IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAYNE PHARMA INTERNATIONAL PTY LTD.,	:	
Plaintiff,	:	
v.	:	C.A. No. 15-438-LPS
MERCK & CO., INC., and MERCK SHARP & DOHME CORP.,	:	
Defendants.	:	

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MEMORANDUM OPINION

December 27, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

In this patent infringement action, Mayne Pharma International Pty Ltd. ("Mayne" or "Plaintiff") alleges that Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively, "Merck" or "Defendants"), and specifically Merck's Noxafil® tablets, infringe Mayne's U.S. Patent No. 6,881,745, which relates to pharmaceutical compositions for poorly soluble, antifungal drugs. (D.I. 38 at ¶ 64) Now before the Court is the matter of claim construction. The parties submitted technology tutorials (D.I. 62, 63) and claim construction briefs (*see* D.I. 64, 66, 92, and 100). Both parties also submitted expert declarations (*see* D.I. 65, 67, 68, 93, 94, 101), which the Court has considered. The Court held a claim construction hearing on October 24, 2016. (*See* D.I. 111 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."

Id. at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope

using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to

establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. "consisting essentially of"[1]

Plaintiff customary legal meaning, which is "necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel characteristics of the invention"
Defendants Indefinite; non-limiting
Court Not proven indefinite Customary legal meaning, which is "necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel characteristics of the invention"

The term "consisting essentially of" is a transition phrase that "signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Merck contends that the asserted claims containing these terms are indefinite.

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A party challenging the validity of a patent or claim has the burden of establishing invalidity by clear and convincing evidence. *See id.* at 2130 n.10 (citing 35 U.S.C. § 282); *see also Microsoft Corp. v. i4i Ltd. P'ship*, 564 S. Ct. 2238, 2242 (2011).

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[1]This term appears in claims 9 and 12 of the '745 patent.

The first basis on which Merck contends that "consisting essentially of" in claims 9 and 12 is indefinite is that the specification does not shed sufficient light on the basic and novel properties of the claimed invention. (D.I. 66 at 9) In response, Mayne describes the basic and novel characteristic of the invention as being the improved bioavailability of an azole antifungal drug in the fasted state. (D.I. 64 at 8) Mayne identifies several passages in the '745 patent for support. To start, the patent's title is "Pharmaceutical Compositions for Poorly Soluble Drugs." The abstract reads, in part: "The present invention provides a pharmaceutical composition of a practically insoluble drug, wherein the composition may be administered with food or without food." In the background of the invention, the patent outlines previous attempts to improve bioavailability of practically insoluble drugs. Col. 1 l. 25 - col. 2 l .46. According to the specification, many of these attempts were limited to administration with food. Col. 2 ll. 26-32 ("[I]t has been reported that many such drugs are formulated into dosage forms that should only be administered with food."). Thus, the patent describes "[t]he present invention [as] provid[ing] a pharmaceutical composition of a practically insoluble drug, wherein the composition may be administered with food or without food." Col. 2 ll. 49-51. The specification goes on to state that "[b]y utilising compositions in accordance with the present invention, it has been found that drugs previously considered to present bioavailability problems may be presented in dosage forms with superior bioavailability." Col. 7 ll. 22-25. Further, the examples in the specification report improved bioavailability (compared to a commercially-available formulation) for an embodiment of the claimed composition using the active ingredient itraconazole, stating that this embodiment "need not be administered with food." Col. 7 ll. 25-34.

The Court agrees with Mayne that a person of ordinary skill in the art reading the patent

would have reasonable certainty as to the basic and novel properties of the claimed invention. Such a person would readily ascertain that the basic and novel characteristic of the present invention is the improved bioavailability of an azole antifungal drug in the fasted state. As described above, the specification is replete with language and examples that support this conclusion.

Merck next argues that the asserted claims are indefinite because "improved" is a relative term, and there is no baseline from which to measure "improvement" in bioavailability. (D.I. 92 at 4) "Although terms of degree are not inherently indefinite, the patent must provide some standard for measuring that degree such that the claim language provides enough certainty to one of skill in the art when read in the context of the invention." *GE Lighting Sols., LLC v. Lights of Am., Inc*, 2016 WL 6301307, at *2 (Fed. Cir. Oct. 27, 2016) (internal quotations marks and alterations omitted).

Merck did not clearly articulate this alternative argument until the claim construction hearing. (*See* Tr. at 15-16) Its opening brief focused on the "basic and novel properties" argument addressed above (D.I. 66 at 10), as did its answering brief (*see* D.I. 92 at 3). While the "improved bioavailability" argument is mentioned in Merck's answering brief (*see id.* at 4), Mayne's briefs and expert declarations do not (unsurprisingly) address this point. While indefiniteness can be a matter of claim construction, *see Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008), and is ultimately a question of law, that question of law may be predicated on underlying factual questions, *see Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1299 (Fed. Cir. 2010). Here, given the state of the record, the Court is

unable at this time to make a final determination as to indefiniteness.[2]

Merck further contends that "consisting essentially of" is not limiting and should be construed as "comprising." Generally, "consisting essentially of" has a standard legal meaning in the context of patent claims. *See PPG*, 156 F.3d at 1354. Here, the prosecution history confirms that this standard legal meaning is the one the patentee intended; the phrase was adopted to overcome prior-art rejections. (*See* D.I. 64 at 9) After the examiner rejected the original "comprising" claims, the patentee, in a supplemental amendment, added new claims that were identical except that they used the transition "consisting essentially of." (*See* D.I. 54 Ex. D) The examiner then cancelled the "comprising" claims and allowed the "consisting essentially of" claims. (*Id.*)

Therefore, the Court adopts Mayne's proposed construction (subject to Merck's opportunity to attempt at a subsequent stage of the proceedings to met its burden of proving indefiniteness by clear and convincing evidence). *See PPG*, 156 F.3d at 1356 (rejecting construction that "would have the effect of converting the critical claim language from 'consisting essentially of' to 'comprising'"). The customary legal meaning of "consisting essentially of" is "necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel characteristics of the invention."

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[2]Further, the parties do not agree as to the identity of a person of ordinary skill in the art and have not fully developed the record on this issue. However, neither side contends that this dispute must be resolved in order to construe the claims. (*See* Tr. at 50-51, 54)

B. "Wherein" Clauses

"wherein in vivo the composition provides a mean C_{MAX} of at least 100 ng/ml, after administration in the fasted state"[3]

Plaintiff "wherein after administration the composition provides a mean maximum plasma concentration of the azole antifungal drug in humans in the fasted state of at least 100 ng/ml"
Defendants Indefinite, or alternatively Non-limiting and meaning "wherein in a living plant or animal the composition provides a mean Cmax of at least 100 ng/ml after administration of 100 mg of the azole antifungal drug in the fasted state"
Court "wherein after administration the composition provides a mean maximum plasma concentration of the azole antifungal drug in humans in the fasted state of at least 100 ng/ml"

"wherein in vivo the composition provides a mean AUC of at least 800 ng.h/ml, after administration in the fasted state"[4]

Plaintiff "wherein after administration the composition provides a mean area under the plasma concentration vs. time curve for the azole antifungal drug in humans in the fasted state of at least 800 ng.h/ml"
Defendants Indefinite, or alternatively Non-limiting and meaning "wherein in a living plant or animal the composition provides a mean AUC of at least 800 ng.h/ml after administration of 100 mg of the azole antifungal drug in the fasted state"
Court "wherein after administration the composition provides a mean area under the plasma concentration vs. time curve for the azole antifungal drug in humans in the fasted states of at least 800 ng.h/ml"

[3]This term appears in claim 9 of the '745 patent.

[4]This term appears in claim 12 of the '745 patent.

The parties present several disputes regarding these two "wherein" clauses: whether the "wherein" clauses are indefinite, the meaning of "in vivo," and whether these terms are limiting. But the parties agree that these disputes essentially all reduce to a single question: whether the wherein clauses are limited to humans, as Mayne contends, or encompass all animals, as Merck asserts. On this point the Court agrees with Mayne.

"[T]he patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002); *see also In re Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011). Therefore, claim language that "is only a statement of purpose and intended result," that "does not result in a manipulative difference in the steps of the claim," is generally not limiting. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). Thus, generally, "[a] 'whereby' [or 'wherein'] clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim," *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1172 (Fed. Cir. 1993), and "is not given weight," *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003). "However, when the 'whereby' [or 'wherein'] clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329-30 (Fed. Cir. 2005) (finding clause limiting where it "is more than the intended result of a process step," "is part of the process itself," and is "an integral part of the invention").

Here, the "wherein" clauses are material to patentability. The specification of the '745

patent states that "an aim of the present invention [is] to provide a pharmaceutical composition with improved bioavailability for drugs that are considered to be practically insoluble." Col. 2 ll. 34-36. The examples then describe the inventive pharmaceutical compositions by comparing the C_{MAX} and AUC parameters obtained for those compositions to a prior-art formulation. Col. 9 ll. 50-62. During prosecution, the specific parameters were used to distinguish the claimed invention from the prior art. (*See, e.g.*, D.I. 56 Ex. D at 93 ("Gillis '015 fails to disclose or suggest a pharmaceutical composition including about 100 mg of an azole antifungal drug wherein in vivo the composition provides a mean C_{MAX} of at least 100 ng/ml, after administration in the fasted state. Gillis '015 also fails to disclose that the composition also provides an AUC of at least 800 ng.h/ml and a reduced food effect compared to the drug after administration in the fasted state."), 96-97)

Even so, Merck contends that the claims are not limited to humans, but cover all species, and therefore the claims are indefinite, because whether the pharmacokinetic parameters of the claims are met by use of a particular compound will vary depending on the species to which the compound is being administered. For instance, administering a 100 mg dose of a drug to a human and to a non-human will result in widely varying C_{MAX} and AUC measurements, due to differences in blood volume and metabolism. (D.I. 66 at 11-12) Hence, according to Merck, a person of ordinary skill in the art would not know with reasonable certainty whether a composition is covered by the claims or not.

In support of its position that the claims cover any animal,[5] Merck focuses on the patent's

[5]Although its briefing was unclear on this point (*see, e.g.*, D.I. 66 at 1-2, 13, 20), at the hearing Merck clarified that it does not contend that the specification's definition of "in vivo" requires the claims to include application to plants. (*See* Tr. at 69-70)

definition section, which includes the statement that "[t]he term 'in vivo' in general means in the living body of a plant or animal." '745 patent col. 3 ll. 37-38. But this means just what it says: ***in general***, "in vivo" means "in the living body of a plant or animal." It does not mean that the patent's claims containing "in vivo" necessarily cover administration of a compound to every species, human and non-human alike.[6]

Merck also notes that the patent uses the term "humans" only once, when defining the term "drug." Col. 3 ll. 21-23 ("The term 'drug' will be widely understood and denotes a compound having beneficial prophylactic and/or therapeutic properties when administered to, for example, humans."). Merck also points to the Kai reference described in the background of the invention, col. 1 l. 63 - col. 2 l. 11, which Merck asserts is a study in beagle dogs (Tr. at 82). However, as Mayne notes, other portions of the specification would make reasonably clear to a person of ordinary skill in the art that the claims are limited to humans. The specification's in vivo data is obtained exclusively from humans.[7] *See* col. 9 ll. 35-36 ("8 male volunteers were dosed"); *id.*, col. 10, ll. 13-14 ("8 health[y] male adult subjects"). The "volunteers" of this study must, by definition, be humans; other species do not "volunteer" for pharmaceutical studies. (D.I. 100 at 17) The patent also describes *in vitro* dissolution studies performed at pH levels of 1.2 and 6.0, col. 8 ll. 33-44, conditions which a person of ordinary skill would recognize as mimicking the pH environments of the human digestive system (D.I. 64 at 13). And while the

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[6]The Court concludes that the term "in vivo" requires no additional construction.

[7]Merck argues that the C_{MAX} and AUC data presented in the examples is inconsistent with the data displayed in the figures. (D.I. 66 at 12) Even assuming this is true, Merck does not explain how any inconsistency in the data calls into question Mayne's assertion that all in vivo data was collected from human subjects.

Kai reference involved a study of dogs, the dogs were being used as a proxy to assess the likely results of administration to a human. (*See* Tr. at 57-58)

Merck has failed to prove, by clear and convincing evidence, that a person of ordinary skill in the art would lack reasonable certainty that the claims are limited to humans. This is so despite the undisputed fact that administration of a 100 mg dose of an antifungal azole drug will produce different blood plasma results in different species. As Mayne's expert explained, because it is "well-known and documented that azoles produce a variation in pharmacokinetic values between species," a person of ordinary skill "would immediately understand" – given the results reported from administration of an about 100 mg dose – "that the claims of the '745 patent are directed to humans only." (D.I. 101 at ¶¶ 25-26)

Construing the claims to cover administration only in humans does not, contrary to Merck's contentions, violate claim construction principles by importing an example into the claims. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1346-47 (Fed. Cir. 2015) ("caution[ing] against limiting the claimed invention to preferred embodiments or specific examples in the specification"); *Hill-Rom*, 755 F.3d at 1371. The Court is obligated to give a claim term "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13. Here, as described above, a person of ordinary skill in the art, in the context of this patent, would understand the claims to be limited to humans. *See Ruckus Wireless, Inc. v. Innovative Wireless Sols.*, LLC, 824 F.3d 999, 1003-04 (Fed. Cir. 2016).

Accordingly, the Court adopts Mayne's construction of the "wherein" clauses.

C. "pharmaceutical composition"[8]

Plaintiff "a medicinal drug preparation"
Defendants Non-limiting preamble, meaning "any composition suited for pharmaceutical use"
Court Limiting, and meaning "any composition suited for pharmaceutical use"

The parties disagree about whether "pharmaceutical composition" is a limiting preamble that requires construction. "Generally, the preamble does not limit the claims," *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002), unless "it recites essential structure or steps" or "is necessary to give life, meaning, and vitality to the claim," *Catalina Mktg.*, 289 F.3d at 808 (internal quotation marks omitted). A preamble may, therefore, be limiting if it: (1) provides antecedent basis for a claim term, (2) is essential to help understand the claim terms, (3) provides any additional steps or structure that is underscored as important by the specification, or (4) was relied on during prosecution. *See id.*

The preamble to claims 9 and 12 recites: "A pharmaceutical composition, consisting essentially of . . . ." '745 patent col. 1 ll. 15-16, 33-34. This preamble is limiting because it provides antecedent basis for the term "the composition," which appears in the wherein clauses of claims 9 and 12. Col. 11 ll. 26, 43.

The parties further disagree as to the ordinary meaning of "pharmaceutical composition." Mayne argues that an ordinarily skilled artisan would understand "pharmaceutical composition" to mean "a medicinal drug preparation for administration to patients." (D.I. 64 at 3-4) Merck

[8]This term appears in claims 9 and 12 of the '745 patent.

proposes that the ordinary meaning is "any composition suited for pharmaceutical use." (D.I. 66 at 18) The Court agrees with Merck. Mayne's construction narrows the scope of the claims in a manner not warranted by the intrinsic evidence, particularly as the specification does not even use the words "medicinal" and "preparation." Accordingly, the Court will construe "pharmaceutical composition" as "any composition suited for pharmaceutical use."

D. "azole antifungal drug"[9]

Plaintiff "a compound with an azole moiety suitable for use as an antifungal medication"
Defendants "a compound with an azole moiety having beneficial prophylactic and/or therapeutic antifungal properties when administered to, for example, a human"
Court "a compound with an azole moiety having beneficial prophylactic and/or therapeutic antifungal properties when administered"

The parties agree on the meaning of the terms "azole" and "antifungal." The parties dispute only the meaning of "drug" in this limitation.

Mayne contends that the ordinary meaning of "drug" is a compound "suitable for use as a medication." (D.I. 64 at 6) Merck argues that the ordinary meaning of "drug" is broader, encompassing "a compound . . . having beneficial prophylactic and/or therapeutic antifungal properties when administered to, for example, a human." (D.I. 92 at 14) The Court largely agrees with Merck.

The specification recognizes that the term "drug" has a meaning "that will be well understood by a skilled addressee," but defines it "for ease of reference" as "a compound having

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[9]This term appears in claims 9 and 12 of the '745 patent.

beneficial prophylactic and/or therapeutic properties when administered to, for example, humans." '745 patent col. 3 ll. 7-10, 21-23. The Court adopts this definition as its construction, except omits the final phrase, "to, for example, humans." The Court's construction of the "wherein clauses" already makes clear that the claims are limited to administration to humans.

E. "polymer having acidic functional groups"[10]

Plaintiff No construction necessary, or alternatively "polymer having acidic functional groups when it is in the pharmaceutical composition before administration"
Defendants Plain and ordinary meaning; not time limited to before administration Indefinite
Court "polymer having acidic functional groups when it is in the pharmaceutical composition before administration"

The parties dispute whether the polymer having acidic functional groups must be in the pharmaceutical composition before administration or whether the polymer having acidic functional groups can form in the body after administration. Merck argues that the claim is silent on timing and, therefore, the polymer can be present before or after administration of the pharmaceutical composition. (D.I. 92 at 16-17) The Court disagrees.

The ordinary usage of the term "pharmaceutical composition" describes the composition before administration. (*See* D.I. 101 at ¶ 21) As Mayne's expert explains (without contradiction from Merck's expert), after administration the "pharmaceutical composition" ceases to be a

[10]This term appears in claims 9 and 12 of the '745 patent.

"pharmaceutical composition." (*Compare* D.I. 101 at ¶ 21 *with* D.I. 94 at ¶¶ 29-33) A person of ordinary skill would appreciate that the polymers having acidic functional groups are used to form the pharmaceutical composition, and therefore the polymers having acidic functional groups must be present before administration. (*See* D.I. 65 at ¶ 39)

Merck also argues that this term is indefinite because the specification only provides examples of polymers with acidic functional groups (*see* '745 patent col. 5 ll. 25-36), but there is no reasonable certainty as to which polymers besides those listed in the specification come within the scope of the claims. However, Merck's own expert, Dr. Elder, opined that "[a]cidity is a concept commonly understood by formulators" and "the phrase's components are easily understood." (D.I. 67 at ¶¶ 48, 50) Therefore, the Court finds that Merck has not carried its burden of showing, by clear and convincing evidence, that the term is indefinite.

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.