

Working Guidelines

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Q238

Second medical use and other second indication claims

Introduction

- 1) This question seeks to determine the type, scope and enforcement of patent protection for new uses of known chemical compounds when a known substance is found to have a new therapeutic use. For convenience, these guidelines will refer to such use as 'second medical use'. Various types of second medical use are described below.
- 2) The granting of patent protection for second medical uses potentially provides an important incentive for the identification and development of solutions for unmet medical needs. Second medical use patents can also be a major tool of the originator pharmaceutical industry as part of patent lifecycle management. However, the additional research and development work is time-consuming and expensive. Patent protection is important, but sufficient incentive to encourage research into second medical uses lies in the potential availability of enforceable patent rights of effective scope.
- 3) Currently, whether patent protection for second medical uses is permitted at all, and if so, the form of permissible claims, varies from country to country. The ability to enforce permissible claims, and the scope of protection afforded, also varies between jurisdictions. Lack of harmonisation impacts both originator and generic pharmaceutical companies by creating uncertainty both for patent holders and assumed infringers.
- 4) The granting of patent protection for second medical uses gives rise to competing positive and negative impacts on the provision of effective medicines to the public. Patent protection may permit pharmaceutical companies to generate the revenues required to fund further innovation. This is of long term benefit to the public. However, the reduction in price facilitated by generic market entrants also provides a public benefit in terms of the cost to governments who fund pharmaceuticals, and to the public buying them.
- 5) For at least the above reasons, there is uncertainty as to the appropriate level of patent protection for second medical uses.

Previous work of AIPPI

- 6) AIPPI has previously explored issues relating to second medical use during workshops held at a number of recent AIPPI meetings.
 - a) Paris Congress (2010) - Pharma 4 Workshop entitled 'Selected patent issues regarding pharmaceutical inventions'. This workshop examined the patentability of pharmaceutical

inventions beyond the molecule per se. Second medical use inventions were considered along with a number of other categories of pharmaceutical inventions.

- b) Hyderabad Forum/ExCo (2011) - Pharma Workshop 1 entitled 'Protection of new medical treatment in patent law'. This workshop examined first and second medical use, and practices for providing incentives for investing in new uses of known compounds.
 - c) Helsinki Forum/ExCo (2013) - Pharma Workshop 2 entitled 'Second medical use patents'. This workshop examined the scope and enforceability patent claims directed to new uses of known medicaments. Topics canvassed included:
 - availability of protection;
 - contributory infringement;
 - protection from liability for patent infringement of various classes of persons/institutions;
 - tensions between patent law and drug regulatory regimes.
- 7) Notably, each expert panel for the above workshops included speakers providing United States (**US**), Indian and European perspectives. In light of the important role second medical use plays in public health, and the economic impact of patent protection for second medical use claims for the pharmaceutical industry, governments and the public, it is timely that AIPPI study this topic from a broader perspective.
- 8) Further, while previous AIPPI Working Questions have encompassed issues relating to second medical use, notably in the context of Q202 'The impact of public health issues exclusive patent rights' (Boston 2008) and Q209 - 'Selection inventions: The inventive step requirements, other patentability criteria and scope of protection' (Buenos Aires, 2009), AIPPI has not yet studied second medical use as a dedicated question.

Scope of this question

- 9) There are various types of second (or 'further') medical use, examples of which are listed under the heading 'Types of use' below. All such uses are encompassed within the term 'second medical use' as used in these guidelines, and are within the scope of this question.
- 10) This question is confined to issues of permissibility of second medical use claims, the types of any permissible claims, and their scope of protection and therefore enforceability, both in terms of direct and indirect infringement (referred to in these guidelines as 'contributory infringement'). Given the important considerations outlined in the introduction, this question also seeks to explore relevant policy considerations.
- 11) Other than as relevant to the permissibility of second medical use claims, the patentability of methods of medical treatment per se ('first medical use') is outside the scope of this question. It was established in Q202 that methods of medical treatment are patentable subject matter only in Australia and the US¹, yet many more countries than these permit at least some form of second medical use claims.
- 12) While considerations of validity, particularly novelty and inventive step, may be relevant to the underlying rationale for the permissibility (or otherwise) of second medical use claims, unless

¹ Summary Report Q202, 'The Impact of public health issues on exclusive patent rights', Part I, Question 5). See further paragraph 46) below.

relevant to the scope of this question as set out in paragraph 9) above, the assessment of novelty and inventive step, and other validity considerations are outside the scope of this question.

- 13) Subject to the same qualification, issues of patent term extension, compulsory licensing, entitlement and Supplementary Protection Certificates (where available) are also outside the scope of this question.

Discussion

Types of use

- 14) The classic case of second medical use is where a drug is initially developed for a particular therapeutic purpose, and ongoing or later research finds that the drug is useful for another therapeutic area. This occurred with aspirin. Originally used as an antipyretic and analgesic, it was subsequently found to be useful as an anticoagulant, and later as an anti-stroke medication and an anti-ischaemic. A more recent example relates to the pyrazolopyrimidinone group of compounds which were well-known for treating heart and vascular disease. In 1994, Pfizer found that one of the compounds, sildenafil citrate, was also useful for treating erectile dysfunction. Marketed as Viagra, the product has been extremely successful with annual sales of billions of dollars.
- 15) There may also be drugs for which the first known use of the compound did not succeed, but a new use results in an important medicine. Nimodipine (marketed by Bayer as Nimotop) was originally developed for the treatment of high blood pressure. It is not frequently used for this application, and its main use now is for cerebral disorders. Other drugs in this category include Evista (raloxifene hydrochloride), which was originally developed as an anticancer agent, and is now being marketed as a treatment of osteoporosis, and Straterra (atomoxetine) originally developed as an antidepressant, which is now marketed only for Attention Deficit Hyperactivity Disorder (ADHD).
- 16) Sometimes compounds previously discovered for non-medical uses are subsequently found to be effective for medical uses. A related example is the ongoing debate over the potential for various medical uses of marijuana.
- 17) In the decision of the Enlarged Board of Appeal (**EBA**) of the European Patent Office G2/08², a new dosage regime was held to be patent eligible where that was the only novel feature of a known drug to treat a known illness. The claim in issue was directed to the use of a sustained-release nicotinic acid in the treatment of abnormal levels of lipids in the blood. The novel feature was providing the drug 'once per day prior to sleep'. In G2/08, the EBA also found that novelty may reside in features such as the class of patients to be treated, a different method of administration or a different technical effect.

Protection

- 18) Article 27(1) TRIPS states that patents shall be granted to 'any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. It is open to question whether TRIPS *requires* protection for second medical use claims, although some commentators argue that denying patentability to second medical use claims is contrary to TRIPS, particularly Article 27(1).
- 19) Article 27(3)(a) TRIPS permits exclusions from patentability of diagnostic, therapeutic and surgical methods of treatment of humans or animals. Some members justify denial of patent protection to second medical use claims on the basis that such claims are related to or simply

² 19 February 2008.

another form of a method of medical treatment, and therefore permissibly excluded from patentability.

- 20) The rationale for denying patent protection for second medical use may be based on a strict view of novelty - that is, the chemical structure of the compound is already part of the art. Some commentators have also suggested that conferring novelty in relation to second medical use claims conflates the separate patentability requirements of novelty and inventive step.³ This view does not attribute any novelty or inventive step to identifying and choosing to pursue a known compound for use in treating a disease or condition for which it had not previously been used. (See further paragraphs 34) - 39) below.)
- 21) India, Egypt, Philippines, and countries of the Andean Pact⁴ are examples of countries that do not allow patent protection for second medical uses. In India, prior to January 2005, chemical and pharmaceutical compounds were not patentable at all. Following various TRIPS related reforms, the Indian Patents Act still today prohibits as patentable subject matter a mere new use of a known substance.
- 22) Article 21 of Decision 486 of the Common Intellectual Property Regime of the Andean Community provides that 'products or processes already patented and included in the state of the art... shall not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent'. This prohibition is not targeted specifically at second medical use claims - it applies to all fields of technology. Nevertheless, when Peru passed a legislative decree in 1997 clarifying that patents may be granted for new uses if the requirements of novelty, inventiveness and industrial applicability were met, thereby permitting the Patent Office of Peru to grant Pfizer a patent in relation to Viagra, upon complaint by the generic industry association of Peru, the Andean Tribunal of Justice ruled that the government of Peru had violated the regional patent legislation in granting that patent.
- 23) In the European context, prior to the decision of the EBA in G05/83⁵, Article 52(4) of the European Patent Convention (**EPC**) 1973 was an obstacle to patent protection for second medical use claims. The effect of Article 52(4) was that, somewhat artificially, methods of medical treatment were accepted as inventions but excluded from patentability as being incapable of industrial application. In G05/83, the EBA approved 'Swiss-type' claims to circumvent Article 52(4) in relation to second medical uses. (See further sections headed 'Types of Claims' and 'Concepts of 'treatment', 'treating', 'used to treat' etc' below.
- 24) By contrast, the position was settled in the US prior to the recodification of the US patent law in 1952 which included a definition of 'process' (as patent eligible subject matter) which includes 'a new use of a known process, ..., composition of matter or material'.⁶
- 25) In Australia, while the patentability of methods of medical treatment and second medical uses had been regarded as settled law for some decades, a recent challenge by the Canadian generic manufacturer, Apotex, brought the issue on appeal before the High Court of Australia. In a final

³ Juan Pablo Coy Navarro, 'A critical study of the denial of first and second medical use patents in the Andean Community; the Viagra case', dissertation submitted in partial fulfilment of the requirements for the Master of Laws degree in International Economic Law at the University of Warwick, September 2003.

⁴ Bolivia, Columbia, Ecuador and Peru.

⁵ 5 December 1983.

⁶ Section 100(b), *US Patent Act* (1952), 35 USC.

decision delivered in December 2013⁷, it was put beyond doubt that methods of medical treatment and second medical uses are patentable in Australia.⁸

Types of claims

26) Notably, only the US and Australia allow claims to a method of treatment per se; other countries allow for claims to the use of a compound to prepare a medicament to treat a disease (Swiss-type claims); some allow claims to pharmaceutical formulations for a particular purpose, or claims to the compound when used to treat disease.

27) As noted above, the EBA decision G05/83 permitted the Swiss-type claim, which is a process claim. So called after the then-practice of the Swiss Federal Intellectual Property Office, Swiss-type claims typically take the form:

'Use of substance X in the manufacture/preparation of a medicament for the treatment of condition Y'

The claim to *'use of substance X in the manufacture/preparation of a medicament'* is directed to a method of manufacture rather than being considered a claim to a method of medical treatment. Similarly, *'... for the treatment of condition Y'* describes the use of the medicament and is the basis for the novelty of the claim (see, however, the discussion of issues regarding the concepts of 'treatment', 'treating' and 'use to treat' in paragraphs 34) - 39) below).

28) Separately, around the same time of the G05/83, the German courts developed their own type of second medical use claim in the form:

'Use of substance X for the treatment of condition Y'

29) When EPC 2000 came into force in December 2007, the exclusion of methods of treatment was transferred from Article 52(4) to Article 53(c), thereby ending the fiction that the bar to patentability was for lack of industrial applicability. Article 54(5) codified the effect of G05/83 by providing for novelty of second medical use claims.

30) The EBA decision G2/08 determined that Swiss-type claims were no longer necessary under EPC 2000. Instead, a method of treatment can be protected by a product claim typically in the form:

'Substance X for use in the treatment of condition Y'

Since January 2011, the European Patent Office (**EPO**) has not permitted Swiss-type claims; claims must now be in the EPC 2000 'purpose-limited' product claim format. Nevertheless, given the long life of patents, the two claim formats will continue to coexist for some time, giving rise to questions of scope. (See further paragraph 42) below.)

31) US claims covering second medical use take a 'method of treatment' route rather than a 'use' route. The 'use' claim format is generally not accepted in the US, as issues of indefiniteness may arise for a claim to a process absent setting out the steps involved in the process. Some examples by way of comparison are set out below.⁹

⁷ *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors* [2013] HCA 50.

⁸ This decision has not, however, finally resolved all issues regarding the validity of second medical use claims under Australian law.

⁹ Adopted from the presentation by Elizabeth Doherty, Finnegan LLP, Pharma Workshop 2: Second Medical Use Patents – The US Perspective', AIPPI Helsinki Forum/ExCo, 6 September 2013.

Example – general	
'Use' claims	US 'method of treatment' claims
<ul style="list-style-type: none"> 'Use of compound X for treatment of disease Y' 'Use of compound X for manufacture of a medicament for treatment of disease Y' 'Compound X for use in treating disease Y' 	<ul style="list-style-type: none"> 'A method of treating a patient suffering from disease Y comprising: <ul style="list-style-type: none"> administering an effective amount of compound X to the patient'
Example – specific treatment group	
<ul style="list-style-type: none"> 'Use of compound X for treatment of disease Y in a patient with a blood level of biomarker A of at least 5pg/mL' 	<ul style="list-style-type: none"> 'A method of treating a patient suffering from disease Y comprising: <ul style="list-style-type: none"> obtaining a measurement of the level of biomarker A in the blood of the patient; and administering an effective amount of compound X to the patient if the level of biomarker A is above 5pg/mL'
Example – new dosage regime	
<ul style="list-style-type: none"> 'Use of compound X for treatment of disease Y, <ul style="list-style-type: none"> wherein 10-30µg/mL of compound X is administered subcutaneously once every 7 days to the patient in combination with a chemotherapy agent' 	<ul style="list-style-type: none"> 'A method of treating a patient suffering from disease Y comprising: <ul style="list-style-type: none"> administering compound X to the patient in an amount of 10-30µg/mL subcutaneously once every 7 days; and administering a chemotherapy agent to patient'

- 32) In Canada, where methods of medical treatment do not constitute patent eligible subject matter, the US approach is not open to patentees. Accordingly, Canada also adopts a 'use' route to claims drafting (similar to the German use – style claim), eg:

'A use of compound X for treating condition Y'

- 33) In Australia, 'method of treatment', 'use' and 'Swiss-style' claim formats are all permissible and often used together in the same claim set on the basis that they have (or at least may have) different scopes for both validity and enforcement purposes.

Concepts of 'treatment', 'treating', and 'used to treat' etc

- 34) An integer which is common and fundamental to all types of second medical use claims is that the identified compound is 'for', 'prepared for' or 'used' in a method 'to treat' or for the 'treatment of' one or more specified diseases, conditions or symptoms.
- 35) On one view, the words 'method of treating' in second medical use claims mean nothing more than some unspecified degree of efficacy and safety. By contrast, such claims could be interpreted as defining a 'method of treating' the specified disease or condition that is sufficiently safe and efficacious to be administered by medical practitioners to patients requiring treatment for that disease or condition.
- 36) Another potential issue relating to the 'treatment' integer of second medical use claims is defining its limits and, in particular, distinguishing it from other physiological effects of the compound or

method, including those which are beneficial. Does 'treatment' capture any improvement, however small, in the definitive factors of the disease or condition? Or does treatment involve achieving some specific therapeutic outcome?

- 37) Whether or not a second medical use claim is infringed may turn on whether or not the prescribing doctor has deliberately administered (or prescribed) the identified compound to a person suffering from the specified disease or condition for the purpose of treating that specific disease or condition, rather than some other disease or condition. Whether 'treatment' (according to whatever standard is adopted) is in fact achieved by the claimed second medical use is also fundamental to the utility or industrial applicability of second medical use claims.
- 38) The very recent High Court of Australia decision in *Apotex v Sanofi-Aventis*¹⁰ included comments which demonstrate a preparedness to interpret second medical use claims as incorporating an 'intention' requirement. Although made in the context of discussing indirect infringement, the High Court clearly stated that the administration of the identified compound must be deliberately directed to treatment of the specific condition and not another condition, even where the specific condition may also be treated.
- 39) This approach to construction not only effectively narrows the enforceable scope of second medical use claims but could have significant ramifications for their validity by making them more difficult to anticipate or prove obvious but easier to challenge for insufficiency of description, lack of support or fair basis and/or lack of clarity.

Enforcement

- 40) Debate as to how infringement is established for a second medical use patent arises by reason of the inherent nature of a second medical use claim. When any patent to the compound or the first medical use expires, competing generic products may legitimately enter the market. Where no patent for the compound or any 'first' medical use exists, the compound may legitimately be used for treatments or other purposes other than the patented second medical use. However, the reality of practices around marketing, prescribing, dispensing and using pharmaceutical products mean that such generic or competing products may be prescribed or used for treatments that infringe second medical use patents.
- 41) The form of any permissible second medical use claim necessarily dictates construction and therefore the scope of protection and enforceability. By definition, the acts which constitute infringement are different for product claims versus process claims. By way of example, the UK Patents Act provides that a product claim will be (directly) infringed by disposing, offering to dispose of, using, importing or keeping the product. A process claim will be infringed by using or offering to use the claimed process (subject to knowledge requirements), or by disposing, offering to dispose of, using, keeping or importing a product obtained directly by means of the claimed process. There are corresponding provisions in the Unified Patent Court Agreement.
- 42) There has also been debate as to whether EPC 2000 format claims are identical in scope to Swiss-type claims. While it is clear that Swiss-type claims are process claims, and EPC 2000 claims are product claims with a specifically restricted use, the explanatory notes to the Swiss proposal to Article 54(5) EPC 2000 suggested that the protection offered by new Article 54(5) 'is equivalent, as far as the further uses are concerned, to that offered by the Swiss type claim'. However, since then, the Federal Supreme Court of Switzerland has stated:

¹⁰ *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors* [2013] HCA 50 at [278] [285].

*'It is to be expected that the new claim category according to Article 54(5) EPC 2000, that of purpose-limited claim, will result in broader protection for the patentee than was previously the case ...'*¹¹

- 43) Whether as a matter of regulation, encouragement or practice, in many countries medical practitioners prescribe by reference to the active ingredient of a product, not the product name. The dispensing pharmacist may be unaware of the indication for which the product is prescribed, may in some circumstances be (legally) able to supply a generic product even where the prescription uses the originator's product name, or may even be positively incentivised by drug reimbursement policy to use a generic substitute rather than the originator brand.
- 44) Where the patent(s) to the product per se and/or the first medical use has/have expired or never existed in a given jurisdiction or anywhere at all, but there is an unexpired patent to the second medical use, whether the originator can sue for infringement may depend on whether the generic product is approved for, and/or its product information leaflet¹² specifically refers to, the patented second medical use. Other relevant factors may also include what steps (beyond labelling considerations) the generic manufacturer proposes to take to prevent its products being used in accordance with the patented second medical use, such as periodic notifications to doctors and/or pharmacists or the inclusion of indication notifiers within prescribing and/or dispensing software or systems. In any case, there is potentially a basis for both direct and contributory infringement of the second medical use claims. This will often involve the relatively simple case of 'on-label use', being the (in this context, infringing) use of a generic medicine in accordance with its approved indication(s).
- 45) However, where the generic product is only approved for a non-patented use, or the product information leaflet of the generic product either carves out any reference to the patented use ('skinny labelling') or expressly disclaims it, generic substitution in these circumstances may not give rise to a direct infringement. These scenarios are referred to as 'off-label use' and 'cross-label use' respectively – off-label use being the use of an active ingredient for the treatment of a condition other than that for which it has been authorised, and cross-label use being the use of a generic medicine for a condition carved out (or even expressly disclaimed) by the generic manufacturer but which was included on the originator's product information leaflet or other regulatory data. In these scenarios it may be difficult for the patentee to show that the drug is manufactured or sold for the patented second medical use. This has been the outcome of various decisions in the UK, Germany and, more recently, Australia.
- 46) The particular requirements for contributory infringement can differ markedly between jurisdictions. However, contributory infringement often involves some element of knowledge (actual or constructive) that the product supplied will be put to an infringing use. This means any outcome will be highly fact dependent. In two 2010 judgements of the UK Court of Appeal concerning liability for indirect infringement¹³ (by supplying any of the means relating to an essential element of the invention) it was established that the knowledge and intention requirements of the UK provision were satisfied if, at the time of supply or offer of supply, 'the supplier knows or it is obvious in the circumstances, that ultimate users will put the invention into effect'.
- 47) A similar outcome may have been expected in Australia until the High Court decision in *Apotex v Sanofi-Aventis*. While the court confirmed that methods of medical treatment and second medical

¹¹ Swiss Federal Supreme Court, BGE 137 III 170 (Alendronate).

¹² Sometimes also referred to as a 'Patient Information Leaflet'.

¹³ *Grimme Maschinenfabrik v Scott* [2010] EWCA Civ 1110; *KCI v Smith & Nephew* [2010] EWCA Civ 1260.

use claims are patentable, Sanofi-Aventis was left with an ultimately unsatisfactory outcome on contributory infringement. The claim at issue was for a method of preventing or treating psoriasis by administering a composition containing the active ingredient leflunomide. The compound was the subject of an earlier expired patent. Apotex sought to market a generic version of leflunomide which was registered only for psoriatic arthritis and rheumatoid arthritis. The court held that this proposed supply would not infringe the patent, overturning the first instance and the Full Federal Court appeal decision in this regard. This is because the claim was construed as being the deliberate administration of the compound to prevent or treat psoriasis. The court also found that Apotex had no reason to believe that its product would be used by recipients contrary to the indications in Apotex's approved product information.

- 48) The issue of 'skinny labelling' has been the subject of much recent commentary. At one end of the spectrum, in Australia, the draft report of the recent Pharmaceutical Patents Review recommends that the Australian Patents Act should be amended to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement where reasonable steps have been taken to ensure that the product will only be used in a non-infringing manner. There should be a presumption that 'reasonable steps' have been taken where the product has been labelled with indications which should not include any infringing indications¹⁴. Whether or not they strike the appropriate balance or would be effective, a major objective of such proposals is to assist courts in reconciling the tension between, on one hand, potentially depriving a patentee the benefit of a properly granted statutory monopoly and, on the other hand, improperly extending the monopoly to effectively capture non-infringing uses and shut out generic competition entirely.
- 49) In Europe, the general rule is that the product information for a generic product must contain the same information as that of the originator product, including indications, dosages and method of administration¹⁵. However, a generic may carve out from relevant product information any references to indications or dosage forms which are protected by existing patents. The permission for a carve out is obtained at national level. Whether the carve out need explain why certain indications or dosage forms are missing is a matter of choice for the individual member state.
- 50) At the other end of the spectrum, while US Federal Regulations permit a similar approach to Europe, many US states require pharmacies to replace the branded drug with the approved generic for all indications, even if some are not listed on the generic product label. Under Federal Regulations, if there are any label differences relating to safety or efficacy indications must remain on the label. It therefore seems that the scope or utility for 'skinny labelling' may, in practice, be narrower in the US.
- 51) Assuming infringement can be established, courts may still hesitate to grant an injunction to prevent infringing use of a second medical use patent where the reality will be that not all of the marketed generic drug is being deployed for an infringing use. Taking the Australian *Apotex v Sanofi-Aventis* case, if (despite the faith shown by the High Court) doctors prescribe or pharmacists dispense, whether knowingly or otherwise, leflunomide for psoriasis, courts may be uncomfortable in granting an injunction even if the injunction is expressly limited to the infringing use. Reasons for reluctance could include the uncertainty of the scope of the injunction and the difficulties in monitoring compliance.

¹⁴ Recommendation 6.4, Pharmaceutical Patents Review, Draft Report, April 2013.

¹⁵ Eg Article 11 of Directive 2001/83/EC of the European parliament and of the council of 6 November 2001 on the community code relating to medicinal products for human use.

- 52) In the US, doctors and hospitals are protected from liability for patent infringement. US 'method of treatment' style second use claims are enforced on the basis of induced or contributory infringement. The manufacturer and/or distributor is sued in relation to the product used by the doctor or patient. Induced infringement involves actively encouraging others to infringe a patent claim. This can be done by using packet instructions, or marketing, sales or advertising practices that encourage others to perform the claimed process. Practical difficulties in relation to proof of infringement may arise if the claimed process is not on the generic product's product information leaflet.
- 53) As the only country other than the US which permits methods of medical treatment as patentable subject matter, Australia notably does not include a similar protection from patent infringement for doctors and hospitals. While there was previously a suggestion that medical practitioners who wished to use patented methods and medical treatment should seek a compulsory licence¹⁶, commentary from High Court justices in the recent *Apotex v Sanofi-Aventis* case suggests that activities or procedures of doctors and other medical staff when physically treating patients should be regarded as excluded from patentability, and therefore patent infringement, altogether. This outcome would be more in keeping with paragraph 5) of Resolution Q202¹⁷, which at present Australian law is not. However, as a practical matter, originator pharmaceutical companies have clear commercial disincentives for suing doctors who prescribe their medicines and patients who purchase and consume them.

Questions

I. Current law and practice

Groups are invited to answer the following questions under their national laws. If those national and regional laws apply to a set of questions, please answer the questions separately for each set of laws.

Please number your answers with the same numbers used for the corresponding questions.

- 1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?
- If yes, please answer Questions 2) to 7) inclusive before proceeding to the questions in Parts I and II. If no, please proceed directly to the questions in Parts II and III.*
- 2) If the answer to Question 1) is yes, please answer the following sub-questions.
- What is the basis for patent protection?
 - What types of second medical use are patentable? *See, for example, paragraphs 14) - 17) above.*
 - Are any types of second medical use impermissible subject matter? *See, for example, paragraphs 14) - 17) above.*
 - What forms of second medical use claims are permissible? *See, for example, paragraphs 26) - 33) above*
 - What forms of second medical use claims are not permissible? *See, for example, paragraphs 26) - 33) above.*

¹⁶ *Bristol-Myers Squibb & Co v FH Faulding & Co Ltd* (2000) 170 ALR 439.

¹⁷ Resolution Q202, 'The impact of public health issues on exclusive patent rights', Boston Congress (2008), paragraph 5:

'To the extent that the patent law permits patentability of methods of medical treatment, the law should provide for an exception to the rights of the patentee, allowing medical personnel to use patented methods of medical treatment, without the authorisation of the patentee, in circumstances where it is not practicable to negotiate the licence before treatment.'

- f) Has any guidance been provided by courts or the national patent office in relation to the meaning, scope and/or effect of 'treatment', 'treating' or 'use to treat' integers in second medical use claims? *See, for example, paragraphs 34) - 39) above.*
- 3) If your country permits second medical use claims:
- a) Who may be liable for infringement of such claims? For example:
- i) the party marketing the drug with label instructions which describe the patented use;
- ii) the physician prescribing the drug for such use;
- iii) the pharmacist dispensing a drug for such purpose;
- iv) the patient using the drug for such purpose?
- b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?
- c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.
- 4) If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?
- 5) If the answer to Question 4) is yes, please answer the following sub-questions in that context.
- a) Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts which constitute infringement.
- b) Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?
- c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?
- d) If yes to c), what standard of knowledge is required? *See, for example, paragraphs 38) and 47) above.*
- 6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?
- 7) What relief is available for infringement of a second medical use claim:
- a) at a preliminary / interim / interlocutory level?
- b) by way of final relief?
- 8) In respect of Question 7)a), can a preliminary / interim / interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?
- 9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?
- II. Policy considerations and proposals for improvements to your current system**
- 10) If your country permits second medical use claims, please answer the following sub-questions.
- a) What are the policy reasons behind permitting such claims?
- b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

- c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?
 - d) If there is any empirical or anecdotal data available, please address the following.
 - i) What is the prevalence of second medical use claims in your country?
 - ii) What is the profile of patentees for second medical use claims in your country?
- 11) If your country does not permit second medical use claims, please answer the following sub-questions.
- a) What are the policy reasons behind not permitting such claims?
 - b) Would such claims serve the interests of relevant stakeholders?
 - c) Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?
- 12) To what extent does your country's law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

III. Proposals for substantive harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions *without* regard to their existing national laws.

- 13) Is it desirable to permit second medical use claims?
- 14) Is harmonisation of laws relating to second medical use claims desirable?
- 15) Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.
 - a) Types of second medical use constituting permissible subject matter. *See, for example, paragraphs 14) - 17) above.*
 - b) Types of any second medical use constituting impermissible subject matter. *See, for example, paragraphs 14) - 17) above.*
 - c) Form of permissible claims. *See, for example, paragraphs 26) - 33) above.*
 - d) Form of impermissible claims. *See, for example, paragraphs 26) - 33) above.*
 - e) Who may be liable for infringement.
 - f) Any parties/institutions that should be exempted from infringement or liability for infringement.
 - g) Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.
 - h) Relief available upon a finding of infringement:
 - i) at a preliminary / interim / interlocutory level; and
 - ii) by way of permanent relief.
 - i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.

The Groups are invited to comment on any additional issues concerning any aspect of second medical use claims that they deem relevant.