Question Q238

National Group:	AIPPI Sweden
Title:	**Second medical use or indication claims**
Contributors:	Lennart ARVIDSON, Magnus DAHLMAN, Ivan HJERTMAN, Louise JONSHAMMAR, Anneli JÖNSSON, Birgitta LARSSON, Camilla LIDÉN, Niklas MATTSSON, Rune NÄSMAN, Christopher TEHRANI, Jonas WESTERBERG
Reporter within Working Committee:	Louise JONSHAMMAR, co-reporter Jonas WESTERBERG
Date:	May 7, 2014

The Swedish Group wishes to make the following introductory comments.

Like patent law in other countries, Swedish patent law is based on international agreements, such as the Paris Convention for the Protection of Industrial Property (Paris Convention), the Patent Cooperation Treaty (PCT), the European Patent Convention (EPC), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the Patent Law Treaty (PLT).

To that effect, patents valid in Sweden may either have been granted by the Swedish Patent and Registration Office or by the European Patent Office (EPO). Regarding the legal framework and practice in relation to second medical use claims at the EPO, we refer to the Working Guidelines (WGL) of this question.

The EPC and the development within the EPO have been given particular weight by the Swedish Supreme Administrative Court and the Swedish Supreme Court. Sweden became a party to the EPC in 1978 and the Swedish Patents Act is highly harmonized with the PCT and the EPC. Also, practise in Sweden develops in conformity with the EPC as interpreted by the EPO.

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)?

Yes, provided that the ordinary patentability criteria are met. The Swedish Patent and Registration Office's assessment of patentability is harmonized with the practice of the EPO and with the PCT.

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.

a) What is the basis for patent protection?

The basis for patent protection for second medical use inventions in Sweden is found in Sections 1d and 2 of the Swedish Patents Act.

Section 1d corresponds to Article 53(c) of the EPC2000 and thus prohibits the grant of patents for methods directed to surgical or therapeutic treatments and to diagnostic methods practiced on humans or animals, while it acknowledges the patentability of products, including compounds and mixtures of compounds for use in such methods. It was added to the Patents Act after the entry into force of EPC2000. Before EPC2000, the EPC and the Patents Act excluded such methods from patentability already on the ground that they were not considered to be patentable inventions.

In Section 2 of the Swedish Patents Act, the novelty criteria are set. This paragraph comprises a provision corresponding to Article 54(5) EPC2000, providing that the novelty requirement does not prevent the grant of a patent for a known substance or a known mixture of substances for specific use in a method referred to in Section 1d, if such use is not known.

According to Section 15 of the Swedish Patent Rules (issued by the Swedish Patent and Registration Office), the claims of a second medical use invention must contain a precise definition of the medical application.

b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

The guidelines for the examiners at the Swedish Patent and Registration Office define a new second medical use as the *provision of a new medical effect of a known substance*. This medical effect needs to be "specifically provided" in the application. No more details regarding the concept of a medical effect are given. However, it is the Swedish Patent and Registration Office's standard practice to follow the EPO in this respect. The Guidelines for Examination in the EPO (GL) and Case law of the EPO Boards of Appeal (BoA) and Enlarged Board of Appeal (BoA) provide additional, although not extensive, information on this subject.

The EPO GL state that where a substance or composition is already known to have been used in a "first medical use", it may still be patentable under Article 54(5) for any second or further use in a method according to Article 53(c), provided that said use is novel and inventive. There are no special conditions that a further medical use has to fulfill. According to European case law before EPC2000, where the composition has already been suggested for therapeutic use, rather any use would allow a further medical use claim to the preparation of the composition for that further medical use, irrespective of in what detail that use is specified, subject to the use being novel and inventive. This line of reasoning applies also to the EPC2000 and the "specific use" of Article 54(5) EPC as confirmed by EBoA (G2/08).

In this context, it is still clear that mere scientific knowledge needs to find an

application in the form of a *defined, real treatment of a pathological condition* in order to make a technical contribution to the art and to be considered as an invention eligible for patent protection. However, it is a fact that the question of what qualifies as a "pathological condition", as referred to in the GL, has not yet been fully answered by the BoA. This is instead determined on a case-by-case basis. The *functional* definition of a pathological condition is allowable if instructions, in the form of experimental tests or testable criteria, are available from the patent documents or from the common general knowledge, allowing the skilled person to recognize which conditions fall within the functional definition.

Clearly, any "specific use", in accordance with Article 54(5) EPC may also extend to a new dosage regimen, the treatment of specified patient groups and the identification of new clinical situations when the disease/pathological condition is already known.

In conclusion, all types of second medical uses which are mentioned in paragraphs 14-17 of the WGL constitute potentially patentable subject matter according to Swedish practice.

c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

The Swedish practice of what constitutes impermissible subject matter follows the practice of the EPO. A second medical use ("specific use") which does not fulfill Article 54(5) EPC is not permissible because it will not be considered novel. In this respect however, the concepts of novelty and inventive step may overlap due to the fictional novelty of a purpose-limited product claim by virtue of its second medical use.

Subject matter constituting mere explanations of a hitherto unknown underlying medical effect of a previously known treatment, which does not in itself lead to a contribution to the art, is not patentable.

d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.

The Swedish Patent and Registration Office will not grant patents on applications filed after January 29, 2011 with "Swiss type" claims. The claims shall instead be drafted as purpose limited product claims. Such claims may be formulated in the following manner: "Product X for use in the treatment of disease Y".

This amendment to Swedish practice was performed in line with the publication in the Official Journal of decision G2/08 of the EPO EBoA on September 20, 2010. Together with this publication, it was confirmed that for European applications filed from January 29, 2011, the EPO does not allow Swiss type claims. The decision had no retroactive effect.

For applications filed before that date, Swedish practice allows second medical use claims in the "Swiss type" form in accordance with the set practice of the EPO.

e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.

As stated above, for Swedish patent applications filed on or after January 29, 2011, "Swiss type" claims are no longer allowed. Claims in applications having a filing date before this date may contain "Swiss type" claims.

The claim formats mentioned in paragraphs 28 and 31 of the WGL (German and US type claims) are not permissible according to Swedish practice, since Section 1d of the Swedish Patents Act excludes from patentability methods of treatment, surgery or diagnosis. This exclusion is considered to apply also to claims in the form “use of product for treatment”, e.g. 'Use of substance X for the treatment of condition Y'.

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 WGLs.

No guidance has yet been provided by the Swedish Patent and Registration Office in this respect. There is still uncertainty regarding the possible difference in scope of protection provided by claims drafted in applications filed before and after the entry into force of the EPC2000 and the issuance of G2/08 of the EPO EBoA (“Swiss type claims” versus “purpose-limited product claims”).

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?

There are no restrictions according to the Swedish Patents Act regarding who can be held liable for infringement of second/further medical use claim. A patient however, is exempt from liability under the Swedish Patents Act, since a patient’s use is not a professional use.

In this context, it should be noted that a pharmacist can be exempt from liability if he/she occasionally comes to use the invention by producing a mixture in accordance with the prescription of a doctor in an individual case. This exemption is however not likely to generally exempt the pharmacists from all potential liability from infringement of a second/further medical use claim.

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

As noted in our reply to question 3 a) above, pharmacists have a professional exemption for some cases (but not all). The other exemptions according to the Swedish Patents Act are not related to specific parties but rather to specific types of use. Hence, the exemptions are (i) non-professional use, (ii) use of the invention where the rights have been exhausted (parallel trade), (iii) experimental use, (iv) use of a reference medicament for regulatory approvals, (v) prior use rights and (vi) compulsory license.

In this context, it should be noted that there is no exception from liability for medical practitioners, although the EPO in recent practice seems to expect such exceptions (see further the answer to question 8 below).

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

From a patent law stand point, both direct and indirect infringement would be available for enforcement depending on who the claimed infringer is and what the claimed infringement action is.

As for the specific groups mentioned in 3 a), there might arguably be some difference depending on whether the second/further medical use claim has been drafted under the EPC1973 ("Swiss type" claims) or EPC2000 regime. According to the patent formulation envisaged under EPC2000, there is no longer any reference to "use for the manufacture of" ("Swiss type" claims). This difference may arguably mean that e.g. a clinician could be held directly liable for infringement under the EPC2000 regime, whereas the same measures by a clinician under EPC1973 arguably could only be enforced via indirect infringement (unless the indirect protection for products manufactured according to a patented method is applied).

It should be noted that that there is no Swedish case law on this subject matter as far as the Swedish group has been able to ascertain.

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?

Yes, provided that it can be demonstrated that the manufacture and/or supply of the generic product is intended (also) for the patented indication, such acts would constitute a direct infringement of the relevant patent. The relevant intention would normally be evident from the marketing authorisation for the generic drug. Notably, the application for and grant of a marketing authorisation is not in itself considered to be an infringing act.

In case the intended use of the generic product is not primarily a use for the patented indication (e.g. if the marketing authorisation for the generic product does not cover the patented indication), but it can nevertheless be demonstrated that the supplier knows, or it is obvious under the circumstances, that the product is also suited and intended for the patented use, liability for contributory infringement may occur for the supplier. In case the product is considered to be staple goods, contributory infringement requires that the supplier attempts to induce the subsequent use of the product for a patented indication. See the Swedish reports on contributory infringement in Q204 and Q204P for further details in this respect.

In respect of different categories of users that may be liable for use, please see the answer to question 3 above.

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.

The exclusivity afforded by a (purpose limited) product patent covers, among others, the manufacture, offering, supply and use of a patent protected product. Therefore, each of the suggested acts is a form of direct infringement, provided that the product is intended for, or the use covers, the patented indication.

The act of supplying the product could, under certain circumstances, constitute contributory infringement; see the answer to question 4 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?

Each of the acts of manufacture, supply or use can *per se* constitute direct infringement.

The supply of products can sometimes constitute contributory infringement, but a certain connection with the (intended) infringing use is required (see the answer to question 4).

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

For direct infringement, an intention to use the product for the patented indication must be demonstrated to exist at the time of the manufacture or supply of the product. In case of generic drugs, such intention is usually evidenced by the approved indications in the marketing authorisation.

Contributory infringement may occur in case the supplier knows or ought to know under the circumstances, that the product is suitable and intended for use in the patented indication.

d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.

For direct infringement on behalf of a manufacturer or supplier, there must be a subjective intention that the product shall be used also for the patented indication.

For contributory infringement to occur, it is sufficient that the supplier of the product ought to have known that the product is suitable and intended for use in the patented indication.

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

Infringement requires the plaintiff to prove his case. Swedish law does not restrict the sources of evidence that a party may use (free presentation of evidence) and Swedish courts have the right to freely evaluate the strength of all the evidence presented by the parties (free assessment of evidence). Hence, the courts apply the free assessment of the evidence provided by the parties. In particular, the court determines whether the claimed infringing compound meets the specifications in the patent claim. When the claim e.g. refers to a small molecule, this determination may be a simple task. Complicating factors may occur with claims relating to a biomolecule or requiring certain properties of the compound.

The court goes on to determine whether the medical indication stated in the claim coincides with a medical indication identified by the defendant for its product. There appears to be no experience from "skinny labelling" in Sweden so far, and this determination thus appears to have been a simple task.

The legal test on infringement in a final judgement is of course that the patent is valid and that the infringing action is fully proved.

For an interlocutory injunction, the standard of proof is less burdensome for the plaintiff. It is sufficient to show probable cause of infringement and that it can

reasonably be expected that the defendant, by continuing the infringement, diminishes the value of the exclusive right of the patent. Even if there is clear case of infringement, a strong case of invalidity presented by the defendant may prevent an interlocutory injunction.

For an infringement investigation as part of evidence protection measures, the standard of proof is still lower; the plaintiff is only required to show that it can be reasonably assumed that infringement has occurred/occurs/will occur.

The evidence provided to the court to substantiate infringement is usually in writing, such as drug approval documents, catalogue texts or package leaflets. Oral (expert) evidence is often relied on in connection with arguing the issue of validity of the patent, but also occurs to supplement the written evidence on infringement.

Case law on infringement of second medical use is scarce. In one case, the courts in Sweden have dealt with a supplementary protection certificate to a basic patent claiming a first medical indication, but referring to a specific illness, a case which illustrates the topic of the current question.

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

a) at a preliminary / interim / interlocutory level?

There is no relief available which is specific to infringement of second medical use claims, but the general provisions in the Patents Act apply.

Infringement investigations as part of evidence protection measures
If it can reasonably be assumed that someone has committed an infringement, contributed thereto or attempted or prepared an infringement, Swedish courts may, in order to preserve evidence relating to the infringement, order that an investigation shall be undertaken with respect to that person in order to search for objects or documents which can be assumed to be of importance for the investigation of the infringement.

An infringement investigation as part of evidence protection measures may be granted before or after infringement proceedings have been initiated, but only if the reasons speaking in favor of the measures outweigh the disadvantages or other harm caused to the person against whom it is directed or to any other opposite interest. If the applicant and the defendant are competitors, one obvious risk is that trade secrets of the defendant are disclosed through the infringement investigation.

In order to be effective, the application for an infringement investigation should be an initial measure before an application for summons is submitted (or be filed together with the application for summons).

The main rule is that the defendant shall be given the opportunity to respond before the decision is taken. However, if there is a risk of sabotage – in other words if a delay (or communication of the application or decision to the opposite party) would entail a risk that objects or documents would be removed, destroyed or distorted, a court may issue an order without communicating the application with the alleged infringer (*ex parte*).

Information orders
If the patent holder shows *probable cause* that someone has committed an infringement (or attempted or made preparations thereto), a court may, under penalty of a fine, order one or several parties to provide information to the applicant

concerning the origin and distribution networks for the goods or services in respect of which the infringement has been committed. An information order may be issued only if it can be assumed that the information would facilitate an investigation about the infringement.

An information order can be rendered before or after infringement proceedings have been initiated. The information may in particular include the names and addresses of the manufacturers, distributors, suppliers, intended wholesalers and retailers as well as information on how many products that have been manufactured, delivered, received or ordered, and the price obtained for the goods or services. A proportionality test applies - an information order may be issued only if the reasons speaking in favour of the measure outweigh the inconvenience or other harm that the measure would cause the party against which it is directed or any other opposite interest. In addition, there is no duty to supply self-incriminating information.

Injunction under the penalty of a fine
The patentee has the option to submit a claim for an interlocutory injunction either prior to, or during, main infringement proceedings. This option is frequently used and the claim is normally presented as part of the proceedings on the merits. As a main rule, the defendant shall be given an opportunity to respond and the court normally rather thoroughly examines the question of infringement and validity (if raised as a defense) before deciding on a request for an interlocutory injunction. However, if a delay could cause irreparable harm, the court may issue an injunction without giving the defendant an opportunity to respond (a decision *ex parte*). In practice, the court rarely finds that there are sufficient reasons to issue an injunction *ex parte*.

To succeed with a claim for an interlocutory injunction, the patentee must show *probable cause* that the patent is being infringed. Furthermore, it must be established that there are good reasons to believe that the defendant, by continuing the infringement, will depreciate the value of the exclusive right provided by the patent. The plaintiff must also present a sufficient security (normally a bank guarantee), covering the damage that the defendant may suffer as a result of the injunction. According to general principles of law, the court must balance the opposite interests of the parties in each individual case.

The courts are required – within the frame of the claims raised by the plaintiff – to ensure that an interlocutory injunction fulfills the requirement of being unequivocal and concrete. The Supreme Court has stated that it falls upon the duties of the court to fully ensure that said requirements are met. The court is furthermore obligated to ensure that the injunction issued is no wider than necessary in the case at hand. In line herewith, the court can issue an injunction more limited in scope than what has been requested by the plaintiff.

If these conditions are met, an interlocutory injunction relief may be issued which bars the defendant from continuing the infringing activities under a penalty of a fine (payable to the Swedish Crown). If the defendant violates the injunction, a separate action must be brought in order for the penalty to be awarded.

b) by way of final relief?

In infringement proceedings the court may – depending on what the patentee has claimed – impose some or all of the following sanctions and security measures (the same sanctions and security measures are available to a licensee).

The court may prohibit, under a penalty of a fine, the defendant from continued infringement.

Since 1 April 2009, it is possible to obtain an injunction also to prevent preparations for a patent infringement and attempts to infringe a patent. This applies to both interlocutory and final injunctions. The reason for amending the rule was to implement the provisions of the Enforcement Directive relating to imminent infringements.

The patentee may be awarded compensation. Should the court find that the infringement has been committed with intent or through negligence, the defendant can be held liable to pay "*reasonable compensation for the use of the invention*", i.e. an amount which corresponds to an estimated reasonable license fee.

In addition, the defendant can be held liable to pay compensation for any "*further damage caused by the infringement*", e.g. compensation for the patentee's lost sales, unnecessary costs for production means and decreased goodwill. In this respect, consideration shall also be taken to the patentee's interest in protecting the patent from being infringed. At the assessment of compensation the court may also take into account the profits made by the defendant as a result of the infringement. It is, however, not possible to claim punitive damages or a transfer of the defendant's profits.

When an infringement is committed without intent or negligence, the infringing party can only be held liable to pay compensation for the use of the invention if, and to the extent, this is found reasonable. In general, this compensation never exceeds an estimated reasonable license fee.

The court may – to the extent this is found reasonable – order that infringing goods shall be recalled from the market, destroyed, altered or impounded for the remainder of the patent term.

The court may order an infringing party to pay and arrange for suitable measures in order to spread information of a judgment on patent infringement.

As an alternative to an action for sanctions as described above, a patentee is entitled to seek a declaratory judgment to establish that the patent prevents another party's activities. This requires that there is uncertainty in this respect and that this uncertainty is to the detriment of the patentee.

Finally, it should be mentioned that an infringing party might also be subject to criminal conviction for intentional / gross negligent acts of infringement. The Public Prosecutor may bring indictment only after a complaint from the patent proprietor and if the indictment for particular reasons is required in the public interest. These provisions are rarely used in practice.

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?

As further elaborated under question 7 a), in order to obtain an interlocutory injunction a patent holder must *inter alia* convince the court that it is likely that the patent is infringed and that the infringement is likely to cause harm. This standard of proof can be met in various ways. A patent holder can for instance use documents indicating how the product is composed or analyse samples of the product.

Given that the "statements" in the product packaging or information leaflet specifically refer to the patented use as outlined in the claims – and given that the other general

conditions for interlocutory injunction are met – this could be deemed sufficient proof to justify an interlocutory injunction.

As for the question whether writing of a prescription could be sufficient basis, the following can be stated. In its decision of 29 October 2004 (T 1020/03) the Boards of Appeal of the EPO stated *inter alia* that it was assumed that national legislations were enacted to protect for instance physicians from being sued for patent infringement for merely prescribing a composition for a course of therapy (see i.a. paragraph 16 of said decision). The Swedish Patents Act does not include any specific exemption to that effect for physicians or health care professionals. Section 1d of the Swedish Patents Act deals with exemptions to patentability and not with the issue of infringement. Nor do the exemptions under Section 3 cover this specific scenario.

The exclusive right conferred to a purpose limited product patent encompasses all professional use of the product, including the professional medical use of the product. Thus, professional use of a substance in a health care setting with regard to the patented medical use could theoretically be argued to constitute infringement and thus suffice as basis for an injunction. Case law unfortunately provides no guidance in this respect.

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

As opposed to an interlocutory injunction – which as outlined above under 7a) stipulates that the plaintiff shows probable cause – for final injunctions to be rewarded, full evidence must be presented.

The plaintiff in an infringement case has the primary burden of proof for establishing the infringement.

According to Swedish case law, a special evidence rule applies if the infringer of a process claim alleges that information regarding his process is a trade secret. In such a case, it would still rest on the patentee to prove the infringement. The evidentiary requirement would, however, be met already if the patentee shows that it is likely that the product was manufactured in accordance with the process patent. In Swedish legal doctrine it has been argued that in most cases this evidence rule probably leads to the same result as a rule of reversed burden of proof.

For information purposes, it can be mentioned that prior to 1968, Swedish patent law provided for a reversal of the burden of proof if the infringement litigation concerned a process patent for the manufacturing of a new product.

II. Policy considerations and proposals for improvements to your current law

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?

Due to the fact that changes to the Swedish Patents Act regarding the admissibility of second medical use claims have been made only to adapt to the European Patent Convention and the practice at the EPO, there has been no discussion in Sweden on policy reasons behind permission of such claims. During the diplomatic conference in preparation of EPC2000, it was explicitly stated that first medical use deserves a higher level of protection than second/further medical uses. A legal framework for such differentiated levels of protection was considered to provide the right balance, as a matter of fairness to the proprietors. Hence, the aim behind the reform was to codify

current legal practice which treated inventions of first and further uses differently in terms of the scope of grantable claims. It was put forward that the admissible breadth of protection should remain a matter for the future development of the law on the basis of practice at the EPO and in the courts.

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

As noted above, during the diplomatic conference in preparation of EPC2000, it was explicitly stated that first medical use deserves a higher level of protection than second/further medical uses. A legal framework for such differentiated levels of protection was considered to provide the right balance, as a matter of fairness to the patent proprietors.

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

No official standpoint or view in either direction has been published, or discussed in public.

d) If there is any empirical or anecdotal data available, please address the following.

There is no empirical data available and unfortunately no way of obtaining such empirical data, as second medical use claims are not monitored for any statistical purpose.

i) What is the prevalence of second medical use claims in your country?

By anecdote, one may get the impression that second medical use claims are common in all patent applications relating to chemical compounds that may be used for medicinal purposes. There are patent applications before the Swedish Patent and Registration Office pertaining only to second medical use claims, but those applications are rare.

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

No specific profile can be identified. The impression, by anecdote, may be that all patent applications relating to a chemical compound that may be used for medicinal purposes, claim also a first and (or) a second medical use, if possible. This is of course done in case the examiner finds prior art that destroys novelty for the compound as such and for a first medicinal use of the compound.

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?

Prosecution
According to Swedish patent prosecution practice, second medical use claims must be more extensively supported, for example by experimental evidence in the patent document, than first medical use claims. However, as the requirement of experimental evidence is not clearly defined, there is a degree of uncertainty included in patent applications related to second medical use.

Litigation
Today, any second medical use of a known drug can be patented in Sweden with claims drafted in a format such as 'Substance X for use in the treatment of condition Y". Before January 2011, claims for a new medical indication were drafted in the Swiss type format. Although such claim format is no longer accepted, there are now two different claim formats to consider in patents in force. The different claim formats may provide a slightly different scope of protection.

Enforcement of second medical use claims in Sweden is rare. Therefore, practice is unclear due to lack of case law.

Experimental use and special exemption for use for regulatory purposes
The EU Directive 2001/83, relating to medicinal products for human use, provides that: "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 [of Article 10] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplemental protection certificates for medicinal products ["SPCs"]".

This is known as the EU Bolar provision or "Bolar exemption", and has been implemented in the Swedish Patents Act but it is then limited to use only for the purpose of gaining regulatory approval for generic products in the EEA (cf. "use of a reference medicament" in question 3b) above).

In the Swedish Patents Act, there are two exemptions from infringement regarding experimental use: (i) A general statutory experimental use exemption for acts done for "experimental purposes relating to the subject matter of the invention"; and (ii) the aforesaid "EU Bolar provision" for acts done in purpose of gaining regulatory approval.

The different scope of the safe harbor provided by the general statutory experimental use exemption, and the difference in implementation of the EU Bolar provision across the EU member states, may impact the choice of country in which pharmaceutical companies conduct preclinical tests and clinical trials. In a worldwide perspective, there are further uncertainties, as an example, the Bolar exemption is more limited and restricted in Europe than in the US.

Medical registration/Marketing Approval and Data Exclusivity
In Sweden, it is possible to apply for medical registration via four different routes: Centralized European registration; Mutual recognition; Decentralized registration; and National registration. The registration of new pharmaceuticals is based on EU Directive 2001/83/EC. It is possible to obtain a marketing approval for a new medical indication and new medical use of an already known compound. The marketing approval influences the patent protection since it is possible to apply for a Supplementary Patent Certificate based on the patent covering the second medical use and the first marketing approval granted for a therapeutic indication of the product which falls within the scope of that patent.

In Europe, the originator of a drug may obtain 8 years data exclusivity, 2 years market exclusivity, and 1 year provisional extension (e.g. new medical indication (the second

medical use)). A new registration application will not be approved until previous market exclusivity has expired. Since the clinical data included in the first marketing authorisation of the drug will not be available until after 8 years, a registration application for second medical use may not be granted until the marketing approval has expired.

In conclusion, when a new medical use has been developed, by the originator or a generic company, the different parameters of patent protection, the protection offered by data exclusivity and the regulatory authorization, are not synchronised and therefore require complex strategic considerations.

III. Proposals for 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?

Yes.

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

Yes. Without harmonisation, different claim constructions are necessary in different jurisdictions, for example before the USPTO and before the EPO. Such differences directly hinder the development of the Patent Prosecution Highway and are costly to the applicants which are forced to redraft a patent application to fit the practice in each respective jurisdiction.

Lack of certainty of the scope of patent protection and of safe harbour provided, for example by the different implementations of the EU Bolar provison, as well as lack of harmonisation between countries worldwide, result in a complex decision making for the pharmaceutical industry - both the originator and the generic companies.

Therefore, regarding the protection of the new medical use, harmonisation would be desirable with respect to:
- patent claim format protecting second medical use
- requirement of support for the new medical use in the patent prosecution
- scope of experimental use with the purpose of seeking regulatory approval for a new medical indication and/or new medical use.

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/WGLs.

The Swedish Group suggests that a permissible second medical use is any use which constitutes a novel truly useful therapeutic application. The therapeutic application may be in the form of a known substance or composition for use in a treatment/prevention of a novel pathological condition, or a novel treatment/prevention approach for an already known substance in an already known pathological condition. Examples of the latter approaches are e.g. novel dosage regimes, patient groups etc. These second medical uses have already been acknowledged as eligible for patent protection through case law of the Enlarged Board of Appeal of the EPO, and the Swedish Group would support that as an

international standard.

Hence, general patentability criteria, i.e. establishment of novelty and inventive step, should be applied when examining an invention directed to a second medical use, complemented by the principles expressed in EPO case law. We foresee some risk that applying particular "permissible subject matter criteria" might be a difficult task, causing more uncertainty than clarification. Therefore, the Swedish Group doesn't support pointing out specific subject matter to form a standard of permissibility.

In this context, it should be noted that providing protection for second medical uses should not restrain the activities of medical and veterinary practitioners. Accordingly, second medical use patents should not have a hindering effect on these professional groups or make them liable for infringement when treating patients. The switch from Swiss type claims to purpose-limited product claims, however, does not appear to have secured this purpose. Still, in light of the intention of this switch, the possibility of different scopes of protection between the different claim types (Swiss type vs. purpose-limited product protection) has not been taken into account for the determination of permissible subject matter for second medical uses. The Swedish Group instead suggests that this is to be regulated by other measures (see the answer to question 15c) below). A product claim in the purpose-limited form should not be interpreted as a method of treatment, but as a limitation of a product claim by virtue of its intended use.

The above discussion is likely also applicable to legislation allowing patent protection for methods of treatment.

b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

The Swedish Group suggests that no subject matter is regarded as impermissible as long as it fulfills the general patentability criteria in respect of novelty and inventive step.

Hence, as long as the principle (as expressed in EPO case law) that "any specific use" is a broader concept than "a disease" is applied, the Swedish group does not consider it necessary to dismiss any particular subject matter as impermissible other than on the grounds already stated in general patent law and established practice under the EPC.

c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

In line with the discussion under questions 15a) and 15b), the Swedish Group suggests that a purpose-limited product claim, e.g. in the form "Product X for use in the treatment of disease Y" should be permissible. The scope of protection allocated to such a claim is discussed in question 15a).

Also, national law should provide a general exemption from infringement for medical and veterinary practitioners when treating patients. Despite the intended scope of protection for a purpose-limited product claim, we see that such an exemption is necessary to avoid any broader interpretation of the scope of protection provided by this claim type, which would not be in line with the intention of the legislator.

d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

The Swedish Group has previously, in its national group report on Q202 *The impact of public health issues on exclusive patent rights,* stated that
"The Swedish Patents Act and the European Patent Convention (EPC) do not allow patents for methods for surgical or therapeutic treatment or for diagnostic methods that are intended for use on humans or animals. The Swedish group would not suggest a change in the Swedish Patents Act and the EPC that would allow such patents."
This opinion is still valid.

In line with the above (see question 15c), the Swedish Group is of the opinion that use and method claims should be impermissible. Still, and further in line with the above, an exemption from infringement for medical and veterinary practitioners when treating patients should be implemented in national law to avoid a broader interpretation of a purpose-limited product claim.

e) Who may be liable for infringement?

Except as stated in question 15f) below - all individuals/entities who use or contribute to a use of the invention, and which are not otherwise exempted from the exclusive rights afforded by the patent (for example by experimental use exemptions, etc.).

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

An aspect that can be highlighted in this respect – and which has been discussed in inter alia decisions by the EPO Boards of Appeal as well as in the Swedish preparatory works and legal literature – is the possible introduction of a general exemption for medical and veterinary practitioners and related healthcare or veterinary entities.

In its decision of 29 October 2004 (T 1020/03) the Boards of Appeal of the European Patent Office briefly touched upon said issue. Therein the Boards of Appeal stated the following:

"/.../ *Provided the Contracting States have such provisions, and this can fairly be assumed as it is necessary to protect physicians from being sued for patent infringement for merely prescribing a composition for a course of therapy, or a nurse administering such a composition /.../, then neither in the case of use for a first medical indication or for any further medical indications can the patent proprietor sue the physician, or nurse*, /.../" (paragraph 16 in said decision).

Opinion G 1/04 of the Enlarged Board of Appeal (OJ 2006, 334) also mentions that a "*comprehensive protection of medical and veterinary practitioners"* can be achieved by enacting legal provisions on the national level of the Contracting States of the EPC (see p. 6.1).

No such provisions have been enacted in Sweden. In the Swedish preparatory works and legal literature it has been suggested that Europe – as has been the case in the USA – should introduce legislation for physicians, i.e. to abolish the ban on patents for therapeutic, surgical and diagnostic methods and instead provide medical practitioners with immunity from infringement actions.

The Swedish Group is of the opinion that such an introduction of a general exemption for medical and veterinary practitioners would be of value (even in the scenario where the current ban on patents for therapeutic, surgical and diagnostic methods would not

be abolished). Such an exemption would serve as an added clarification of the legal status quo and be in spirit with the aforementioned statements of the Boards of Appeal.

As regards the question of which parties/institutions that would be encompassed by said exemption the Swedish Group is of the opinion that it shall include any natural person who is licensed by the authorities to perform the medical and veterinary activity.

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.

Reference is made to the answer to question 4 regarding the current situation. The Swedish Group considers that this scope of protection is adequate.

h) Relief available upon a finding of infringement:

i) at a preliminary / interim / interlocutory level; and
ii) by way of permanent relief.

Reference is made to the answer to questions 7 a) –b) regarding currently available sanctions. The Swedish Group considers that this range of relief is adequate.

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

The level of proof required for establishing the facts in interlocutory measures shall be lower than that required for obtaining final relief. The Swedish Group considers that the requirement to show probable cause of infringement for obtaining interlocutory relief is adequate.

For final relief, the standard of proof for the facts invoked in support of infringement should be “on the preponderance of the evidence/ balance of probabilities”.

Other Aspects of Relevance for Second Medical Use Patents

The Swedish Group notes that there are regulatory aspects which directly affect and complicate the infringement issue in relation to second medical use claims.

Even if the Swedish Group is not in favor of a general system of “patent linkage” in the regulatory area (e.g. in respect of granting marketing approvals) it seems that there is a need for some kind of coordination between the regulatory systems and the patent system in order to both give effective protection to patents claiming a second medical use and allowing third parties to exploit off patent first medical uses without – involuntarily - running afoul of patent protection.

For a third party who desires to exploit a first use of an active ingredient that has become off patent, but at the same time respect the patented second medical use, the available course of action is to obtain a marketing approval for the generic product that covers the first medical use only (a so called carve out or skinny labelling).

In the Swedish context there are three aspects that complicate the situation both for the patentee of the second medical use and the third party wanting to exploit the first medical use;

a) The free prescription right of physicians. This means that cross-label and off label prescription is possible. Notably a prescription does not even have to state the indication for which the medication is prescribed. This means that the generic product approved only for the first medical use may be prescribed also for the patented second medical use.
b) The mandatory substitution of generic medicines at the pharmacy level. This means that a generic product may be provided by the pharmacy for the second medical use even if the prescription states the original product sold by the patentee (or his/hers licensees).
c) The lack of limitation of government subsidies to use of a pharmaceutical product in an approved indication, which means that also cross-label and off label use benefits from such subsidies.

Hence, there is room for improving the regulatory provisions to improve the practical protection of the patentee and minimize the risks for unintended infringement of second medical use patents. This issue is of course outside the scope of the current Question, but the interplay between patents and the regulatory framework in the pharmaceutical area could be made the object of a separate Question.

SUMMARY

The Swedish Group is of the opinion that it is desirable to permit second medical use claims. Harmonisation of laws relating to second medical use claims is desirable. Also, harmonisation is desirable with respect to patent claim format protecting second medical use, requirement of support for the new medical use in the patent prosecution, and scope of experimental use with the purpose of seeking regulatory approval for a new medical indication and/or new medical use. The Swedish Group suggests that a permissible second medical use is any use which constitutes a novel truly useful therapeutic application. Purpose-limited product claims, e.g. in the form “Product X for use in the treatment of disease Y”, should be permissible. No subject matter should be regarded as impermissible as long as it fulfills the general patentability criteria in respect of novelty and inventive step. Use and method claims should be impermissible. All individuals/entities who use or contribute to a use of the invention, and which are not otherwise exempted from the exclusive rights afforded by the patent, should be liable for infringement. National law should however exempt from infringement medical and veterinary practitioners, when treating patients. A product claim in the purpose-limited form should not be interpreted as a method of treatment, but as a limitation of a product claim by virtue of its intended use. The Swedish Group considers that the current scope of protection as provided by the EPC is adequate, as are the sanctions currently available under Swedish law. For final relief, the standard of proof for the facts invoked in support of infringement should be “on the preponderance of the evidence/balance of probabilities”.