Patents and experimental use Freehills' submission on ACIP's Options Paper

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1 Introduction

Freehills is a national Australian law firm and Freehills Patent & Trade Mark Attorneys is an associated patent and trade mark attorney firm. Together they advise clients in litigation and commercial matters involving patent rights, and assist clients to register patent rights.

This submission focuses only upon the implementation and practicality of the Options set out in ACIP's Options Paper. It does not seek to comment upon what the underlying policies and objectives should be as it considers that researchers and industry are better placed to provide submissions on whether such policies and objectives are in the national interest or not.

2 Certainty

Freehills agrees with the Law Council of Australia's submission that there are reasonable arguments both ways as to whether an experimental use exemption is part of the common law in Australia, and that it is desirable that the existence of such an exemption be expressly confirmed. The current state of the law makes it very difficult to clearly advise clients as to their rights in relation to experimental activities.

While much of the focus of our comments below is on the issue of certainty, we acknowledge that this is only one of the relevant considerations in assessing the merits of the various Options.

3 Guiding principles for an experimental use exemption

The different Options proposed in ACIP's Paper embody varying degrees of guidance for the court.

An 'experimental use' exemption will and does mean different things to different people, and has developed to mean different things under the laws of different countries. Unless some guidance is provided to Australian courts in relation to the parameters of an experimental use exemption, we consider they will have difficulty in applying any legislated experimental use exemption to the particular facts before them. For the same reasons, it will be difficult for lawyers to advise clients on the scope of such an exemption until such time as case law develops (which may be a long time).

It may be that if uncertainty exists regarding the scope of any experimental use exemption that is legislated for, then the courts would obtain guidance by looking to ACIP's final report and any relevant second reading speeches.[1]

We consider that it would be preferable for the relevant guiding principles to be embodied more directly in any legislated exemption, either as part of the express delimitation of the exemption, or as express considerations as part of a mandated balancing exercise to be undertaken by the court.

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[1] Section 15AB Acts Interpretation Act 1901.

The guiding principles should make the following issues clear (or clearer):

- what experimental purposes fall within the exemption;
- related to the above issue, whether the experimental purposes must relate to the subject matter of the invention and how this is to be determined;
- the role and relevance of any commercial purpose of the experimenter in defining the boundary of the exemption;
- whether impact upon the patentee's commercial interests is relevant and, if so, what commercial interests and/or impacts are relevant (including their timing); and
- whether the exemption covers upstream and downstream activities (and if so, what).

4 Commercial purpose

Overseas experience, particularly in the United States, has shown that restricting an experimental use exemption to activities that have no commercial purpose (for the experimenter) results in a very limited exemption, although we note that none of ACIP's proposed Options adopts this approach.

Assuming that ACIP recommends that Australian law should incorporate a substantive experimental use exemption, then we agree that it should not be limited to experiments that lack *any* commercial purpose. We do not, however, necessarily think that commercial purpose should be irrelevant to the scope of an experimental use exemption. We address this issue in section 5.5 below, where we also outline some of the difficulties associated with the relevance of commercial purpose on the part of the experimenter.

5 Limiting the exemption by boundaries or by balancing interests

The various Options set out in ACIP's Paper for an experimental use exemption appear to roughly fall within three broad categories:

(1) the scope of the exemption is by reference to whether the activity falls within a defined type of activity (C3, C5, C8?);

(2) the scope of the exemption is by reference to whether the activity is an exempt activity by reference to guidelines (C2,C6, C8?, D2);

(3) the scope of the exemption is by reference to a balancing of interests by reference to guidelines (C4, C7).

5.1 Category (1) – defined activities

We have some concern (subject in part to our comments in section 5.3 below regarding 'dominant purpose') that the Options in category (1) above would:

- be difficult to draft with precision as a statutory amendment; and
- would risk being over-inclusive such that would-be infringers may be able to modify their activities in such a way as to fall within the exemptions, notwithstanding that their actions may not be in advance of those policies

> underlying the legislated exemption. For example, a would-be infringer may devise a highly speculative experimental regimen with the stated aim of determining whether an improvement to the patented invention exists, but which in truth is motivated by the exploitation of the invention (eg by sale of the resulting product).

Similarly, if the defined activities include exclusionary components in the definition, this may lead to an unintentionally narrow exemption (the most obvious candidate as an exclusionary component is the broad 'commercial purpose' issue discussed in section 4 above).

5.2 Category (2) – activity defined by guidelines

This category of Options is similar to category (1), although a greater level of flexibility *may* exist as to whether the activity falls within the exemption or not. We are uncertain whether greater flexibility concerning what types of activities fall within the experimental use exemption necessarily addresses the issues of potentially overly strict operation either in favour of patentees or would-be infringers/experimenters.

5.3 Dominant purpose requirement

Options C3 and C8 include reference to a dominant purpose requirement, while Options C5 and C6 appear to contemplate only that the relevant purpose be *a* purpose.

It seems likely that an exemption that requires that the defined purpose be *a* purpose could be taken advantage of by would-be infringers, while an exemption that requires the defined purpose to be the *sole* purpose may have little practical use to would-be experimenters (since we consider that it will always be possible for a patentee to construe some other purpose on the part of the experimenter, for example an ancillary future commercial purpose). A dominant purpose test would give a court a greater role in seeking to ensure that the experimental use exemption performed the role that it perceived as advancing the policies underlying its inclusion in the Patents Act.

5.4 Category (3) – a guided balancing exercise

This category of Options appears to permit a more extensive exercise of discretion by the court in attempting to advance the policies that it perceives to underlie the inclusion of an exemption in the Act. Such a category also appears to be most closely supported by the TRIPS Agreement, article 30 of which provides as follows:

> *Members may provide limited exemptions to the exclusive rights conferred by a patent, provided that such exemptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*

While the 'dominant purpose' test in the category (1) and (2) Options would permit a court to undertake some level of balancing of interests, the ability of the court under those Options to directly consider and balance the impact of the relevant activity upon each of: (a) the patentee's direct commercial interests; and

(b) the third party's (and the public's) interests in the relevant experiments, would be more limited.

We think there is attraction in an Option that permits the court to consider all of the relevant facts, including the impact upon the *legitimate interests* (as to which see section 5.5 below) of the patentee, and allowing the court to exercise its judgment as to whether the activity is exempt or not. The additional flexibility would in our view better equip the court to effectively deal with a wider range of factual circumstances. Given that we consider it will be unusual for experimental activities into the subject matter of the invention to significantly impact upon the patentee's legitimate interests, we do not think that such an Option would substantially decrease the 'certainty' for the public.

In implementing such an Option, the general structure of sections 51AB and 51AC of the Trade Practices Act may provide some guidance.

5.5 Commercial effect upon the patentee

To the extent that a balancing exercise Option were adopted, then it seems clear that one of the criteria that a court would be required to consider would be the commercial effect upon the patentee. The comments below are not restricted to such an Option though.

If an Option involving consideration of commercial effect on the patentee (or commercial purpose of the experimenter) were to be recommended by ACIP, then we think that careful consideration should be given to the issue of *what type* of commercial effect the court should/may consider.

Page 31 of the ACIP Options Paper quotes a submission which suggests that the patentee's commercial interests in:

- not having its patent rights found to be invalid (or, by extension, restricted);
- not having others design around the patent; and
- not having others secure patent rights in improvements (or, by extension, inhibit the patentee from securing such patent rights by publicly disclosing the experimental results);

are relevant commercial interests that should be considered. Others would consider that experimental activities directed at these issues are precisely the type of activities that should be covered by an experimental exemption.

If such experimental activities are considered by ACIP to properly form the subject of an experimental use exemption, then it seems to us that a court should not consider the indirect commercial impacts upon the patentee set out in the bullet points above. (For our part, we do not consider that these interests are covered by the words 'legitimate interests of the patent owner' in article 30 of TRIPs.)

On the other hand, we expect that a court should be permitted to, under such an approach, consider whether the experimental activities are *directly* resulting in lost sales or royalties for the patentee. In our view, it is likely to be unusual in practice for experimental activities on the subject matter of an invention to have a direct impact upon a patentee's direct commercial interests and therefore, unless

clear guidance is provided, we can envisage patentees seeking to argue that indirect commercial impact is relevant to the scope of the exception.

Relevance of the experimenter's commercial purpose

The *relevant* 'commercial purpose' of the experimenter also ties in here, in our opinion. The experimenter's commercial purpose may be a direct one (even if it is ancillary to the experimental purpose) where, for example, it sells or uses the products manufactured by a patented process under experimental consideration. Or it may be an indirect one, such as a desire to patent any improvements discovered and charge royalties for licensing that patent.

Based upon our understanding of the general objectives underlying an experimental use exemption, as discussed in the ACIP papers, the relevant consideration of the *experimenter's* commercial purpose should, in fact, be how that experimental purpose impacts upon the *patentee's* legitimate interests. This impact may, for example, be the royalty that the patentee could reasonably have charged the experimenter based upon the commercial benefits *directly* enjoyed by the experimenter (it being assumed against the experimenter that it was prepared to pay for the benefit received).

In our view, one of the difficulties that has arisen in some overseas jurisdictions is that the commercial purpose of the experimenter has been identified as being sometimes relevant to the scope of the exemption (because of an awareness that, in certain circumstances, there is a connection with the patentee's legitimate interests), but no limitation upon this has developed to exclude from consideration irrelevant[2] commercial purposes.

Applicability to the Options

The related issues of commercial purpose and impact upon the patentee's legitimate interests are, in our view, the most difficult issues for the implementation of an appropriate and robust experimental use exemption.

Based on our understanding of the principles that are generally considered to underlie an experimental use exemption, we think that there will only be a relevant impact upon the patentee's *legitimate interests* where it can be shown that the experimenter had a *direct* commercial purpose, as explained above.

We have difficulty in conceiving of any examples where a would-be experimenter would unavoidably have a direct commercial purpose as part of any relevant experiments. It follows that we think that if a direct commercial purpose is proven on the part of the experimenter then there is an adverse impact upon the patentee's legitimate interests such that the exemption should not apply.[3] (That is, the balancing of interests should be resolved in the patentee's favour, since the impact was avoidable.)

Our concern, however, is that it may be difficult to clearly define such a direct commercial purpose or impact as part of an exclusionary component of a statutory experimental use exemption. A balancing option, or an option such as B or C1,

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[2] 'Irrelevant' based on our understanding of the policies generally underlying an experimental use exemption.

[3] In practice we expect that any damages would then be limited to those commensurate with the degree of the experimenter's commercial purpose and that injunctive relief should only be directed towards the direct commercial aspects of the experimenter's activities.

may therefore more readily permit a court to itself correctly identify such an exclusionary commercial purpose.

6 Upstream and downstream issues

For many inventions, a practical issue for a would-be experimenter may be that it does not have the skills or resources to either manufacture the necessary starting materials, or to conduct relevant aspects of the experiment. We are particularly aware that this can be a practical issue in the pharmaceutical and biological science areas. The intention of any experimental use exemption may be undermined if the supplier of the raw materials, or the party contracted to conduct aspects of the experiment, could themselves be sued for patent infringement.

In relation to the supplier of raw materials, the contributory infringement section (s 117) of the Patents Act contains a hypothetical enquiry relating to the use to which the materials would be put – the supplier could be guilty of infringement under this section even where the purchaser itself were covered by an experimental use exemption. (Where the supplier was itself directly infringing the patent claims, for example a product claim or a method of manufacture claim, then it may be that different issues arise – these issues should still be considered as part of the introduction of an exemption.)

Related to this issue, however, may be the question of whether an alternative commercial supply from a party licensed by the patentee exists (and the reasonableness of the terms of that supply).

We expect that this issue would need to be addressed in an amendment that is ancillary to the primary experimental use exemption amendment, as we think that the issues are distinct (although clearly strongly interrelated) from those involved in determining whether the experimenter's activities are exempt or not.

It is also possible that a skilled contractor who is contracted to perform an experiment (by someone who themselves would be protected by the exemption) may not fall within the scope of an experimental use exemption (depending upon how such an exemption were drafted). For certain industries, we expect that this may have a practical impact upon the ability of a party to conduct experiments upon a patented invention.

7 'Experimenting on' and experimental purpose

An issue addressed in the Options Paper is that of the European approach which looks at whether the experimental purpose relates to the subject matter of the invention.

We are uncertain whether ACIP has formed the view that experimental activities which do relate to the subject matter of the patented invention are coextensive with those activities which do or should fall within an experimental use exemption, or whether this is only a useful criterion to determine the scope of such an exemption.

Alternatively, the concept of experimentation on the subject matter of the invention may be useful in order to more clearly define the permitted uses in those

Options which take that approach (in order to make it clear that experimentation which simply employs the patented invention is not covered, presuming that this is ACIP's intention).

Where patent claims fall within the 'method of manufacture' or 'method of use' type of claim, then testing whether an experiment relates to the subject matter of the invention appears to us to be a simpler question to answer compared with product claims. Nevertheless, provided that the underlying principles and guidelines are made clear in relation to the recommended Option, we expect that a court would be able to sensibly address the issues arising in relation to product claims also.[4]

8 Language used in a statutory exemption

Very briefly, particular care should be taken with the language used in any statutory exemption, and how such language compares with the activities contained in the inclusive definition of 'exploit' in Schedule 1 of the Patents Act. Difficulties already exist in sections 118 and 119 of the Patents Act for this reason.

Care should be taken that the exemption covers the full range of applicable activities in the definition of exploit, and not simply 'use'. As an example, certain experimental activities would also require the experimenter to be protected from infringement for 'making' a product and 'keeping' a product for the purpose of 'using' it.

9 Options

Most of our comments regarding the various Options are contained in the sections above. We set out some comments below regarding some more specific aspects of the Options.

9.1 Option A – Expressly preclude experimental use from allowable activity

We agree that this would provide much greater clarity under Australian law. We make no comment regarding whether such an option would be in Australia's interests or not.

9.2 Option B – No change

In our view, it is difficult to advise clients what the current law is regarding experimental use, which we do not consider to be very satisfactory. Nevertheless, we accept that this situation may still be preferable to the statutory adoption of a poorly worded or inappropriate experimental use exemption which may increase uncertainty or have unreasonable and unintended consequences.

[4] Perhaps in the manner referred to on page 43 of the ACIP Options Paper in the second last quoted passage, being that taken by the German Supreme Court.

9.3 Option C1 – Definition of exploitation does not include experimental use

In our view this would improve the clarity of the law insofar as it removes the possibility that there is simply no experimental use exemption under the scheme of the Patents Act.

In a practical sense, the content of the ACIP paper proposing such an amendment, and any second reading speeches, may also provide greater certainty regarding the scope of such an exemption.

Many issues would, however, remain uncertain. This would particularly be the case if the secondary materials referred to above did not contain a clear explanation of what principles were intended to be advanced by the inclusion of the exemption.

9.4 Option C2 – General exemption with specific examples and/or guidelines

It seems likely that the inclusion of guidelines or non-binding examples would increase the certainty of the scope of an experimental use exemption, compared with the situation today, and compared with Option C1.

Much of the value or otherwise of this option is likely to come down to the drafting of those guidelines, and whether they themselves create any uncertainties. We refer in section 3 of this submission above to this issue. In principle, for example, what is it that ACIP expects would differentiate Option C2 from Option C4?

In our view it would be preferable for ACIP to decide upon the preferred approach based upon the submissions provided to it, rather than leaving aspects of the correct approach for the courts to determine out of necessity.

9.5 Option C3 – Exemption for experimenting 'on the subject matter of the invention'

Despite the reservations of ACIP, we do not understand there to be significant difficulties with determining whether the purpose of an experiment relates to the subject matter of the invention, or whether it instead simply uses the subject matter of the invention.

As discussed beneath heading 5.3 above, we consider that the inclusion of a 'dominant purpose' requirement should minimise the prospect of an overly strict application of an exemption.

As discussed in section 7 above, we do not know whether ACIP has determined that experimentation upon the subject matter of inventions is coextensive with the appropriate scope of an experimental use exception.

9.6 Option C4 – Exemption for fair experimentation – copyright fair dealing analogy

This is the first of the Options that involves a significant balancing exercise (the dominant purpose requirement of Option C3 does to a lesser extent).

While we note that the ACIP Paper includes references questioning the relevance of an analogy to copyright, we do not consider that this Option requires such an

analogy for support and therefore observations regarding differences between copyright law and patent law seem to be just that.

This Option, as presently explained, does not address the issue of what experimental purposes are approved of, the relevance of the subject matter of the invention, or what commercial effects are to be considered (issues discussed above).

Assuming that proper guidance is given to the court either in the exemption as drafted, or perhaps in secondary materials, then it seems to us likely that a court would be capable of weighing up these considerations and applying them to the facts before it in a manner aimed at advancing the underlying purpose of the experimental use exemption as it understood it.

While ACIP has raised ‘uncertainty’ as one of the cons regarding this Option, we consider that the issue of certainty is likely to be most strongly affected by the particular implementation of such an Option and that the advantages of increased flexibility for the court would outweigh any incremental decrease in certainty (see our comments in section 5.4 above).

9.7 Option C5 – Exemption for exclusive permitted uses

We agree with ACIP’s observation that this Option appears to lack flexibility. As the Option is explained, it also appears to be an Option that might risk ‘misuse’ by would-be experimenters seeking to artificially place their activities within an exempt act as defined.

It is not clear to us whether ACIP is recommending that the exempt acts be limited to those acts specified.

We presume, also, that the exempt acts are to have a nexus with the patent itself, but note that the first exempt act refers to ‘an invention’ rather than ‘the invention’ which, in the fourth category of acts, we understood to be a reference to ‘the invention’ the subject of the patent in suit.

9.8 Option C6 – Exemption for inclusive uses

This Option has the same inherent problems of Option C5, except that flexibility is provided in relation to other exempt acts.

What is not clear to us, however, is how the court is to determine what properties or attributes such acts should possess. We refer to section 3 of our submission above in relation to this issue.

9.9 Option C7 – Exemption for fair experimentation, with inclusive permitted uses (C4 + C6)

Some issues that we consider exist with this Option include the following (but which may depend upon how the Option is to be implemented):

- how the court is to determine what purposes and characters are important and should persuade the court in either direction;
- what the relevance of the subject matter of the invention is. Is this intended to tie into the purpose and character of the act? If so, how is this to be explained? Is it somehow to involve a quasi-incorporation of Option C3,

that is, a consideration of whether the experimentation is on the subject matter of the claimed invention?

- how is an Option that appears to set up a balancing exercise for the court to dovetail with an Option which inclusively defines permitted 'acts of fair experimentation'? The inclusion of permitted acts appears to us to cut across the flexibility embodied in the first half of the proposal. (It may be that the permitted acts could be recast as permitted purposes for the experimentation.)

9.10 Option C8 – Exemption for experimenting 'on the subject matter of the invention', with inclusive permitted uses (C3 + C6)

We note the observation by ACIP in relation to Option C3 that ACIP considers the concept of experimentation on the subject matter of the patent to be unclear. We do not necessarily understand this concern from our review of the Options Paper.

To the extent that it depends upon finer distinctions or the particular factual details of the relevant scenario, we do not understand how the inclusive definition of exempt acts will address this issue. Perhaps the answer is in the detail of the Option.

9.11 Option D1 – Modify pre-grant provisions to restrict patent rights to the utility disclosed

In our view the ACIP review into experimental use is not the place for a consideration of the issues underpinning this Option, and a far more extensive enquiry would be required before introducing statutory amendment to alter the scope of patent claims. We do not consider that the concept of 'restricting the scope of a patent claim to the utility disclosed in the specification' is as simple as the articulation of that concept in this Option.

Moreover, while ACIP's comment on this Option says that the Option 'solves the root of the problem', we neither understand that the 'problem' has been expressly defined by ACIP, nor that this Option would necessarily address all aspects of the 'problem' as perceived by different parties. For example, why would experimentation to determine how an invention works not involve an exercise of the 'utility' of the invention, or is the concept of 'utility' to incorporate some level of commercial flavour? If so, how does this Option address the breadth or nature of that commercial flavour?

As an example, a patent may include a claim for a method of manufacturing a compound. That patent is likely to have 'utility' for the purpose of section 18(1)(c) provided that there is some conceivable use for that compound. Any experimentation into that method is likely to also produce the compound using the patented method. But here the discussion of limiting the patentee's monopoly to its 'utility' so as to protect such experimental use seems to us to have a focus upon the commercial nature of what the experimenter is doing – are they selling the compound or using it in a commercial application? The same issue applies for product claims.

It seems to us that the difficulty of a proposal that limits the scope of a patentee's monopoly to its 'utility' in this sense is that it imports a commercial criterion

which, as explained in section 4 above, risks having an extremely narrow experimental use exemption.

9.12 Option D2 – Introduce an exemption for acts that don't benefit from the utility disclosed

We have great difficulty understanding what is meant by 'a benefit or utility' which appears to us to be a highly subjective concept (and while the word 'utility' appears familiar as a common reference to the section 18(1)(c) requirement, it appears to refer to a quite distinct concept in this context, similar to that discussed in Option D1 above). The reference to 'described to a sufficient degree in the patent' also appears to us to be a highly uncertain concept.

Similarly to Option D1, we are also uncertain as to whether the proposal would even necessarily address all types of experimental uses that might be thought to be covered by such an Option.

Also like Option D1, we consider that the concept may be both attractive in principle and easy to articulate in general terms, but is one which would potentially have far-reaching impact and which should be considered in far greater detail and not in the context solely of an experimental use exemption.

9.13 Option E – Statutory licensing for experimental use

It seems to us that such an option is more likely to be relevant to the use of 'research tools', for example in the genetic research area. We imagine, but do not know, that the 'value' to a user could not be as readily estimated as it can in the copyright area (which is, for example, able to roughly correlate audience size with value for music broadcasters).

It further appears to be an administratively burdensome option, and one whose parameters are difficult to understand (the difficulty of using commercial or non-commercial use as part of a definition of relevant uses is discussed in section 4 above).