

Response To The Advisory Council On Intellectual Property Issues Paper Concerning Patents And Experimental Use Options Paper.

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There is no common law 'experimental use' exemption in Australia.

Introduction

According to s. 5 of the *Commonwealth of Australia Constitution Act* (the *Constitution*):

... all laws made by the Parliament of the Commonwealth under the Constitution, shall be binding on the courts, judges, and people of every State and of every part of the Commonwealth, notwithstanding anything in the laws of any State ...

In *Dow Jones & Co v Joseph Gutnick*¹ the High Court of Australia held that:

No principle of the common law may be inconsistent with [the *Constitution's*] language or implications [*Lange v Australian Broadcasting Corporation* (1997) 189 CLR 520 at 562-567]. Nor may the common law be inconsistent with valid applicable legislation, whether federal, State or of a Territory [*Brodie v Singleton Shire Council* (2001) 206 CLR 512 at 602 [231]-[232]; *Conway v The Queen* (2002) 76 ALJR 358 at 371 [65]-[66]; 186 ALR 328 at 345-346; *Zhang* (2002) 76 ALJR 551 at 579 [143]-[145]; 187 ALR 1 at 39-40.]

In the context of this Inquiry the applicable federal legislation is the *Patents Act, 1990* (Cw). It is submitted that s.13 of the 1990 law removes the common law experimental use exemption.

The Common Law prior to the *Patents Act, 1990* (Cw)

At Federation, the common law that had been received into law by the colonies became part of the fabric of a single unit of law² that applied to the States and to the Commonwealth by effect of the *Constitution*.. So, although the common law of England survived in Australia at Federation, its relevance and application was dependent upon the *Constitution* itself. From that moment onward however, the common law became the common law of Australia³ and its development began to be influenced by conditions in Australia, as compared to conditions in England. These conditions, however, not only included the *Constitution* and the statutory laws of the Commonwealth, the States and Territories, but also other factors such as the need for “substantial judicial innovation”⁴ brought upon by changes in the economic, political⁵ or technological environment.⁶

¹ *Dow Jones & Co v Joseph Gutnick* [2002] HCA 56 (High Court of Australia). In *Lange v Australian Broadcasting Corporation* (1997) 189 CLR 520 the High Court held, “Of necessity, the common law must conform with the Constitution. The development of the common law in Australia cannot run counter to constitutional imperatives[67]. The common law and the requirements of the Constitution cannot be at odds.”

² Sir Owen Dixon wrote, “We therefore regard Australian law as a unit.” *Sources of Legal Authority*, reprinted in *Jesting Pilate*, (1965) 198 at 199 as cited with approval by the High Court of Australia in *Lange v Australian Broadcasting Corporation* (1997) 189 CLR 520 [footnote 60].

³ “Since 1901, the common law - now the common law of Australia - has had to be developed in response to changing conditions.” See *Lange v Australian Broadcasting Corporation* (1997) 189 CLR 520.

⁴ *Dow Jones & Co. v Joseph Gutnick* [2002] HCA 56 [76] (High Court of Australia).

⁵ *Mabo v Queensland [No 2]* (1992) 175 CLR 1 at 42 (High Court of Australia).

⁶ *Dow Jones & Co. v Joseph Gutnick* [2002] HCA 56 [76-77] (High Court of Australia).

To this extent, the common law 'experimental use' exemption to patent infringement as expressed in *Freason v Loe*⁷ in England in 1878, although received into Australian law, became subservient to the *Constitution*, which pursuant to s.51(xviii)⁸ reserved the power to make laws with respect to 'patents of inventions' exclusively to the Commonwealth.

In 1903, the Commonwealth passed its first *Patents Act*. Then in 1952, the Commonwealth passed a second *Patents Act*. In this regard, it is important to appreciate that the 1903 and 1952 laws⁹ were more or less identical to the English Patent Acts of 1883¹⁰ and 1949¹¹ respectively and the reasons for this legislative conformity were explained by both the Knowles Committee¹² appointed in 1935 and the Dean Committee¹³ appointed in 1950 as being related to the need not to 'trouble' Australian and British inventors with 'differing laws'.¹⁴

Accordingly, it stated with some confidence that the intention evidenced by the Commonwealth Parliament in terms of the Patent Acts of 1903 and 1952 was that the statutory law, and the common law that developed around those statutes, were to be closely aligned with that of England.

With respect to the development of the common law concerning the experimental use exception, Lord Diplock's speech in the House of Lords decision in *Bristol-Myers Co v Beecham Group Ltd*¹⁵ is illuminating. The reason for this being that the Patents Act, 1949 (UK) which was the subject of that appeal and the Patents Act, 1952 (Cw) defined the exclusive right granted to the patentee in the same way, namely to 'make, use, exercise and vend' the invention. In considering the meaning of this term in the context of s.14 (prior use as a ground of opposition) and s.32 (prior use as a ground of revocation) of the Patents Act, 1949 and whether Beecham's manufacture and sale of the patented substance before the priority date of the patent was a relevant 'prior use', Lord Diplock explained,

... in construing the words 'used' and 'use' ... it is legitimate to consider the sense in which they were employed by the judges before the passing of the 1932 Act in cases dealing with *prior use* as a ground for revocation of a patent or *as a defence to an action for infringement*. In those cases they were construing the word 'use' in the phrase: 'such manufactures which others at the time of making such letters patent and grants shall not use' appearing in s 6 of the Statute of Monopolies itself, and thus in the light of the mischief against which that statute had been directed.¹⁶

In other words, given that not every kind of prior 'use' as in 'prior use' came within the ground of revocation or defence to infringement, it followed that not every kind of 'use' as in 'post-grant' came within the exclusive rights of the patentee. If the specific 'use' was sufficient to make out the ground of revocation or defence to infringement, then clearly it was not a 'use' that came within the patentee's monopoly.

⁷ *Freason v Loe* (1878) 9 Ch. D. 48.

⁸ "Section 51(xviii) of the Constitution empowers the Parliament, subject to the Constitution, to make laws for the peace, order and good government of the Commonwealth with respect to 'Copyrights, patents of inventions and designs, and trade marks'." See *The Grain Pool of WA v The Commonwealth* (2001) 202 CLR 479 at para. 11 (High Court of Australia).

⁹ See S. Ricketson, *The Future Role of Australian Intellectual Property Law Reform and Administration*, (1992) 3 (1), AIPJ, 3-30, 10-12.

¹⁰ Patents, Designs and Trade Marks Act, 1883 (UK).

¹¹ Patents Act, 1949 (UK).

¹² Knowles Committee Report [5].

¹³ Dean Committee Report [5].

¹⁴ See S. Ricketson, *The Future Role of Australian Intellectual Property Law Reform and Administration*, (1992) 3 (1), AIPJ, 3-30, 12.

¹⁵ *Bristol-Myers Co v Beecham Group Ltd* [1974] AC 646, [1975] RPC 127 (House of Lords).

¹⁶ *Ibid*, per Diplock LJ, (Emphasis added).

According to Lord Diplock, the ‘use’ of the patented invention, which in that case was *ampicillin trihydrate*, an antibiotic, had to be a specific kind of ‘use’, namely a use “by way of trade whether by buying it or selling it with a view to profit or making it for the purposes of sale”.¹⁷

On the facts of the case, Beecham had manufactured and sold the patented substance “commercially for profit”¹⁸ and so his Lordship held that he did not need to delve into the kinds of “non-commercial uses”¹⁹ that could also come within the meaning of the word ‘use’. In his opinion, if the use was motivated by profit then it was a ‘prior use’. However, despite not delving into non-commercial uses he held that an activity motivated by “some other purpose from which [the defendant] derives a practical benefit”²⁰ would also come within the meaning of ‘use’.

In terms of this Inquiry, the question for consideration in the light of Lord Diplock’s reasoning is whether an experimental use of a patented invention was a ‘use’ within the meaning of the previous patent legislation? The answer, according to the reasoning of Lord Diplock appears to be yes, if the experimental use was either motivated by profit or enabled the derivation of a practical benefit to the user.

In *Smith Kline And French Laboratories Limited and Another v Douglas Pharmaceuticals Limited*²¹, the New Zealand Court of Appeal considered the *Patents Act*, 1953 (NZ) in the context of whether the importation of a patented substance into NZ for submission to the Department of Health for regulatory approval to market the substance after the patent had expired was a ‘use’ within the meaning of the patentee’s right to ‘make, use, exercise and vend’. It was held that it did so constitute a ‘use’. Hardy Boy J explained the narrowness of the experimental use exemption thus,

Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself, and does no more than further his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance him in the actual market place, then he infringes, *for the market place is the sole preserve of the patentee*.²²

Under the 1952 law, research institutions such as universities and not-for-profit institutions that conducted experiments with the use of a patented invention outside of the market place did not, on either Lord Diplock’s or Hardy Boy J’s reasoning, infringe the patentee’s monopoly right. Therefore it is likely that a common law experimental use exemption existed in England prior to 1977 and Australia prior to 1991 and this frankly, explains, as ACIP noted at page 35 of the Options Paper, why “[m]any researchers assumed that, while there is no explicit general experimental use exemption in Australian law, there is an implicit exemption that allows them to freely experiment with patented subject matter.”

The changing legislative landscape between the UK and Australian patent law - 1977 and beyond

Prior to the enactment the *Patents Act*, 1990 (Cw) it is noteworthy first, that in 1977 the UK Parliament enacted the *Patents Act*, 1977 (UK) signifying a substantial departure in UK patent law from the *Patents Act*, 1949 (UK); second, that the then Minister, the Honourable Barry

¹⁷ *Ibid*,

¹⁸ *Ibid*,

¹⁹ *Ibid*,

²⁰ *Ibid*,

²¹ *Smith Kline And French Laboratories Limited and Another v Douglas Pharmaceuticals Limited* [1991] FSR 522 (NZ Court of Appeal).

²² *Ibid*, per Hardy Boy J. (Emphasis added)

Jones MP, was critical of the “archaic words and hidden meanings”²³ used in the *Patents Act*, 1952 (Cw).

When the ‘plain English’ *Patents Act*, 1990 (Cw) came into operation in May 1991 it witnessed the final detachment of Australian patent law from UK patent law, both legislatively and at common law and the implementation of a patent scheme that appeared similar to, but was in some respects significantly different from the scheme that it replaced. Apart from the obvious use of ‘plain language’ in the new legislation,²⁴ the amendments to the previous scheme included a change in the definition of the patentee’s exclusive right from “to make, use, exercise and vend” under the 1952 law to “exploiting the patented invention” under the 1990 law.

It is important for this Inquiry not to underestimate the significance of this change in language, contrary to the assertion by some commentators who have confidently asserted that the use of ‘plain English’ in the 1990 law did not detract from the “developed case law concerning the ‘hidden meanings’ of the 1952 law.”²⁵

Firstly, in s.13 of the 1990 law defined the patentee’s exclusive right as the right to “exploit the invention”. The definition of ‘exploit’ in the Schedule defined the exclusive right to:

include the making, hiring, selling or otherwise disposing; the offering to do any of the foregoing; *the use of*, the importing of, or the keeping of for any of the foregoing purposes, the patented invention.

Importantly, the patentee’s right was inclusive and the use of the word ‘include’ emphasised that the exclusive right was not limited to the specific activities specified therein, but included *any activity* that was inconsistent with the patentee’s right to ‘exploit’. True it is that the word ‘use’ appeared in the 1990 law, but it did so in the context of the definition of ‘exploit’, a word that did not exist in the 1952 law.

The *Shorter Oxford English Dictionary* defines ‘exploit’ to mean, “advantage; furtherance; to utilise for selfish purposes”.²⁶ In the context of the use of an article or thing, this word means selfish or complete use. It does not *per se* contain an inherent limitation with respect to the extent of such use so that an activity that does not come within the realms of trade and commerce is excluded from its meaning. There is nothing in the definition of the word ‘exploit’ which suggests that the relevant use must be motivated by financial gain or the *derivation of some practical benefit*, to use the words of Lord Diplock.

Secondly, at about the same time as the Commonwealth Parliament passed the 1990 law it passed the *Circuit Layouts Act*, 1989 (Cw). Given the proximate time during which these two pieces of legislation were debated in the Parliament, it is relevant to note that the *Circuit Layouts Act*, 1989 (Cw) provided in s.17(c) that the owner of the eligible layout had a right to the exclusive right “to exploit the layout *commercially* in Australia”. Putting to one side the fact that the Parliament was considering different legislation, it nevertheless considered the ambit of the respective monopoly rights and in doing so distinguished them by the use of the word “commercially”. Arguably, the monopoly right under the *Circuit Layouts Act*, 1989 (Cw) was intended to be narrower than the monopoly right under the *Patents Act*, 1990 (Cw).

This intention to create a narrower monopoly right was reinforced by s.8 of the *Circuit Layouts Act*, 1989 (Cw) which provided that an act of ‘commercial exploitation’ to have occurred:

...if the layout...is:
(a) sold, let for hire or otherwise distributed *by way of trade*;

²³ Hansard, 1 June 1989, p3479.

²⁴ The exception to the general use of plain language was the retention of the reference to s.6 of the *Statute of Monopolies*, 1623 (Imp).

²⁵ J. McKeough and A. Stewart, *Intellectual Property In Australia*, 2nd Edition, Butterworths, 1997, 324.

²⁶ The *Shorter Oxford English Dictionary*, Clarendon Press, 1987.

- (b) offered or exposed for sale or hire, or other distribution *by way of trade*; or
- (c) imported for the purpose of sale, letting for hire, or other distribution *by way of trade*.

In other words, *commercial exploitation* was confined to activities ‘by way of trade’.

By contrast, not only did the 1990 law lack this level of specificity in the definition of ‘exploit’, but the word ‘exploit’ was defined expansively by the word ‘included’ meaning that the patentee’s monopoly right included within its ambit both non-commercial as well as commercial *exploitative* activities.

This suggested that if an institution such as a university or not-for-profit institution carried out a non-commercial activity that made ‘use’ of the patented invention, even if such use was for the purpose of academic and private research, that use infringed the patentee’s monopoly right simply because the ‘use’ *per se* derogated from the monopoly right. That derogation occurred because the word ‘exploit’ was not specifically confined to activities “by way of trade”.

If Parliament had intended to narrow the patentee’s exclusive right to activities “by way of trade” it could easily have adopted the same approach in the 1990 law as it did in the *Circuit Layouts* law, but it did not.

Thirdly, by the time the Commonwealth Parliament debated the proposed 1990 law, the *Patents Act, 1977* (UK) had been in operation for thirteen years and in contrast to the previous *Patents Act, 1949* (UK) it contained a specific experimental use exemption to infringement. Section 60(5) of the 1977 (UK) Act provides:

- An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if --
- (a) it is done *privately and for purposes* which are *not commercial*;
 - (b) it is done for *experimental purposes* relating to the subject-matter of the invention.

This specific exemption was inserted in the UK legislation not because of any desire on the part of the UK Parliament to maintain consistency with the common law, but because of the *European Patent Convention 1973*, to which the UK was bound, provided for such an exemption.²⁷

Section 60(5)(a) therefore restricted the patentee’s monopoly right in the UK to activities conducted for the purposes of trade and commerce. Section 60(5)(b) however, went further and provided that even if an experiment was conducted for the purposes of trade and commerce, that activity would be outside of the patentee’s monopoly right if *it related to the subject-matter of the invention*.

In considering s.60(5)(b), Lord Dillon held in *Monsanto Co v Stauffer Chemical Co and Another*²⁸ that “the word ‘experiment’ is an ordinary word in the English language and has never been a term of art in UK patent law”. It is likely the case that neither did it in Australian patent law.

Nevertheless, the distinction between the activities of subparagraphs (a) and (b) reinforced the fact that an experiment conducted for non-commercial research was exempted not under subparagraph (b), but under subparagraph (a). There was no need for the researcher to rely on the more specific ‘experimental use’ exemption in (b). On the other hand, if a researcher was to conduct an experiment associated with a commercial organisation, for example, a pre-clinical drug trial, the criteria of subparagraph (a) would not be met, but the criteria of (b)

²⁷ “Section 60 was, as section 130(7) shows, enacted to bring UK patent law into line with the corresponding provisions of the community Patent convention and I have no reason to suppose that the signatories of that Convention were concerning themselves with the minutiae of earlier UK patent law.” Per Lord Dillon in *Monsanto Co v Stauffer Chemical Co and Another* [1985] RPC 515 (UK Court of Appeal).

²⁸ *Ibid.*

would be provided it involved *the subject matter of the invention* and not the *invention* defined in the claims.

Clearly, the UK Parliament in 1977 provided a more restricted monopoly right than did the Commonwealth Parliament in 1990. Frankly, if the Commonwealth Parliament had intended to exclude ‘private’ and ‘non-commercial’ or ‘experimental’ activities from the patentee’s monopoly right to ‘exploit’, it could have easily followed the example followed by the UK and the European Union, but again, it did not.

The point that is conclusively made by the actions of the UK Parliament and the Commonwealth Parliament is that the common law that applied under the *Patents Act*, 1949 (UK) and the *Patents Act*, 1952 (Cw) was changed by subsequent patent legislation and so *Frearson v Loe* ceased to apply in the UK in 1977 and in Australia in 1991. As the High Court explained in *Dow Jones & Co v Joseph Gutnick*²⁹ “the common law [cannot] be inconsistent with valid applicable legislation, whether federal, State or of a Territory”.³⁰

Therefore, it is respectfully submitted that beyond s.78 of the 1990 law there is no common law nor statutory experimental use exemption in Australia.

The Consequence for Option B under the 1990 Law

What this means is that if Option B is ultimately the position which ACIP recommends it will, in effect, be recommending that there be no experimental use exemption in Australia.

It is submitted that as the law presently stands, the fact that there is no experimental use exemption is against the best interests of Australia.³¹

The Uselessness of the Distinction between Commercial and Non-Commercial Activities

The experimental use exemption should not be predicated on the distinction made between ‘commercial’ and ‘non-commercial’ activities. Such a distinction is practically useless because as the CAFC held in *Madey v Duke University*,

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.³²

Even though, we are here not concerned with the specific formulation of the US common law experimental use defence, the CAFC decision is illustrative of the narrowness of the exemption once the threshold is determined by activities that are non-commercial in nature or unrelated to the user’s ‘legitimate business’.

Another recent example of the problems that arise in the field of scientific research is illustrated by *Integra Lifesciences v Merck KgaA, The Scripps Research Institute and Cheres*³³ At issue was not the common law experimental use defence considered in *Madey*,

²⁹ *Dow Jones & Co v Joseph Gutnick* [2002] HCA 56 (High Court of Australia).

³⁰ *Ibid.*

³¹ The anecdotal evidence of the problems faced by independent diagnostic laboratories in Australia during the 1990’s with respect to the development of an adequate immunoassay for hepatitis C virus (HCV) in the face of the patent granted to Chiron Corporation (AU 624105) makes the case forcefully for a specific statutory experimental use exemption. What is outstanding about the dire situation that faced the Australian Red Cross and Australian health authorities in the 90’s with respect to HCV, is that despite the fact that there were two independent reports prepared by teams of experts in infectious diseases strongly recommending that immunoassays be made that were unrelated to the Chiron licensed immunoassays, no action was taken by any State or federal government under the compulsory licensing provisions of the 1990 law to remedy the situation.

³² *John M.J. Madey v Duke University*, 01-1567, (United States Court of Appeals for the Federal Circuit.)

³³ *Integra Lifesciences v Merck KgaA, The Scripps Research Institute and Cheres*, (2003) US. App. LEXIS 27796 (United States Court of Appeals for the Federal Circuit.)

but the ambit of an express statutory experimental use defence under s.271(e)(1)³⁴ of the *Food, Drug, and Cosmetic Act* (FDA exemption).

In *Merck*, the US Supreme Court gave leave to appeal³⁵ (granted in January 2005) against a decision of the CAFC which held that a scientist (Dr. David Cheresch) and the institution that employed him (The Scripps Research Institute) had infringed a patent because they had been involved in conducting experiments on behalf of a drug manufacturer (Merck). Through an agreement, Merck funded Scripps to conduct experiments on specific proteins. The success of these experiments eventually led Merck to apply for permission to conduct clinical drug trials as part of a statutory requirement administered through the Food & Drug Administration (FDA). In accordance with this process the FDA was mandated to assess whether “the drug involved represents an unreasonable risk to the safety of persons who are the subjects of the clinical investigation”.

Before the CAFC, Dr. Cheresch and the Scripps Institute argued that their activities were exempt from infringement under the FDA exemption.

The CAFC disagreed. It held that the experiments conducted by Dr. Cheresch and the Scripps Institute were not “solely for uses reasonably related” to the FDA process because they were conducted prior to the application to the FDA for permission to conduct clinical drug trials. According to the CAFC, the FDA exemption only applied if the nexus between the experiments and the application to the FDA was directly related, and in any event, not where the experiments were conducted in the “hunt for drugs that may or may not later undergo clinical testing for FDA approval”.³⁶

In its *amicus curiae* brief filed with the US Supreme Court in support of the grant of leave to appeal, the United States Acting Solicitor-General argued that the CAFC’s view of the law was “likely to restrict significantly the development of new drugs”³⁷ and that the CAFC decision posed “a direct and substantial threat to new drug research by dramatically narrowing the scope”³⁸ of the FDA exemption.

Importantly, the Acting US Solicitor-General explained that “although the patent system provides important incentives for innovation, pre-clinical research into investigational new drugs is of tremendous importance to the public health.”³⁹ In other words, it was in the best interests of humanity that there be limits placed upon the scope of the patentee’s monopoly rights irrespective of the incentive to innovate which is so fundamental to the *raison detre* of the patent system.

In terms of the effect which the CAFA’s decision has had on research generally in the United States, the Acting US Solicitor-General submitted that the “FDA is aware of anecdotal evidence that the decision is adversely affecting the legal advice given on drug researchers regarding their ability to use patented inventions in new drug research”.⁴⁰

Given that today there are thousands of patents that have been granted with respect to biological research tools, natural proteins and the recombinant manufacture of natural proteins,⁴¹ there exists such complex webs of patent rights that it is almost impossible for a

³⁴ “It shall not be an act of infringement to make, use, offer to sell, or sell ... a patent invention ... solely for uses reasonable related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” s.271(e)(1) *Food, Drug, and Cosmetic Act* (US).

³⁵ *Merck KgaA, The Scripps Research Institute and Cheresch v Integra Lifesciences* 03-1237 (US Supreme Court).

³⁶ *Op cit*, 32.

³⁷ *Merck KgaA, The Scripps Research Institute and Cheresch v Integra Lifesciences* 03-1237 (2003) U.S. Briefs 1237, December 10, 2004. (US Supreme Court).

³⁸ *Ibid*.

³⁹ *Ibid*.

⁴⁰ *Ibid*.

⁴¹ The term ‘natural proteins’ includes proteins as they exist in nature or such proteins that have been isolated or purified. In *Kirin-Amgen v Hoerhst Marion Roussel* [2004] UKHL 46 the House of Lords did not distinguish between an isolated natural protein and the natural protein. In that case it held that an isolated form of a natural

researcher into new drugs or diagnostics not to be seriously concerned about the possibility of infringing one of more patents in the conduct of their research.

The message from *Merck* is that even if a statutory research exemption exists, the language used to frame the exemption must be sufficiently broad so as not to be practically useless in the context of the reality of the relationships that exist between commercial entities and research entities in the modern world. However, as the CAFC pointed out, “to embrace all aspects of new drug development activities would ... effectively vitiate the exclusive rights of patentees owning biological tools”.⁴² This point by the CAFC raises the real issue.

At the time when the common research exemption was formulated in England and the United States, the types of inventions which were the subject of patents did not extend to biological research tools and natural proteins as they do today. As a consequence of the blurring of the boundaries of patentable subject matter so as to include biological research tools, genes, proteins and the processes of their manufacture, the creation of a workable statutory research exemption is almost impossible. Where or how to draw the line between research activities that come within the exclusive rights of patentees and those that do not whilst at the same time balancing the incentive for innovation between patentees and researchers is problematic and frankly, cannot be resolved unless the ambit of patentable subject matter is narrowed so that biological research tools, natural or isolated proteins, genes, and the process of their manufacture are expressly excluded as patentable subject matter.

To simply examine the issue of an experimental use exemption in isolation to the ambit of patentable subject matter is absurd because the two are inextricably linked.

Conclusion

Therefore, it is respectfully submitted that while **Option B** is clearly unacceptable, the solutions generally encompassed by Options C1, C7 and C8 are all problematic as the US courts are finding in *Madey* and *Merck*.

Option C1 is not a solution because the real issue is where or how to draw the line between research activities that come within the exclusive rights of patentees and those that do not whilst at the same time balancing the incentive for innovation between patentees and researchers. How does one provide researchers who are today also funded by commercial entities with the freedom to conduct research with respect to innovative drugs and diagnostics when they will need to use patented biological research tools in their research?

Option C7 is not a solution because how can there be ‘fair experimentation’ when that experimentation involves the complete use of a patented biological research tool? We are here not concerned with the ‘fair use’ of a copyrightable work. Here, the problem is, that the research will involve the use the complete invention and not merely a part of it. Moreover, unless the exemption is clearly defined, the possibility of ensuing litigation will only act as a further disincentive to research in any event.

Option C8 is not a solution because the distinction between “the subject-matter of the invention” and “the invention” is meaningless simply because the ambit of the patentees monopoly is not defined by the “subject-matter of the invention” but is defined by the claims in the patent. Apart from the fact that it is unclear as to what is meant by the phrase “the subject-matter of the invention”, the UK Department of Trade and Industry has acknowledged (as pointed out at 43 of the ACIP Options Paper) that “the extent of the patent research exemption” is “uncertain” and this is “widely seen as problematic”. The point is that if a researcher conducts an experiment on the “subject-matter of the patent”, whatever that means, and does not ‘use’ the invention as defined by the claims of the patent there will be no infringement regardless. The exemption under s.60(5)(b) is only useful if experiments on the

protein was not ‘new’ given that the natural protein was part of the state of the art as at the priority date of the patent. Per Lord Hoffmann, para 132.

⁴² *Ibid*, at 18-19.

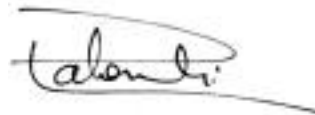
“subject-matter of the patent” enable the researchers to use the invention as defined in the patent claims. If not, there is no need for the (b) exemption because there is no infringement. Everyone is free to research outside of the technology defined by the claims.

In *Kirin-Amgen v Hoechst Marion Roussel Ltd*⁴³ the House of Lords explained that the specification is separate and distinct from the claims and although the two are related it is the claims that define the scope of the monopoly. Their Lordships’ reversed both the Court of Appeal and the trial judge and found the patent invalid and were critical of the trial judge because he had, in their opinions, defined the invention without paying any “attention to the claims”.⁴⁴ They held the patent invalid because the patentee had gone too far and had sought to patent the protein *per se* when the protein was not new.

The importance of this decision in the context of this Inquiry lies in the manner in which their Lordships’ scaled back the ambit of the patentee’s monopoly. In doing so, they opened up research in a field of science that had been blocked for twenty years by the patent.

It is therefore respectfully submitted that a solution to this complex issue can only be developed by a referral by the Australian Attorney-General to the Australian Law Reform Commission instructing it to conduct a full and proper Inquiry into both the ambit of patentable subject matter together with the application of an experimental use exemption.

Submitted to ACIP on Thursday, February 24, 2005.



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⁴³ *Kirin-Amgen v Hoechst Marion Roussel Ltd* [2004] UKHL 46, paras 109-110 (House of Lords)

⁴⁴ *Ibid*, para 76.