

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE )  
RENAL PHARMA LTD. and VIFOR )  
FRESENIUS MEDICAL CARE RENAL )  
PHARMA FRANCE S.A.S., )  
 )  
Plaintiffs, ) C.A. No. 18-1996 (MN)  
 )  
v. )  
 )  
ANNORA PHARMA PRIVATE LTD. and )  
HETERO LABS LIMITED, )  
 )  
Defendant. )

**MEMORANDUM ORDER**

At Wilmington this 30th day of April 2020:

As announced at the hearing on April 20, 2020, IT IS HEREBY ORDERED that the disputed claim terms of U.S. Patent No. 9,561,251 (“the ’251 Patent”) are construed as follows:

1. “iron oxy-hydroxide in high loading of 10 to 80% (w/w)” shall be given its plain and ordinary meaning (claims 1 & 27)
2. “wherein iron oxy-hydroxide is present in an amount of 30 to 65% (w/w)” shall be given its plain and ordinary meaning (claim 4)
3. “iron oxy-hydroxide in an amount of 30 to 65% (w/w)” shall be given its plain and ordinary meaning (claim 17)

The parties briefed the issues (*see* D.I. 57) and submitted an appendix containing intrinsic evidence (*see* D.I. 58; *see also* D.I. 40), and Plaintiffs provided a tutorial describing the relevant technology (D.I. 59). The Court carefully reviewed all submissions in connection with the parties’ contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 68) and applied the following legal standards in reaching its decision:

## I. LEGAL STANDARDS

“[T]he ultimate question of the proper construction of the patent [is] a question of law,” although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). “[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.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although “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. *Id.* at 1314. “[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 . . . [as] it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). 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. “Even when the specification describes only a single embodiment, [however,] 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) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

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) (en banc), *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, courts “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. 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.” *Phillips*, 415 F.3d at 1318. 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, although 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).

## I. THE COURT'S RULING

The Court's ruling regarding the disputed claim terms of the '251 Patent was announced from the bench at the conclusion of the hearing as follows:

. . . At issue in this case, we have one patent, U.S. Patent No. 9,561,251, and three terms in dispute. The arguments are essentially the same for each term. I am prepared to rule on the disputes today. I will not be issuing a written opinion as to the terms, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that [although] I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the '251 Patent, the portions of the prosecution history submitted, the related patent applications and the other material included in the joint appendix. I have reviewed the tutorial submitted. There was full briefing on the disputed issues and there has been argument here today. All of that has been carefully considered.

Now as to my rulings. As an initial matter, I am not going to read into the record my understanding of claim construction law generally and indefiniteness. I have a legal standard section that I have used earlier, including in my relatively recent order in *Quest Diagnostics Investments LLC v. Laboratory Corporation of America Holdings*, C.A. No. 18-1436-MN. I incorporate that law and adopt it into my ruling today and will also set it in the order that I issue.

As to the person of ordinary skill in the art, the parties offered slightly different definitions in their papers,<sup>[1]</sup> but there are not any disputes as to who such a person is that are relevant to claim construction.

The first disputed term is “iron oxy-hydroxide in high loading of 10 to 80% (w/w)” as used in claims 1 and 27 of the '251 Patent. Plaintiffs assert that the term has its “plain and ordinary meaning” in which iron oxy-hydroxide in high loading means 10 to 80% (w/w). Defendants propose that this term means “iron oxy-hydroxide in high loading of more than 35.68% to 80% (w/w).”

Here, I agree with Plaintiffs and construe the term to have its plain and ordinary meaning. That construction is consistent with the ordinary meaning of the words stated. It is also supported by the intrinsic evidence. The specification defines “high loading” at

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<sup>1</sup> (Compare D.I. 57 at 3 (Plaintiffs' definition), with *id.* at 21 (Defendants' definition)).

column 5, lines 31 through 34, stating “[t]he term ‘high loading’ as used herein indicates that the iron oxy-hydroxide is present in an amount of 10 to 80% (w/w), more preferably 30 to 65% (w/w).”<sup>[2]</sup> The claims use “high loading” consistent with that definition.

Additionally, examples in the patent have formulations containing less than 35% iron oxy-hydroxide.<sup>[3]</sup> Those percentages include water in the formulation, and it is appropriate to include water in light of the claim language and the specification, which states that the weights expressed are given in relation to the total weight of the formulation.<sup>[4]</sup> I note in addition that even if water were not included, there appear[] to be examples in the patent [*e.g.*, Examples 1c, 2d and 3a-d] that contain less than 35% [and less than 32%] iron oxy-hydroxide.

Defendants argue that patentees disclaimed a portion of the claimed range in the specification, pointing to five paragraphs in the “Background” section of the ’251 Patent that refer to the lack of available high loading formulations and that address prior art disclosures.

As the Federal Circuit has repeatedly held, “[t]he standard for disavowal of claim scope is . . . exacting.”<sup>[5]</sup> Disavowal requires that “the specification make[] clear that the invention does not include a particular feature.”<sup>[6]</sup> The specification must be “both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer.”<sup>[7]</sup>

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<sup>2</sup> (’251 Patent at 5:31-34).

<sup>3</sup> (*See, e.g.*, ’251 Patent at Examples 1a-c, which have 31.75% FeOOH, including 5% water); *see also id.* at Examples 2a-d).

<sup>4</sup> (*See* ’251 Patent at 5:28-30 & Claim 1).

<sup>5</sup> *Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513 (Fed. Cir. 2015) (quoting *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012)).

<sup>6</sup> *Openwave*, 808 F.3d at 513 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001)).

<sup>7</sup> *Openwave*, 808 F.3d at 513 (quoting *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1322 (Fed. Cir. 2012)).

Here, the specification states that “phosphate absorbers with high iron loadings are still not available.” And then it notes that problems with ease of administration and storage and stability exist.<sup>[8]</sup>

Defendants argue that in the four succeeding paragraphs, each addressing [a] piece of prior art, there is a formulation referenced that contains up to 32% for a tablet or 35.68% of iron oxy-hydroxide.

I do not read these paragraphs as a clear and unmistakable disavowal of claim scope. When read in the context of the entire Background section and the entire specification, it is not clear that these statements refer to final dosage forms suitable for oral administration that contain up to 35.68% iron oxy-hydroxide (or 32% per a tablet). To the contrary, as I have already noted, the specification refers to the invention dosage forms that have high loading of iron oxy-hydroxide and includes Examples as part of the invention with final formulations that include less than 35.68% and less than 32% iron oxy-hydroxide.

Moreover, at the end of the Background section the Defendants rely on, the patent distinguishes the prior art, referring to the compositions of the invention as those in which iron oxy-hydroxide “can be successfully formulated in [the] form of an oral delivery system with high loadings,” which are able to “achieve both high loadings and suitable disintegration characteristics while maintaining a minimal size and thus are able to overcome the drawbacks of currently known formulations.”<sup>[9]</sup>


The second disputed term is “wherein iron oxy-hydroxide is present in an amount of 30 to 65% (w/w)” and the third disputed term is “iron oxy-hydroxide in an amount of 30 to 65% (w/w).” For each of these, Plaintiffs again assert the ordinary meaning should apply. Defendants assert that the appropriate range for the second term is 35.68% to 65%, and in the third term, in a claim limited to a tablet, the appropriate range is 32% to 65% (w/w).

The disputes here are the same as those addressed in connection with the first term. For the reasons I have already stated, I will give these terms their plain and ordinary meaning and I do not find that there was a clear and unmistakable disavowal that limits the stated ranges.

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<sup>8</sup> ('251 Patent at 1:40-44).

<sup>9</sup> ('251 Patent at 2:62-63 & 3:2-5).

  
The Honorable Maryellen Noreika  
United States District Judge