The Institute of Patent and Trade Mark Attorneys of Australia

A.C.N. 004 194 263
A.B.N. 78 004 194 263

The Australian Federation of Intellectual Property Attorneys

Terry Moore
Director, Office of the Director General
IP Australia
PO Box 200
Woden, ACT 2606

Dear Terry,

Re: **Response to IP Australia Consultation Paper entitled "Getting the Balance Right"**

We make the following submissions on behalf of the members of The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) and The Australian Federation of Intellectual Property Attorneys (FICPI Australia) in response to this Consultation Paper.

A. The Institute of Patent and Trade Mark Attorneys of Australia (IPTA)

1. IPTA is a voluntary association, which includes in its membership, registered patent attorneys, registered trade mark attorneys and student members who are in the process of qualifying for registration. The membership of IPTA includes over 87% of the patent attorneys located in Australia. In fact, because the official figures include a number of people known to be retired and even deceased, it is believed that IPTA members make up more than 90% of patent attorneys in active practice in Australia. Whilst a majority of the patent attorneys who are members of IPTA are in private practice in one of the firms in Australia, IPTA also has members working in industry and members who practice as barristers. IPTA members represent over 80% of the patent applicants in Australia. The clients represented by IPTA members include large local and foreign corporations, SMEs, universities, research institutes, and individual inventors. In addition to the filing and prosecution of patent applications in Australia, IPTA members also represent and advise clients and their employers respectively in relation to patent rights granted to others, in particular in relation to validity and infringement of patents granted or likely to be granted by IP Australia. Exposure of IPTA members to commercial interests of both those seeking or who have obtained patent protection and those who are directly affected in the market place by the grant or potential grant, gives IPTA a broad understanding of the impact of the Australian patent system and the patent systems of many other countries.

Level 2, 302 Burwood Road, Hawthorn, Victoria 3122, Australia
PO Box 419 Hawthorn Victoria 3122
Tel 61 03 9819 2004 Fax 61 03 9819 6002
Email mail@ipta.com.au Internet www.ipta.com.au

Level 23, 367 Collins Street, Melbourne, Victoria 3000, Australia
PO Box 323, Collins Street West, Victoria 8007
Tel 61 03 9614 1944 Fax 61 03 9614 1867
Email greg.chambers@pof.com.au Internet www.ficpi.org.au

B. The Australian Federation of Intellectual Property Attorneys (FICPI Australia)

1. FICPI Australia is an organisation drawing its members from experienced registered patent attorneys and registered trademark attorneys in Australia who are proprietors or partners in patent and trade mark attorney firms conducting business in Australia. Many of the members of FICPI Australia are also members of IPTA, with a corresponding range of clients, responsibility and exposure to legal and commercial IP issues.

2. FICPI Australia is a national association of the Fédération Internationale Des Conseils En Propriété Industrielle (FICPI), a non-political organisation of intellectual property attorneys in private practice in some 86 countries. One of the stated aims of FICPI is to liaise with national and regional IP offices as well as other groups, such as WIPO, to provide a balanced perspective of the needs of IP users, whether owners of IP or not.

C. Interests

1. IPTA and FICPI Australia members ("our members") have a direct interest in the patent system. It provides the very basis for the patent attorney profession. Nonetheless, neither IPTA nor FICPI considers that it is in the interest of their members to lend support to patent reform only in cases where patenting opportunities are broadened.

2. The business interests of patent attorneys are best served by a robust and credible patent system. Unless the system is viewed as being workable and balanced to both patentees and those who are affected by the grant of patent rights, public support for the system will diminish. In this regard, we consider that the interests of our members are closely aligned with those of the Australian public and industry in ensuring that this country maintains best practice in relation to the grant and enforcement of patent rights. Changes to patent law, and the uncertainty that follows, often increases the amount of work for patent attorneys and other IP professionals. However, we consider this to be of little value to our membership if Australia does not provide a patent system that is well regarded and considered by the Australian community to operate in the best interests of Australia and Australian industry.

3. There are significant costs associated with obtaining, maintaining and enforcing patent rights and clearly a large proportion of our members are at least in part beneficiaries. Nonetheless, our members do not support a system that gives rise to unnecessary costs in the obtaining of patent rights. For example, our members did not support the introduction of s45(3) despite the fact that it was financially beneficial for many of our members. As explained below, some of the proposals put forward in "Getting the Balance Right" cause our members considerable concern in this regard.

4. In order to fully respond to the proposals put forward, IPTA and FICPI Australia have consulted widely. We have also engaged senior and junior counsel to assist in the formulation and preparation of our submissions. Consultations have taken place with our membership, our members' clients and a number of influential sources outside

Australia. Our representatives have met with representatives of the American Intellectual Property Law Association (AIPLA) including Teresa Rea, Crowell & Moring, President AIPLA, Washington DC; Chief Judge Paul Michel of the United States Federal Circuit Court; Gordon Kit Esq., Senior Counsel, Sughrue Mion PLLC, Washington DC; Paul Davinsky, McDermott, Will & Emery, Washington DC; Dr William Christiansen, Seed IP, Seattle; Lord Justice Hoffmann; Lord Justice Jacob; Justice Kitchin; Justice Floyd; Simon Thorley QC, London; Andrew Waugh QC, London; Colin Birss QC, London; Claire Baldock, Boult Wade Tennant, London; Aiden Robson, Reddie & Grose, London; Dr Bill Tyrrell, GlaxoSmithKline, Brentford; Trevor Cook, Bird & Bird, London; Dr Mark Weaver, Director, EPO, and Dr Guy Glod, Examiner, EPO; Jon Gowshall, Forrester & Boehmert, London and Dr Markus Engelhard, Boehmert & Boehmert, Munich.

D. Executive Summary

1. The proposals for patent reform outlined in the Consultation Paper (the Paper) are premised on the assumption that the patent system as it operates in Australia is currently unbalanced in favour of patentees and the applicants for patent rights. We do not believe that the Paper adequately explains why it is believed that the current system lacks balance between rights holders on the one hand and the general public on the other. It is not the experience of our members, nor have we received feedback from clients, that the current Australian system lacks balance between patent rights holders and those not holding patents wishing to develop new technologies. We are concerned that significant reforms are proposed to adjust the current balance without underlying targeted research. Both IPTA and FICPI are also concerned that proposed reforms intended to promote balance do so from the perspective of patent grant only. The breadth of the monopoly conferred by a patent can only properly be assessed by considering both grant and enforcement. Much of the Paper makes reference to proposed reform with an eye to patent grant rules in overseas countries. We consider this analysis "unbalanced" unless one also considers the rules of infringement in those overseas countries and how they compare with those operating in Australia.

2. Despite these misgivings, IPTA and FICPI Australia do support various of the proposals, as detailed below. We are, however, concerned that the introduction of a package of proposals all aimed at reducing the opportunities for patent applicants may be misinterpreted by Australian industry as an "anti-patent" push. We consider that a balanced approach would include necessary reforms to deal with problem areas that have been identified in the past, such as the grace period not extending to prior secret use, the need to repeal s.102(2C), the need to amend section 96 and the need to extend privilege under section 200.

3. We consider that the principal questions raised in the Paper (the two questions in section 7) would have been more constructively formulated if question 1 asked whether the respondent agreed in principle with the positions outlined in the Paper (i.e. that the stated problems exist), and then if question 2 asked whether the proposals set out in the Paper were considered the best solutions to such problems. We have endeavoured to address the proposals by considering these questions.

4. Our members believe that many of the problems identified in the Paper relate to practices and procedures within IP Australia, and that the solution to these problems can, for the most part, be found within our current law. Our members do not believe that IP Australia's current approach to search and examination discharges the responsibilities placed on it by provisions of the Patents Act 1990; the approach lacking the vigour applied by Patent Offices in Europe, the US, UK and Japan. IP Australia also does not, in our experience, effectively apply the "balance of probabilities" test demanded of it by s49. The changes proposed to include utility as an issue for consideration in examination and to introduce a "balance of probabilities" test for all grounds of examination, re-examination and opposition are welcomed by our members, but such changes will be of value only if IP Australia takes steps to ensure that this standard is effectively applied. Although our members do not believe that IP Australia has made a case in its Paper for many of the proposed changes, we have nevertheless considered the proposed changes and provide the following summary of our members' views on the proposals.

5. The following paragraphs D6-21 summarise our members' views on the specific proposals put forward by IP Australia, with those views being amplified in Section F on pages 13-45. Section E on pages 8-12 summarises our members' general concerns with IP Australia's Consultation Paper, Section G on pages 46-48 is a summary of our submission, while Appendix 1 on pages 49-59 contains a comparison of the law of sufficiency/enablement in Australia and other jurisdictions and Appendix 2 on pages 60-65 contains comments on patent thickets.

3.1 Proposed change

Amend s40 of the Act to:

- introduce descriptive support requirements analogous to those applied in other jurisdictions including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.

6. Our members support this proposed change in part. Since the change proposed by IP Australia would introduce a descriptive support requirement more onerous than currently applied in Europe, the UK or the US, we propose the following amendment to bring our law into closer conformity with the law of the UK:

> *"The specification shall describe the invention in a manner which enables the invention to be performed substantially across the scope of the claims by a person skilled in the art without undue experimentation, including the best method known to the applicant of performing the invention."*

7. We consider that the current wording of s40(2)(a) should be retained for the purpose of assessing the description requirement for innovation patents, and that the "fair basis" requirement of current s40(3) should be retained.

8. See our detailed comments in Paras F3-14 on pages 13-15.

3.2 Proposed change

Amend s40 and s102 and of the Patents Act to:

- explicitly indicate that the requirement for full description is met if the description of the claimed invention was sufficient at the filing date to allow the skilled addressee to perform the invention without undue experimentation.

9. Our members support this proposed change in principle, subject to considerations set out below in more detail in Paras F15-19 on page 16.

3.3 Proposed Change

Amend reg 3.12(1)(b) of the Patent Regulations to:

- replace the 'fair basis' requirement for establishing the priority date of claims with a descriptive support requirement analogous to those applied in other jurisdictions, and to that proposed for s40.

10. Our members do not support this proposed change as we consider that it would have an adverse effect on Australia and Australian industry. We consider that current s40(1) should be retained, as should regulation 3.12(1)(b). See our comments in Paras F20-23 on pages 16-17.

4.1 Proposed change

Amend s7(2) of the Patents Act to :

- remove the limitation that common general knowledge be confined to that existing in Australia

11. Our members support this change in principle, subject to considerations set out below in more detail in Paras F38-43 on page 20 and the introductory comments in Paras F24-37 on pages 17-19.

4.2 Proposed change

Amend s7(3) of the Patents Act to:

- remove the requirement that prior art information for the purpose of inventive step

must be such that a person skilled in the art could be reasonably expected to have been ascertained, while retaining the requirements that prior art be understood and regarded as relevant.

The definition of the prior art base for inventive step will not change.

12. Our members do not support this proposed change. We consider that this change would have an adverse effect on Australia and Australian industry, and would remove an important element of the inventive step test which guards against hindsight analysis. The proposed change is unnecessary and would raise the obviousness threshold in Australia above the thresholds that apply in Europe, the UK and the US.

13. See our detailed comments in Paras F44-96 on pages 21-30.

4.3 Proposed change

The proposed change seeks to:

- revise the inventive step test to a test where the claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.

14. Our members do not support this proposed change as it would provide an inappropriate test for a large class of inventions; it removes the flexibility required in the assessment of obviousness/inventive step and would, to no advantage, put Australian law at odds with the laws of our major trading partners to the detriment of Australia and Australian industry.

15. See our detailed comments in Paras F97-135 on pages 30-38.

5.1 Proposed change

Amend the Patents Act and/or Regulations to:

- include usefulness among the grounds considered during examination and re-examination and clarify that the requirement for usefulness is only satisfied if the patent specification discloses a specific, substantial and credible use for the invention.

16. Our members support this proposed change in part, and consider that usefulness can be considered during examination and re-examination provided appropriate guidelines are supplied to Examiners. These utility concepts could be explained in the Examiners' Manual for the assistance of Examiners and applicants. Our members do not support the inclusion of a new test for utility based on the USPTO guidelines as we consider that the words "specific", "substantial" and "credible" are inherently unclear.

17. See our detailed comments in Paras F136-151 on pages 38-42.

5.2 Proposed change

Amend s.45 of the Patents Act to:

- include prior use among the grounds considered during examination and re-examination.

18. Our members support this proposed change, but note that it is unlikely that Examiners will have sufficient evidence during examination or re-examination to maintain a rejection based on prior use. We do, however, recognise that the ability to place information regarding possible prior use on file could serve a useful function for third parties wishing to oppose a patent application or seek revocation.

19. See our detailed comments in Paras F152-162 on pages 42-43.

5.3 Proposed change

Amend s.98 of the Patents Act to:

- expand the grounds for re-examination to all of the grounds considered during normal examination.

20. Our members support this proposed change, as discussed in detail in Paras F163-167 on pages 43-44.

6 Proposed change

Amend the Patents Act to:

- clarify that 'balance of probabilities' is the standard of proof applied to all requirements during examination, re-examination and opposition proceedings.

21. Our members support this proposed change, as discussed in detail in Paras F168-169 on pages 44-45.

E. The IP Australia Consultation Paper

1. As alluded to in the summary above, our members have serious concerns in relation to some aspects of the Paper, and the approach taken by IP Australia in developing its proposals and presenting them for public consultation. A summary of our concerns is set out below:

- The Paper does not make a sufficient case for many of the proposals;

- IP Australia should have first raised concerns and sought input from IPTA and FICPI Australia, as well as other stakeholders such as the Law Council of Australia and AMPICTA, to obtain ideas for addressing any perceived problems, rather than putting forward such an extensive suite of proposed amendments for public consultation without sufficient supporting information. Many of the proposals are of such a significant nature, with the potential to cause significant adverse consequences for our national patent system and Australian industry, that they should be referred to ACIP or a similarly constituted independent body for detailed consideration and consultation.

- The scope of the proposed amendments to patentability/specification requirements set forth in the Paper is more extensive than reforms introduced in the 1990 Act, and yet IP Australia appears to be looking to move forward with amendments to the Act without conducting appropriate research in relation to the potential impacts of the proposed amendments.

- Insufficient consideration has been given in the Paper to the consequences of the proposed amendments, particularly insofar as they could adversely affect Australian industry, which for the most part is made up of SMEs lacking the financial and research resources of large multinational companies. The Paper proceeds on the unproven assumption that what is appropriate for countries such as the US, the UK and Japan is necessarily good for Australia.

- The Paper seeks comments only from users of the system, not non-users who may be affected by the system, and in particular those adversely affected by overly broad patents issued by IP Australia.

- Many statements said to be facts in the paper are unsupported by evidence, over-stated, misleading or incorrect. These include:

    - **Australia's patentability standards are set at a level that is lower than the standards set in countries who are our major trading partners** (page 3 and para 10). No evidence is put forward to support this statement, and. when examined closely, we do not consider the proposition to be correct. By way of example only, the Paper does not examine the breadth of the rights granted in some countries of the EPC and the US where the doctrine of equivalents can give rise to protection that extends beyond the literal language of the claims as granted. Also, even if true, which we question, no evidence is provided to support a view that there is

a problem with the current patentability standards when considered in total.

- **Our standard for full description of inventions is lower than elsewhere** (page 3 and para 10). No evidence is put forward to support this statement, and it is not clear from the document that there is any problem in Australia with respect to our standard for full description. In the absence of any detailed research on the part of IP Australia in relation to this statement, IPTA and FICPI Australia, with the assistance of Katrina Howard SC and others, conducted detailed and extensive research to be in a position to effectively compare Australia's description requirements with those of the US, the UK and Europe. A summary of this research is provided in **Appendix 1**.

- **[As] is our standard for inventive step** (page 3 and para 10). Again no evidence is provided in the Paper that our standard is lower than those of our major trading partners, nor is their any explanation as to why this would be a problem, even if true.

- **These [differences] allow the grant of broader patents in Australia than elsewhere, and allow the grant of patents that may disclose less information about inventions that they claim than is disclosed elsewhere** (page 3). No evidence has been provided to support the view that Australian courts have any difficulty assessing whether or not a patent claim is too broad based on our current legislation. IP Australia is responsible for granting patents, and we consider that most problems with breadth of granted patents can be dealt with by improving examination processes and practices within IP Australia. Also, for most inventions patented in Australia, the description in the specification corresponds substantially with the description in the specification of the corresponding patents granted in foreign jurisdictions. Therefore, the level of disclosure in these Australian specifications is in the most part the same as the level of disclosure elsewhere.

- **Studies show that for countries which are net importers of technology it is advantageous to have patent thresholds set at levels at least as high as the thresholds set for countries with which they conduct the majority of their technology trade** (para 4). While we do not accept that the thresholds in Australia are not comparable to those of our major trading partners, the studies referred to by IP Australia did not consider whether lower thresholds might in fact be preferable in a country like Australia, where individuals, SMEs, etc. may have difficulty in meeting high patentability/description thresholds overseasparticularly when patent protection is only required in the region, for example in Australia, New Zealand and parts of Asia. In fact, the extremely high thresholds proposed by IP Australia, which in many cases exceed thresholds set in other countries, are inconsistent with the public statements released in connection with the introduction of the innovation patent, and the desire to lower thresholds for the benefit of local SMEs. Raising thresholds above any requirements stipulated in international treaties/agreements to which

Australia is a party is, we believe, contrary to the interests of Australian industry.

- **Strong thresholds also ensure that unduly broad patents do not prevent local innovators from conducting follow on innovation and improving an existing technology. Low thresholds and resulting broad patents allow earlier patentees to carve out too broad a monopoly, suppressing competition and deterring follow on innovation and improvements to existing technology** (para 5). This is overly simplistic. High thresholds and narrow patents (particularly where there is no doctrine of equivalents) can reduce the incentive to innovate and can devalue patents, making it easier for competitors to invalidate or evade patents. This, in turn, provides a disincentive to disclose inventions, thereby defeating one of the aims of the patent system. The publication requirement, together with the experimental use exemption proposed by ACIP, will ensure that Australian industry can take part in follow-on innovation, and the established system of IP licensing can allow access to earlier innovations.

- **Strong thresholds also ensure that Australians do not pay more for technology than is paid elsewhere** (para 6). The Paper does not provide any evidence that this is the case, and that patentees increase the cost of a product supplied in Australia on the basis of the breadth of the patent granted.

- **Aligned thresholds also reduce the costs for Australian applicants seeking patent protection overseas and for foreign applicants seeking patents in Australia as they reduce the need for applicants to modify their applications to address disconformities between Australian and overseas thresholds** (para 7). No evidence has been presented that costs to Australian applicants filing overseas will be reduced if Australian law is amended as proposed, and no discussion or consideration of the effect on Australian industry of lower costs for overseas applicants to obtain patents in Australia is provided. Should lowering costs for foreign applicants be an aim for IP Australia, when it comes at the expense of local industry? Furthermore, there are no international standards with which to align, and as the standards overseas change regularly, we consider it unwise to attempt to enshrine in our legislation a threshold in relation to an aspect of our law which could change when the issue is considered again by a foreign court. In any event, applications filed by Australian applicants need to be modified overseas to deal with different laws and enforcement regimes, and often different prior art cited by foreign Patent Offices. It should also be noted that Australian applicants intending to pursue patent protection overseas rely on their Australian patent attorneys to draft their patent specifications in a form suitable for meeting overseas requirements as well as Australian requirements.

- **Although there is no global standard for patent thresholds, and differences exist between the patentability thresholds set in jurisdictions such as US, Europe, Japan and UK, there currently is a**

greater degree of consistency between each of these countries than there is between any of these countries and Australia (para 8 and para 44). This statement is not supported by any evidence in the Paper, and we do not consider it to be correct.

- **The US, Europe and Japan all require that the patent specification provide sufficient details of the invention to enable the reader to produce everything across the full scope of the invention claimed** (para 17). This statement is not supported by evidence and is incorrect. We are not aware of any patent law that requires the reader of a specification to be able to produce something throughout the full scope of the claim. The amount of disclosure required to support a particular claim will depend on a number of factors, such as the In re Wands (MPEP 2164.01(a)) factors considered under US law.

- **Higher requirements, similar to those in US, Europe and Japan, also appear in the PCT and in the draft SPLT** (para 18). We are not aware of any such "higher" requirements for full description in the PCT, and it should be noted that work on the draft SPLT has ceased, at least for the foreseeable future.

- **Requiring the specification to provide sufficient detail to make the invention across the full scope of the claims ensures the quid pro quo is met** (para 19). This is not necessarily the case. Once an invention is disclosed, how to make and use it might be evident from the common general knowledge. It is also possible that plausible methodology set out in a patent specification might not work for particular embodiments, but that a skilled person could readily devise an alternative method for making or using the embodiment on the basis of common general knowledge, or common approaches, without the need for inventive activity. This could be the case where an applicant generalises a chemical synthesis to cover the generic scope of compounds claimed. Once the compounds are identified they could be readily made, even if the generic synthesis offered in the specification does not work for all compounds. Restricting the applicant's protection to the specific compounds that could be accessed by the generic method offered in the specification does not ensure that the applicant receives adequate protection for the invention. In other words, the high standard of disclosure proposed by IP Australia can result in lack of useful protection for the patentee.

- Reference is made to **raising the bar** (para 30). The Paper refers to the KSR decision in the US. This decision brings the US approach to the determination of inventive step closer to the approach in Australia by allowing the court to consider any problem faced by those skilled in the art, not just the problem stated by the patentee, and also by including common sense within the knowledge of the skilled person. The Paper also refers to comments of policy makers in the EPO regarding raising the bar in Europe however these comments have been widely criticised, and should not be used to justify any changes to Australia's approach to inventive step.

- **In contrast, in other jurisdictions, although the prior art must pass the test of being considered relevant, and therefore understood by a skilled person, there is not the requirement that the skilled person would have been expected to have looked for and found prior art** (para 38, para 40 and para 44). This statement is not true as "ascertained" or an equivalent concept is part of UK, European and US law. The word "relevant" is not sufficient on its own to exclude from consideration documents that would not have been consulted by a skilled person in the first place.

- **Meeting "ascertained" requirement places extra evidentiary burden** (para 40). This is not correct, as evidence to this point is still needed in litigation in the US, the UK and Europe.

- **In jurisdictions such as the EPC account is taken of situations where it is routine in the art to conduct testing or combine particular approaches in order to solve a particular problem or in order to find a better way of doing things. As such it sets a lower requirement for establishing a lack of inventive step than the Australian requirement in that it accepts that in certain circumstances some degree of routine experimentation would be standard practice for a skilled worker in the art** (para 42). This is not correct in relation to the law in the UK or Europe. The recent House of Lords decision in *Conor Medsystems Inc v Angiotech Pharmaceuticals Incorporated*[1] has adopted a test for inventive step which is very closely based on the test applied in the High Court decision in *Aktiebolaget Hassle v Alphapharm Pty Ltd*[2].

- The question is raised: **whether there is a greater potential for the development of patent thickets in Australia than elsewhere?** (para 29 and para 46). No evidence of patent thickets in Australia is presented and we are not aware that they are a significant problem in Australia (see **Appendix 2)**. It is likely that cost factors limit the number of jurisdictions in which large multinational companies file their patent applications and this may explain why they do not file as many patent applications in Australia. Lower costs in Australia, or making it simple for overseas applicants to obtain Australian patents, may result in thickets. We submit that it would be inappropriate to encourage patent filings here in cases where there is no intention to make a product or process available to the Australian market. This can be contrasted to South Africa where patent applications are filed to secure quick and cheap patents without any intention of marketing a product or process in South Africa.

[1] *Conor Medsystems Inc v Angiotech Pharmaceuticals Incorporated [2008] RPC 28*
[2] *Aktiebolaget Hassle v Alphapharm Pty Ltd (2002) 212 CLR 411*

F. Detailed Comments

1. Our detailed comments on the changes proposed by IP Australia are set out below:

Section 3 – Raising Patentability Standards - Full Description and Fair Basis:

2. The overall premise of the proposed reforms as set out in paragraph 10 is: "Australian standards for full description and fair basis …….are set at levels that are lower than the levels set for equivalent criteria in major jurisdictions, such as the US, Japan, and the European Patent Convention and levels set by the Patent Cooperation Treaty".

3.1 Proposed change

Amend s40 of the Act to:

- introduce descriptive support requirements analogous to those applied in other jurisdictions including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.

3. Paragraphs 12 and 13 of the Paper recognise that the requirements of "full description" (sufficiency) and "fair basis" are the means by which the patents legislation governs the notion that a patent monopoly is a reward for disclosure. If the standards are too high or too low, the policy of granting patents with monopoly breadths that are acceptable to patentees in return for giving information to the public such that they can make and use inventions will not be achieved.

4. Paragraphs 14 to 16 describe the tests for sufficiency and fair basis in Australia. Recent High Court decisions have established that under the current legislation it is only necessary that a patent specification enable the person skilled in the art to produce one thing within each claim. They have also established that "fair basis" only requires consistency between the description and the claims, such that the claims do not "travel beyond" the invention described. These tests, which are at the root of the concerns of IP Australia, are addressed in detail below.

5. Paragraph 17 states: "There is a notable difference between the full description and fair basis requirements in Australia and requirements in the US, Europe and Japan. The US, Europe and Japan all require that the patent specification provide sufficient details of the invention to enable the reader to produce anything across the full scope of the invention claimed."

6. The concerns expressed by IP Australia do not appear to be an issue with respect to mechanical claims, but may be an issue with respect to chemical or biotech claims. Paragraph 17 recognises the issue with respect to such claims: "This [requirement to

enable the reader to produce anything across the full scope of the invention claimed] means that where the claim defines a broad class of invention the specification must provide sufficient details to make any member of that class. For example, where a patent claims a broad class of chemicals, all of which possess a particular chemical or physical property, the specification must provide sufficient detail to enable the reader to make any member of the class. This contrasts with the Australian situation where the requirement is simply that there is sufficient detail to produce something, potentially only one thing, within the scope of the claim. Returning to the chemistry example, Australia's lower standards allow for situations where the specification only provides details sufficient to enable production of one member of a class of chemicals but not all members."

7. As a preliminary point, it is important to note that in overseas jurisdictions, there is no requirement that the specification provide directions for the making of every alternative embodiment. Therefore, we consider that it is important that any change to the Australian legislation be in terms which are not absolute (hence, the use of the word "substantially" in our proposed amendment, see below). Secondly, it is important to note that, at the examination stage, overseas jurisdictions do not require absolute proof that the patent is enabled substantially across the full scope of the claims, but that it is plausible (or credible) that the patent is so enabled.

8. It is also important to remember that, in Australia, unlike important overseas jurisdictions, there is a suite of requirements that deal with related issues. In particular, the UK and Europe no longer have separate requirements of "fair basis" (although "support" can be taken into account on examination) and "utility". Therefore, any comparison between the standards of sufficiency or full description in Australia and in the UK and Europe needs to take into account these other requirements in Australia. So, taking the chemistry example above, an Examiner in Australia cannot reject a claim to a broad class of chemical compounds on the basis that it is not plausible or credible that all of the compounds can be made (as can be done in the UK/Europe), provided that he or she is convinced that one compound can be made. However, if utility or usefulness were a ground of examination an Examiner could theoretically reject such a claim on the basis that it is not plausible or credible that a compound that can be made will achieve the promises made in the specification.

9. As a further preliminary point, it is important to recognize that there is no precise harmony between overseas jurisdictions regarding the law in relation to sufficiency or full description. However, although the approach taken is different in the US, the UK and Europe, each country broadly requires enablement across the scope of the claims (i.e. one way is not necessarily enough). (These tests are discussed in Appendix 1). It is therefore likely that the present test for sufficiency in Australia (as articulated by the High Court), when taken alone, represents a lower standard than that required in any other jurisdiction, as recognized in paragraph 19 of the Paper.

10. We consider that even when one also considers the availability of the requirements of fair basis and utility in Australia, the test for sufficiency or full description may need to be raised for chemical inventions in order to promote the credibility of the Australian patent system. The ground of inutility can make up some of the ground, but it is not necessarily available when a compound cannot be made as opposed to one that can be made but not used. The need to change the law in order to enhance its credibility is

emphasised by the very public criticism of our law of sufficiency by the House of Lords in the recent decision in *Generics (K) Ltd v H Lundbeck A/S* (2009) UKHL 12 (*Lundbeck)* in retaliation for the obiter comments of the High Court in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 62 IPR 461 (*Lockwood v Doric).* Although it would be desirable for the legislation to remain broad and for any change to be brought about by case law, for the reasons explained in **Appendix 1**, this is not a likely scenario in the near future.

11. Finally, in choosing a new standard in Australia, it is important to note that the law in various overseas jurisdictions is in a state of flux. In the UK, the law of sufficiency as laid down by the House of Lords in *Biogen Inc v Medeva Plc* (1996) 36 IPR 438 (*Biogen v Medeva)* has been recently revisited in *Lundbeck*. In the US, the test of "written description" (similar to fair basis) is under challenge. Further, there are proposed changes to the legislation in the US that would bring the law closer to that in Europe. In contrast, the legislation in Europe is most unlikely to change, as it requires the agreement of many signatories to the European Patent Convention. Accordingly, if Australia wishes to harmonise its law with overseas jurisdictions, policy dictates that it move closer towards Europe, as are other jurisdictions.

12. It is not clear whether the change proposed by IP Australia is intended to replace the requirements of fair basis and sufficiency. The conclusion our members have reached is that the requirement of fair basis should be retained (in the way explained by the High Court in *Lockwood v Doric*, it is similar to the requirement of support in other jurisdictions), but that the requirement for sufficiency could be set out in more detail in the legislation.

13. IPTA and FICPI Australia propose the following amendment, which, apart from the requirement for disclosing the best method, is similar to the UK / European legislation together with case law requiring enablement substantially across the scope of the claims:

> *"The specification shall describe the invention in a manner which enables the invention to be performed substantially across the scope of the claims by persons skilled in the art without undue experimentation, including the best method known to the applicant of performing the invention."*

14. As a side issue, while the Australian test for sufficiency may be too narrow and the standard in need of clarification, the standard for utility may be too high and need to be lowered (one thing within a claim that does not work should not in all cases lead to invalidity of that claim).

3.2 Proposed change

Amend s40 and s102 and of the Patents Act to:
explicitly indicate that the requirement for full description is met if the description of the claimed invention was sufficient at the filing date to allow the skilled addressee to perform the invention without undue experimentation.

15. In principle we do not disagree with this amendment. However we point out that in implementing an amendment care would be required to ensure that conflict or uncertainty with regard to other existing provisions was not introduced.

16. In particular, Section 6 already sets a temporal requirement for satisfying full description in relation to micro-organism related inventions, effectively providing a time period up until the day before publication for ensuring that the specification contains the required deposit details. Any amendment to indicate that the full description requirement is to be met at the filing date will need to expressly exclude, or in some other manner take into consideration, the otherwise conflicting provisions of subsection 6(c) and sub-regulations 1.5(3) and 1.5(4).

17. Also, each of subsections 45(1)(a) (examination), 59(c) (opposition) and 138(f) (revocation) are couched in the present tense, that is to say, these subsections indicate that at the time of examination, opposition or revocation, the specification must comply with either Section 40 or subsection 40(2). Therefore, any amendment to introduce the proposed temporal limitation for compliance with the full description requirement will need to be made specifically to subsection 40(2) (rather than, say, the introduction of a further subsection) to ensure that at examination, opposition or revocation, it is the specification at the time of filing that is taken into consideration.

18. The current proposal makes no mention of the "best method" aspect of section 40(2)(a). It is assumed that any change to section 40(2)(a) will, either explicitly or implicitly, also require that the best method known to the applicant be present in the specification at the filing date.

19. On a final note, although we agree in principle with the implementation of the proposed amendment, we point out that such an amendment may potentially be very detrimental to individual applicants or "self-filers", who often do not fully understand or appreciate the statutory requirements, by denying them the opportunity to subsequently correct deficiencies in the description of the invention in specifications which they file.

3.3 Proposed Change

Amend reg 3.12(1)(b) of the Patent Regulations to:

- replace the ‘fair basis’ requirement for establishing the priority date of claims with a descriptive support requirement analogous to those applied in other jurisdictions, and to that proposed for s40.

20. Our members do not support this proposed change. The law on fair basis insofar as it relates to priority claims is well settled. In this regard there is a large body of case law which is of assistance in applying the so called "Mond Nickel" rules for the assessment of priority entitlement. The High Court in its decision in *F Hoffman-La*

Roche & Co AG v Commissioner of Patents (1971) HCA 3; (1971) 123 CLR 529 (22 February 1971) considered the question of priority entitlement with respect to priority claims in the chemical field. No problem has been identified by IP Australia with the current test, and we believe it would not be in the best interests of Australia or Australian industry to raise the requirements for a valid priority claim. Our members believe that it is appropriate for the standard of description necessary for a priority application to be lower than that required for a complete application, since, in this context, the sole purpose of the priority application is to establish a priority date, and not to provide a full description of the invention. This difference is currently reflected in the different wording used in s40(1) relative to s40(2).

21. Any change to raise the standard of description required for priority purposes will be particularly detrimental to individual applicants and self filers who will have the most difficulty in meeting a higher standard of description at the provisional application stage.

22. We also believe that it is inappropriate for IP Australia to look to the laws of the US and UK/EP for guidance in relation to the level of disclosure required for priority purposes. In relation to the US, priority of invention is awarded to the first to invent, rather than the first to file, and the process of awarding priority of invention relies on laboratory notebooks and other materials extrinsic to the priority application itself. It is also important to note that the very strict "photographic" test for priority which operates in the UK/EP is much criticised, both within and outside the jurisdiction, as it can act to deny applicants protection for their inventions due to minor differences in wording between a priority application and the UK/EP application.

23. Our members do not support any change to s40(1) and believe it would be inappropriate to amend regulation 3.12(1)(b) to apply some higher standard for priority entitlement.

Section 4 - Raising Patentability Standards – Inventive Step

24. Again, a premise of the proposed reforms as set out in paragraph 10 is:
"Australian standards for …**inventive step** are set at levels that are lower than the levels set for equivalent criteria in major jurisdictions, such as the US, Japan, and the European Patent Convention and levels set by the Patent Cooperation Treaty".

25. The law of inventive step is the cornerstone of the patent system and therefore it is not surprising that there is significant debate both in Australia and around the world about possible changes to the level of inventiveness required to secure a patent monopoly. If changes are to be made to the level of inventiveness required, our members consider that there should be a full and detailed consideration of the standard of inventiveness that is beneficial to Australian interests. With respect, the Paper includes only a cursory and largely unsupported justification for proposed changes despite this area being one of the most important areas of Australian patent law.

26. Debate about the level of inventiveness required in other jurisdictions, such as the United States and Europe, illustrates that the law in those jurisdictions is not settled. It continues to change depending on the domestic situation and interests of local

intellectual property users. There is likely to be continuing tension between innovators wishing to maximise their monopoly and those who seek to compete in the exploitation of that invention. This involves striking a balance between competing interests such as the desire to foster innovation through grant of monopolies and the conflicting desire to promote competition. Choosing the appropriate level for inventiveness is therefore not as simple as seeking conformity with select foreign laws.

27. The Paper nominates three aspects of the law of inventive step where it contends there is a significant divergence between Australia and other jurisdictions or what it terms "*international norms*". It proceeds on an underlying assumption that the level of inventiveness is set too low in Australia. This is not explored or justified within the Paper and it cannot be taken for granted.

28. The underlying rationale of the Paper appears to be that the law of inventive step diverges from that in other countries and as a result it is deficient. Each of the proposed changes to the law of inventive step appears to be predicated on a desire to ensure conformity with either Europe, the United States or another major trading partner. No real explanation is given why conformity is considered important. With respect, while conformity is one factor to be taken into account in formulating changes to the law, our members consider that a deeper reasoning and analysis should follow before implementing these proposals. Merely because the proposals purport to reflect either the law in the United States or Europe does not make such laws necessarily beneficial for users or the Australian public.

29. Before addressing each of these areas, it is useful to put the Australian law of inventive step into context internationally. There is no international norm or standard test for inventive step. The test for inventiveness is applied differently as between Australia's major trading partners. These jurisdictions have significant differences in their laws and do not conform to each other. Conformity to both European and United States law is not possible in these circumstances.

30. Furthermore, the three proposals for change in Australia have been said by IP Australia to align with the laws of either Europe or the United States. Those laws include other approaches and differences which are not the subject of discussion in the Paper. Such differences highlight the difficulty of considering only one aspect of Australian law at a time and comparing it to a selected foreign regime. It is not appropriate to isolate concepts outside of their operation in the law of that country as a whole. Whilst there are benefits to ensuring conformity in laws, conformity must be carefully considered as a whole and approached so that all changes fit into the Australian patent system and benefit users and third parties.

31. The Paper, in discussing inventive step standards, refers to the concept of "*patent thickets*"[3] arising in Australia and suggests that these thickets may result from the present inventive step requirements set out in the Patents Act 1990. As discussed above in E1 and in **Appendix 2**, there is no evidence to suggest that the level of inventiveness currently required by the Act has resulted in such a situation. In fact, the evidence suggests otherwise.

[3] Paragraph 29

32. The possibility of patent thickets also needs to be considered in light of the implementation of the innovation patent system, both in respect of the level of inventiveness (or innovation) required and the practice of grant prior to certification. Despite suggesting a change to the description requirement for innovation patents by proposing amendment to s40, the Paper does not otherwise deal with innovation patents which are granted for a low level of inventiveness termed "*an innovative step*"[4]. If a low level of inventiveness encourages patent thickets, the first place to deal with such thickets would be a consideration of the innovation patent system.

33. Whilst our members do not see patent thickets as being present and posing a problem in Australia, we consider that the possibility of patent thickets developing in Australia can be avoided by a stringent examination process, for both standard patents and innovation patents. The examination process is an effective means of ensuring that only valid patent rights are granted. Weakness in examination, rather than an inappropriate level of the test for inventive step, is more likely to foster patent thickets and unnecessary patent litigation.

34. Our members consider that one of the most important ways to prevent undesirable patent thickets and a number of unmeritorious patents is to implement a more rigorous search and examination procedure. It is costly for the public to take proceedings in the Federal Court to invalidate or challenge patent rights. The practical reality is that only a small number of patents are ever put under the scrutiny of challenge because of the cost and risk of litigation. This leaves IP Australia with the vital role of ensuring, through examination, that only valid patent rights are granted.

35. In a practical sense, the law and threshold of inventive step is theoretical and means little outside the context of Federal Court proceedings if there is not an efficient mechanism put in place to ensure that invalid claims are strictly tested prior to grant. One particular concern of our members therefore centres around the rigour (or lack thereof) of current examination procedures.

36. The presence of a more stringent examination procedure (rather than changes to the law of inventive step) will have the practical effect of ensuring that undesirable patents with a low threshold of inventiveness are not granted. This will result in a net benefit to all users of the Australian patent system. Our members therefore consider that the focus of any review of inventiveness, and of the patent system in general, should seek to consider the stringency and scope of current examination processes and aim to improve such processes where they are found lacking.

37. Further to the above general comments on the approach adopted by IP Australia for dealing with its concerns on inventive step, the following detailed comments are provided in answer to IP Australia's proposed changes.

4.1 Proposed change

[4] Patents Act 1990 Section 18(1A); See also *Delnorth Pty Ltd v Dura-Post (Aust) Pty Ltd* [2008] FCA 1225 (13 August 2008) at paragraphs [52] and [53] which discuss the differences between inventive step and innovative step. Confirmed on appeal in [2009] FCAFC 81, 30 June 2009

Amend s7(2) of the Patents Act to :

- remove the limitation that common general knowledge be confined to that existing in Australia

38. Our members agree in principle with a proposed change relating to amendment of section 7(2) of the Patents Act to remove the limitation that common general knowledge be confined to that existing in Australia.

39. The present section 7(2) refers to: "*the common general knowledge as it existed in the patent area*". The term "*patent area*" is defined in schedule 1 to be Australia. Presumably, the proposal seeks to remove reference to the words "*patent area*" as confining the common general knowledge.

40. Care must be taken in proposing such an amendment to ensure that it does not result in a need in patent litigation to lead evidence from experts in a number of jurisdictions to show commonality of knowledge on an international scale. Our members also believe that it would be beneficial to associate the reference to common general knowledge with the relevant art.

41. We also point out that in fields where the common general knowledge can be fairly said to be uniform around the world, experts from other countries will be accepted as qualified under our current law. For example, recently, in *Alphapharm Pty Ltd v H Lundbeck A/S*[5] the Federal Court of Australia considered evidence from a range of experts around the world (not just those resident in Australia) to identify the knowledge of the hypothetical skilled chemist.

42. The mere existence of the internet and global communication does not mean that each and every field will be truly global – if that was the case the change would effectively be otiose because the common general knowledge in Australia would be the same as elsewhere in the world.

43. Our members are also mindful that any amendments should have the effect of ensuring that the parties lead evidence from a uniform and precise base of common general knowledge relevant to the field of the invention. For example, we wish to avoid a situation where parties are able to choose experts depending on differing levels of knowledge in different countries to suit their respective cases.

4.2 Proposed change

Amend s7(3) of the Patents Act to:

- remove the requirement that prior art information for the purpose of inventive step must be such that a person skilled in the art could be reasonably expected to have been ascertained, while retaining the requirements that prior art be understood and

[5] [2008] FCA 559 (24 April 2008)

regarded as relevant.

The definition of the prior art base for inventive step will not change.

44. Our members disagree with this proposed change and believe that any valid concerns insofar as they impact on examination (and the lack of evidence available at that stage) can be dealt with by regulation or other changes.

Implementation of section 7(3)

45. The requirements of s7(3) were implemented after a significant consultation period and the publication of the IPAC Report (1984), which included as part of recommendation [13]:

> "We recommend that the common general knowledge in the art be treated as including disclosures in recorded form publicly available anywhere in the world which a skilled person working in the art at the time should **reasonably have been expected to find, understand and regard as relevant.**" [Emphasis added]

46. The IPAC report came after detailed consideration over a number of years of published reports on patent systems in Australia and overseas, submissions by stakeholders, commissioned studies, seminars and materials prepared by the Patent Office.

Removal of the requirement under section 7(3)

47. In summary, the removal of this requirement will:

(a) remove the flexibility inherent in the present system;

(b) result in little, if any, cost saving for patent litigation;

(c) result in greater uncertainty (and cost) by virtue of an expansion of the prior art base for inventive step; and

(d) improperly allow invalidation of patents on the grounds of inventive step even though the person skilled in the art would not have ascertained the prior art reference (i.e. found).

The ascertained requirement of section 7(3) does not result in significant additional costs for litigation

48. The Paper suggests that the present requirement of s7(3) of the Patents Act 1990 results in additional costs for litigation. It cites the decision of *Commissioner of Patents v Emperor Sports Pty Ltd*[6] (Emperor Sports) as an example of a decision where the Federal Court found that information in US Patents would not have been ascertained. It then suggests that evidence may be necessary to establish the ability of

[6] Commissioner of Patents v Emperor Sports Pty Ltd [2006] FCAFC 26 (10 March 2006)

the skilled person and this in turn has the potential to introduce significant additional costs to litigating patent disputes.[7]

49. There is no evidence cited to suggest that the ascertained requirement under s7(3) would or does "*significantly*" result in additional costs in the litigation of patent disputes. The mere suggestion that evidence may be required to establish this criterion does not lead one to the inevitable conclusion that such evidence unnecessarily adds a significant cost to patent litigation.

50. On the contrary, the determination of whether a patent involves an inventive step is almost exclusively a matter that is determined by reference to expert evidence. This occurs independently of the requirements of s7(3) as the test for inventive step is, by its very nature, a matter that requires expert evidence on obviousness because it is ultimately a factual matter and therefore deserving of expert evidence.[8]

51. It is the position of our members that the deletion of the ascertained requirement under s7(3) would not result in any significant or other cost savings in patent litigation. If there is any cost saving, it would be slight given that experts are generally called to give evidence on obviousness (and the processes that they would have followed).

52. As explained below, removal of the test is more likely to introduce uncertainty and the additional cost that flows from such uncertainty.

Alternative avenues for dealing with IP Australia concerns about section 7(3)

53. The Paper suggests that the result in Emperor Sports is an undesirable outcome. However, it must be considered in the context of a decision which relates to re-examination and the first instance decision dealt at length with the onus required during re-examination procedures.[9] Any evidentiary issues arising during re-examination can possibly be dealt with by specific changes to the onus of proof during re-examination. There is no evidence to suggest that the present wording of s7(3) causes difficulty outside the examination/re-examination context.

54. Our members support a rigorous examination process and, subject to further research and formulation, considers that any perceived problems with the "ascertained" requirement of s7(3) could be dealt with in other ways – rather than deleting the requirement entirely. Our members believe that the requirement of s7(3) as it stands serves an important function in determining inventive step.

55. It is useful to consider other avenues for dealing with any perceived problems that arise from the presence of "ascertained" within s7(3). IP Australia appears to be concerned about the administrative difficulties that the requirement of "*ascertained*" under s7(3) poses for it. This is a matter of examination practice and procedure.

[7] See parapgraph [37] of the IP Australia Paper
[8] See Alphapharm at paragraphs [94] to [99] where the Court discusses obviousness as a factual question.
[9] See Emperor Sports Pty Ltd v Commissioner of Patents FCA 996 (25 July 2005)

56. It may be that the "*balance of probabilities*" test, if properly applied during examination, would allow an Examiner to raise and properly maintain an inventive step objection based on a published reference, supported by an explanation as to why the examiner believes that the reference would satisfy s7(3). The Courts have in the past stated that the opinion of an Examiner carries weight as technical opinion of the person skilled in the art, and this could be sufficient to allow the Examiner to meet the criteria under s7(3)[10]. In other words, it is not clear that Emperor Sports necessarily goes so far as to require that independent evidence be produced during examination or re-examination to show that a citation would be ascertained (in all circumstances). An Examiner with technical expertise may be able to make that assertion in some circumstances, provided it is properly supported. Of course, pursuant to Emperor Sports, an Examiner cannot make a blanket statement that a document would naturally be "*ascertained*" without considering the field and putting themselves in the position of the person skilled in the art. Our members consider that there is scope for the Examiner to properly uphold a citation under s7(3) in the appropriate circumstances where the Examiner can develop a reasoned basis to support their view that the document would be ascertained.

57. Any residual administrative problems that arise in determining whether a citation is ascertained could be dealt with by implementing administrative changes to assist in proof and determination of documents under s7(3) during examination, re-examination and possibly opposition. For example, provisions could be enacted, either through statute or regulation, mandating that a published document relied upon to prove lack of inventive step could be assumed to meet the requirements of s7(3) until the patent applicant/patentee proves otherwise. This would be consistent with IP Australia's view that there are a large number of areas where the internet and the global environment dictates that a document would be ascertained. It would also leave it open to a patentee or patent applicant to rely on the section in the appropriate circumstance where the reality is that the document would not be ascertained (and thereby retain the flexibility of s7(3) in its current form).

58. Although not the subject of the IP Australia proposal, a similar evidentiary framework could be put in place in dealing with other evidentiary matters during examination, re-examination and opposition. For example, such changes could consider the proof of common general knowledge and publication date of a document.

Flexibility is a fundamental aspect of the "ascertained" criteria of section 7(3)

59. The Paper suggests that the requirements of s7(3) are not aligned with the "*global innovation environment*" where there is more ready access to information via the internet and electronic means.[11] We disagree.

60. Inventiveness in each case needs to be considered according to its technology and the steps taken by the person skilled in the art (at the priority date). It cannot be said that, merely because the internet exists and there is an amount of widely available information, all inventors (or persons skilled in the art) would automatically access (and ascertain) that information in all fields.

[10] See paragraph [37] of Commissioner of Patents v Sherman [2008] FCAFC 182 (20 November 2008)
[11] Paragraph [38] of the IP Australia paper

61. The Paper appears to suggest that, because the internet exists, in ALL fields of technology the person skilled in the art should be taken to be familiar with the content of the internet (and all other information) throughout the world. This test proposed by IP Australia is presumptive and lacks flexibility. It will be the case that in some technologies a person skilled in the art will search far and wide. In others, the person skilled in the art will for practical reasons be limited in his or her knowledge and create an invention in that context. s7(3) as it stands reflects the realities that face inventing in a particular field, and could be considered to provide a sliding scale depending on the level of sophistication of a particular art field.

62. It may be that in some fields, such as chemistry, the person skilled in the art would consider a wide range of publications both on the internet and through a range of scientific journals. In other areas of technology, mainly lower technology and mechanical areas, experience shows the person skilled in the art is unlikely to consult as widely.

63. The current requirements of s7(3) ensure that one needs to consider the question of "*ascertained, understood and regarded as relevant*". Each of these three words add flexibility.

64. To the extent that the Paper suggests the result in Emperor Sports is wrong, or somehow repugnant or unfair, it is useful to consider the main passages within that decision where the Court considered the steps that would have been taken by the person skilled in the art in ascertaining the relevant prior art document.

65. Emperor Sports was a proceeding concerning the Commissioner and her appeal. She was unsuccessful both at first instance and on appeal to the Full Court. On appeal, the Full Court, Heerey, Kiefel & Bennett JJ, unanimously found that it could not be expected that the person skilled in the art (a Rugby League or Australian Rules coach, referee, umpire or administrator) would conduct a search in the United States Patent Office.[12]

66. The previous practice by IP Australia was to assume that the person skilled in the art would conduct a patent search and therefore US Patents would inevitably be ascertained in all circumstances.[13] It is easy to criticise this approach as it makes no reference to any field of technology. It proposes a "one size fits all" approach that is similar to the one now adopted by Proposal 4.2. The Full Federal Court criticised the Commissioner's approach at paragraph [34] and [35] of the Emperor Sports decision:

> 34 The *Australian Patent Office Manual of Practice and Procedure* says (par 4.2.5.1):
>
> > *"Examiners should generally proceed on the basis that it would be reasonably expected that the person skilled in the art would conduct a search of patent literature, including the patent specifications of major countries, and that [subject to certain exceptions not relevant*

[12] See paragraph [35]
[13] See paragraph [34] of Emperor Sports

> *for present purposes] any patent document located in a patentability search would reasonably be expected to be ascertained by the person skilled in the art."*
>
> We would not wish to cast any doubt on the general correctness of that statement. However, in its own terms it allows that **it is not necessarily universally applicable**; there may be situations where it would not be reasonable to have such an expectation.
>
> 35 The present case is such a situation. **Simply stated, we think it self-evident that it could not be reasonably expected that a Rugby League or Australian Rules coach, referee, umpire or administrator would conduct a search in the United States Patent Office. Such an expectation would be fanciful rather than reasonable.** [Emphasis added]

67. Proposal 4.2 ignores the reality that there are situations where s7(3) is operable, and following the reasoning of the Full Court in Emperor Sports, there are situations where it is not reasonable to have an expectation that the person skilled in the art would have conducted a patent search. Instead of dealing with this reality, Proposal 4.2 seeks to dispense with the "ascertained" requirement provided by s7(3) altogether as inconvenient.

68. IP Australia's approach to the Emperor Sports decision, as reflected in the Paper, appears to suggest that the "ascertained" test is not aligned with the global innovation environment and should therefore be removed.

69. The Paper ignores the flexibility that is provided within the test of s7(3). The Full Court acknowledged the test in s7(3) was a factual one that needed to be applied depending on the situation. When the Full Court considered the situation, they considered that the person skilled in the art would not have, in the circumstances of that invention, conducted a search.

70. Rather than acknowledging the flexibility of the test and acknowledging that the person skilled in the art does not always have access to all information found on the internet and other sources, the Paper seeks to ignore that fact. It proceeds on the presumption that all areas of technology are truly international and that all persons skilled in the art will always undertake extensive searches. This is an oversimplification of matters and has been considered by four judges of the Federal Court to be not generally applicable in all cases[14].

71. The reality is that people do not always appraise themselves of the entire prior art ever published, particularly in practical and low technology fields. For example, a person working day to day in some mechanical fields is less likely to consult literature (and patent specifications from overseas) than a person working in more technically or academically based fields such as chemistry.

72. Emperor Sports highlights the fact that there are some areas of technology where people do not conduct patent searches. It is easy for professionals to immerse

[14] Being the first instance judge and all three judges on appeal in Emperor Sports.

themselves in patents and the internet and forget that the wider world does not see patents in the same way. Not every person looking to develop a new invention searches the internet or patents to provide themselves with the state of technology. If every such person did, then the ascertained requirement of s7(3) would be otiose, which it is not. It is more than just an unnecessary evidentiary hurdle; it is a hurdle that has been put in place for a specific reason (which is expanded below).

73. This highlights what our members consider are the real advantages of having the present requirement of s7(3). It provides a flexible test that is dependent on the technology. In many technologies, the requirements will be met and the evidentiary burden of proving the requirements will either be small or non-existent. In some areas, particularly low technology areas, the requirement of s7(3) will not be met because the reality is that the person skilled in the art would not, in practical reality, have "*understood, ascertained or regarded it as relevant*" a particular citation.

74. Our members contend that the application of s7(3) has an important function.

75. Where the field is truly global and searches are extensive, it will be met and its evidentiary burden will be low in the overall context of evidencing a lack of inventive step. Evidence meeting the requirements of s7(3) can be adduced.

76. Where the criteria of s7(3) cannot be met, it forms an important function in limiting the prior art base information that is available for the purposes of determining inventive step. The Patents Act 1990 should not shy away from a concept merely because it requires evidence to establish. A framework can be put into place to regulate that evidence or provide presumptions as to its existence if necessary.

77. Consider the application of s7(3) in *Insta Image Pty Ltd v KD Kanopy Australia Pty Ltd*[15]. The invention in question concerned an improvement in a collapsible shelter for a caravan. When considering the matter on appeal, the Full Court made the following observations on the evidence:

> 114 Her Honour's conclusion that no additional information was required by s 7(3) of the Act to be taken into account was supported by the evidence. **There was evidence that persons skilled in the art would not have read the earlier US patents and, confronted with the task of designing a portable collapsible canopy, would not have ascertained, understood and regarded as relevant the information contained in those patents.**

78. In other words, the Court considered that the documents should not be used because, pursuant to s7(3), the person skilled in the art would not have ascertained, understood and regarded those documents as relevant.

79. Our members believe that this is a sensible outcome. If the document would not ultimately be ascertained, understood or regarded as relevant, it cannot be said to form a useful starting point for the person skilled in the art. As a consequence, it is appropriate that it should not be available for consideration under s7(3).

[15] [2008] FCAFC 139 (1 August 2008)

The "ascertained" criteria of Section 7(3) has an important role in guarding against hindsight

80. One of the most difficult aspects of determining lack of inventive step is to put hindsight out of one's mind. The difficulties of hindsight have often been lamented by the Courts in Australia and overseas. See for example, the statement of Gleeson CJ, Gaudron, Gummow and Hayne JJ in *Alphapharm* at paragraph [21]:

> 21. The defendant to an infringement action who cross-claims for revocation on the ground of obviousness bears the onus of establishing that case. This obliges the defendant to lead evidence looking back to the priority date, sometimes, as here, many years before trial. In those circumstances, the warnings in the authorities against the misuse of hindsight are not to be repeated as but prefatory averments and statements of trite law. The danger of such misuse will be particularly acute where what is claimed is a new and inventive combination for the interaction of integers, some or all of which are known. It is worth repeating what was said by Lord Diplock in *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd (*16):
>
> "Once an invention has been made it is generally possible to postulate a combination of steps by which the inventor might have arrived at the invention that he claims in his specification if he started from something that was already known. **But it is only because the invention has been made and has proved successful that it is possible to postulate from what starting point and by what particular combination of steps the inventor could have arrived at his invention**. It may be that taken in isolation none of the steps which it is now possible to postulate, if taken in isolation, appears to call for any inventive ingenuity. It is improbable that this reconstruction *a posteriori* represents the mental process by which the inventor in fact arrived at his invention, but, even if it were, inventive ingenuity lay in perceiving that the final result which it was the object of the inventor to achieve was attainable from **the particular starting point** and in his selection of the particular combination of steps which would lead to that result." [Emphasis added]

81. It is tempting, and often easy, to look at an invention with knowledge of that invention and developments after the priority date to suggest that it is obvious. The High Court, and other Courts around the world, has long tried to avoid allowing a hindsight analysis creeping into the test of obviousness.

82. Section 7(3) has the effect of prescribing a starting point from which inventive step is to be assessed. It has the effect of prescribing a starting point that is consistent with information that an inventor (and person skilled in the art) would have available to them at the start of their development.

83. If the reality is that an inventor (and person skilled in the art) would not have ascertained a particular document, it cannot logically form the starting point of their inquiry. A similar thing can be said about the requirements for understood and regarded as relevant.

84. Section 7(3) therefore limits the prior art base in a wholly reasonable and fair manner. It ensures that documents that would otherwise not have been consulted are not used to subsequently suggest that they would have been consulted and rendered the invention obvious. Without the "ascertained" requirement in s7(3) it is all too tempting to look at a document and reconstruct an invention to suggest that it lacks inventiveness. This is to succumb to the temptation of looking at the invention with hindsight. Our members are concerned that removal of ascertained in s7(3) will undermine the test for inventive step and result in more argument on inventive step tainted by hindsight.

Practical problems with expanding the prior art base

85. The determination of whether a patent involves an inventive step is one of the most difficult, and often subjective, matters of patent law. Unlike novelty, which relies on an analysis of a document (or act) and comparison with the claims of a patent, the test for inventive step relies on predicting what a person skilled in the art would have done at the relevant priority date.

86. If the prior art base for inventive step is expanded, the number of documents which can be relied upon to invalidate a patent will consequently rise. This in turn has the potential to cause greater uncertainty in the validity of patent rights.

87. Presently, the prior art base relevant to an assessment of inventive step is limited by those documents prescribed by s7(3). Deleting this requirement expands the prior art base to documents outside the field of the patent and documents that might have been published but are not readily ascertainable.

88. For example, the document might well be published in a library or journal publication of only limited circulation or publication. It will be difficult to ascertain and would not have been ascertained by the person developing the relevant invention. A search of reasonable scope is conducted and the document is not identified because it is an obscure document. A patent is granted. Later the patentee commences proceedings and the document is identified after significant further searches are conducted. The document is then used as a basis to allege lack of inventiveness.

89. Our members believe that this is one foreseeable scenario that could result. It is undesirable because the expansion of the prior art base means that the patentee has less certainty. The patentee had conducted a reasonable search to solve the problem faced but could not reasonably be expected to search every possible location, including those outside their art field. If they did then there would be a substantial and unbearable cost burden. If the patentee did not, which is the practical reality, the patentee lives under the prospect that, despite novelty, an obscure document could be successfully used to challenge its monopoly on the basis of lack of inventive step. This uncertainty is undesirable and has the consequence of weakening already granted patents.

90. The deletion of ascertained in s7(3) also has the potential to encourage challengers to patent rights to spend significant sums in search of prior art using search terms directly obtained from the words of the claims in the hope of finding prior art capable

of invalidating a patent. These documents would not have been found without knowledge of the invention and therefore without hindsight.

Consistency with Overseas Jurisdictions

91. Our members are not aware of the words of s7(3) being present in the legislation of any overseas jurisdictions. This fact is not, however, conclusive that those words should be deleted from Australian law or that the test is not present in overseas jurisdictions. It is submitted that the words of s7(3), as initially conceived by the IPAC Report, reflect matters which are in fact considered in overseas jurisdictions.

92. More specifically, it is submitted that other overseas jurisdictions have manifested similar requirements in the case law built up around inventive step. The consequence is that although the Patents Act 1990 may appear in form to diverge from the prior art base for assessing inventive step in other jurisdictions, such as Europe and the United States, the reality is that, in substance, documents that are not "*understood, ascertained or regarded as relevant*" are excluded during the assessment of inventive step in those jurisdictions.

93. For example, in the Boards of Appeal of the European Patent Office decision in Case No. T0870/96 – 3.4.2 the Boards of Appeal was called to consider the appropriate prior art from which to commence the assessment of inventive step. In considering what document should be adopted it stated as follows:

> "There, as the Board has pointed out repeatedly in the past (see e.g. decision T 66/97, not published OJ EPO), such a generically different document cannot normally be considered as a realistic starting point for the assessment of inventive step. In accordance with established practices of the Boards of Appeal (see the decisions cited as examples in "Case Law of the Boards of Appeal of the European Patent Office"), EPO 1996, Chapter I, D-3.2: "Choice of the closest starting point"), when trying to evaluate a skilled person's capabilities and behaviour in the problem-and-solution approach, as closest prior art a "bridgehead" position should be selected, which said skilled person would have **realistically** taken under the "circumstances" of the claimed invention insofar as these circumstances can be retrieved in one item of prior art. Consequently, among these "circumstances", aspects as the designation of the subject matter of the invention, the formulation of the original problem and the intended use and effects to be obtained should generally be given more weight than the maximum number of identical technical features."
>
> [Emphasis added]

94. The present words of s7(3) in the Patents Act 1990 lead to a "realistic" starting point for selecting an appropriate prior art document to use for the purposes of assessing inventive step.

95. Thus, the law in Europe is not dissimilar even though it does not use the identical wording within the relevant statute. In substance, the law in Europe seeks to make an analysis of the person skilled in the art's behaviour and make a choice of prior art depending on the steps that the skilled person would realistically have taken. As it stands, s7(3) is precisely modelled on the steps that a skilled person would have

realistically taken and is therefore not inconsistent or repugnant to the law in other jurisdictions.

96. Similar considerations apply in the United States where documents which would not have been consulted, for example because they are in a different art field, can be excluded from an inventive step assessment.

4.3 Proposed change

The proposed change seeks to:

- revise the inventive step test to a test where the claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.

97. Our members disagree with IP Australia's proposal to introduce a specific test for assessing inventive step.

98. The effect of Proposal 4.3 is to remove one set of wording which it is submitted is consistent with international norms and to replace that wording with other, less precise wording. This is undesirable and will lead to more, rather than less, uncertainty.

The position in Australia

99. Australia's requirement for inventive step generally accords with the principles governing the examination of international patent applications. That is, both the Patent Co-operation Treaty (PCT) and the Patents Act 1990 Act ask the same question: whether the claimed invention *involves an inventive step*? Both answer that question affirmatively if the invention is not "*obvious to a person skilled in the art*" at the priority date of the claim.

100. Section 18(1) of the 1990 Act relevantly provides that:

> *" (1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:*
>
> *(b) when compared with the prior art base as it existed before the priority date of that claim:*
>
> *(ii) involves an inventive step; …"*

101. Article 33 of the PCT describes international preliminary examination for an application filed under that treaty as follows:

> *(1) The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed*

invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable.

(3) For the purposes of the international preliminary examination, a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art.

…

(5) The criteria described above merely serve the purposes of international preliminary examination. Any Contracting State may apply additional or different criteria for the purpose of deciding whether, in that State, the claimed invention is patentable or not. …"[16]

102. Rules 64 and 65.2 of the Regulations under the PCT provide that the relevant date for testing inventive step is the priority date.[17]

103. It can therefore be seen that the statutory test in Australia is consistent with the wording of the PCT and implementing Proposal 4.3 would move Australia away from (rather than towards) consistency.

Statutes in other jurisdictions

104. Section 1(1)(b) of the *Patents Act* 1977 (UK) provides that a patent may be granted only for an invention if it involves an inventive step. Section 3 of the UK Act states that "[a]n invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) …". Section 2(2) of the UK Act provides:

"The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way."

105. Article 52 of the European Patent Convention (EPC) provides that *"European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."* Article 56 of the EPC provides:

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these

[16] Article 33(5) of the Patent Cooperation Treaty is similar to article 2(2) of the Patent Law Treaty adopted in Geneva on 1 June 2000 which provides that: "Nothing in this Treaty or the Regulations is intended to be construed as prescribing anything that would limit the freedom of a Contracting Party to prescribe such requirements of the applicable substantive law relating to patents as it desires." Similarly, the Paris Convention for the Protection of Industrial Property provides no fetter on each member country's right to prescribe the tests for patentability in that country.

[17] Rule 65.1 of the PCT

documents shall not be considered in deciding whether there has been an inventive step.

106. Article 54, paragraph 3 refers to earlier filed but later published European applications.

107. According to Section 28.3 of the Canadian Patent Act:

"The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

(a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and

(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere."

108. In the United States the test for obviousness is set out in 35 U.S.C. 103, subsection (a) of which appears as follows:

"(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

109. The reference to section 102 is a reference to prior art which would be considered to anticipate the claimed invention.

110. Therefore, each of Australia and its major trading partners require that patentable inventions have an inventive step or are not obvious, tests which are accepted as either sides of the same coin. The question is always whether the invention would be obvious to a person skilled in the art. The only difference between the Australian statute and those applying in Australia's major trading partners is the state of knowledge the skilled person may have resort to when considering obviousness. Accordingly, if Australia were to insert into the 1990 Act a test for obviousness as proposed in the Paper, Australia's statute would be starkly different to those applying in its major trading partners.

The High Court on inventive step

111. The Australian High Court in *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411 (*Alphapharm*) held that it was improper to use the "*obvious to try*" or "*worthwhile to try*" test for determining whether a patent is obvious and so lacked an inventive step. The majority held at [72]:

"the statute does not ask whether a particular avenue of research was obvious to try so that the result claimed therefore is obvious; the adoption of a criterion of validity expressed in terms of "worth a try" or "obvious to try" and the like begs the question presented by the statute. In a sense, any invention that would in fact have been obvious under the statute would also have been worth trying."

112. Our members do not disagree with that conclusion. It is patently correct. In concluding that the "obvious to try" test was inappropriate, the High Court considered that the application of that test in the UK should not be followed, the majority holding:[18]

"Later English decisions applying the 1977 UK Act to chemical and biotechnological patents treat what was said by Diplock LJ in Johns-Manville as synonymous with "worth a try" and "well worth trying out". On that basis, a number of patents have been held invalid for obviousness. These cases include Genentech Inc's Patent upon which Alphapharm relied. The outcome may reflect the approach in European law that "the assessment of inventive step depends upon the extent to which a skilled person would have been technically motivated towards the claimed invention". But cases such as Genentech mark a divergence from the treatment of obviousness in the decisions of this court. The Full Court of the Federal Court recognised this in ICI Chemicals & Polymers Ltd v Lubrizol Corp Inc."

[Footnotes omitted]

113. The House of Lords in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* (2008)[19] (*Conor HL*) has recently made clear that the "obvious to try" test in the UK can only apply where there is a fair expectation of success. The High Court in *Alphapharm* criticized the "worthwhile to try" test adopted by the Full Court of the Federal Court below, but the Full Court's test did not include the requirement of a "fair expectation of success". As Lord Hoffman, who gave the leading judgment in *Conor HL*, observed:[20]

"Jacob LJ ... correctly summarised the authorities, starting with the judgment of Diplock LJ in Johns-Manville Corporation's Patent *[1967] RPC 479, by saying that* ***the notion of something being obvious to try was useful only in a case in which there was a fair expectation of success****. How much of an expectation would be needed depended upon the particular facts of the case. As Kitchin J said in Generics (UK) Ltd v H Lundbeck A/S* (2007) RPC 32, para 72*:*

"The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the

[18] *Alphapharm* at [70]
[19] [2008] RPC 28; [2008] UKHL 49
[20] *Conor HL* at [42]. Lord Walker of Gestingthorpe also appeared to accept that that form of the obvious to try test could apply in certain circumstances but referred, with apparent approval, to Sir Hugh Laddie's criticism that the obvious to try test was unworkable or irrational because the "more commercially attractive the solution and the more pressing the public clamour for it, the harder it will be to avoid an obviousness attack".

possible avenues of research, the effort involved in pursuing them and the expectation of success."" [Emphasis added]

114. Hoffman LJ followed his own holding when sitting in the Court of Appeal in *H. Lundbeck A/S v Generics (UK) Limited & Ors*[21] (also decided after *Alphapharm*) that there is a need for a "high expectation" or "real prospect" of success before something can be said to be obvious as "obvious to try". In that case, there were a number of avenues of research open to the skilled man and he would not have taken the claimed route "unless satisfied there was a "real prospect" that the necessary reaction would work":

*"The claimants' case that the diol route was obvious to try was based upon Dr Newton's opinion that there was a "**high expectation** that the experiment would be a very facile ring closure and that it would work." But the judge rejected this assessment. Once he had done so, his conclusion that the diol route was not obvious seems to me unassailable."* [Emphasis added]

115. The High Court, in denouncing use of the "obvious to try" test for obviousness also observed at [73] and following that, in the United States, "any criterion which adopts a notion of "obvious to try" has been rejected in a long series of decisions upon §103 of the 1952 US Act." The High Court quoted the following passages of Judge Rich in two separate cases in the United States:

*"Slight reflection suggests, we think, that there is usually an element of "obviousness to try" in any research endeavor, that it is not undertaken with complete blindness but rather with **some semblance of a chance of success,** and that patentability determinations based on that as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of "research.""*[22]

[Emphasis added]

And:

*"[F]or many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a **possibility of unexpected results**, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious."*[23] [Emphasis added]

116. Our members consider that the highlighted parts of Judge Rich's statements above indicate that the obvious to try test his Honour rejected did not include a "*fair expectation of success*" element. Regardless, since the High Court's decision in Alphapharm, the United States Supreme Court in *KSR International Co v Teleflex Inc*

[21] [2008] EWCA Civ 311, [2008] RPC 19 at [25]
[22] *Application of Tomlinson* 363 F 2d 928 (1966) at 931
[23] *Re O'Farrell* 853 F 2d 894 (1988) at 903

(2007)[24] (*KSR*) has clearly overruled the line of authority relied on by the Australian High Court.[25] The Supreme Court held in KSR:[26]

> *"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has* ***good reason to pursue*** *the known options within his or her technical grasp. If this leads to* ***the anticipated success,*** *it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."* [Emphasis added]

117. Thus, the US now also permits an "obvious to try" test in circumstances where there is "good reason to pursue…the anticipated success". This is fundamentally akin to the "fair expectation of success" approach taken in the UK.

118. The High Court in *Alphapharm* considered[27] that the United States' approach (now overruled by *KSR*) was close to that adopted in *Minnesota Mining and Manufacturing Co v Beiersdorf (Aust) Ltd* (1980) 144 CLR 253; 29 ALR 29 and *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262; 34 ALR 213. However, neither of those cases rejected the use of the "obvious to try" test with a fair expectation of success element. The test applied by Aickin J in *Wellcome Foundation*[28] was:

> *"whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not."*

119. As the majority in *Alphapharm* explained, the test was whether the experiments were "part of" that inventive step claimed in the patent or whether they were "of a routine character" to be tried "as a matter of course"?[29] The majority went on to observe that Aickin J's test had an affinity with a test for obviousness proposed by Graham J in *Olin Mathieson Chemical Corp v Biorex Laboratories Ltd*:[30]

> *"****Would the notional research group at the relevant date,*** *in all the circumstances, which include a knowledge of all the relevant prior art and of the facts of the nature and success of chlorpromazine,* ***directly be led as a matter of course to try*** *the -CF3 substitution in the "2" position in place of the -C1 atom in chlorpromazine or in any other body which, apart from the -CF3 substitution, has the other characteristics of the formula of claim 1****, in the expectation that it might well produce a useful alternative to or better drug than chlorpromazine or a body useful for any other purpose?"*** [Emphasis added]

---

[24] *KSR International Co. v. Teleflex, Inc.* 550 U.S.__ S. Ct. 1727, 82 U.S.P.Q.2d 1385 (30 April 2007); see also Blows, J. *Obviousness: did the High Court of Australia get it wrong?* (2007) 20(6) AIPLB 93
[25] See Blows, J. *Obviousness: did the High Court of Australia get it wrong?* (2007) 20(6) AIPLB 93.
[26] *KSR* 550 U.S. ___ S. Ct. 1727, 82 U.S.P.Q.2d 1385 (30 April 2007) at p.17
[27] *Alphapharm* at [76].
[28] (1981) 148 CLR 262 at 286; 34 ALR 213 at 228
[29] *Alphapharm* at [52]
[30] [1970] RPC 157

120. In *Olin Mathieson* the invention was a solution to a known problem in the art, namely finding alternatives to an existing drug. Accordingly, Graham J's test can be summarised as: "Would the skilled person be directly led as a matter of course to try the claimed process in the expectation that it might well produce an answer to the problem". The majority in *Alphapharm* held that this approach should be accepted.[31] Therefore, the test for obviousness expressly approved by the majority in *Alphapharm* has the same "expectation of success" requirement applied to the "obvious to try" test in the United States and the UK. Canada has also recently approved the "obvious to try" test in that form.

121. On 6 November 2008, the Supreme Court of Canada (seven judges sitting) in *Apotex v Sanofi-Synthelabo Canad Inc & Ors* (2008) SCC 61 (*Apotex v Sanofi)* considered the Court of Appeal's decisions in *Conor CA* and *H. Lundbeck A/S v Generics (UK) Limited* and the US Supreme Court's decision in *KSR, Apotex v Sanofi-Synthelabo Canada Inc & Ors* and concluded:[32]

> *"For a finding that an invention was "obvious to try", there must be evidence to convince a judge on a balance of probabilities that it was more or less* ***self evident*** *to try to obtain the invention.* ***Mere possibility that something might turn up is not enough.****"* [Emphasis added]

122. That is, in Canada the "obvious to try" test is only able to be used where there is a reasonable expectation of success not a "mere possibility something might turn up".

123. Accordingly, our members are of the view that, in Australia, in certain circumstances, inventive step may be tested by asking whether it was obvious to try the claimed invention with a reasonable expectation of success. There is no need to "*revise the inventive step test to a test where the claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success"*.

124. It is appropriate to keep the test for inventive step as broadly stated in section 7 of the 1990 Act and let the Courts develop that test as societal norms and policy change. It also seems appropriate to allow Australian courts to take guidance from development and interpretation of the test for obviousness or inventive step in other jurisdictions rather than be pinned down to a very prescriptive test.

The obvious to try test has limited applicability

125. The Canadian Supreme Court in *Apotex v Sanofi* observed that the "obvious to try" (with a reasonable expectation of success) test was not appropriate to be used for all kinds of inventions. Rothstein J (who delivered the leading judgment) held at [68]:

> *"In areas of endeavour where advances are often won by experimentation, an "obvious to try" test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an "obvious to try" test since there may*

[31] *Alphapharm* at [53].
[32] *Apotex v Sanofi-Synthelabo Canad Inc & Ors* (2008) SCC 61at [66]

be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances."

126. That paragraph was under the heading "When Is the Obvious to Try Test Appropriate?" and was followed by the sentence "If an "obvious to try" test is warranted …". Accordingly, the Canadian Supreme Court implicitly recognized that the "obvious to try" test was not appropriate for all kinds of inventions. The antithesis of "advances … won by experimentation" are inventions which lie in the identification of a solution to an unknown problem. That is, how can it be said to be obvious to try something when there is no need or desire to try it?

127. In *KSR* the United States Supreme Court noted that the "obvious to try" test should be used where there was "a design need or market pressure to solve a problem." Implicitly, the Supreme Court recognised that the "obvious to try" test was not appropriate where the invention lay in the identification of the problem or a solution to a new or unappreciated problem. Similarly, the House of Lords in *Conor HL* recognised that the "obvious to try" test was not appropriate in all circumstances.

128. The majority of the High Court in *Alphapharm* was also aware of this problem. Their Honours paraphrased Aickin J's conclusion in *Wellcome Foundation*[33] as follows:[34]

"(i) inventions may be the result not only of long experiments and profound research but also of chance, sudden lucky thought or mere accidental discovery; (ii) not all inventions are to be classified as successful solutions to a problem which had presented a "long-felt want"; (iii) to the contrary, inventions which are an advance of contemporary expectations and thus reveal an "unfelt want" may well involve an inventive step; and (iv) in cases falling within (iii), experiments and research would throw no light on the quality of what was claimed as an inventive step."

129. The majority in *Alphapharm* observed that the "directly be led as a matter of course to try with an expectation of success" test for obviousness was not appropriate when the invention lay in perceiving "the true nature of the problem" to which "straightforward experiments" then would provide the solution.[35] It can be assumed that the High Court would take a similar view as to the application of the "obvious to try" (with a reasonable expectation of success) test for obviousness.

130. What the Paper proposes is to apply a "one size fits all" test for obviousness which does not in fact make sense for all kinds of inventions. The Paper proposes that the test for obviousness be whether it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success.' What is meant by "suggested" is not clear. Does it mean, for example, suggested "by the patent" or "by the prior art"? If it is to be suggested by the:

---

[33] *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 272, 279, 287; 34 ALR 213 at 217-18, 223, 229-30

[34] *Alphapharm* at [38]

[35] *Alphapharm* at [52].

(a) prior art, then inventions which lie in perceiving the true nature of the problem can never be found lacking inventive step because there can be no suggestion in the prior art;

(b) patent, then inventions which lie in perceiving the true nature of the problem to which straightforward experiments then would provide a solution will always be found lacking inventive step.

131. Either approach fails to strike an appropriate balance between the needs of inventors and society. What is meant by "approach, alternative or method" in IP Australia's proposal is equally confusing. To proceed with such a test would create great uncertainty.

132. Our members are of the view that the present test for inventive step as stated in section 7 of the 1990 Act provides the Courts with a suitably flexible regime in which to test the validity of a patent for obviousness. Importantly, the law as it stands is largely analogous to that of its major trading partners so that the Courts in Australia can, where appropriate, take guidance from the development of the law of obviousness in those jurisdictions. The proposed change to the test for inventive step will not only fail to achieve its stated aim, but further distance Australia from the law in the jurisdictions of its major trading partners.

133. IP Australia's proposal to revise the test for inventive step is exactly the kind of thing Lord Diplock warned against in *Johns-Manville Corp's Patent* [1967] RPC 479 at 493-4:

> *"I have endeavoured to refrain from coining a definition of "obviousness" which counsel may be tempted to cite in subsequent cases relating to different types of claims. Patent law can too easily be bedevilled by linguistics, and the citation of a plethora of cases about other inventions of different kinds. The correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act in some particular verbal formula.* ***I doubt whether there is any verbal formula which is appropriate to all classes of claims.****"* [Emphasis added]

134. The last sentence was emphasised by the majority of the Australian High Court with apparent approval in *Alphapharm* at [37]. With respect, this is precisely what is proposed by Proposal 4.3 – introduction of an unnecessary verbal formula that attempts to coin a definition of obviousness.

135. Our members submit that there is no better wording than the core words "inventive step" themselves, such as presently exist in the Patents Act 1990.

Section 5 – Improving Certainty - Requirements Considered During Examination, Re-examination and Opposition

136. A premise of the proposed reforms as set out in paragraph 11 of the paper is:

"Currently, there are inconsistencies between the grounds that the Commissioner of Patents can consider during examination, re-examination and opposition proceedings".

5.1 Proposed change

Amend the Patents Act and/or Regulations to:

- include usefulness among the grounds considered during examination and re-examination and clarify that the requirement for usefulness is only satisfied if the patent specification discloses a specific, substantial and credible use for the invention.

137. The Paper states that "[u]sefulness relates to the principle that patents should not be granted for inventions that are not useful i.e. that have no practical application or that do not work. Currently, usefulness is only a ground for opposition and revocation through the courts, and is not among the criteria assessed during examination." It is proposed in the Paper that the Patents Act and/or Regulations be amended to "include usefulness among the grounds considered during examination and re-examination and clarify that the requirement for usefulness is only satisfied if the patent specification discloses a specific, substantial and credible use for the invention."

138. Our members support the inclusion of "usefulness" as a ground to be considered during examination and re-examination. However, our members oppose any amendment of the Patents Act and/or the Regulations as proposed by IP Australia to "clarify that the requirement for usefulness is only satisfied if the patent specification discloses a specific, substantial and credible use for the invention" for the reasons set forth below.

139. The Paper states that it is the aim of the Paper to "raise Australian standards to a level that is more consistent with the general levels set in countries such as the US, Japan and European countries with which we conduct the majority of our technology trade." (Paragraph 8)

140. It is notable that while, for example, the US[36], the EPC[37] (and therefore the UK Patents Act) and Japan[38] provide for patents to be granted for inventions which are,

[36] 35 U.S.C. §101: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

[37] Article 52 of the EPC: "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application." Similarly Section 1 of the UK Patents Act: "A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say - (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application....."

[38] Article 29 of the Japanese Patents Act - "(1) An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention....."

inter alia, useful or, as it is also worded, industrially applicable, there is no provision in any of their Acts to govern what must be included in the patent specification in order to satisfy the requirement for usefulness. Instead, in the aforementioned jurisdictions, guidelines are provided to Examiners for examination of patent applications to ensure they meet the required threshold of usefulness.

141. In the US, Code 35 provides conditions for patentability in respect of novelty and inventive step, 35 U.S.C. 102 and 35 U.S.C. 103 respectively, but there are no conditions for patentability in respect of usefulness enshrined in the Code. The US Patent Rules too are silent as to the treatment of usefulness in examination. Thus 37 CFR §1.104 entitled "Nature of Examination" is silent as to the treatment of usefulness but deals with the rejection of claims for want of novelty or obviousness.[39] Instead, the issue of utility (usefulness) is dealt with in the Manual of Patent Examining Procedure (MPEP)[40]. §§2107.01-2107.03 of the MPEP sets out the guidelines to be followed by Examiners in making a rejection based on lack of utility.

142. Hence, if the Australian Patents Act and/or Regulations were to be amended to include the requirement that the patent specification discloses "a specific, substantial and credible use for the invention", it would result in a divergence in practice between Australia and the US.

143. With regard to Europe, Article 57 of the EPC governs industrial applicability but the Article merely provides that: [a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. There is therefore no requirement in Europe for the patent specification to disclose a "specific, substantial and credible use for the invention.". Likewise, the Regulations do not require that the patent specification disclose "a specific, substantial and credible use for the invention". Rule 42(1)(f) of the EPC Regulations specifies that the description shall "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable." Hence, it is only in the specific circumstances set out in Rule 42 that it is necessary to specify the industrial applicability of the invention.

144. Similarly to the US MPEP, the Guidelines for Examination in the European Patent Office[41] contain information to assist an Examiner in examining for industrial applicability. There is also no requirement in the Guidelines that the Examiner must examine for a "specific, substantial and credible use for the invention".

145. Once again, if the Patents Act or Regulations was amended as proposed by IP Australia, it would result in a divergence between the way usefulness/industrial applicability is assessed in Europe and in Australia. Even adoption of a "specific, substantial and credible" test in assessing usefulness during examination/re-

---

[39] 37 CFR §1.104(c)(2)

[40] 37 CFR §706.03(a) II & 37 CFR §§2107.01 - 2107.03

[41] Guidelines: Part C, Chapter IV - Patentability - 5. Industrial Application.

examination would impose a far higher threshold of usefulness on Australian applicants than applies in Europe.

146. Article 29 of the Japanese Patents Act does not seek to limit how industrial applicability must be set out in the patent specification. Moreover, the Examination Guidelines for Patent and Utility Model (sic) in Japan are silent as to a generic test for assessing industrial applicability[42]. Instead, the Guidelines list specific examples of matters which are regarded as not being industrially applicable.

147. In summary, none of Australia's major trading partners has any specific requirement enshrined in its legislation or regulations governing how usefulness/industrial applicability is to be assessed. In the case of the three major trading partners referred to above, the manner in which usefulness/industrial applicability is assessed is set out in guidelines for Examiners.

148. Our members support usefulness being examined during examination and re-examination, but are strongly of the view that specific requirements for assessing usefulness should be enshrined in the Act and/or Regulations. As is the case in other jurisdictions, our members are of the view that the Examiner's Manual is the appropriate place for guidelines for examining for usefulness.

149. It is noted that the USPTO Revised Interim Utility Training Materials[43] direct to Examiners to assess whether any asserted utility is specific and substantial and, if so, to then determine whether such asserted utility is credible (page 3). It appears that these Training Materials were established to deal with issues which are specific to biotechnology and chemical compound matters. Our members do not believe that such a test is appropriate for all technologies. Such a test could have adverse, unintended consequences. For example, what would be the case if a use is asserted in the specification which is not met by the invention as claimed but the invention as claimed has another use? Such a new use may not meet the "specific" leg of the test as contemplated.

150. Our members are also concerned that the words "specific, substantial and "credible" are of uncertain scope. For example, does "substantial" mean very significant or simply non-trivial? Does "credible" mean something more than simply plausible? How specific does a utility have to be? There is also the danger that, even if these terms are defined, for example, as set out in the USPTO Training Materials referenced above, Examiners may place too high a threshold on the terms "specific" and "substantial". Not only would this impose a usefulness threshold in Australia which is higher than in the other jurisdictions, it would also place a greater evidentiary burden on an Australian patent applicant than an applicant in those jurisdictions. We also believe that including a test requiring a "specific, substantial and credible" use would result in greater uncertainty for patent applicants and the loss of an entire body of jurisprudence relating to the present test for "usefulness". It is noteworthy that neither TRIPS nor the AUSFTA requires such a test.

---

[42] Examination Guidelines for Patent and Utility Model in Japan - Part II - Requirements for patentability - Chapter 1 - Industrially Applicable Inventions

[43] Accessible at: www.uspto.gov/web/menu/utility.pdf

151. We recommend that the present test for usefulness, i.e. whether or not the invention as claimed fulfils its promise, be retained and that the Examiner's Manual be updated to assist Examiners in examining for usefulness based on the existing test. Examination of the utility requirement could take into account concepts such as "sound prediction" or "plausibility". Such an approach has been adopted in Canada[57].

5.2 Proposed change

Amend s.45 of the Patents Act to:

- include prior use among the grounds considered during examination and re-examination.

152. Our members do not object to this proposed change, but question its value.

153. It appears this proposed change would require the deletion of s45(1A) and s98(2) of the Patents Act which exclude prior art information made publicly available only through the doing of an act.

154. At the present time information made publicly available only through doing an act, such as sale or public demonstration cannot be considered during examination or re-examination of an application. Presumably, this is because information relating to prior use is not readily available to the Examiner. As a result, prior use has been restricted to opposition and revocation proceedings where suitable evidence provided by an opponent or party seeking revocation may be relied on.

155. It is proposed in the Paper that the situation has now changed and information relating to prior use is readily available through the internet, and that Examiners would not need to rely on evidence provided by third parties to allege prior use.

156. We point out, however, that in order to establish that a prior use has occurred, clear evidence is required. Thus, any information obtained by an Examiner from the internet would need to establish that the product or process used was a product or process encompassed by the claimed invention, that the alleged use occurred before the priority date, that the use was a public use that made all of the required information available to the public, and that the information is a true record of a prior use.

157. In Europe, prior use is available as a ground of rejection during examination, opposition and revocation. In the Guidelines for Substantive Examination, Chapter IV, part 6.1 indicates that the state of the art available to the Examiner will consist of written description, either alone or in combination with an earlier oral description or use. The Guidelines state:

"The only other problem likely to arise for the Examiner is where:

[57] Apotex Inc v Wellcome Foundation Ltd., [2002] 4 S.C.R. 153, 2002 SCC 77

(i) a document reproduces an oral description (e.g. a public lecture) or gives an account of a prior use (e.g. display at a public exhibition); and

(ii) only the oral description or lecture was publicly available before the "date of filing" of the European application, the document itself being published on or after this date.

In such cases, the Examiner should start with the assumption that the document gives a true account of the earlier lecture, display or other event and should therefore regard the earlier event as forming part of the 'state of the art'. If, however, the applicant gives sound reasons for contesting the truth of the account given in the document then again the Examiner should not pursue the matter further".

158. The standard of proof required in the EPO is a "beyond reasonable doubt" standard.

159. Under United States jurisprudence, the standard of proof required of prior knowledge or use is one of "clear and convincing evidence" (Barbed Wire Patent Case [33 F. 261 (C.C.N.D. Iowa 1888) rev'd 143 U.S. 275 (1892)]. This standard has been applied in subsequent cases of alleged prior use (*Eibel Process Co. v. Minnesota & Ontario Paper Co*. 261 U.S. 45(1923), *Woodland Trust v Flowertree Nursery Inc.* (148 F. 3d 1363 (Fed Ct 1998).

160. In light of the above overseas guidelines and jurisprudence, and the standard of evidence required to establish prior use of a claimed invention, we could consider that if an applicant/patentee contests a prior use objection, it appears unlikely that the objection could be maintained during examination or re-examination.

161. Therefore, the effect of expanding the grounds of examination and re-examination to include the ground of prior use is likely only to have the effect of placing information of alleged prior use on the record so that it may be further investigated and supported by evidence by a third party during opposition or revocation proceedings.

162. While our members have no objection to the amendment in principle, we consider it unlikely that an Examiner could maintain an objection of prior use if it was contested by the applicant/patentee.

5.3 Proposed change

Amend s.98 of the Patents Act to:

- expand the grounds for re-examination to all of the grounds considered during normal examination.

163. Our members do not object to this proposed amendment.

164. Currently re-examination is available to the Commissioner after acceptance of an application but before grant, or to the Commissioner, the patentee or any other person after the grant of the patent, or it may be directed by a court during court proceedings. Re-examination at present only addresses the issue of whether the claims are novel and inventive in light of the prior art base as it existed before the priority date. No other grounds of re-examination are available.

165. Re-examination requested by the patentee or a third party is an inexpensive and rapid means of ascertaining the validity of a claim in light of prior art that may not have been identified before grant of a patent.

166. In 2000, the Patents Act 1990 was amended to include new s97(1) allowing the Commissioner to re-examine a patent application after acceptance but before grant in light of newly identified prior art not considered during examination. This amendment allows the Commissioner to re-examine an accepted specification in light of documents submitted in evidence in an opposition that was withdrawn before consideration of the documents or in light of documents cited in the results of documentary searches notified by the Patent Office under s45(3). In this case there is no requirement to re-examine the claims on the basis of other grounds, such as section 40 matters, as it is unlikely that new information relating to these matters would have become available since the examination of the application.

167. There may be some benefit to patentees or third parties requesting re-examination after grant to be able to affirm the validity of granted claims in light of new information or when there is case law that affects other patentability criteria.

Section 6 – Improving Certainty – Balance of Probabilities

168. A premise of the proposed reforms as set out in paragraph 11 is:
"Currently, there are inconsistencies between ……..the standards of proof applied (by the Commissioner of Patents in examination, re-examination and opposition proceedings) and the …….standards applied by the courts in revocation proceedings".

6 Proposed change

Amend the Patents Act to:
clarify that ‘balance of probabilities’ is the standard of proof applied to all requirements during examination, re-examination and opposition proceedings.

169. Our members do not object to this proposed amendment, but believe that a detailed review should be conducted to ascertain whether this will result in any "issue estoppel" should an unsuccessful opponent wish to pursue revocation on the basis of grounds considered during opposition. If such issues arise, consideration should be

given to whether this will result in unforeseen consequences, and whether any of these consequences detract from the operation of Australia's patent system.

G. Summary of submission

1. The title page of the Paper suggests that the current IP rights system in Australia lacks balance. From the executive summary, IP Australia appears to be suggesting that there is a lack of balance in Australia between the patent system on the one hand and competition on the other. The Paper also states that for the system to support innovation the exclusive rights associated with the grant of a patent need to be balanced by:

   - Access to information about new inventions

   - Patent standard set a level that does not discourage local innovators from conducting follow-on innovation and without certainty in the validity of granted patents.

2. Our members believe that it is very important for the Australian patent system to be balanced but do not accept that there is a lack of balance of the type suggested by IP Australia in the Paper. We also believe that a great many factors need to be balanced in order for the patent system in Australia to function effectively for the benefit of Australians and Australian industry while, at the same time, meeting international obligations. The issues identified by IP Australia in this Paper, while important issues in contributing to a balanced system, represent a mere subset of the factors which need to be balanced for effective working of the patent system.

3. We believe that a number of factors have not been taken into consideration by IP Australia in preparing the Paper, some of which are mentioned in our submissions. Of particular concern is the lack of attention given to the make up of Australian industry and the resources that may be available to Australian industry in preparing the patent applications, particularly when an applicant only wishes to pursue patent protection in Australia, New Zealand and parts of Asia. It is also not possible to consider the balance of the patent system without giving due consideration to issues relating to infringement, and taking into account the way in which the doctrine of equivalents operates in some countries to expand the scope of claims beyond their literal scope.

4. Above all, our members are concerned that IP Australia, in considering the issues discussed in the Paper has not looked more closely at its own practices and procedures to see whether those can be improved to provide better quality examination and better quality patents. For example, it is clear to our members that the current approach of IP Australia examination, which relies largely upon foreign patent offices for conducting searches and examination on Australian applications derived from overseas, does not lead to quality patents in Australia. The patentability standards in Australia are set by a combination of case law and legislation. It is only possible to achieve quality in the examination process if Australian patent applications are examined to those standards. Accordingly, examination conducted under the PCT or foreign standards are only of limited use. It is also apparent to our members that although aspects of current examination are to be conducted by applying a "balance of probabilities" standard, this does not appear to be occurring. There appears to be some disincentive within IP Australia for Examiners to maintain objections and issue

further reports. One contributing factor might be the lack of credit given to Examiners for maintaining objections and raising further reports.

5. In the Paper, IP Australia has indicated that it is important for the system to provide certainty in the validity of granted patents. This can only be achieved if patent applications are examined against Australian standards. Raising patentability standards in Australia without a consequential improvement in the rigour of search and examination conducted by IP Australia will not achieve the desired result, but rather is more likely to lead to the granting of more patents that do not meet Australian patentability standards.

6. In summary, our members believe that the current patent system in Australia is well balanced and needs little, if anything, in the way of amendment to improve that balance. In fact, our members believe strongly that implementing amendments on the scale proposed by IP Australia in the Paper is most certain to result in a system which is unbalanced. In view of the variety of interests which need to be balanced within a patent system, any changes to the system should be made in a carefully considered manner, allowing an appropriate amount of time to monitor the effects on the system of those changes. Our members believe that the high frequency of changes to Australian patent law, particularly in connection with substantive patentability requirements, reduces certainty for both applicants and third parties and contributes to Australia's poor reputation in this area. It should be noted that Australia already has three different tests for inventive step depending on the filing date of the patent application. A fourth test is now proposed. This is to be contrasted to the situation in the United States and Europe, where amendments to patent legislation are rare. In the United States, in particular, case law is relied upon to set the appropriate patentability standards based on the applicable legislation.

7. Our members believe that any shortcomings identified by IP Australia in the Paper could he addressed by stricter implementation of the balance of probability standard in examination of novelty and inventive step, and changes to the practices and procedures of IP Australia to ensure better quality search and examination. Our members do not have any objection to expanding the grounds for examination and re-examination, and in applying the "balance of probabilities" standard to the grounds considered during examination, re-examination and opposition. In particular our members believe that examination of usefulness and introduction of appropriate guidelines for the examination of usefulness or utility could be all that is required to enable rejection of unduly speculative claims, particularly in the chemical area.

8. Our members have considered IP Australia's specific proposals on their merits. We have done this to the greatest extent possible given the short time frame available. Our members hope that the views expressed in these submissions will be taken into account as IP Australia considers the best way forward to ensure that the patent system in Australia operates in the best interest of Australia and Australian industry, while meeting international obligations. In view of the substantial nature of the proposed changes, we urge IP Australia to refer any concrete proposals for amendment to ACIP or a similarly constituted independent group for detailed consideration before implementation.

9. IPTA and FICPI Australia will be pleased to answer any queries which may arise from these submissions, and to participate in further discussions in connection with any concrete proposals to amend Australia's patent legislation.

Yours sincerely

Michael J Caine
Convenor - Legislation Committee
Institute of Patent & Trademark Attorneys of Australia

Greg Chambers
Secretary
FICPI Australia

cc: Linda Tocchet, The Institute of Patent and Trade Mark Attorneys of Australia, Level 2, 302 Burwood Road, Hawthorn, Victoria 3122 – by email linda@ipta.org.au

Acknowledgments:

IPTA and FICPI Australia would like to acknowledge the extensive work done by Katrina Howard SC in travelling to the US, UK and Germany to conduct research in relation to the way sufficiency of description is assessed in those jurisdictions, and her work in comparing Australian inventive step law to the tests for inventive step applied in the UK and US. Our members also wish to gratefully acknowledge the following persons for discussing these issues with Katrina Howard SC. These discussions have formed the basis for some of these submissions, although they do not necessarily reflect the views of any such persons:

USA – Gordon Kit Esq. Senior Counsel, Sughrue, Mion PLLC, Washington DC; Teresa Rea, Crowell & Moring, President AIPLA, Washington DC; Paul Davinsky, McDermott, Will & Emery, Washington DC.

UK – Lord Justice Hoffmann; Lord Justice Jacob; Justice Kitchin; Justice Floyd; Simon Thorley QC, Head of Chambers, 3 New Square, counsel, inter alia, in Lundbeck; Andrew Waugh QC, 3 New Square, counsel, inter alia, in Lundbeck; Colin Birss QC, 3 New Square; Claire Baldock, Boult Wade Tennant, London.

Europe - Dr Mark Weaver, Director, EPO, and Dr Guy Glod, Examiner, EPO; Jon Gowshall, Forrester & Boehmert, London; Dr Markus Engelhard, Boehmert & Boehmert, Munich.

IPTA and FICPI Australia would also like to thank representatives of the American Intellectual Property Law Association, Chief Judge Paul Michel of the United States Federal Circuit Court; Dr William Christiansen, Seed IP, Seattle; Aiden Robson, Reddie & Grose, London; Dr Bill Tyrrell, GlaxoSmithKline, Brentford; and Trevor Cook, Bird & Bird, London for their contributions and useful insights into the issues raised by IP Australia.

APPENDIX 1

THE CURRENT AUSTRALIAN TESTS – SUFFICIENCY

1. The decisions of two differently constituted High Courts in *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1 (*Kimberly-Clark)* and *Lockwood v Doric* have generally been taken as authority that a patent will be sufficient if you can produce one thing only within each claim without (in different terms) undue experimentation.

2. *Kimberly-Clark* is regarded as binding authority on the issue of sufficiency, despite the fact that this case was decided on an entirely different point, based on earlier UK legislation, as to whether there was a requirement that the complete specification "sufficiently and fairly describe and ascertain the nature of the invention" as opposed to "the manner in which the invention [was] to be performed" (see para [25]). Further, the *Kimberly-Clark* case concerned a patent for a nappy, not a patent to a class of products, e.g., chemical or biological compounds. No issue arose as to whether there was a need for enablement across the full scope of the claim.

3. Although the point was *obiter dicta* in *Lockwood v Doric*, the High Court made very strong statements supporting the view expressed in *Kimberly-Clark* at [103]: "…but Doric, while willing to attempt to sap life from *Kimberly-Clark*, prudently eschewed any attack upon that binding authority".

4. The "one way only" approach of *Kimberly-Clark* has been applied by Australian Courts in relation to all types of patents, including chemical patents, as well as by IP Australia.

5. In *Eli Lilly and Company v Pfizer Overseas Pharmaceuticals* (2005) FCA 67 (10 February 2005) (the Viagra case), Eli Lilly argued that *Kimberly-Clark* was not binding authority on the question of "enablement" because it was concerned with a different question (as noted above), being a description of the nature of the invention as opposed to how to perform it. Eli Lilly also argued that the decision concerned a "mechanical-type" patent only, as did the authorities relied upon by the Court (e.g. *Valensi*, referred to in *Blanco White*, cited by the Court at [25]) and that the test must be applied differently in relation to chemical patents, as in the Viagra patent. That is, the claim in *Kimberly-Clark* was a species and should not be applied to chemical cases involving a genus (i.e., *Kimberly-Clark* is inapt for genus claims). Further, the current UK law, which derives from the same case as ultimately relied upon by the High Court in *Kimberly Clark* (*Valensi*), requires a higher standard for chemical cases than "one way only" in all cases (see below).

6. The Full Court noted at [330] that, whether or not the statement in *Lockwood v Doric* was *obiter*, it was a considered statement of a unanimous bench of the High Court and should be followed by a judge at first instance. They held (at [333]) that one embodiment was enough. The Court also noted at [335] that Eli Lilly reserved the right to argue before the High Court that the test in *Kimberly-Clark* and in *Lockwood v Doric* was *obiter* and was not intended to lay down a universally applicable principle for determining sufficiency.

7. In theory, it should be possible to persuade the High Court to come to a different view in relation to a chemical patent based on the distinctions made above in relation to *Kimberly Clark* and *Lockwood v Doric*. However, as demonstrated in the Viagra case, it would be difficult, if not impossible, to persuade a lower Court that you need to be able to produce more than one thing within a genus claim in a chemical patent. We return to this point below.

THE CURRENT AUSTRALIAN TESTS – FAIR BASIS

8. In *Lockwood v Doric*, the High Court reaffirmed the "travels beyond" test in *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 180 CLR 236 (*Olin v Super Cartridge)* at [57]:

> "The question whether the claim is fairly based is not to be resolved…by considering whether a monopoly in the product would be an undue reward for the disclosure. Rather **the question is a narrow one**, namely whether the claim to the product being new, useful, and inventive, that is to say, **the claim as expressed, travels beyond the matter disclosed in the specification**." [Emphasis added]

9. The comparison is between the claims and matter described in the specification, not just a preferred embodiment: para [77]. The claims must reflect the description of the invention in the light of the specification as a whole: para [87].

10. In the *Viagra* case, the Full Court referred to the "travels beyond" test of *Olin v Super Cartridge* at [270] and held that "the claim, read as a whole, travels well beyond the range of compounds, large as it may be, which is disclosed in the body of the specification" at [276].

11. However, the claim was to a class of compounds restricted only by mechanism of action (PDEv activity) whereas the specification only described compounds of formula I. Therefore, the decision was a relatively easy one, based on the principles in *Lockwood v Doric* as the claim travelled beyond the disclosure in the specification.

12. The Court in the *Viagra* case did not have to consider the particular question of whether a broad claim to a class of compounds travelled beyond the disclosure where only one example was described.

13. Thus, theoretically, this argument still appears to be available post *Lockwood v Doric*. However, if one looks at the narrow question of whether the claim travels beyond the matter disclosed (as taught in *Olin v Super Cartridge*), one must leave aside questions of enablement and utility, including the concept of sound prediction (see below).

14. In conclusion, the law of fair basis in Australia is similar to the requirement of support in the UK and Europe, such that it is almost a formality, with the description and the claims being consistent. In the UK/Europe, fair basis was not retained as a ground of invalidity of a patent, presumably because it added nothing to sufficiency and was not effective as is sufficiency in ensuring that the invention can be made.

The concept of "sound prediction"

15. The concept of "sound prediction" espoused in *Olin Mathieson Chemical Corporation v **Biorex** Laboratories Limited* (1970) RPC 157 appears to have been developed by Graham J in the context of fair basis as the defendant had failed to plead inutility (see page 193). But *cf Apotex Inc v Wellcome Foundation Ltd*., (2002) 4 S.C.R. 153, 2002 SCC 77 and other cases in Canada where the Courts have applied the principle of sound prediction to the assessment of the utility requirement.

16. The concept of "sound prediction" is plainly relevant to utility – it is similar to the concept of "plausibility" that is used by the European Patent Office in determining whether there is an inventive step across the scope of the claim (see below).

17. In Australia, the ground of inutility still exists (although it no longer exists in the UK/Europe). The current state of the law appears to be that if it can be proved that one example within the scope of the claim does not work, then the claim will be bad for inutility: *Ranbaxy Australia Pty Ltd v Warner-Lambert Co LLC* (2008) 77 IPR 449 (*Ranbaxy)*. Therefore, there is no need to take such an approach to fair basis. The High Court in *Lockwood v Doric* used the phrase "travels beyond", similarly to the language used in *Olin v Biorex*, but this is in terms of equivalence between "disclosure" of the invention and scope of claims, rather than "sound prediction".

18. Moreover, the approach taken in *Olin v Biorex* was based on the concept of "consideration" and "width of claim". Barwick CJ in the passage from *Olin v Super Cartridge* quoted by the High Court in *Lockwood v Doric* made it clear that this was **not** relevant to the issue of fair basis.

19. Thus, it is uncertain whether the approach of "sound prediction" is available in Australia post *Lockwood v Doric*.

20. In conclusion, the issue facing IP Australia regarding the broad scope of chemical / biotech genus claims is most appropriately dealt with by the grounds of inutility and insufficiency, rather than fair basis. In the case of such genus claims, the question is whether compounds within the scope of the claims can be made and are useful. The question of "sound prediction" apparently only came about in English law where the ground of inutility could not be relied upon and relates more to prediction as to whether the compounds will be useful for some therapeutic activity. It is based on the concept of consideration for width of claim, which approach has been rejected by the Australian High court. Further, this approach bypasses the important question of whether the compounds can actually be made, leaping straight to the issue of whether they would be useful (which relates to our ground of utility).

<u>The decision in Genetics Institute v Kirin-Amgen and comments on Biogen v Medeva</u>

21. The decision of Heerey J in *Genetics Institute, Inc v Kirin-Amgen, Inc* (No 3) (1998) FCA 740 (25 June 1998) is the only decision of a Federal Court regarding biotechnology, in particular, on issues relating to fair basis and sufficiency. The judge did not clearly address these issues separately, nor the principles applied, but one can glean from the decision that the judge apparently accepted that fair basis required

disclosure and sufficiency required enablement across the breadth of the claims (which goes against the notion that the statement in *Kimberly-Clark* was a universally applicable principle).

22. The judge appeared to approve the following principle from *Biogen v Medeva*, although he distinguished it on the facts as the Amgen patent disclosed the coding sequence (i.e. unlocked the key to the castle, so that the protein could then be obtained by any known means):

> "In fact the Board in Genentech I/Polypeptide expression was doing no more than apply a principle of patent law which has long been established in the United Kingdom, namely, that **the specification must enable the invention to be performed to the full extent of the monopoly claimed.** If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. **The patentee need not show that he has proved its application in every individual instance. On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them.**
>
> Thus if the patentee has hit upon a new product which has a beneficial effect but cannot demonstrate that there is a common principle by which that effect will be shared by other products of the same class, he will be entitled to a patent for that product but not for the class, even though some may subsequently turn out to have the same beneficial effect: see *May & Baker Ltd. v. Boots Pure Drug Co. Ltd.* (1950) 67 RPC 23, 50. On the other hand, if he has disclosed a beneficial property which is common to the class, he will be entitled to a patent for all products of that class (assuming them to be new) even though he has not himself made more than one or two of them."
>
> The fundamental difference which distinguishes the present case from *Biogen* is that in the Amgen patent the coding sequence is disclosed. The patent thus discloses a "principle capable of general application" and discloses a beneficial property which is common to the class. It cannot be said of it that it "discloses no principle which would enable other products [of the class] to be made". [Emphasis added]

23. The first emphasized passage appears to be inconsistent with *Kimberly-Clark*, but consistent with US law (see below). Interestingly, however, the second emphasized passage is partly consistent with the oft-cited passage from Kimberly-Clark. That is, the patent must enable discrete methods and products – this is equivalent to enabling something within the scope of **each claim** unless a single claim includes discrete methods and products. Also, the passage in [25] of *Kimberly-Clark* plainly derives from UK law, which the UK courts have held have long established the principle of enablement across the **full extent** of the monopoly claimed. Therefore, in theory, the law should be the same in both countries. It seems that the decision in *Kimberly-Clark* is used as the point at which they diverged, but it did not consider the question of enablement across the full scope of the claim. It did not apparently intend to bring about a change in the law of sufficiency.

24. The High Court in *Lockwood v Doric* approved Kimberly-Clark, even though sufficiency was not in issue in that case. Further, the High Court gratuitously took the

opportunity to criticize *Biogen v Medeva* at [67]. However, this passage contains errors and misconceptions. In particular, the "rule" in *Kimberly-Clark* is not simply the ability to make "a single embodiment" within the scope of a patent – you need to be able to make at least one thing **within each claim**. The Court also simply ignored that the "rule" is taken from English law, namely *Blanco White,* referring to *Valensi* (a mechanical case), which has not been interpreted in the UK as requiring enablement of only one thing within the scope of the claims. Nor did the Court refer to the *Amgen* case, where Justice Heerey had considered and apparently approved *Biogen v Medeva* in the context of a biotech patent.

25. In retaliation, the House of Lords took the opportunity to take a swipe at our law of sufficiency in the recent decision in *Lundbeck*. At [56], they stated: "The Australian High Court does not even accept the correctness of the conclusion in *Biogen* that the description and specification must amount to an enabling disclosure across the full width (and not merely in relation to one among other embodiments) of the invention: the amusing comments on *Biogen*…stress the independence of Australian from United Kingdom patent law and show that there is very little scope to argue any point at all on insufficiency in Australia".

26. Given the attitude of the High Court in *Kimberly-Clark* and *Lockwood v Doric* and Eli Lilly's failed attempt to persuade a single judge of the Australian Federal Court in the *Viagra* case that sometimes more than one way to perform the claimed invention is required (together with the embarrassing comments of the House of Lords in *Lundbeck*) it may be appropriate in Australia to raise the standard via change to the legislation, as opposed to waiting for the case law to develop. This will be much more expedient and cost effective (so that everyone does not have to litigate the issue) and will (hopefully) provide clarity and certainty for the profession in Australia and applicants here and overseas.

COMPARISON WITH US LAW

27. 35 USC 112 provides that "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out the invention."

28. This contains the intertwined concepts of written description and enablement. Interestingly, the s40(2)(a) requirement of "full description" is broad enough to include the concepts of both enablement and support (as required in the US) but the High Court in *Kimberly-Clark* found that it only incorporated the concept of enablement of one thing within each claim.

29. In terms of policy and the *quid pro quo* for obtaining a monopoly, these are important requirements. In the case of a mechanical patent, a single example may be enough, but often a single example will not meet these requirements – this is particularly so in the unpredictable arts, for example, chemistry and biotechnology.

30. The law is changing with respect to enablement and written description. Historically,

very few patents were found invalid because they did not meet the requirements of 35 USC 112, but the recent decisions are in relation to written description.

31. Note, however, that there has been a recent challenge to the requirement for written description (Ariad has petitioned the Federal Court for an *en banc* rehearing of *Ariad v Eli Lilly* asking the Court to eliminate the written description test as a distinct requirement of patentability under 35 USC Section 112, paragraph 1, 2009).

32. In the US, a patent must be enabled in some form across the full scope of the claims, although this requirement is not explicitly set out in the statute. It is from the case law, where the Courts have implicitly read this into the statute eg see *In re Wright* 1993 referred to in USPTO Manual at 2164.01(a). See also 2164.01(b), which states "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 USC 112 is satisfied", citing *In re Fisher*, 1970.

33. Accordingly, the US recognizes that what is required may differ depending on the type of claim. At 2164.03, the Manual states: "A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. However, in applications directed to inventions in arts where the results are unpredictable [such as in the chemical and biological arts], the disclosure of a single species usually does not provide an adequate basis to support generic claims." (Unfortunately, the Australian Courts have so far refused to recognize this important distinction.)

34. At 2164.06(b), the Manual gives examples of decisions in which the disclosure was held to be nonenabling. See, in particular, *Enzo*, *In re Wright* and *In re Goodman*. In *re Goodman* is a clear example, where the claims were to a method of producing protein in any plant cell. The method had been shown in the patent application to work in dicots. There was no evidence in the patent application that the method was operable in monocots. Similarly, in *In re Wright*, the claims covered vaccines against all RNA viruses as well as avian RNA viruses, and the evidence established that the claims were only enabling for avian RNA viruses, not all viruses.

35. In Australia, the same result could be achieved on the basis that the claimed invention lacks utility. The current law in Australia is that if something within the scope of the claims can be shown not to work, the whole claim is likely to be invalid: see *Ranbaxy*. However, the problem with the low standard for sufficiency still exists even though our law of utility appears to have a higher standard for a patentee than in the US (where you can have some inoperative embodiments and still have a valid claim). This is because, in Australia, it will not always be possible to show that a patent lacks utility even where it would not comply with the US requirement of enablement, as it is not always possible in Australia to demonstrate the technology does not work if it cannot first be made (ie theoretically it could be made and work). *Enzo* is an example of a situation where the utility requirement is met in Australia (as well as in the US), although the claim is not enabled across the full scope of the claims. In that case, the US Court held that claims directed to genetic antisense technology were invalid because the breadth of enablement (only in *E. coli*) was not commensurate in scope with the claims (generic to any organism). The teachings were

found to provide no more than a "plan" or "invitation" for those of skill in the art to experiment using the technology in cell types other than *E. coli*. However, since the technology was shown to be useful in *E. coli*, the claims met the utility requirement in the US.

36. The situation cannot be remedied by the doctrine of fair basis, as this does not look at whether something can be made and works, as opposed to whether it is disclosed consistently with the claims.

37. It is also important to note that s112 refers to "make and use", whereas the requirement of "full description" in s40(2)(a) has generally been interpreted to mean describe the invention and how to **make** it, not how to use it.

38. If our legislation were to be amended to be in harmony with the US law, the following amendment would deal with the issues of "enablement across the scope of the claims", as well as "make and use" and "undue experimentation" (similar to the *Kimberly-Clark* requirement of no prolonged study or new inventions etc.) It seems that this last requirement could be included to avoid doubt, even though it is not explicitly present in 35 USC 112.

39. A word such as "substantial" is required so that a genus claim does not fail if one thing within the claim is not enabled. 2164.08(b) of the USPTO Manual states: "The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim non-enabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art."

40. A possible amendment to bring law into line with that in the US would be:

"The specification shall describe the invention fully, including the manner and process of making and using it, such that a person skilled in the relevant art can make and use the same without undue experimentation substantially across the scope of the claims, including the best method known to the applicant of performing the invention."

COMPARISON WITH UK LAW

41. As noted above, lack of "fair basis" as such is no longer a ground of attack of a patent under UK law although to be granted a patent must have an enabling disclosure and support the claims.

42. Section 14(3) of the Patents Act 1977 states:

"The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."

43. In the UK (as in Europe), it is clear that the patent must enable the invention claimed, substantially across the width of the claims. Thus, where there is a claim to a class of

chemical compounds, substantially all of the compounds must be enabled without undue burden – occasional failures will be tolerated (as in the US).

44. Beyond this, however, the approach in the UK is neither simple to understand nor straightforward. The question of disclosure and width of claim is a philosophical one that goes to the heart of patent law, and the Courts have taken the approach in the UK (as in Europe) that the issue of sufficiency is connected with invention or technical contribution. (However, this theme, which is universal in the UK/Europe, was rejected by the High Court in *Lockwood v Doric,* along with *Biogen v Medeva,* discussed further below.)

45. The leading case is *Biogen v Medeva*. This decision reflected a view that the patentee should not be able to claim more than he or she had invented. On the facts, the patentee had only invented one way of achieving a product and therefore was not entitled to a monopoly over all ways of making the product. Lord Hoffmann held that the patent was insufficient because it covered methods that owed nothing to the inventive contribution of the patent (i.e., they owed nothing to what Professor Murray did). This decision attempted to grapple with the tension between the desire for all things within a claim to be enabled and the fact that inventions can be made within existing patents (e.g. the Wright Bros and balloon analogy in *Biogen*) by relating the allowable width of the claim to the nature of the invention.

46. The House of Lords in *Lundbeck* is the most recent statement of the law of sufficiency in the UK. In this case, as there was only one product (produced by one inventive method) within the scope of the claim, Lundbeck were entitled to the product however made. Each case will therefore depend on the facts. In *Biogen v Medeva* the House of Lords found the claim (a product by process claim) was insufficient whereas in *Lundbeck* the claim (to a single product) was sufficient.

47. The House of Lords noted that "insufficiency" (enablement) and "support" (akin to fair basis) are closely connected: see paras 15 to 19, *Lundbeck.* The requirement for "support" "reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported…": para 19, *Lundbeck.* Thus, "the disclosure must be such as to enable the invention to be performed…**to the full extent of the claims**": para 20, *Lundbeck.*" [Emphasis added]

48. The House of Lords recognized that sufficiency of a claim must be related to the particular product: para 22, Lundbeck. They gave a nappy as an example of a simple product (the very product in question in *Kimberly-Clark*) and a flying machine or recombinant DNA organisms as examples of more complex products. They also gave as an example patents for large classes of chemical compounds, which are required so that competitors cannot exploit the inventive concept without infringement (because there is no expansive doctrine of equivalents in the UK, nor Australia).

49. "Statements of general principle relating to inventions with many embodiments may be irrelevant to an invention which consists of a single chemical compound": para 25, *Lundbeck.* That was why *Biogen* did not provide a direct answer to the appeal: para 26 *Lundbeck.* In *Biogen*, the "technical contribution" was not of lasting importance and the patent was insufficient to sustain a claim to every method of using

recombinant DNA technology to produce HBV antigens: para 33, *Lundbeck*.

50. Importantly, Lord Mance noted at paragraph 51, *Lundbeck*, that "what the description discloses must…enable a skilled person to make the patented product across its full width or extent. **This does not mean that it must also enable the skilled person to make it by all possible methods**" [Emphasis added]

51. The link between the invention and the law of sufficiency in the UK was highlighted in the decision of Floyd J in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Company Ltd* (2008) EWHC 2345 at [118] (13 October 2008):

> "Mr Waugh QC, who argued this part of the case on behalf of Lilly, said that the effect of this judgment was that even in the case of a compound selection patent which owes its very existence to the special advantage contributed by the disclosure of the specification, the sufficiency requirement is satisfied provided that the person skilled in the art is able to make the compound. This, he said, will remain true even if it is established that the claimed advantages do not in fact exist. If correct, this is a remarkable conclusion. The patentee's only contribution to the art would have been the misrepresentation of the advantages of his invention. I believe that the proposition is incorrect."

52. The approach in the UK can be summarized as follows:

> Step 1 – can you make everything within the claim?
>
> Step 2 – acknowledge that you can have inventive improvements and therefore the patent with only be insufficient if the whole of the claim is not dependent on the invention disclosed (eg a selection invention).
>
> Step 3 – is there (classic) insufficiency? For example, if you don't know the test to be applied because it is not described sufficiently, or where an important component of the invention is not publicly available, it is insufficient.

53. It is important to note that the concept of justifying the width of the monopoly in terms of "technical contribution" is one that has not been adopted by the Australian Courts. Even if "technical contribution" is the same as "inventive step" (eg para 45, *Lundbeck*), the Australian Courts have never considered that either fair basis or sufficiency is to be judged by reference to inventive step. It is true that there is no justification in the statute for doing so. The High Court reaffirmed in *Lockwood v Doric* that each of the grounds is separate and distinct, and that there is no reason to introduce concepts of "inventiveness" or "meritoriousness" or "technical contribution" into the fair basis question: see para [46], see also [50] to [54]. Thus, the approach in the US is closer to our approach, but has the same effect of requiring enablement across the width of the claims.

COMPARISON WITH THE POSITION IN EUROPE

54. Article 83 EPC provides: "The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".

55. The approach under the EPC is similar to that in the UK. In Lundbeck, the House of Lords referred to the decision of the European Technical Board of Appeal in *Exxon v Fuel Oils T409/91* (1994) OJ EPO 653,: "…the present case is comparable to cases where a group of chemical compounds is claimed, and not all of the claimed compounds can be prepared by the methods disclosed in the description or being part of the common general knowledge…In the latter case, it was not held sufficient for the purpose of Article 83 EPC to disclose a method of obtaining **only some** members of the claimed class of chemical compositions". Cited at para 38, *Lundbeck*.

56. This states the desired position in Australia (which is not the current position). It is the law of sufficiency, not fair basis (support) that is appropriate to achieve this position.

57. What *Exxon* did was to stress that the skilled person has to be able to perform the invention **in the whole range claimed**: "The question whether the disclosure of one way of performing the invention is sufficient to enable a person skilled in the art to carry out the invention in the whole range claimed is a question of fact that must be answered on the basis of the available evidence, and on the balance of probabilities in each individual case." '., the underlying purpose of the requirement of support by the description... and of the requirement of sufficient disclosure is the same, namely to ensure that the patent monopoly should be justified by the actual technical contribution to the art.'

58. This is very similar to the analysis of Lord Justice Hoffmann in *Biogen v Medeva*.

59. The approach of the EPO is clear and straightforward. It is a two step process.

60. First, the Examiner will decide if the patent is sufficient (Article 83). This is determined on the basis of what is contained in the patent specification and what is common general knowledge. In the case of a chemical claim, the question is, can you make them all? It only needs to be plausible that you can make them all - you don't need to show you can make them all. However, allowance is made for some compounds not being able to be made. (The case law uses the phrase "substantially across the whole width" of the claims, which allows for inoperative embodiments: see *Genentech I/Polypeptide Expression* (T 292/85) (1989) OJ EPO 275.

61. Secondly, if the patent is sufficient, the Examiner will consider the question of inventive step (Article 56). This is applied using a problem solution approach. In chemical cases, the patentee relies upon an effect to establish inventive step. The Examiner will determine if there is a proper association of the inventive step (effect) across the claim. The Examiner will find the closest prior art and then look at the effect shown over the prior art. That is, is the problem solved by the invention across the whole scope of the claim? If not, the claims must be limited to the scope that is commensurate with the inventive step. For example, where the inventive step / effect

is achieved with cobalt but the claims include platinum, the claim can be limited to the scope that solves the problem, i.e. cobalt.

62. There must be a credible reason as to why the claimed invention will work (i.e. achieve the effect) across the whole scope of the claims. The patent specification as filed must contain sufficient data to render "plausible" the technical effect alleged for the invention. (See T0609/02; T0898/05; and T1329/04).

63. In terms of policy, this is a fair situation, so that you do not get a claim for things that do not involve an inventive step (this is the same approach that Hoffmann LJ took in *Biogen v Medeva*). It also leaves room for improvement inventions, eg selection inventions, which are within the scope of the claim but may have a different effect and therefore involve a different inventive step.

64. See generally Case Law of the Boards of Appeal 5th Edition 2006 at II.A.3, II.A.4 and 8.8.2.

65. The same result can be achieved in Australia under the ground of utility. The question is whether the claim will work across the whole scope with respect to the effect promised in the specification? That is, if the claim includes chemical compounds that do not have the effects promised, then the claim is bad for lack of utility.

CONCLUSIONS

66. On the issue of sufficiency, both the US and UK/Europe are consistent in requiring enablement across the breadth of the claims. Australia is arguably out on a limb on this issue. The current legislation could provide for this – using the words "full description" – but that is not the way it has been read by the High Court and lower courts. For the reasons given above, although it is possible to argue that that the comments in *Kimberly-Clark* were *dicta* and were not intended to lay down a general principle for all classes of patents, the throw away comments of the High Court in *Lockwood v Doric* mean that it will be very difficult to persuade a Court to come to a different conclusion in the case of a chemical patent (as it was in the Viagra case), certainly at a level lower than the High Court. It therefore might take years for the case law to develop on this issue. The law of fair basis and/or utility do not deal with this particular issue of concern.

APPENDIX 2

COMMENTS ON PATENT THICKETS

Introduction

1. In order to identify whether patent thickets currently exist in Australia, we conducted a review of the economic literature discussing patent thickets in order to first understand the nature of patent thickets. From our review, it appears that a patent thicket can be defined as:

> *a situation in which many unrelated entities within a particular jurisdiction each own one or more patents that are collectively necessary to the production of a single product which in turn necessitates the need to obtain multiple patent licences from each patentee in order to avoid patent infringement that would arise if the single product were to be produced in the particular jurisdiction.*

2. In other words, patent thickets are jurisdictional and appear in technological fields where a single product is covered by many patents that are owned by different patentees. The core feature of a patent thicket therefore appears to be the number of patentees involved[44] rather than the number of patents pertaining to a single product or service. Hence, a single product that is covered by several patents that are all held by the same patentee would not give rise to a patent thicket.[45]

3. It is unclear from the reviewed literature as to the minimum number of different patentees[46] that need to be observed before a patent thicket can be declared to exist in a particular jurisdiction, but it appears that the number is at least in the tens if not hundreds, or possibly thousands.[47] Technologies that have been characterised as having patent thickets or the potential for patent thickets include financial business

---

[44] Ayres, I. & Parchomovsky (2007) Tradable Patent Rights *Stanford Law Review* 60: 863, 871,-872, 874, 876.

[45] Shapiro. C. (2000) Navigating the Patent Thicket: Cross Licences, Patent Pools and Standard Setting. *Innovation Policy and the Economy* 1: 119, 120.

[46] See for example, Bessen, J. (2003) Patent Thickets: Strategic Patenting of complex Technologies accessed 17 May 2009 at: http://www.researchoninnovation.org/thicket.pdf in which Bessen J. only refers to a 'large number of patent holders' when discussing patent thickets.

[47] Clarkson, G. & deKorte, D. (2006) The Problem of Patent Thickets in Convergent Technologies *Annals New York Academy of Sciences* 1093: 180, 188. In Ayres & Parchomovsky, *supra* note 1, at page 872, an example of a patent thicket is given in which there are twenty different patentees. According to a survey by Peter Detkin in 2002, there are over 90,000 US patents relating to microprocessors that are held by over 10,000 parties, see slide 5 of Detkin P. (2002) A Semiconductor Patent Survey accessed on 25 May 2009 at: http://www.ftc.gov/opp/intellect/020228peterndetkin.pdf

methods[48], computer software[49], biotechnology,[50] nanotechnology[51] and semi-conductor technology[52].

4. It follows that in order to identify a patent thicket, one would need to identify a single product within one of these technologies and analyse the number of entities that own one or more patents that relate to the single product.

Search methodology for identifying patent thickets

5. As it appears from the reviewed economic literature that patent thickets pose a problem in the United States[53] and that patent thickets concerning carbon nanotube (CNT) technology have the potential to form[54] if they are not already present, we conducted a comparative patent analysis between the US and Australia to see if there are CNT patent thickets in either of these countries. As carbon nanotubes possess valuable properties that enable their use in a variety of applications including biomedical, diagnostic and therapeutic applications as well as in conductors, diodes, photovoltaic cells, electrodes, electric discharge tubes and transistors, it is reasonable to expect that a variety of players have already obtained CNT patents in each country.

6. In order to assess whether CNT patent thickets exist in Australia or in the US, an aspect common to both Australian patents and US patents had to be identified as the field by which to search each of the national patent registers. Although both Australian and US patents bear one or more International Patent Classification (IPC) codes, the IPC scheme does not presently contain a precise patent class that directly pertains to carbon nanotubes. It was therefore decided that a title keyword-based search of the national patent registers would be conducted. The reason the search had to be limited to the title as opposed to the full-text is that the publicly accessible patent database provided by IP Australia currently only enables keyword searching in the title of the available patent specifications.

7. Although a number of different keywords can relate to CNT including ‘carbonaceous cylinders’, ‘carbon/graphite nanofibres’ and ‘quantum dots’[55], it appears that the

---

[48] Australian Ministry for Innovation, Industry, Science and research (2008) Venturous Australia-Building Strength in Innovation, Chp. 7, 84 accessed on 29 May 2009 at: http://www.innovation.gov.au/innovationreview/Documents/NIS_review_Web3.pdf

[49] Subramanian, S. (2008) Patent Trolls in Thickets: Who is Fishing Under the Bridge? *European Intellectual Property Review* 5: 182.

[50] Heller, M. (1998) Can Patents Deter Innovation? The Anti-Commons in Biomedical Research *Science* 280 (5364): 698.

[51] Clarkson, G. & deKorte, D. *supra* note 4 at 180.

[52] Shapiro. C. *supra* note 2 at 121.

[53] Subramanian supra note 6 at 183. See also United States Federal Trade Commission (2003). To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy 3, Chp 3, accessed on 19 May 2009 at: http://www.ftc.gov/os/2003/10/innovationrpt.pdf .

[54] Clarkson, G. & deKorte, D. *supra* note 4 at 188, 189.

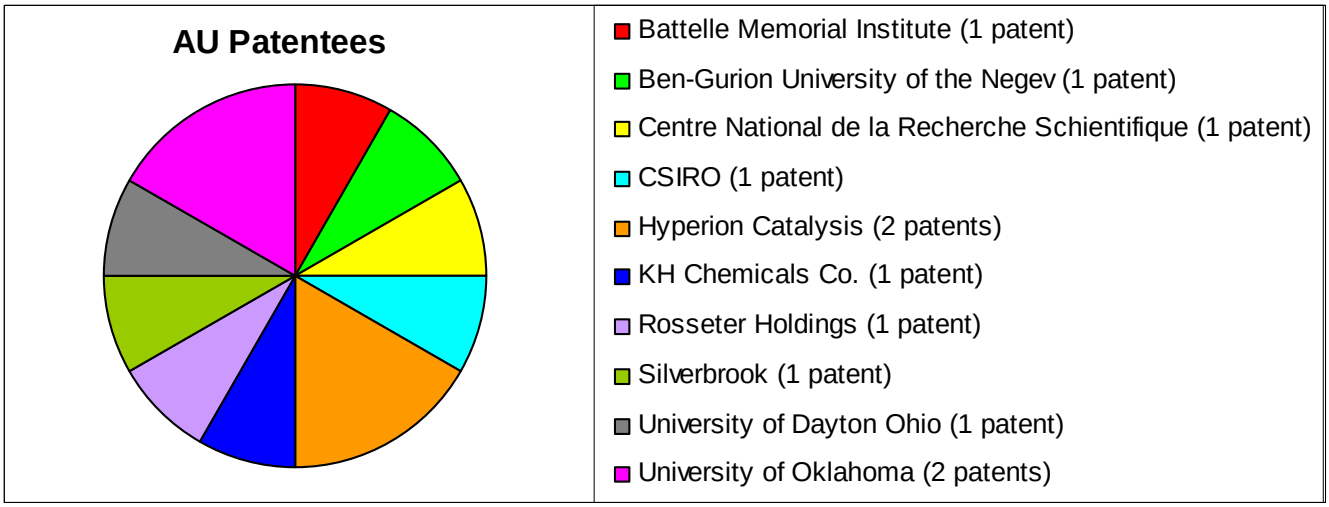
[55] Clarkson, G. & deKorte, D. *supra* note 4 at 183, 187.

phrase ‘carbon nanotubes’ is a commonly used term within both the patent and non-patent literature relevant to the art. Therefore a search was conducted on 18 May 2009 for Australian patents and US patents that contain in the title the phrase ‘carbon nanotubes’ and that were in force on the date of the search. Neither search was limited by any date. Patent applications were not included within the scope of either search, as it is uncertain as to whether the applications will even be granted and therefore pose an infringement risk.

Results of comparative analysis and discussion

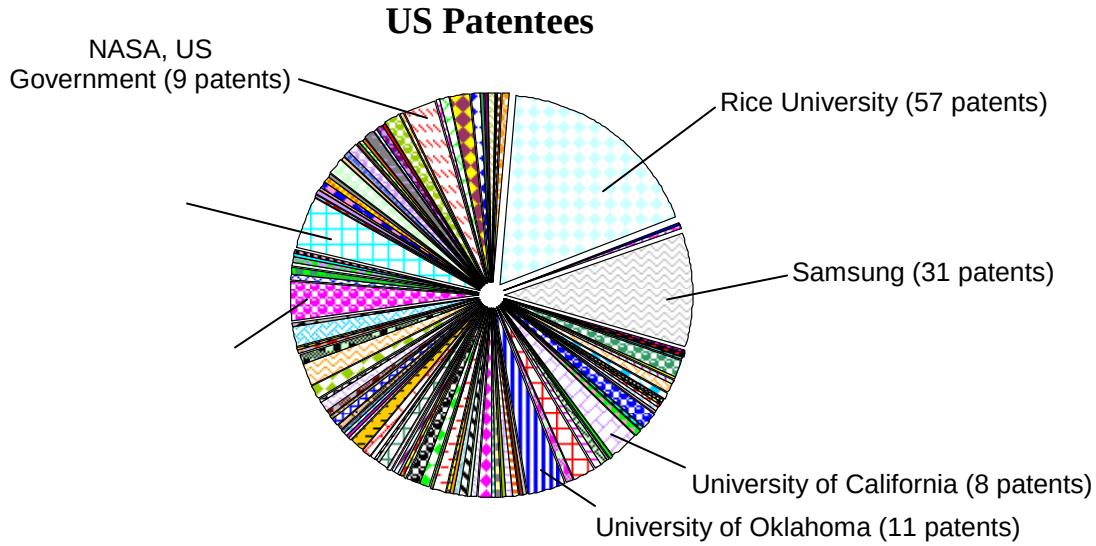
8. Figures 1 and 2 show the results of the search. As can be seen in Figure 1, the search of the Australian national patent register revealed only 12 in force Australian patents that contain the phrase ‘carbon nanotubes’ in the title. The number of distinct patentees attributed to the retrieved patents was 10.

Figure 1 - Results of the Australian CNT Patent Search



In contrast, the search of the US national patent register revealed 322 in force US patents that are owned by **109 different patentees** as shown in Figure 2.

Figure 2 – Results of the United States CNT Patent Search



- Agency of Industrial Science and Technology
- Air Force, US Government
- Alliance for Sustainable Energy
- Ambit Corp.
- Applied Nanotech Holdings
- Arrow Capital Corp. & Japan Asia Investment Co.
- Auburn University
- Batelle Memorial Institute
- Ben-Gurion University of the Negev
- Boston College
- Canada National Defence
- Canon K.K.
- Carbon Solutions
- Cdream Corp.
- Centre National de la Recherche Schientifique
- Centre National de la Recherche Schientifique & Universite Louis Pasteur
- Chiao Tung University
- Clemson University
- Commissariat A L'Energie Atomique
- Commissariat A L'Energie Atomique & Centre National de la Recherche Schientifique
- CSIRO
- Dupont
- Eikos Inc.
- Electronics and Telecommunications Research Institute
- Fife Batteries Ltd
- Forschungszentrum Karlshrue GMBH
- Fuji Xerox Co.
- Fujitsu
- Futaba Corporation
- Gas Technology Institute
- General Electric Company
- Georgia Tech Research Corporation
- Haddon, Robert & Chen, Jian
- Hon Hai Precision
- Hon Hai Precision & Tsinghua University
- Honda
- Honda & Alliance for Sustainable Energy
- Honeywell International
- Hyperion Catalysis
- Hyundai
- IBM
- Iljin Nanotech
- Iljin Nanotech & Pohang University
- Industrial Technology Research Institute
- Infineon Technologies
- Institute of Advanced Industrial Science and Technology & SII Nanotechnology
- Institute of Metal Research of the Chinese Academy of Sciences
- Intel
- Japan Fine Ceramics Center
- Kemet Electronics
- KH Chemicals Co.
- Korea Advanced Institute of Science and Technology
- Kyunghee University
- Lee Cheol
- Leland Stanford University
- LG Electronics
- Little, Reginald
- Lockheed Martin
- Los Alamos National Security
- Lucent Technologies
- Materials and Electrochemical Research
- Micron Technology
- Moskovits, Martin
- Motorola
- Nanodynamics
- Nano-Proprietary
- Nantero
- NASA, US Government
- NASA, US Government & Leland Stanford University
- NAVY, US Government
- NEC Corporation
- New York State University
- Noritake Co.
- Northwestern University
- Notre Dame University
- Penn State University
- Pettit, John
- Rensselaer Polytechnic Institute
- Rice University
- Rosemount Inc.
- Rosseter Holdings
- Samsung
- Samsung & Lee, Young-Hee
- Schiavon, Mauro
- Showa Denko K.K.
- SI Diamond Technology
- Silverbrook
- Sony
- STMicroelectronics
- Storage Technology Corporation
- Technische University
- TECO Nanothech
- Toray Industries
- Toyota
- Transpecific
- Unidym
- Universita' Degli Studi di Trieste
- University of Arizona
- University of California
- University of Central Florida
- University of Connecticut
- University of Dayton Ohio
- University of Florida
- University of Kentucky
- University of North Texas
- University of Oklahoma
- University of Singapore
- University of Toronto
- University of Washington
- University of Western Michigan
- UT-Batelle
- Xidex
- Yale University

9. Although, it can be argued that not all of the retrieved patents may need to licensed, as the subject matter of the claims will dictate whether a patent is relevant to a particular product or not, at the very least the search results show that a considerably greater amount of time and money will need to be expended in determining the number of patent licences that would need to be negotiated in the US than in Australia.

10. The search results also raise an important point. In order for patent thickets to form in the first place, many different entities have to seek patent protection in the jurisdiction of interest. If a particular jurisdiction, A, is not as of high commercial importance to a particular technological sector as another jurisdiction, B, then it is reasonable to expect that both the number of patent filings and the number of entities from the particular technological sector pursuing patent protection in jurisdiction A will be considerably lower than in jurisdiction B. This expectation is supported by statistical data recently reported by the World Intellectual Property Organization (WIPO). For example, over 300,000 patent applications were filed in the United States in 2006

according to WIPO, whereas in Australia, over 10,000 patent applications were filed.[56] This lower filing trend in Australia compared to the United States is a consistent trend over all the number of years sampled.[57] Moreover, the number of US patent filings by US residents over GDP in 2006 was reported by WIPO[58] as approximately 20, whereas the number of AU patent filings by Australian residents over GDP was reported as 5. The consistently lower number of patent filings in Australia when compared to the United States calls into question the premise that patent thickets could form as readily in Australia as in the US.

[56] World Intellectual Property Organisation (August 2008) World Patent Report: A Statistical Review accessed on 1 June 2009 at: http://www.wipo.int/ipstats/en/statistics/patents/wipo_pub_931.html#a12

[57] Ibid, see raw data accessed on 1 June 2009 at: http://www.wipo.int/ipstats/en/statistics/patents/csv/wipo_pat_appl_from_1883_list.csv

[58] World Intellectual Property Organisation, *supra* note 13 accessed on 1 June 2009 at: http://www.wipo.int/ipstats/en/statistics/patents/wipo_pub_931.html#g11