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Supreme People's Court Upholds China's First Patent Linkage Ruling – Decision Released

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On August 28, 2022, ??????? published the first patent linkage decision from the Supreme People's Court (SPC). The SPC upheld the Beijing IP Court ruling that Wenzhou Haihe Pharmaceutical Co., Ltd.'s application for marketing authorization for a generic form of "Aidecalcidol Soft Capsule" did not fall within scope of protection of the relevant patent. China's patent linkage system prevents marketing authorization for a generic prior to the expiration of the patent term on the branded equivalent unless the Beijing IP Court or the China National Intellectual Property Administration (CNIPA) rules that the generic does not fall within the scope of the relevant patent rights or is invalid.

On November 10, 2021, the Beijing IP Court announced that the plaintiff of the case, Chugai Pharmaceutical Co., Ltd., a subsidiary of Roche, claimed that it was the patentee as well as the holder of the marketing license for the patented drug "Aidecalcidol Soft Capsule", and the patent involved in the drug was CN 2005800098777.6 entitled "ED-71 preparation." The plaintiff discovered that the defendant Wenzhou Haihe Pharmaceutical Co., Ltd. had applied to the National Medical Products Administration (NMPA) for a generic drug marketing license application named "Aidecalcidol Soft Capsule". The public information on the Chinese listed drug patent information registration platform showed that the defendant had made a 4.2 category statement regarding the generic drug (the generic drugs do not fall into the scope of protection of the related patents). Therefore, the plaintiff filed a drug patent linkage lawsuit with the Beijing Intellectual Property Court in accordance with the provisions of Article 76 of the Amended Patent Law, requesting the court to confirm that the generic drug "Aidecalcidol Soft Capsule" that the defendant applied for registration fell into the scope the rights of Patent No. 2005800098777.6 enjoyed by the plaintiff.

The Beijing IP Court held:

> The technical solution used by the generic drug involved is neither the same nor equivalent to the technical solution of claim 1 of the involved patent, so the technical solution does not fall within the protection scope of claim 1 of the involved patent. Since claims 2-6 are dependent claims of claim 1, if the technical solution of the generic drug involved does not fall within the protection scope of claim 1, it also does not fall within the protection scope of claims 2-6. Accordingly, the plaintiff's claim that the involved generic drug falls within the protection scope of claims 1-6 of the involved patent cannot be established, and the court will not support it.

In the decision, the Supreme People's Court stated there were two key points:

> 1. In the process of drug marketing review and approval, disputes arising from the patent rights related to the drug to be registered between the drug marketing license applicant and the relevant patentee or interested parties are only one type of the related patent rights between the two parties – often referred to as drug patent link disputes. For chemical generic drugs, the drug regulatory department of the State Council conducts drug marketing review and approval based on the application materials of the generic drug applicant, and decides whether to suspend the approval of the relevant drugs according to the effective judgment made by the people's court *[or the China National Intellectual Property Administration]* on such disputes within the prescribed time limit. Therefore, when judging whether the technical solution of a generic drug falls within the scope of patent protection, in principle, it should be compared and judged on the basis of the application materials of the generic drug applicant. If

the technical solution actually implemented by the generic drug applicant is inconsistent with the declared technical solution, it shall bear legal responsibility in accordance with the relevant laws and regulations on drug supervision and administration; if the patentee or interested party believes that the technical solution actually implemented by the generic drug applicant constitutes infringement, a separate lawsuit for patent infringement may also be filed. Therefore, whether the technical solution actually implemented by a generic drug applicant is the same as the application materials is generally not within the scope of examination to confirm that the dispute falls within the scope of patent protection.

2. The court of second instance held that both the donation [to the public] rule and the estoppel rule can constitute a restriction on the application of the principle of equivalence, both of which aim to achieve a reasonable balance between equitably protecting the interests of the patentee and safeguarding the interests of the public. If the conditions for limiting the application of the principle of equivalence are met, there is usually no need to judge whether the two features constitute similar means, functions, and effects, and whether those skilled in the art can conceptualize them without creative work. In this case, since Haihe Company claimed the application of the estoppel rule by virtue of the amendment of the claims by Chugai Pharmaceutical Co., Ltd., and claimed the application of the donation rule by the patent text as the result of the amendment, the court of second instance first rendered a judgment on whether the rules on estoppel should be applied on the basis of the amendment of the claims by the patentee.

The case numbers are:

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The full text of the decision courtesy of ??????? is available here (Chinese only).

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