Summary Report

Question Q209

Selection Inventions – The Inventive Step Requirement, Other Patentability Criteria and Scope of Protection

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Background

The Executive Committee of AIPPI has included on the agenda of the 2009 AIPPI ExCo Meeting the issue of so-called "selection inventions". As discussed further in this report, the selection invention regime essentially allows for patenting of inventions which fall within an earlier disclosure under certain circumstances. The subsequent selection invention is therefore usually borne out of an earlier, more generically-defined, disclosure. A selection patent may involve, for example, the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly disclosed previously, within a larger known set or range.

AIPPI previously studied "protection of groups of chemical substances and selection inventions" under Q81. The resulting summary report indicated that the question of selection inventions should continue to be studied. Although Q84 entitled "selection inventions" was subsequently established, no further working guidelines or Group reports were published. Therefore, the Committee's view is that the question of selection inventions is a pertinent and relevant issue in the context of patentability, and an issue which (for reasons which shall be explored later in this report) requires greater harmonisation across Groups.

As highlighted by the Working Guidelines issued by the Reporter General, 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, and where that advantageous property is not possessed by the prior-disclosed wide class of compounds. Furthermore, a new "use" may be considered to fall under the concept of a selection invention or at least to relate to this concept – for example, a new use may be found for a known chemical compound or material – and it may potentially be claimed as a "use" or a method, or as a product intended for such new use.

This report looks at a number of areas where there are significant discrepancies between countries as to the approach to selection inventions (including the patentability requirements and the scope of protection available), where there is a need for greater harmonisation, including proposals as to which areas should be harmonised.

The questions posed to the AIPPI National Groups have been met with a good level of interest. In total, the Reporter General received 39 reports from the following countries: Argentina, Australia, Austria; Belgium, Brazil, Canada, Chile, China, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Germany, Hungary, Indonesia; Italy, Japan, Korea, Mexico, Netherlands, New Zealand; Norway, Panama; Paraguay, Peru, Philippines, Portugal, Romania; Russia; Singapore, South Africa, Spain, Sweden, Switzerland, Turkey, United Kingdom, and the United States.

The individual Group reports largely provided clear answers to the working guideline questions and a majority of them also gave comprehensive and detailed information about specific rules and case law as to the extent to which selection inventions are permissible. In this respect, the reports from Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Korea, Netherlands, New Zealand, Romania, Singapore, Sweden, United Kingdom and the United States were particularly helpful.

Due to the high number of Group reports, and the differences in the presentation of the national legal solutions, this summary report cannot be considered as a replacement to the detailed rules explained by each individual Group or the case law and examples used by the Groups to illustrate them in practice. Therefore, if particular information is required or specific legal issues arise, it is advisable to refer to individual Group reports.

Substantive law

The Working Guidelines asked the Groups to summarise the legal position on selection inventions in their respective jurisdictions, and more specifically, which types of inventions are recognised as selection inventions.

The first important distinction to make is that certain jurisdictions have special rules or regimes for selection inventions, whereas other jurisdictions do not recognise the concept of a "selection invention" at all. In the latter case, no special provisions apply and the normal patentability criteria will generally be the only relevant criteria, i.e. selection inventions in themselves are not excluded from patentability, provided they meet the general conditions of patentability.

Significantly, no special rules purportedly apply in the majority of the European Groups. For example, in Belgium, Denmark, Estonia, Finland, Germany, Italy, Norway, Portugal, Spain and Turkey, there are no regimes which specifically apply to selection inventions. Outside Europe, there are a significant number of Groups in which no special regimes exist; for example, in Argentina, Ecuador, Mexico, New Zealand, Panama, and Singapore. In Paraguay, no selection inventions are patentable except a second use of something known.

Special rules or guidance on selection inventions do apply in a minority of Groups, i.e. in Australia, Austria, Czech Republic, China, Japan, Korea, the Netherlands, Philippines, Romania, Sweden and the UK.

Additionally, in Canada and the US, although selection inventions are not a distinct category of inventions under the prescribed patent law, such inventions have nevertheless been recognised in certain cases (typically in the fields of chemistry, pharmaceuticals and biotechnology).

As regards the technical fields where selection inventions are available, the clear approach in virtually all Groups is that there are no specific limitations on the types of protectable selection inventions. For Groups where no special criteria apply in the first place, this approach is not surprising given that normal patentability criteria do not generally impose limitations on patentable fields. However, even for those countries where separate "selection invention" regimes exist, equally, there are no restrictions on the fields in which such inventions are available.

What is therefore surprising is that, despite the fact that no express restrictions exist, selection inventions consistently only appear in the chemical, pharmaceutical and material science fields. For example, in South Africa, even though there is very little case law on selection inventions and the applicable criteria, the limited case law relates solely to chemically-related products. In practice, it is virtually impossible to find concrete examples of selection inventions in different fields. Notably, in New Zealand, although the courts have (in a number of cases) stated that selection inventions are patentable in the mechanical and electrical fields, there still remains no specific example of case law in New Zealand which actually affirms this point. The Australian Group mentioned that patents had been granted in respect of selection inventions related to optical fibre cables and some other mechanical cases. Therefore, although no such restrictions exist, the notion that selection inventions may apply in any given field appears to be largely theoretical with little or even no practical impact.

The US Group attempted to categorize and discuss selection inventions based on claims to compounds, ranges and new uses. Countries such as Argentina apparently limit the types of selection inventions to particular conditions for processes and compounds (at least on the level of examination guidelines), while no statutory limitations exist. The French, Chinese and Japanese Groups mentioned that selection inventions are possible in the field of mechanical engineering.

Novelty

The Working Guidelines asked the Groups to summarise the position on selection inventions as regards novelty – specifically, whether merely carving a range out of a broad prior disclosure is sufficient to make a selection invention novel and/or whether a different advantage or use, or the same advantage with an unpredictable improvement is regarded as novel.

Certain countries such as Argentina, Singapore, and Russia do not require new advantages or unexpected improvement for novelty purposes, while China, Estonia, and Peru require some sort of new technical teaching. Ecuador, Mexico, Philippines as well as EPO member countries follow similar principles to those discussed in the EPO's guidelines for examination.

With respect to numerical ranges, carving out from a broad range of prior disclosure is generally not in itself sufficient to make selection novel. This is the case for the vast majority of countries (including South Africa, Japan, Philippines, Singapore, New Zealand, Australia, Austria, Czech Republic, Estonia, Finland, Germany, the Netherlands, Portugal, Spain, Sweden, the UK, Belgium, Denmark, Turkey, Canada, the US, Panama and Argentina).

With respect to compounds, the landscape is slightly different. For example, in countries like the US and Germany, novelty is not found when the compound in question is merely named, but instead is found if there is sufficient teaching, e.g. it may be possible to establish novelty by selecting various substituents from a list of specific sites on a generic chemical formula.

The UK Group discussed the Ranbaxy case (2005) and stated that novelty is in part dependent on the advantage. For the UK Intellectual Property Office, the size of the class from which a member or members have been chosen is not relevant to the question of novelty of a selection invention.

As noted above, in certain jurisdictions, considerations for novelty are no different for selection inventions as compared to any other type of invention, i.e. the selection invention will only lack novelty if it is anticipated by the prior art. Where special rules for selection inventions do apply, then in some cases (though not always), there often exists certain guiding criteria. For example, in Sweden, an invention is novel only if the given sub-range is narrow, it is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range, the selected range is not an arbitrary specimen of the prior art, and the features of the selection invention should not have been clearly or implicitly described in the prior art.

Additionally, a common trend amongst Groups is that the larger the class from which the selection is made (i.e. the prior disclosure), the more likely the selection is to be novel and possibly non-obvious.

With respect to novelty, many Groups reported that novelty is closely connected to (or at least considered with) overall patentability – i.e. it is not assessed separately from inventive step or non-obviousness. In fact, it seems difficult to single out novelty from the overall requirements of novelty and inventive step because in the case of selection inventions, a single prior art document is likely to be relevant to both novelty and inventive step requirements.

Inventive step or non-obviousness

The law on obviousness and inventive step varies from one country to another. At the same time, the standards for obviousness and inventive step are of the utmost importance and are day-to-day problems for all those involved in patents. In recent years, common themes seem to have emerged through many years of harmonization efforts. Detailed discussions on such issues are clearly beyond the scope of our study on selection inventions.

No Group clearly suggested the existence of inventive step/obviousness criteria designed specifically for selection inventions.

The Working Guidelines asked the Groups to summarise the position on experimental data in relation to inventive step. Specifically, the Guidelines asked whether experimental data or evidence can be submitted after the initial patent filing and whether there exist prerequisites or limitations on the late submission of data. The approach is somewhat divided across jurisdictions. For example, data cannot be submitted after the initial filing in South Africa, Singapore, New Zealand, Czech Republic, Italy, Turkey, and Ecuador. However, the late submission of data to support inventive step is permitted in other countries (subject to the usual restrictions on no added matter) e.g. Japan, Korea, Philippines, Australia, Estonia, Finland, Germany, Netherlands, Portugal, Romania, Spain, Belgium, Denmark, Canada, the US, and Argentina.

In those Groups where further evidence can be submitted, sometimes strict criteria exist as to what evidence is allowed - for example, in the UK, Belgium, Spain, the Netherlands, Japan and Korea - factual evidence in support of the purported advantage may be added later but only if the advantage was stated, suggested or foreshadowed in the application as filed.

In Germany, the Patent Office can at any time demand evidence that the purported effect in the patent application can be achieved.

In contrast to this approach, no prerequisites or limitations exist regarding the late submission of data in Denmark, Finland, Norway, and the US. Argentina has a 90-day period after the filing date for supplementing the as-filed specification. Experimental data can be submitted later, but it cannot form part of the specification.

It is therefore clear that the approach to late submission of data varies considerably across Groups. It appears that the late submission of data is either not allowed at all, or if it is, then the qualifying criteria which apply appear to vary significantly from Group to Group.

Sufficiency and/or written description requirements

As the US Group noted, support or written description requirement is a requirement separate from sufficiency or enablement. Reviewing the submitted Group reports, we note that the requirement of support or written description has been well developed in limited jurisdictions, such as Europe, the US, Canada, Korea and Japan.

On this area of sufficiency, the Groups were asked four questions: (1) the threshold for sufficiency; (2) 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.

As regards, the threshold for sufficiency, generally speaking, a majority of Groups noted that the same level of written description or support requirement is applicable to a selection invention, while at the same time, the majority of Groups stressed the importance of disclosing “advantages” over the prior art primarily because of the need to demonstrate a technical contribution to the art.

In relation to the timing for submission of experimental data and the time frame within which sufficiency or written description requirements must be satisfied the vast majority of countries use the date of filing or priority date.

Countries such as Switzerland, Canada and the US do not require experimental data for sufficiency or written description requirements. For example, US law requires descriptions to show that the inventor was in possession of the claimed invention as of the filing date. Possession may then be shown by a description of an actual reduction to practice of the invention or by a description of relevant identifying characteristics of the invention. "Descriptive means" includes words, structures, figures, diagrams, and formulas.

A number of countries such as Germany, the Netherlands, and Denmark apparently allow later submission of experimental data to cure the lack of sufficiency or support when put in dispute. On the other hand, countries such as Korea and Japan require that the support requirement has to be satisfied at the time of initial filing and later submitted experimental data does not cure the deficiency.

The next area explored by the Working Guidelines is whether all members of a selected class are required to possess the requisite advantage (or whether the patentee is excused if one or two examples fall short). It is clear that where there is some guidance on this area of law, there is no requirement that all members of a selected class are required to possess the requisite advantage. For example, this is the case in Singapore, New Zealand, Australia, Austria, Estonia, Finland, Netherlands, Romania and Argentina. In these countries, the general rules of sufficiency and enablement apply, i.e. all that is required is that the description should be sufficiently clear and complete, and the specification should be clearly and fairly set out so that a skilled person can carry out the invention (trial or experimentation is generally permissible). Therefore, provided a skilled person is able to carry out and work the invention, then it does not matter that one or two examples fall short.

Interestingly, a different approach has been taken in the UK, France, Sweden, Japan, Korea and Canada. Under UK case law, for example, all members need to possess the requisite advantage which is alleged to have been identified by the selection. Although strict compliance with this rule has been doubted in a subsequent decision, the position is that it is still "good" law because it has not been expressly overruled.

With regards to "new use" selection inventions, Groups were asked whether it would it suffice to claim a particular range or selection of components associated with the new use or whether the new use would need to be recited in the claims. It appears that this area is unclear (or at the very least, has not been explicitly addressed) in a number of jurisdictions. A number of Groups either reported that there was no case law or did not directly address these issues. For example, the position in South Africa, Japan, Philippines, Czech Republic, Norway, Portugal, Turkey, Mexico and Panama is unclear on these points.

As regards the need to expressly recite the "new use" in the claims of the selection patent, this is not a requirement in the majority of jurisdictions (for example, in Singapore, Austria, Romania, Spain, the UK, Belgium, Denmark, Japan, Canada and the US). However, a number of Groups commented that it would be advisable or needed if the protection sought was for use of that invention. Those Groups which stated that the use would need to be recited include Korea, Finland, Germany, Italy and Argentina.

Infringement

The Groups were asked to briefly consider the issue of infringement in relation to new use selection inventions, namely the requirements to establish infringement and whether the intention of an alleged infringer plays a role in the determination of infringement.

The Working Guidelines contemplated two different situations in relation to "use", namely where the new use is not specifically claimed as well as claims with the new use embodied within it. In a number of jurisdictions, liability for infringement will be established even if the alleged infringer uses the product for a use that realizes an advantage or use that is different from those discussed in the body of the specification and not recited in the claims. For example, in Estonia, the UK, Spain and Belgium, where the claims merely define a product without reference to any advantage in the claims, then any person who undertakes a restricted act with respect to that product will infringe even if the act does not relate to the advantage of the selection invention.

Other Groups reported that use by the alleged infringer must be for the same purpose as the advantage – this is the case in Japan, Philippines, Australia, Finland, Norway and Sweden.

In Japan, for example, the new use must be indicated as a use by the manufacturer or seller for that party to infringe. However, the act of manufacturing or selling the product without indicating the use is considered to infringe the patent when carried out in the knowledge that the party to which the product is being supplied is using the product for the new use (and in this sense, the intention of the alleged infringer plays a role in the determination of infringement).

The intention of the infringer is not relevant in most Groups – for example, in Korea, Czech Republic, Estonia, Netherlands, Romania, Sweden and the UK. However, the approach is fairly divided across jurisdictions and there is still a significant number of Groups where intent of the infringer is relevant to some extent in finding liability of the infringer (e.g. Philippines, New Zealand, Austria, Finland and Spain).

Policy considerations & harmonisation

The Dutch policy behind the law on selection inventions was expressed in The Hague Court of Appeal relatively recently. One of the conclusions drawn from that decision is that, if one were to assume that all species within a known disclosure are "publicly available", then a specific species with a surprisingly better effect (for example) would not be patentable as the prior disclosure would be considered novelty-destroying. The consequence of this is that it does not provide would-be patentees with an incentive to research into further improvements (within a known prior disclosure) and, furthermore, arguably unjustly rewards patentees with broad and speculative patent claims. These consequences are clearly not desirable.

This policy view was also noted in the UK Report, where the point made was that the treatment of selection inventions is needed to properly incentivise R&D. This is especially true in the chemical and pharmaceutical fields, where the prior, generic disclosure can embrace thousands or even millions of permutations. Allowing patent protection in sub-sets or sub-groups of an initial range (provided those sub-sets or sub-groups have not been explicitly disclosed previously) prevents large tracts of compounds from being rendered "inaccessible." Therefore, blocking these permutations or sub-groups from further study by denying selection patents may weigh against the public interest.

Despite these policy considerations, it is interesting to see that a number of Groups (even in those jurisdictions where selection invention regimes exist) called into question whether selection inventions should be treated as a separate or special "class" of inventions. For example, the Australian Group expressed the view that no separate regime should exist and instead, these type of inventions should be treated in accordance with the normal patentability criteria for any other type of invention. The Swedish Group was also of the opinion that no extra or special regulations should apply to selection inventions. This issue was raised by the UK Group, who commented that this is a particularly important question to address in light of the fact that the EPO has tended to reject the idea of a separate "selection invention" regime.

It seems that a number of those Groups who do have special selection invention regimes appreciate that there may be a need to reconsider this approach. This is not an entirely surprising outcome: the current state of play in these countries is that selection inventions are treated almost as "special" cases and only exist in certain fields (i.e. mainly the pharmaceutical and chemical fields) rather than in all types of industry.

Further public policy considerations were noted. Some Groups (for example, Romania) expressed the view that the efforts of the inventor should be rewarded for his attempts to more fully understand the complexities of an individually selected chemical compound (for example) and any technical challenges they faced in developing that compound. However, the view of most Groups appears to be that it should in fact be irrelevant how much effort has been invested by the inventor to arrive at a selection when determining whether a selection patent should be

granted, and the considerations relevant to the grant of any patent should depend only on traditional criteria, such as novelty and inventive step.

A number of Groups commented that the general criteria governing patentability of selection inventions should be harmonised and in particular, the standards for analysing novelty and inventive step. For example, the Korean Group made the point that there appear to be a number of cases where selection inventions are denied patent protection on the basis of novelty, despite the fact that the invention possesses unexpected and remarkable effects (and would therefore perhaps be afforded patent protection in other Groups). Thus, a clear and consistent standard seems to be necessary.

.A harmonised standard is needed on the questions of 1) when it is necessary to disclose advantageous features of a selection invention and 2) when it is necessary to provide evidence of such advantageous features. The lack of conformity on this point among the various jurisdictions is harmful to the patent system overall and introduces uncertainty.

Finally, as the US Group pointed out, the intent of the infringer to obtain a claimed property or to perform a claimed use should probably not be a requirement of proof for infringement. A requirement of intent by the infringer obfuscates the infringement analysis, adds economic cost and uncertainty, and encourages litigation

Conclusions

Based on the approaches in the various jurisdictions and the views expressed in the Group reports, it appears that there are a number of issues which require further consideration. Such issues include:

- What would be a common definition of “selection invention” for the purpose of our resolution? Is it possible or necessary? Should mechanical, electrical or electronic inventions be covered? Should a new use be a category of selection inventions?

- Whether there is a need to provide for a separate selection invention regime given the need to further incentivise research and development? Is it against the public interest to treat potential selection inventions in accordance with "normal" patentability criteria? Is there a need to harmonise this approach, given that (for e.g.) the EPO takes the view that selection patents should not be subject to a special regime?

- If selection inventions do require additional rules; guidance and/or separate regimes to some extent (even if it is just by way of clarification on what the rules on novelty and obviousness are), should these rules or regimes pertain explicitly to only certain fields or areas of technology? Is there a need for selection inventions outside the chemical and pharmaceutical industries?

- On novelty, should there be specific and harmonised guidance as to how broad or generic the prior disclosure needs to be before a selection might be novel?

- Should there be more clear guidance as to how a prior disclosure should be interpreted beyond the explicit teaching. If a wide class of chemical compounds is defined in the prior teaching by reference to a formula, should a selection of specific compounds which were not explicitly named (but fell within the formula) be novel over the prior art, and is it possible for us to come up with general guidelines?

- Additionally, should there be special or harmonised guidance on what constitutes a "novel" invention – e.g. as regards a new advantage or use? What degree of improvement over the prior art is required for the selection to be 'novel'?

- What should the approach be as to the late filing of evidence or data? Should the filing of any late data to overcome lack of novelty or inventive step be allowed? Should it be required that the feature that the data supports has been disclosed in the application as filed?

- We may wish to formulate harmonised standards on such questions as: 1) to what extent advantageous features should be disclosed at the time of initial filing – do statements alone suffice or is experimental data required, and 2) when is it permitted to provide evidence of such advantageous features. Should any special considerations apply in this regard for selection inventions

- On sufficiency, should the selected class possess the requisite advantage in its entirety, or is it sufficient that only a majority of the selected class possesses the advantage?

- On infringement, the potential problem which arises is that third parties may infringe a selection patent in some jurisdictions even where that party is not using the invention for the purported advantage (as described in the body of the specification but not in the claims). This is the case whatever the actual intention of the third party. Is this a satisfactory result or should the purported advantage and/or the intention of the infringer be taken into account in considering infringement? If the advantage is recited in the claims should the intention of the third party play any role in the determination of infringement?