

Generic should sue the Minister of Health, Labour and Welfare instead of filing a DJ action, says IP High Court



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The Japanese patent linkage system has problems such as difficulties associated with patent decisions, lack of involvement of patent experts, and lack of transparency and predictability. A generic company raised the issue so that relief may be obtained through the court.

Summary of the case

Eisai R & D Management Co., Ltd. (Eisai RD) owns a patent entitled ‘Use of Eribulin in the Treatment of Breast Cancer.’

Eisai Co., Ltd. (Eisai) began manufacturing and selling “Halaven Injection 1mg (Eribulin Mesilate formulation), an antineoplastic medicinal product”, with effectiveness and efficacy regarding “inoperable or recurrent breast cancer”.

Nipro Corporation (Nipro) filed a declaratory judgment (DJ) action against Eisai RD and Eisai seeking a

declaration of non-infringement and non-existence of the obligation to pay damages.

Nipro alleged that Eisai RD is substantially enforcing an injunction against Nipro by taking advantage of the patent linkage. Under the current system, Nipro could only file a request for an invalidation trial at the JPO, which is a time-consuming and roundabout process; therefore, the most direct and effective means is to seek a declaration of non-infringement, etc.

Judgment of August 30 2022, Tokyo District Court

The Tokyo District Court (Presiding judge Shibata) dismissed the claim, holding as follows.

The Joint Notification by Two Division Directors dated June 5 2009 titled “Approval examination of generic drug for medical treatment under the Pharmaceutical Affairs Act and handling of drug patents related to National Health Insurance (NHI) price listing” states that it is the policy of the Minister of Health, Labour and Welfare not to grant marketing authorisation (MA) of generic products when a patent exists for the active ingredient of the originator product or for some effectiveness and efficacy of the originator product.

The notification also states that, with regard to the listing of generics in the NHI price listing, if a company wishes to list an item having a possibility of patent disputes, the policy is that coordination with the originator company, the patent holder, shall be arranged in advance and only those items considered to be in stable supply in the future will be listed.

According to the above, Nipro alleged that in this case, the Minister of Health, Labour and Welfare will not authorise the marketing of Nipro’s medicinal product, which is a generic of Eisai RD/Eisai’s product. Based on these circumstances and the evidence, there is not a high probability that the Minister of Health, Labour and Welfare will authorise the marketing of Nipro’s medicinal product in the near future, and that Nipro’s medicinal product will be listed in the NHI price listing.

Judgment of May 10 2023, IP High Court

Nipro appealed to the IP High Court and alleged as follows.

Because the Ministry of Health, Labour and Welfare (MHLW) is unable to determine whether generic products infringe the patents owned by the originator company, MA will not be granted under the patent linkage system if a substance patent or a use patent formally

exists, which causes a serious legal problem. The situation where such patent linkage becomes a problem itself is a situation of legal dispute.

Eisai RD and Eisai alleged as follows.

If, as Nipro alleges, the “practice based on the Joint Notification by Two Division Directors is the cause of the lack of the right to demand an injunction or damages”, and that this is a problem, then Nipro should file an administrative lawsuit against the MHLW. Even if Nipro were to obtain the DJ, the judgment is not legally binding on the MHLW, and it is not clear whether the MHLW would grant MA in accordance with the said judgment.

The IP High Court (Presiding judge Otaka) dismissed the appeal, holding as follows.

Even if it is a problem for Nipro that the Minister of Health, Labour and Welfare does not grant authorisation for the marketing of Nipro’s medicinal product because of the existence of the patents according to the practice based on the Joint Notification by Two Division Directors, that is a dispute under public law between Nipro and the Minister of Health, Labour and Welfare, not a legal dispute between individuals; i.e., Nipro and Eisai RD/Eisai. Such a dispute under public law should be remedied by legal means such as filing an action for the declaration of illegality of inaction against the application for authorisation or filing an appeal to the Minister of Health, Labour and Welfare.

Practical tips

Nipro’s strategy to obtain MA from the MHLW by obtaining a DJ of non-infringement and non-existence of the obligation to pay damages did not work. Nipro’s allegation that generic products would never be authorised based on the patent linkage was taken against it, and was used as a reason to dismiss Nipro’s claim.

In response to Nipro’s allegation, the IP High Court clearly stated that “it should be remedied by legal means such as filing an action for the declaration of illegality of inaction against the application for authorisation or filing an appeal to the Minister of Health, Labour and Welfare.”

It is pointed out that “Nipro, who had harshly criticized the MHLW in its lawsuit, is sure to be supported by many generic companies who have so far been weeping over the Joint Notification by Two Division Directors when it comes to commencing an administrative lawsuit against the MHLW.” The future outcome should be closely watched.