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

Questions

General
Groups are asked to give a summary of the legal position as regards a patent for a purported selection invention in their jurisdiction in relation to the following:

1) Legal developments on selection inventions
What specific types of inventions are recognized under the concept of selection invention and are patentable in your jurisdiction?

Background Law
The Singapore Patents Act (“SPA”) does not specifically recognise a category of “selection inventions”. However, such inventions are not excluded from patentability provided they meet the general conditions of patentability that an invention must be novel, possess an inventive step and be industrially applicable.

In Singapore, the usual understanding of a selection invention is that of a later filed patent based on a selection of compounds from those have been described in wider and more general terms in the earlier patent. The selection invention typically covers a group of members which have a particular advantage and peculiar character which is unique to the members within that group.

A new use of a known compound may be patentable under the SPA, but this is usually not considered within the understanding of “selection inventions”. Nonetheless, it may be of interest and we set out the relevant provision namely Section 14(7) of the SPA below:

In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

Thus far, there is no specific case law in Singapore regarding selection patents nor are there any guidelines issued by our Patent Office. However, UK case law is considered to have persuasive value in Singapore. Although it is not binding, recent cases in UK such as Dr Reddy’s Laboratories v Eli Lilly [2008] EWHC 2345 (Pat), may be used as a guide in future should this issue arise in Singapore.

Do you have any examples of selection inventions in a field other than chemical, pharmaceutical or material science fields?

No.
2) Novelty

Groups are asked to discuss any issues that should be considered with respect to the novelty of selection inventions. For example, is merely carving a range out of a broad prior art disclosure sufficient to make a selection invention novel? Is a different advantage or use, or the same advantage with an unpredictable improvement required for a selection invention to be novel?

**General Law on Novelty**

The general statement of law with regard to novelty in Singapore is as follows. An invention shall be taken to be new if it does not form part of the state of the art (s 14(1) of the SPA). Section 14(2) and (3) of the SPA provides that the state of the art shall be taken to comprise all matter which at the time before the priority date of the invention has been made available to the public (in Singapore or elsewhere) by written or oral description, use or in any other way, and includes, in certain circumstances, matter contained in an earlier patent application, whose priority date predates that of the invention.

Singapore courts have cited with approval the judgment of the Court of Appeal in *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457 at 485-486. In the latter case the Court of Appeal said:

“If the prior inventor’s publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee’s claim if carried out after the grant of the patentee’s patent, the patentee’s claim will be shown to lack the necessary novelty”.

The point of reference is that known as of the date of publication of the prior art, read in the light of common general knowledge.

There is also a requirement that the disclosure must be ‘enabling’, i.e. sufficient so as to enable the skilled addressee to put the invention into practice: *Asahi Kasei Kogyo KK’s Application* [1991] RPC 485.

**Novelty for Selection Inventions**

As mentioned above, UK case law may be instructive in Singapore, and therefore relevant in ascertaining patentability of selection inventions.

The criteria for a classical ‘selection invention’ were set out in the UK case of *IG Farbenindustrie*, and approved in *Du Pont*. Following these criteria, in order to be a valid selection invention:

- a patent must be based on some substantial advantage (or avoidance of a substantial disadvantage) attributable to the selected members;
- the whole of the selected class must have that advantage; and
- the selection must be in respect of a character that can fairly be said to be peculiar to the selected group.

However, these criteria may cover not only novelty but inventive step issues.

The recent UK case of *Dr Reddy’s -v- Eli Lilly* is helpful with regard to the issue of novelty. In that case, the learned Judge Floyd J referred to the recent UK decision on enantiomers in *Generics v Lundbeck* [2008] EWCA Civ 311. In that case, it was held that a general ‘Markush’ formula does not necessarily destroy the novelty of all the compounds contained within it. Given the large number of compounds disclosed by such a formula, “attention would focus on the compounds actually described”. Moreover, such a disclosure cannot be said to contain “a clear description of, or clear instructions to do or make, something which would infringe the patentee’s claim.” On the facts, Floyd J decided that none of the prior art cited against Eli Lilly’s patent, including a ‘Markush’ formula that covered
olanzapine, destroyed the novelty of the patent because olanzapine was not specifically named or exemplified. Neither was olanzapine obvious in light of the prior art cited.

Floyd J also expressed, in obiter, doubt whether satisfying the criteria in IG Farbenindustrie, would prevent a finding of anticipation if there had been a specific prior disclosure.

Hence, if Singapore adopts a similar position, it would appear that there must not be any specific prior disclosure of any member of the selected group, even if it has a special advantage. Carving a range out of a broad prior art disclosure may be sufficient in respect of novelty, provided that there has been no specific disclosure of the selected group.

The requirement of a different advantage or use or same advantage with an unpredictable improvement appears to be directed more towards the issue of inventive step. In considering novelty, the main issue centres on whether or not the compound has been disclosed.

3) Inventive step or non-obviousness

Groups are asked to discuss the inventive step or non-obviousness requirements in their jurisdiction. If experimental data is used to back up the inventive step or non-obviousness requirement can it be submitted after initial patent filing? Are there any prerequisites or limitations on the late submission of data?

General Law on Inventive Step

The general law on inventive step for patents generally also applies to selection inventions. Section 15 of the SPA provides that an invention must involve an inventive step. An “inventive step” is, in turn, defined as one which is:

[Not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 14(2) and without having regard to section 14(3)].

The state of the art under s 14(2) of the SPA is not only relevant to the discussion of novelty, but is also considered when determining whether an invention is ‘obvious’ for the purposes of adjudicating inventive step.

For an invention to qualify for inventive step a person skilled in the art must not be able to apply known processes forming part of the state of the art to the manufacture of the claimed product. ‘obviousness’ must be assessed with reference to the state of knowledge existing at the date of the patent.

Singapore courts have endorsed and accepted the oft-cited four-step “Windsurfing test” laid down by the English Court of Appeal in Windsurfing International Inc v Tabur Marine (Great Britain) Ltd [1985] RPC 59 (“Windsurfing”) at 73–74 (and adopted by the court in Merck & Co Inc v Pharmaforte Singapore Pte Ltd [2000] 3 SLR 717 at [50]):

There are, we think, four steps which require to be taken in answering the jury question. The first is to identify the inventive concept embodied in the patent in [the] suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being “known or used” and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.

Experimental Data

Under the SPA, there is a requirement that a patent specification cannot be amended in a manner which would result in subject-matter being added to the specification. Therefore,
if experimental data is to form part of the specification, it must be included at the time of filing.

It may be possible to refer to experimental data during the course of prosecution. There are however, no guidelines as to when such data may be taken into account, and this may be in the discretion of the Examiner in considering arguments in the response.

4) Sufficiency and/or written description requirements

Groups are asked to discuss the sufficiency or written description requirements in their jurisdiction. There may be several aspects to this question:

1) the threshold for sufficiency:

Singapore does have sufficiency requirements in respect of patents. The sufficiency requirement is set out in Section 25(4) of the SPA states that:

The specification of an application [for a patent] shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art.

In the case of *Ng Kok Cheng v Chua Say Tiong*, the phrase “clearly and completely” contemplates that the patent specification need not set out every detail necessary for the performance of the invention, but can leave the skilled man to use his skill to perform the invention.

Furthermore, the test of sufficiency has been referred to in the local case of *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd and Another Appeal* [2008] 1 SLR 335; [2007] SGCA 50:

[T]he disclosure must enable the invention to be performed to the full extent of the monopoly claimed: see Biogen Inc v Medeva plc [1997] RPC 1 [at] 48.

Whether the specification is sufficient or not is highly sensitive to the nature of the invention. The first step is to identify the invention and decide what it claims to enable the skilled man to do. Then, one can ask whether the specification enables him to do it. …

There are also two further considerations.

First, the specification of the patent must embrace an embodiment of the invention asserted in each of the claims with sufficient particularity to enable the invention to be understood and carried into effect by those in the industry without making further inventions or prolonged study of the matter. The specification must be set out clearly and fairly so that any individual desirous of carrying out the invention may obtain full knowledge of its practical aspects. But, it is not necessary that the specification be so detailed that this notional individual can perform the invention without any trial or experiment at all.

Second, the description of the invention should not be unnecessarily difficult to follow, and must not contain any traps or seriously misleading statements which the reader cannot correct (see Halsbury’s Laws of Singapore vol 13(3) (LexisNexis, 2007) at para 160.367).

The skilled person is taken to be trying to make the invention work. If the skilled person would quickly realise that one method would work and another would fail, the specification is not insufficient because the claim is expressed in terms broad enough to include both methods.

2) the allowable timing for submission of experimental data;

Experimental data cannot be submitted after filing to fulfil the requirement of sufficiency.
3) the time frame within which sufficiency or written description requirements must be satisfied; and

The patent specification per se must meet the requirement of sufficiency at the time of filing. It is not possible to amend the patent specification to add new matter after filing.

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?

The monopoly in the claim must be coextensive with the novelty. Hence, the claim cannot be broader than the scope of the class of members with the asserted or proven advantages.

If novelty and inventiveness lies in a particular requisite advantage, then all the selected class should possess that novelty and the description should be sufficiently clear and complete. However, the specification does not have to be complete in every single detail. The specification must be set out clearly and fairly so that any individual desirous of carrying out the invention may obtain full knowledge of its practical aspects. Trial or experimentation is permissible, and if a skilled person is able to correct and work the invention despite the fact that one or two examples fall short, the description may be sufficient.

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?

It would depend on the nature of the invention. If the “selection invention” is a new use of a known compound, then the new use must be expressed in the claims. The novelty of the invention must be co-extensive with the monopoly. If however the selection invention comprises compounds within a certain range which have not been disclosed before, it may not be necessary for the utility to be expressed.

Generally speaking, there is a requirement for industrial applicability under the SPA, namely all patents must be industrially applicable or useful in some way.

5) Infringement

If a certain advantage or superior results were the reasons for the grant of a patent on a selection invention, does such advantage or superior result have to be implicitly or explicitly utilised by a third party for an infringement to be established?

It does not have to be implicitly or explicitly utilised by a third party for infringement to be established. Whether or not infringement is proven is dependent on the scope of the claims and whether the alleged infringing act reads on the claims.

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?

6) Policy

Groups are asked to give a short commentary as to the policy that lies behind the law on selection inventions in their jurisdictions, and then to consider whether or not such policy considerations are still valid today as technology continues to advance.
As selection inventions are not treated as a separate category under the SPA, it is difficult to express any particular policy which underpins selection inventions.

In terms of policy considerations, the Singapore Group considers that there may be an “evergreening” concern that selection patents may lead to double patenting or extending the time limit of exclusivity.

On the other hand, this must be balanced with protection for patent owners who should be rewarded if their inventions can satisfy the requirements of novelty, inventive step and industrial applicability. If selection inventions can satisfy these criteria, then the inventions should not be deprived of protection. The issue of double patenting then would not arise.

7) Novelty

In example 1, would the prior disclosure of the compounds containing the generic class of radicals anticipate any claim to a specific compound having a particular radical, or group of specific compounds having a selection of particular radicals in your jurisdiction? In the analysis, does it matter how wide the prior disclosed generic class of compounds is – i.e. would the analysis be different if the prior disclosed generic class consisted of 1,000,000 possible compounds (very few of which were specifically disclosed) as opposed to merely, say, 10?

If novelty can be established, then it should not matter whether there is 1,000,000 possible compounds as opposed to 10 compounds. However from a practical perspective, it may be harder to establish novelty, and indeed inventive step, if the selection is made from 10 compounds.

8) Inventive step or non-obviousness

In example 2, would any of the three possibilities constitute an inventive step over the prior art in your jurisdiction? Further, if, say, scenario (iii) does constitute an inventive step over the prior art, what scope of protection should the inventor be able to obtain? Should the inventor be able to obtain protection for the products per se (that happen to have this advantageous property), or should any patent protection available be limited to the use of the products for the advantageous property (as an adhesive) not possessed by, and not obvious over the prior art?

It would appear that only Scenario (III) would be considered to have inventive step. The inventor should be able to claim the product per se provided it is novel and inventive. Even if you include the advantageous property, it would not confer novelty if the product has already been disclosed. The claim must be defined (even if to the product per se) to ensure that all members of the class have this advantageous property.

9) Sufficiency and/or written description requirements

To what extent are all members of the class selected by the patentee required to possess the requisite advantage in your jurisdiction? Is there an absolute requirement that all of the selected class possess the relevant advantage, or is the patentee excused if one or two examples fall short?

Please see Q4 above.

10) Infringement

By reference to example 3, to what extent is evidence of the knowledge of the advantageous property of the selection, or intention of the infringer as to its supply, required to find infringement in your jurisdiction?
Establishing product patent infringement does not require proving knowledge and intention. For process patent, it must be shown that the infringer knew or that it was obvious to a reasonable person in the circumstances that use of the process would be an infringement of the patent. Whilst there is no provision for contributory infringement under SPA, knowledge or intention may remain relevant in relation to claims of joint tortfeasorship or conspiracy to infringe.

11) Policy

Groups are asked to consider, in respect of example 1 / 2, whether it matters how much effort the inventor has invested in arriving at his selection in order to found a valid selection patent. The answer to this question is closely related to the policy considerations that underpin the grant of selection patents and the incentive / reward equation involved. The inventor may have expended considerable time and money in trawling through the whole host of possible compounds encompassed by the prior disclosed generic class, and the particular selection that he has made may constitute a leap-forward in the field. Surely the inventor should be rewarded for his efforts and obtain protection? On the other hand, it could be argued that such considerations may have been relevant in an age when the inventor’s efforts actually involved many man-years of careful and painstaking laboratory work, but are now increasingly irrelevant in an age of combinatorial synthesis when large varieties of different compounds can be manufactured in a fraction of the time. Are such considerations relevant?

As mentioned above, selection inventions are not treated as a separate category under the SPA, and it is difficult to articulate any particular policy which underpins selection inventions.

However, the Singapore group has discussed possible policy considerations in this area. First, one consideration may be whether such inventions are deserving of, or merit protection. With the advance of technology and scientific tools available to industry, it may be more difficult to establish that there is inventive step in certain inventions if the invention may be derived from a systematic (albeit laborious) process of trial and error.

If the technology is available to make selection inventions more easily discoverable, then should protection exist for such inventions?

However, it does appear that our law in Singapore has safeguards to ensure that the invention merits protection. To illustrate, in assessing inventive step, it is established in case law that if various techniques and processes were available which the man skilled in the art thought were worth trying out to yield beneficial results, or if the same could be said to be ‘lying in the road’ for the research worker to use, then it may be easier to establish that the invention is obvious.


With regard to effort that the inventor has invested, the Singapore Group is of the view that this in itself is not necessarily relevant to the question of inventive step. However, in cases where the effort and investment is great, it may be more difficult it is to show that the invention is obvious because that information would not be in the “common general knowledge” of the person skilled in the art or not so readily available.

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.

The Singapore Group is of the view that selection inventions should not have a different e.g. higher standard of patentability than other types of inventions. Currently in Singapore, selection inventions are treated in the same manner as other inventions.

However, it might be useful to have some guidelines as to novelty, inventive step and sufficiency in this area of selection inventions as they are in a special category. There should also be consensus on how novelty and inventive step should be interpreted, particularly since these issues are closely related. For example, should the particular advantage or utility of the selection invention be considered when assessing the question of novelty?

The Singapore Group also considers that the issue of infringement of selection inventions may merit further consideration as to what comprises infringement of a selection invention, particularly when the peculiar characteristic or advantage of the selection invention is not offered as a feature of the alleged infringing product.

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

The Singapore Group is of the view that the issues mentioned above on harmonisation would merit further discussion.

**Summary**

Under Singapore Patents Law, selection inventions are not treated differently in terms of patentability criteria from other types of inventions. Briefly, a selection invention is considered novel if it has not been disclosed in the prior art, regardless of whether it has the specified advantage or peculiar property of the selection invention. For inventive step, the selection invention must not be obvious to a person skilled in the art. There is also a requirement that the specification shall disclose the invention clearly and completely so that it may be performed by a person skilled in the art. Experimental data may be not be added to the patent specification but may be submitted in the response to the Examiner.

The Singapore Group is of the view that selection inventions should continue be treated in the same manner as other types of inventions as above. However, guidelines as to how novelty, inventive step, sufficiency and infringement may be assessed is worthy of further discussion and harmonisation.