Question Q202

National Group: Sweden Suède Schweden

Title: **The impact of public health issues on exclusive patent rights**

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The Swedish Group wishes to make the following introductory comments.

The Working Guidelines for Q 202 clearly express in the Introduction, section 4), that this question only looks at limitations on patent protection applicable to medicines and other medical products at a general level, notably in cases of public health crises. Further, it is specified that aspects of trademark law, competition law, medical and health care law, as well as issues of patentability, e.g. exclusions based on public policy or morality grounds, are not to be covered by the question, nor the issue of access to affordable medicines in developing and least developed countries.

While the aspect of data exclusivity is not mentioned in the Guidelines, the Swedish Group understands that also that aspect is excluded from consideration as being a regulatory issue rather than a patent law issue. Data exclusivity will therefore not be taken up in the comments below.

The Swedish Group notes that the Working Guidelines for Q 202 focuses on improved protection of public health by *limitations* of the exclusive rights of a patent. However, it is important to notice that rather than taking into account only limitations of patent rights – with the risk of undermining the positive effects of the patent system – *incentives* for development of new products may also have the effect of such improvements (see our answer to question 2, below).

However, the question Q202 is by the Working Guidelines effectively limited to considering technical patent law aspects.

On the level of the European Union, where Sweden is one of 27 member states, one of the foundations is the concept of a single market and that distortions of the functioning of the single market are not accepted. In the field of patent law this means that harmonised law and rules are very important, as otherwise elements in the patent system which are available in one member state but not in other member states may be used in order to obtain commercial advantages.

I) Analysis of current law and case law

The Groups are invited to answer the following questions under their national laws:

1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

   Yes, Swedish patent law provides a statutory experimental use exception (Section 3, paragraph 3, item 3 of the Swedish Patents Act). As is the case in many other

European countries, the exception is derived from the draft Community Patent Convention of 1975. The exception is applicable in relation to the use of a patented invention for experiments which relate to the invention itself, such as for the purposes of creating improvements to the invention or evaluating its utility. Research and experimental activities performed with the help of the patented invention, such as where the invention itself is used as a research tool in the same manner as is intended under the patent, is not covered by the exception. That is, the patented invention must be the object of the experiment as such, not merely a tool used in the experiment.

The exception is applicable regardless of the setting, i.e. the experiment may be conducted in a commercial or in a non-commercial/academic setting. The exception is, furthermore, applicable irrespective of the purpose of the experimental activities. Consequently, experiments conducted with a commercial purpose as well as experiments conducted with a non-commercial/academic purpose are covered by the exception.

The scope of the exception is yet to be considered or clarified in Swedish case law with significant precedential value. The impact of European case law, which in our understanding varies between the different European jurisdictions, on the Swedish exception's scope and applicability, is yet to be determined by Swedish courts.

2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

Is a Bolar-type exception recognized under your patent law?
Yes. Directive 2001/83/EC as amended by Directive 2004/27/EC has been implemented into the Swedish Patents Act (Section 3, paragraph 3, item 4). This paragraph exempts infringement studies, trials, investigations and practical requirements relating to a reference medicinal product, insofar as these are necessary for the grant of a marketing approval for a human or veterinary medicinal product, in accordance with the Swedish Medicinal Products Act or corresponding European provisions.

A 'reference medicinal product' shall mean a medicinal product authorised for marketing in an EU member state.

If so, under which conditions?
To fall under the exception, any activity must relate to procedures necessary for the grant of a marketing approval in Sweden or the European Union, or for a scientific report on a pharmaceutical for exclusive marketing outside the EU.

What is the scope of the Bolar exception?
The language used in the Patents Act is taken almost word-by-word from the directive and allows for future interpretation by the courts. It is however acknowledged in the preparatory works that the exception covers a number of different uses and practical requirements, which may also differ depending on what kind of drug is studied. Ultimately, it is the Medical Products Agency's position on what documentation is necessary in the individual case that decides what use of patent protected inventions shall fall under the exception. It was not considered possible to give an exhaustive list of exempt uses.

The exception is intended to only relate to the reference medicinal product and should not extend to any other protected method, substance or combination of protected substances, according to the preparatory works. Notably, the preparatory works do not mention protected apparatus, such as administration devices. It is however probable that a protected administration device that is necessary for a clinical trial, would also fall under the exception.

The exception would include biological products, if these are to be considered as reference medicinal products, cf. Article 10.4 of Directive 2001/83 as amended by Directive 2004/27. The use of research tools and other products would only be covered by the exception if they are substantially related to the reference medicinal product and their patent rights need to be infringed in order for performing any trial or investigation requested by the MPA.

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions?

EU/EEA

Sweden is a member of the European Union (EU) and therefore the principle of regional exhaustion of patent rights applies in Sweden. This means that parallel imports of patented medicines, medical devices or other goods are allowed as soon as the products have been put on the market within the EU or European Economic Area (EEA), by or with the consent of the patent holder. However, member states which have recently joined the EU, have agreed to an IP transitional mechanism in the Treaty of Accession, which gives the patent holder rights to object to parallel importation from the new member states into Sweden under certain conditions. This means that with regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria or Romania the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product *filed* in Sweden at a time when such protection *could not be obtained* in one of the above-mentioned new Member States for that product, may *rely on the rights* granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in Sweden where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent. The IP transitional mechanism refers to a “pharmaceutical product”. The scope of that wording – e.g. if it includes also medical devices or similar - has not been defined by the Swedish Courts.

Outside of EU/EEA

The patent holder can prevent products (patented medicines, medical devices or similar) that were put on the market outside of the EU/EEA territory and then parallel imported into Sweden, even if the products were put on the market by the patent holder or with the patent holders consent.

Do the same principles apply if the products originate from markets where they were made available under a compulsory license?

EU/EEA

According to the Swedish Patents Act (Section 3, paragraph 3, item 2) regional exhaustion occurs when the product (includes patented medicines, medical devices or similar) has been put on the EU/EEA market by or with the patent holders consent. If a

product is put on the market under a compulsory license there is no consent and the patent right is not exhausted in Sweden.

Outside EU/EEA
Similarly, a product made under a compulsory license outside of the EU/EEA would not exhaust the patent holders rights to exclusivity in Sweden. Further, the TRIPs agreement also requires that compulsory licenses only be issued for goods intended chiefly for the domestic market (Article 31 f.)

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

Yes, the Swedish Patents Act (Section 3, paragraph 3, item 5), excludes *preparation in a pharmacy of a medicine in accordance with a physician's prescription in individual cases or acts with the medicine so prepared* from the exclusive right conferred by a patent.

The exception means that pharmaceutical staff can always expedite medicine in a pharmacy to an individual with a physician's prescription without risking to infringe a patent. The exception is only valid for individual cases where a physician has issued a prescription to a specific person. Hence, preparing a patented medicine to keep in stock, or selling a medicine prepared under the exception to someone else than the individual with the prescription, would be an act of infringement.

The Swedish Patents Act was influenced by Article 31 c) of the Community Patent Convention in this respect. It is considered from the wording *"in accordance with a physician's prescription in individual cases"* that the preparation intended in Section 3, paragraph 3, item 5 must be extemporaneous, which is explicit in the Community Patent Convention.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Not applicable in Sweden.

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

Compulsory licenses are available under Swedish patent law. Compulsory licences have not been used in Sweden, at least not under the current patent law.
A compulsory licence can be granted by the competent court, Stockholm District Court, (Section 65, paragraph 3 of the Swedish Patents Act), which determines the conditions of the compulsory licence and the compensation to the patent holder. The court can change the conditions of a granted licence and determine new conditions, if the circumstances change considerably (Section 50 of the Swedish Patents Act).

A compulsory license can only be granted to anyone who can be expected to have the capability to use the invention in an acceptable manner and to comply with the conditions of the compulsory licence. The applicant for the compulsory licence must show that he without success has tried to obtain a licence under reasonable conditions from the patent holder. If a compulsory licence is granted the patent holder can nevertheless use the invention and sell licences (Section 49 of the Swedish Patents Act)

If an applicant for a compulsory licence fulfils the conditions above, then a compulsory licence to use an invention can be granted in Sweden in the following different cases:

1. If the patent holder has not made reasonable use of the protected invention in Sweden after three years from grant and after four years from the application date, provided that there is no acceptable explanation to why the invention has not been used. In this respect use in Sweden is equal to import from an EES-state or a WTO-state (Section 45 of the Swedish Patents Act).
2. If there is a patent where the use of the invention protected by that patent is dependent on another patent. It is required that the applicant for the compulsory licence shows that his invention is a significant technical contribution and of great economical importance as compared to the other patented invention (Section 49 of the Swedish Patents Act). Item 2 is also applicable to plant protection (Section 46a of the Swedish Patents Act).
3. If it is required by the public interest and is of extreme importance (Section 47 of the Swedish Patents Act).
4. If anyone has used an invention or made serious preparations for using an invention subject to a patent application before the application was published. There must be very special reasons. In the literature it has been mentioned that one example of such very special reason is a matter affecting the national economy. The infringer must not have had any knowledge of the application and must not have had any reasonable possibilities to gain knowledge about the application (Section 48 of the Swedish Patents Act).

Compulsory licences can also be granted in Sweden for the manufacture of pharmaceutical products for export to countries with public health problems according to EC 816/2006, see question 7 below.

Compulsory licences have not been used in Sweden at least not under the current patent law originating from 1967.

7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

Ratification of Article 31bis TRIPS is a matter of EU competence.

On November 19, 2007, the Council of the European Union confirmed that the protocol amending TRIPS, done at Geneva on 6 December 2005, will be binding on the Member States of the European Union. Hence, Sweden is bound by Article 31bis TRIPS.

With regard to the Treaty establishing the European Community, in particular Articles 95 and 113, considering the need for uniform implementation of the WTO decision of August 30, 2003 to ensure that the conditions for the granting of compulsory licences for export are the same in all Member Stats and to avoid distortion of competition for operators in the single market as well as preventing re-importation into the territory of the Community, implementation of the Decision is a matter of Community law.

The WTO decision of August 30, 2003, was implemented in Sweden by European Community legislation, i.e. the European Parliament and Council has, on May 17, 2006, adopted Regulation 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Compulsory licences have not been granted in Sweden for the exportation of pharmaceutical products. Sweden has stated that it will not use the system for importation of pharmaceutical products.

8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

There are no special provisions for the government in this regard, except for expropriation as discussed below. The government may also request a compulsory license as discussed under question 6.

9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

The Swedish government has the right to expropriate the right to an invention if expropriation is considered necessary in the public interest (Section 78 of the Swedish Patents Act). However, the government may only exercise such right when Sweden is at war or in danger of war.

A wider applicability was in fact discussed during the preparatory work of the present provision. It was, however, concluded that states of emergency other than war or danger thereof would not be as pressing. Provisions for expropriation under such circumstances could therefore be provided if or when such a need arises.

This right of expropriation covers "inventions" and is thus not limited to patented inventions. Consequently, both patent applications and inventions which have not yet been the object of an application may be expropriated. Furthermore, licences including, but not limited to, compulsory licences, may also be the object of expropriation under the present provision.

The right to an invention may be expropriated in full or in part, i.e. either in the form of a license or in the form of a complete transfer of rights. The government may either grant itself or a third party (such as an industrial actor with suitable production capabilities) the expropriated rights. The original right holder is entitled to receive reasonable compensation in respect of the expropriated rights.

Furthermore, inventions, subject to a patent or not, classified as a “defence invention” can be expropriated by the Swedish government under the Swedish Act on defence inventions (Sections 13 and 18) if it is of significant importance to the Swedish defence. An invention may, but does not need to, be classified as a defence invention if it

pertains to what the government has classified as “war equipment”. The current definition of war equipment includes nuclear, biological and chemical weapons and “products designed for military use and for protection against the action of weapons”. This could potentially include drugs for protection against chemical, biological or nuclear weapons.

To our knowledge, the government has never expropriated a patent or an invention. However, as this could be a question of national security, such an expropriation would not necessarily come to the public’s knowledge.

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

Swedish patent law does not provide for any specific information tools equivalent to the Orange Book which exists in the US. It does however contain some general provisions in Article 56 which may potentially be used to obtain information as to whether a marketed pharmaceutical is covered by patent protection.

The Swedish Patents Act, Section 56, paragraph 2, provides that if someone directly or indirectly states that a product is patent protected or the subject of a patent application without giving information of patent number or patent application number, such information shall be provided on request.

In addition to this, Swedish patent and pharmaceutical regulatory laws contain the following means for helping facilitate access to medicines, medical devices, diagnostics etc:

- As discussed under question 3 above, the concept of regional exhaustion of patent rights means that pharmaceuticals manufactured in the EU/EEA can be more readily imported into the country.
- The Swedish Patents Act (like the patent legislation of many countries pursuant to international conventions) contains a prohibition against patenting of surgical or therapeutic treatment or diagnostic methods practiced on the human body.
- The regulatory regime for pharmaceutical benefits in Sweden contains a scheme which enables manufacturers of generics to make an application to the relevant government agency for inclusion in the benefits scheme without stating if and when the applicant intends to market the drug. In a recent decision by Svea Court of Appeal, it was held that under the regulatory regime for pharmaceutical benefits in Sweden, manufacturers of generics may – prior to the expiry of the patent or supplementary protection certificate covering the original drug – agree with the relevant governmental agency on its sales prices for the generic drug to the Swedish pharmacy retail monopolist. The judgment has been appealed to the Swedish Supreme Court which has granted a leave to appeal.

II) Proposals for adoption of uniform rules

The Groups are invited to put forward proposals for adoption of uniform rules regarding health-sensitive limitations of patent rights with a view to protecting public health. More specifically, the Groups are invited to answer the following questions:

1) Should patent law provide for

– *research and experimental use exception*
Yes, a research and experimental use exception stimulates further innovation by balancing the patent holder's right to exclude others. The exception facilitates research in respect of the patented invention's utility and encourages further research through which improvements to the patented invention and/or new independent inventions may be generated. A research and experimental use exception facilitates use of the information disclosed in the patent application process during the time the patent is valid. Thus, the exception can be viewed as an integrated element of patent law's requirement of disclosure.

– *Bolar exception*
This is acceptable, provided that the introduction of a Bolar exception is balanced with compensating rights, such as a system for patent term extension.

– *parallel import of patented medicines*
The Swedish group notes that regional exhaustion of patent rights is generally applied in the EU/EEA area (see the response to question 3 in section I). The Swedish group is not in favour of extending this regional exhaustion to countries outside the EU/EEA area.

– *individual prescriptions exception*
Yes, however the person preparing a medicine under such an exception shall be deemed to have the right to carry out the invention only in the case of the original prescription.

– *medical treatment defence*
Not applicable in Sweden. The medical treatment defence can apparently only be applicable if it is possible to patent medical treatments as such. 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.

– *compulsory licensing*
Yes, however only under strictly defined circumstances. The Swedish Group sees a danger in the calls for extensive use of compulsory licensing which are made in developed as well as in developing and least developed countries. Those calls are often based on extensive interpretation of the grounds for “compulsory licensing”, especially under TRIPS Article 31(b): “national emergency or other circumstances of extreme urgency”, or TRIPS Article 30. Widespread compulsory licensing based on a premise that practically any medicine for any disease could be deemed to fall under those provisions would erode the patent system to an extent where incentives for research and development for new products might be weakened or even eliminated.

– *Expropriation*
If at all to be applied, it must be allowed only as a final resort under the most extreme circumstances. In the event of a public health crisis, specific provisions for expropriation should be provided, rather than implementing a wider general governmental right to expropriate, which would need to be interpreted under the

circumstances present at the time of the crisis. Furthermore, there is a need for increased awareness, guidance and uniformity in the application of provisions on expropriation so as to limit the influence of temporary political views in an affected state. The Swedish group has not, however, elaborated further on which normative actor that may be in the position to provide such guidance to promote increased uniformity.

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

No, not under the constraints of the Q202 Working Guidelines.

If so, under what circumstances? If not, why not?
Improvements might be achieved by introduction of patent listings (what has become known as "patent linkage"), meaning that the originator of the product would submit to an authority, e.g. the medicinal authority, a list of the patents which are relevant for the product. For generic products that would mean an improved legal certainty on the patent position of the product. However such a system should then at the same time oblige the medicinal authorities to take the listed patents into account when dealing with product registration files.

2) *Dou you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

Incentives for development of new products, for example on basis of market exclusivity for a limited time, may well have the effect of such improvements. Examples here on EU level are the systems for what is called „paediatric exclusivity", Regulation (EC) No 1901/2006 dated December 12, 2006, which may provide a six months extension of the time of a Supplementary Protection Certificate, SPC, and Regulation (EC) No 141/2000 dated 16 December 1999 on so called orphan medical products, which may provide a 10 years market exclusivity in return for development of such product.

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

It is important that countries provide market rules and opportunities which are equal and foreseeable for all actors on the market. That applies also to the field of patents. Harmonisation of the exceptions from patent rights is therefore desirable. For a regional market such as the EU, with established common rules for its member states, this is especially important. Increased globalisation means that differences in these respects between countries/regions have more immediate consequences.

In the view of the Swedish Group, the experimental use exception is a realistic example of an area where harmonisation could be accomplished.

National Groups are invited to comment on any additional issue concerning the impact of public health issues on the patentee's exclusive rights which they find relevant.

Summary

The impact of public health issues on the patent system should take into account not only the effect of limitations of patent rights, but also the effect of incentives for development of new products.

Harmonisation of exceptions from patent rights is generally desirable, especially for regional markets such as the EU. A realistic area for harmonisation could be the experimental use exception.

Zusammenfassung
Der Einfluss von Themen der öffentlichen Gesundheitspflege auf exklusive Patentrechte sollte nicht nur die Auswirkung von Einschränkungen der Patentrechte, sondern auch die Auswirkung von Anreizen für Entwicklung neuer Produkte berücksichtigen.

Die Harmonisierung der Ausnahmen von Patentrechten ist allgemein wünschenswert, vor allem für regionale Märkte wie die EU. Die AusnahmeN zur Benutzung zu Forschungs- und Versuchszwecken könnte ein realistischer Bereich für Harmonisierung sein.

Résumé
L'influence des questions de santé publique sur les droits de brevet devrait prendre en compte non seulement l'effet des limitations des droits de brevet, mais aussi l'effet des encouragements pour le développement de nouveaux produits.

L'harmonisation des exceptions des droits de brevet est généralement désirable, en particulier pour les marchés régionaux comme l'Union européenne. L'exception d'utilisation à des fins de recherché ou d'expérimentation pourrait être un réaliste domaine de l'harmonisation.