IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 16-853-GMS
	)	CONSOLIDATED
AUROBINDO PHARMA LTD., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM

Pending before me are several evidentiary issues raised by the parties in connection with a patent infringement trial commencing on March 5, 2018. (D.I. 294-1, Ex. 8 & Ex. 8.1). I will address two of these evidentiary issues below.

I. CLAIM CONSTRUCTION

In the Proposed Joint Pretrial Order, Plaintiff Amgen, Inc. ("Amgen") argues that the Markush groups in the binder and disintegrant limitations should be "open sets." (D.I. 294-1, Ex. 8 at ¶ 2(b)). Amgen also urges that Defendants should be precluded from raising any claim construction issues**,** and that the time to raise this issue was at the Markman hearing. Id. at ¶ 2. Conversely, Defendants urge that the Markush groups are "closed." (D.I. 294-1, Ex. 7.1 at p. 318-19, ¶¶ 32-33).

Claim construction is a "fluid process," *Cadence Pharma., Inc. v. Innopharma Licensing LLC*, 2016 WL 3661751, at *3 n.2 (D. Del. July 8, 2016), and that process is "not final until judgment is entered," *Eaton Corp. v. Parker-Hannifin Corp*., 292 F. Supp. 2d 555, 572 n.2 (D.

Del. 2003). Until then, "[t]he court may re-construe the claims if it finds the original claim construction to be in error based upon a more developed record," and/or "may add claim constructions for terms that become disputed through the course of trial." *Eaton Corp.*, 292 F. Supp. 2d at 572 n.2.

Here, the claim construction issues Defendants now raise appear to have developed after the Markman hearing. Because these issues will substantially effect how the parties present their theories of infringement or non-infringement at trial, I will resolve this dispute now.

Independent claims 1 and 20 of United States Patent No. 9,375,405 ("the '405 patent") contain three Markush groups defining the list of excipients permitted for use as diluents, binders, and disintegrants. (D.I. 294-1, Ex. 7.1 at p. 36, ¶ 21).

Claim 1 states:

> (1) A pharmaceutical composition comprising:
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> (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
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> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof;
>
> (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; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidine (sic), sodium starch glycolate, croscarmellose sodium, and mixtures thereof, wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

(D.I. 294-1, Ex. 7 at 4).

A Markush group "lists alternative species or elements that can be selected as part of the claimed invention." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp*., 831 F.3d 1350, 1357 (Fed. Cir. 2016). It is typically expressed in the form: "a member selected from the group consisting of A, B and C." *Abbott Labs. V. Baxter Pharm. Prods., Inc*., 334 F.3d 1274, 1280 (Fed. Cir. 2003). "The members of the Markush group (A, B, and C in the example above) ordinarily must belong to a recognized physical or chemical class or to an art-recognized class." Manual of Patent Examining Procedure § 803.02. By claiming a Markush group, a patentee "has indicated that, for the purpose of claim validity, the members of the claimed group are functionally equivalent." *Ecolochem, Inc. v. S. Cal. Edison Co.*, 1996 WL 297601, at *2 (Fed. Cir. June 5, 1996); *see also In re Driscoll*, 562 F.2d 1245, 1249 (CCPA 1977) ("It is generally understood that ... the members of the Markush group ... are alternatively usable for the purposes of the invention.").

As noted above, the parties dispute whether the Markush groups for the binder and disintegrant elements in the '405 patent are closed. (D.I. 294-1, Ex. 8 at ¶ 2(b)). Amgen argues that, even if the Markush groups are closed, it may still rely on the doctrine of equivalents to demonstrate infringement of the binder and disintegrant elements. (D.I. 298).

A. The Markush Groups Are Closed

"Use of the transitional phrase 'consisting of' to set off a patent claim element creates a very strong presumption that that claim element is 'closed' and therefore 'excludes any elements, steps, or ingredients not specified in the claim.'" *Multilayer*, 831 F.3d at 1358 (quoting *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001) (internal brackets omitted).

Shire Dev., LLC v. Watson Pharma., Inc., 848 F.3d 981, 986 (Fed. Cir. 2017) (quoting *Multilayer*, 831 F.3d at 1359) ("consisting of" or " consists of" creates a very strong presumption that the claim is closed). "Overcoming this presumption requires 'the specification and prosecution history' to 'unmistakably manifest an alternative meaning,' such as when the patentee acts as its own lexicographer." *Watson*, 848 F.3d at 984 (quoting *Multilayer*, 831 F.3d at 1359).

Amgen argues that the Markush groups for the binder and disintegrant elements are open, because the preamble to claims 1 and 20 use the term "comprising." (*See* D.I. 294-1, Ex. 7 at p. 226 (stating "[a] pharmaceutical composition comprising"); D.I. 298 at 2). The transitional term "'comprising' can create a presumption that the recited elements are only a part of the device, [and] that the claim does not exclude additional, unrecited elements." *Multilayer*, 831 F.3d at 1358 (quoting *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001)). Thus, I must determine the effect of the presumably open-ended term "comprising" in the preamble in conjunction with the presumably closed Markush groups in the body of the claim.[1]

[1] Several cases cited by Amgen do not address claims containing both the term "comprising" and a Markush group. *See, e.g.*, *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1282 (Fed. Cir. 1986); *In re Crish*, 393 F.3d 1253 (Fed. Cir. 2004). *Mannesmann* and *Crish* affirmed the basic proposition that, with the term "comprising," a defendant does not defeat infringement by showing that its composition contains additional unrecited elements. *Mannesmann*, 793 F.2d at 1282; *Crish*, 393 F.3d at 1257. But the additional unrecited elements in those cases were not alternatively used for the purposes of the Markush group members. For example, in *Mannesman*, the additional unrecited elements—the "slag-stopping and backbone bars"—were not alternative species of the recited claim element—the cooling pipe coil. 793 F.2d at 1282.

The Federal Circuit recently addressed this issue in *Multilayer*, 831 F.3d 1350. There, the patent claimed a Markush group for resins, stating in relevant part:

> A multi-layer, thermoplastic stretch wrap film containing seven separately identifiable polymeric layers, comprising:
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> ….
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> (b) five identifiable inner layers, with each layer being selected from the group consisting of linear low density polyethylene ["LLDPE"], very low density polyethylene ["VLPDE"], ultra low density polyethylene ["ULDPE"], and metallocene-catalyzed linear low density polyethylene ["mLLDPE"] resins; said resins are homopolymers, copolymers, or terpolymers, of ethylene and C3 to C20 alpha-olefins;

Id. at 1353. "The district court construed element (b) as closed to unrecited resins—i.e., types of resin other than LLDPE, VLDPE, ULDPE, and mLLDPE." *Id*. at 1358. Before evaluating whether the plaintiff had overcome the "very strong presumption" that the Markush groups were closed, the court explained what a closed Markush group meant. "[I]f a patent claim recites 'a member selected from the group consisting of A, B, and C,' the 'member' is presumed to be closed to alternative ingredients D, E, and F." *Id*. The court explained, that to construe the Markush group "as open not only to the four recited resins but also to any other polyolefin resin conceivably suitable for use in a stretchable plastic cling film … would render the '055 patent's Markush language—'each layer being selected from the group consisting of'—equivalent to the phrase 'each layer comprising one or more of.'" *Id*.

The claim terms in *Multilayer*,—i.e., use of "comprising" in the preamble and a Markush group with the transitional phrase "consisting of"—are similar to the claim terms before me. And, I am, of course, bound by Federal Circuit precedent. Accordingly, there is a very strong presumption that the binder and disintegrant elements in the '405 patent are closed to unrecited

binders and disintegrants unless Amgen points to sufficient evidence to overcome this presumption.

In *Multilayer*, plaintiff pointed to the specification of the '055 patent as evidence of "an unmistakable intent to open the Markush group of element (b) to unrecited resins." *Id*. at 1359. Several passages of the specification, including three dependent claims and two of the three embodiments, described inner layers with unrecited resins. *Id*. at 1359-60. The court nevertheless concluded that "the specification of the '055 patent, including its dependent claims, [was] insufficient to overcome the very strong presumption, created by the patent's use of the transitional phrase 'consisting of,' that the Markush group of element (b) is closed to resins other than the four recited." *Id*. at 1360-61.

Here, Amgen is unable to point to anything, other than the use of "comprising" in the preamble, to support its argument that the Markush groups for the binder and disintegrant elements are open to unrecited elements. Considering that the evidence in *Multilayer*, which specifically described the use of unrecited resins, was not enough to overcome the presumption, what Amgen offers in comparison cannot be enough, particularly when Multilayer similarly used "comprising" in the preamble. Accordingly, I conclude that Amgen has not overcome the very strong presumption that the Markush groups for the binder and disintegrant elements are closed to unrecited binders and disintegrants.

In reaching the above conclusion, I have considered that, when examining similar language, the court in *Maxma v. ConocoPhillips, Inc*., 2005 WL 1690611 (E.D. Tex. July 19, 2005), took a different tack. In *Maxma*, a Texas district court addressed a Markush group for carrier liquid. The claim stated in relevant part:

> In a fuel additive for a hydrocarbon fuel, the composition comprising:
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> (a) at least 90 wt. % of a carrier liquid selected from the group consisting of a hydrocarbon fraction in the kerosene boiling range having a flash point of at least 100 F. and an auto-ignition temperature of at least 400 F., a C1–C3 monohydric, dihydric, or polyhydric aliphatic alcohol, and mixtures thereof;

Id. at *4. Based on the open-ended "comprising" in the preamble, the court concluded that "the presence of the recited composition will infringe the claim, even if other structures or ingredients are also present." *Id*. at *5. Thus, the plaintiffs had to "prove the presence of one of the members of the [Markush] group" for carrier liquid. *Id*. But "the [additional] presence of some unlisted ingredient in the accused product that otherwise meets the court's definition of a carrier liquid" would not defeat infringement. *Id*. In other words, the court rejected defendant's argument that the closed Markush group meant the "accused composition may include only one of the recited carrier fluids." *Id*. Under the rules laid out in *Maxma*, if the claim recited "a member selected from a group consisting of A, B, and C," then a defendant's composition met the claim limitation if it included member "A" as well as unlisted member "D." As a result, *Maxma* is not consistent with the rules of construction outlined in *Multilayer*. More importantly, *Maxma* pre-dates *Multilayer* and, therefore, did not apply the "very strong presumption" that Markush groups are closed. *Multilayer*, 831 F.3d at 1358; *see also Watson*, 848 F.3d at 986 (referring to the presumption as "exceptionally strong"). Given the above, I decline to follow *Maxma* on this particular issue.

Finally, I note that there are only a few instances where defendants use as binders or disintegrants both a recited member and unrecited alternative. There are a greater number of instances where defendants use only an unrecited alternative, and Amgen has cited no case showing that even an "open" Markush group would allow it to prove that Defendants'

composition meets the Markush group limitation based on unrecited alternatives only. Indeed, even in *Maxma*, the court was clear that plaintiff could not discharge its burden by "establish[ing] [only] the presence of a substance meeting the court's definition of 'carrier liquid' that is not within the group of listed alternatives." *Id*.; *see also Bristol-Myers Squibb Co. v. Mylan Pharms. Inc*., 2013 U.S. Dist. LEXIS 188207, at *23 (D. Del. Oct. 17, 2013) (allowing the x-ray powder diffraction pattern to include additional 2θ values, but requiring that the x-ray powder diffraction pattern include at least six of the eleven 2θ values, as required by the Markush group language).

B. The Doctrine of Equivalents

Amgen also argues that even if the Markush groups are closed, it may still prove infringement under the doctrine of equivalents. "[T]he [claim] drafter's choice of the phrase 'consisting of' does not foreclose infringement under the doctrine of equivalents." *Vehicular Techs. v. Titan Wheel Int'l*, 212 F.3d 1377, 1383 (Fed. Cir. 2000). Thus, it appears that a patentee may still rely on the doctrine of equivalents to prove infringement of an element containing a closed Markush group. *See, e.g*., *Intervet Inc. v. Merial Ltd*., 617 F.3d 1282, 1286, 1290-1292 (Fed. Cir. 2010) (holding that a district court "erred in…barring the doctrine of equivalents from its infringement analysis" of a claim covering "[a] vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1 to 13 of porcine circovirus type II"); *E.I. Du Pont de NeMours & Co. v. Heraeus Precious Metals N. Am. Conshohocken LLC*, 2013 WL 2659533, at *3 (D. Or. June 7, 2013) (rejecting an argument that plaintiff was "foreclosed" from arguing that any compound not listed in a claimed Markush group was an equivalent).

Given the above, Amgen is not precluded from relying on the doctrine of equivalents to prove that a defendant infringed the binder or disintegrant elements, even though the Markush group for those elements are closed.[2]

II. LATE IDENTIFIED WITNESS

In the parties' Proposed Joint Pretrial Order, defendant Dr. Reddy's Laboratories ("DRL") identified Movva Snehalatha ("Snehalatha") as a potential witness that "may be called at trial." (D.I. 293-1, Ex. 4.1). Amgen argues that DRL should either be precluded from calling Snehalatha as witness, because DRL failed to timely identify her or, be ordered to produce Snehalatha for a deposition in advance of trial. (D.I. 294-1, Ex. 8 at ¶ 1(d)).

Fed. R. Civ. P. 26(a)(1) provides that, early in the case, a party must disclose "the name ... of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses." Fed. R. Civ. P. 26(a)(3) provides that a party must "promptly" disclose the name of a witness it may present at trial other than solely for impeachment. Finally, Fed. R. Civ. P. 26(e) states that a party must supplement its disclosures in a "timely manner." If a party fails to timely identify a witness as required by Fed. R. Civ. P. 26(a) or (e), "the party is not allowed to use that … witness to supply evidence … at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). It is left to the trial court's discretion to determine whether a party provides

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[2] The court is aware that Defendants plan to present several arguments as to why Amgen cannot invoke the doctrine of equivalents, including prosecution history estoppel. Nothing herein should be construed as precluding or prejudging those arguments.

substantial justification for their delay or if the delay is harmless. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 2007 WL 979854, at *12 n. 12 (D.N.J. Mar. 30, 2007). In exercising its discretion, the court should consider: "(1) the prejudice or surprise in fact to the opposing party, (2) the ability of the party to cure the prejudice, (3) the extent of disruption of the orderly and efficient trial of the case, and (4) the bad faith or willfulness of the non-compliance." *Stambler v. RSA Sec., Inc.*, 212 F.R.D. 470, 471 (D. Del. 2003) (quoting *Greate Bay Hotel & Casino v. Tose*, 34 F.3d 1227, 1236 (3d Cir. 1994)).

As no testimony has been taken, I do not yet have the necessary context of Snehalatha's testimony. Nor do I know when Snethalatha was first identified as a witness, or why she was not identified earlier. That said, and in order to avoid further conflict on this issue, Snehalatha shall be produced for deposition before to March 5, 2018. *See Impax Labs. Inc. v. Lannett Holdings Inc.*, 2016 WL 9240617, at *1 (D. Del. Aug. 24, 2016) (allowing late-identified witness to testify at trial where opposing party was amenable to a pre-trial deposition as a remedy).

III. CONCLUSION

An order consistent with this memorandum will be entered.

/s/ Mitchell S. Goldberg

Dated: February 27, 2018

MITCHELL S. GOLDBERG, J.