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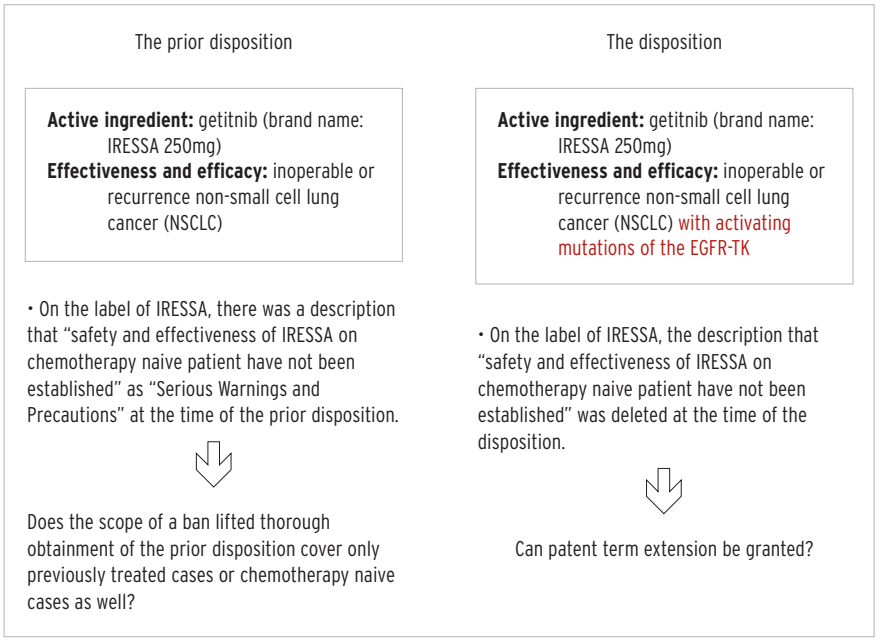
Patent term extension and the label description

A new judgment has been given regarding patent term extension, following the two judgments that we recently discussed. This latest ruling is based on the earlier judgment of IP High Court Grand Panel (May 30 2014, the Avastin case) which we introduced in our article "IP High Court gives new ruling on patent term extension". The IP High Court made a ruling on the issue of whether the court can consider the description of the label besides the description of a written approval in determining whether a ban was lifted through obtaining the disposition.



Summary of the case

AstraZeneca UK is the owner of a patent for an invention titled "Quinazoline derivatives, its production and medicinal preparation for attaining anticanceric action containing said quinazoline derivative". AstraZeneca obtained import approval for Iressa (gefitinib tablet) 250mg (the prior disposition) and obtained registration of patent term extension based on the prior disposition. The effectiveness and efficacy of the medicine on the prior disposition was "inoperable or recurrence non-small cell lung cancer (NSCLC)".

After this, AstraZeneca obtained an approval of partial changes in manufacturing approval (the disposition), whereby the effectiveness and efficacy were changed to "inoperable or recurrence non-small cell lung cancer (NSCLC) with activating mutations of the EGFR-TK".

AstraZeneca filed an application for patent term extension based on the disposition. However the JPO rejected the application and dismissed an appeal. AstraZeneca appealed to the IP High Court seeking to revoke the decision of JPO.

Background to the case

On the label of Iressa, there was a description that "safety and effectiveness of Iressa on chemotherapy naive patient have not been established" as "Serious Warnings and Precautions" at the time of the prior disposition. According to AstraZeneca, Iressa could not be used practically for the first line treatment because of this description. Thereafter, safety and effectiveness on the first line treatment was confirmed in the particular cases of patients with activating mutations of the EGFR-TK. Therefore AstraZeneca obtained the disposition and deleted the above description from the label of Iressa. According to AstraZeneca, Iressa became able to be used for the first line treatment practically for the first time because of the disposition.

The issue in this case is whether or not the scope of the ban lifted through obtainment of the disposition had already been achieved through obtainment of the prior disposition, and whether a court can consider the description of the label when determining the scope of a ban lifted.

Judgment of September 25, 2014 IP High Court

The IP High Court upheld the JPO decision. When determining the fulfilment of the requirement provided in Patent Act Article 67-3(1)(i), a court should analyse concretely whether a ban could be evaluated to have been lifted through obtainment of the prior disposition.

On the written approval of the prior disposition, there is no description such as chemotherapy naive or previously treated. The prior disposition does not regard EGFR-mutant or EGFR mutation negative tumours, or chemotherapy naive or previously treated. Therefore, the prior disposition had lifted the ban on the act of using the medicine by the use method that is identified by the effectiveness and efficacy of the disposition "inoperable or recurrence non-small cell lung cancer (NSCLC)", and on the act of manufacturing, selling, etc the medicine on the premise of its use by the aforementioned use method.

Holding the above, the Court concluded that the requirement of rejection provided in Article 67-3(1)(i) was fulfilled. The Court responded to AstraZeneca's allegation that the effectiveness and efficacy of the prior disposition was "previously treated inoperable or recurrence non-small cell lung cancer (NSCLC)" because the description of the label was actually a part of the prior disposition as follows.

"Serious Warnings and Precautions" in the label is that described by AstraZeneca and cannot be deemed as part of the prior disposition by the minister of health, labour and welfare. It is difficult to read the wording of the warning as limiting the effectiveness and efficacy of the prior disposition to "previously treated" (banning from using Iressa in chemotherapy naive patients). It is because the description is merely a "warning" and it does not indicate that Iressa does not have effectiveness and efficacy in chemotherapy naive patients or restrict the use of Iressa for these patients.

Analysing a process of the examination on the prior disposition, both the intention of AstraZeneca and the con-

tents of approval by the minister of health, labour and welfare did not limit the effectiveness and efficacy of the prior disposition to a previously treated case. When the Pharmaceutical and Medical Devices Agency inquired whether AstraZeneca would limit the applied effectiveness and efficacy from "non-small cell lung cancer" to appropriate subject such as "previously treated inoperable recurrence non-small cell lung cancer (NSCLC)", AstraZeneca answered that limiting to the previously treated case would result in the loss of treatment opportunity with Iressa for the aged who were unsuited to chemotherapy with the former anticancer drug or patients whose general condition was bad, and proposed to describe the warning in the label. In light of the above, AstraZeneca maintained the effectiveness and efficacy as "non-small cell lung cancer" without limiting the scope of the approval to the previously treated case and sought to be able to use Iressa in chemotherapy naive patients.

The Court rejected AstraZeneca's allegation that doctors could not use Iressa in chemotherapy naive patients and pharmaceutical companies could not manufacture and sell it to be used for those patients because the warning in the label was important to doctors and pharmaceutical companies.

Furthermore, the Court cited in dicta the criteria of the Grand Panel judgment in the Avastin case and mentioned as follows: a scope of a ban lifted should be determined on the basis of the description on the written approval regarding import or manufacture and sales of a medicine provided in the Pharmaceutical Affairs Law. This court's judgment is based on the above criterion and this court had analysed whether there are special circumstances to decide otherwise regarding the scope of the ban lifted.

Practical tips

According to the Grand Panel judgment in the Avastin case, the court should determine a scope of a ban lifted on the basis of "ingredient, quantity, dosage, administration, effectiveness and efficacy" described in the written approval. In this case, whether the court can consider the description other than the written approval was an issue and the Court declined to consider the description of the label. However, the Court indicated in dicta that it might consider the description other than the written approval if special circumstances exist. How the special circumstances will be satisfied is not clear. Further developments are expected.