

Biomedical Patents: Innovation and Access, Trust and Mistrust

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Abstract

Public trust in biomedicine may be adversely affected by knowledge of private sector involvement in the public sector research effort and patenting of genes and other foundational research tools by public sector organizations. Yet the private sector has a vital role to play in funding research and bringing products to market. Moreover, appropriate steps need to be taken to secure return for investment, usually by taking out patents. The appropriateness of patenting genetic technologies, particularly gene sequences and other research tools, is a matter of ongoing controversy. Although there is limited evidence that gene patents and other research tool patents are negatively impacting on research, innovation and access to new healthcare products by consumers, this could occur more frequently in the near future. There is a clear need for discussion of options for improving access to these patents, including exemptions from infringement, compulsory licensing and government use, and other more cooperative access strategies, and for increased involvement of the public in these discussions and strategies.

Introduction

One of the most widely debated concerns in policy forums, law reform inquiries and academic commentary associated with patent law and biotechnology is the impact of gene and related patents on biomedical research, the biomedical industry and the supply of biomedical healthcare products to consumers. Yet to a large extent the public has not been engaged in these debates. This paper analyses the impact of patenting on biomedical research, innovation and access to healthcare and considers the roles of public trust and public consultation in this area. The aims of this paper are fourfold:

- to point to some of the key concerns in this area;
- to review key empirical studies that have attempted to evaluate the factual basis for these concerns;
- to canvass some of the legal and other solutions aimed at addressing these concerns; and

- to place these issues within the broader context of public trust in biomedicine as a whole.

It should be noted that this paper is not attempting to provide a comprehensive account of the vast body of literature in this area. To do so would go far beyond the purpose of this publication. Rather, the approach in this paper is to use a number of leading articles in the most prestigious science journals and some of the most highly regarded policy reports, together with my own work, to illustrate and support the points made herein.

Various premises underlie this paper. The first is that public trust is necessary in biomedicine, particularly in the more controversial areas. Without it, there is the risk that such research could be brought to a halt.¹ Recent passage of legislation allowing therapeutic cloning in Australia illustrates the importance of public trust and public engagement in biomedicine.² Although the parliamentarians considering the legislation were likely to have been influenced by expert advice on the merits of such research, evidence from parliamentary debates shows that public support for therapeutic cloning clearly played a vital role in persuading them to vote in favour of the Bill. On a more practical level, unless the public has trust in biomedical research and biomedical researchers, they will refuse to participate in the research endeavour. For example, the UK Biobank project will not succeed unless it has 500,000 willing participants who are prepared to donate tissue samples and allow access to their medical records.

The second premise is that the public trusts public sector researchers more than their private sector counterparts. A number of surveys of public opinion presented in this collection of papers and elsewhere clearly illustrate the point that public trust in biomedical science waxes and wanes depending on the source of information. One clear feature is that researchers in the public sector are much more likely to be trusted than those in the private sector. It seems that one reason for this is that public sector

¹ D Chalmers and D Nicol 'Commercialisation of Biotechnology: Public Trust and Research' (2004) 6 *International Journal of Biotechnology* 116.

² *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth), amending the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning Act 2002* (Cth).

researchers are seen to be driven more by benevolence than their private sector counterparts, for whom profit is a dominant motive.³ On the one hand, the public may put aside their concerns about the moral acceptability of particular technology if they believe it is being pursued in the public interest. But on the other hand, their views are likely to change if they believe that profit is paramount.

To some extent at least, the ability of a biomedical company to be profitable depends on the value of its intellectual property, particularly its patents. Patents provide their owners with a temporary monopoly, a period of time during which they have exclusive rights to make, use and sell their inventions. Patent owners profit from their patents by including a royalty component in the price of products developed using the patented invention, or selling the patent or licensing their rights over the patented invention to others, facilitating the collection of licence fees and royalties. One might predict that public views on patenting and commercialisation of biomedical inventions may be skewed to the negative because of the dominant profit focus, leaving aside the complex moral issues associated with 'patenting life'. There is limited evidence on the views of the public about patenting of biomedical inventions. What evidence there is suggests that there is a level of discomfort, although it is not completely clear what is driving this discomfort.⁴ It is tentatively suggested here that that public trust in public sector biomedical research is likely to be negatively affected if the public is provided with information about the involvement of the private sector in public sector research and the extent to which the public sector is involved in patenting of biomedical inventions, irrespective of whether these views arise from concerns about the profit motive or about more deep seated moral concerns about patenting of genes, stem cells and other foundational research results.

The third premise is that private sector involvement in biomedical research is essential to the success of the research endeavour. The biomedical biotechnology industry is largely

³ C Critchley, 'Public Opinion and Trust in Scientists: the Role of the Research Context, and the Perceived Motivation of Stem Cell Researchers' *Public Understanding of Science* in press.

⁴ For a brief review 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

formed around pre-product development research.⁵ Information presented at this symposium and elsewhere illustrates that the dividing line between public and private sector biomedical research is becoming more and more illusory. Public sector organizations are increasingly being encouraged to undertake research with economic benefit, to secure their intellectual property through patents and trade secrecy and to transfer their technology to industry. Private sector biotechnology companies are seen to be clustering around public sector research organizations. Collaborations, partnerships and funding arrangements are common in this area. Arrangements providing for ownership and licensing of intellectual property rights are commonplace. Companies are being spun out off public research organizations, taking with them researchers and research materials and results. Commercialisation and patenting are becoming the new norms in public sector research. One can only assume that the public is generally unaware of these close ties with the private sector, for why else would there be such a divergence of public opinion with regard to public and private sector researchers? If the true nature of the close relationship between the public and private sector in biomedicine became common knowledge, it is not unreasonable to suppose that the public could form the view that profit outweighs benevolence in the public sector as well as the private sector. It seems logical to suppose that as a result there could be a crisis of public trust in biomedical research as a whole.

The fourth premise is that public access to new healthcare developments also requires private sector involvement. If the benefits of biomedical research are to be realised in the form of new diagnostics, drugs and therapies, it is necessary to engage the private sector because here lies the necessary skills to develop raw research results and transform them into marketable products. The road from initial discovery to products on the shelf is long and tortuous for most drugs and therapies, although not so difficult for diagnostics. Public sector organizations generally do not have the expertise or facilities to enter into product development, nor should they because this is not part of their mission. There are exceptional circumstances where the public sector could take a more proactive role in

⁵ R Eisenberg and R Nelson 'Public vs. Proprietary Science: a Fruitful Tension?' (2002) 77 *Academic Medicine* 1392

product development (the development of drugs for treating tropical diseases is one example). But for the most part, engagement with the private sector is crucial. It is unlikely that the public would disagree with this conclusion, provided that the rationale is properly explained.

The fifth premise is that the survival of companies in the biomedical sector is dependent on their patents. Private sector organizations have obligations to their funders, employees and shareholders as well as the public. Profit is part of their *raison d'être*. Yet biotechnology companies struggle to survive. Attracting sufficient venture capital to allow for development of products or value adding for licensing on to other companies downstream in the product pipeline is fraught with difficulties. The generally accepted view is that good patents and clean title are crucial and that patent rights should be pursued with some vigour. Yet in the drive to patent and to profit, the pathway to developing new healthcare products could be blocked. This will particularly be the case if the owners of important patents take too aggressive an approach in exercising their rights, or if there are simply too many rights holders in a particular area. In such circumstances, potential new products may be lost because promising lines of research are abandoned, or their entry onto the market may be unnecessarily delayed, or they may end up being too costly to be of real benefit to society as a whole, or they may not be of the best possible quality.

So, we have a number of paradoxes. In the area of biomedicine, public trust is important, and the public tends to have lower trust of the private sector than the public sector, in no small part because of the profit motive. Yet aside from the obvious benefits in furthering scientific knowledge, the public is only likely to benefit from biomedical research if the private sector is involved in product development. But it does not necessarily follow that the best products from the public benefit perspective will be developed, particularly if the drive is to profit at all costs. How might these paradoxes be reconciled?

The aim of this paper is to discuss possible solutions from the patent perspective. First, it is necessary to explore whether or not biomedical patents do in fact have a negative

impact on innovation, blocking or delaying the development of the best possible healthcare products. Secondly, other consequences of biomedical patents will be discussed. Some of the various strategies for improving the relationship between patents and product development will then be considered, focusing on both the legal and industry perspectives. Finally, the theme of public trust will be revisited and a suggestion will be made for more actively engaging the public in the process of biomedical research and development.

Biomedical patents and innovation

This paper does not seek to enter into the debate about the legality of patenting of genes and other fundamental research tools in biomedicine. The legal position is that a product like a gene sequence or protein that has been isolated from nature and synthetically produced in the laboratory is likely to be patentable provided that it fulfils the essential patent criteria of novelty, inventive step and industrial applicability.⁶ Thousands of gene patents have been granted and many more are awaiting examination. Similarly, patents can be granted for newly developed methods, materials and equipment (collectively referred to as research tools) in biomedical research.

Research tools can be defined as the technological developments that enable particular lines of research to be pursued, but of themselves may have no direct therapeutic or diagnostic application.⁷ Gene sequences can be powerful tools in biomedical research and product development because they have wide ranging applications. A major review of gene patenting published by the UK-based Nuffield Council on Bioethics identified four different uses of gene sequence information: in diagnostic testing, as research tools, in gene therapy and in the production of therapeutic proteins.⁸ Other important research tools include recombinant DNA technology, the polymerase chain reaction and taq

⁶ For a useful summary of the relevant law see Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (London: Nuffield Council; 2002) at 47-64 (the Nuffield Discussion Paper) at 21-36. See also D Nicol, 'On the Legality of Gene Patents' (2005) 29 *Melbourne University Law Review* 809.

⁷ Nuffield Discussion Paper, above n6 at 56.

⁸ Nuffield Discussion Paper, above n6 at 47-64.

polymerase, which is the enzyme used in the reaction, embryonic stem cell technology, intron sequence analysis, and various others.⁹ These research tools are often referred to as foundational because they allow whole areas of research to be developed. When these fundamental research tools are patented their owners have powerful rights and the financial returns can be lucrative. The best and most cited example of this is recombinant DNA technology, which has been described as ‘arguably the defining technique of modern molecular biology’ and ‘the founding technology of the biotechnology industry’.¹⁰ At the same time, the patents claiming the technology are described as ‘the most successful patent[s] in university licensing’ with returns of US\$139 million by 1995.¹¹

It is probably safe to say that the availability of these foundational patents has some positive effects on innovation. For example, possession of such intellectual property rights can assist small start-up biotechnology companies in attracting investment.¹² However, foundational patents could also stifle innovation if they are used in such a way as to block off whole areas of research.¹³ Hence, in this area the patent monopoly could be too great a reward for the holder, too great an impediment for the rest of the industry and too great a cost for the consumer to bear. The impact could be detrimental, not just in terms of innovation, but also from the perspective of other public interests like access to health care and freedom of scientific research. We need to know whether there are accepted norms of behaviour in this area and what can be done with rogue players who don’t do the right thing, who use their patents in a way that can have a powerful negative impact.

The risks associated with patenting of foundational biomedical inventions have been discussed by a number of commentators. One concern is that such broad patents could

⁹ See, for example, National Research Council (NRC), *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington DC: National Academy of Sciences, 1997) (the NRC Report).

¹⁰ NRC Report above n9 at 40.

¹¹ NRC Report above n9 at 40-41.

¹² See, for example, OECD, *Patents and Innovation: Trends and Policy Changes* (OECD; 2004) at 22, available on the OECD website at <http://www.oecd.org> (last accessed 3 March 2004) (the OECD Report) at 5 and 22.

¹³ See the OECD Report, above n12 at 9.

block other research if the owners vigorously enforce their exclusive rights to work the patent. They may do this by refusing to enter into licensing negotiations. But licensing can still be blocking if the costs of negotiation are expensive, if there are restrictive terms in the license, or if the royalties or license fees are posed at too high a level. In effect this can amount to a constructive refusal to license.

Another concern is that even if it is possible to get permission to work in the patented area, innovation can be deterred if there are simply too many patents. The potential for such a situation to arise was eloquently discussed by Michael Heller and Rebecca Eisenberg in 1998; they claim that a tragedy of the anticommons could arise in biomedicine.¹⁴ A tragedy of the commons can occur when too many owners each have a privilege to use a resource and no one has the right to exclude.¹⁵ What Michael Heller and Rebecca Eisenberg posit is the reverse of this, the anticommons, where there is under-use of scarce resources because too many owners can block each other. Their basic argument is that the creation of too many concurrent fragments of intellectual property rights in future products leads to too many tollbooths on the road to product development. Too many licenses have to be negotiated and too many promises of reach-through rights have to be made. They say the existence of an anticommons in biomedical research is inevitable because there are so many property rights on the road to product development. One of the consequences of an anticommons situation could be project abandonment: researchers will redirect their research out of areas that might be particularly promising into other areas because it is too hard to get access.

It is important in assessing the likely success of the biomedical sector of the biotechnology industry in the future to know whether or not these theoretical concerns are actually occurring in practice. Are there blocking patents? Do people routinely restrict access? And are there multiple patents on the road to product development such that people cannot develop their technology? The evidence suggests while it may well be the case that multiple broad patents have been issued in biomedicine, this does not appear to

¹⁴ M Heller and R Eisenberg 'Can Patents Deter Innovation? The Anti-commons in Bio-medical Research' (1998) 280 *Science* 698

¹⁵ G Hardin, 'The Tragedy of the Commons' (1968) 162 *Science* 1243.

have resulted in an anticommons. In particular, the work of John Walsh and his colleagues in the US suggest that while the preconditions for an anticommons may well exist, the industry as a whole is finding ways of working around the problem.¹⁶ My research in Australia and other research in Europe supports these findings.¹⁷ These studies consistently report prolific licensing activity. Industry players are able to license out their own technology or license in the technology they need to secure freedom to operate. It is common, in fact pretty much the norm, to see non-exclusive licensing of foundational research tools. This makes good sense: when a key research tool has been patented the most profitable way of transferring the technology will generally be to non-exclusively license it, as demonstrated by the recombinant DNA story. Other options include inventing around problematic areas, or simply ignoring patents. The patent holder is responsible for policing their own patent, and unless they have mechanisms in place to assiduously check for who is using their technology, it is likely that many bench users of research tools will be undetected. One final option is challenging patents that have a high likelihood of being invalid.

Other consequences of patenting biomedical inventions

The empirical data discussed above seems not to support the hypothesis that patenting of biomedical inventions necessarily has a negative impact on innovation and development of new healthcare products. But does this mean that the impact is entirely positive? There are a number of ways that biomedical patents have the potential to impact negatively in this area.

¹⁶ JP Walsh, A Arora and WM Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds.), *Patents in the Knowledge-Based Economy* (Washington: National Academies Press, 2003) at 287, available at:

<http://books.nap.edu/books/0309086361/html/285.html#pagetop> (also see Walsh et al, 'Working Through the Patent Problem' (2003) 299 *Science* 1021).

¹⁷ 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), available at: <http://www.ipria.org/publications/reports.html> (also see Nicol and Nielsen, 'Australian Medical Biotechnology: Navigating a Complex Patent Landscape' (2005) *European Intellectual Property Review* 313); J Straus, H Holzapfel and M Lindenmeir, *Empirical Survey on Genetic Invention and Patent Law*, (Munich: 2002) (copy on file with the author); 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) available at: http://www.dti.gov.uk/5397_DTIPatentStudy.pdf.

First, in the public sector research arena, it has already been mentioned that fundamental changes have been occurring over the last three or four decades to culture of science. Researchers now have to tailor their research proposals to be more outcome-driven than in the past and have to consider the commercial application of their research. In some respects this is a good thing: research that has practical outcomes should be encouraged. However, this neglects the importance of chance research findings. Not all research should be purely outcome-driven. Patent requirements are also changing the way that research findings are reported. The new culture of commercialization and patenting inevitably brings with it a movement from an open research culture to a closed culture, where the paradigm of collegiality changes to one of secrecy.¹⁸ There are also other more practical problems created by this commercialization drive. Research organizations have had to enter into the commercial market in terms of dealing with their own intellectual property. Thousands of dollars are spent on running technology transfer offices, but the returns are often small and the time frames are long.¹⁹

Traditionally, public sector research organizations have not been pursued for patent infringement, either because they are legally protected or because it is considered to be an inappropriate business strategy from the public relations perspective. In the new commercialised research environment, however, these legal and practical protections become less tenable. In theory, research organizations should be facing increasing demands to enter into licensing arrangements with patent holders. However, further empirical research by John Walsh and his colleagues suggests that in the US at least patent licensing is actually having a minimal impact on the public sector.²⁰ They found that enforcement of patents against public sector researchers is still rare, and for the most part these researchers are, to a large extent, ignoring the risk of patent infringement. Hence, it would appear that the requirement that public sector researchers have to enter into licensing agreements is not the norm at present.

¹⁸ See Chalmers and Nicol, above n1 at 121-123.

¹⁹ Y Benkler, 'Commons-based Strategies and the Problem of Patents' (2004) 305 *Science* 1110 at 1110-1111.

²⁰ JP Walsh, C Cho and WM Cohen 'View from the Bench: Patents and Material Transfers' (2005) 309 *Science* 2002.

The results of the Walsh study are interesting, particularly from the US perspective. Following the decision in *Madey v Duke University*²¹ it appears that the law in that jurisdiction will offer very limited protections to researchers from patent infringement actions. The court in *Madey* refused to protect any conduct that is ‘in keeping with the alleged infringer's legitimate business, regardless of commercial implications’.²² Consequently, Duke University was liable because use of a patented invention in a research project was held to further the University’s legitimate business objectives. In Australia it is even less clear what sort of protection researchers have.

Although Walsh’s study suggests that licensing is having minimal impact, it also indicates that researchers are finding it increasingly difficult to get access to materials. In the past one of the routine practices in science was sharing research materials with colleagues. This practice is becoming increasingly formalised: researchers are asked to enter into complex materials transfer agreements that set out the terms for the transfer. There is also evidence from outside the US that some patent holders are requiring research organizations to enter into research licenses.²³ Hence, whilst there is only limited evidence of detrimental consequences of patenting of biomedical inventions for the public research sector, it is sufficient to make us stop to reflect on the adequacy and appropriateness of current laws and practices.

Problems can also arise from the innovation perspective. Even though we can’t say that there is a clear anticommons at present, the industry could still face challenges resulting from a complex web of broad foundational patents. Perspectives will change, depending on where the player is situated in the stream from upstream research to the downstream product development. Those in the middle are likely to encounter some of the most difficult problems because they have to license in technology from more upstream players and on-license their own technology. They have the cost of maintaining patents

²¹ 307 F 3d 1351 (Fed Cir, 2002).

²² *Ibid* at 1362.

²³ D Nicol ‘Balancing Innovation and Access to Healthcare through the Patent System - An Australian Perspective’ (2005) 8 *Community Genetics* 228.

and they have to make sure that their technology is clean, or, in other words, that they have freedom to operate. The face inevitable transaction costs, which are difficult to accurately calculate. It is also difficult to accurately assess how often projects are simply abandoned because the landscape is too cluttered or because a single patent holder holds out, making unrealistic demands in terms of licensing. As such, there are inevitable problems in terms of the impact on innovation, although we have no clear idea of exactly how much, or how high the detriment is.

There is more compelling evidence of negative impact in terms of access to health care through US research from a group led by Jon Merz and Mildred Cho. One of their research projects examined the availability of genetic testing for haemochromatosis.²⁴ Haemochromatosis is a fairly pernicious disease causing increased accumulation of iron in the blood and taken to its natural course it leads to organ failure and various other problems. Tests are available for haemochromatosis in the US but the Merz and Cho study found that enforcement of the patent rights actually caused a number of diagnostic facilities to stop offering those tests. Other research indicates more widespread adverse consequences of patent enforcement in terms of availability of genetic tests.²⁵ My own work provides no such compelling evidence from the Australian perspective, but widespread concern within the genetic testing community.²⁶ It would appear that the concern expressed by this community, in common with that of other similar groups around the world, has largely been generated by the actions of Myriad Genetics in enforcing its patents related to breast cancer susceptibility testing.²⁷ These and similar actions by other patent holders have attracted considerable attention in the popular press,

²⁴ J Merz, A Kriss, D Leonard, and M Cho, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577.

²⁵ MK Cho, S Illangasekare, MA Weaver DGB Leonard and JF Merz, 'Effect of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

²⁶ Nicol and Nielsen, above n17 at 198-201.

²⁷ Nicol and Nielsen, above n17 at 202-205. Also see J Paradise, 'European Opposition to Exclusive Control over Predictive Breast Cancer Testing and the Inherent Implications for US Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy' (2004) 59 *Food and Drug Law Journal* 133

and it is likely that as a result there has been an increase in the social unease about gene patents,²⁸ although clear empirical evidence relating to this point is lacking.

The role of law and the need for law reform

In combination, the theoretical concerns about biomedical patents, the empirical studies and the patent disputes reported in the popular press have led to a veritable deluge of policy and law reform proposals.²⁹ Relevant sources include, but are not limited to, inquiries by Australian Law Reform Commission (ALRC)³⁰ and the Canadian Biotechnology Advisory Council,³¹ a discussion paper by the Nuffield Council on Bioethics in the UK,³² numerous inquiries and reports in the US³³ and also at the international level, particularly by the OECD.³⁴ As a general rule, these inquiries and reports all tend to suggest that the existing patent system is not quite in balance as it relates to owners and users of biomedical inventions and that there needs to be change. However, it is well recognised that the balancing exercise is a complicated one and that wholesale reform of the patent system isn't going to produce the desirable outcomes. For example, the ALRC said that a nuanced approach is essential, an approach that shifts the balance but not so far that it detrimentally impacts on the developing Australian biomedical industry. There is no suggestion in any of this documentation that gene patents should be prohibited, although there have been a series of recommendations to improve the standards for examination. Rather, the main direction of proposals for law reform has been about how patents are enforced and used.

²⁸ 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.

²⁹ Ibid.

³⁰ Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health Report* 99 (2004).

³¹ Canadian Biotechnology Advisory Council, *Report: Human Genetic Materials, Intellectual Property and the Health Sector* (2006).

³² Above n6.

³³ For example, the NRC Report, above n9; SA Merrill, RC Levin and MB Myers (eds), *A Patent System for the 21st Century* (2004).

³⁴ Above n12.

The first key area where calls for clarification have been made relates to the types of uses that should be exempt from infringement actions. One argument is that any experimentation to test whether the invention does what it has claimed to do is legitimate and non-infringing. This is often referred to as *experimentation on* the invention. This is seen to be legitimate, because the patent bargain requires the owner to disclose both how to perform the invention and how the invention has utility. It should be permissible for others to test the owner's claims. But this protection would not be available for all non-commercial research. For example, research using the polymerase chain reaction would not be protected because this amounts to *experimentation with*, as opposed to experimentation on the invention. If such research were declared to be exempt from infringement, it could make research tool patents pretty well worthless. Added to this, the law reform agencies have consistently concluded that in the increasingly commercialised research environment it is simply too difficult to single out and protect non-commercial research from infringement. As a consequence, research organizations cannot rely on the law to protect them from infringement actions. On the other hand, we have seen that in practice most companies would never bother to enforce their patents against universities.

Other considerations in law reform inquiries have included closer analysis of the role of patent use without the authorisation of the patent owner. In Australia, for example, it is possible to obtain a compulsory license from the Federal Court if the patent holder isn't meeting the 'reasonable requirements of the public'.³⁵ The basis for this provision is that the patent system is designed to encourage innovation, and if the owner is not actually utilizing the invention to the full somebody else should be allowed to step in. The law reform inquiries suggest that the role of compulsory licensing in biomedical research warrants closer scrutiny. There is also provision in Australian patent law that allows for the government to use a patented invention for the services of the country or the state.³⁶ This is similar to a compulsory license and in some countries no distinction is made between the two. The ALRC concluded that the provision of healthcare could be included

³⁵ Sections 133 and 135 *Patents Act 1990* (Cth).

³⁶ Section 163 *Patents Act 1990* (Cth).

in the notion of services of the country and that Australian patent legislation should be amended to affirm this. A number of the reports also suggest that competition law should play a greater role to ensure that the patent owner does not actually go beyond the rights given in the grant of the patent.

All of these recommendations make good sense. However, two points must be made. First, from the Australian perspective, the ALRC report was tabled in 2004, but the government is yet to respond. Australia is not out of step in this regard: it would seem that there is a consistent pattern of lack of law and policy reform despite recommendations supporting change.³⁷ The second point is that even if these recommendations were to be adopted, there is some doubt as to whether they would have a real, genuine impact in terms of research, innovation and access to healthcare.

Industry initiatives

Rather than waiting for law reform, the industry itself is taking the initiative in developing strategies to facilitate research, innovation and access. The ALRC and other law reform agencies have certainly played a role in this regard because, as well as law reform, they recommended that various industry and other organizations should take a role in terms of the development of guidelines and codes of conduct. A number of top-down initiatives have emerged both as a result of these inquiries and independent of them. For example, the US National Institutes of Health (NIH) released Guidelines relating to the dissemination of biomedical research resources in 1999³⁸ and Best Practices for licensing of genomic inventions in 2005.³⁹ Together, these documents emphasise the importance of broad dissemination of genomic inventions and other foundational research tools with minimal encumbrances. The Best Practices state that:

³⁷ Caulfield et al, above n28 at 1094.

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.

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

Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community.

They go on to explain that where exclusive licensing is required, it may be possible to limit the license to a particular field (for example, use in the development of antisense molecules in therapeutic protocols), with non-exclusive licensing in other fields (for example, diagnostic testing or use as a research probe). In 2006, member countries of the OECD agreed to a set of guidelines for licensing of genetic inventions cast in similar terms.⁴⁰ A comprehensive empirical study of licensing practices by US academic institutions indicates that these policy statements reflect existing practice, particularly in the large, experienced academic institutions.⁴¹ In particular, where exclusive licenses are utilised, they tend to be restricted to particular fields of use.

Bottom up initiatives are also emerging from within the industry itself. One of these is the open access model: putting research results that might otherwise lead to patentable inventions out into the public domain. The Human Genome Project is a clear example of this. 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.⁴² GenBank is the publicly accessible repository of the sequence information produced by the HGP.⁴³ 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 is taken, for example ascribing function to a

⁴⁰ OECD, *Guidelines for the Licensing of Genetic Inventions* (2006).

⁴¹ L Pressman, R Burgess, RM Cook-Deegan, SJ McCormack, I Nami-Wok, M Soucy and L Walters, 'The Licensing of DNA Patents by US Academic Institutions: an Empirical Study' (2006) 24 *Nature Biotechnology* 31.

⁴² '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 D.R. Bentley, 'Genomic Sequence Information Should Be Released Immediately and Freely in the Public Domain' (1996) 274 *Science* 533.

⁴³ Available at: <http://www.ncbi.nlm.nih.gov/>.

particular gene sequence. 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.⁴⁴

One of the problems with putting material into the public domain is that control is lost and the risk of capture is high. This is the risk that someone will use this information and claim intellectual property rights in such a way that they close off whole areas of use of the material. It could be argued that intellectual property rights are needed to stop capture, in much the same way that the Open Source Initiative uses copyright as a tool to protect user rights. A series of collective rights initiatives are emerging in the biotechnology industry, dealing with issues relating research, innovation and access to healthcare, which are premised on possession of valid patents. To date, most of the commentary on such arrangements has focused on patent pooling and cross licensing. These arrangements enable the consolidation of patent rights so that negotiating licenses is streamlined and transaction costs are consequently reduced. The use of clearinghouse mechanisms is also being explored as a means of reducing the transaction costs in licensing-out and accessing biomedical patents, particularly licensing of research tools between research organizations. 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.⁴⁵ Clearinghouses are already being established. In the US, 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.⁴⁶ There have been calls for the role of clearinghouse mechanisms to be

⁴⁴ Single nucleotide polymorphisms ('SNPs') are changes to single letters of the DNA code which can be used to map patterns of human variation across the globe. 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) at: http://www.wellcome.ac.uk/doc_WTD003500.html.

⁴⁵ G Graff and D Zilberman 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 3 *Intellectual Property Strategy Today* 1.

⁴⁶ R Atkinson *et al*, 'Public Sector Collaboration for Agricultural IP Management' (2003) 301 *Science* 174

examined more fully in relation to licensing of biotechnology patents in general⁴⁷ and specifically in relation to licensing of gene patents for clinical diagnosis.⁴⁸ Open source style initiatives are also cropping up in biotechnology. CAMBIA is an organization based in Australia that has set up the BIOS Initiative, the aim of which is to create a quasi-open source licensing regime in agricultural biotechnology.⁴⁹

Admittedly, these are isolated examples within an industry where the exclusive rights model and the so-called ‘bunker mentality’ prevails.⁵⁰ Nevertheless, they do signal a shift within the industry to consider more cooperative mechanisms for intellectual property management. It is interesting to note that the majority of these initiatives are emerging in the agricultural sector of the biotechnology industry. It is uncertain whether the landscape is sufficiently similar in biomedicine for direct translation of these models into that sector. I am currently undertaking a project with colleagues at the Australian National University, which will include an analysis of this particular issue.⁵¹ Others are also focusing their attention on such issues in other jurisdictions,⁵² and the OECD is also carrying out related work.⁵³

Public trust

These initiatives that are being established by the biotechnology industry itself to facilitate intellectual property exchange would seem to be positive steps with regard to research, innovation and access to healthcare. However, one problem with them from the public’s perspective is that they could still be seen as clubs for players who have a commercial interest, who are still aiming to protect their interest rather than considering

⁴⁷ OECD, *Patents and Innovation: Trends and Policy Changes* (Paris: OECD; 2004) at 2.

⁴⁸ 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, E Van Zimmern, B Verbeure and G Matthijs, ‘Models for Facilitating Access to Patents on Genetic Inventions’ (2006) 7 *Nature Review Genetics* 143.

⁴⁹ For further information see CAMBIA: <http://www.cambia.org/daisy/cambia/home.html>

⁵⁰ D Nicol and J Hope ‘Cooperative Strategies for Facilitating Use of Patented Inventions in Biotechnology’ (2006) 24 *Law in Context* 85,

⁵¹ *Ibid.*

⁵² See, for example, Van Overwalle et al, above n48.

⁵³ OECD, *Compendium of OECD Activities on IPR Interim Edition* (2006) at 2.

the public benefit. These public concerns are likely to be exacerbated if the regulators of the patent system are seen as being captured by the industry. Patent offices are the regulators we are talking about here: they have the task of examining patent applications, requiring modifications where necessary and deciding whether to grant or refuse. If their examination practices are seen as being too lenient then the perception of capture is likely to be high. Criticisms of examination practices are often raised in the academic literature, and in the late 1980s and early 1990s it was probably fair to say that the bar for gene related patents was quite low. However, since then, the bar has been significantly raised in a number of jurisdictions as a result of modification of examination guidelines and judicial decisions. A recent empirical study suggests that, as a result of these developments, there has been an increased stringency in examination practices in the last few years.⁵⁴ Such findings should have a flow on effect in terms of public trust in the patent examination process.

Levels of public trust and mistrust are not constant across the various areas of biotechnology. Research relating to genetic modification of crops, for example, suffers from a greater level of mistrust than biomedicine.⁵⁵ Public mistrust may be particularly problematic in some of the more controversial areas of biomedicine and as a consequence special attention needs to be paid to the types of mechanisms that should be put into place to alleviate public concerns in these areas. In the area of human genetic databanking, in particular, much of the success of the research drive is predicated on voluntary supply of tissue and medical records and public trust is vital. As a general rule, payment for participation is not considered to be a serious option, because of long-standing concerns about the commodification of human tissue. Some commentators have argued that there is no fundamental ethical barrier to paying participants a fair price for use their material,⁵⁶ but the view that they should be paid is not widely supported at the present time. In the

⁵⁴ MM Hopkins, S Mahadi, P Patel and SM Thomas, 'DNA Patenting: the End of an Era?' (2007) 25 *Nature Biotechnology* 185.

⁵⁵ See, for example, G Gaskell et al, *Europeans and Biotechnology in 2005: Patterns and Trends. Final Report on Eurobarometer 64.3* (European Commission's Directorate-General for Research; July 2006); Eureka Strategic Research, *Community Attitudes to Biotechnology* (Eureka Project 4001 prepared for Biotechnology Australia; June 2007); Australian Centre for Emerging Technologies and Society, *Swinburne National Technology and Society Monitor 2006* (Swinburne University of Technology; 2006).

⁵⁶ For example, see Corrigan, this volume.

alternative, benefit sharing is being mooted as an ethically appropriate means of balancing the conflicting interests involved in human genetic databanking and as a means of promoting public trust.⁵⁷ However, the notion of benefit sharing does not readily fit within traditional policies for intellectual property management and exchange.

The incorporation of benefit sharing provisions in intellectual property policies of databanks like UK Biobank and others would provide an explicit acknowledgment of the vital role that members of the public play in such research endeavours. It could be argued that such provisions are not necessary, because the promise of new healthcare developments is sufficient to satisfy any obligation to provide benefits to participants in biomedical research. Indeed this is the argument that is put forward to support the lack of explicit benefit sharing provisions in the UK Biobank Draft Access and IP Policy. However, this may not be sufficient to protect public trust and encourage participation. If researchers and databank operators try to satisfy obligations to provide for benefit sharing by means of trite statements of future possibilities, then rather than promoting trust, they could further erode it. This is not to say that the only benefit that should be considered is financial benefit. The umbrella of benefit sharing could also include more indirect benefits, such as preferential access to new healthcare developments, as well as genuine efforts to fully disclose all relevant information, particularly information about the process of commercialisation, and to explicitly recognise the input that participants have made. Now is an opportune time for all parties engaged in databanking to seriously consider how to implement appropriate benefit sharing arrangements. Benefit sharing should not be seen as a threat to the commercial success of the endeavour but as an important component in its success. In order to further facilitate public trust, the process of developing appropriate benefit sharing arrangements must incorporate the principles of transparency and consultation. Public involvement in the governance of human genetic databanks may also be appropriate.

⁵⁷ D Nicol 'Public Trust, Intellectual Property and Human Genetic Databanks: the Need to Take Benefit Sharing Seriously' (2006) 3 *Journal of International Biotechnology Law* 89.

Embryonic stem cell technology is one of the other controversial areas of biomedicine. The public in Australia and elsewhere, both through their representatives and directly, have supported the passage of legislation allowing this technology to be undertaken. They have put their trust in the researchers and developers of the technology. Maintenance of this trust will require transparency at the very least, but it may require more direct public involvement in the research and commercial development of the technology. For this reason, a group of us have suggested that the patent pool model discussed in the last section could be expanded as a means of preserving public confidence.⁵⁸ Under this proposal, the pool would have an independent governance body charged with promoting the public good in its decision-making about access and licensing. It is proposed that all decisions of this body would be open to public scrutiny and it would be required to balance the necessity of industry involvement, the interests of researchers, ethical issues, and the desire to keep licensing terms reasonable to ensure that the public has access to valuable technologies.⁵⁹ This proposal is in the early stage of formulation and comments are invited. It may be that such a structure would be unworkable in the commercial biomedical environment. But, in such an important area of technology, strategies such as this, which focus on the intersection between innovation and public trust, warrant further debate.

Conclusion

In the final analysis we can see is that the process of technology transfer in biomedicine can be exceedingly complex. There is a risk of blocking by the owners of foundational patents and the increasing complexity of the patent landscape is adding to the risk that the process of innovation will slow. There are additional consequences in terms of restrictions on freedom of research and delays in access to new healthcare developments. But in fact, evidence that these issues are emerging is mixed.

⁵⁸ Caulfield et al 'Trust, Patents, and Public Perceptions' above n4.

⁵⁹ Ibid.

It is vitally important to achieve an appropriate balance between the negative and the positive outcomes of patenting of foundational biomedical inventions. Such patents are necessary, but they must be used properly. Open access is appropriate in some areas but not all. The law can provide some redress against rogue patent owners, but it is a blunt tool. Initiatives coming from the industry itself are likely to provide more nuanced and balanced approaches, but a major hurdle may be motivating the industry as a whole to act. There will be no one mechanism for achieving the right balance in terms of freedom of research, innovation and access to healthcare. Public trust and public consultation are factors that should play key roles in any of these mechanisms.

The next five or so years will be interesting in observing the extent to which the biomedical industry is willing to work cooperatively for its own commercial good but also for the greater public good. During this time, it will be necessary to collect further evidence of industry experiences relating to patenting and other commercialisation strategies and industry attitudes towards the cooperative models discussed above. It would also be helpful to test the economic viability of some of these models. Just as importantly, data should be collected on public attitudes towards patenting and commercialisation in biomedicine and public views on appropriate of benefit sharing and public consultation models aimed at fostering and maintaining public trust.