Patent Term Extension and Scope of Patent Rights

In early 2017, the IP High Court established new criteria by which the scope of a patent right may be extended and redefined the manner in which subtle differences between the invention, the components comprising the invention, the production method of the invention, and other aspects of the invention could be judged relative to a competitor's product which may or may not infringe upon the invention.

This was in response to a case brought by Debiopharm International SA against Towa Pharmaceuticals KK., for allegedly infringing the Debiopharm patent protecting a pharmaceutically stable preparation of an oxaliplatin solution (Japanese Patent No. 3547755B). Towa manufactured and sold generic forms of oxaliplatinum and also included an equivalent amount of glycerin relative to oxaliplatinum, whereas Debiopharm's oxaliplatin solution was composed of only oxaliplatinum and water and was free of other additives. The IP High Court deemed that Towa's product was not in itself and/or obtained based on a superficial difference relative to Debiopharm's oxaliplatin and its method of preparation. Therefore, Towa's product cannot be judged to be substantially identical to that of Debiopharm.

Patent Term Extension: Background

Owing to the necessity of verifying the safety and efficacy of medicinal and agrochemicals prior to making them commercially available for use by consumers or on farms producing food for consumers, the approval and testing regimens tend to continue for a greater period of time compared to, for example, the approval and testing regimens for a mechanical or an electronic apparatus, and thus, could substantially limit the time that the approved medicinal or agrochemical could be protected by the eventually granted patent.

The Patent Term Extension System was designed in order to extend the scope of a patent for up to five (5) years beyond the time that the patent would have expired so as to compensate for the lengthy approval and testing regimens often required in the

fields of medicine and agrochemicals.

At the same time, a generic medication or drug having the same active ingredients, bioequivalence, intended effect, dosage, mode(s) of administration, etc., may be approved approximately eight (8) years after the innovator medication or drug was approved. This system is seen as being beneficial for both a) the biotech - pharmatech industry as they are able to obtain an adequate return on their R&D, and b) consumers who can eventually purchase cheaper medications having the same quality as the innovator medication.

The Supreme Court had previously ruled (Genentech Inc. v. the Commissioner of Japan Patent Office, decision by the Supreme Court of Japan, November 17, 2015, Hei 26 (gyo-hi) 356) that an application for a patent term extension would be rejected if the medicine or drug (in this case, the anti-VEGF antibody Avastin) to be covered by the patent term extension included a new feature(s) (i.e., dosage, indications, mode(s) of administration, effect, etc) which may be different from and were not covered in the original patent. This would constitute a new drug. As the previously patented drugs do not provide coverage for the newly-approved drugs which are different due to the dosage, indication, etc., time-consuming regulatory approval for the new invention, i.e., the "newer version" of the patented medicine or drug would be required.

Returning to the Debiopharm International SA vs. Towa Pharmaceuticals KK case (IP High Court Decision H28 (ne) No. 10046, January 20, 2017); unlike Debiopharm's patented invention for oxaliplatin, Towa included glycerin in their formulation. The metrics used to define "substantially the same" in order to judge whether a generic medication or drug is substantially the same as an innovator medication or drug would be clarified by this case.

Debiopharm argued that since Towa's oxaliplatinum contained the same amount of oxaliplatin, carried the same indication, and used Debiopharm's clinical trial data in order to attain regulatory approval, there were no substantial

differences between the two medications. Towa argued that the inclusion of glycerin in their oxaliplatinum resulted in a medication having greater stability, and thus, constituted a feature having a substantial difference.

The IP High Court ruled that "substantially the same" should be determined by comparing the patented drug and the potentially infringing drug in terms of the ingredients, dosage, mode(s) of administration, indications, effect, etc. These comparisons must also be viewed in light of the common knowledge of a person skilled in the art at the time. In short, any difference between the patented medicine and the potentially infringing drug must be minor (i.e., does not provide a novel effect) in order for the two drugs to be considered "substantially the same".

The addition of glycerin was viewed as being an inventive step exceeding a slight variation or difference relative to the features of Debiopharm's patented drug. Thus, the High Court concluded that Towa's oxaliplatinum did not infringe the Debiopharm patent.

Note: The Doctrine of Equivalents (DOE) may not be applied in order to determine the scope of "substantially the same". If the allegedly infringing product contains an ingredient or step, etc., which was intentionally excluded from the scope of the patented invention, a special circumstance exists by which it can be judged that the allegedly infringing product is not "substantially the same", and accordingly, there has been no infringement.

Given that the Japanese government has expressed the intention of raising the proportion of the market that generic non-patent-protected pharmaceuticals occupy to 80% by 2020, and has begun a large-scale advertising campaign to educate the public as to the safety and low cost associated with generics, it appears that the issue of determining the scope of "substantially the same" will surely be revisited in the future.