Summary Report

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Question Q238

Second medical use and other second indication claims

Introduction

'Second medical use' for the purpose of this question refers to new therapeutic uses of known chemical compounds.

The granting of patent protection for second medical uses provides an important incentive for the identification and development of solutions for unmet medical needs. Incentivising pharmaceutical companies to generate the revenues required to fund further innovation is of long term benefit to the public. However, price reductions facilitated by competing generic products also provides a public benefit in terms of the cost to governments who fund pharmaceuticals, and to the public who buy them.

Whether patent protection for second medical uses is permitted at all, and if so, permissible claim format, varies between countries. The scope of any protection also varies. Lack of harmonisation impacts both originator and generic pharmaceutical companies by creating uncertainty for both patent holders and assumed infringers.

This question examined the type, scope and enforcement of patent protection for second medical uses.

The Reporter General received a total of 41 reports.

Reports were received from the National Groups of Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, the Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Japan, Latvia, Mexico, the Netherlands, New Zealand, Paraguay, Peru, the Philippines, Portugal, Republic of Korea, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Turkey, the United Kingdom (***UK***), Uruguay, the United States of America (***US***) and Venezuela. In addition, a report was received from the Caribbean Regional Group which encompassed responses from the Dominican Republic and El Salvador.

Reports received after 30 June 2014 are listed above but their content is not included in the summary.

A summary of the responses received before 30 June 2014 follows. Where percentages of responses are given, they are to the nearest 5%.

In Part IV, an attempt has been made to draw some conclusions and provide guidance to the Working Committee.

I. Current law and practice

1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?[1]

Thirty-three Groups (approximately 85%) answered this question in the affirmative: Austria, Belgium, Brazil, Bulgaria, Canada, China, The Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Latvia, Mexico, the Netherlands, New Zealand, the Philippines[2], Portugal, Korea, Singapore, South Africa, Sweden, Spain, Switzerland, Turkey, UK and US.

Argentina, Egypt, Paraguay, Peru, Uruguay and Venezuela do not permit patents covering second medical uses. Based on the Caribbean Regional Group report, second medical use claims are not permissible in the Dominican Republic. In El Salvador, the present status is under appeal.

The reasons (where provided) are as follows.

Country	**Reason**
Argentina	Joint Resolution issued by the Patent and Trade Mark Office and the Ministries of Health and Industry, as incorporated in the internal examination guidelines of the Patent and Trade Mark Office. (However, the patent law does not expressly prohibit or permit second medical use claims. Based on the hierarchy established by the Argentinian Constitution, the PTO guidelines may be unconstitutional.)
Caribbean	*Dominican Republic*: Statutory prohibition on a patent for a previously patented product based on different use.
	El Salvador: Patent Office objection based on lack of novelty. (The patent law does not expressly prohibit or permit second medical use claims. The status quo is under appeal to the Patent Office.)
Egypt	• Lack of inventive step • Patent Office objection as a mere 'discovery'.
Paraguay	Deemed 'excluded subject protection' by statute.
Peru	-

[1] If yes, the Groups were asked to answer the remaining questions in Part I before proceeding to the questions in Parts II and III. If no, the Groups were asked to proceed directly to the questions in Parts II and III. For questions 2) to 9), where a number or percentage of respondents or Groups is referenced, it is a percentage of those 32 Groups who reported that their country permits second medical use claims.

[2] Paragraph 21) of the Working Guidelines for this Question (***WG***) erroneously cited the Philippines as a country that does not allow patent protection for second medical uses. The Philippines Group Report confirms that second medical uses are permitted.

Country	Reason
Uruguay	• Statutory prohibition on new patent protection for prior art patented product and processes to which a different use is attributed. • Statutory exclusion of diagnostic, therapeutic and surgical methods for the treatment of persons and animals from patentable subject matter.
Venezuela	-

2) If the answer to Question 1) is yes, please answer the following sub-questions

a) What is the basis for patent protection?

Approximately ⅓ explained that there is no express statutory basis for patent protection for second medical use claims. In a number of countries, the relevant patent office guidelines make it clear that second medical use claims are permitted.

Otherwise, there is express permission for second medical use claims, although in a number of jurisdictions, that is subject to an express prohibition on methods of medical treatment.

b) What types of second medical use are patentable?

The Groups were directed to the examples of types of second medical use set out in paragraphs 14) to 17) of the WG (defined below for convenient reference in this summary report):

- a drug initially developed for a particular therapeutic purpose later found to be useful for another therapeutic area;
- drugs for which the first known use of the compound did not succeed, but a new use results in an important medicine,

(collectively, ***Additional Medical Use Examples***);

- a compound with a non-medical use subsequently found to be effective for a medical use (***New Medical Use Examples***);
- new dosage regime / new patient class / different method of administration / different technical effect (***G2/08 Use Examples***)[3].

Approximately 75% responded that the above are patentable, or that there are otherwise no restrictions on the types of use that are patentable.

Some Groups expressed doubts as to the patentability of some or all of the G2/08 Use Examples.

China and France do not permit patents where the only novel feature lies in the dosage regime, and such use may encounter difficulties in patentability in Bulgaria, Canada and the UK (see further 2)c) below). The Korean Group noted that there are several pending cases disputing earlier rulings that a claim to a new dosage form lacks novelty.

The Israeli and Mexican Groups reported divisions of opinion within their Groups as to the patentability of G2/08 Use Examples.

[3] As explained in paragraph 17) of the WG, the Enlarged Board of Appeal (***EBA***) decision of the European Patent Office (***EPO***) G2/08 (19 February 2008) found that novelty could reside in these features.

c) Are any types of second medical use impermissible subject matter?

Approximately 75% responded that there were no *types* of use that constitute impermissible subject matter, albeit with some noting that second medical use claims will be subject to the restrictions on permissible subject matter applicable to all patents, eg if use is contrary to public order or morality.

The UK Group reported that the UK Intellectual Property Office (***IPO***) practice is stricter than EPO practice having regard to second medical use claims based on novel patient groups and recognition of a new technical effect.

- While recent EPO practice suggests that treatment of a specific patient group may provide novelty if the patient group or sub-group is not expressly identified in the prior art, the UK IPO may take into account implicit disclosure of the patient group in the prior art.
- The UK IPO does not consider a newly discovered technical effect confers novelty if the prior art discloses the use of the same agent for the same purpose, whereas the EPO may allow claims relating to a genuinely new use.

The French Group reported that France diverges from the EPO practice which allows claims for new dosage regimes. In France, a posology is characterised as a therapeutic treatment method as it is for the physician to assess the dose required for the treatment of their patient.

d) What forms of second medical use claims are permissible?

Most Groups set out the forms of second medical use claims that are permissible in their country, and in most cases, those claims can be characterised as:

- method of treatment claims;
- Swiss-type claims[4];
- German-type or Canadian-type 'use' claims[5] (***Bare Use Claim***);
- EPC 2000-style purpose-limited product claims (***Purpose-limited Product Claim***).

Form of claim	**Permissible**	**Percentage**
Method of medical treatment	Australia, Russia[6], US[7]	Approximately 10%
Swiss-type	Australia, Austria, Brazil, Bulgaria, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan,	Approximately 85%

[4] Typically of the form: 'Use of substance X in the manufacture/preparation of a medicament for the treatment of condition Y.'

[5] Typically of the form: 'Use of substance X for the treatment of condition Y.' This form is sometimes also referred to as a 'bare' use claim, and is defined as such in this report for convenience.

[6] Paragraph 26) of the WG – erroneously, it seems - stated that only Australia and the US allow claims to a method of medical treatment per se. It seems that Russia also allows such claims.

[7] The only permissible claim format in the US.

Form of claim	Permissible	Percentage
	Mexico, Netherlands, New Zealand, Philippines, Russia, Singapore, Spain, South Africa, Sweden, Switzerland, Turkey, UK	
Bare Use Claim	Australia, Canada, China, Czech Republic, Germany, Italy, Russia, Turkey	Approximately 20%
Purpose-limited Product Claim	Austria, Bulgaria, Canada, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Latvia, Mexico, Netherlands, Portugal, Russia, Singapore, Spain[8], Sweden, Switzerland, Turkey, UK	Approximately 75%

Some Groups reported that Swiss-type claims are the only permissible form of claim in their country, eg Brazil, China, New Zealand, South Africa and Switzerland (for Swiss national patents).

Some Groups in Europe reported that claims must now (since January 2011) be in the Purpose-limited Product Claim format, whereas other Groups reported that their patent offices continue to allow Swiss-type claims.

Some Groups reported that method of manufacture claims are permissible, eg:

- Finland – 'Method for manufacturing a medicament for the treatment of condition Y, characterised by using substance X.'
- Japan – 'A method for manufacturing a pharmaceutical product using an ingredient extracted from humans.'

The Israeli, Japanese and Korean Groups also reported that kit format claims are available, eg in Japan, 'A treatment kit for disease W.'

e) What forms of second medical use claims are not permissible?

Some Groups drew a distinction between *forms* of claims that are impermissible, and exclusions from patentability *per se*, eg in many countries, methods of medical treatment are excluded from patentability irrespective of the form of the claim[9].

Form of claim	Impermissible	Percentage
Method of medical treatment[10]	Austria, Belgium, Brazil, Bulgaria, Canada, China, Czech Republic, Denmark, Finland, France,	Approximately 85%

[8] Subject to the Spanish Parliament approving a new Patents Act which was approved by the Spanish Government in April 2014.

[9] In Canada, not only are method of treatment claims that clearly recite a 'method' not permissible, so too are use claims that are deemed to include method steps, ie any use that implies an active step by the person performing use is deemed to be a method rather than a use, even when written in use form.

Form of claim	Impermissible	Percentage
	Germany, Hungary, Ireland, Israel, Japan, Korea, Latvia, Mexico, New Zealand, Philippines, Portugal, Singapore, South Africa, Spain, Sweden, Switzerland, Turkey, UK	
Swiss-type[11]	Denmark, Eurasia[12], Korea, Netherlands[13], Portugal, Sweden, UK, US	Approximately 20%-25%
Bare Use Claim[14]	Austria, Belgium, Brazil, China, Denmark, Eurasia, Finland, France, Ireland, Israel, Japan, Korea, Mexico, New Zealand, Philippines, South America, Sweden, UK, US	Approximately 60%
Purpose-limited Product Claim[15]	Australia, Brazil, China, Eurasia, Japan, Korea, New Zealand, Singapore, South Africa, US	Approximately 30%

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?

Just under ⅔ stated that no guidance has been provided. Other Groups reported guidance, as follows.

'Treatment'

Case law in Canada requires that the treatment cure or prevent a disease or condition in humans or animals.

In Denmark, a court has ruled that the treatment has to be for a new disease, rather than treatment at a different point in the cycle of, or preventative treatment for, the same disease.

Similarly, the Korean Patent Court has held that 'treatment' generally encompasses treating a disease, but also alleviating or preventing a disease or enhancing health conditions.

[10] Includes claims to therapeutic methods. Note that a number of Groups also separately mentioned diagnostic methods (China, Finland, Ireland, Japan, Sweden, Switzerland, Turkey) and methods of surgery (Finland, Germany, Ireland, Japan, Sweden, Switzerland, Turkey). All Groups who reported that these claim forms are impermissible also reported that claims to methods of medical treatment are impermissible in their country.

[11] In a number of responses, this is by reason of the EPO not permitting Swiss-type claims from January 2011. By contrast, for Swiss national patents, any claims other than Swiss-type claims are impermissible.

[12] In Russia, a patent can be obtained by either the Russian national or Eurasian regional patent systems. The Russian Group reports that the Russian national system permits a broader range of second medical use claims, whereas the Eurasian system is more restrictive.

[13] Now regarded as a method of treatment excluded from patentability under Article 53(c) EPC 2000.

[14] A number of countries regard the German-type claim as an impermissible method of treatment claim. By contrast, Germany does not construe such claims in this way.

[15] A number of countries regard the Purpose-limited Product Claim 'compound for use' claim as lacking novelty if the compound is known.

'For treatment' / 'for use in treatment'

Courts in the UK interpret 'for treatment' or 'for use in treatment' as 'suitable for and intended' or 'destined' for treatment. This requires a level of therapeutic efficacy both in consideration of validity and infringement.

Intention to treat

The Australian High Court recently decided that a necessary requirement of a second medical use claim is that there be an intention to treat or prevent the specific medical condition described. Therefore novelty will only be destroyed if the prior art discloses an intention to treat the medical condition claimed (in addition to all other features of the claim).

Efficacy

In Australia, an invention must have some economic utility. This will require at least some efficacy. Further, if the patent promises a particular efficacy which is not in practice achieved, the patent may not fulfil the requirement of 'usefulness'.

In Canada, a mere scintilla of utility is required for validity, unless the patent promises more.

The Russian Group reported that at least some efficacy in the treatment of a particular disease or condition should be demonstrated.

The Austrian Group reported that its Supreme Court has required that the intended purpose of the medical treatment is achieved to a substantial extent.

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?***

A number of Groups pointed out that infringement may depend upon the form of the claim, and that the various scenarios at i) to iv) above could result in liability for direct or indirect infringement, or both.

Some Groups analysed the way they expected the law would be applied in their country, in the absence of little, if any, case law. Accordingly, some of the results reported in column 3 in the table below may represent hypothetical possibilities or probabilities. Likewise, the results reported in column 5 are in some cases extrapolated from column 3.

Where a Group expressed real doubt, or the members of the Group could not form a concluded view, those views are not reported below.

Party[16]	Liability/probable or possible liability (direct or indirect infringement)	Percentage	No liability/ unlikely	Percentage
Party marketing the drug with label instructions which describe the patented use	Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Latvia, Mexico, Netherlands, New Zealand, Philippines, Portugal, Korea, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Turkey, UK, US	100%	N/A	N/A
Physician prescribing the drug for such use	Australia, Austria, Canada, Finland, Germany, Ireland, Japan, Russia, Singapore, South Africa, Spain[17], Sweden, Switzerland[18](?), US	Approximately 45%	Belgium, Brazil, Bulgaria, China, Czech Republic, Denmark(?) France, Hungary, Italy, Netherlands, New Zealand, Philippines, Portugal, Korea, Switzerland(?)[19], Turkey, UK	Approximately 55%

[16] A number of Groups reported that, even where there is or could be liability arising in scenarios ii) to iv), the practical and/or commercial reality is that, there are few, if any, examples of infringement being pursued in those circumstances.

[17] Assuming approval of the new Spanish Patents Act – see footnote 8.

[18] 'Probably yes' for a Purpose-limited Product Claim (untested in Switzerland).

[19] 'Possibly no' for a Swiss-type claim (relying on *obiter dicta* in EBA G2/08; Swiss Federal Supreme Court judgment BGE 137 III 170).

Party[16]	Liability/probable or possible liability (direct or indirect infringement)	Percentage	No liability/ unlikely	Percentage
The pharmacist dispensing a drug for such purpose	Australia, Austria[20], Belgium, Bulgaria, Canada, Czech Republic, Denmark, Finland, France, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Philippines, Korea, Russia, Singapore, South Africa, Sweden, Spain[21], Switzerland[22], UK, US	Approximately 80%	Brazil, China, Germany, Hungary, Latvia, Portugal, Switzerland[23], Turkey	Approximately 20%
Patient using the drug for such purpose	Australia, Canada, South Africa, US	12.5%	Austria, Belgium, Brazil, Bulgaria, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Latvia, Netherlands, New Zealand, Philippines, Portugal, Korea, Russia, Singapore, Spain, Sweden, Switzerland, Turkey, UK	87.5%

[20] For a Purpose-limited Product Claim.

[21] See footnote 17.

[22] See footnote 19.

[23] See footnote 18.

The party marketing the drug with label instructions which describe the patented use

A number of Groups reported that liability in this scenario could be dependent on the form of the claim and/or on having requisite knowledge or intention.

This scenario nonetheless presents the clearest case of infringement.

In Germany, liability arises when the party offering or selling the drug adds such label instructions as will constitute an 'obvious or manifest arrangement' for the claimed use. However, cases have diluted this concept, eg:

- in one case, no infringement was found where the purpose of treating the specific patient group was not mentioned in the label instructions, but the generic product could be used in more than 50% of the patients in the patented indication;
- a recent decision found that information about the drug in marketing materials by sales people, even if employees of the generic drug manufacturer, was not sufficiently attributable to the product, and therefore did not constitute a manifest arrangement of the drug for the protected purpose.

Physician prescribing the drug for such use

Groups variously reported that the rationale for excluding liability in this scenario may include:

- act of prescribing a drug not qualifying as an infringing act;
- exclusion of methods of medical treatment from patentability;
- policy-based exemptions to enable physicians to take actions considered suitable for their patients;

The US Group explained that medical practitioners are exempt from liability for 'performance of a medical activity' that constitutes infringement. A 'medical activity' is limited to 'the performance of a medical or surgical procedure on a body'. The exemption does not extend to use of a patented drug, practice of a patented use of a drug or practice of a process of biotechnology patent.

Pharmacist dispensing a drug for such purpose

Again, some Groups reported that liability may depend on requisite knowledge or intention.

Other Groups reported specific exclusions from liability, eg extemporaneous preparation as per a physician's prescription (see further 3)b) below), and dispensing of a combination/mixed drug (Japan, Korea).

Patient using the drug for such purpose

Subject to the general caveat that there are very few, if any, reported cases of patients being pursued for patent infringement, many Groups reported an exemption for personal or non-commercial use, which encompasses patients. See further 3)b) below.

b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?

Many Groups responded to this question on the basis that their law exempts certain acts or uses from infringement or liability for infringement, rather than particular parties or classes of parties.

The table at 3)a) above attempts to reconcile the answers reported under 3)a) above with the responses to this question 3)b), to demonstrate the cases where particular parties may be exempt from infringement or liability for infringement of second medical use claims.

The table below attempts to categorise various classes of acts as reported by the Groups, concentrating on non-infringing uses, but limited to the context of second medical use claims.

Exempt/non-infringing use	**Where available?**	**Percentage**
Private/non-commercial use	Austria, Belgium, Brazil[24], Bulgaria[25], Denmark, Finland, Germany, Hungary, Ireland, Japan, Russia, Singapore, Sweden, Switzerland, UK	Approximately 45%
Extemporaneous preparation of a prescription[26]	Belgium, Brazil, Bulgaria, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Philippines, Russia, Singapore, UK	Approximately 45%

A number of Groups also referred to more general exemptions from infringement or non-infringing use, eg prior use[27], exhaustion/parallel trade[28], goods in transit and compulsory licensing, as well as the Bolar exemption (regulatory approval) and experimental use.

c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details

Approximately 75% reported that second medical use claims may be enforceable on the basis of direct or indirect infringement or both: Australia, Austria, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Japan, Netherlands, New Zealand, Philippines, Korea, Singapore, Spain, Sweden, Switzerland, Turkey, UK, US.

There was variation as to whether, in circumstances where any of the scenarios in 3)a)i) - iv) above result in infringing use:

- such use could constitute both direct and indirect infringement;
- particular scenarios gave rise to one or other form of infringement; or
- direct or indirect infringement would arise by virtue of the particular circumstances within a scenario.

[24] Plus an additional requirement that there be no economic prejudice to the patentee.

[25] Same additional requirement as for Brazil.

[26] This generally refers mixing together of ingredients for a prescription, being a manual process for individual orders. One Group queried the relevance of an 'extemporaneous preparation' exemption today when few pharmacists compound drugs but rather sell pre-packaged product.

[27] Prior use is subject of a separate AIPPI study see Study Question – Patents Committee – Prior User Rights. Also to be debated at the AIPPI Congress in Toronto, 2014.

[28] For example, acts done with products put on a market by the patentee or with the patentee's consent.

The remaining Groups reported that, in the absence of their law drawing any distinction or recognising the concept of indirect infringement, such claims are enforceable on the basis of direct infringement only.

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?

Generally, it will be an infringement if a party makes and/or supplies a generic version of a drug and includes instructions to use the drug in accordance with any patented uses. As a number of Groups explained, the various acts must be directed to a use which would infringe the second medical use claim. Otherwise the monopoly granted by that claim is unduly extended. 'Use' may be further qualified by the type of use/the party using, as explained in 3) above.

Infringement may also depend on the claim format. For example, some Groups observed that for Swiss-style claims it would be expected that infringement would require some evidence that the drug has been *manufactured* for a use or uses which includes the particular indication defined in the claim.

Accordingly, the majority of Groups were not in a position to answer this question definitively. As the UK Group explained, in circumstances of generic manufacture/supply, the situation is complicated and any finding of infringement may depend on the following:

- whether the generic version of the drug is actually being used for the patented use either by way of cross-label'[29] or 'off-label'[30] use;
- whether or not the generic manufacturer/supplier has taken any steps to label their generic drugs so as to exclude the patented use ('skinny labelling');
- with cross-label use, whether it can be established that the generic manufacturer/supplier would have known, or it would have been obvious to a reasonable person in the circumstances that supply of the generic drug would be used for a patented therapeutic indication.

The Australian High Court recently held[31] that limiting the product information for the drug to non-patented indications was 'an emphatic instruction to recipients' to restrict use of the product to uses other than used in accordance with the patented method. At the first opportunity to apply this decision, the Full Federal Court (a lower but nonetheless authoritative court) made it clear that it is a question of fact whether there is a 'reason to believe' that the generic drug would be put to an infringing use.

[29] Cross-label use arises in the following context. Branded medicine (M) has a label or is authorised/registered for non-patented indication (A) and patented indication (B). A generic obtains a marketing authorisation for a generic version of M for indication A and carves out indication B from its label or product information, so that the medicine has a 'skinny label' for A only. The generic version of M is in fact used for patented indication B, notwithstanding the carve out of indication B.

[30] Where a medicine (branded or generic) is used for a non-authorised/registered indication, so that indication will not appear on the label of or product information for the medicine, eg branded medicine (M) is authorised for indications A and B but M is used for an unauthorised/unregistered condition C.

[31] *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA50.

Similarly, a number of Groups reported that 'skinny labelling' *per se* will not be determinative of whether infringement may be found. A number of Groups also reported that the regulatory framework around marketing authorisation and product substitution may result in generic products being dispensed for patented indications.

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

All Groups who responded to this question[32] answered in the affirmative, subject to any exemptions from infringement or liability for infringement, or caveats, described in answering questions 3) and 4) respectively above.

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?

The Groups who answered this question[33] were almost unanimously in the affirmative.

The Danish and UK Groups expressed some doubts, dependent on the particular circumstances. In Denmark, if the infringing use is not described in marketing or product information, it is unclear whether, and under what circumstances, infringement will take place.

The UK Group provided a detailed analysis of the differences between Swiss-type claims (being 'process' claims) and Purpose-limited Product Claims. In particular, complexities arise with Swiss-type claims where the steps of formulation of the active pharmaceutical ingredient into the final commercial product and the inclusion of the product label indicating the patented use are undertaken by different parties. The status of intermediate links in the chain before the person who uses or offers the product (and therefore profits from) an infringing use is not always clear. Purpose-limited Product Claims differ from standard product claims in that knowledge on the part of the alleged infringer is not a statutory requirement for a standard product claim. However, it may be necessary to read intention into a Purpose-limited Product Claim to find infringing use – otherwise, the purpose element of the claim has no meaning.

c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?

Of the Groups who answered this question,[34] 55% either responded in the affirmative or reported that, while in principle, knowledge is not an element of direct infringement, the nature of a second medical use claim means that knowledge will or may be a requisite element: Australia, Austria, Belgium, Brazil, Canada, Finland, France, Germany, Ireland, Israel, Netherlands, Sweden, Switzerland, Turkey, UK and US.

[32] Four out of the 33 Groups did not answer this question, presumably on the basis of prior responses to the effect that there was insufficient case law in their respective countries.

[33] See footnote 32.

[34] See footnote 32.

The remaining 45% of the Groups who answered did so in the negative, at least in relation to direct infringement:[35] China, Czech Republic, Denmark, Hungary, Italy, Japan, Mexico, Philippines, Portugal, Korea, Russia, South Africa and Spain.

d) If yes to c), what standard of knowledge is required?

Twenty Groups responded to this question, being approximately ⅔ of the Groups who responded to question 5)c) above in the affirmative.

Again, it is apparent that the claim format, and whether or not the liability arises under direct or indirect infringement, will dictate the answer to this question.[36]

In regard to direct infringement of a purpose-limited product claim, as described in 3)b) above, the UK Group reported that English courts have struggled with the concept of direct infringement. Some degree of knowledge or intention may need to be established but it is not clear what would need to be proved. The Danish Group reported that knowledge or reason to believe might be the standard where a product is in fact used for a patented second medical use purpose, but this is not clear if the product is only promoted for another purpose. The German Group also expressed uncertainty as to whether, in those circumstances, the necessary subjective link could be established.

The French Group explained that the criteria will depend on the nature and perpetrators of the relevant acts. For example, the manufacturer of the active ingredient may have no knowledge of the therapeutic indications for which the ultimate product will be marketed, whereas the manufacturer of the medicament may, by reason of their contribution to the regulatory process, have such knowledge or it may otherwise be obvious that the medicament is capable and intended for a particular therapeutic use. The company that ultimately markets the product has the requisite knowledge. Requirements of confidentiality may dictate that a pharmacist is not aware of a customer's pathological condition, and therefore would not know the indication for which they are dispensing a particular product.

6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?

Some Groups focussed on evidentiary requirements, rather than legal tests, the latter having been discussed in answering earlier questions. A number of Groups also pointed out that no specific legal tests have been established by their courts for determining infringement of a second medical use claim. Rather, their courts apply general principles for determining infringement, whether that be literal infringement, infringement under the doctrine of equivalents, etc.

A number of Groups reported that mere sale or supply will not be sufficient to establish infringement in the context of a second medical use claim - that would extend the monopoly to the product or use per se. The patentee must demonstrate that it is the 'second medical use' element of the claim that has been exploited, rather than the known 'first medical use'. This may be express or by implication.

[35] The Danish, Italian, Japanese and Spanish Groups noted that knowledge is not required for direct infringement but is for indirect infringement.

[36] The Finnish and Turkish Groups noted that there is no case law in their respective countries to guide an answer.

As noted above, claim format will often play a key role in determining whether the appropriate infringement analysis is one of direct or indirect infringement, and the extent to which knowledge or intention is relevant. Also as discussed above, the identity of the alleged infringer may also be relevant – certain parties, whether as a class *per se* or by reason of acts they perform – will be exempt from infringement or liability for infringement.

In terms of the factual matters that a court may take into account in determining infringement of a second medical use claim, a number of Groups reported that any and all circumstances may be taken into account. Particular cited factors included:

- content of product label[37], eg whether a patented indication is included or not, whether the particular dosage relates to a patented use;
- scope of marketing approval;
- scope of any subsidy or other pricing approval information;
- any promotional activity or dissemination of technical or other information;
- supply and sales including tender documents;
- internal documents, eg business plans, budgeting documents;
- size of market and sales volumes, eg where the market for the first (non-infringing) medical use is much smaller than the second (infringing) medical use;
- prescribing practices of physicians;
- dispensing practices of pharmacists, including practices around substituting generic products in place of originated products;
- evidence from patients as to the manner in which they in fact use pharmaceutical products and the indications or conditions for which they use them;
- steps taken by a defendant to avoid infringing uses.

The above factors may have more or less relevance depending on claim format and whether the alleged infringing product is a 'skinny labelled' product.

Of the above list, the product label was the most commonly cited matter that a court will use in determining infringement, but the extent to which a court would regard that as definitive differs. In a number of jurisdictions, the issue has not yet arisen and so has not yet been tested by the courts.

It is also important to note that it is unlikely that any one factor will be determinative. Depending on the circumstances, certain factors may be given more weight than others.

7) What relief is available for infringement of a second medical use claim:

a) at a preliminary / interim / interlocutory level?

Most of the Groups reported that the relief available for infringement of a second medical use claim is the same as that available for any other patent claim. All Groups[38] reported that injunctions are

[37] References 'product label' include references to product information, which need not be labelled on the product as such, eg a product information sheet distributed with or available in relation to the product.

available at a preliminary / interim / interlocutory level[39]. Some Groups reported that the scope of the injunction may be limited by reason of it being in respect of a second medical use claim, eg to restrain only supply for patented uses, or with instructions for particular uses.

Other forms of relief available at a preliminary / interim / interlocutory level include:

- various measures to preserve evidence;
- orders to provide information / preliminary evidence.

Distinct from injunctive relief, the US Group noted the stay available to a party who files an infringement action on an Orange Book listed patent against a filer of a generic application seeking approval to market the drug claimed in that patent. The FDA is prohibited from approving the generic application for 30 months from the filing of the infringement action, without which the generic filer cannot market the drug. Canada has a similar system, although the stay is 24 months.

b) by way of final relief?

The Groups generally reported that the final relief available for infringement of a second medical use claim is the same as that available for other types of patent claims. Key forms of relief include a final injunction and/or monetary relief (damages, reasonable royalty, account of profits etc).

Other forms of relief – the scope of which may be tailored to the specific infringing (second) use - vary between jurisdictions and may include:

- declarations of infringement/validity;
- publication of judgment;
- delivery up or destruction of infringing product;
- recall/removal from channels of commerce;
- orders to provide information;
- rectification measures, eg advertisements in relevant magazines, letters to distributors and/or consumers etc;
- legal costs[40].

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?

[38] Other than one Group who reported that there is insufficient court practice to determine if its courts would allow a preliminary injunction in the case of a second medical use claim

[39] Note that, in some countries, these terms may be used interchangeably or may reflect some difference in the length or nature of the injunction, but in any event distinguish an injunction other than one granted by way of final relief on the merits. Note also that some Groups were making assumptions based on the applicable principles in their law, there being no or insufficient case law to draw from specific to second medical use claims. Other Groups reported that interlocutory injunctions, whether in this context or more generally, are very difficult to obtain in their respective countries, despite being theoretically available, eg Canada and Russia.

[40] See also AIPPI's studies and resolutions: Q219 – The availability of injunctions in cases of infringement of IPRS; Q236 – Relief in IP proceedings other than injunctions or damages.

The majority of the Groups responded under the caveat that, in determining whether to grant a preliminary / interim / interlocutory injunction, courts will look at additional factors beyond a *prima facie* case of infringement, including for example:

- *prima facie* case of validity;
- balance of convenience;
- likelihood of irreparable harm in the absence of preliminary relief;
- public interest factors.

Accordingly, while few Groups gave an unqualified answer, approximately ⅔ reported that their courts do or would give considerable weight – which may in some cases amount to a *prima facie* case – to statements in product packaging for the purposes of analysing infringement in the context of a preliminary / interim / interlocutory injunction. This appears to be the case for at least Australia, Belgium, Brazil, China, Czech Republic, Denmark, Germany, Hungary, Ireland, Italy, Japan, Korea, Netherlands, New Zealand, Singapore, South Africa, Spain, Sweden, Switzerland, Turkey, UK and US.

A number of Groups noted that prescriptions do not carry any indication of the condition to be treated, so would be unlikely, without more, to be persuasive to establish a *prima facie* case of infringement, additional evidence would be required.

9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?

This question was directed to the *level* or *standard* of proof required to obtain a final injunction. As set out in the following table, that standard differs.

Standard	**Country**
Balance of probabilities[41] / Preponderance of evidence	Australia, Canada, Israel, Philippines, UK, US
High degree of probability / proof	Korea (high degree of probability / ordinary person would have no doubt), Turkey ('highest level of proof')
Free evaluation of evidence by the judge[42]	Belgium, Denmark, Finland, France, Germany (?), Italy (?)[43], Spain, Sweden

Note that in common law countries, a final injunction is always a discretionary remedy. Even if the requisite standard of proof is met, the court may always take into account the particular factual circumstance of the case such as the conduct of the parties and the implications of granting a final injunction in deciding whether to grant a final injunction.

[41] While some other common law country Groups (eg Ireland, New Zealand and Singapore) did not specify a standard, it is expected that, being common law countries, the balance of probabilities would be the applicable standard.

[42] As explained by the French Group: the law does not impose on the judge any degree of conviction in order to consider an assertion of fact as proven - there is no 'standard of proof'. Rather, the judge has complete freedom in terms of assessing proof.

[43] The German Group reported that the Court has to be 'fully convinced that all the preconditions for the final injunction are met'. The Italian Group reported that 'full and clear evidence of the infringing acts (including circumstantial evidence thereof)' must be submitted. Query whether these approaches permit free analysis of the evidence by the court.

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?

Of the 33 Groups whose countries presently permit second medical use claims, policy reasons include the following:

- no specific statutory exclusion from patentability;
- protect / promote / incentivise pharmaceutical R&D / innovation[44];
- benefits to patients, eg maintaining health care standards, treatments for new indications, safety profile already known or enhanced through further development, enhanced treatment methods with reduced side effects, etc;
- simpler / cheaper R&D (including domestic R&D);
- harmonisation[45];
- difficulty in identifying new molecules;
- to circumvent exclusions on methods of medical treatment from patentability.

Additional factors cited by the Australian High Court in *Apotex v Sanofi-Aventis* as the basis for Australia's long-standing acceptance of method of treatment claims (including second medical use claims) were:

- methods a medical treatment are capable of being applied in commerce or industry and are therefore able to satisfy the basic subject-matter requirement that an invention have 'economic utility';
- there is no normative distinction between methods of treatment of the human body which are cosmetic and those which are medical;
- claim format should not decide patentability.

b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

Approximately 75% (of the Groups whose countries permit second medical use claims) generally consider that the claims as are currently permissible strike the right balance, with some qualifications, for example:

- while the right balance exists in relation to the permissible scope of claims, the difficulty in enforcing them might disadvantage patentees (Belgium, Spain);

[44] Including to incentivise research in fields where the market is small, eg Orphan drug indications.

[45] In many cases European harmonisation was referenced, although a number of other countries also referenced harmonisation more generally.

- the balance is a fine one and competition law has a role to play in preventing patent abuse (France, Israel);

The New Zealand Group considers Swiss-style claims to be an acceptable fall-back position in the absence of method of treatment claims, but would prefer method of treatment or purpose-limited product claims.

The German Group considers that patentees are at a disadvantage due to the combination of 'skinny labelling' and the way in which the theory of 'obvious or manifest arrangement' is applied by their courts (so far in relation only to a Swiss-type claim).

The US Group reported that certain permissions for 'skinny labelling' under the Hatch-Waxman Act may cause difficulty in proving infringement of second medical use claims, in which case the patent provides less protection for the patentee.

The Australian, Mexican, Swiss, UK and US Groups reported that there is no real consensus as to whether the claim formats permissible in their countries are considered to strike the right balance.

The UK Group reported a great deal of uncertainty relating to the enforceability of second medical use claims, eg who is liable for infringement, the acts which constitute infringing acts, the knowledge requirement, the scope of remedies available.

c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?

Approximately 55% (of the Groups whose country permits second medical use claims) answered in the negative.

While the Dutch Group considers that second medical use claims strike a fair balance between the interests of relevant stakeholders, as long as it is difficult for patentees to prove infringement in cases of 'skinny labelling', originators may be discouraged from making R&D investments.

Concern in relation to enforceability is a recurrent theme.

Some Groups consider that medical use claims best serve the interests of originator companies, without necessarily criticising that outcome.

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?

Most Groups reported that there is no empirical data available.

Where data is available:

- the Danish Group reported that over 1,000 patent applications registered with the Danish Patent and Trade Mark Office in 2013 and 2014 (to date) are likely to contain second medical use claims;
- the German Group reported that approximately 10% of all patent applications in the pharmaceutical area, filed with the German Patent and Trade Mark Office and the EPO designating Germany, have a second medical use claim as the main claim;
- the Japanese Group reported that since 1 January 2000, 27,070 applications for second medical use patents have been filed with the Japanese Patent Office;

- the Mexican Group reported that nearly 20% of patent applications in the pharmaceutical field have some kind of medical use claim, with a steady increase in the last 10 years. This is currently approximately 25% of more than 15,200 pharmaceutical patents.

Anecdotally, the Canadian, New Zealand, Swedish and US Groups reported that second medical use claims are common. Conversely, the Spanish Group reported that there are few national patents directed to second medical uses.

ii) What is the profile of patentees for second medical use claims in your country?

Again, most of the Groups reported that there was no empirical data available.

Where data is available:

- according to Danish Patent and Trade Mark Office, the prevalence of second medical use claims in applications for Danish patents and validated European patents is increasing;
- the German Group reported that most of the patent applications with a second medical use claim as the main claim published 2000 - 2013 were filed by originator pharmaceutical and biotechnology companies;
- the Japanese Group reported that:
    - approximately ⅓ of the second medical use patents reported above (27,070) are held by originator companies, with just over half of these held by foreign originator companies;
    - domestic generic companies hold more second medical use patents than foreign generic companies.

Anecdotally, a number of Groups reported that the profile of patentees for second medical use claims tend to be originators: Brazil, Israel, Italy, Mexico (predominantly), Netherlands, Korea and US.

The Finnish and Russian Groups reported that second medical use claims are used by both originators and generics. The Mexican and UK Groups also report generic use of second medical use claims.

The Canadian, Swiss and UK Groups report a varied profile of patentee, including research institutions, universities, hospitals, and start-ups, as well as multinational or established pharmaceutical and biotech companies.

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?

In addition to any reasons set out under 1) above, the following countries which do not permit second medical use claims provided the following information.

Country	Policy – 11)a)	Would stakeholder interests be served? – 11)b)	Detrimental to some stakeholders – 11)c)
Argentina	• The local generic pharmaceutical industry has traditionally been opposed. • But the law does not prevent protection. • No sound legal policy reason for this de facto prohibition.	Yes, particularly the interests of parties undertaking relevant R&D.	• Would better serve the interests of originator companies and research organisations (including domestic company/organisations who may currently seek protection outside Argentina). • Would be detrimental to companies not focussed on innovation.
Caribbean	*Dominican Republic*: Protection of the national generic pharmaceutical industry.	*Dominican Republic*: No answer.	*Dominican Republic*: • May not serve the interests of the national pharmaceutical industry, the present prohibition is designed to safeguard. • Would serve the interests of foreign industry.
	El Salvador: Lack of regulation of second medical use claims in domestic IP legislation.	*El Salvador*: No.	*El Salvador*: No.
Egypt	• Lack of inventive step. • Patent Office objection as a mere 'discovery'.	Medicines based on a second medical use may be registered, but the prohibition of second medical use claims means that proprietors face competition – favouring consumers (lower prices) but decreasing incentives for inventors to enter the local market. This may be offset by the size of the local market (population nearing 90 million).	• Would better serve the interests of inventor pharmaceutical companies and the consumer (access). • May adversely affect competitors and consumers with respect to pricing, although the government can mitigate this by mandatory pricing/licensing.
Paraguay	Deemed 'excluded subject protection', ie statutory prohibition on new patent protection for prior art to which a different use is attributed.	No.	• Favourable to companies with second medical use products. • Harmful to the remaining pharmaceutical industry.

Country	Policy – 11)a)	Would stakeholder interests be served? – 11)b)	Detrimental to some stakeholders – 11)c)
Peru	• Peru's interpretation of TRIPS Article 27 (patents may be granted for products or processes but only if they are new, inventive and industrially applicable). • Compliance with Andean Community regulations which expressly prohibit second medical use patents. • Lack of novelty.	Yes, in relation to the pharmaceutical industry but query the affect on consumers and competition in the market.	• Could benefit R&D pharmaceutical companies. • Possible effect on free market competition.
Uruguay	• Lack of novelty. • Second medical use claims are effectively prohibited treatment claims. • Lack of industrial application. • The social, legal and economic desire for certainty relating to a clear time limit for a patent monopoly. • Shortening the time in which drugs may be available for exploitation by a third party.	Yes, some stakeholders could benefit but the present position reflects a desire for legal consistency and public health concerns.	• The absence of second medical use claims may discourage industry to invest in research and innovation. • Could also function as a potentially indefinite extension of patent rights with an inevitable compromise of social, legal and economic interests.

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?

Of 37 Group responses, approximately ⅓ reported no noticeable effect or could not say whether there is any effect. The Dutch Group speculated that limited case law may indicate that effects are marginal, but equally may indicate that originators are sceptical regarding their chances of effectively enforcing their second medical use claims in the environment of 'skinny labelling'.

The Argentinian and French Groups reported that the effect is to reinforce the division between originator and generic pharmaceutical companies – in Argentina, the balance lies with generic companies due to the absence of second medical use claims; in France, the balance is reversed.

The Australian, UK and US Groups report that second medical use claims have an important role to play including in the context of mature pharmaceutical markets.

Again, a common theme was that the existing state of the law has insufficient or uncertain scope of protection for second medical use claims. Various factors cited include 'skinny labelling', lack of harmonisation between regulatory and patent laws and, again, uncertainty with regard to enforceability.

The Egyptian, Paraguay and Uruguay Groups reported the absence of second medical use claims has a favourable effect on pricing and availability of pharmaceuticals.

III. Proposals for substantive harmonisation

13) Is it desirable to permit second medical use claims?

The 39 Group responses were almost unanimous in the view that it is desirable to permit second medical use claims. In some cases, answers were qualified by such factors such as the need to satisfy other requirements of patentability and striking the appropriate balance on access to medicines.

The Argentinian and Egyptian Groups both support the permissibility of second medical use claims, despite the same not presently being available in their respective countries. Within the Caribbean Group, El Salvador would support second medical use claims whereas the Dominican Republic may not.

14) Is harmonisation of laws relating to second medical use claims desirable?

The same 39 Groups consider that harmonisation is desirable. To the extent any qualifications were expressed, these included:

- avoiding *per se* or subject matter prohibitions which create artificial approaches (Australian Group);
- harmonisation which lowers the level of protection and thereby reduces the motivation to invest in research (German Group);
- consideration for differing development levels and particular public health needs (Mexican Group).

There were also views that harmonisation should extend not only to claim format but also to the scope of protection, and that harmonisation should also occur at the regulatory level.

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

Use	Group	Percentage[46]
Any use (provided ordinary criteria of patentability is met)[47]	Australia, Belgium, Brazil, France, Hungary, Ireland, Italy,	Approximately 30%

[46] Being the percentage of Groups who responded to this question or 15)b).

[47] These Groups are therefore included as supporting all subsequent categories of use.

Use	Group	Percentage[46]
	Sweden, Switzerland, UK	
Additional Medical Use Examples	Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Caribbean, Czech Republic, Denmark, Egypt, France, Finland, Germany, Hungary, Israel, Ireland, Italy, Japan, Korea, Mexico, Philippines, Portugal, Singapore, South Africa, Sweden, Switzerland, Turkey, UK, US	Approximately 95%
New Medical Use Examples	Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Caribbean, Czech Republic, Denmark, France, Finland, Germany, Hungary, Israel, Ireland, Italy, Korea, Mexico, Philippines, Portugal, Singapore, South Africa, Sweden, Switzerland, UK, US	Approximately 90%
G2 / 08 Use Examples	Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Czech Republic, Denmark, France, Finland, Germany, Hungary, Israel, Ireland, Italy, Japan, Korea, Latvia, Sweden, Switzerland, UK, US	Approximately 70%

b) Types of any second medical use constituting impermissible subject matter

A number of Groups addressed permissible/impermissible claim format in responding to this question – those responses are encapsulated in 15)c) and d) below.

Of the Groups who addressed *types* of use (27 Groups), the majority expressed the view that, subject to fulfilling other patentability criteria, there should be no impermissible subject matter, or the current practice – which would permit claims based on the examples of the types of use referred to in 2) above - should continue to be permitted.

The Portuguese and Turkish Groups would not permit claims based on G2/08 Use Examples. Similarly, the South African Group would not permit claims on new dosage regimes which, although novel, are considered to have an ever-greening effect, thus raising issues about access to healthcare.

c) Form of permissible claims

The 35 Group responses are reported in the following table. Those Groups that did not respond do not consider second medical use claims are desirable.

Form of claim	**Country**	**Percentage[48]**
Method of treatment	Australia, Bulgaria, Canada(?)[49], Ireland[50], Japan[51], Russia[52], Turkey, US[53]	Approximately 20% - 25% (depending on Canada)
Swiss-type	Australia[54], Belgium, Brazil, Bulgaria, Canada, China[55], Czech Republic, Finland, Germany, Ireland, Israel, Italy, Mexico, Philippines, Portugal, Russia, Singapore, South Africa	Approximately 50%
Bare Use Claim	Argentina, Australia[56], Bulgaria, Canada, Caribbean (El Salvador), China, Czech Republic, Germany, Ireland, Italy, Korea, Russia, Turkey	Approximately 40%
Purpose-limited Product Claim	Australia, Belgium, Brazil, Bulgaria, Canada, Caribbean (El Salvador), China, Czech Republic, Denmark, Egypt, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Latvia, Mexico, Netherlands, Korea, Russia, South Africa, Spain, Sweden[57], Switzerland, Turkey, UK	Approximately 85%

[48] Being the percentage of Groups who responded to this question.

[49] Based on the Canadian Group's response this and 15)d) below, it would appear that the Canadian Group would support method of treatment claims.

[50] Provided medical practitioners, including diagnostic technicians, cannot be sued for infringement.

[51] See footnote 50.

[52] Russia is listed here and in relation to Swiss-type and use claims on the basis they are presently permissible claim formats in Russia and the Russian Group does not suggest they should be abandoned.

[53] US Group reported that many US practitioners consider method of treatment claims to be the most desirable format, as this avoids the need to rely on the intended use recited in the claim (as an exception to the general rule in the US that product claims are not limited by their intended use).

[54] Only amongst a claim set also including 'method of use' and/or 'use' claims.

[55] China is listed here and in relation to use claims on the basis they are presently permissible claim formats in China and the Chinese Group does not suggest they should be abandoned.

[56] The Australian Group would also permit a 'method of use' claim format.

[57] The Swedish Group also considers that there should be a general exemption from infringement for medical and veterinary practitioners when treating patients so as to avoid an overly broad interpretation of the scope of protection provided by a Purpose-limited Product Claim.

A number of groups (eg Israel and Switzerland) commented that claim format should play less of a role in allowing patent protection. The Swiss Group considers the scope of protection conferred by second medical use claim is more important than the claim format.

d) Form of impermissible claims

Of the 33 Group responses, the Australian, Bulgarian, Canadian, Irish and Swiss Groups (approximately 15%) do not consider any form of claim should be impermissible - in the case of the Swiss Group, provided that Purpose-limited Product Claims are permissible.

Form of claim	**Impermissible**	**Percentage**[58]
Method of treatment	Argentina, Austria, Belgium, Brazil, Caribbean, Czech Republic, Denmark, Finland, France, Germany, Hungary, Israel, Italy, Latvia, Mexico, Netherlands, Philippines, Portugal, Korea, Russia, Singapore, South Africa, Sweden, Turkey	75%
Swiss-type	Israel[59], Japan, Turkey, UK	12.5%
Bare Use Claim	Brazil, Denmark, Finland, France, Hungary, Israel, Mexico(?)[60], Netherlands, Portugal, South Africa, Sweden	Approximately 35%
New dosage regime	Caribbean (El Salvador), Egypt, South Africa	Approximately 10%

A number of the Groups who oppose method of treatment claims do so on the basis that there is no immunity for medical personnel from patent infringement. The Russian Group considers methods of treatment could be optionally removed from national patent laws, despite currently permitting methods of medical treatment.

e) Who may be liable for infringement

From 33 Group responses, the Australian and Caribbean Groups consider that, at least in principle, anyone may be liable for infringement, whether directly or indirectly[61]. The other Groups would limit liability as recorded in the following table.

A number of the parties or acts described in the table necessarily overlap. This reflects the fact that, for example, some Groups responded that anyone acting commercially ought to be liable for infringement, whereas other Groups were more specific in their responses. The general and the

[58] Being the percentage of Groups who responded to this question.

[59] While all members of the Israeli Group object to method of treatment claims, it would appear that at least some members also object to any form of claim other than a purpose-limited product claim.

[60] This is presumed on the basis that the Mexican Group considers that claims which comprise 'indirectly or explicitly, methods of therapeutic treatment'. It is assumed that the Mexican Group will consider a Bare Use Claim to be an indirect method of medical treatment.

[61] These Groups are therefore included as supporting all parties who may be liable for infringement in the table below.

specific are reported below to assist the Working Committee in trying to reach consensus if, in the foregoing example, it was considered that liability should arise in relation to some, but not all, commercial acts.

Party	**Proposed by**	**Percentage[62]**
Anyone acting commercially / benefitting financially	Australia, Austria, Belgium[63], Brazil, Bulgaria, Caribbean, Denmark, Finland, France, Netherlands*, Spain, Sweden[64], Turkey, UK[65]	Approximately 40%
Manufacturer	Australia, Canada, Caribbean, China, Germany, Hungary, Ireland, Israel[66]*, Italy, Japan* Latvia, Mexico*, Netherlands*, Philippines, Russia, Singapore, South Africa, Spain, Switzerland, US	Approximately 60%
Importer	Australia, Caribbean, Italy, Japan*, Philippines, Russia, Singapore, Spain, Switzerland, US	Approximately 30%
Marketer	Australia, Caribbean, Hungary*, Japan*, Latvia, Netherlands*, Philippines, Korea*, Singapore, South Africa, Spain, Switzerland, US	Approximately 40%
Distributor / Wholesaler / Supplier / Sellor/ Other party who puts an infringing product on the market	Australia, Caribbean, China, Czech Republic, Germany, Hungary, Israel*, Ireland, Italy, Mexico, Philippines, Russia, Singapore, Spain, Switzerland	Approximately 50%
Physician[67]	Australia, Austria, Caribbean, Finland, Germany, Philippines, UK[68]	Approximately 20%

[62] As a percentage of the Groups who responded to this question.

[63] There was division within the Belgian Group as to whether prescribing or administering a medicament (by physicians or related) should qualify as an infringing acts and if so, whether they should be exempt from infringement.

[64] Other than doctors and patients.

[65] The UK Group proposes a structure which sets exemption from liability to be by reference to activities rather than particular parties, and in the broader context of reform to the regulatory system. See further 15)i) and 16) below.

[66] The Israeli Group reported a division of opinion as to its proposal: (1) manufacturer, insurer, wholesale, pharmacist; (2) anyone putting a product onto the market which states on the product label that the drug is indicated for the patent abuse.

[67] Conceptually, this encompasses doctors, medical practitioners and may include related medical staff etc, but there is no uniformity which would allow a precise class to be identified.

[68] Depending on the circumstances.

Party	Proposed by	Percentage[62]
Pharmacist	Australia, Caribbean, Israel, Italy, Netherlands[*], Russia, US	Approximately 20%
Patient	Australia, Caribbean, US	Approximately 10%

[*] = Qualified by intention, eg if a manufacturer, intentional manufacture for an infringing use; if marketing, marketing for an infringing use, eg by reference to the product label etc.

The Spanish and Swiss Groups would add another element to the above intention qualification, ie knowledge or, in light of the circumstances, should have the requisite knowledge, *but does not take adequate measures* to prevent infringing use.

f) Any parties/institutions that should be exempted from infringement or liability for infringement

In collating the 34 responses to this question, it has been assumed that the ordinary exemptions from infringement, eg experimental use would also apply.

Party	Proposed by	Percentage[69]
Physicians[70]	Argentina, Brazil, Bulgaria, Canada (?)[71], China, Egypt, France, Hungary, Ireland, Israel[72], Italy, Japan, Latvia, Mexico, Netherlands, Portugal, Korea, Russia, Singapore, South Africa, Sweden[73], Switzerland[74], Turkey[75], US	Approximately 75%
Hospitals	Argentina, Canada (?)[76], Hungary, Japan	Approximately 10%
Pharmacists	Argentina, Bulgaria[*], Canada[77], China, Denmark[*], France[78], Hungary,	Approximately 50%

[69] As a percentage of the Groups who responded to this question.

[70] See footnote 67.

[71] The Canadian Group proposes that 'possibly' physicians, hospitals and pharmacists should be exempt.

[72] Provided the physician is not jointly liable for infringement with the manufacturer.

[73] The Swedish Group would extend exemption from practitioners to veterinary practitioners and 'related health care and veterinary entities'.

[74] The Swiss Group would not exempt certain parties or institutions from liability, but rather provide that second medical use claims may not be enforced against certain parties or institutions.

[75] Other than in 'off label' cases.

[76] See footnote 71.

[77] See footnote 71.

Party	Proposed by	Percentage[69]
	Ireland, Italy*, Japan, Latvia, Mexico (?)[79], Singapore*, South Africa, Switzerland[80], Turkey[81]	
Patients	Austria, Belgium, Brazil, Bulgaria, Canada, China, Denmark, Finland, France, Germany, Hungary, Israel, Ireland, Italy, Japan, Latvia, Mexico, Netherlands, Philippines, Portugal, Korea, Russia, Singapore, South Africa, Spain, Switzerland, Turkey, UK+	Approximately 80%

* = In some cases this is qualified, eg the 'extemporaneous' exception noted described at footnote 23 above (Denmark, Italy, Singapore).

+ = The UK Group proposes a structure which sets exemption from liability to be by reference to activities rather than particular parties, and in the broader context of reform to the regulatory system. See further 16) below.

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

Of the 31 responses, either by reason of answers to this question or earlier responses, the focus of the acts referenced was commercial acts or otherwise circumstances where the infringer benefits from the infringing use (it being assumed from the context that this is a commercial rather than a health benefit). In particular, the acts of manufacturing, importing, offering for sale, selling, using (at least in a commercial setting) were variously mentioned by most of the Groups who responded to this question. The caveat in most cases was that the act needs to be directed to the patented use, as otherwise the monopoly in relation to the product or use covered by the second medical use claim will be unduly extended. As the French Group explained:

> *It should be possible for each commercial act (manufacture, implication, holding, offer for sale, sale, use, etc.) to constitute an act of infringement of a second medical use, provided that this act contributes to the implementation of the patented second medical use.*

Some Groups take a position that knowledge, at least in relation to direct infringement, is irrelevant (eg China, Germany, Spain). Query whether that position can be encompassed within a standard favoured by many of the Groups - knowledge or an analysis of circumstances that point to

[78] Hospital pharmacists only.

[79] The Mexican Group reported that some members of the Group consider those involved in health care services (eg physicians, patients), being persons not part of the distribution chain, should be exempt, and that others in the Group consider that pharmacists should also be exempt.

[80] See footnote 74.

[81] Where merely carrying out physician's instructions.

infringing use occurring, irrespective of knowledge or intention. Knowledge may also have an impact on any award of damages.

The main variation in the proposals was in relation to whether the approved indication in a marketing authorisation or product label should be definitive in this context. Some Groups considered that if the marketing authorisation or product label references an indication which falls within the claims of a patent, that is sufficient to constitute an act of infringement. Other Groups consider that if a product is approved for more than one indication of which one (but not all) falls within the patented claim, infringement should only be found where the infringing acts are in relation to the particular patented indication(s).

Many Groups advocate an approach which investigate the facts of the particular case. The UK Group provides a standard which the Working Committee may consider useful:

> *Where a party has taken reasonable, effective steps to prevent or discourage infringing use of the medicament, then no liability for patent infringement should be found. The burden to establish objective intention should remain with the patentee; however, the burden to show that such reasonable and effective steps have been taken would fall upon the alleged infringer.*

The UK Group goes onto provide a list of factors that could be taken into account (a number of which were also mentioned by other Groups), including at least:

- the labelling of the medicament, including whether there was an option for a 'skinny label', whether that has been adopted, and whether the label needs to include any reference to carved out indications;
- any marketing or promotional activity carried out by the alleged infringer;
- internal documentation of the alleged infringer, including (for example) minutes of budgeting meetings, business planning documents, and other documentary evidence of its pre-launch planning and conduct;
- any steps taken by the alleged infringer to cause/prevent or discourage/encourage infringing use, for example by writing to physicians or relevant professional bodies;
- assessment of the economics of the relevant market, including relevant sizes of the markets for the different indications and the volume of the allegedly infringing product on the market[82];
- prescription practices of relevant professionals, including whether the indication is conveyed to the person who chooses the particular products to be administered; and
- administration practices, eg is it a medical professional who selects and administers the precise medicament, or is it dispensed from a pharmacy?

[82] With the caveat that a full analysis of such evidence may be burdensome and expensive, possibly requiring the involvement of experts, so should not be demanded in every case.

h) Relief available upon a finding of infringement:

i) at a preliminary / interim / interlocutory level; and

From the 34 responses, all Groups considered that the relief available for infringement of a second medical use claim should be the same as that available for any other patent claim, or otherwise propose that preliminary / interim / interlocutory injunctions should be available for infringement of second medical use claims.

Some Groups also proposed that measures to preserve evidence, eg seizure (Germany, Italy, Philippines) or delivery up (South Africa) should be available at this level, as should orders to provide information or preliminary evidence (Germany, Italy, Sweden).[83]

ii) by way of permanent relief

From the 33 responses, the Groups generally proposed that the final relief available for infringement of a second medical use claim should be the same as that available for other types of patent claims. Forms of relief would therefore include:

- a final injunction, the scope of which may need to be tailored to the relevant infringing use so as not to extend the scope of the monopoly unduly;
- monetary relief, such as damages, reasonable royalty, account of profits, fine etc.
- declarations of infringement / validity;
- publication of judgment;
- delivery up or destruction of infringing product;
- recall / removal from channels of commerce;
- orders to provide information;
- rectification measures, eg advertisements and relevant magazines, letters to distributors and/or consumers;
- legal costs.[84]

A number of the Groups also proposed specific measures relevant to infringement of second medical use claims, particularly in the context of labelling and dispensing practices.

For example, the Spanish Group proposed that courts should be able to make orders requiring the defendant to put in place measures that track final use of the product and to insert a notice in the product information stating that the product must not be used for a patented purpose. In addition, courts should be able to make orders:

- obliging physicians to specify the use for which the product is prescribed;
- obliging pharmacists to record the indications for which the product has been sold;
- requiring indication alerts within prescribing and dispensing software systems.

[83] See footnote 40.

[84] See footnote 40.

Similarly, the French Group proposed that in cases where the product is sold for another use, it should be possible to order the infringer to remove from the product label any reference to the second medical use, and to add to the product label (and any other commercial documents) a reference indicating that the product must not be used for the second medical use found to be infringing. This measure alone may go some way, but may not address the problem in its entirety, given that the size of the market for the infringing vs non infringing use may dictate what actually happens in practice irrespective of a direction not to use for the infringing second medical use.

The UK Group proposed that in the scenario contemplated by the French Group, it may be justifiable for an injunction which prevents a generic product from being on the market for any use, not just the second medical use. This is because the 'skinny label' product in such a market would effectively earn a windfall as a consequence of cross-labelling prescribing for the second medical use. On the other hand, an injunction barring all generic sales would be inappropriate where the overall market for the drug is dominated by the first medical use. The Spanish Group's proposal may provide a more wholistic approach and avoid some of the arbitrary outcomes identified by the UK Group, but would necessitate considerable regulatory reform.

i) In each case for h)i) and h)ii), the level of proof for the granting of such relief

The two themes were that the standard of proof for the grant of relief should not differ from the standard for any other patent claim, and that the current standards are generally acceptable.

In general, it is accepted that the standard for preliminary / interim / interlocutory relief is lower than final relief.

For preliminary / interim / interlocutory relief, the majority of Groups would favour a *prima facie* or like standard of actual or imminent infringement, including described in terms of there being a likelihood of infringement, eg 'probable' act of infringement, 'serious threat of infringement', etc.

Other factors at the preliminary / interim / interlocutory level include:

- whether damages would ultimately be an adequate remedy in a finding on the merits;
- irreparable harm to the patentee;
- balance of convenience as between the patentee and the alleged infringer;
- public interest.[85]

In relation to final relief, the Groups generally proposed standards consistent with the standards reported at 9) above. A balance of probabilities or preponderance of evidence test is favoured by Australia, Canada, Israel, Philippines, Singapore, Sweden, UK and US.

The seemingly higher standards reported under 9) above for Korea ('high degree of probability') and Turkey ('highest level of proof') are favoured by these Groups.

Also as reported above, in a number of jurisdictions, there does not appear to be an articulated standard, but rather the court is permitted to determine on the evidence whether infringement has been proved to a degree sufficient to warrant final relief. As noted at 9) above, in common law countries, the grant of final relief is always discretionary, which allows the court to take the particular circumstances of any case into account. Similarly, the Chinese Group reports that the

[85] See footnote 40.

court will also consider such factors as the public interest and whether the grant of final relief will cause significant imbalance of interests between the parties.

16) The Groups were also invited to comment on any additional issues concerning any aspect of second medical use claims that they deemed relevant

The German, Swedish and UK Groups noted that there are regulatory issues which directly affect and complicate issues relating to proof of infringement and therefore enforceability of second medical use claims. These Groups each proposed that harmonisation of the regulatory framework could assist in providing greater certainty.

The UK Group proposed that a harmonised regulatory system with the following characteristics would support a simpler and more effective enforcement regime for second medical use patents.

- *Prescribing*: a mechanism by which the indication for which the drug is prescribed should be noted on the script. To help maintain patient confidentiality, each authorised indication of a drug could be identified by a code which is included on the prescription.
- *Dispensing*: pharmacists should be obliged to dispense only drugs which are authorised for the indication represented by the code on the prescription. A product with a 'skinny label' could not be dispensed against a prescription for the carved out indication.
- *Reimbursement*: linked to the indication for which the drug is prescribed / dispensed rather than the drug *per se*. So if a generic version of a drug comes onto the market with a 'skinny label', it will only be reimbursed for its approved indication.
- *'Skinny labelling'*: consistent with the position in Europe, the regulatory system should enable generic companies to adopt a practice of using 'skinny labels' so that only those indications for which the generic drug has obtained marketing authorisation as specified on the drugs label, and any additional authorised indications for the branded product which are still covered by a patent, can be excluded from the generic label.

IV. Conclusion

There is broad support for the proposition that second medical use claims should be permitted, that being the case in most jurisdictions already. There is also broad support for harmonisation of laws relating to second medical use claims.

There is broad support for second medical use claims being permitted for the Second Medical Use Examples and New Medical Use Examples. While, amongst the G2 / 08 Use Examples, there was less consensus, it is still the case that more than 50% of the Groups would support those examples as being permissible subject matter, perhaps with dosage regimes being the most controversial.

As to the form of permissible claims, the majority of Groups would support a Purpose-limited Product Claim, whereas other claim formats have lower support. However, the Working Committee might like to consider the comments of some of the Groups in this context to the effect that the form of claim should play less of a role in allowing patent protection than the scope of protection conferred by the claim itself.

In relation to method of treatment claims, the majority of Groups do not presently permit such claims in their national law, and the majority proposed that such claims continue to be

impermissible in a harmonised system. However, a number of the Groups who oppose method of treatment claims appear to do so on the basis there is no immunity for medical personnel from patent infringement. Query, if provision for that immunity was made more Groups would consider that claims to methods of medical treatment should be permissible.

In relation to who may be liable for infringement, there seems to be a reasonably high level of support for commercial acts, and relatively less support for non-commercial acts. There is broad support for the proposition that physicians and patients should be exempted from infringement or liability for infringement, less so for pharmacists.

There seems to be a broad proposition for a factual investigation being necessary. Factors which could be taken into account are set out under 15)g) above.

In relation to the relief available upon a finding of infringement, there is broad support for the proposition that the relief available (both at preliminary / interim / interlocutory level and by way of permanent relief) should be the same for a second medical use claim as for any other type of patent claim. There is also broad support for the proposition that the standard of proof required to obtain relief at a preliminary / interim / interlocutory level should be lower than that required for the grant of permanent relief. Where discretion already exists as to the nature and scope of relief, there was no suggestion that the status quo be changed.

More broadly, three key themes emerged to varying degrees in many of the Groups' responses:

- uncertainty of claim scope, often because there is little if any case law upon which to draw, or by reason of permissible claim format;
- uncertainty in relation to enforceability, particularly by reason of the varying approaches courts have taken to the issue of 'skinny labelling'; and
- the interplay with the regulatory framework and the role it may play in any harmonised system. In this regard, see the proposals on the Spanish Group at 15)g) above.

In addition to the above, the Working Committee should have regard to a number of AIPPI resolutions that touch upon some of the issues addressed by the Groups in responding to this question, eg:

- Q236 – Relief in IP proceedings other than injunctions or damages (2013, Helsinki);
- Q219 – The availability of injunctions in cases of infringement of IPRs (2011, Hyderabad);
- Q204P - Liability for contributory infringement of IPRs – certain aspects of patent infringement (2010, Paris);
- Q204 – Liability for contributory infringement of IPRs (2008, Boston).

To the extent that any aspect of a resolution in relation to this Working Question traverses the subject matter of the above resolutions, the Working Committee should take care to ensure that such resolution is either consistent with prior resolutions or a basis for any different position is articulated.