Pharmaceutical polymorph patents are regarded as effective means and imported encyclopedias to authorities to extend the life cycle of pharmaceutical patent protection. Therefore, the examination practice criteria for pharmaceutical polymorph patents have been further utilized in China while the amount of patent applications is increasing. The clinical research of pharmaceutical polymorphs commenced in 1980s internationally. It was used in clinical trials in China. However, due to research institutions and pharmaceutical enterprises recognize the importance of pharmaceutical polymorphs after the first awareness of the significant efficacy difference between separated isomers and the homolane are.

In China, there are specific rules even pharmaceutical polymorph patents are reviewed in the Patent Examination Board. The Patent Examination Board serves as the authority to examine inventive power in deciding whether an application for pharmaceutical polymorph patent is inventive or not. In patent examination practice, China has no way back from the authorization of pharmaceutical polymorph patents. Such European countries as France, Italy, and Germany have, however, the threshold has increasingly tightened in recent years, and as a result, a large portion of already-authorized pharmaceutical polymorph patents were invalidated by the Board. The Board considered the patent invalid for failing to satisfy the present examination requirement. Based on a review of recent court administrative judgments on invalidation or invalidation decisions made by the PRB, we can assert that the PRB should be accused of the inventiveness of almost all pharmaceutical polymorph patent applications with unsatisfactory content examination standards.

Pharmaceutical polymorph patents are granted properties with chemical product patents and renewable local patent. This article would aim the current inventive standards for pharmaceutical polymer 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 criteria for inventive assessment under the Patent Examination Board, both of which claim the same inventive content, whether a polymer invention can produce an unexpected technical effect in the core evaluation standards.

1.1 Standard Evaluation: the "Three-Step Approach"

1.1.1 Relevant Rules

Article 25 of the current Patent Law of the People’s Republic of China (2009) stipulates that “inventiveness derives from the creative thinking, the novel, positive contributions, substantial differences and indicate valuable advancements, and the utility must possess subjective features over the existing.”

Section II of Chapter 6 of Part II of the Patent Examination Guidelines (2017) clarifies the general procedures and standards for inventive assessment, i.e., (1) defining the concept of inventive; (2) determining the distinguishing features of the invention and the technical problem actually solved by the invention; and (3) comparing the invention and the prior arts. The inventive is referred to as the “Three-Step Approach” and the general rule in assessing patentable subject matter.

Section II of Chapter 6 of Part II of the Patent Examination Guidelines (2017) further provides supplementary factors to be considered in assessing inventive content following the “Three-Step Approach.” These factors include an inventor’s endeavors, unexpected technical effect, commercial utility, availability, admissible commercial success, etc.

1.1.2 Examination Standard

When applying the “Three-step Approach” for polymorph patents, it is generally presumed that there is a universal technical solution in the prior art to prepare the crystal form of active pharmaceutical ingredients. From a structural perspective, crystal is a composition which forms from a crystal structure forming, from a stability perspective, if there is a need to improve the stability and partly of an amorphous compound, a person skilled in the art would naturally know that a crystal form of a certain compound can be potentially formed from a crystall. So, if it is not structurally different and functionally and by professional pure technical skill the crystal form cannot be used, then the inventive content of a person skilled in the art can be observed.

In short, following the “Three-step Approach,” it is generally recognized as an “obvious” technical solution to prepare a new polymorph based on a known compound or a known polymorph that has been recognized as obvious from the prior art. For a compound having an obvious technical effect, it is generally required to have an unexpected technical effect in order to be considered patentable.

1.2 Relevant Rules for Chemical Inventions

Since polymorphs are a type of chemical products, the inventive assessment of polymorph patents can follow the basic special provisions on examination of chemical inventions in Chapter IV of Part II of the Patent Examination Guidelines (2017). That is, if a compound is similar in its structure to a known compound, it would be expected that the new compound is expected to have unexpected use or effect. If the new compound has a use or effect that is not structurally different, then it is generally considered to be an obvious technical solution. In this case, the inventive content of a person skilled in the art can be observed.

There were debates on whether a claimed polymorph is similar in structure to a known compound or a known polymorph. In a decision made by the Chinese Supreme People’s Court (see below), it was clarified that if a compound is similar in structure to a known compound or a known polymorph, these criteria are satisfied. Therefore, the claim would naturally possess higher bioavailability.

1.3 Statistical Analysis of Judicial Assessment of Inventiveness of Pharmaceutical Polymorph Patents

In China, the lack of specific rules over pharmaceutical polymorph patents is an issue. In patent examination practice, China in the early days had a lower threshold for authorization of pharmaceutical polymorph patents. Scientists and researchers were inclined to authorize pharmaceutical polymorph patents in China without the amount of patent applications is increasing. The current inventive standards for pharmaceutical polymer patents in China and propose some strategic suggestions for potential patent applicants.

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

In order to review the judicial situation regarding inventive assessment of pharmaceutical polymorph patents in China, the author referred to the keyword “pharmaceutical” “inventiveness” “polymer” 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 consultation). These eight judicial precedents were made between 2010 and 2016, including one decision issued by the PRB and seven decided by the People’s Court. The eight judicial precedents were made between 2010 and 2016, including one decision issued by the PRB and seven decided by the People’s Court. The eight judicial precedents were made between 2010 and 2016, including one decision issued by the PRB and seven decided by the People’s Court.
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 applied 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 note 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, 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. 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 have better chances to be accepted 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 be unpredictable. 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 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.