

**Submission to the Australian Law Reform
Commission in response to its Discussion Paper 68**

Gene Patenting and Human Health

**Intellectual Property Research Institute of Australia
(IPRIA)**

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Table of Contents

1. Preface.....	3
2. Executive Summary	4
3. Submissions in relation to proposals 6.3 and 6.4.....	8
4. Submissions in relation to proposals 8.2 and 8.3.....	11
5. Submissions in relation to proposal 9.1.....	15
6. Submissions in relation to proposal 14.1.....	17

1. Preface

The Intellectual Property Research Institute of Australia (IPRIA) is a national centre for multi-disciplinary research on the law, economics and management of intellectual property. It is based at the University of Melbourne, and is a joint venture of the Faculty of Law, the Faculty of Economics and Commerce, and the Melbourne Business School.

IPRIA was established in 2002 as part of the Federal Government's Innovation Statement, *Backing Australia's Ability*. IPRIA's research focuses on ways to improve the protection, management and exploitation of intellectual property by business, research institutions and other users of the IP system, and on supporting high quality policy development by government in areas relating to intellectual property. It seeks to use the outcomes of its research to create and contribute to public debate on key issues relating to intellectual property. Part of IPRIA's missions is to provide objective contributions to law reform efforts.

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The submission in relation to experimental use does not necessarily reflect the unanimous view of all members of IPRIA. Any questions specifically directed towards this aspect of the submission should be directed to Saba Elkman (03 8344 1136) in the first instance as it is based on his research.

2. Executive Summary

Through its Discussion Paper the ALRC has sought submissions in relation to a broad range of issues surrounding gene patenting and human health. IPRIA has limited the scope of its submissions to recommendations regarding the following proposals:

Proposal 6.3 (Usefulness Criterion)

The ALRC has proposed that ‘usefulness’ be made an additional criterion for assessment in patent applications. IPRIA supports this proposal, however we recommend that the new criterion of usefulness should be renamed the ‘utility criterion’ in order to differentiate it from the old concept of usefulness. Renaming the criterion will highlight that there has been a change in the law and indicate clearly that a departure from existing jurisprudence is intended.

Proposal 6.4 (Usefulness Guidelines)

In proposal 6.4 the ALRC recommends that guidelines should be written to assist patent examiners in applying the new usefulness requirement set out in proposal 6.3. These guidelines have the aim of changing the way in which the usefulness/utility requirement is applied. IPRIA agrees with the aim of the proposal, but does not think that this aim will be achieved via guidelines, as they are not legally binding. IPRIA recommends that in order to effectively implement the proposal it is necessary to amend the *Patents Act 1990 (Cth)* (**the Act**).

Proposal 8.2 (Establishing Panels of Experts)

The ALRC proposes that the Act should be amended to allow panels of experts to be established to advise patent examiners in assessing patent applications. Adoption of proposal 8-2 may bring decisions made by the panels of experts under the ambit of the ADJR Act. If this is the case, there will be an obligation to accord natural justice in relation to these decisions. This could increase the time and costs associated with examination of patents. In light of these possibilities, IPRIA recommends that the ALRC should give further consideration to likely administrative law consequences before a decision is made to establish panels of experts.

Proposal 8.3 (Appointments to Panel of Experts)

In proposal 8.3 the ALRC recommends that IP Australia should ensure that appointments to the panel of experts reflect a balance of independent scientific and legal expertise. If an expert panel procedure is introduced, careful consideration should be given to the level of expertise of panel members: by IP Australia when appointing panel members and by examiners when evaluating and giving weight to the evidence of those members. Careful consideration must also be given to the composition of expert panels in order to ensure that they provide patent examiners with advice/evidence which is relevant and admissible in light of the standards of the hypothetical skilled but unimaginative addressee.

Proposal 9.1 (Searchable Online Database)

In proposal 9.1 the ALRC recommends that that 'a comprehensive database of information about Australian patents should be developed by IP Australia'.¹ IPRIA supports this proposal. We recommend that information about court proceedings involving patents be placed on such a database, with such basic information as the existence of court proceedings relating to the patent, and the court file number. Information about court proceedings involving Australian patents should be obtained by amending the Act to include an obligation for Australian courts to report patent proceedings to IP Australia.

Proposal 14.1 (Experimental Use)

IPRIA submits the research exemption should not be characterised by the ALRC as a defence. As noted above, the danger of such a characterization is that it assumes that, *except for* those situations specifically stated in the defence, the rights of the patent owner are, in effect, absolute. It is more principled, and more desirable, to conceive of the role of any 'exemption' as both:

¹ ALRC Discussion Paper, [9.109]

- a. clarifying (or defining) the *scope of the patent owner's rights*, so that certain uses are not 'infringements but for the defence', but rather, uses outside the purview of the patent owner's right; and
- b. resolving the genuine conflict between the rights of the patent owner and the needs of the researcher in the specific set of circumstances where it arises.

Most importantly, IPRIA submits the ALRC should explicitly acknowledge that the exemption does not preclude further judicial interpretations of, and refinements to, the concept of exploitation. The potential for courts to interpret this concept should be left open.

IPRIA also submits the ALRC should explicitly consider:

- a. how the law should handle the "fruits" of experimental use; and
- b. the question of mixed purposes.

3. Submissions in relation to proposals 6.3 and 6.4

Recommendation in relation to 6.3 – the new criterion of usefulness should be renamed the ‘utility criterion’ to differentiate it from the old concept of usefulness.

The ALRC has suggested in proposals 6.3 and 6.4 that a new concept of usefulness be introduced. The aim of the ALRC is to change the law in regards to the usefulness requirement.

We agree with the approach taken by the ALRC in regards to making ‘usefulness’ an additional criterion for assessment in patent applications. However, in order to achieve a change in the law, the ALRC should ensure that it is clear to all concerned that a departure from existing jurisprudence is intended. In order to achieve clarity on this point, we would recommend that the new criterion of usefulness be renamed the ‘**utility criterion**’ in order to differentiate it from, and to avoid importation of the jurisprudence associated with, the old concept of usefulness.

As noted in Discussion Paper 68, submissions and consultations have indicated that there is ‘considerable confusion about the application of the ‘usefulness requirement’². Naming the reworked criterion ‘usefulness’ seems likely to continue this confusion. Using the new terminology of ‘utility’ to describe the new criterion will remove it from the confusion associated with the current understanding of usefulness.

We note that IP Australia has also suggested that an ‘an entirely new criterion of utility’ be introduced³.

² Paragraph 6.185

³ Paragraph 6.174

Recommendation in relation to proposal 6.4 – Changes to the concept of usefulness/utility should be made via amendments to the *Patent Act* rather than via IP Australia Guidelines.

We support the proposal by the ALRC that the new usefulness/utility⁴ criterion should require that the claimed usefulness/utility be ‘specific, substantial and credible’ to a person skilled in the relevant art. It is clear that making a ‘specific, substantial and credible’ usefulness/utility a requirement of patentability is (as argued by Nicol and Nielsen) a significant departure from previous interpretations of the usefulness criterion as applied by the Federal Court.⁵ In other words, the ALRC is proposing a reform of the *law* relating to the usefulness criterion.

In proposal 6.4 the ALRC recommends that guidelines should be written to assist patent examiners in applying the new usefulness/utility requirement.

IPRIA submits that guidelines are not the best option for implementing an effective change in the usefulness/utility requirement. Guidelines are only suggestions for the way in which legal principles should be interpreted and applied. They are not legally binding. In particular, courts are not bound to follow or take into account IP Australia guidelines when making decisions.

In order to effectively implement a change in the way the usefulness/utility requirement is interpreted IPRIA recommends that it is necessary to amend the Act. Such amendments could be accompanied by guidelines in order to assist examiners to make assessments under the Act. In particular, guidelines could be drafted which further explain the new criterion of a usefulness/utility requirement in the context of biotechnology patents, and give practical examples of how this would be applied.

The recommendation that any change to the usefulness/utility concept should be enacted is supported by several observations made in the Discussion Paper. For example, at paragraph 6.147 it is noted that there is some concern that guidelines in

⁴ The new criterion suggested by the ALRC in proposal 6.3 is called the ‘usefulness/utility’ concept in this part of the submission, so as to differentiate it from the current concept of usefulness.

⁵ See ALRC Discussion Paper 68, paragraph 6.157

the United Kingdom similar to those suggested by proposal 6.4 may not be upheld by courts if challenged. Further, at paragraph 6.148 it is noted that New Zealand has recommended that changes to the usefulness requirement be implemented via amendment of its *Patent Act*.

4. Submissions in relation to proposals 8.2 and 8.3

Recommendation in relation to proposal 8.2 - IPRIA recommends that the ALRC should give further consideration to the administrative law consequences associated with the introduction of panels of experts.

Proposal 8-2, if adopted, will give rise to a number of administrative law consequences, to which the ALRC should give further consideration. In general terms, the introduction of expert panels may provide additional ‘decisions’ in respect of which an applicant may seek judicial review during the examination process. This may lead to a more protracted examination process, thereby delaying the grant of patents.

Under the *Administrative Decisions (Judicial Review) Act 1977 (Cth)* (“*ADJR Act*”), a reviewable decision may arise if ‘the statute provide[s] for the making of a finding or ruling on that point so that the decision, though an intermediate decision, might accurately be described as a decision under an enactment’.⁶ Such decisions are subject to review on a range of grounds provided for in the Act. Even if those decisions do *not* fall within the scope of a reviewable ‘decision’ for the purposes of the *ADJR Act*, they may nevertheless be subject to judicial review pursuant to section 39B of the *Judiciary Act 1903 (Cth)*. Alternatively, those decisions may be classified as ‘conduct’ for the purposes of the *ADJR Act* and thus subject to review on this basis.⁷

Depending on the drafting of the legislation, it is possible that the following decisions may represent reviewable ‘decisions’ for the purposes of the *ADJR Act*:

1. The examiner’s decision as to whether or not to consult or seek the advice of the expert panel.
2. The decision of the expert panel may itself be a ‘decision’ for the purposes of the Act. Furthermore, to the extent that that decision is required to be

⁶ *Australian Broadcasting Tribunal v Bond* (1990) 170 CLR 321, per Mason CJ.

⁷ *ADJR Act*, section 6.

incorporated in a ‘report or recommendation,’ the making of that report or recommendation may itself be deemed to be a ‘decision’ for the purposes of the Act.⁸

3. Those decisions of the examiner (eg, findings of novelty, inventiveness, etc) which incorporate the advice or findings of the expert panel or which fail to take into account the advice or findings of the expert panel.

An obligation to accord natural justice will arise if the above decisions fall within the definition of a ‘decision’⁹ or ‘conduct’¹⁰ for the purposes of the *ADJR Act* or are subject to review pursuant to section 39B of the *Judiciary Act*. An obligation to accord natural justice may require that the applicant be given an opportunity to be heard in relation to each of the ‘decisions’ above, for example, by presenting submissions to the expert panel and/or presenting submissions to the examiner as to the weight that s/he should accord to the advice of the expert panel.

Natural justice would seem to require, at a minimum, that the applicant be provided with a copy of the expert panel’s report (if any) and be notified of the content of any communications between the examiner and the expert panel, upon which the examiner has relied for his or her decision.¹¹ However, paragraph 8.53 of the Discussion Paper appears to suggest that parties will only be retrospectively informed of the examiner’s decision to seek the advice of an expert panel.

It is not clear that these administrative law consequences can be avoided, except to the extent that appropriately worded legislation discloses a clear intention to exclude or modify the requirements of natural justice.¹² Therefore, a recommendation by the ALRC involving the use of expert panels therefore represents a policy choice by the ALRC to increase the costs and processes at the point of examination of a patent, to which the ALRC should give further consideration.

⁸ *ADJR Act*, section 3(3).

⁹ *ADJR Act*, section 5(1)(a).

¹⁰ *ADJR Act*, section 6(1)(a).

¹¹ To the extent that the above decisions fall within the definition of a ‘decision’ for the purposes of the *ADJR Act*, an obligation to provide reasons for those decisions will arise under section 13 of the *ADJR Act* independently of the requirements of natural justice.

¹² Mark Aronson and Bruce Dyer, *Judicial Review of Administrative Action* (2nd ed, 2000) 356.

Recommendation in relation to proposal 8.3 – If an expert panel procedure is introduced, careful consideration should be given to the level of expertise of panel members: by IP Australia when appointing panel members and by examiners when evaluating the evidence of those members.

IPRIA recommends that if an expert panel procedure is introduced, IP Australia should give careful consideration to the composition of the panel of experts to ensure that they are able to provide patent examiners with advice/evidence which is relevant and admissible. This can be achieved by ensuring that the level of experience of panel members is not too far removed from the level of experience of the hypothetical person contemplated by the Act.

Further, examiners should take the qualifications or expertise of members of the expert panel into account when deciding how much weight to accord the ‘evidence’ of those panels. While the evidence of experts may be relevant and admissible, it is submitted that particular care may need to be taken in relation to the weight that is attached to the evidence of ‘overly qualified’ experts and the manner in which such evidence is used. This is illustrated in relation to the question of inventiveness.

First, inventiveness is assessed from the perspective of the non-inventive or unimaginative but still skilled worker in the field. To the extent that members of an expert panel are removed from the experience of the non-inventive or unimaginative person skilled in the art, the weight that can properly be attached to their advice with respect to inventiveness is diminished.¹³

Second, inventiveness is assessed in light of common general knowledge either considered separately or together with ‘a combination of any 2 or more pieces of prior art information; being information that the skilled person ... could ... be reasonably expected to have ascertained, understood, regarded as relevant and ... combined’: s. 7(3) (b). Experts may possess a greater capacity to ascertain, understand, regard as

¹³ *Braas & Co GMBH v Humes Ltd* (1993) 26 IPR 273.

relevant and combine documents than the hypothetical skilled worker in the art, thus leading to the potential for divergent views among expert panels and the hypothetical skilled worker contemplated by patent law.

Further, to the extent that members of an expert panel are ‘overly qualified’ to make the assessments required under patent law (ie. in a way which is too far removed from the experience of the relevant hypothetical person), and the decision or advice of that panel is taken into account by the examiner in arriving at his or her conclusion, then this may itself provide a ground of review under the *ADJR Act*, namely, taking an irrelevant consideration into account.¹⁴

¹⁴ *ADJR Act*, section 5(2)(a).

5. Submissions in relation to proposal 9.1

Recommendation in relation to proposal 9.1– the database should include information about court proceedings concerning Australian patents.

IPRIA supports the ALRC’s aim of making information about patents in Australia more readily accessible, and agrees with the ALRC that ‘a comprehensive database of information about Australian patents should be developed by IP Australia’.¹⁵ We submit that it would also be desirable to include in such a database information about **court proceedings** concerning Australian patents.

Information about ongoing or settled court proceedings is relevant to companies which are accused of infringement, or which are considering licensing or otherwise dealing with a patent. Such companies may want to know whether a patent is already the subject of legal proceedings, or has, for example, been upheld as valid in the past. The reporting of such proceedings would also enable the government to gain a more complete picture of IP enforcement in the courts, which is relevant to determining whether the patent system as a whole is meeting its objectives.

At present, the only way to find out whether a given Australian patent has been litigated in Australian courts is to search for references to the patent or patent number in issued judgments of the courts. Generally only lawyers would know how to conduct such a search. In addition, such a search will not reveal current proceedings or those settled prior to the issue of any judgment.

The United States *Patents Act* provides a model which could be adopted in Australia. Under the US *Patents Act*, the courts are required to inform the USPTO within a month of proceedings being filed relating to a patent.¹⁶ The clerk of the court must inform the Director of the names and addresses of the parties, the name of the inventor, and the designating number of any patents included in the action. In

¹⁵ ALRC Discussion Paper, [9.109]

¹⁶ *US Patents Act*, 35 U.S.C. §290. Similar obligations apply in relation to trade marks (15 U.S.C. §1116) and in relation to copyright (17 U.S.C. §508(a)). Copyright proceedings must be notified to the Register of Copyrights.

addition, once a decision is rendered or a judgment issued, the clerk of the court is required to inform the Director. This information is available via commercial database providers, and has been the basis of a number of recent studies of the patent enforcement system in the United States.¹⁷

IPRIA recommends that the Act be amended to include a similar obligation for Australian courts to report patent proceedings to IP Australia. The information provided to IP Australia should include at least the patent number and the court file number,¹⁸ which would enable an interested person to find out more about the proceedings directly from the courts. Ideally, the information would also include names of the parties, the designating number of any patents included in the action, and as well as how any such proceedings are terminated (whether settled, or withdrawn, or the subject of a judgment). IPRIA further submits that such information (or at least the court file number) should be included in the ‘comprehensive online database’ which is the subject of the ALRC’s Proposal 9-1.

¹⁷ See, for example, Lanjouw & Schankerman, “Protecting Intellectual Property Rights: Are Small Firms Handicapped?”, Forthcoming, *Journal of Law and Economics* (2004)

¹⁸ IPRIA notes that Australian courts allow members of the public equipped with a court file number to search public terminals and find out whether proceedings are ongoing. The database available at public terminals in the Federal Court is particularly useful.

6. Submissions in relation to proposal 14.1

Proposal 14-1 The Commonwealth should amend the *Patents Act 1990* (Cth) to establish a new defence to a claim of patent infringement based on the use of a patented invention to study or experiment on the subject matter of the invention; for example, to investigate its properties or improve upon it. The legislation should make it clear that the existence of a commercial purpose or intention does not affect the availability of the defence.

Introduction: The Research Exemption in Context

We support the view of the ALRC that patent owners should not be entitled to control certain experimental uses. We are therefore supportive of the aims of the ALRC proposal. We consider it important, however, that such an exemption should have a strong basis in patent law principles.

This submission provides such a foundation by locating the issue within the context of the rationales¹⁹ which underlie patent law. It is important that the issue of experimental uses not be seen as simply a matter of creating a limited, ‘tacked-on’ defence based on some particular social policy justification. The ALRC Proposal 14-1 is presently of this type. In our view, this characterisation as a *defence* encourages us to understand it to be a limited incursion into the rights of the patent owner: suggesting that the rights of the patent owner are otherwise absolute. The better view is that exempting experimental uses is simply a question of clarifying the appropriate scope of the patent owner’s exclusive rights and remedies.

Patent law is informed by a quid pro quo rationale: the state awards monopoly rights in return for the disclosure of some specific and substantial utility. This same reasoning implies that the reward should be commensurate with the disclosure – meaning that *the rights conferred should extend as far as the specific and substantial utility disclosed – and no further*. This idea lies at the heart of this submission. If

¹⁹ Namely, the quid pro quo rationale and the ‘reward-by-monopoly thesis’ which represents the flip-side of the quid pro quo bargain, (ie. the quid pro quo rationale viewed from the perspective of the patentee’s entitlement to be rewarded).

accepted, it follows that many experimental uses do not fall within the scope of the patent owner's rights. Only in relation to certain uses of process, method or use claims is there a genuine clash between the rights of the patent owner and the interests of the researcher.

In the case of *product* patents, the very uses of a patented product which the ALRC proposes to exempt from infringement via Proposal 14-1 are uses which, applying a *quid pro quo* rationale, do not fall within the patent owner's monopoly in the first place.

This is because the patentee does not generally disclose the use of a patented product as an object of investigation. Even if they do disclose and claim the product as an object of scientific investigation, since the benefit of such use is contingent upon further research by third parties, this is not a disclosure sufficient to justify the award of a patent. Hence, since the rights of the patent owner should only extend to the utility they have disclosed, they do not extend to such experimental uses.

Enacting a research exemption represents a practical way in which some coherence can be restored to the way product patents are dealt with in patent law. Specifically, a research exemption is a means of ensuring that patent law operates in accordance with the *quid pro quo* rationale, by excluding from the product patent owner's monopoly certain uses of a product which that rationale suggests should never have been seen as falling within the scope of the patent owner's monopoly at all. In fact, properly it is not really a defence at all in the context of product patents; it is not a question of 'excusing' certain uses of such products from infringement. Rather, it better defines the scope of the patentee's rights by clarifying that experimental uses are not a form of use which a patent owner has a right to prevent. These issues relating to product patents are explained further in part one.

In relation to method, process, and use claims, the situation is somewhat more complicated. Once again, however, once we accept that under the *quid pro quo* rationale the rights conferred on a patent owner should extend as far as the specific and substantial utility disclosed and no further, we can better understand how exempting experimental uses fits with the overall scheme of patent law.

Some uses of process patents – those where the contribution of the patent owner is not appropriated – should not fall within the patent owner’s monopoly. Part 2.1 deals with these scenarios.

However, in other cases involving process patents, there is a genuine conflict between the patent owner’s right to be rewarded, and the researcher’s interest in using the process for the purposes of experimentation. These are situations where the researcher does gain the precise benefit which the patentee disclosed: something for which, the underlying rationales of patent law²⁰ suggest, the patentee should be rewarded. These situations are dealt with in Part 2.2. We argue that the interests of the patentee should be protected by: (i) addressing the consequences of ‘mixed purposes’; and (ii) imposing a duty of restitution: two necessary components of a principled research exemption which are not sufficiently addressed in the ALRC Discussion Paper.

Two things follow from the arguments presented in this submission.

First, we submit the research exemption should not be characterised by the ALRC as a defence. As noted above, the danger of such a characterization is that it assumes that, *except for* those situations specifically stated in the defence, the rights of the patent owner are, in effect, absolute. It is more principled, and more desirable, to conceive of the role of any ‘exemption’ as both:

- a. clarifying (or defining) the *scope of the patent owner’s rights*, so that certain uses are not ‘infringements but for the defence’, but rather, uses outside the purview of the patent owner’s right; and
- b. resolving the genuine conflict between the rights of the patent owner, and the needs of the researcher in the specific set of circumstances where it arises.

²⁰ Namely, the quid pro quo rationale and the ‘reward-by-monopoly thesis’ which represents the flip-side of the quid pro quo bargain, (ie. the quid pro quo rationale viewed from the perspective of the patentee’s entitlement to be rewarded).

It would be possible, we submit, to frame the exemption in such a way that it will not be open to the interpretation that the rights of the patentee are otherwise absolute. Most importantly, we submit the ALRC should explicitly acknowledge that the exemption does not preclude further judicial interpretations of, and refinements to, the concept of exploitation. The potential for courts to interpret this concept should be left open.

Second, the ALRC should explicitly consider:

- a. How the law should handle the “fruits” of experimental use: it is arguable that there should be an obligation of restitution on experimenters who gain, and retain the benefit of the invention through their experimental use; and
- b. The question of mixed purposes: while we agree that a commercial purpose should be irrelevant, the ALRC should consider the relevance of an intention to retain the benefit of the invention.

Part One: The Research Exemption and Product Patents

A basic idea that underlies patent law is that there should be a quid pro quo. In other words, society is entitled to receive the benefit of a ‘substantial utility’ as the ‘quid pro quo’ for any patent monopoly it confers. This much is straightforward.

But the concept of the quid pro quo is not merely a justification for *conferring* a patent. It also implies that the principles which give rise to the justification for the award of a patent (the conditions for patentability and, in particular, utility) should be consistent with the principles which determine the nature of the rewards which are consequent upon the grant of a patent (the nature of the exclusive rights).

As a matter of principle, a quid pro quo requires not just ‘some’ benefit in return for a (broad) monopoly. Logically it also requires that the monopoly – the patent owner’s rights – should only extend as far as the benefit disclosed by the inventor. This benefit corresponds with the utility actually disclosed in the specification and which is thus available for use by the public upon publication of the specification. Other benefits may arise from a patented invention, which are not available to the public on publication of the specification: those not disclosed and/or those requiring further research or investigation to actualize their value. In relation to these benefits, however, since there is no ‘quo’ - the public has not received these benefits from the patent owner – it owes the patent owner no ‘quid’ in the form of a monopoly over such benefits, or utilities.

In summary, if the justification for conferring a patent is contingent upon the existence of an invention which is of ‘substantial utility’ ‘in currently available form’²¹, then the scope of rights conferred by a patent should extend no further than the scope of the substantial utility which the inventor has actually disclosed in the specification and which is thus in ‘currently available form’ (the patentee’s “utility contribution”).²²

²¹ *Brenner v Manson*, 383 U.S. 519, 16 L.Ed. 69, S.Ct. 1033, 148 USPQ 689 (1966).

²² Stephan Gruber and Jurgen Kroher, ‘Patentability of Pharmaceutical Inventions – A Comparison of the Legal Situation in Germany and Some Common Law Countries’ (1984) *IIC* 588, at 730: ‘the quid pro quo principle ... ties the claim for a monopoly to the extent of the disclosed invention’.

The argument in this part is that, if we need to enact a research ‘exemption’ in relation to product patents,²³ it is because product patents violate these basic principles underlying patent law. Exempting experimental uses simply restores the balance implied by the ‘quid pro quo’.

Product patents, as presently awarded, confer the exclusive right to make, use, sell, etc. patented *things* (compounds, substances, products etc.) for *any*²⁴ purpose. This *violates* the ‘quid pro quo’ because the existence of *one* utility in respect of a patented product is sufficient to confer exclusive rights to the use of that product for *any*²⁵ utility or purpose, notwithstanding the fact that the patentee has not conceived of, and/or has not disclosed to the public, the benefit of using the product for those other purposes.²⁶

One way to deal with this – to ensure that patents granted reflect the quid pro quo rationale – would be to abolish product patents, or rather, to revise the rights granted by a product patent. Specifically, the right to make, use or sell a patented product should arguably be restricted to the right to make, use or sell that product for the purpose(s) disclosed in the specification. This, however, would be contrary to Australia’s international obligations under TRIPS.

Nevertheless, Australia can exempt certain research uses from being infringements consistent with its obligations under TRIPS. Australia should take this opportunity, because it goes part of the way towards restoring the consistency between patent law and a quid pro quo rationale.

²³ Process patents are considered further below

²⁴ W R Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (3rd ed, 1996) 158. This is subject to the possibility that another party may obtain a 'mere use claim' in respect of that patented thing, namely, upon the discovery of a 'new use' for that patented thing: W R Cornish, *Intellectual Property* 158-9.

²⁵ *Ibid.*

²⁶ A similar conclusion is reached in *Chisum on Patents*, in which Chisum suggests that a strict application of the quid pro quo rationale (referred to as the “metes and bounds argument”) would call into question the justification for conferring patents in respect of compounds *per se* (Chisum on Patents, § 4.02[2], 4-12):

“The logic of the “metes and bounds” argument leads to the conclusion that patents should never issue on chemical compounds *per se* but should be restricted to methods of making compounds and methods of using compounds – a position that has been suggested by commentators but not yet recognised in the American patent system.”

Does the patent owner have the exclusive right to make or use the invention as an object of scientific investigation?

The research exemption proposed by the ALRC would exclude from the patent owner's monopoly the right to conduct research for the purpose of understanding or investigating the nature of the invention, including efforts at understanding the invention for the purpose of improving an existing utility or to identify a new utility. Research for the purpose of discovering something not presently known about the invention falls within this concept of experimental use. We refer to this as 'use of a product (or invention more generally) as an object of scientific investigation or experimentation'.

It was argued above that, consistent with the quid pro quo of patent law, the rights of a patent owner should extend no further than the scope of the substantial utility which the inventor has actually disclosed in the specification and which is thus in 'currently available form' (the patentee's "utility contribution").

Making or using a patented product as an object of scientific investigation' is not generally a utility which is actually disclosed in the specification. Even if a specification disclosed the possibility of using a patented product as an object of scientific investigation, a claim to the use of a product as an object of investigation does not satisfy the utility requirement. As the US Supreme Court pointed out in *Brenner v Manson*, the use of a product as an object of scientific inquiry does not qualify as a 'specific' and 'substantial' utility for the purposes of patent law because the benefit of such use is not in 'currently available form'.²⁷

²⁷ In *Brenner v Manson*, above n 21, the US Supreme Court was required to consider whether a chemical process was 'useful' merely by virtue of the fact that it yielded a compound which was the subject of serious scientific investigation (at 532). The utility of the compound – other than as a possible object of scientific investigation – had yet to be demonstrated (at 529). Whilst acknowledging the important role of the compound in its capacity as an object of investigation, the Court held that a contribution of this nature fell short of a 'substantial utility' for the purposes of patent law because the benefit of the compound was not 'in currently available form'.

The ALRC also acknowledged that the US standard of utility would preclude the grant of a patent in respect of an ‘invention’ whose utility or practical value is contingent upon further research or investigation:

The ALRC considers that ... [t]he standard of usefulness demonstrated in an application should satisfy the ‘specific, substantial and credible’ test ... **such a standard would preclude a patent being granted over ... [an] invention when further research or investigation is required to understand its practical application.**²⁸

This result is correct as a matter of policy because if the value of an ‘invention’ (ie. its utility) is contingent upon the *inventive* thought or further research of others, then the patentee has neither created nor disclosed a utility ‘*in currently available form*’. Rather, the value of the ‘invention’ is potential and is contingent upon further research/inventiveness by a researcher.

It follows that the very uses of a product patent which would be excluded from the patent owner’s rights by a ‘research exemption’ are no more than uses which, applying the quid pro quo rationale, would not fall within the patent owner’s monopoly. Thus the research exemption is a means of ensuring that patent law is more consistent with the quid pro quo rationale. It defines the scope of the patent owner’s monopoly: rather than being infringements requiring a defence, such experimental uses of a product are simply outside the appropriate scope of a patent owner’s rights. It should be noted that this reasoning does not resolve the issue of experimental use with respect to method, process and use claims (discussed in Part 2 below).

Therefore, it is sensible – and indeed, in accordance with the principles underlying patent law – to take advantage of the opportunity to enact a research exemption²⁹ because such an exemption operates (in substance though not in form) as a limitation upon the exclusive rights conferred by a product patent. While it would be even *more* consistent with the quid pro quo rationale to abolish product patents entirely, a

²⁸ ALRC Discussion Paper 68, *Gene Patenting and Human Health*, Paragraph 6.188.

²⁹ Pursuant to Part II, section 5, Article 30 of TRIPS.

research *exemption* is the best that one can practically hope for in the current international context, and though formally classified as an ‘exemption’ to infringement, the *substance* of the exemption simply represents an principled limit on the product patentee’s rights.

Part Two: Research Exemption and Method, Process and Use Claims

Summary of Part 2

The situation with respect to experimental uses of *process* or method patents is more complicated. This is evidenced by the many areas of conflict outlined in the ALRC's Discussion Paper. In our submission, the proposal as presently framed does not adequately deal with two key issues in this area: the problem of mixed purposes, and how to ensure the researcher does not gain an 'unjust enrichment' through their experimental use. In this part of the submission, we offer some ways of addressing these issues.

As with product patents, in some circumstances, use of a patented method or process as an object of investigation should not be classified as an act of 'infringement' and, therefore, a research exemption should not be required to sanction it. This is true where the researcher does not obtain the benefit, or utility disclosed by the inventor. In particular, section 1 of Part Two argues that a revised concept of 'infringement' may provide a basis for researchers to lawfully engage in a limited range of experimental uses of patented processes without the need to act under the cloak of protection afforded by a research *exemption*.

In other circumstances, however, there is a conflict between the rights of the patent owner and the needs of the researcher. These are situations where the researcher does gain the precise benefit which the patentee disclosed: something for which the patentee should be rewarded. In these circumstances, an exemption *is* required, to resolve this conflict. We argue that the interests of the patentee should be protected, by: (i) addressing the consequences of 'mixed purposes'; and (ii) imposing a duty of restitution.

1. Appropriation of the utility contribution should be a necessary condition of infringement

Generally when we consider patent law's quid pro quo it is from the perspective of society and, in particular, society's 'entitlement' to a sufficient reward in exchange for conferring a monopoly right. Thus, the quid pro quo rationale affirms that a patent is *not* justified absent the disclosure of a substantial utility in currently available form.

But there is another perspective - the quid pro quo rationale has a "flip-side" - namely, the perspective which focuses upon the *patentee's* side of the disclosure-for-monopoly exchange. From this perspective, inventors positively *deserve* to be rewarded for their intellectual labours in the form of a monopoly right. This perspective recognises that *an inventor is entitled to be rewarded for creating and disclosing the substantial utility in the specification because s/he has created its value*. This perspective gives expression to a patentee's entitlement to his or her utility contribution in *positive* terms and thus focuses upon the patentee's side of the disclosure-for-monopoly exchange. It is this side of the coin which, in our submission, the ALRC has not sufficiently recognised in its proposal.

If the patentee has a right to be rewarded for originating their utility contribution, the doctrine of infringement gives practical content to that entitlement by preventing the appropriation of that utility contribution by third parties.³⁰

Appropriation of the patentee's utility contribution should thus be a necessary condition of infringement. If the use of an invention as an object of experimentation does not generate the utility contribution, there should be no infringement.

For example, in relation to a patented method of inoculating chickens by means of injecting a vaccine into the developing embryo through the egg, the 'substantial utility' of the method arguably consists in the fact that it produces chickens which are

³⁰ One of the means by which patent law seeks to preclude such unfair retention is via the remedy of an injunction. Specifically, an injunction prevents third parties from engaging in conduct which would otherwise confer upon those third parties the benefit of the utility contribution. Where such infringement cannot be prospectively prevented by means of an injunction, the remedy of damages and/or an account of profits is available to retrospectively ameliorate the injustice.

immune to a specific disease from a specific point in time, thereby increasing the probability of their survival.³¹ Therefore, if eggs which have been injected with the vaccine are destroyed prior to the point in time at which the embryo is rendered immune to disease, then it is arguable that the researcher has not appropriated the benefit of the patentee's utility contribution. This should not, as a matter of principle, be considered an infringement. To the extent that this is currently seen as 'using' the patented invention, that is not consistent with the rationales of patent law.

Only if one claims that the use of a patented process for the purpose of studying the nature of that process is, in itself, a substantial utility for the purposes of patent law does the patentee deserve to be remunerated for uses of his or her invention in this experimental capacity. However, by analogy with the reasoning explored in Part 1, the value of a process when used in this experimental capacity is arguably contingent upon the intellectual effort of a third party and thus should not fall within the scope of the patentee's monopoly because it is not in 'currently available form'.

In principle, then, the right to 'exploit' a patented process or method should not be interpreted to include every physical 'use' of the patented process or method. 'Use' in the definition of 'exploit' in Schedule 1 of the *Patents Act* 1990 (Cth)³² should be interpreted (or explicitly limited) to extend only to those 'uses' in which the utility contribution is generated and retained.

If such a revision were made, then some experimental uses of patented processes and methods (like the vaccine example above) would be lawful on the basis that such conduct does not properly fall within the concept of 'infringement' or 'exploitation', notwithstanding the absence of a formal research exemption to sanction the use.

³¹ This is a variation of the facts in *Embrex, Inc. v Service Engineering Corp.*, 216 F.3d 1343; (Fed. Cir. 2000), in which the patented method of inoculation conferred immunity upon the developing embryos during their development in the egg.

³² 'exploit, in relation to an invention, includes:

- (a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- (b) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.'

Once again, to the extent that the ALRC proposal exempts these experimental uses, it is simply ensuring the consistency of patent law with its underlying rationales. In other words, the quid pro quo rationale provides a firm foundation for the exclusion of such uses from the exclusive rights of the patent owner.

2. A solution where the utility contribution is generated in the context of experimental use

However, there are other contexts in which the patentee's utility contribution **will** be 'generated' during experimental uses of an invention. In such circumstances, the intended goal, benefit or end result disclosed in the specification will be realised. This will frequently occur in relation to process, method and use claims, in which the invention must actually be used in order to study its properties. For example, imagine there is a patented process for producing gold. It may be necessary to produce large quantities of gold in order to properly understand the process of production itself, thereby generating the utility contribution. Traditional accounts of the research exemption, and the ALRC Proposal 14-1, do not appear to address this scenario and/or fail to identify how the law should respond in such circumstances. Should the researcher be entitled to retain the benefit? Or does it belong to the patentee?

If the patentee's entitlement to his or her utility contribution is to be respected, the law should develop principles and/or remedies in order to ensure that the utility contribution is not retained by the researcher and is restored to the inventor. An *obligation of restitution* should, therefore, be imposed in order to adequately protect the patentee's interest in his or her utility contribution. In the case of the example above, such restitution would involve a transfer to the patentee of all gold generated during the experimental act.³³

However, what happens if restitution cannot so easily be made? For example, experimental subjects may experience headache relief during experimental trials to discover new indications for aspirin. In this situation, the value of the utility

³³ Significantly, it is not necessary to sell the gold in order to understand the process itself, and thus such sale should not qualify as an experimental act.

contribution (in the form of headache relief) is retained but cannot be physically disgorged thereafter.

Legal principles are also required to resolve these circumstances in which restitution cannot be so conveniently made. In particular, how should the law respond in circumstances where an invention is made or used for experimental purposes and:

- (i) the utility contribution is generated and must be retained by the researcher if the experimental conduct is to proceed;
- (ii) however, the researcher does not intend to retain the benefit of the utility contribution but rather s/he intends to use the invention as an object of experimentation.

In essence, patent law appears to be confronted with a choice between:

- (i) preventing researchers from using the patented method or process as an object of investigation (by means of an injunction) in order to prevent an appropriation of the utility contribution (“Option 1”); or
- (ii) allowing researchers to use the patented method or process as an object of experimentation and thereby gain a benefit which they do not deserve to retain by virtue of the fact that the utility contribution properly belongs to s/he who has created its value, namely, the patentee (“Option 2”). This is the effect of the ALRC proposal as it is currently drafted.

The injustice of Option 1 consists in the fact that it confers upon the patentee the exclusive right to use the invention as an object of investigation in the quest for research insights (“Z”), whereas we have argued that the patentee does not deserve to extend the scope of his or her monopoly to that extent.³⁴ Option 1 would thus result in a reward which is disproportionate to the patentee’s actual achievement because it would confer the benefit of the utility contribution plus the windfall benefit of the

³⁴ Because the benefit of such a use is contingent upon the inventiveness of others and is thus not in ‘currently available form’: *Brenner v Manson*, above n 21.

exclusive right to attempt to gain research insights, contrary to the principle in *Brenner*.

The injustice of Option 2 consists in the fact that the patentee's entitlement to his or her utility contribution is not adequately respected because it is retained by the third party.

However, there is a third option: namely, to allow the research to proceed (by removing the inventor's right to restrain the research via an injunction) but require restitution.

The main options and their consequences can be illustrated as follows:

OPTIONS	Consequences for patentee	Consequences for 3 rd parties
1. No research exemption	Remuneration in respect Y + exclusive right to gain Z	No opportunity to gain Z
2. Research exemption without restitution	No remuneration in respect of Y but no exclusive right to gain Z	Receives the benefit of Y + opportunity to gain Z
3. Research exemption with restitution	Remuneration in respect of Y but no exclusive right to gain Z	Receives opportunity to gain Z

Where:

Y = the substantial utility disclosed by the patentee in the specification, ie. his or her utility contribution.

Z = the potential benefit of research insights consequent upon the use of an invention as an object of investigation.

This submission argues that the most principled approach is as follows:

- A research exemption should be enacted which renders it lawful to make or use a patented invention as an object of experimentation;
- In order to properly safeguard the interests of the patentee in being rewarded for the origination of his/her utility contribution, the exemption should be subject to a duty to restore the value of the utility contribution to the patentee. Depending on the context, this duty of restitution can be discharged by:
 - (i) physically returning the utility contribution, where possible; or
 - (ii) compensating the patentee if it is necessary to retain the utility contribution in order to achieve the experimental purpose (eg. if it is not possible to conduct an experimental trial involving aspirin without retaining the benefit of headache relief).
- Furthermore, it will be necessary to determine *the extent to which* an intention to retain the benefit of the utility contribution (as opposed to an intention to understand the invention itself) can make a contribution to the decision to engage in the relevant conduct. This is discussed further below.

In essence, the approach which is most consistent with principle does not grant to the patentee an absolute right to restrain all³⁵ uses of his or her invention (via an injunction). Instead, experimental uses should be allowed, subject to the patentee's a right to be remunerated in circumstances where the invention is used as an object of investigation and the utility contribution is retained.

The effect of this approach is to 'disentangle' the entitlements of the respective parties by avoiding the injustice inherent in options 1 and 2 above.³⁶

This approach is just from the perspective of both the patentee and the researcher:

³⁵ See qualification in footnote 24 above.

³⁶ The means by which this is achieved is to substitute the patentee's *prima facie* right to restrain such use (via an injunction) with a right to remuneration/restitution.

- The patentee has lost the prima facie right to an injunction but has not otherwise suffered any loss (provided that restitution in respect of the utility contribution is made) because s/he has no right to be remunerated for use of the invention as an object of investigation.
- Depending on the extent to which the researcher is motivated by an intention to retain the utility contribution (and thereby gain values by mere imitation or copying) versus an intention to understand the invention (and thereby create new values by identifying a new utility or improving an existing utility) the researcher's conduct may not be contrary to the policies of patent law because it is consistent with the patent law policy of rewarding the identification of novel and inventive uses.
- There is no unjust gain by the researcher if the utility contribution is disgorged.

Mixed purposes

Another issue which Proposal 14-1 does not specifically address is the question of 'mixed purposes', namely, circumstances in which a researcher is motivated by an intention to retain the benefit of the utility contribution **and** an intention to understand the nature of the invention itself.

There are many contexts in which a researcher may be motivated by a wish both to understand the nature and properties of a patented process or method *and* gain the benefit of the utility disclosed in the specification. For example, doctors may be motivated by a concern to *both*:

- a. Better understand the properties of a known drug: ie, identify new indications for the drug; and
- b. Retain the benefit of its known properties: for example, by ensuring their patients receive the disclosed or known benefit of the drug.

Proposal 14-1 does not provide a clear solution in such circumstances, namely, where the primary or dominant motivation for using the invention is to derive its intended benefit (ie. the utility contribution), rather than to understand its properties or nature. Therefore, it is necessary for any legislative solution to address this scenario in order to promote the certainty which researchers and patentees require.

Three possible approaches are set out below, ranging from the most stringent (ie the most protective of the patentee) to the least stringent (ie the most favourable to researchers).

Strict approach

According to the strict approach, infringement would arise if retaining the benefit of the utility contribution is a cause/reason for the defendant's conduct, even if the primary or dominant purpose is experimental in nature. This would ensure that the research exemption is not used as a means for disguising acts which are described as experimental but which are actually motivated by a wish to retain the utility contribution.

It could be argued that this test is necessary in order to properly protect the patentee from the potential abuse of rights that are consequent upon forensic difficulties in establishing the requisite state of mind.

The strict approach has the potential to render the research exemption of little practical value, in light of the difficulty researchers would face in proving the absence of any intention to retain the utility contribution.

Moreover, it is not clear that the mere existence of an incidental wish to retain the utility contribution is, of itself, so contrary to the policies of patent law as to justify the invalidation of the defence.

Primary Purpose Test

An approach which is more favourable to researchers is to allow experimental use to proceed (notwithstanding the existence of mixed purposes), unless the researcher possesses a *primary or dominant purpose* of retaining the benefit of the utility contribution.

More favourable approach to researchers

Alternatively, a more lenient approach would be to ask whether the experimental conduct would have occurred in the absence of the researcher's intention to retain the utility contribution. If yes, then the research would be permitted. However, if the 'research' would not have occurred in the absence of an intention to retain the utility contribution, then such conduct is arguably not properly classified as 'research' at all and should be regarded as infringement.³⁷

This approach, when supplemented by an obligation of restitution, arguably provides a reasonable balance between the interests of the patentee and the researcher.

Mixed purposes and the ALRC Proposal

The ALRC does not explicitly deal with 'mixed' purposes, employing the distinction between 'experimentation *on* a patented invention and research involving the use of a patented invention' (para 14.134), as the basis for distinguishing between conduct which falls within the scope of the exemption and conduct which falls outside the scope of the exemption respectively. This point is made in the context of rejecting the relevance of commercial motivations:

... the existence of a commercial purpose or intention (even if a dominant purpose) should not be relevant to the application of an experimental use defence, so long as experimentation is on, rather than simply using, the patented invention (14.143) ... It

³⁷ An alternative way of conceptualising this test is to ask whether the experimental motive or purpose was, of itself, sufficient to cause the researcher to engage in the conduct. If a wish to understand the nature of the invention is, of itself, a sufficient cause of the decision to conduct the experiment, then the existence of other motivations is arguably irrelevant for the purpose of distinguishing between exempt and non-exempt research.

may be that some commercially-oriented research falls outside the scope of [the] defence [proposed by the ALRC]; if so, this is not because the research has a commercial objective but because it is not experimentation on the subject matter of the invention ... (14.146).

The ALRC itself acknowledges the difficulty in distinguishing between experimentation *on* an invention and research involving the use of a patented invention (14.138), however, it is submitted that this difficulty arises because the concepts are not sufficiently precise. For example, the Discussion Paper states that ‘most research *using* patented inventions will not be covered by [the proposed defence]’ because the scope of the proposed defence is limited to study or experimentation on the subject matter of the patented invention’. (14.146). However, this distinction fails to address circumstances in which it is necessary to *use* the invention in order to investigate its properties. For example, how would the distinction apply in circumstances where it is necessary to use a patented process for producing gold in order to understand the nature of the process itself?

It is submitted that the distinction between exempt or non-infringing experimentation and non-exempt or infringing experimentation can be made more coherent if the inquiry focuses on the distinction between an intention to retain the benefit of the utility contribution and an intention to engage in experimental conduct. An intention to retain the benefit of the utility contribution arguably corresponds with, and more accurately captures, the concept of non-exempt experimentation: that is, what the ALRC describes as research involving the *mere use* of the patented invention. In contrast, an intention to use the invention as object of experimentation³⁸, ie for the purpose of understanding the nature and properties of the invention, arguably corresponds with, and more accurately reflects, the concept of experimentation which properly falls within the scope of the exemption. This latter is referred to by the ALRC as experimenting *on* the patented invention.

An intention to gain the benefit of the utility contribution represents an attempt to profit by merely copying the ideas of the patentee, whereas an intention to use the invention as an object of investigation (ie. as a stepping stone for *generating* new

³⁸ ie for the purpose of understanding the nature and properties of the invention

research insights, understandings, etc) represents an attempt to *create* values via the independent use of the researcher's mind. The first method of gain represents a form of 'free-riding' which should be contrary to the policies of patent law, whereas the latter method represents a form of productive activity which patent law should reward.³⁹

The ALRC Discussion Paper is right to reject the relevance of commercial motivations vis-a-vis the research exemption. The use of an invention for experimental purposes should be legitimate, notwithstanding the fact that such use is motivated by an ultimate purpose of financial gain for the following reason. It is submitted that the relevant consideration in terms of evaluating the conduct of the researcher is the *nature* of the gain and, in particular, the particular means by which that gain is obtained, rather than the mere existence of a wish for financial gain.

The subjective motivations of the researcher thus remain relevant to a determination of whether or not the research exemption should properly apply. While the ALRC is correct to dismiss as irrelevant the *commercial* nature of those motivations, it remains necessary to consider whether, and to what extent, the researcher intended to retain the benefit of the utility contribution and/or use the invention as an object of investigation. It is submitted that these are the critical questions.

³⁹ This explains why the US emphasis on commerciality *per se* is not correct. It fails to differentiate between legitimate and illegitimate methods of gaining a commercial advantage in the context of the use of a patented invention.