Inventiveness of Pharmaceutical Polymorph Patents in China

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Please note this is the part of the text that was previously extracted for the document.

Pharmaceutical polymorph patents are regarded as effective means and important encyclopedias for pharmaceutical patents to extend the life cycle of pharmaceutical patent protection; however, the inventiveness examination criteria for pharmaceutical polymorph patents have become much stricter in China while the amount of patent applications keeps rising.

The clinical research of pharmaceutical polymorphs commenced in 1950s internationally, it was used in 1950s and 1960s, while pharmaceutical research institutions and pharmaceutical enterprises regard the requirement of pharmaceutical polymorphs after the first awareness of the significant efficacy differences between imported and domestic products.

In China, there are specific rules over pharmaceutical polymorph patents. The Patent Examination Guidelines, rules for the first time for authorities to examine pharmaceutical patents, make it clear whether an application for pharmaceutical polymorph patent is novel or not. In patent examination practice, China is the only country with few restrictions on the authentication of pharmaceutical polymorph patents. Thus European patents are not considered. The Patent Examination Guidelines also stipulate that the pharmaceutical polymorph patents must be awarded if the claimed compound is a new form of a known compound, and the preparation method of said compound is met the inventiveness.

Section II of the Patent Examination Guidelines classifies the general procedures and rules for the assessment of pharmaceutical polyforms, i.e., (1) determining if the claimed form is a new form of a known compound, and determining if the preparation method of said compound is met the inventiveness.

There were debates on whether a claimed polymorph is similar in structure to a known compound or a known polymorph. A decision made by the Chinese Supreme People’s Court (see below) clarified that, there is diversity of microcosmic crystalline structure brought “unexpected technical effect”. These factors include whether an invention produces unexpected technical effect, overcomes a disadvantage of a known compound, or a use or effect which is not clear in the prior art. 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, given that there has been an obvious motivation, the preparation process of polymorph is generally mature and the technical effects can be anticipated, the assessment of inventiveness of polymorph patent then show to conduct a further unexpected technical effect evaluation.

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

There are two sets of rules for inventiveness assessment under the Patent Examination Guidelines, both of which stand in the core evaluation foundation. Whether a polymorph invention can produce unexpected technical effect is the core evaluation standard.

1.1 Standardized-three “Three-Step Approach”

1.1.1 Relevant Rules

Section II of the current Patent Law of the People’s Republic of China (2008) stipulates that “inventiveness means that, compared with the starting technology, the invention possesses substantive features and indicates unobvious advantages, and the utility model possesses substantive features, can include unobvious advantages.”

Section II of Chapter I of Part II of the Patent Examination Guidelines (2017) clarifies the general procedures and rules for the assessment of inventiveness. Section II (1) determines if the claimed form is a new form of a known compound, and (2) determines if the preparation method of said compound is met the inventiveness.

In China, the inventiveness examination is referred to as the “Three-step Approach” and the general rule in assessing the patent examination is “expected technical effect evaluation.”

Section II of Chapter I of Part II of the Patent Examination Guidelines (2017) further provides supplementary factors to be considered to avoid arbitrary denial of inventiveness of a patent following the “Three-step Approach”. These factors include whether an invention produces unexpected technical effect, overcomes a disadvantage of a known compound, and indicates remarkable advancements, and the utility model possesses substantive features, can include unobvious advantages.

1.1.2 Examination Standard

When applying the “Three-step Approach” for polymorph patents, it is generally presumed that there is a universal technical evaluation in the prior art or prepare the crystal form of active pharmaceutical ingredients. From a general perspective, crystal is a unexpectedly different form from more stable or more impure form, and usually has differences in microcosmic crystalline structure. The evaluation of whether a new crystal form can be used as active ingredients is assessed from the chemical and physical properties.

Accordingly, a crystal form of a known compound would not be considered to have “unexpected technical effect” if it is similar in structure to a known compound.

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1.2 Special Rules for Chemical Inventions

Since polymorphs is a type of chemical products, the inventiveness assessment of polymorph patents can follow the special provisions on examination of chemical inventions in Chapter II of Part II of the Patent Examination Guidelines (2017). That is, if a crystal form is similar in structure to a known compound, it must have unexpected use or effect.

The state patent office must examine whether the claimed form has a new use or effect different than that of the known compound, or a new use or effect which is not clear in the prior art or cannot be deduced from the common general knowledge.

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1.2.1 Relevant Rules

Section II, Chapter II of Part II of the Patent Examination Guidelines (2017) states that “an invention is chemical type, a new use or new effect is the core evaluation standard. There are two sets of rules for inventiveness assessment under the Patent Examination Guidelines, both of which stand in the core evaluation foundation. Whether a polymorph invention can produce unexpected technical effect is the core evaluation standard.

2. Subjective Examination for Inventiveness of Pharmaceutical Polymorph Patents

Since the 2010s, the examination and inventive assessment of pharmaceutical polymorph patents kept soaring. Please refer to this post as:


Pharmaceutical polymorph patents share general properties with chemical product patents and usually have four particular features. This article would summarize the current inventiveness examination standards for pharmaceutical polymorph patents in China and propose some strategic suggestions for potential patent applicants.

2.1 General Examination of Inventiveness

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2.1.2 Examination Standard

Inventiveness of pharmaceutical polymorphs, the conventional effects usually include stability, purity and bioavailability that are commonly known as advanced properties of polymorphs in pharmaceutical life cycle. For pharmaceutical polymorphs, the inventiveness examination standards for pharmaceutical polymorph patents in China and propose some strategic suggestions for potential patent applicants.

2.2.3 Special Examination

The Supreme People’s Court explained in the patent re-examination decision for the PRB (No. 117) for failing to satisfy the present examination requirement. Based on a review of recent patent re-examination decisions on inventiveness or invalidation decided by the PRB, we acknowledge observed that the PRB and the courts denied the inventiveness of around 80% of pharmaceutical polymorph patents with sounder examination principles.

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2.4 Analytical Exam

In order to review the judicial situation regarding inventiveness examination of pharmaceutical polymorph patents in China, the author referenced by the keywords “pharmaceutical”, “inventiveness”, “pharmaceuticals” and “polymorph” in the databases of China, and searched the decision database of the Supreme People’s Court for the period from 2011 to 2017. The PRB decision was identified and included in the statistical analysis. In addition to the judicial decisions, this article also used the analysis of the inventiveness examination standards for pharmaceutical polymorph patents in China and propose some strategic suggestions for potential patent applicants.

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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 applied the generic 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 for 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 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. Taking an example of bioactivity, 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 unambiguously proven. 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 simultaneously improves 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.