A COMPARATIVE ANALYSIS OF THE AUSTRALIAN PATENT OFFICE'S EXAMINATION OF BIOTECHNOLOGY REACH-THROUGH PATENT CLAIMS

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In an earlier study we analysed how the United States Patent and Trade Mark Office, the European Patent Office and the Japan Patent Office (jointly referred to as the 'Trilateral Offices' or TOs) assessed reach-through patent claims in biotechnology, under the requirements of 'utility', 'written description' and 'enablement' (as they are referred to in the US). We found that any claim that was a reach-through claim was assessed to be invalid by the TOs, and therefore filtered out from grant. This study analyses how the same claims from the TOs' study are assessed by the Australian Patent Office (APO), under the equivalent Australian requirements of 'manner of manufacture and description of use', 'clarity, succinctness and fair basis', and 'full description and best method'. We find that under Australian practice not all types of reach-through claims are filtered out from grant of a patent. This suggests that one or other of the patent offices is applying the wrong standard in examination of these claims. In our view, the examination standard applied by the APO is too lenient. The Australian legislation should be reformed by adopting patentability requirements that mirror the utility, written description and enablement requirements of the TOs.

I INTRODUCTION

A *Objectives*

In this study we seek to determine whether – and, if so, how and why – the practice of the Australian Patent Office ('APO') differs from the practice of the United States Patent and Trade Mark Office ('USPTO'), the European Patent Office ('EPO') and the Japan Patent Office ('JPO') (jointly referred to as the 'Trilateral Offices' or 'TOs') in relation to the examination of a hypothetical set of reach-through claims in the field of biotechnology. To do this we must first determine which requirements of the Australian patent legislation, the *Patents*

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Act 1990 (Cth), the APO considers to be equivalent to the requirements of utility, written description, and enablement (as they are referred to in the US). Next we aim to establish the degree of agreement between the APO and the TOs on the validity of different types of biotechnology patent claims, including reach-through claims. Finally, we propose to identify the type of claims for which differences in examination outcome are observed, and deduce the reasons why the APO arrives at these different results.

B *Reach-Through Claims and Why They Matter*

The term 'reach through claim' generally refers to a type of claim drafted in patent specifications, particularly those in the field of biotechnology. Reach-through claims are drafted with intention to seek monopoly rights broad enough to cover products or processes that are as yet undeveloped but that are suggested or speculated to be possible, at least in theory. In the field of biotechnology, the product or process sought to be covered by the monopoly rights are the results of development of an initial biological invention. For example, if the initial biological invention is the nucleotide sequence of a gene, reach-through claims may be drafted to as yet undeveloped drugs or for therapies that are suggested or speculated to be possible with information provided by the nucleotide sequence of the gene. Reach-through *claims* are to be distinguished from reach-through *licences* and reach-through *remedies*.[1]

Reach-through claims have been the subject of some disapproval.[2] This disapproval is perhaps due to the perceived intent of such claims, which seek rights over inventions that are beyond the legitimate boundaries of the initial intellectual property. However, the reason for a patent applicant adopting reach-through claiming strategies is precisely to try and capture the value of future inventions. Start up companies that deal with technological innovations find it critical to obtain intellectual property rights to attract investments and raise capital required to sustain the research and development of their technologies.[3] Patents help attract such capital and it is commonly assumed that the broader the rights provided by a patent claim, the more valuable the patent.

1 Rebecca S Eisenberg, 'Reaching Through the Genome' in Scott Kieff (ed), *Perspectives on Properties of the Human Genome Project* (2003) 50. Reach-through *claiming* has been described as a strategy that involves issuing patents that are broad enough to cover future discoveries enabled by prior inventions. In reach-through *licensing*, the patent holder restricts access of a patented research-enabling technology to users that agree, as a term of the licence, to share a piece of the action in future products. Sometimes the piece of action takes the form of a royalty on future product sales, and sometimes it takes the form of a licence to use future inventions made in the course of the research. A reach-through *remedy* is a damage award for infringement that is measured as a reach-through royalty on sales of products developed through unlicensed use of a research tool.

2 See, eg, Frank P Grassler, *US Treatment of Reach-Through Claims and Reach-through Royalties*, section 1.00 <http://www.sdipla.org/events/past/grassler/ReachThru.htm> at 3 October 2003; Stephen G Kunin et al, 'Reach-through Claims in the Age of Biotechnology' (2002) 51 *American University Law Review* 609, 638.

3 Rebecca Eisenberg, 'Patenting Research Tools and the Law' in National Academy Press, *Intellectual Property Rights and Research Tools in Molecular Biology* (1997) <http://stills.nap.edu/html/property/2.html#chap2>, 6; Kunin et al, above n 2.

A reason suggested against the broad rights provided by a reach-through claim is that the scope of the granted monopoly will extend to products and processes that will be invented by someone else[4] and therefore is inappropriately broad. An inappropriately broad patent, in practice, might have the consequence of giving a right for the exclusive use of scientific information that has become available as a result of an invention, rather than a right for an exclusive use of an invention. One of the effects of the grant of an exclusive use of scientific information is to create inappropriate barriers for accessing patented technology,[5] and this may in fact discourage the development of further inventions by persons other than the patentee. The element of uncertainty as to what acts constitute an infringement is greater when the monopoly right is for exclusive use of information that became available as a result of the invention, rather than just for exclusive use of the invention described in the specification. Since disincentives for innovation and greater uncertainty regarding what comes within the scope of a patent monopoly are inconsistent with the objectives of a patent system, these outcomes would be reasons against adopting inappropriately broad patent rights.

C *Previous Considerations on the Validity of Reach-Through Claims*

The legal literature on this topic to date is limited. In those few writings that do substantively consider the patentability of reach-through claims, a reach-through claim has been described rather than defined, and the descriptions have been within the field of biotechnology. The common conclusion on the patentability of reach-through claims is that they are not valid.

In 2001, the Trilateral Offices reported an increasing number of reach-through claims being filed in the field of biotechnology, and decided that there was a need to understand the examination practices of each of the three Patent Offices towards such types of claims.[6] This gave rise to Trilateral Project B3b study on reach-through claims, the outcomes of which are contained in the *Report on Comparative Study on Biotechnology Patent Practices* ('TOs Report').[7] The TOs Report provides an account of how each of the three TOs assesses the validity of a hypothetical set of biotechnology claims that include reach-through claims. Some, but not all, of those claims were found to be invalid by each of the three TOs.[8] Kunin et al have provided an analysis of the assessment undertaken by the USPTO for the TOs

4 Grassler, above n 2.

5 See Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698; Dianne Nicol and Jane Nielsen, 'Patents and Medical Biotechnology: An empirical analysis of issues facing the Australian Industry' (2003) Occasional Paper 6, Centre for Law and Genetics <http://www.ipria.org/publications/pubfliers/BiotechReportFinal.pdf>; Jane Neilsen, 'Reach-through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-competitive Reach' (2004) 32(2) *Federal Law Review* 169.

6 EPO, JPO and USPTO, *Report on Comparative Study on Biotechnology Patent Practices* (2001) Trilateral Project B3b <http://www.uspto.gov/web/tws/B3b_reachthrough.pdf> at 27 September 2003.

7 Ibid.

8 See Amanda S Y Lim and Andrew F Christie, 'Reach-through Patent Claims in Biotechnology: An analysis of the examination practices of the United States, European and Japanese Patent Offices' (2005) 3 *Intellectual Property Quarterly* 236.

Report.[9] Both the TOs Report and Kunin et al define a reach-through claim simply as one that 'claims a future invention based on a currently disclosed invention'. Neither the TOs Report nor the Kunin et al article expressly identifies which of the claims in the hypothetical claim set are in fact reach-through claims.

Grassler has written on how US patent law validity requirements would apply to biotechnology reach-through claims.[10] He identifies three types of biotechnology reach-through claim that he considers to be representative: the claim to small molecules *per se*; the claim to methods of screening for small molecules; and the claim to functional uses of small molecules. In Grassler's view, both the USPTO and the US courts would find that such claims do not satisfy the requirement of written description.[11]

In a recent case heard by the United States Court of Appeals for the Federal Circuit, *University of Rochester v GD Searle & Co*,[12] a number of the claims in issue were directed to methods 'for selectively inhibiting PGHS-2[13] activity in a human host' by 'administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to [or in] a human host in need of such treatment'. Bohrer has referred to this claim as a reach-through claim, because it embraces the use of the disclosed target (that is PGHS-2) by claiming the method of affecting the target's activity.[14] The Court of Appeals in the *Rochester* case affirmed the decision of the district court[15] that the University of Rochester patent[16] was invalid for failing to comply with the written description requirement of the US patent legislation.[17]

The United Kingdom Patent Office ('UKPO') has undertaken a hypothetical examination of the claims from the *Rochester* case, in recast form.[18] The assessment of the UKPO was that a reach-through claim, whose subject matter is a compound identified by a claimed method would be unclear, not supported by the description of invention in the patent specification, and would lack sufficiency of disclosure.

9 Kunin et al, above n 2.

10 Grassler, above n 2.

11 Ibid.

12 358 F.3d 916 (2004) ('*Rochester*').

13 PGHS-2 is a protein produced in response to inflammatory stimuli, and is thought to be responsible for inflammation associated with disease such as arthritis.

14 Robert A Boher, 'Between a Rock and a Hard Place: University Research after Merck and Madey and the University of Rochester' (2005) 24 *Biotechnology Law Report* 713, 715.

15 *University of Rochester v G.D. Searle & Co*, 249 F.Supp.2d 216 (2003).

16 US Patent No 6,048,850.

17 35 USC 112, first paragraph.

18 UKPO, 'The Patentability of "Reach-Through" Claims' (2004) 33(3) *Chartered Institute of Patent Agents Journal* 125. The claims of US Patent No 6,048,850 relevant for considerations of the reach-through issue are in the form of methods of treatment of the human body by therapy, and so would not be considered as capable of industrial application in the United Kingdom. The UKPO have therefore recast some of the claims of US Patent No 6,048,850 to illustrate how reach-through claims might appear in a UK patent application. These recast claims are directed to '[a] non-steroidal compound identified' by a method, and '[a] non-steroidal compound (of claim X) for use in therapy by selectively inhibiting PGHS-2 activity in a human host'.

D *Definition of Reach-Through Claims*

In contrast to the previous writings that seek to define a reach-through claim in an *illustrative* manner, a recent paper seeks to define a reach-through claim in *conceptual* manner.[19] Reach-through claims are claims to subsequent and future inventions that have some relationship to the invention disclosed in the patent specification (hereafter 'the current invention').[20] More particularly, however, we define a reach-through claim to be one seeking monopoly over subject matter which is not the current invention, but which is defined in terms of a relationship to the current invention and in circumstances where there is no certainty as to how to obtain this subject matter. In one example, drawn from the biotechnology context, a current invention could be a protein or gene disclosed in the patent specification while a reach-through claim will seek to claim subsequent and future inventions that are defined using some characteristic of the disclosed protein or gene.

Three reach-through claim types in the biotechnology context have been previously identified.[21] The first biotechnology reach-through claim type consists of product claims that seek to protect molecules that modulate the activity of the current invention; in other words, claims to molecules that modulate the biological function of a protein or gene. A claim to a receptor agonist, a molecule that activates a receptor[22] protein, is an example of this type of reach-through claim.

The second biotechnology reach-through claim type consists of process claims that are directed to methods of treating a disease using a molecule that is claimed to modulate activity of the current invention. A claim to a medical application of a non-specified receptor agonist is an example of this second reach-through claim type. The non-specified receptor agonist used in the method application is not defined by its structure but rather by its ability to modulate the expression of a protein or gene (the current invention). The characteristic common to the first two types of reach-through claims is that it is not reasonably certain that the subject matter can be obtained.

The third reach-through claim type in the biotechnology context consists of claims that seek to protect molecules derived from the current invention; in other words, molecules derived from the protein or gene. A claim to a monoclonal antibody[23] is an example of this type of claim. We classify this claim type as 'quasi reach-through' because, although an antibody is not the current invention, the technology used to derive antibodies is now well-developed and production of an antibody

19 See Lim and Christie, above n 8, 240-1.

20 See EPO, JPO and USPTO, above n 6; Kunin et al, above n 2.

21 See Lim and Christie, above n 8, 239.

22 Receptors are structures which are specific for some molecules such that the adherence of such molecules to the receptors will effect biologic activity. Examples of receptors are: alpha and beta receptors on the blood vessels; the beta-1 receptor of the heart; the histamine receptor on mast cells. This definition of receptors is given by the *Biotech Life Science Dictionary* <http://biotech.icmb.utexas.edu/search/dict-search.html> at 17 April 2006.

23 A monoclonal antibody is a single species of antibody. An antibody is a protein which is produced by an animal as a result of the presence of a foreign substance in the body and which acts to neutralise or remove that substance.

toward a molecule is a matter of routine. An antibody can be produced once the sequence of a protein is known. In contrast to the first two types of reach-through claims, it is reasonably certain that the subject matter of a quasi reach-through claim can be obtained.

The underlying concept of a reach-through claim is that information made available through the current invention is used to 'catch' the subject matter of the reach-through claim. In one example of a claim to a receptor agonist, the biological feature of activation of the receptor protein is a characteristic that is being used to define the reach-through claim subject matter in terms of the current invention (the receptor protein). This characteristic provides a definition of a receptor agonist in terms of a relationship to the receptor protein, and the receptor protein is not the subject matter of the reach-through claim. Furthermore, a receptor agonist which activates the receptor protein is not a product derived from the receptor protein. The subject matter of a reach-through claim is not a product derived from the current invention.[24]

II RESEARCH METHODOLOGY

A *Background*

A previous study[25] analysed the TOs Report to determine how the TOs assessed biotechnology reach-through claims with respect to each of the patent law requirements of utility (industrial applicability),[26] written description (clarity and support of claims)[27] and enablement (sufficiency of disclosure).[28] It was found that any claim that we categorised as a reach-through claim was assessed to be invalid by the TOs. The patent law requirement of written description alone or enablement alone would operate to invalidate the reach-through claims of that study. The analysis showed that application of the three mentioned patent law requirements by the TOs do in fact filter out from grant reach-through claims in biotechnology.

In this study we analyse how the same claims from the Trilateral Project B3b are assessed under Australian examination practices. To do this, we invited the APO to assess these claims from the Trilateral Project B3b.

24 This definition is consistent with that of the UKPO. The UKPO has construed a claim to a non-steroidal compound identified by a claimed method to protect any non-steroidal compound identified as possessing the desired activity when the claimed method is performed. The UKPO noted that the non-steroidal compound is simply identified by the method; it is not produced, obtained or modified by the assay: see UKPO, above n 18.

25 See Lim and Christie, above n 8.

26 In the US, the utility requirement is provided by 35 USC 101. In Europe and Japan, the requirement for industrial applicability is provided, respectively, by *European Patent Convention* ('EPC') art 57 and *Japanese Patent Law* s 29(1).

27 In the US, the written description requirement is provided by 35 USC 112, first paragraph. In Europe and Japan, the requirement for clarity and support is provided, respectively, by EPC art 84 and *Japanese Patent Law* s 36(6).

28 In the USA and Japan, the enablement requirement is provided, respectively, by 35 USC 112 [1], and *Japanese Patent Law* s 36(4). In Europe, the requirement for sufficiency of disclosure is provided by EPC art 83.

B *Overview of Cases and Claims of the Trilateral Project B3b*

A detailed description of the Trilateral Project B3b is given in an earlier study.[29] In summary, the report on the Trilateral Project B3b describes the patent practices of the USPTO, EPO and JPO in an area of biotechnology dealing with biological molecules and uses of such molecules in methods of identification (assays) and methods of disease treatment. Four hypothetical cases, each with a very similar set of five or six claims, were used for the comparative study.

Table 1 summarises the characteristics of the cases used in Trilateral Project B3b. It is convenient to pair the 4 separate cases into two groups. In one group of cases (Group A), homology searches were used to predict some relationship between biological molecules. In the second group of cases (Group B), experimental methods were used to determine a relationship between a biological molecule and a specific disease.

Table 1: Characteristics of the Cases used in Trilateral Project B3b

Group / Case / Characteristic	A 1	A 3	B 2	B 4
Method used to support asserted function of specified receptor protein	Homology search	Homology search	Experimental	Experimental
Knowledge of the relationship between specified receptor protein and a specific disease or biological function	Unknown	Unknown	Confirmed eg, obesity	Confirmed eg, obesity
Example of receptor agonists identified from screening method	None	Described	None	Described

Within each group, one case provides examples of agonists that have been identified while the other case does not provide any such examples. Where no examples are provided, there are 5 claims which may be classified according to subject matter, namely, one each for:

(i) a specified receptor protein,

(ii) a screening method for identifying agonists of the specified receptor protein,

(iii) a non-specified receptor agonist identified by the screening method,

(iv) a method of medical application of a non-specified receptor agonist, and

29 See Lim and Christie, above n 8, 241-3.

(v) a monoclonal antibody which recognises the specified receptor protein.

Where examples are provided, there are the six claims, namely, one each for the above five claims and an additional claim to a method of medical application of a specified receptor agonist (being one of the example agonists identified by the claimed screening method).

The four patent specifications were drafted with the intention of being taken to have complied with the novelty and inventive step (non obviousness) requirements.[30] The three Patent Offices individually assessed each claim for validity under the equivalents of the following three US patent law requirements: (i) utility, (ii) written description, and (iii) enablement.[31] For the EPO these requirements are, respectively: (i) industrial application, (ii) clarity and support, and (iii) sufficiency of disclosure requirements.[32] For the JPO, these requirements are, respectively: (i) industrial applicability, (ii) clarity of claims, and (iii) description of enablement requirements.[33] These three patent law requirements are referred hereafter by the US terminology — namely: 'utility', 'written description' and 'enablement'.

C *Reach-through Claims of the Trilateral Project B3b*

Table 2 summarises the types of the claims of the Trilateral Project B3b in terms of a reach-through concept previously described.[34] Of the six different claim types, classified above according to subject matter, the claims to a specified receptor protein and the claims to a screening method for identifying agonists of the specified receptor protein are *not* reach-through claims. The claims to non-specified receptor agonists identified by the claimed screening method, and the claims to medical applications of non-specified receptor agonists *are* reach-through claims.[35] A claim to a medical application of a specified receptor agonist, which had been identified by the claimed screening method, for the treatment of an unspecified disease is also a reach-through claim. We have classified the claims to a monoclonal antibody which recognises a specified receptor protein as *quasi* reach-through claims. In a similar way, the claims to a medical application of a specified receptor agonist, which had been identified by the claimed screening method, for treatment of a specific disease are *quasi* reach-through claims.

30 We assume that this was done so as to focus the Trilateral Office examiners solely on other patentability requirements.

31 35 USC 101, 35 USC 112 [1], 35 U.S.C 112 [1] respectively.

32 EPC arts 57, 84, 83 respectively.

33 *Japanese Patent Law* ss 29(1), 36(6)(ii), 36(4) respectively.

34 See Lim and Christie, above n 8, 240-1.

35 Our interpretations are consistent with those of the UKPO. The UKPO have outlined, by examples, that a claim to a compound identified by a screening method and a claim to a use of a compound so identified, in therapy, are reach-through claims: see UKPO, above n 18.

Table 2: Descriptions and Categorisation of the Claims from the Trilateral Project B3b

Claim No.	Subject Matter	Type of Claim
1	Specified receptor protein	Not reach-through (NRT)
2	Screening method	NRT
3	Non-specified receptor agonist	Reach-through (RT)
4	Medical application of a non-specified receptor agonist	RT
5	Medical application of a specified receptor agonist for an unspecified disease	RT
5	Medical application of a specified receptor agonist for a specific disease	Quasi reach-through (QRT)
5	Monoclonal antibody	QRT
6	Monoclonal antibody	QRT

This categorisation is based on the way we have conceptualised a reach-through claim; namely, as a claim that is directed not to the current invention but to subject matter that is defined in terms of a relationship to the current invention and in circumstances where there is no certainty as to how to obtain this subject matter. In these four cases the receptor protein is the current invention — hence, a claim to it is not a reach-through claim. While a monoclonal antibody is not the current invention, the technology used to derive antibodies is now well developed, such that it is reasonably certain that an antibody can be produced once the sequence of a protein is known. Such a claim is, therefore, more properly classified as quasi reach-through. By similar reasoning a claim directed to a medical application of a *specified* receptor agonist for the treatment of a specific disease is more properly classified as quasi reach-through. This claim is not directed to the current invention but the information contained in the specification has described the subject matter of the claim to the extent where there is reasonable certainty of obtaining the claimed invention. The remaining types of claims —to a non-specified receptor agonist identified by the claimed screening method, to a medical application of a non-specified receptor agonist, and to a medical application of a specified receptor agonist for the treatment of an unspecified disease — are neither a claim to the current invention nor a claim to subject matter which may be obtained with reasonable certainty. Such claims are, therefore, reach-through claims.

D *APO Analysis of the Claims*

The APO, on request, assessed the same claims from the Trilateral Project B3b[36] with the same questionnaire used in that project. The following questions were asked in the questionnaire of the Trilateral Project B3b:

1. Do the following claims satisfy clarity, enablement, support and written description requirements? If not, explain why.
2. Do the following claims satisfy the industrial applicability or utility requirements? If not, explain why.
3. If there are any comments on the kind of evidence, argument, and/or claim amendment that may overcome any rejection for failure to satisfy the requirement of 1 and/or 2 above, please state them.

The APO responded to the request with a short document outlining the results of its examination of the claims from the Trilateral Project B3b. This document also included a general discussion about which sections of the *Patents Act 1990* (Cth) the APO determined to be relevant for undertaking the equivalent assessments. The Australian patent law requirements are not the same as those used by the TOs. The APO therefore had to determine how examination practices in Australia would map to the patent law requirements analysed in Trilateral Project B3b.

We provide a discussion below of how the three patent law requirements used by the TOs – that being utility, written description and enablement, as referred to in the US[37] – map to equivalent Australian patent law requirements. In doing so, we clarify and elaborate on the APO's mapping determination, using the examination practices of the APO as set out in the *Manual of Practice and Procedures* ('*APO Manual*').[38]

The assessment of the claims by the APO comprised a table summarising the examination result of each claim under the equivalent Australian patent law requirements, as well as a brief discussion of the reasons for arriving at the result. In most instances, the APO grouped several claims together and provided a single discussion for arriving at the results of the individual claims.

We analysed the document provided by the APO that outlined their response to the questions mentioned above. We then had further communications with the APO, in order to arrive at a fuller understanding of the assessments of the APO.[39] In the sections that follow, we summarise the outcomes of the APO's assessments and we explain our understanding of the reasons for these outcomes.

36 EPO, JPO and USPTO, above n 6.

37 For a discussion of these requirements in each of the three jurisdictions, see Lim and Christie, above n 8, 243-9.

38 APO, *Manual of Practice and Procedures* <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm>. at 28 February 2006.

39 These communications sought clarification and expansion of the APO's reasoning for certain of the assessments provided in the document. These communications also enabled the APO to incorporate into its assessments certain changes made to the law by subsequent court decisions on the scope of the requirements of fair basis and full description.

III AUSTRALIAN LAW AND PRACTICE

A *Relevant Grounds of Examination*

Here we explain which sections of the *Patents Act 1990* (Cth) the APO considers to be relevant for undertaking the equivalent assessments in respect of the Trilateral Project B3b claims. The equivalent Australian patent law requirements are mapped to the three patent law requirements used by the TOs; these being the patent law requirements of utility, written description and enablement, as they are referred to in the USA. The outcomes of that mapping are summarised in Table 3 and are elaborated in the following text.

Table 3: Equivalent examination requirements of the TOs and the APO

USPTO	EPO	JPO	APO
Utility	Industrial application	Industrial application	Manner of manufacture; Description of use
Written description	Clarity and concision; Support	Clarity of claims	Clarity and succinctness; Fair basis
Enablement	Sufficiency of disclosure	Description of enablement	Full description; Best method

1 *Utility Equivalent*

The Australian equivalent of the US patent law requirement of utility is considered by the APO to involve assessments of ss 18(1)(a), 18(1)(c) and some aspects of 40(2)(a) of the Australian *Patents Act 1990* (Cth). Section 18(1)(c) relates to whether an invention is useful; that is, whether or not the invention works. As s 18(1)(c) is not assessed during examination of patents,[40] this requirement of the Australian *Patents Act 1990* (Cth) was not discussed by the APO in its assessment of the claims considered in this study. The APO considered, therefore, that the equivalent of the US requirement of utility is primarily an assessment of whether the invention is a manner of manufacture (s 18(1)(a)) and whether the specification has described a use for the invention. This assessment will necessarily take into account aspects of s 40(2)(a) because the specification must describe the invention in sufficient detail for a person skilled in the art to identify a specific use. We will refer to those aspects of s 40(2)(a) that are assessed for the utility-equivalent requirement as a 'description of use'. It is noted here that s 40(2)(a) also establishes the requirement that the specification provides sufficient detail to put the use into practice. In their

40 APO, above n 38, [2.9.4].

response the APO addressed this requirement under the Australian patent law equivalent of the US requirement of enablement.

Although there is the requirement that the specification disclose a specific use, it is not an absolute requirement that the specification exemplify that specific use. In order to satisfy s 18(1)(a), and the 'description of use' requirement of s 40(2)(a), the APO stated that the use may be explicitly disclosed in the specification or may be readily discernible based on the disclosure in the specification in combination with the prior art. The APO also stated that a potential use for the invention which can be inferred from the specification may be sufficient to satisfy s 18(1)(a) and the description of use requirement of s 40(2)(a). For example, in the field of biotechnology where the invention is a protein, it is sufficient for the specification to disclose that the protein is a member of a class of proteins that are known to play a role in specific physiological functions. From this information, the APO considered that it can be inferred that the proteins have a potential use in the manipulation of these physiological functions. However, disclosure of nothing more than a generic use of a protein is not sufficient. Examples of generic use of a protein, cited by the APO, were use of the protein as a source of amino acids[41] and use of the protein as an antigen[42] for raising antibodies[43].

2 *Written Description Equivalent*

Section 40(3) of the Australian *Patents Act 1990* (Cth) states that 'the claim or claims must be clear and succinct and fairly based on the matter described in the specification'. The requirements of this section have the elements of: (i) clarity of claims; (ii) succinctness of claims; and (iii) fair basis of claims on matter described in the specification. The APO considers that these requirements of s 40(3) broadly cover the US patent law requirement of written description.

According to the *APO Manual*, in order to comply with the clarity requirement of s 40(3), the claims must be clear; that is, the meaning and scope of the claims must be capable of precise determination.[44] The APO would make an objection for lack of succinctness if a claim is unnecessarily prolix, or if a claim entails significant repetition of different and separate claims.[45] It appears that, in practice, the APO assesses for the requirement of succinctness of claims and for the requirement of clarity of claims simultaneously.[46]

41 An amino acid is any of a class of 20 molecules that are combined to form proteins in living things. This definition of an amino acid is given by the *Biotech Life Science Dictionary*, above n 22.

42 An antigen is a substance (eg, a virus or bacterium) that causes an immune system response. This definition of an antigen is given by the *Biotech Life Science Dictionary*, above n 22.

43 An antibody is a protein that is produced in response to an antigen (often a virus or bacterium). It is able to combine with and neutralize the antigen. This definition of an antibody is given by the *Biotech Life Science Dictionary*, above n 22.

44 APO, above n 38, [2.11.7.2]. It is noted that at the time of writing the manuscript for this article, the chapter on 'Specifications' in the *Manual of Practice and Procedures* is in the process of being amended.

45 Ibid.

46 Ibid.

In order to satisfy the fair basis requirement provided in s 40(3), the claims must clearly define the monopoly sought, and the scope of the monopoly must be consistent with, and restricted to, the invention disclosed in the specification. The APO stated that this means that claimed subject matter must be matter that is consistent with the invention or principle described in the specification.[47]

There is no requirement that the application contain an example covering every embodiment that falls within the scope of the claims. Rather, the APO considers that if it is reasonable to predict that general methods or theoretical examples disclosed in the specification could be routinely applied to produce the claimed subject matter, the claimed subject matter is fairly based with no further requirement that the method or example be explicitly described or be actually put into practice. During examination, unless there is either evidence to the contrary or a clear inconsistency between the definition of the invention in the claims and the description of the invention in the specification, the applicant is given the benefit of the doubt that the invention performs in the way,[48] and within the range, described in the specification. As such, the APO considers that if it can be reasonably predicted that an explicitly described example can be extended to the full range of matter claimed, or that a general method can be routinely applied to produce what is claimed, the claims will meet the requirement of fair basis.

3 *Enablement Equivalent*

The provision contained in s 40(2)(a) of the *Patents Act 1990* (Cth) requires a complete specification to 'describe the invention fully, including the best method known to the applicant of performing the invention'. The APO considers that s 40(2)(a) of the *Patents Act 1990* (Cth) broadly covers the US patent law requirement of enablement.

Section 40(2)(a) relates to the level of disclosure in the specification; there must be sufficient detail in the specification to enable a skilled person to identify the claimed invention and to make and use the invention without the need for further experimentation. In the *APO Manual,* two elements are considered relevant: (i) whether the nature of the invention is fully described; and (ii) whether the best method of performing the invention known to the applicant is fully described.[49] An objection that the specification does not fully describe the nature of the invention is only taken if the specification is drafted in such a way that the examiner is unable to gain *any* idea of what the invention actually is.[50] For the purposes of describing the best method of performing the invention, there is no obligation on the applicant to describe more than a single preferred embodiment of the invention.[51] Furthermore, the method of performance may be described in general terms and

47 Ibid [2.11.7.3].

48 Ibid [2.11.6.6].

49 Ibid [2.11.6.1].

50 Ibid [2.11.6.5].

51 Ibid [2.11.6.6].

need not include an actual example.[52] The APO will not make an objection if the applicant can describe the invention so that the method of performance is implicit in the specification without the inclusion of an example.[53] Unless there is either evidence to the contrary or a clear inconsistency between the definition of the invention in the claims and the description of the invention in the specification, the applicant is given the benefit of the doubt that the invention performs in the way, and within the range, described in the specification.[54]

B *APO's Assessment of the Claims*

The outcomes of the APO's assessments of the claims of the Trilateral Project B3b, under each of the requirements equivalent to utility, written description and enablement, are set out in Tables 5, 6 and 7 in the Appendix. Those tables also show the outcomes of the assessments of the same claims by the TOs.

In Table 4, below, we combine the APO and TOs assessments under the individual requirements, to show the *overall* validity of each of the claims. That is to say, we show in Table 4 whether or not the claim was considered to satisfy all three of the patent law requirements being assessed. It will be noted from Table 4 that there are a number of claims in respect of which the APO reached a conclusion on validity that is different to the conclusion reached by the TOs. These differences are emboldened in the Table.

Table 4: Comparisons of the Assessments of Overall Validity of Claims by the APO against Assessments of Overall Validity of Claims by the TOs[55]

	Case	**1**	**1**	**3**	**3**	**2**	**2**	**4**	**4**
	Group	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**B**
	Office	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**
Specified Receptor Protein	Claim 1	Y	N	Y	N	Y	Y	Y	Y
Screening Method	Claim 2	Y	N	Y	N	Y	Y	Y	Y
Non-specified Receptor Agonist	Claim 3	N	N	N	N	N	N	N	N

52 Ibid.

53 Ibid.

54 Ibid.

55 "Y' means the claim satisfied all the requirements of utility (or equivalent), written description (or equivalent), and enablement (or equivalent); 'N' means that one or more of these requirements were not met; and '----' means this claim was not applicable.

Medical Application of Non-specified Receptor Agonists	Claim 4	N	N	N	N	Y	N	Y	N
Medical Application of Specified Receptor Agonists	Claim 5	----	----	N	N	----	----	Y	Y
Monoclonal Antibody	Claim 5	Y	N	----	----	Y	Y	----	----
Monoclonal Antibody	Claim 6	----	----	Y	N	----	----	Y	Y

Comparisons of the conclusions of the Patent Offices on the overall validity of claims, illustrated in Table 4, show that there is only 64% agreement between the APO and the TOs when assessments on the overall validity of claims are made with a *combination* of the patent law requirements. That is to say, eight of the 22 claims which the TOs found invalid were allowed by the APO.

Comparisons of conclusions of the Patent Offices on the validity of claims assessed with a *single* requirement have been made in Tables 5, 6 and 7 in the Appendix. These tables show that there is 50%, 86% and 46% agreement between the APO and the TOs when validity of the claims is assessed with the single requirement of the equivalent of utility, written description or enablement, respectively. For each different conclusion reached, the result was always that the APO found that a particular requirement was satisfied where the TOs found that the equivalent requirement was not satisfied. That is to say, where the APO differed from the TOs, the APO was always more generous in its assessment.

It should be noted that the comparisons made in each table take into account the full set of claims used in Trilateral Project B3b. This claim set is made up of claims that are reach-through, quasi reach-through and non reach-through. This is mentioned here because we want to draw attention to the fact that the APO appears to be differing from the TOs even in regard to examination practices of non reach-through biotechnology claims. This finding means that the APO appears to allow claims that are assessed by the TOs as being invalid, regardless of their reach-through state.

Of the eight claims that were assessed to be valid by the APO but invalid according to the TOs, six of these claims lacked both the requirements of utility and enablement when assessed by the TOs.[56] The subject matters of these six claims are a specified receptor protein (two claims), a screening method for identifying receptor agonists (two claims), and a monoclonal antibody (two claims). Each of these claims is a claim in one of the two cases (case 1 or case 3) where homology searches were used to predict some relationship between the biological molecules.

56 See Tables 5 and 7 in the Appendix.

This means a disease or biological function had not been specified for the claimed receptor protein. The lack of stipulation of a disease or biological function formed the underlying basis for the reasons why, under the practices of TOs, these claims did not satisfy either of the requirements of utility or enablement. In contrast, under Australian practice, each of these six claims satisfied the equivalent of those requirements (manner of manufacture/description of use, and full description, respectively).

The remaining two of the eight claims assessed to be valid by the APO but invalid according to the TOs are claims to a medical application of non-specified receptor agonists where a disease or biological function has been specified. These claims were assessed by the TOs to lack the requirements of both written description and enablement.[57] In contrast, the assessment of the APO was that these claims satisfied the equivalent of these requirements (fair basis and full description, respectively).

C *Comparison of the Application of the Validity Requirements*

1 *Utility Equivalent*

The Australian equivalents to the requirement of utility are manner of manufacture and description of use. The assessment of the TOs was that only 11 claims of the Trilateral Project B3b — those where a specific disease had been described[58] — satisfied the utility requirement. In contrast, all the 22 claims were assessed by the APO to satisfy the equivalent of the utility requirement.

It appears that whilst the APO states that its examination practice requires a specification to disclose a specific use to satisfy the manner of manufacture requirement of s 18(1)(a) and the description of use requirement of s 40(2)(a), 'specific' seems to be interpreted broadly. These requirements will be satisfied if the specification discloses a use of a compound which is a use in the treatment of a specific disease or a use as a reagent in a specific assay. However, the requirements will also be satisfied if it can be inferred from the specification that there was a potential use; say, use of a compound for further characterisation of a physiological pathway. It would seem that use for the purposes of characterisation of a physiological pathway is much less specific and of a different genus compared to use in the treatment of a specified disease.

2 *Written Description Equivalent*

The Australian equivalents of the written description requirement are clarity of claims, succinctness of claims, and fair basis of claims. The assessment of the APO was that all the claims met the requirement of clarity. The APO made no express reference to assessment for succinctness. Because it appears that, in

57 See Tables 6 and 7 in the Appendix.

58 For the particular claims that satisfied this requirement under the practice of the TOs, see Table 5 in the Appendix.

practice, the APO assesses for the requirement of succinctness of claims and for the requirement of clarity of claims simultaneously, we have assumed that in the absence of express references to lack of succinctness, all the claims in this study were assessed by the APO to have met the requirement of succinctness. It follows that, where a particular claim was assessed by the APO to not satisfy the equivalent of the requirement of written description, it was because the claim was considered to lack fair basis.

Of the 10 claims that TOs considered did not satisfy the written description requirement, three were considered by APO to satisfy the Australian equivalent.[59] A striking observation is made in regard to the assessment of one of these claims: a claim to a screening method for identifying receptor agonists where a disease was not specified, and the specification did not contain any description indicative of the activated state of the receptor protein (case 1, claim 2). This claim did not satisfy any of the requirements of utility, written description or enablement according to the TOs. Under the Australian practice, however, the equivalent requirements were all satisfied. In regards to the requirement of written description, under the practices of the TOs this requirement was not satisfied because the specification did not describe any activity for the receptor protein that is identified as the activated state of the receptor protein. The specification therefore did not describe any criteria for identifying agonists of the receptor protein, and so did not describe the criteria for designing a screening method. In contrast, the assessment of the APO was that the same specification was restricted to methods that are based on assessing the activation-state of the specified receptor protein, and therefore fair basis was satisfied under Australian practice. It is not clear to us how such a disclosure could describe to the skilled person the activity of the specific receptor that could be indicative of the activated state of the receptor protein. There appears to be no underlying principle on which to design a screening method, and therefore the scope of the monopoly cannot be clear.

3 *Enablement Equivalent*

The Australian equivalents to the requirement of enablement are full description and best method. Each specification of a case from Trilateral Project B3b only provides an outline of the specification describing the invention in general terms. The APO therefore assumed, for the purposes of this study, that there was compliance with the requirement of 'best method'. It follows that, where a particular claim was assessed by the APO to not satisfy the equivalent of the requirement of enablement, it was because the specification was considered to lack a full description of the invention.

Of the 15 claims that TOs considered did not satisfy the enablement requirement, 12 were considered by APO to satisfy the Australian equivalent.[60] One explanation

59 For the particular claims that satisfied this requirement under the practice of the APO, see Table 6 in the Appendix.

60 For the particular claims that satisfied this requirement under the practice of the APO, see Table 7 in the Appendix.

for these discrepancies is the more liberal approach of the APO regarding disclosing a specific use for the claimed receptor protein. Where a specific disease had not been described but a physiological process had been disclosed in the specification, under the Australian practice the specifications satisfied the requirement of full description for each of the claims for a specified receptor protein, a screening method for identifying receptor agonists, and a monoclonal antibody. Under the practices of the TOs, the specifications of each of these claims where a disease had not been specified did not satisfy the requirement of enablement. The assessment of the TO was that those specifications that only disclosed a physiological process but did not specify a disease did not describe to a skilled person how to use the claimed invention without undue experimentation. For example, a claim to a specified receptor protein where a disease had not been specified did not satisfy the enablement requirement under the practices of the TOs because, although a skilled person can prepare the receptor protein from the recited peptide sequence, it would be undue burden for the skilled person to perform the invention over the whole area that included the determination of the specific function of the claimed receptor protein. In contrast, the assessment of the APO was that there was support in the specification for how to use the receptor protein for the further characterisation of the physiological process in respect of which the receptor protein is involved, even where a specific disease had not been described.

There also appears to be a significant discrepancy between the APO and TOs in the requirement that the specification describe to a skilled person how to make the claimed invention without further experimentation. In particular, it is observed that under the practices of the TOs, a specification that did not provide a description of any particular biological process in which the receptor protein is involved — and therefore that did not describe any activity of the specified receptor which could be monitored — did not satisfy the enablement requirement because the specification did not describe how a skilled person could perform a screening method for identifying receptor agonists. In contrast, the assessment of the APO was that the same specification provided disclosure of general methods that are credible and consistent with current practice in the art, and therefore full description was satisfied under Australian practice.[61] It is not clear to us how such a disclosure could describe to the skilled person the activity to be observed in order to identify activation of the specific receptor. Without this information there would be no underlying principle to inform the skilled person on how to design a screening method.

The low threshold for compliance with the requirement of full description under Australian practice is also observed in the reasoning for how objections for lack of full description may be overcome. Where a disease had not been specified, the two claims for a medical application of a non-specified receptor agonist and the one claim to a medical application of a specified receptor agonist did not satisfy the full description requirement. The APO concluded that the specifications were silent with respect to any disease associated with the receptor protein and there were no directions as to how a skilled person would readily determine a disease

61 It is noted that, during examination of a patent, the 'benefit of the doubt' is given to the applicant.

that can be treated using a non-specified or even a specified agonist. Interestingly, the requirement of manner of manufacture and description of use were satisfied for these three claims. Significantly, however, the APO suggested in its comments that if a disease can be described in terms of a biological activity that is an outcome of some interactions concerning the receptor protein, the objection for full description would not be made. An example of such a claim, provided by the APO and drafted in the context of case 3 of the Trilateral Project B3b, is as follows:

> A method for treatment of disease associated with reduced activity of a G-protein coupled receptor,[62] comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.

An objection for lack of full description would not be taken by the APO for this claim. Of relevance for the present discussion is the fact that the specification of case 3 of the Trilateral Project B3b does not disclose any specific disease, but rather describes that the activation of a receptor protein induces a cascade of a G-protein coupled receptor. The APO made no mention regarding the generality of biological outcomes that can be used to describe the disease but it appears that a non-specific description would suffice to remove an objection for lack of full description. The APO did state that the biological activity used to describe the disease to be treated needs to be an outcome of a direct interaction of an agonist with the receptor protein, and that compounds that modulate the activity of the receptor protein at a distance were not included within the scope of the claim.

D *Validity and the 'Reach-through' Issue*

In this section of the paper we compare the APO's and the TOs' assessments of validity of the claims in light of the reach-through concept we previously defined.

1 *Reach-through Claims*

A claim to a medical application of a specified receptor agonist for the treatment of an unspecified disease, a non-specified receptor agonist identified by a screening method, and a medical application of a non-specified receptor agonist, are types of reach-through claims assessed in the Trilateral project B3b. These reach-through claims were all assessed by the TOs to be invalid. A claim to a medical application of a specified receptor agonist for the treatment of an unspecified disease, and a claim for a non-specified receptor agonist were likewise assessed by the APO to be invalid. Also in agreement with the results of the TOs was the assessment by the APO that a claim to a medical application of a non-specified receptor agonist was invalid where a disease or biological function had not been specified for the

62 G-protein coupled receptor is a generic term that is used to refer to cell surface receptors that couple to GTP-binding proteins. These G-protein coupled receptors include receptors for molecules that can be as unrelated as thyroid stimulating hormone, rhodopsin and neurotransmitters. Our description of G-coupled proteins has been adapted from the definition given by the *Dictionary of Cell and Molecular Biology* (3rd ed) <http://on.to/dictionary> at 25 November 2005.

claimed receptor protein. However, in contrast to the TOs, the APO found a claim to a medical application of a non-specified receptor agonist to be valid where a disease or biological function had been specified for the claimed receptor protein.

Under the Australian practice, a claim to a medical application of a specified receptor agonist for the treatment of an unspecified disease does not satisfy either the requirement of fair basis or the requirement of full description, but will satisfy the requirements of manner of manufacture and description of use. According to the TO, this claim does not satisfy any of the patent law requirements of utility, written description or enablement.

Under the Australian practice, only the fair basis requirement operated to filter out from grant reach-through claims whose subject matter is a non-specified receptor agonist. The requirements equivalent to utility and enablement were both assessed by the APO to have been satisfied for all claims for a non-specified receptor agonist. Under the practices of the TOs, in contrast, these claims satisfy neither the requirement of written description nor the requirement of enablement. Only the requirement of utility was assessed by the TOs to have been satisfied for these claims, and only where a disease was specified for the claimed receptor protein. Therefore, the only agreement between the assessments of the TOs and the APO for reach-through claims whose subject matter is a non-specified receptor agonist is the fact that these claims do not satisfy the written description requirement.

Under Australian practice, the fact that the requirement of full description is satisfied for a claim to a non-specified receptor agonist is very significant for an assessment of the validity of this reach-through claim type. Under the practices of the TOs, the requirement of enablement is *not* satisfied for a claim to a non-specified receptor agonist. Therefore, under examination practices of the TOs, either one of the requirements of written description or enablement will operate to filter out from grant reach-through claims for a non-specified receptor agonist. The important contrast under Australian practice is that only the requirement of fair basis will operate to invalidate this reach-through claim type. The requirement of full description will not invalidate a reach-through claim to a non-specified receptor agonist.[63]

The TOs considered that all the specifications did not provide a disclosure of a representative number of structurally related compounds that were receptor agonists, and consequently the skilled person would not know how to make any non-disclosed compounds falling within the scope of the claim. Even if examples of receptor agonists identified from the screening method had been recited in the specification, the assessments of the TOs were that a claim to a genus of receptor agonist would not satisfy the requirement of enablement without a general structural formula for a larger group of compounds that plausibly act as receptor agonists. In contrast, the conclusion of the APO was that all claims for a non-specified receptor agonist were fully described for the following reason: since the non-receptor agonist may be a

63 In contrast to the APO, the assessment of the UKPO is that reach-through claims whose subject matter is a compound identified by a claimed method would be unclear, not supported by the description of invention in the patent specification, and would lack sufficiency of disclosure: UKPO, above n 18.

pre-existing compound, and the method of identification of a non-specified receptor agonist has been described, it can be assumed that the skilled person can readily determine how to synthesise the non-specified receptor agonist once they have identified this. In our opinion, identification of a product from a screening method does not teach a skilled person how to synthesise the product. This was, in effect, the argument of the TOs which stated that a screening method for finding a product is not equivalent to a positive recitation of how to make the product.

Another significant difference between the practices of the APO and the TOs is that reach-through claims whose subject matter is a medical application of a non-specified receptor agonist will not be completely filtered out from grant in Australia. While these reach-through claims were all assessed by the TOs to be invalid, under the Australian practice, a claim to a medical application of a non-specified receptor agonist will be invalid only when a disease has not been specified for the claimed receptor protein. According to the TOs, neither the requirement of written description nor the requirement of enablement will be satisfied for a claim to a medical application of a non-specified receptor agonist regardless of whether a disease has been specified for the receptor protein; this being a result similar to that for reach-through claims whose subject matter is a non-specified receptor agonist. In contrast, both the requirements of fair basis and full description will be satisfied according to the APO for a claim to medical application of a non-specified receptor agonist where a disease has been described for the specified receptor protein. Neither fair basis nor full description was satisfied where a disease was not specified for the claimed receptor protein. Therefore these two requirements, whether alone or in combination, are not able to completely filter out from grant in Australia the reach-through claim whose subject matter is a medical application of a non-specified receptor agonist.

In Australia there is the anomalous result that, where a disease has been specified for the claimed receptor protein, a claim to a medical application of a non-specified receptor agonist is valid while a claim to the non-specified receptor agonist itself is invalid. If fair basis has not been satisfied for a claim to a non-specified receptor agonist when a disease has been specified, then we strongly doubt that fair basis is satisfied for a claim to *a medical application of* a non-specified receptor agonist when a disease has been specified. This is because specifying a disease will still not define the full range of receptor agonists that fall within the scope of the claim to a medical application of a non-specified receptor agonist. This was, in effect, the conclusion of the TOs, which reasoned that when a claim to a non-specified receptor agonist does not satisfy the written description requirement, a claim to a medical application of a non-specified receptor agonist will also fail to satisfy the written description requirement. In contrast, the assessment of the APO was that a claim to a medical application of a non-specified receptor agonist, where a disease has been specified, satisfied fair basis because the APO regarded the scope of the diseases to be treated in the claimed medical application to be limited to methods of treating the specified disease, and the scope of the receptor agonists available for use in the claimed medical application to be limited to those that activate the receptor protein by direct interaction with the receptor protein.

We recognise that, under Australian law, it is permissible to limit a claim by reference to the result,[64] so long as, in the case of an article, the limitation is sufficient to characterise the construction of the article claimed.[65] Applying this principle of law in the present situation, the result of the reference is the specified receptor protein becoming activated upon direct interaction with a receptor agonist. Limitation by reference to attaining an activated state of the receptor *protein* does not sufficiently characterise the full range of receptor *agonists* that would fall within the scope of the claim. A definition of a receptor *agonist* in terms of a characteristic of the receptor *protein* does not, for example, provide any defining structural characteristic(s) common to each member of the range of receptor agonists. It is not clear which receptor agonists are included and which are excluded from the scope of the claim, even when a disease is specified and so, in our view, the claim to a medical application of a non-specified receptor agonist is not fairly based. Limitation of receptor agonists to those identified in the screening method would not cure the fair basis problem because there would still be no structural characteristic(s) of the receptor agonists that would define the whole genus of receptor agonists claimed. There would also no way of distinguishing any of the receptor agonists that fall within the scope of the claim from those in the prior art.

Under the Australian practice, a claim to a medical application of a non-specified receptor agonist could satisfy the requirement of full description by mentioning a disease associated with a claimed receptor protein. The APO reasoned that disclosure of the involvement of a specified receptor protein in a specific disease, and a disclosure of a method of identifying agonists of the receptor protein, will provide sufficient information for the skilled person to develop, using standard methods of treatment that are well known in the art, a medical application of a non-specified receptor agonist. It is not clear to us that there are standard methods of treatment, and it is also not clear to us how formulation of a medical application of any of the receptor agonists could be fully described. Formulation of a medical application using the full range of receptor agonists claimed cannot be fully described because protocols for medical application depend upon the nature of the compound being administered. This was, in effect, the reasoning of the TOs, which concluded that, without undue experimentation, a person skilled in the art would not know how to perform the medical application claimed over a full range of receptor agonists that may be identified from a screening method. It is recognised that Australian law only requires the stipulation of a single preferred embodiment of the invention for a specification to fully describe the claimed invention.[66] However, it is difficult to see how formulation of a medical application for the full range of receptor agonists claimed can be fully described. This is because, firstly, there is no defining structural characteristic(s) for a larger group of compounds that plausibly act as receptor agonists and, secondly, protocols for medical application depend upon the nature of the compound being administered.

64 *No-Fume Ltd v Frank Pitchford & Co Ltd* (1935) 52 RPC 231.

65 *Mullard Radio Valve Co Ltd v British Belmont Radio Ltd* (1939) 56 RPC 1.

66 *Kimberly Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1.

2 *Quasi Reach-through Claims*

Two of the claim types used in Trilateral Project B3b are quasi reach-through claims; namely, a claim to a monoclonal antibody which recognises a specified receptor protein, and a claim to a medical application of a specified receptor agonist for treatment of a specific disease. A claim to a monoclonal antibody was assessed by the APO as valid regardless of whether a disease or biological function had been specified and associated with the claimed receptor protein. In contrast, the TOs would have invalidated a claim to a monoclonal antibody, where a disease or biological function had not been specified and associated with the claimed receptor protein, on the grounds that such a claim would not have satisfied the requirements of utility and enablement.

A claim to a medical application of a specified receptor agonist for treatment of a specific disease was assessed by the APO and the TOs as satisfying all three of the patent law requirements.

3 *Non Reach-through Claims*

Two of the claim types used in Trilateral Project B3b are neither reach-through nor quasi reach-through; these claims are non reach-through claims. The non-reach-through claims are a claim to a specified receptor protein, and a claim to a screening method for identifying agonists of the specified receptor protein. Both these claim types were assessed by the APO as valid regardless of whether a disease had been specified and associated with the claimed receptor protein. Where a disease had not been specified or a biological function had not been associated with the claimed receptor protein, assessments by the TOs would have invalidated a claim to a specified receptor protein and to a claim to a screening method for identifying receptor agonists, on the grounds that such claims would not have satisfied the requirements of utility and enablement.

IV CONCLUSIONS

A *Findings*

Under Australian practice, not all types of reach-through claims in the field of biotechnology are filtered out from grant of a patent. This is because the Australian patent law requirements of fair basis and full description (being the equivalents of the US requirements of written description and enablement, respectively), whether alone or in combination, are unable to invalidate all types of reach-through claims. In comparison, all types of reach-through claims in the field of biotechnology are filtered out from grant by the TOs. Under the practice of the TOs, either one of the patent law requirements of written description or enablement operate to invalidate a reach-through claim.[67]

67 Lim and Christie, above n 8, 264-5.

The fact that half of the claims of the Trilateral Project B3b lacked the requirement of utility under the practices of the TOs, whereas all the claims satisfied the Australian equivalent of this requirement (namely, manner of manufacture and description of use) under the practice of the APO, strongly suggests that a lower threshold applies in Australia. When considering the equivalent of utility, the APO really only asks if there is any use for the invention described in the specification. An implication of a potential use — say, use of a non-specified receptor agonist for characterisation of the physiological process in respect of which the receptor protein is involved, even where a disease or biological function had not been described with the receptor protein — was considered by the APO as sufficient to satisfy both manner of manufacture and description of use. Under the practices of the TOs, a specific disease or biological function must have been described in the specification in order for utility to be satisfied for all the claims of the Trilateral Project B3b.

The apparently lower threshold for satisfaction of the Australian patent law requirement of description of use appears to be reflected in assessments for satisfaction of the Australian patent law requirement of full description (being the equivalent of the US requirement of enablement). For example, a specification was considered by the APO to have fully described to the skilled person how to use a receptor protein or a monoclonal antibody where a disease had not been specified. Under the practices of the TOs, a peptide sequence recited for the specified receptor protein would allow a skilled person to prepare the receptor protein and monoclonal antibodies towards the receptor protein. However, where a disease had not been specified for the receptor protein, it was considered by the TOs that there would be undue burden for the skilled person to perform the invention that included determination of the specific function of the receptor protein, and so the claim would not satisfy the requirement of enablement.

It appears that whilst the patent law requirements of written description or enablement are sufficient to filter out from grant reach-through claims in the field of biotechnology when such claims are examined by the TOs, under the Australian practice the equivalent requirements (namely, fair basis and full description, respectively) will not always filter out from grant such reach-through claims. Furthermore, overall validity assessments of all claims, whether reach-through or quasi reach-through or non reach-through, found greatest discrepancies in examination practices for the requirements of utility and enablement. In assessments using either one of these requirements, the APO and TOs were in agreement only for about half of the claims of the Trilateral project B3b.

B *Consequences*

It would seem that the differences between the APO and the TOs in examination practices observed, even in this limited study using the claims of the Trilateral Project B3b, are very significant. The results show that the APO may be granting Australian patents that are less robust than those being granted by the TOs. In light of the fact that more that 80% of patents world-wide are granted by the TOs,[68] obtaining a biotechnology patent with reach-through claims in Australia will not provide a good indication of whether a similarly drafted patent will withstand the examination practices of the US, Europe and Japan. In fact, the results show that that some patents with reach-through claims will be granted in Australia but will not be able to withstand examination in either the US, Europe or Japan — or, indeed, in all three of the TOs.

This situation is problematic, for at least two reasons. First, having different examination outcomes in respect of the same claims leads to different levels of patent protection around the globe. These international discrepancies in protection result in increased transaction costs for patentees and competitors of patentees, which in turn lead to a reduction in net welfare from the patent system. It is for this reason that key patenting countries have committed to increasing the level of harmonisation within their respective jurisdictions – a fact reflected in the provisions of the recent Free Trade Agreement between Australia and the US.[69]

Second, and more importantly, the very fact of a different examination outcome in respect of the same claims means that one or other of the patent offices is applying the wrong standard to examination of these types of claims: either the TOs are applying a standard that is too high, or the APO is applying a standard that is too low. It has been previously written that the monopoly rights of a patent should not 'reach-through' to further possible inventions that could result from the invention disclosed; and thus, that patents should not be granted for claims that are reach-through claims.[70] In our opinion, therefore, it is the APO that is applying the wrong standard to the examination of biotechnology patent reach-through claims.

For these reasons, we believe that the current situation should be addressed, so as to bring Australian-granted biotechnology patents into alignment with the equivalent patents granted by the major Patent Offices of the world. The most obvious and direct way to achieve that outcome is for the Australian patent legislation to adopt patentability requirements that mirror the utility, written description and enablement (and equivalent) requirements of the US, the EPC and Japan, and for the APO to adopt examination practices in relation to those requirements that mirror the practices of the TOs.

68 EPO, JPO and USPTO, *The Website of the Trilateral Co-operation* (2007) The Trilateral Co-operation <http://www.trilateral.net> at 24 August 2007.

69 Art 17.9 of the *Australia-United States Free Trade Agreement done at Washington, DC on 18 May 2004* is concerned with patents. Paragraph 14 of that Article provides: 'Each Party shall endeavour to reduce the differences in law and practice between their respective systems, including in respect of differences in determining the rights to an invention'.

70 Lim and Christie, above n 8, 266.

APPENDICES

Table 5: Comparisons of the APO and TOs Assessments of the Utility (or equivalent) requirement

	Case	**1**	**1**	**3**	**3**	**2**	**2**	**4**	**4**
	Group	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**B**
	Office	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**
Specified Receptor Protein	Claim 1	(Y,Y)#	N	(Y,Y)	N	(Y,Y)	Y	(Y,Y)	Y
Screening Method	Claim 2	(Y,Y)	N	(Y,Y)	N	(Y,Y)	Y	(Y,Y)	Y
Non-specified Receptor Agonist	Claim 3	(Y,Y)	N	(Y,Y)	N	(Y,Y)	Y	(Y,Y)	Y
Medical Application of Non-specified Receptor Agonists	Claim 4	(Y,Y)	N	(Y,Y)	N	(Y,Y)	Y	(Y,Y)	Y
Medical Application of Specified Receptor Agonists	Claim 5	-----	-----	(Y,Y)	N	-----	-----	(Y,Y)	Y
Monoclonal Antibody	Claim 5	(Y,Y)	N	-----	-----	(Y,Y)	Y	-----	-----
Monoclonal Antibody	Claim 6	-----	-----	(Y,Y)	N	-----	-----	(Y,Y)	Y

The Australian equivalent to the utility requirement is an assessment of s 18(1)(a) (manner of manufacture) and some aspects of s 40(2)(a). The collective assessment is represented in this table in the following order: (manner of manufacture, description of use).

'N' means that the requirement was not met.

'Y' means that the requirement was met.

'-----' means this claim was not applicable.

Table 6: Comparisons of the APO and TOs Assessments of the Written Description (or equivalent) requirement

	Case	**1**	**1**	**3**	**3**	**2**	**2**	**4**	**4**
	Group	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**B**
	Office	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**
Specified Receptor Protein	Claim 1	Y	Y	Y	Y	Y	Y	Y	Y
Screening Method	Claim 2	Y	N	Y	Y	Y	Y	Y	Y
Non-specified Receptor Agonist	Claim 3	N	N	N	N	N	N	N	N
Medical Application of Non-specified Receptor Agonists	Claim 4	N	N	N	N	Y	N	Y	N
Medical Application of Specified Receptor Agonists	Claim 5		-----	N	N		-----	Y	Y
Monoclonal Antibody	Claim 5	Y	Y		-----	Y	Y		-----
Monoclonal Antibody	Claim 6		-----	Y	Y		-----	Y	Y

'N' means that the requirement was not met.

'Y' means that the requirement was met.

'-----' means this claim was not applicable.

Table 7: Comparisons of the APO and TOs Assessments for the Enablement (or equivalent) requirement

	Case	**1**	**1**	**3**	**3**	**2**	**2**	**4**	**4**
	Group	**A**	**A**	**A**	**A**	**B**	**B**	**B**	**B**
	Office	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**	**APO**	**TOs**
Specified Receptor Protein	Claim 1	Y	(Y,N)#	Y	(Y,N)	Y	(Y,Y)	Y	(Y,Y)
Screening Method	Claim 2	Y	(N,N)	Y	(Y,N)	Y	(Y,Y)	Y	(Y,Y)
Non-specified Receptor Agonist	Claim 3	Y	(N,N)	Y	(N,N)	Y	(N,N)	Y	(N,N)
Medical Application of Non-specified Receptor Agonists	Claim 4	N	(N,N)	N	(N,N)	Y	(N,N)	Y	(N,N)
Medical Application of Specified Receptor Agonists	Claim 5		-----	N	(N,N)		-----	Y	(Y,Y)
Monoclonal Antibody	Claim 5	Y	(Y,N)		-----	Y	(Y,Y)		-----
Monoclonal Antibody	Claim 6		-----	Y	(Y,N)		-----	Y	(Y,Y)

The enablement requirement is assessed in two parts: 'how to make' and 'how to use' the claimed invention. The assessment is represented in this table in the following order: (How to Make, How to Use).

'N' means that the requirement was not met.

'Y' means that the requirement was met.

'-----' means this claim was not applicable.