

SUBMISSIONS TO QUESTIONS RAISED IN ACIP OPTIONS PAPER ON PATENTS & EXPERIMENTAL USE, DECEMBER 2004

EXECUTIVE SUMMARY FOR QUESTION 5 – OPTIONS PREFERRED, AND REASONS

- 1.1 We do not support Option B.
- 1.2 We do not support Option C1.
- 1.3 We do not support Option C7, for the following reasons:
 - (a) there are difficulties with transferring copyright concepts such as fair dealing into patent law. The danger is that fresh legislation with a copyright background will be interpreted in light of that background, despite any inappropriateness in the context of patent law;
 - (b) there are difficulties with the qualifier of “fair” which unnecessarily complicates this Option and leaves it with less than desirable clarity;
 - (c) each of the bulleted factors in the fair dealing list has its own problems, which we make individual submissions on.
- 1.4 We support Option C8, for the following reasons:
 - (a) it is limited to conduct that has the “sole or dominant purpose” of experimentation;
 - (b) the combination may overcome some of the problems of Options C3 and C6;
 - (c) whatever level of harmony the provision ultimately has with European law may reduce the uncertainty of the new Australian provision, and as the ACIP Paper notes, may reduce some costs to exporters.
- 1.5 However we have four significant concerns with Option C8:
 - (a) the concept of research “on” an invention as opposed to research “with” an invention;
 - (i) the concept of research “on” an invention will need further explanation and guidance, particularly as the exemption is intended to apply to research tool inventions. It is not sufficient that clarification on this point is left to resolution by the courts on an incremental basis. We believe that inclusion of a statement of intention as to operation of the provision, and relevant guiding principles, should be included in the explanatory memorandum to the legislation;
 - (ii) in order to clarify the concept of research “on” an invention, the object of the experimentation should be examined. Where the object is to gain further knowledge about the invention itself, or as patented, this should be exempt. However, where the object is to gain further knowledge about another object, or how to achieve a new purpose or use, this should not be exempt;
 - (b) the historical and interpretive difficulties surrounding the use of the term “subject matter” in relation to patentable inventions;
 - (i) the process of construing what is the “subject matter” of the invention is crucial because it defines the scope of permissible research “on” an invention. However, we are concerned as to the use of the term “subject matter” because of its history of imprecision and uncertainty in patent law, and particularly because it tends to denote the issue of “inventive step”, a concept which the exemption should not rely upon to any extent.

It would therefore be more suitable to ask whether the experiment was “on the invention” rather than “on the subject matter of the invention”;

- (ii) The *Clinical Trials I* case provides some assistance in locating the proper legal analytical foundation for our approach of simply construing the “subject matter of an invention” to be the invention itself, or the invention as patented:
 - (A) The German Court of Appeal in the *Clinical Trials I* case in fact approached similarly worded legislation in this manner with, we submit, the correct analysis and result;
 - (B) The German Supreme Court in the *Clinical Trials I* case approached the legislation with an incorrect analysis and result, and further it introduced difficult issues of technical contribution, inventive merit and reward (which are issues sometimes discussed in relation to inventive step) to support its conclusion, which we say should not be introduced into the exemption;
 - (C) The Court of Appeal’s analysis, consistent with our approach, is the only analysis which does not render the value of research tools nugatory;
 - (D) The Court of Appeal’s analysis fits better with the current tenor of Australian High Court decisions, which have quarantined the issue of inventive step (inventive merit, etc) away from other aspects of patent law. It also fits with the principle of Australian law that requires protection of a product patent against all unauthorised uses.
- (c) the outer reaches of the concept of research “on”;
Our approach as outlined above fits well with TRIPs Article 30.
- (d) the inclusion of the fourth bulleted point in the inclusive list of permitted acts, which is intended to guide application of the exemption provision.

We are concerned as to the inclusion of “improvements” as an example of permitted acts of experimentation because the term:

- (i) has conceptual/policy difficulties, particularly as it seems to assume the typical model of improvement rather than severable improvements; an exemption for these kinds of development are harder to justify in policy terms;
- (ii) has clarity problems;
- (iii) is not a reliable indicator of a “permitted act” because research objectives in the area of improvements are unclear and probably subject to change; and
- (iv) because the likely impact of the legislative Option as a whole will hinge critically upon the interplay between interpretations of “improvements” and “experiments on”.

It would therefore be more suitable to omit the term “improvement” from the list of permitted acts.

In any event, we believe that many experiments in pursuit of the traditional form of “improvement”, which appears to have been assumed as the permitted act, would likely be exempt as research “on the [subject matter of the] invention”, and possibly also within the first of the permitted acts, because the object would be to gain more information about the invention, ie. how it worked and how its qualities, character, composition, etc could be changed to enhance that same invention.

If these concerns can be adequately addressed, we believe Option C8 is the best of the four Options short-listed by ACIP.

SUBMISSIONS

We refer to the bulleted list of questions that submissions should address as set out on page 17 of the ACIP Options Paper.

QUESTION 1 ARE THERE ANY NEW ARGUMENTS FOR AND AGAINST EACH OF THE OPTIONS?

- 1.1 Since the options presently falling for further serious consideration by ACIP are limited to Options B, C1, C7 and C8 we confine our comments to these options only (ACIP's "preferred options" per page 17 of the Paper).
- 1.2 Our arguments for and against these options are largely outlined below in our response to Question 5, although these overlap to some degree with our brief submissions on Questions 1 and 2.

Option B – impact on the research sector

- 1.3 Given the wide-ranging responses in the various submissions, it is evident that there is significant ambiguity on the fundamental question as to the presence or absence of an implicit experimental use exemption for legal experts, patentees and researchers alike. At first glance, the it would appear simpler to do nothing and allow the question to be settled in court at some distant time. However, the changing research climate and growing awareness of the potential impact of a lack of clarity on the exemption provides impetus to deliver a workable solution.
- 1.4 The heterogeneity of the submissions made to ACIP suggests that continuing with the *status quo* leads to those organisations who are aware of the issues making their own decisions as to whether an exemption is in fact implied, and as to the extent of the putative exemption's reach, without legal guidance and without any level of acceptable legal certainty. This is a hard call for legal experts, let alone most scientific organisations (even if they have some expertise and resources at their disposal). It is a particularly onerous burden for SMEs. Different organisations inevitably come to different conclusions, and unwittingly expose themselves to varying levels of risk. The end result of this may be an increase in litigation and a net reduction in innovation productivity, which would clearly not be to the public benefit.
- 1.5 We acknowledge that there is presently a paucity of empirical evidence on current and future adverse indications of a lack of research exemption. However, as we noted in our previous submissions, absence of evidence is not evidence of absence. What *is* clear from the overall tenor of the submissions to ACIP is that there is a serious level of uncertainty regarding the Australian legal position on the basic question of whether an experimental use exemption exists at all. If a properly crafted research exemption can be formulated that will address the admitted uncertainty which lies at the root of potential problems, there seems little reason to wait for manifestation of the problems themselves before acting.
- 1.6 Similarly, if the government can legislatively act now upon recommendations formulated by ACIP after extensive public and stakeholder input, there seems little reason to leave the clarification process on the basic question to the common law process. Answering the question of whether a research exemption exists is a fundamentally important issue that deserves as wide a public canvass as possible, in forums just such as this ACIP inquiry, rather than being decided incrementally in the adversarial forum of the courts where decisions will likely be confined by the particular facts at hand (and the depth of the pockets of participants). The present inquiry has the opportunity to look at all the issues together and address them in a bipartisan manner, which is crucial in an area such as this where, very commonly, researchers are also patentees and therefore have a vested interest in as balanced a regime as possible.
- 1.7 While the outcome will likely not be perfect (compromises rarely are), it is important to note that any resulting exemption should not be viewed the *entire and final solution* to the perceived experimental

use problem.¹ In fact, the exemption is simply a starting point – further clarity and detail will be added by the courts, a point repeatedly recognised in the ACIP options paper. The task at hand is to provide the best starting point possible by providing decision-makers with helpful legislation and ancillary information, hopefully reducing the scope for disparate decision-making. Other areas may provide further and complementary solutions, eg. the interplay of experimental use with competition law, compulsory licensing, etc. These areas would be well deserving of their own inquiry. A complex problem like this will likely necessitate a complex and multi-faceted solution, but this is no reason to forestall commencement of the clarification process itself.

¹ See for example, Mueller JM, 'No 'dilettante affair': rethinking the experimental use exception to patent infringement for biomedical research tools', (2001) 76 Wash LR 1; Derzko NM, 'In search of a compromised solution to the problem arising from patenting biomedical research tools', (2004) 20 Santa Clara Computer & High Tech LJ 347.

QUESTION 2 WHAT IS THE LIKELY EFFECT OF EACH OPTION ON PARTICULAR SECTORS OF THE ECONOMY?

2.1 The following comments are confined to the likely effect each option would have on the research sector in Australian Universities and not-for-profit research-intensive organisations.

Option B – effect on research institutions

2.2 The effects of doing nothing will likely percolate to research organisations and to individual researchers over time. It is the employers which take on the burden of risk associated with their researcher's activities. In a corporation where employee activity is closely monitored, this may not be an issue. However, for large research institutions and universities, a significant source of discovery and invention, researchers are not so fettered to the corporate yoke and consequently the prime risk takers are generally unaware of the myriad of research activities undertaken by individuals. Such organisations will not know whose patents are being researched "on", and by whom, and thus would not be able to assess the risk of their own activities. A non-risk averse organisation may not care whether an implicit research exemption exists and choose to adopt the "damages will be minimal" approach, which would not effect research activities unless litigation is threatened. A more risk averse organisation (which may include SMEs as well as research institutions, as both face similarly tight financial constraints) may assume there is no research exemption and attempt to curtail various research activities using their own guidelines, which would have deleterious flow-on effects to innovation.²

Option C1 – effect on research institutions

2.3 There are inherent dangers in modifying the definition of exploit to exclude experimental use without further defining the term. The option effectively means that, despite the enactment of what should be clarifying legislation, researchers will have to wait until a sufficiently detailed body of case law develops before they actually get the benefit of any legal certainty. Until then, there is a high risk that they will interpret this definition with significant differences according to who is doing the research, and who owns the patent the subject of the experimentation. In research organisations, this is likely to bring in the troublesome distinctions such as whether the experiments are commercial, the purpose etc. Does low risk experimentation (ie. high chance of success) constitute experimental use? Given that the word "experiment" is defined as trials or tests, the term experimental use could conceivably be widely misconstrued by researchers in the absence of clear guidance. For the patent holder of research tools (ie. methods of screening, kits for the lab), a broad interpretation of experimental use may have the effect of rendering their invention useless, encouraging free-riding and reducing overall innovation in this field.

Option C7 – effect on research institutions

2.4 No submission. Please see our detailed comments in relation to Question 5.

Option C8 – effect on research institutions

2.5 Contingent upon the ultimate drafting of the legislation, and guidance to interpretation embodied in the explanatory memorandum, it is considered that Option C8 would not significantly affect current research activities or levels of innovation **in the short term**. Moreover, Option C8 is likely to maintain the current research activities, innovation and diffusion of knowledge *ceteris paribus* **in the longer term** – the prime advantage of this Option. Given the prevailing views on infringement at research-intensive institutions, it is difficult to see Option C8 fostering innovation or improved

² Again, we are cognisant of the paucity of present evidence on this likelihood but revert to our comments under question 1 above.

efficiencies **by itself** (as noted above, it is not the entire and final solution). If this Option maintains the *status quo* in terms of the level of research activities, this is a desirable outcome. However, given that its main aim is to provide a more acceptable level of legal certainty in which to operate, it does have the potential to avoid the manifestation of significant research “shyness” in future as we outlined in our previous submissions.

**QUESTION 3 WHAT IS THE LIKELY EFFECT OF EACH OPTION ON
RESPONDENTS' OWN PARTICULAR BUSINESS AND RESEARCH
ACTIVITIES?**

3.1 No submission.

QUESTION 4 IS THERE ANY OTHER OR NEW EMPIRICAL EVIDENCE AVAILABLE FOR THE AUSTRALIAN ENVIRONMENT?

4.1 No submission.

QUESTION 5 WHICH OPTION(S) DOES THE RESPONDENT PREFER AND FOR WHAT REASONS?

Option B

- 5.1 We do not support “Option B” of no change, for the reasons outlined above and in our previous submissions.

Option C1

- 5.2 We do not support “Option C1” of modifying the definition of “exploit” in Schedule 1 of the *Patents Act 1990* to preclude experimental use without further guidance on the term, as outlined above.
- 5.3 We agree that Option C1 would only require minimal amendment of the principal Act and would provide some indication that there is an inherent limit on the scope of patent rights. However, we feel that the issue raised by the last “pro” bullet point on page 9 of the Options Paper can equally be grouped with the “con” bullet point – the main difficulty is that the lack of inbuilt guidance in this Option means that it fails to provide any reasonable indication as to how courts might interpret the provision, and therefore provides little real relief from the present ambiguities.
- 5.4 Moreover, without further guidance on the scope of this inherent limitation, we submit that the impact of such a legislative amendment would have an unknown and unquantifiable effect on calculated risk-taking, promotion of innovation, and economic growth: that ambit being vacated under this Option for the courts to determine. Leaving disputants to the adversarial and often costly court system (especially for patent litigation³) with the scope of privative patent rights determined incrementally based on specific and narrowly defined circumstances over long periods of time, provides little relief to patentees or researchers where transaction costs are almost certain to increase – at least in the foreseeable future.
- 5.5 We therefore feel that the ease of introduction of this Option is offset by the fact that it does not tangibly advance the level of clarity on the issue of experimental use for either researchers or patentees – and we are mindful that, in today’s research climate, many participants are in fact both researcher and patentee.

Option C7

- 5.6 We do not support “Option C7” of an exemption for “fair experimentation” on an invention with inclusive permitted uses.
- 1. Difficulties with copyright analysis in patent law**
- 5.7 We note that in this Option, the first set of bulleted issues (on page 13) to be considered when deciding whether an act is to be classified as “fair experimentation” are essentially those from section 40(2) of the *Copyright Act 1968*, amended *mutatis mutandis* for the patent law context.
- 5.8 We appreciate that several submissions thought there were lessons to be learned from the copyright fair dealing/fair use exemptions. However, as with the IPTA and Nicol/Nielson submissions, and for the reasons outlined in our previous submissions, we do not believe that analogies between the patent and copyright regimes on this issue can be pushed very far except on a very broad and general level. They are not helpful in making a meaningful contribution to resolving the present ambiguities in a legally cohesive, principled manner.
- 5.9 In particular, as Nicol/Nielsen point out, much of the relevant copyright literature is American and has limited value in Australia.⁴ Lahore cautions against drawing any conclusions on Australian

³ See for example Judge T.S. Ellis III, ‘Distortion of Patent Economics by Litigation Costs’ at <<http://www.law.washington.edu/casrip/Symposium/Number5/pub5atcl3.pdf>> (3 March 2005).

⁴ At page 9.

copyright law and fair dealing in light of American cases on fair use, due to legislative differences.⁵ Any value such decisions have in the context of *patent* law is virtually obliterated given the number and nature of differences between the patent and copyright regimes, as we noted in our previous submissions.⁶ American commentary drawing analogies between these two regimes also provides little insight, because of the differences in American and Australian patent law (see, for example, Mueller’s discussion of transformative uses in copyright and the American doctrine of equivalents in patent law,⁷ which has no counterpart in Australian law: *Prestige Group v Dart Industries*).⁸

5.10 The real and practical danger here is that fresh legislation which has all the hallmarks of another area of law with a rich case history, and where some broad analogies can be drawn, may well be interpreted in light of that other area of law despite its inappropriateness. Decision-makers faced with some guidance or none at all will tend to opt for the former,⁹ hence we discuss in more detail in paragraphs 5.14 and following some of the difficulties inherent in applying the copyright points in a patent law context.

2. Difficulties with use of the general qualifier “fair”

5.11 Quite apart from our objection to importing copyright principles of “fair dealing” into patent law, a significant disadvantage in this Option is that it focuses on what is perceived to be “fair” experimentation. This unnecessarily complicates matters and leaves the Option with less than desirable clarity.

5.12 For example, even if researchers’ use of a patented invention is for the sole or dominant purpose of experimentation, they would then confront the possibility that an argument may be constructed that somehow their use was not “fair” in the circumstances. This is especially true if their experimentation resulted in successful outcomes, as the patentee would be highly motivated to challenge any conclusion that the experimentation was indeed “fair”.

5.13 Alternatively, as the Option currently stands, it may exempt otherwise infringing conduct even though not for the sole or dominant purposes of experimentation, because it was held to be “fair” in the particular circumstances. This strains the credulity of the exemption as an experimental use exemption. It begins to wander into the territory of a general defence to infringement under the guise of an experimental use exemption, and could seriously prejudice a patentee’s legitimate interests *contra* Article 30 of TRIPs.¹⁰

3. The bulleted factors in the fairness deliberation

(a) The factors provide little guidance – additional issues may be considered

5.14 This point follows directly from our concerns expressed in paragraphs 5.11 to 5.13 above. We note that the first set of four bulleted points is intended to provide guidance on the factors that might bear upon the “fairness” deliberation. While all of these factors “must” be considered, they are not exhaustive. Essentially this is a mandatory but inclusive list only of potentially relevant factors, much like the copyright legislation, which Ricketson criticises as giving “insufficient guidance as to what will, or will not, in a specific instance amount to a fair dealing ...”. Indeed, inclusion of the same points in the copyright legislation has given “rise to the question of what other factors (not

⁵ Lahore J, Rothnie WA, *Copyright and Designs*, (Butterworths, Sydney, 2004) at [40,135].

⁶ We note that Nicol/Nielsen also discuss this point at page 9.

⁷ Mueller, above n1.

⁸ *Prestige Group (Australia) Pty Ltd v Dart Industries Inc* (1990) 19 IPR 275; 26 FCR 197. On transformative uses, please see our submissions further below.

⁹ See, for example, the way that the language of common law Convention disconformity in early patent law crept into the legislation to govern what previously had been the common law of undue claim width and mainstream disconformity law as well; because of its origins the language was immediately interpreted by courts in a manner at odds with Parliament’s intentions: McBratney A, “The “problem child” in Australian patent law: “fair” basing”, (2001) 12(4) AIPJ 211.

¹⁰ On the TRIPs issue, please see our submissions further below.

mentioned) may still be relevant in the assessment of whether a particular dealing is fair.”¹¹ For example:

- (a) A Singapore case on a similarly worded provision suggested that the public interest should be taken into account.¹² Such decisions add weight to the concern expressed above regarding an unintended widening of the exemption. Insofar as a public interest approach would depend to any extent on an investigation of the inventive merits of a broadly claimed invention to determine whether or not its full breadth should be protected, it may conflict with recent case law of the Australian High Court, but again there is sufficient ambiguity to argue the point;¹³
- (b) When would be the appropriate time to measure the “fairness” or otherwise of conduct? Before or after the results were known? Again here, the door may be implicitly opened to public interest factors. Experiments that would stand almost no chance of exemption at the time they were engaged in might nevertheless qualify as “fair” after producing highly beneficial results;
- (c) Would “fair” take into account the probability of success of the experimentation (eg. high risk experimentation may require more research effort than low risk experimentation)?

(b) There are problems with each of the factors

5.15 In addition, we believe that each factor listed in the first set of bulleted points is problematic for the following reasons:

(i) The first bulleted point

5.16 The first bulleted point relates to purpose and character. In copyright law, these are said to be discrete but related inquiries:¹⁴

- (a) An inquiry into purpose is directed at the motives of the user, and “clearly any commercial aim that lies behind the research or study will be relevant ...”.¹⁵ The short point to be made here is that the tenor of many submissions to ACIP, and ACIP’s own conclusion, was that the commercial/non-commercial distinction is too blurred to be of any real use in guiding the exemption. Reintroducing the same distinction as a guide to what will or will not constitute “fair” experimentation is no answer to its deficiencies;
- (b) An inquiry into character deals with what the “user actually does with the ... material.”¹⁶ In this regard, copyright law has given rise to the notion of “transformative” use. While this is predominantly an American concept, it has been cited in Australia in *De Garis v Neville Jeffress Pidler Pty Ltd*.¹⁷ The principle behind transformative use is that the use is more likely to be fair if it adds value and creates a new copyright work, thus furthering the aim of the copyright legislation.¹⁸ The concept of transformative use tends to leave the market for the original work intact and does not unduly prejudice an a copyright owner’s interests, in

¹¹ Ricketson S and Creswell C, *The law of intellectual property: copyright, designs and confidential information*, (2nd ed, Lawbook Co, Sydney, 2002) at [11.35].

¹² *Ibid.*

¹³ See for example *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 177 ALR 460; *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 212 ALR 1. See our further submissions on this point below.

¹⁴ Ricketson, above n11.

¹⁵ *Ibid.*

¹⁶ *Ibid.*

¹⁷ (1990) 18 IPR 292 at 301, as discussed in Lahore, above n5 at [40,145] and Ricketson, above n11 at [11.35].

¹⁸ See eg. Mueller, above n1 at 44.

compliance with the well known three-step requirement in Article 9(2) of the Berne Convention (similar to Article 30 of TRIPs¹⁹).

5.17 On a broad level it could be said that unauthorised use of, eg. a patented research tool might produce a new and different invention and so further the aims of the patent system. However, upon closer examination the concept presents problems in the patent law context. The major value of inventions such as these (unlike copyright works) is in facilitating further invention. Allowing transformative use to qualify as fair experimentation would “effectively vitiate the exclusive rights of patentees owning biotechnology tool patents ... [and] would swallow the whole benefit of the Patent Act”, to borrow the words of one American judge.²⁰ The obvious prejudice to the patentee’s interests would not comply with Article 30 of TRIPs.²¹ In patent law, the more appropriate distinction is that between experimenting *on* and experimenting *with*, which we discuss below in our submissions on Option C8.

5.18 Another concern with the first bulleted point is that, again, there is no guidance as to the stage at which purpose and character is to be measured. Since experimentation can evolve over many years, it is subjected to both changing purposes and character.

(ii) *The second bulleted point*

5.19 This point requires consideration of the “subject matter of the invention” when determining whether potentially exemptible conduct is fair. In copyright, it is said that the guideline relating to the “nature of the work ... appears to contemplate that there are some works or adaptations which, by their very nature, are more susceptible to unfair dealings, for example, artistic works, short literary works such as poems and stories, and the like.”²² While this is also true of patented inventions, the ease of misappropriating an invention does not necessarily indicate that the use is unfair, any more than its technical difficulty is a reliable indicator of fairness. We do not believe the subject matter of an invention should have any bearing upon the issue.

5.20 A further danger is that considerations directed to the “subject matter of the patent” could pave the way for decision-makers to exempt conduct, or refuse to exempt it, according to their perception of an invention’s value, perhaps the contribution it makes to the social good, or the benefits of its inventive step²³ (again implicitly inviting public interest considerations as mentioned above). For example, while decision-makers might allow only a relatively narrow band of conduct to qualify as fair experimentation on new television technology, they may be much more willing to exempt conduct on inventions in the life/health sciences such as genetic testing kits or processes. Such patentees deserve no less protection than patentees in other fields. Our concern is that the Option allows differing tolerances of incursions into a patent owner’s rights according to the subject matter or field of technology. It therefore also runs the risk of contravening Article 27 of TRIPs which states that patent rights are to be “enjoyable without discrimination as to ... the field of technology”.

(iii) *The third bulleted point*

5.21 This point requires consideration of the “availability of the invention in the marketplace” when determining whether potentially exemptible conduct is fair. Once again, there is a misfit between this concept, which is appropriate for the copyright arena, and patent law.

¹⁹ See IPR Helpdesk publication, ‘Patenting and the research exemption’, http://www.ipr-helpdesk.org/documentos/docsPublicacion/html_xml/8_BP-Patenting-and-the-Research-Exemptio%5B0000003268_00%5D.html (25 February 2005).

²⁰ *Integra Lifesciences I, Ltd v Merck KGaA* U.S. App. Lexis 27796 (CA Fed Cir, 2003), per Rader J (certiorari granted by the Supreme Court in *Merck KGaA v Integra Lifesciences I*, 2005 US Lexis 614 (US, 2005)). Here, Rader J was speaking on the possibility of extending a legislative exemption (35 USC §271(e)) to allow unauthorised use of a patented tri-peptide segment of fibronectin to identify drug candidates that inhibited angiogenesis.

²¹ There are also problems with “improvements” to patented inventions, which might also be considered “transformative”; we discuss the conceptual/policy and definitional difficulties associated with improvements below.

²² Ricketson, above n11 at [11.35].

²³ We discuss this problem further below in our submissions.

- 5.22 In copyright law, the use may not be considered fair where there is the “possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price.” The notion is not problematic because, in a familiar example, if works are published as a commodity item they will generally be readily available to all at a commercially dictated rate. If so, “s40 should not be used simply for the sake of convenience ... the user should purchase their own copy, bearing in mind that insubstantial parts can always be reproduced freely as well as portions that fit within the minima outlined in s40(3)”.²⁴ If such works are not available in a reasonable time at a reasonable price, the provision may allow unauthorised use as “fair”.
- 5.23 This notion causes difficulty in the patent arena. Certainly, if an invention is widely and cheaply available then unauthorised use would be unfair; but delay, difficulty or expense in obtaining access does not indicate that unauthorised use is fair. Unlike the example of publications, just because an invention has been made does not mean the public has a reasonable expectation that timely access will be granted to all comers at an ordinary commercial rate. A patent holder has every right to make a strategic decision to either licence widely on a non-exclusive and easily accessible basis, or to licence sparingly, perhaps on an exclusive basis to a single licensee. The latter decision may have some impact on the availability of the invention in the marketplace. Not all who wish to licence the invention may be able to do so. This consequence is squarely within the notion of what the patent “monopoly” is intended to achieve – the patent owner’s control of just how and where the invention is made available or used, by whom, and for how much. Infringing conduct in the absence of a licence should not be excused under the guise of “fair” experimentation simply because the patent owner has exercised their legitimate right to control availability of their invention.
- 5.24 We note that if there is a serious issue as to whether the marketplace is being properly supplied with the invention, then third parties have recourse to section 133 of the *Patents Act 1990* (although, as we commented in our previous submissions, this provision is in dire need of further reform itself).
- 5.25 A further pertinent consideration that makes the availability inquiry inappropriate is that patent rights are often bestowed well before the invention is available in the marketplace, if the marketplace is indeed defined as the eventual consumers. It is doubtful whether this inquiry can be applied to either upstream inventions or inventions that for regulatory reasons, take several years to reach the marketplace.
- (iv) *The fourth bulleted point*
- 5.26 This point requires consideration of the “commercial effect” of conduct on the patent holder when determining whether potentially exemptible conduct is fair. In copyright, it is said that the guideline, which requires decision-makers to look at the effect of the dealing upon the potential market for or value of a work, “underlines the requirement that the dealing should *not damage the economic interests* of the copyright owner ... this is clearly required by the stipulation in art[icle] 9(2) of the Berne Convention that there should be no ‘conflict with the normal exploitation of the work’.”²⁵
- 5.27 While financial harm is obviously relevant to deciding whether experiments on a patented invention are fair or not, given the copyright focus on market size and value, there is a danger that reliance will be placed on such factors to the exclusion of considering harm to other broader (perhaps more difficult and less easily quantifiable) factors, such as strategy and business planning, that are so important in patent commercialisation. Article 30 of TRIPS, like the Berne Convention, states that exemptions must “not unreasonably conflict with a normal exploitation of the patent” (i.e. cause adverse commercial effect) **and** must “not unreasonably prejudice the *legitimate interests* of the patent owner”. A decision-maker may hold certain conduct to be fair in economic or financial terms, but it may nevertheless in a very real sense unreasonably prejudice the patent owner’s legitimate (business) interests *contra* Article 30. Consideration of the *commercial* effect of the conduct on the patent holder may not encompass the kind of broader issues that might affect a patent owner’s *legitimate* interests. In fact, it is unclear just what kind of issues will or will not arise for consideration under the “commercial effect” formulation.

²⁴ Ricketson, above n11 at [11.35].

²⁵ *Ibid.* Emphasis added.

- 5.28 In any event, the exemption of *any* conduct for which the patentee could otherwise sue would likely cause *some* level of adverse commercial effect (at the very least, it removes a legal right the patentee would otherwise arguably have). The uncertainty then arises: just how adverse does the commercial effect upon the patentee have to be before it will disqualify conduct as “fair” experimentation? Where would the tolerable range of acceptable adverse commercial effect lie? Again, a wide variety of differing views in the decision-makers would likely lead to a difficult and complex area of case law.
- 5.29 We recognise that the Option’s notion of “fairness” would be interpreted in light of the inclusive list of fair permitted uses in the *second* set of bullet points on page 13. We make further submissions on these points below. Nevertheless, we believe that in the interests of attempting to achieve the most clarity and guidance from any exemption, the introduction of the additional qualifier of “fair” experimental use is inappropriate and unwarranted and consequently we do not support the Option.

Option C8

- 5.30 We support this Option with respect to its wording as stated on page 13 that the exemption only be available if experimentation is “the sole or dominant purpose of the act”. We believe this will have the beneficial effect of guarding against unintended widening of the exemption, as discussed in our submissions regarding Option C7. It also fits well with the other precautions ACIP has mentioned, such as its choice of the term “experimentation” rather than “research” (since experimentation relates more directly to seeking the unknown and testing principles).
- 5.31 On a broad level, we agree that the combination of Options C3 and C6 may in fact overcome some of the problems inherent in the meaning of “on the subject matter of the invention”, given that the inclusive list of permitted acts will provide at least some assistance in interpretation. However, we submit that there are four very significant issues that deserve further consideration here:
- (a) the concept of research “on” an invention as opposed to research “with” an invention;
 - (b) the historical and interpretive difficulties surrounding use of the term “subject matter” in relation to patentable inventions;
 - (c) the outer reaches of the concept of research “on”; and
 - (d) the inclusion of the fourth bulleted point in the inclusive list of permitted acts, which is intended to guide application of the exemption provision.

1. Research “on” the invention

- 5.32 The exemption of experimentation “on” the subject matter of a patented invention avoids the difficulties of s60(5)(b) of the United Kingdom legislation, which exempts an experiment if it “relates to” the subject matter of an invention. As noted in our previous submissions, the “relates to” formulation risks unduly broad interpretation by the courts as far as it is directed towards permitted acts. However, there will likely be circumstances where experimentation “on” an invention is intertwined with and not easily separated from experimentation “with” the invention (as noted in the first bulleted point in the “con” list on page 14 of the ACIP Options Paper).

(a) Research “on” will need further explanation and guidance

- 5.33 Due to the potential difficulties of the research “on” and research “with” distinction, further guidance will be needed. The difficulties become most acute in the area of research tools. The ACIP Options Paper states:

“The particular issue of patented research tools being used primarily for their intended experimental purposes is not specifically addressed in the following options. ACIP considers that, under any of the options, the courts have the ability to reach reasonable judgments on research tools in a manner that does not unfairly single out and devalue patents for such inventions.”²⁶

²⁶ At 6.

5.34 We do not believe it is acceptable to ignore what is potentially a very serious flaw in this Option. Leaving the issue to be decided incrementally by the courts may well be easier than confronting it. However, if the value of the Option is to provide courts with legislative guidance, surely this value is lessened by such a significant area of ambiguity in the absence of further interpretive assistance. American experience shows that common law resolution of the research tools issue will be a long, hard road and will require litigants with deep pockets indeed.²⁷ In fact, in the *Merck v Integra Lifesciences* case there was a 2:1 split in the US Court of Appeals for the Federal Circuit on the basic question of whether the invention was even a research tool, let alone the sharp division as to how it should be treated in light of a legislative exemption.

5.35 A significant number of submissions to ACIP referred to the need for further interpretive assistance such as guidelines, statutory examples, etc. ACIP considered these as a means of informing a general exemption (see discussion of Option C2, page 10), but did not find the Option workable. However, the number of submissions suggesting the need for extra guidance reflects a real concern to provide the highest level of clarity for decision-makers. The suggestion should be adopted, at least, to clarify the distinction between research “on” and research “with”, and how it is intended to operate regarding research tools. The ancillary assistance need not be in the Act, and need not be in the form of specific examples or scenarios that would need constant updating. The explanatory memorandum could include a clear indication of the intention behind the exemption, and principles for approaching any perceived difficulties or limitations in areas such as this. The approach would probably be more useful and more widely applicable than specific examples.

(b) How to clarify research “on”?

5.36 The issue then is how to provide further clarity regarding the concept of research “on” an invention, which would be exempt, and research “with” an invention, which generally would not. The Department of Health and Aging submission gives some good examples of the present difficulty:

*“A concern is that in some fields of technology, including biotechnology, with its tendency towards broad patents, it may be difficult to make a distinction between research on the invention and research with the invention. While research with, or using the polymerase chain reaction (PCR) process is readily definable, as is research directed towards improving the process, there is less clarity where genes are involved. Research using knowledge of the structure of a gene, directed towards identifying treatment for disease associated **with** abnormal forms of the gene, may be regarded as research with the patented invention. Research intended to identify variation within the gene may be regarded as research on the invention.”²⁸*

“On the other hand, a case has been put by patent lawyer Philippe Ducor that ... some research tools, such as genes, which are not themselves marketable products but simply inputs to further research should be subject to a research exemption.”²⁹

“... clinical diagnostic testing, which can be regarded as technology subject to commercial application, could in principle be thought of as research on the invention. This is in the sense that it is research directed towards identifying the exact structure or properties of the “invention” in the specific individual being tested.

*The distinction between genetic testing and clinical diagnosis is also clouded by the fact that, **although the objectives may differ**, the processes are generally identical.”³⁰*

²⁷ See for example the case law leading up to the *Madey v Duke University* case (307 F.3d 1351 (Fed. Cir 2002), which involved a traditional research tool (patented laser device). Certiorari was denied by the US Supreme Court, although not for want of trying by the litigants. More recently, see the *Merck v Integra Lifesciences* case (2005 US Lexis 614 (US, 2005)), which involves use of patented tri-peptide segment of fibronectin. The latter case will be argued by the parties at US Supreme Court level later this year.

²⁸ At 9.

²⁹ At 10.

³⁰ At 9. Emphasis added.

- 5.37 To start with first principle, and at the risk of stating the obvious, examining the objective of the experimental use can provide substantial assistance in clarifying the matter. The crux of the distinction between research “on” and research “with” lies in the objective of the exercise and its intended result. The question might be: what knowledge base is it that this experimentation seeks to expand? If it is knowledge of the invention itself, or the invention as patented, this would tend to indicate the experiment should be exempted. Regard could be had to the first three of the inclusive list of permitted acts³¹ which appear to be relatively reliable indicators of research “on” an invention:
- (a) determining how the invention works (ie. gaining knowledge about the invention itself). This might include investigating the properties of the invention such as its structure or the composition of its components, for example by examining the effects of external factors on the invention or how they interact with the invention. “External factors” could include the conditions under which the invention performs a certain function. In the context of a gene patent, these could relate to the type of cell in which the gene is expressed, the stage of development at which the gene is expressed and the actions of hormones and other regulatory elements on the expression of the gene;
 - (b) determining the scope of patent claims (ie. gaining knowledge about the invention as patented);
 - (c) determining the validity of patent claims (ie. gaining knowledge about the invention as patented).
- 5.38 The contrasting situation is where the objective of the experiment is to expand knowledge of something else. This would tend to indicate that the conduct is simply research using, or “with”, the invention, which should not be exempted. Regard could be had to conduct with the objective of:
- (a) determining the action or effect of the invention on other objects (ie. gaining knowledge about the other object, not the invention itself). In the context of a gene patent, the exemption would therefore not extend to research into the effects of the functional product on other molecules or cell components;
 - (b) determining whether the invention could be used to achieve a new purpose (ie. gaining knowledge about how to achieve the new purpose, not the invention itself). We realise that this scenario is more contentious because at the same time this kind of experiment could provide further information about the properties or uses of the invention. However, we provide more detail on our position in paragraphs 5.46 and following below.
- 5.39 Others have discussed the merit in this approach. On the issue of research tools, the National Institutes of Health (NIH) states that the distinction between researching on a patented invention with the objective of studying “the underlying technology”, and research with a patented invention with the objective of studying “something else” is:
- “a sensible distinction. It is difficult to imagine how a broader research exemption could be formatted without effectively eviscerating the value of patents on research tools.”*
- 5.40 Nevertheless, Alcorn states that “‘research on’ versus ‘research with’ amounts to a distinction without a difference.” She believes it can be reduced to a simple choice of perspective – whether to support the second innovator or the patent owner – and is therefore “fraught with line-drawing. Ultimately, what one may consider ‘research on,’ another may consider ‘research with,’ and significant consequences flow from making such a determination.”³² We do not believe that the distinction is reducible to a choice of perspective. We appreciate that when applying the distinction, as Strandburg notes, “difficult line-drawing issues may still arise in particular cases”,³³ but this is

³¹ See below for our discussion of the fourth permitted act of “developing an improvement”.

³² Alcorn MJ, ‘Biotechnology law: a tale of peptides and lasers: is Integra Lifesciences I Ltd v Merck KGaA the end of the experimental use defence for biomedical innovation, or does §271(e) of the Patent Act save the day?’, (2004) 57 Okla L Rev 381 at 399.

³³ Strandburg KJ, “What Does the Public Get? Experimental Use and the Patent Bargain” (draft August 23, 2003), at 50, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=438023 (26 February 2005).

largely because, factually, there are many aspects of an invention that can be experimented on and many different kinds of experiment. Some of these will be directly and closely linked to the subject matter of the invention, and some will not. This is where the discussion in the following section can assist.

2. The “subject matter of the invention”

5.41 Arriving at a construction of “subject matter of the invention” is extremely important because it will define the scope of permissible research “on” the invention. The terminology, and the construction process itself, each present their own challenges.

(a) Historical problems

5.42 Some may assume that the phrase “subject matter” of the invention is relatively straightforward. The Oxford English Dictionary defines it as, *inter alia*, the matter operated upon in an art; the matter out of which a thing is formed; the ground, basis, or source of something.³⁴ However, in patent law there has been a history of imprecision and uncertainty surrounding the phrase, although it was often used to denote the issue of inventive step or obviousness.³⁵ For this reason, Viscount Simon in the House of Lords urged its removal from the 1949 British Patents Bill, and the draftsman deleted all use of it.³⁶

5.43 In the context of this inquiry, and for similar reasons to those outlined above regarding use of copyright terminology, it would be unfortunate to colour a new provision with language suggesting in any way that the appropriate inquiry should be whether the experimental use was on the inventive step of the invention or outside it. This is particularly so given that inventors do not even have an obligation to state in their specification what their inventive step is.³⁷ The non-obviousness or inventive step inquiry is hard enough for triers of fact with access to the prior art and expert evidence, let alone a researcher with no legal experience trying to work out whether their proposed experiment will be exempt or not.

5.44 Accordingly, it would be preferable to simply ask whether the experiment was “on the invention” rather than “on the subject matter of the invention”. Permitting experimentation “on the invention” leads more naturally to an inquiry as to whether the conduct is upon the invention as claimed, rather than some other elusive concept. It also makes more sense because infringement only occurs when all the essential elements or integers of an invention as claimed are present in the unauthorised conduct; there is no infringement if something less occurs. An exemption to remove liability for infringement is therefore only necessary for unauthorised experiments on an invention as claimed. The issue is not simply one of semantics, as will be seen in the next section.

(b) What is the “subject matter of the invention”?

5.45 In some circumstances it will be a relatively simple matter to discern the subject matter (nature) of an invention. In the Department of Health example, the subject matter of the PCR research tool is “readily definable” as the process. The gene patent is more difficult, but we maintain that the most appropriate construction is that its subject matter comprises the gene itself and its attendant information on composition, structure and sequence. Construction simply as the product claimed avoids the pitfalls of limiting “the subject matter” of an invention to its inventive step, merit or technical contribution, or its utility as disclosed in the specification, and is more consistent with the current trend of Australian High Court authority. It also avoids being side-tracked by the issue of

³⁴ Oxford English Dictionary, (Oxford University Press, Oxford, 2005), the definition of “subject matter” at http://80-dictionary.oed.com.ezproxy.library.uq.edu.au/cgi/entry/50240739?single=1&query_type=word&queryword=subject+matter&first=1&max_to_show=10 (26 February 2005).

³⁵ See McBratney A, above n9 at 223; see also the High Court’s comments in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 212 ALR 1 at 17.

³⁶ See McBratney, *ibid*.

³⁷ *AMP Inc v Utilux Pty Ltd* (1971) 45 ALJR 123; *revd* on other grounds: *Utilux Pty Ltd v AMP Inc* (1974) 48 ALJR 17.

whether the invention can be properly classified as a research tool, and further whether it is a pure or partial research tool.³⁸

(i) *The Clinical Trials I case*

- 5.46 The difficulties in construing the “subject matter of the invention” are most obvious for composition of matter inventions where all uses are claimed, as with the gene patent example. In such cases, as noted above in paragraph 5.38(b), it may not be immediately clear whether research to explore and verify a new use would be considered exempt or an act of infringement. Construction of the subject matter as the invention as claimed tends to clear away the ambiguities and is more analytically sound.
- 5.47 The *Clinical Trials I* case³⁹ lends some assistance in locating the proper legal analytical foundation for this position. What makes the decision relevant for present purposes is the German Appeal Court’s and Supreme Court’s analyses of whether the privilege should apply and, in particular, how they arrived at their respective conclusions that the trials for finding new indications were, or were not, “relat[ed] to the subject matter of the patented invention.” We do not advocate application of any German-specific law in the Australian context; it is the analytical aspect of the case that provides assistance.
- 5.48 In *Clinical Trials I*, the patent claimed human immune interferon obtained by genetic engineering, ie. recombinant human interferon-gamma as a polypeptide of defined amino acid sequence. The defendants imported interferon-gamma under a compulsory licence granted by the German Patents Court. Under this licence, they made and sold a pharmaceutical composition for treating certain forms of rheumatoid arthritis. They also conducted clinical studies on the active substance of interferon-gamma to find further possible indications for it (including cancer, AIDS, allergies, leukaemia, asthma and chronic hepatitis). The patentee sued for infringement. The Appeal Court below held that the experimentation privilege in §11 No 2 of the German Patents Act 1981 did not apply to the clinical trials and ordered their discontinuation. The Federal Supreme Court held that the privilege did apply.
- 5.49 We submit that, for reasons that will be detailed further below, the reasoning of the Appeal Court is preferable. With respect, the approach of the Supreme Court should not be followed, as it tends to conflict with Australian authority and would also disproportionately prejudice the research tool patentee’s interests.
- 5.50 To provide adequate context, the analysis of the Appeal Court below is worth quoting at length:

“§11 No 2 ... excludes from the effect of a patent acts for experimental purposes related to the subject-matter of the patented invention, which in the case of a substance (product) patent is the nature of the substance. The significance and scope of this provision must be seen in the context that patent law is intended to promote industrial development and not impede further development of novel techniques. Accordingly, the purpose of §11 No 2 ... is to except from the patent experiments on the subject-matter of the patented invention, and thus necessarily also the preparation of an embodiment of this subject-matter for such experiments. For a substance (product) patent, this means that experiments carried out on the substance itself, for example to obtain details of its nature in order to establish whether it can in fact be prepared, whether it is sufficiently pure or can be obtained sufficiently pure, or whether it actually has the properties of the active substance interferon-gamma, must be permitted.

The defendants have not carried out such experiments ... [t]he presented cases of clinical trials on humans did not relate to the nature of the active substance protected in the claims of the patents in suit, its nature was not investigated; the teaching concerning this in Claim 1 was accepted. For those involved in the experiments, the subject-matter of the invention is of interest only because of the use which is thought to be possible. The intention was to establish whether and, where appropriate, with which administration form and dosage

³⁸ See Derzko, above n1 at 352-353.

³⁹ *Klinische Versuche (Clinical Trials) I (Case X ZR 99/92)* [1997] RPC 623 (Federal Supreme Court of Germany).

interferon-gamma is able to cure or alleviate certain human diseases. The clinical trials thus related to uses of the subject-matter of the invention. §11 No 2 of the Patents Act does not cover that situation.

Moreover, a privilege in respect of experiments on the use of a substance (product) patent is not compatible with the principle of patent law that the product patent not only grants protection from acts of production but also reserves to the proprietor all possible uses of the product formed according to the invention, in particular irrespective of whether the inventor has already recognized the individual possibilities. If the inventor himself is able to prevent novel and inventive uses of the substance, then it follows that experiments relating purely to the use can be prevented. Comprehensive protection by the product patent is not ensured if third parties were to be permitted to investigate the subject-matter of this patent for uses not disclosed in the patent by acts which would be covered by §9 of the Patents Act per se [ie. the section stating that only the proprietor is permitted to use the patented invention]. This would put the third party in the position of himself obtaining a use patent for the subject-matter of the product patent and thus even excluding, with the aid of this patent, the proprietor of the product patent from carrying out certain uses. It is not the purpose of the rule in §11 No 2 of the Patents Act to endanger the economic value of a product patent in this way.”⁴⁰

5.51 To summarise the steps in this analysis:

- (a) the exemption permits experiments “related to the subject-matter of the patented invention”, ie. those performed “on the subject-matter of the patented invention”;
- (b) for a substance (product) patent, permitted acts are those on the substance itself, determining details of its nature, ie. whether it can be prepared, is sufficiently pure or can be obtained sufficiently pure, whether it actually has the properties of the active substance, as well as making the subject-matter for these experiments (see our comments in paragraphs 5.37 to 5.38 above);
- (c) the impugned acts did not relate to the invention as claimed, ie. the “nature of the active substance protected in the claims” but to *further uses* of the invention. These did not fall under the exemption;
- (d) exempting investigation of further uses would conflict with the fact that patent law protects products claimed *per se* against not only making, but using, the product even if those uses are not set out in the specification. If the patentee can prevent others using the product for a new use, it can also prevent experiments to find the new use. Otherwise patent rights would be seriously derogated from – it would be like granting another patent over the same substance for the new use.⁴¹

5.52 In contrast, the Federal Supreme Court reasoned (emphasis added):

⁴⁰ Grounds of Judgment, III.2.

⁴¹ This is not permitted except in narrow circumstances. Product patents claiming the known composition itself but merely limited to a new use are granted for finding the *first* medical indication of a substance: Article 54(5) of the European Patent Convention; Guidelines for Examination in the European Patent Office, Part C, Chapter IV at 4.2; *cf.* the law of selection patents for chemical inventions. Bare use patents for new use of known properties of a substance often encounter inventive step difficulties, although new use of a known material overcoming difficulties not resolvable by routine techniques may be acceptable: Part C, Chapter IV, at 1.1(iii), 1.2(ii). In relation to novelty, if a new “technical effect” is demonstrated as a functional technical feature of the claim (ie. new advantage, not just new use) it *may* be patentable: Case G2/88 (*Mobil*), but *cf.* recent conflicting case law *Robertet SA/Deodorant Compositions* [2000] OJEP 1. The UK Patent Office does not follow the *Mobil* approach: UK Patent Office Manual at 2.14. Use patents for second medical indications are not allowed due to the European prohibition on patenting methods of surgery, therapy and diagnosis. In Australia, patents claiming nothing but a new use of an old substance are also unobtainable and will encounter patentability problems, because in the state of knowledge the “new purpose is no more than analogous to the purposes for which the utility of the substance is already known.” However if invention can be found in a new method of using the material, or some new adaptation of it to serve the new purpose, or taking advantage of a previously unknown or unsuspected property of the material, it may be patentable: *National Research Development Corporation v Commissioner Of Patents* (1959) 102 CLR 252.

“... in the absence of a legal definition of the subject-matter of the invention in the Patents Act, it might at first sight appear obvious to interpret this term in accordance with the alternatives in §9 of the Patents Act, according to which the **subject-matter of the patent can be a product, a process or a use**. This reference might indicate that, within the framework of §11 No 2 of the Patents Act, a distinction is to be made between the product, that is to say the active substance interferon-gamma, and its use as **two different subject-matters**. However, [the exemption] refers -- unlike §9 of the Patents Act -- not to the "subject-matter of the patent" but to the "subject-matter of the patented invention". This term can also be understood ... to mean that the subject-matter of the invention is the **claimed technical teaching**, which also **includes the use of the inventive substance**. ...

Viewed from this starting point, the wording of the Act when examined naturally rather indicates that §11 No 2 of the Patents Act in principle exempts **all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use**. There are then included, for example, utilization acts for experimental purposes undertaken with the subject-matter of the invention in order to discover the effects of a substance or possible new uses hitherto unknown. Since the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests ...”⁴²

5.53 Once again, to summarise the steps in this analysis:

- (a) under §9 [similar in effect to our section 13 and definition of “exploit”], the patentee’s exclusive rights attach to a product, a process or a use. This might imply that the exemption also distinguishes between products and uses *as two different subject-matters*;
- (b) however §9 refers to the “subject-matter of the patent” and §11 No 2 to the “subject-matter of the patented invention.” The latter means the *claimed technical teaching, including use* (ie. the subject matter of a patented substance includes its uses);
- (c) since the subject matter is the substance *and* its uses, the exemption permits all experiments if they gain information on further uses (ie. these experiments are “on” the “subject matter”);
- (d) since there is nothing to indicate otherwise in the express wording, the exemption allows not only verification of information in the specification but also obtaining further research results, regardless of any commercial motive.

5.54 The court goes on to engage in discussion of German-specific issues such as the principle of freedom of research and the social obligation of property. It identifies the patentee’s “inventive contribution” as the unambiguous identification and isolation of interferon-gamma and making it available as a substance for any desired use.⁴³ In return for this contribution the patentee could control when and how *he* used the substance. However, the legislature had limited patent rights via the principle of free research and the public interest in further technical development, in enacting §11 No 2.

5.55 The experiments at issue were thus permissible, despite the outcome that product patentees in the pharmaceutical sector risked “being seriously impeded in the exclusive utilization of [their] patent by a massing of experimental projects, especially when third parties aim at, and achieve, use patents based on the results found in the experiments. However, this risk is intrinsically present with every product patent.”⁴⁴ In view of the patentee’s contribution of providing the product, it was inappropriate to allow it a reward for uses found only with an inventive step made by a third party.⁴⁵ In any event, while experimental use was exempt from infringement, commercialisation of the

⁴² Grounds of Judgment, III.4(a).

⁴³ Grounds of Judgment, II.2.

⁴⁴ Grounds of Judgment, III.6(b). Note that use patents are different to the product patents limited by use as discussed above n41.

⁴⁵ Ibid.

product for the new use would allow sufficient reward, because the patentee would have to grant a licence for the product.⁴⁶

(ii) *Problems with the Supreme Court's analysis*

5.56 There are some real difficulties with the Supreme Court's analysis. The most glaring is that the court elides the nature of the invention with the nature of patent rights in the invention. Patented inventions may be products, processes, uses. Patent rights include the exclusive right to make (if a product), and the right to use. For a use patent, its nature is use, and one of the rights is use. For a product patent, its nature is the product, and one of the rights is also use. The Supreme Court says it would be wrong to treat a product and its use as *two separate subject-matters*, but in fact there is only ever one subject matter (the product) and its accompanying right (use). The Court says that the subject matter (product) *includes* use (right). With respect, this incorrectly conflates the issue of subject matter of the invention with the exclusive rights attaching to the invention. Using this expanded definition of "subject matter", the court is then able to conclude that experiments to find a new use were in fact experiments on the subject matter of the product invention.

5.57 The court supports its decision with analysis of the patentee's technical teaching or inventive contribution. It firstly states the technical teaching includes the substance itself as well as uses of the substance, to fit with its assessment of subject-matter as including use.⁴⁷ Indeed it notes that the Appeal Court viewed the inventor's contribution as "the identification and isolation of interferon-gamma and the making available of this protein as a substance *for any desired use*", and that this point was not disputed.⁴⁸ However, later the Supreme Court narrows the inventor's contribution to "providing this product," to fit with its assessment of the narrower merit of the invention that deserved reward: since the patentee had only made the product available it should not be rewarded for new uses found by inventive actions of third parties.⁴⁹ This clearly demonstrates the unreliability and slipperiness of entering into assessments of technical contribution or merit.

(iii) *The preferable analysis*

5.58 We submit that the analysis applied by the Appeal Court is correct, and that it is clearer, simpler and more sound than that of the Supreme Court. Not only does it avoid the elision problem, but it avoids entering into the very murky area of technical contribution or merit. As noted above, the obviousness or inventive step inquiry is a very difficult matter for decision-makers equipped with relevant prior art and expert evidence, let alone a researcher without legal training. If the exemption is to be workable at all, the notion of "subject matter" should not rely to any extent on difficult concepts such as technical contribution or merit.

5.59 The *Clinical Trials I* differences in approach are clearly demonstrated by reference back to the Department of Health gene patent example given previously. Under the Court of Appeal's reasoning, as we (and apparently the Department of Health, at least in the first instance) would expect, research:

- (a) to identify variation within the gene, or clinical testing to find its exact structure or properties, would be exempt research "on" the invention (ie. gaining knowledge about the invention itself);
- (b) using the knowledge of gene structure to find treatment for disease, including via clinical trials, would be non-exempt research "with" the patented invention (ie. gaining knowledge about how to achieve the new purpose, not the invention itself).⁵⁰

⁴⁶ Grounds of Judgment, III.6(c).

⁴⁷ Grounds of Judgment, III.4(a); therefore the court could exempt "all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject matter of the invention, including its use."

⁴⁸ Grounds of Judgment, II.2, emphasis added.

⁴⁹ Grounds of Judgment, III.6(b).

⁵⁰ The Ducor argument that research tools, such as genes, that are not marketable on their own but inputs to further research is thus irrelevant as it says nothing about the subject matter of the invention. The marketability or otherwise of an invention is not at issue.

5.60 As the NIH commented, this is the only outcome that does not effectively render the value of research tools nugatory. To achieve any other result will involve straining the construction of the “subject matter” of an invention, eliding the separate aspects of a patented invention and engaging in difficult assessments of merit. It also opens the door to an increasingly broad interpretation of the exemption provision: *Clinical Trials II*.⁵¹

(iv) *Issues of inventive step (inventive merit, technical contribution), sufficiency and fair basis*

5.61 The approach recommended in paragraphs 5.58 to 5.60 above also fits best with current Australian patent law because it:

(a) keeps issues of inventive merit or technical contribution quarantined from the issue of whether, and how, an exemption will be applied in any given case; and

(b) is consistent with other important Australian patent law principles.

(1) Quarantining the exemption/“separate treatment”

5.62 We agree with IPRIA’s submission to the extent that it suggests that the principles underlying the grant of a patent should be consistent with principles determining the nature of a patentee’s rewards. That is, the principles relevant for assessing patentability or invalidity should ideally carry over into the way that the exemption impacts upon a patentee’s “monopoly.” This makes for a cohesive approach to patent law. In this regard, we note that several Australian High Court cases have adopted a “separate treatment” approach, ie. that issues of inventive merit or inventive step must not creep into assessment of other aspects of patent law.

5.63 This important line of case law indicates that it would be wrong to import notions of technical contribution or inventive merit into the analysis of whether or not an experimental use exemption should apply, or how broadly or narrowly a patentee’s scope of rights should extend. For example:

(a) in *Advanced Building Systems v Ramset*,⁵² the High Court held that the Full Federal court had erred by revoking a patent because it was not an invention (manner of manufacture), on the basis that it did not have sufficient “inventive merit”. The court held that the analysis of inventive merit had no distinct and independent doctrinal meaning and, in fact, led into error through imprecise legal analysis;⁵³

(b) in the *Kimberly-Clark* case, the High Court unanimously adopted as correct the statement of Barwick CJ in *Olin v Super Cartridge* that the issue of fair basis was not to be resolved by considering policy-type questions such as whether the monopoly “would be an undue reward for the disclosure” (ie. balancing the breadth of monopoly and the merit or technical contribution of the invention);⁵⁴

(c) in the *Lockwood* case, the High Court reiterated that “inventiveness,” “meritoriousness” or the “technical contribution” made by the specification are relevant only to issues of inventive step, not fair basis. It also adopted *Advanced Building Systems’* assessment of the

⁵¹ *Klinische Versuche (Clinical Trials II) (Case X ZR 68/94)* [1998] RPC 423, where the Federal Supreme Court held that clinical trials are permissible to obtain data for clinical approval, even if for the same indication as the patented product, and even if commercially motivated. The only limitations were if the volume could no longer be justified on research grounds, or if done with a purpose of persistently disturbing or hindering the patentee’s distribution of the product. Some commentators doubt the use of this case as any broad precedent for bioequivalence testing: Veron P, ‘Experimental use exemption for clinical trials: Europe vs. North America’, seminar presented to Licensing Executives Society, Milan, 12 December 2002, <http://www.italy.les-europe.org/docs/veron.pdf> (28 February 2005). In the UK, it was held in *Auchincloss v Agricultural & Veterinary Supplies Ltd* [1997] RPC 649 (upheld on appeal, [1999] RPC 397) that making and experiments to obtain official approval were not exempt under section 60(5)(b).

⁵² *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* [1998] 152 ALR 604.

⁵³ *Ibid* at 612 per Brennan CJ, Gaudron, McHugh and Gummow JJ. Note that this decision therefore considerably read down the court’s previous decision in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1994) 183 CLR 655; 132 ALR 117.

⁵⁴ *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1; *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 180 CLR 236 at 240.

imprecision of “inventive merit,” and added more generally that the grounds of invalidity “are, and must be kept, conceptually distinct.”⁵⁵

5.64 Even where there has only been (what some might view as) a rather limited disclosure of the invention as claimed, issues of inventiveness, merit or technical contribution must still be excluded from questions such as the determination of fair basis. The *Kimberly-Clark* and *Lockwood* cases make it clear that, in Australian patent law, an invention is sufficiently disclosed (under the section 40(2)(a) requirement to describe an invention “fully”) if the skilled person can make a *single embodiment*.⁵⁶ This rule for sufficient disclosure has been criticised by some commentators in policy terms, as having the potential to over-reward the inventor. It has an impact upon how broadly an invention may be described and claimed, and yet retain fair basis.

5.65 The respondent in *Lockwood* had relied in argument on the *Biogen* House of Lords case,⁵⁷ where a patent related to a DNA sequence coding for hepatitis B virus antigen to stimulate the production of antibodies. The priority document described one recombinant procedure for making the necessary antigen, but the claim at issue covered any recombinant method. The House of Lords held the claim was too broad. Lord Hoffman called the rule of sufficient disclosure “mechanistic and impoverished”. So far as support for the claims went, the policy concern was that:

“[t]he technical contribution made in such cases deserves to be recognised. But care is needed not to stifle further research and healthy competition by allowing the first person who has found a way of achieving an obviously desirable goal to monopolise every other way of doing so.”⁵⁸

5.66 However, our High Court rejected the *Biogen* case as inapplicable to the Australian law on fair basis, especially given that the rule of sufficient disclosure was expressly acknowledged in the *Kimberly-Clark* High Court case:

“This criticism of an important aspect of Australian law, as reflected in s40(2)(a) of the Act, suggests that current United Kingdom law is no guide to Australian law on s40(3).”⁵⁹

5.67 Thus, where the specification in *Lockwood* broadly described certain “means” that a skilled person would have no trouble making, but had only included one preferred embodiment of those means, and where the description of the invention in the body of the specification matched the broadly drafted first claim, there was no lack of fair basis.⁶⁰ The acceptable breadth of a claim for the purposes of fair basis was not to be read down by public policy considerations as discussed in *Biogen*, inventive merit, or a hunt for a more elusive concept that would narrow down the breadth to whatever was “truly” disclosed⁶¹ by the specification. Fair basis could not be used to circumvent what some would see as the “stifling” rule of sufficient disclosure.

5.68 If an otherwise valid claim may be considered both sufficient and fairly based under *Lockwood*, then it stands to reason that the same claim will be enforceable according to its full breadth against third parties for infringement purposes. In light of current High Court authority, and unlike the Supreme Court’s discussion in *Clinical Trials I*, it should be no answer to say “the patentee has a valid and broadly worded claim, but its real merit (technical contribution, or what is “truly” disclosed) only extends so far, so we should exempt all experiments that operate outside or add value to this merit.” The focus should remain solely on construction of the subject matter of the invention, ie. the nature

⁵⁵ *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 212 ALR 1 at 11-12, 14.

⁵⁶ *Ibid* at 19-20.

⁵⁷ *Biogen Inc v Medeva plc* [1997] RPC 1 (HL).

⁵⁸ *Ibid* at 52.

⁵⁹ (2004) 212 ALR 1 at 19.

⁶⁰ The invention was a “combination” product claim with six integers. Integers (i)-(v) were those of a known or typical “deadlatch” assembly; integer (vi) was a new integer described broadly as “lock release means”. Integer (vi) was denoted in a figure simply by an empty square, however it was held that the skilled person could make such a “means” without further instruction. The combination of integers (i)-(v) plus (vi) was the invention as described and claimed.

⁶¹ *Doric Products Pty Ltd v Lockwood Security Products Pty Ltd* (2001) 192 ALR 306 per Hely J (first instance) at 347.

of the invention itself, or as patented, as suggested in paragraphs 5.37 to 5.38 above. One of the chief benefits of the research “on”/research “with” distinction, and our approach in construing what will or will not comprise the subject matter of an invention, is that, like current Australian law, it:

*“reduce[s] the question to an objective analysis of the nature of the research in question ... [it] is a factual question that can be evaluated by judges and juries without the need for policy-driven balancing.”*⁶²

(2) Consistency with other patent law principles

5.69 The *Lockwood* and *Kimberly-Clark* cases also provide a further useful analogy, and an additional reminder of another important aspect of our patent law that would conflict with the German Federal Supreme Court’s analysis. A patentee can claim broadly if the skilled person is equipped to make a single embodiment of the invention, yet the patentee’s right extends to preventing others from making anything that falls within the broad claim, not just the precise embodiment taught by the specification. Similarly, a patentee of a product patent need only disclose sufficient utility,⁶³ but can prevent others from any uses, not just those disclosed in the specification. As Cornish puts it, the principle is that:

*“... a claim to a thing gives a monopoly over whatever it is to be used for – and is correspondingly broad.”*⁶⁴

5.70 If the focus remains, as we have suggested, on construing the subject matter of an invention simply as the invention itself or as patented, then any exemption for experiments to find further uses for a product invention would (as the Court of Appeal in *Clinical Trials I* points out) conflict with the full protection of product patents against all potential uses. Such experiments would instead have to be classified as non-exempt research “with” an invention. This is the outcome anticipated and recommended in paragraph 5.38(b) above, and the discussion here shows it also has a good fit with Australian patent law.

(v) The research tools “definition” debate

5.71 In the *Merck v Integra Lifesciences* case, Judge Newman (in dissent) takes issue with the majority’s discussion of the patented invention (tri-peptide segment of fibronectin) as a research tool, calling it a “misperception” and “misdefinition”. The judge instead views the peptides as “not a ‘tool’ used in research, but simply new compositions having certain biological properties.”⁶⁵ She concludes (similarly to the Supreme Court in *Clinical Trials I*) that use of the peptides was essentially research “on” the technology of the peptides and should have been exempt under the common law research exemption.⁶⁶ As Derzko suggests, a counter-argument can easily be made that the use was not intended to study the peptides at all but to determine events downstream of receptor binding (ie. changes in intracellular biochemical activity). The objective was to study the goal of manipulating receptor functions and altering disease progression.⁶⁷

5.72 Much has been written on the acceptable definition for “research tools”.⁶⁸ We make no submission on this point as it is largely outside the scope of the present inquiry. However, we do say that:

⁶² Strandburg, above n33.

⁶³ Sufficient utility simply requires that the invention should enable the addressee to achieve the result claimed by the patentee: Dwyer JW, Dufty A, Lahore J, Garnsey J, *Patents, Trade Marks & Related Rights* (Butterworths, Sydney, 2004) at [12,970]. This is unlike American law which requires a utility to be “specific, substantial and credible”.

⁶⁴ Cornish W and Llewelyn D, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, (5th ed, Sweet & Maxwell, London, 2003) at [4-46].

⁶⁵ Above n20 at 50-51.

⁶⁶ Rather remarkably, Newman J came to this conclusion despite the *Madey v Duke University* case, above n27, which effectively excluded all commercial research from the scope of the common law exemption, and also despite the fact that the common law exemption was not even at issue or argued as grounds in the appeal.

⁶⁷ Above n1 at 399.

⁶⁸ See for example Derzko, above n1.

- (a) while the effect of the experimental use exemption on research tools must be taken into account in policy terms when formulating the wording of the exemption and any ancillary explanatory information,
- (b) the process of classifying an invention as a research tool or not, or the further distinction of the tool as a pure or partial research tool, should have no bearing on the issue of construing the “subject matter of the invention” for the purposes of an Australian experimental use exemption.

3. The outer reaches of “research on”

5.73 One further comment should be added in relation to the research “on”/research “with” test. The effect of the exemption must not contravene TRIPs Art 30 – it must not interfere with normal exploitation of the patent and must not prejudice the legitimate interests of the patentee. It is not sufficient to formulate an exemption by drawing a distinction between experimentation that “will *effectively destroy* the value of the invention to the original inventor ... and where the experiments do not have this effect.”⁶⁹ We believe that our position on the issue of research “on”/research “with”, and the further issue of construing the subject matter of an invention, falls more properly within the confines of TRIPs Article 30.

4. Improvements

5.74 We now turn to the inclusion of the list of “permitted acts” and, in particular, the inclusion of the fourth bulleted point on page 13, “developing an invention.” This point appears deceptively straightforward. Indeed, many submissions adverted in some way to the issue of improvements. However, we discern four major difficulties:

- (a) the notion of “improvements” encounters conceptual/policy difficulties, especially for severable improvements;
- (b) the notion of “improvements” has clarity problems; it is at best a slippery and grey classification, susceptible of considerable uncertainty;
- (c) it has little value as a reliable indicator of what should be a permitted act of research “on” an invention, as research objectives are unclear and subject to change; and
- (d) the likely impact of the legislative Option as a whole will hinge critically upon the interplay and relative interpretations of “improvements” and “experiment on”.

(a) Conceptual/policy difficulties

5.75 The first problem is that as the fourth bulleted point stands, *any* experimentation to develop an “improvement” would be exempt from infringement proceedings. Implicitly, it appears that the traditional view of an improvement – incremental advance, reliant on the base technology – is applied. However, improvement is a very grey concept, as further outlined in paragraphs 5.78 and 5.79 below, and may not be reliant to any extent on base technology. Depending on the classification (improvement, new invention) that is ultimately accepted by a trier of facts, very different results ensue, which are not always justifiable in policy terms:⁷⁰

5.76 If the court accepts that the experiments produced an improvement, the conduct is exempt.

Conceptually, justification for this position is apparent under the traditional view of improvement, ie. where it relies on the base patented technology to the extent of reading onto a claim: the technology is advanced, and even though the experimentation was exempt from infringement proceedings, the original patentee must be compensated by some kind of (presumably royalty-bearing or cross-) licence arrangement before the improvement can be commercialised.

However, justification is more difficult to find for severable improvements that do not rely on the base patented technology. In such cases, not only is the experimentation exempt, but the original patentee receives no compensation at all for the use of their invention during commercialisation. It

⁶⁹ Submission of John Richards Esq at 2.

⁷⁰ In the following discussion, we assume that at least one of the policy rationales for the patent system is to stimulate invention by providing reward to patentees (and so preventing Arrow’s market failure prompted by free-riding).

seems even more difficult to find justification where the severable “improvement” can also be commercialised across other technology sectors or fields of use. In such cases, it may be preferable to treat the generation of such “improvements” as non-exempt experimentation “with” the earlier patented technology.

- 5.77 If the court accepts that the experiments produced a new invention rather than an improvement, the conduct is not exempt and would be exposed to infringement proceedings.

Conceptually, justification for this position is apparent whether or not the working of the new invention relies on the base patented technology. Since the base technology was not advanced but new technology invented, any experimentation is treated as non-exemptible, ie. research “with” not “on” the invention. The original patentee therefore receives compensation for use of their invention during the new invention’s experimental (research and development) stage. If the new invention relies on the earlier patent, it is fitting that the original patentee will also receive compensation during commercialisation. However, much hangs on the classification of the development as a new invention rather than an improvement; this issue is discussed further below.

(b) Clarity problems

- 5.78 Apart from the conceptual/policy difficulties surrounding severable improvements, the glaring problem is that the outcome in every case will turn on what can be a very fine distinction between “invention” and “improvement”. A potential infringer will call their conduct an experiment to generate an improvement to base technology. A patentee will invariably label the very same conduct as use of their patented invention to develop a new invention that differs significantly from the base technology. Case law in the area of licensing technology suggests that the term “improvement” is capable of endless dispute. Just how much of the original technology must be retained? How minimal or significant does the advance have to be?

- 5.79 We foresee great difficulties in determining how generally the term “improvements” ought to be construed. In practice, we find this term arises consistently as a contentious issue in patent licence agreements and we have never yet been able to provide adequate boundaries for its definition. Ideally, we would wish to see this matter addressed in an explanatory memorandum but there is only so much guidance that can be provided on this point *ex ante* in an abstract context. The difficult work would probably still have to be done by the courts on a case-by-case basis according to the facts at hand. We therefore feel that the clarity problems inherent in the term are a serious detractor from its use in guiding application of the legislation. The permitted acts must be those beyond contention, ie. the clearest examples of permissible use of a patented invention. The real difficulties with the clarity of the term “improvement” means it is unsuited for the task.

(c) Use as an indicator of a “permitted act”

- 5.80 There is a further problem in using the “developing an improvement” point as an example of a permitted act of experimentation. Exempt permitted acts are those “on” the subject matter of the invention, ie. as submitted above, acts with the objective of expanding knowledge about the invention. The first three bullet points are reasonable indicators of this kind of activity. However, just as the distinction between “improvement” and “invention” is so tenuous and unclear, the researcher’s objectives when working in the area of improvements will usually be just as unclear and probably subject to change, and so will not be able to provide a reliable indicator of a permitted act.
- 5.81 We concede that in a simple case research may be prompted by, and conceptualised as, a problem in the original technology to be overcome. Efforts may be directed at various aspects of the original technology in order to ameliorate or solve the problem, resulting in an improvement. In such cases the objective is clearly to expand knowledge about the invention itself and would be exempt.⁷¹ However, research does not usually proceed in this linear fashion: many dead ends, subsidiary problems, complicating factors and sometimes impossibilities arise along the way. Such factors may prompt initial efforts to be amended or abandoned, and new theories tested and tried, which may result in a new invention rather than an improvement to the original technology. Untangling the research process to find out when and to what extent the objective of the project had changed would

⁷¹ Although as noted in paragraphs 5.75 and 5.77 above, whether this should be so for severable improvements is arguable.

be a nigh impossible task. Indeed, the objective may not have even changed: it may be that in trying to find out more about the invention a serendipitous discovery is made which necessarily means the outcome is not an improvement but a new invention. Or the objectives may be mixed and multiple in nature. How would liability for infringement for any non-exempted part be apportioned?

- 5.82 For these reasons, we do not support the inclusion of the fourth bullet point on page 13, “developing an improvement to the invention”. In particular, we feel that before inclusion of the point could proceed it would be desirable to resolve the policy concerns noted above, find some acceptable definitional clarity, and have its value as an indicator of a permitted act much more clearly established.
- 5.83 In any event, we believe that many experiments in pursuit of the traditional form of “improvement”, which appears to have been assumed as the permitted act, would likely be exempt as research “on the [subject matter of the] invention”, and possibly also within the first of the permitted acts, because the object would be to gain more information about the invention, ie. how it worked and how its qualities, character, composition, etc could be changed to enhance that same invention.
- 5.84 To reiterate, and for the avoidance of doubt, we do not believe that experimentation for improvements would be excluded from the protection of the experimental use exemption. Indeed, our comments in the paragraph immediately above indicate to the contrary. This is something that should be decided factually and incrementally. We simply do not believe the difficulties bound up in the notion of “improvement” allow its use as an example of a permitted act.

(d) *Interplay and relative interpretations of “improvements” and “experiment on”*

- 5.85 The inherent difficulties in the scope and ambit of the words “improvements” and “experiment on” have been discussed at length previously in this submission. The impact of the fourth “bullet point” of permitted acts under this Option must be considered in the context of the drafting of the Option as a whole. We submit there are two potential scenarios here:
- (a) if the “experiment on” part of the legislative amendment is clearly interpreted as distinct from and separate to “experiment with”, what is traditionally viewed as improvement-related conduct may well be exempt anyway. There is no need to incorporate the interpretive difficulties associated with using “improvement” as an example of a permitted act;
 - (b) if the “experiment on” part of the legislative amendment is ambiguous and not clearly distinct from “experiment with”, then we submit that the interpretive difficulties associated with the word “improvements” is of critical importance and may have a profound impact upon innovation and economic growth. If such an exemption included improvements in a broad sense, then the experimenter could deprive the original patentee from revenue that is due to him by virtue of his patent monopoly, without sufficient justification. This is especially so in circumstances involving borderline calls as to “improvement” versus “invention” and severable inventions.
- 5.86 We therefore believe the “improvements” point should be omitted as a “permitted act”.

Conclusion

Overall, we believe that if decision-makers are provided with the inclusive list of permitted acts (comprising the first three points) and a clear explanation of the intent behind the provision in the explanatory memorandum, they should be in a position to make the decision in a guided and appropriate manner on the facts before them. It is noted, however, that the explanatory memorandum will require some significant elucidation on matters relating to “improvements,” the distinction between research “on” versus “with,” and the construction of the “subject matter of the invention”, to avoid problems such as free-riding in accordance with intellectual property rights policy. We have continuing concerns about the terms “subject matter” and “improvements” and believe the best course is to omit them.

Nevertheless, we believe this Option will lead to greater clarity than either Options C1 or C7. As noted in our previous submissions, the European exemption such as that enacted in the United Kingdom is certainly not free of its own problems. However, a partial level of harmony between the provisions could reduce the uncertainty of the new Australian provision as there would be existing and persuasive UK authority on various aspects of the exemption that could assist our courts in interpreting our provision. And as with all

persuasive legal authority, our courts would be free to either accept or reject such assistance in a reasoned and principled manner as appropriate for the Australian context. In addition, as the Options Paper notes on page 14, the partial harmony with European laws may reduce some costs to exporters.

We reiterate that it may be worthwhile to engage in further research of similar provisions, especially in Europe, prior to settling on the precise formulation to be included in our legislation. We recognise that no solution will be crystal clear and free of ambiguities. However, despite some shortcomings, we believe that Option C8 is the best of the four Options short-listed by ACIP and will provide a workable solution provided the concerns we have expressed can be adequately addressed.

If we can be of any further assistance, please let us know.

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