

Beijing Intellectual Property Court Accepts China's First Drug Patent Linkage Litigation Case

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On November 10, 2021, the Beijing Intellectual Property Court [announced](#) that it accepted its first drug patent linkage litigation case. In contrast, an alternative patent linkage adjudication mechanism seems more popular with the [China National Intellectual Property Administration \(CNIPA\)](#) [announcing](#) that as of October 27, 2021 they had accepted 12 cases. China implemented a patent linkage system in their amended patent law, which became effective June 1, 2021 (Article 76 of the [Patent Law of the People's Republic of China \(2020\)](#)). The Chinese patent linkage system prevents marketing approval of generic drugs until after the expiration of patents covering the drugs or uses.

Article 76 of the amended Patent Law, which was implemented on June 1, 2021, added a settlement mechanism for disputes arising from patent rights related to drugs applied for registration. In this regard, the NMPA and CNIPA jointly issued the "[Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes \(Trial\)](#)." The Supreme People's Court also promulgated the "[Regulations of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drugs Applied for Registration](#)."

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 "Idicalcidol 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 NMPA for a generic drug marketing license application named "Idicalcidol 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 "Idicalcidol Soft Capsule" that the defendant applied for registration fell into the scope the rights of Patent No. 2005800098777.6 enjoyed by the plaintiff. Upon examination, the Beijing Intellectual Property Court held that the plaintiff's action complied with the requirements for litigation conditions for patent linkage actions for pharmaceutical products, and registered the case as a case according to the law.

In contrast, CNIPA earlier announced that it had received 23 requests for administrative adjudication

and accepted 12 of them seemingly proving administrative adjudication to be more popular route.

More information on China's patent linkage system can be found [here](#).

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