

Patent Term Extension Case
IP High Court, en banc
Case H25 (Gyo-Ke) 10195, Judgment on May 30, 2014 (H26)

Summary authored by Yoshiki KITANO

FACTS

The plaintiff owns a patent titled "vascular endothelial cell growth factor antagonists", and obtained a marketing approval designated by Cabinet Order under the Pharmaceutical Affairs Act (the "Approval") for a medicine that is covered by the patent. Prior to the Approval, the plaintiff had obtained a marketing approval (the "Prior Approval") for a medicine whose active ingredient and the indication are the same as, but whose dosage and administration are different from, the medicine that is the subject of the Approval. Accordingly, the Approval was for a partial change to the medicine approved by the Prior Approval.

The plaintiff filed an application for a patent term extension of the patent based on the Approval. The Japan Patent Office rejected the application under the provision of Article 67-3 (1) (i) of the Patent Act, which stipulates that an application for the patent term extension is rejected where the approval designated by Cabinet Order is not deemed to have been necessary to practice the patented invention. According to the decision by the JPO, the practice of a patented invention is the act of manufacturing, selling, etc. a medicine that is identified by all matters that are not only stated in the written approval of the medicine but also the limitations of the patented invention. The claims of the patent do not contain dosage- or administration-related limitation. The JPO determined that the Approval was not necessary to practice the patented invention because of the Prior Approval.

ISSUE

Whether the patent term extension is available based on a new approval for manufacturing and sales of a medicine where there was a prior approval for a medicine whose active ingredient, the effectiveness, and efficacy are the same as, but whose dosing and administration are different from, those of the medicine that is the subject of the new approval.

HOLDING

It is available.

In order for a JPO examiner to refuse the application for the patent term extension based on the provision of Article 67-3 (1) (i) of the Patent Act, the examiner must demonstrate that at least one of the following requirements (i) and (ii) is not met.

- (i) A ban was lifted by the approval designated by Cabinet Order
- (ii) The relevant act on which the ban was lifted by the approval designated by Cabinet Order falls within the scope of the practice of the patented invention.

The scope of the practice of a patented invention on which the ban is lifted by the approval under the Pharmaceutical Affairs Act covers the act of manufacturing, selling, etc. a medicine that is identified by ingredient, quantity, dosage, administration, effectiveness and efficacy, among other matters examined such as name, side effects, and other matters relating to safety. Accordingly, the Prior Approval did not lift the ban on the act of manufacturing, selling, etc. the medicine that is identified by the dosage and administration that were approved by the Approval. Therefore, it is impossible to determine that either the requirement (i) or (ii) is not met.

The Court rescinded the JPO decision.

Additional Remarks:

It is reasonable to understand that the scope of a patent that is directed to a medicine, and whose term was extended pursuant to Article 68-2 of the Patent Act, is identified by "the ingredients (not limited to active ingredient)", "effectiveness and efficacy", and "dosage and administration."

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Original document (Japanese):

http://www.ip.courts.go.jp/app/files/hanrei_jp/226/084226_hanrei.pdf

English translation:

N/A