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Interpreting Standards of Amendments to Markush Claims in Invalidation Proceedings from the Perspective of a Retrial by the Supreme People's Court of China

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Interpreting Standards of Amendments to Markush Claims in Invalidation Proceedings from the Perspective of a Retrial by the Supreme People's Court of China

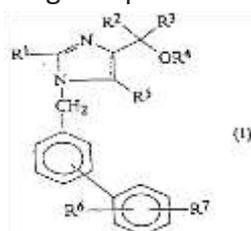
In Patent Law, a Markush claim is a special type of claim commonly used in the chemical and pharmaceutical fields when there are a number of variables in one claim and each variable has multiple options. Once a compound claimed by a Markush claim is patented, its scope of protection can extend to all the compounds encompassed therein regardless of their effect.

In China, *the Guidelines for Patent Examination 2010* contains provisions regarding the unification of Markush claims, but are otherwise silent on this subject.¹ The nature of Markush claims and the criteria for amendments has long been a subject of practical and theoretical discussion.²

On the retrial of the "Administrative Judgment No. 41 [2016], Retrial, Administrative Division, Supreme People's Court", following three years of careful deliberation, the Supreme People's Court of China finally released a judgement which clarified the nature of Markush claims and the criteria for amending such claims in invalidation proceedings. This judgement will likely resolve issues where trial court's criteria has been different and provides guidance for judging similar cases in the future.

1. Introduction of the retrial case (Patent number: ZL97126347.7)

Claim 1: A pharmaceutical method for manufacturing a composition for treating or preventing hypertension, which comprises of mixing at least an antihypertensive agent and a pharmaceutically acceptable carrier or diluent, the antihypertensive agent being the following compound of the formula (I) or a pharmacologically acceptable salt or ester.



Where R¹ represents an alkyl group having 1 to 6 carbon atoms, R² and R³ are the same or different and represent an alkyl group having 1 to 6 carbon atoms, R⁴ is a hydrogen atom or an alkyl group having 1 to 6 carbon atoms, R⁵ is a carboxyl group, a group of the formula -COOR^{5a} (wherein R^{5a} represents (5-methyl-2-oxy-1,3-dioxolane-4-yl) methyl) or a group of the formula -CONR⁸R⁹ (wherein R⁸ and R⁹ are the same or different and represent a hydrogen atom, an unsubstituted alkyl group having 1 to 6 carbon atoms, an alkyl group substituted with a carboxyl group having 1 to 6 carbon atoms, or an alkyl group substituted

¹ Guidelines for Patent Examination 2010, part II, Chapter 10, 8.1 Unity of Markush Claims.

² Invalidation trial for ZL94115915.9, ZL97197460.8

with alkoxy carbonyl group having 1 to 6 carbon atoms in its alkyl group (excerpt from Claim 1)).

The following points were the points of contention in the retrial: (1) whether Markush claims are a general technical solution or an aggregate of specific compounds in parallel, and (2) whether the deletion of the options of variables of Markush claims is allowed in an invalidation proceeding.

In the invalidation proceeding, the patentee amended claim 1 made against the reasons for invalidation as follows:

- (1) Deleted "or ester" from "or a pharmacologically acceptable salt or ester".
- (2) Deleted "an alkyl group having 1 to 6 carbon atoms" from the definition of R⁴.
- (3) Deleted other definitions from the definition of R⁵ except "a carboxyl group and a group of the formula -COOR^{5a} (wherein R^{5a} is (5-methyl-2-oxo-1,3-dioxolane-4-yl) methyl)."

Although the Patent Reexamination Board accepted the above amendment (1), the amendments (2) and (3) above were not accepted because of the provisions of Article 68 of the Patent Law Implementation Regulations.³

The Beijing First Intermediate People's Court maintained the invalidation trial decision of the Patent Reexamination Board.

However the Beijing Municipal High People's Court overturned the trial decision stated as follows:

Compounds contained in Markush claims are in parallel and a selective relationship, and any compound should be considered to be an independent technical solution. Since the scope of protection is reduced by deleting part of the options of a certain variable of the Markush claim, the amendment fulfills the provisions of Article 68 of the Patent Law Implementing Regulations.

The Supreme People's Court overturned the decision of the Beijing Municipal High People's Court and held as follows:

The Markush claim is not an aggregate of specific compounds, but is instead an aggregate of Markush variables, and the entire claim is a single general technical solution and appears as a single or plurality of compounds in parallel only in specific situations. Since Markush claims are very general, once patented, the scope of protection is extended to all the compounds having an identical structure, which maximizes the benefit to the patentee. On the other hand, from a conceptual perspective of patent law, a considerable degree of rights for the

³ Rule 68: In the course of the examination of the request for invalidation, the patentee for the patent for invention or utility model concerned may amend its or his claims, but may not broaden the scope of patent protection.

patentee equates to greater restrictions on the public. In the interest of fairness, interpretation of Markush claims should be strictly limited.

With regard to the amendment of Markush claims in an invalidation proceeding, allowing the deletion of any option of any variable will lead to uncertainty regarding whether a new scope of protection will arise even though the benefits enjoyed by the public will not be curtailed. Should such deletion be allowed, not only will it be impossible to provide stable predictability to the public, but there will be no contribution to maintaining the stability of the system concerning the examination of patents.

2. Analysis

Generally, an investment of more than one billion dollars is required to develop a single new medicine. Original pharmaceutical manufacturers have a constant desire for the highest possible degree of protection in order to effectively prevent other companies from increasing their market share simply by making slight changes to the structure of an invention's active compound. It can be said that Markush claims arose just to satisfy the desires of manufacturers. The increase in both the type and quantity of substituents due to the advancement of technology has led to complications compared to when the system of Markush claims was created. There are two different approaches regarding nature of Markush claims; the aggregate and holistic approaches, which provide an insight into why the Beijing Municipal High People's Court and the Supreme People's Court issued completely different rulings in China.

A. The aggregate approach

The aggregate approach is where selectable options in Markush claims correspond to parallel technical solutions and deletion of one or more options from two or more of the parallel technical solutions is allowed. No matter how many variables or options there are in the Markush claim, it is theoretically possible to calculate the number of technical solutions included in the claims. For example, an aggregate approach can be viewed as a basket containing a large number of eggs. Specific compounds included in the claims are analogous to the eggs. Deleting some of the options of variables means that some eggs are removed from the basket, thus reducing the scope of protection. Therefore, amendments by way of deletion should be allowed because they do not create a new scope of protection which satisfies the criteria for the amendment of claims in invalidation proceedings.

However, the aggregate approach does present some problems. First, it does not provide for selection inventions because all the compounds included in Markush claims are specific compounds which are disclosed. Any selection invention chosen from one of those specific compounds is not recognized under the patent law due to the fact that there can be no novelty.

In addition, if deleting some options of an amendment (equivalent to the deletion of multiple compounds) is permitted in invalidation proceedings, some options will always be deleted to avoid the prior art as a countermeasure against invalidation trials. In some cases, those deletion would be infinite. Even though we can predict that the patentee will amend the claims by deleting some options, it would be impossible for the public to predict which part of the scope of protection will be deleted and which would be retained. Making amendments by deleting some compounds from the aggregate violates the requirement of maintaining the clarity and stability requirement for patent rights post public announcement.

B. The holistic approach

The other approach is called a holistic approach, where a Markush claim constitutes one technical solution as a whole, and only deletion of the entire claim can be permitted. The holistic approach is a general technical solution based on a specific structural effect relation, which can be conceptualized as a three-dimensional network including actual points and virtual points woven from different dimensions by several lines.⁴ The actual points are the specific compounds disclosed in the specification, while the virtual points are the compounds included in the scope of protection which are not specifically disclosed in the specification. According to the holistic approach, deletion of any option of any variable is equivalent to cutting away a part of the three-dimensional network's connections which will disturb the integrity of the three-dimensional network.

However, the holistic approach also has its problems. For example, in a substantive examination, obtaining a patent right by partially deleting an option of some variable when, for example, an inadequacy in the novelty, inventive step or support requirement is pointed out by the examiner, is a common amendment strategy employed by applicants. The criteria for amendment of Markush claims not being unified in substantive examinations and invalidation proceedings presents a problem.

Despite these issues, the retrial case clearly showed that the Supreme People's Court adopted the holistic approach with regard to Markush claims. There is no doubt that each court will refer to this retrial case as a precedent when presented with similar cases in the future.

3. Our recommendations for patent practice

Since China has decided to adopt the holistic approach, we would like to make the following recommendations for patent practice.

Although the holistic approach was adopted by the Supreme People's Court, and according to such approach no option can be deleted in an invalidation proceeding, there still is a

⁴ Discussion on the deletion of parallel technical solutions in patent invalidation proceedings. Xiaolan Ren

possibility that options can be deleted and each case should be analyzed separately. For example, in the case of only one clearly defined variable and limited options of the variable in a Markush claim, deletion of one or some options would still be permitted. In other words, only when the compound represented by the general formula of a Markush type is simple, the options are limited within specific substituents, and "it appears as a single compound only in a specific case"⁵, can it be recognized that the compounds are in a parallel relationship and deletions would be allowed.

Based on the holistic approach, in the case of a compound represented by the general formula of Markush type as a prior art, it cannot be recognized that all the compounds contained in the general formula are disclosed. However, if the prior art relates to a general formula of $1 \times n$ (that is, the variable is one and the option of the variable is some specific substituent), 2×2 (that is, the number of variables is two and the option of each variable is also two), it is recognized that all the compounds contained in the general formula are disclosed and can be used to evaluate the novelty and inventive step of an application. Such Chinese patent practices are similar to those in Europe.⁶

Next, there is a risk that the independent claim may be uncorrectable and invalidated during the invalidation proceeding. Therefore, we recommend that claims are drafted in the form of an inverted pyramid, where the core compounds to be protected are placed at the bottom, a plurality of dependent claims of a plurality of ranges including the core compounds are placed in the middle, and the independent Markush claim is placed at the top. This structure will allow the dependent claims of subordinate range or specific core compounds themselves to be protected even if the independent claim or the dependent claim having an intermediate range is invalidated.

Furthermore, in general, the applicant or the patentee usually drafts claims in the form of "a compound represented by a general formula and its pharmacologically acceptable salt, its ester, or the hydrate thereof". As in the case of amendment (1) in the above mentioned retrial case, amendments deleting its pharmacologically acceptable "salt, its ester, or the hydrate thereof" are currently accepted in invalidation proceedings because such amendments are the equivalent of deleting a parallel technical solution in which the aggregate approach is applied.

There are also amendments deleting some options of variables in the invalidation proceedings which are not permitted; however, such amendments are still permitted at the substantive examination. The criteria for amendment at the invalidation proceeding are stricter than those used during the substantive examination because patent rights stabilized through public announcement have a pronounced influence on the public. Such strict

⁵ Administrative Judgment No. 41 [2016], Retrial, Administrative Division, Supreme People's Court

⁶ Examiner's manual, section on substantive examination, Chapter 10, Examination of Invention Applications in the Field of Chemistry, the Amendment of Markush Claims.

criteria may be the best way to protect the patentee's interest and promote innovation. Therefore, for applicants, we believe that the best course of action is to revise the scope of the protection of Markush claims by sufficiently utilizing opportunities for amendment at the substantive examination in order to reduce the risk of future invalidation.

The information in this letter is provided as general information and is not meant to be provided as specific professional advice.

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