

China IP Developments in Biotech/Pharma

Can several alternate groups in a Markush claim be arbitrarily deleted during invalidation?

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Since 2010, the Patent Review Board (PRB) has published the top 10 patent invalidation cases of the year in April of each year. The selection criteria are high social concern, significant impact on the related industry, or involve difficult legal issues and important examination criteria. In the next few newsletters we will highlight cases that cover topics we think are significant and relevant to the biotech/pharma industry.

Can several alternate groups in a Markush claim be arbitrarily deleted during invalidation?

This case (Beijing Winsunny Harmony Science & Technology Co., Ltd. v. Daiichi Sankyo Co., Ltd) describes an invalidation request of Daiichi Sankyo's Chinese invention patent 97126347.7 related to processes of preparing pharmaceutical compositions for treating or preventing hypertension. The patent covered the marketed hypertension drug *Olmесartan medoxomil*.

During the invalidation, the patentee made select amendments to multiple Markush groups, deleting particular individual components from several different R groups of a molecule. The issue at hand is whether these amendments are allowable during an invalidation proceeding, which typically has very strict rules regarding amendments.

In short, it boils down to how the courts interpret a Markush claim. Does it refer to a general technical solution or parallel embodiments of several technical solutions? If it is one general solution, should you really be able to pick and carve away at its scope? Does doing so create a new scope that has a different technical effect than the original invention? If so, is that allowable?

The Patent Review Board (PRB) and the Beijing High People's Court (BHPC) disagreed on how to interpret Markush claims. The PRB felt that arbitrary amendments should not be allowed because a Markush claim is directed towards a general technical solution. Arbitrarily deleting

elements during invalidation would thus create new scopes of protection that could have different technical solutions.

The BHPC thought that Markush groups represented alternate parallel technical solutions, and thus deleting one or more options just narrowed the scope of the claim. The Supreme People's Court (SPC) ruled that the amendments were allowable. Additionally, the SPC indicated that such types of amendments may be allowed during invalidation as long as the amendments did not generate a scope that possessed a new function or technical effect.

Applicants should be aware that amendments which carve out a new scope with improved technical effect (as compared to the original scope) may not be allowable. During an invalidation proceeding, it will be difficult to amend claims to a narrower scope with improved technical results to overcome inventive step. Instead, at the time of drafting, applicants should draft several dependent claims directed towards alternate scopes with varying qualities of efficacy, including very narrow claims covering the best, most efficacious compounds. It is risky to rely on being able to carve out scope from broader claims during an invalidation challenge.

A side note on inventive step . . .

Interestingly, this case also briefly discussed inventive step. The petitioners argued that the patent lacked inventive step because a specific embodiment in the patent had equivalent technical effect as a prior art compound. The PRB disagreed and emphasized that inventiveness is actually a three-step determination, and it is inappropriate to directly apply just the "unexpected technical effect" test to see if claims are inventive or not.

Sources: [Lexology](#), [Sanyou IP Group](#)

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