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The Fast and the Furious: Article 76 Proceedings in China Proceed with Speed

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Article 76 of the Fourth Amendment[1] to the Chinese Patent Law links regulatory approval of a generic drug and patent protection of the brand-name drug. It establishes a legal framework similar to the Hatch-Waxman Act in the United States for resolving drug patent disputes before approval of the generic drug product.

Under Article 76, when filing a New Drug Application (NDA), a patent holder must submit a Patent Registration Form to the Drug Patent Information Registration Platform[2] maintained by the Center for Drug Evaluation (CDE) of the National Medical Products administration (NMPA). In turn, a generic drug applicant seeking marketing authorization of a generic version of the branded drug must submit one of the four types of certifications against each listed patent:

Type I: No relevant patent is listed on the Patent Registration Platform;
Type II: The relevant listed patent has expired or was invalidated;
Type III: The generic drug product will not enter the market before the expiration of the relevant listed patent; and
Type IV: The generic applicant believes the relevant listed patent to be invalid or not infringed.

If the generic applicant files a Type IV Patent Certification, asserting the relevant listed patent is invalid and/or will not be infringed by the generic applicant's drug product, the patent holder may institute a civil judicial infringement proceeding against the generic applicant in (1) the IP courts; (2) special IP tribunals in local courts; and/or (3) administrative adjudications in the China National Intellectual Property Administration (CNIPA).

In April of 2022 – less than a year since Article 76 became effective – pharmaceutical companies have swiftly turned to these new venues for patent dispute resolution, and both the Beijing IP court and CNIPA have quickly resolved disputes between brand-name and generic companies under Article 76. The court and the CNIPA made these decisions well within the requisite 9-month stay period for marketing authorization approval, at a pace much faster than Hatch-Waxman litigation in U.S. district courts.

Article 76 litigation Before the Beijing IP Court

The first patent linkage case resolved under Article 76 since the enactment of the Fourth Amendment is *Chugai Pharmaceutical Co. Ltd. v. Wenzhou Haihe Pharmaceutical Co., Ltd.* ("Haihe"). In that case, the Beijing IP court held the generic drug manufactured by Haihe does not fall in the scope of patent protection of CN1938034B, owned by Chugai Pharmaceutical Co. Ltd. (aka, Sino-Foreign Pharmaceutical Co., Ltd.), and as such, Haihe does not infringe the patent.

The CN1938034B[3] patent covers the aidecalcidol soft capsules drug product used to treat osteoporosis which is marketed by Chugai. Chugai registered the patent in the Patent Information Registration Platform as required by Article 76, and Haihe submitted a generic drug application for aidecalcidol soft capsules with a Type IV certification, asserting it does not infringe CN1938034B.

On November 10, 2021, Chugai timely filed an Article 76 suit with the Beijing IP court, asking the court to declare that Haihe's generic drug product infringes CN1938034B. On April 15, 2022, the Beijing IP court handed the generic company a victory, holding Haihe does not infringe CN1938034B because Haihe's generic drug product is neither the same as nor equivalent to the technical solution used to prepare Chugai's marketed drug, thus Haihe's generic drug is not covered by CN1938034B.

Article 76 litigation Before the CNIPA

As discussed above, unlike the Hatch-Waxman Act in the United States, which provides a statutory framework for resolving patent disputes in the federal court system, Article 76 dispute resolution can be conducted before the CNIPA as well as the IP courts. The first patent linkage litigation decided by the CNIPA is *Purdue Pharma v. Yichang Renfu Pharmaceutical Industry Limited Liability Company*. In that case, as with the Chugai litigation before the Beijing IP Court, the CNIPA found in favor of the generic manufacture, holding the generic drug product manufactured by Renfu does not fall in the scope of protection of Purdue Pharma's patents listed in the Patent Information Registration Platform.

The patents at issue include 201210135209.X (CN102657630B),[4] ,201510599477.0 (CN105267170B), and 201010151552.4 (CN101812065B), which cover the drug product oxycodone hydrochloride sustained release tablets manufactured by Purdue Pharma to relieve severe pain. Renfu submitted a generic drug application for oxycodone hydrochloride sustained release tables with a Type IV certification, asserting it does not infringe the patents. Purdue Pharma filed an Article 76 proceeding with the CNIPA, requesting the CNIPA to declare Renfu's generic product drug falls within the scope of the listed patents. On April 25, 2022, the CNIPA determined that the generics does not fall in the scope of the protection of the patents and Renfu's generic drug product does not infringe the listed Purdue Pharma patents.

Takeaways:

Article 76 litigation in China is fast and furious. The speed under which the Beijing IP court and CNIPA handled these cases resolves any doubt concerning whether the 9-month stay of regulatory review under Article 76 would provide sufficient time for patent infringement proceedings to play out in the IP courts and the CNIPA. Litigants should be well prepared and have a well-formed strategy before entering proceedings under Article 76.

For brand-name companies, choosing and listing strong patents in the Patent Information Registration Platform is crucial. Typically, formulation patents may not as strong as patents protecting the active pharmaceutical ingredient (API) and may be easily designed around. The success of Article 76 proceedings will depend on maintaining a strong and comprehensive patent portfolio to protect all aspects of drug development, including APIs, methods of treatment, routes of administration, combinations, and polymorphs, and the like. Such patent protection would provide the patent owner with more options to develop more robust strategies when litigating against generic companies.

For generics companies, filing a Type IV certification and asserting non-infringement of the listed patents appears to be a winning strategy under Article 76. Accordingly, generics companies should invest time and resources in early-stage product development to diligently review relevant blocking patents and potential designing around options. For example, replacing excipients in a formula of the brand-name drug product while maintaining its therapeutic efficacy may provide a winning non-infringement argument in both the IP courts and the CNIPA.

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Footnotes

[1] The Fourth Amendment to the Chinese Patent Law, https://www.cnipa.gov.cn/art/2020/11/23/art_2197_155169.html (last visited June 28, 2022). The Fourth Amendment became effective as of June 1, 2021.

[2] 中国上市药品专利信息登记平台 (cde.org.cn)

[3] Claim 1 of the CN1938034B is translated as follows:

A preparation comprising:
(1) (5Z, 7E)-(1R, 2R, 3R)-and 2-(3-hydroxyl propoxyl group)-9,10-secocholesta-5,7,10 (19)-triolefins-1,3,25-triol;
(2) oils and fats; and
(3) antioxidant.

[4] A representative claim of the CN102657630B is translated as follows:
A solid pharmaceutical composition for extended release, wherein the composition comprises at least the following:
(1) at least one polyethylene oxide, having an approximate molecular weight of is at least 1,000, 000 based on rheology measurement, and
(2) at least one activating agent of an opioid analgesic, wherein said opioid analgesic is oxycodone hydrochloride, and wherein the composition comprises 5mg to 20mg oxycodone hydrochloride, and wherein the composition comprises at least 80 wt% of polyethylene oxide that has an approximate molecular weight of at least 1,000, 000 based on rheology measurement.