IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD. et al.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 18-390-LPS
LUPIN ATLANTIS HOLDINGS SA, et al.	:	
Defendants.	:	

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MEMORANDUM OPINION

September 5, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S. ("Plaintiffs") filed suit against Defendants Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. ("Defendants") on March 12, 2018, alleging infringement of U.S. Patent No. 9,561,251 (the "'251 Patent"). (D.I. 1) The patent-in-suit relates to pharmaceutical compositions of iron oxy-hydroxide in high loading.

Presently before the Court is the issue of claim construction. The parties completed briefing on May 24, 2019. (D.I. 62, 65, 72, 75) The Court held a claim construction hearing on July 1, 2019. (D.I. 91) ("Tr.")

I. LEGAL STANDARDS

A. CLAIM CONSTRUCTION

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)).

B. INDEFINITENESS

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 claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015). A defendant must prove

indefiniteness by clear and convincing evidence. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

II. CONSTRUCTION OF DISPUTED TERMS[1]

A. "essentially non-bioabsorbable"[2]

Plaintiff Plain and ordinary meaning, otherwise: upon oral administration, the iron oxyhydroxide is not absorbed by the human body in a clinically significant amount
Defendant Indefinite
Court Upon oral administration, the iron oxyhydroxide is not absorbed by the human body in a clinically significant amount

Defendants argue this term is indefinite because the '251 Patent does not "provide any guidance for a POSA [person of ordinary skill in the art[3]] to determine . . . what level of iron bioabsorbability" constitutes "essentially non-bioabsorbable." (D.I. 62 at 4) (footnote omitted) Plaintiffs respond that, as a term of degree, an exact numerical value is not required, and the specification and prosecution history provide sufficient guidance as to the bounds of the term. (D.I. 65 at 9-10) Defendants have not met their burden of proving by clear and convincing evidence that the term is indefinite.

Terms of degree are not inherently indefinite. *See Sonix Tech. Co., Ltd. v. Publications Intl., Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017). Rather, when evaluating indefiniteness, the Court must determine whether the patent "provide[s] enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364,

[1] The Court will also adopt the parties agreed-upon constructions.

[2] This term appears in claim 29 of the '251 Patent.

[3] Although the parties' characterization of the POSA in this case differ, neither argues that the Court must resolve their dispute over who the POSA is in order to resolve the claim construction disputes. (*See, e.g.*, Tr. at 53)

1370 (Fed. Cir. 2014). For a term of degree to be "reasonably certain," the Court must look at the term itself and any description or examples provided in the intrinsic record. *Sonix Tech.*, 844 F.3d at 1377.

The '251 Patent begins by distinguishing iron deficiency treatments (which are intended to "liberat[e] iron") from iron-based phosphate absorbers such as the claimed invention. '251 Patent, col. 1 l. 60-col. 2 l. 2; *see also id.* at col. 3 ll. 6-10 ("The inventive compositions have a low iron release rate of below 2.5% w/w, which is essential for phosphate absorbers. In contrast thereto, compositions used for treating iron deficiency have a high iron release rate and thus are completely different [from] the inventive compositions."). The specification then states that, "***due to their chemical nature***[,] the iron oxy-hydroxides used and administered in accordance with the present invention ***essentially are not absorbed by the human body***, i.e. they are essentially non-bioabsorbable." '251 Patent, col. 4 ll. 63-67 (emphasis added).

Based on the description in the specification, a POSA would know the bounds of the claim term with reasonable certainty. Although the claim does not set forth a specific amount of iron oxy-hydroxide that may be absorbed, a POSA would know that any absorption would be minimal and unintentional compared to the absorption of iron deficiency treatments. A POSA would also know that the lack of bioabsorption may be attributed at least in part to the iron oxy-hydroxide's inherent chemical structure, as the '251 Patent does not propose any sort of modification that would render the structure especially non-bioabsorbable. Whether a particular product exhibits absorption of iron oxy-hydroxide in a "clinically significant amount" may present a factual dispute that will have to be resolved at a subsequent stage of this litigation.

B. "iron release rate below 2.5% w/w"[4]

Plaintiff The iron release measured in water at a pH of 3 according to European Pharmacopeia chapter 2.9.3 using standard dissolution equipment and parameters as described in the monograph, where iron content is analyzed by titration after 2 hours, wherein the quantity of iron dissolved after 2 hours is less than 2.5% w/w
Defendant Indefinite
Court The iron release measured in water at a pH of 3 according to European Pharmacopeia chapter 2.9.3 using standard dissolution equipment and parameters as described in the monograph, where iron content is analyzed by titration after 2 hours, wherein the quantity of iron dissolved after 2 hours is less than 2.5% w/w

The '251 Patent claims a measurement of the "iron release rate." Plaintiffs propose that the rate is measured in accordance with Example 8 of the specification: under "European Pharmacopeia chapter 2.9.3 using standard dissolution equipment and parameters as described in the monograph." (D.I. 65 at 11) (citing '251 Patent, col. 14 ll. 48-53) Defendants argue the term is indefinite because "a POSA would have understood that there are other methods, aside from those discussed in the European Pharmacopeia ('EP') monograph, that could be used to measure dissolution, each yielding potentially different results," and that "the EP monograph . . . omits critical testing conditions, including the specific apparatus and agitation speeds." (D.I. 62 at 8) The Court disagrees. Defendants have not shown that a POSA would look to testing methods other than the one described in the specification, or that the EP monograph itself renders the claim is indefinite.

Under the Supreme Court's *Nautilus* standard, when claiming a measurement "the patent and prosecution history must disclose a single known approach or establish that, where multiple

[4] This term appears in claim 30 of the '251 Patent. While the parties dispute how much of the term to construe – "iron release rate" (Plaintiffs) or "iron release rate below 2.5% w/w" (Defendants) – the Court will construe Defendants' term for the sake of thoroughness.

known approaches exist, a [POSA] would know which approach to select," "[p]articularly . . . where different approaches to measurement are involved." *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 630 (Fed. Cir. 2015) (citing *Nautilus*, 134 S. Ct. at 2124).

Defendants, however, seek to impose on patentees an overly-strict reading of *Nautilus*: one requiring that patentees who claim a measurement must also clearly and unambiguously identify a single method of measurement expressly tied to the claim limitation, with implicit or explicit disavowal of all other methods. (D.I. 62 at 10; D.I. 72 at 5) The Court is not persuaded that this is the standard. If a specification describes one, and only one,[5] reference or method to calculate a claimed measurement as part of an example, as the '251 Patent does, it may be (as it is here) that the record reveals no reason to believe a skilled artisan (or the Court) would look to any other method of measurement. *See Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1022 (Fed. Cir. 2009) (concluding that "reduction in bacterial density in the wound by at least 50%" is not indefinite even though "several methods for calculating reduction in bacterial density are available" because "the specification discloses one particular method.").

Nor is the Court persuaded that the process described in the EP monograph renders the claim indefinite. Defendants' expert, Dr. Chambliss, opines that four factors – type of dissolution apparatus, agitation speed, pH, and ionic strength – may impact release rate but are inadequately prescribed in the Patent and EP monograph, leaving a POSA unable to measure release rate. (D.I. 64 at ¶¶ 44-45) Dr. Chambliss, however, speaks only in generalities; he fails to provide evidence that the different methods described in the EP monograph would, in fact,

[5] The specification describes using European Pharmacopeia chapter 2.9.3, which Plaintiff's expert characterizes as a "well-known pharmaceutical reference guide." (D.I. 67 at ¶ 32)

produce different results, especially as to iron oxy-hydroxide.[6] Opposing Dr. Chambliss' declaration is Plaintiffs' expert, Dr. Williams, who responds that two of the factors (pH and ionic strength) are addressed in the Patent (D.I. 77 at ¶ 12) (citing '251 Patent, col. 14 ll. 51-52), and explains how a POSA would arrive at the other two variables (*id.* at ¶¶ 12-21), using Table 9b as a reference point (*id.* at ¶¶ 23-24). This battle of expert declarations leads the Court to conclude that the record lacks clear and convincing evidence of indefiniteness.[7]

C. "not bound as a complex compound"[8]

Plaintiff Plain and ordinary meaning, otherwise: not forming any intramolecular bonds such that a water-soluble stabilization agent can be removed by washing the stabilized iron oxy-hydroxide with water
Defendant Indefinite
Court Not forming any intramolecular bonds such that a water-soluble stabilization agent can be removed by washing the stabilized iron oxy-hydroxide with water

[6] Defendants have not shown that different testing methods would produce different results. *See Teva,* 789 F.3d at 1341, 1344-45 (holding claim indefinite where molecular weight could be measured three different ways and those ways ***would yield different results***, yet patent and prosecution history did not provide guidance as to which measure to use). Defendants quote *Dow Chemical*, 803 F.3d at 630-34, for the proposition that they need only show different methods ***might*** "produce different results," but in that case, as the Federal Circuit stated, "***[t]here [wa]s no question*** that each of these four methods may produce different results" based on the ***plaintiff's own expert testimony***. *Id.* at 633 (emphasis added).

[7] Before the claim construction hearing, Defendants filed a motion for leave to file a supplemental expert declaration (D.I. 86), which Plaintiffs opposed (D.I. 88). While the Court will grant the motion, and the Court has considered the contents of the proposed declaration (D.I. 86-1), the supplemental declaration does not alter the result with respect to any of the disputed terms. The supplemental declaration primarily rebuts Dr. William's opinions as to how a POSA would arrive at two undisclosed factors (dissolution apparatus and agitation speed) but the new opinions (like the earlier ones) do not constitute clear and convincing evidence.

[8] This term appears in claim 31 of the '251 Patent.

Defendants argue a POSA would not be able to determine the scope of the claim because "[t]he specification does not provide any information on ***how*** the stabilizing agent can be 'bound' and ***what the scope*** of a 'complex compound' can be." (D.I. 62 at 12) Plaintiffs respond that a POSA with even elementary knowledge of iron chemistry would know that iron can form complexes, and that the claim expressly excludes stabilization agents from forming a complex with the iron oxy-hydroxide. (D.I. 65 at 14) The Court agrees with Plaintiffs.

The specification refers to a prior art stabilizing agent that does not bind to the iron complex. '251 Patent, col. 4 ll. 48-53 ("As described in EP 0868125 B1 [the] stabilization agent usually is not bound as a complex compound to the iron oxy-hydroxide."). From this, a POSA would be reasonably certain that in the claimed invention the iron oxy-hydroxide cannot be bound in such a way as to form a complex. The specification also states that "a water-soluble stabilization agent can be removed by washing the stabilized iron oxy-hydroxide with water." (*Id.* at col. 4 ll. 45-63) This provides a POSA reasonable certainty that any interaction between the stabilization agent and the iron oxy-hydroxide is less than the interaction between the stabilization agent and water.

In a June 28, 2012 Amendment, the patentee also distinguished cited prior art by stating (emphasis omitted):

> Iron oxide dextran is polynuclear iron dextran complex in which the dextran is coordinatively bound to the iron oxy-hydroxide cores. To the contrary, the iron oxy-hydroxide of the present invention is not a polynuclear carbohydrate complex compound. Carbohydrate, which can be added [to the claimed invention] as a stabilizer, is not bound as a complex . . . and can be removed by washing, which is not the case in the iron oxide dextran complexes disclosed by [the prior art] . . . . [In the prior art], the carbohydrate forms a firmly-bound ligand and new iron complex compound.

The specification and prosecution history, taken together, support Plaintiffs' proposed construction: that not being bound as a complex means not forming any intramolecular bonds,

such that a water-soluble stabilization agent can be removed by washing the stabilized iron oxy-hydroxide with water.[9] Defendants have failed to prove by clear and convincing evidence that the term is indefinite.

D. "rapid disintegration"[10]

Plaintiff Plain and ordinary meaning
Defendant Indefinite
Court Disintegration that begins upon administration and, on average, takes no longer than 3 minutes to complete

Defendants argue that "rapid disintegration" lacks any "objective boundaries," particularly as to what is "rapid." (D.I. 62 at 15-16) Plaintiffs respond that, based on common knowledge and the specification, a POSA would know what the term means. (D.I. 65 at 16) At the hearing, Plaintiffs agreed to a construction that would require disintegration to begin upon administration and, on average, take no longer than 3 minutes to complete. (Tr. at 75) Again, the Court agrees with Plaintiffs.

The specification states that "[i]n the case of orally administrable, rapidly disintegrating dosage forms, disintegration takes place immediately upon administration allowing to quickly release the active agent or forming small particles containing the active agent in the oral cavity," and that "[s]uitable disintegration rates range from 1 second to 3 minutes." '251 Patent, col. 9 ll. 54-58.

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[9] Extrinsic evidence also supports this construction. Plaintiff's expert persuasively opines that it was well-known that certain metals, such as iron, can form a "coordination complex" or "complex" with other ions or molecules, and that a POSA would know what "***not*** being bound as a complex" entails. (D.I. 66)

[10] This term appears in claim 34 of the '251 Patent.

"Because the intrinsic evidence here provides a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine the scope of the claims," the term is not indefinite, regardless of the fact that the claim does not specify a "precise numerical measurement." *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1335 (Fed. Cir. 2010) (internal brackets and quotation marks omitted). A POSA would know with reasonable certainty that "rapid disintegration" refers to disintegration that begins upon administration and, on average, is dissolved in approximately less than 3 minutes. A trier of fact will then be able to evaluate (if necessary) whether a particular pharmaceutical composition disintegrates "rapidly."

III. CONCLUSION

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