Patent examination of pharmaceutical polymorphs is regulated by several laws and regulations. Pharmaceutical polymorphs are claimed in the patent claims of the primary patent application and are analyzed for their technical effects during the examination process. The examination is conducted in accordance with the Examination Guidelines, and the technical effects may include stability, purity, and bioavailability.

Inventiveness of Pharmaceutical Polymorph Patents in China
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Inventiveness of Pharmaceutical Polymorph Patents in China
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Pharmaceutical polymorph patents are regarded as effective means of monopolizing pharmaceuticals. For this reason, some companies may file several patent applications for different polymorphs of the same compound in order to prolong the market exclusivity of the pharmaceutical. However, the technical effects of these polymorphs may be similar or different. Therefore, it is necessary to analyze the technical effects of the polymorphs to determine the inventiveness of the patent.

The technical effects of pharmaceutical polymorphs are usually related to their stability, purity, and bioavailability. Therefore, the inventiveness of the polymorph is determined by its stability, purity, and bioavailability. The stability of the polymorph is determined by its ability to maintain its structure and activity under various environmental conditions. The purity of the polymorph is determined by the concentration of the active ingredient in the formulation. The bioavailability of the polymorph is determined by the extent to which the active ingredient is absorbed and distributed in the body.

Inventiveness of pharmaceutical polymorph patents is a key factor in the duration of the patent. Therefore, it is necessary to analyze the inventiveness of the polymorph to determine whether the patent is valid. The inventiveness of the polymorph is determined by its ability to provide a new technical effect. Therefore, the technical effect of the polymorph must be novel and non-obvious. The technical effect of the polymorph must be superior to the prior art.
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 generic standards of "Three-Step Approach" plus the "Unexpected Technical Effect" examination, and the rest four were against 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 standard for inventiveness review of polymorph inventions is 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. Among inventions, their stability, purity and bioavailability of a polymorph are considered to be conventional, "new performance" of a new polymorph are preferred to be introduced in the application. Taking an example of bioavailability, if a new polymorph is able to bring reduction of side effects, change of indications or suitable groups, it will be recognized that the new polymorph has a "new performance", and accordingly shows a "qualitative change" of the technical effect.

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 recognized that such "quantitative change" is a "unexpected technical effect" of the new polymorph.

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.