Question Q238

National Group: South Korea

Title: Second medical use or indication claims

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Reporter within Working Committee: [Please insert name – last name in CAPITAL letters please]

Date: [Please insert date]

Questions

I. Current law and practice

Groups are invited to answer the following questions under their national laws. If those national and regional laws apply to a set of questions, please answer the questions separately for each set of laws.

Please number your answers with the same numbers used for the corresponding questions.

1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?

   ➔ Yes

   If yes, please answer Questions 2) to 7) inclusive before proceeding to the questions in Parts I and II. If no, please proceed directly to the questions in Parts II and III.

2) If the answer to Question 1) is yes, please answer the following sub questions.

   a) What is the basis for patent protection?

   ➔ Although the Korean Patent Act (KPA) does not include a specific provision for medical use or second medical use inventions, second medical use claims have been allowed since July 1, 1987 because a provision defining “a use of a chemical compound” as a non-patentable subject matter in the old KPA was deleted from the amended KPA effective July 1, 1987. Further, the Korean Intellectual Property Office (KIPO) provides Examination Guidelines concerning medicinal inventions.

   b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

   ➔ The types of second medical uses recited in paragraphs 14) – 16) WGLs are patentable. For example, a new therapeutic indication and a new drug formulation are patentable. Further, in the case where a side effect is reduced in a special subject patient group (e.g., hepatically impaired patients), a
claimed invention limiting the patient group is recognized as a second medicinal use invention\(^1\). A combination of two or more known drugs can also be patentable as a second medicinal use invention if it exerts a significant effect of a known use or new medicinal use.

c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

→ Regarding the new dosage regime recited in 17) WGLs, the Korean Supreme Court ruled in 2009 that claim limitations related to an administration regimen, such as the dosing interval and unit dosage, must be ignored when assessing the patentability of a pharmaceutical composition invention\(^2\). This ruling has been followed by a number of subsequent Patent Court decisions where a new dosage regime is not recognized as a typical medicinal use that can be protected by patent law. However, this is still controversial and several cases disputing the principle above are currently pending at the Intellectual Property Tribunal and the Patent Court.

d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.

→ KIPO Examination Guidelines stipulate that medicinal use claims should be in a product format, generally in the form of “a pharmaceutical composition for treating disease Y comprising compound X.” Medicament and kit formats are also permissible.

e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.

→ Claims other than product-type claims, treatment method claims, and claims commencing with the term “use” including a Swiss-type claim, etc. are not allowable. Further, according to the KIPO Examination Guidelines, since the claim format “compound X for use in treating disease Y” is considered to claim “compound X per se, not a medicinal use, such a claim is only allowable when “compound X per se is patentable.

f) Has any guidance been provided by courts or the national patent office in

\(^1\) In re Merelle Pharmaceutical Inc, Patent Court 2002 Heo 4460 issued on July 11, 2003: “B. Whether the invention in this case corresponds to a second medical use invention... (omitted)... In light of the above, the invention (limited to hepatically impaired patients) provides a new effect in that a terfenadine acid derivative having antihistamine activity does not cause heart disease because it does not reduce action potentials and currents of various heart cell membranes, contrary to conventional terfenadine that may cause side effects related to heart disease in patients with impaired hepatic function. Accordingly, the subject invention is supposed to be a second medicinal use invention based on the discovery that a terfenadine acid derivative has a second new pharmacological effect as described above, which differs from the medicinal use of terfenadine, in addition to the first pharmacological effect of terfenadine.”

\(^2\) In re Merck, Supreme Court 2007 Hu 2933 issued on May 28, 2009: "Claim 9 of the subject patent is directed to a composition invention characterized by a dosing interval and a dosage amount of bisphosphonate, which is a known substance. However, such technical features are not elements constituting the presently claimed medicinal composition but rather correspond to a method of administering the medicinal composition to a human being. Since the technical features correspond to a medical activity using a medicament, which cannot be patented, or do not relate to the final product per se obtained based on the description of the claim that can be compared with the cited prior art, they cannot be considered in assessing the inventiveness of the Claim 9 invention."
relation to the meaning, scope and/or effect of 'treatment', 'treating' or 'use to treat' integers in second medical use claims? See, for example, paragraphs 34) - 39) above WGLs.

➔ There is no provision in the KPA on the definition of "treatment". The Patent Court held that the definition of "treatment" generally encompasses not only treating a disease but also alleviating or preventing a disease or enhancing health conditions (Patent Court 2007 Heo 13827 issued on June 26, 2008). For reference, the KIPO Examination Guidelines concerning medicinal inventions define "medicine" as a drug used for the purpose of diagnosis, treatment, alleviation, management, or prophylaxis of a disease of an animal including a human, except for devices, cosmetics, and foods.

On a related issue, for a medicinal use invention, Korean patent practice requires that the original specification contain quantitative pharmacological data for the claimed active ingredient, unless the relevant pharmacological mechanism was established before the filing date of the patent application. Since this is related to the enabling description requirements, the later addition of such data to the specification is not allowed (for constituting new subject matter), nor can such data be cited in an office action response. The Korean Supreme Court has also affirmed the KIPO practice above since 2001.

3) If your country permits second medical use claims:

a) Who may be liable for infringement of such claims? For example:

   i) the party marketing the drug with label instructions which describe the patented use;

➔ Liable.

Marketing a drug with label instructions describing the patented use would be considered as one of the acts specifically stipulated in Article 2 of the KPA (i.e., in the case of an invention of a product, acts of manufacturing, using, assigning, leasing, importing, or offering to assign or lease (including displaying for the purpose of assignment or lease).

   ii) the physician prescribing the drug for such use;

➔ May not be liable.

Although there is no case law on this issue, the act of a physician prescribing a drug for a patented use would not constitute any direct infringement since prescribing is not likely considered as an act of “using” the drug under the KPA.

In theory, if the prescribing actively instructs and guides a pharmacist to dispense a drug for a patented use, it might be construed as aiding and abetting the infringement of a patent under general tort theory under the Korean Civil Act (KCA). That is, under the KCA, one who aids and abets an illegal act is jointly and severally liable for the illegal act. However, in light of the relationship between physicians and pharmaceutical companies, aiding and abetting of infringement would not likely be asserted in actual cases.

   iii) the pharmacist dispensing a drug for such purpose;
May be liable for the general act of dispensing a drug for a patented use but is not liable for dispensing a combination drug under an exemption provision of the KPA.

Under Article 96(2)³ of the KPA, a patent right for a combination drug manufactured by mixing two or more medicines or a method thereof does not extend to a pharmacist’s act of dispensing medicines under the Pharmaceutical Affairs Act.

Although there is no case law on whether the exemption provision even applies to a pharmacist’s general act of dispensing under the Pharmaceutical Affairs Act, given the provision of the KPA only specifying a combination drug or its preparation method, the pharmacist’s act of dispensing a drug for a patented use is likely to infringe a patent which has been granted on a drug or a method but not a combination drug or a preparation method thereof.

iv) the patient using the drug for such purpose?

Not liable.

A patient’s use would not be considered as an infringing act under the KPA since it is for personal use, not for commercial purposes.

b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?

As discussed in question a), ii) a physician’s prescribing and iv) a patient’s use are likely to be exempt from patent infringement. Further, iii) a pharmacist’s dispensing is exempt from patent infringement of a combination drug or its preparation method claim.

c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.

Yes, they are enforceable on the basis of both direct and indirect infringement if the requirements under the KPA are fulfilled.

The “working of an invention” means any of the following acts defined in Article 2 of the KPA, and any unauthorized working of a patented invention for business is considered to constitute infringement (“direct infringement”) (Article 94 of the KPA):

³ Article 96 (Limitations on a Patent Right)
(1) The effects of the patent right shall not extend to the following:
   (i) Working of the patented invention for the purpose of research or testing (including research or testing for the purpose of drug approval according to the Pharmaceutical Affairs Act and agrochemicals registration according to the Agrochemicals Control Act);
   (ii) Vessels, aircrafts or vehicles merely passing through the Republic of Korea, or machinery, instruments, equipment or other accessories used therein; or
   (iii) Articles existing in the Republic of Korea at the time the patent application was filed
(2) The effect of a patent right for the invention of a medicine (i.e., a product used for diagnosis, therapy, alleviation, medical treatment, or prevention of a human disease) that are manufactured by mixing two or more medicines, or for the invention of a process for manufacturing medicines by mixing two or more medicines, do not extend to acts of dispensing medicines under the Pharmaceutical Affairs Act or to medicines dispensed by such acts.
(a) In the case of an invention of a product, acts of manufacturing, using, assigning, leasing, importing, or offering to assign or lease (including displaying for the purpose of assignment or lease) the product;
(b) In the case of an invention of a process, acts of using the process; and
(c) In the case of an invention of a process for manufacturing a product, acts of using, assigning, leasing, importing, or offering to assign or lease the product manufactured by the process in addition to the acts mentioned in item (b).

The KPA provides that any of the following acts is considered to constitute indirect Infringement under Article 127:

(i) an act of making, assigning, leasing, importing, or offering to assign or lease articles used exclusively for the production of a patented article; or
(ii) an act of making, assigning, leasing, importing, or offering to assign or lease articles used exclusively for the practice of a patented process.

Thus, in order to establish indirect infringement under the KPA, it must be shown that an accused product has no alternative use except for use for the patented article or process. An alternative use should be commercially or economically practical in the art, and a theoretical, experimental, or temporarily feasible use is not considered as an alternative use under Korean case law. While Korean courts found indirect infringement in a few cases, there has been no case law recognizing indirect infringement of a medicinal use claim.

For a second medical use patent, it would be very unlikely that indirect infringement would be found since, by definition, the medicine has an alternative use (i.e., the first use).

4) If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?

⇒ Yes, if a party makes or supplies a generic version of a drug for a use that falls within the scope of a medical use patent, such an act constitutes patent infringement.

In principle, however, if a party makes or supplies a generic version of a drug for a use that does not fall within the scope of a medical use patent, such an act does not constitute patent infringement.

Recently, a Korean district court held in a preliminary injunction case that even though the product information leaflet of the generic product carved out the patented use ("skinny labeling"), the generic company's act can be found to constitute infringement under the KPA (see Warner-Lambert Company LLC et al. v. Samjin Pharm. Seoul Central District Court 2013 Kahap 1717 decided on February 5, 2014).

In this case, the district court has noted a number of facts based on which the generic company is liable for patent infringement. They include: (i) the generic company made and sold the generic product for the patented pain indication (obtaining an approval for the patented pain indication as well as non-patented indications and listing a drug price reimbursement with the relevant authorities); (ii) the generic company began manufacturing and marketing the product for the pain indication; (iii) although the generic company deleted the pain indication only from the revised leaflet without changing the approved indications of the generic product, the leaflet still
contained in the general warning section that the product is effective for the pain indication; (iv) as of the court decision date, the generic product was being prescribed significantly for the pain indication; (v) as of the court decision date, the generic product was listed in a number of hospitals as one of the pain indication drugs; and (vi) the sales volume of the generic product has been continuously increased.

From the above facts, although the generic company argued that they deleted the pain indication from the leaflet and did not market the product for the pain indication, the court held that the generic company’s manufacturing and selling the generic product for the non-patented use directly infringes the second medicinal use patent at issue.

5) If the answer to Question 4) is yes, please answer the following sub questions in that context.

a) Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts which constitute infringement.

➔ Yes, each of the acts fulfills the direct infringement requirements defined in Article 2 of the KPA.

b) Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?

➔ Yes, the acts should be made in connection with the patented use.

c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?

➔ No, such knowledge is not required for either direct or indirect infringements.

d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.

➔ N/A

6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?

➔ The “all element rule” is the most fundamental principle for determining infringement4, where for a second medical use patent, in general, the medical use should be one of the key elements at issue. Neither an intent to infringe nor knowledge of infringement is required for patent infringement.

There are no legal tests or evidentiary requirements specifically prescribed in the KPA. In practice, an infringement activity may be typically proven by evidentiary materials.

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4 Supreme Court 98 Hu 2351 rendered on November 14, 2000: “when a claim of a patent comprises a plurality of elements, it is considered that an organic integration of each element is protected as a whole, but each element is not protected separately, thus, in case that the (Ka)ho utility model, which is compared with the subject patented invention, has of some of the essential elements described in the claim of the patented invention but lacks the others, such (Ka)ho utility model, in principle, does not fall within the scope of the claim.”
showing production, supply, sale, etc., of a product for the patented use, e.g., promotional materials, prescriptions, bidding materials, etc.

7) What relief is available for infringement of a second medical use claim:

- The KPA provides the following types of civil remedies for patent infringement: (i) injunctive relief (preliminary or permanent) under Article 126; (ii) compensation of damages under Article 128; and restoration of injured business goodwill or reputation under Article 131. The provisions above also generally apply to remedies for infringement of second medical use claim.

a) at a preliminary / interim / interlocutory level?

- At the request of the petitioner, the court may issue a preliminary injunction against infringement and may make other orders to prevent infringement.

When a preliminary injunction order is issued, the court may:
(a) prohibit the respondent from continuing the manufacture or sale of the goods which infringe the petitioner’s right;
(b) direct that the infringing articles or other articles used for infringement be transferred to the custody of a court bailiff; and
(c) instruct the court bailiff to post an appropriate public notice of the order on the premises of the respondent.

The injunction is enforced by the bailiff at the expense of the petitioner.

However, no remedies other than a preliminary injunction are available in a preliminary injunction action. If a patentee wishes to seek damages and a permanent injunction, it must file a main infringement action.

b) by way of final relief?

- The petitioner may bring a main action for a permanent injunction, damages and/or other remedies. Other remedies in the main action may include a court order requiring the respondent to place a public apology for infringing the goodwill or reputation of the petitioner in the news media such as a daily newspaper, although this latter remedy is not likely to be granted by the court.

8) In respect of Question 7)a), can a preliminary / interim / interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?

- Since a preliminary injunction is available upon a prima facie showing of infringement, statements provided in the product packaging or based on the writing of a prescription would suffice for granting a preliminary injunction.

However, the necessity for provisional relief is additionally required. In deciding the necessity for provisional relief, courts balance between irreparable harm to the plaintiff from ongoing infringement and economic harm to the defendant from the grant of injunction. Courts also consider the adequacy of damages to redress the injury to the plaintiff from infringement and the likelihood of invalidation of the patent concerned, although a patent is presumed to be valid until it is held to be invalid in a final decision of a patent invalidation action.

9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?
Regarding the level of proof in a civil action, the Supreme Court held that proving a factual issue requires a high degree of probability and a level of judgment requiring that an ordinary person would not have a doubt (Supreme Court 2008 Da 6755 issued on October 28, 2010).

II. Policy considerations and proposals for improvements to your current law

10) If your country permits second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind permitting such claims?

➔ The policy reasons behind permitting second medical use claims would be to encourage innovation, research and development for developing new drugs, which will contribute to public health and medical industry.

b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

➔ Generally, yes. However, current Korean patent practice after the Supreme Court ruling in 2009 regarding a new dosage regime (see I.1.2) c) above) could be unfavorable to originators.

c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?

➔ If a new dosage regime is recognized as a valid element of a claimed invention and properly compared with the prior art when assessing the patentability, second medical use claims will be considered to strike a fair balance between the interests of relevant stakeholders.

d) If there is any empirical or anecdotal data available, please address the following.

i) What is the prevalence of second medical use claims in your country?

➔ Although there is no statistics for the prevalence of second medical use claims, we have seen several invalidation actions against secondary medical patents and relevant patent litigations against generic companies in recent years.

ii) What is the profile of patentees for second medical use claims in your country?

➔ The patentees for second medical use claims are mostly originators.

11) If your country does not permit second medical use claims, please answer the following sub questions.

➔ N/A

a) What are the policy reasons behind not permitting such claims?

b) Would such claims serve the interests of relevant stakeholders?
c) Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?

12) To what extent does your country’s law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

⇒ The Korean Supreme Court ruling in 2009 regarding a new dosage regime (see I.1.2c) above) can negatively affect the pharmaceutical industry (particularly, originators) since it may discourage the research and development efforts by originators.

III. Proposals for harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions without regard to their existing national laws.

13) Is it desirable to permit second medical use claims?

⇒ Yes.

14) Is harmonisation of laws relating to second medical use claims desirable?

⇒ Yes.

15) Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.

a) Types of second medical use constituting permissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

⇒ All types recited in paragraphs 14) - 17) above should be permitted under harmonized laws. In particular, the new dosage regime recited in paragraph 17) should be considered to claim a type of second medical uses.

b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

⇒ None

c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

⇒ Any form that can properly claim a second medical use invention, such as a purpose-limited product claim or use claim with a preamble “use,” should be permissible under harmonized laws.

d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

⇒ A method of treatment claim may not be permitted under harmonized laws.

e) Who may be liable for infringement?

⇒ A party marketing a drug with label instructions for a patented use should be liable for infringement under harmonized laws.
f) Any parties/institutions that should be exempted from infringement or liability for infringement.

⇒ Physicians’ acts of prescribing a drug for public health and patients’ personal use should be exempt from infringement under harmonized laws.

g) Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.

⇒ A party producing or selling a drug with label instructions for a patented use should be liable for infringement under harmonized laws.

Even if a party producing or selling a drug with label instructions for a non-patented use (skinny labeling or cross-labeling), if it is highly likely that the drug is actually prescribed for a patented use, the party should be liable for infringement under harmonized laws. In this regard, please refer to Warner-Lambert Company LLC et al. v. Samjin Pharm. Seoul Central District Court 2013 Kahap 1717 decided on February 5, 2014 (see I.4) above).

h) Relief available upon a finding of infringement:

i) at a preliminary / interim / interlocutory level; and

ii) by way of permanent relief.

⇒ A preliminary injunction, permanent injunction, compensation of damages and other remedies (e.g., public apology) should be available upon a finding of infringement under harmonized laws.

i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.

⇒ A preliminary injunction for h)i) should be granted based on a *prima facie* showing of infringement; and a permanent injunction, compensation of damages or other remedies (e.g., public apology) should be granted based on the standard of proof requiring that a legal or factual issue be proven by a high degree of probability under harmonized laws.
SUMMARY

This report explains the types, scope and enforcement of patents for new uses of known chemical compounds when a known substance is found to have a new therapeutic use ("second medical use"). To provide sufficient patent protection for a second medical use, the Korean Group proposes that harmonized laws should be adopted. Under the harmonized laws, all types of second medical uses should be allowable including new dosage regime inventions. Further, all claim formats such as a purpose-limited product claim or use claim should be permissible except for a treatment method claim. Regarding enforcement, a party marketing a drug with labeled instructions for a patented use should be liable for infringement under the harmonized laws. In case of skinny labeling or cross-labeling, if it is highly likely that the drug is actually prescribed for a patented use, the party should be liable for infringement.