

Study on Supreme Court Decision 2017DA245798

1. The subject case

Case No.: 2017DA245798 Prohibition of patent right infringement, etc.

Subject Patent: Korean Patent No. 10-386487
titled "NEW QUINUCLIDINE DERIVATIVES AND PHARMACEUTICAL COMPOSITIONS THEREOF"

Date of Decision: January 17, 2019

2. Gist of the decision

(1) The scope of the effects of a patent right with an extended term for a pharmaceutical drug should be determined with a focus on whether it is identical in terms of a specific active ingredient expected to exhibit a therapeutic effect for a specific disease, therapeutic effect and use to the pharmaceutical drug for which an item approval has been granted under the Pharmaceutical Affairs Act in order to work the patented invention. Even when the pharmaceutical drug for which the patentee has acquired an item approval under the Pharmaceutical Affairs Act differs from the Respondent's pharmaceutical drug (hereinafter, referred to as "the infringing product") in terms of a pharmaceutically acceptable salt or the like, the effects of the patent with an extended term should be deemed to extend to the infringing product if the infringing product can be easily selected by a person having ordinary skill in the technical field to which the invention pertains (hereinafter, referred to as "a skilled person in the art") and the therapeutic effect from the pharmacological action of the active ingredient absorbed into the human body or its use is substantially the same.

(2) The specification of the present patent states, in addition to an ammonium salt, a succinic acid, a fumaric acid and the like as selectable organic acids capable of forming a salt with solifenacin, which is the active ingredient. Given that the fumarate of the Respondent's Product is categorized as 'Class 1,' which is a pharmaceutical salt commonly used with succinate, and that it is well known that the processes of administration and absorption of solifenacin succinate into the body are identical to those of solifenacin fumarate, modifying succinate to fumarate is no more than a matter that can be easily selected by a skilled person in the art. Accordingly, although the Respondent's Product differs in salt from the present approved pharmaceutical drug, the modified salt can be easily selected by a skilled person in the art and the therapeutic effect by absorption into the human body is substantially the same; thus, it should be deemed to be in the scope of the present patent whose term was extended.

3. History of the case

(1) The present patent is a substance patent characterized by a 'compound having a specific basic structure having a therapeutic effect for symptoms of overactive bladder, and the specification of the present patent states, in addition to an ammonium salt, a succinic acid, a fumaric acid and the like as selectable organic acids capable of forming a salt with solifenacin, which is the active ingredient.

(2) The Petitioner obtained on March 20, 2007 an import item approval from the Commissioner of Food and Drug Safety for 'Vesicare tab 5mg and 10mg (solifenacin

succinate),' which is the approved pharmaceutical drug concerning the present patent for treatment, with its efficacy being treatment of symptoms of overactive bladder.

(3) The Petitioner filed an application for extension of the term of the present patent by the period taken to acquire the import item approval for the pharmaceutical drug. On August 21, 2007, it was decided to grant the extension of the term of the present patent by 18 months and 16 days, whereby the expiration date of the patent has been moved from December 27, 2015 to July 13, 2017.

(4) On July 25, 2016, the Respondent was granted, by the Commissioner of Food and Drug Safety, an item approval for pharmaceutical drug production and sales for a prescription drug 'A-care tab 4.98mg and 9.96mg (solifenacin fumarate).' The Respondent product is a 'salt-modified pharmaceutical drug' where only a salt was modified from "succinic acid" to "fumaric acid," and its active ingredient "solifenacin," is the same as that of the present patent. The Respondent submitted bioequivalence test data to be granted the item approval for pharmaceutical drug production and sales.

(5) The Petitioner filed a suit to seek prohibition of production and the like of the Respondent's product and damages on the grounds that the Respondent's act of producing or selling the Respondent's product constitutes infringement of the present patent having an extended term, but the Seoul Central District Court rejected the suit (Seoul Central District Court Decision 2016GAHAP525317 of November 3, 2016).

(6) The Respondent appealed the decision, but the Patent Court rejected the appeal on the following grounds: (i) effects of a patent with an extended term apply to pharmaceutical drugs that are considered as substantially the same item and for which one item approval for production and sales is to be granted or to pharmaceutical drugs that do not need to be granted a separate item approval for pharmaceutical drug production and sales, but the Respondent's product is a pharmaceutical drug that needs to be granted a separate item approval for production and sales, and thus, the effects of the present patent with an extended term do not apply to the Respondent's product; (ii) it is hardly be deemed that the Respondent's product and the Vesicare tab are substantially identical to each other on the grounds that the difference between them in their components is a minor difference or a difference in formality when considered as a whole; and (iii) the patent term extension system is intended to provide an extended term of a patent by the period taken to obtain an approval under the Pharmaceutical Affairs Act or the like in which the patented invention could not be worked and not intended to broaden the technical scope of the patented invention, and ... if it is deemed to be within the scope of the effects of the patent with an extended term in light of the doctrine of equivalents, ... the scope of its effects would become excessively broad (Patent Court Decision 2016NA1929 of June 30, 2017).

4. Comments

A. Finding 1: provision of a standard about the scope of effects of a pharmaceutical patent with an extended term

(1) Relevant provision of the Patent Law

Article 95 of the old Patent Law (before revision by Law No. 11117 on December 2, 2011) provided the following as to the scope of effects of a patent with an extended term:

Effects of a patent with an extended term shall apply only to working of the patented invention for the products on which approval, etc. for registration

of the extension is based (products used for specified purposes, if the purposes of such products are specified in the approval, etc.)

(2) Patent Court's decision on the present case

The Patent Court's decision on the present case finds that effects of a patent having an extended term apply only to pharmaceutical drugs that are considered as substantially the same item and for which one item approval for production and sales is to be granted or to pharmaceutical drugs that do not need to be granted a separate item approval for pharmaceutical drug production and sales, and thus, the effects apply only to products that are almost identical to the approved pharmaceutical drug.

Given that the Patent Court decision interprets the scope of the 'products used for approved purposes' of Article 95 of the old Patent Law to be almost identical to the scope of the approved product itself, it seems that, in the decision, the scope of effects of a patent with an extended term is interpreted to be too narrow and that the decision is erroneous in considering the 'products used for approved purposes' only, without taking the 'working of the patented invention' into account.

(3) Implications of the present decision and future issues

The Supreme Court decision finds that 'the scope of effects of a patent with an extended term for a pharmaceutical drug should be determined with a focus on whether it is identical in terms of a specific active ingredient, therapeutic effect and use to the pharmaceutical drug for which an item approval has been granted in order to work the patented invention,' which seems to sufficiently reflect the intent of the provision of Article 95 of the old Patent Law.

That is, the decision interprets the scope of the 'products used for approved purposes' to be broader than that of the approved product itself and to include the products having the same effective ingredient, therapeutic effect and use as those of the approved pharmaceutical drug and provides that effects of a patent for a pharmaceutical drug with an extended term apply to working of the patented invention for the products used for the approved purposes.

The decision is the first decision by the Supreme Court presenting standards on how to determine effects of a patent with an extended term for a salt-modified pharmaceutical drug. Given this, the standards based on which the decision has been made would affect lower courts' future decisions on whether or not a salt-modified pharmaceutical drug constitutes infringement of the patent for its original pharmaceutical drug with an extended term.

However, given that the present decision does not provide generic standards for determination on the 'scope of the pharmaceutical drugs having the same active ingredient, therapeutic effect and use as those of the approved pharmaceutical drug,' it would be expected that a conflict in legal principles may arise over a case in different circumstances (e.g., where the infringing drug is not a salt-modified pharmaceutical drug) in the future.

B. Finding 2: whether salt modification from a succinic acid to a fumaric acid can be easily selected by a skilled person in the art

(1) The present decision provides that, effects of a patent with an extended term apply to a

salt-modified pharmaceutical drug, if the modification of the salt can be easily selected by a skilled person in the art.

(2) The grounds for the decision are as follows: the specification of the present patent states a succinic acid, a fumaric acid and the like as organic acids capable of forming a salt with solifenacin; fumarate and succinate are in the same class of commonly used salts; and it is well known that the processes of administration and absorption of solifenacin succinate into the body are identical to those of solifenacin fumarate.

(3) The grounds for the present decision seem to provide a standard for determination on how easily a salt is selected. However, according to the grounds for the decision, in a salt-modified pharmaceutical drug, a salt that is not commonly used and has a low association with a salt of an approved pharmaceutical drug needs to be selected in order to have difficulty of the selection of the salt recognized. Accordingly, pharmaceutical companies seeking to develop a salt-modified pharmaceutical drug would experience difficulties in selecting a salt to be modified.

Additionally, although the decision provides that determination on effects of a patent for a salt-modified pharmaceutical drug with an extended term can be made based on whether it is easy to select the salt modification and then presents a specific standard for determination on how easy the selection can be made, special circumstances may be involved where, for example, a salt-modified pharmaceutical drug satisfies these standards but in fact it was not easy for a skilled person in the art to select the salt modification due to obstacles in selecting the salt or synthesizing the salt-modified pharmaceutical drug, and a conflict may occur over such cases.

C. Finding 3: whether the therapeutic effect from the pharmacological action of the active ingredient absorbed into the human body or its use is substantially the same

(1) The present decision finds that if a therapeutic effect from a pharmacological action of an active ingredient absorbed into the human body as a salt-modified pharmaceutical drug or its use is substantially identical to that of a patent with an extended term, effects of the patent with an extended term apply to the salt-modified pharmaceutical drug.

(2) In regard to 'identical use' in the present finding, a decision by the Intellectual Property Trial and Appeal Board (IPTAB), 2015DANG992 of September 11, 2015, provides that effects of the patent with an extended term do not apply to a pharmaceutical composition that has the main component that is the same as the component based on which the term of the patent has been extended but has a different use. Given this, it can be said that it has been established that effects of a patent with an extended term do not apply to a salt-modified pharmaceutical drug having a different use.

(3) However, the following controversy may be observed over the finding that effects of a patent with an extended term do not apply to a salt-modified pharmaceutical drug having 'a different therapeutic effect.'

First, a salt-modified pharmaceutical drug is intended to provide efficacy that is equivalent to the original drug by using the same effective ingredient as that of the original drug, and for acquisition of an item approval for production and sales of a salt-modified pharmaceutical drug, it is necessary to submit bioequivalence test data showing that administration of the salt-modified pharmaceutical drug resulted in a blood concentration of the active ingredient that is equivalent to the concentration achieved by administration

of the original. In this light, it would not be easy to have a salt-modified pharmaceutical drug recognize to have a therapeutic effect that is different from that of its original drug.

That is, in consideration of the purpose of development of a salt-modified pharmaceutical drug, a salt-modified pharmaceutical drug satisfying the requirement presented in the finding could not be easily developed. Accordingly, the generic drug manufacturers are expected to strongly oppose the finding.

Additionally, according to the standard present in the decision, it seems that a salt-modified pharmaceutical drug is required to have a significantly improved therapeutic effect over the approved original drug, which corresponds to a remarkable effect required for recognition of inventive step of a pharmaceutical invention, and there may be controversies over the degree of the significantly improved therapeutic effect required.