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Report Q209

in the name of the Hungarian Group
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Selection Inventions - the Inventive Step Requirement, other Patentability Criteria and Scope of Protection

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:

1) *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?

Inventions recognized under the concept of selection inventions in Hungary are those based on an inventive selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly disclosed previously from a larger known group, set or range (in the following: generic class).

Selection inventions are patentable in all technical fields in Hungary, provided that the general patentability criteria are met. Selection inventions are usually in the chemical, pharmaceutical or material science fields, and there are very few examples of selection inventions in other technical areas. One of the most typical selection inventions is a single compound selected from a broad group of compounds.

In relation to inventions based on a new use of a chemical compound or material, three alternatives are conceivable:

- a) The chemical compound or material was explicitly disclosed in the prior art and a new use thereof has been found.

These inventions relate usually to second or subsequent medical uses or indications, and are generally **not** considered to fall under the concept of selection invention (in the following: "**new use of a known compound**"). We still deal with this case in some points of our report, as such inventions are somewhat related to the concept of selection inventions.

- b) The chemical compound or material is within the generic class without being explicitly disclosed in the prior art, and a new use is the basis of the selection.

This is a classical selection invention (in the following: "**new use of a selected compound**").

- c) The chemical compound or material was explicitly disclosed in the prior art and a range of general ways of use is the generic class.

This is also considered to fall under the concept of selection invention. If a range of general ways of use of a known chemical compound or material is known in the prior art, an invention relating to a particular "usage" or "dose" of e.g. a medical product is regarded as a selection invention relating to that particular use of the given product (in the following: "**selected use of a known compound**").

2) 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 is considered to be novel if the selected elements, sub-sets or sub-ranges have not been explicitly disclosed previously, and their disclosure can not be directly and unequivocally derived from the generic class.

Advantages, unpredictable improvements are not relevant to novelty.

3) 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?

A selection invention is based on an inventive step if the selection exhibits advantages, superior results or unpredictable improvements such as new utility not disclosed for the generic class.

Experimental data can be used to back up the inventive step requirement and it can be submitted even after the filing date. However, at least a qualitative reference to said experimental data must be present in the application on the filing date.

4) 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?

1) *the threshold for sufficiency*

All members of the class selected by the patentee are required to possess the requisite advantage in Hungary. As the advantage is the basis of the selection, being also the essence of the inventiveness, this is an absolute requirement, none of the examples may fall short.

High probability has to be showed that a range selected from a generic class possesses the requisite advantage. The required threshold for sufficiency varies depending on the given technical field. If e.g. a temperature range is selected from a much broader range, it has to be evidenced at least via examples that some values of this selected temperature range possess the requisite advantage. In case of a group of selected compounds covered by a generic formula, limited generalisation is allowed, and practically only the exemplified compounds and their closest analogues can be claimed.

2) *the allowable timing for submission of experimental data;*

Experimental data can be filed during the pendency of an application, i.e. even after the filing date. Furthermore, experimental data can also be filed during nullity proceedings. Such data can serve to distinguish the selection invention from the prior art by providing evidence of advantages, superior results or unpredictable improvements.

3) *the time frame within which sufficiency or written description requirements must be satisfied;*

Sufficiency or written description requirements must be satisfied on the filing date.

4) *the breadth of claim scope that can be supported by a limited number of examples of asserted or proven advantages*

According to a long established Hungarian practice, at least one example is required for each practical "sub-range" in the claimed range of possible embodiments in order that the claimed scope is sufficiently supported by the description. The applicable sub-ranges are generally determined by the practice of the Hungarian Patent Office. The number of examples must be enough to evidence that the selection works indeed.

Generally, the more examples are given, the more well-founded support is present for the claimed scope.

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?

- a) The invention relates to a "**new use of a known compound**": it is necessary to recite the utility in the claims (typically: Swiss type claims).
- b) The invention relates to a "**new use of a selected compound**": it is sufficient to claim a particular range without reciting the utility (typically: product protection claims).
- c) The invention relates to a "**selected use of a known compound**": it is necessary to recite the utility in the claims, as this utility is the basic inventive feature (typically: dosage claims).

5) *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?

No.

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?

- a) The claimed invention relates to a **“new use of a known compound”**: manufacturer is not infringing.
- b) The claimed invention relates to a **“new use of a selected compound”**: manufacturer is infringing.
- c) The claimed invention relates to a **“selected use of a known compound”**: manufacturer is not infringing.

As to points a) and c), manufacturing might qualify as a contributory infringement (if all the conditions of contributory infringement are fulfilled), for which the same legal consequences apply as for direct infringement. In such cases the intention of the alleged infringer may play a role (see AIPPI Resolution Q204).

Furthermore, a patent owner may also request an injunctive relief

- against any person whose services are used for the infringing activities, and
- against acts directly threatening with infringement.

6) *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 policy according to answer to Q1 above is presently valid in Hungary. This policy seems not to be affected by the development of technology. The general examination and nullification rules apply to patenting selection inventions. However, generally speaking, inventive step is to be substantiated more profoundly in these cases. On the other hand, there is only a sporadic case law in Hungary for patenting selection inventions and for enforcing these patents.

7) *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?

According to the Hungarian practice, the prior disclosure of the compounds containing the generic class of radicals usually does not anticipate any claim to a specific compound having a particular radical, or group of specific compounds having a selection of particular radicals. With reference to Q2 above, the analysis of novelty is not influenced by how wide the prior disclosed generic class of compounds is.

8) *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?

Scenario (i) would certainly constitute an inventive step over the prior art in Hungary, which is not the case for scenarios (ii) and (iii) as there are no distinguishing advantages in those cases.

9) *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?

See our answer to Q4(1) above.

10) *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?

No such knowledge is required to find infringement in Hungary.

11) *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?

In the opinion of the Hungarian Group, the extent of efforts as such should not be taken into account in the granting procedure, as this aspect is not "rewarded" for other types of inventions either. The general examination rules should apply to the selection inventions.

Harmonisation

12) *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.*

For novelty, inventive step and sufficiency the harmonised standards should be in line with the answers to Q2 to Q4 above.

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

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

Summary

Selection inventions are patentable in all technical fields in Hungary, provided the general patentability criteria are met. A selection invention is based on an inventive step if the selection exhibits advantages, superior results or unpredictable improvements such as a new utility not disclosed for the generic class. All members of the selected range are required to possess the requisite advantage. At least one example is to be disclosed for each practical "sub-range" in the selected range of possible embodiments in order that the claimed scope is sufficiently supported by the description. The number of examples must be enough to evidence that the selection works indeed.

Résumé

Les inventions de sélection sont brevetables en Hongrie dans tous les domaines techniques, à condition de satisfaire aux critères généraux de brevetabilité. Une invention de sélection est fondée sur une activité inventive si la sélection présente des avantages, des résultats supérieurs ou des améliorations imprévisibles tels qu'un usage nouveau encore non exposé pour la classe générique. Tous les membres de la gamme sélectionnée doivent posséder l'avantage revendiqué. Il faut exposer au moins un exemple pour chaque sous-ensemble de l'ensemble sélectionné des applications possibles afin que l'objectif revendiqué soit fondé de manière suffisante sur la description. Le nombre des exemples doit être suffisant pour mettre en évidence que la sélection est véritablement opératoire.

Zusammenfassung

Auswählerfindungen sind patentierbar auf allen technischen Gebieten in Ungarn, wenn die Erfindung sonst der allgemeinen Kriterien der Schutzfähigkeit entspricht. Die Auswählerfindung beruht auf erfinderischer Tätigkeit, wenn die Auswahl Vorteile, vorzüglichere Eigenschaften oder unvorsehbare Verbesserungen, wie z.B. eine neue, auf die generelle Klasse bisher nicht beschriebene Anwendung aufweist. Alle Ausführungsformen des ausgewählten Bereiches müssen den gewünschten Vorteil besitzen. Es ist mindestens ein Beispiel für jeden praktischen "Unterbereich" in dem ausgewählten Bereich der möglichen Ausführungsformen zu präsentieren, damit die Beschreibung den beanspruchten Schutzzumfang ausreichend unterstützt. Die Anzahl der Beispiele soll genügend sein um die Funktionsfähigkeit der Erfindung beweisen zu können.