Questions

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?

(Response)

According to the Working Guidelines, a selection invention is the selection of (i) individual elements; (ii) sub-sets or; (iii) sub-ranges, which have not been explicitly disclosed previously within a larger known set or range (Item 1 of the Working Guidelines).

In Japan, the patentability of a selection invention included in the category of above-mentioned (i), (ii) or (iii) is discussed mostly in the chemical field, such as compounds, pharmaceuticals, glass and resin compositions.

However, with regard to the issue of (iii) above, there are some legal precedents in other technical field. For examples, in the case “a method for determining the amount of explosive charge used in simultaneous confined blasting” or “a vibration control device”, the relationship between selection of specific controlled variables or selection of specific numerical range and patentability was the point of dispute (However, patentability has not been found in either case). Therefore, with regard to the inventions which are defined by sub-range, even in fields of other than chemical, pharmaceutical or material science, selective inventions can be found.

In Japan, however, the patentability of inventions defined by a numerical range is often assessed by inventiveness in which optimization through numerical limitation is the main question. In that sense, discussion over patentability of inventions defined by a numerical range is often separated from the discussion of the patentability of selection inventions, because in the latter, novelty from the standpoint of selection should be taken into consideration.
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?

(Response)

Where prior arts simply show generic and inclusive or provide a large number of various alternatives, and where there is no clear evidence to support the concrete effects of a specific alternative or combination (herein collectively referred to as 'alternative'), then a selection invention claiming said specific alternative is often deemed to be novel and patentable. The main reason for finding novelty of the selection invention in this case is that said specific alternative has not been substantially disclosed by the prior document. In such cases, different effects or same but unforeseeable and significant effects are not so important to find novelty.

In Japan, however, when patentability of an invention is asserted on the ground that it is a selection invention, different effects or same but unforeseeable and significant effects are often strictly required to find patentability. It is because, in Japan, as stated in several old court decisions, the patentability of selection inventions is considered as follows.

"With respect to a prior invention which expresses all or some of its structural elements as a generic concept, a 'selection invention' refers to an invention which is expressed with a subordinate concept contained within that generic concept and which selects as its structural elements those which have not been specifically disclosed in the publication of the prior invention. Where this invention succeeds in generating a prominent effect not disclosed in publications describing the prior invention; that is, an effect which is qualitatively different or which is qualitatively the same but remarkable and outstanding compared to the effect of the prior invention; said invention shall merit the admission of patentability as an invention which is independent and separate from the prior invention." (1985 (Gyo-ke) No. 51)

The JPO Examination Standards show similar idea as described in the decision. In this regards, when the applicant or right holder clearly asserts that the invention is a selection invention, "significant effects not disclosed in the prior arts; that is, different effects or same but remarkable and outstanding effects compared to the effects led by the prior invention" is strictly required in the practice to find the patentability.

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?

There are no special criteria for determining inventive step in a selection invention. Rather, decisions are made according to the same criteria applied to the normal inventive step in other types of patents. However, as stated in the response to 'Novelty' above, when making a clear assertion that the invention is a 'selection
invention’, there is a tendency in Japan to rely on legal precedents and to require that there be an effect which is qualitatively different or qualitatively the same but remarkable and outstanding, as well as strictly requiring the description of said effect in the specification.

The admissibility to submit experimental data to back up the inventive step after initial patent filing depends upon the details provided in the specification and in subsequent data submissions. This rule is basically the same for selection inventions and other types of inventions.

For example, experimental data to prove an effect for which there is no description whatsoever in the specification, or experimental data to prove an effect which, despite being described in general terms, cannot be foreseen based on the common general technical knowledge of a person skilled in the art, usually cannot be submitted after the initial patent filing. On the other hand, submission of experimental data may be permitted subsequent to filing where the performance of an effect which is similar to the alternative already described in the specification serves to validate technical common knowledge with respect to the effect of a different alternative which can be inferred based on the common technical knowledge of a person skilled in the art.

However, as stated above, when making a clear assertion that the invention is a ‘selection invention’, there is a stricter requirement to adequately describe the experimental data in the initial patent application and it is generally difficult to assert patentability via the subsequent submission of experimental data because the selection invention is itself a selection of a specific range of components from a range of components which has already been disclosed and, as such, its patentability is very closely related to its advantageous effect.

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?

(Response)

(1) Selection inventions are subject to almost the same level of written description requirements as non-selection inventions. However, in addition, selection inventions are required to describe where their advantage lies relative to a prior invention (i.e. whether they possess an inventive step) and in many cases they must describe experimental data to prove this assertion.

In order to assert or prove an advantage within the scope of a claim it is generally necessary to provide enough embodiments in the specification to enable a person
skilled in the art to understand that said advantage can be achieved throughout the entire scope of the claim. On the other hand, even if the number of specific embodiments disclosed in the specification would be limited, this does not immediately mean that the scope of the claim will be restricted. Under the JPO’s present operating guidelines, if an embodiment shows that the a part of claimed invention does not have any advantage, it is not permitted to claim the scope including such an embodiment. Inventions characterized by numerical limitations are also required to prove the advantage throughout the entire scope being claimed.

(2) Unless otherwise specified, experimental data must be appeared in the specification at the time of filing and it is not possible to remedy insufficient descriptions by way of subsequent experimental data submissions. However, if a person skilled in the art is able to infer an advantage relative to a prior invention based on the description in said specification or drawings, the advantage which has been argued and proven by the applicant using experimental data in a post-filed written argument etc. may be considered.

(3) Said requirements must be satisfied upon filing of the application.

(4) Even when asserting a new utility, it is enough to claim a particular range or selection of components which have been found to be associated with such a new utility and then it is not usually 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?

(Response)

When a patent is granted for a substance, infringement of that patent occurs regardless of the application in which the substance is used by a third party, and this judgment is also applied to selection inventions as long as they are protected under a substance patent. Accordingly, if a certain substance is patented as a selection invention, the act of manufacturing or selling the substance is considered to be an infringement of that patent regardless of whether or not the certain advantage or superior results which constituted the reason for the selection invention are being utilized.

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?

(Response)

The requirements for establishing infringement when a selection invention is claimed as a new use are considered to be the same as those for establishing infringement of a common utility patent. In other words, if a new use is patented for a certain product, any conduct involving the manufacture or sale of products indicating that use would be deemed to constitute infringement of the patent, and this also applies to situations where a selection invention is claimed as a new use. Therefore, the act of manufacturing or selling products to be used for the new use which indicate said use will infringe upon the patent, but the act of manufacturing or selling products to be used for the new use which do not indicate said use will not infringe upon the patent.
However, even the act of manufacturing or selling the product without indicating the use is considered to infringe upon 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, although there are no relevant legal precedents to date. In this sense, the intention of the alleged infringer plays a 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.

(Response)

No policy discussions have been held in Japan on how to handle selection inventions during the prior implementation of the substance patent system or at any other time. It is therefore unclear as to whether there were any policies behind the legislation relating to selection inventions.

The problem with selection inventions per se is currently perceived to be a practical or operational issue of whether or not they correspond to inventions described in publicly-known documents (mainly patent documents).

**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?

(Response)

If the prior invention was a very wide generic concept consisting of 1,000,000 compounds, then a selection invention within that range would typically be readily admitted. Contrarily, if the prior invention was very limited and contained, for instance, 10 compounds, then the selection invention would typically be very hard to admit. That is because the extent to which the contained compounds are limited determines how easy it is to confirm the properties of compounds not disclosed in the prior invention.

The matter of whether or not a selection invention will be realized is therefore influenced by how widely the prior invention is disclosed.

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?

(Response)

Example (i) and (ii) would not constitute an inventive step but example (iii) would. Admitting inventive step in example (iii) would result in the granting of a patent right with respect to not only the product limited to that use but also to products not limited to that use. As such, the subject of patent protection for products not limited to that use would be the products *per se*. The scope of patent protection is, in principle, determined according to the description of the patent claims (literal interpretation of each of the structural components and the doctrine of equivalents) and this principle applies to both use inventions and selection inventions. However, speaking in more specific terms, actions such as estoppel may occur as a result of descriptions which are excessively limited or details of assertions made during examination, and the scope of the patent protection may be subject to a limited interpretation due to elements other than the actual structural elements described in the patent claim. This type of specific interpretations also applies to the normal scope of protection and is not applied exclusively to selection inventions.

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?

(Response)

As is the case in example 2, even a general explanation of the invention's advantages in the specification would have to be demonstrated with a considerable number of embodiments in order to satisfy the sufficiency requirement. On the other hand, even if the number of specific embodiments disclosed in the specification would be limited, this does not immediately mean that the scope of the claim will be restricted. Under the JPO's present operating guidelines, if an embodiment shows that a part of claimed invention does not have any advantage, it is not permitted to claim the scope including such an embodiment.

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?

(Response)

Even if a competitor has manufactured the claimed compound and supplied it with no instructions as to its use, the act of manufacturing and selling the compound in the knowledge that the party to which the product is supplied is using the product as an adhesive is considered to infringe upon the patent. Therefore, in example 3, evidence of the knowledge of advantageous property of the selection or intention of the infringer as to its supply would be required to find 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?

(Response)

With respect to examples 1 and 2, the matter of how the novelty and inventive step are established in Japan is outlined in the responses to questions 7 and 8 above. In both cases, the amount of effort invested in arriving at a selection does not constitute an element for decision on patentability.

In Japan, the notion of 'selection invention' has been recognized by the courts of law, and the JPO has also published the examination guidelines based on such courts' decisions. However, none of these precedents or guidelines admits any special treatment for 'selection invention'.

The question of how much effort was invested in arriving at a selection is, in most cases, equivalent to the question of how much trials and errors were made, and activities of trials and errors in themselves are not considered creation of technical idea. Thus, in Japanese practice, the amount of expended effort is not considered a contributing factor in grant of a patent.

As a matter of policy, because ‘failures’ as such within the trial-and-error process are in themselves of no positive use, granting a patent right simply on the basis of numerous failures is beyond the power of the granting authorities and requires amendment to Japan's patent law, and we do not believe such an amendment would be able to gain public support.

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.

(Respone)

Decisions on patentability should be made with the emphasis on whether or not the subject invention exhibits an unforeseeable advantageous effect relative to the prior invention, such as an effect which is qualitatively different or qualitatively the same but remarkable and outstanding. In regards to decisions on novelty in particular, novelty should be admitted when the prior invention does not specifically disclose the subject selection invention, while decisions on whether or not the prior invention contains a specific disclosure should be made in
consideration of the common general technical knowledge of a person skilled in
the art, and not all matters which can be included in a generally-worded
description should be deemed as a specific disclosure.

- The specification upon filing of the application must, in order to facilitate clear
understanding of the reasons for selecting the specific range and alternatives,
contain a description of data relating to the operational effect in support of said
reasons. The addition of other experimental data relating to said operational
effect in order to further support an assertion of inventive step shall essentially be
taken into account even when submitted during the examination process.

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

(Response)
None.

Q14 Groups are asked to outline any other potential issues that merit discussion
within AIPPI as regards selection inventions.

(Response)
- When asserting a qualitatively different effect as the advantageous effect: (1) is it
necessary to prove that the area lying outside of the selected range does not
contain said qualitatively different effect, or; (2) is it necessary to prove that the
selected range does not contain an effect which is qualitatively the same as that
of the area lying outside of the selected range?

- Does the criteria for determining the patentability of the selection invention differ
according to whether or not the inventors or applicants of the cited patented
invention and the selection invention are the same?

- In a selection invention for a new compound for pharmaceutical use, data relating
to pharmacological activity has been described in the specification upon filing but
will an assertion of inventive step indicating additional data on stability and
adverse effects in order to assert patentability in relation to the cited invention
which discloses an inclusive range (class) having the same pharmacological
activity be admitted during the examination process?

- Does the exercise of a patented selection invention (species patent) infringe
upon the cited patented invention (genus patent)? Also, does the exercise of a
cited patented invention which overlaps with the patented selection invention
infringe upon the patented selection invention?

- While the patenting of a new antigenic protein may result in the automatic
granting of a patent to its generic antibody, an invention of an antibody which
targets a disease involving the same antigen and which was designed to be used
as a pharmaceutical drug to counter said antigen has been admitted as being
completely different from the aforementioned generic antibody patent in terms of
selectivity, humanization technology and stability and has been granted a patent.
Although the relationship between this type of generic antibody invention and an
antibody invention designed for use as a pharmaceutical drug also ostensibly
constitutes a species-genus relationship, should it be deemed a selection
invention and does the exercise of such specific antibody for use as a
pharmaceutical drug infringe upon the patent covering generic antibody?