

A Comparative Analysis of The Australian Patent Office's Examination of Biotechnology Reach-through Patent Claims

Amanda S.Y. Lim and Andrew F. Christie

Intellectual Property Research Institute of Australia

The University of Melbourne

Intellectual Property Research Institute of Australia

Working Paper No. 09.06

ISSN 1447-2317

May 2006

Intellectual Property Research Institute of Australia

The University of Melbourne

Law School Building

Victoria 3010 Australia

Telephone: 61 (0) 3 8344 1127

Fax: 61 (0) 3 9348 2353

Email: info@ipria.org

www.ipria.org

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

Amanda S.Y. Lim¹ and Andrew F. Christie²

ABSTRACT

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. Our analyses utilised a comparative study undertaken by the TOs towards biotechnology patent claims when assessments were made for the patent law requirements of utility, written description and enablement, as they are referred to in the USA. 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. The patent law requirement of written description alone or enablement alone would operate to invalidate the reach-through claims of that study.

This study analyses how the same claims from the Trilateral Offices' study are assessed by the Australian Patent Office (APO). Firstly, we determine that the APO in their examinations map the patent law requirements of 'utility', 'written description', and 'enablement' to the equivalent Australian patent law requirements of 'manner of

¹ Researcher, Intellectual Property Research Institute of Australia, University of Melbourne. The authors acknowledge with thanks the comments of Kimberlee Weatherall.

² Davies Collison Cave Professor of Intellectual Property, and Director of the Intellectual Property Research Institute of Australia, University of Melbourne.

manufacture and description of use’, ‘clarity, succinctness and fair basis’, and ‘full description and best method’, respectively. We then compare the biotechnology patent examination practices of the APO with those of the TOs in respect to each of the mentioned patent law requirements. Finally, we analyse the approach of the APO towards reach-through claims in biotechnology. We find that under Australian practice not all types of reach-through claims in the field of biotechnology are filtered out from grant of a patent. The Australian patent law requirements of fair basis and full description, whether alone or in combination, are unable to invalidate all types of reach-through claims. It seems, therefore, that the APO is more generous than is the TOs in relation to reach-through claims in biotechnology.

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 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) 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 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 nucleotide³ 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*.⁴

³ A nucleotide is a subunit of DNA or RNA consisting of a nitrogenous base (adenine (A), guanine (G), thymine (T), or cytosine (C) in DNA; adenine, guanine, uracil (U), or cytosine in RNA), a phosphate molecule, and a sugar molecule (deoxyribose in DNA and ribose in RNA). Thousands of nucleotides are linked to form a DNA or RNA molecule. This definition of nucleotide is given by the Biotech Life Science Dictionary <<http://biotech.icmb.utexas.edu/search/dict-search.mhtml>> at 26th April 2006.

⁴ Eisenberg R. S., ‘Reaching Through the Genome’, in Kieff (ed) *Perspectives on Properties of the Human Genome Project*, Advances in Genetics, 50. Amsterdam: Elsevier Academic Press, 2003. 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 research-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.

Reach-through claims have been the subject of some disapproval.⁵ 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.⁶ 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.⁷

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 else⁸ 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

⁵ See, eg, Grassler, F. P., *US treatment of Reach-through Claims and Reach-through Royalties*, section 1.00 <<http://www.sdipla.org/events/past/grassler/ReachThru.htm>> at 3rd October 2003; and Kunin et al, 'Reach-through claims in the age of biotechnology' (2002) 51 *American University Law Review* 609, 638.

⁶ Eisenberg, R., 'Patenting Research Tools and the Law' in *Intellectual Property Rights and Research Tools in Molecular Biology* 6 (National Academy Press 1997), <<http://stills.nap.edu/html/property/2.html#chap2>>; Kunin et al, 'Reach-through claims in the age of biotechnology' (2002) 51 *American University Law Review* 609.

⁷ It is important to note here that reach-through claims are not simply broad claims that read on undisclosed embodiments. Patent claims can legitimately protect variations of an invention that can be achieved through work which is routine and predictable. A patent provides a *qui pro quo*: exclusive use of an invention for a limited time in return for its disclosure to the public. What patent law aims to provide is a system which enables the drawing of appropriate boundaries to distinguish and protect an invention which has been properly disclosed by the inventor. A reach-through claim is an attempt to extend the boundaries of a patent monopoly to further possible inventions that may result as a consequence of information provided through the invention described in the patent specification; see Lim A. S. Y. and Christie A. F., '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.

⁸ Grassler, F. P., *US treatment of Reach-through Claims and Reach-through Royalties* <<http://www.sdipla.org/events/past/grassler/ReachThru.htm>> at 3rd October 2003.

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,⁹ 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

⁹ See Heller, M. A. and Eisenberg R. S., 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698; Nicol, D. and Nielsen, J '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/publiers/BiotechReportFinal.pdf>>; and Neilsen, J., 'Reach-through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-competitive Reach' (2004) *Federal Law Review* 32(2):169.

types of claims.¹⁰ 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').¹¹ The TOs Report provides an account of how each of the three TOs assess 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.¹² Kunin et al have provided an analysis of the assessment undertaken by the USPTO for the TOs Report.¹³ 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.¹⁴ 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.¹⁵

¹⁰ European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Report on Comparative Study on Biotechnology Patent Practices* (2001) Trilateral Project B3b <http://www.uspto.gov/web/tws/B3b_reachthrough.pdf> at 27th September 2003.

¹¹ Ibid.

¹² See Lim A. S. Y. and Christie A. F., '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.

¹³ Kunin et al, 'Reach-through claims in the age of biotechnology' (2002) 51 *American University Law Review* 609.

¹⁴ Grassler, F. P., *US treatment of Reach-through Claims and Reach-through Royalties* <<http://www.sdipla.org/events/past/grassler/ReachThru.htm>> at 3rd October 2003.

¹⁵ Ibid.

In a recent case heard by the United States Court of Appeals for the Federal Circuit, *University of Rochester v Serle*,¹⁶ a number of the claims in issue were directed to methods “for selectively inhibiting PGHS-2¹⁷ 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.¹⁸ The Court of Appeals in the *Rochester* case affirmed the decision of the district court¹⁹ that the University of Rochester patent²⁰ was invalid for failing to comply with the written description requirement of the US patent legislation.²¹

The United Kingdom Patent Office (UKPO) has undertaken a hypothetical examination of the claims from the *Rochester* case, in recast form.²² 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.

¹⁶ (2004) 358 F.3d 916.

¹⁷ 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.

¹⁸ Bohrer, R. A., ‘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.

¹⁹ *University of Rochester v G.D. Searle & Co.*, (2003) 249 F.Supp.2d 216.

²⁰ US Patent No 6,048,850.

²¹ 35 U.S.C. 112, first paragraph.

²² UKPO, ‘The Patentability of “Reach-Through” Claims’ (2004) *Chartered Institute of Patent Agents Journal* 33(3) 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. OUR 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 by us seeks to define a reach-through claim in *conceptual* manner.²³ 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”).²⁴ 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 our 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.

We have previously identified three reach-through claim types in the biotechnology context.²⁵ 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

²³ Lim A. S. Y. and Christie A. F., ‘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.

²⁴ See European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Report on Comparative Study on Biotechnology Patent Practices* (2001) Trilateral Project B3b <http://www.uspto.gov/web/tws/B3b_reachthrough.pdf> at 27th September 2003; and Kunin et al, ‘Reach-through claims in the age of biotechnology’ (2002) 51 *American University Law Review* 609.

²⁵ Lim A. S. Y. and Christie A. F., ‘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.

gene. A claim to a receptor agonist, a molecule that activates a receptor²⁶ 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 antibody²⁷ 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 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

²⁶ 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.mhtml>> at 17th April 2006.

²⁷ 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.

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 our 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.²⁸

II. RESEARCH METHODOLOGY

A. BACKGROUND

Our previous study²⁹ 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)³⁰, written description (clarity and

²⁸ 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, The Patentability of “Reach-Through” Claims (2004) *Chartered Institute of Patent Agents Journal* 33(3) 125.

²⁹ Lim A. S. Y. and Christie A. F., ‘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.

³⁰ In the US, the utility requirement is provided by 35 U.S.C. 101. In Europe and Japan, the requirement for industrial applicability is provided, respectively, by EPC Article 57 and Japanese Patent Law Section 29(1).

support of claims)³¹ and enablement (sufficiency of disclosure)³². We 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. Our 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 Australian Patent Office (APO) to assess these claims from the Trilateral Project B3b.

B. OVERVIEW OF CASES AND CLAIMS OF THE TRILATERAL PROJECT B3B

A description of the Trilateral Project B3b is given in our earlier study.³³ 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

³¹ 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 Article 84 and Japanese Patent Law Section 36(6).

³² In the USA and Japan, the enablement requirement is provided, respectively, by 35 USC 112, first paragraph, and Japanese Patent Law Section 36(4). In Europe, the requirement for sufficiency of disclosure is provided by EPC Article 83.

³³ Lim A. S. Y. and Christie A. F., '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.

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	A 1	A 3	B 2	B 4
Characteristic				
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 e.g., obesity	Confirmed e.g., 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
- (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.³⁴ 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.³⁵ For the EPO these requirements are, respectively, (i) industrial application, (ii) clarity and support, and (iii) sufficiency of disclosure requirements.³⁶ For the JPO, these requirements are, respectively, (i) industrial applicability, (ii) clarity of claims, and (iii) description of enablement requirements.³⁷ 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 the reach-through concept we have previously described.³⁸ 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

³⁴ We assume that this was done so as to focus the Trilateral Office examiners solely on other patentability requirements.

³⁵ 35 U.S.C. 101, 35 U.S.C. 112, first paragraph, and 35 U.S.C. 112, first paragraph, respectively.

³⁶ European Patent Convention (EPC) Article 57, EPC Article 84, and EPC Article 83, respectively.

³⁷ Japanese Patent Law Section 29(1), Japanese Patent Law Section 36(6)(ii), and Japanese Patent Law Section 36(4), respectively.

³⁸ Lim A. S. Y. and Christie A. F., ‘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.

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.³⁹ 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.

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

³⁹ 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, *The Patentability of ‘Reach-Through’ Claims* (2004) *Chartered Institute of Patent Agents Journal* 33(3) 125.

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, at our request, assessed the same claims from the Trilateral Project B3b⁴⁰ with the same questionnaire used in that project. The following questions were asked in the questionnaire of the Trilateral Project B3b:

⁴⁰ European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Report on Comparative Study on Biotechnology Patent Practices* (2001) Trilateral Project B3b <http://www.uspto.gov/web/tws/B3b_reachthrough.pdf> at 27th September 2003.

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 our request with a brief document⁴¹ outlining the results of its examination of the claims from the Trilateral Project B3b. This document included general discussions of 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. A discussion of how the three patent law requirements used by the TOs – that being utility, written description and enablement, as referred to in the US⁴² – map to equivalent Australian patent law requirements is given below. We use the examination practices of the APO as a basis of this mapping determination.

The assessment of the claims by the APO comprised a table summarising the examination result of each claim under the equivalent Australian patent law

⁴¹ The document with the assessment of the APO consists of 6 pages of text. This document is on file with the authors.

⁴² For a discussion of these requirements in each of the three jurisdictions, see Lim A. S. Y. and Christie A. F., '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.

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. In the sections that follow, we explain the reasons and conclusions of the APO on a claim by claim basis.

III. AUSTRALIAN LAW AND PRACTICE

A. RELEVANT GROUNDS OF EXAMINATION

The paragraphs that follow seek to explain which sections of the *Patents Act 1990* (Cth) the APO determined 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; that being the patent law requirements of utility, written description and enablement, as they are referred to in the USA.

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,⁴³ 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, 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 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

⁴³ Australian Patent Office, *Manual of Practice and Procedure*, para 2.9.4 <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> at 28th February 2006.

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 acids⁴⁴ and use of the protein as an antigen⁴⁵ for raising antibodies⁴⁶.

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, 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.⁴⁷ The APO would make an objection for lack of succinctness if

⁴⁴ 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 <<http://biotech.icmb.utexas.edu/search/dict-search.html>> at 24th November 2005.

⁴⁵ A substance (e.g. a virus or bacterium) that causes an immune system response. This definition of an antigen is given by the Biotech Life Science Dictionary <<http://biotech.icmb.utexas.edu/search/dict-search.html>> at 24th November 2005.

⁴⁶ 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 <<http://biotech.icmb.utexas.edu/search/dict-search.html>> at 24th November 2005.

⁴⁷ Australian Patent Office, *Manual of Practice and Procedure*, para 2.11.7.2 <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> at 28th February 2006. It is noted that at the time of writing the manuscript for this article, the chapter on ‘Specifications’ in the *Manual of Practice and Procedure* is in the process of being amended.

a claim is unnecessarily prolix, or if a claim entails significant repetition of different and separate claims.⁴⁸ It appears that, in practice, the APO assesses for the requirement of succinctness of claims and for the requirement of clarity of claims simultaneously.⁴⁹

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.⁵⁰

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,⁵¹ and within the range, described in the specification. As such, the APO considers that if it can be reasonably predicted that an explicitly described

⁴⁸ Ibid.

⁴⁹ Ibid.

⁵⁰ Australian Patent Office, *Manual of Practice and Procedure*, para 2.11.7.3 <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> at 6th March 2006. It is noted that at the time of writing the manuscript for this article, the chapter on 'Specifications' in the *Manual of Practice and Procedure* is in the process of being amended.

⁵¹ Ibid, para 2.11.6.6

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 of Practice and Procedure*, two elements are considered relevant:⁵² (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. 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.⁵³ For the

⁵² Australian Patent Office, *Manual of Practice and Procedure*, para 2.11.6.1 <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> at 28th February 2006. It is noted that at the time of writing the manuscript for this article, the chapter on ‘Specifications’ in the *Manual of Practice and Procedure* is in the process of being amended.

⁵³ Australian Patent Office, *Manual of Practice and Procedure*, para 2.11.6.5 <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> at 28th February 2006. It is noted that at the time of writing the manuscript for this article, the chapter on ‘Specifications’ in the *Manual of Practice and Procedure* is in the process of being amended.

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.⁵⁴ Furthermore, the method of performance may be described in general terms and need not include an actual example.⁵⁵ 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.⁵⁶ 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.⁵⁷

B. ASSESSMENT OF THE CLAIMS

Table 3 summarises the assessments by the APO of the overall validity of each of the claims from the Trilateral Project B3b, and compares them with those of the TOs regarding the overall validity of each claim.

⁵⁴ Australian Patent Office, *Manual of Practice and Procedure* para 2.11.6.6 <http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm> at 28th February 2006. It is noted that at the time of writing the manuscript for this article, the chapter on ‘Specifications’ in the *Manual of Practice and Procedure* is in the process of being amended.

⁵⁵ Ibid.

⁵⁶ Ibid.

⁵⁷ Ibid.

Table 3: Comparisons of the Assessments of Overall Validity of Claims by the APO against Assessments of Overall Validity of Claims by the TOs⁵⁸

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
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

The reasons for the conclusions of the APO on each claim for each of the requirements are summarised in Tables 4, 5 and 6 in the Appendix, and described in detail below.⁵⁹

⁵⁸ '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.

⁵⁹ Each specification of a case from Trilateral Project B3b only provides an outline of the specification describing the invention in general terms. The APO has therefore assumed, for the purposes of their assessment regarding the equivalent of the US requirement of enablement, that the 'best method' requirement has been complied with. Therefore, in this study, we will not discuss assessments for description of 'best method' and refer only to assessments for full description of the invention. 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 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.

1. Specified Receptor Protein

(a) Utility Equivalent

The assessment of the APO was that all of the claims for a specified receptor protein in all four cases met the requirements for manner of manufacture and description of use. The APO considered that, in all of the cases, the specification described the claimed receptor protein in terms of a specific disease or physiological pathway. This was considered sufficient to support a specific use for the claimed receptor protein and was distinguished from generic uses applicable to all proteins, such as use in the generation of antibodies, use as a source of amino acids or use to characterise the unspecified activity of the protein *in vivo*.

(b) Written Description Equivalent

A claim to a specified receptor protein in all four cases was assessed by the APO to have met the requirements for both clarity and fair basis. The APO considered a claim to a specified receptor protein to be restricted to subject matter whose isolation or preparation requires use of the sequence information provided in the specification.

(c) Enablement Equivalent

According to the APO, in each of the cases the specification fully described the receptor protein. There was an explicit description of the peptide sequence of the receptor protein which enabled a skilled person to make the receptor protein without the need for further experimentation.

The APO considered that a specification which described a receptor protein to be directly involved in modulation of a specific disease was a specification that fully described how to use the receptor protein to specifically characterise and modulate this disease. A specification which did not describe a receptor protein to be directly involved in modulation of a specific disease, but disclosed that the receptor protein is a member of a known class of receptor proteins that are implicated in a wide range of physiological process, was also considered by the APO to be a specification that fully described how to use the receptor protein. This was because the APO considered 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.

2. Screening Method

(a) Utility Equivalent

The assessment of the APO was that all of the claims for a screening method for identifying receptor agonists in all four cases met the requirements for manner of manufacture and description of use. In all cases the specification was considered to have described a specific use for the claimed receptor protein. It appears that because the claimed receptor protein was assessed to have a specific use, the APO considered that the specification therefore had also described a specific use for a screening method which involved the claimed receptor protein.

(b) Written Description Equivalent

A claim to a screening method for identifying receptor agonists was assessed by the APO to have met the requirements for both clarity and fair basis in all four cases. The APO considered that the claims were restricted to methods that are based on assessing the activation-state of the specific receptor protein disclosed in the specification.

(c) Enablement Equivalent

The APO assessed that in all of the cases the specification fully described the screening method for identifying receptor agonists. According to the APO, where there is a disclosure of general methods that are credible and consistent with current practice in the art, there is no requirement that the specification also demonstrate successful application of these methods. The specification was considered to have sufficient detail to enable a skilled person to perform the screening method without the need for further experimentation.

The APO considered that a claim to a screening method for identifying agonists of the receptor protein itself describes a use of the screening method. Therefore a specification will fully describe how to use a screening method of identifying a receptor agonist regardless of whether the specification had described a specific disease to be associated with the receptor protein.

3. Non-specified Receptor Agonist

(a) Utility Equivalent

The assessment of the APO was that all of the claims for a non-specified receptor agonist in all four cases met the requirements for manner of manufacture and description of use. The APO considered that, in all of the cases, the specification described the claimed receptor agonist in terms of a specific disease or physiological pathway. This was considered sufficient to support a specific use for the claimed receptor agonist.

(b) Written Description Equivalent

A claim to a non-specified receptor agonist in all four cases met the clarity requirements but did not meet the requirement for fair basis. The claims were considered not to be restricted to subject matter whose sequence or chemical structure was based on, or derived from, the sequence of the receptor protein. The APO reasoned that although use of the receptor protein is required to identify the claimed receptor agonist, this use is not use of the receptor protein to produce the receptor agonist; rather, it is use of the receptor protein to produce information about the receptor agonist. The APO made the assumption that the receptor agonist is a pre-existing compound that is unchanged by the identification method. The identification method simply identifies an inherent characteristic of a receptor agonist; that is, the method identifies a particular compound as being able to bind to the receptor protein and modulate the activity of the receptor protein.

The APO stated that the only way that the fair basis objection might be overcome would be if there had been disclosure of a specific receptor agonist in the specification and the claim was restricted to that receptor agonist.

(c) Enablement Equivalent

According to the APO, in all cases the specification fully described the non-specified receptor agonist. In arriving at the conclusion that the non-specified receptor agonist is fully described, the APO made the assumption that, because the non-specified receptor agonist is a pre-existing compound (for example, a known drug or component of a known library), its synthesis can be readily determined by the skilled person by reference to the prior art or the specification. In addition, the APO also concluded that methods steps used for the screening are routinely practiced in the art and could be readily conducted by the skilled person with the receptor protein in hand. As such, there was sufficient support in the description for a method of identifying and producing a non-specified receptor agonist. The reasoning of the APO appears to be that the non-specified receptor agonist itself is fully described because (i) the method of identification of a non-specified receptor agonist can be described, (ii) the non-specified receptor agonist may be a pre-existing compound, and (iii) it can be assumed that the person skilled in the art can readily determine how to synthesize the non-specified receptor agonist once they have identified it.

The APO considered that a specification which described a receptor *protein* to be directly involved in modulation of a specific disease was a specification that fully described how to use a receptor *agonist* to specifically characterise and modulate this disease. A specification which did not describe a receptor protein to be directly involved in modulation of a specific disease, but disclosed that the receptor protein is a member of a known class of receptor proteins that are implicated in a wide range of

physiological process, was also considered by the APO to be a specification that fully described how to use a receptor agonist. This was because the APO considered that there was support in the specification for how to use the receptor agonist for the further characterisation of the physiological process in respect of which the receptor protein is involved. The APO noted, however, the requirement for full description may not be met where there is no discussion of a disease, and no discussion of a physiological process.⁶⁰

4. Medical Application of Non-specified Receptor Agonist

(a) Utility Equivalent

The assessment of the APO was that all of the claims for a medical application of a non-specified receptor agonist in all four cases met the requirements for manner of manufacture and description of use. The APO considered that, in all of the cases, the specification described the claimed receptor agonist in terms of a specific disease or physiological pathway. This was considered sufficient to support a specific use for the claimed receptor agonist.

(b) Written Description Equivalent

The claims for a method of treatment using a non-specified receptor agonist in all four cases met the requirement of clarity but did not meet the requirement for fair basis

⁶⁰ The APO explained that where a disease has not been explicitly described, but a physiological process has been disclosed in the specification, the requirement of full description will be satisfied where it is reasonable to predict that a disease can be inferred from the disclosure of the physiological process. For example, if a peptide identified to be a receptor agonist disrupts a physiological process, then the APO reasoned that it is reasonable to predict that a disease can be inferred as a result of this disrupted physiological process. The specification would therefore have fully described how to use the receptor agonist. However, where there has been no disclosure of any physiological process that the receptor agonist affects, then it is unlikely that the specification would have fully described how to use the receptor agonist.

where the disease associated with the claimed receptor protein was not disclosed. The claims in which the disease was not specified were said to lack fair basis because the method of treatment claimed could not be routinely engineered based on the sequences and information provided in the specification. The APO considered that the specification disclosed that the claimed method of treatment involved activation of the receptor protein and use of a receptor agonist, but the specification did not provide a principle by which a person skilled in the art could predict the range of diseases associated with activity of the receptor protein. This lack of fair basis objection might be overcome if there was evidence that it was well known that the claimed receptor protein was involved in a specific disease at the priority date and the claims were restricted to treatment of this specific disease.

Where the disease associated with the claimed receptor protein was specified, the APO considered a claim to a method of treatment using a non-specified receptor agonist to be fairly based.

The APO made clear that an agonist is a compound that directly interacts with the receptor.⁶¹ Therefore, the APO stated that there may be fair basis problems where claims are not restricted to use of compounds that clearly work by direct interaction with the receptor protein. The APO considered that the specification provided a principle that can be used to identify compounds that directly interact with the receptor protein, but this principle does not extend to compounds that modulate the

⁶¹ The APO based the definition of the term 'agonist' on that given in Henderson's Dictionary of Biological Terms, Eleanor Lawrence (ed), 12th edition. An agonist is defined as 'any substance that mimics the function of a natural ligand'. The APO infers from this that the agonist is therefore interacting directly with the receptor.

activity of the receptor protein at a distance. The use of compounds which activate a first compound that in turn activates the receptor protein would be considered outside the scope of the invention. A claim to the use of a compound that modulates the activity of the receptor protein, at a distance, for treatment of a specific disease would lack fair basis. In contrast, a claim to the use of a receptor agonist that directly activates the receptor protein, for treatment of a specific disease, is fairly based.

(c) Enablement Equivalent

As discussed above, the APO considered that in all cases the specification fully described the non-specified receptor agonist. However, the specification fully described the medical application of the non-specified receptor agonist only where there is a description of a specific disease that can be treated by the non-specified receptor agonist. The APO reasoned that disclosure of the involvement of the receptor protein — and therefore agonists of the receptor protein — in a specific disease, plus 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.

According to the APO, the specification fully describes a medical application of a non-specified receptor agonist where there has been disclosure in the specification of a disease associated with the receptor protein. If the specification was silent with respect to any disease associated with the receptor protein, there would be no provision of any directions as to how the skilled person would readily determine a

disease that can be treated using the non-specified receptor agonist. In that situation, the specification would not fully describe a medical application of a non-specified receptor agonist. The APO noted, however, 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 of lack of full description would not be made. The APO made no mention regarding the generality⁶² of the biological outcomes which can be used to describe a disease. It seems, however, that the required biological activity needs to be an outcome of a direct interaction of an agonist with the receptor protein.

5. Medical Application of Specified Receptor Agonist

(a) Utility Equivalent

The assessment of the APO was that all of the claims for a medical application of a specified receptor agonist met the requirements for manner of manufacture and description of use. The APO considered that, in all of the cases, the specification described the claimed receptor agonist in terms of a specific disease or physiological pathway. This was considered sufficient to support a specific use for the claimed receptor agonist.

⁶² The APO provided one example of a claim which described a disease in terms of a biological activity that is an outcome of some interactions concerning the receptor protein; this example being a disease associated with reduced activity of a G-protein coupled receptor. A fuller analysis of this example is made in our discussion below. 'G-protein coupled receptor' is a generic term that is used to refer to a cell surface receptor that couples to GTP-binding proteins. G-protein coupled receptors include receptors for molecules that can be as unrelated as thyroid stimulating hormone, rhodopsin and neurotransmitters. It therefore appears that a disease only needs to be described in a very non-specific way for the objection of lack of full description to be avoided. Our description of G-coupled proteins is based on the definition given by the Dictionary of Cell and Molecular Biology, Third Edition <<http://on.to/dictionary>> at 25th November 2005.

(b) Written Description Equivalent

The claims for a method of application of a specified receptor agonist met the requirement of clarity in all cases, but only met the requirement of fair basis only where the disease to be treated was disclosed. The reasons for this assessment are the same as set forth above, regarding claims for medical application of a non-specified receptor agonist.

(c) Enablement Equivalent

According to the APO, the specification fully describes a medical application of a specified receptor agonist where a specific disease that can be treated with the specified receptor agonist has been described in the specification. If the specification was silent with respect to any disease that can be treated with the specified receptor agonist, the specification would not fully describe a medical application of the specified receptor agonist. This is because there would be no provision of any directions as to how the skilled person would readily determine a disease that can be treated using the specified receptor agonist. The APO reasoned that disclosure of the involvement of the receptor protein — and therefore agonists of the receptor protein — in a specific disease, plus 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 specified receptor agonist.

According to the APO, the specification fully describes a medical application of a specified receptor agonist where there has been disclosure in the specification of a

disease associated with the receptor protein. If the specification was silent with respect to any disease associated with the receptor protein, there would be no provision of any directions as to how the skilled person would readily determine a disease that can be treated using the specified receptor agonist. In that situation, the specification would not fully describe a medical application of a specified receptor agonist. The APO noted, however, 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 of lack of full description would not be made. The APO made no mention regarding the generality⁶³ of biological outcomes which can be used to describe a disease. It seems, however, that the required biological activity needs to be an outcome of a direct interaction of an agonist with the receptor protein.

6. Monoclonal Antibody

(a) Utility Equivalent

The assessment of the APO was that all of the claims for a monoclonal antibody in all four cases met the requirements for manner of manufacture and description of use.

The APO considered that, in all of the cases, the specification described the claimed receptor protein in terms of a specific disease or physiological pathway. Since a monoclonal antibody can be used as a tool for further characterisation of the disease or the physiological pathway in respect of which the receptor protein is involved, a monoclonal antibody towards a receptor protein would be a manner of manufacture, and the requirement for description of use was satisfied.

⁶³ The example discussed above in n 62, which was provided by the APO, regarding how an objection of lack of full description can be avoided for a claim towards a medical application of a non-specified receptor agonist can also apply, here, to a claim to a medical application of a specified receptor agonist.

(b) Written Description Equivalent

A claim to a monoclonal antibody in all four cases was assessed by the APO to have met the requirements for both clarity and fair basis. The APO considered a claim directed to a monoclonal antibody to be restricted to subject matter whose isolation or engineering requires use of the sequence information provided in the specification.

(c) Enablement Equivalent

According to the APO, in each of the cases the specification fully described the monoclonal antibody. As there was an explicit description of the peptide sequence of the receptor protein in each case, there was sufficient detail in the specification to enable a person skilled in the art to prepare monoclonal antibodies by methods routine in the art of making monoclonal antibodies based on information provided by the peptide sequence of a protein.

The APO also considered each specification to have fully described how to use the monoclonal antibody, regardless of whether a specific disease associated with the receptor protein was mentioned in the specification. This was because the APO considered that, where no specific disease was mentioned, there was support in the specification for how to use the monoclonal antibody for the further characterisation of the physiological process in respect of which the receptor protein — against which the monoclonal antibodies have been raised — is involved. Where a specific disease is described in the specification, the APO considered that the specification provided

support for how to use the monoclonal antibody in the further characterisation, treatment or diagnosis of the specific disease.

C. NOVELTY AND INVENTIVE STEP ISSUES

The requirements of novelty and inventive step were intended to be satisfied in all of the cases for the purposes of the analysis of the patent claims in the Trilateral Project B3b. The APO, however, considered that it was unlikely that the receptor protein met the requirements of novelty and inventive step in those situations where the specification did not disclose a specific disease or biological function that is associated with the claimed receptor protein. The receptor proteins were identified as members of a known family of receptors, either R-receptors or G protein-coupled receptors, based on their homology with these receptor protein families. Apart from the generic description — R-receptors or G protein-coupled receptors — for members of these known families of the receptor proteins, the APO stated that there was no further information in the specifications to further distinguish the claimed receptor proteins. Although there may be sequence differences between the receptor protein claimed by the applicant and those receptor proteins in the prior art, the APO considered that these differences may be nothing more than those expected to exist between different members of the same receptor protein family. In addition, the APO stated that there is no evidence that the sequence differences contributed to any unexpected differences in function or activity of the receptor protein. As such, the receptor protein claimed by the applicant represented nothing more than a technical equivalent of receptor proteins in the prior art, and so was not novel. A claim directed to the applicant's receptor protein also lacked an inventive step.

In cases where the receptor protein was identified on the basis of homology with known proteins, the APO considered that the lack of novelty and inventive step would extend to claims for monoclonal antibodies, screening methods of identifying receptor agonists, receptor agonists, and medical application of receptor agonists. Monoclonal antibodies might lack novelty because they are monoclonal antibodies that have been raised to other members of the protein family, especially if there was the suggestion that the monoclonal antibodies were produced towards conserved regions present in members of the protein family. Receptor agonists may lack novelty because the receptor agonist is a pre-existing compound that is a known compound. However, a specific receptor agonist may be both novel and inventive if it pre-exists as a member of a known library but the independent members of this library have not been isolated or characterised. Although the library is known and the specific receptor agonist is a member of this known library, there may not have been any previous disclosure clearly identifying this particular receptor agonist as a member of the library.

In cases where the specification discloses a specific disease, or where the biological function has been associated with the receptor protein based on experimental work rather than on the basis of homology with known proteins, the APO considered that there is nothing to suggest that the receptor protein would not meet the requirements of novelty and inventive step. This conclusion that the requirements of novelty and inventive step are met would also extend to claims to monoclonal antibodies.

However, even where a specific disease has been disclosed in the specification, the receptor agonists are still likely to lack novelty because they may be pre-existing compounds that are known — although, as discussed above, a receptor agonist that is

a member of a library may be both novel and inventive if it has not been previously isolated. The medical application of a receptor agonist for a specified disease may also lack novelty or lack an inventive step if the medical application includes specific receptor agonists that are known to be, or that have been suggested to be, efficacious in the treatment of the specified disease.

It is recognised that, in practice, the overall validity of claims must take into account the outcome for the requirements of novelty and inventive step. For the purposes of this paper, however, we will base our discussions and conclusions only on assessments for the requirements of the Australian equivalents to the US requirements of utility, written description, and enablement, because these requirements were the focus of analyses of the TOs in the Trilateral Project B3b.

IV. DISCUSSION

A SUMMARY OF OUTCOMES

Comparisons of conclusions of the Patent Offices on the overall validity of claims, made in Table 3, show that there is 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; 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 4, 5 and 6. 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.⁶⁴ 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.

B. COMPARISON OF VALIDITY REQUIREMENT

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. These six claims (three claims in two cases) are claims in the two cases where homology searches were used to predict some relationship between the biological molecules. 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

⁶⁴ The Australian equivalents of these requirements are, respectively, 'manner of manufacture and description of use', 'clarity, succinctness and fair basis', and 'full description and best method'.

enablement. In contrast, under Australian practice, each of these six claims satisfied the requirements of manner of manufacture, description of use and full description.

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). We have previously defined⁶⁵ claims to a specified receptor protein or a screening method for identifying receptor agonists as claims that are not reach-through, while a claim to a monoclonal antibody has been defined by us as a quasi reach-through claim.

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 both the requirements of written description and enablement. In contrast, the assessment of the APO was that these claims satisfied the requirements of fair basis and full description, respectively. We have previously defined⁶⁶ claims to a medical application of non-specified receptor agonists as claims that are reach-through.

All the 22 claims of the Trilateral Project B3b were assessed by the APO to satisfy the Australian equivalent of the utility requirement, while the assessment of the TOs was that only 11 claims — those where a specific disease had been described — satisfied the utility requirement. It appears that whilst the APO states that its examination

⁶⁵ Lim A. S. Y. and Christie A. F., '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.

⁶⁶ *Ibid.*

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.

The more liberal approach of the APO regarding disclosing a specific use for the claimed receptor protein can also partly explain the discrepancies between assessments by the APO and the TOs under the requirement of enablement. 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 practice⁶⁷. 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.

⁶⁷ It is noted that, during examination of a patent, the 'benefit of the doubt' is given to the applicant.

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 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 receptor⁶⁸, 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

⁶⁸ 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, Third Edition <<http://on.to/dictionary>> at 25th November 2005.

3 of the Trilateral Project B3b⁶⁹ 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. As mentioned above, 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 description⁷⁰. 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.

A striking observation is made in regard to assessments of 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. The reasons for discrepancies concerning satisfaction of manner of manufacture, description of use and full description have been discussed above. Under the practices of the TOs, the requirement of written description 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

⁶⁹ European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Report on Comparative Study on Biotechnology Patent Practices* (2001) Trilateral Project B3b <http://www.uspto.gov/web/tws/B3b_reachthrough.pdf> at 27th September 2003.

⁷⁰ Refer to discussion in n 62 above.

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.

C. VALIDITY AND THE ‘REACH-THROUGH’ ISSUE

We will now discuss the assessments of validity of the claims by the APO 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 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 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.⁷¹

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 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

⁷¹ 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, *The Patentability of "Reach-Through" Claims* (2004) *Chartered Institute of Patent Agents Journal* 33(3) 125.

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 not 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,⁷² so long as, in the case of an article, the limitation is sufficient to characterise the construction of the article claimed.⁷³ Applying this principle of law in the present situation, the result of 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

⁷² *No-Fume Ltd. v Frank Pitchford & Co. Ltd.* (1935) 52 RPC 231.

⁷³ *Mullard Radio Valve Co. Ltd. v British Belmont Radio Ltd.* (1939) 56 RPC 1.

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.⁷⁴ 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.

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.

⁷⁴ *Kimberly Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1.

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.

V. CONCLUSIONS

Under Australian practice, not all types of reach-through claims in the field of biotechnology are filtered out from grant of a patent. In comparison, all types of reach-through claims in the field of biotechnology are filtered out from grant by the TOs; either one of the patent law requirements of written description and enablement operated to invalidate a reach-through claim.⁷⁵ The Australian patent law

⁷⁵ Lim A. S. Y. and Christie A. F., '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.

requirements of fair basis and full description, whether alone or in combination, are unable to invalidate all types of reach-through claims.

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 equivalent of this requirement 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 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 description of use assessed under the Australian patent law requirement equivalent to utility also appears to be reflected in assessments for the requirement of full description. 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 skill person to prepare the receptor protein and monoclonal antibodies towards the receptor protein; but where a disease had not been specified for the receptor protein, it

was considered there would be undue burden for the skilled person to perform the invention that included determination of the specific function of the receptor protein.

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 requirements of fair basis and full description 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.

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 than 80% of patents world-wide⁷⁶ are granted by the TOs, 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 can, and should be, addressed to bring the quality of

⁷⁶ Trilateral website <http://www.uspto.gov/web/tws/tsr99/1intro.htm>

Australian granted biotechnology patents into better alignment with patents granted by the major Patent Offices of the world.

APPENDIX

Table 4: 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 5: 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 6: 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”, “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.

IPRIA Working Papers

No.	Title	Author(s)
09/06	A Comparative Analysis of The Australian Patent Office's Examination of Biotechnology Reach-Through Patent Claims	<i>Lim / Christie</i>
08/06	The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays	<i>Gans / Hsu / Stern</i>
07/06	Research Use of Patented Knowledge: A Review	<i>Dent / Jensen / Waller / Webster</i>
06/06	Managing Knowledge Flows through Appropriation and Learning Strategies	<i>Jensen / Webster</i>
05/06	Market Power, Brand Characteristics and Demand for Retail Grocery Products	<i>Jensen / Webster</i>
04/06	Trade Marks and Market Value in UK Firms	<i>Greenhalgh / Rogers</i>
03/06	Intellectual Property Activity by Service Sector and Manufacturing Firms in the UK, 1996-2000	<i>Greenhalgh / Rogers</i>
02/06	Start-Up Commercialisation Strategy and Innovative Dynamics	<i>Gans</i>
01/06	Decision-Making and Quality in the Patent Examination Process: An Australian Exploration	<i>Dent</i>
19/05	A Quantitative Analysis of Australian Intellectual Property Law and Policy-Making Since Federation	<i>Caine / Christie</i>
18/05	Measuring Intangible Investment	<i>Hunter / Webster / Wyatt</i>
17/05	Perfect Price Discrimination with Costless Arbitrage	<i>Gans / King</i>
16/05	Has Investment in Start-Up Firms Driven Incumbent Innovative Strategy? Evidence from Semiconductor and Biotechnology Venture Capital Funded Firms	<i>Dewo / Gans / Hirschberg</i>
15/05	Communication in the Digital Environment: An empirical study into copyright law and digitisation practices in public museums, galleries and libraries	<i>Hudson / Kenyon</i>
14/05	A Comment on the Copyright Exceptions Review and Private Copying	<i>Weatherall</i>

13/05	The Culture of Trade Marks: An Alternative Cultural Theory Perspective	<i>Bosland</i>
12/05	Strength of Partnership as a Key Factor in Collaboration between Universities and Industry for Production of IP: A Study of Applications to the BHERT Awards	<i>Mann</i>
11/05	Repeated Interactions & Contract Structure: Evidence from Technology Development Contracts	<i>Ryall / Sampson</i>
10/05	Operationalizing Value-Based Business Strategy	<i>Gans / MacDonald / Ryall</i>
09/05	Determinants of International Patent Examination Outcomes	<i>Palangkaraya / Jensen / Webster</i>
08/05	Intellectual Property Strategy and Business Strategy: Connections Through Innovation Strategy	<i>Samson</i>
07/05	An Empirical Investigation into Patent Enforcement in Australian Courts	<i>Weatherall / Jensen</i>
06/05	Patent Application Outcomes Across the Trilateral Patent Offices	<i>Jensen / Palangkaraya / Webster</i>
05/05	The Effects on Firm Profits of the Stock of Intellectual Property Rights	<i>Griffiths / Jensen / Webster</i>
04/05	Capitalised Intangibles and Financial Analysis	<i>Matolcsy / Wyatt</i>
03/05	Reach-through Patent Claims in Biotechnology: An Analysis of the Examination Practices of the United States, European and Japanese Patent Offices	<i>Lim / Christie</i>
02/05	Venture Capital Taxation in Australia and New Zealand	<i>Stewart</i>
01/05	The New Right of Communication in Australia	<i>Christie / Dias</i>
18/04	Trends in the Value of Intellectual Property in Australia	<i>Griffiths / Webster</i>
17/04	On Technology Locks and the Proper Scope of Digital Copyright Laws – <i>Sony</i> in the High Court	<i>Weatherall</i>
16/04	Techniques for Measuring Intangible Capital: A Review of Current Practice	<i>Wyatt / Webster / Hunter</i>

15/04	Achieving the Optimal Power of Patent Rights	<i>Jensen / Webster</i>
14/04	On The Interaction Between Patent Policy and Trade Secret Policy	<i>Erkal</i>
13/04	The Determinants of Research and Development and Intellectual Property Usage among Australian Companies 1989 – 2002	<i>Griffiths / Webster</i>
12/04	Regulating Private Copying of Musical Works: Lessons from the U.S. Audio Home Recording Act of 1992	<i>Elkman / Christie</i>
11/04	<i>Droit de Suite</i> Down Under: Should Australia Introduce a Resale Royalties Scheme for Visual Artists?	<i>Hudson / Waller</i>
10/04	The Research Exemption to Patent Infringement: A Doctrine In Search of a Principle	<i>Elkman</i>
09/04	SMEs and their Use of Intellectual Property Rights in Australia	<i>Jensen / Webster</i>
08/04	Catching Up or Standing Still? National Innovative Productivity Among “Follower Nations”. 1978 – 1999	<i>Furman / Hayes</i>
07/04	Patent Length and the Timing of Innovative Activity	<i>Gans / King</i>
06/04	Moving Beyond Tacit and Explicit: Four Dimensions of Knowledge	<i>Casselman / Samson</i>
05/04	Examining Biases in Measures of Firm Innovation	<i>Jensen / Webster</i>
04/04	Principle or Compromise?: Understanding the original thinking behind statutory licence and levy schemes for private copying	<i>Gaita / Christie</i>
03/04	Patterns of Trademarking Activity in Australia	<i>Jensen / Webster</i>
02/04	Protecting Indigenous Signs And Trade Marks Under The New Zealand Trade Marks Act 2002	<i>Morgan</i>
01/04	Patent Renewal Fees and Self-Funding Patent Offices	<i>Gans / King / Lampe</i>
12/03	Accounting for Intangible Assets: A Conceptual Framework for Measurement and Reporting on Intangible Assets	<i>Wyatt / Abernethy</i>

11/03	The Decision to Patent, Cumulative Innovation, and Optimal Policy	<i>Erkal</i>
10/03	The Protection of National Icons under the Trade Marks Act 1995	<i>Morgan</i>
09/03	An Analysis Of The Approaches Of The Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences	<i>Howlett / Christie</i>
08/03	Accounting for Intangible Assets: Theory and Evidence on the Influence of Technology and Property Rights Related Conditions	<i>Wyatt</i>
07/03	Using Patent-Based Metrics to Understand the Value of Companies	<i>Matolcsy / Wyatt</i>
06/03	The Economics of Patent Design: A Selective Survey	<i>Lampe / Niblett</i>
05/03	An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)	<i>Howlett / Christie</i>
04/03	The Rise of Trade Marking in Australia in the 1990s	<i>Loundes / Rogers</i>
03/03	Forces Shaping Firms' Decisions To Innovate: Evidence from Large Australian Organisations	<i>Webster</i>
02/03	Virtual Markets for Virtual Goods: An Alternative Conception of Digital Copyright	<i>Eckersley</i>
01/03	Managing Ideas: Commercialization Strategies for Biotechnology	<i>Gans / Stern</i>
07/02	Intellectual Property Rights: A Grant of Monopoly or an Aid to Competition	<i>Gans / Williams / Briggs</i>
06/02	Intellectual Capital: Accumulation and Appropriation	<i>Hunter</i>
05/02	The Product Market and the Market for "Ideas". Commercialization Strategies for Technology Entrepreneurs	<i>Gans / Stern</i>
04/02	When does Funding Research by Smaller Firms Bear Fruit?	<i>Gans / Stern</i>
03/02	Network Externalities and the Myth of Profitable Piracy	<i>King / Lampe</i>

- 02/02** When Does Start-Up Innovation Spur the Gale of Creative Destruction? *Gans / Hsu / Stern*
- 01/02** Intangible and Intellectual Capital: A Review of the Literature *Webster*

Electronic copies of all IPRIA working papers are available at:
www.ipria.org/publications/workingpapers.html