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Cooperative Intellectual Property in Biotechnology

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Abstract

This paper briefly considers some of the perceived problems associated with the exclusive rights model of patent management in biotechnology. It then goes on to explore the range of legal options for dealing with some of these perceived problems, together with alternative co-operative approaches that are currently under discussion in various forums, including open access models. This review shows that there are many parallels in the issues currently being debated in the information technology and biotechnology industries in relation to the copyright and patent regimes of intellectual property.

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1. Introduction

Patenting of genes and other genetic research tools attracts heated debate in the academic, policy and popular literature for a wide variety of reasons.¹ This paper focuses on one aspect of the debate: the extent to which patents of this nature actually fulfil their purpose of encouraging innovation. The main purpose of this paper is to present an overview of some of the strategies that are currently being debated as means of promoting innovation in this area. This paper aims to provide an introduction to this topic for the non-biotech specialist, particularly for those whose main area of interest is the relationship between copyright law and the intellectual commons. Although this paper deals with quite different subject matter from the other papers in this special issue of *SCRIPT-ed*, it will be seen that there are significant commonalities in the approaches being developed and discussed for unlocking intellectual property. Although there are major points of distinction between the patent and copyright regimes, and between biotechnology and information technology, there is considerable alignment in both the regulatory and industry-generated models being proposed for promoting innovation in each area. Implementation of some of these models is at a much more mature stage in the information technology arena, and there is the potential for expertise and experience in this discipline to be translated into biotechnology language. This paper aims to provide some of the necessary background in biotechnology and patenting to facilitate engagement with information technologists, with the ultimate aim of finding the most robust models for ensuring that the great promise of biotechnology is put into practice, for the benefit of society as a whole.²

Before these complex issues can be explored, it is first necessary to explain some basic terminology. Research tools are the technological developments that enable particular lines of research to be pursued.³ Gene sequences have a range of possible uses both as research tools and also in diagnostic testing, gene therapy and the production of therapeutic proteins.⁴ Many thousands of applications have been made for patents claiming gene sequences and a large number of patents have already been granted.⁵ There are also a wide variety of other important genetic research tools,

¹ There is a vast body of literature on this debate, far too extensive to list fully here. A useful starting point is a special issue of the journal *Academic Medicine*: D Korn and SJ Heinig (guest eds) "Public Versus Private Ownership of Scientific Discovery: Legal and Economic Analyses of the Implications Human Gene Patents" (2002) 11(12) *Academic Medicine* pp1301-1399. Many of the leading academic commentators on this topic in the US have papers in this issue of the journal.

² It should be noted that this paper does not aim to enter into the debate about the translation of open source principles into biotechnology. This issue has been canvassed extensively elsewhere. See particularly J Hope, *Open Source Biotechnology* (Canberra: Australian National University PhD Thesis, 2004) @ <http://rssh.anu.edu.au/~janeth>.

³ Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (London: Nuffield Council; 2002) at 56 (the Nuffield Discussion Paper).

⁴ Nuffield Discussion Paper, *ibid* at 47-64.

⁵ K Jensen and F Murray, "Intellectual Property Landscape of the Human Genome" (2005) 310 *Science* 239.

including, for example, recombinant DNA technology, the polymerase chain reaction and intron sequence analysis, each of which has also been patented.⁶ The term genomics is used throughout this paper to embrace both gene sequences and other fundamental genetic research tools. For the present purposes, it is unnecessary to go further and attempt to more precisely define what does or does not come under the umbrella of genomics. This is just as well, because the terminology is complex and unsettled. Indeed, basic concepts like what constitutes a gene still continue to be debated.⁷

Genomics is the core technology of the biotechnology industry.⁸ As a consequence, genomic patents are valuable commodities. Patents are widely seen as the lifeblood of the biotechnology industry,⁹ the survival of which is dependant on attracting venture capital and angel investment for further research and development and on being able to on-license technological developments to downstream product developers rather than making those products itself. However, genomic patents are particularly controversial because they lie at the interface between discovery and invention and signal a move away from patenting end products towards patenting basic scientific information.¹⁰ Nevertheless, many countries see the biotechnology industry as crucial to their future economic growth and governments are making policy decisions aimed at encouraging innovation in this area, including facilitating patenting of genomic inventions, providing financial support for commercialisation of public sector inventions, particularly through spin off and start up companies, and encouraging partnerships between the public and private sectors.¹¹

2. The problem with patents

There is increasing concern that the rush to patent in this area could actually slow the pace of genomic research and could stifle innovation in the downstream sectors of the biotechnology industry.¹² There are two primary concerns: first, owners of broad

⁶ See, for example, National Research Council, *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington DC: National Academy of Sciences, 1997).

⁷ H Pearson, "What Is a Gene?" (2006) 441 *Nature* 399.

⁸ See, for example O Vukmirovic and S Tighman, "Exploring Genome Space" (1999) 405 *Nature* 820

⁹ See, for example, JP Walsh, A Arora and W Cohen "Effects of Research Tool Patenting and Licensing on Biomedical Innovation" in W Cohen and St Merrill (eds.), *Patents in the Knowledge-Based Economy* (Washington: National Academies Press, 2003) at 286-287, @

<http://books.nap.edu/books/0309086361/html/285.html#pagetop> (Walsh et al: Patenting).

¹⁰ RS Eisenberg, "How Can You Patent Genes?" (2002) 2 *The American Journal of Bioethics* 3.

¹¹ See generally P Kanavos, "Determinants of Market Structure in the International Biopharmaceutical Industry", in OECD, *Economic Aspects of Biotechnologies Related to Human Health: Part II: Biotechnology, Medical Innovation and the Economy: The Key Relationships* (Paris: OECD, 1998). For an example of country-specific strategies, see *Biotechnology Australia, Australian Biotechnology: A National Strategy* (Canberra: AGPS, 2000).

¹² Rebecca Eisenberg, in particular, frequently refers to this issue in her work. See, for example, RS Eisenberg, "Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?" in RC Dreyfuss, DL Zimmerman and H First (eds.), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, (Oxford: Oxford University Press, 2001).

genomic patents could restrict or refuse access, blocking off whole areas of research and development;¹³ secondly, if there are too many genomic patent rights in a particular area, negotiating freedom to operate with all rights holders may simply be too difficult. Even where it is possible to negotiate licenses with all relevant rights holders, high transaction costs, license fees and stacking of royalty obligations may make projects so unattractive that they are abandoned.¹⁴ Restrictions on access and the so-called anticommons effect resulting from multiple fragmented ownership rights¹⁵ could seriously undermine the development of the biotechnology industry as a whole. Isolated examples of patent holders driving hard bargains and jealously guarding their rights have exacerbated these concerns.¹⁶ Despite this, there has been little compelling evidence that these concerns are eventuating across the biotechnology industry as a whole. In fact, available evidence suggests the contrary. It seems that, for the most part, genomic rights holders tend to license widely, and users engage in a number of strategies to ensure that their research and development programs can continue, including licensing-in, inventing around, litigating to challenge patent validity, or simply ignoring the genomic patents that would otherwise block their research.¹⁷ In the public research sector, in particular, the available evidence suggests that researchers are rarely impeded in their research programs by genomic patents,¹⁸ despite the absence of a clear exemption from infringement for research use in most jurisdictions and well publicised case law in the US indicating that public sector research is not immune from infringement.¹⁹

¹³ On the broad problem of blocking patents in areas of cumulative innovation see: R Merges and R Nelson, "On the Complex Economics of Patent Scope (1990) 90 *Columbia Law Review* 839; S Scotchmer, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law" (1991) 5 *Journal of Economic Perspectives* 29.

¹⁴ M Heller and RS Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 *Science* 698.

¹⁵ *Ibid.*

¹⁶ T Caulfield, RM Cook-Deegan, FS Keiff and JP Walsh, "Evidence and Anecdotes: an Analysis of Human Gene Patenting Controversies" (2006) 24 *Nature Biotechnology* 1091 (Caulfield et al: Evidence).

¹⁷ Walsh et al: Patenting, above note 9 at 287 (also see JP Walsh, A Arora and W Cohen, "Working Through the Patent Problem" (2003) 299 *Science* 1021); J Straus, H Holzapfel and M Lindenmeir, *Empirical Survey on Genetic Invention and Patent Law*, (Munich: 2002) (copy on file with the authors); D Nicol and J Nielsen *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Centre for Law and Genetics Occasional Paper No. 6; 2003) @ <http://www.ipria.org/publications/reports.html> (also see D Nicol and J Nielsen, "Australian Medical Biotechnology: Navigating a Complex Patent Landscape" (2005) *European Intellectual Property Review* 313); Intellectual Property Institute on behalf of the Department of Trade and Industry, *Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice* (2004) @ http://www.dti.gov.uk/5397_DT_i_Patent_Study.pdf; N Thumm, *Research and Patenting in Biotechnology: A Survey in Switzerland* (Swiss Federal Institute of Intellectual Property; 2003) @ <http://www.ige.ch/E/jurinfo/j100.htm#2>; Committee on Intellectual Property Rights in Genomic and Patent Research and Innovation, National Research Council of the National Academies, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health* (National Academies Press; 2005).

¹⁸ See particularly JP Walsh, C Cho and W Cohen, "View from the Bench: Patents and Material Transfers" (2005) 309 *Science* 2002 (Walsh et al: Material Transfers).

¹⁹ *Madey v Duke University* 307 F 3d 1351, 1360–1 (Fed. Cir. 2002).

So far so good, particularly if all we are concerned about is the impact of genomic patents in the upstream public research sector. The empirical evidence appears to suggest that there is unlikely to be an appreciably detrimental impact in this sector at the present time. It should be noted that more difficulties do, however, arise for researchers when they need to obtain tangible materials in addition to the intangible right to use from the rights holder.²⁰ Furthermore, there seems to be more compelling evidence of both restrictive licensing and the anticommons effect in some downstream sectors, particularly in the diagnostics sector of biomedicine²¹ and in agriculture.²² In any event, the lack of evidence should not make us complacent that all is well with the industry, even despite the fact that the patterns are fairly consistent across industry sectors and across jurisdictions.²³ Empirical researchers do recognise the limitations in their evidence, and the difficulty in measuring such matters as the extent of abandonment of research projects when the patent landscape is too cluttered or when particularly problematic patents are encountered.²⁴

Although much of the policy debate and academic commentary has focused on these access issues, the difficulties faced by genomic patent holders in commercialising their technology should not be ignored.²⁵ Securing patent rights is expensive and requires careful management. Finding partners and negotiating suitable licensing arrangements is costly and time consuming, and there may be inequality of bargaining power, particularly where public sector organisations or small upstream biotechnology companies have to deal with big pharma. Enforcement of patents for basic research tools is particularly difficult because use generally occurs in secret behind laboratory doors.

This all seems to paint a picture of an industry in crisis. On the one hand, genomic rights holders could, if they chose, drive hard bargains that impede downstream development, but, on the other hand, downstream users could force rights holders into a position where they have to hand over too much for too little. Rights holders could also, if they choose, impede academic research and forestall access to new healthcare products, particularly genetic tests. The true situation is not necessarily as gloomy as this. Such highly competitive behaviours are probably quite common across many industry sectors, particularly in new and rapidly developing industries where ‘gold rush’ type mentality might be expected. Market forces are likely to temper these behaviours, particularly those of rogue players who seek to aggressively enforce and

²⁰ Walsh et al: Patenting, above note 9.

²¹ See particularly M Cho, S Illangasekare, M Weaver, D Leonard and J Merz, “Effect of Patents and Licenses on the Provision of Clinical Genetic Testing Services” (2003) 5 *Journal of Molecular Diagnostics* 3; J Merz, A Kriss, D Leonard and M Cho, “Diagnostic Testing Fails the Test” (2002) 415 *Nature* 577.

²² R Atkinson *et al*, “Public Sector Collaboration for Agricultural IP Management” (2003) 301 *Science* 174-5.

²³ Caulfield et al: Evidence, above note 16.

²⁴ Nicol and Nielsen, above note 16 at 190-191. See also Caulfield et al: Evidence, above note 16; ER Gold et al, “Continuing the Debate on Existing Evidence about Gene Patents” *Nature Biotechnology* in press.

²⁵ See generally Nicol and Nielsen, above note 17 at 93-123.

expand their legitimate entitlements. We will also see later in this paper that, in at least some areas of genomics research, the norms of open science and sharing of raw research data are still alive and well. But in biotechnology, where advances are rapid and the potential to provide benefit to society is high, it may not be appropriate simply to wait for market forces to achieve the right balance, or to rely on the good grace of industry participants to do the ‘right thing’. New strategies are needed, but care is required in choosing the right strategies. If the rights provided to genomic innovators are significantly eroded, they may well decide to change from patenting to trade secrecy, which could have a more seriously negative impact on research and downstream innovation.

3. Regulating patent use

We have seen in the last section that there are deep-seated theoretical concerns about the ‘problem’ of genomic patents. Despite the limited evidence of factual manifestations of this problem, there is still ongoing unease about it in many sectors of society, including national and international policy makers, granting bodies, public sector researchers, participants in various sectors of the industry, academic commentators and those members of the public who know enough about the subject matter to form views about it.²⁶ As a result, there has been wide-ranging exploration of the legal options for regulating the use of genomic patents in the academic, legal and policy literature over the last five or so years.

At present, it is largely left to patent holders to decide for themselves what strategies they will employ in utilising their patent rights. The patent system provides much more limited regulatory control over how the relevant intellectual property rights should be used than the copyright system. In the past few years, a number of law reform agencies around the world have been examining the two interlinked questions of what types of gene patents should be allowed and how their use should be regulated.²⁷ None of these agencies has recommended wholesale prohibition of genomic patents, but all emphasise the need to limit the availability of patents to true inventions that have clear industrial applicability. These agencies have also called for greater clarity in the regulatory controls over the use of genomic patents, particularly the provisions in patent law relating to exemption from infringement for experimental use and compulsory licensing and government use. Despite the consistency of these recommendations, actual reform of the law proceeds at snail’s pace.²⁸ In any case, the extent to which the law reform proposals that are on the table will actually fix the problems with genomic patents is a moot point.

²⁶ There has been little public engagement on this topic and evidence about what the public thinks about gene patents is exceedingly limited. See T Caulfield, E Eisiendel, J Merz and D Nicol “Trust, Patents, and Public Perceptions: The Governance of Controversial Biotechnology Research” (2006) 24 *Nature Biotechnology* 1352.

²⁷ For example: Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* Report 99 (2004); SA Merrill, RC Levin and MB Myers (eds), *A Patent System for the 21st Century* (2004); Canadian Biotechnology Advisory Council, *Report: Human Genetic Materials, Intellectual Property and the Health Sector* (2006).

²⁸ On this point, see particularly Caulfield et al: Evidence, above note 16.

The ongoing debate about the adequacy or otherwise of the fair use and fair dealing provisions in copyright law would probably be well known to some readers. Other articles in this special issue provide details of this debate.²⁹ The position with regard to patent exemptions is even more problematic. Some countries have express exemptions from infringement in their legislation, whereas others rely on the common law. Some, including Australia, have no legislative provisions and no decided authorities on the common law position. Despite this uncertainty, it is generally accepted that some research uses of patented inventions should be exempt. There is even some academic support for a copyright-style fair use provision.³⁰ Conceptually, there is linkage in the need for such exemptions in both patent and copyright: both are necessary to properly maintain the balance between owners and users of intellectual property. However, this is probably where the analogy ends and it is difficult to see how the fair dealing/use provisions could be directly translated into patent law because of the fundamental differences between the copyright system and the patent system. Instead, the widely accepted view in patent policy discussions is that experimental use of a patented invention should be exempt, but that the exemption should be limited to experimentation *on* the patented invention (testing the invention to assess whether it achieves what is claimed in the patent or experimenting on the invention to improve or modify it).³¹ This means that the exemption would not extend to non-commercial research *with* the invention. As a consequence, it is unlikely that the use of patented genomic research tools, even in the basic research context, would be covered by an experimental use exemption.³²

There has been some academic commentary supporting the use of compulsory licensing as an alternative to exemption from infringement, particularly with regard to research tool patents. Katherine Strandburg, for example, has proposed a two-tier scheme in which research tool patent holders would have a period of complete exclusivity followed by a period during which compulsory licenses would become available.³³ However, this scheme does not seem to clearly fit within the types of compulsory licensing regimes that are provided for in most patent legislation, where one-off applications are made to the court or the patent office and decided on case-by-case basis, following full hearing on the merits. It has more similarities with the educational and other automatic licensing provisions in copyright law. Strandburg's two-tier scheme could be an appropriate mechanism for facilitating access to research tools on the one hand, while ensuring that research tool patent holders secure appropriate benefits from their patents on the other.³⁴

²⁹ Note to editor: include reference to Melissa de Zwart's article.

³⁰ As discussed in detail from the perspective of US patent and copyright law in M O'Rourke, "Towards a Doctrine of Fair Use in Patent Law" (2000) 100 *Columbia Law Review* 1177.

³¹ Australian Law Reform Commission, above note 27 at 336-343; Advisory Council on Intellectual Property *Patents and Experimental Use* (Canberra: Australian Government; 2004) at 19; Canadian Biotechnology Advisory Committee, above note 27 at 25-26.

³² J Barton, "Patents, Genomics, Research and Diagnostics" (2002) 77 *Academic Medicine* 1339 at 1342; Australian Law Reform Commission, above note 25 at 342-343.

³³ K Strandburg, "What Does the Public Get? Experimental Use and the Patent Bargain" (2004) *Wisconsin Law Review* 81.

³⁴ Nicol and Nielsen, above note 16 at 239-241.

One of the difficulties with a licensing scheme of this nature is that it could offend against the stringent requirements in Article 31 of the Agreement on Trade-related Aspects of Intellectual Property (TRIPs) relating to use without authorization of the rights holder. However, if the scheme were voluntary in nature it may fall within the permissible exemptions in Article 30 of TRIPs. Although the Australian Law Reform Commission (ALRC) explored the option of establishing a statutory licensing regime in its inquiry into gene patenting and human health, ultimately it concluded that there was insufficient need for such a complex system at the present time.³⁵ However, there may come a time when this option needs to be revisited.

In patent law, a compulsory licence is a court or administrative order requiring the patent holder to grant a licence to work the invention, and government use is use of the invention by the government for the purposes of the state. Compulsory licensing and government use are permissible under Article 31 of TRIPs provided that certain conditions are complied with. Compulsory licensing and government use provisions are already included in patent law in many jurisdictions, but the circumstances in which they are allowed vary significantly from country to country. In the United States, for example, the primary ground on which compulsory licences are issued is to remedy anti-competitive conduct, while in France the focus is more on the public interest.

Despite the existence of these provisions, both compulsory licensing and government use have been used rarely, if at all.³⁶ It could be argued that their mere existence may encourage parties to enter into voluntary licensing arrangements. In the alternative, it may be that they are not used because procedurally they are too slow, too expensive and/or too uncertain. If they are to provide real assistance to researchers or downstream users unable to access essential genomic technologies they must be more than hollow threats. Law reform agencies have generally recommended that amendments are required in both of these areas to secure an appropriate balance between patent rights, research use and downstream access. Even with these amendments, the limitations on compulsory licensing and government use prescribed in the TRIPS Agreement may prove too great a barrier in most instances.

4. Other initiatives

The lack of clear legal solutions to the ‘problem’ associated with enforcement and use of genomic patents has encouraged academic commentators, policy makers and the industry itself to seek out other solutions. It is recognised that, at the very least, the process of licensing-in and licensing-out, particularly with regard to patent searching and negotiating licenses, needs to be streamlined. Where broadly applicable research tools are involved, there may be the capacity to have fairly standard form, non-exclusive licensing. The Organisation for Economic Cooperation and Development (OECD) has been exploring this issue for a number of years and in February 2006 the

³⁵ Australian Law Reform Commission, above note 27 at 552.

³⁶ However, developing countries are starting to use these mechanisms for manufacturing generic versions of patented pharmaceuticals. See, for example, Ministry of Public Health and National Health Security Office Thailand, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand* (2007) @ <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf>

OECD Council approved *Guidelines for the Licensing of Genetic Inventions*.³⁷ In summary, these Guidelines aim to foster innovation and to achieve a balance between return on investment on the one hand, and dissemination of information and access to healthcare products on the other. According to the Guidelines, best practice will generally require broad licensing of genetic inventions for research and investigation and licensing for health applications on such terms and conditions that ensure widest public access to healthcare products and services. As a general rule, the OECD recommends that such inventions should be non-exclusively licensed, although in some limited circumstances exclusive licensing may be appropriate, provided that sufficient safeguards are in place to ensure that the invention is sufficiently exploited.

The OECD Guidelines reflect policies for licensing of genomic inventions within US public funding agencies. The National Institutes of Health (NIH) released guidelines relating to the dissemination of biomedical research resources in 1999³⁸ and for licensing of genomic inventions in 2005.³⁹ Together, these guidelines emphasise the importance of broad dissemination of genomic inventions with minimal encumbrances and recommend that non-exclusive licensing should be pursued as a matter of best practice. A comprehensive empirical study of licensing practices by US academic institutions indicates that these guidelines reflect existing practice, particularly in the large, experienced academic institutions.⁴⁰ In particular, where exclusive licenses are utilised, they tend to be restricted to particular fields of use. This tends to suggest that a common sense approach is already being taken with regard to licensing of public sector innovations in order to maximising dissemination on the one hand and commercial opportunities on the other.

Hence, it would appear that market solutions are already emerging, at least amongst the well-resourced US Ivy League institutions. However, technology transfer offices in academic institutions elsewhere are unlikely to have the same skills-base and bargaining powers. Even in industrialised countries like Australia, there is a broad range of expertise and quality in technology transfer across public sector organizations: some have dedicated incorporated entities, others have single officers.⁴¹ Licensing guidelines will doubtless provide invaluable assistance to them, but more could be done. The task of finding partners, negotiating licenses, and settling on prices and other license terms is still onerous.⁴² One of the crucial issues in attracting partners is ensuring clean title, but searching through patent databases can be time consuming and costly.⁴³ Good knowledge of the patent landscape and

³⁷ OECD, *Guidelines for the Licensing of Genetic Inventions* (2006) OECD, Paris.

³⁸ NIH, "Principles and Guidelines for Recipients of NIH Research grants and Contracts on Obtaining and Disseminating Biomedical research Resources: Final Notice" (1999) 64 *Federal Register* 72090. See also National Research Council, above note 6.

³⁹ NIH, "Best Practices for the Licensing of Genomic Inventions: Final Notice" (2005) 70 *Federal Register* 18413.

⁴⁰ L Pressman et al, "The Licensing of DNA Patents by US Academic Institutions: an Empirical Study" (2006) 24 *Nature Biotechnology* 31.

⁴¹ Nicol and Nielsen, above note 17 at 105-110. See also Productivity Commission, *Public Support for Science and Innovation*, Research Report (Canberra: Productivity Commission; 2007) pp284-293 @ <http://www.pc.gov.au/study/science/finalreport/index.html>

⁴² Nicol and Nielsen, above note 17 at 110-122.

⁴³ Nicol and Nielsen, above note 17 at 132-134.

negotiating skills are crucial in ensuring that technology generated in the public sector is disseminated in a fair way for a fair price. Prospective licensing partners also benefit from bargaining with skilled operators who have a good sense of the value of the technology and the terms that it is worthwhile to spend time negotiating. Yet the cost of running high quality technology transfer offices is beyond the reach of many public sector organizations, and it is questionable whether such investment is worthwhile in the long run, because returns rarely match investment.⁴⁴ It is argued here that more collaborative approaches warrant at least some consideration. This argument applies equally to the private sector as well as the public sector, particularly to those small biotechnology companies that have been spun out from public sector research organizations.

One option that has been mooted to facilitate both licensing-out and access is to establish some type of collective rights arrangement. To date, most of the commentary on such arrangements has focused on patent pooling and cross licensing. These arrangements enable the consolidation of intellectual property rights so that negotiating licenses is streamlined and transaction costs are consequently reduced. Other benefits include distribution of risks and sharing of additional technical information.⁴⁵ Some commentators have suggested that these types of private arrangements could ameliorate some of the problems arising from the proliferation of genomic patents.⁴⁶ Others have expressed doubt as whether there is sufficient incentive for patent holders to willingly enter into voluntary arrangements of this nature.⁴⁷ One of the significant difficulties is that such arrangements could encourage collusion and price fixing, which would raise competition law considerations.⁴⁸ As a consequence, complex rules have been formulated by competition law agencies in a number of countries to assist in avoiding breaches.⁴⁹ These guidelines recognise that, if properly constructed and regulated patent pools can be procompetitive, rather than anticompetitive.

The use of clearinghouse mechanisms is also being explored as a means of reducing the transaction costs in licensing-out and accessing genomic patents, particularly licensing of research tools between research organisations. A clearinghouse could perform one or more of the following functions: facilitating the search for technology that is available for licensing or free use; smoothing the progress of negotiations; and monitoring or enforcing negotiated agreements.⁵⁰ Clearinghouses are already being

⁴⁴ Y Benkler, "Commons-based Strategies and the Problem of Patents" (2004) 305 *Science* 1110 at 1110-1111.

⁴⁵ J Clark et al, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (United States Patent and Trademark Office; 2000) at 9-10.

⁴⁶ See particularly R Merges, "Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations" (1996) 84 *California Law Review* 1293. See also Clark et al, *ibid* at 8.

⁴⁷ See particularly Heller and Eisenberg, above note 14.

⁴⁸ S Carlson, "Patent Pools and the Antitrust Dilemma" (1999) 16 *Yale Journal on Regulation* 359.

⁴⁹ For example, US Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (US Department of Justice; 1995).

⁵⁰ G Graff and D Zilberman "Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology (2001) 3 *Intellectual Property Strategy Today* 1; G Graff, A Bennett, B Wright,

established. In the United States, for example, the Public Intellectual Property Resource for Agriculture (PIPRA) facilitates sharing of access to agricultural technologies by US-based public-sector agricultural research institutions.⁵¹

There have been calls for the role of clearinghouse mechanisms to be examined more fully in relation to licensing of biotechnology patents in general⁵² and specifically in relation to licensing of gene patents for clinical diagnosis.⁵³ There has also been one proposal for the establishment of a royalty collection clearinghouse in diagnostics, modelled somewhat on the copyright collecting societies.⁵⁴ It is certainly important to explore models for facilitating access in diagnostics, because there is more compelling evidence of access problems here than elsewhere.⁵⁵ However, adoption of the collecting society model may be too extreme a response to this need. Indeed, it could be an inappropriate response if leads to more rigorous enforcement of patent rights, particularly if those patents are of uncertain validity. Some readers with expertise in the copyright arena may well already have doubts about the extent to which collecting societies actually facilitate access to copyright works and whether or not it would be appropriate to translate this model into other areas of intellectual property.

Why, then, should patent pools and clearinghouses be in contemplation at all? They could be used to lock up information rather than facilitate its dissemination. They might encourage rights holders to seek rents where they would otherwise have accepted a certain level of unauthorised use, thereby increasing, rather than decreasing the anticommons effect. Considerable costs might be expended in set up and administration. Unless the clearinghouse or patent pool has an independent source of funding these costs will have to be relayed to users.⁵⁶ Potential licensors might be reluctant to relinquish their exclusive right to manage their own intellectual property. There is also a risk that these collective rights arrangements could just be markets for obsolete or otherwise unwanted technology.

All of these concerns and more are legitimate, but it doesn't follow that further discussion of these options should be abandoned. These and like arrangements have captured the imagination of commentators and policy makers alike for a wide variety of reasons. Patent pools, in particular, could reduce the risk of blocking and anticommons effects. Clearinghouses are likely to enhance partnering opportunities

and D Zilberman "Intellectual Property Clearinghouse Mechanisms for Agriculture: Summary of an Industry, Academia, and International Development Round Table" (2001) 3 *Intellectual Property Strategy Today* 15 @ <http://www.biodevelopments.org/ip/> (accessed 20 September 2003).

⁵¹ Atkinson et al, above note 22.

⁵² OECD, *Patents and Innovation: Trends and Policy Changes* (Paris: OECD; 2004) at 2.

⁵³ Human Genome Organisation, *Statement on the Scope of Gene Patents, Research Exemption, and Licensing of Patented Gene Sequences for Diagnostics* (2003) at 3-4; G Van Overwalle et al, "Models for Facilitating Access to Patents on Genetic Inventions" (2006) 7 *Nature Review Genetics* 143.

⁵⁴ E Van Zimmeren et al, "A Clearing House for Diagnostic Testing: the Solution to Ensure Access To and Use of Patented Genetic Inventions?" (2006) 84 *Bulletin of the World Health Organisation* 352.

⁵⁵ See Cho et al and Merz et al, above note 21.

⁵⁶ Note that PIPRA is funded by the Rockefeller and McKnight Foundations.

and dissemination of technology. Both have the capacity to significantly reduce transaction costs and patent search costs. Concerns about the impact of more rigorous enforcement could be countered if price distinctions were made between academic and non-academic users or use for humanitarian and commercial purposes.⁵⁷ Debate about the efficacy of both of these types of cooperative arrangements is in its infancy. Economic modelling needs to be performed, the industry needs to be consulted to assess the level of interest in arrangements of this nature, and trials need to be undertaken before we can get a clear idea about the extent to which such mechanisms could actually smooth the innovation path in biotechnology.

5. Open access models

If structured appropriately, collective rights arrangements may well have the capacity to balance the rights of owners and users of genomic technology. But these are not the only proposed solutions. In parallel with these discussions, others are looking to more commons-based approaches for managing genomic technology.⁵⁸ Copyright models provide some useful analogies in this regard. However, it is necessary to bear in mind that the issues associated with licensing-out and access to patented technologies are far more complex than for copyright, in part because of the high cost of obtaining and maintaining patents.

One simple way to deal with this problem is to avoid patenting altogether, but in many instances it is necessary to secure patent rights to avoid the risk that the technology will be captured by someone who makes a minor incremental improvement through which they claim broad patent rights which they then aggressively enforce.⁵⁹ Defensive patenting could play a key role in such circumstances. In such situations, an appropriate strategy may be to adopt the open source model from software for licensing genomic patents.⁶⁰ However, there are significant differences between the software model and the genomic model, indicating that the analogy is not exact. Some of the factors that need to be taken into account include the costs involved in undertaking genomic research and the multiple steps that must to be undertaken to progress from genomic research to commercial products, together with the costs of registering and maintaining patents. Other alternatives to patenting include keeping the technology secret, or allowing access subject to contractual limitations on use, both of which may end up being more problematic than patenting. The question that remains to be answered is when might open access be an appropriate strategy for genomic technology?

There is much to be said for foregoing controversial intellectual property rights in favour of open access to raw data and research materials. Such strategies rely on the traditional norms of publication of scientific results and exchange of research materials. The Human Genome Project (HGP) provides a good illustration of the way that this open access approach can be employed in genomics. The HGP commenced

⁵⁷ This is the approach taken by PIPRA. See <http://www.pipra.org/>

⁵⁸ For example Benkler, above note 44.

⁵⁹ M Shaffer Van Houweling, "Cultivating Open Information Platforms: A Land Trust Model" (2002) 1 *Journal of Telecommunications and High Technology Law* 12

⁶⁰ Hope, above note 2.

in 1990, and from the outset it was a collaborative venture, both between institutions and between countries. The goals of the HGP were to map all of the genes and to systematically sequence the genetic code for the entire human genome. In 1996 HGP participants agreed in the Bermuda Declaration that primary genomic sequences should remain in the public domain and that they should be rapidly released.⁶¹ GenBank is the publicly accessible repository of the sequence information produced by the HGP.⁶² There are a number of advantages to be gained by putting this information in the public domain: first, it reinforces the norm of open science; secondly, it devalues competing proprietary sequence databases; and thirdly, it effectively excludes the patenting option until some additional step was taken, for example ascribing function to a particular gene sequence. On this third point it should be noted that the patentability of raw sequence data is questionable in any case, because it does not satisfy the requirement for industrial applicability or utility.

In addition to the HGP, there are a number of other international collaborative sequencing ventures, notable examples of which are the SNP Consortium and the HapMap Project. Both also make sequence information available in publicly accessible databases.⁶³ In both models, the patentability of the data is questionable and it makes good sense to make the data freely available. It is interesting to note, however, that each of these initiatives has considered placing restrictions on use of publicly disclosed information to avoid capture of early stage data and patenting and restrictions on access for other users. For example, a licence was drafted, although never adopted, for Human Genome Project sequence data.⁶⁴ In the early stage of the HapMap project it was felt necessary to impose restrictions on the use of data. In order to register for access to the online database participants were required to accept the terms of a clickwrap licence.⁶⁵ The licence was essentially copyleft in nature, requiring users to undertake that they would not restrict others from accessing or using the data produced by the project. This obligation attracted some controversy, because it marked a significant change in philosophy from the open access approach,

⁶¹ “International Strategy Meeting Agrees Principles of Early Data Release for Human Genome Sequencing” (1996), press release by the Wellcome Trust, London, 17 April 1996. Participating countries included the UK, the USA, France, Germany and Japan. See also DR Bentley, “Genomic Sequence Information Should Be Released Immediately and Freely in the Public Domain” (1996) 274 *Science* 533.

⁶² <http://www.ncbi.nlm.nih.gov/>.

⁶³ One of the lead funding agencies of both projects, the Wellcome Trust, describes these ventures as two global partnerships that are characterising variations in the human genome. It states that single nucleotide polymorphisms (“SNPs”) are changes to single letters of the DNA code, which occur in about one in every 1000 nucleotides. The SNP Consortium is mapping these SNPs, whereas the HapMap Project is investigating the combinations of SNPs that are inherited together: Wellcome Trust, *The SNP Consortium and the International HapMap Project* (2005) @ http://www.wellcome.ac.uk/doc_WTD003500.html. See also DA Chokshi and DP Kwiatkowski, “Ethical Challenges of Genomic Epidemiology in Developing Countries (2005) 1/1 *Genomics, Society and Policy* 1.

⁶⁴ J Sulston and G Ferry, *The Common Thread* (Random House: London; 2002) pp211–213.

⁶⁵ <http://www.hapmap.org/cgi-perl/registration>. See also Chokshi and Kwiatkowski, *ibid* at 8. Free access to data is a common feature of all large scale international public sequencing projects. See: The Wellcome Trust, *Sharing Data from Large-scale Biological Research Projects: a System of Tripartite Responsibility*, Report of a meeting organised by the Wellcome Trust and held on 14-15 January 2003 at Fort Lauderdale, USA @ http://www.wellcome.ac.uk/doc_wtd003208.html.

although others saw it as an effective safeguard against capture.⁶⁶ Perhaps it was fortunate that the licence was no longer required once further data had been placed in the public domain, which occurred about 15 months into the project.

The Genetic Association Information Network (GAIN) is the latest development in this area. GAIN is public-private partnership that include corporations, private foundations, advocacy groups, concerned individuals, and the US National Institutes of Health.⁶⁷ Its focuses on understanding the genetic factors influencing risk for complex diseases. Its stated aim is to release data as broadly and rapidly as possible, taking into account obvious privacy concerns.

The Science Commons has adopted a similar approach in promoting to access to research materials.⁶⁸ As most readers may already know, the Science Commons is an offshoot of the Creative Commons. It aims to promote innovation in science by lowering the legal and technical costs of the sharing and reuse of scientific work. The Science Commons Licensing Project aims to develop a standard open framework for managing transfer of research materials including cell lines, model animals, DNA constructs and screening assays.⁶⁹ Similarly, participants in the Biobricks Project at the Massachusetts Institute of Technology are developing a Registry of Standard Biological Parts for use in synthetic biology projects.⁷⁰ The purpose of the Registry is to record and index biological parts that are currently being built and offer synthesis and assembly services to construct new parts, devices, and systems.

These and other related endeavours will provide interesting experiments in ascertaining the extent to which innovation in biotechnology can be promoted in the absence of intellectual property rights. It is probably too early in these experiments to make any assessment of their likelihood of success, although some cautionary tales are emerging. In particular, despite the free and open approach taken by the HGP, the gold rush to patent genes continued unabated. Open access does not call a halt to patenting – it perhaps merely delays the inevitable. This may well be a good thing, if it keeps basic science open, provided that it also preserves the opportunities for commercialisation of downstream innovations.⁷¹ But for the open access business model to succeed, it is likely that financing by government or some other benefactor will be particularly crucial, except in the rare cases where the road from research to market is particularly short and the strategy of first to market is likely to succeed. This may well be a valid business model in the information and communications technology industry but is less likely to be so in biotechnology, where the road to

⁶⁶ A Kent, “Patients and IP – Should We Care?” (2006) 3 *SCRIPT-ed* 260.

⁶⁷ http://www.fnih.org/GAIN/GAIN_home.shtml

⁶⁸ <http://sciencecommons.org/>

⁶⁹ <http://sciencecommons.org/licensing/scmta>

⁷⁰ <http://parts.mit.edu>. See also The Bio Fab Group, “Engineering Life: Building a Fab for Biology” (2006) 294 *Scientific American* 34; A Rai and J Boyle, “Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons” (2007) 5(3) *PLoS Biol* e58.

⁷¹ On this point see also A Rai, “Open and Collaborative Research: a New Model for Biomedicine” in R Hahn (ed) *Intellectual Property Rights in New Technologies: Biotech and Software* (AEI-Brookings Press; 2005).

market is considerably longer and more tortuous. Not all worthy research projects can be funded by a Wellcome Trust.⁷²

If the benefactor is big pharma it will doubtless have its own agenda in mind, and this must, as a matter of common sense, involve maximising return on investment for shareholders. Small biotech is the industry sector that is most likely to feel the cost of arrangements between the pharmaceutical industry and the public research sector aimed at opening up genomic research and development. The biotechnology industry in many countries has formed around the interface between product and pre-product development.⁷³ In Australia, for example, most biotechnology companies are small to medium enterprises and in medical biotechnology they are generally involved in functional genomics, drug discovery and some enabling technology.⁷⁴ They stand to be the biggest losers if too much public disclosure destroys the patentability of true inventions on the road to drug discovery. Some might not be too concerned about this eventuality. However, it would seem to be in direct conflict of government policy in many countries supporting the development of the biotechnology sector.

The challenge will continue to be finding an appropriate place to draw the line between pre-commercial open access data and research materials and commercial proprietary technologies. Funding agencies could play an important role in this regard. Government policy in many countries supports commercialisation and patenting of public sector research because it is perceived to be in the national interest.⁷⁵ Funding agencies have implemented this policy by supporting applied research and facilitating technology transfer. However, there will be instances where the national benefit may be better served by release of research results into the public domain. In Australia, in its comprehensive report on the relationship between gene patenting and human health, the ALRC recognised this point, recommending that public funding agencies should be prepared to place conditions on grant funding, requiring, in exceptional circumstances, that research results should either be placed in the public domain or, if patented, widely licensed.⁷⁶ In a submission to the ALRC on this point, the author and colleagues made the following comment:

We do not see that the implementation of this Proposal would in any way impinge on commercialisation in the normal course of events for 'commercialisable' research. We see that the circumstances in which the NHMRC or ARC would impose such conditions as being strictly limited foundational research discoveries of the nature of the human genome project, the SNP project and the HapMap

⁷² The Wellcome Trust was the main funding agency for the UK component of the Human Genome Project, the SNP Project and the HapMap Project.

⁷³ R Eisenberg and R Nelson "Public vs. Proprietary Science: a Fruitful Tension?" (2002) 77 *Academic Medicine* 1392

⁷⁴ D Nicol and J Nielsen "The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development" (2001) 23 *Sydney Law Review* 347

⁷⁵ The most obvious example is the United States, where specific legislation has been enacted for this purpose: the *Bayh Dole Act 1980*.

⁷⁶ Australian Law Reform Commission, above note 27 at 289.

*project. In our view, these projects should be freed from the fetters of commercialisation.*⁷⁷

6. Conclusion

This paper has sought to canvass some of the options for developing cooperative approaches to management of innovation in genomic technology. It is unlikely that any one strategy will provide the perfect solution. Rather, a combination of approaches will be needed. Different strategies are likely suit different ecological niches within the biotechnology industry as a whole. Models are only just emerging, and there will need to be a period of experimentation before they can be fully evaluated. Despite ongoing concerns about the bunker mentality of the biotechnology industry, this new phase of open discussion generates a sense of optimism that individuals within the industry do have the flexibility and the will to work around what might otherwise be intractable problems and to focus on the greater good. Time will tell whether this optimism is warranted.

⁷⁷ This quote is part of the Centre for Law and Genetics' submission to the Australian Law Reform Commission inquiry, extracted by the Australian Law Reform Commission, above note 27 at 285.