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Japan: Problem of Japan's patent linkage system comes to the surface by a set of IP High Court decisions

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The "patent linkage system" is in general a system wherein market approval of generic drugs is linked with the status of the originator drug's patents, for the purpose of early resolution of patent disputes and ensuring the stable and consistent supply of generic drugs. Japan has not statutorily adopted the patent linkage system, but the system is said to have been adopted in the Ministry of Health, Labor and Welfare (MHLW)'s notification level, under which marketing approval shall not be granted for a generic drug while the originator's patent covering the active ingredient is existing. Also, among indications and dose and administrations approved for the originator's drug, those covered by the originator's patents shall be carved out from the marketing approval for a generic drug. However, there are some problems in the Japanese system, and one of them is that the process of determination of whether or not a generic drug is covered by the originator's patents is not open to the public. Further, in practice, when the originator's patent is invalidated through an invalidation trial at the JPO, marketing approval is sometimes granted for the generic drug or the previously carved-out indications or dose and administrations, "without" waiting for the invalidity decision to become final.

This problem has come to the surface by a set of decisions rendered by the IP High Court on December 21, 2021 (Case Nos. 2020 (Gyo-Ke) 10077~10083). The first instances of the cases were invalidation trials at the JPO filed by a number of generic companies[1] against a medical use patent of Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), Japanese Patent No. 4178032, covering some indications of a pharmaceutical product called Abilify®, a 5-HT_{1A} receptor partial agonist ("Otsuka patent").

As a background, although generic drugs of Abilify® had been approved, the approved indication thereof was only "schizophrenia" among the indications for Abilify®; and its other indications "depression" and "manic episodes of bipolar disorders" had been curved out from the approval, probably due to the existence of the Otsuka patent.

The JPO held on May 12, 2020 that the inventions of Claims 1, 4 and 5 of the Otsuka patent for the treatment of "bipolar I disorder" and/or "bipolar II disorder" did not satisfy the enablement and support requirements and were thus invalid. The reasons for invalidity were that the descriptions in the specification were insufficient and that there was no common general knowledge at the time of the filing of the patent application that a 5-HT_{1A} receptor partial agonist could be used for the treatment of bipolar disorders, although the patent specification provided *in vitro* data showing the

claimed compound is a 5-HT_{1A} receptor partial agonist. On the other hand, the JPO found that the invention of Claim 2 of the Otsuka patent for the treatment of “depression” met the enablement and support requirements and was thus valid, since there was common general knowledge that a 5-HT_{1A} receptor partial agonist could be used for the treatment of depression

After the JPO decisions in July or August of 2020, the MHLW approved the generic drugs of Abilify® to add the indication of “manic episodes of bipolar disorders” which corresponds to Claims 1, 4, and 5.

In December 2021, however, the IP High Court revoked the JPO’s decisions regarding Claims 1, 4 and 5 for the reason that they were based on an erroneous finding. The court found that it was common general knowledge at the time of the filing of the patent application that a 5-HT_{1A} receptor partial agonist in general was effective for the treatment of “depressive episodes of bipolar disorders.”

The IP High Court decisions are currently being appealed to the Supreme Court but if eventually the cases are referred back to the JPO and the inventions of Claims 1, 4 and 5 are decided to be valid, there would be potential patent infringement disputes, and it may turn out that the additional indication of the generic drugs should not have been approved.

The outcome of these cases is still uncertain, but it could give rise to discussions in the MHLW to review and change its practice, so that even in a case where an originator’s patent is invalidated by the decision of the JPO, marketing approval for generic drugs will be granted only after the decision becomes final.

References[+]

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