



Markush Claims: Drafting Considerations from Chinese Perspective

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Markush claims, which recite lists of alternatively useable members, to be formatted as “selected from the group consisting of A, B, and C,” has been often adopted in the field of chemistry, especially in the field of medicine. In some cases, while this format is adopted to represent a general chemical formula, the alternatively useable members would share a single structural similarity and a common use. Markush claims can cover a large scope of protection in a very simple way and are sometimes favored. This article addresses how to draft a Markush claim in discussions of some invalidation cases.

I. Provisions on the amendment of claims during invalidation proceedings

The Patent Examination Guidelines (2010) stipulates that during invalidation proceedings, the amendment of invention and utility model patent documents should be limited to the claims. Thus, (i) The subject matter of the claim shall not be changed; (ii) Compared with the granted claims, the protection scope of the patent shall not be expanded; (iii) It should not go beyond the technical features in the original specification and claims; and (iv) Generally, technical features not included in the granted claims shall not be added.

In view of the above, the specific ways of amending claims are generally limited to the deletion of claims, the deletion of technical solutions, the further definition of claims, and the correction of obvious errors.

The deletion of a technical solution refers to the deletion of one or more technical solutions from two or more technical solutions in the same claim.

The further definition of the claims means that

one or more technical features described in other claims are added to the claims to narrow the scope of protection.

II. Typical cases involving the amendment of Markush claims

1. Daiichi Sankyo Co., Ltd. v. Beijing Wansheng Pharmaceutical (CN97126347.7, Invalidation Decision No. 16266 of PRB, Beijing Higher People's Court (2012) Gao Xing Zhong Zi No. 833, Supreme People's Court (2016) Zuigaofa Xingzai No. 41)

Supreme People's Court (2016) Zuigaofa Xingzai No. 41 is related to a patent invalidation administrative litigation retrial case involving the Patent Reexamination Board, Daiichi Sankyo Co., Ltd. (the patentee) and Beijing Wansheng Pharmaceutical (the invalidation requester), which is the Supreme People's Court Guiding cases for 2016. In this case, the Supreme People's Court determined the nature of Markush's claims, and provided the guidance on the amendment of Markush claims during invalidation proceedings.

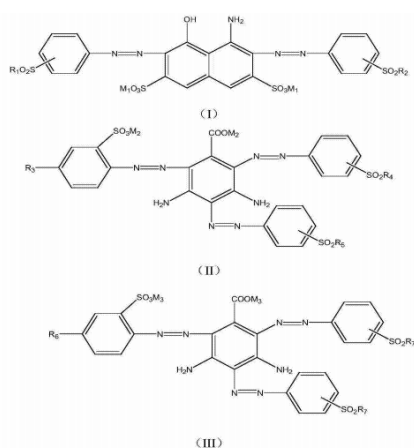
In this case, the Supreme People's Court clearly determined that Markush claims have strong generalization capabilities. Once authorized, the patent will cover all compounds with the same structure, performance or function, and the rights of the patentee will be maximized. From the perspective of fairness, the interpretation of Markush claims should be strict. No matter how many variables and combinations are contained in the Markush claims, they should be regarded as a general combination. Markush claims should be regarded as a collection of Markush members, rather than a collection of many compounds. Markush members can only be expressed as a single compound under certain circumstances, but generally speaking, Markush members are a class of compounds with common properties and functions. During the invalidation proceedings, amendments to Markush claims must be strictly restricted. The principle for amending Markush claims should be that it should not produce a class or single compound that has new properties and effects due to the amendment, but at the same time the individual factors must be sufficiently considered. If the patent applicant or the patentee is allowed to delete any option of any variable, even if the deletion narrows the scope of protection of the claim, which will not harm the rights of the public, it is uncertain whether there will be a new scope of protection. Not only does it fail to give the public a stable expectation, it is also not conducive to maintaining the stability of the patent system.

The Supreme People's Court has set forth a very strict standard—the amendment shall not produce a class or a single compound that has new properties and effects, and a deletion of Markush members is not allowable, which unified the standard for "deleting modification" of Markush claims and has been strictly enforced in practice. Following the standard, the Reexamination and Invalidation Department (Patent Reexamination Board) of the State Intellectual Property Office has strictly restricted the amendments of Markush claims,

and did not accept any deletion of certain options of Markush members in Markush claims.

2. *Huntsman Advanced Materials (Switzerland) Co., Ltd. v. Zhejiang Ruihua Chemical Co., Ltd. (CN201610153397.7, Invalidation Decision No. 35381 of PRB)*

The case involves a black reactive dye composition, which is characterized in that it includes a component A composed of one or more compounds of formula (I), a component B composed of one or more compounds of formula (II), a component C composed of one or more compounds of formula (III) and optional auxiliary agents:



Wherein, M_1 , M_2 , M_3 are each independently hydrogen, potassium, sodium, lithium or ammonium; R_1 , R_2 are each independently $-\text{CH}=\text{CH}_2$ or $-\text{C}_2\text{H}_4\text{OSO}_3\text{M}_1$, R_3 , R_6 are each independently $(\text{C}_1 \sim \text{C}_4)$ alkyl or $(\text{C}_1 \sim \text{C}_4)$ alkoxy, one of R_4 and R_5 is $-\text{CH}=\text{CH}_2$, the other is $-\text{C}_2\text{H}_4\text{OSO}_3\text{M}_2$, and R_7 is $-\text{CH}=\text{CH}_2$ or $-\text{C}_2\text{H}_4\text{OSO}_3\text{M}_3$.

During the invalidation proceeding, the patentee amended "R₃ and R₆ are each independently $(\text{C}_1 \sim \text{C}_4)$ alkyl or $(\text{C}_1 \sim \text{C}_4)$ alkoxy" in claim 1 to "R₃, R₆ are each independently $(\text{C}_1 \sim \text{C}_4)$ alkyl", that is, deleting the option " $(\text{C}_1 \sim \text{C}_4)$ alkoxy". However, the Patent Reexamination Board held in the Invalidation Decision that claim 1 is a typical Markush claim. The patentee's amendment of "deleting some options in the definitions of R₃ and R₆" does not belong to the deletion of parallel technical solutions, nor does

it belong to further limitation of claim 1 by technical features recited in other claims. Therefore, the revised text submitted by the patentee does not comply with the provisions of amending claims during invalidation proceedings and is not accepted.

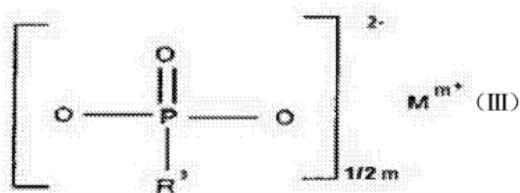
3. Clariant Coatings (Shanghai) Co., Ltd. v. Guangzhou Jinkai New Materials Co., Ltd. (CN 201610057649.6, Invalidation Decision No. 38769 of PRB)

The case involved an additive composition for polymers, including:

Component A: 80wt%-99.99wt% of dialkyl phosphinate having the structure represented by formula (I),

Component B: 0wt%-20wt% alkyl phosphonite having the structure represented by formula (II);

Component C: 0.75wt%-0.9wt% phosphite having the structure represented by formula (III);



wherein R³ represents H; M is Mg, Ca, Al, Zn, Fe; m is 2 to 3;

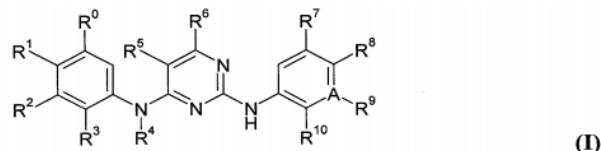
Component B is 0wt%, component C is not 0wt%, and the sum of A, B and C components is always 100wt%.

During the invalidation proceeding, the patentee amended the claims, deleting the technical solution in which M in component C is Mg, Ca, Zn, Fe from claim 1. The Patent Reexamination Board held in the Invalidation Decision that in the independent claims 1, 5, and 9 of the granted patent, the change in the structure of component C will not affect the structure of other components A and B, and the component R³ in C represents H, which is not a variable. Therefore, the variables in component C are only M and m, but since m represents the valence of the metal M, its value is uniquely

determined by metal M. Thus, the actual variable is only M. M's choice can be regarded as a parallel technical solution, and as a result, the patentee's amendment is acceptable.

4. Miao Dongyang v. Novartis Co., Ltd. (CN201010234711.7, Invalidation Decision No. 38388 of PRB)

The case involves a compound of formula I or a pharmaceutically acceptable salt thereof,



wherein,

R⁰ is hydrogen or halogen;

R¹ is hydrogen, halogen or a substituted or unsubstituted 5- or 6-membered heterocyclic group containing 1, 2 or 3 heteroatoms selected from N, O and S;

R² is hydrogen or C₁-C₈ alkyl;

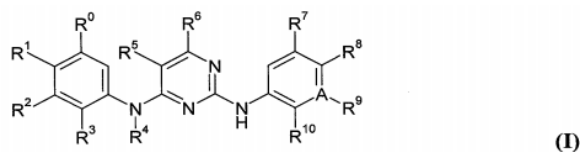
R³ is C₁-C₈ alkylsulfinyl, C₁-C₈ alkylsulfonyl, C₅-C₁₀ arylsulfonyl, unsubstituted or substituted carbamoyl or unsubstituted or substituted sulfamoyl; or adjacent substituents R² and R³ form -CH₂-NH-CO- or -CH₂-NH-SO₂- or a substituent pair in which NH is substituted by C₁-C₈ alkyl;

.....

5. The compound of formula I according to any one of claims 1 to 4, wherein: R⁰, R¹ or R² is hydrogen.

During the invalidation stage, the patentee amended claim 1 to:

1. the compound of formula I or a pharmaceutically acceptable salt thereof,



wherein,

R⁰ is hydrogen or halogen;

R¹ is hydrogen;

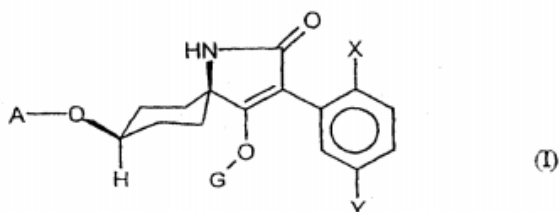
R² is hydrogen or C₁-C₈ alkyl;

...

The Patent Reexamination Board held in the Invalidation Decision that in the amended claims submitted by the patentee, the patentee amended the technical solution of the claim 5 in which R¹ was hydrogen as claim 1, and deleted the technical solution of the original claim 5 in which R⁰ or R² is hydrogen. The above-mentioned amendments comply with Article 33 of the Patent Law and the provisions on amendments in invalidation proceedings.

5. Cangzhou Kerun Chemical Co., Ltd. v. Bayer Intellectual Property Co., Ltd. (CN 03821634.5, Invalidation Decision No. 39597 of PRB)

The case involved a compound of formula (I),



Wherein, the substituents are defined as follows:

X is CH₃, Y is CH₃, A is CH₃ and G is H;

X is Br, Y is CH₃, A is CH₃ and G is H;

X is CH₃, Y is CH₃, A is CH₃ and G is...

X is Br, Y is CH₃, A is CH₃ and G is...

X is CH₃, Y is Br, A is CH₃ and G is...

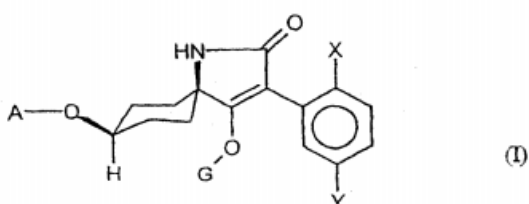
X is Br, Y is CH₃, A is CH₃ and G is...

X is Br, Y is CH₃, A is CH₃ and G is...; or

X is Cl, Y is CH₃, A is C₂H₅ and G is...

During the invalidation proceeding, the patentee amended claim 1 to:

1. A compound of formula (I)



wherein the substituents are defined as follows:

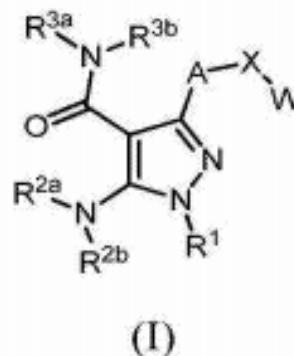
X is CH₃, Y is CH₃, A is CH₃ and G is...

The Patent Reexamination Board held in the Invalidation Decision that the original claim 1 relates to 8 specific compounds, which essentially protects 8 parallel technical solutions. The patentee deleted some parallel

technical solutions from claim 1, which complies with the provisions on the amendment of claims in invalidation proceedings.

6. Zhang Jiufei v. Pfizer (CN 201380065731.8, Invalidation Decision No. 41239 of PRB)

The case involves a compound of formula (I) or a pharmaceutically acceptable salt thereof,

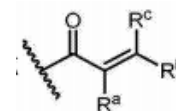


wherein

.....

R¹ is a 4-8 membered nitrogen-containing heterocyclic group, which is substituted by R on the nitrogen and optionally further substituted by 1, 2, 3, 4 or 5 substituents independently being (C₁-C₄) alkyl;

R is cyano, cyano (C₁-C₃) alkyl or ,



R^a is hydrogen, halogen, cyano, (C₁-C₆) alkoxy, halo (C₁-C₆) alkoxy, (C₁-C₄) alkylthio, (C₁-C₄) alkylsulfonyl, or (C₁-C₆)alkyl optionally substituted with halogen, hydroxy, (C₁-C₆)alkoxy or halogenated (C₁-C₆)alkoxy;

R^c is selected from hydrogen, halogen, cyano, (C₁-C₆)alkoxy, halo(C₁-C₆)alkoxy, (C₃-C₆)cycloalkyl, C(=O)R^d and (C₁-C₆) alkyl optionally substituted with 1, 2 or 3 R^f which is independently selected from halogen, hydroxyl, N(R^e)₂, (C₁-C₆)alkoxy and halogenated (C₁-C₆)alkoxy;

...

During the invalidation proceeding, the patentee made following amendments: deleting the substituents of R^a and R^c other than hydrogen from claims 1 and 18, that is, deleting from claims 1 and 18 the substituents in the definitions of R^a "halogen, cyano, (C₁-C₆) alkoxy,

halo (C₁-C₆) alkoxy, (C₁-C₄) alkylthio, (C₁-C₄) alkylsulfonyl, or (C₁-C₆)alkyl optionally substituted with halogen, hydroxy, (C₁-C₆)alkoxy or halogenated (C₁-C₆)alkoxy;" and the substituents in the definitions of R^c "halogen, cyano, (C₁-C₆)alkoxy, halo(C₁-C₆)alkoxy, (C₃-C₆)cycloalkyl, C(=O)R^d and (C₁-C₆) alkyl optionally substituted with 1, 2 or 3 R^f which is independently selected from halogen, hydroxyl, N(R^e)₂, (C₁-C₆)alkoxy and halogenated (C₁-C₆)alkoxy".

The Patent Reexamination Board held in the Invalidation Decision that in the granted text of this patent, claims 1 and 18 respectively protect a compound of the general formula or a pharmaceutically acceptable salt thereof, which contain 8 and 3 variables, respectively. Each group can vary within a certain range, and claims 1 and 18 belong to typical Markush claims. The above-mentioned amendments made by the patentee to the Markush claims do not belong to the deletion of the parallel technical solution, nor do they belong to the situation where the technical features recorded in other claims are used to further limit claim 1 to narrow the scope of protection. Therefore, the amended claims submitted by the patentee does not comply with the provisions on the amendment of claims in invalidation proceedings and are not accepted.

III. Case analysis and drafting suggestions

Regarding the amendments made by the patentee to the claims during invalidation proceedings, the Patent Reexamination Board accepted these amendments in some cases, but rejected others. Below is a summary.

Case No.	Amendments	Result
Case 1	Deleting "or ester" from claim 1,	Accepted,
	Deleting "alkyl group having 1 to 6 carbon atoms" in the definitions of R ⁴ from claim 1, and deleting the groups rather than carboxyl group and the formula COOR ^{5a} (where R ^{5a} is (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl) in the definitions of R ⁵ from claim 1	Not accepted
Case 2	Deleting (C ₁ ~ C ₄)alkyl from R ₃ and R ₆	Not accepted
Case 3	Deleting the technical solution in which M in component C is Mg, Ca, Zn, and Fe	Accepted
Case 4	Amending the technical solution of the claim 5 in which R ¹ was hydrogen as claim 1, and deleting the technical solution of the original claim 5 in which R ⁰ or R ² is hydrogen	Accepted
Case 5	Deleting some parallel technical solutions from Claim 1	Accepted,
Case 6	Deleting the substituents of R ^a and R ^c other than hydrogen from claims 1 and 18	Not accepted

From the summary, it can be found that when there are multiple Markush members, the Patent Reexamination Board hardly accepts any amendment to the Markush claims by deleting one or more options in one or more Markush members (cases 1, 2 and 6). When Markush claims can be determined as parallel technical solutions, it is acceptable to delete some of the technical solutions (cases 3 and 5). When the independent claims are further defined by the technical features of the dependent claims, and some of the parallel technical solutions are

deleted as needed, the Patent Reexamination Board may also accept such amendments (Case 4).

The guiding cases of the Supreme People's Court and the above invalidation cases established a strict standard regarding amendment of Markush claims during the invalidation proceedings. However, according to some cases, if the application document is reasonably laid out and designed, the strict standard may not apply.

Therefore, it is recommended that the claims should be laid out reasonably during the drafting stage of the application document, and the rules regarding the amendment of Markush claims during invalidation proceedings should be taken into consideration, so as to avoid the inability to make acceptable amendments to Markush claims at invalidation proceedings. Specifically, during the drafting stage of application documents, the following points need to be noted:

1. For Markush claims, we should further define different options of different Markush members in the dependent claims.
2. We should analyze the effect of each Markush member in a specific compound on the activity of the compound. For those important Markush members that can affect the activity of the compound, we should define them in the dependent claims individually or in a parallel manner.
3. For those options of Markush members clearly recited in specific compounds, we should define them in the dependent claims individually or in a parallel manner.
4. The specific compounds actually used are defined in the dependent claims individually or in a parallel manner.



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Mr. Wang specializes in patent prosecution, reexamination, invalidation, and counseling, including drafting and prosecuting patent applications, preparing opinions for patent validity, infringement, and freedom-to-operate, and representing clients in administrative cases in the technical fields of polymer science, pharmaceutical chemistry, pesticides, chemical engineering, electric chemistry, and so on. He has gained extensive experience in providing legal advice on patent matters for domestic and foreign global companies. Since March 2004, he has handled more than 1,000 patent cases of Fortune 500 companies.