First Judgment Rendered concerning Infringement by Extended Patent Right in Japan

Debiopharm International vs Towa Pharmaceutical, Tokyo District Court, No. 2015(wa)12414, March 30, 2016

The first litigation pertaining to infringement of an extended patent right under the patent term extension (PTE) system was judged by Tokyo District Court (*Debiopharm International vs Towa Pharmaceutical, Tokyo District Court, No. 2015(wa)12414, March 30, 2016*). The Court construed the scope of the extended patent right extremely narrowly, and decided that the extended patent right covering the brand-name version of oxaliplatinum was not infringed by its generic version.

1. Background

Debiopharm owns the patent JP 3547755, which original expiration date was August 7, 2015, but the patent term was extended for 4 years 5 months 22 days, 2 years 9 months 21 days, or 11 months 21 days respectively depending on its corresponding authorized indication. Claim 1 of JP 3547755 is as follows:

"1. A pharmaceutically stable preparation of oxaliplatinum for a parenteral administration, consisting of a solution of oxaliplatinum in water at a concentration of 1 to 5 mg/ml and having a pH of 4.5 to 6, the oxaliplatinum content in the preparation being amounting to at least 95% of the initial content and the solution remaining clear, colourless and free of precipitate after storage for a pharmaceutically acceptable duration."

Towa obtained a generic marketing authorization and started to sell the product in December, 2014. Debiopharm initiated litigation seeking an injunction in 2015.

2. Decision

(1) Art. 68-2 of the Japanese Patent Law

< Art. 68-2 >

"Where a patent term is extended, such patent right shall not be effective against any act other than working of the patented invention for the authorized product (the authorized product used for the usage, in case that the usage of the product is also authorized) which constituted the basis for the patent term extension."

The Court first construed Art 68-2. The scope of an extended patent right covers **only** working of the "authorized product (used for the usage)" which could not be worked until the necessary authorization, and that the scope does not cover any other working of patented inventions. "Product" and "usage" in the authorization are required to be defined to determine the scope.

Examination for a marketing authorization is made by the items: "name, ingredients, quantity, dosage, administration, indication, usage, side effects, other matters including quality, efficacy and safety" of each medical product (Art. 14(2) of the Pharmaceutical and Medical Device Law). In consideration with the purpose of the PTE system, "product" and "usage" in Art. 68-2 are defined respectively by the following items:

Product : ingredients, quantity

Usage : dosage, administration, indication, usage
In addition, the Court stated the scope may extend to an equivalent or substantially same product of “the authorized product used for the usage”.

(2) Authorized product used for the usage
The ingredients in Debiopharm’s product constituting the basis for the PTE are “oxaliplatinum” and “water for injection”, and no other ingredients are included. On the other hand, Towa’s product includes “oxaliplatinum”, “water for injection” and further “concentrated glycerin”.
Since Debiopharm’s product and Towa’s product are different in ingredients, Towa’s product is not “the authorized product used for the usage”.

(3) Equivalent or substantially same product
The patented invention is directed to a preparation in which all ingredients are characteristic. The specification of the patent stated “this preparation does not include any other ingredients”, and during its prosecution Debiopharm stressed “the purpose of the present invention is that the solution of oxaliplatinum does not include an acidic agent, alkaline agent, buffer or any other additives”.
Towa’s product includes further “concentrated glycerine”, which has a new effect of reducing decomposition by adding the same to a preparation.
Thus, Towa’s product is not an equivalent or substantially same product.

<The reporter’s Comments>
Debiopharm won another infringement litigation against Nihon Kayaku based on other patent JP 4430229 on March 3, 2016 (*Tokyo District Court, No. 2015(wa)12416, March 3, 2016*), but in this litigation against Towa they failed. Debiopharm will probably appeal this judgment to the IP High Court.
The reasoning in the present judgment is similar to the comment described in the judgement of the Gland panel of the IP High Court (*Genentech, Inc. vs. the JPO: IP High Court, Nos. 2013(gyo ke)10195 to 10198*). I believe that this judgment was made because Art. 68-2 is inaccurate by using the term “product”, not “active ingredient” used in US Patent Law and EU Directive.
Innovative pharmaceutical companies will be in a hard situation, if this judgment is further affirmed by higher courts. Now, the Japan Patent Office started to revise the Patent Law to clarify the regulation in registration and scope of the PTE.

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