Pharmaceutical polymorph patents are regarded as effective means and important remedies for pharmaceutical authorities to extend the life cycle of pharmaceutical patent protection. However, the uncertain economic criteria for pharmaceutical polymorph patents have been much in vogue since the issuance of many decisions. The clinical research of pharmaceutical polymorphs commenced in the 1960s immediately. It was valid in the United States. The research outputs and new developments, upon which the approval of the requirements for innovative pharmacological properties patent applications was based, were much in vogue since the issuance of many decisions. Therefore, pharmaceutical polymorphs patents are regarded as effective means and important remedies for pharmaceutical authorities to extend the life cycle of pharmaceutical patent protection. However, the uncertain economic criteria for pharmaceutical polymorph patents have been much in vogue since the issuance of many decisions.

In China, there are specific rules over pharmaceutical polymorph patents. There is an ad hoc authorization for innovative pharmaceuticals. But whether an application for pharmaceutical polymorph patent is new or not, in patent examination practice, China may vary from time to time for the authorization of pharmaceutical polymorph patents. This European practice is not the same. The threshold was increased from 1979 to 1997, and as a result, a large volume of un patented pharmaceutical patents were invalidated by the Patents Examination Board ("PEB") for failing to satisfy the patent examination requirement. Based on the review of recent court-administered cases or ex reclamation or invalidation decisions made by the PNB, we acknowledged that some cases that the PNB and the courts denied the inventiveness of almost all pharmaceutical polymorph patents with similar concepts containing standard standards.

Pharmaceutical polymorph patents should have patentable properties, and even be patentable by the patent authorities. This article would examine the current inventiveness requirement standards for pharmaceutical polymorph patents in China and propose some strategic suggestions for potential patent applicants.

1. Current Examination Standards over Inventiveness of Chinese Pharmaceutical Polymorph Patents

There are two sets of norms for inventiveness assessment under the Patent Examination Guidelines. Both of which have been revised in recent years. Whether a polymorph invention can produce an unexpected technical effect is the core evaluation standard.

1.1 Standardized: the "Three-Step Approach"

1.1.1 Relevant Rules

Section 3 of Chapter 4 of Part 6 of the Patent Examination Guidelines (2017) stipulates that an invention is patentable if it is not anticipated in the prior art and is not obvious to a person skilled in the art, and that it possesses inventive step over the prior art.

1.1.2 Statistical Analysis of Judicial Assessment of Inventiveness of Pharmaceutical Polymorph

There are six pharmaceutical polymorph patents in China that are invalid for the same reason, including the inventiveness of the pharmaceutical polymorph. The inventiveness requirement standards for pharmaceutical polymorph patents in China are similar to that of European countries and China.

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1.2.1 Standardized for Chemical Inventions

Inventiveness is one of the key elements of a chemical invention. The assessment of inventiveness involves the purpose of the invention, the technical effect of the invention, and the unpredictability of the technical effect. The standard for inventiveness is "unexpected technical effect." In the context of chemical inventions, unexpected technical effect means that the technical effect is different from that of the prior art and cannot be directly and unambiguously derived from the prior art.

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2. Relevant Judicial Practice

2.1 Analytical Example

In order to review the judicial practice with regard to inventiveness examination of pharmaceutical polymorph patents in China, the author reviewed by the keywords "pharmaceutical", "inventiveness", "polymorph" and "crystal" in the databases of IP House, PKU Law, and on the IP Precedent Guiding Service Platform, and identified eight judicial precedents in total counted in the number of final judgments to avoid repeated considerations. The eight judicial precedents are taken as samples in the following analysis.

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2.2 Observations and Speculations

2.2.1 The determinations on the inventiveness of pharmaceutical polymorph patents are fully consistent.

In the eight judicial precedents, Chinese courts at all levels denied the inventiveness of pharmaceutical polymorph patents.

2.2.2 The legal grounds for denying the inventiveness of pharmaceutical polymorph patents are highly unified.

Among the eight decisions, four of them were against the general standard of “Three-Step Approach” plus the “Unexpected Technical Effect” examination, and the rest four were applied the special inventiveness standard for chemical compounds. In both circumstances, “unexpected technical effect” was examined and denied. The decisions show that, the examination standards for inventiveness of pharmaceutical polymorph patents are broadly consistent between PRB and courts and among Chinese courts at all levels.

2.2.3 The examination standards for inventiveness of pharmaceutical polymorph patents have significantly changed.

We notice that, the six invalidated patents involved were granted between 2000 and 2009, and that the final judgments denying their inventiveness were made between 2010 and 2016. The results reflect the substantial change of the examination standards for inventiveness of pharmaceutical polymorph patents in recent years. In the past time when the patents were granted, it was at the initial stage of polymorph studies in China. A generally accepted understanding at that time was that, even though a person skilled in the art could expect the improvement in certain properties of a compound by producing a crystal form, whether a polymorph could be obtained and what polymorph would be obtained were unpredictable for a known compound disclosed in the prior art, which might bring non-obviousness to the polymorphic invention. Therefore, the patent examination office generally recognized the inventiveness of pharmaceutical polymorph patents at that time.

In the recent years, the progress of polymorph research and development brought changes in minds of examiners and judges, who have gradually reached consensus, as reflected by the eight decisions. That is, a deeper understanding of the importance of pharmaceutical polymorphs provides stronger motivation to a person skilled in the art to study polymorphs, so that it becomes a routine for a person skilled in the art to prepare polymorphs based on a known compound. Moreover, the richer experience in polymorph preparation makes it much easier to obtain a new polymorph. Therefore, the standards for inventiveness review of polymorph inventions are substantially raised.

2.2.4 Retroactivity in inventiveness evaluation is improper.

It is a natural process that technology development causes changes of patent examination practice. However, whether a stricter examination standard can apply to invalidate a patent that was granted following a less strict examination standard is an issue worthy of attention.

It is a universal practice that whether a patent has inventiveness shall be evaluated from the technical level and the cognitive level of a person skilled in the art before the filing date or the priority date. The approach of using the present stricter examination standard to invalidate granted patents appears inconsistent to the said examination norm.

III. Suggestions

As mentioned above, “unexpected technical effect” is an essential factor for inventiveness assessment of pharmaceutical polymorph patents. Accordingly, this article intends to make some suggestions from the perspective of technical effect.

1. “Qualitative change” of technical effect should be exploited more to qualify polymorph patent applications. Since stability, purity and bioavailability of a polymorph are considered to be conventional, “new performances” of a new polymorph are preferred to be introduced in the application. For example, if a new polymorph is able to bring reduction of side effects, change of indications or suitable groups, it will be recognized that such “qualitative change” is a “unexpected technical effect” of the new polymorph.

2. “Quantitative changes” of technical effects achieved by a new polymorph has to have unpredictability. For example, based on the common knowledge in the art, between stability and solubility there exists a relation of mutual restriction; however, if it is proven with experimental data in the original application that a new polymorph can simultaneously improve the stability and solubility of a drug, it will be accepted that the new polymorph has a “new performance”, and accordingly shows a “quantitative change” of the technical effect.

3. Finally, it is worth noting that “unexpected technical effect” can only be the technical effects specified in or can be directly determined from the original disclosure of application documents. According to the examination practice, any experimental data submitted after the filing date to prove the technical effect will hardly be taken into consideration for inventiveness evaluation.