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China Intellectual Property

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China introduces pharma-friendly revisions to Patent Examination Guidelines

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Did you know?

The Chinese National Intellectual Property Administration (CNIPA) revised Patent Examination Guidelines came into force on 15 January 2021. The changes significantly relax the patentability requirements for inventions in the pharmaceutical, chemical and biotech field.

Why does this matter to you?

The revised guidelines focus on the examination criteria for novelty and inventive step in relation to the rapidly developing field of chemical and biotech inventions. Coupled with the Fourth Amendment to the Patent Law, which will come into effect on 1 June 2021, the changes should be welcomed by applicants, especially those with more difficult cases, or those who faced problems under the old guidelines.

- The amendments further strengthen the grounds for consideration of post-filing supplementary data by Examiners. This was previously problematic for pharmaceutical patent applicants as the courts and CNIPA adopted a strict approach to the submission of supplementary data. The amendments set out two specific examples which provide guidance as to when this kind of data should be considered in support of the patentability of a claimed invention:

    1. The originally filed specification described the manufacture and blood pressure lowering effect of a compound, together with an experimental method for measuring the blood pressure lowering ability, but **without any experimental result data**. The applicant was able to supplement with post-filing data showing the blood pressure lowering effect of the compound for consideration and examination by the Examiners as the effect of the compound in lowering blood pressure is disclosed in the specification.
    2. The original specification provided data showing the claimed compounds have an IC50 value between 10-100nM. Post-filing data directly comparing the IC50 values of the claimed compounds versus the prior art was stated as appropriate to be considered by the Examiner in assessing inventive step.

- The revised guidelines increase the burden on Examiners when raising a lack of novelty objection in relation to a chemical compound, clarifying that a lack of novelty objection may be raised only "if the chemical name, molecular formula (or structural formula) and other structural information of the compound, is disclosed in a reference such that those skilled in the art believe that the claimed compound has been disclosed". This remedies the presumptive nature of a lack of novelty objection in such circumstances. In the past, an objection could have been raised based on a simple mention of the compound in a reference document, or if the reliance on the physical and chemical parameters, or other parameters, or preparation methods of the claimed compound, was disclosed in a reference document.

- The revised guidelines also introduce a provision clarifying that a compound is not novel *"if the structural similarities and differences between the compounds as claimed and disclosed in a reference document cannot be determined, and **those skilled in the art have reasons to believe** that two are the substantially the same after consideration of the physical and chemical parameters, preparation and experimental effects, and other factors provided in the reference document".* This emphasises that the perspective of a person skilled in the art is paramount in determining novelty of an invention.

- With regard to inventive step of compounds and biotech inventions, significant amendments clarify the position of the previous "unexpected technical effects" requirement of the 2019 Guidelines, refocusing on the need to apply the general

"three-step approach". The revised guidelines provide that, regardless of whether the claimed compounds are similar in structure to the known compounds, a "problem-solution approach" should be used to determine whether the compounds are inventive.

- Changes to the definition of monoclonal antibodies should help improve protection for such technology. In addition to defining a monoclonal antibody by reference to the hybridoma, the revised guidelines explicitly state that an antibody may be defined with respect to its structure, an example being: "A monoclonal antibody of antigen A, comprising VHCDR1, VHCDR2, and VHCDR3 shown in amino acid sequences of SEQ ID Nos: 1-3, and VLCDR1 VHCDR2, and VHCDR3 shown in amino acid sequences of SEQ ID Nos: 4-6". This has the benefit of covering monoclonal antibodies that cannot be defined by means of hybridoma and allowing a more accurate description of the characteristics of a monoclonal antibody.

- The revised guidelines also provide the possibility of protecting a non-limiting composition claim, where only one property or use, is disclosed in the specification.

Want to know more?

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