

‘Market and Statutory Solutions to Biotechnology Transfer’

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Introduction

Patent law has the difficult role of regulating an area of human activity which by its nature is full of innovative change. Not only does it extend to cover new emerging industries, but especially within new and complex technologies like biotechnology, it arguably covers products and services not previously contemplated within the traditional concept of mechanical invention. Any proposed law reform must confront the changes affecting the biotechnology

industry, and the challenge of using a coherent economic analysis to evaluate these policies. The changing role of public research institutes and universities, the commercialisation of their research, and the impact of a growing research and development sector need to underpin our assessment.

This essay will argue that the vertical distance (conception to end product) of the biotech industry is so large that two markets are forming. It will then

argue that different economic forces operate on the two, and more importantly that the analysis of the 'upstream' section of the biotech market is too uncertain to construct a platform for policy reform.

What has been driving the analysis of currently proposed reforms would seem to be a fear that patenting is removing from the public domain opportunities for R&D, ultimately at the cost of social benefits and eventually the pace of innovation. This essay will argue that this is a misrepresentation, and that there is a greater risk of a tragic underuse of patents. There are real obstacles faced by the industry in searching out commercial licenses, avoiding contractual terms which slow the pace of diffusion into the market of innovation, and in protecting the integrity of intellectual property. If they cannot be overcome then patents with broad claims will not only overlap other patents, but will create 'thickets' of patents that prevent innovation. There is not so much the risk of an anti-commons forming so much as the risk of a tragedy within the anti-commons itself.

In arguing that legislative views are disproportionately influenced by the fear of an anti-commons forming, the essay will canvas the statutory measures of regulation on offer. 'Grace Periods' attempt to reconcile academic freedom and the secrecy that surrounds the filing of a patent application. Many legislatures have modified their patent requirements to include 'utility' in order to solve concerns over the suitability of certain subjects for patenting, such as genetic sequences. Determining the validity of a patent in light of a utility is fairly narrow, and there may be a difference between this scope and the purposive construction given patent claims during infringement proceedings. In other words the effect on what is removed or remains in the public domain is not clear.

The most debated statutory intervention would be the 'Research Exemption' or defence to patent infringement. While New Zealand has no statutory test for experimental exemption, Australia is currently debating a law reform, the results of which have heavily influenced NZ (Cabinet has agreed that a patented use exemption be drafted into the draft Patents Bill). The legal tests for this exemption across some important jurisdictions are briefly compared along with the options recommended by the Australian Advisory Council on Intellectual Property (ACIP). The tests lend themselves to an evaluation in two parts since they most often try to determine two issues: The relation of the experimental act to the subject matter of the patent, and whether a commercial dimension is involved.

This essay will argue that the presence of a commercial test is needed in principle, but that reliance on determining commercial intentions, or a proviso that experimental exemptions do not conflict with a patentee's commercial interests, are unworkable and beg the question. An outcomes-based commercial test would provide certainty in practice-based application and have a financial impact on the R&D sector which is minimal. It would make sense to attach such a test to the stability of the downstream biotech market as opposed to the uncertainties of the upstream R&D market, where the sensitivity of the 'blocking patents' situation should be sufficient to encourage innovation. Furthermore, the interaction of an outcomes-based commercial test with whether the experimental acts are related to the subject matter of the patent will create a clear test with an appropriate amount of flexibility.

It will also be argued that the efficiency of the unregulated market has produced solutions better targeted to the danger of a tragedy of anti-commons.

R&D Products and Services

DNA, the subject matter of much biotech research, is different from chemical compounds since there is a finite amount of genes in the human genome. DNA sequences have multiple uses as either diagnostic tests, research tools, gene therapy treatments, or the production of therapeutic proteins.¹ Biotech inventions are also often better described in functional terms (almost as a laboratory technique or product which produces a desired result), not structural, and are therefore more of a research tool sourcing new information. Therefore the addition of 'utility' as a requirement for patent grant has done much to calm concerns that biotech subject matter is incompatible with the patent system.

Biotech is also set apart by different regulatory requirements (government approval for sale and standards setting) over the industry spectrum. Medical device and diagnostic tests, for instance, are less onerous than that for pharmaceutical products. Such unusually lengthy clinical testing and regulatory approval cut significantly into the patent term by many years, arguably requiring an extension to the patent terms of drugs. The provision permitting use of an existing patent in seeking regulatory approval for another only benefits generic manufacturers. While NZ has provided this 'springboard' to imitation manufacturers, it has not balanced this with

¹ *Australian Law Reform Commission 'Genes and Ingenuity: Genes and Human Health' (2004) Chp 13 'Overview of the Biotechnology Sector*
<http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>
 (accessed 10/06), at 13

an extension of patent term to existing drug patentees.²

Biotech is also heavily reliant on research tools. Most innovation is built on what has gone before, which is why the 'products' of the R&D sector are patents, research tools, and results data/research services.

Industry Context

The biotechnology industry relies heavily on securing patents, often a small to medium sized enterprise's only assets. Without them technology is easily copied and the large R&D costs invested cannot be recovered. The majority of biotech projects in Australia and New Zealand are aimed toward end products in human and animal health, with high costs involved in clinical testing and regulatory approval.³ The pharmaceutical industry has a high product line failure rate, with only one in twelve compounds in preclinical development (prior to testing on humans) entering the market, each product costing almost a billion dollars over seven years of development.⁴ End products consequently require an aggressive marketing strategy, the challenge being to generate sufficient revenue to support such expensive product development. There is a high attrition rate in the industry due to this high financial risk.

Research in the sector is cumulative by nature, with many different stakeholders conducting research along every stage over a very long research spectrum. There are patents at every stage along the product development pipeline with downstream developers (closer to an end product that can be sold to the public or large consumer body such as a health system) requiring the 'products' of upstream researchers. Patents over invented research tools and technological inventions are the 'products' that the upstream segment of the industry transfers downward in ways that recoup their costs and fund further research. The patent portfolio is what attracts venture capital and collaborating partnerships, and the rise of the venture-capital industry in the 1970's paralleled the drive toward IP capture.⁵ Another reason for the commercialisation of research occurring earlier along the pipeline is that especially in biotechnology the distance between basic research and its immediate

application has narrowed as opposed to the wide gap seen in the chemical and electrical industries.⁶

The industry in Australia and New Zealand could be categorised as upstream,⁷ there being limited available venture capital investment or the established industry structure required for advanced development and end stage product testing. Local industry cannot afford to develop products through stage III clinical trials, so the goal is to in-license where necessary to add value to inventions and then license those projects on.⁸ Given the low odds of projects reaching end-product stage, companies have to functionally validate molecular targets and hopefully have entered phase II clinical trials.⁹ The result is a strong desire to gain access to larger (international) markets. Gaining and maintaining exposure among international investors and communicating the potential of products is a challenge.¹⁰ Patents, as end products in themselves, are then vitally important for the industry in New Zealand, more particularly the complex transfer of their associated rights and technology.

The Role of Public Research Institutions

The University Enterprise

Between 1995-1999 university and corporate DNA sequence patent applications were equal in number in Australia.¹¹ Traditionally the goals of university research have been met through public dissemination of research results, scholarly debate and publication,¹² but the traditional 19th century research university is looking very different in the 21st century. Although always a teaching and vocational institution,¹³ resources are shifting from the liberal arts toward commercial subjects. Universities have shed some of their traditions to take on persona as public sector organisations or commercial corporations, becoming the 'enterprise university'.¹⁴ This is particularly evident in the changes in governance and management structures.

² J Ballance, 'Implications of the Patents Bill for biotechnology inventions' [2005] *New Zealand Intellectual Property Journal* 95, at 96

³ Op cit.

⁴ H Rang et al, *Pharmacology* (5th ed, 2003), at 748

⁵ *Australian Government Advisory Council on Intellectual Property: Patents and Experimental Use (2005)* (ACIP Report) <http://www.acip.gov.au> (accessed 10/06), at 12 (Ref as ACIP in footnotes)

⁶ R Merges, 'Property Rights Theory and the Commons: The Case of Scientific Research' in E Frankel et al (ed), *Scientific Innovation, Philosophy and Public Policy* (1996)

⁷ K Hooper & L Thorburn, *2002 BioIndustry Review - Australia & New Zealand* (2002)

⁸ D Nicol & J Nielsen 'Patents and Medical Biotechnology: An Empirical Analyses of Issues Facing the Australian Industry' (2003) *Centre for Law & Genetics Occasional Paper No.6*, at 259

<http://www.ipria.org/publications/publiers/BiotechReportFinal.pdf> (accessed 10/06), at 111

⁹ Ibid.

¹⁰ Ibid, at 112

¹¹ ALRC, above n1

¹² A Monotti & S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), at 325

¹³ Ibid, at 29

¹⁴ Ibid, at 39

However the likelihood that universities will become completely privatised into the knowledge sector of the market seems premature,¹⁵ which means that while their new drive to patent brings them into competition with the private R&D sector they are still publicly funded. Although government funding has declined, it still subsidises a large part of tertiary education, and future sources of cash flow will realistically come from fee paying students, consulting, and continuing education.¹⁶

Still, with the emergence of the enterprise university there has come the drive to commercialise university IP. No longer is the goal to transfer knowledge to the community, but universities now enter into the high-risk business activity of R&D, forming start-up companies and licensing or assigning IP to that company with the expectation of return and a share of equity in the company.¹⁷ However, in reality IP is unlikely to become a steady source of funding. In the university setting it has been likened to an insurance policy or a gamble on a unlikely chance that a patent will become lucrative.¹⁸

Having said that, the net benefits may well be an enhanced staff profile, beneficial understandings between university and industry, increased resource capability and targeted knowledge exchange, and educational opportunities for staff and students.¹⁹ But the increasing commercialisation of university research results raises a difficult tension between market strategies and the university's commitment to freedom of inquiry,²⁰ particularly the conflict between open disclosure and the confidentiality required for exploitation.²¹ Surprisingly perhaps, the evidence shows higher publication rates occur from public institutes with formal partnerships with industry.²² The concern has still resulted in 'grace periods' (discussed below).

Impact on Market Dynamics

It is very early to tell what impact on the market this increasingly direct competition between public and private sector will have. It could be a concern that the public sector is unable to weather aggressive business interactions, with GTG's behaviour (discussed below) as an indicator of what's to come. The financial security that publicly funded institutions enjoy compared to private enterprise justifies an aggressive approach from industry, but then again the target is publicly funded and not a private risk. While

start-up companies have often been used by universities to commercialise a single product, this produces considerable risk since the venture rests on one hopeful success. While better risk assessment and business models will help both universities and public research institutes, there is often no profit motive, which may warrant a different approach from industry. (The problems with making such commercial distinctions are discussed below)

Economic Analysis of Innovation Markets

Different market forces are acting at opposite ends of the biotech pipeline due to the increasing length of time and resources it takes to bring technology to an end product which is accessible to the more general consumer. The balance of benefits and costs between producers and consumers depends on the reduction of monopolistic control in the product market.²³ This is a 'static' analysis with its primary concerns being 'allocative efficiencies'.²⁴ Patents don't fit into this concept because licensing creates long-term effects, and because such 'long run' or 'dynamic' effects compound over time, they overcome any static loss that they caused.²⁵ Static analysis of market forces has little role to play then in an innovation market.²⁶

The products in technology-driven industries only give their firms a transitory market power due to rapidly changing technology.²⁷ This poses significant problems for analysis since a market is usually defined in terms of 'demand and supply responses to a significant and non-transitory increase in the price of a product/service'.²⁸ Not only are there not enough relevant transactions to determine market price, but the technology and license agreements (and their value) differ widely from one contract to another.²⁹ The concept of a separate technology market is an unworkable analytical tool regardless of the actual existence of such markets.³⁰ The number of transactions in the R&D sector will have to increase to provide the relevant data, however the inherent flexibility of that market may continue to defy a unifying model, especially since R&D capacity is so speculative. "It would appear that most technology transactions would be more comfortably analysed with reference to the downstream market" seems a prevailing conclusion.³¹

¹⁵ Ibid, at 40

¹⁶ Ibid, at 551

¹⁷ Ibid, at 531

¹⁸ Op cit.

¹⁹ Ibid

²⁰ Ibid, at 526

²¹ Ibid, at 432

²² Nicol, above n 8, at 52

²³ A Gutterman, *Innovation & Competition Policy: a Comparative Study of the Regulation of Patent Licensing & Collaborative Research & Development in the United States & European Community* (1997), at 437

²⁴ Ibid

²⁵ Ibid, at 442

²⁶ Ibid, at 443

²⁷ Ibid, at 444

²⁸ Ibid, at 453

²⁹ Ibid, at 454

³⁰ Ibid.

³¹ Ibid.

Previously, economists theorised that the largest firms present at product-end stages would also be those investing in R&D, however the evidence shows that the relationship between firm size and innovative input/output is proportional.³² The small to medium sized firms often producing the more radical innovations. The relevance is that while market structure (the regulatory control of monopolistic conditions) had previously been thought to determine the level of innovative activity, competition of a different kind is the key. Demand is determined by the anticipated profit, while supply is determined by the growth of more knowledge producing firms.³³ The competition in this market is then heavily dependent on low entry barriers to new 'suppliers', challengers with new ideas to force the innovative pace.³⁴

The innovative market is dependent on low entry requirements (reduced licensing transaction costs, for instance). While difficult to analyse it is advisable that policy debate look to the downstream market to determine the most predictable commercial implications.

The Risk of a Growing Anti-Commons

The result of public research entering competition with private industry is that the results of that publicly funded research become commodified. Information intended for the public domain is now privately owned as intellectual property. There is also the risk that access by the public sector to this resource is denied. However, industry has often made the distinction between commercial and non-commercial when setting licensing fees. Genetic Technologies Limited (GTG), an Australian company, recently issued a non-commercial research license to the University of Sydney.³⁵ The patent describes a process of using non-coding regions of DNA to detect mutation in active coding regions, or intron sequence analysis.³⁶ The patent is essentially a research tool for genetic analysis. In the US the Applera Corporation is legally challenging the validity of the patent.

Of significance has been the company's diligent persistence in requiring public and private research institutions to enter license agreements with it, this raising concerns of a growing anti-commons with restrictions on accessing GTG's technology.³⁷ To contrast the royalties though, note that the largest commercial license fee charged from an Australian company was AU\$7.5 million, while the nominal fee

charged to the University of Sydney was AU\$1,500. The combined total paid by all the New Zealand research institutes to GTG was only NZ\$450,000. Nevertheless, the Auckland District Health Board refused payment and the matter was settled during mediation.³⁸

The issuing of licenses to non-commercial public research institutions and universities is controversial since it will encourage others to do the same. The fear of a growing anti-commons has arguably been sensationalised in the media.³⁹ This particular case is cited as one of the main catalysts of the call for a 'research exemption'.⁴⁰ A reaction which arguably ignores the balance that GTG tried to achieve between continued investment in research tool innovation and cognisance of the financial resources and market sector that public institutions operate in.

Tragedy within the Anti-Commons

It is normal for stake-holders to strengthen their market control by creating obstacles for competition through strategic patenting. While monopoly rights of exclusive exploitation are necessarily part of the patent incentive, there is the fear of a tragedy of the anticommons. This would occur when unsuccessful bargaining and prohibitive transaction costs prevent the exchange of intellectual property rights, creating a tragic wide-spread under-use of the resource. This can be inadvertently created by the increase in broad patents forming patent thickets.⁴¹

Although the existence of valid patents over widely used research tools does increase the risk of restrictive practices there is not yet any empirical evidence of an anti-commons developing. US studies⁴² report a risk but little evidence of an anticommons in biomedical research.⁴³ A recent Australian study reported exclusionary practices, being normal occasions of exclusive patent control, though there being little difficulty within the industry in gaining access to broadly applicable research tools.⁴⁴ Though reach-through rights (giving the licensor control over future improvements/on-licensing/uses within a restricted research field) and

³² Ibid, at 440-1

³³ Ibid

³⁴ Ibid, at 442

³⁵ ACIP, above n5, at 33

³⁶ Nicol, above n8, at 11

³⁷ Op cit.

³⁸ Ibid.

³⁹ The controversy described erupted into Australian public debate after a documentary on Australia's ABC, referred to in Nicol, at 9 (footnote 7)

⁴⁰ Op cit.

⁴¹ M Heller & R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, at 700

⁴² J Walsh, A Arora & W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen & S Merrill (ed), *Patents in the Knowledge-Based Economy* (2003)

<http://books.nap.edu/books/0309086361/html/285.html#pagetop> (accessed 10/06)

⁴³ Nicol, above n8, at 57

⁴⁴ Ibid, at 254

royalty fee terms extend the negotiations and raise the costs of this access slightly, on average a research project encounters less than five such patents.⁴⁵ The researchers in that study recommend a research exemption but link it explicitly with the costs of negotiating licenses and paying fees in order to preserve the progress of research with no commercial implications.⁴⁶

If anything it is the uncertainty alone and the fear created by the controversy over an increase in infringement suits that may create an overly cautious research community. Whether this would necessarily impede research, considered against the evidence in the US, Australia and Germany which reports no impeded access, is still a debatable question.⁴⁷ There is no evidence that New Zealand patentees are enforcing patents against non-commercial researchers.⁴⁸ Although there is no clear evidence of a market failure, the slow pace of case law development in this area has increased frustration at the lack of certainty.⁴⁹ Any legislative move will now have significant effect given that patentee's will immediately enforce their rights when their scope becomes clearly defined.

The most pressing concerns regarding the risk of widespread tragic underuse and misuse within the patented field of biotechnology are briefly discussed below.

Searching for Partners

The industry is desperate for streamlined mechanisms for searching out commercial partners.⁵⁰ When it comes to conducting a research project there are usually less than ten patents which may be infringed and in which case a license needs to be negotiated (usually more than three is considered onerous).⁵¹ The royalty percentage asked can be higher the further along the development.⁵² While biotech companies would like to license to larger multinationals, it very often seems that licensing to the plethora of small US biotech companies is more secure.⁵³ Searching through that web of patent holders and securing a relationship is very complex and expensive.

⁴⁵ Ibid

⁴⁶ Ibid, at 38

⁴⁷ Ibid, at 36 discussing A McBratney et al's submission

<http://www.acip.gov.au/expuseoptsubs/Amanda%20McBratney%20et%20al.pdf> (accessed 10/06)

⁴⁸ *A Research Exemption for the Patents Act: Progress Report on Policy Work, Associated Minister of Commerce, July 2005*

http://www.med.govt.nz/buslt/int_prop/research-exemption/cabinet/200509/200509.pdf (accessed 10/06), at 4-5

⁴⁹ Op cit, at 37

⁵⁰ Nicol, above n8, at 106

⁵¹ Ibid, at 182-3

⁵² Ibid, at 113

⁵³ Ibid

License Terms

Bargaining out the terms of the actual license agreement will take into account:

- 'reach-through rights' to future inventions (being royalties or licenses over future inventions). This is a very difficult territory since the degree and nature of improvement being specified is very speculative. It is also argued by some that this conflicts with the purpose of patenting which permits the recovery of award for only that particular patented invention⁵⁴;
- Exclusivity (usually only drug patents are exclusive) though field-of-use restrictions are then employed to prohibit sharing technology or achieving alternative commercial ends for instance;
- Reversionary rights if the technology is not developed within a limited time-frame; and even a retention of a right to research.
- The Fees will depend on the downstream value of the product or process and not the cost to the licensor in bringing the technology to the current point.⁵⁵

The industry in Australia and New Zealand is characterised as naive in its bargaining, especially with regard to over-valuation, usually by universities and research institutions.⁵⁶ However, when negotiations fail it is often felt that the negotiator is to blame for poor understanding of their product, the other party's position, and especially egos that disrupt business relationships.⁵⁷ Having said that, while there is evidence of patent-blocks (overlapping patents), the perception is that 99.99% of the time a license can be negotiated.⁵⁸ Broadly applicable foundational patents have been found to be licensed widely and non-exclusively.⁵⁹

Patent Enforcement

Infringement can occur through inadequate patent searching (sometimes in unrelated fields), vague patent scope, and uncertain scope of experimental defence. Detecting infringement involves scanning the art base: the internet, journals, magazines, databases, identified competitors, etc. Having the resources to pursue infringers is costly and it is usually left to the private sector, the larger companies and multinationals. A common tactic is to lodge a claim in court and employ PR strategies to encourage quick and effective negotiation of a license.⁶⁰ Some feel that patent holders fail the system if they do not have the resources to protect their property and commercialise it to full financial potential.⁶¹ It may

⁵⁴ Allen, above n 93, at 383

⁵⁵ Op cit, at 120

⁵⁶ Ibid, at 108 and 135

⁵⁷ Ibid, at 122

⁵⁸ Ibid, at 142-3

⁵⁹ Walsh, above n 47, at 323

⁶⁰ Op cit, at 214-6

⁶¹ Ibid, at 217-218

also be considered a duty to shareholders and collaborative partners, as well as other holders of IP.

Solutions

The New Zealand Patent's Bill 2005, still an exposure draft, is of particular importance to the biotechnology sector given the more stringent requirements for grant of patent and its uncertain silence on matters such as grace periods and research exemptions from infringement. Rather than the Bill's focus on the patentability of subject matter and the scope of that patent, it has been suggested that at least an equal consideration of the issues facing the exchange of existing patent rights would be more productive.⁶² So it is encouraging that just three months ago the NZ Cabinet agreed that an experimental use exception be incorporated into the draft Patents Bill.⁶³ Their direction, though, that it be drafted similarly to the final recommendation of the ACIP report leaves much room for discussion (below).

However, the Bill, and recent moves to amend it, have centred the debate around statutory measures. This essay will continue to explore these first before looking at how market-based solutions have approached the most pressing of concerns (discussed immediately above).

Statutory Measures

Grace Periods

Although all scientific research inherently involves a period of non-publication while theories are validated and improved, unguarded disclosures destroy the 'novelty' of an invention and are inconsistent with a patenting strategy. Industry sponsored research agreements can attempt to withhold university publication of research findings.⁶⁴ In Australia there is a 'grace period'⁶⁵ which excludes any disclosure by the applicant within the year prior to filing the complete specification from inclusion into the 'prior art' when determining novelty or obviousness. New Zealand does not have a grace period, and this is considered detrimental to biotech research in NZ.⁶⁶ The fear is that R&D investment will shift out of the country to jurisdictions where pre-filing disclosures will not prejudice patent filing.⁶⁷ Not only would a grace period remove a 'penalty' for unwitting

disclosures (the growth of the internet compounds this risk), but it would encourage the aims of the patent system in rewarding early dissemination of knowledge.⁶⁸

However, a grace period is not as clearly applied as absolute novelty. There is the risk that third parties may further disclose what was an initial 'grace' disclosure into the art base without indicating the source of their knowledge.⁶⁹ However, the evidential problems of tracing that disclosure to one protected by a grace period would not be far more strenuous than current searches of the prior art base to determine novelty. Australia, though, includes further disclosures after the initial public disclosure within the grace period of the first.⁷⁰

There remains the risk that another applicant (B) will file a specification before the person (A) who initially publicly disclosed the information does.⁷¹ Though public disclosure by B not derived from person A will naturally cause A's application to fail for want of novelty, B's application is also void for want of novelty due to A's disclosure. The risk of being 'pipped to the post' in a first to file system should not be affected because B's application, if it is underived from A's and is filed before A's application, trumps A's.⁷² (Many researchers may be working simultaneously on a possible invention, there being a race to the patent office) The problem is that A's disclosure, made early with the hopeful protection of a grace period, has now entered the prior art base too and will invalidate B's patent application. Both A and B loose out.

As a safety net for researchers, though, an international common general grace period is strongly favoured by the public research sector. Commercial laboratory publications and investor portfolios mean that the grace period would be of growing importance to the private sector R&D too. The US, Australia, and Japan all use grace periods (43% of the patent applications filed in Japan by universities and R&D institutes utilised the grace period).⁷³ While Europe has yet to decide, the importance and strength of our trading partners bordering the Pacific mean that New Zealand should consider drafting a grace period into the Patents Bill.

Patent Grant - Utility

The scope of patent grant has been altered to ensure that broad patents are not granted. Previously a ground for patent revocation, that a patent be 'useful'

⁶² G Graff & D Zilberman, 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 3 *IP Strategy Today* <http://www.biodevelopments.org/ip/index.htm> (accessed 10/06)

⁶³ http://www.med.govt.nz/templates/ContentTopicSummary____20388.aspx

⁶⁴ Monotti, above n 12, at 253

⁶⁵ Patents Act 1990 (Cth) s24(1)a (introduced April 2002)

⁶⁶ Ballance, above n 2, at 96

⁶⁷ http://www.european-patent-office.org/news/pressrel/2000_07_25_e.htm (accessed 10/06)

⁶⁸ Monotti, above n 12, at 259

⁶⁹ *Ibid*, at 260

⁷⁰ *Ibid*, at 264

⁷¹ *Ibid*.

⁷² *Ibid*.

⁷³ *Ibid*, at 265

now requires that an invention has specific, credible and substantial utility.⁷⁴ The criteria is based on United States guidelines.⁷⁵ Utility must be credible to a technician reading the patent specification, disclose a purposeful use specific to that invention, and have application in a 'real world context' (existing research area).⁷⁶ More particularly the USPTO will not grant patents to proteins based on DNA sequence alignments and predicted protein function, and EST patents will not cover rights over subsequent discovery of the whole gene.⁷⁷

These limitations on granting broad and speculative patents address the arguments of many commentators concerned about the impact of thickets⁷⁸ of broad patents on the R&D sectors. Similarly to the recent amendments to the United Kingdom Patents Act 1977 requiring industrial utility of gene sequence applications, already required through the UKPO's practice guidelines since 2002, this provision tries to ensure that research determining the unknown function and use of genes can continue.⁷⁹ As discussed in 'R&D Products and Services' above, biotech patents are unique, and gene patents especially so. Gene sequences do not accommodate discrete patent claims easily since genomes are actually multiple intersecting 'mini-ecosystems' and a single protein may require multiple genes for expression.

The concern over the patenting of biotech subject matter and its scope has also been over the patenting of novel processes which soon become vital research techniques, though routine.⁸⁰ If such patents are granted then any restriction in access will impact the research across the industry. It is still uncertain whether the addition of 'utility' as a qualifier will ease the load off other requirements of novelty and obviousness when it comes to assessing patent claims and preventing the granting of overly broad patents in this area.⁸¹

Construction of Patent Claims

Patents are legally defined by the language of the patent claim, and not by the actual invention, which means that narrowly written claims risk being

⁷⁴ Clause 13(iii) of the Draft Patents Bill
www.med.govt.nz/buslt/int_prop/patentsreview/index.html
(accessed 10/06)

⁷⁵ www.uspto.gov/web/menu/utility.pdf (accessed 10/06)
discussed in ft 3

⁷⁶ Ballance, above n2, at 98

⁷⁷ Ibid.

⁷⁸ A patent thicket being a web of IP rights all of which a company must gain access to in order to commercialise new technology without infringing those rights.

⁷⁹ Above n48

⁸⁰ J Thompson & M Bednarek, 'Strategies for Maximising Protection Under an Evolving Doctrine of Equivalents' (1996) 18(4) *European Intellectual Property Journal* 237-241

⁸¹ Ibid.

ineffective against patents that imitate them through the difference of an insubstantial feature.⁸² However the doctrine of equivalents or 'pith and marrow' provides relief in this situation. The application of that doctrine is a matter of dispute, an example being its formulation as a purposive construction of the claim specification while considering the scope of monopoly a skilled addressee would take from those specifications.⁸³

When assessing the patent to see if another is infringing it, a purposive construction is given to the specifications, which is arguably less narrow. There is an attractive simplicity in having the legitimate interests of the patentee only extend to the specific, credible and substantial utility specified.⁸⁴ While 'utility' is a requirement of patent grant, asserting the specified utility as the complete scope of the patent claim are two different things.⁸⁵ It is uncertain whether 'utility' will draw a patent claim toward this purposive construction.⁸⁶

Illustrative of the uncertainty is *KirinAmgen v Hoechst (TKT)*⁸⁷ which compared the existing patent claiming exogenous DNA insertion with a new potential claim for a DNA 'switch' insertion, both being claims for the endogenous expression of EPO (the most profitable biotech protein product). The issue was whether a skilled addressee would equate 'host cell' as limited to the process of exogenous DNA. In the UK this case turned on the purposive construction of specifications, expressed as the extent of monopoly that a skilled addressee would understand the specification to express. This was because that monopoly cannot extend over new technology and prevent market entry of competitive innovators. However, in the US the courts held that the first claim was a product-by-any-process claim, so disclosing the exogenous process covers the endogenous too. In the UK product-by-process claims were only permitted for their purpose in describing the product when other means, such as molecular weight, failed.

It is suggested that the introduction of 'utility' as a requirement for patenting will not address the reasons that call for the doctrine of equivalents (discussed in 'The Economics of Improvement' below) and that the ACIP was right to discount this idea.⁸⁸

⁸² M Lemley, 'The Economics of Improvement in Intellectual Property Law' (1997) 75 *Texas Law Review* 989, at 1003

⁸³ *Kirin Amgen v Hoechst* [2004] UKHL 46

⁸⁴ ACIP, above n5, at 50

⁸⁵ Ibid, at 49

⁸⁶ Ibid.

⁸⁷ *KirinAmgen v Hoechst* [2004] UKHL 46

⁸⁸ Op cit.

The result is that patent specifications alone are not going to help delineate the extent of a patentee's rights when it comes to picking a point at which to call it experimental use.

Research Exemption

A patent specification discloses all relevant details to the public. Although some say that this would obviously mean that the public is allowed to use this knowledge for further research, this must be balanced by the patentee's right to exploit the use of their patent technology.⁸⁹ Private companies are less likely to see the patent 'contract' as one where the state allows a monopoly in exchange for disclosure than that patentees must be compensated for refraining from withholding information and managing trade secrets, behaviours which benefit them alone.⁹⁰

An experimental or research use defence to patent infringement would enable the testing of patent validity, determine whether an invention falls within the scope of an existing patent, build a scientific profile of inventions, promote development of that invention and secondary innovation seeking improvements, and it may be able to remove the cost of technology access (patent searching) without shifting this cost onto the patentee through unreasonable restriction of their commercial market.⁹¹

NZ Situation

While we await the drafting of a research exemption, and enactment of the Patents Bill, our leading case formulates the exception as applying to private experimentation regardless of a commercial goal, but **not** to research which uses the patented invention to advance the researcher's commercial interest in the actual market place.⁹² The distinction is between research with or without a commercial focus,⁹³ does not exempt public institutions⁹⁴ and provides no guidance on the distinction between experimental and commercial.⁹⁵ The NZ Ministry of Economic Development in consultation with the Ministries of Health and Research, Science and Technology prepared a document facilitating industry consultation. In that document NZ's options for legislative clarification of an experimental use exemption are intentionally based on the preferred options from ACIP's report, and Cabinet has agreed

that the exemption be based on ACIP's wording in its final report.⁹⁶

Australia & ACIP Options

Legislative change in Australia is inevitable⁹⁷ and the ACIP recommendations underwent more consultation than the Australian Law Reform Commission's (ALRC) report before it.⁹⁸ The Federal government is yet to respond. Many possible options for reform were debated in the ACIP report, but this essay will focus on the options which received the most positive feedback in that consultation.

'Fair Use' Option⁹⁹ - It proposed a 'fair use' experimentation, similar to the copyright fair dealing provisions. But the analogy between copyright and patents doesn't hold for a few reasons: literature assists in research while inventions may be part of that research,¹⁰⁰ and patents provide stronger protection and are harder to acquire than copyrights. The analogy could also work negatively in that copyright case law would be turned to for guidance. While in principle 'fairness' will always have an attractiveness, in reality the discretion involved creates uncertainty and flexibility so the most promising options are below.

Exclusive Permitted Experimental Uses¹⁰¹ (Option B for purposes of Table 1) - limited the exception to acts determining operation, scope, validity and developing improvement, without further discretion. While clear, this option was considered too inflexible by ACIP, their evaluation is discussed further.

Experimenting, being the Dominant Purpose, "On" the subject matter of the invention, with Inclusive Permitted Uses¹⁰² (Option A for purposes of Table 1)

- In Europe the test to determine the exemption asks whether the acts are "related to" the subject matter (more detail in the Table 1). ACIP later concluded that this option's use of "on" instead of "related to" did not promote the clarity desired. Not only did ACIP find that 'on' added nothing to 'related to subject matter', but that the test's additional test to determine a dominant purpose was too complex to work. The wording was returned to 'related to' and the guidelines that the acts include those determining operation/validity/scope and seeking an improvement were retained but with the introduction of a proviso that the exemption not unreasonably conflict with the

⁸⁹ Ibid, at 11

⁹⁰ Ibid, at 14

⁹¹ ALRC, above n1, 'Experimental Use Exemption' at 324 (ref from now as ALRC above n91)

⁹² *Smith Kline & French Laboratories Ltd v AG* [1991] 2 NZLR 560, Hardie Boys J

⁹³ Ballance, above n2, at 97

⁹⁴ Above n48, at 5

⁹⁵ G Lynch & J Scarlett, 'Experimental Defence to Patent Infringement' *Baldwin Shelston Waters* <http://www.bsw.com>

⁹⁶ Op cit, at 2 &

http://www.med.govt.nz/templates/ContentTopicSummary____20388.aspx

⁹⁷ Ibid, at 7

⁹⁸ ALRC, above n1 and above n91

⁹⁹ ACIP, above n5, at 54-5 & 57-8

¹⁰⁰ Ibid, at 55

¹⁰¹ Ibid, at 56

¹⁰² Ibid, at 59 - 61

patentee's exploitation of their patent. This is discussed further below in 'Commercial/non-commercial Distinction', though the proviso was intended as a safety net to prevent any possible conflict with TRIPS Article 30 which states:

'Members may provide limited exception to the exclusive rights conferred by a patent, provided that such exception do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of their parties.' However, earlier in the report, ACIP agreed that an experimental exemption would meet compliance regardless.¹⁰³ This inconsistency aside, the effect of the proviso is critiqued below in 'Commercial Intention'. The two most promising ACIP options debated in the consultation are indicated in Table 1.

International Comparison

For ease of understanding, the key international positions will be presented and simultaneously compared in Table 1 on the following page. This table only aims to illustrate the different positions before an analysis of possible experimental use exemptions from patent infringement, drawing on some of the difficulties experienced in other jurisdictions. There is **no** evidence that experimental use exemptions are in decline. Both the academic and business communities in America have expressed concern over the narrow ruling in *Madey v Duke University* (see table), with considerable support for statutory research exemptions.¹⁰⁴ Not only has the American Intellectual Property Law Association recently drafted model experimental use exemptions that cover purposes 'related to scientific enquiry' and those 'seeking improvements' (discussed below),¹⁰⁵ but it is the second time a bill has been proposed in the US to introduce research exemptions.¹⁰⁶ This essay will not reflect on the complexities of industrial lobbying and the nature of congressional politics in the US. Furthermore, the UK and EU seem intent on preserving their respective research exemptions.¹⁰⁷

¹⁰³ Ibid, at 26

¹⁰⁴ *National Academy of Science Report: A Patent System for the 21 Century* (www.nap.edu) discussed in F Bor, 'Infringement applied to biotechnology research tools' [2006] *European Intellectual Property Report* [2006], at 9

¹⁰⁵ R Armitage, AIPLA Special Committee on Patent Legislative Strategies, 'Codification of the law on experimental use' (2004) *AIPLA*

¹⁰⁶ F Bor, 'Infringement applied to biotechnology research tools' [2006] *European Intellectual Property Report* [2006], at 9

¹⁰⁷ Ibid. at 13

Table 1 Shows paraphrased presentations of the current legal positions in key jurisdictions, and ACIP's options, ordered from most restrictive to most liberal. Countries where the tests are drawn from case law are seen as having very uncertain guidance on the scope and existence of an exemption. Trends are indicated in italicised brackets.

Conservative

US <i>case</i> ¹⁰⁸	Experimentation/Scientific inquiry not in furtherance of alleged infringer's legitimate business. (<i>Likely to be corrected due to extreme narrowness</i> ¹⁰⁹ and the implications for publicly funded research institutes 'in legitimate business') ¹¹⁰
Canada	Experimentation related to the subject matter of the patent and is not for profit. (<i>The case</i> ¹¹¹ <i>Canadian Biotechnology Advisory Committee is likely to recommend the exemption be for study of the patent subject matter to investigate, improve or develop new products or processes, placing Canada just above Germany below</i>) ¹¹²
New Zealand <i>case</i> ¹¹³	Private experimentation without a commercial focus
Australia <i>case</i> ¹¹⁴	Experimentation without a commercial advantage.
Option B	Experimental use is permitted for acts determining operation of the invention, scope and validity of the claim, and developing improvements to that invention only.
Option A	Experimentation <i>on</i> the subject matter, experimentation being dominant purpose, includes acts which determine operation/scope/validity & develop improvement.
UK	Experimental purposes related to the subject matter of the patent, and may have a <i>Statute</i> ¹¹⁵ commercial end in view. ¹¹⁶
Europe/Germany <i>Statute</i> ¹¹⁷	Experimental purposes related to the subject matter of the patent, regardless of commercial purposes (and includes trials for regulatory approval ¹¹⁸ and clinical trials ¹¹⁹). (<i>Most of the EU utilised the CPC style provisions and is likely to follow Germany's lead</i>) ¹²⁰
Japan <i>Statute</i> ¹²¹	All experimental inquiry or study (therefore includes regulatory trials)

Liberal

¹⁰⁸ *Madey v Duke University* 307 F 3d 1351 (Fed Cir, 2002)

¹⁰⁹ Federal Trade Commission (US), *To Promote Innovation: the proper balance of competition and patent law policy* (2003), at 37

¹¹⁰ T Saunders, 'Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine' (2003) 113 *Yale Law Journal*

¹¹¹ *Micro Chemicals Ltd v Smith Kline & French Inter-American Corporation* (1971) 25 DLR (3d) 79 and the exemption is recognised by implication only in *Patent Act 1985* (Canada) s 55.2(6)

¹¹² *Canadian Biotechnology Advisory Committee: Rationalising Patent Law in the Age of Biotechnology* (Advisory Memorandum) (Sept 2004 with full report released late 2005 on <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/Home>)

¹¹³ *SmithKline & French Laboratories Ltd v AG* [1991] 2 NZLR 560

¹¹⁴ No Australian court has ruled on the matter but the defence could be assumed from *Frearson v Loe* (1876) 9 ChD 48

¹¹⁵ *Patents Act 1977 (UK) s60(5)*

¹¹⁶ *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515

¹¹⁷ *German Patent Act 1981 s11.2* following closely the draft EU Community Patent Convention 1975 Article 27(b)

¹¹⁸ *Klinische Versuche (Clinical Trials) II* (1997) RPC 623, Federal Supreme Court of Germany

¹¹⁹ *Klinische Versuche (Clinical Trials) I* (1998) RPC 423, Federal Supreme Court of Germany

¹²⁰ M Rimmer, 'The Freedom to Tinker: Patent Law and Experimental Use', (2005) 15(2) *Expert Opinion on Therapeutic Patents* 184

¹²¹ *Japanese Patent Act 1909 s69.1*

In Germany ‘subjected matter’ was equated to the patent itself and its uses in order to facilitate reasoning that in that case¹²² could allow for clinical trials (seeking new therapeutic uses and dosages of a drug and not merely seeking dosage information for regulatory approval).¹²³ While clinical trials seeking new uses are arguably exempt, it is the *reasoning* which alarms commentators since it equates the subject matter of the product/process with the *use* of that product/process, the later being a legal right.

Some say that the issue is whether the invention is being experimented on for its own sake¹²⁴ or that the frequency of use should be an aid to decision.¹²⁵ Experiments and clinical trials require repetition, and research which seeks not just to improve an inventive product/process, but discover new uses and alternatives does not necessarily benefit the first invention. But the reasoning behind a research exemption is precisely to encourage secondary innovation. The challenge is to enable this but appropriately compensate the patentee.

ACIP formulated a final option after rejecting the ones it raised in consultation.¹²⁶ It preferred to disregard an ‘*on* and not *with* the invention’ test for the European style ‘purposes related to the subject matter’. However this option also provided that the permissible acts of experimentation would be those that include determining the operation, scope and validity of the claim as well as seeking an improvement to the invention. These clearly indicate the ACIP’s preference for drawing that line at acts which predominantly benefit the invention/enhance the process. The final recommended option (which NZ will follow during legislative drafting) was

‘The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent. Acts done for experimental purposes relating to the subject matter of the invention include: determining how the invention works, determining the scope of the invention, determining the validity of the claims, and seeking an improvement to the invention.’

¹²² *Klinische Versuche (Clinical Trials) I* (1998) RPC 423, Federal Supreme Court of Germany

¹²³ *Op cit*, at 46 & 70 discussing submissions and consultation by A McBratney (University of Queensland) noted above n47

¹²⁴ W Cornish, M Llewelyn & M Adock, *Intellectual Property Rights & Genetics* (2003), at 71

¹²⁵ ALRC, above n 91, at 327

¹²⁶ ACIP, above n5, at 72

Commercial / non-commercial Distinction

- Commercial Intention

While the current NZ exemption turns on the commercial purposes of experimentation, some submissions to ACIP considered it more appropriate to ask whether the experimentation affected the commercial interests of the patentee.¹²⁷ Since there is likely to be a commercial element in testing by any third party, and since the future impact of a secondary innovation developed to end product is difficult to predict, the question of commercial intent or impact is too uncertain a legal test and very difficult for project managers to apply. The commercial element was therefore not incorporated into any of the ACIP options presented for consultation. The question of unreasonable interference with the patentee’s normal exploitation of their invention/rights is so central though that it returned in the ACIP’s final redrafting of a recommended option.¹²⁸

If experimentation on patent inventions is permitted then the challenge is how to distinguish between research which meets the patent system’s goal of innovation without reducing the scope of control of the patentee and consequently the incentive that drives the patent system. Research which competes in the patentee’s commercial market by using their patent and reduces the potential for financial return is clearly antithetical to the patent incentive. A distinction between commercial and non-commercial research would recognise this, but there would be great uncertainty in such definition due to mixed motives, sponsorship share and unpredictable future returns.

ACIP re-introduced consideration of the commercial element by laying a proviso over the option that the experimental acts do not unreasonably conflict with the normal exploitation of the patent. Some commentators hoped that this proviso would prevent non-incremental improvements, which do not result in a cross-license/compensation to the original patentee, from coming under the exemption.¹²⁹ But the test, designed to determine the appropriate scope of patent rights, then asks that experimental use not conflict with those rights, which begs the question again. It also disregards the uncertainty in determining commercial intentions and the effect on the market for products such as research tools. Project managers individually may exercise too wide a discretion in using the research exemption without considering the cumulative effect throughout the market.

¹²⁷ *Ibid*, at 45

¹²⁸ *Op cit*.

¹²⁹ *Ibid*, at 70 noting A McBratney’s concerns

The ACIP proviso re-introduces a variable 'reasonableness' test of conflict with the patentee's commercial interests. Given that the greatest need expressed by the vast majority of submission to ACIP was for certainty regarding everyday research decision making activities¹³⁰ it is difficult to see why ACIP refused to define 'Exclusively Permitted Uses'. Given that ACIP expressed considerable concern at the slow pace of case law development in this area, and that case law contains a high risk of developing law which does not take the broad picture into account,¹³¹ it is surprising that ACIP rejected this option as inflexible and re-introduced variables into its final option so that 'courts have sufficient flexibility'.¹³² Are the tests designed for courtroom application with consequent turning to patent attorneys for guidance, or for daily application by a research decision maker?

- Outcomes Based

It is hard to imagine an experimental act (or any cognitive human act for that matter) void of intention or purpose. And while purpose may be private and nebulous, the outcome it is directed toward has a public (market place) impact. Purpose can be determined on an objective bases by accessing what the activity is designed to do. Experimentation and research only make a public and marketplace impact when they directly result in the commodification of those findings into a patent that can be assigned or licensed.¹³³ It is the commercial test which has caused controversy and international variation. What is being asked of the legislature is a test which considers commercial implications and can be applied with certainty in everyday situations.

The only test which removes the need for prediction is the existence of a measurable outcome. ALRC recommended avoiding a commercial test, reasoning that if commercially-oriented research fell outside the exemption this would be due to the act not being related to the subject matter and would not depend on the commercial objective.¹³⁴ However, no commercially oriented research would fall within the exemption since any outcomes which result in potential commercial gain can only come from use unrelated to the subject matter (or the patenting of non-incremental enhancement of the subject)

- Evaluating Outcomes Based Commercial Distinction

¹³⁰ Ibid, at 56

¹³¹ Ibid, 34 - 37

¹³² Ibid, at 72

¹³³ A Allen, 'Biotechnology, Research and Intellectual Property Law' (2002) 8 *Canterbury Law Review* 365, at 382

¹³⁴ ALRC, above n91, at 333

Economics of Improvement

Given that the promotion of secondary (further) innovation is the reason for considering a research exemption it is surprising that there is no mention of the procedures followed in the event that secondary innovation takes place. Particularly that if a given act results in an incremental improvement to an invention, then any further use of that patented invention in the improved form, for purposes unrelated to the subject matter of the primary invention, will usually require a license between the parties. All activities unrelated to the subject matter but which use it, such as the identification of potential drugs, receptors, drug targets, and the development of diagnostic tests which all use recombinant DNA technology, PCR taq polymerase, gene sequences and receptors, and the methodology in GTG's patent, result in outcomes which never benefit the first patentee. Such unrelated use would not occur without the investment and disclosure of these technologies, and as such their use would be misappropriation or free-riding without compensation to the patentee through licensing.

The doctrine of equivalents discussed above in 'Construction of Patent Claims' is used to determine whether a new claim of improvement falls within the scope of the pre-existing patent. But regardless, improvers who demonstrate an inventive and useful leap over the prior art qualify for patent grant. Improvers can obtain a patent, however that patent can still infringe the patent which is already part of the prior art. Neither patent holder can use the patented improvement without infringing each other. The patents 'block' each other and force the parties to negotiate a license. Only an improvement so radical that there is a change in principle, such as producing blood factor VIII:C from recombinant DNA technology instead of blood donation,¹³⁵ would in principle offer the patented improvement relief from literal infringement of an earlier patent. However this 'reverse doctrine of equivalents' is usually rejected by courts to maintain certainty in the system of patent incentives.¹³⁶

Normally, if a person does not own property then they will not seek to improve/invest in it. But in applying the doctrine of equivalents the courts do not take into account the *value* of the improvement.¹³⁷ The 'economics of innovation markets' (above) argued that competition and not allocated property interests promotes invention. So the value of property as an allocative efficiency, under a static analysis, is irrelevant when balancing incentives. The 'blocking patents' situation does this balancing, and

¹³⁵ *Scripps Clinic & Research Foundation v Genetech Inc* 927 F 2d 1565 (Fed Cir 1991)

¹³⁶ Lemley, above n82, at 1011

¹³⁷ Ibid, at 1006

is called a system of divided entitlements.¹³⁸ Normally, a person without ownership in property would seek an entitlement to it, by approaching the owner, before improving the property. However, the quantity of permission seekers and the difficulty in determining the potential for an improvement create a logistical impossibility, and a reticence from would be improvers. This is called Arrow's information paradox.¹³⁹ But the 'blocking patent' situation provides a bargaining power to improvers and therefore an incentive to invest in that possible improvement before gaining approval (license) from the original inventor. Better than compulsory licensing schemes, it still treats licensing as something to be worked out in the market rather than the courts, which for the parties concerned is more efficient.¹⁴⁰

There is no need, therefore, for further measures such as a research exemption to facilitate improvement that produces moderate and radical advances in innovation. The seeking of a minor improvement could perhaps benefit from an experimental exemption, though using that invention with its minor improvement should still be an infringement if the balance of incentives discussed above is to be maintained. Given that moderate and radical improvements are already catered to, the costs and uncertainty associated with designing an experimental exemption to cover acts seeking, but not developing, minor improvements is not worth the low value that minor enhancements offer.

Improvements which do not result in 'blocking patents' or radical improvements which qualify for non-infringing patents should normally be infringement of the original patent and compensate that patentee without the help of exemption. It also provides an incentive that researchers decide the likelihood of commercialising results early in the research cycle and approach patentee's then to negotiate licenses, since a refusal to license negates the research. It is, though, often in both parties' interests to overcome blocking patents. The factors in such negotiations are no different than those determining upfront fee quantum and the likelihood of successful commercialisation and appropriate royalties that already face license negotiations. If a researcher approaches a patentee later in the development when market potential is more predictable the licensee's bargaining position will be stronger, but the licensor will be justified in setting a higher royalty given the potential commercial gain of the licensee.

¹³⁸ Ibid, at 1043

¹³⁹ Ibid, at 1051

¹⁴⁰ Ibid, at 1071

Foundational Technologies

The concern of a growing anti-commons must kept in perspective, for it is this concern which tries to extend the experimental exemption further than the system of entitlements would allow. It must be remembered that work unrelated to the patent subject matter would obviously not occur in the absence of the technology in question. The question of whether that technology is obvious or novel is a question determined at patent examination. Some technologies do become foundational in that they become vital throughout the industry. Even in the presence of competition there may be little alternatives, but curtailing a patentee's rights if their patented technology becomes so successful is at odds with the patent incentive. It says "be innovative, but not too revolutionary in your innovation". Whichever company agreed to pay GTG AU\$7.5 million in licensing fees has certainly calculated this foundational technology as crucial in developing further patents/providing a marketable service.

Impact on Revenue Streams for Research Institutions

The fact is that a legal test depending on outcomes will remove a revenue stream from patent holders. A research project could progress for five years with the firm intention of patenting an improvement, but fail. With no patent to show for their work they still used a patented invention to test ideas related to the subject matter. Given the large financial loss of such a failed project, the risks and uncertainty should not be extended if innovation on prior inventions, the core of the patent system, is to be encouraged.

An outcomes-based test would extend the experimental defence over all acts related to the subject matter of the patent which does not result in a new patent. If there is no patent then the acts were exempt all along. If there is a new patent then the blocking patents situation will create sufficient incentive for parties to negotiate. If they don't agree then on a whole the system is still more certain with only a static inefficiency. The long term benefits will compound and outweigh the instances of static loss.¹⁴¹ It can never be perfect in every individual case, and blunt tests should not be progressed in the face of no empirical evidence of wide-spread patent blocking. It is in any patent holder's interests to license widely, more incentives or even compulsion to this end would do more harm than good. (The effect on revenue stream is further demonstrated in Fig 1 on page 16)

Support from Economics of Innovative Markets

The patent system does not promise an inventor the recovery of cost or the establishment of a monopoly. Patents only prevent free-riding, which enables an

¹⁴¹ Gutterman, above n23, at 442

inventor to secure an economic return, but that is dependent on the invention's social and economic value and the presence of alternative products and improvements (competition).¹⁴² Whether not-for-profit or commercial, all research institutions have to purchase expensive equipment and pay salaries. They may have different financial risks and pressures, but the complexity as private and public sector markets intersect prevents a workable distinction. The volume of submissions received from public research institutes that expressed concern at such a test, given their own trend to set commercial objectives early in the research cycle,¹⁴³ demonstrates a very different understanding of the patent system.

The debate over a research exemption becomes incredibly divided because the fundamental understandings of the system differ so greatly. The discussion on the under-use of innovative resources creating an anti-commons incorrectly identifies this as risking a significant 'dead weight' loss to society. However, such a loss is cancelled if the invention would not have even existed if it had not been for the incentive (patent system).¹⁴⁴ Ultimately, intellectual property is not a response to allocative distortions in information dissemination and the pace of innovation, but instead creates a scarcity in order to provide the possibility for economic return to investment and keep the cycle going.¹⁴⁵ Drawing the perimeter of an experimental research exemption at the point where there is a commercial outcome does not automatically provide investors with cost recovery (although higher returns are needed to fuel investment) nor does it automatically deprive researchers of material.

The economics of the innovation market (discussed at the beginning of this essay) are currently without uniform analysis, and expert economists still prefer an analysis from the perspective of the downstream consumer-product market.¹⁴⁶ This supports an outcomes-based commercial test, where a patent is the first, or at least most clearly identifiable, commercial 'product' in the innovation pipeline. Although the analysis of innovation markets depends on downstream factors, it was argued earlier that barriers to upstream entry are more important an indicator of competition. By tying transaction costs to downstream commercial outcomes, the cost of entry upstream is clearly reduced.

Certainty of Practice-based Application

There is sufficient certainty in the practice-based application of a test which looks to the existence of a patent and uses the 'blocking patents' situation. It can be demonstrated through the question flow chart below at Fig 1 (following page).

In the interests of certainty a requirement that outcomes be non-commercialised (un-patentable) would strike a balance between impact on the demand for a research tool in the market and a particular researcher's ability to pay.

Proposed Test

A proposed test would be two-fold: that the activity is (A) for experimental purposes related to the subject matter of the patent AND (B) that there be no direct outcome capable of commercialisation (patenting being the threshold point for capture of commercial potential). Given the discussion above on blocking patents, the inclusion of (B) removes the infringement that acts seeking minor improvements would be over the original patent. What (B) disregards is the market effects on demand in the interests of promoting minor improvements, since moderate and radical improvements take care of themselves through 'blocking patents'. While only allowing experimentation to determine operation/scope/and validity seem restrictive, the extension of the defence over acts seeking improvement is attractively objective when linked to the possibility of patenting that improvement. Patent holders can wait for 'actual improvements' to come to them seeking a license when blocking occurs instead of attempting to track potential improvers' activities.

The reason why (A) cannot also be expressed in terms of a technical outcome is that both experimental use and unrelated use result in no or minimal technical alterations to the invention. The wording 'purposes related to the subject matter' recognise that the nature of the activity is one and the same with its intended technical or scientific outcome. In other words (A)'s purpose must be to enhance scientific understanding of the invention's operation, scope and validity, or a technical enhancement or improvement.

¹⁴² Ibid, at 446

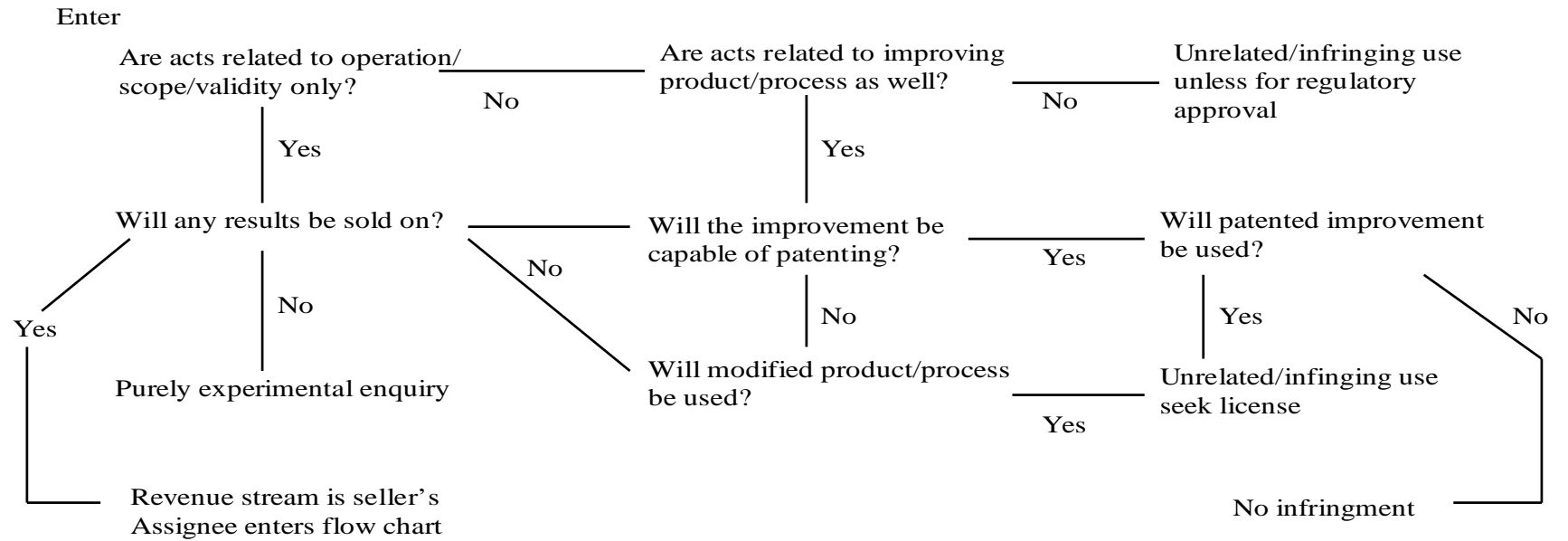
¹⁴³ ALRC, above n91, at 325

¹⁴⁴ Gordon, 'On the Economics of Copyright, Restitution and Fair Use: Systematic Versus Case by Case Responses to Market Failure' (1997) 8 *Journal of Law & Information Science* 7, at 31

¹⁴⁵ M Lemley, 'Property, Intellectual Property and Free Riding' (2005) 83 *Texas Law Review* 1031

¹⁴⁶ Gutterman, above n23, at 454

Fig. 1 Application of Experimental Exemption test to all avenues of revenue for Research Institutes



(B) operates as a check, though more objective than the ACIP proviso. Whether or not an outcome is commercialised, the production of outcomes even *capable* of commercialisation affect market demand for an invention or research tool. (B) is a very restrictive commercial test similar to ‘defenses other than experimental’ in the UK where even a possible commercial application precludes the defence.¹⁴⁷ It is perhaps too restrictive and not sensitive enough in light of the discussion above on a commercial-outcomes based test.

If patent holders cannot negotiate their way through a patent block then that patented improvement is of no value to its holder, so the exemption still applies and the original patent holder cannot sue for the research undertaken before grant of the improvement’s patent. There is no commercial outcome here. So test (B) needs to be clarified to read ‘and that experimental act does not directly result in a patented improvement which can be exploited without infringing another patent.’ This leans closer toward the position in Europe and away from current practice in New Zealand and Australia where a commercial license would be required if there was a fee for service, a revenue stream through invoice, or the research intends a direct commercial outcome.¹⁴⁸

An example of its application in a difficult area:

- Determining further functions of a patented genetic sequence (which will have described a particular utility in its specification) or its interrelation with other sequences is not an ‘improvement’ as such but seeks new uses. If that knowledge results in applying for a new-use-of-an-existing-invention patent then that patent compensates secondary innovation while a license fee will compensate the first patentee in the cross-licensing arrangement which ‘unblocks’ the patents.

Interaction of the two parts of the test

The objective commercial test helps define ‘related to’ better. The activity must be so directly related to the subject matter that any commercialisation beyond that act cannot occur. It must be remembered that in Europe where ‘related to subject matter’ is the test there is considerable uncertainty,¹⁴⁹ and that the liberal judgments on commercial intent all tend to relate to cases regarding regulatory approval of drugs,¹⁵⁰ for which separate provisions have now been enacted. New Zealand¹⁵¹ and Canada¹⁵² already

have broad regulatory review provisions over all products, not restricted to drugs. Australia’s only apply to drug patents which have had their patent term extended due to the considerable delay in gaining regulatory approval for the first drug.¹⁵³ The US does the same, so it places NZ at odds with these trading partners in that we have allowed generic drugs to start their trials sooner without balancing this with extension of the novel patentee’s monopoly. Given that ‘regulatory approval’ cases can be distinguished from ‘experimental use’ cases, the development of overseas case law around ‘related to subject matter’ rather than commercial intent will be more applicable.

While ACIP’s final wording, which will be closely followed by NZ, is very robust, it would be unfortunate to not address the residual uncertainty this formulation holds (with particular reference to commercial outcomes discussed above).

Market Solutions

The private sector has designed solutions to the obstacles it faces, apart from the concerns and statutory measures most often the focus of legislatures. Some of these solutions are canvassed below to demonstrate a sensitivity and efficiency unmatched by statutory measures, resulting in more win-win situations and increased productivity.

Collective Approaches

Cross-licensing, Patent Pools & Collective Rights Organisations

Two or more parties may enter into a reciprocal licensing arrangement to license each other’s patents (often the solution to a blocking patents situation). Large scale cross-licensing is termed a patent pool. While there is no evidence of this in the biotech sector in New Zealand and Australia it is being promoted as an effective form of collaborative relationship for the industry in the US and is likely to become more prevalent as the patent landscape increases in complexity.¹⁵⁴

Essentially all the licensors grant non-exclusive licenses to the pool (so they can still license to parties outside the pool), the appropriate patents being selected by an independent expert (along guidelines to prevent members from agreeing to share rather than challenge patents of dubious validity). The patents are licensed to interested parties using a royalty rate that is distributed according to each licensor’s patent share in the pool or some other appropriate formula (the restrictive terms are usually limited to grant-back provisions).¹⁵⁵ Patent pools

¹⁴⁷ ALRC, above n91, at 319

¹⁴⁸ Nicol, above n8, at 221

¹⁴⁹ Intellectual Property Institute ‘Patents for Genetic Sequences: the competitiveness of current UK law’ (2004), at 6

¹⁵⁰ *Monsanto v Stauffer* [1985] RPC 15 (CA) & *Klinische Versuche (Clinical Trials) II* (1997) RPC 623

¹⁵¹ *Patents Act 1953 (NZ) s68B*

¹⁵² *Patent Act 1985 (Canada) s55.2(1)*

¹⁵³ *Patents Act 1990 (Cth) s78*

¹⁵⁴ *Ibid*, at 211

¹⁵⁵ United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?*

reduce the transaction costs, especially for future licensees, through removing negotiations, and they also have the effect of distributing the risks of R&D over a collective and promote the exchange of information not covered by patents.¹⁵⁶

Exclusively licensed products would not fit within this model, but bioinformatics, gene sequences and other research tools that should ideally be broadly licensed could.¹⁵⁷ Industry compliance would be higher¹⁵⁸ due to the prospect of private contractual solutions. Previously, governments have either purchased key patents and placed them in the public domain or have mandated compulsory licensing, but private institutions have often formed effective collective rights organisations such as copyright enforcement in music, industry-wide and smaller patent pools (in the aviation parts and glass manufacturing industries in the US famously)¹⁵⁹ and standard setting patent pools (for the various DVD formats and mobile entertainment/software/audio formats (MP3) over many manufacturers).¹⁶⁰

The key trends within the biotechnology industry are continued company consolidation (normal considering the high rate of attrition) yet fragmented IP ownership (considering the complexity and diversity in the industry), with increased emphasis on multi-disciplinary interfacing.¹⁶¹ The result of this information overload is that there are now many 'clearing houses' or databases to match up providers, services and information with suitable contracts and a fee scheme, so much so that there is a need for a clearing house of clearing houses.¹⁶²

However, technology clearing houses, such as that being set-up in the Australian bioagricultural industry, need to be able to identify relevant IP claims and establish an appropriate pricing scheme over a wide range of products, which is difficult to do.¹⁶³ The clearing house must also be a watchdog against patents with poor validity and this can be expensive to monitor.¹⁶⁴

Unilateral Approaches

IP Management/ Commercialisation Services

(2000), at 13

<http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf> (accessed 10/02/06)

¹⁵⁶ Ibid, at 9

¹⁵⁷ Nicol, above n8, at 243

¹⁵⁸ Ibid, at 244

¹⁵⁹ Above n160, at 4 - 5

¹⁶⁰ Graff, above n62, at 3-4

¹⁶¹ A Krattiger, 'Financing the Bioindustry and Facilitating Biotechnology Transfer' (2004) 8 *IP Strategy Today*, at 7 <http://www.biodevelopments.org/ip/index.htm> (accessed 10/06)

¹⁶² Ibid, at 20

¹⁶³ Graff, above n62, at 9

¹⁶⁴ Ibid.

Management consultants like KPMG implement institutional policies and partnership strategies to open up opportunities for commercialisation. However, independently contracted commercialisation agents are considered highly effective with the most efficient business model.¹⁶⁵ Companies such as BTG Ltd (dedicated to biomedical technologies in US, UK and Japan)¹⁶⁶ and RCT Ltd (biomedical and biotech in US), and joint ventures in Australia (BioVentures Australia) and UK (Cambridge Research BioVentures), are some of the largest contractors.¹⁶⁷

The companies license-in for the technologies they manage, assuming maintenance and defence of that IP against infringement, and seek venture capital and R&D funding. They manage the development in forms ranging from start-up or spin-off projects¹⁶⁸ to placing them in incubators or 'science parks' where young firms share resources, technical support and critical business exposure in one place.¹⁶⁹ These companies may also provide funding themselves, in which case their assigned equity can approach 25% to 75% of the potential end product market value.¹⁷⁰ Essentially they are pooling necessary technologies devoted to core innovations that they aim to manage, increasing considerably their portfolio. BTG Ltd, for instance, manages over 350 technologies, 6,000 patents and 400 licenses.¹⁷¹

The quality and quantity of firms such as these are increasing, and very importantly the technologies they manage are usually the higher risk niche products that big pharma aren't interested in, ... yet. Very often the technologies come from universities, and also from the small to medium sized research and biotech firms that tend to take these risks. Commercialisation firms are the most efficient match makers and locators of funding given their strategic self-interest.

Conclusions

The emergence of the innovation market challenges traditional analysis of patent law and innovation. But the lowering of entry barriers to that market and clearly defining the entitlements to the products of investment in that market are clear needs. The introduction of an experimental use exemption to New Zealand is to be applauded. However, the final wording from ACIP arguably still requires a commercial component that is outcomes-based. This

¹⁶⁵ Above n 160, at 27

¹⁶⁶ Ibid, at 26

¹⁶⁷ Monotti, above n12, at 440-442

¹⁶⁸ Often single product commercialisation ventures set-up by a university or research institute and operating separately.

¹⁶⁹ Op cit, at 441 & 456

¹⁷⁰ Ibid, at 442

¹⁷¹ Krattiger, above n166, at 26

would more clearly balance the needs of the innovation markets with the concern over a growing anti-commons.

Having said that, how closely NZ follows ACIP now rests with the pen of the legislative drafts-person. It is hoped that the influence of legal argument surrounding commercial outcome and intent will be more clearly circumscribed before the EU & UK cases above are mined beyond recognition in this regard.

Furthermore, the private sector's initiatives at tackling a tragic underuse of that anti-commons demonstrate an adaptability to this rapidly changing technology market unlikely to be matched by statutory measures.

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