and d_5? The outcomes of the utilitarian analysis above are summarised in Table 5.3

Table 5.3 Comparison of Utilitarian arguments *versus* potential policy options

Decision	**Utilitarianism**		
	Valorisation Model	**"Utility through control"**	**Global Health for All**
decision **d₁:** (no veto, no compensation)	↓↓↓↓	↓↓↓	↑↑↑↑
decision **d₂:** (total veto)	↑↑↑↑	↑↑↑	↓↓↓
decision **d₃:** (limited veto)	↑↑	↑↓	↑↑
decision **d₄:** (limited veto + compensation)	↑↑↑	↑↓	↑†
decision **d₅:** (no veto, but compensation)	↑	↓	↑↑↑†

† Subject to levels of compensation.

[649] Milius (n 318), 198

Again, up arrows signify support for the decision. Down arrows signify lack of support for the decision. Queries denote where no clear answer can be drawn. The weighting of support shown is to be considered *within* a justification, there is no attempt to represent weighting as between justifications.

Clearly decision d_1 (no veto, no compensation) does not support the valorisation model of achieving the utilitarian aim of preservation of biodiverse environments and/or traditional knowledge whereas decisions d_2, d_3 d_4 and d_5 do (to varying degrees) support it.

Our first question is to ask to what extent is it important to have a veto to use downstream use *at all*. Is option d_5 alone enough to create a perception of value sufficient in the minds of the relevant actors to achieve the utilitarian ends of preservation of the environment/traditional knowledge associated with genetic resources *per se* or do we need a true, independently exercised, veto of some sort?

Let us assume that we can determine a reasonable mechanism for determining "respective contribution" as between the indigenous group and a downstream user. The indigenous holders of the right would receive some compensation and downstream users who had made a contribution would gain some recognition in terms of paying less. Would that create a sufficient perception of value to affect the behaviour of the relevant actors?

The first impact is likely to be upon the perception of value within an indigenous group. Realistically no mechanism for determining "respective contribution" is fool proof - even within the most ostensibly transparent determinative mechanism, mistakes are made – there is always an element of what we might call "litigation risk". However, within systems where there may be an imbalance of resources and of legal representation, potential bias within the determinative mechanism and/or corruption, there will likely be a greater perception that such a system cannot be relied upon to deliver a just reward. Where a veto is in place there is likely to be a clearer and more certain path to achieving value than with a separate determination of contribution. With an enforceable veto a third party will need to negotiate compensation through licence payments or be unable to use the subject matter of the veto rights. Provided that royalty rates are broadly equivalent to that which would be paid under our imaginary compensation regime then a veto regime will likely create more (and more easily accessed) value.

Third party users (potential licensees) will also likely perceive more value in veto rights than in a right which gives the right holder a right to compensation (again assuming the rates of both to be broadly similar). One advantage of being a licensee (especially an exclusive licensee) is that the licensee obtains an advantage over competitors that are not licensees. Under option d_5, where there is a determination of compensation relative to contribution it would likely be open to a number of downstream users to seek "permission" to use in return for payment. As well as such a being likely to be exceptionally difficult to administer, it would also likely deny the opportunity for the degree of exclusivity (and with it value) that potential licensees could see under mechanisms which granted a veto of some form.

We need to look now between those options (d_2, d_3 and d_4) which deliver an element of veto. Although the causal complexity between imposition of rights and utilitarian effect in the valorisation model cannot convincingly predict the extent to which valorisation will actually achieve the utilitarian goals (if at all), taking a simplistic rule-utilitarian "more scope is likely to provides more effect" view then d_2 is likely to provide a greater utilitarian effect than either d_3 or d_4.

Certainly the point about the likely perceived value of a veto over a compensatory mechanism set out above will apply when comparing option d_4 (limited veto + compensation) to d_2 (total veto). However, as this element is in respect of a second use (which may never arise) the difference in perceived value (although likely to be there) may not be significant.

When looking as between the utilitarian efficacy of d_3 or d_4, we need to ask whether the imposition of a requirement for compensation to be paid (d_4) enhances the perceived value of the subject matter of the rights relative to a situation in which such compensation is not required (d_3). Of course, the difference in scarcity as between the subject matter in the rights in d_3 or d_4 is marginal and such small differences may have little true effect on a perception of value (especially when arraigned against the greater economic forces of logging, mining and ranching). However, the requirement to pay compensation is likely to have some impact on perception of value *within* the indigenous group holding the rights. As such there would seem to be an argument to prefer d_4 over d_3.

Turning now to the global health utility discussed in Chapter 4 we find that d_2 (a total right to veto) exacerbates the indigenous rights versus global health conflict, whereas decision d_1 (no veto) arguably removes this conflict entirely. Decision d5 essentially provides total freedom to pharmaceutical companies to exploit traditional knowledge associated with genetic resources in return for a payment of compensation.

Both d_3 and d_4 might be said to strike something of a balance between valorisation and the indigenous rights versus global health conflict, with decision d_4 (no total veto but a right to compensation commensurate with contribution) perhaps providing the best balance. With this option (d_4), pharmaceutical companies remain free (in part) to serve the needs of global health (subject to paying compensation), whist value as perceived by the indigenous rights holders is perhaps marginally enhanced relative to decision d_3.

Of course, the true availability of the traditional knowledge to the furtherance of global health goals under options d_4 and d_5 would, in practice, rely on the level of compensation not being such as to render as unworthwile the commercial risk of engaging in drug discovery and development. [650]

When comparing the five policy decisions against the achievement of "utility through control" we of course find that decision d_1 (no veto, no compensation) cannot create that utility and decision d_5 (no veto but compensation) is unlikely to, whereas d_2 (total veto) clearly would.

What we cannot easily determine is whether a *partial* veto as in d_3 or d_4 would fail to meet that "utility through control" goal. To what extent would conceding some control of downstream activity affect this utility? This determination will depend on the cultural norms and customary practice of the indigenous group in question. It seems likely, however, that if absolute control is important this will be a commodity that cannot be easy partitioned without destroying the total utility.

[650] In this regard, the overall compensation load would need to be considered in the event that numbers of indigenous groups were able to make valid claims.

In deciding between d_3 or d_4, it is, as discussed above, unlikely that the presence, or absence, of compensation would have much of an effect on this utilitarian goal if the desire for control is key. Again, however, this is a question which is reliant upon very specific cultural norms and customary practice which of the indigenous group in question.

As was the case with the valorisation model, we find that pursuing the "utility through control" goal through provision of a total veto on all downstream use (decision d_1) is potentially completely at odds with the achievement of a "global health" utility. Perhaps more so even than with the valorisation model (where the number of beneficiaries could be large) we may here find ourselves "weighing" a utility for a potentially small group of people (an indigenous group) against the utility of potentially millions of people who would have benefitted from the new treatment but who are denied by a veto right. However, we cannot always assume that the indigenous group will be small and the class of "deprived" patients large. One can certainly envisage a situation in which the indigenous group (or even collection of indigenous groups) entitled to control is large and the number of deprived patients is small – for example sufferers from a rare "orphan" disease.

Even if we were able to predict the number of persons impacted by a policy, weighing competing utilities on the basis of numbers of individuals is inherently flawed. How does one compare the upset caused to the member of an indigenous group who has lost control of a piece of traditional knowledge concerning a genetic resource with the suffering of parents denied a treatment for their child's cancer? Even if we look to a Derclaye & Taylor-style [651] assessment of broader well-being versus mere Benthamite or Millian "happiness" (which one might imagine would place greater weight upon those denied treatment) we still find we are attempting to compare "biscuits and hyacinths".[652]

[651] Derclaye & Taylor (n 388)

[652] Carl Sandburg, *Good Morning, America* (Harcourt Brace, New York 1928)

This brings us back again to the fundamental difficulty with any utilitarian account – one cannot realistically measure a societal hedonic calculus and even to attempt to do so would require a delineation of *which* particular society you are measuring – a delineation that could be fraught with problems of arbitrary definition and partiality.

Notwithstanding this inherent difficulty in weighing directly competing utilities, one can still seek to assess which policy options *tend* to the advantage of all utilities. Therefore whilst decision d_1 (no veto) cannot aid the "utility through control" utility and d_2 cannot aid the global health utility, and *vice versa*, the "partial" veto options (d_3 and d_4) both aid, in part, the global health utility. However, as discussed above, whether a partial degree of control if sufficient to meet an indigenous group's desire to control information in accordance with customary norms is unclear but perhaps unlikely. When looking as between option d_3 and d_4, as previously discussed, the presence or absence of a requirement for compensation is unlikely to impact upon the "utility through control" utility but may impact the global health utility depending on levels of compensation.

5.5 A Rawlsian Distributive Justice Analysis

As discussed in Chapter 3, to the extent that underlying philosophical justifications for such rights in traditional knowledge associated with genetic resources can be determined, the question of whether the allocation of property which arises out of following those justifications gives rise to a fair distribution of property across society still remains. The role of a distributive justice approach in the current analysis is to determine how, if there is to be such a right, it might it best be arranged to maximise the least negative outcome for affected individuals.

5.5.1 Application of "maximin" analysis to the scope of positive right problem

Could a Rawlsian original position "maximin" analysis be applied to the current question of whether a positive right in traditional knowledge associated with genetic resources should extend to cover serendipitous discoveries of second uses? How might it work?

Such a maximin analysis requires determination between certain decisions. Those decisions have been outlined at the start of this chapter but are worth reiterating here for convenience:

- in decision **d_1** it is decided there should be no veto right to traditional knowledge associated with genetic resources *at all*;

- in decision **d_2** it is decided that there should be an veto right to traditional knowledge associated with genetic resources which extends to all and anything which is derived *in fact* from the original piece of traditional knowledge, without limitation;

- in decision **d_3** it is decided that although there should be an access right to traditional knowledge associated with genetic resources it is also decided that any such access right should not extend to preventing the use of a product arising out of a truly serendipitous discovery (even where such discovery would not *in fact* have been made without the lead provided by the traditional knowledge associated with genetic resources);

- in decision **d_4** it is decided that although there should be an access right to traditional knowledge associated with genetic resources it is also decided that any such access right should not extend to preventing the use of a product arising out of a truly serendipitous discovery (even where such discovery would not in fact have been made without the lead provided by the traditional knowledge associated with genetic resources). However, any such use is subject to a compensatory mechanism based on an apportionment determined by an assessment of relative contributions; and

- In decision **d_5** it is decided that although there should be an access right to traditional knowledge associated with genetic resources, it is also decided that any such access right should not extend to preventing any downstream use of a product. However, any such use is subject to a compensatory mechanism based on an apportionment determined by an assessment of relative contributions.

In terms of possible circumstances, we will assume two separate situations. In Rawls's original maximin analysis [653] the person in the "original position" has to imagine herself as an individual. In this current analysis she imagines herself as two distinct groups. In circumstance C_1 the person in the original position finds herself as an indigenous group

[653] John Rawls, *A Theory of Justice* (n 380), 153

in possession of the traditional knowledge associated with genetic resources. In circumstance C_2 the person in the original position finds herself a drug company that are seeking to utilise downstream uses inspired by C_1's traditional knowledge associated with genetic resources.

Of course, being in the original position behind the veil of ignorance, our person cannot tell whether she will be fall into circumstance C_1 (indigenous group) or C_2 (drug company). How then would our person in the original position seek to maximise the potential minimum?

The immediate problem in our analysis is that we cannot easily allocate definite monetary values to each circumstance. However, although we cannot put monetary figures to the outcomes, we might attempt to crudely represent gain and loss table as set out in Table 5.4.

Table 5.4 Indigenous group *versus* drug company maximin analysis

Circumstances

Decisions	**C_1**	**C_2**
d_1	-	↑↑↑↑
d_2	↑↑↑↑	-
d_3	↑↑	↑↑
d_4	↑↑↑	↑
d_5	↑	↑↑↑

The relative outcomes of decisions d_1 and d_2 are easy to approximate (occupying as they do the extreme positions of the five options). However, in the light of such raw approximation, discriminating between the outcomes of decisions d_3, d_4 and d_5 is more difficult.

Taking decision d_5 first, here drug company C_2 is free to use any downstream use inspired by the C_1's knowledge, provided it pays appropriate compensation to C_1. It is hard to evaluate the relative gain as between C_1 and C_2 as this will depend on the contribution to be paid by C_2. However, C_2 has a freedom to use any downstream use without being subject to any absolute veto and this is likely a better option for C_2 than would be options d_3 and d_4.

Although under decision d_5, C_1 is entitled to a compensation stream, determination of that stream may be in practice subject to uncertainty (as outlined above) and it would not have the strength of negotiating position to arrive at royalty payments (in relation to uses up to a serendipitous discovery) as it would have under options d_3 and d_4.

Under decision d_4 indigenous group C_1 are entitled to *both* absolute control of downstream use "up to" the serendipitous discovery *and* receive compensation for use arising out the serendipitous discovery. This is arguably a better outcome for C_1 than would be decision d_3 where C_1 are denied any degree of control of use arising out the serendipitous discovery.

In reality (subject to the level of compensation payable to indigenous group C_1) the difference in loss for C_2 as between decisions d_3 and d_4 may be small relative to the C_2's total wealth. However, d_3 clearly ranks as a better decision for C_2 than would d_4.

However, what we find in this exercise is that although we might come to a realistic assessment of how to rank the various options for each party, it is much harder in an abstract situation to assess the relative gains and losses *as between* C_1 and C_2. In truth, *much* hangs on how one measures advantage. Without knowing how a determination of compensation based on contribution would work in practice, we find ourselves essentially unable to say whether that process would provide a better outcome for C_1 than would negotiation of royalties for permissions to use. Accordingly we cannot realistically determine as between the "middle" options (d_3, d_4 and d_5) but would likely seek to avoid options d_1 and d_2.

5.5.2 Criticisms of an original position maximin analysis

Before we place too much reliance upon any maximin analysis we need to appreciate the problems inherent in such analyses.

Since publication of *A Theory of Justice* many reasons have been advanced for the inappropriateness of persons in the original position entering into a maximin analysis.

[654] One of the chief criticisms is put forward by pharmacologist, philosopher, and game theorist, John Harsanyi.[655] Harsanyi argued that, although it was right to reason from an original position, the use of the maximin test was inappropriate as it takes no account of the probabilities of the various circumstances arising. Rawls objects to using any probabilities in the original position - in the absence of *empirical* probabilities (which are impossible to determine) he rejects the use of *subjective* or *logical* probabilities. Harsanyi believes this to be wrong.

In taking no account of the probabilities of the various circumstances occurring, the maximin approach forces the person in the original position to take account of extreme, but unlikely, events. Harsanyi uses the example of a person in New York who is offered two jobs – one dull and badly paid in New York, one fulfilling and well paid in Chicago. Although the choice might seem easy, Harsanyi notes that for those engaging in a maximin analysis they must consider the possibility (no matter how slim) that the New Yorker will die in travelling to the job in Chicago. As death is the worst of the possible outcomes available in the gain/loss table, maximising the minimum results in the New Yorker taking the dull post in New York. Having no regard for real world probabilities the "maximinimizer" will always take the most risk adverse position.

Harsanyi notes that as a result of Rawls's maximin approach, and the difference principle arising out of it, the person in the original position has to evaluate any institutional framework as if she *was sure* that she would become the poorest member of a particular society.

Of course this approach has appeal in its very simplicity. However, Harsanyi notes that this can have strange effects when applied to extreme situations and can result in an excessive focus on the situation of one extremely disadvantaged individual to the disadvantage of a greater number of members of society. Harsanyi notes in a postscript to his paper that Rawls [656] challenged Harsanyi's extreme counterexamples on the basis

[654] Olantunji A Oyeshile, "A Critique of the Maximin Principle in Rawls's Theory of Justice" (2008) 3(1) Humanity & Social Sciences Journal 65

[655] Harsanyi (n 440)

[656] John Rawls, "Some Reasons for the Maximin Criterion" (1974) 63 American Economic Review 141

of scale, stating that "*maximin is a macro not a micro principle*".[657] Harsanyi describes this as a "*singularly inept defense*" [658] on the basis that although his extreme counterexamples refer to small-scale situations, they are readily scaled-up and also, on the more fundamental basis, that the basic principles of morality cannot be in some way scale-dependent. He asks at what point on the scale should maximin apply and at what point should it not?

Harsanyi is a self-confessed utilitarian. Having stressed the flaws in a maximin analysis, he argues that a more appropriate test to apply in when making decision under uncertainty is the *expected-utility maximization test* in which a decision maker cannot help but act as if she tried to maximise her expected utility [659] computed on the basis of some set of *subjective* probabilities (what she perceives is the likelihood of a particular circumstance coming to pass). Harsanyi argues that if the person in the original position applies the expected-utility maximization test in which she will weigh up all the possibilities and their probabilities, she will arrive at an outcome which not only enhances her chances of personally being in a better position when the veil of ignorance is removed, but also leads to an overall improvement in wealth of society – essentially a rule utilitarian approach. In addition, such an approach avoids the extreme positions seen with the maximin approach.

For Harsanyi, [660] the maximin approaches are most successful when dealing with differences in circumstance with similar probabilities of occurrence. This is because here the analysis actually begins to resemble that seen using expected-utility maximization test. Accordingly, the outcomes of maximin analysis of such circumstances are usually consistent with a utilitarian approach.

In the light of Harsanyi's criticisms, what criticisms might we level at the maximin analysis performed in Table 5.4? Could we perform an expected-utility maximization

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[657] John Rawls, "Some Reasons for the Maximin Criterion" (n 657), 142

[658] Harsanyi (n 440), 605

[659] Determined by calculating the weighted average of all possible outcomes possible within a set of circumstances, with the weights being assigned by the probability that any particular circumstance will occur.

[660] Harsanyi (n 440), 605

test on the circumstances set out in that table, and how would that compare to the maximin analysis performed?

As mentioned above, we cannot apportion accurate figures to the gains and losses attributable to each decision in each circumstance, but we have an understanding of the relative extremes (and that decisions d_3 d_4 and d_5 create outcomes which are positioned between two extremes arising in decisions d_1 and d_2). However, this tells us little in itself as to the similarity of this maximin test to an expected-utility maximization test on the same facts.

What can we say about probability of outcomes? We can have no way to determine *empirical* probabilities for the two posited circumstances - we cannot realistically know our chance of becoming a pharmaceutical company or an indigenous group. However, although there are a large number of pharmaceutical companies there are also a large number of indigenous groups, so perhaps the best we can say is that the probabilities are not too divergent. If that is correct, this does not represent one of Harsanyi's situations of *extremely* divergent probabilities.

5.5.3 Problems with determination of advantage

In the maximin analysis set out in Table 5.4, it was stated that much hangs on how one measures advantage and whether it is absolute or relative. This is correct. However, it will likely be immediately apparent that the greatest difficulty facing the analysis in Table 5.4 is that it is attempting to examine *relative* advantage in a very narrow way indeed. It looks merely at advantage derived from having a positive right over downstream use of traditional knowledge associated with genetic resources and does not consider the larger picture.

Whether one would want (on the removal of the veil of ignorance) to "be" Glaxo SmithKline plc or the Mentawai peoples of Indonesia is no doubt a matter of personal taste, but there is no doubt that from a monetary position you would be better off being Glaxo SmithKline (or even a small trading subsidiary thereof) than the alternative.

Herein lies the problem of a "narrow" maximin analysis – considering only the immediate rights in question it produces a solution which on the face of it appears strange. Indeed, one of the extreme "negative" outcomes to be avoided is "being" in the pharmaceutical company C_2 under decision d_2! From a monetary perspective you would more likely in the vast majority of cases want to "be" C_2 and avoid "being" C_1. We might represent this by a great (and constant) preponderance of "up" arrows on a revised analysis (see Table 5.5).

Table 5.5 Indigenous group *versus* drug company "broader situation" maximin analysis

Circumstances

Decisions	C_1	C_2
d_1	-	↑↑↑↑↑↑↑↑↑↑↑↑↑↑
d_2	↑↑↑↑	↑↑↑↑↑↑↑↑↑↑↑↑↑↑
d_3	↑↑	↑↑↑↑↑↑↑↑↑↑↑↑↑↑
d_4	↑↑↑	↑↑↑↑↑↑↑↑↑↑↑↑↑↑
d_5	↑	↑↑↑↑↑↑↑↑↑↑↑↑↑↑

In this case the worst-case scenario (the one you would most want to avoid) is now being C1 under d_1 (an indigenous group with no positive rights in traditional knowledge associated with genetic resources *at all*) whereas the situation which "maximises the minimum" is now d_2 (where any right to veto use extends to preventing *all* uses including those arising out of a truly serendipitous discovery).

In the Table 5.4 analysis we had great trouble differentiating between the relative gains and losses made by either side in decisions d_3 and d_4 and d_5. By holding the gain on the C_2 side of the equation as constant (and overwhelming) the relative ranking of the different decisions on the C_1 side of the equation becomes the important factor.

Of course, the exercise of holding the advantage to C_2 as constant *in all cases* does not necessarily reflect the true situation – C_2 will of course be disadvantaged *to a degree* in that it will have to make royalty or compensation payments or indeed decline from pursuing a research strategy if consent is not granted. In respect of smaller drug companies such payments may well make a significant difference. Even for a large company being unable to pursue a research lead could have a major effect. However, provided we accept the limitations of our assumptions (predominantly that the company is permitted to make royalty payments in return for consent to use) this approach does allow us to perform a maximin analysis which would otherwise be denied to us. Accordingly, (with this proviso) the ranking order of policy choices established in this analysis (namely d_2, d_4, d_3, d_5, d_1) will be taken forward into the analysis in Chapter 5.

5.6 A communitarian justification

As was discussed in Chapter 3, Gibson has advanced a communitarian justification which arises out of a claim to community and assures that an identified community should be able to control their own information under conditions to be determined by the communities and in accordance with their customary laws, values, and traditional practices. Although arising from a different philosophical base, it was identified in Chapter 3 that this right has some echoes with a right required to achieve a "utility through control" goal in which utility for an indigenous group is created (or perhaps more accurately preserved) though the control of information in accordance with their customary practice. This is though a right that may be tempered by concepts of equity where competing interests are to be evaluated.

Gibson does not explicitly address the question of the proximal-distal scope of the right. She does refer to "extinguishment" of rights, stating:

> "Community custodianship over resources cannot be extinguished by subsequent creation of intellectual property rights, according to the concept of community resources set out here. Therefore, where a community consents to traditional resources being used, the model may require that this in no way extinguishes their rights to that knowledge. Therefore, consent in one instance will not justify subsequent open access, or delivery into the "public domain" and the model may require fresh consent for every use of a particular aspect of traditional knowledge. While blanket consent may be easier in its practical application, the argument for fresh consent acknowledges the importance of the use of knowledge to the decision to grant consent by the community. Blanket consent cannot anticipate the many uses to which knowledge may be put once it is appropriated in this way.

> Nevertheless, this ideal does not preclude the granting of blanket consent where appropriate. For instance the conditions and terms of the appropriation and use may be qualified in agreements to allow for blanket consent." [661]

According to this account:

i) The creation of subsequent intellectual property does not extinguish the right to knowledge; and

ii) The granting of consent in relation to one use does not extinguish the requirement for users to obtain prior informed consent in relation to a second use.

In relation to point i), it is not clear what "subsequent" means in this respect. Within the context of the rest of the paragraph it suggests that where consent has been granted to use and that use has led to the creation *by others* of intellectual property that does not lead to a wholesale waiver of the rights of the indigenous peoples to control of the knowledge. What it is not saying, in itself, is that all downstream uses are controllable.

In relation to point ii), depending on the terms of consent granted in relation to the first use, it seems unlikely that a use arising out of a serendipitous discovery would be considered to fall within the ambit of the first use – almost by definition it could not be envisaged as part of the first use. If it is not so envisaged then it would not be a part of the *informed* consent granted by the holders of the knowledge. Although, that might seemingly suggest that use of a serendipitous discovery is non-consensual we cannot be sure. In her comment about "blanket consent" Gibson certainly envisages that there may be many downstream uses. However, we cannot determine whether *use* of a serendipitous discovery (or other distal downstream activity) constitutes *use* (or should constitute *use*) of the original information.

We saw in Chapter 3 that Gibson considers a requirement for free and prior informed consent before traditional knowledge can be used by others to be "fundamental" to her

[661] Gibson (n 193), 292

model and an essential element of legitimate use or appropriation. This suggests that Gibson is looking to a right to veto non-consensual use over a right to compensation.

Gibson of course highlights the role of the relevant indigenous group in consenting to the use of their knowledge under conditions to be determined by the communities and in accordance with their customary laws. To an extent then the decision over what would constitute a downstream activity is to be decided under customary laws. It is unlikely that the specific question of control second uses will have been addressed under such law, other than a general notion of a desire for absolute control (as was discussed in relation to the "utility through control" goal). Again the question of the appropriateness of compensation in lieu of control is unlikely to have been addressed under such law. Again we may imagine that a desire for absolute control would be deemed more appropriate but we cannot be sure of that and such determinations (if any) will of course vary from situation to situation.

Gibson envisages a duty upon those seeking to use what they ought reasonably to believe to be a traditional knowledge or natural/genetic resources to make reasonable efforts to ascertain and contact the relevant community to obtain consent to use of the knowledge. We again have to ask whether *use* of a serendipitous discovery constitutes *use* (or should constitute *use*) of the original information which triggers such duty. Again this account gives us no clear guidance in this respect.

Turning to the policy options, d_1, d_2, d_3, d_4 and d_5 we see that Gibson's communitarian justification strongly opposes d_1 (no veto, compensation). It would also seem to oppose option d_5 (no veto but with compensation). However, as between options d_2, d_3 and d_4 we have little guidance - other than that the decision should rest with the indigenous peoples.

5.7 Restorative/corrective justice ("reparations")

As discussed in Chapter 3, Munzer has recently proposed the grant of rights to control traditional knowledge as part of a package of broader "reparations" for past wrongs committed upon a traditional group.[662]

Munzer essentially sets out a simple philosophy that as wrongs have been committed they should be repaired and that a grant of rights to control traditional knowledge could form a part of a suite of appropriate reparations. Munzer establishes a set of conditions precedent to be met before a claim to reparations can be made. However, it is crucial to note that determination of damage (wrong) and requirements for repair are to be determined on a case by case basis. Also, there is no requirement, whatsoever, for any *specific* link between the type of wrong and the remedy, nor necessarily a clear link between the magnitude of the wrong and the remedy. [663] We cannot determine what right is appropriate in the light of the wrong. Of course, if the "wrong" happens to be a particular example of misappropriation of genetic resource and associated traditional knowledge the broad remedy may be more easily determined, if not its detail.

Given this *smörgåsbord* approach, there seems to be no reason in principle why the protection to be granted cannot include the grant of an absolute veto (through injunctive relief) alongside the award of compensation. However, Munzer deliberately avoids advocating a specific set of intellectual property rules. Munzer anticipates that a defence may be available where the potential defendant "lacks a moral duty to rectify the wrongs and undo the harm caused". [664] This seems entirely at odds with the concept of a broad award of reparations for past acts unconnected with current activities, or parties. We are not given a sense of what equitable conduct might give rise to this "defence". Might extremely distal downstream use of traditional knowledge associated with genetic resource fall within this sphere of equity? We simply cannot say.

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[662] Munzer (n 225)

[663] Munzer (n 225), 62

[664] Munzer (n 225), 62

Overall, such uncertainties, and inherent case-by-case specificity, make the translation of Munzer's reparation justification to a set of generally applicable principles for broader application exceptionally difficult.

One might imagine that Munzer's broad desire of reparation for past wrong may weigh into other assessments of equitable considerations between putative indigenous right holders in traditional knowledge associated with genetic resource and those looking to develop follow-on concepts. However, even if philosophically valid, the uncertainty in Munzer's proposal (teamed with its inherent case-by-case specificity of application) makes it impossible to know how much "weight" should be allocated.

5.8 Human Rights Justifications

In Chapter 3 we saw that UNDRIP Article 11 embodies a right to practise and revitalize indigenous cultural traditions and customs and provides that indigenous people's cultural, intellectual, religious and spiritual property should not be taken "without their free, prior and informed consent or in violation of their laws, traditions and customs provides". However, it does not do more than establish that there should be "effective" redress which "may include restitution". We also saw that Article 31 provides that indigenous peoples specifically have the right to maintain, control, protect and develop their knowledge of the properties of fauna and flora. Neither Articles give any indication as to the proper scope of those rights in relation to downstream use.

As previously stated, although UNDRIP does not establish a binding set of laws, it would seem appropriate that we determine whether rights in traditional knowledge associated with genetic resources supported by other justifications are at least compliant with the rights envisaged under UNDRIP. This is not easy. As has been discussed in Chapter 3 UNDRIP provides no guidance as to what "effective redress" (which "may include restitution") and "control" mean in this context and particularly whether a veto is envisaged. On the analysis provided in Chapter 3 we can, however, say that howsoever the wording of Article 11 is interpreted, compensation for misappropriation is likely to be the *minimum* redress envisaged. The minimum redress available under Article 31 remains entirely unclear.

Examining the four policy options, d_1, d_2, d_3 d_4 and d_5, we see that option d_1 (no right whatsoever) is not compliant with UNDRIP which envisages some control. However, as to distinguishing between options d_2, d_3 d_4 and d_5 we have little guidance – d_2, d_3 d_4 are all remedies greater than compensation for misappropriation, whereas d5 could be argued to reflect the minimum compensation envisaged within UNDRIP.

5.9 Conclusions

The key outcomes from the above analysis are set out below. As can be seen different philosophical justifications have generated differing outcomes (see Table 6.1 in Chapter 6). The discussion of how (if at all) those outcomes can be synthesised is addressed in the following chapter.

5.9.1 Utilitarianism

There are significant problems in linking valorisation of traditional knowledge associated with genetic resources with the identified utilitarian aims of enhancement of biodiversity and preservation of traditional culture (or a conflation of both). Within the utilitarian account there is also a serious conflict between granting indigenous peoples an *absolute* veto over all third party use of traditional knowledge associated with genetic resources and the enhancement of global health for all. The "utility through control" utility has the possible advantage of a short causal link between the creation of the right and the creation of utility, but suffers from uncertainty due to variation in the type of control required under customary law from indigenous group to group. If giving rise to a total veto, it also is likely to conflict with the global health for all utility.

5.9.2 Natural Rights

A Lockean labour-desert natural right to ownership of knowledge broadly supports a right based upon contribution rather than no right at all (decision d_1).

Neither d_2 (total veto) nor d_3 (limit veto) nor d_4 (limited veto with compensation) nor d_5 (no veto but compensation) are inconsistent with the Lockean account. However, given the problem of defining contribution, the account can give us no concrete guidance as to which of those four approaches is more justified.

Looking at the question of which approach is more justifiable as between d_3 and d_4, we might intuitively say that, as between the two, provision of compensation commensurate with degree of contribution would appear more fundamentally consistent with a

Lockean account than not providing any compensation at all. We should note, however, that since the Lockean approach cannot give us any absolute guidance as to the definition of contribution, it might be difficult to say that a situation where the degree of contribution was so minimal as not to warrant compensation was inconsistent with a Lockean justification.

Realistically all we can conclude is that all options other than d_1 are consistent with a labour-desert account.

Rights based upon personality such as those proposed by Kant, Fichte and Hegel are not supportive of any positive right to control ideas.

5.9.3 Rawlsian maximin

Provided one looks at the *proportionate* advantage to each side of each of the proposed decisions (essentially applying the difference principle) decision d_2 (an absolute veto on all downstream use) is the situation the person in the original position would choose as maximising the minimum. The order of "least-worst" options seen on that maximin analysis is d_2, d_4, d_3, d_5, d_1.

5.9.4 Communitarian justification

The communitarian account suggests that indigenous peoples should have a significant degree of control over information which is their community resource. Such doctrine would appear to exclude decision d_1. However, there is little explicit guidance from this doctrine as to whether very distal uses, including uses arising out of serendipitous discoveries should be considered as use of the traditional knowledge.

5.9.5 Restorative/corrective justice ("reparations")

The uncertainties, and inherent case-by-case specificity, make the translation of Munzer's reparation justification to a set of generally applicable principles for broader application exceptionally difficult.

5.9.6 UNDRIP

Compensation for misappropriation is likely to be the *minimum* redress envisaged under UNDRIP. Option d_1 (no right whatsoever) is not compliant with UNDRIP which envisages some degree of control. However, in distinguishing between options d_2, d_3, d_4 and d_5, UNDRIP gives us little guidance as all are remedies greater than (or in the case of d_5 equivalent to) compensation for misappropriation.

Chapter 6

Synthesis of Findings & Further Analysis

"Poetry is the synthesis of hyacinths and biscuits."

Carl Sandburg *Good Morning, America (1928)*

6.1 Introduction

As we have seen from Chapter 5 of this work, the results of the application of the various philosophical justifications to our question of whether a right to prevent third party use of traditional knowledge associated with genetic resources should extend to coverage of serendipitous discoveries of second uses are wide ranging and, in some cases, directly contradictory.

Table 6.1(on the next page) is an attempt to present the answers derived from each approach within a single matrix.

As with the other results tables seen in Chapter 5, up arrows signify support for the decision. Down arrows signify lack of support for the decision. Queries denote where no clear answer can be drawn. Again the weighting of support shown is to be considered *within* a justification; there is no attempt in this matrix to represent weighting as between justifications.

Table 6.1 Summary Matrix of Results from Various Approaches

Decision	**Utilitarianism**			**“Natural Rights”**				**Maximin (Rawls)**	**Commun-itarian (Gibson)**	**Repar-ation (Munzer)**	**UNDRIP**
				Lockean “labour-desert”	“Right based on Personality”						
	Valoris-ation Model	Utility through control	Global Health		Kantian	Fichtean	Hegelian				
decision **d**$_1$: (no veto, no compensation)	↓↓↓↓	↓↓↓	↑↑↑	↓↓	↑↑↑	↑↑↑	↑↑↑	↓	↓↓↓	↓↓↓	↓↓↓
decision **d**$_2$: (total veto)	↑↑↑↑	↑↑↑	↓↓↓	↑	↓↓↓	↓↓↓	↓↓↓	↑↑↑↑	?	?	↑
decision **d**$_3$: (limited veto)	↑↑	↑↓	↑↑	↑	↓↓↓	↓↓↓	↓↓↓	↑↑	?	?	↑
decision **d**$_4$: (limited veto + compensation)	↑↑ ↑	↑↓	↑†	↑	↓↓↓	↓↓↓	↓↓↓	↑↑↑	?	?	↑
decision **d**$_5$: (no veto but compensation)	↑	↓	↑↑↑†	↑	↓↓↓	↓↓↓	↓↓↓	↑	↓↓	?	↑

† Subject to levels of compensation.

6.2 How might we achieve synthesis?

Looking at these findings we are immediately presented with a problem: How are we to come to any synthesis of these results? One approach may be to simply read across the table to find which decision finds the least contradiction across the application of justifications. Arriving at such a "least contradictory" outcome has clear strengths, it sets the framework for further examination and helps us to focus on key points of conflict. However, such an approach treats all justifications as being of equal validity and all of equal applicability. We need an approach which though maintaining simplicity is more nuanced and which takes into account an assessment of applicability of justification.

We also have a deeper problem. Many of the underlying justifications outlined here are philosophically incompatible. However, as was previously stated, it is not the aim of this study to reconcile widely differing philosophical justifications – for example to demonstrate the inherent primacy of utilitarianism over natural rights theories, or indeed *vice versa*. How then might we go about a synthesis whilst avoiding this high level conflict? Naturally, such a question is not unique to our current problem and approaches to examining such potentially conflicting inputs has long exercised legal theorists. The key approaches can be summarised as "overlapping consensus" and "incompletely theorized agreements".

In *A Theory of Justice*, Rawls [665] suggests that within a nearly just society there is no need for strict consensus of views on a political conception of justice, merely a sufficient "overlapping consensus". For Rawls the overlapping need not be perfect:

> "Both sides must believe that however much their conceptions of justice differ, their views support the same judgment in the situation at hand, and would do so even if even if their respective positions be interchanged." [666]

Rawls subsequently developed this concept [667, 668] and highlighted that within a stable society the adherents of different views did not merely a get along together in a "*modus*

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[665] John Rawls *A Theory of Justice* (n 645), 340

[666] John Rawls *A Theory of Justice* (n 645), 340

vivendi" founded upon each group primarily pursuing their own interest (which was itself served by not disturbing the "treaty" with the other side) but by having sufficient genuine "shared ground" or "public reason" notwithstanding their differing philosophical starting points. It is this possession of shared ground that gives the overlapping consensus its stability and security.[669] It does not unravel as might a merely pragmatic treaty arrangement between opposing groups within society.

Rawls' overlapping consensus is a means by which individuals can find true agreement at higher levels of theoretical abstraction when agreements about certain particulars are untenable.[670] It has been described as depending

> "in effect, on there being a morally significant core of commitments common to the "reasonable" fragment of each of the main comprehensive doctrines in the community". [671]

Crucially the existence of disagreement about some lower level particulars does not of necessity destroy the higher level consensus.

Together with Posner [672, 673] Sunstein argues for a different approach to legal reasoning which minimises the reliance upon philosophical theory. He describes three classes of "incompletely theorized agreements":

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[667] John Rawls, "The Idea of an Overlapping Consensus" (1987) 7(1) Oxford Journal of Legal Studies 1

[668] John Rawls, *Political Liberalism* (Columbia University Press, New York 1993), 134

[669] John Rawls, "The Idea of an Overlapping Consensus" (n 667), 12

[670] Yavar Bathaee, "Incompletely Theorized Agreements: An Unworkable Theory of Judicial Modesty" (2006) 34(5) Fordham Urban Law Journal Article 2, 7
(http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=2158&context=ulj)
(Accessed September 2015)

[671] Fred D'Agostino, "Original Position" in Edward N Zalta (ed) *The Stanford Encyclopedia of Philosophy* (Summer 2003 Edition)
(http://plato.stanford.edu/archives/sum2003/entries/original-position/>.) (Accessed September 2015)

[672] Richard A Posner, *Overcoming Law* (Harvard University Press, Cambridge MA, 1995)

[673] Richard A Posner, *Law, Pragmatism and Democracy* (Harvard University Press, Cambridge MA, 2005), 24

i) incompletely theorized agreements on a *general principle*. Such agreements are incompletely theorized in the sense that people who accept the principle need not agree on what it entails in particular cases. The agreement is incompletely theorized in the sense that it is *incompletely specified*;

ii) agreement on a mid-level principle, but disagreement about the more general theory that accounts for it *and* about outcomes in particular cases; and

iii) incompletely theorized agreements on particular outcomes (who wins and who loses a case), accompanied by agreements on the low-level principles that account for them. Such low-level principles include the "ordinary material of legal doctrine" that have ambiguous relations to high-level theories, and that are compatible with more than one such high-level theory. [674, 675, 676]

Sunstein suggests that where people diverge on some (relatively) high level proposition they may be able to agree if they lower the level of abstraction. [677] Common agreement on legal problems can be arrived at by seeking an "incompletely theorized agreement" by looking to an level of theory (low- to mid- to high-) on which you can find convergence/common ground and incompletely theorising (essentially "agreeing to disagree") about those higher-level areas on which you disagree. This approach is arguably the "inverse" of Rawls' "overlapping consensus" approach.[678]

The approach means that instead of creating a broad theory concerning the law ahead of its application, Sunstein's incompletely theorized agreements allow resolutions to

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[674] Cass R Sunstein, "Incompletely Theorized Agreements" (1995) 108 (7) Harvard Law Review 1733

[675] Cass R Sunstein, *Legal Reasoning and Political Conflict* (Oxford University Press, Oxford 1996), 35

[676] Cass R Sunstein, "On Legal Theory and Legal Practice" in Ian Shapiro and Judith Wagner DeCew (eds) *Theory and Practice NOMOS XXXVII* (New York University Press, New York 1995)

[677] Sunstein "Incompletely Theorized Agreements" (n 674), 1740

[678] Bathaee (n 670)

evolve by way of "casuistical judgments at the point of application". [679] It is essentially a bottom-up, as opposed to Rawls' "top down", approach. One way of achieving such casuistical judgments is through the use of analogical reasoning in which the case in hand is compared to those cases with an equivalent fact pattern and equivalent decisions made. [680]

This approach has been greatly criticised [681] and chief amongst these critics is Dworkin. [682] His concern is essentially that legal decision makers should not be shy of using theory as guidance. For Dworkin, Sunstein and Posner's reliance on "pragmatism" and Sunstein's "theoretically modest" approach to problem solving, encourage (and allow) an avoidance of theory.

In truth Sunstein's position may not be entirely contrary to that of Dworkin, indeed as highlighted by Dworkin, [683] Sunstein has stated that:

> "some cases cannot be decided *at all* without introducing a fair amount of theory. Moreover, some cases cannot be decided *well* without theory. If a good theory is available and if judges can be persuaded that the theory is good, there should be no taboo on its judicial acceptance." [684]

Of course, that relies on there being a sole, obvious and incontrovertible "good" theory and not a contradiction of a number of difficult to reconcile theories.

In relation to our current question, it is hard to see how one might apply Sunstein's "theoretically modest" approach. As was discussed in Chapter 3, where one is seeking to limit third-party use of an idea the *only* guide we can find as to the extent of such control can be the theoretical justification(s) for creating (or not creating) such control.

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[679] Sunstein, *Legal Reasoning and Political Conflict* (n 675)

[680] Cass R Sunstein, "On Analogical Reasoning" (1993) 106 Harv L Rev 741, 744

[681] Bathaee (n 670)

[682] Ronald Dworkin, *Justice in Robes* (The Belnap Press of Harvard University Press, Cambridge, MA, 2006), 66

[683] Dworkin (n 682), 71

[684] Sunstein, *Legal Reasoning and Political Conflict* (n 675), 54

If we avoid such theoretical guidance we might arrive at the imposition of essentially arbitrary limits, or the misapplication of precedent from other laws (such as patent law) which although they might appear superficially similar, are different both in terms of history, subject matter of protection and underlying theoretical justification.

Rawls was describing a "shared ground" approach in terms of the broader governance of society, rather than in relation to the determination of a particular (low-level) legal problem. However, he does allow us not to be inhibited by inherent high-level philosophical conflicts. If we can find agreement in the low-level application of conflicting higher level theories we need not be concerned that the justifications originate from different philosophical places. The reconciliation of conflicting low-level applications is altogether more difficult, even if those may not, of necessity, destroy a higher level consensus in other respects.

Taking his inspiration from Rawls's overlapping consensus approach, Merges [685] accepts a theoretical pluralism of high level (what he refers to as "foundational") principles. He sees utilitarian, deontological and other accounts as giving rise to a shared body of "mid-level" principles which are equally valid whichever high level justification you consider the more supportable. As he puts it:

> "Midlevel principles provide our common space, our place of engagement. They are like a musical score, allowing us all to play together, even if we disagree about the deep wellsprings or ultimate significance of our shared performance, our common musical practice. The midlevel principles allow us to be tolerant about questions of ultimate importance. In my theory, the conceptual hierarchy includes a ground floor that is airy and capacious. There is room at the bottom." [686]

Merges proposes four such mid-level principles:

(i) efficiency – enhancement of the efficiency of an economy;

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[685] Robert P Merges, *Justifying Intellectual Property* (Harvard University Press, Cambridge, MA 2011), 10

[686] Merges, *Justifying Intellectual Property* (n 685)

(ii) non-removal – information and ideas in the public domain must not be taken away or privatised;

(iii) proportionality – the scope of an IP right ought be commensurate with the magnitude of the contribution underlying the right; and

(iv) dignity – the dignity interest can be thought of as an invisible string that connects individual creators with their works, and that survives even a formal act of legal alienation.

In further support of a midlevel approach Merges states:

> "The more systemic view supplied by Rawls's way of thinking can get us out of the unproductive and often divisive trap of thinking that each individual rule of IP must balance out perfectly. Rawls's approach frees us from this excessively internalist perspective and ought to be embraced for that reason alone."[687]

Merges (himself a previous advocate of the law and economics school) has separately stated that:

> "I have come to believe that utilitarian foundations are inadequate in the IP field. The data required by a comprehensive utilitarian perspective are simply not in evidence in this field -- at least not yet. Put simply, I do not think we can say with the requisite degree of certainty that IP systems create net positive social welfare. Yet I still had the intuition that IP rights are a valuable social institution. Which is what led me to search for alternate foundations. Hence Part I of [Justifying Intellectual Property], in which I describe foundational commitments growing out of the ideas of Locke, Kant and Rawls. These deontic conceptions provide a better set of foundational commitments for the IP field, in my view. Others of course disagree, which is why the midlevel principles are so important as a shared policy language for those with divergent foundational commitments."[688]

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[687] Merges, *Justifying Intellectual Property* (n 685), 21

[688] Robert P Merges, "Book Club: Justifying IP - Midlevel Principles: Response to Jonathan Masur" (2013) (http://prawfsblawg.blogs.com/prawfsblawg/2013/01/book-club-justifying-ip-midlevel-principles-response-to-jonathan-masur.html) (Accessed September 2015)

However, as might be anticipated, Merges' approach has put the mid-level "cat" amongst the theoretical "pigeons". Masur has described Merges' work as:

> "one of the most sweeping, significant, and brilliant books about intellectual property to be published in years".[689]

In marked contrast, Blankfein-Tabachnick has recently criticised Merges midlevel approach as "untenable". [690] Blankfein-Tabachnick contends that:

> "[Merges'] midlevel principles conflict with important liberal "foundational" accounts of property, thereby calling into question the justificatory force such principles might hold. Moreover, contrary to Professor Robert P. Merges' view, different foundational principles, whether maximizing wealth, net aggregate value, or the position of the least well-off, will yield different substantive outcomes in IP cases. Accordingly ... any project conjoining this set of midlevel principles with maximizing distributive principles cannot be sustained. A sophisticated understanding of IP, its theory, and crucially its legal doctrine and practice, does not, and should not, include midlevel principles understood to be consistent with such variously competing foundations." [691]

Whilst, broadly speaking, concepts of non-removal, proportionality and dignity (the former two demonstrating a distinctly Lockean "flavour" [692] and the latter obvious echoes coming from Kantian/Fichtean rights based in personhood) would seem relatively uncontroversial, Merges' continued adherence to elements of a utilitarian model (in his efficiency mid-level principle) remains counter to those for whom such a utilitarian approach is fundamentally flawed.

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[689] Jonathan Masur, "Jonathan Masur on Rob Merges' "Justifying Intellectual Property" :The New Institutional Philosophy of Rob Merges" (2013) http://www.law.uchicago.edu/news/jonathan-masur-rober-merges-justifying-intellectual-property (Accessed September 2015)

[690] David H Blankfein-Tabachnick,"Intellectual Property Doctrine and Midlevel Principles" (2013) 101(5) California Law Review Art 1315. See also David H Blankfein-Tabachnick, "Book Review: Does Intellectual Property Law Have Foundations? A Review of Robert Merges's Justifying Intellectual Property" (2013) 45 Conn L Rev 995

[691] Blankfein-Tabachnick (n 690), 2

[692] Merges, *Justifying Intellectual Property* (n 685),10

Perhaps there is some suspicion of the seemingly "Damascene conversion" of such a previously staunch advocate of the law and economics school. Masur states it is akin to seeing Richard Posner:

> "arguing that contract and tort law are fundamentally grounded in theories of fairness and distributive justice". [693]

Merges himself has defended the presence of economic efficiency within his midlevel principles thus:

> "The only question that needs to be answered is whether a body of IP law can be envisioned that is consistent with these systems of philosophical thought. If so, the foundational question has been successfully answered. Then it's on to the operational level - designing actual institutions and rules to implement a workable IP system. In my view this is where the efficiency principle comes into play: one important design principle for IP law is and should be getting from our IP system the greatest social benefit at the lowest net cost (as best we can estimate these values). Efficiency is an operational (midlevel) principle, in other words. It does not (and in my view cannot) justify the existence of the field. But it can serve us well in crafting the detailed operations of the field -- once we decide, consistent with ultimate commitments, that it makes sense to have such a field in the first place." [694]

Citing Merges' attempt at this reconciliation of these deontological and utilitarian approaches, Fromer [695] has recently highlighted that the utilitarian economic incentive to invent provided by patent law also provides "expressive incentives" to inventors to develop their personality through invention (although she ignores the fact Kant, Fichte and Hegel were not supportive of control over ideas *per se*).

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[693] Jonathan Masur, "Jonathan Masur on Rob Merges' "Justifying Intellectual Property":The New Institutional Philosophy of Rob Merges" (2013) http://www.law.uchicago.edu/news/jonathan-masur-rober-merges-justifying-intellectual-property (Accessed September 2015), 1

[694] Merges, "Midlevel Principles: Response to Jonathan Masur" (n 688), para 9

[695] Jeanne C Fromer, "Expressive Incentives in Intellectual Property" (2012) 98 Va L Rev 1745

The validity (or otherwise) of Merges' mid-level principles (particularly the presence of a utilitarian account within those principles) remains to be determined by the academic community and no doubt the finding of a Rawlsian "shared ground" will continue to stimulate a vigorous ongoing debate.

Accordingly, the present study adopts a conservative analytical approach which might be described as seeking a "least contradiction", but with giving due concern for theoretical conflict. Closer to the approach of Rawls than Sunstein, it seeks to find what common consensus there is between the outcomes suggested by different philosophical justifications. However, if these clash it seeks to give appropriate weight to the appropriateness and suitability to the justifications in conflict to the situation under examination. This approach is in line with the pluralistic account advocated by Resnik [696] (mentioned above) which acknowledges that the analysis of different intellectual property rights requires differing assessments of competing moral values in the light of the particular facts and circumstances which affect that right. It is also consistent with the pluralistic approach appealing to concepts of "utility, autonomy, privacy and justice" advocated by Milius.[697]

6.3 A synthesis

Our first step in this examination is to look at the relevance of the natural rights justifications. The rights based upon personality (following the philosophies of Kant, Fichte and Hegel) all fail to support a veto/compensation right on the basis that ideas *per se* (as opposed to the protection of expression or of a right to attribution) cannot be the proper subject matter of such a right.

When looking at our other natural rights head, we also saw that significant arguments have been raised as to whether the problems of origination/individuation are so severe within a natural rights account as to entirely undermine application of a Lockean labour-desert justification. Even if a Lockean account *does* give us an underlying foundation for the existence of a right (and reminds us of the important of balancing the rights of

[696] David B Resnik, "A Pluralistic Account of Intellectual Property" (2003) 46(4) Journal of Business Ethics 319, 319

[697] Milius (n 318), 197

claimants to intellectual property with those of “commoners”) its application *in particulars* is greatly limited by the origination/individuation problems, notably in questions of degree.

If, as a heuristic tool, we accept at this stage that any protection offered in respect of ideas *per se* has to be the result of *positive* (as opposed to natural) law, then we are left looking at the non-natural rights justifications. Table 6.2 summarises the results seen in Table 6.1 but excludes the natural rights justifications.

<u>Table 6.2 Summary Matrix of Results without Natural Rights Justifications</u>

Decision	**Utilitarianism**			**Maximin (Rawls)**	**Communitarian (Gibson)**	**Reparation (Munzer)**	**UNDRIP**
	Valorisation Model	**“Utility through control”**	**Global health**				
decision $\mathbf{d}_1$: (no veto)	↓↓↓↓	↓↓↓	↑↑↑	↓	↓↓↓	↓↓↓	↓↓↓
decision $\mathbf{d}_2$: (total veto)	↑↑↑↑	↑↑↑	↓↓↓	↑↑↑↑	?	?	↑
decision $\mathbf{d}_3$: (limited veto)	↑↑	↑↓	↑↑	↑↑	?	?	↑
decision $\mathbf{d}_4$: (limited veto + compensation)	↑↑↑	↑↓	↑†	↑↑↑	?	?	↑
decision $\mathbf{d}_5$: (limited veto but compensation)	↑	↓	↑↑↑†	↑	↓↓	?	↑

† Subject to levels of compensation

Looking across the remaining justifications, we find that none of the approaches (save for the utilitarian global health justification in respect of vetoes alone) favour a complete absence of veto/right to compensation. So a maximum consistency approach suggests that we are looking toward *some* type of veto/ right to compensation.

Examining the four types of veto/right to compensation in play: decision d_2 (total veto), decision d_3 (limited veto), decision d_4 (limited veto with compensation) and decision d_5

(no veto but compensation), we saw that our Rawlsian *maximin* analysis most favoured a total veto (d_2), followed by d_4 (limited veto + compensation), followed by decision d_3 (limited veto), followed by d_5 (no veto but compensation).

We also saw that none of these decisions are entirely inconsistent with the achievement of utilitarian goals through valorisation of traditional knowledge, UNDRIP or the communitarian justification.

Broadly speaking, Munzer's reparations approach favours control. However, as discussed in Chapter 5, the uncertainties surrounding the reparation justification are so great as to really be of no assistance in the current analysis.

Although it was more consistent with a global health utility than any of the veto options, it was argued that option d_5 (no veto but compensation) was unlikely to create the same perception of value amongst relevant actors as would a veto (provided that the compensation provided under the determinant mechanism was broadly equivalent to royalties that would be paid under a licence) as the absence of a veto mechanism would preclude the creation of exclusive licensees who could rely upon their competitors being excluded from the market.

Of all the *veto* options, d_4 (limited veto + compensation) and decision d_3 (limited veto) would appear on first examination to be more consistent with the preservation of global health utilitarian justification. Both approaches allow pharmaceutical companies to use a serendipitous discovery without *absolute* hindrance. If we consider the global health utilitarian justification to be an important determinant, this leaves us with a choice between d_4 (limited veto with compensation) and decision d_3 (limited veto without compensation). Of these two choices decision d_4 (limited veto with compensation) is more strongly supported by the Rawlsian maximin analysis.

The question of whether d_4 is more likely to provide value to traditional knowledge than d_3 (limited veto without compensation) is somewhat more moot. As was discussed in Chapter 3, the mechanism by which the creation of value in traditional knowledge achieves the utilitarian goals of preservation of the environment/traditional knowledge (or a conflation of the two) is most likely to be through the subjective perception of some economic value in the knowledge amongst all the actors (both indigenous and third party) involved in a situation in which the preservation of the environment and/or traditional knowledge is pitted against development which might lead to the destruction or diminution of the environment/traditional knowledge.

As was also stated in Chapter 3, notwithstanding a scepticism in relation to the overall efficacy of a valorisation model, the perception amongst all the concerned actors of *some* value in genetic resources and in traditional knowledge associated with those resources (created through the existence of a right to control use) must be better than *no* perceived value whatsoever (created through the absence of a right to control use). As between option d_4 and d_3 then, the requirement to pay compensation is likely to have little effect on value as perceived by third parties, but is likely to have an impact on perception of value within the indigenous group holding the rights. As such there would seem to be an argument here to prefer d_4 over d_3.

In relation to achieving a "utility through control" utilitarian goal, it was argued in Chapter 5 that this goal was most likely to be achieved through a total veto (option d_2) whereas options d_4 (limited veto + compensation) and decision d_3 (limited veto only) may or may not achieve this utility depending on the indigenous group concerned. This utility was unlikely to be achieved (or achieved only minimally) through option d_5.

As was also discussed in Chapter 5, seeking a resolution of the conflict between the "utility through control" and "global health" utilities is exceptionally difficult. Those options which are likely to fulfil the goal of "utility through control" will work against the global health utility and *vice versa*. This conflict certainly highlights the difficulties (and perhaps the potential futility) in attempting to compare and rank such differing utilities.

Earlier in this analysis we the excluded the Lockean labour-desert justification due to inherent uncertainties of origination and individuation. However, in formulating a *positive* law we may at least seek some consistency with *natural* law principles where we can. This may be particularly true where we are looking at rights based on *contribution* – as we have seen the concept of contribution is fundamental to all positive intellectual property laws and it seems not unreasonable to apply a contribution requirement to a positive law relating to the protection of traditional knowledge associated with genetic resources. That said, however, perhaps all we can safely say from our labour-desert analysis is that all options, other than d_1 (no veto/compensation), are consistent with a labour-desert account. Not a contribution which takes us particularly far.

So, overall, in applying a "least contradiction" analysis we find that decision d_4 (limited veto with compensation) would might seem to give us the least contradictions across most analyses. However, if we re-examine the non-natural law justifications in Table 6.2, we find that this is arguably a strange result. In fact all the justifications favour (or are least consistent with) option d_2 – a total veto - *save alone* for the "global health" utility. We must therefore ask ourselves to what extent the global health utility would truly be undermined by the existence of an *absolute* veto on all downstream use.

The veto envisaged in d_2 does give an absolute right for an indigenous group to prevent *any* downstream use of traditional knowledge associated with genetic resources, notwithstanding that the use may considered by many to be very distal to the original understanding. There is no doubt that in this case (d_2) one cannot entirely rule out a situation in which a new (perhaps serendipitously discovered) treatment may be denied to the world by an indigenous group choosing to exercise their right of veto absolutely (or seeking to licence the right at a royalty level which was not viable for licensees).

However, although this is entirely *possible*, we might ask whether it is *likely*. The exercise of an absolute veto without the grant of a licence would likely mean that the indigenous group would be unlikely to enjoy any economic benefit sharing of the fruits of the downstream exploitation of the information. One might imagine that the drive to partake in benefits of being a licensor would be strong. However, such a drive is likely to be based upon a Western-economic perspective. It is entirely possible to imagine a situation in which absolute control is deemed by a group to be more important than such benefits. Simply put, without further work, we cannot say what would be the actual likelihood of a new drug being denied to the global population. However, if one were to pursue the total veto policy proposal this *always* have to remain a possibility.

We must also note that it is significantly in the broader interest of the global pharmaceutical industry that the great reserve of biologically active compounds which are to be found in the flora, fauna, fungi and bacteria of biodiverse environments are preserved and can be located. If it is more likely that a total veto will more strongly serve the protection of our ways of accessing such compounds, then the risk of an occasional absolute veto might be outweighed by the overall instrumental utility of the preservation of such knowledge and the relevant environment/genetic resources. At this point we simply do not know. This is point which will be returned to in the Conclusions section of this work at Chapter 7.

That brings us back again to the question of whether a total veto serves to create a greater perception of value in the appropriate traditional knowledge than would option d_4 (limited veto plus compensation). Here one might argue that the majority of the perceived value in the knowledge is created by the control of the first use rather than any downstream second (or subsequent) use which may, or may not, arise. However, as was highlighted in the valorisation model analysis, where one is seeking to create an optimum perception of value there is significant merit in a simple to understand and simple to administer system. Again, this is a point to which we will be returning in the concluding chapter (Chapter 7).

6.4 The workability of a limited veto

As mentioned looking over the entire picture, option d_4 would appear to meet many of the requirements for a justifiable "consensus" position. In practice, however, whether it represents such a "consensus" (or indeed is at all workable) might depend upon the details of how the normative concept was brought into positive law.

There are two crucial questions which need to be addressed in this regard:

a) If the compensatory mechanism is based on an apportionment determined by an assessment of relative contributions, how do we assess those relative contributions?

b) What *is* a truly serendipitous discovery?

As we will see, both questions are (very) closely related.

6.4.1 Assessment of "contribution"

Questions of "contribution" in intellectual property law have most commonly focussed upon the determination of the degree to which an infringer's use of an infringing concept or product has contributed to the infringer's overall profits and the extent therefore to which infringer need account for those profits to the intellectual property right holder. [698, 699] In this respect, much of the work of the courts has been to assess contributory causes to profits made. [700, 701, 702, 703] Attention has similarly been paid to assessment of royalty rates within non-voluntary patent licensing. Mechanisms for determining such rates exist [704, 705, 706] and similar principles as exist in the apportionment of an account of profits are applied in a non-voluntary patent licensing context where the patent in question covers part of a complex object.[707]

All these approaches are essentially based on apportionment of *commercial* value and do not (it is argued here) assist in our present investigation. We need to recognise that the assessment of contribution which is important in relation to options d_4 and d_5 does not relate to the splitting of profits between infringing and non-infringing activities but to an assessment, in a particular situation, of the various epistemic elements of the "discovery" which have been brought by the contributing parties. This question is arguably much closer to the question of determination of the in-imitativeness of a

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698 See: Lionel Bentley, "Accounting for Profits Gained by Infringement of Copyright: When does it end?" (1991) 13(1) EIPR 5

699 See also Alexander J Stack, A Scott Davidson & Stephen R Cole, "Accounting of Profits Calculations in Intellectual Property Cases in Canada" (2001) 17(2) CIPR 405

700 See for example: *Redwood Music Ltd v Chappell and Co Ltd* [1982] RPC 109

701 See also: *Beloit Canada Ltée v Valmet OY* (1994) 55 (3d) CPR 385 (FCTD Canada)

702 See also: *The Wellcome Foundation Ltd et al v Apotex* (1999) 82 3d CPR 359 (FCTD Canada)

703 See also: *Celanese International Corp v BP Chemicals Ltd* [1999] RPC 203

704 Elli Välimäki,"Calculation of Royalties in Compulsory Licensing of Pharmaceutical Patents in Europe – How Much is Justified?" (2011) Nordic Journal of Commercial Law Special Edition

705 Jerome H Reichman, "Non-voluntary Licensing of Patented Inventions Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA." UNCTAD-ICTSD Project on IPRs and Sustainable Development (2003)

(http://www.ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf) (Accessed September 2015)

706 World Health Organisation Health Economics and Drugs TCM, "Remuneration guidelines for non-voluntary use of a patent on medical technologies" WHO/TCM/2005.1
(http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf) (Accessed September 2015)

707 World Health Organisation (n 706), 61

follow-on concept in the light of the concepts that have gone before, than it is to the splitting of profits or commercial value.

In relation to patents, the question of in-imitativeness is structured as whether the new right is novel or inventive and is (in relation to both tests) set as a binary "yes or no" in the light of prior art and (sometimes) the common general knowledge. What patent offices do not do (and indeed are not required to do) is determine whether a new patent application is made up of, say, 95% "old" contribution and 5% "new" contribution.

Indeed, in much patent practice and case law, great efforts are made to simplify the process by the use of formulaic tests which seek to narrow down that which the claimed invention will be tested against. [708, 709] For an extreme example, in the EPO inventive step is assessed using a highly formulaic "problem-solution" [710] test based upon selection of a single closest piece of prior art [711] and determination of an "objective technical problem" [712] posed by that prior art which the claimed invention successfully solves.

We saw in our analysis of the Lockean labour-desert justification in Chapter 5 that the crucial question was what constituted a "contribution". That thorny question remains where one is looking to create an apportionment based on contribution. Of course, if our grounds for creating the right are based on *positive* (rather than natural) law it is always open to law makers to arrive at positive law solution. However, in reality the formulation of a mechanism to fairly balance contribution to a discovery is fraught with difficulty. On what basis might we determine that one part of a discovery is more important than another? Do we/how do we factor in the effluxion of time? Are newer contributions to be given weighting over older contributions?

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[708] See for example: *Graham et al v John Deere Co of Kansas City et al* (1966) 383 US 1 (USSC)

[709] See also: *Pozzoli Spa v BDMO SA & Anor* [2007] EWCA Civ 588

[710] EPO Guidelines G-VII 5 (see also Case Law of the EPO Boards of Appeal I.D.2)

[711] EPO Guidelines G-VII 5.1(see also Case Law of the EPO Boards of Appeal I.D.3.1)

[712] EPO Guidelines G-VII 5.2(see also Case Law of the EPO Boards of Appeal I.D.4.1)

In addition, we have assumed that the determination would be between two parties: the indigenous group and the serendipitous "discoverer", but there may be many partial contributions by others which could greatly complicate our (already difficult) bipartite determination.

What is common to these questions is that they refer to relative contribution made in relation to a serendipitous discovery. Therefore, in many ways we actually find that these questions bring us back to the core question of what constitutes a "true" serendipitous discovery?

6.5 Serendipity and "Retrospective Obviousness"

In Chapter 4, it was highlighted that where a serendipitous discovery has been made, the crucial element is that there has been an entirely non-obvious, or unexpected, revelation of a new feature (use) of the "thing" (for example ligand) obtained from the genetic resource to which the traditional knowledge relates.

Accordingly, when examining the policy options (d_1 to d_5) earlier in this work we defined a "serendipitous discovery" of a second use to mean a discovery in which the second use is truly unexpected in the light of the *current* understanding of the underlying biology when the discovery of the second use is made.

However, it was also highlighted in Chapter 4 that not all steps to a new use will appear so momentous; some second uses may be reached (without a serendipitous leap) through a step-wise process in which researchers progressively understand more about the underlying biological target of a ligand. It was also stated that, even though a serendipitous discovery will *appear* unexpected at the time that it is made, as soon as the discovery of an unexpected second therapeutic benefit has been made, it will initiate research into the biological processes underlying the two apparently different (but in fact linked) therapeutic effects. This further work might be said to eventually render the discovery *retrospectively* obvious (just as such work performed ahead of the discovery could render if *prospectively* obvious).

Of course, *retrospective* obviousness would seem to be oxymoronic. When we ask whether something is obvious we are inherently asking whether it is obvious *at the time* the question is being asked of us. We may debate what materials and other understandings we might compare a discovery with, but all the materials and understandings to hand can have only been created *in the past*.

This focus on the date upon which a question is asked is a fundamental element within existing intellectual property laws. Notably the priority date of a patent application (and what is knowledge is within the state of the art at that date) are critical to determining the novelty [713] and inventiveness [714] of a patent. The requirement that patent novelty and obviousness be determined at a certain date stems from the fact that patents are registered rights which have to be applied for and which have a fixed monopoly period – in one sense they have to have a start date otherwise they would not have an end date.

As previously mentioned (see Chapter 5.3.1.1, above) , most intellectual property rights have an end date, a "*self-defined expiration, a built-in sunset*" is for Hughes [715] what enhances the social neutrality of intellectual property rights. Limiting the term of protection balances the negative of denying of others an opportunity to use the subject matter of the right and in the long-term allows for an expansion of the common weal. The start date within patent law is central to the determination of the "contribution" made by the invention and of whether it is deserving of patent protection at the date it is applied for. The requirement of a start date also "cements" what is claimed. Most patent laws contain strict rules as to post-application amendment [716] and the addition during prosecution of "added-matter" which does not form a part of the original application. [717]

The UK Court of Appeal's invalidation Pfizer's patent surrounding the effect of cyclic-guanosine monophosphate (cGMP) - specific phosphodiesterase (PDE) Type 5 inhibitors (including sildenafil citrate (Viagra)) on erectile dysfunction, presents an

[713] See for example Article 54 EPC

[714] See for example Article 56 EPC

[715] Hughes (n 244), 296

[716] See for example Article123(3) EPC

[717] See for example Article 123(2) EPC

excellent example of a “surprising” second therapeutic use rendered obvious by prior publication of the understanding of the underlying biological mechanism. [718, 719]

During a study examining the effect of sildenafil on angina pectoris (affected through a dilatation effect on cardiac blood vessels), it was observed that the drug had a “second” effect on penile erectile tissue. Such a discovery could have been seen as a non-obvious serendipitous discovery. Indeed Pfizer, the sponsors of the study, certainly felt so and, after further work, filed a patent for the effect of the drug on erectile dysfunction. However, ahead of this filing a group led by Snyder at Johns Hopkins University had been examining the effect of nitric oxide (NO) on the relaxation of blood vessels. The group suspected that NO was a neurotransmitter responsible for the regulation of smooth muscle tone in the wall of blood vessels. During their studies they discovered that nitric oxide synthase (NOS, the enzyme which catalyses the production of NO) is found in localised concentrations in the erectile material of the penis. Given that the inhibition of NOS also inhibited penile erections, Snyder’s group suggested that the release of NO in penile erectile tissue is responsible for causing penile erections.[720] As it was also understood that NO mediated its effect on vascular smooth through cGMP, it was a short step to understand that an inhibitor of cGMP inactivation (such as sildenafil) would have an stimulatory impact on blood flow in erectile tissue. [721, 722]

The *Pfizer* case demonstrates that timing is crucial.

As has been discussed above (at 5.3.1.1) the way in which traditional knowledge associated with genetic resources is created and held is such that it is difficult to see how a right to control its use can have a *fixed* duration. This lack of fixed duration may pose a distinct (and unique) challenge in relation to the assessment of in-imitativeness of follow-on developments.

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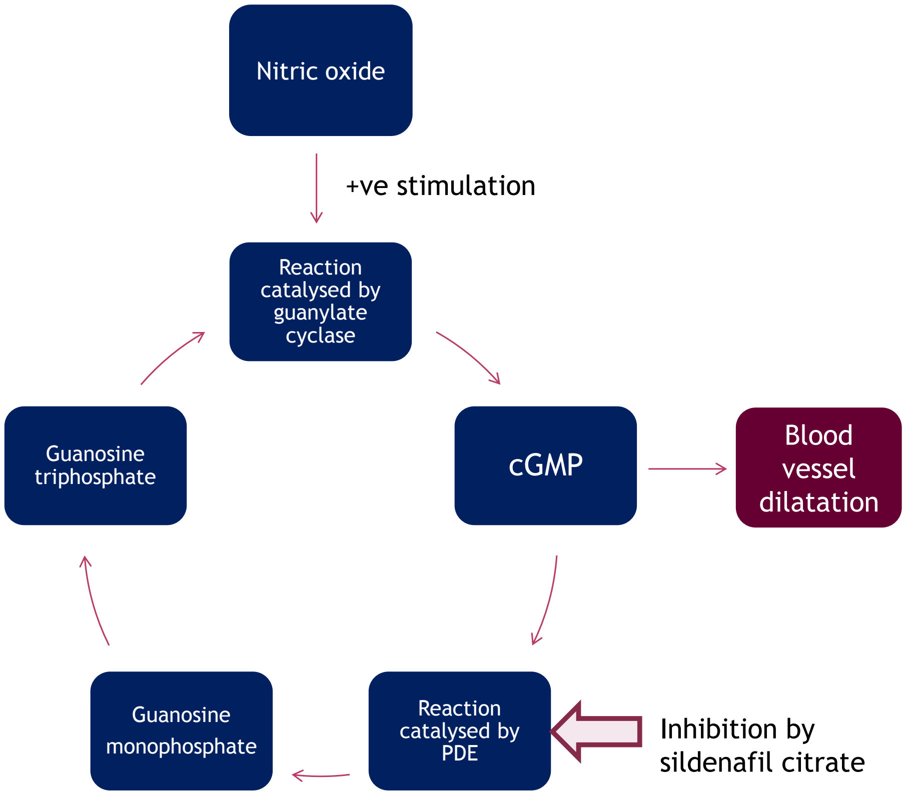
[718] Yinliang Liu, “The Tale of Viagra Patents: Comparative Studies of the Global Challenges in China and Other Countries” (2013) 18 JIPR 523

[720] AL Burnett, CJ Lowenstein, DS Bredt, TS Chang, and SH Snyder “Nitric oxide: a physiologic mediator of penile erection” (1992) 257(5068) Science 401

[721] SH Snyder, “Forty years of neurotransmitters” in TA Ban, D Healy, and E Shorter (eds) *From Psychopharmacology to Neuropsychopharmacology in the 1980s and the Story of CINP As Told in Autobiography* (Animula, Budapest, Hungary 2002) 36

[722] Thomas A Ban, “The role of serendipity in drug discovery” (2006) 8(3) Dialogues Clin Neurosci 335

Figure 6.1 Schematic representation of the biochemical mechanism of action of sildenafil citrate



Let us consider then the situation in which we have a subsisting right to control downstream use of an idea which has an *infinite* temporal duration. We are immediately forced to ask at what point in time we should determine that any new downstream development of that idea is "non-obvious" in the light of that right.

When the new discovery of a second use is made (say the effect of plant A on disease Y in our North versus West scenario) at time α, it may seem to be unexpected (or serendipitous). Now let us imagine that research work is being done in parallel which uncovers that A has its effect of disease X through physiological mechanism "P". This work also uncovers that disease Y is also caused through mechanism P. We are now at time β. Had the finding of the effect of A on Y been made after time β then it is unlikely that the finding would be a non-obvious discovery – indeed it would most likely be considered the natural consequence of the effect of A on joint physiological process P (just as was the case for Pfizer with sildenafil as discussed above).

If we assume that the discovery of the joint effect through mechanism P is inevitable we might ask ourselves this: Is the appearance of "serendipity" merely an artefact of the time at which we have chosen to test it? Although we cannot know with certainty when it will be determined, we do know that with enough time the *entire* biological benefit of A will be uncovered – all of which can trace its causal "inspiration" from the awareness that A can treat disease X.

So with a right with a duration in perpetuity, could not the indigenous group holding that right at a date well beyond that upon which the serendipitous discovery was made say "now we understand that your discovery and ours are linked through common biology and accordingly we now seek to claim absolute control over your new downstream use"?

To stop such a claim being successful one would have to envisage that the making of a third party serendipitous discovery of a second use would in some way "cement" the claim of the indigenous group such that, even were the serendipitous discovery to subsequently become obvious, the indigenous group's claim against the serendipitous discoverer (or perhaps other third parties using that discovery) would be barred.

In truth the workings of such a bar could be complex. We would also still be left asking what degree of discovery would be required to "cement" the indigenous claim. Would the bar work in favour of the serendipitous discover alone, or also in favour of other third parties using that discovery? How would the bar work in relation to subsequent serendipitous discoveries? Would that subsequent serendipitous discoverer benefit from a new bar to the indigenous claim? What would constitute such a subsequent serendipitous discovery in the light both of the original traditional knowledge and the first serendipitous discovery and the work on biological mechanism triggered by that discovery?

However, as was discussed above, such complexities *can* be solved through the formulation of positive law, but we need to consider what philosophical justification can be made for such a bar to/cementation of the indigenous claim in the first place – essentially why is serendipity *special*?

Although it is framed in a different way, this question is essentially just the same as that addressed earlier in this work and analysed in relation to policy options d_1 to d_5 above.

Restricting the scope of the indigenous claim beyond a serendipitous discovery is arguably the same as seeking a bar to /cementation of the claim upon the making of a serendipitous discovery. Accordingly, the conflicting justifications that we have seen in relation to policy options d_1 to d_5 remain the same. We are essentially left again with the fundamental conflict we have seen between (on the one hand) a promotion of global health utility and (on the other hand) the other analysed (non-natural law) justifications.

Looking at the overall utilitarian considerations, one might perhaps suggest that the creation of a bar on the indigenous claim could create an incentive for researchers to search for serendipitous discoveries (perhaps through the testing of newly discovered ligands against a range of biological targets). However, one might consider that pharmaceutical companies are provided with more than sufficient incentive to investigate the effects of ligands through existing patent systems, without requiring enhancement of such incentive through a limitation of indigenous rights.

Paradoxically, such a bar might (in theory at least) encourage a certain ignorance as to the underlying physiology of a ligand which was subject to an indigenous right to control. The less you know about the underlying biology, the more likely a discovery will be "serendipitous". However, whether a drive to avoid an ongoing indigenous right would seriously influence such investigation (which would be crucial to the development of the first use of the ligand as a therapeutic agent) is highly questionable. Indeed the "search" for serendipitous discoveries would be likely to unavoidably throw "unwelcome" light upon underlying biological mechanisms in any event.

So, as regard non-natural law justifications we would appear to be in much the same place as we were with our initial consideration of policy options d_1 to $d_{5.}$

We might, however, ask whether giving the positive right (of whatever type) an infinite temporal duration has a complicating impact on the labour-desert justification for the right. In Chapter 5 we discussed the different treatments of "inchoate" and "inherent" claims, concluding that a labour-desert analysis was broadly supportive of an inchoate claim and with it a partial veto (even if the exact details of degree of contribution were difficult, perhaps impossible, to pin down) and perhaps less supportive of an inherent claim. However, overall it was concluded that the uncertainties of the labour-desert account were such as to provide us with little concrete guidance other than that a positive right of some sort was supported.

In looking at a right of control with infinite duration we do have one factor which is likely to be constant throughout and that is the *initial* contribution made by the indigenous group – the discovery of an effect of the genetic resource which was deserving of a right to control. It is that contribution which should be compared to the chain of new third party discoveries which are made during the (infinite) duration of the right. Each new discovery, in effect, creates a new contribution which is to be tested against the original. If we are seeking to determine whether there should be a bar to an ongoing claim, we need to ask whether there is a degree of third party contribution which is of sufficient merit to warrant that bar.

That contribution would need to be significant enough to somehow "stand above" the mass of smaller steps, such that even though the same place was reached (the understanding of a second use) the step was itself great enough to break the chain. Here, of course, the labour desert account fails us – we are looking again at questions of *degree*. Of course, determining such differential contribution (practically, and theoretically, difficult to determine in any event) would continually change with time as incremental developments were made rendering an ongoing assessment essentially impossible in any event.

However, stepping back from such difficulties one might ask oneself, if the same "total" of third party contribution is reached (the understanding of a second use) should it really matter whether it is reached by way of a series of small steps, or by one larger one?

From this point we might ask is it the nature of the second use which provides grounds for a break in causation, rather than how that second use is arrived at?

6.6 "Coincidental" second uses

Looking at the question of scope from the perspective of a right of "infinite" duration also gives us a further insight which was not quite so apparent in our previous analysis.

We envisaged above that, with sufficient time, it would inevitably become obvious that the fact that A's effect of X and on Y was mediated through joint physiological mechanism P and that accordingly in the long life of the right to control downstream use what might have initially appeared to be "serendipity" would actually be an artefact of the time at which the discovery was considered. However, the appearance of "retrospective obviousness" in that analysis is entirely reliant upon a shared underlying *physiological* mechanism.

How though might we consider the position where a serendipitously discovered second use is *unrelated* to a shared underlying physiological mechanism? Perkin's discovery of mauveine whilst attempting to synthesise quinine provides an ideal example for analysis.

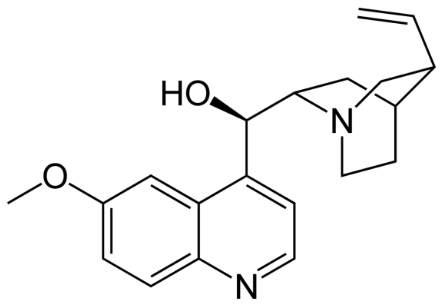


Figure 6.2 Structural formula of Quinine [723]

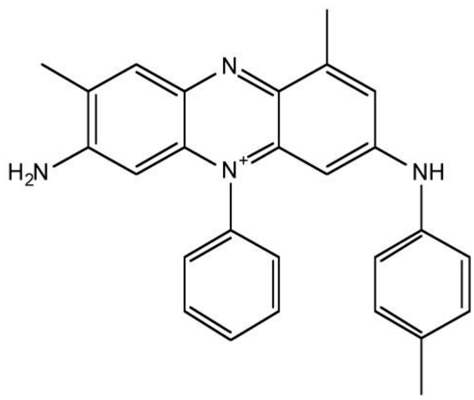


Figure 6.3 Structural formula of Mauveine B [724]

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[723] Created by Liaocyed, 2011. Licensed under CC BY-SA 3.0

Although Perkin would not have attempted the oxidisation of aniline with potassium dichromate *but for* an attempt to synthesise quinine, his discovery of mauveine was clearly an accident. It could have easily happened in a different context by someone looking for an entirely different end result. Perkin's finding was in no way reliant upon the biological properties of quinine. In addition, as can be seen in Figures 6.2 and 6.3, mauveine[725] is not a chemical derivative of quinine. [726]

As has been discussed, the discovery of mauveine was the stimulus for the growth of the synthetic dyes industry which in due course led to the development of antibiotics (such as the sulphonamide Prontosil) based on synthetic dyes. However, the biochemical mechanism by which those compounds have their antibiotic effect (as an antimetabolite which competes within the bacterial cell with *para*-aminobenzoic acid for incorporation into folic acid) [727] is entirely unrelated to the way in which it is likely that quinine has its pharmacological effect (through a plasmodium-selective inhibition of haematin biocrystallization) [728]. Further, the biological target of quinine (the eukaryotic malaria-causing plasmodium [729]) is taxonomically entirely unrelated to the prokaryotic bacterial target of antibiotics. So, although there is a true causation *in fact* link between the understanding of the indigenous peoples of the Andes that the bark of the *quina quina* tree has fever-controlling properties, the use of mauveine dye, and the use of the sulphonamides to treat bacterial infection, one cannot say that either of those downstream uses is *inevitably* derived from the use of quinine as an anti-malarial. Nor

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[724] http://cnx.org/contents/172bedba-3064-47ac-add6-882d338cb0df@3/Ammonia:-From-Uses-in-Agriculture

[725] Meth-Cohn & Smith (n 590)

[726] O'Neil (n 464), 1444

[727] W Barry Wood, Jr "Studies on the antibacterial action of the sulfonamide drugs. I. The relation of *p*-aminobenzoic acid to the mechanism of bacteriostasis." (1942) 75(4) J Exp Med 369

[728] DJ Sullivan, "Theories on malarial pigment formation and quinoline action" (2002) 32 (13) Int J Parasitol 1645

[729] SM Rich, FH Leendertz, G Xu, M Lebreton, CF Djoko, MN Aminake, EE Takang, JLD Diffo, BL Pike, BM Rosenthal, P Formenty, C Boesch, FJ Ayala, and ND Wolfe, "The origin of malignant malaria" (2009) 106 (35) Proceedings of the National Academy of Sciences 14902

indeed were such uses inherently present within the original indigenous understanding of the use of *quina quina* bark.

It was mentioned above that the question of whether the "cementation" of the indigenous claim is appropriate will come down to a determination of the issues discussed in relation to policy options d_1 to d_5 - notably the question of a preservation of global health utility versus other justifications.

However, whatever may be the outcome of that analysis, we need to ask whether the imposition of a bar (or not) should apply *only* where the first use and second use arising out of the traditional knowledge inspiration are *biologically* linked.

Realistically, it seems difficult to argue that a "mauveine-like" second use (which is neither inevitably derived from the original knowledge nor was inherently present within the original indigenous understanding) should *ever* be subject to downstream control. It is hard to see that any of the justifications for a positive protection in indigenous knowledge could justify control over this type of non-inevitable downstream uses. Crucially, looking to the utilitarian account, it seems difficult to argue that their exclusion would lead to a diminution in the perceived value of traditional knowledge associated with traditional knowledge.

However, as we have established, mauveine is an entirely different compound to quinine. What might the situation be where we have a non-biologically linked second use of quinine *itself*? Let us imagine quinine is found to have a rust inhibiting effect in diesel fuel. It seems entirely unlikely that such an effect would be related to its biological effect(s) and more likely that it is a purely accidental, unrelated effect. Again there would be a causal linkage *in fact* back to the indigenous knowledge of the properties of the *quina quina* tree. However, it is highly unlikely that the rust inhibiting effect of quinine was inherent in the original indigenous use of the bark. Could the discovery of the rust-inhibiting effect be said to be an inevitable consequence of the original understanding?

Unlike Perkin's discovery of mauveine, this is not a situation which could have as equally happened without a knowledge quinine. However, notwithstanding the duration of the positive right, it seems difficult to see a point at which the rust inhibiting effect would ever be *retrospectively obvious* in relation to an underlying mechanism, or that the effect would inevitably be reached.

Again, from a utilitarian perspective it would seem difficult to argue that the exclusion of this type of non-inevitable downstream use from coverage of a positive right would realistically lead to a diminution in the perceived value of traditional knowledge associated with traditional knowledge.

However, even if we accept that such uses should be excluded from a right of veto/compensation, we are left with a difficult question of how to determine whether a second use is coincidental or is, in fact, related to a underlying shared physiological mechanism.

We could fairly obviously determine at the time that the discovery was made that the discovery of mauveine was in no way an *inevitable* result of understanding that the *quina quina* tree had fever reducing properties. As stated, one could have come to an understanding of the structure of quinine, or of its biological effect, without ever having reacted aniline with potassium dichromate, and indeed one could have thought to react aniline with potassium dichromate without seeking to synthesise quinine. Their connection is *entirely* coincidental. This obviousness of coincidental connection is arguably true for our imagined rust inhibiting effect of quinine - it would one imagines be relatively easy to demonstrate that the effect had no biological basis (unless the effect was on organisms living within the diesel fuel!).

However, at the time the discovery of a second use is made it is not always immediately apparent that there is no ground for assuming *physiological* linkage. In the early 1990's it was discovered that quinine serves as a way of increasing the sensitivity of certain cancer cells to cytotoxic therapy. [730] It might be that this effect is mediated through a common physiological pathway as the inhibition of haematin biocrystallization seen in the effect of quinine on plasmodium, or not. It appears that ATP–dependent transporters

[730] B Chauffert, H Pelletier, C Corda, E Solary, L Bedenne, D Caillot, and F Martin, "Potential usefulness of quinine to circumvent the anthracycline resistance in clinical practice" (1990) 62(3) Br J Cancer 395

may have a role in multidrug resistance in cancer [731] and that antimalarial drugs have an effect on such transporters, [732] but the linkage is far from proven.

Quinine provides a yet further example of this type of complexity. There is some evidence for a mild effect of quinine on muscle cramps [733] which could potentially be caused by a direct effect of the compound on membrane excitability in neurons and muscle cells. [734] Again the linkage to a underlying mechanism for haematin biocrystallization (the anti-malarial mechanism) or an effect on ATP–dependent transporters is currently unclear.

As was highlighted in Chapters 1 and 4, many biologically active ligands have been honed by millions of years of evolution to be exquisitely specific for biological mechanisms. It might seem unlikely then that a biologically-active ligand would evolve specificity for two entirely separate biological systems. Indeed, the more complex the structure of the ligand and the more specific its interaction with its target receptor, the more likely it might seem for this to be true. One might then argue that, on balance, one might be safe in most situations to assume that two apparently separate *biological* uses are actually mediated through the same mechanism – even when one does not yet know what that mechanism is. However, there can be no certainty that such an assumption is correct in all situations.

How do we resolve this problem of determination? In relation to use of a ligand (or derivative of a ligand) which is the subject matter of the traditional knowledge then arguably the onus should be upon the discoverer of the second use to demonstrate that the mechanism of action was different from the biological mechanism underlying the

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[731] Michael M Gottesman, Tito Fojo & Susan E Bates "Multidrug resistance in cancer: role of ATP–dependent transporters" (2002) 2 Nature Reviews Cancer 48

[732] Sanna R Rijpma, Jeroen JMW van den Heuvel, Maarten van der Velden, Robert W Sauerwein, Frans GM Russel and Jan B Koenderink**,** "Atovaquone and quinine anti-malarials inhibit ATP binding cassette transporter activity" (2014) 13 Malaria Journal 359

[733] S El-Tawil , T Al Musa, H Valli, MPT Lunn, R Brassington , T El-Tawil, and M Weber, "Quinine for muscle cramps" (2015) Cochrane Report (http://www.cochrane.org/CD005044/NEUROMUSC_quinine-for-muscle-cramps) (Accessed September 2015)

[734] Xi Lin, Shanping Chen , Daniel Tee, "Effects of Quinine on the Excitability and Voltage-Dependent Currents of Isolated Spiral Ganglion Neurons in Culture" (1998) 79(5) Journal of Neurophysiology 2503

use originally uncovered by the indigenous rights holders. That the onus should reasonably lie with the third party discoverer is based upon the time, difficulty, skill-set and background knowledge required to demonstrate a shared biological mechanism.

This brings us to a further, perhaps more difficult, question. How should we treat the Rosy Periwinkle case? In the Rosy Periwinkle case study described in Chapter 4, the original stimulus to explore the extract of the plant was a folk understanding that an infusion of the plant would treat diabetes. However, the clinical effects of the vinca alkaloid drugs used in therapy today, vincristine and vinblastine (and their derivatives), are as anti-cancer drugs (an effect mediated through an inhibition of cell division in rapidly dividing cells), not as anti-diabetes agents. If Rosy Periwinkle extract *does* has an effect on diabetes and given our current knowledge, it is hard to imagine how there is a shared underlying mechanism which links an anti-diabetes effect with the effect vincristine and vinblastine have on cell division. Indeed, it would seem more likely that the plant would mediate its antidiabetic effect through one or more of the other 130 or so alkaloids now understood to be present in the plant. [735]

Putting to one side the difficulties and appropriateness of obtaining consent to use in this particular case, [736] if we could assume that an indigenous group could have made a valid claim to a diabetes efficacy, it would have by no means been apparent at the time when vincristine and vinblastine were discovered that the effects were unrelated. Indeed, what would Lilly have needed to demonstrate? Perhaps once the effects of vincristine and vinblastine on tubulin and mitotic spindles were recognised (in the 1970's) it may have become apparent that the effects were likely unrelated. However, one would have to entirely exclude this biochemical effect from the benefits provided in relation to diabetes. It is hard to prove a negative in any event, and exceptionally difficult in an environment such as drug discovery - absence of evidence is not evidence of absence.

[735] R van der Heijden, DI Jacobs, W Snoeijer, D Hallard, and R Verpoorte, "The Catharanthus alkaloids: pharmacognosy and biotechnology" (2004) 11(5) Current Medicinal Chemistry 607

[736] Dutfield "Protecting the Rights of Indigenous Peoples" (n 15), 64

6.7 Conclusions

This chapter has covered a significant amount of, often difficult, ground. Details of the conclusions reached in this chapter are set out in Chapter 7 (at 7.3, 7.4 and 7.5) and to avoid repetition they will not be reiterated here. However, there are some points which are worth highlighting. As is discussed at the beginning of this chapter, achieving a synthesis of competing justifications is inherently difficult. However, the performance of the exercise does help shape a structured appreciation all the aspects which need to be brought to mind when looking to shape policy decisions. Notably, here the exercise brings us to a focus upon competing utilities as a key area for further theoretical and practical consideration. This synthetic approach has also, in the current case, taken us to consider a deeper analysis of the workability of the "least conflicting" policy decision which in itself brings us back to a deeper analysis of the meaning of second uses and of serendipity.

Perhaps the most surprising outcome of that further analysis is the complicating impact of the nature of a right to control knowledge which is of unlimited temporal duration. As has been discussed above, one can make out arguments for why a right to control traditional knowledge has to be of unlimited duration. However, it may yet be that it is that unlimited temporal scope (within a right to control information) which is one of the more theoretically radical, and difficult, elements of the new rights.

The next chapter seeks to bring together the conclusions of each section of this work and determine what overall conclusions can (and cannot) be arrived at.

Chapter 7

Conclusions

"Property is not the natural and obvious and
inevitable concept that most people think it is."

Robert A. Heinlein *Stranger in a Strange Land* (1961)

7.1 Introduction – aims of the work

Highlighting the origins of the concept of prior informed consent within the field of medical ethics, Dutfield has suggested that the "stretching" of that concept from medical ethics into the area of misappropriation of genetic resources and traditional knowledge of has been done "*without sufficiently thinking through the practicalities, without much theoretical refection and without necessary consideration of political economy*"[737] He goes on to cite Burns' warning on the probability of unintended outcomes:

> "The best-laid schemes o' mice an' men, Gang aft agley," [738]

It has been the aim of the current work to investigate one such underexplored (and crucial) practicality (the justifiable downstream scope of a *sui generis* positive right to control downstream use of traditional knowledge associated with genetic resource

[737] Dutfield "Protecting the Rights of Indigenous Peoples" (n 15), 66

[738] Robert Burns from "To a Moose, On turning her up in her nest with the Plough November, 1785" in *The Poems of Robert Burns, Introduction by James MacKenna* (Collins London and Glasgow 1945), 116. To which me may well reply with the next stanza: "An' lea'e us nought but grief an' pain, For promis'd joy!"

within the context of drug discovery) and to redress the paucity of theoretical refection in relation to that area.

We saw in Chapter 2 of this work that what seems to be missing from the "positive" rights in relation to "traditional knowledge associated with genetic resources" under the Protocol is any principle or guidance for determining a balance which combines fair protection for the traditional knowledge/genetic resources rights holders with a reasonable degree of legal certainty for third parties. Where such knowledge serves as a research "lead" for further development, the Protocol gives no clear guidance as to how far that knowledge can have a "reach through effect" into new scientific discoveries or at what stage would a downstream researcher be considered "free" of the traditional knowledge right.

Chapter 2 also concludes that although traditional knowledge *associated with* a genetic resource is a species of information, it is of an unrelated type to the informational component of a genetic resource. Traditional knowledge *associated with* a genetic resource (though it may serve as a gateway to their study) is not related to, and stands separate from, DNA or epigenetics (or indeed biochemicals produced through the expression of the genome of a resource). Accordingly, arguments which are applied to extend the definition of a genetic resource cannot properly be used to extend the definition of traditional knowledge associated with a genetic resource. Equally, however, the definition of a genetic resource does not delimit the meaning or scope of traditional knowledge associated with a genetic resource and, in principle, the downstream scope of a right to control such traditional knowledge cannot be curtailed by considerations which would apply in relation to genetic "information". In this respect the traditional knowledge associated with a genetic resource is a broader, and less proscribed, concept than the genetic information held *within* the resource.

Although the uncertainty of the Protocol acted as a stimulus for the current work, the question of what is a *justifiable* scope for such a right is broader than can be answered by an examination of the Protocol itself (or indeed of any other extant or proposed positive right). As was discussed in Chapter 3, the inherent non-rivalrous and non-excludable nature of knowledge is such that its use can only be controlled through the imposition of positive law. However, for the limits of the scope of that positive law to be justifiable they must be supported by the philosophical reasons for the existence of that right.

In Chapter 4, this work went on to empirically examine the processes by which new drugs (or new uses for old drugs) are discovered. A key finding of that empirical study is the many ways by which an original piece of traditional knowledge can be admixed to a greater body of existing information regarding a clinical problem, and that there may be further admixture to the original information of discoveries derived from it and subsequent admixture to other, "parallel", information which is not derived from it. The study also found that these processes may themselves go through several feedback iterations and that, overall, the original information within the traditional knowledge may become significantly "diluted" by other information before a useful drug is arrived at. It was also noted that any such downstream discovery based on the inspiration of a piece of traditional knowledge will *always* be causally linked *in fact* to the original inspiration. However, (as was further discussed in Chapter 6 of this work), although one can correctly envisage the drug discovery process as chains of causation with flows of information, one can also envisage it as a field of inputs of competing contributions which are concomitant with those flows of information. Here with increasing admixture of information, the information arising from the contributions of the indigenous originators is progressively diluted within a morass of competing contributions sitting on the back of an entanglement of information.

The examination of the topography of drug development in this work also revealed that many drug discovery efforts could be described as sequential and accumulative. Here (although there is a substantial increase in the volume of additional knowledge) the underlying nature of the contribution made by the traditional knowledge to the downstream product arguably remains unchanged.

Taking inspiration from long interface between patent law and the drug discovery process for inspiration, this work identified the unexpected ("serendipitous") discovery of a new use for a particular genetic resource (or the compounds found in a particular genetic resource or their chemical derivatives) as a putative "crux point" at which a third party downstream contribution affects a "step change" in the *nature* of the downstream product, when compared to the original contribution.

Some case studies highlighting the types of serendipitous discoveries which have been made in drug discovery processes (inspired by or derived from genetic resources) were described. These were:

a) The discovery by Paul Gibson and Lawrence Craven of the blood thinning (and with it cardio- and cerebro-protective) effects of aspirin;

b) The discovery by Carl Koller of the local anaesthetic effects of cocaine;

c) The discovery by William Perkin of the aniline dye, mauveine, whilst attempting to synthesise quinine (its stimulus of the aniline dye business and its in turn leading to the discovery of sulphonamide antibiotics); and

d) The discovery by Ralph Noble (and others) of the anti-tumour effects of vinca alkaloids extracted from the Rosy periwinkle.

Taking a serendipitous discovery to mean one where the second use is non-obvious *at the time* the discovery is made, in Chapter 5 of this a number of potential policy decisions in respect of the scope of a veto surrounding such discoveries were tested against the philosophical justifications for the existence of a positive right in traditional knowledge associated with genetic resources.

7.2 Application of philosophical justifications

In applying the philosophical justifications, significant difficulties were encountered in relation to the application of natural rights justifications. It was argued that rights based in personality do not support a positive right to control knowledge *per se*.

Although application of a Lockean labour-desert right to supported *some* form of positive right (as opposed to no right at all), inherent problems with determination of origination and individuation arising out of the uncertainty of the meaning of "contribution" meant that, in the end, little concrete guidance could be determined in terms of justifiable downstream scope.

Within the consequentialist account, three key utilitarian goals were identified:

a) the preservation of traditional knowledge and culture within its indigenous setting;

b) the preservation of the environment within which the genetic resources associated with the relevant knowledge are found; and

c) an inherent utility in directly controlling the knowledge (termed "utility through control").

It was posited that these first two goals (or a conflation of both) might be achieved through creating a perceived value in the minds of relevant actors (although it was acknowledged that there causal certainties in this regard). It was argued that the greatest likelihood of perceived value was through granting a veto right which extended to *all* downstream use. It was also argued that the "utility through control" goal would be achieved without the need for creating value and again the likelihood of achieving that utility was enhanced by providing a veto which covered *all* downstream use.

However, it was noted that, within the broader utilitarian account, the granting of veto rights over traditional knowledge associated with genetic resources could conflict with the potential enhancement of "global health" which would be provided by allowing pharmaceutical companies freedom to use their resources and expertise to develop drugs without hindrance.

Looking at the application of a right from the perspective of distributive justice, it was found that provided one looks at the *proportionate* advantage to each side of each of the proposed decisions (essentially applying the difference principle) the granting of an absolute veto on *all* downstream use is the situation the person in the original position would choose as maximising the minimum – that is avoiding the worst outcome.

It was noted that the communitarian account for positive rights over traditional knowledge suggests that indigenous peoples should have a significant degree of control over information which is their community resource. However, it was found that there is little explicit guidance from this doctrine as to whether very distal uses, including uses arising out of serendipitous discoveries, should be considered as use of the traditional knowledge.

In respect of the restorative/corrective justice account recently proposed by Munzer,[739] it was found that the uncertainties (and inherent case-by-case specificity) make the translation this reparation justification to a set of generally applicable principles for broader application exceptionally difficult.

In relation to the application of UNDRIP, it was found that compensation for misappropriation is likely to be the *minimum* redress envisaged under that Declaration. Accordingly, any positive right which delivers this or more will be compliant with UNDRIP. However, UNDRIP gives no guidance in terms of determining the downstream scope of such a right.

7.3 Synthesis

Chapter 6 examined the potential options for using "mid-level" techniques to achieve synthesis of our potentially conflicting philosophical justifications. It was concluded that Sunstein's "theoretically modest" approaches were inappropriate when all we could realistically use to determine a justifiable scope was *theory*. Although Merges' application of Rawls' overlapping consensus approach was examined, since this approach is untried a somewhat more conservative "least contradiction" (teamed with a ready appreciation of the applicability and relevance of a particular theory) analysis was undertaken.

It was found that the policy option tested which demonstrated the least contradiction across all justifications was a veto on downstream use which did not extend beyond the making of a serendipitous discovery but which involved a mechanism under which the indigenous holders were compensated for third party use of the serendipitous discovery on the basis of comparative contribution (termed in this work option d_4)

Although option d_4 does represent a least contradiction approach, when one re-examines the non-natural law justifications employed in this work it was found that all those justifications favoured (or are least consistent with) a total veto on downstream use - *save alone* for what was identified as the "global health" utility. This particular conflict will be addressed further below.

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[739] Munzer (n 225)

7.4 What is serendipity?

In Chapter 6 having identified the "limited veto plus compensation" policy option as that being least conflicting across the justifications employed, the workability of that option was analysed. The key question arrived upon was how should we determine what a "serendipitous discovery" actually is.

In examining this point it was identified that the way in which traditional knowledge associated with genetic resources is created, and held, is such that it is difficult to see how a right to control its use can have a *fixed* duration. It was also identified that this lack of fixed duration may pose a distinct (and unique) challenge in relation to the assessment of in-imitativeness of follow-on developments. The situation was considered in which we have a subsisting right to control downstream use of an idea which has an *infinite* temporal duration. We are here immediately forced to ask at what point in time should we determine that any new downstream development of that idea is "non-obvious" in the light of that right.

Chapter 6 went on to establish that given this *infinite* temporal duration, if an indigenous claim to a positive right *was* to be limited to a serendipitous discovery then a bar to an ongoing claim would have to be put into place on the making of a serendipitous discovery. However, it was argued that the philosophical grounds for establishing a bar were, in fact, the same as those analysed in respect of scope.

However, we are left here a logical *lacuna* (or perhaps more correctly a "whirlpool"). These grounds cannot realistically tell us *how* to define a serendipitous discovery. Each new third party discovery creates a new contribution which is to be tested against the original contribution of the indigenous people claiming the right. If we are seeking to determine whether there should be a bar to an ongoing claim we need to ask whether there is a degree of third party contribution which is of sufficient merit to warrant that bar. That contribution would need to be significant enough to stand above the mass of smaller steps such that even though the same final epistemological "place" was reached (the understanding of a second use) the step was itself great enough to break the chain. It was argued that here the labour desert account (again) fails us – we are looking at questions of degree.

However perhaps the hardest observation to reconcile in determining a meaning of serendipitous second use is this. If the same "total" amount of third party contribution is reached (the understanding of a second use) should it (where one has a right of control of unlimited duration) really matter whether it is reached by way of a series of small steps or by one larger one?

In addition, determining differential contribution (theoretically difficult to determine in any event) would continually change with time as incremental developments were made rendering an ongoing assessment essentially impossible in any event.

Perhaps the most surprising outcome of the analysis of the meaning of serendipity is the complicating impact of the nature of a right to control knowledge which is of unlimited temporal duration. As has been discussed above, it may yet be that it is that unlimited temporal scope within a right to control information which is one of the more radical elements of the new rights. Clearly this is an area that may reward further theoretical investigation.

7.5 Coincidental discoveries

If we assume that determining what is meant by a "serendipitous" discovery is essentially impossible, we need to ask whether the *nature* of the second use gives us grounds for a break in causation, rather than how that second use is arrived at?

Chapter 6 went on to examine this question. Of course the key to this question is determining what a second use *is* in this context.

It was argued that coincidental discoveries (such as the discovery of mauveine by William Perkin whilst seeking to synthesise quinine where the finding could have as easily happened without a connection to quinine and could not have been inevitably arrived at) should not be considered second uses covered by a right to control downstream use. It was also argued that uses which were unrelated to any "claimed" biological effect of the genetic resource (such as an unrelated physical effect) should be excluded as these would not be inevitably arrived at when examining the biological effect. Of course, if the original knowledge related to a *physical* property the analysis would be different.

However, it was argued that the question of whether different biological effects should be considered to be different uses is difficult. It was pointed out that what appear initially to be second uses can turn out to be linked through a common physiological mechanism. It might be argued that such second uses are essentially the same as the first as (in the fullness of time) they would inevitably be arrived at. However, at the time such a second use was uncovered this would not be apparent and indeed one would require a significant amount of scientific research to disprove the linkages.

Chapter 6 then went on to examine how one might deal with the rosy periwinkle – vinca alkaloid case. Here it was suggested that the originally disclosed anti-diabetic effect (if present) was probably mediated through a different alkaloid present in the plant rather than vincristine and vinblastine which mediated the plant's anti- tumour effects. It was also pointed out that such an assumption could only be made in the light significant study into the alkaloids of the plant and their biological effects.

7.6 Overall Conclusions

The *leitmotif* of this work is the complexity of the drug discovery process. A significant part of this work has been an attempt bringing that complexity within the bounds of analysis. Indeed, the key contribution of this work has been to investigate the interface between the complexity of the drug discovery process and a right to control traditional knowledge associated with genetic resources, and to identify and analyse a number of further theoretical, and practical, complexities which arise from the creation of workable and philosophically-justifiable policy options at that interface.

Envisaging the drug discovery process as one of epistemic dilution with a concomitant conflict of contribution does appear to provide us with a lens to see (at least on a larger scale) potential points where we might further analyse the justifiable downstream scope of a positive right in traditional knowledge associated with genetic resources. However, when we come to analyse the question on a smaller scale we find that the inherent uncertainties (in both origination and individuation) of the contribution-based natural rights model for the existence of rights to control intangible intellectual products leaves us with significant inherent uncertainties.

The synthesis exercise performed in Chapter 6 arrives at a preferred putative policy optioned where the right of veto extends as far as the making of a serendipitous discovery of a second use for a product of a genetic resource. In respect of the second use under this policy option the right holder has no veto but has a right to be compensated according to their "contribution". However, as was discussed in the latter parts of Chapter 6, this solution (option d_4) leads us to face a number of significant practical and/or theoretical difficulties.

These will include:

a) determining a definition of "serendipitous discovery";

b) determining a definition of a "second use";

c) determining how one would go about compensating a party on the basis of their "contribution";

d) determining what "contribution" means;

e) assuring a contributing party that the determinant mechanism for compensating contribution was fair, transparent, and followed due process;

f) assuring a contributing party that the determinant mechanism for compensating contribution would provide as reliable compensation as a negotiated royalty for granting permission to use;

g) ensuring that a compensatory mechanism in some way mitigated the negative effects on potential licensees denied an opportunity for an exclusivity advantage over competitors;

h) determining whether a second use is (or is not) actually linked to the first use through a shared physiological mechanism; and

i) determining whether a second use is mediated (or is not mediated) through a second ligand present in the genetic resource.

Some of these problems can, of course, be addressed through the imposition of positive law. However, some solutions are likely to be arbitrary as the application of natural rights contribution-based approaches are (as has been seen) very difficult.

Even if such solutions can be arrived at to the operation of the d_4 option, the evidential and administrative burden in determining questions of contribution and such points as whether a second use is (or is not) actually linked to the first use through a shared physiological mechanism or determining whether a second use is mediated (or is not mediated) through a second ligand present in the genetic resource is likely to be extremely onerous.

The analysis throughout this work suggests that simplicity both in the operation of a positive right (and in the message which is received by relevant actors) enhances perceived value which has greater likely efficacy (though no certainty) in achieving the utilitarian goals of the right of preservation of the traditional knowledge and the environment in which the genetic resource is found. Complexity in operation (notably in the examination of whether or not the "new" biological effects seen on a serendipitous discovery are physiologically related to the original indigenous "claim" or otherwise) is likely to work counter to the consequentialist justification for this option.

From a Rawlsian "difference principle" perspective, it is highly likely that a pharmaceutical company will possess greater legal and scientific expertise to argue its position relative to an indigenous group. Complexity of operation of the right (again particularly is the assessment of evidential questions) will likely advantage the pharmaceutical researchers relative to the indigenous actors.

7.6.1 A simpler solution?

In the light of the problems seen with the partial veto option and the "failure" of a contribution-desert model when looking at smaller-scale problems, we might ask again, is there justification for a broad, simpler, right to control *any* downstream use which uses a non-coincidental (effectively biologically-mediated) use?

Given the inherent problems we have seen with the natural rights accounts, the question of whether such a broad scope is justifiable falls back on the utilitarian account and (arguably) its compliance at least with other non-natural rights accounts.

From a utilitarian perspective we noted in Chapter 6 that (but for the question of a global health utility, to which we will return) there existed a justification for a total veto over downstream use. It is worth noting that coverage of *all* biological effects arising out of genetic resource gives us a simplicity in operation which works in support of the valorisation model. It seems unlikely in this regard that the exclusion of "co-incidental effects" – essentially those which were unrelated to the biological effects of the genetic resource - would have an impact upon perceived value. In any event, such co-incidental effects are likely to be rare.

Outside of the valorisation model, a veto right to control all downstream biological uses of a genetic resource (based upon traditional knowledge associated with that genetic resource) also directly meets the goal of "utility through control".

In relation to the other non-consequentialist accounts (communitarian, "Munzerian" reparations or UNDRIP) there seems is no reason why such a broader right would be excluded. Using the Rawlsian maximin analysis used above, the broader a right given to the indigenous group the better the right complies with the difference principle. As mentioned above simplicity of operation and reduced evidential burdens also supports the difference principle.

If one does want to look to a contribution-reward justification for such a right, the argument here may be that the indigenous people's contribution which warrants a positive right is simply the opening the "gateway" into the biology of the genetic resource. However, as we have seen the application of such a model outside of broad sweeping statements (whilst acting as a useful reminder to consider conflicting parties) is difficult to apply.

7.6.2 Indigenous culture, the environment, and spiritual happiness vs. global healthcare – a squeeze?

The performance of the synthetic analysis in Chapter 6 brings us to a focus upon competing utilities as a key area for further theoretical and practical consideration.

Overall we appear to be "squeezed" on that analysis between the great complexities of operating a veto option which does not cover serendipitously discovered second uses (but which, in part, ameliorates the global healthcare utility concerns identified) and a total veto which avoids complexity and looks to meet the utilitarian justification of preservation of traditional knowledge, genetic resources, and the environment in which they are found, but which runs counter to allowing pharmaceutical companies to freely develop pharmaceuticals for the benefit of global health without the risk of imposition of a veto on their activity.

In considering this squeeze, we firstly need to note (as was discussed in Chapter 6) that not all rights to a total vetoes would be exercised *absolutely*. It is possible that many total vetoes would be used to ensure the receipt of royalties for permission to use, so (subject to royalty rates) not significantly limiting the activities of pharmaceutical companies. However, we simply do not know to what extent this would happen. What we certainly can say is that if a total right to veto *all* downstream biological use does exist, we will also have to accept the possibility that an indigenous group will choose to veto a potentially important therapeutic product.

Given we have here conflicting consequentialist goals, we may arguably arrive at a better understanding of the justificatory balance between our competing policy options if we had a better sense of the degree to which the conflicting policy options might actually achieve their aims, or interfere with the achievement of the aims of the conflicting policy. The empirical assessment of these competing risks and probabilities is outwith the scope of the current work but further work in that respect may aid our determination of whether such a broad veto over downstream use would be justifiable. Crucial here might be an empirical understanding of the likelihood that indigenous groups would seek to apply an absolute veto rather than follow a licensing route, which may, in turn, reflect the degree to which they value an absolute restriction over the use of their knowledge over its commercialisation.

One further approach to investigating this dilemma might be to examine to particular exceptions in relation to public access to medicines and major global health crises [740] and such examination would again form the basis for further research.

However, when looking any such question we always need to recall that the argument essentially boils down to this: Is indigenous traditional knowledge sufficiently at risk of extinction that it is worth the risk of potential restriction over drug discovery and development activity?

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[740] For discussion of mechanisms to provide public access to medicines (notably the interface between public health policy and TRIPs obligations) see Duncan Matthews, *Intellectual Property, Human Rights & Development: The Role of NGOs and Social Movements* (Edward Elgar, Cheltenham 2011), 15

Perhaps we should conclude this work with this observation: Millions of years of evolution have honed compounds within all forms of life on Earth which have astoundingly exquisite selectivity and potency in biological systems. They are remarkably useful tools. As highlighted by Atkins,[741] the extinction of species potentially extinguishes our sources of new molecular tools. Similarly, the extinction of indigenous knowledge potentially extinguishes our ability to locate such new molecular tools. If such tools disappear they are unlikely ever to be regained.

[741] Atkins (n 398), 13

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