

# *The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development*

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## **1. Introduction**

Biotechnology has the capacity to profoundly influence medical practice and human health. Prospects include designer drugs tailored to an individual's unique genetic profile, one stop diagnostic testing and genetic profiling, and modification of the genome by gene therapy.<sup>1</sup> However, despite the publicity associated with the completion of the first draft of the human genome sequence, a great deal more research and development is required if these prospects are ever to become realities. The process of discovery, testing and conducting clinical trials that is required for any new drug, diagnostic or therapy is expensive and time consuming. Where biotechnology processes are used there is the prospect that costs will be significantly reduced in the long term. It is likely, however, that in the short term costs will be compounded given the complexity of the human genome and the early stage of the research effort. Yet the rewards are likely to be great, both in social welfare and economic terms.

The biotechnology industry has made major contributions to new and improved technologies in the areas of agriculture and medicine. It has become much more willing to participate in and sponsor the primary research phase in the development of new genetic technologies, whereas in the past private sector involvement tended to be restricted to the commercialisation of research undertaken in the public sector. This increase in collaboration between the public and private sector and increase in funding of primary research has been largely responsible for the success of the Human Genome Project and other ventures being undertaken in parallel with it.

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1 See, for example, Kathryn Brown, 'The Human Genome Business Today' (2000) *Scientific American* (July) 40.

The international biotechnology industry is undergoing massive growth.<sup>2</sup> The industry in the United States of America is well established, and is developing rapidly in Europe, Canada and Japan. A number of trends in the international industry are apparent, most notably a preponderance of alliance and merger activity between companies and sharing of intellectual property rights (IPRs).<sup>3</sup> This trend reflects the highly research intensive nature of the operations of biotechnology companies.

Australia has a proud record in medical and agricultural biotechnology research and has a well established agricultural biotechnology industry. Medical biotechnology in Australia is moving into a newly industrialised phase, and companies face a number of hurdles.<sup>4</sup> Both the state and federal governments in Australia have shown strong support for the biotechnology industry, mainly in terms of assistance in providing capital and infrastructure. The Federal Government has stated its vision for biotechnology as: '[c]onsistent with safeguarding human health and ensuring environment protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment'.<sup>5</sup> It has implemented a number of initiatives aimed at assisting the development of the Australian biotechnology industry.<sup>6</sup>

The regimes protecting IPRs may prove to be a significant barrier for the development of the Australian industry. The patent regime is particularly important. Patenting is vital to the pharmaceutical and medical biotechnology industries because of the costs and long lead time between the discovery of a new drug, diagnostic or therapy and the acquisition of marketing approval (estimated to take around 12 years for most pharmaceuticals).<sup>7</sup>

There is no doubt that an effective patent system is crucial to the biotechnology industry in order to reward and encourage innovation. However, it is becoming apparent that the same regime may hinder the research efforts of Australian

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2 See Panos 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) at 44–53.

3 For example, in a recent deal, Orchid and AstraZeneca formed a three-year collaboration to conduct studies into a number of genetic diseases; a summary of the deal, reported on 13 February, is provided at: <<http://www.genomeweb.com/articles/view-article.asp?Article=200121395916>> (16 February 2001).

4 These include financing innovation, obtaining expertise in management, regulatory constraints and policies, marketing products and penetrating international markets.

5 Biotechnology Australia, *Australian Biotechnology: A National Strategy* (Canberra: AGPS, 2000) at 7 (hereinafter the *National Strategy*).

6 See the *National Strategy*, id; Biotechnology Australia, *Developing Australia's Biotechnology Future: Discussion Paper* (Canberra: AGPS, 1999); Health and Medical Research Strategic Review, *The Virtuous Cycle: Working Together for Health and Medical Research: Final Report* (Canberra: AGPS, 1999) (hereinafter the *Wills Review*); Commonwealth of Australia, *Review of Business Taxation: A Tax System Redesign: Final Report* (Canberra: AGPS, 1999).

7 For example, in a US study in 1990, the average cost of producing a new drug was \$US230 million; cited in P A Power, 'Interaction Between Biotechnology and the Patent System' (1992) 3 *AIPJ* 214 at 220.

companies by restricting access to essential research tools and technologies. This problem has been generally acknowledged by the US Patent and Trademark Office,<sup>8</sup> but little work has been done in the Australian context to determine its extent.

Increasingly, broad patent rights are being sought by both public and private institutions to protect their research results.<sup>9</sup> If broad patents are used to deny access to essential research tools and technologies, this will directly impact on the health care sector and consumers because many products may never be developed. If companies are able to negotiate access to these essential requirements, prohibitive licence fees and strict licence terms will have a flow-on effect on the price of products passed on to consumers. Unless a proper legal framework is in place, the great promises offered by medical biotechnology may never be achievable, or may be so expensive that they are only available to a small and exclusive sector of the Australian population.

The establishment of a proper legal framework will be challenging because of a number of levels of complexity surrounding the issue. The density of the science of genetics is matched by equal depth in the structure of the biotechnology industry. The rules and regulations governing the environment in which that industry operates add a further compounding layer. As a first step, it is necessary to map these layers of complexity in order to establish a foundation upon which an assessment can be made of legal issues needing further examination. The particular focus of this article is an examination of the existing legal framework surrounding the grant of patents and whether it is adequate to overcome problems brought about by broad patent claims. The article further considers the necessity of expanding the field of inquiry by analysing ways in which the use of patents can be regulated both through the existing framework, and through competition law.

Part 2 of this article considers recent and future scientific developments in biotechnology. Part 3 analyses what factors determine the structure of the biotechnology industry in Australia and internationally. This paper concentrates on the medical biotechnology industry. Although many of the statistics presented do not distinguish between medical, agricultural and other forms of biotechnology, the medical component of the industry is significant, and therefore trends in the industry as a whole are presumed to reflect trends in this component.<sup>10</sup> Part 4 examines the growth of medical biotechnology patent activity and discusses the implications of this regulatory framework for the development of the biotechnology industry, particularly in a small market like Australia. Part 5 discusses the legal issues associated with the granting and use of biotechnology patents.

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8 US Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) at 8.

9 See Michael Heller & Rebecca Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

10 Human health therapeutics comprise approximately 42 per cent of biotechnology assets worldwide; above n2 at 45.

## 2. *Advances in Genetic Technology*

### A. *The Human Genome Project*

The Human Genome Project officially commenced in 1990<sup>11</sup> and in 1996 an international public sequencing consortium<sup>12</sup> was established to complete the sequencing. In parallel, companies in the private sector also invested significant funds in genome sequencing. In particular, Perkins Elmer funded sequencing efforts by scientists at Celera Genomics led by Dr Craig Venter. Dr Venter developed an innovative 'shotgun' technique, which enables rapid sequencing of the human genome.<sup>13</sup>

In June 2000 a joint announcement was made by the public sequencing consortium and Celera Genomics that a rough draft of the entire human genome had been completed. In February 2001 articles detailing the sequences were published by the public sequencing consortium and the Venter team in *Nature*<sup>14</sup> and *Science*,<sup>15</sup> respectively. It is currently estimated that the sequencing effort will be completed by 2003, at the latest.

Despite this apparent unanimity, the sequencing effort has been marred by tensions between the public and private sectors, principally associated with access to information.<sup>16</sup> One of the key features of the public sequencing effort has been the rapid release of sequence information. The public sequencing consortium pledged in 1996 in the Bermuda Declaration that primary genomic sequences should remain in the public domain and should be rapidly released.<sup>17</sup> The consortium honoured that pledge, releasing sequence information online within 24 hours of its production.<sup>18</sup>

The private sequencing effort, on the other hand, is characterised by the protection of sequence information through IPRs, in the form of patents and data protection. Although sequence information is freely available through the public sequencing effort, private sequencers are predicting that they will make large profits out of licensing their patents and making their databases available to

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11 A history of the Human Genome Project is provided by the United States National Human Genome Research Institute: <<http://www.nhgri.nih.gov/HGP/>> (26 February 2001).

12 The International Nucleotide Sequence Database Collaboration: see <<http://www.ncbi.nlm.nih.gov/collab/>> (26 February 2001).

13 For an explanation of the sequencing strategies used by the Public Sequencing Consortium and Celera, see above n1 at 42.

14 (2001) 409 (6822) *Nature* (multiple articles).

15 (2001) 291 *Science* (multiple articles).

16 This is in effect a microcosm of the whole of biotechnology as the research base moves from the public to the commercial sector.

17 See Wellcome Trust, *International Strategy Meeting Agrees Principles of Early Release for Human Genome Sequencing: Press Release* (17 April 1996).

18 Internet sites for sequence information include the NIH's GenBank site: <<http://www.ncbi.nlm.nih.gov/GenBank/index.html>> (26 February 2001); the Japanese DNA Databank: <<http://www.nig.ac.jp/>> (26 February 2001) and the European Molecular Biology Laboratory: <<http://www.ebi.ac.uk/embl/index.html>> (26 February 2001).

subscribers. The attraction of these databases is that value has been added in the form of annotations to the sequence information.

The cost of access to private databases varies widely, depending on whether the subscriber is academic or commercial. The Australian National Health and Medical Research Council, for example, reached an agreement with Celera Genomics, allowing access to Celera's human, mouse and *Drosophila* databases. Participating institutions will be required to pay an annual licence fee of \$6000.<sup>19</sup> In comparison fees for private sector usage are much higher, reportedly up to \$15 million.<sup>20</sup> Similarly, academic researchers can access patented tools and techniques more easily than their private sector counterparts. One of the reasons for this is that basic research is exempt from patent infringement in a number of jurisdictions.<sup>21</sup>

### **B. Role of the Biotechnology Industry Post-Human Genome Project**

It is generally recognised that the Human Genome Project is not an end in itself, but a starting point for further research and product development. It is anticipated that the mass of information provided through the Project will ultimately be used in the development of drugs, diagnostics and therapies to alleviate human suffering caused by disease. This new phase of research and development has been referred to as the post-genomic era.<sup>22</sup> It can be divided into four main research categories:<sup>23</sup>

- category one: structural genomics and proteomics, involving the assignment of gene sequences to particular proteins and characterisation of those proteins;
- category two: functional genomics and transcriptomics, involving the elucidation of which genes are switched on or off at particular stages of the human life cycle and the detection of variation between individuals;
- category three: targeted drug discovery and pharmacogenomics. Targeted drug discovery includes the process of identifying potential genetic targets for drugs, testing drug precursors, conferring drug related features on appropriate precursors and conducting safety and efficacy tests. Pharmacogenomics has been defined as '... the study of how genetic differences influence the variability in patients' responses to drugs'.<sup>24</sup> The perceived need for this technology comes from the knowledge that most drugs only provide an appropriate outcome to a low percentage of those

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19 Reported in *Today's Life Science* (July/August 2000) at 6.

20 See, for example, 'Celera Announces Three New Academic Subscribers to its Database' *GenomeWeb News* 18 October 2000: <<http://www.genomeweb.com/articles/view.asp?Article=2000101813273>> (19 October 2000).

21 See, for example, *Roche Products Inc v Bolar Pharmaceutical Co* 733 F 2d (1984).

22 See, for example, Ognjenka Vukmirovic & Shirley Tilghman, 'Exploring Genome Space' (2000) 405 (6788) *Nature* 820 at 821.

23 Alexander Julian, 'Genomics Primer' *BioSpace.com* 20 July 2000: <[www.biospace.com/articles/genomics.primier.print.cfm](http://www.biospace.com/articles/genomics.primier.print.cfm)> (5 October 2000).

24 Allen Roses, 'Pharmacogenetics and the Practice of Medicine' (2000) 405 (6788) *Nature* 857 at 857.

people to whom they are prescribed.<sup>25</sup> Pharmacogenomics will enable accurate predictions to be made about the safety and efficacy of particular drugs for individual patients;

- category four: enabling technology. The three research categories listed above can only proceed against a back-drop of continually evolving enabling technologies. Two of these are bioinformatics and gene chip technology.

Bioinformatics has been described as ‘... the backbone computational tools and databases that support genomic and related research’.<sup>26</sup> It plays a vital role in all aspects of functional and structural genomics, proteomics, drug discovery and pharmacogenomics.<sup>27</sup>

Gene chip or microarray technology is crucial to a number of research categories, particularly transcriptome analysis. Gene chips are tiny glass chips covered with thousands of holes containing short fragments of DNA or mRNA.<sup>28</sup> The fragments bind to complementary sequences of DNA or mRNA in extracts from tissue samples spread over the chip. The leading company in the field is Affymetrix, which owns a patent on gene chip technology and the trademark GeneChip.

Biomedical research has traditionally been the province of the public sector. The emergent industry research base, driven by the promise of huge profits to be made from product development, is likely to dominate this post-genomic era. Traditionally the first and fourth categories have been the domain of public sector research, with the second lying at the traditional interface between the public and private sectors. However, private sector investment is now encroaching on all four research categories.

Privatisation requires that participants in all four categories now actively pursue their IPRs in order to provide a return for investors. One of the flow-on effects is that it is now more difficult for companies focusing on downstream research and development (categories two and three) to conduct their research unless they can negotiate access to essential research tools and technologies from upstream and enabling companies (operating in categories one and four).<sup>29</sup>

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25 Id at 858–861.

26 Jason Reed, ‘Trends in Commercial Bioinformatics’ (2000) *Oscar Gruss: Biotechnology Review* at 1: <<http://www.oscargruss.com/?/healthtech.nsf/vwSpecialReportsWeb>> (5 October 2000).

27 eBioinformatics Ltd was one of the first bioinformatics companies and was incorporated in Australia. It has now merged with Empatheon Inc, a United States company to form Entigen Corporation.

28 David Lockhart & Elizabeth Winzeler, ‘Genomics, Gene Expression and DNA Arrays’ (2000) 405 (6788) *Nature* 827.

29 Companies at the furthest upstream end of the continuum produce gene sequence data and companies at the furthest downstream end produce drugs. Many other companies fall somewhere between the two ends.

### 3. *The Structure of the Biotechnology Industry*

#### A. *The Structure of the International Biotechnology Industry*

The biotechnology industry broadly encompasses the following companies or institutions:

- Pharmaceutical companies (focusing on targeted drug discovery in category three, above);
- Core biotechnology companies (categories one to four);
- Genomic companies (category one); and
- Public research institutions (generally categories one and four).

The international industry is primarily comprised of core biotechnology companies,<sup>30</sup> which are mainly small or medium sized enterprises. A small number of large core biotechnology companies are active in the industry, as well as most of the multinational pharmaceutical companies. Although genomic companies are classified as core biotechnology companies, the focus of their business differs from that of other core biotechnology companies in that their emphasis is on sequencing and their products are research tools. In addition, public research institutions are important in the process of performing basic research and producing research tools, and providing enabling technology to core biotechnology companies.

It is becoming increasingly difficult to accurately characterise individual companies by their research interests because of a growing trend for them to expand into other categories. A notable example is the recent acquisition of Rosetta Inpharmatics Inc, a category four bioinformatics company, by Merck & Co Inc, a top tier pharmaceutical company.<sup>31</sup> Nevertheless, the research taxonomy described above provides a useful means of identifying the principal activities of companies.

Initially, core biotechnology companies were a US phenomenon, but the number in other countries is on the increase. As at mid 2000, the number of core biotechnology companies in the US remained relatively steady at 1273.<sup>32</sup> In Europe the number increased 16 per cent over the year from 2000 to early 2001, to 1570.<sup>33</sup>

The industry in the US is well established. It comprises small recently established core biotechnology companies, and longer established larger

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30 Core biotechnology companies are companies whose business is entirely or substantially biotechnology related: See Ernst & Young, *Australian Biotechnology Report* (Canberra: AGPS, 1999) at 5; *Wills Review*, above n6 at 131.

31 For details see 'Merck Acquires Rosetta Inpharmatics Inc' 11 May 2001: <<http://www.merck.com/finance/press/051101.html>> (6 June 2001).

32 Ernst & Young, *Convergence: Ernst & Young's Biotechnology Industry Report. Millenium Edition* (California: Ernst & Young LLP, 2000) at 14. Note that the number of US companies has actually decreased since this figure was obtained in 1999 due to merger activity.

33 Ernst & Young, *Integration: Ernst & Young's Eighth Annual European Life Sciences Report* (London: Ernst & Young International, 2001) (hereinafter *Integration*) at 4.

companies that have made biotechnology part of their portfolio. Research and funding institutions are an important component of the US industry.

The structure of the dominant US industry has provided a model for both the Canadian and European industries. The Canadian industry has seen a recent increase in the level of investment in biotechnology, with the result that the industry is rapidly expanding. The European industry has recently achieved a scale comparable to the industry in the US. However, approximately 90 per cent of European investment in biotechnology is still directed towards the more mature US industry.<sup>34</sup> Germany boasts the largest number of biotechnology companies, the number having risen by over 150 per cent in the past three years to nearly 350 companies.<sup>35</sup> The industry is also active in the United Kingdom, France, Sweden, Switzerland, the Netherlands, Finland, Belgium, Denmark, Italy, Ireland, Norway and Spain. The United Kingdom sector of the industry also comprises nearly 300 companies.<sup>36</sup>

The industry in Japan differs markedly from these other industry sectors. Small, core biotechnology companies do not exist in Japan. Rather, the pharmaceutical and health care related companies, and food corporations have tended to diversify into biotechnology.<sup>37</sup>

### ***B. Trends in the Structure of the International Industry***

The structure of the biotechnology industry is not static. The industry in the US, and to an increasing extent the European Union, is characterised by an increasing number of strategic alliances and mergers. Licensing agreements form the most common type of alliance,<sup>38</sup> although other forms include joint ventures, and research alliances.

Companies and institutions within the industry are involved in alliance and merger activity for a number of reasons. By far the most compelling reason is the high cost of research and development together with the increased marketing power of the allied or merged entity.<sup>39</sup> The industry as a whole is highly research oriented. Financing is difficult for most start-up biotechnology companies, and the high costs of research and development force many companies to either enter into strategic alliances with, or be acquired by, larger biotechnology companies or pharmaceutical companies. In addition, the high technical and commercial risks of product development mean that companies need to share risk and have significant product pipelines. These agreements result in the sharing of IPRs over genomic information and bioinformatics tools in return for funds for research and development. Indeed, access to IPRs may be a major factor influencing a company's decision to enter into an alliance.

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34 Above n2 at 52.

35 *Integration*, above n33 at 7; Ernst & Young, *Evolution: Ernst & Young's Seventh Annual European Life Sciences Report* (London: Ernst & Young International, 2000) (hereinafter *Evolution*) at 5.

36 Above n33 at 7.

37 Above n2 at 53.

38 *Id* at 51.

39 *Evolution*, above n35 at 32; *Integration*, above n33 at 7–8.



It would appear, in the US at least, that the nature of these strategic alliances is changing. As company executives become more aware of the value of their products, they are tending to develop products to a later stage before entering into alliances, and in some cases are insisting on retaining greater rights to royalties in licence agreements. Technology access agreements have also assumed more importance, with many pharmaceutical and biotechnology companies now obtaining non-exclusive licences to enabling technology.<sup>40</sup>

The multinational pharmaceutical companies are buying up the IPRs of core biotechnology companies, or entering into agreements allowing them access to the IPRs of smaller companies. The main reasons for this trend are considered to be a desire by pharmaceutical companies to increase their product pipelines given that many lucrative, or 'blockbuster', drug patents are about to expire, and the need to maintain revenue growth rates.<sup>41</sup> In line with this trend, a large proportion of the drug targets of many major pharmaceutical firms now come from genomic databases.

The resultant industry structure is characterised by an increasing number of large entities with a portfolio of extensive patents comprising broad, overlapping patent rights.

### **C. Factors Relevant to Market Structure**

In a comprehensive analysis of the structure of the international biopharmaceutical industry, Kanavos identified a number of determinants of market structure specific to the biopharmaceutical industry.<sup>42</sup> Kanavos also examined the trends apparent in the biopharmaceutical industry and examined how these trends impact on market structure.<sup>43</sup> Of the factors identified, industrial policy, health care reform, the issue of financing innovation, public policy research and public perceptions play a crucial role in the formation of the industry.<sup>44</sup> The biopharmaceutical industry is particularly research-intensive and is characterised by long product development lead times and relatively limited product pipelines. As such, a number of barriers to entry, unique to pharmaceuticals, impact on the structure of the industry. These include research and development costs, the ability of firms to penetrate markets, the marketing ability of firms, concentration levels, competition policy, price and product competition, and the level of integration within the industry.

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40 Above n32 at 48. An example is provided in the Report: Abgenix has licensed its technology for generating antibody product candidates to numerous biotechnology and pharmaceutical companies, notably Human Genome Sciences. Abgenix retained the right to use the technology, and at the same time has licensed the right to use technology from Human Genome Sciences.

41 *Ibid.* See also *Evolution*, above n35 at 34 for the reasons why pharmaceutical firms seek to acquire top tier biotechnology firms.

42 Above n2 at 41–129.

43 Kanavos adopted a generally mainstream approach, but used a theoretical framework which examined factors affecting structure, conduct and performance in an interrelated way. He stated (at 44) that this approach has been the approach of recent theoretical frameworks that have moved away from early mainstream empirical literature.

44 Above n2 at 106.

Barriers to entry have been recognised as being the most important determinant of market structure when examining whether a market is competitive.<sup>45</sup> The ability of companies to enter an industry is important as a means of promoting competition and improving the allocation of economic resources. Barriers to entry are perceived as being anti-competitive in that they result in fewer entries and allow incumbents to enjoy above average profitability.<sup>46</sup> The study of entry and entry barriers is thus important in determining why the structure of any particular industry has taken on a particular form.

One of the main barriers to entry facing biotechnology companies in Australia and in other sectors of the international industry is the prohibitive cost of research and development and the related barriers of financing and levels of investment.<sup>47</sup> In addition, many companies encounter problems subsequently when further funding is required, and this has resulted in the trend of alliances and mergers discussed above.

It is clear that a number of other factors may also constitute barriers to entry, including IPRs. It is well recognised that effective patent protection is crucial to this industry, primarily because biotechnology and pharmaceutical companies need to recoup substantial research and development expenditure. Kanavos points out that the effectiveness of the patent systems of various countries has had an important effect on the development of the biopharmaceutical industry in those countries.<sup>48</sup> At the same time, given the trend of the international industry toward alliances and sharing of IPRs, the net effect is likely to be the closing off of whole areas of research and development.

#### **D. The Australian Industry**

##### *(i) The Size and Composition of the Australian Industry*

Australia has a number of strengths in medical biotechnology, including world class expertise in research, geographical advantages in terms of expanding regional markets, appropriate structures to promote close cooperation between the public and private sectors and an internationally recognised clinical trial system. Despite this, development and commercialisation of scientific discovery is generally weak. One factor behind this is inadequate management and understanding of intellectual property.<sup>49</sup>

The Australian industry is a small player in the international medical biotechnology industry. Nevertheless, it is evident that the industry is in a growth

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45 See the definition of competition enunciated in *Queensland Co-operative Milling Association Ltd and Defiance Holdings Ltd* (1976) 25 FLR 169 at 188–189, and the elements of market structure which need to be examined in order to determine whether a market is competitive. This definition has been extensively quoted and is regarded as being the seminal definition of competition in Australian competition law.

46 See George Yip, *Barriers to Entry: A Corporate-Strategy Perspective* (1982) at 7.

47 See, for example, Ernst & Young and Freehills, *Australian Biotechnology Report 2001* (Canberra: AGPS, 2001) at 49; above n2.

48 Above n2 at 87–93.

49 *Wills Review*, above n6 at 12; *Biotechnology Australia*, above n6 at 24.

phase given recent increases in Australia in the number of core biotechnology companies. In 2001 the number of core biotechnology companies was estimated to be 35 listed companies and 155 private unlisted companies.<sup>50</sup> In another recent survey the number was estimated to have increased to 185.<sup>51</sup>

Most companies are of a relatively small size. There is also some representation by multinational pharmaceutical companies in Australia, such as Glaxo SmithKline, FH Faulding & Co, Novartis and Bristol Myers Squibb. Approximately 47 per cent of biotechnology companies in Australia are involved in biotechnology applications relating to human health.<sup>52</sup> Medical biotechnology companies in Australia are generally involved in functional genomics and drug discovery (categories two and three from Part 2B). Some enabling technology is provided by a small number of biotechnology companies (category four) and research institutions.

A number of Australian states and territories have exceptional research bases, and governments recognise the importance of government sponsored investment aimed at promoting collaboration between the university research bases and infrastructure, and companies with the ability to commercialise products. The importance of the private sector as an investor in publicly researched innovation is well recognised.<sup>53</sup> Often, biotechnology products are commercialised through technology transfer companies associated with the various universities.

A number of Cooperative Research Centres are also involved in biotechnology research and the commercialisation of biotechnology products. These Centres compete by application for Commonwealth funding. Cooperative Research Centres comprise university researchers, government research institutes and private sector businesses. At last count, about 24 of a total of 91 Cooperative Research Centres have had significant biotechnology programs.<sup>54</sup>

The Australian biotechnology industry suffers from a shortage of venture capital, a problem which is certainly not specific to this industry.<sup>55</sup> There is also a limit to the extent of public investment available in Australia, a related issue being the level of investor confidence in biotechnology. This may also prove to be a barrier to commercialisation in the absence of alliance activity between firms in

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50 Ernst & Young and Freehills, above n47 at 9. Note that the definition of 'core' biotechnology companies in this report expanded slightly on the definition employed in the 1999 report; see Ernst & Young, above n30 and Ernst & Young and Freehills, above n47 at 4.

51 BioAccent, *Victorian Biotechnology and Bioscience Based Industry Report* (Victoria: State Government of Victoria, 2000). The report prepared by BioAccent employs the definition of biotechnology used by Ernst & Young, above n30. Note that these reports also contain details of companies which operate in related areas and which are not classified as core biotechnology companies.

52 Ernst & Young and Freehills, above n47 at 13.

53 The importance of the research system to the sustainability of biotechnology firms is also stressed: see CHI Research Inc. *Inventing Our Future: The Link Between Australian Patenting and Basic Science* (Canberra: AGPS, 2000) at 62.

54 Ernst & Young and Freehills, above n47 at 64.

55 *Wills Review*, above n6 at 136, 152; *Biotechnology Australia*, above n6 at 28; Ernst & Young, above n30 at 41.

the life science sector in Australia. The key to overcoming this is perceived to lie in merger and joint venture activity amongst Australian life science or biotechnology companies, and perhaps more importantly, in foreign investment in Australian biotechnology companies.<sup>56</sup>

(ii) *Australia — Branch Office or Specialised Niche Market?*

Many major international companies, particularly US and European companies, are active in Australia, through ownership of Australian companies, research collaborations with Australian companies, or licensing agreements. Even so, there is some concern that many Australian biotechnology companies suffer from a lack of international exposure.<sup>57</sup> The importance of investment by the international pharmaceutical sector in particular, has been stressed.<sup>58</sup>

Many of the biotechnology companies in Australia which have successfully brought a product to market, have done so with the assistance of strategic alliances and agreements with other biotechnology, or pharmaceutical, companies. An example is Biota Holdings Ltd, which formed an alliance with Glaxo Wellcome to market its flu drug Relenza. There is also a growing trend toward international business alliances outnumbering local alliances.<sup>59</sup>

The difficulty this presents from a national perspective is that the benefits from Australia's research base could all flow offshore. This will often be compounded by Australian researchers being forced to negotiate agreements with powerful multinational companies, that have superior resources and bargaining power.

#### **4. Policy Implications of Patents for the Australian Biotechnology Industry**

##### **A. Biotechnology Patents and Access to Research Materials**

Patent law requires that patent applications satisfy certain criteria, which can be separated into two components:

- invention criteria, including novelty, inventive step and utility (in Australia the utility criterion requires inquiry into whether the invention is a manner of manufacture and whether it is useful);<sup>60</sup> and
- description criteria, including clarity and lack of ambiguity, sufficiency and fair basis.<sup>61</sup>

56 Ernst & Young and Freehills, above n47 at 47; *Wills Review*, above n6 at 193.

57 Ernst & Young, Hay Group & Strategic Industry Research Foundation, *Benchmarking Study of R&D Costs in Selected Segments of the Australian Biotechnology Industry: Final Report* (Canberra: AGPS, 2001); *Wills Review*, above n6 at 193.

58 *Wills Review*, id at 157.

59 Ernst & Young and Freehills, above n47 at 47.

60 Section 18(1) *Patents Act* 1990 (Cth) (hereinafter *Patents Act*). For a summary of the case law interpreting these statutory requirements see Sam Ricketson & Megan Richardson, *Intellectual Property: Cases Materials and Commentary* (2<sup>nd</sup> ed, 1998) at 577–674.

61 Section 40 *Patents Act*. See also Ricketson & Richardson, id at 674–693.

The seminal US Supreme Court case of *Diamond v Chakrabarty*<sup>62</sup> in 1980 was the first instance in which a court recognised that living organisms, just as much as non-living things, were patentable. That decision has been generally accepted in the US and other jurisdictions. In Australia, living organisms are considered to be patentable by the Commissioner of Patents,<sup>63</sup> although the issue has not yet received judicial consideration. It is widely recognised that the *Chakrabarty* decision provides the necessary authority for granting biotechnology patents and encouragement for investment in the emergent biotechnology industry.

Biotechnology patents are defined here to include any patents that employ biotechnological techniques or tools.<sup>64</sup> Gene patents<sup>65</sup> are the most upstream category of biotechnology patents and also the category that has attracted the most criticism. It is recognised in the international literature that gene patents may potentially hinder access to technology for the purposes of further basic research and commercial exploitation of gene related inventions.<sup>66</sup> As Eisenberg points out, attitudes to the patenting of genes will vary depending on which niche of the biotechnology market particular companies occupy.<sup>67</sup> She has stated:

Patents on DNA sequences are likely to have different impacts on firms that occupy different market niches in the biotech industry .... One firm's research tool is another firm's end product.<sup>68</sup>

Downstream biopharmaceutical companies have voiced opposition to certain gene patents, particularly those that claim fragments of gene sequences of unknown function known as expressed sequence tags (ESTs).<sup>69</sup> Their justification is that such patents block access to essential research tools and may inhibit patenting of downstream biotechnology inventions.<sup>70</sup> The difficulty is that upstream biotechnology companies must be guaranteed some return for their investment.

Since Australian companies generally fall into research categories two and three they rely on upstream patent holders granting access to essential research tools and materials, necessitating negotiation of a number of licence agreements. Companies will be assisted in these negotiations by forming alliances and becoming part of a vertically integrated network. At the same time, in forming such alliances, companies may be precluded from access to patents held by competitors of participants in the network. Given that most Australian companies

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62 206 USPQ 193 (1980).

63 In *Rank Hovis McDougall Ltd's Application* (1976) 46 AOJP 3915, for example, a patent was allowed for a new strain of micro-organism that could be used to produce an edible protein.

64 Both IP Australia and the United States Patent and Trademark Office have a category for biotechnology patents.

65 Defined here to mean any patent that includes in its claims a claim to a human gene sequence.

66 Above n9. This article is widely recognised as being the authoritative statement on this issue.

67 Rebecca Eisenberg, 'Genomic Patents and Product Incentives' in Bartha Maria Knoppers, Claude Laberge & Marie Hirtle (eds), *Human DNA: Law and Policy* (1997) at 374.

68 *Ibid.*

69 *Ibid.*

70 See, for example, C Thomas Caskey & Alan Williamson, 'Merck, SmithKline and Patents' (1996) 381 *Nature* 360.

undertake downstream research and development, blocking patents and stacking licences could well be a barrier to entry for them.

### **B. Empirical Data on Biotechnology Patents**

In moving from the theoretical to the empirical level, it is difficult to obtain accurate data on both the quantum of patenting of biotechnology inventions and licensing of those patents. There can be no doubt that the number of patent applications for biotechnology inventions has risen dramatically throughout the world.

#### *(i) Gene Patents*

All of the major sequencing companies have filed patent applications for gene sequences covering large tracts of the human genome. For example, Incyte has filed applications covering portions of more than 50 000 genes, including 7000 that are full-length, and has been granted 500 gene-related patents.<sup>71</sup>

In October 2000 the UK *Guardian* newspaper commissioned GeneWatch UK, an independent 'watchdog' body, to analyse the quantum of gene patenting applications. GeneWatch reported that when it started its survey, 9364 patent applications had been filed worldwide for inventions relating to the human body. Those applications included claims to 126 672 whole or partial human genes. By November 2000 the number of gene sequences claimed had increased by 34 500. GeneWatch also noted that, owing to the backlog of some three to four years in examination by Patent Offices, 60–70 per cent of these patents had not yet been granted.<sup>72</sup>

Accurate statistics are harder to obtain in Australia because there is no simple method of estimating the number of gene patent applications filed with IP Australia. The authors have conducted preliminary studies, indicating patent applications filed with IP Australia include claims to human genes, gene fragments and gene products.<sup>73</sup>

The following trends have been detected from these preliminary studies:

- the majority of gene patent applications are initiated by way of international Patent Cooperation Treaty<sup>74</sup> applications;
- the majority of applicants and/or inventors are foreign, mainly from the US, Japan and Europe;

71 'Incyte Genomics Reaches Milestone With The Issuance of Its 500th Gene-Related Patent' 17 August 2000: <[http://www.incyte.com/company/news/2000/08\\_500th\\_patent.shtml](http://www.incyte.com/company/news/2000/08_500th_patent.shtml)> (7 June 2001).

72 *The Guardian* 'Special Report: The Ethics of Genetics' 15 November 2000: <<http://www.guardianunlimited.co.uk/genetics>> (16 November 2000).

73 See also, Charles Lawson, 'Patenting Genes and Gene Sequences in Australia' (1998) 5 *JLM* 364; Charles Lawson & Catherine Pickering, 'Patenting Genetic Materials — Failing to Reflect the Value of Variation in DNA, RNA and Amino Acids' (2000) 11 *AIPJ* 69.

74 The *Patent Cooperation Treaty* 1970 treats a single international application for a patent as having the same effect as if applications had been filed in each of the countries in which protection is requested.

- applications from the US are made by private companies, public institutes and the US government, in roughly equal proportions; and
- the majority of applications lapse before reaching the first examination stage.

It is difficult to verify the exact number of human genes that have been successfully patented worldwide. The GeneWatch survey indicates that as many, if not more, gene sequences have been claimed in patent applications as there are human genes (according to recent estimates of 30 000–40 000<sup>75</sup>). Although some of these claims can be accounted for as variants of the same gene within a single application, it appears likely that there will be a significant degree of overlap in claims between competing applications. Accordingly, it seems certain that some of these applications will fail to fulfil the essential patenting criteria. Further, a large number of applications will not be pursued through the examination process by the applicants, but will be allowed to lapse.

The importance of the work by GeneWatch and others is that it dramatically illustrates the so-called 'gene patent rush'.<sup>76</sup> Even if a large number of patent applications do fail or lapse, on current interpretations of patenting criteria it is likely that a significant number will succeed.<sup>77</sup> Consequently, patents will be granted for many of the genes in the human genome, and the commercial exploitation of those genes will be controlled by the patent holder. Access by downstream companies will therefore be restricted.

#### (ii) *Biotechnology Patents*

IP Australia has provided the authors with statistics on the total numbers of patent applications and grants in Australia.<sup>78</sup> In summary, the statistics show that, up to 1998:

- of the 5000–11 000 patents granted each year in Australia, only around ten per cent originate in Australia. US inventors dominate, holding over 45 per cent of the patents granted in 1996;
- of the 2000 or so patent applications filed in the biotechnology category, only around 2 per cent originate in Australia;<sup>79</sup>
- in real terms the number of biotechnology patents filed by Australian residents increased from 26 in 1988 to 46 in 1998, showing that Australian biotechnology is in a growth phase.

Doubtless, the number of applications filed in the biotechnology category will have risen significantly over the last three years. However, it seems unlikely that the percentage originating in Australia will have changed dramatically. As such,

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75 J Craig Venter, 'The Sequence of the Human Genome' (2001) 291 *Science* 1304.

76 'Whose Life Is It Anyway?' *The Guardian* (15 Nov 2000): <[www.guardianunlimited.co.uk](http://www.guardianunlimited.co.uk)> (16 November 2000).

77 See section 5A, below.

78 The authors thank Jodi Lawler & Rod Crawford from IP Australia for providing this data.

79 Note that the biotechnology category includes both medical and agricultural biotechnology. It also includes gene patents.

non-Australian companies and institutions hold most biotechnology patents granted in Australia.<sup>80</sup>

A report commissioned by the Australian Research Council and the CSIRO indicates that the number of Australian invented patents filed in the US closely matches the number of Australian invented patents filed in Australia.<sup>81</sup> During the five-year period, between 1994–1998 there was a 249 per cent increase in Australian invented biotechnology patents from the previous five-year period, further supporting the conclusion that Australian biotechnology is in a growth phase.<sup>82</sup> Nevertheless, US inventors continue to file the vast majority of biotechnology patents in the US.<sup>83</sup> The number of Australian co-invented patents generally is increasing, and a large number of co-invented patents are US–Australian collaborations.<sup>84</sup>

The report concluded that the performance of Australian inventors in the biotechnology category was stronger than the performance of Australian inventors generally.<sup>85</sup> Despite this, biotechnology patent activity relative to gross domestic product remains average<sup>86</sup> and the number of biotechnology patents filed and held by Australian inventors remains low in relative terms.<sup>87</sup>

*(iii) Exploitation of Patents and Licensing Practices*

It has been estimated that over 90 per cent of current US patents are never exploited, suggesting that many of them are obtained for blocking purposes.<sup>88</sup> Given that most biotechnology patents in Australia are held by foreigners, it is likely that a large number are obtained for blocking purposes and will lie dormant. Although there may be many reasons why technology may not be exploited,<sup>89</sup> the result is clearly detrimental to the industry and to the health care sector as a whole.

It is difficult to obtain comprehensive information on licensing of biotechnology patents. There is no requirement in Australia for intellectual property licence agreements to be registered. However, company reports indicate prolific licensing activity and this is borne out by the extent of alliance activity already discussed. Half of the companies surveyed by Ernst & Young in 1999

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80 For a discussion on the impact of this on the exploitation of Australia's genetic resources, see Charles Lawson & Catherine Pickering, 'The Conflict for Patented Genetic Materials Under the Convention on Biological Diversity and the Agreement on Trade Related Aspects of Intellectual Property Rights' (2001) 12(2) *AIPJ* 104.

81 Above n53 at 29.

82 *Id* at 32.

83 Over the five-year period between 1994–1998, US inventors filed 6 847 biotechnology patents and 10 218 pharmaceutical patents: see *id* Table 6a at 71.

84 Nearly half of all Australian co-invented patents are US–Australian collaborations. This figure has increased from 5 per cent in the first half of this decade to over 15 per cent in the last five years: *id* at 26.

85 *Id* at 26–29. In terms of general patenting activity, Australian invented patents in the US represent approximately 0.5 per cent of patents filed.

86 *Id* at 28.

87 See *ibid* Fig 7.

88 See comments, above n32 at 66.

89 *Id* at 66–67.



reported intellectual property licensing activities with a total of 181 licences acquired and 219 licences issued.<sup>90</sup> Of the licences acquired, 45 per cent were acquired from overseas companies. Of the licences issued, 78 per cent were issued to overseas companies,<sup>91</sup> confirming that Australian companies are compelled to seek alliances and financing arrangements with overseas companies.

There is evidence that an inability to obtain licences is a problem for the industry. For example, about 21 per cent of the companies surveyed by Ernst & Young had, at some time, abandoned at least one project because further work or commercialisation was blocked by another company's IPRs. Some 8 per cent of companies surveyed were involved in patent infringement litigation in the 12 months preceding the survey. This figure was considered to be fairly low by international standards, but was unsurprising to the authors of the report given Australia's low levels of corporate litigation generally.<sup>92</sup>

## 5. *Addressing Access Problems*

If biotechnology patents, particularly gene patents, do impede access to research tools and techniques, legal frameworks for removing those impediments must be considered. There are a number of options that can broadly be divided into:

- restricting the grant of biotechnology patents by raising the bar on when the patent criteria are satisfied; and
- compelling and regulating the way in which biotechnology patents are used.

### A. *Restricting Grant of Biotechnology Patents*

Specific limitations may be imposed on biotechnology patents by the legislature through amendments to the *Patents Act*, by the Federal Court through its interpretation of the patenting criteria<sup>93</sup> or by the Patents Office of IP Australia through its application of the law during the examination process. The extent to which these three bodies may be able and/or willing to impose such limitations is discussed below.

#### (i) *International Obligations*

All members of the World Trade Organisation are required to incorporate certain standards of intellectual property protection in their national laws, as provided in the *Agreement on Trade-Related Aspects of Intellectual Property Rights* 1994 (TRIPS). Article 27 requires that the key elements of novelty, inventive step (non-obviousness) and industrial applicability (utility) must be satisfied for all patentable inventions. Limited exclusions from patenting are allowed:

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90 Ernst & Young, above n30 at 35.

91 Ibid.

92 Ibid.

93 The Federal Court hears revocation proceedings after grant (*Patents Act* s138) and appeals from first instance decisions of the Commissioner of Patents in opposition proceedings after acceptance but before grant (*Patents Act* s60).

- when it is necessary to prevent the commercial exploitation of the invention to protect *ordre public*<sup>94</sup> or morality;
- for diagnostic, therapeutic and surgical methods for the treatment of humans or animals (methods of medical treatment);
- for plants and animals, but not micro-organisms;
- for biological processes for producing plants and animals, but not technical processes.

Based on Article 27, biotechnology patents do not have to fulfil any special patenting requirements. Moreover, it is not permissible for member countries to impose restrictions on patenting that fall outside the ambit of Article 27. However, limitations may be achieved in one of two ways:

- through the allowable exclusions. Each country has the choice of whether or not to incorporate the exclusions into its national patent laws;
- through interpretation of the invention criteria. Countries are not restricted in the way that these criteria are interpreted, provided that they do not generally exclude patents for inventions in a particular field of technology.

Minor amendments have been made to the *Patents Act* to ensure compliance with TRIPs.<sup>95</sup>

It is probably fair to say that neither the legislature nor the courts would ever seriously consider any general or specific exclusion of biotechnology inventions from patenting. In any case, an express exclusion of biotechnology patents or gene patents would be contrary to TRIPs.

### (ii) Allowable Exclusions

Both Australia and the US have few express exclusions from patenting. Most notably, s18(2) *Patents Act* 1990 (Cth) excludes human beings and the biological processes for their generation.<sup>96</sup> In Europe, on the other hand, exclusions in the European Patent Convention largely mirror the provisions in TRIPs. Early Australian case law suggested that methods of medical treatment were excluded from patenting on ethical grounds.<sup>97</sup> However, the Full Federal Court in *Bristol Myers Squibb v F H Faulding & Co Ltd*<sup>98</sup> rejected the existence of this exclusion. The judgments in that case, particularly that of Finkelstein J, further suggest that

94 *Ordre public* is a French term, with no direct English translation. It is taken from the European Patent Convention. In *Plant Genetic Systems T356/93* (1995) OJEP 545 it was held that *ordre public* covers protection of public security, physical integrity of individuals as part of society and protection of the environment.

95 Through the *Patents (World Trade Organisation Amendments) Act* 1994 (Cth).

96 In a recent amendment to the *Patents Act* a new category of innovation patents was created. Plants and animals other than micro-organisms are excluded from this category: ss18(3) and (4).

97 For a discussion of these cases see Dianne Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3(3) *JLM* 231 at 239–241. The courts read ethical considerations into the curious 'general inconvenience' provision that originated in section 6 of the English *Statute of Monopolies* 1624 and survives in the definition of invention in Schedule 1 of the *Patents Act*.

98 [2000] FCA 316 (2000) 46 IPR 553.

arguments for exclusion based on ethical or moral grounds are unlikely to find favour with that Court.

Even if the Federal Court were prepared to hear arguments against patent validity based on ethical or moral grounds or if the legislature were to introduce an *ordre public*/morality clause, European experience suggests that this would be unlikely to unduly impede patenting of biotechnology inventions.<sup>99</sup>

(iii) *Interpreting Inventive Step for Biotechnology Inventions*

Inventive step requires an analysis of the prior art: what has gone on before in the field including what is generally known and what is written. The question addressed is whether the teachings from the prior art make the invention obvious to an ordinary person skilled in the field. A number of important cases in the US indicate that this requirement will generally be easy to satisfy for gene sequence claims under US law.<sup>100</sup> Even though the prior art might disclose the structure of the protein that gene sequence codes for and general methods for isolating a gene when the protein is known, this does not render the claimed sequences obvious. Commentators have expressed concern that if the inventive step requirement is too easily satisfied, patents are granted for inventions that have little or no inventive merit.<sup>101</sup>

In Australia, the test for inventive step has a number of technical requirements<sup>102</sup> that are not necessary to discuss for the purpose of this article. There has been no judicial consideration of the inventive step requirement for gene and other biotechnology patents, although Deputy Commissioners for Patents have considered this issue in a number of opposition proceedings.<sup>103</sup> The decisions relating to the inventiveness of gene sequence claims have been criticised for setting too low a threshold that is too much in favour of the first to sequence.<sup>104</sup>

99 The *ordre public*/morality exclusion did not prevent patenting of inventions involving genetically engineered animals in *Oncomouse* T19/90 [1990] OJEP0 476; genetically engineered plants in *Plant Genetic Systems* T356/93 (1995) OJEP0 545; and human genes in *Relaxin* [1995] OJEP0 388. Article 6 of the European Biotechnology Directive (Directive 98/44/EC On The Legal Protection of Biotechnological Inventions) lists the types of inventions that the exclusion is aimed at, including cloning and germ line gene therapy, and uses of human embryos for industrial or commercial purposes. A suggestion has been made that a public policy requirement should be added to the patent criteria in Australia: see Miranda Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11(4) *AIPJ* 202.

100 See particularly *In Re Bell* 991 F2d 781 26 USPQ2d 1529 (1993) and *In Re Deuel* 51 F3d 1552 (1995).

101 See, for example, John Barton, 'Reforming the Patent System' (2000) 287 *Science* 1933.

102 See *Patents Act* ss7(2) and (3) and *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Limited* (1980) 144 CLR 253.

103 Discussed by Lawson & Pickering, above n73 at 73–76.

104 *Id* at 76. At the time of writing, the Patents Amendment Bill 2001 is before the Federal Parliament. Amongst other matters, the Bill seeks to raise the threshold for the grant of patents in Australia by expanding the prior art base against which the novelty and inventive step requirements are measured. The text of the Bill is available at: <<http://search.aph.gov.au/search/ParlInfo.ASP?action=view&item=0&from=browse&path=Legislation/Ccurrent+Bills+by+Title/Patents+Amendment+Bill+2001/Text+of+the+bill&items=1>> (20 July 2001).

It is important for the development of Australian patent law that an appropriate case is brought before the Federal Court to give it the opportunity to lay down concrete guidelines as to the inventive step requirements for biotechnology inventions.

(iv) *Interpreting Industrial Applicability (Utility) for Biotechnology Inventions*

This requirement has been the focus for debate in the US as a result of the filing of large numbers of EST patents. The US Patent and Trademark Office (USPTO) recently revised its Guidelines on the utility requirement.<sup>105</sup> The revisions are specifically directed at patent applications for ESTs where gene function is not known. The Revised Guidelines require the disclosure of specific, substantial and credible utility, which would usually be met by disclosure of the protein made by the gene. Although these revisions will prevent the grant of some gene patents, the USPTO has emphatically stated that it does not oppose gene patents per se. In its view, research is spurred and not inhibited by patents, and provided the statutory requirements are met, the USPTO is required to grant gene patents.<sup>106</sup>

In Europe, the Biotechnology Directive similarly states that industrial applicability for gene patents requires the applicant to specify which protein or part of a protein is produced by the sequence or what function it performs.

In Australia, utility has two components:

- the manner of manufacture test,<sup>107</sup> which requires that the invention has commercial applicability;<sup>108</sup>
- the usefulness test,<sup>109</sup> which requires that the invention produces the result promised.<sup>110</sup>

Discoveries are excluded from patenting through the manner of manufacture test because they lack the requisite commercial applicability.<sup>111</sup> On this basis, the mere identification of a naturally occurring gene or gene sequence is likely to be an unpatentable discovery. However, the utilisation of that knowledge to make a synthetic gene sequence is likely to be a patentable invention.<sup>112</sup> The legislation and case law provide no further guidance as to the extent to which commercial applicability must be identified.<sup>113</sup>

105 *Federal Register*, 66(4) January 5 2001 Notices at 1092. Utility is one of the essential patenting criteria (the others being novelty and non-obviousness). To satisfy the utility requirement, a patent application must disclose that the invention is practically useful: *Brenner v Manson* 383 US 519 (1966).

106 *Id* at 1094, 1095.

107 Section 18(1)(a) *Patents Act*.

108 The leading case on the interpretation of this provision is *National Research Development Corporation v Commissioner of Taxation* (1959) 102 CLR 252 (hereinafter *NRDC*).

109 Section 18(1)(c) *Patents Act*.

110 See, in particular, *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1993) 25 IPR 119.

111 See *NRDC*, above n108 at 264.

112 See the decision of the Deputy Commissioner of Patents in *Kirin-Amgen Inc v Board of Regents of University of Washington & Anor* (1995) 33 IPR 557.

113 See *Lawson & Pickering*, above n73 at 72.

The Intellectual Property and Competition Review Committee (IPCRC) recently completed a major review of intellectual property and its interaction with competition law.<sup>114</sup> As part of its review of patent law, the IPCRC recommended that the manner of manufacture test should be retained, but that the Patent Office should adopt the examination practice of requiring specific, substantial and credible utility as part of the usefulness test.<sup>115</sup> There is some attraction in this proposition, particularly because it ensures consistency in examination practice with the US. However, there are also some difficulties with it:

- as the *Patents Act* is currently worded, the Patent Office is not required to examine the usefulness requirement (*Patents Act* s45). This difficulty could be circumvented through s45(1)(c) which would allow for an enquiry into usefulness to be added to the list of matters prescribed for examination in Regulation 3.18 of the Patents Regulations 1991 (Cth);
- the specific, substantial and credible utility requirement marks a radical change from previous interpretations of the usefulness criterion by the Federal Court, which require only that the invention as claimed attains the result promised by the patentee.<sup>116</sup>
- the precise nature of the new requirement has not yet been fully ascertained in the US.

(v) *Interpreting the Description Requirements for Biotechnology Inventions*

In addition to satisfying the invention criteria, a patent application must also fully describe the invention. From the applicant's point of view it is vital to make claims that are broader than the strict confines of the invention because biotechnology inventions are too easy to 'invent around'. However, if patents are too broad they will impact detrimentally on research and product development because whole areas will be closed off to anyone who is unable to negotiate access rights with the patent holder. This is particularly likely where broad claims are granted at the upstream end of the research-development continuum. Examples include:

- patents arising out of the discovery of a gene sequence of known or unknown function, where all subsequent uses of the sequence are claimed; or
- patents arising out of the development of a particular technique to solve a particular problem, where all other uses of the technique are claimed.

In the US the courts have imposed limitations on the breadth of patent claims through the description requirements.<sup>117</sup> Whilst it is accepted that applicants are not required to disclose every possible use encompassed by their claims, there must be sufficient disclosure to teach those of ordinary skill how to make and use the invention as broadly as is claimed.

114 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report* (Canberra: AGPS, 2000) (hereinafter the IPCRC Report).

115 *Id* at 149 and 154.

116 *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd & Anor* (1988) 11 IPR 289; *Rescare Ltd v Anaesthetic Supplies Pty Ltd*, above n110.

117 See the recent cases: *The Regents of the University of California v Eli Lilly and Co* US Court of Appeals for the Federal Circuit 96-1175, 22 July 1997 and *Enzo Biochem Inc v Calgene Inc* US Court of Appeals for the Federal Circuit 98-1438, 24 September 1999.

In Australia, the breadth of patent claims for biotechnology inventions was considered in *Genetics Institute Inc v Kirin Amgen Inc (No 3)*.<sup>118</sup> The invention under consideration involved the use of recombinant DNA technology to produce commercial quantities of erythropoetin (EPO), an important and rare protein which plays a major role in regulating the rate of red blood cell formation. The main claim was for a purified and isolated polypeptide having the primary structural conformation and one or more of the biological properties of naturally occurring erythropoetin, unlimited by species or by specific structure. Heerey J held that the claim was permissibly wide because the gene sequence for EPO was a principle of general application and therefore it was acceptable for the claim to be made in correspondingly general terms.

The *Genetics Institute* decision signals that as a general rule broad claims to gene sequences and their products may be accepted where the method of isolating the full gene sequence is disclosed. In the circumstances, the elucidation of the EPO sequence was a major breakthrough. However, sequencing is now much more routine and requires very little in the way of inventive skill. Granting broad patent rights may be too great a reward for such endeavours. Further judicial consideration is essential on this point.

(vi) *Implications for Legal Development*

There are no specific limitations on patenting biotechnology inventions in Australia and it is unlikely that the legislature will create express limitations in the foreseeable future for reasons of political expediency and compliance with international obligations. Limitations may be placed on biotechnology patent claims through interpretation of the invention and description criteria by the Federal Court and the Patents Office.

To date, the Patents Office has received little or no judicial guidance and has tended to give an expansive interpretation of those criteria. This arises in part because the Patents Office is required to give the applicant the benefit when patent validity is in doubt.<sup>119</sup> This 'benefit of doubt' test means that patents are often too easily granted and are consequently open to challenge through their entire 20-year life.<sup>120</sup> This is disadvantageous both to patent holders, because they cannot rely on patent validity and to users, because they may either be denied access to or be required to pay licence fees on patents that may, if challenged, be invalid.

118 (1998) 156 ALR 30.

119 *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232; *International Business Machines Corporation v Commissioner of Patents* (1991) 22 IPR 417.

120 The benefit of doubt test was criticised in the IPCRC Report, above n114 at 166–167 and in the report by the Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (Canberra: AGPS, 1999) at 15. The Patents Amendment Bill 2001, currently before the Federal Parliament, will, if passed, replace the benefit of doubt test for the novelty and inventive step requirements with a more stringent test similar to the balance of probabilities test more generally used in civil matters. See second reading speech of Warren Entsch 28 June 2001: <<http://search.aph.gov.au/search/ParlInfo.ASP?action=view&item=1&from=browse&path=Legislation/Current+Bills+by+Title/Patents+Amendment+Bill+2001/Second+reading+speeches&items=5>> (20 July 2001).

In practice it is logical for patent holders and users to attempt to negotiate licences and for patent holders to ignore minor infringements rather than risk the costs of litigation. More importantly, downstream users may be reluctant to challenge patent validity because raising the bar on upstream patents may have the same effect on their potential downstream patents. This explains the lack of judicial precedents.

Given this lack of precedent, the IPCRC recommended that the Patent Office should initiate test cases where substantial areas of uncertainty exist.<sup>121</sup> However, it seems incongruous for the same body that grants patents to take responsibility for challenging their validity. Ideally, challenges to patent validity should be made by a public interest body with financial support from the Federal Government. Guidance as to appropriate limitations on the grant of biotechnology patents will only emerge if the Federal Court is given the opportunity to consider and carefully evaluate such issues. In the interim it is likely that many biotechnology patents will be granted and survive unchallenged. Consequently, regulation of their use becomes a paramount consideration.

### ***B. Compelling and Regulating the Use of Biotechnology Patents***

Freedom of contract dominates the way in which patents are used and the terms on which they are licensed. It should be remembered that a patent is a statutory bargain between the patentee and the public; not only does the patentee have an obligation to work the patent, but also to work it within the bounds of the grant. In circumstances discussed in this article, neither of these obligations may be fulfilled. Compulsory licences are one mechanism by which these obligations may be compelled. In conjunction with competition law, compulsory licences may alleviate some access issues.

#### *(i) Compulsory Licences — Grounds for Issue*

A compulsory licence is an order requiring the patentee to grant a licence to work the invention, in effect limiting the patentee's exclusive right to exploit the invention. Compulsory licences may be an effective means to ensure not only that patents are worked, but also that they do not hinder the process of competition in the Australian industry. They may not always offer a complete solution: the circumstances in which they may be granted are limited, and the term for which they are effective depends on how long the reasons for their granting continue to exist. Nevertheless, they may present a solution in some instances and more extensive use of compulsory licences should be investigated.

Article 31 of TRIPS implicitly allows compulsory licensing of patents.<sup>122</sup> The circumstances in which TRIPS allows the issue of compulsory licences are:

- situations of national emergency or extreme urgency;
- cases of non-commercial public use;

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121 IPCRC Report, above n114 at 154.

122 Article 31 also contains detailed conditions for the grant of compulsory licences. Most importantly, in many cases a prior request for a licence must have been made, and the licensee must provide adequate compensation to the patent holder.

- cases of anti-competitive practices;
- dependent patent cases where the exercise of one patent will infringe another.

The grounds referred to in Article 31 are not exhaustive, and WTO member states may determine other relevant grounds. Generally, the grounds found in national legislation fall into the following categories:<sup>123</sup>

- refusal to deal;
- non-working and inadequate supply;
- public interest;
- anti-competitive practices;
- governmental use;
- facilitation of the use of dependent patents;
- specific compulsory licences for medicines; and
- licences of right, which allow importation by a licensee where the patentee imports a major portion of the product into the member state and carries out a minor production step in the member country.

Clearly the most relevant grounds for the purposes of addressing the problems raised in this article are refusal to deal, public interest, facilitation of the use of dependent patents and anti-competitive practices.

(ii) *Compulsory Licences — The Australian Position*

The *Patents Act* allows for the issue of compulsory licences on the first three grounds, but not for anti-competitive practices. In the US, the primary ground on which compulsory licences are issued is to remedy anti-competitive conduct.<sup>124</sup> Tens of thousands of patents have been licensed under anti-trust decrees,<sup>125</sup> making the US a country with vast experience in the granting of compulsory licences.<sup>126</sup>

Section 133 of the *Patents Act* provides for the issue of non-exclusive compulsory licences for:

- failure to work an invention where exploitation of the patent is necessary to satisfy the ‘reasonable requirements of the public’ (provided reasonable attempts have been made to obtain a licence by the applicant);<sup>127</sup> and
- cases of dependent patents where the new product involves an important technical advance of considerable economic significance on the other invention.<sup>128</sup>

123 Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, Working Paper 5 (Buenos Aires: South Centre, 1999) at 10–21, available at: <<http://www.southcentre.org/publications/complicense/toc.html>> (9 April 2001).

124 F Michael Scherer, ‘Comments’ in Robert Anderson & Nancy Gallini (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998) at 106.

125 *Ibid.*

126 See above n123 at 14.

127 *Patents Act* ss133(2) and (3A).

128 *Patents Act* s133(3B).



Section 135 defines what is meant by 'reasonable requirements of the public'. Essentially, where a new or existing trade or industry in Australia is unfairly prejudiced, or the demand in Australia for a patented product is not reasonably met, this will provide grounds for the grant of a compulsory licence.

These compulsory licensing provisions would, in many cases, provide a solution to the problem of access to biotechnology patents. However, the provisions have rarely been utilised.<sup>129</sup> Compulsory licensing provisions are used far more extensively in other jurisdictions.<sup>130</sup>

The IPCRC accepts that a compulsory licensing system, by its very existence, may have the effect of influencing the terms on which licences are negotiated.<sup>131</sup> Studies have shown that a compulsory licensing scheme, rather than inhibiting R&D, actually acts as a spur to innovation.<sup>132</sup> Note however that given the under-utilisation of the Australian scheme, this aim may not be met. The inequality in bargaining power between many companies, particularly start-up companies, may mean that the threat of a compulsory licensing application is non-existent.

The IPCRC recommends some changes to the compulsory licensing provisions within the *Patents Act* including the repeal of s135, and the amendment of s133(2).<sup>133</sup> The effect of this amendment would be to replace the 'reasonable requirements of the public' provision with a provision allowing for the grant of a compulsory licence where the public interest would be met by enhanced competition in the market.<sup>134</sup> The Report recommends that compulsory licensing orders be obtainable on application to the Australian Competition Tribunal with rights of appeal to the Full Federal Court.<sup>135</sup> Presumably this would go some way towards expediting the application process.

Enhanced access to the compulsory licensing provisions is highly desirable. It is particularly encouraging to note that the recommendations focus on the importance of compulsory licensing to the competitive process. It is unclear as to the form this provision would take, and how it would interact with the restrictive trade practices provisions in Part IV of the *Trade Practices Act 1974* (Cth) (hereinafter the *Trade Practices Act*). Presumably, the provision would only be invoked where there is a contravention of Part IV.

There is no guarantee that this provision would increase the number of applications for compulsory licences given that the onus will still generally remain on companies to instigate applications. Intellectual property use has traditionally

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129 The only reported judicial decision in Australia is *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation Co* (1969) 119 CLR 572.

130 See above n123.

131 IPCRC Report, above n114 at 162. See also above n123 at 23–24.

132 See, in particular, above n124.

133 IPCRC Report, above n114 at 162–163.

134 The basis of the recommendation is a view that the provision as currently drafted is outmoded and fails to secure the goals of a compulsory licensing system. The terms of s133 are considered to be concerned with the promotion of domestic industry rather than '... securing the best use of resources and achieving high levels of productivity'. Further, it is considered that s133 is deficient in that it lacks an explicit competition test; id at 162.

135 Id at 163.

been an area where government oversight has been lacking. Again, it is inappropriate for the Patent Office to intervene in the use of patents it has granted. However, the same considerations do not apply to the Australian Competition and Consumer Commission (ACCC), the body charged with monitoring anti-competitive conduct.

The notion of compulsory licences as a remedy for anti-competitive conduct may provide the necessary impetus for increased utilisation of the remedy, especially given the ACCC's potential role. Arguably, the inclusion of a provision in the *Trade Practices Act* rather than the *Patents Act* may be more effective in giving the ACCC greater scope and incentive to investigate anti-competitive practices associated with biotechnology patents. Nevertheless, regardless of the forum for the amendment, complex competition law considerations arise.

### (iii) *Some Practical Limitations of Compulsory Licences*

Compulsory licences appear to be an appropriate mechanism by which to solve some access problems, but in practical terms their utility must be questioned. The problem faced by any government bold enough to enforce the issue of compulsory licences is generally censure from major trading partners—under pressure from powerful patent holders.

In addition, for a compulsory licensing scheme to be effective, a licensee would need to be able to obtain compulsory licences in all those jurisdictions in which patents have been granted, principally in the US, the European Union and Japan. At present there is no international consensus on the circumstances for the granting of compulsory licences, so that a company wishing to commercialise an invention in the major markets of the world would need to obtain licences in the jurisdictions referred to above. Obtaining a compulsory licence in Australia would not enable commercialisation on an international basis. This presents a further hurdle to Australian biotechnology companies.

### (iv) *Competition Law as a Vehicle for Reform*

It is generally recognised that intellectual property law and competition law share common goals.<sup>136</sup> Both aim to benefit the consumer: intellectual property laws through the encouragement of innovation, leading to new products; and competition laws through the control of prices by competition. However, there are many ways in which the use of IPRs can be anti-competitive.<sup>137</sup> Thus the interface between IPRs and competition law is a complex one, as is evidenced by the breadth of economic and legal literature on the topic.<sup>138</sup>

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136 See, for example, *id* at 22–27.

137 See, for example, Trade Practices Commission. *The Application of the Trade Practices Act to Intellectual Property. Background Paper* (Canberra: AGPS, 1991).

138 See the National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999) (hereinafter the NCC Report) and the references cited therein. Recent international works include Alan Gutterman, *Innovation and Competition Policy* (1997) and Robert Anderson & Nancy Gallini (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998).

The Australian government addressed this issue at length in the IPCRC Report and in another recent report.<sup>139</sup> Both reports discuss the issue of when patent usage is anti-competitive. However, to date this issue has not been addressed specifically in relation to the biotechnology industry. Due to the limiting effect of broad upstream biotechnology patents, it is evident that the use of biotechnology patents may give rise to particularly acute competition law issues.

Some instances in which anti-competitive concerns arise include:

- mergers which lead to patent ‘bundling’;
- refusal to license patents;
- the terms on which patents are licensed;
- obtaining patents for blocking purposes;
- patent pooling and cross licensing;
- licensing ‘bundles’ of patents;
- entering into licences as part of infringement proceeding settlement agreements.

This list is not intended to be comprehensive, and extensive issues arise on each ground which are outside the scope of this article. The complexity of these issues in the biotechnology context is illustrated by the Ciba-Geigy and Sandoz (now Novartis) merger. The US Federal Trade Commission required the grant of a number of non-exclusive compulsory licences at a specified royalty rate.<sup>140</sup> The licences were granted on the basis that the companies (including Chiron, which the merged entity would also control) were actual or potential competitors in respect of some of their products.<sup>141</sup>

The ability of the government to monitor the use of biotechnology patents is important in light of these issues. Given the inability or unwillingness of many biotechnology companies to independently initiate investigation or litigation, there may be a role for the ACCC to take a more proactive stance. Of course, it is clear that no competition authority has the resources to monitor the use of IPRs and investigate every potential breach. Many anti-competitive practices concerning the use of patents will invariably go unchecked.<sup>142</sup> However, a more vigilant competition law regime coupled with an effective remedy in the form of compulsory licensing is one option that requires further investigation.

At the international level, there is growing cooperation between national competition authorities; the US has signed Antitrust Enforcement Assistance Agreements with a number of countries, including Australia.<sup>143</sup> On a practical level, some cohesion between competition authorities is evident. A preliminary framework, at least, exists for cooperation on this level.

139 IPCRC Report, above n114; NCC Report, *ibid*.

140 For details see above n123 at 16.

141 *Ibid*.

142 See, in particular, an address by Joel Klein, former Acting Assistant Attorney-General, Antitrust Division, US Department of Justice, *Cross Licensing and Antitrust Law*, 2 May 1997: <<http://www.usdoj.gov/atr/public/speeches/1123.htm>> (28 March 2001).

143 The text of this Agreement dated 27 April 1999 is available at: <<http://www.usdoj.gov/atr/public/international/docs/usaus7.htm>> (11 August 2000).

## 6. *Conclusion*

Biotechnology companies face unique challenges for the following reasons:

- the research intensive nature of the industry;
- the massive increase in patent activity in the area of biotechnology;
- the preponderance of upstream patents with broad claims;
- the reliance of downstream companies on access to patented research tools and techniques.

Challenges facing the emergent Australian industry may be particularly acute given first, the need for Australian biotechnology companies to seek foreign investment and alliances to fund research and expand into international markets. Secondly, access to essential research tools and technologies requires negotiation of a considerable number of licence agreements with patent holders. This is complicated because the majority of biotechnology patents are held by non-Australian upstream companies and institutes. By entering into alliances, companies may find that their ability to acquire all the licences they need to conduct their research is impeded.

Although the Federal Government has put forward a number of initiatives to promote the establishment of a biotechnology industry in Australia, consideration of issues associated with access to intellectual property, particularly access to research tools and techniques, is notably absent. It is vital that these issues are canvassed by the federal government at an early stage of investment in the Australian biotechnology industry. A patent law regime in line with international obligations is essential in order to encourage innovation and investment in the industry. Yet this same regime may inhibit research and product development. The balance is a fine one and the very system that has as its primary purpose the reward of innovation, may in some instances have the obverse effect.

It is unrealistic to assume that all impediments to the growth of the industry could be removed. However, it should be recognised that the existing balance may weigh too heavily against the industry as a whole. Further work is necessary to assess the imbalance and to investigate potential solutions. While it is desirable to consider changes to patent standards as a starting point, it is unlikely in the short term that the rules governing the grant of patents will change considerably. Broad upstream patents will continue to be granted and the validity of existing patents will remain unchallenged. It is more likely that resolutions will come from the legal framework for use of patents, and there is certainly scope for further investigation in this area.