China National Intellectual Property Administration (CNIPA) and China National Medical Products Administration (NMPA) Jointly Published Details of Pharmaceutical Patent Linkage Guideline

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The CNIPA and the NMPA jointly published <**Methods for Early Resolution of Drug Patent Dispute** (Pilot Program)> on July 4, 2021, which has immediately come into effect on the same day (hereinafter referred to as the "**Methods**").

It means that any pharmaceutical patent disputes between the branded and generic companies can now resort to the Methods (or commonly known as pharmaceutical patent linkage system) for early resolution in China.

Some of the key objectives and contents of the Methods are highlighted below in this article.

I. It specified the types of patents that can be put on the Patent Listing Platform for Authorized Drugs in China (Hereinafter referred to as the "Platform")

- **Chemical drugs**: (i) patents in relation to pharmaceutical active ingredient; (ii) patents in relation to pharmaceutical composition comprising active ingredient; or (iii) medical use patents;

- **Biological preparations**: (i) patents in relation to active ingredients of sequence structures; or (ii) medical use patents;

- **Traditional Chinese Medicines (TCMs)**: (i) TCM composition patents; (ii) TCM extract patents; or (iii) medical use patents.

  Importantly, the Methods clarified that patents in relation to intermediate products, metabolites, crystal forms, methods of preparation and/or methods of measuring/testing can't be listed on the Platform.

II. It clarified how to make Statement (I, II, III and IV) and challenge the patent

The generic drug applicant must file the marketing authorization application by submitting one of the four Statements.

- Type I Statement: There were no patents listed on the Platform in relation to the drug;

- Type II Statement: The patents listed on the Platform were either terminated or invalidated, or have been licensed to the generic drug applicant;

- Type III Statement: The generic drug applicant promises to delay the marketing of the drug until the patents listed on the Platform are expired; or

- Type IV Statement: The patent listed on the Platform shall be declared invalid, or the generic drug did not fall within the scope of the patent.

The generic drug applicant must be responsible for the accuracy of the Statement. The NMPA will lay open of the Statement to the public and the generic drug applicant must send a Notice to the Marketing Authorization Holder (MAH) about Statement and the grounds of such Statement, within 10 working days from the date when the drug authorization application is received by the NMPA. According to the Methods, said Notice must be at least sent to email addresses of the MAH displayed on the Platform.

In particular, the Methods also clarified that, if **Type IV statement** is made on the ground in which "the drug does not fall within the scope of the patent(s)", then the Statement must include the technical solution of the generic drug, a comparison analysis chart between the claim(s) and the generic drug, together with relevant technical evidence.

III. It specified the method of triggering the 9-month stay period

The patentee or the party of interest in relation to chemical drug patent could file an opposition against Type IV Statement (not applicable to Type I, II and III Statement), within 45 days from the date when the generic drug applicant files the marketing authorization application. The opposition must be filed to either the CNIPA or the Court. When the CNIPA or the Court receives the opposition as filed, they will send a Notice to both of the NMPA and the generic drug applicant. Then the NMPA will set a 9-month stay period, calculated from the date when the CNIPA or the Court receives the case.

Importantly, during the stay period, the NMPA will **not** stop the technical examination for the drug, but will only stop the marketing authorization and hold off issuing a license for drug authorization.

Interestingly, according to the Methods, generics of biologics and TCMs are excluded from the 9-month stay period. In other words, if patents of biologics or TCMs are challenged under Type IV Statement and if the patentee files an opposition against said Type IV Statement, the NMPA will **not** set a stay period for such cases.

From this perspective, there seems to be no good incentives for MAHs of biologics (or TCMs) to list their patents on the Platform.

IV. It clarified the events where the NMPA shall resume the activity of marketing authorization

If any of the three events below occurs, then the 9-month stay period will be terminated and the NMPA will resume its normal activity of marketing authorization.

- (i) The CNIPA or the Court decides that the chemical generic drug does not fall within the claimed scope of the patent, or the parties reach a settlement;

- (ii) The CNIPA or the Court decides that the patent right be declared invalid; OR

- (iii) The NMPA fails to receive any decision from the CNIPA or fails to receive any judgement or mediation agreement from the Court within the stay period.

If the NMPA, during the marketing authorization, receives a judgement from the Court or a decision from the CNIPA indicating that the chemical generic drug falls within the scope of the patent, then the NMPA will postpone the marketing authorization until close to the expiry of the patent term.

In our opinion and according to our experience, 9 months are relatively short for the CNIPA or the Court to make a timely decision or judgement, especially for complicated cases such as pharmaceutical patent disputes. So, we are concerned that a large number of “early resolution” cases may end up with item (iii) above, where the CNIPA or the Court failed to make timely decision within the 9-month stay period.

V. It clarified the applicability of market exclusivity for the first generic

For the first chemical generic that successfully challenged the patent under Type IV Statement, the NMPA will grant it a 12-month market exclusivity. This means that the NMPA will **not** approve any other generics of the same kind within 12 months from the date of obtaining the market authorization.

Interestingly, a successful patent challenge herein means a successful challenge under Type IV Statement and the patent must have been declared invalid during the opposition proceeding.

So the question is, would it be considered a successful challenge if the patent is “partially invalidated” such that the generic drug no longer falls within the

scope of the patent? We will wait for the NMPA and the CNIPA to answer that.

If you have any questions on this topic, please feel free to contact Elliot ZHOU at patent@foundin.cn.