Working Guidelines

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Question Q209

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

Introduction

1. A selection patent is a patent granted for making an inventive selection from a field that is already known. Selection inventions may involve the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly disclosed previously, within a larger known set or range.

2. Selection patents have traditionally been seen in the chemical and pharmaceutical industries. For example, a selection patent may involve a claim to a particular group of compounds having certain advantageous properties, where that group is selected from a prior-disclosed wide class of compounds, where that advantageous property is not possessed by the prior-disclosed wide class of compounds. Also, in the field of alloys, within a broadly defined class of alloys, a specific range of compositions may give rise to a special property due to a previously unknown mechanism such as newly discovered phase transition. Such a range, if it is new, can form a selection invention. Finally, selection inventions can also be found in engineering and manufacturing processes, where a special selection in a process of particular operating conditions (e.g. temperature and pressure) within a known range produces unexpected effects in the operation of the process or the properties of the resulting product. Selection inventions may also be found in other technological areas, such as biotechnology, material science and telecommunications.

3. Further, a new use may be considered to fall under the concept of selection invention or at least to relate to this concept. Typically, a new use may be found for a known chemical compound or material. It can be claimed as a "use" or a method or as a product intended for such new use.

4. To be patentable an invention needs to be new, non-obvious or inventive, sufficiently disclosed, and, of lesser importance to the current question, enabled. A selection patent is no different. Selection patents can cause difficulties, however, both in terms of their patentability and their enforceability. It has been suggested, in some jurisdictions, that selection patents constitute a special case to "normal" rules on patentability.

5. As regards validity, a difficulty with selection patents may arise on how the patentee chooses to craft his selection, both when attempting to define the selection from the wider class (that had previously been disclosed) and when attempting to define the inventive feature of the selection. Of course, the same principles of patentability still apply, but there

may be difficulties in applying these principles when the prior-disclosed group and the selection are similar in terms of how they are named or defined.

6. As regards infringement, the difficulty that arises is the same as that which arises with patents claiming new uses for old products[1], such as "Use of Product X as [new use]" (where product X had been known for many years for an old use. The difficult issue (which is yet to be tackled by the courts in many countries) is whether evidence of the intention of the infringer is required to arrive at a finding of infringement of such a claim.

Previous work of AIPPI

7. AIPPI studied "Protection of groups of chemical substances and selection inventions" under Q81. This study resulted in an interesting Summary Report and a very short resolution stating essentially that the question of selection inventions should continue to be studied. Q84 entitled "Selection inventions" was subsequently established, but no working guidelines and no group reports were published.

Novelty

8. The founding principle upon which the novelty of a selection invention rests is that a general disclosure is not to be regarded as a specific disclosure of everything embraced by the general disclosure, thereby permitting claims to protect further discoveries within (or selected from) the prior general disclosure. Of course, much depends upon the way in which the patentee has crafted his claim. The issue is best considered by reference to an example.

Example 1

Say a prior art document discloses a chemical compound characterised by a specified structure including a substituent group designated "R". This substituent "R" is defined so as to embrace a generic class of broadly-defined functional groups such as all alkyl or aryl radicals, either unsubstituted or substituted by a halogen and/or a hydroxyl group, although for practical reasons only a very small number of specific examples are given. The (later) alleged invention consists of the selection of a particular radical or particular group of radicals from amongst the generic class, where the selected radical or group of radicals were not specifically disclosed in the prior-art document. The resulting compounds are described as having a new, advantageous property, say as adhesives, not possessed by the prior art examples.

9. While it may also relate to the question of inventive step or non-obviousness, merely finding a new range or combination may not be considered to give rise to novelty. A different property or advantage, or a similar advantage of unpredictable extent may be required if an invention is to qualify as a novel selection invention.

Non-obviousness or Inventive Step

10. The law on inventive step will vary from jurisdiction to jurisdiction. Although we are beginning to see a shift in the approaches taken by the courts around the world as to what is or what is not obvious (most notably in the *KSR* decision in the USA), differences remain.

[1] Such claims will be familiar to European patent practitioners as MOBIL claims, following the EPO case *MOBIL/Friction reducing additive* [1990] OJ EPO 93 or, in the pharmaceutical sector, as medical use claims.

11. As regards selection patents, once it has been established that novelty arises in the particular selection that the inventor has made, a patent for that selection will only be valid if the selection is non-obvious or inventive.

12. Since a selection invention, when a patent is granted on it, cuts out a certain scope of monopoly from the public domain accorded with the prior art, it may be justifiable to require more data to support the purported inventive step, for example a higher level of criticality associated with the inventive level of the selection invention or superior results in comparison with what was known prior to the invention.

Example 2

In the selection that the inventor has made in example 1, i.e. specific compound having a particular radical, or group of specific compounds having a selection of particular radicals, the resulting compounds may be:

(i) neither described as having nor shown to possess any advantageous properties (as adhesives) not possessed by the specific prior art examples;

(ii) described as possessing advantageous properties compared with the compounds specifically referred to in the prior art, but these properties are ones which the person skilled in the art would expect such compounds to possess, so that he is likely to be led to make this selection; or

(iii) described as having advantageous (adhesive) properties but there are no indications which would lead the person skilled in the art to this particular selection as opposed to any other members of the generic class in order to achieve the advantageous (adhesive) properties.

Sufficiency or Written Description Requirements

13. The new, inventive selection must also be sufficiently disclosed so that the skilled addressee of the patent is able to put the invention disclosed in the patent into effect. The invention will necessarily be required to be disclosed across the full breadth of the monopoly claimed. Again, much depends on exactly how the patentee has defined his selection.

14. So as to ensure the grant of a valid patent, the patentee will want to strike a careful balance between inventive step (by defining the advantage possessed by the selection so that it is as far away from the prior art as possible) and sufficiency (so that all the members of the claimed selection possess that advantage).

15. It can also be an issue at what timing experimental data supporting a selection invention should be submitted to a patent granting authority. Because selection itself is the key to any selection invention, the identification of prior art and data supporting the selection may have to be included in the originally filed specification. Alternatively, it may be possible to later submit experimental data that helps to distinguish the selection invention from prior art by providing evidence of new advantages or superior results during prosecution before the patent granting authority. It may also be possible that experimental data proving the existence of inventive step or non-obviousness may be dealt with differently from that supporting the breadth of a patent claim.

Infringement

16. As alluded to above, a difficult issue that arises with claims to products having a particular advantageous property is the extent to which evidence of the advantageous property is required for a finding of infringement. The advantageous property is often found by use of the product, and the selection patent may be drafted either as: (i) a product claim, (which exploits the selection's advantageous property); or (ii) a use claim, claiming the use of the selection for a new use (again which exploits the selection's advantageous property). This is best illustrated by our example above:

Example 3

In the selection that our inventor has made, the claim extends to the use of a particular compound arising from a selection as an adhesive (where the adhesive nature of the compound is the advantageous property not possessed by the prior disclosed generic class of compounds). A competitor manufactures the claimed compound and supplies it with no instructions as to its use.

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?

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?

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?

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?

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?

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.

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?

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?

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?

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?

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?

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.

Q13 Groups are also asked to recommend any issues for harmonisation not referred to in Q11 above.

Q13 Groups are asked to outline any other potential issues that merit discussion within AIPPI as regards selection inventions.

Note:
It will be helpful and appreciated if the Groups follow the order of the questions in their Reports and use the questions and numbers for each answer.