JAPAN

ABE & PARTNERS
Osaka

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Tokyo and Osaka courts rule on combination patents

The expiry of blockbuster drug patents intensifies disputes between brand-name pharmaceutical companies and generic drug manufacturers. This case is one such dispute. In some cases, a brand-name pharmaceutical company restrains a generic pharmaceutical manufacturer from selling generic drugs based on combination patents after the single brand-name drug patent has expired.

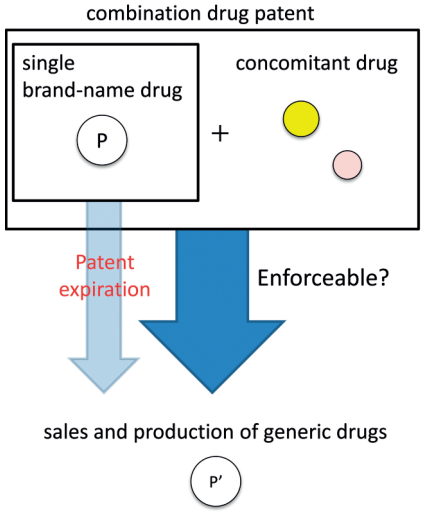
In this case, the patent for Actos, the blockbuster drug for type 2 diabetes mellitus of which annual worldwide sales in 2011 were about Y300 billion ($3 billion) and annual home sales in 2011 were about Y30 billion ($300 million), expired in 2011. The defendants' generic versions of Actos were then listed in the National Health Insurance drug price list and were scheduled to be produced and sold.

Facts of the case

Takeda Pharmaceutical, the patentee of Actos, sued 18 generic pharmaceutical manufacturers, including Teva and Sandoz, for infringement of two patents regarding combination drugs of pioglitazone, an active ingredient of Actos, and other agents. Takeda sued 10 manufacturers in Tokyo and eight manufacturers in Osaka. Our firm represented one of the defendants. Both the Tokyo District Court and the Osaka District Court dismissed Takeda's claim, but for different reasons. Both judgments became final and binding.

Takada's main allegations were indirect infringement and direct infringement. Regarding indirect infringement, Patent Act Article 101(ii) provides that for the invention of a product, production or sale, etc of "any product … to be used for the producing of the said product and indispensable for the resolution of the problem by the said invention" with knowledge falls under indirect infringement.

Courts denied prolonging life of a single brand-name drug patent



Takeda alleged that the patent was an invention of a product "P+α", and (i) prescribing P', a generic drug of P, together with α by doctors, (ii) preparing P' together with α by pharmacists, (iii) taking P' together with α by patients fell under "the producing of" P+α, and P' fell under "indispensable for the resolution of the problem by the said invention". Accordingly, Takeda alleged that production and sale of P' indirectly infringed the patent.

Regarding direct infringement, focusing on cases where P' was used together with α, Takeda alleged that the defendants practised the patented invention making use of following acts as their tools; (i) prescription together by doctors, (ii) prescription together by pharmacists, (iii) taking together by patients. Takeda further alleged that the defendants actively induced doctors etc to use "P+α" combination because in the label of the defendants' drugs, there is a description regarding dosage of combination use with α.

Osaka decision

In its judgment of September 27 2012, the Osaka District Court denied indirect infringement because the defendants' drugs did not fall under "any product to be used for the producing of the said product" (Patent Act Article 101(ii)). The court interpreted a claim of the patent restrictively by considering the purposes of Patent Act Article 29 (1) which leads to the interpretation that a patent shall not be granted for medical activities and Article 69 (3) which provides that a patent for the invention of a medicine shall not be effective against the act of prescription by doctors or preparation of a medicine by pharmacists.

Accordingly, the Court held that the acts of simply using P' together with α such as (i) prescribing together by doctors, (ii) preparing together by pharmacists and (iii) taking together by patients did not fall under "the producing of the said product".

Furthermore, the court denied direct infringement because the acts by doctors, pharmacists and patients did not fall under "the producing of the said product" and the defendants could not make use of the acts of doctors etc. The Court denied direct infringement by active inducement as well.

In addition to the non-infringement ruling, the court held that the patent was invalid.

Tokyo decision

In a judgment of February 28 2013, the Tokyo District Court denied indirect infringement, but for different reasons from the Osaka District Court. The Court did not judge "the producing of the said product" but held that the defendants' drugs did not fall under "indispensable for the resolution of the problem by the said invention" (Patent Act Article 101(ii)). The Tokyo District Court established new criteria: regarding an invention of multiple product combination, an existing component would not fall under "indispensable for the resolution of the problem by the said invention" unless there are "special circumstances" such as the existing component is produced or sold for the invention.

The Court denied there were special circumstances because in the label of the defendants' drugs here were no descriptions to recommend using pioglitazone in combination with α or descriptions that pioglitazone were to be used in combination with α. Therefore the defendants' drugs were not produced or sold for the invention.

Furthermore, the Court denied direct infringement because the question of how to use pioglitazone or other agents was at the doctors' discretion and therefore the defendants could not make use of acts of doctors etc as their tools. The Court denied direct infringement by active inducement as well.

Unlike the Osaka District Court, the Tokyo District Court did not judge the validity of the patent.

Impact on corporate strategy

This is the first case regarding indirect infringement of combination drug patents. Similar disputes may arise in

the future. Both judgments are important as they have a great influence on corporate strategy, first for brand-name pharmaceutical companies who own combination drug patents, in terms of whether they can prolong life of expired single patents by combination drug patents, and second for generic pharmaceutical manufacturers, regarding whether production and sale of generic drugs of single brand-name drugs infringe the combination drug patents.