EXPLORING THE PARAMETERS OF THE GENE PATENT DEBATE

ANTON HUGHES

INTRODUCTION

The South Pacific is host to a diverse range of people, fauna and flora. Deep within their genetic codes lie secrets which may bring about breakthroughs in a wide range of applications including medicine and agriculture. Many parts of the biotechnology industry have turned to bioprospecting as a routine part of their research and development efforts. Despite the theoretical protections of the Convention on Biological Diversity,[1] recent history has given many a reason to question whether this is better termed biopiracy.[2] On the other hand, a successful collaboration between bioprospectors and local communities may aid conservation and bring enhanced prosperity to the region.[3]

Miranda Forsyth recently discussed the limitations of western style intellectual property systems to adequately protect traditional forms of knowledge.[4] However, with Fiji and the Solomon Islands being members of the World Trade Organisation (WTO), and Vanuatu, Samoa and Tonga likely to soon follow,[5] western-style intellectual property systems will continue to impact upon the South Pacific region for some time to come. This is because WTO members are required to implement minimum levels of intellectual property protection under the TRIPS agreement,[6] or face the threat of trade sanctions.[7]

This article hopes to shed further light on the debate by examining some of the key issues relating to gene patents. It is argued that gene patents bring into sharp focus some of the overriding problems with the patent system, especially the failure to provide a suitable level of protection for incremental innovations.

GENERAL ISSUES

Patent law is the oldest and strongest form of intellectual property, and the primary way by which the biotechnology companies recoup a return on their investment. Under Article 27.1 of TRIPS, ‘patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application’.[8]

Before looking in more detail at the elements of patentability of genetic materials, it is worth considering the seemingly obvious question of why gene patents are so controversial. Although it may seem that new technologies bring with them new problems, it is submitted that patents involving genetic materials and technologies are simply an area where broader problems with the patent system are particularly visible.[9] Some of reasons for this are:

1. Gene patents are the most upstream category of biotechnology patents.[10] (Downstream patents cover final products, such as actual drugs. Upstream patents cover the various components used to make these final products.) As such, the anti-commons effect[11] will be

strongly felt if too much protection is given (for example the debate about whether expressed sequence tags are too far upstream to warrant intellectual property protection). This problem is exacerbated by the inherent difficulty in "inventing around" gene patents – something Boyle argues has traditionally provided a safety valve in the patent system through which many of the unwanted side effects of patent monopolies have been avoided.[12]

2. The biotechnology industry depends on significant investment in research and development at significant risk of failure. Without enough protection for innovators, it is argued, the great benefits of biotechnology will not be realised.[13]

3. The human genome is often characterised as inherently shared, and hence at odds with the exclusive rights afforded to intellectual property holders. This is most commonly stated as "you can't own a gene".[14]

4. Advances in genetic research impact on a broad range of industries notably medical research, agriculture and waste processing.[15] This list is likely to grow as new applications are discovered.

5. The appropriate limits of ownership in genetic research is been the subject of a great deal of social, ethical, religious, environmental, scientific and legal debate.[16] If the system fails, there are a lot of eyes watching.

The limitations of the system in relation to gene patents apply across all the technologies for which patents are available. Although gene patents represent in many ways a unique problem domain, an approach which focuses purely on this one area of technological development runs the risk of creating a solution which fails to hold up when the next controversial wave of technology comes along.[17]

A number of criticisms of the patent system turn on a more detailed examination of specific elements of Article 27.1 of TRIPS: novelty, inventive step and utility. These elements are considered individually below.

NOVELTY

In the context of gene patents, the novelty requirement centres around whether genes, which already exist in nature, can truly be said to be new. However, since the reasoning in the US Supreme Court case of *Diamond v Chakrabarty*[18] made a distinction between living organisms as they exist in nature, and things isolated from their surroundings as a result of human intervention. This isolation makes the information in the gene available in a way in which it is not in nature, and is thus a novel product.[19]

This distinction also has implications for attempts the attempts to make the South Pacific a 'life form patent-free zone'.[20] Although Article 27.3(b) of TRIPS allows governments to exclude plants, animals and 'essentially' biological processes from the requirement of Article 27.1 that patents be available in 'all fields of technology', isolated organisms are unlikely to fall within the exception. Thus any movement towards a life form patent-free zone would bring WTO member countries into conflict with their TRIPS obligations and liable to face trade sanctions. The likelihood of a patent-free zone also seems less likely in light of the recent agreement between the Government of Samoa and the University of California, Berkeley asserting Samoa's sovereignty over a gene sequence from the mamala tree that looks promising as an anti-AIDS drug.[21]

INVENTIVE STEP

The requirement of Article 27.1 that inventions must involve an inventive step means that compared to what is already known,[22] the invention would not be obvious to a skilled person working in the area. This element has received little judicial consideration in Australia in the context of genetic materials and

technologies, although the Australian Patent Office procedures provide some guidance as to the current approach. Lawson's analysis of the reasoning taken by the Patent Commissioner's delegates in*Synaptic Pharmaceutical Corporation v Astra Aktiebolag*[23] and *Takeda Chemical Industries v Hoffman-La Roche Aktiengesellschaft*[24] clearly shows that inventive step is likely to be satisfied by the identification and isolation of genetic material in most circumstances.

In his analysis of these opposition proceedings, Lawson illustrates how the objective test of inventive step becomes 'an individual assessment of the facts in the particular matter'.[25] In practice this makes it very difficult to oppose the grant of a patent because the opposing party must prove that the selection of particular choices, preferences, techniques, probes and other details actually made was obvious.[26]

The Patent Office seems reluctant to deny legal protection where a significant investment of time and effort has been made. Given the magnitude of the investment, such an approach is to be expected. To see this pressure, we need look no further than the old 'benefit of the doubt' test enunciated in *Commissioner of Patents v Microcell.*[27]

This lowering of the bar falls within a general conception that the age of the Internet and globalisation requires suitably strengthened intellectual property regime to protect the rights of IP creators against infringement on a global scale. The argument is that the easier it gets, the more IP protection should be available. As Boyle puts it, "[i]f a little bit of protection is good, then a lot is better".[28]

Regardless of the sympathies of the courts and the Patent Office, the fact is that lowering the bar of inventiveness in order to protect routine applications of technical know-how is having a dramatic effect. The traditional balancing act between the rights of the inventor and the public interest has been skewed in favour of the inventor.

The broad scope of gene patents once awarded, combined with their use as a defensive mechanism, presents a real risk to the flow of information so vital to follow-on innovators.[29] Valuable knowledge is removed from the public domain, and downstream research becomes an unenviable lottery[30]. Many suggestions have been made as to how to protect the patent system from itself. Whilst compulsory licensing[31] and greater competition law powers[32] and a newly defined utility requirement[33] may go some way to lessening the impact of these problems for awarded patents, they deal with the effects rather than the cause of the problem.

A stricter application of the inventive step requirement will play an important role in ensuring vital access to information. Additionally, a higher threshold may result in fewer patent applications, something that could give patent examiners more time to consider each application. In this way, the costs associated with the award of erroneous patents may be reduced.[34]

However, this increased stringency only goes a part of the way to dealing with the problem. Conspicuous by its absence in the literature is the actual method by which the threshold can be raised. The only concrete proposition this author has seen is Barton's suggestion that the inventive step should only be satisfied 'when the approach taken seemed quite unlikely to work and still proved successful.'[35] This highlights the inherent difficulty in coming up with an acceptable definition which will work with the case-by-case approach taken by the Patent Office.

To illustrate this point, consider the attempt was recently made by the Australian government to raise the required standard of inventiveness by expanding the prior art base definition, and replacing a presumption of validities with a 'balance of probabilities' test.[36] In Lawson's analysis of *Tekada Chemical Institute*, which was decided before the passage of the new legislation, he states that the amendments were unlikely

to change the outcome.[37]

One approach would be to raise the inventiveness threshold. However it is submitted the effect would be short lived unless there is a very effective system of rewarding incremental innovation. At the present time in Australia, this is the province of innovation patents. A lesser availability of standard patents would mean an abundance of innovation patents. Unfortunately, however, innovation patents do little to avoid the difficulties outlined with their "big brother" the standard patent. The term of the patent is much shorter, but upstream patent holders are still given an unfettered right to exclude, and follow-on innovators will still be faced with negotiating access to the tools they require. The result may well be a more aggressive enforcement of patent rights in order to recoup costs within this shorter time frame.

Reichman's historical analysis of systems applying proprietary protection measures to incremental innovations[38] illustrates how hybrid systems[39] cycle through periods of under then overprotection, without ever getting the balance right.[40] Further, he finds no evidence of any real advantage in countries with these regimes over those countries with much weaker systems of protection.[41] The patent system when applied to truly non-obvious inventions is effective in redirecting the flow of investment to solving new problems,[42] but the strong protection patents afford will always be a problem when applied to incremental innovations.

The reason these hybrid systems have been introduced is because trade secret law no longer adequately protects the contributions of minor innovators. At the time of the Industrial Revolution, innovators naturally had a competitive advantage because of the lead-time involved in reverse engineering. Competitors had to choose between reverse engineering a product, thus giving the original innovator a first mover advantage, or negotiating with the innovator. Those who misappropriated the first innovator's know-how were liable for compensation under trade secret law.

As the pace of technology increased, this lead-time all but disappeared and with it the first-mover competitive advantage. It is submitted that raising the inventive step threshold can only work when the gap left by trade secret law is protected by a modern equivalent. This 'compensatory liability scheme' would work as follows.[43] Incremental innovators who register their innovations are given an artificial lead time. During this period, other researchers who use these innovations in their own products will not be liable to compensate the original innovator, provided they pay a fee.[44] There is no need to seek permission from upstream innovators. At the end of this period of protection the knowledge therein passes into the public domain. Other important features of the proposed system are as follows:

- a requirement of novelty similar to the trade secrets equivalent
- a national register of claims by which these innovations are made known
- an infringement test based on substantial identity
- parties should be able to vary their obligations by negotiation

The obvious benefit of such a system is that upstream innovators are not given disproportionate power to control the use of their discoveries. In return, subsequent innovators must contribute to the research and development costs of the first innovator.

In economic terms, Reichman's investigations conclude that first time innovators will be no worse off under this compensatory liability scheme. He argues for a percentage return on gross profit arising from the returned profit. Also talks about a lottery effect, which can only really happen with this system. The system gives upstream researchers an ability to share in the benefits of downstream innovations in a manner somewhat like reach-through licensing agreements.[45] The difference is that the market dictates the value of their contribution.[46]

Another benefit is the enrichment of the commons. Incremental innovations are added to the pool of common general knowledge, and single innovators are unable to remove their contributions from the commons through the proprietary right to exclude. Given the importance of the prior art base in assessing inventiveness, this system will contribute to the prior art to make sure that only truly non-obvious inventions are awarded patents.

Finally, the ease of access to informational inputs results in more complementary, and less duplicated research.[47]

A liability rule approach strikes an appropriate balance between the need to encourage investment in research and development, whilst reflecting the importance of shared information in the technical community. It is also compatible with the distributed collaboration and incremental innovation which pervades the biotechnology industry. With such a system in place, the patent system can be reserved for the protection of truly non-obvious inventions, something it does well.

Best of all, the whole system can be established without falling foul of TRIPS requirements, and without changing the rights of existing patent holders. Perhaps the greatest hurdle faced in creating this commons is that with proprietary thinking so entrenched, it may be difficult to get through parliaments. It is also likely that those who are benefiting from broad patents at the present time may resist such reforms, claiming it will affect their ability to attract investment.[48]

UTILITY

Without a utility requirement, the problem is that patents will be awarded for 'inventions' based on pure speculation. With no need to demonstrate utility, there is nothing to encourage innovators to complete a commercial realisation of their research. Without it, innovators are likely to simply patent their inventions at the earliest possible opportunity, then wait for someone else to realise their developments, whilst collecting a licensing fee.[49] This requirement was introduced relatively recently in the US, and was a key recommendation of the recent Australian Law Reform Commission Report into gene patents.[50]

The requirement of utility provides important way to distinguish between inventions consistent with commercialisation of technology and incremental innovations which, if useful, are really only useful for further research, and should be protected through compensatory liability rules described in relation to inventive step above. Requiring 'specific, substantial and credible utility' is a step in the right direction, as patent protection is only effective when used as a reward for commercialisation.[51] However, the Nuffield Council in the UK have voiced concerns that a 'credibility' test may be not be going far enough, as it may be satisfied by a mere 'theoretical possibility,' which still sets the bar too low.[52] Given that the implementation of this requirement will require new legislation,[53] the possibility of adopting the stronger European standard, 'capability of industrial application'[54] would be a preferable criterion.

If a utility requirement is to be used to limit broad claims and improve access to research tools, then this utility needs to act as a descriptive requirement as well. The Nuffield Council have pointed out that once utility is proven and a gene patent is awarded in the US, a subsequent non-obvious and novel use for the genetic material is found, the patent covers this subsequent use.[55] This is also likely to be the case in Australia.[56] It is submitted that the claimed utility could be used to effectively limit the ambit of claims.

Finally, one commentator has pointed out that adding a utility requirement puts an additional burden on patent examiners. A proper assessment of utility will require the examiners to be 'fully conversant with the field and the technology at stake'.[57] Whilst this is a good idea anyway, it is to some extent dependant on reducing the number of patent applications by increasing the threshold of other criteria.[58]

CONCLUSION

This article has explored some key themes of the gene patent debate. Rather than being a specific problem domain, gene patents simply bring into sharp focus the inability of the patent system to afford the proper level of protection to incremental innovations. By extending the strong protections of the patent system to sub-patentable innovations, some researchers are receiving gains disproportionate to their efforts, and the tragedy of the anti-commons looms.

Whilst the compensatory liability scheme described herein requires legislative support before it can become a feature of western intellectual property systems, it is of immediate interest to South Pacific countries considering *sui generis* biodiversity protection schemes, and communities negotiating bioprospecting collaboration agreements. Its fundamental compatibility with a culture of access makes it a unique way to protect common ownership of natural resources against the award of disproportionately broad patent rights.

---

[1] http://www.biodiv.org/convention/articles.asp at 12 Dec 2004.

[2] For a typical example, see Keith Perry, 'Getting a Fair Price for Indigenous Remedies' *The Guardian*, 21st December 2000, http://www.guardian.co.uk/appeal2000/story/0,7369,414139,00.html at 12 Dec 2004.

[3] Successful collaborations are possible, as a recent example of a three way collaboration between Panama, the University of Utah and the Smithsonian Tropical Research Institute shows. See 'A Realistic Way to Save Rainforests, Exploit Plant Defenses, Build Local Drug Discovery Industry,' University of Utah News Release, September 2003, http://www.utah.edu/unews/releases/03/sep/medplant.html at 12 Dec 2004.

[4] Miranda Forsyth, 'Intellectual Property Laws in the South Pacific: Friend or Foe?' (2003) 7(1) *Journal of South Pacific Law*. <http://law.vanuatu.usp.ac.fj/jspl/2003%20Volume7Number1/forsyth> Accessed 16 September 2004.

[5] Vanuatu, Samoa and Tonga are currently observer governments of the World Trade Organisation. Observer governments must start accession negotiations within five years of becoming observers. See "Understanding the WTO – Members".

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm at 12 Dec 2004.

[6] The full text of the TRIPS agreement can be found at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm at 12 Dec 2004.

[7] Disputes between WTO Members about TRIPS obligations are subject to the WTO's normal dispute settlement procedures, which may result in multilateral trade sanctions.

[8] For the full text of patents section of the TRIPS agreement see http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5 at 12 Dec 2004.

[9] See James Boyle, 'Enclosing the Genome: What the Squabbles over Genetic Patents Could Teach Us', in F. Scott Kieff (ed), *Perspectives on the Human Genome Project* (2003). http://www.law.duke.edu/ip/pdf/enclosing.pdf at 12 Dec 2004. See also Jerome H. Reichman, 'Saving the Patent System from Itself:

Informal Remarks Concerning Systemic Problems Afflicting Developed Intellectual Property Regimes' in F. Scott Kieff (ed), *Perspectives on the Human Genome Project* (2003). http://www.law.duke.edu/ip/pdf /savingPatent.pdf at 12 Dec 2004.

[10] See Dianne Nicol & Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347.

[11] See the discussion below in relation to inventive step.

[12] See Boyle, above n 9. See also Nuffield Council on Bioethics, *The ethics of patenting DNA* (2002) at para 5.12. http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication_310.html at 12 Dec 2004.

[13] See for example Fintan R. Steele, 'Specific, Substantial and Credible' (2001) 3(2) *Molecular Therapy* 127.

[14] For an excellent (albeit short) summary of the wide range of views encapsulated by this statement see James Boyle, 'The Second Enclosure Movement and the Construction of the Public Domain' (2003) 66 *Law & Contemporary Problems* 33. http://law.duke.edu/journals/lcp/downloads /LCP66DWinterSpring2003P33.pdf at 12 Dec 2004.

[15] Sahil Gupta, 'The problems raised by biotechnological inventions for patent scope interpretation,' (2002) *Lex-e-Scripta*, http://www.inter-lawyer.com/lex-e-scripta/articles/patent-scope.htm at 12 Dec 2004.

[16] For a discussion of the need to include public policy considerations, see Miranda Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform' (2000) 11 *Australian IP Journal* 202.

[17] For example a solution tailored specifically to meet the issues involved in gene patents may fail when applied to the problem domain of nanotechnology.

[18] 206 USPQ 193 (1980).

[19] This view is also accepted in other jurisdictions. In relation to the EU, see EC Directive 98/44/EC Article 5(2). In relation to Australia see *Rank Hovis McDougall Ltd's Application* (1976) AOJP 3915 where a patent was allowed for a new strain of micro-organism.

[20] See *Treaty for a Lifeforms Patent-Free Pacific* (1995), cited in Aroha Te Pareake Mead, 'Resisting the Gene Raiders' 293 *New Internationalist Magazine* http://www.newint.org at 12 Dec 2004.

[21] See 'US University Shares Drug Royalties with Samoa for Tree Gene (30/9/04)' http://www.uspolicy.be/Article.asp?ID=42BFB6BC-1E57-484B-9D0D-826324CF7AC7 at 12 Dec 2004.

[22] Also referred to as the "prior art base".

[23] [1998] APO 49 (9 September 1998) cited in Charles Lawson, 'Patenting genetic materials' unresolved issues and promoting competition in biotechnology' (Working Draft) at 16. http://www.cccp.anu.edu.au/publications/LawsonIPWorkshop.pdf . Accessed 9 September 2003.

[24] [1996] APO 3 (18 January 1996). Cited in Lawson above n 22 at 17.

[25] Lawson, above n 22 at 18.

[26] Ibid.

[27] (1959) 102 CLR 232.

[28]Boyle, above n 14.

[29] This is the "tragedy of the anti-commons" See Michael A. Heller & Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

[30] See Jerome H. Reichman, 'Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation', (2000) 53 *Vanderbilt Law Review* 1753. Reichman aptly illustrates it as a choice between paying now, or risking infringement proceedings later. It is a choice which alleged infringers of Genetic Technologies patents are resolving in favour of the former. See also Australian Broadcasting Corporation, *Four Corners: Patently a Problem*. Transcript available at http://www.abc.net.au/4corners/content /2003/transcripts/s922059.htm at 12 Dec 2004.

[31] See Lawson, above n 2. See also Nicol and Nielsen, above n 10. See the IPCRC report and government response. Whilst an analysis of the pros and cons of such a solution goes beyond the scope of this question, the preferred approach seems to be issuance of compulsory licenses when certain competition law criteria are met.

[32] See Nicol & Nielsen, above n 10.

[33] To be dealt with in more detail below.

[34] See John H. Barton, 'Reforming the Patent System' (2000) 287 *Science* 1933. Barton points out that the US Patent office is currently only able to spend an average of 25 to 30 person-hours on each patent application.

[35] Ibid.

[36] *Patents Amendment Act 2001.*

[37] See Lawson above n 22.

[38] See Reichman above n 29.

[39] Hybrid systems combine some elements of the weak copyright and strong patent style protections. The first hybrid system, designs law, was introduced in the nineteenth century. Reichman also places the more recent plant breeders' rights and circuit designs regimes in this category.

[40] An Australian example of this cycle may be found by comparing the innovation patent regime with its predecessor, the petty patent system. It would seem we are entering a period of overprotection. See IP Australia, *Introduction of the Innovation Patent*,

http://www.ipaustralia.gov.au/patents/what_innovation_review.shtml at 12 Dec 2004.

[41] See Reichman above n 29.

[42] Ibid.

[43] Ibid at 1781-91.

[44] Ibid. Reichman suggests a figure between 3% and 9% of profits as a general rule, although recognises that this figure may need to be tailored to suit different industries.

[45] '"Reach-through licensing" is licensing of technology/intellectual property, typically patent rights, with royalties based on a percentage of sales, where the licensed technology/intellectual property, such as basic research, is not incorporated into the end product.' Thomas J. Kowalski & Christian M. Smolizza, 'Reach-through licensing: a US perspective' (2000) *Journal of Commerical Biotechnology* http://pharmalicensing.com/features/disp/963567614_396edffe132c5 at 3 Jan 2004.

[46] This is in stark contrast to the patent system where upstream innovators are likely to overvalue their own patents. See Boyle, above n 9.

[47] Ibid.

[48] See for example Ken Garber, Homestead 2000: The Genome. *Signals Magazine*. <http://www.signalsmag.com/signalsmag.nsf/0/FD168FB6E882568950015E2D0> (quoting various biotechnology and pharmaceutical executives). For the imbalance in lobbying strength between this group and those who would gain by reform, see Mandeville et al, *Economic Effects of the Australian Patent System*, extracted at <http://swpat.ffii.org/papers/mandeville1982/index.en.html>.

Last accessed 19th September 2003.

[49] See Boyle, above n9.

[50] Australian Law Reform Commission, "Genes and Ingenuity: Gene Patenting and Human Health," ALRC 99, June 2004, Recommendation 6-3.

[51] See the discussion above in relation to inventiveness.

[52] Nuffield Council, above n 12 at para 3.36. See also Lawson & Pickering above n 39.

[53] See Nicol and Nielsen above n 10.

[54] European Patent Convention, s52(1) and s57. Discussed in Nuffield Council, above n 40 at para 3.35.

[55] Nuffield Council, above n 12 at 3.37.

[56] This is consistent with the approach taken by Heerey J in *Genetics Institute v Kirin-Amgen*, above n 38.

[57].Steele sbove n 13.

[58] See the discussion above in relation to inventiveness.