Question Q209

National Group: **Dutch Group**

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

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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?*

In accordance with the Working Guidelines, a selection invention is the selection of individual elements, *sub*-sets, or *sub*-ranges, which have not been explicitly disclosed previously, within a larger known set or range. In other words, a selection invention is directed to a species of a genus that was already disclosed in the prior art. For patentability, the selection of the sub-range of subject matter must have an improved technical effect. Selection inventions are common in the pharmaceutical field, biotechnology, material science and chemistry. The Dutch group found no examples in Dutch case law of selection inventions in other fields, such as electronics or mechanics.

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?

Selection inventions deal with the selection of individual elements, subsets, or sub-ranges, which have not been explicitly or implicitly mentioned, within a larger known set or range.

For novelty of a selection, it is required to determine whether the selection is disclosed in *an* individualised (concrete) form in the prior art. The Dutch Courts follow the decision practice of the EPO in this respect. Notably, the Court of Appeal in The Hague appears to have applied an even stricter test for potentially novelty-destroying prior art by ruling in a recent case (28 February 2008, docket no. 2007/272) concerning novelty of an enantiomer vis-à-vis a racemic mixture,

that the enantiomer was novel, since no one had prepared the enantiomeric pure substance or had actually 'had it in hand' yet at the priority date.

Selection from a single list of specifically disclosed elements does not confer novelty. Selection from two or more lists of elements to come to a specific combination of features not specifically disclosed in the prior art, confers novelty. An example of the above principle is the selection of a specific chemical from a known generic formula having two or more lists of substituents (e.g. R1 and R2, and wherein R1 and R2 can be H, Cl, OH, COOH, F etc.), whereby the selected compound is the result of selection of specific substituents from the two or more lists of substituents (e.g. wherein R1 = H and R2 = Cl).

A sub-range selected from a broader numerical range of the prior art is considered novel, if a) the selected sub-range is narrow compared to the known range, b) if the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the endpoints, **and** c) if the selected range is not an arbitrary specimen of the prior art, but another invention (purposive selection, new technical teaching). The new technical effect occurring within the selected range may also be the same effect as that attained with the broader known range, but to a greater extent. For novelty, requirement c) is met when the effect is a different effect, not necessarily a surprising effect (the latter being a matter of inventive step).

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?

For selection inventions, the normal test for inventive step applies. Dutch courts normally apply the *problem-solution-approach*. This means that the selection must not be obvious to the skilled person departing from the closest prior art and the objective technical problem.

Experimental data to back up the inventive step requirement can in principle be submitted after the initial patent filing. Such experimental data can for instance be submitted during opposition proceedings before the EPO and also during court proceedings in the Netherlands. Experimental data can even be submitted during court proceedings in appeal, as appeal proceedings in the Netherlands are *de novo* proceedings. The other party in court proceedings can however object to late submission of experimental data on procedural grounds, e.g. in the event that the data are submitted at the very last moment and the late submission qualifies as a violation of due process or a violation of the principle of hearing both sides of the argument.

For an example of late submission of data, see Court of Appeal of The Hague, 21 February 2008, docket no. 06/1466 (Ranbaxy v. Warner-Lambert), relating to a

patent in which a small group of compounds was selected from a large group of compounds and protected (inter alia) atorvastatin. It was stated in the patent that the compounds in the selected group possessed a surprising (improved) anti-cholesterol activity. This surprising activity was made plausible on the basis of new tests, submitted after filing during the examination procedure of the EPO. These new tests were accepted by the EPO and the Court of Appeal of The Hague also accepted the surprising (improved) activity on this basis.

On a side note, the Dutch group notes that in Court of Appeal of The Hague 27 January 2009, case no. 105.005.369 (Sahajanand v. Angiotech), relating to the selection of the compound paclitaxel for the coating of a drug eluting stent, it was decided that the patent did not have to contain experimental data to prove that the product indeed works (although the other party in court proceedings is allowed to submit experimental data proving that the product does not work). Experimental data were however submitted after filing by the patentee during opposition proceedings before the EPO.

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?

1) The sufficiency of disclosure requirement in the Dutch Patent Act is the same as the requirements under article 83 EPC. First of all, the Dutch group notes that it is not aware of any case law invalidating a selection invention patent on the ground of lack of a sufficient disclosure. In general, it may therefore be said that the sufficiency of disclosure requirement does not go beyond what is examined by the EPO during prosecution and that the threshold as such is not very high. For selection inventions, the threshold is not expected to be substantially higher than for other inventions.

The position of the Dutch Courts regarding sufficiency of disclosure in general is that if a skilled person, based on the description supplemented with his common general knowledge is able to carry out the invention, the invention is enabled. There is no additional requirement and the case law essentially requires an invention to "work". The Court of Appeal held in a recent case (27 January 2009, Sahajanand/Angiotech, cited above, par. 11.2) that if the patent granting

authority deems a patent "to work" it is up to the plaintiff to show that it does not “work”.

2) Presenting data to back up sufficiency of disclosure after initial filing is subject to the same criteria as the filing of data for inventive step. Hence, reference is made to the answer to Q3 above.

3) Although the Dutch Group is unaware of any case law to affirm this, the Dutch group believes that the sufficiency of disclosure requirement entails that a skilled person should be able to carry out the selection invention. The decisive date for fulfilling the sufficiency requirement is the date of filing or priority.”

4) Again, in the absence of concrete case law, in principle, the Dutch Group believes that experimental data to support a selection is not required, as long as the selection (and its claimed benefits) actually works.

There is no requirement in Dutch patent law that <u>all</u> elements of a claimed group must possess the claimed advantages. There is a reasonable balance to be found. However, as a general rule, the Dutch Group believes that for selection inventions (which are inventive due to the advantages of the selected species) the requirements may be somewhat stricter, especially where it concerns a narrow selection.

Further, the essential features of an invention must be disclosed in sufficient detail, so the person skilled in the art knows how to put the invention into practice. Depending on the facts of the particular case, a single example may suffice - even where a very broad field is claimed - where the patent contains sufficient information to allow the person skilled in the art, using his common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill. Reference is made to District Court of the Hague 4 February 1998, BIE 1999, 13

The Dutch Group understands the last part of Question 4 to refer to the situation in which a new use is the sole inventive aspect of a “selection” invention. As a preliminary remark, the Dutch Group notes that this is not a real “selection invention” as explained above, but rather an invention relating to a further use. Within the originally disclosed genus, the selected compound or group of compounds would be nothing but non-inventive variants.

From this it follows, that claiming the novel (and inventive) use of a compound selected from a genus which was disclosed for another purpose should be done in the form of a use-claim. If the new use were to be claimed as a product *per se* claim, this would mean that the (prior art relevant for the) genus would take away the inventive step of the species being nothing but a non-inventive variant.

Q5 <u>Infringement</u>

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?

In the absence of case law on this issue, the Dutch Group notes that a selection patent might lead to a claim for a novel product, which is inventive due to a certain unexpected improvement over the disclosed genus. The scope of protection of such product claim is determined in accordance with art. 69 EPC and the Protocol. The essence of a product claim is that it covers all uses of the product. According to the Dutch Group, it follows from this that it is irrelevant whether or not an infringer makes use of the advantage or superior result of a selected product.

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?

In the absence of case law on this issue, the Dutch Group notes that the requirements to establish infringement of a use claim are not different than the requirements for any other (method) claim. The scope of protection is to be determined in accordance with art. 69 and the Protocol. The intention of an alleged infringer does not play a role.

Pursuant to section 73(1) of the Dutch Patent Act 1995, there is an indirect infringement if the infringer offers or supplies any means regarding a material aspect of the invention for application of the invention to any third party who does not have permission from the patentee to use the invention. In the case of indirect infringement, it is a requirement that the infringer knows, or that it is evident considering the circumstances, that those means are suitable and intended for that application. Reference is made to Question 10 for further examples.

Q6 <u>Policy</u>

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 behind the law on selection inventions has relatively recently been expressed in a decision of the Court of Appeal of The Hague (the specialized Dutch appeal court for patent matters). If one would assume all species within a known genus to be publicly available, even a species with e.g. a surprisingly better effect would not be patentable as the known genus would be considered novelty destroying. This would not stimulate research into improvements within the known genus and, moreover, an undesired reward would be granted for the broad and speculative claiming of a genus. Such consequences are deemed undesirable (see Court of Appeal The Hague, 28 February 2008, docket no.

2007/272; with reference to Singer/Stauder (2000), art. 54 - 10; see also Singer/Stauder, *The European Patent Convention* (2003), art. 54 - 10).

The Dutch group sees no reason why such policy considerations would not still be valid today. In particular the stimulation of research into improvements remains desirable.

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?*

For the basic principles regarding the assessment of novelty, please refer to the answer to Question 2.

Regarding the example: In case the prior art discloses a group of compounds only by the disclosure of a generic formula, a specific compound (or groups of compounds) is considered novel as long as the specific compound was not specifically disclosed in said prior art. In other words, as long as the specific compound or the group of specific compounds is not specifically exemplified in the prior art, the invention is considered to be novel. It does not matter whether the prior disclosed generic class consisted of 1,000,000 possible compounds as opposed to 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?

(i) No; (ii) No; (iii) Yes.

For the scope of protection of a patented invention as under (iii), see the answer to Q5 above.

Q9 Sufficiency and/or written description requirements

Reference is made to the answer to Question 4 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 would in any case not amount to direct infringement, since this would require that all features of the claim are adopted by the infringer, either literally or by means of equivalence. The claim in example 3 extends to the use of the compound as an adhesive and there can thus only be direct infringement if the compound is used as an adhesive. The mere manufacture and supply of the compound as such does not infringe the claim directly.

However, the question arises whether the supply of the compound under circumstances may contribute to infringement and, hence, should be considered an indirect infringement. Pursuant to section 73(1) of the Dutch Patent Acts 1995, there is an indirect infringement if the infringer offers or supplies any means regarding a material aspect of the invention for application of the invention to any third party who does not have permission from the patentee to use the invention. Additionally, it is a requirement that the infringer knows, or that it is evident considering the circumstances, that those means are suitable and intended for that application.

Therefore, with regard to example 3, it must first be assessed whether the compound as such qualifies as 'a means regarding a material aspect of the invention'. It has been suggested in the literature that all features of the claims of a patent are material aspects of the invention. Following this suggestion, the offering or sale of the compound in example 3 would be considered a means regarding a material aspect of the invention. However, outside the context of selection inventions, the Supreme Court has ruled that only those features that distinguish the invention from the state of the art are material aspects of the invention (the *Senseo* case). It is as of yet not known whether the courts would adopt such strict criterion also when dealing with indirect infringement of a selection invention. If they would do so, it does not seem likely that, with regard to example 3, the courts would consider the compound as such a means regarding a material aspect of the invention. After all, one could argue that the use of the adhesive property distinguishes the claim from the prior art and not the compound itself.

Furthermore, in order to find indirect infringement in example 3, the compound should in any case be offered or sold for application of the invention (by whom is not relevant), whilst the manufacturer knows, or while it is evident considering the circumstances, that those means are suitable and intended for that application. However, it is not a requirement that the infringing use of the compound is being promoted or advertised (as it is not in example 3). There should thus only be some (objectified) knowledge of the patent and the possibility of infringement. The patentee would not have to bring evidence of this knowledge on the part of the manufacturer, if such knowledge can be deduced from the circumstances of the case.

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 amount of effort invested by the inventor as such is not relevant for the question whether or not a selection patent is valid (compare also District Court The Hague 28 May 2008, reg. nos. AWB 06/8641 OCT95 and AWB 07/3972 OCT95, in respect of a request for a supplementary protection certificate). Like other inventions, selection inventions need to meet *objective* criteria in order to qualify for patent protection; the amount of effort invested is, to the contrary, a *subjective* criterion. Patentability is to be assessed from the perspective of the skilled person, not the actual inventor.

For purposes of completeness, the Dutch group notes that secondary indicia (such as long felt need, age of documents and the overcoming of a prejudice) may be taken into account as auxiliary indications for inventive step when objective evaluation of the prior art does not provide a clear picture. The presence of such secondary indicia however needs to be established on the basis of objective evidence, and not (solely) on the basis of the efforts of the actual inventor.

Q12-14 **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.

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.

Throughout this document, the Dutch Group has emphasised the scarcity of case law on selection inventions in the Netherlands. Many of the Dutch Group's

answers are based on case law of the Boards of Appeal of the European Patent Office. As such, the Dutch Group expects considerable "harmonisation" of the Dutch and the EPO approaches. In the absence of this, this Dutch group would encourage such harmonisation with a view to legal certainty.

The Dutch Group does not believe that the amount of effort invested by the inventor should play a part in assessing the validity of a patent. Like other inventions, selection inventions need to meet *objective* criteria (reference is also made to Question 11).

Apart from the issues already raised in the Questions and Working Guidelines, there are no additional recommended issues for harmonisation or other potential issues that the Dutch Group believes would merit discussion with AIPPI.

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