

China IP Developments in Biotech/Pharma

No % homology? How to craft allowable claim scope around sequences to comply with China's strict written description requirements

November 2018

It is well known that China has strict requirements when it comes to adequate written description and support in the specification. Chinese Patent Law Article 26(4) says that "all claims must be supported by the description and shall define the extent of the patent protection sought for in a clear and concise manner."

In unpredictable arts, such as chemistry and biology, the breadth of protection is highly dependent on the number and scope of the specific examples in the specification. The resultant narrow claims that are often issued in China are easy to design-around, thus making Chinese patents less attractive for biotech inventions with few actual examples.

We summarize a Top 10 IP Cases of 2016 regarding an invalidation request of Novozymes' Chinese invention patent (CN98813338.5) by Jiangsu Boli Biological Products Co. Ltd. Novozyme's patent relates to an isolated glucoamylase with improved thermal stability and many uses, such as converting starch into glucose. The claims were written in a way that included a functional limitation (having "glucoamylase activity") plus a scope defined in one or more of the following ways: "comprising" a SEQ ID, consisting of a SEQ ID plus 99% homology, and source, e.g., derived from a particular strain.

For support, the specification described two sequences, SEQ ID NO: 7 and 14, both of which were isolated enzymes from a strain of the filamentous fungus *T. emersonii* that had glucoamylase activity.

The court rejected claims that merely defined the enzyme using either open-ended "comprising" language or percent homology language, saying the scope was too open-ended and not supported by the examples. However, the court allowed claims that further narrowed the claim to cover sequences made by a particular strain. The court reasoned that

only a very narrow set of sequences could possibly be made from the strain, and thus the limitation was adequately supported by the two examples.

As a practice point, consider multiple ways of defining your invention (e.g., "source" was the winner here, but the possibilities depend on the situation). There are many creative ways to define your invention: the more examples showing the "reasonable, predictable scope" of the active species, the better. Ideally, focus on describing how the function is linked to the structure or other properties (e.g., structural and functional domains of a polypeptide, source, method of preparation, physicochemical properties, etc.).

Sources: [lungtin unitalen](#)

We will keep you updated for further development. Stay tuned for more important updates on IP law in China.

Please contact us with any questions: eip@eipgroup.asia.

Eagle IP are experts in patent law and we offer a one-stop service for your global IP needs.