

Archetype IPSM

Federal Circuit Friday

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January 2020

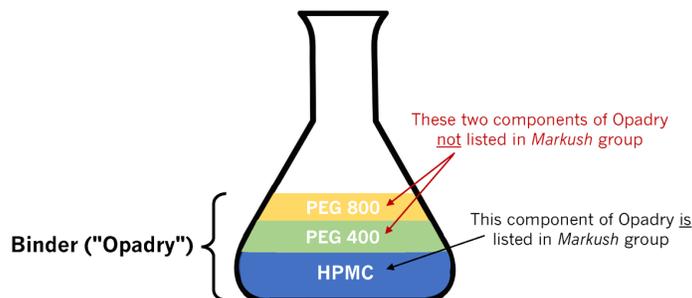
In *Amgen v. Amneal Pharmaceuticals* (January 7), the Federal Circuit corrected a misconception about interpretation of *Markush* claim limitations¹ regarding the extent to which *Markush* language "closes" the scope of a claim regarding the presence of unlisted materials, compounds, etc.

The specific issue in this case was whether a claim limitation using a *Markush* group to define a pharmaceutical "binder"² precluded the presence of any binders other than those listed in the group. In relevant part, the claim provided as follows (italics added):

A pharmaceutical composition comprising:

(c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, *hydroxypropyl methylcellulose*, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof;

The accused product used "Opadry" as its binder, Opadry being the trade name for a binder that contains hydroxypropyl methylcellulose ("HPMC"), polyethylene glycol ("PEG") 400, and PEG 800. Because HPMC is recited in the *Markush* group but PEG is not, the question was whether the presence of PEG 400 and 800 took the product outside the scope of the claim limitation.



The Federal Circuit held that it didn't matter that Opadry includes PEG 400 and PEG 800 – the HPMC in the Opadry "counted" as the HPMC of the *Markush* group. There were two essential reasons: (1) the claim at issue uses the transition phrase "comprising," thereby not precluding the presence in the accused product of components (including binders) in addition to those positively recited; and (2) the claim limitation at issue recited "at least one binder," thereby expressly not precluding the presence of binders in addition to those in the *Markush* group.

So far this is a pretty unremarkable application of the basic rules for *Markush* group limitations, so why was this issue litigated all the way to the Federal Circuit? Because Amneal relied on a couple of earlier cases involving *Markush* groups to argue – successfully in the district court – that the use of the phrase "consisting of" in the *Markush* portion of the binder limitation "closed" the claim, limiting the binder of the accused product to the specific binders listed in the *Markush* group such that an accused product using

¹ A "Markush" claim limitation allows a defined set of options for a particular element of the invention to be included in a single claim rather than having a long series of dependent claims to capture those variations – e.g., "An apparatus comprising . . . a widget selected from the group consisting of A, B, C, or D" can be claimed rather than having four separate claims, one for each of the A, B, C, and D widget options.

² A "binder" is a component of a pharmaceutical dosage form that helps hold the other components together in a tablet form. See, e.g., REMINGTON - THE SCIENCE AND PRACTICE OF PHARMACY (21st ed. 2006), p. 891.

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Opadry as the binder did not infringe because Opadry is not listed in the Markush group, either by name or by its combination of components. In essence, Amneal argued that the "binder" limitation of the claim applied to *all* compounds in an accused product that perform a "binding" function.

That reasoning was *completely wrong as a matter of law* in the context of the claim at issue here, but it is worth looking at those two earlier *Markush* cases to understand more clearly how *Markush* groups limit claim scope.

In *Multilayer Stretch Cling Film Holdings v. Berry Plastics*,³ the claim at issue included the following in relevant part:

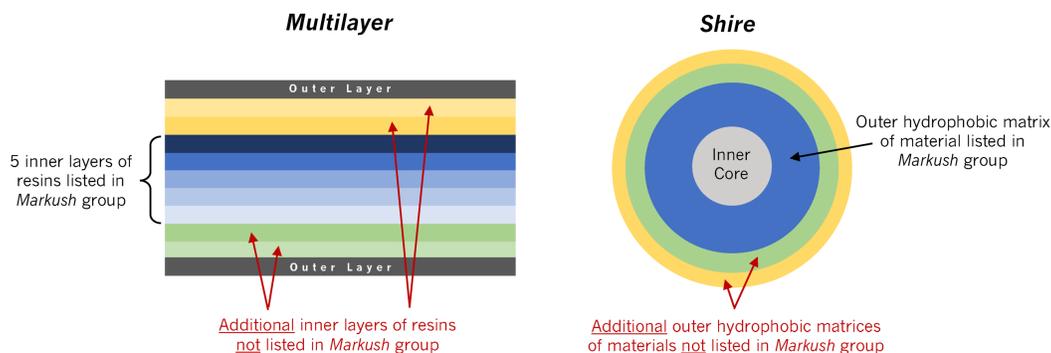
A multilayer, thermoplastic stretch wrap film . . . comprising:

(b) five identifiable inner layers, with each layer being selected from the group consisting of linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, and metallocene-catalyzed linear low density polyethylene resins;

Each of the five inner layers was limited to the resins listed in the *Markush* group such that an accused stretch wrap film would not infringe if any of its "five identifiable inner layers" included a resin in addition to those listed in the *Markush* group. This is a consequence of the "consisting of" language in the *Markush* limitation – "consisting of" is a term of art in patent law that "creates a very strong presumption that that claim element is 'closed' and therefore 'exclude[s] any elements, steps, or ingredients not specified in the claim.'"⁴ However, there was no holding or dicta in the *Multilayer* case suggesting that there could not be inner layers in addition to the five expressly recited or that those additional layers could not contain resins other than those listed in the *Markush* group.

*Shire v. Watson Pharmaceuticals*⁵ involved a *Markush* limitation regarding the composition of an "outer hydrophobic matrix" of a controlled release pharmaceutical dosage form. The *Markush* group was interpreted as limiting the outer matrix composition to the set of compounds recited in the *Markush* group such that an accused product having an additional compound in its outer hydrophobic matrix did not infringe. The claim did not preclude, or limit the composition of, additional outer hydrophobic matrices.

Both *Multilayer* and *Shire* are wholly consistent with and support the Federal Circuit's decision in *Amgen v. Amneal*. The "five identifiable inner layers" of *Multilayer* and the "outer hydrophobic matrix" of *Shire* are analogous to the "at least one binder" of *Amneal* – in each case the composition of the *Markush*-claimed component was limited to the members of the *Markush* group. The additional binders in *Amneal* are analogous to additional inner layers beyond the five defined layers in *Multilayer* and to additional outer hydrophobic matrices beyond the one defined matrix in *Shire* – none of those additional components were subject to the restrictions of the *Markush* groups.



³ 831 F.3d 1350 (Fed. Cir. 2016).

⁴ *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001).

⁵ 848 F.3d 981 (Fed. Cir. 2017).