

Question Q209

National Group: Sweden

Title: **Selection Inventions – the Inventive Step Requirement, other Patentability Criteria and Scope of Protection**

Contributors: Dag HEDEFÄLT, Ida CHRISTENSEN, Katarina DAHLENBORG, Ulf DAHLGREN, Bengt DOMEIJ, Ivan HJERTMAN, Birgitta LARSSON, Cecilia THAM

Datum: February 16, 2009

Introduction

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) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Some countries have constitutional regulations or apply general principles of law according to which international agreements may become part of their national law without requiring further measures. Other countries as e.g. Sweden, other Nordic countries and common law countries apply a different order according to which a specific national regulation is required for a self executing effect of treaties to which the country in question has adhered.

In view of the above observations, international agreements for patents ratified by Sweden are incorporated into the Swedish Patents Act and its ancillary regulations. It follows that Swedish courts and other national authorities apply the Swedish Patents Act and its ancillary regulations, i.e. international agreements for patents can not be referred to as such by applicants or litigating parties.

The EPC and the development within the European Patent Office have been given particular weight by the Swedish Supreme Administrative Court and the Swedish Supreme Court.

Sweden is a Member State of the European Union (EU). Thus the EU legislation applies for Sweden as defined in the Swedish Act (SFS 1994:1500) in the same manner as for other EU member states: EU Directives are to be implemented into Swedish law, whereas EU Regulations are directly applicable.

Questions

General

Groups are asked to give a summary of the legal position as regards a patent for a purported selection invention in their jurisdiction in relation to the following:

Q1 Legal developments on selection inventions

What specific types of inventions are recognized under the concept of selection invention and are patentable in your jurisdiction? Do you have any examples of selection inventions in a field other than chemical, pharmaceutical or material science fields?

Selection inventions are recognized as a special category of inventions in the Swedish case law and in the Guidelines issued by the Swedish Patent and Registration Office (Guidelines part B5 1:1). Selection inventions can e.g. be sub-intervals selected from a known numerical interval or particular chemical compounds selected from a larger group of compounds. In order to be patentable, the selection must be associated with an improvement in a known technical property. If a different technical use has been found for a known product or process, this would typically not be regarded as a selection invention.

The Swedish group is not aware of any Swedish case law concerning selection inventions in a field other than chemical, pharmaceutical or material science fields.

When the prior art is a patent, the legal effect of a patent on a selection invention is not different from that of a dependent patent in any field.

Q2 Novelty

Groups are asked to discuss any issues that should be considered with respect to the novelty of selection inventions. For example, is merely carving a range out of a broad prior art disclosure sufficient to make a selection invention novel? Is a different advantage or use, or the same advantage with an unpredictable improvement required for a selection invention to be novel?

A selection invention should be relatively limited in proportion to prior art, but does not need to have a different advantage or use, or the same advantage with an unpredictable improvement to be novel.

Issues that can be relevant for the consideration of novelty:

- A specific combination of features, each of which has been selected from a relatively long list is considered to be novel (the "two-lists principle") (see Case Law of the Board of Appeal of the European Patent Office 5th ed., Dec. 2006, part I.C.4.1). A selection from a single list of specifically disclosed elements does not possess novelty. However, exceptions are made within the field of chemistry, in that a selection from a single list does possess novelty when either (i) the list is long and examples or any directions of preparation are missing or (ii) the list is extremely long.
- A sub-range selected from a broader numerical range of the prior art is considered to be novel if each of the following criteria is fulfilled: the sub-range is narrow, sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range, and the selected range is not an arbitrary specimen of the prior art (see Case Law of the Boards of Appeal of the

European Patent Office, 5th ed., Dec. 2006, part I.C.4.2.1 and the Swedish Court of Patent Appeals number 05-333).

- For a selection invention to be novel, the features of the selection invention should not have been clearly implicitly described in the prior art.

Q3 Inventive step or non-obviousness

Groups are asked to discuss the inventive step or non-obviousness requirements in their jurisdiction. If experimental data is used to back up the inventive step or non-obviousness requirement can it be submitted after initial patent filing? Are there any prerequisites or limitations on the late submission of data?

Experimental data which is used to back up the inventive step requirement can be submitted after initial patent filing. Generally, the purpose of the submission of such experimental data is often to provide evidence that the subject-matter is able to solve the technical problem in the manner that is stated in the application as filed. More particularly, in the case of selection inventions the aim is usually to prove advantageous or superior effects as compared to what is disclosed by the prior art.

Prerequisite: In order for such late-submitted experimental data to be taken into account in the decision regarding the requirement of inventive step, a prerequisite is that in the application as filed there must already be certain support (at the minimum a statement) concerning the effects which are to be proved by said experimental data. On the contrary, if the late-submitted experimental data would fail to back up the statements in the application as filed, and instead for example would show that the subject-matter involves a new technical effect or constitutes a solution of a new/different technical problem as compared to what is disclosed in the application as filed, said data would not be taken into account when deciding whether the inventive step requirement is fulfilled. See Case Law of the Boards of Appeal of the European Patent Office, 5th ed., Dec. 2006, part I.D.4.4 regarding T386/89. See also the Swedish Court of Patent Appeals number 90-185, where late-submitted experimental data in combination with data present in the application as filed showed sufficiency of disclosure (support from the description as filed) and evidence of an unexpected effect, which resulted in the fulfilment of an inventive step.

Q4 Sufficiency and/or written description requirements

Groups are asked to discuss the sufficiency or written description requirements in their jurisdiction. There may be several aspects to this question: (1) the threshold for sufficiency; (2) the allowable timing for submission of experimental data; (3) the time frame within which sufficiency or written description requirements must be satisfied; and (4) the breadth of claim scope that can be supported by a limited number of examples of asserted or proven advantages. With respect to item (1), please discuss to what extent all members of the class selected by the patentee are required to possess the requisite advantage in your jurisdiction. Is there an absolute requirement that all of the selected class possess the relevant advantage, or is the patentee excused if one or two examples fall short? Also, with respect to item (4) above, if a new utility is asserted as a selection invention, would it suffice to claim a particular range or selection of components which have been found to be

associated with such a new utility or would it be necessary to recite such a new utility in the claims?

In general, the requirements for sufficiency and written description requirements are the same as for any invention. There are no specific requirements for selection inventions in Swedish case law, but the presumption is that an invention based on a selection has to face higher requirements.

The Swedish Group has discussed the different aspects mentioned:

(1): The threshold for sufficiency is established in Section 8 of the Swedish Patents Act: “[...] The patent application shall contain a description of the invention [...] The description shall be so clear as to enable a person skilled in the art to carry out the invention with guidance thereof. [...]”. The fact that the invention relates to a chemical compound does not imply that a specified use must be disclosed in the patent claim. However, the description must disclose a use of the compound.

Swedish practice also provides that the invention shall be sufficiently disclosed across the full breadth of the claim. Regarding the question if there is an absolute requirement that all embodiments possess the relevant advantage, see comments Q9, below.

(2): Experimental data for submission regarding sufficiency and written description requirements are handled differently from data to support existence of inventive step.

When an application for a patent is filed, the process of making the invention must have been completed. The requirement of sufficiency of disclosure ensures that a patent is only granted if there is a corresponding contribution to the state of the art. Such a contribution is not present as long as the person skilled in the art is not able to carry out the invention.

(3): The decisive date for fulfilling the sufficiency requirement is the date of filing or priority, as the case may be. Deficiencies in this respect cannot be remedied during the proceedings before the Swedish Patent and Registration Office. (Please see EPO: G 0002/03)

(4): Absolute product protection, i.e. claiming the product per se, is allowable also for a “selection invention” but it depends on the prior art situation. If the selection is a narrow group with a new utility within a broad prior art scope then claiming the product per se is acceptable. However, if the prior art is overlapping or almost overlapping with the “selection” and the product is not considered to be new, then the invention needs to be claimed in the form of the new use, i.e. use claims. (cf. “second medical use claims” and “non-medical use claims”).

Q5 Infringement

If a certain advantage or superior results were the reasons for the grant of a patent on a selection invention, does such advantage or superior result have to be implicitly or explicitly utilised by a third party for an infringement to be established?

If a selection invention is claimed as a new use, what are the requirements to establish infringement? Would a manufacturer of a product that may be used for the new use infringe the patent? Does the intention of an alleged infringer play any role in the determination of infringement?

While a certain advantage or superior results may be important for obtaining a patent for a selection invention, it will not be necessary for establishing patent infringement that the advantage or superior results actually are utilised by the infringer. Thus, in principle, the use of a selection invention, irrespective of whether an advantage or superior results are achieved or not, is enough for establishing infringement.

In case of a patent that relates to a new use, it will be necessary for establishing infringement that the infringer actually uses the invention. The same principles as for other patents apply to inventions claimed as a new use. If a party, e.g. a manufacturer of a product that may be used for the new use does not himself use the invention, the question whether he has infringed the patent should be assessed according to the same principles as contributory infringement. Patent infringement is assessed on objective grounds. Thus, the intention of an infringer is not relevant for the question of infringement as such, but may be relevant for the assessment of damages and other remedies. However, if the principles for contributory infringement are applied in relation to a patent for a new use the intention may play a role.

Q6 Policy

Groups are asked to give a short commentary as to the policy that lies behind the law on selection inventions in their jurisdictions, and then to consider whether or not such policy considerations are still valid today as technology continues to advance.

The concept of "selection invention" is not specifically mentioned in the Swedish Patents Act. It is also not specifically mentioned in the EPC. The concept of "selection invention" is however mentioned in the Examination Guidelines at the EPO as well as in the Examination Guidelines at the Swedish Patent and Registration Office. Such Guidelines do not have the force of law, but they nevertheless constitute the current applicable practice at the patent offices. Accordingly, it is recognised in practice that there is a category of inventions termed "selection inventions". The general requirements for patentability apply of course also for selection inventions.

It has been decided by the Swedish Supreme Administrative Court that the EPO practice is leading for the Swedish patent practice. Accordingly, Swedish practice in regard to selection inventions is based on and follows EPO case law.

With Reference to the Examples

Q7 Novelty

In example 1 would the prior disclosure of the compounds containing the generic class of radicals anticipate any claim to a specific compound having a particular radical, or group of specific compounds having a selection of particular radicals in your jurisdiction? In the analysis, does it matter how wide the prior disclosed generic class of compounds is – i.e. would the analysis be

different if the prior disclosed generic class consisted of 1,000,000 possible compounds (very few of which were specifically disclosed) as opposed to merely, say, 10?

The invention is considered to be novel if the subject-matter is a specific compound or a group of specific compounds, whereas the prior art discloses a family of compounds defined only by a general structural formula including this specific compound or group of specific compounds (see Case Law of the Boards of Appeal of the European Patent Office, 5th ed., Dec. 2006, part I.C.4.1.2). That is, provided that the specific compound or the group of specific compounds is not preferred or exemplified in the prior art, the invention is considered to be novel. It does not matter how wide the prior disclosed generic class of compounds is (see Case Law of the Boards of Appeal of the European Patent Office, 5th ed., Dec. 2006, part I.C.3.2.6, first paragraph).

Q8 Inventive step or non-obviousness

In example 2 would any of the three possibilities constitute an inventive step over the prior art in your jurisdiction? Further, if, say, scenario (iii) does constitute an inventive step over the prior art, what scope of protection should the inventor be able to obtain? Should the inventor be able to obtain protection for the products *per se* (that happen to have this advantageous property), or should any patent protection available be limited to the use of the products for the advantageous property (as an adhesive) not possessed by, and not obvious over the prior art?

In example 2, scenario (iii) would constitute an inventive step over the prior art while scenarios (i) and (ii) would lack an inventive step according to Swedish practice. In scenario (iii), the inventor should be able to obtain protection for the products *per se*, i.e. an absolute product protection. No limitation has to be made to the use of the products for the advantageous property.

Q9 Sufficiency and/or written description requirements

To what extent are all members of the class selected by the patentee required to possess the requisite advantage in your jurisdiction? Is there an absolute requirement that all of the selected class possess the relevant advantage, or is the patentee excused if one or two examples fall short?

The Swedish group has not found any Swedish case law regarding selection inventions and non-working embodiments. In general, we presume that the requirements on a selection invention are higher.

EPO Case Law has addressed sufficiency versus inventive step and stated that if a claim comprises non-working embodiments, this may have different consequences, depending on the circumstances. If a technical effect is expressed in a claim and thereby constitutes a real technical feature, there may be lack of sufficient disclosure. Otherwise, if the effect is not expressed in a claim but rather is part of the problem to be solved, it may be a question of whether a given problem is solved by all embodi-

ments falling under the claim, which results in a problem of inventive step (T0602/05), which also refers to G 1/03.

EPO Case Law has also addressed non-working embodiments in relation to the use of disclaimers. In G1/03 and G2/03 the Enlarged Board disagreed with the view that disclaimers may be used for merely excluding non-working embodiments (Case Law of the Boards of Appeal of the European Patent Office, 5th ed., Dec. 2006, part II B,1.2.1a). The Enlarged Board held that a claim comprising non-working embodiments might have different consequences, depending on the circumstances. According to the Enlarged Board, where there were a large number of conceivable alternatives and the specification contained sufficient information on the relevant criteria for finding appropriate alternatives over the claimed range with reasonable effort, the inclusion of non-working embodiments was of no harm. However, care should be taken if non-working embodiments give rise to lack of reproducibility of the claimed invention since this might become relevant under the requirements of inventive step or sufficiency of disclosure as discussed above.

Q10 Infringement

By reference to example 3 to what extent is evidence of the knowledge of the advantageous property of the selection, or intention of the infringer as to its supply, required to find infringement in your jurisdiction?

Example 3 is typically a contributory infringement situation and should be assessed as such, irrespective of whether it concerns a selection invention or not. Since the product in the example may be used for various purposes – old use and new use – in order to find infringement it will normally be necessary for the right owner to provide evidence that the manufacturer of the compound had knowledge of the advantageous property of the new use. Since in the example there is an alternative – old – use it will probably also be necessary for the right owner to provide evidence that the manufacturer induces third party to use the advantageous properties of the compound. If no other evidence can be provided to prove inducement, the absence of instructions as to the use of the compound may result in the finding of non-infringement.

Q11 Policy

Groups are asked to consider, in respect of example 1 / 2, whether it matters how much effort the inventor has invested in arriving at his selection in order to found a valid selection patent. The answer to this question is closely related to the policy considerations that underpin the grant of selection patents and the incentive / reward equation involved. The inventor may have expended considerable time and money in trawling through the whole host of possible compounds encompassed by the prior disclosed generic class, and the particular selection that he has made may constitute a leap-forward in the field. Surely the inventor should be rewarded for his efforts and obtain protection? On the other hand, it could be argued that such considerations may have been relevant in an age when the inventor's efforts actually involved many man-years of careful and painstaking laboratory work, but are now increasingly irrelevant in an age of combinatorial synthesis when large varieties of different

compounds can be manufactured in a fraction of the time. Are such considerations relevant?

The basic consideration under European and accordingly Swedish practice is that it is the final claimed invention that is judged as to patentability. The road to get to the invention on the part of the inventor, whether that was "by inspiration or by transpiration", is in principle irrelevant. However it may be an argument for inventive step if it can be shown that the prior art shows that much effort had been made to solve the problem behind the claimed invention, but that no positive result had been reached.

Harmonisation

Q12

Groups are asked to analyse what should be the harmonised standards for the patentability of selection inventions. In particular, the items discussed in Q1-Q6 and the examples discussed in Q7-Q10 above should be referred to.

The Swedish group is of the opinion that the general principles of patentability – novelty, inventive step and industrial applicability – shall apply also for selection inventions. Neither the EPC, nor the Swedish Patents Act mention selection inventions, and the Swedish Group does not want specific regulations in the patent law regarding selection inventions.

When applying the patent law and practically assessing novelty and inventive step for selection inventions, special guidelines are necessary (as is the case for other special types of inventions, such as biotechnical inventions). It is of course desirable that such guidelines are harmonized all over the world. The Swedish Group has found the EPO practice, as discussed above, to be a balanced one and suggest this to be a good starting point for further discussion.

For instance, a selection invention should be relatively limited in proportion to prior art, but not necessarily have a different advantage or use, or unpredictable improvement, to be novel. A specific combination of features, selected from a relatively long list should be considered novel. A selection from a single list of specifically disclosed elements is however not novel. There should be exceptions within the field of chemistry, in that a selection from a single list can possess novelty under certain circumstances. A sub-range selected from a broader numerical range of the prior art should be considered to be novel if: the sub-range is narrow, sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range, and the selected range is not an arbitrary specimen of the prior art. Novelty should require that the features of the selection invention were not implicitly described in the prior art.

Q13

Groups are also asked to recommend any issues for harmonisation not referred to in Q11 above.

The question of harmonizing the views on establishing infringement is important for all kinds of patents, so also for patents on selection inventions. This should preferably be part of further discussions.

Q14

Groups are asked to outline any other potential issues that merit discussion within AIPPI as regards selection inventions.

Summary

The Swedish group is of the opinion that the general principles of patentability – novelty, inventive step and industrial applicability – shall apply also for selection inventions. There should not be any specific regulation in patent law for selection inventions. When applying the law and practically assessing novelty and inventive step for selection inventions, special guidelines are necessary, which should be harmonized. The Swedish Group has found the EPO practice to be a balanced one and suggest this to be a good starting point for further discussion.

The question of harmonizing the views on establishing infringement should preferably also be part of further discussions.

Zusammenfassung

Die Schwedische Gruppe ist der Meinung, dass die allgemeinen Grundsätze der Patentierbarkeit – Neuheit, Erfindungshöhe und industrielle Anwendbarkeit – auch für Auswählerfindungen zur Anwendung kommen müssen. Im Patentgesetz sollte es für Auswählerfindungen keine besondere Regelung geben. Bei Anwendung des Gesetzes und praktischer Bewertung der Neuheit sowie des erfinderischen Fortschritts sind bei Auswählerfindungen besondere Richtlinien erforderlich, die harmonisiert sein sollten. Die Schwedische Gruppe hat die EPO Praxis als ausgewogen erachtet und schlägt diese als guten Ausgangspunkt für weitere Diskussionen vor.

Die Frage der Harmonisierung der Auffassungen bei der Festlegung von Patentverletzungen sollte vorzugsweise ebenfalls Teil von weiteren Diskussionen sein.

Résumé

Le groupe suédois est d'avis que les principes généraux de brevetabilité – nouveauté, activité inventive et application industrielle - doivent également s'appliquer aux inventions sélectives. Une réglementation spécifique sur les inventions de sélection n'est pas indispensable au sein de la loi relative aux brevets. En appliquant la loi et en procédant à la vérification des critères de nouveauté et d'activité inventive s'agissant d'inventions de sélection, des lignes directrices sont nécessaires, celles-ci devant être harmonisées. Le groupe suédois a conclu que la pratique de l'OEB est équilibrée et suggère que celle-ci soit le point de départ de discussions plus approfondies.

Il serait également souhaitable de poursuivre les discussions sur la question de l'harmonisation des points mettant en évidence un acte de contrefaçon.