Summary authored by Naoki OKUMURA

Case Information

Case	Bevacizumab case
Court, case No.	Third Petty Bench of the Supreme Court 2014 (Gyo-Hi) 356
Date of judgment	November 17, 2015
Parties	Appellant : JPO Director Appellee : Genentech Inc.,

FACTS

Appellee, Genentech Inc., owns Japanese patent No. 3398382 entitled "vascular endothelial cell growth factor antagonists" ("**Patent**"). On September 18, 2009, Appellee obtained marketing approval ("**Present Approval**") under the Drug and Medical Equipment Act (previously known as the "Pharmaceutical Affairs Act") for a medicine ("**Medicine**") that falls within the scope of the Patent. Prior to the Present Approval, Appellee had obtained marketing approval ("**Prior Approval**") for a medicine ("**Preceding Medicine**") whose active agent, bevacizumab, and indication, incurable/unresectable advanced/recurrent colorectal cancer, were the same, but whose dosage and administration were different from the Medicine. The dosage and administration of the Medicine is stated as follows:

> "In combination with other anticancer drugs, adults are ordinarily infused intravenously with bevacizumab at a dose of 7.5 mg/kg (weight) administered for an interval of at least 3 weeks."

On the other hand, the dosage and administration of the Preceding Medicine is stated as follows:

> "In combination with other anticancer drugs, adults are ordinarily infused intravenously with bevacizumab at a dose of 5 mg/kg (weight) or 10 mg/kg (weight) administered for an interval of at least 2 weeks."

The Present Approval allowed manufacture and sale of the Medicine for a combination of XELOX treatment (treatment with one 3-week cycle requiring intravenous infusion for only two hours and oral administration) and bevacizumab treatment. This combination treatment had not been allowed under the Prior Approval.

Appellee filed an application requesting term extension of the Patent, claiming that there had been a period where Appellee could not implement the Patent without the Present Approval. However, the Japan Patent Office ("**JPO**") examiner rejected the application and the JPO trial board also denied Appellee's request.

Appellee filed a suit against Appellant, the JPO Director, seeking revocation of the decision, and the IP High Court Grand Panel rescinded the JPO decision.

ISSUE

The applicability of Article 67-3(1)(i) of the Patent Act, which stipulates that the examiner shall reject an application for patent term extension, if the disposition under Article 67 (2) is not deemed to have been necessary for implementation of the patented invention.

HOLDING

In cases where prior approval and subject approval have been issued, if, upon a comparison of them, the manufacture and sale of a medicine covered under the prior approval includes the manufacture and sale of a medicine covered under the subject approval, subject approval shall not be necessary for implementation of the patented invention as concerns an application for patent term extension. Whether or not subject approval is necessary for implementation of a patented invention shall be decided by comparing the preceding approval and subject approval. It shall not be decided based on all matters qualifying as matters specifying the patented invention.

Marketing approval of a medicine pursuant to the Drug and Medical Equipment Act allows manufacture and sale of a medicine identified by each by of the examination matters, namely, "name, ingredient, quantity, dosage, administration, efficacy, effect, side-effects, and other matters relating to the quality, effectiveness and safety" of the medicine. However, given the purpose of the patent term extension system,

it is not considered appropriate to compare both approvals based on examination matters that are not directly related to the medicine's substantial identity in light of the type and subject matter of the patented invention, for which the patent term extension is at issue. The reason is that such a comparative examination would have the consequence of granting a patent term extension by comparing both approvals on the basis of examination matters that do not interfere practice of the patented medicine invention.

Therefore, in cases where subject approval and prior approval have been issued, when, upon comparison of both approvals in regard to the examination matters directly related to the substantial identity of the medicine in light of the type and subject matter of the patented invention for which a patent term extension is at issue, it has been found that manufacture and sale of the medicine under the prior approval includes manufacture and sale of the medicine under the subject approval, then such shall not be found necessary for implementation of the patented invention with regard to the application for patent term extension.

Here, in regard to the present case, the present invention is related to a composition for cancer, which comprises an effective amount of vascular endothelial growth factor antagonist and is a product invention whose subject matter is an ingredient of the drug. The examination matters that directly relate to the substantial identity of the medicine are: ingredient, quantity, administration, dosage, efficacy and effects. The Present Approval allowed manufacture and sale of the Medicine for combination treatment of XELOX treatment and bevacizumab treatment for the first time, a combination treatment not allowed under the Prior Approval.

Thus, in this case, manufacture and sale of the Preceding Medicine is not found to include manufacture and sale of the Medicine.

It is concluded that the judgment of the IP High Court shall be affirmed. The Appellant's argument cannot be accepted.

November 2015

Original Document (Japanese):

http://www.courts.go.jp/app/files/hanrei_jp/467/085467_hanrei.pdf

English Translation:

N/A