

**PATENTS AND EXPERIMENTAL USE:
ISSUES PAPER
ADVISORY COUNCIL ON INTELLECTUAL PROPERTY INQUIRY**

DR MATTHEW RIMMER

LECTURER

ACIPA, FACULTY OF LAW,
THE AUSTRALIAN NATIONAL UNIVERSITY

MS KRISHNA RAJENDRA

RESEARCH ASSISTANT

ACIPA, FACULTY OF LAW,
THE AUSTRALIAN NATIONAL UNIVERSITY

The Australian Centre for Intellectual Property in Agriculture, Faculty Of Law,

The Australian National University, Canberra, ACT, 0200

Work Telephone Number: (02) 61254164

E-Mail Address: Matthew.Rimmer@anu.edu.au

Introduction

The Australian Centre for Intellectual Property in Agriculture (ACIPA) is a research centre based at the law schools of the Australian National University in Canberra and Griffith University in Brisbane. It commenced operations in September 2000 to undertake research in issues relating to intellectual property law, and apply that knowledge to the scientific community and industry and rural bodies. The Centre's ultimate purpose is to foster an active environment in which Australia better protects and capitalises the products of research and innovation.

As part of its policy activities, ACIPA hosted a symposium, "Freedom To Tinker: Patent Law and Scientific Research", on the 19th March 2004. This symposium considered whether Australian patent law should have a defence for research use, and, if so, what its scope should be. It explored the impact of such an exemption upon a number of important industries - such as agriculture, biotechnology, health care, and information technology. It also examined the repercussions of such a defence for universities, research organisations, and educational institutions.

Strikingly, there has a great deal of consensus amongst the government speakers at the symposium. Mr Brian Opeskin discussed the proposals of the Australian Law Reform Commission from the Discussion Paper, *Gene Patenting and Human Health*. The Commission has proposed that the Australian Government should recognise a defence for experimental and research use to facilitate access to both genetic technologies and stem cell research:

The ALRC has concluded that it is desirable to remove uncertainty about the existence and scope of an experimental use defence in Australian law. Such a reform received broad support in submissions. The existing uncertainty is unhelpful to the research community and commercial organisations. It has the potential to lead to under-investment in basic research and hinder

innovation because researchers are concerned that their activities may lead to legal action by patent holders.¹

The Commission rejects the narrow, procrustean view of the research exemption adopted by the United States Court of Appeals in *Madey v Duke University*, which held that the defence was limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry".² It maintains that a statutory defence should be broadly based, and resemble the law of the United Kingdom and other member states of the European Union. It notes: "Moreover, basing a new defence on the European Union model would promote harmonisation of Australian patent law with the law of a major trading bloc, and would give Australian courts the benefit of considering European case law in applying the new provisions".³

Mr Doug Waterhouse, the registrar of the Plant Breeders' Rights Office, also supported the introduction of a research exemption in the patent system. He emphasized that a research exemption in relation to plant breeder's rights had been in operation in Australia for the last seventeen years. S 16 of the *Plant Breeder's Rights Act 1994* (Cth) provided "any act done in relation to a plant variety covered by plant breeder's rights that is done: (a) privately and for non-commercial purposes; or (b) for experimental purposes; or (c) for the purpose of breeding other plant varieties; does not infringe the plant breeder's rights". Mr Doug Waterhouse maintained that there should be a defence for experimental use in both plant breeder's rights and patent law for reasons of harmony and equivalence.

The other speakers provided an insight into the impact of the research exemption upon particular industries. Mr Geoff Budd, Counsel for the Grains Research and Development Corporation, was supportive of the creation of a research exemption from the perspective of the research and development community. Professor Simon Eastaerl of the Human Genetics Group at the John Curtin School of Medical Research in the Australian National

¹ Australian Law Reform Commission. *Gene Patenting and Human Health*. Discussion Paper 68. Sydney: Australian Law Reform Commission, February 2004, p 407-408.

² *Madey v. Duke University* (2002) 307 F.3d 1351.

³ Australian Law Reform Commission. *Gene Patenting and Human Health*. Discussion Paper 68. Sydney: Australian Law Reform Commission, February 2004, p. 410

University, and the Scientific Advisory Committee of Genetic Technologies Limited was not inclined to support a broad based research exemption. He emphasized the need for better licensing practices and digital rights management. Dr Thomas Faunce, a Lecturer at the Faculty of Law and the Medical School of the Australian National University was concerned about the impact of the United States-Australia Free Trade Agreement. Ms Miranda Lee, the Executive Officer of the Australian Digital Alliance discussed the relevance of a research exemption in the field of information technology.

In light of this symposium, ACIPA welcomes the opportunity to make a submission to the Advisory Council on Intellectual Property issues paper, "Patents And Experimental Use". It is concerned that there is great uncertainty whether researchers can rely upon a defence for experimental use. ACIPA recommends that the Commonwealth should amend the *Patents Act* 1990 (Cth) to establish a new defence to a claim of patent infringement based on the use of a patented invention to study or experiment on the subject matter of the invention; for example, to investigate its properties or improve upon it. The legislation should make it clear that the existence of a commercial purpose or intention does not affect the availability of the defence. ACIPA believes that such a research exemption is in keeping with our international obligations. Indeed, it is of the opinion that a defence for experimental use is compatible both with the TRIPS Agreement of the World Trade Organization and the recently concluded United States-Australia Free Trade Agreement.

ACIPA maintains that a defence for experimental use is a unique policy reform - because it would enable researchers to use a patented invention without either seeking permission from the patent owner or paying royalties. It can be distinguished by these characteristics from a number of other policy options. Thus, licensing, patent pools, and open source licensing depend very much up the patent holder providing permission for an invention to be shared in that way. Furthermore, compulsory licensing can compel a patent holder to give access to patented inventions - but the user is still obliged to pay royalties. Nonetheless, ACIPA observes that a defence for experimental use can be supplemented by additional reforms to patent law. The threshold patent criteria of novelty and

inventive step could be tightened, in line with the dissenting judgment of Justice Kirby in *Aktiebolaget Hassle v Alphapharm Pty Limited*.⁴ The compulsory licensing provisions in the *Patents Act* 1990 (Cth) need to be modernised to reflect contemporary concerns about competition policy. There should be greater use of creative licensing, patent pooling, and open source licensing to share patented technology. However, none of such reforms could be considered to be a substitute for the recognition of a defence of experimental use.

⁴ *Aktiebolaget Hassle v Alphapharm Pty Limited* [2002] HCA 59

Question 1

- (a) What is your understanding of current law on an experimental use exemption in Australia?
- (b) What is the basis of this understanding and how certain are you of it?
- (c) How has your understanding affected your research and development behaviour?

In Australia, there has been great uncertainty whether researchers can rely upon a defence for experimental use.

Some speculate that such a defence can be inferred from old English case law. In *Frearson v Loe*, Jessel MR stated that "if a man makes things merely by way of bona fide experiment... that is not an invasion of the exclusive rights granted by the patent".⁵

In *New York University v Nissin Molecular Biology Institute Inc*, a delegate of the Commissioner of Patents relied upon the case of *Frearson v Loe* in interpreting the words "experimental purposes" in regulation 3.25 (4) of the *Patents Regulations* 1991 (Cth).⁶ This provision addresses the uses that a third-party may make of a sample of a micro-organism deposited under the Budapest Treaty; it does not provide a defence to a claim of infringement. The Commissioner's delegate indicated that the term "experimental purposes" should be construed analogously too those experimental uses that do not give rise to an infringement of a patent.

Others argue that an implied experimental use defence may exist in Australian law, as it does in other common law jurisdictions. An experimental use defence might also be inferred from s 9 of the *Patents Act*, which excludes use 'for the purpose of reasonable trial or experiment' from the definition of 'secret use'.⁷ It could be argued that the patent holder should not be able to later claim that trial and experimentation by others during the

⁵ *Frearson v Loe* (1876) 9 ChD 48.

⁶ *New York University v Nissin Molecular Biology Institute Inc*. (1994) 29 IPR 173

⁷ *Patents Act* 1990 (Cth) ss 9(a), 18(1)(d).

life of the patent amounts to infringement of the holder's exclusive rights⁸. However, such an argument is difficult to make because the purpose and the nature of the experiments that an alleged infringer might want to conduct will be different from those of a prospective patent holder.

Despite an assumption that the experimental use exception applies in Australia, the evidence that Australian law recognizes research use as a defence is equivocal.⁹ This uncertainty in the law has implications for all relevant actors, including researchers who re-define, or "self-define"¹⁰ the scope of their potential research activity. The defence is used to the boundaries of their research until it becomes commercial venture.

There is no express defence of research or experimental use of patented inventions from liability for infringement in the *Patents Act 1990* (Cth). It would seem there is no compelling precedent or statutory direction that provides for a defence of experimental use.

⁸ Smith, C. 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 15.

⁹ Opeskin, B. *Inventions, Patents and Research*. Paper presented to 'Freedom to Tinker: Patent Law and Scientific Research Symposium', ACIPA, Canberra, 19 March 2004.

¹⁰ Ibid.

Question 2: What lessons, if any, do overseas experience and law hold for an experimental use exemption in Australia? In particular, are any of the overseas approaches to be preferred for Australia?

Overseas, there has been much debate about the boundaries of the defence for experimental use.

In the case of *Madey v Duke University*, the United States Court of Appeals for the Federal Circuit denied that the experimental use defence inoculated uses that were solely for research, academic or experimental purposes.¹¹ It held that the defence was very narrow and was limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry". The Court of Appeals stressed that the defence did not immunize any commercial use or conduct that is in keeping with the alleged infringer's legitimate business. Accordingly, it found that the educational institution Duke University could not rely upon the defence because the projects "further the institution's business objectives, including educating and enlightening students and faculty". The Supreme Court of the United States refused to hear an appeal against the decision of the Court of Appeals.

In the case of *Integra Lifesciences I Ltd. v Merck*, there was further discussion of the scope of experimental use defence in the United States.¹² In this case, the owner of patents for a pharmacologically useful peptide sued competitors for patent infringement. In dissent, Pauline Newman held:

The majority's prohibition of all research into patented subject matter is as impractical as it is incorrect. The information contained in patents is a major source of scientific as well as technologic knowledge. Indeed, in many areas of technology, technical information is not published outside of patent documents. A rule that this information cannot be investigated without

¹¹ *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

¹² *Integra Lifesciences Ltd v Merck KgaA* (2003) 331 F. 3d 860.

permission of the patentee is belied by the routine appearance of improvements on patented subject matter, as well as the rapid evolution of improvements on concepts that are patented.¹³

There was sharp criticism in her judgment of the decision in *Madey v Duke University*.

The decision of the Court of Appeals in *Madey v Duke University* has been widely criticised in public debate. Professor Rebecca Eisenberg notes: "Although the *Madey* decision did not extinguish the experimental use defense entirely, it eviscerated it to the point that it is essentially useless to research universities".¹⁴ She comments that the "seemingly disingenuous opinion... neither conforms to the implications of precedent nor explains the reasons for steering the law in a different direction but pretends that prior courts never meant to give research science special treatment".¹⁵ Eisenberg concludes: "Perhaps the experimental use defense could have evolved on a case-by-case basis as a tool for mediating between the private interests of patent owners and the public interest in unfettered scientific progress, but the Federal Circuit has shown no appetite for such a nuanced role. If universities are unhappy with the current state of the law, they may need to go to Congress to fix it".¹⁶

In an opinion, Dr Tim Sampson considers the application of the common law "experimental use defence" in light of economic theory.¹⁷ He draws upon the work of Adam Smith in the *Wealth of Nations*, the famous economic text which was contemporaneous with the first case on the experimental use defence, *Whittemore v Cutter*.¹⁸ Sampson argues that "the decisions in *Madey* and *Integra* are, in reality, divorced from general economic considerations and as such their possible but unintended impact will be a general impoverishment of patentees and the beggaring of fundamental

¹³ Ibid.

¹⁴ Eisenberg, R. "Patent Swords And Shields", *Science*, 14 February 2003, Vol. 299, p. 1018-1019.

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ Sampson, T. "Madey, Integra And The Wealth Of Nations", *European Intellectual Property Review*, 2004, Vol. 26 (1), p. 1-6.

¹⁸ *Whittemore v Cutter* (1813) 29 F. Cas 1120.

research, whether carried out in US universities or elsewhere".¹⁹ He observes: "It would, at least in the opinion of the author, have been better for the United States to adopt the European approach to experimental use, which seeks to strike a balance between the non-commercial and commercial phases of research".²⁰ Sampson concludes with a Shakespearean allusion that as "the short sighted patent proprietors now howling for the end of the common law defence, should have remembered that 'consuming means soon preys upon itself'".²¹

The Federal Trade Commission was critical of the decision of the Federal Court in *Madey v Duke University* in its recent report:

The Federal Circuit's ruling in *Madey v. Duke University* has a potential to upset the equilibrium regarding research uses of patented inventions and may heighten any problems raised by uncertainty over the reach of the experimental use defense. This warrants continued attention as the implications of these recent developments in the law become better understood.²²

In its workshops, the Federal Trade Commission considered three scenarios in relation to the scope of the research exemption. One involved research on a patented invention to see how or if it works. Panelists generally supported a research exemption for this purpose. A second scenario involved research to improve a patented invention, either creating a blocking situation (in which both the initial and the follow-on innovator need licenses to use the other's invention) or designing around the initial patent. Panelists expressed a range of views – from support through uncertainty and doubt – whether this research should be exempted. Third, there is the possibility of using a patented item as a research tool to create an unrelated product. Panelists generally voiced objections to exempting patented items produced for use by researchers.

¹⁹ Sampson, T. "Madey, Integra And The Wealth Of Nations", *European Intellectual Property Review*, 2004, Vol. 26 (1), p 1.

²⁰ Id, p 6.

²¹ Id, p 6.

²² Federal Trade Commission. *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, A Report by the Federal Trade Commission, October 2003, p 37, <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>

Michigan Democrat Congresswoman, Lynn Rivers, has introduced legislation into the House of Representatives of the Congress aimed at preserving research innovation, and quality patient care in the field of genetic testing. She declared: "Evidence is mounting that the patenting of human genes is both inhibiting important biomedical research and interfering with patient care".²³

The Genomic Research And Diagnostic Accessibility Act 2002 (US) HR 3697 has three major provisions. Section 2 exempts from patent infringement those individuals who use patented genetic sequence information for non-commercial research purposes. Section 3 would exempt medical practitioners utilising genetic diagnostic tests from patent infringement remedies. This section builds on an existing legislative reform in the United States which exempts health care providers from patent infringement suits when they use a patented medical or surgical procedure.²⁴ Such a measure was put in place after an uproar over the case of *Pallin v Singer*,²⁵ in which an eye surgeon was sued for patent infringement in respect of a surgical procedure. Section 4 of the bill would require public disclosure of genomic sequence information contained within a patent application when public funds were used in the development of the invention.

The Genomic Science And Technology Innovation Act 2002 (US) HR 3966 calls for an in-depth study by the White House Office of Science and Technology Policy on the impact of Federal patent policies on the rate of innovation, the cost, and the availability of genomic technologies.

However, biotechnology firms are hostile to the introduction of the two bills into Congress. Rochelle Seide and Michelle Seide from the law firm Baker Bolts complain: "If enacted, each of these [bills] would threaten future biotech innovation in the United

²³ Rivers, L. "Introduction Of *The Genomic Research And Diagnostic Accessibility Act* of 2002 H.R. 3967 and *The Genomic Science And Technology Innovation Act* of 2002 H.R. 3966", Congressional Record, 14 March 2002, E353.

²⁴ *A Bill to Limit The Issuance Of Patents On Medical Procedures*, House of Representatives 112, 104th Congress, 1st Session, 3 March 1995.

²⁵ *Pallin v Singer*(1995) 36 USPQ (2d) 1050; and S. Shulman, "The New Medical Licenses", in *Owning The Future* (Boston: Houghton Mifflin Company, 1999), 33-59.

States".²⁶ The pair believed that the attempt to limit the rights available to a gene-patent holder was misguided. Furthermore, they argue that the proposed study of the impact of gene patents is biased in its methodology. At the time of writing, the complementary bills have been referred to the Subcommittee on Courts, the Internet, and Intellectual Property for further consideration and discussion.

By contrast, in the European Union, the patent defence for experimental use has been broadly defined - including both non-commercial and commercial activities.

Many European Union nations exempt from liability for patent infringement "acts done for experimental purposes relating to the subject-matter of the patented invention".²⁷ Under present European Union law there are separate provisions which on the one hand exempt use which is private and non-commercial, and, on the other hand, experimental use. In consequence courts across Europe have shown increased willingness to treat experimental research as exempt from patent liability even though it has a commercial purpose.²⁸ However, there remain important limitations to the research exemption. Most notably, the exemption does not include research using a patented research tool which is not itself the subject of the further experimentation. Nor does it cover tests which merely replicate the invention. Nevertheless, the United Kingdom Department Health inquiry into Intellectual Property and Health reports "While the evolving European position on the research exemption does give rise to ambiguities, at least it can be said that a more coherent dynamic prevails in Europe than in the US."²⁹

In its recent discussion paper on *Gene Patenting and Human Health*, the Australian Law Reform Commission argued that researchers would benefit from the introduction of a

²⁶ Seide, R. and LeCointe, M, "Two New Bills Present Challenges To DNA Patentability", *GenomeWeb News*, 24 June 2002.

²⁷ Article 27(b) of the *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01.

²⁸ For the UK, see *Monsanto v. Stauffer* [1985] RPC 515. For recent confirmation of the new approach in France, *Wellcome Foundation v Parexel International & Flamel*, Tribunal de Grande Instance de Paris, 20th February 2001: *Intellectual Property News* Issue 17, July 2001.

²⁹ Two decisions of the German Supreme Court treat clinical trials of pharmaceuticals as falling under the exception.

defence for experimental use into the Australian patent legislation. It has advocated a broad-based defence of experimental use, in line with the European Union.

This submission supports the ALRC recommendations in their discussion paper³⁰. Rather than adopt the stringent US model of *Madey v Duke University*, Australia should follow the more liberal European model of a defence of experimental use.

³⁰ *Gene Patenting and Human Health*, ALRC Discussion Paper 68, 2004, chapter 14.133.

Question 3: What are the constraints for an experimental use exemption (or possible alternatives) under any of the international agreements to which Australia is a signatory?

It is axiomatic that any proposed new experimental or research use defence needs to be consistent with Australia's international obligation.

However, the defence of experimental use does not go beyond international norms and practices. The European Union and the United States of America have long recognized the defence of research exemption as a legitimate limited exception to the exclusivity of rights granted to the patent holder. By adopting the European model of experimental use, such a position is not constrained by multilateral agreements. It seems clear that the enactment of an experimental use defence into Australian law, covering acts done for experimental purposes relating to the subject matter of the patented invention,³¹ would not conflict with the provisions of the TRIPS Agreement, as it would constitute an appropriately limited exception to patent rights. Nor, as it currently stands, would the Australia-US Free Trade Agreement impede the introduction of the laws based on the European laws on experimental use into Australian law.

The amendment of the *Patents Act* 1990 (Cth) to include new defences would be entirely consistent with Australia's obligations under the TRIPS Agreement.

Article 30 of the TRIPS Agreement does note that "members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions 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 third parties".

The defences that have been mooted do not go beyond international norms and practices. The European Union and the United States of America have long recognised the defence

³¹ That is, consistent with United Kingdom law: *Patents Act 1977* (UK) s 60(5)(b); and *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01 art 27(b).

of research exemption as a legitimate limited exception to the exclusive rights conferred by a patent. The United States of America developed the limited liability for medical practitioners in respect of patent infringement.

Moreover, Article 27 (3) (a) provides that members may also exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans and animals". Furthermore, Article 27 (3)(b) stresses that members may also exclude from patentability plants and animals other than micro-organisms. However, members must provide for the protection of plant varieties either by patents or by an effective sui generis system. Such qualifications suggest that the patent system can be specifically tailored to deal with life forms - such as plants, animals and humans. Moreover, there would also be the opportunity to design special defences in such fields.

Article 17.9.3 of the United States-Australia Free Trade Agreement provides that "each party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of third parties".

This article echoes the language of the TRIPS Agreement. It would be sufficiently broad to accommodate a research exemption modelled upon the broad defence of European Union. This article of the United States-Australia Free Trade Agreement does not compel Australia to adopt the standard in *Madey v Duke University*. Neither does it restrict the United States Congress from legislating to provide for a broader defence for experimental use than is currently provided in *Madey v Duke University*.

Question 4: Is there any *empirical* evidence that the balance between the incentives for innovation and the ability to use innovations, particularly for research and development, is being significantly affected by the absence of an explicit experimental use exemption (or some other provision) in Australian patent law?

Strong empirical evidence exists to suggest that post-grant measures and incentives for innovation and the ability to use innovations for research and development is being affected by the absence of an explicit experimental use provision in Australian patent law.

The controversy over Genetic Technology Limited's patents with respect to non-coding DNA highlights problems with the lack of an experimental use defence.³² In May 2003, Genetic Technologies announced that the University of Utah had agreed to buy a research license to its non-coding patents for what it called a peppercorn fee - US\$1,000. This in effect made null the unwritten assumption on the defence of experimental use. Chief Scientific Officer of Sequenom Inc, Dr Charles Cantor, compared the pressure pressed upon researchers from Genetic Technology Limited in Melbourne akin to "blackmail"³³. Further, potential increases in license fees are not a viable option and would blow clinical and laboratory programs out of most science researchers budgets. Dr Mervyn Jacobson, founder and executive chairman of Genetic Technologies Limited in Melbourne sees no room for the exemption in the future of Australian patent law because, "Research these days, in general, is big business".³⁴

Part of the controversy can be attributed to a lack of understanding of the scope of experimental use as a defence. Research conducted by Dr Dianne Nicol and Jane Nielsen confirms that many Australian researchers and research institutions harbour erroneous assumptions about the scope of an existing experimental or research use defence. They note that some respondents to their 2003 survey of research institutions "put forward the

³² "Patently a Problem" Interview by Jonathon Holmes, *Four Corners*, Australian Broadcasting Corporation, 8.30pm 11 August 2003.

³³ Ibid.

³⁴ Ibid.

argument that all research as such is exempt, whether it is conducted in research institutions or private sector".³⁵ Based on the survey results, Nicol and Nielsen looked at the scope of what they term the "practice-based research exemption", that is, where the line is drawn between basic research, which is assumed to be exempt, and commercial research, about which there is no such assumption".³⁶

³⁵ See Nicol, D. and Nielsen, J. *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 218.

³⁶ Ibid, 218.

Question 5: Are there any overwhelming arguments for consideration of *pre-grant* conditions for patents as a complement or alternative to an experimental use exemption under Australian law?

There are arguments for the consideration of pre-grant considerations for patents as a complement to an experimental use exemption under Australian law. There remain problems with the application of patent criteria of novelty, inventive step and utility as highlighted by the *Alphapharm* case³⁷. The *Alphapharm* case reinforces the need for a wider range of defences, such as experimental use.

In *Aktiebolaget Hassel v Alphapharm Pty Ltd*, the majority of the High Court held that, in assessing whether or not the inventive step requirement has been satisfied, the issue is whether a notional research group in the field 'would have been led directly as a matter of course to pursue one avenue in the expectation that it might well produce the [claimed compound]'. The Court found that the results of a 'routine literature search' that have not entered into the common general knowledge are not relevant to an assessment of inventiveness. Further, the Court stated that: "The tracing of a course of action which was complex and detailed, as well as laborious, with a good deal of trial and error, with dead ends and the retracing of steps is not the taking of routine steps to which a hypothetical formulator was taken as a matter of course."

In the oral proceedings of the *Alphapharm* case, Justice Kirby argued that there was a need for the test of novelty and inventive step of the *Patents Act* 1990 (Cth) to reflect the complexities of contemporary science:

But the Act talks to science and invention at different stages. Its origins lie in earlier centuries and nowadays science, in the field of nuclear physics and the field of biology and in the field of informatics, has gone beyond the scope, immediate Eureka-type exclamations, it is more complex, and therefore, if the Act is to speak with relevance to science and technology as they exist today, the ultimate question that has to be addressed is whether in that moving context what is obvious moves with that change and therefore that with the advance of the availability of information,

³⁷ *Aktiebolaget Hassel v Alphapharm Proprietary Limited* [2002] HCA 59.

including through the Internet and so on, that you face up to the reality of that factual substratum to which the statute speaks.³⁸

Justice Kirby adds: "I have read somewhere there are 160,000 patents outstanding, many of them computer generated in the field of genomics for determination by the European Patent Office and the United States Trademarks and Patents Office. The policy would tend to favour, in the advance of science and technology, the need for real inventiveness and, as it were, a loosening up, if anything, of the *3M* test, so that in contemporary science and technology you would re-express that test, perhaps in a slightly different way... to require really and truly inventiveness and to disqualify for any obviousness, softening the obvious, strengthening the inventiveness".³⁹

In his dissenting judgment in *Aktiebolaget Hassle v Alphapharm Pty Limited*, Justice Kirby maintains that there is a need to engage in a statutory interpretation of obviousness and inventive step.

When a statute becomes encumbered in such a way as to obscure its operation and obfuscate the meaning of the simple words used (such as here, "obvious" and "inventive step"), it is time to return to basics. As was said long ago, in another area, courts must arrest the practice, common amongst lawyers, that introduces "lamentable and disgraceful technicalities". The Act is not set apart from the development of general principles for the interpretation of Australian statutes. True, it has ancient predecessors and a long history. It is concerned with large and valuable property interests. It is reasonable that parties should seek predictability in the operation of statutory language, drawn from judicial approaches to that language in the past. But in the end the duty of courts is owed not to judicial synonyms or lawyers' metaphors used to explain the language of the statutes. The duty is to the statutory language itself.

From time to time, specialist lawyers need to be brought back to such basic principles. Otherwise, they may take possession of provisions enacted by the Parliament and read them with spectacles focussed only on the glosses of decisional history. There is no justification for treating the Act differently from other federal statutes. I remain of the opinion that I stated in the context of another Act that has likewise become entangled in unnecessary decisional verbiage: "It is hubris

³⁸ Justice Kirby, Alphapharm transcripts, <http://www.austlii.edu.au/cgi-bin/disp.pl/au/other/hca/transcripts/2001/S287/1.html>

³⁹ Justice Kirby, Alphapharm transcripts, <http://www.austlii.edu.au/cgi-bin/disp.pl/au/other/hca/transcripts/2001/S287/1.html>

on the part of specialised lawyers to consider that 'their Act' is special and distinct from general movements in statutory construction which have been such a marked feature of our legal system in recent decades. The Act in question here is not different in this respect. It should be construed, like any other federal statute, to give effect to the ascertained purpose of the Parliament."

The role of the tests of novelty and obviousness in patent law has been described, correctly in my view, in this way: "One possibility whereby an unnecessary dead-weight loss could arise is if patent protection is granted for a non-innovative product or process. In this case society might incur a monopolistic welfare cost without obtaining a new product or process in return. This point alerts us to the fact that the tests of novelty and non-obviousness in the patent law fulfil the useful economic function of preventing undeserved monopoly profits. This potential misuse of monopoly rights must be prevented by strict application of the screening criteria in the patent law."⁴⁰

Justice Kirby observes the key criteria by which the inventive step test should be applied:

It is not diligence and determination or the input of time, labour, skill and effort or the expenditure of resources that meet the criteria in the Act. Something more is needed. And this, it seems to me, presents the substantive difference between the approach I favour, and that of other members of this Court.

As Mustill LJ puts it: 'If the criteria for patentability are pitched too low there is a risk that mere hard work or superiority of resources, or simple good luck, will entitle a researcher to a monopoly, the commercial and social justification for which is by no means, given the risk of stultifying the development of industry by open competition.'⁴¹

Justice McHugh makes similar comments: "A judge trying the obviousness issue is not bound, as a matter of law, to determine that issue by reference to persons who are not 'particularly imaginative or inventive'. Nor is the judge, in a case like the present, bound to ask 'whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not'. Not is the judge bound to ask whether a notional research group would be directly led, as a matter of course, to try the approach of the 'inventor' in the expectation that it might well produce a useful result or alternative."

⁴⁰ *Aktiebolaget Hassle v Alphapharm Pty Limited* [2002] HCA 59

⁴¹ *Aktiebolaget Hassle v Alphapharm Pty Limited* [2002] HCA 59

The Federal Trade Commission report, "To Promote Innovation", provides a number of creative reform proposals with respect to novelty and inventive step in the United States.⁴² It recommends that Congress tighten legal standards to determine whether an invention is "obvious":

It is important to protect against the issuance of obvious patents that may confer market power and unjustifiably raise costs. Requiring concrete suggestions beyond those actually needed by a person with ordinary skill in the art, and failing to give weight to suggestions implicit from the art as a whole and from the nature of the problem to be solved, is likely to result in patents on obvious inventions and is likely to be unnecessarily detrimental to competition. The Federal Circuit's most recent articulations of the suggestion test seem to signal greater appreciation of these issues and would better facilitate implementation of the test in ways sensitive to competitive concerns.⁴³

The Federal Trade Commission urges that in assessing obviousness, the analysis should ascribe to the person having ordinary skill in the art an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art. Requiring concrete suggestions or motivations beyond those actually needed by a person of ordinary skill in the art, and failing to give weight to suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art, errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.

The Federal Trade Commission urges that in assessing obviousness, the analysis should ascribe to the person having ordinary skill in the art an ability to combine or modify prior art references that is consistent with the creativity and problem solving skills that in fact are characteristic of those having ordinary skill in the art. Requiring concrete suggestions

⁴² Federal Trade Commission. *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, A Report by the Federal Trade Commission, October 2003, <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>

⁴³ Federal Trade Commission. *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, A Report by the Federal Trade Commission, October 2003, <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>

or motivations beyond those actually needed by a person of ordinary skill in the art, and failing to give weight to suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art, errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.

Accordingly, the Commonwealth should amend the *Patents Act* 1990 (Cth) to raise the standards of 'novelty' and 'inventive step' in light of the judgment of Justice Kirby in the Alphapharm case.

Question 6: Does fair dealing (or fair use) in copyright law hold any lessons for "experimental use" in Australian patent law? For example, could any of the provisions for fair dealing/use be translated into an experimental use provision in patent law? Or do differences in the nature and application of copyright and patent rights limit the analogies between the two systems?

Some analogies can be drawn between experimental use exemptions for patents and the fair use provisions in copyright.

In the United States, Donna Gitter observes: "Congress also should codify an experimental-use exemption for public-sector researchers at the federal level and nonprofit researchers".⁴⁴ She notes: "Such an exemption is appropriate for biotechnology research, especially research relating to homologous DNA sequences, since later inventions often contribute significant information about a particular sequence's function, thereby transforming scientists' understanding of that sequence".⁴⁵

Gitter argues that the defence of fair use in copyright law would be provide a useful model for a defence of experimental use.⁴⁶ Section 107 provides:

Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include -

⁴⁴ Gitter, D. "International Conflicts Over Patenting Human DNA Sequences In The United States And The European Union: An Argument For Compulsory Licensing And A Fair Use Exemption", *New York University Law Review*, 2001, Vol. 76, p. 1623. See also Gilat, D. *Experimental Use And Patents* 1995; and Barash, E. "Experimental Uses, Patents And Scientific Progress", *North-Western University Law Review*, 1997, Vol. 91, p. 667.

⁴⁵ Gitter, D. "International Conflicts Over Patenting Human DNA Sequences In The United States And The European Union: An Argument For Compulsory Licensing And A Fair Use Exemption", *New York University Law Review*, 2001, Vol. 76, p. 1623.

⁴⁶ O'Rourke, M. "Toward a Doctrine of Fair Use In Patent Law", *Columbia Law Review*, 2000, Vol. 100 (5), p 1177.

- (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
- (2) the nature of the copyrighted work;
- (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
- (4) the effect of the use upon the potential market for or value of the copyrighted work.

The fact that a work is unpublished shall not itself bar a finding of fair use if such finding is made upon consideration of all the above factors

The open-ended defence of fair use - with an inclusive list of protected activities and a list of relevant factors - would be a good model for the United States.

Fair use turns on the degree to which the infringer has added substantial value to the original work and 'transformed' it in some way.⁴⁷ In *Campbell v Acuff-Rose*, the United States Supreme Court held that the defence of fair use supported the transformative use of copyright material.⁴⁸ Justice Souter comments:

The central purpose of this investigation is to see, in Justice Story's words, whether the new work merely 'supersede[s] the objects' of the original creation, or instead adds something new, with a further purpose or different character, altering the first with new expression, meaning, or message; it asks, in other words, whether and to what extent the new work is 'transformative.' Although such transformative use is not absolutely necessary for a finding of fair use, the goal of copyright, to promote science and the arts, is generally furthered by the creation of transformative works. Such works thus lie at the heart of the fair use doctrine's guarantee of breathing space within the confines of copyright, and the more transformative the new work, the less will be the significance of other factors, like commercialism, that may weigh against a finding of fair use.⁴⁹

The Supreme Court moved away from the past emphasis in fair use decisions upon the commercial nature of the use. It specifically rejected the argument that *Sony v Universal City Studios* called for a presumption that every commercial use of copyrighted material

⁴⁷ *Campbell v Acuff-Rose Music* (1994) 127 L Ed 2d 500.

⁴⁸ *Campbell v Acuff-Rose Music* (1994) 127 L Ed 2d 500.

⁴⁹ *Campbell v Acuff-Rose Music* (1994) 127 L Ed 2d 500.

was unfair.⁵⁰ It claimed that the authority calls for "a sensitive balancing of interests", so that the commercial use of an activity was weighed along with other factors in fair use decisions.⁵¹

The notion of "transformative use" might be useful in delimiting the scope of experimental use.

50 *Sony Corporation Of America, et al. v University City Studios Inc.* (1984) 78 L Ed 2d 574.

51 *Campbell v Acuff-Rose Music* (1994) 127 L Ed 2d 500.

Question 7: Do basic, applied or hybrid research have different needs with respect to the patent system? If so, how can the patent system accommodate these differences?

Although the use of hybrid motivation may be useful to characterise research in the field of biomedical sciences and in other areas, the extent to which research for academic, industrial and commercial purposes overlap means that such categorisations of basic, applied or hybrid research do not provide a useful schema to assess changes to the patent system for the purpose of making explicit an experimental use defence.

Question 8: Is there any evidence for a "patent thicket" or "tragedy of the anti-commons" problem in research and development? If so, what are the issues/effects?

Strong empirical evidence exists to support that the current patent system in Australia is creating the growth of patent thickets which generates the, so-called "tragedy of anti commons"⁵². Contrary to the Bendekgey and Hamlet-Cox study, this has resulted in the under-use of patents and thus decline in investment in patents as well as research innovation in Australia.⁵³

⁵² Heller, M. and Eisenberg, R. "Can Patents Deter Innovation? The Anticommons in Biomedical Research", *Science*, 1 May 1998, Vol. 280, p. 698 www.sciencemag.org.

⁵³ Merz, J. *Diagnostic Testing Fails the Test* *Nature* vol. 415 (2002), p. 577. Also, "Patently a Problem" Interview by Jonathon Holmes, *Four Corners*, Australian Broadcasting Corporation, 8.30pm 11 August 2003.

Question 9: Does biotechnology, and genetic technology in particular, have special issues that warrant special treatment under patent law with respect to experimental use?

Biological inventions and gene patents do present issues that warrant special treatment under patent law in respect to experimental use. The Australian Law Reform Commission suggests that experimentation on patented genetic materials aimed at discovering another function of a genetic sequence or its interrelation with another genetic sequence should generally be covered by such a defence. The defence of experimental use should also extend to experimentation or research on the patented gene aimed at improving the invention. This approach is consistent with the views of Professor Rebecca Eisenberg, who suggested that the proper scope of an experimental use defence should include research 'in the field of the invention, which could potentially lead to improvements in the patented technology or to the development of alternative means of achieving the same purpose'.⁵⁴

⁵⁴ Eisenberg, R. "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 *University of Chicago Law Review* 1017, 1078. Also Rai, A. "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science" (1999) 94 *Northwestern University Law Review* 77, 139.

Question 10: What is the justification for an experimental use exemption?

Question 11: Is a criterion based upon whether the experimentation is *on the invention itself* as opposed to experimenting *with* an invention for *its intended purpose (use)* a useful criterion for determining "experimental use" in Australian patent law?

Question 12: If so, is it sufficient by itself?

Question 13: Should an experimental use exemption cover only the situation where experimentation is the *sole* purpose of the use of the invention?

Question 14: If not, what are alternatives or supplementary criteria for an experimental use exemption?

The justification for an experimental use exemption announced by the ALRC in their discussion paper is premised on the duty of disclosure of the patent holder. The compensation for disclosure is the payment of royalties. An experimental use defence may be seen as a going one step further than the disclosure requirement. While the disclosure of the innovation is made to the public, the defence of experimental use is likely to be limited to people within similar scientific and technological fields and academia, who may wish to comment or to use this inventive step to undertake further research or experimentation. This process allows for the development of new or improved inventions which is a fundamental tenet of the patent system. Without recourse to the experiment exemption researchers would be allowed only to read about the patented invention, without being able to experiment with the invention to see if and how it works.⁵⁵

The trend in modern European law offers useful criteria for determining "experimental use" in Australian patent law. Following the ALRC's recommendations the list of criterion may include:

⁵⁵ Australian Law Reform Commission. *Gene Patenting and Human Health*. Discussion Paper 68. Sydney: Australian Law Reform Commission, February 2004. Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States, 17 March 2000, WT/DS114/R, 56. See also Sampson, T. "Madey, Integra and the Wealth of Nations" (2004) 26 *European Intellectual Property Review* 1.

- experimentation *on* a patented invention and research involving the *use* of a patented invention;
- the purpose or intention of experimentation or research, in terms of its technical, scientific or commercial motivations;
- the technical, scientific or commercial outcomes of experimentation or research;
- or
- the nature of the organisation conducting the experimentation or research, for example whether the organisation is a commercial or not-for-profit entity.⁵⁶

The key element of a defence of experimental use should be that the requisite relationship between the experimentation or research and the patented invention exists. That is, that experimentation is on a patented invention or that research involves the use of a patented invention. However, experimentation to gain further knowledge about the patented invention and its uses should be covered.

In support of the Australian Law Reform Commission recommendations, under an experimental use defence, the following acts should not constitute patent infringement:

- (a) testing an invention to determine its sufficiency or to compare it to prior art;
- (b) tests to determine how the patented invention worked;
- (c) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
- (d) experimentation for the purpose of ‘designing around’ a patented invention;
- (e) testing to determine whether the invention met the tester’s purposes in anticipation of requesting a licence; and
- (f) academic instructional experimentation with the invention.⁵⁷

⁵⁶ Australian Law Reform Commission. *Gene Patenting and Human Health*. Discussion Paper 68. Sydney: Australian Law Reform Commission, February 2004.

Question 15: Are improved licensing practices by research organisations a whole or partial alternative to an experimental use exemption in Australia?

Question 16: If so, how could licensing practices be improved to provide better outcomes for researchers?

Recognising the importance for protecting, developing and commercialising knowledge and research resources, seven agencies⁵⁸ worked together to develop "...a consistent national framework for the management and exploitation of intellectual property (IP) generated by publicly funded research."⁵⁹

The nine principles were developed in order: "...to assist researchers, research manager and their research institutions, in ensuring that they have access to best practice for the identification, protection and management of IP, and therefore, to maximise the national benefits and returns from public investment in research."⁶⁰

The principles are expected to evolve over time and cover:

- the importance of having and IP policy;
- identification, protection and ownership of IP;
- assessment and management of IP;
- importance of sharing benefits and recognising the rights and needs of all stakeholders in the exploitation of IP; and
- transparency, reporting and potential conflict of interest issues.

Commercialisation of outcomes is viewed as requiring a case-by-case approach and is left for the individual institutions and organisations to define.

⁵⁷ Ibid. Also, Statement of Legislative History of Title V of Patent Competitiveness and Technological Innovation Bill 1990 (US) in H Wegner, *Patent Law in Biotechnology, Chemicals & Pharmaceuticals* (2nd ed, 1994), 465.

⁵⁸ The seven agencies were - The Australian Research Council; The Australian Tertiary Institutions Commercial Companies Association; The Australian Vice-Chancellors' Committee; The Department of Education, Training and Youth Affairs; The Department of Industry, Science and Resources; IP Australia; and The National Health and Medical Research Council.

⁵⁹ *National Principles of Intellectual Property Management for Publicly Funded Research.*

⁶⁰ Ibid

It is noteworthy that the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) stated that they "...do not wish to hold a stake in direct ownership of IP nor do they intend to benefit directly from commercial outcomes of the research funded through their financial support."⁶¹

Arguably, though, there is need for greater government regulations on intellectual property management in respect of collaborations between the private sector and the public sector.

In an article in *Law and Contemporary Problems*, Rebecca Eisenberg and Arti Rai comment upon the nature of technology transfer under the Bayh-Dole Act:

Under the Bayh-Dole Act, determinations of what to patent are assigned in the first instance to the institution receiving federal research funds--typically a university in the case of NIH-sponsored biomedical research. Universities, in turn, have delegated this task to technology transfer professionals who are charged with building patent portfolios that will bring in revenue to the university. If the university declines to pursue patent rights on a particular invention, the sponsoring agency may claim ownership. If neither institution wants to patent the invention, the investigator may do so. In other words, if anyone involved in the research--the grantee, the sponsor, or the investigator--thinks the invention is worth patenting, that party may prevail over anyone who believes the invention should be left in the public domain. As noted earlier, the research sponsor may vary these rules in the terms of a funding agreement only in "exceptional circumstances," and only by complying with burdensome procedural safeguards.⁶²

Eisenberg and Rai argue that "the decision of Congress to divest funding agencies of any significant discretion to restrict patenting makes much less sense than it did in 1980".⁶³

Eisenberg and Rai comment upon the creative role played by the National Institutes of Health in relation to access to intellectual property

⁶¹ Ibid

⁶² Rai, A. and Eisenberg, R. "Bayh - Doyle Reform And The Progress Of Biomedicine", *Law And Contemporary Problems*, 2003, Vol. 66, p. 289.

⁶³ Ibid.

Left to their own devices, universities may be unable to take sustained collective action in favor of the public domain. For this reason, the role of NIH is crucial. On a number of occasions, NIH has been able to use hortatory strategies to convince academic institutions to act collectively to keep basic research information in the public domain. For example, leaders of the National Human Genome Research Institute ("NHGRI"), together with the Wellcome Trust and academic researchers at the major human genome mapping centers, resolved in February 1996 that "all human genomic DNA sequence information generated by centers funded for large-scale human sequencing should be freely available and in the public domain in order to encourage research and development." ... NIH undertook a similar strategy for SNPs... The hortatory efforts of NIH to constrain its grantees in pursuing intellectual property rights have not been limited to genome-related projects. A more general statement of "Principles and Guidelines for Sharing of Biomedical Research Resources," adopted by NIH in December 1999, also attempts to guide NIH grantees in the deployment of their proprietary rights... The goals that NIH has sought to promote through these various hortatory statements are broadly consistent with the stated goal of the Bayh-Dole Act: "[T]o promote the utilization of inventions arising from federally supported research or development."⁶⁴

Nonetheless, the authors are concerned that the National Institutes of Health has acted outside the scope of its statutory authority, however, at least with respect to patentable inventions, leaving itself vulnerable to a potential legal challenge from a recalcitrant grantee. Furthermore, they observe: "But there is growing evidence that NIH may require authority beyond the bully pulpit to ensure continuing compliance with these norms in the future. Consider, for example, the recent controversy over the broad patent held by WARF on primate embryonic stem cells."⁶⁵

Eisenberg and Rai comment that universities are poor guardians of intellectual property because the immediate gain to be realised from patenting may outweigh the more distant possibility of gain from a university wide regime of collective self-restraint:

Universities face a very significant collective action problem, and traditional norms of open exchange may no longer be sufficiently robust to address this problem. The obstacle to relying

⁶⁴ Ibid.
⁶⁵ Ibid.

solely on universities is particularly large because the primary remaining adherents to open science norms, individual research scientists, do not necessarily make the ultimate decisions about university patenting.⁶⁶

The authors conclude argue that funding agencies should have greater discretion in imposing restrictions on patenting by the recipients of government funding: "We believe that the time is ripe to alter the Bayh-Dole Act to give funding agencies more latitude in guiding patenting and licensing activities of their grantees".⁶⁷

Similarly, in the Report on Intellectual Property Rights and Genetics, the authors submit that the United Kingdom Department of Health needs to play a more active role in relation to gene patents: "The Department needs to develop a coherent policy for both the receipt and the provision of patented material".⁶⁸ It notes that it is clear that the Department of Health will be directly affected by the patenting of genetic material. The impact of these patents will be twofold. The Department will stand as a receiver of patented products and processes. It could also stand as provider of patented products and processes developed by NHS trusts.

The report recommends that the Department of Health should recognise its unique position with regard to healthcare related intellectual property and take an active role in monitoring developments in relevant areas of intellectual property law (most notably patent law). It should, as provider and recipient of intellectual property, support the appropriate use of intellectual property law, and in particular patent law, in protecting inventions involving genetic material.

In light of the ongoing advancements in bioscience and difficulties in establishing and maintaining concrete distinctions between types of genetic innovation, it should focus its

⁶⁶ Rai, A. and Eisenberg, R. "The Public And The Private In Biopharmaceutical Research", Conference on the Public Domain, the Center for the Public Domain, Duke University, 9-11 November 2001.

⁶⁷ Ibid.

⁶⁸ Cornish, W., Llewellyn, M. and Adcock, M. *Intellectual Property Rights And Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector*. Cambridge: Public Health Unit, 2003.

attention not on the type of material being patented but on the way in which the UK Patent Office applies the new guidelines to applications involving biological material, and on equivalent decisions in the EPO and should also endorse the position taken by the Nuffield Council regarding the application of the granting criteria.

It should have in place a mechanism for assessing:

- (i) Whether to send information to the EPO or UKPO during the examination of a patent application which would restrict the scope of any patent on the disclosed genetic invention
- (ii) Whether to challenge the validity of a genetic patent once granted, either in the UK before the Comptroller of Patents or in court; or (for a European patent) by opposition proceedings in the EPO (commenced within 9 months of grant)
- (iii) Whether to challenge any abuse of monopoly in the manner in which a patentee exploits his rights by referring the matter to the UK Office of Fair Trading or the EC Competition Directorate.

The report recommends that the Department of Health should instigate a robust central policy for “licensing in” designed to moderate excessive demands by licensors by considering, as possible options, the use of compulsory licensing, competition law and Crown use. It should adopt a balanced approach for “licensing out”, particularly over the question of exclusivity, and where appropriate the Department should provide model agreements for use by hubs and Trusts.

The report concludes: "The action taken by the Ontario Government and the Dutch Government in respect of the Myriad Genetics patent would indicate that a strong

government line would be by no means unprecedented. Furthermore, The Curie Institute in France is leading the opposition to Myriad BRCA patents at the EPO⁶⁹."

Arguably, Australian funding agencies should follow the lead of the National Institutes of Health, and the United Kingdom department of Health, and play a much more active role in intellectual property management, policy, and litigation.

⁶⁹ The Institute is part of a coalition of 17 French research and clinical agencies, challenging the impact of the BRCA 1 patent through the European Patent Office.

Question 17: In what fields are patent pools a realistic whole or partial alternative to an experimental use exemption in Australia?

Question 18: Are the potential benefits of patent pools likely to outweigh their potential disadvantages?

The Australian Law Reform Commission has considered whether patent pools, patent clearinghouses or collective rights organisations might also help address difficulties in obtaining access to patented genetic materials and technologies.⁷⁰ Members of the United States Patent and Trade Mark Office have published a paper on whether patent pools are a solution to the problem of access in respect of biotechnology patents.⁷¹ They define a "patent pool" as an "agreement between two or more patent owners to license one or more of their patents to one another or third parties".⁷² David Resnik is a champion of such a scheme: "Industry leaders and scientists could choose the path of enlightened self-interest by forming a biotechnology patent pool".⁷³

The Commission recognised that "some participants in the Australian biotechnology sector may find the negotiation of patent licences to be problematic".⁷⁴ The law reform body, though, was not inclined to make proposals specifically aimed at regulating gene patenting licensing practices. It recommended that such matters should be taken up by an industry body: "The ALRC believes that a representative industry body should consider the feasibility of establishing patent pools or patent clearinghouses over particular types of patented genetic materials or technologies".⁷⁵

⁷⁰ Australian Law Reform Commission. *Gene Patenting and Human Health*. Discussion Paper 68. Sydney: Australian Law Reform Commission, February 2004., p. 634.

⁷¹ Clark, J. et al. "Patent Pools: A Solution To The Problem Of Access In Biotechnology Patents", United States Patent And Trade Mark Office, 5 December 2000, <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>

⁷² Ibid.

⁷³ Resnik, D. "A Biotechnology Patent Pool: An Idea Whose Time Has Come?", *The Journal Of Philosophy, Science And Law*, January 2003, Vol. 3, <http://www.psljournal.com/archives/papers/biotechpatent.cfm>

⁷⁴ Australian Law Reform Commission. *Gene Patenting and Human Health*. Discussion Paper 68. Sydney: Australian Law Reform Commission, February 2004, p. 639.

⁷⁵ Id, p. 641.

There was some debate in the inquiry as to whether patent pools could have anti-competitive effects in the marketplace. The Australian Competition and Consumer Commission submitted: "While pooling and cross-licensing can be pro-competitive, there is also the potential for arrangements to be used for blatant price fixing, or marketing sharing, agreements among competitors without any possible pro-competitive justification".⁷⁶ It suggested that patent pools would be less likely to raise competition concerns if they combined complementary patents, did not restrict access to the technology by third parties, and did not facilitate the sharing of commercially sensitive information of competitors in downstream markets.

Patent pooling is not a suitable alternative to a research exemption because the use of the patent is limited to members of the pool. By contrast, the defence of experimental use is available to conceivably the whole public - whether or not they are a member of a pool.

⁷⁶ Id, p. 670.

Question 19: Is compulsory licensing a realistic whole or partial alternative to an experimental use exemption in Australia?

Question 20: For this to happen, do Australia's compulsory licensing provisions need to be changed? If so, how?

In its present form in Australia, compulsory licensing provisions are both cumbersome and unwieldy and have not yet been invoked. If compulsory licensing is to be able to offer any meaningful supplement to the defence of experimental use then there needs to be legislative reform.

Compulsory licensing and forfeiture were intended to address a concern that foreign patent owners might limit domestic prosperity by hindering domestic manufacture and industry development while at the same time extracting monopoly profits.⁷⁷ Promoting domestic industry and development may no longer be imperatives,⁷⁸ but compulsory licensing and forfeiture provide potentially useful tools to implement competition objectives where the patentee seeks to impose high prices and restrict access.

Section 133 of the *Patents Act 1990* (Cth) provides a 'person' may apply for a compulsory license to be made by a 'prescribed court'⁷⁹ three years after the grant of a patent⁸⁰ where 'the reasonable requirements of the public with respect to the patented invention have not been satisfied' and 'the patentee has given no satisfactory reason for failing to exploit the patent'. Where a compulsory license has been granted s 134 provides 'an interested person' may apply to have the patent forfeited for the same reasons. Section 135 defines the 'reasonable requirements of the public' to be unfair prejudice to an existing or potential Australian industry or demand for the patented product or process has not been met in Australia, that trade or industry in Australia is

⁷⁷ Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 28.

⁷⁸ Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 162.

⁷⁹ The 'prescribed court' in this instance is the Federal Court as the regulations do not provide for a court and *Patents Act 1990* (Cth) s 154(1) provides: 'The Federal Court has jurisdiction with respect to matters arising under this Act'.

⁸⁰ *Patents Regulations 1991* (Cth) r 12.1(1).

unfairly prejudiced by conditions attached by the patentee or that the patent is not being commercially worked in Australia.

Menzies J of the High Court in *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation*⁸¹ considered a similar provision to the current s 135 of the *Patents Act 1990* (Cth) in s 110 of the *Patents Act 1952* (Cth) and stated that:

[T]he demand for the patented article has not been reasonably met if the court should be satisfied that, because of its superiority over articles already on the market, potential purchasers would have bought it had it been available. A market for a less efficient article indicates, other things being equal, a market for a more efficient article'.⁸²

In that case, the petitioner imported the patented improved captive bolt tool whereupon the patentee requested the petitioner cease and account for the tools already sold. The petitioner attempted to enter a licensing agreement but was refused as an exclusive licensing arrangement already existed and the licensee would not sub-license. At the time of the petition, the tool was not available to the public in Australia even though it was being manufactured overseas. Menzies J considered this was evidence that the reasonable requirements of the public had not been satisfied at the date of the petition.⁸³ However, at the hearing there was evidence that the exclusive licensee in Australia had good reasons for failing to supply the tool to the public. Further, he had acted reasonably in attempting to develop a tool to be profitably manufactured in Australia and that this was not a belated response to the petition.⁸⁴ Menzies J also considered the petitioner would be an unsuitable company to work the invention in Australia.⁸⁵ The application to grant a compulsory license was therefore refused.⁸⁶

The present s 135 is constructed more broadly than s 110 of the 1952 Act and might be interpreted differently, with a focus on competition principles. In these circumstances the

⁸¹ (1969) 119 CLR 572.

⁸² Ibid 575; the market was to be determined at the time of the hearing.

⁸³ Ibid 578-79.

⁸⁴ Ibid 579-82.

⁸⁵ Ibid 583.

⁸⁶ Ibid 583.

term ‘trade’ might be expected to have a very broad meaning and include every commercial or business transaction as well as non-arm’s length dealings outside the main stream of ordinary commercial activities and without a dominant purpose of profit making.⁸⁷ The terms ‘unfairly prejudiced’, ‘reasonable terms’ and ‘reasonable extent’ require an interpretation that should also promote competition principles. However, despite the apparently broad application of these provisions, and in particular the definition of the ‘reasonable requirements of the public’, they have not been relied on to any extent in Australia.⁸⁸ This might be because they are either (a) too restrictive – too difficult to prove, hedged with qualifications and discretion and too expensive to seek, or (b) very effective – inducing patentees to license in fear of a compulsory license and forfeiture.⁸⁹

In reviewing the patent system in 1984, the Industrial Property Advisory Committee recommended additional discretionary powers for courts to order compulsory licenses as a competition law remedy where the patent related conduct breached Part IV of the *Trade Practices Act 1974* (Cth).⁹⁰ This recommendation extended to including the transfer of know-how together with the patent as a reasonable license term, and that such licenses should allow importation of the patented product or process.⁹¹ The recent Intellectual Property and Competition Review Committee recommended replacing s 135 with a series of conditions that if satisfied would require the order of a compulsory license.⁹² These conditions include that access to the patented invention is required for competition in a relevant market, that there is a public interest in enhanced competition, that the reasonable requirements for access have not been met and that the order would not

⁸⁷ *Re Ku-ring-gai Co-operative Building Society (No 12) Ltd* (1978) 36 FLR 134, 139 (Bowen CJ); 167 (Deane J).

⁸⁸ The only reported cases are *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation*, above n 124 and *Wissen Pty Ltd v Lown* (1987) 9 IPR 124.

⁸⁹ Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 28; and Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 162.

⁹⁰ Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984) 27-32.

⁹¹ *Ibid* 32-33.

⁹² Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 163.

compromise the legitimate interests of the patent owner.⁹³ In applying these conditions the Australian Competition Tribunal was cited for its expertise in applying Part IIIA of the *Trade Practices Act 1974* (Cth) and perhaps suggesting the principles applied in Part IIIA might be relevant in assessing the need for a compulsory license.⁹⁴ There was no other indication of how the broad terms of the conditions might be interpreted, although the Intellectual Property and Competition Review Committee did consider the requirement for competition in a relevant market would mean there was no other option for competition in that market.⁹⁵

Compulsory licenses are potentially the most convenient and effective way to deal with the failings in applying the existing competition elements of the *Patents Act 1990* (Cth). Article 31 of the *Agreement on Trade Related Aspects of Intellectual Property Rights*⁹⁶ (TRIPs) makes express provision for compulsory licensing (or rather, ‘other use without authorisation of the right holder’) as forming part of the minimum standard patent legislation for World Trade Organisation member states. The pre-conditions specified by TRIPs for the grant of a compulsory license are onerous and only follow the failure of the patentee to authorise use on reasonable terms and conditions within a reasonable time (except in national emergencies). There is also express recognition that compulsory licenses are a remedy in any judicial assessment of anti-competitive conduct, and it seems likely this provision would extend to include a suitable remedy following a finding of conduct in breach of the *Trade Practices Act 1974* (Cth). However, there are substantial difficulties in assessing a reasonable royalty and exactly what circumstances merit a compulsory license. Finkelstein J’s assessment that a compulsory license was ‘cumbersome and expensive to apply’⁹⁷ identifies what is probably its biggest disadvantage as a remedy for an anti-competitive patent. Further, the terms and royalty to be paid for the compulsory license should not be under estimated because of the potential

⁹³ Ibid 163.

⁹⁴ Ibid.

⁹⁵ Ibid.

⁹⁶ Part of ‘The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations’ signed by ministers at Marrakech on 15 April 1994 and came into force on 1 January 1995. This agreement formed part of the trade negotiations started in Punta del Este, Uruguay in September 1986 that created the World Trade Organisation.

⁹⁷ *Bristol-Myers Squibb v FH Faulding & Co Ltd*, above n 59, 568.

for trade sanctions and retaliation according to the dispute settlement procedures forming part of TRIPs.

Perhaps a more fruitful area to consider is the exceptions detailed in Arts 7, 8, 30 and 40 which expressly recognise that domestic laws may deal with promoting innovation, technology transfer, remedy anti-competitive practices and regulate intellectual property which adversely affects trade or impedes technology transfer. Further, the recent decision by the World Trade Organisation in Canada – Patent Protection of Pharmaceutical Products⁹⁸ established the potential of domestic patent laws to implement measures to resolve the potentially damaging effects of patenting and promote competition.⁹⁹

The Commonwealth should amend the *Patents Act* 1990 (Cth) to clarify the test for the grant of a compulsory licence. It should clarify the circumstances in which the ‘reasonable requirements of the public’ will not have been satisfied. It should specify that s 135 is not an exhaustive list of the circumstances in which a patented invention would fail to satisfy the ‘reasonable requirements of the public’.

The Commonwealth should amend the *Patents Act* 1990 (Cth) to insert the competition-based test that was recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence. The amendment should also provide for an independent review of the operation of the compulsory licensing provisions in addressing competition concerns arising in relation to patented inventions. This review should be conducted five years after the new test commences operation.

The *Patents Act* 1990 (Cth) should be amended to allow a compulsory licence to be granted to a patent holder who cannot work his or her patent without using another patent for which authorised use cannot be obtained.

⁹⁸ WT/DS/114 (17 March 2000).

⁹⁹ Review in Lawson, L. ‘Canada v European Union – Competition and Patents at the WTO’ (2000) 28 *ACCC Journal* 1.

Question 21: Are open source principles a realistic whole or partial alternative to an experimental use exemption in Australia?

Question 22: Are the potential benefits of open source likely to outweigh their potential disadvantages?

The Commonwealth and its relevant funding agencies should provide support for open source projects to help promote access to genetic databases and scientific information. Although not a substitute for a research exemption, such projects will help the dissemination of genetic information and biological inventions.

The free software foundation¹⁰⁰ and the open source movement¹⁰¹ have been a source of inspiration to public researchers involved in the human genome project. Many researchers have been keen to ensure that scientific information and biological software remains in the public domain through the use of creative contracts. They have sought to live up to the impression that the scientific community is completely open and a place where ideas are shared freely. There are several main clusters of groups within the bioinformatics open source software community.

The first group concerns the Ensembl project. It consists of computer programs for genome analysis and the public database of human DNA sequences. Ensembl is a joint project which is being run by the Sanger Center, the U.K. partner in the publicly funded Human Genome Project (HGP) consortium, and the European Bioinformatics Institute (EBI). It is funded by the medical welfare charity, the Wellcome Trust.

¹⁰⁰ Moody, G. *Rebel Code: Linus Torvalds, Open Source, and the War for the Soul of Software*. London: Penguin Books, 2001, p 26-27.

¹⁰¹ Raymond, E. *The Cathedral and the Bazaar: Musings on Linux and Open Source by an Accidental Revolutionary*. Cambridge, Mass.: O'Reilly and Associates, 1999; Wayner, P. *Free For All: How Linux and the Free Software Movement Undercut the High-Tech Titans*. New York: Harper Business, 2000; and Moody, G. *Rebel Code: Linus Torvalds, Open Source, and the War for the Soul of Software*. London: Penguin Books, 2001.

At the CODE conference at Cambridge University, Tim Hubbard from the Sanger spoke about Ensembl and the Human Genome Project.¹⁰² He stressed the problems in distributing and integrating data about the human genome - namely, that while biological sequence data has been doubling every six months, computer speeds are doubling every eighteen months. Tim Hubbard believes that Ensembl is a means of making the project of genomics 'democratic' so that people can contribute information and share it effectively:

Something like the human genome is too complicated for any person, any group, any company, to have a monopoly on knowledge. On the other hand, if every organisation puts up on a web-site what they think is on the human genome, you have a terrible mess in terms of people trying to understand, comparing one website to another website. So the approach of this open software project is to be as open as possible. Very standard things - open CDS repository; open database; open discussion; everyone can get the software; everyone can do similar bits of work with similar interfaces. That does not address the overlapping of the annotation.¹⁰³

The Ensembl Project is working on client server development. It hopes to ensure that users can participate in the annotation of the human genome, in a democratic and constructive fashion.

The Ensembl project seeks to overcome problems of inter-operability in the field of bioinformatics. They are larger, industry-focused organisations forming within the community who seek to shape the direction of many of the standards for interoperability. Brown and others comment that there are many obstacles to interoperability, not least the historical development of the sector:

Bioinformatics systems were originally developed by relatively isolated research groups in response to local information handling problems. Established research groups have consequently exhibited a reluctance to part with their locally developed systems and their preferred vocabularies and terms of reference for compounds and genes. The degree of flexibility and openness to change by such actors is likely to be limited because of the financial cost of reorganising

¹⁰² Hubbard, T. "Ensembl And The Human Genome Project", CODE Conference, Friday 6 April 2001.

¹⁰³ Ibid.

nomenclatures and data handling systems. If cross matching between data bases is to be as automated as is hoped, these difficulties have to be overcome.¹⁰⁴

Brown and others seize upon a remark by a public database provider that the private sector secured its market by using incompatibility (interoperability) as a main asset.¹⁰⁵ To the question whether interoperability is a technical problem or not, this respondent answered: "Linux, Emboss and other free and open projects clearly demonstrate that the problem is NOT technical, nor is it expenses. But just merely unwillingness of private companies to allow free competition".¹⁰⁶ Others claimed commercial soft-ware changed its data format so that interoperability would be reduced. For public databases this means buying new software might take up a rather large part of their budgets.

The second group is the Bioinformatics.org and the Open Lab. This group offers web hosting and project support for a large set of projects relating to bioinformatics. The projects within the Open Lab are primarily end-user software tools for scientists looking to solve particular biological and bioinformatics problems. Bioinformatics.org are concerned that bioinformatics software has been extremely restrictive, with licenses reaching millions of dollars per institution. Third, the organisation campaigns against any notion of ownership of biological information and will work to develop a public or open licensing plan for information that has already been patented:

When genomics companies patent natural (not engineered) products, such as human genes, they act like prospectors or gold-diggers. They claim ownership of that which they haven't invented or produced: biological information. And they cannot purchase it from anyone who has. This was made very clear as companies filed patents on tens of thousands of human genes during the Human Genome Sequencing Initiative. Some companies went as far as to write software that automatically printed a patent application for each gene found.¹⁰⁷

¹⁰⁴ Brown, N., Nelis, A., Rappert, B. and Webster, A. "Bioinformatics: A Technology Assessment Of Recent Developments In Bioinformatics And Related Areas Of research And Development Including High-throughput Screening and Combinational Chemistry", Final Report for the Science and Technological Options Assessment Unit, European Parliament, 1999, p 53-54.

¹⁰⁵ Id., p 31-32.

¹⁰⁶ Id, p 32.

¹⁰⁷ <http://www.bioinformatics.org>

Bioinformatics.org is interested in the use of licensing and compulsory licensing to gain access to inventions, which has already been patented.

The third group is the Open Bioinformatics Foundation. Its purpose is to act as an umbrella organisation for a handful of projects called the bio projects. This group creates development libraries and tools for programmers in a variety of languages for bioinformatics generally, but mainly to facilitate sequence management and analysis. These projects grew out of the original BioPerl project. The goal of the foundation is to provide financial, administrative, and technical assistance for open source life science projects. Sun Microsystems awarded a hardware grant in support of the Open Bioinformatics Foundation.

The fourth group is the Public Library of Science. This organisation is concerned that access to scientific information has been restricted to those who hold expensive subscriptions. It has circulated a letter proposing a boycott, beginning in September 2001, of journals that do not provide "unrestricted free distribution rights to any and all original research reports ... within six months of their initial publication date".¹⁰⁸ They believe that the record of scientific research and ideas should neither be owned nor controlled by publishers, but should belong to the public, and should be freely available through an international online public library. The Public Library of Science has seized upon the strategies of open source software:

We have had extensive discussions with scientists, publishers and copyright experts about how authors who want to make their work freely accessible and useable can accomplish this while ensuring that they receive proper credit for their work. We have concluded that the best way to do this is for the authors and/or publishers to retain copyright on the work, but to irrevocably license the work to the public domain subject to the condition that proper attribution be given whenever the work is reproduced or redistributed. This practice is analogous to the way in which open source software is produced. By retaining copyright, authors and/or their representatives retain the right to enforce the terms of the license, but not the right to dictate how or by whom the work is used.¹⁰⁹

¹⁰⁸ <http://www.publiclibraryofscience.org>

¹⁰⁹ Ibid.

Establishment of this public library would vastly increase the accessibility and utility of the scientific literature, enhance scientific productivity, and catalyse integration of the disparate communities of knowledge and ideas in biomedical sciences. The Public Library of Science has established two journals - one in Biology and the other in Medicine. It relies upon Creative Commons licences to keep the work in the public domain.

The Commonwealth should explore the development of open source projects in relation to human genetic databases to encourage access to scientific information.