IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Plaintiff,	:	
v.	:	C.A. No. 18-1043-LPS
ACCORD HEALTHCARE INC., et al.,	:	
Defendants.	:	

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MEMORANDUM OPINION

June 5, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiff Novartis Pharmaceuticals Corp. ("Novartis" or "Plaintiff") filed suit against 25 generic pharmaceutical companies ("Defendants") on June 16, 2018, alleging infringement of U.S. Patent No. 9,187,405 ("the '405 patent"). (D.I. 1) The '405 patent "relates [to] uses of an S1P receptor modulator . . . for the treatment or prevention of neo-angiogenesis associated with a demyelinating disease, e.g. multiple sclerosis." ('405 patent at Abstract) The parties dispute the significance of the preambles to the three independent claims of the '405 patent, as well as the meaning of the term "daily dosage." The Patent Trial and Appeal Board ("PTAB") issued a final written decision on a petition for *inter partes* review ("IPR") challenging the validity of claims 1-6 of the '405 patent, on July 11, 2018. (D.I. 430-17 Ex. 43) The PTAB's decision construed the disputed terms using the standard of "broadest reasonable interpretation" ("BRI"). The parties completed claim construction briefing on April 16, 2019 (D.I. 426, 429, 479, 484) and the Court held a claim construction hearing on April 23, 2019 (D.I. 498) ("Tr.").

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) (citation and 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)) (alteration in original) (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 [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)).

CONSTRUCTION OF DISPUTED TERMS

1. Claim Preambles

- **Claim 1 Preamble: "A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising . . ."**

- **Claim 3 Preamble: "A method for treating Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising . . ."**

- **Claim 5 Preamble: "A method for slowing progression of Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising . . ."**

Plaintiffs Limiting statement of purpose, requiring partial effectiveness
Defendant Non-limiting statement of intended effect
Court Limiting statement of purpose

Plaintiff argues that the preambles of claims 1, 3, and 5 of the '405 patent limit the scope of the claims for multiple reasons, including (1) the claims would otherwise be identical, meaning that the doctrine of claim differentiation supports treating the preambles as limiting; (2) the intended purpose of each preamble is "given life" by the claim itself; and (3) the specification and well-reasoned IPR decision further supports this conclusion. Defendants respond that under Federal Circuit law, a claim preamble must affect a "manipulative difference" in the claims to have a limiting effect, except for when a preamble was added to overcome a patentability issue, which did not occur here.

Claim 1 recites as follows (with emphasis added):

> [preamble] A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a ***subject in need thereof***, comprising . . .
>
> [claim body]. . . orally administering to ***said subject*** 2-amino-2-2-(4-octylphenyl)ethylpropane-1,3-diol, in free form or in a

> pharmaceutically acceptable salt form, at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen.

The claim body of claims 3 and 5 are identical.

To be limiting, a preamble must affect a manipulative difference in the claims, provide antecedent basis for a claim term, or breathe life into the claims. *See In Re: Copaxone Consolidated Cases*, 906 F.3d 1013, 1023 (Fed. Cir. 2018); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). Here, the claim preambles supply antecedent basis for the term "said subject" and breathe life into the claims. *See Kropa v. Robie*, 187 F.2d 150, 152 (C.C.P.A. 1951) (analyzing claims where preamble was found limiting, and summarizing those preambles as "necessary to give life, meaning and vitality to the claims or counts"); *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (finding preamble limiting due to "antecedent basis" because it "sets forth the objective of the method, and the body of the claim direct[ed] that the method be performed on someone 'in need'"). The "said subject" of each of the three claims differs because each preamble identifies a different antecedent "subject in need." (*See* D.I. 426 at 11; Tr. at 12-14) This was the conclusion of the PTAB as well: "the words in the preambles inform the scope of 'said subject' in the body of each claim." (IPR at 13-14; Tr. at 12-13)[1] "The preamble thus 'constitutes a necessary component of the claimed invention.'" (D.I. 479 at 5) (quoting *Glaxosmithkline LLC v. Glenmark Pharm. Inc., USA*, 2017 WL 658468, at *7 (D. Del. Feb. 17, 2017))

Defendants contend that other similar antecedent basis arguments have been rejected. (*See* D.I. 484 at 5-6 (citing *Bristol-Myers* and *Copaxone*); Tr. at 41-44) But the claims here are

[1] Adopting Defendants' view that the preambles are not limiting would result in the claims having broader scope than the "broadest reasonable interpretation" given to the claims by the PTAB.

significantly narrower than those involved in Defendants' cases (e.g., they do not refer generically to "a cancer patient" or "a human patient"). (Tr. at 28-29)

While claim differentiation alone may not suffice to make a preamble limiting, *see Bristol-Myers Squibb Co.*, 246 F.3d at 1376, here the "presumption against claim redundancy [works] in harmony with the other canons of claim construction." (D.I. 479 at 6 (citing IPR at 13); Tr. at 14) All three independent claims would have the same scope if the preamble did not add limitations into "said subject," a disfavored (and here unwarranted) result. *See Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005); *CAE Screen Plates, Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("[W]e must presume that the use of these different terms in the claims connotes different meanings."). The Court is persuaded by Plaintiff that "a person of skill would understand the independent claims to cover a different aspect of the disease."[2] (D.I. 426 at 16; *see also* Tr. at 17-21) These different aspects "require different manipulative steps to assess." (D.I. 426 at 16 (citing D.I. 428 (Steinman Dec.) ¶¶ 96-102; D.I. 427 (Jusko Dec.) ¶¶ 69-71; D.I. 430-19 (Steinman IPR Dec.) ¶¶ 118-23; D.I. 430-16 (Lublin IPR Dec.) ¶¶ 43-55); *see also* D.I. 479 at 9 ("This testing is different depending on whether the subject is in need of slowing progression or of reducing, alleviating, or preventing relapses."); Tr. at 22-24)

[2] While the parties do not agree on the qualifications of the person of ordinary skill (*compare* D.I. 479 at 3-4 *with* D.I. 484 at 17 n.6), Defendants do not object to the Court adopting the IPR's description of such a person for purposes of claim construction (*see* Tr. at 58-60). The Court will do so. The Court will also deny Novartis's pending motion for submission of supplemental briefing in support of its claim construction answering brief. (D.I. 513, 537, 549) Should the parties dispute the qualifications of a person of ordinary skill at a later point in this case (for example, in connection with the pending preliminary injunction motion), and should that dispute appear to be material, the Court will consider hearing additional evidence or argument at that time.

Defendants argue that these preambles are nothing more than statements of intended result and, therefore, are not limiting. (D.I. 429 at 8-14; Tr. at 40) The cases on which Defendants rely are unavailing. For instance, in *Copaxone*, "the many different phrasings of intended effect '[did] not change the express dosing amount or method already disclosed in the claims, or otherwise result in a manipulative difference in the steps of the claims.'" (D.I. 429 at 10) (quoting *Copaxone*, 906 F.3d at 1023) Here, by contrast, the preambles affect who and what conditions are treated by the claimed method, through the incorporation of the preambles into the claim term "said subject."[3] The record does not support Defendants' assertion that "the methods captured in the language of each claim are performed in exactly the same way regardless of the desired result recited in the claim preambles;" instead, the claims may be performed on subjects in different stages of MS, or in need of different forms of relief. (D.I. 429 at 11; *see* D.I. 479 at 8 ("Each preamble targets a particular kind of RRMS patient, narrowing the scope of the claim to a particular need (reducing relapses (claim 1) or slowing progression (claim 5) or treating (claim 3).")))

Novartis argues for an additional limitation, that the claims also "require an actual effect." (D.I. 426 at 17; *see also* Tr. at 26 ("It's the discovery that there was actually a reduction in relapses, and then this separate slowing progression based on an observation that the blood vessel growth around the spinal column was reduced at these low doses of fingolimod. That is the core of the invention, and that is reflected in each of these preambles.")) Novartis points to

[3] In describing their interpretation of the claims, Defendants argue that "[t]hese are composition claims and at a daily dose of 0.5 daily milligrams, [] they could technically cover the universe of uses." (Tr. at 39) Fingolimod has indeed been used outside the context of MS, and Defendants agreed with the Court's question that fingolimod "could be [for treating] transplants or it could just be someone curious about fingolimod?" (*Id.* at 39-40) The Court disagrees, the patent is directed toward and limited to treating MS, as is evident throughout the specification and in the claim preambles.

the specification, which reads "there is a need for agents which are ***effective*** in the inhibition or treatment of . . . multiple sclerosis," as well as references in the file history. (D.I. 426 at 18 (quoting '405 patent 9:1-4) (emphasis added); *see also* Tr. at 26-28)) Novartis asserts that the "invention was all about efficacy," relying its own expert reports and portions of the patent describing the results of clinical testing. (D.I. 426 at 18) Defendants respond that "Novartis's attempts to read . . . effectiveness requirements into the preambles, to the extent they are construed as limiting, are unsupported by either the law or the intrinsic evidence." (D.I. 484 at 14) The Court agrees with Defendants and is not persuaded that anything in the claims, specification, or prosecution history warrant reading into the claims an efficacy limitation. While the general purpose of the invention is to achieve a safe and effective manner of treating MS, such efficacy is not a limitation of the claims.[4]

2. "Daily dosage of 0.5 mg"

Plaintiffs The amount of fingolimod administered per day over the course of a multi-day treatment.
Defendant No construction required, plain and ordinary meaning[5]
Court The amount of drug that someone takes in a given day

Plaintiff argues the Court should limit the daily dosage term to a multi-day regimen of 0.5 mg dosages per day. (D.I. 426 at 19; Tr. at 55) Plaintiff's argument rests on the chronic nature of MS ('405 patent at 8:61-64) and the specification's description of clinical trials, which

[4] This conclusion is not inconsistent with that of the PTAB. (*See* IPR at 14-15) (finding that "administration of fingolimod to 'said subject' in the claim body clearly refers to 'a subject in need' of treatment of RR-MS in the preambles," but refraining from addressing "whether the preambles further demand that the orally administered dosage is efficacious," because such a determination "is 'more important for the motion to amend'")

[5] Defendants agreed to the Court's proposed construction at the claim construction hearing. (*See* Tr. at 61)

contrast daily dosing with "intermittent dosing" (defined as every other day or once a week) (*id.* at 11:20-38). Novartis contends that "[a] single, one-time dose is never mentioned – if it had been, then the inventors would have discovered a cure, not just a disease modifying therapy." (D.I. 426 at 19) Novartis cites its expert reports for support that a person of skill would have this understanding. (*Id.* at 19-20; Tr. at 55-56) The PTAB agreed with Plaintiff and construed the term as "the amount of fingolimod administered per day over the course of a multi-day treatment." (*See* IPR at 15-17)

The Court agrees with Defendants that the claim's "plain language recites a method of treating RRMS comprising administering a 'daily dosage of 0.5 mg,'" and may include a single day dosage. (D.I. 429 at 15; *see also* Tr. at 61) "No claim language establishes the length of the dosing regimen, and the specification of the '405 patent does not define the phrase." (D.I. 429 at 15) Defendants point out that when it was used in the prosecution history, "daily dosage was used to describe each individual step occurring in a series of incremental increases," undermining a construction that would require "daily dosage" include multiple steps. (*Id.* at 15-16) (citing D.I. 350-2, Ex. C (July 6, 2015 Amendment) at 3) Additionally, Defendants point out that prior art cited in the patent describes "someone taking this dose just once, just one day and never again." (Tr. at 60)

The Court is persuaded that a person of ordinary skill in the art would likely be aware that "RRMS is a chronic disease and fingolimod is not a single-dose cure." (D.I. 479 at 11) Still, nothing in the intrinsic evidence supports finding that daily dosage is limited to a multi-day regimen. "The inventors of the '405 patent could have drafted numerous claims related to their claimed method of treatment, addressing different embodiments and dosing regimens. They did not." (D.I. 484 at 14) Thus, "[a] proper understanding of the phrase 'daily dosage of 0.5 mg' is

simply the amount of fingolimod given per day to a patient, which encompasses all the examples and descriptions in the specification." (*Id.* at 17)

CONCLUSION

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