



Question Q209

National Group: United States

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

Contributors: John Osha Chair
William Ellis Co-Chair
Rick Neifeld
Janet MacLeod
Drew Meunier
Jeffrey Bergman
David Chernek
Leslie MacDonell
Gau Bodepudi

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SUMMARY:

U.S. law does not denominate selection inventions as a distinct category of invention. Selection inventions are considered by the United States Patent and Trademark Office (“USPTO”) and the United States Federal Courts under the same criteria (statutory subject matter, written description, enablement, best mode, novelty, and non-obviousness) as any other invention. However, a significant body of case law has evolved to determine how these criteria are applied to selection inventions. Most importantly to this topic, the recent U.S. Supreme Court decision in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (“*KSR*”) changed the required analysis for determining obviousness and made it more difficult to patent selection inventions (and other types of inventions) even where the prior art does not explicitly teach the advantageous properties of the claimed selection. Because of the recent nature of the *KSR* decision, guidance from the Federal Courts on precisely how *KSR* affects patentability of selection inventions is limited as of this date.

Novelty and non-obviousness are considered in the context of the degree of predictability of the subject matter area being claimed. Thus, in general, it is more difficult to obtain a patent to a selection invention in a “predictable” art area (e.g., mechanics, electronics) than in an “un-predictable” art area (e.g., chemistry, biotechnology).

Unlike many other jurisdictions, the U.S. law does not require evidence of advantageous properties of a selection invention to be presented in the application as filed. Rather, such evidence is permitted to be submitted in the form of a declaration after the application is filed. The evidence may be, for example, test data prepared after the date of filing the application, comparing the claimed selection or species to a genus or distinct species identified in the prior art by the USPTO examiner.

In the infringement context, infringement is determined based upon the language of the claims without a *per se* limitation to any advantageous property relied upon to distinguish the prior art. Of course, if the advantageous property or, for example, a new use of a known compound is recited directly in the claim, then such property or use is a limitation for purposes of determining infringement. Further, any arguments made or evidence presented to distinguish the prior art may be relevant to claim construction (determining the proper meaning and scope of the claim) and to analysis of infringement under the Doctrine of Equivalents.

QUESTIONS:

GENERAL

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

Q1. Legal developments on selection inventions

Question 1.1

What specific types of inventions are recognized under the concept of selection invention and are patentable in your jurisdiction?

Response

Answering directly, any selection invention claimed in an application meeting the requirements for patentability under U.S. law is patentable. U.S. statutory law does not refer expressly to selection inventions, but rather provides that “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” may be patented, subject to additional requirements. 35 USC § 101. Thus, any selection invention defining a useful process, machine, manufacture, or composition of matter may be patentable in the United States if it meets the other substantive requirements: novelty (lack of anticipation), non-obviousness, written description, enablement, and best mode. 35 USC §§ 102, 103, 112. Novelty, non-obviousness, and sufficiency of description under U.S. law are addressed in responses to other questions.

Recent legal developments in the United States impact the patentability of selection inventions. The U.S. Supreme Court case *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), unquestionably made it more difficult to establish the non-obviousness of any invention, including selection inventions. While *KSR* dealt with a mechanical invention, it reset the standard for obviousness determinations for all inventions.

Under *KSR*, an examiner or a court may go beyond the express teachings of references to consider “the background knowledge possessed by a person having ordinary skill in the art” and “the inferences and creative steps a person of ordinary skill in the art would employ” in determining if the selection would have been obvious. *Id.* at 1740-41. Thus, *KSR* relaxed a former strict requirement for proof relating to inferences.

KSR also states that the success of one of “a finite number of identified, predictable solutions, . . . is likely the product not of innovation but of ordinary skill and common sense,” and if so, is not patentable. *Id.* at 1742. The foregoing passage limits the probative value of the number of elements in a genus in determining obviousness of selected species.

KSR also allows a claim to be held obvious based upon an “obvious to try” standard, stating that the lower court “conclude[d], in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was ‘obvious to try.’” *Id.* This statement in *KSR* was not specific to the mechanical invention at issue. In fact, the Board of Patent Appeals and Interferences (“the Board”) of the U.S. Patent and Trademark Office (“USPTO”) latched onto this statement in a rare precedential decision in a biotechnology case, *Ex parte Kubin*, stating that “‘obvious to try’ may be an appropriate test in more situations than we previously contemplated.” 83 U.S.P.Q.2d 1410. The Board’s decision in *Ex parte Kubin* was appealed to the U.S. Court of Appeals for the Federal Circuit (“the Federal Circuit”), the appellate court with exclusive jurisdiction over patent matters in the United States. The

Federal Circuit heard oral arguments in January 2009 and is expected to render its decision sometime this year.

That said, selection invention patents continue to issue from the USPTO, typically in the areas of chemistry, pharmaceuticals, and biotechnology. This is primarily because these technological areas are recognized by the courts as unpredictable art fields. See *Eisai Co. v. Dr. Reddy's Labs, Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (“To the extent an art is unpredictable, as the chemical arts often are, KSR’s focus on these ‘identified, predictable solutions’ may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.”).

Post *KSR*, the obviousness determination still requires two distinct elements: (1) motivation; and (2) reasonable expectation of success. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1360 (Fed. Cir. 2007). Failure to proffer sufficient proof of either element leads to a conclusion of non-obviousness. *Id.* (finding no prima facie obviousness because defendant could not show either motivation to select the inventors’ chosen starting compound or any expectation that the inventors’ chosen modifications would succeed). In the unpredictable fields of chemistry and biology, it is easy to see the logic and effectiveness of an argument for patentability premised on a lack of reasonable expectation of success. Accordingly, many, though certainly not all, selection invention patents issue because the prior art does not provide a basis for one skilled in the art to reasonably expect success in obtaining the invention as claimed.

Question 1.2

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

Response

After *KSR*, it is less likely for a selection invention in the more predictable art fields to be found patentable. However, a recent opinion of the Federal Circuit explained that, while “*KSR* cautioned us to not be too rigid ..., we may still consider evidence of teachings to combine (and, presumably, not to combine) because, according to the Supreme Court, they ‘capture[] a helpful insight’ into the obviousness inquiry.” *Anderson Corp. V. Pella Corp.*, No. 2007-1536, 2008 SL 4927431, at *6 (Fed. Cir. Nov. 19, 2008). Presumably, a teaching “not to combine” a selected element of a disclosed list of elements, would enable a claim to that selected element to be found non-obvious and therefore patentable.

Q2: Novelty

Question

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

I. CLAIMS TO COMPOUNDS

In United States Patent Law, it is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus. In fact, there may be many species encompassed within a genus that are not disclosed by a mere disclosure of a genus.

However, there are cases in which prior disclosure of a genus class anticipates a claimed species within that genus. To determine whether a prior-disclosed genus class anticipates a claimed species, a case-by-case analysis needs to be conducted. Although there is no clear-cut answer, there are a number of factors that are typically taken into account when determining whether a prior-disclosed genus class anticipates a claimed species within that genus.

A. If the claimed species is well delineated in the prior-disclosed genus class, there is a greater probability the claimed species will be anticipated.

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. For example, if a prior art reference discloses a class of compounds and expressly spells out a definite and limited class of compounds that enables a person of ordinary skill in the art to at once envisage each member of the limited class, then anticipation will most likely be found. But if the members of the class cannot be envisioned, the reference will likely not be found to anticipate the claimed species.

To illustrate, where a broad generic formula of the prior art describes a near infinite number of compounds, and the claim-at-issue is limited to a structure with only one variable substituent, one of ordinary skill in the art would likely not "at once envisage" the claimed subject matter of the reference.

To determine whether one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, one of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged."

B. If the prior-disclosed genus class is a large class, there is a smaller probability the claimed species will be anticipated.

In general, if the genus includes an untold number of species, then anticipation will less likely be found. As an example, the genus alkaline chlorine or bromine solution has been found to not anticipate the species alkali metal hypochlorite, since the genus would include an untold number of species. As another example, where the prior art discloses a generic chemical formula wherein X, Y, Z, P, and R- represent either hydrogen or alkyl radicals, R a side chain containing an OH group, this formula, without more, would not anticipate a claim to 7-methyl-9-[d, l"-ribose]-isoalloxazine, because the generic formula encompassed a vast number and perhaps even an infinite number of compounds.

C. If the prior-disclosed genus class includes a limited number of compounds, there is a greater probability the claimed species will be anticipated.

A very small genus can be a disclosure of each species within the genus. Hence, the disclosure of a small genus may anticipate the species of that genus even if the species are not themselves recited. In particular, where the genus embraces a very limited number of compounds closely related to one another in structure, then anticipation will more likely be found.

As an example, where a prior art reference teaches a generic formula embracing a limited number of compounds closely related to each other in structure, and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound, anticipation will likely be found.

On the other hand, if the genus class would not embrace a very limited number of compounds closely related to one another in structure so as to describe each such compound as surely as if they were identified in the reference by name, then the claimed species will likely not be anticipated.

D. If the prior-disclosed genus class includes a preference or provides guidance that points to the claimed species, there is a greater probability the claimed species will be anticipated.

Disclosure of a chemical genus in a reference may anticipate a claimed species compound where the reference states preferences for the genus or provides guidance that point to the specific compound. For example, if the reference discloses preferred substituents for X, Y, Z, >P, < R, and Rⁿ as follows: where X, P, and Rⁿ are hydrogen, where Y and Z may be hydrogen or methyl, and where R is one of eight specific isoalloxazines, and disclosed a limited generic class consisting of about 20 compounds, where the claimed compound was 1 of these 20 compounds, the reference effectively described the claimed compound and the reference anticipated the claims.

But if the prior art does not disclose a “pattern of preferences” that would limit the species to a narrow class of compounds, then the claimed species will likely not be anticipated. For example, for a prior art reference that disclosed a free base compound (MATTPCA) in combination with a preferred salt (hydrochloride), the prior art reference did not anticipate a patent that claimed the free base compound in combination with a different salt (specifically, a bisulfate salt of a dextrorotatory enantiomer of the free base compound (clopidogrel, MATTPCA)). The prior art reference did not state a “pattern of preferences” that would limit the generic formula of MATTPCA in the prior art reference to a narrow class of compounds that includes the compound as claimed (MATTPCA’s d-enantiomer bisulfate salt).

Furthermore, there is likely no anticipation if the reference’s disclosure is so broad as to be meaningless and provides no insight on how to create a product with the beneficial properties of claimed species. For example, if a reference discloses millions of possible compounds, where no combination of the reference’s preferred compounds would yield the claimed compound and where none of the reference’s preferred compounds resembles the claimed compound, then anticipation will likely not be found.

E. If the species claim covers a discovery of a property or function not disclosed in the prior art genus-disclosure, there is a smaller probability the claimed species will be anticipated.

If the claimed species covers a property or function not disclosed by the prior-disclosed genus class, then the claimed species may not be anticipated. A court in the United States

noted that, generally speaking, there is nothing unobvious in choosing some among many indiscriminately, but where the choice is based on a discovery that some compounds, falling within a prior art genus have special significance, then the species claims will likely not be anticipated.

F. If experimentation is necessary to arrive at the claimed species from the prior-disclosed genus class, there is a smaller probability the claimed species will be anticipated.

In determining whether anticipation of a claimed species exists, courts in the United States may ask whether additional experimentation was necessary to arrive at the claimed species from the prior-disclosed genus class. As an example, there is likely no anticipation where one would have to experiment with a large number of possible intermediates referred to in the prior art reference and successfully piece together the necessary ones to come up with the one generic formula out of a total of twenty-seven generic formulae and then would have to experiment further to discover the specific structure of Red 40.

II. CLAIMS TO RANGES

A. A specific example in the prior art which is within a claimed range anticipates the range.

When, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated if *one* of them is in the prior art. For example, claims to titanium (Ti) alloy with 0.6-0.9% nickel (Ni) and 0.2-0.4% molybdenum (Mo) were anticipated by a graph in a Russian article on Ti-Mo-Ni alloys, because the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo and 0.75% Ni and this composition was within the claimed range of compositions.

B. Prior art which teaches a range overlapping or touching the claimed range anticipates if the prior art range discloses the claimed range with "sufficient specificity."

When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case-by-case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with sufficient specificity to constitute an anticipation under the statute. What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims.

For example, a reference temperature range of 100-500 degrees C did not describe a claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching.

C. Prior art which teaches a value or range that is very close to, but does not overlap or touch, the claimed range does not anticipate the claimed range.

Anticipation under § 102 can be found only when the reference discloses exactly what is claimed. For example, claims to titanium (Ti) alloy with 0.8% nickel (Ni) and 0.3% molybdenum (Mo) were not anticipated by, although they were held obvious over, a graph in a Russian article on Ti-Mo-Ni alloys in which the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo and 0.75% Ni.

III. CLAIMS FOR NEW USES

A claim for a new use of an old compound is novel unless it is exactly disclosed in the prior art.

A. If the claimed species is actually disclosed in the prior-disclosed genus class, then there is a greater probability the use of the claimed species will be anticipated.

If there is a specific disclosure of a claimed species, even if in a list, then it is not the case where a broad genus is disclosed without reference to the potentially anticipating species. In this scenario, there is a greater chance of anticipation of the claimed use. For example, where a patent-at-issue concerned a method of preventing and treating skin disorders by topical application of a composition with ascrobyl palmitate as an ingredient, a prior art reference that taught topical application of a composition that included ascrobyl palmitate as one “among many others” anticipated some of the claims-at-issue.

B. If the prior-disclosed genus class lists a species compound for a given purpose and if the species compound is claimed for a different purpose, then the claimed use may not be anticipated.

Even if the species compound is disclosed in the prior-disclosed genus class, anticipation of the use is not necessarily automatic. For example, where you have a method of using a compound to treat a specific disease and the prior art discloses the compound for another use, then a claim to a new use for the species may not be anticipated.

To illustrate, where a patent claims a method of treating a disease (urolithiasis) by administering an effective amount of 4-amino-1-hydroxybutane-1,1-biphosphonic acid, the species claim was not anticipated by a prior art reference that disclosed various biphosphonic acids including 4-amino-1-hydroxybutane-1,1-biphosphonic acid, but stated that the disclosed compounds are suitable for the production of cosmetic and pharmaceutical preparations. Since the reference did not suggest the claimed therapeutic use, it did not anticipate the claimed use of the species.

Q3: Inventive Step or non-obviousness

Question

Discuss the inventive step or non-obviousness requirements in your 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?

Response

The general issues related to inventive step or non-obviousness are described below. Similar to the response for Q2 novelty / anticipation, non-obviousness for selection patents is taken on a case-by-case basis.

In assessing obviousness under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Objective evidence of non-obviousness, such as commercial success, long-felt but unsolved needs, failure of others, etc., also may be relevant, shedding light on the circumstances surrounding the origin of the subject matter sought to be patented. Recently, the U.S. Supreme Court held in the *KSR* decision that if a person can implement a predictable variation, § 103 likely bars its patentability.

The patentability of a claim to a specific compound or subgenus embraced by a prior art genus is analyzed no differently than any other case by the USPTO. In the case of a prior art reference disclosing a genus, the USPTO is required to look at the following criteria:

- (A) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus;
- (B) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus;
- (C) the predictability of the technology; and
- (D) the number of species encompassed by the genus taking into consideration all of the variables possible.

Once the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus are identified, the Examiner is required to make explicit findings on the similarities and differences between the closest disclosed prior art species or subgenus of record and the claimed species or subgenus including findings relating to similarity of structure, chemical properties and utilities. The Examiner should then consider all relevant prior art teachings and determine whether it would have been obvious to one of ordinary skill in the relevant art to select the claimed species or subgenus from the disclosed prior art genus. This analysis includes considering whether the prior art teaches away from the claimed species or subgenus.

With respect to numerical ranges, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not considered inventive to discover the optimum or workable ranges by routine experimentation. Again, the Examiner is required to consider all relevant prior art teachings, including prior art that teaches away from the claimed range, and determine whether it would have been obvious to one of ordinary skill in the relevant art to select the claimed range.

An obviousness rejection for a selection invention can be overcome by providing evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Experimental data can be provided in the form of an affidavit after the initial patent filing that includes test results demonstrating that unexpected properties exist for the claimed species. These test results can be created after the filing of the application and their submission is not generally considered to raise new matter. There are no prerequisites or limitations on the late submission of experimental data. For example, the specification does not need to disclose proportions or values as critical for applicants to present evidence showing the proportions or values to be critical.

Q4 Sufficiency and/or written description requirements

Question

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

United States patent law requires that the specification provide a written description of the invention, an enabling disclosure, and disclosure of the best mode of carrying out the invention:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. §112, first paragraph.

The written description requirement is distinct from the enablement provision, which requires disclosure of sufficient information to allow one of skill in the pertinent art to make and use the claimed invention in the absence of undue experimentation, and the best mode provision, which requires disclosure of the best mode contemplated by the inventor of carrying out the invention.

In order to comply with the written description requirement, the specification must reasonably convey to one of ordinary skill in the art that, as of the filing date of the application, the inventor was in possession of the claimed invention. Possession may 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 include words, structures, figures, diagrams, and formulas.

The issue of adequacy of written description may arise in assessing whether an original claim is supported by the specification as filed, or whether a claimed invention is entitled to priority of an earlier application. More typically, however, it arises in the context of whether a newly added or amended claim is supported by the specification as filed.

Adequacy of written description is determined on a case-by-case basis and is a question of fact. A literal description of a species or a numerical range is generally sufficient to support

the species or range. However, the subject matter of the claim need not be literally described in the specification if the disclosure reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter.

A claim to a genus or a subgenus generally requires sufficient written description of a representative number of species. In some cases, a claim to a subgenus may be supported by disclosure of a genus and a species falling within the subgenus. In particular, a disclosure that describes a species may be found to support a claim to a subgenus or genus if the disclosure conveys characteristics common to all species. For chemical and biotechnological inventions, a description of a representative number of species by relevant identifying characteristics such as structure, or functional characteristics accompanied by a correlation of structure with function, is required to satisfy the written description requirement for a subgenus or genus. The “representative number” of species is inversely proportional to the predictability of the art.

The patent statute prohibits the introduction of new matter into the specification of an application, and thus adequate written description for the claimed subject matter must be present in the application as filed.

However, experimental evidence to overcome a rejection of obviousness of a species in view of prior art disclosing a genus may be submitted after filing. Evidence of unexpected advantages or superior properties may be submitted by affidavit or declaration. The evidence must be commensurate in scope with the claimed invention. However, evidence of unexpected results for a single species within a subgenus, or a portion of a claimed range, may be sufficient if the skilled artisan could identify a trend or determine a basis to conclude that other species within the subgenus would exhibit the same results.

If a new utility is asserted as the basis for a selection invention and the particular range or selection of components is otherwise novel and nonobvious, the utility need not be recited in the claims. However, if the range or components are otherwise known in the art, it would be necessary to recite the new utility. If the components are not disclosed in the art but the prior art provides a different reason to select the claimed species, subgenus, or range, a recitation of utility (i.e., a method of use claim) would be necessary.

Q5: Infringement

Question 5.1

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

Assuming the advantage or result is not directly claimed, the answer is no. Under U.S. law, advantages and/or superior results may be relevant to the obviousness inquiry. However, once issued, infringement is determined based on the wording of the claims themselves, not on the results or advantages achieved.

Notwithstanding this general rule, the advantages or results may affect the infringement determination in two ways. First, if a doctrine of equivalents analysis is applied to the pertinent element, a court would be unlikely to find an accused product or method to be within the scope of equivalents if the corresponding element in the accused product or

method does not achieve the stated advantage or result (*i.e.*, it would be considered more than an “insubstantial difference”). Second, if an issue of claim construction arises as to one or more term in the pertinent element of the claim, a Court during a Markman Hearing (a hearing to determine claim scope) will, where rational interpretation permits, strive to construe the element in a way limited to elements that achieve the alleged advantage or result.

Bald statements of advantages and results in apparatus claims are not given weight in claim construction under U.S. law. However, a resourceful claim drafter may be able craft an apparatus claim that directly claims an advantage or result. Similarly, such limitations may be incorporated into processes or method of use claims. Where a result or advantage is directly claimed, the accused product or method would need to obtain the result or advantage in order to infringe.

Question 5.2

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

If the selection invention is validly claimed as a new use, the use would be required for infringement. A manufacturer of a product that may be used for the new use would be liable for infringement, if at all, under the theory of indirect infringement. Indirect infringement first requires that there be direct infringement by some party. It then takes two forms: contributory infringement and inducement to infringe.

Contributory infringement liability arises when one “sells within the United States . . . a component of a patented machine . . . knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.” 35 U.S.C. § 271(c) (2005). Thus, in order to prove contributory infringement a patentee must show that an alleged contributory infringer “knew that the combination for which its components were especially made was both patented and infringing.” *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004). In addition, the patentee must show that the alleged contributory infringer’s components have no substantial non-infringing uses.

35 U.S.C. § 271(b) (2005) states, “Whoever actively induces infringement of a patent shall be liable as an infringer.” A finding of inducement requires both an underlying instance of direct infringement and a requisite showing of intent. However, the Federal Circuit has not resolved what level of intent is required. See *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990) (“The plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.”). But see *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) (“Proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement.”)

Intention of the accused infringer does not play any role in the determination of infringement. The intention of the accused infringer is relevant, if at all, only to the amount of damages awarded if infringement is found. U.S. law permits actual damages for patent infringement to be increased up to three times in cases where willful infringement is found (to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted

despite an objectively high likelihood that its actions constituted infringement of a valid patent.)

Q6: Policy

Question

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

The policy consideration behind granting patents on selection inventions is ultimately the same consideration for the granting of *all* patents, namely, to encourage innovation. If inventors received no protection for their innovations, the inventor would have little reason to develop new technologies. Similarly, if inventors of new species of use, products, and processes developed from an analysis of a known genus were provided no protection, the impetus for analyzing what is known in the art would be less.

The U.S. policy on patentability of selection inventions reflects a desire to have a single standard for patentability, regardless of category of invention. Thus, selection inventions are not specifically denominated as such, and are subject to no specific additional requirements for patentability. However, the policy of considering the degree of predictability of the subject matter area as part of the novelty and obviousness inquiries, particularly when taken in view of *KSR*, reflects a desire to tie patentability as closely as possible to the real-life expectations and abilities of a person of ordinary skill in the relevant art. U.S. policy in this area thus strives to achieve a balance between encouraging innovation from within known areas of technology while avoiding usurping obvious and common-sense selections from the public domain.

From the infringement standpoint, the primary policy consideration is to have a clear delineation of claim scope so that patentees and third parties alike can make informed business decisions. This consideration is borne out by a system that limits the claims to a particular advantage, result, or use only when such advantage, result or use is explicitly recited in the claim in limiting fashion. Moreover, for the same reason, U.S. policy avoids introducing a requirement for intent by the infringer to achieve the particular advantage, result, or use (except in the case of inducement to infringe which necessarily involves intent of the inducer) as to do so would introduce limitations beyond the wording of the claims themselves.

The policy considerations above continue to be relevant and valid today.

WITH REFERENCE TO THE EXAMPLES

Q7: Novelty

Example 1

Say a prior art document discloses a chemical compound characterised by a specified structure including a substituent group designated "R". This substituent "R" is defined so as to embrace a generic class of broadly-defined functional groups such as

all alkyl or aryl radicals, either unsubstituted or substituted by a halogen and/or a hydroxyl group, although for practical reasons only a very small number of specific examples are given. The (later) alleged invention consists of the selection of a particular radical or particular group of radicals from amongst the generic class, where the selected radical or group of radicals were not specifically disclosed in the prior-art document. The resulting compounds are described as having a new, advantageous property, say as adhesives, not possessed by the prior art examples.

Question 7.1

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?

Response

A prior disclosure of compounds containing a generic class of radicals would not necessarily anticipate a claim to a specific compound having a particular radical or group of specific compounds having a selection of particular radicals. In the above examples, since the substituent embraces a generic class of broadly-defined functional groups, the selected radical or group of radicals were not specifically disclosed in the generic class, and the resulting compounds have new, advantageous properties not possessed by the prior art examples, all of these factors weigh in favor of a finding of no anticipation of the claimed species.

Question 7.2

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

Yes, the breadth of the prior-disclosed generic class of compounds is relevant to the anticipation analysis. The greater the number of compounds in the prior-disclosed generic class, the less likely the claimed species compound will be anticipated by the prior-disclosed generic class of compounds.

Q8: Inventive Step or Non-obviousness

Question

In Example 2, would any of the three possibilities constitute an inventive step? If scenario (iii) does, what scope of protection should the inventors be able to obtain (products, use, etc.)?

Response

With regard to Scenario (i), the alleged invention would likely be considered obvious because the disclosure indicates nothing to distinguish the claimed species from the genus. Nevertheless, as discussed above, despite the fact that the specification does not describe

any new advantageous properties over the compounds specifically disclosed in the prior art, the inventors could provide evidence in prosecution that the claimed species possesses unexpected properties to demonstrate that the claimed species is not obvious.

In Scenario (ii), the advantageous properties would be expected by one skilled in the art. The claimed species would be considered obvious if it is just combining prior art elements according to known methods to yield predictable results. Thus, the alleged invention would likely be considered obvious. In this case, assuming that the prior art demonstrates that one of ordinary skill in the art would be motivated to use the claimed species or that the claim species is predictable, it would be difficult to use unexpected properties to overcome the obviousness rejection.

In Scenario (iii), there are advantageous properties, and nothing in the prior art would indicate to a person skilled in the art to select the claimed species for the advantageous property. In such a case, a finding of non-obviousness may be supported, as the advantageous property may not be inherent in the prior art, and the results of the combination would not be expected by one skilled in the art. Evidence to support the unexpected property could be provided in the original application or provided during prosecution as discussed above.

With regard to protection that may be obtainable, the composition itself may not be patentable. As noted above, an old composition is not patentable just because of a newly discovered property or use. However, claims directed toward processes or methods of using the composition may be patentable, where such processes and methods are directed take advantage of the unexpected property (i.e., methods using the compound in the same uses as disclosed in the prior art would not be patentable, as the compound and the use are already disclosed). An adhesive comprising the particular species would also be likely patentable.

Q9: Sufficiency and/or written description requirements

Question

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 discussed in Q4, evidence of an unexpected advantage for a single species may be sufficient to support the patentability of a subgenus if there is a basis for the skilled artisan to conclude that other species would exhibit the same advantage. However, if the scope of the claims includes a significant number of inoperative embodiments and undue experimentation would be required to determine the operative embodiments, the claims would be deemed nonenabled.

Q10: Infringement

Question

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

Assuming direct infringement occurs, contributory infringement may be found on the part of the manufacturer if it is aware that the compound is especially made or especially adapted for use in an infringement, and the compound is not a staple article or commodity of commerce suitable for substantial non-infringing use. Intent is not required for contributory infringement.

Again assuming direct infringement occurs, inducement to infringe may be found on the part of the manufacturer if intent to infringe can be shown.

Q11: Policy

Question

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

In general, the manner in which the invention was made is not relevant to patentability. As set forth in 35 U.S.C. §103, “[p]atentability shall not be negated by the manner in which the invention was made.” However, evidence of extensive efforts may be relevant to a determination of nonobviousness, *e.g.*, to show that one of ordinary skill in the art would not have had a reasonable expectation of success based upon the prior art.

With specific reference to the chemical arts, and examples 1 and 2 above, if the species of compounds having advantageous properties not possessed by the prior art examples are in fact non-obvious in view of the disclosure of the genus, there is no policy reason precluding their patentability. This remains true regardless of the amount of time and resources expended in uncovering the new species compounds.

The ultimate policy rationale behind the patent system is to encourage innovation. If an inventor is denied a patent because the inventor did not engage in many years of careful and painstaking laboratory work, the entire ethos of the patent system is called into question.

The question of whether a particular product, process, or use is patentable should depend on the novelty and nonobviousness of the product, process, or use. While the time and resources spent developing a particular product, process, or use may be a secondary consideration in assessing patentability (to show what would or would not have been obvious to a skilled artisan), the policy of encouraging innovation would be undermined by a system that rewarded patents based primarily (or even in part) on the amount of time and resources spent.

HARMONISATION

Q12:

Question

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.

Response

The patentability of selection inventions should be based upon a single, clear standard of patentability that is applicable to all inventions. The time and effort needed to identify the selection should not be a *quid pro quo* for patentability. The standard for patentability of selection inventions should, as with all inventions, consider what is actually taught by the prior art (for example, a limited genus with common properties versus a genus containing an infinite number of compounds) in light of how the members of that genus would realistically be understood by a person of ordinary skill in that art.

Infringement of claims to selection inventions should be determined based upon the language of the claims themselves. Thus, if a specific property or use is claimed, it should be limiting, and if it is not claimed, it should not be limiting. To do otherwise greatly complicates the infringement analysis and creates unnecessary cost and uncertainty in the marketplace.

Intent of the infringer to obtain a claimed property or to perform a claimed use should 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.

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, introduces uncertainty, and invites unintentional loss of rights.

Q13:

Question

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

Response

[none]

Q14:

Question

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

Response

[none]