IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, and NOVARTIS PHARMA AG,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 12-366-RGA-CJB
ACTAVIS, INC. and ACTAVIS ELIZABETH LLC,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

In this Hatch-Waxman action filed by Plaintiffs Novartis Pharmaceuticals Corporation ("NPC"), Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis" or "Plaintiffs") against Defendants Actavis, Inc. and Actavis Elizabeth LLC[1] (collectively, "Actavis" or "Defendants"), Plaintiffs allege infringement of U.S. Patent Nos. 6,465,504 (the "'504 Patent") and 6,596,750 (the "'750 Patent") (collectively, the "patents-in-suit"). Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions as set forth below.

I. BACKGROUND

A. The Parties

Novartis manufactures and sells the drug deferasirox under the trade name EXJADE®. (D.I. 1 at ¶ 1) Novartis is the owner, by assignment, of the patents-in-suit. (*Id.* at ¶¶ 25-26)

[1] Plaintiffs also originally brought suit against Actavis Group hf. and Actavis Group PTC ehf., but those parties were later dismissed. (D.I. 13)

Actavis, Inc., and its wholly owned subsidiary Actavis Elizabeth LLC, are engaged in the business of developing, manufacturing, and distributing generic versions of branded drug products throughout the United States. (D.I. 86 at ¶¶ 11, 13)

B. The Patents-in-Suit

The '504 Patent and '750 Patent share the same title, "Substituted 3,5-Diphenyl-1,2,4-Triazoles and Their Use as Pharmaceutical Metal Chelators[,]" as well as the same abstract. (D.I. 84, ex. 1-2)[2]

1. The '504 Patent[3]

The '504 Patent was issued on October 15, 2002. ('504 Patent) Certain claims of the '504 Patent recite the chemical entity known as deferasirox. (*Id.*; D.I. 70 at 1) Deferasirox is an iron chelator, which is a compound that causes iron to be removed from the body. ('504 Patent, col. 1:28-30; D.I. 70 at 5)

2. The '750 Patent

The '750 Patent was issued on July 22, 2003. ('750 Patent) The patent is directed to methods of using certain compounds, including deferasirox, to treat diseases which cause an excess of metal in the human body or are caused by such an excess of metal. (*Id.*; D.I. 70 at 1) The patent's specification explains that certain disorders (such as Alzheimer's disease) are linked with an excess of metals in the body tissues, and that in other illnesses, an excess of iron occurs

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[2] The patents-in-suit appear on the docket more than once, including as exhibits to the Joint Appendix in Support of Claim Construction Briefing. (D.I. 84, ex. 1-2) Further citations will simply be to the "'504 Patent" and the "'750 Patent."

[3] The parties have not identified any claim construction issues involving the '504 Patent. (D.I. 70 at 1; D.I. 76 at 3 n.3)

in the various tissues (for instance, after repeated blood transfusions or after increased uptake of iron from the gastrointestinal tract). ('750 Patent, col. 1:11-20) When left untreated, such iron overload can cause severe organ damage and can lead to death. (*Id.*, col. 1:29-31) Iron chelators such as deferasirox help to prevent these problems, as they "are able to mobilize and excrete the iron deposited in the organs and thus lower the iron-related morbidity and mortality." (*Id.*, col. 1:31-33) Deferasirox is administered orally in tablet form. (*Id.*, col. 5:31-43)

The '750 Patent contains eighteen claims. (*Id.*, col. 27:19-34:42) Claims 1, 3, 6, 9, and 18 are independent claims and describe "[a] method of treating diseases which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body comprising administering . . . a therapeutically effective amount" of certain compounds, including deferasirox. (*Id.*) Among the other claims of the '750 Patent are Claims 8 and 16, which recite "[a] method of treating iron overload . . . ." and refer back to claims 3 and 9, respectively. (*Id.*, col. 30:36-39, 32:57-61)

C. Procedural History

This case arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 203560 to the United States Food and Drug Administration ("FDA"), which seeks approval to market a generic version of EXJADE®. (D.I. 1 at ¶ 1) NPC is the holder of approved New Drug Application No. 21-882, which covers EXJADE®. (*Id.* at ¶ 27) EXJADE® is deferasirox in tablet form for oral suspension. (*Id.* at ¶ 1)

Plaintiffs filed suit against Defendants on March 21, 2012, (D.I. 1), alleging that Defendants' submission of ANDA No. 203560 infringes at least one claim of each of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). (*Id.* at ¶¶ 33, 38) Further, Plaintiffs allege that upon

FDA approval of Defendants' ANDA, Defendants will infringe the patents-in-suit in violation of 35 U.S.C. § 271(a)-(c) by making, using, offering to sell, and selling its generic deferasirox product and by actively inducing and contributing to infringement by others. (*Id.* at ¶¶ 34, 39)

On June 6, 2012, this case was referred to the Court by Judge Richard G. Andrews to hear and resolve all pretrial matters, up to and including case-dispositive motions. The parties completed initial briefing on claim construction on February 27, 2013. (D.I. 83) The Court held a *Markman* hearing on March 19, 2013. (D.I. 149, hereinafter "Tr.") During the hearing, the Court ordered the parties to submit supplemental letter briefs to address newly disclosed extrinsic evidence and caselaw, (Tr. at 111-12, 136), which the parties filed on March 26, 2013, (D.I. 92, 93).

II. STANDARD OF REVIEW

It is well-understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). The proper construction of claim terms is a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The Court should generally give claim terms their "'ordinary and customary meaning[,]'" which is "the meaning that the term[s] 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) (citations omitted). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent, but rather should endeavor to

reflect their "meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321.

To that end, the Court should look first and foremost to the language of the claims, because "[i]t 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*, 415 F.3d at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be "highly instructive." *Id.* at 1314. In addition, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable" in discerning the meaning of particular claim term. *Id.* This is "[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* Moreover, "[d]ifferences among claims can also be a useful guide," as when "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.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which "may reveal a special definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess." *Id.* at 1316. In that case, "the inventor's lexicography governs." *Id.* Even if the specification does not contain a special definition of the term-at-issue, it "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." *Id.* at 1315 (internal quotation marks and citation omitted). That said, however, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed.

Cir. 2004). In addition to the specification, a court should also consider the patent's prosecution history, if it is in evidence, because it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention[.]" *Phillips*, 415 F.3d at 1317 (citations omitted).

Extrinsic evidence, "including expert and inventor testimony, dictionaries, and learned treatises[,]" can also "shed useful light on the relevant art." *Id.* (internal quotation marks and citations omitted). Dictionaries (especially technical dictionaries) may be useful in this process because they typically provide "the accepted meanings of terms used in various fields of science and technology[.]" *Id.* at 1318. However, the United States Court of Appeals for the Federal Circuit has cautioned that "heavy reliance on [a] dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Id.* at 1321. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (internal quotation marks and citations omitted); *accord Markman*, 52 F.3d at 981.

In utilizing these resources during claim construction, courts should keep in mind that "[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).

III. DISCUSSION

The parties have identified three claim terms from the '750 Patent for construction: (1) "diseases"; (2) "iron overload"; and (3) "treating." (D.I. 65; D.I. 70 at 1-2; D.I. 76 at 7)

Although Plaintiffs assert infringement of multiple claims of the '750 Patent, the use of the disputed terms in claims 3 and 8 is representative. Accordingly, these claims are reproduced below, with the disputed terms highlighted:

> 3. A method of *treating diseases* which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body comprising administering to a subject in need of such treatment a therapeutically effective amount of a compound of formula (II) wherein . . . or a pharmaceutically acceptable salt thereof.

('750 Patent, col. 27:63-28:55)

> 8. A method of *treating iron overload* comprising administering a subject in need of such treatment a therapeutically effective amount of a compound of claim **3**, or a pharmaceutically acceptable salt thereof.

(*Id.*, col. 30:36-39) In addition to their disputes regarding the three claim terms set out above, the parties further dispute whether claims 8 and 16 are independent or dependent claims. (D.I. 65; D.I. 70 at 2; D.I. 76 at 16) The Court perceives these disputes to be live, (D.I. 83 at 2-4; Tr. at 39-40), and to require resolution.

A. "diseases"

The first dispute concerns the term "diseases," which appears in or relates to claims 1-13 and 15-18 of the '750 Patent. ('750 Patent) Plaintiffs argue that the term can be understood by its plain and ordinary meaning, which they assert is "generally understood to include" their proposed construction: "disorders." (D.I. 70 at 8 (internal quotation marks omitted); *see also* Tr. at 13-14) In the parties' Joint Claim Construction Chart, Defendants proposed that this term be construed to mean "disorders of body function, system, or organ[.]" (D.I. 65 at 2) However, in response to extrinsic evidence cited by Plaintiffs, Defendants subsequently modified their proposal for the

term. They now argue that the term's plain and ordinary meaning is "disorders of body function, system, or organ *occasioned by environmental factors, specific infective agents, or genetic defects*[.]" (D.I. 76 at 7-8 & n.6; D.I. 83 at 4 (emphasis added)) For the following reasons, the Court recommends that Defendants' original proposed construction—"disorders of body function, system, or organ"—should be adopted.

In construing this term, the Court looks first to the claim language itself. Claim 3, which is representative of the term's use in other claims, describes a method of "treating *diseases* which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body . . . ." ('750 Patent, col. 27:63-65 (emphasis added)) In determining the proper construction of a claim term, the context of the surrounding words of the claim is important. *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (citing cases); *see also IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109, 1117 (Fed. Cir. 2011) ("We caution that claim language must be construed in the context of the claim in which it appears."); *Phillips*, 415 F.3d at 1314. Here, the surrounding claim language provides certain additional detail about the claimed "diseases." That is, the claim speaks of treating a certain subset of diseases—those that either (1) cause an excess of metal in the body, or (2) are caused by an excess of metal in the body.

This information reveals the problem with the newly added portion of Defendants' proposed construction (i.e., "disorders . . . *occasioned by environmental factors, specific infective agents, or genetic defects*"). The relevant claims of the '750 Patent, in part, explicitly describe a subset of diseases that are "caused by an excess of metal" in the body. Yet as Plaintiffs note, (Tr. at 26-27), the second portion of Defendants' proposal attempts to do the very same thing—it too

defines "diseases" by reference to what they are "occasioned" (or caused) by. Indeed, as to Defendants' proposal, if one simply replaces "occasioned" with its synonym "caused," then claim 3 would, in essence, describe "treating disorders . . . [caused] by environmental factors, specific infective agents, or genetic defects . . . [such disorders being] caused by an excess of metal in a human or animal body . . ." In this way, then, the language of the claims strongly suggests that the term "diseases" should not itself be defined by the factors that cause such "diseases." To do otherwise and adopt this portion of Defendants' proposal would render other portions of the claim redundant and inject confusion, rather than clarity, into the understanding of this term's meaning. *See, e.g.*, *Chalumeau Power Sys. LLC v. Alcatel-Lucent*, Civil Action No. 11-1175-RGA, 2013 WL 5913849, at *4 (D. Del. Oct. 30, 2013) (rejecting proposed construction of claim term "type of device" where the proposal rendered language in a later portion of the relevant claim "redundant"); *AVM Techs., LLC v. Intel Corp.*, Civil Action No. 10-610-RGA, 2012 WL 1134484, at *6 (D. Del. Mar. 30, 2012) (same, as to term "a delay"); *Life Techs. Corp. v. Illumina, Inc.*, Civil Action No. 09-706-RK, 2010 WL 5343177, at *8-9 (D. Del. Dec. 15, 2010) (same, as to term "thin layer").[4]

The Court next turns to the specification, which provides some additional guidance

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[4] Plaintiffs put forward a similar argument that the original, first portion of Defendants' proposal (that reciting disorders "of body function, system, or organ") is improper because it "renders superfluous the specific disease symptoms . . . already in the claims[.]" (Plaintiffs' *Markman* Presentation at Slide 28) More specifically, Plaintiffs assert that "disorders of body function, system, or organ" is "a different way, but a broader way, of saying" "diseases which cause an excess of metal in a . . . body." (Tr. at 26-27) The Court does not agree. The proposed language ("of body function, system, or organ") describes the particular part or aspect of the body that is *affected* by the disease, whereas the claim language "diseases which cause an excess of metal" refers to a particular disease *symptom* (i.e., an excess of metal in the body) that comes about as a result of the disease. Thus, the first portion of Defendants' proposal can co-exist with the claim language without rendering parts of that language superfluous or redundant.

regarding the proper construction of the term. Plaintiffs rely heavily on the specification in arguing for a broad construction—that "diseases" be construed simply to mean "disorders." In doing so, Plaintiffs assert that the specification uses the terms "diseases" and "disorders" interchangeably. (D.I. 81 at 3; Tr. at 25-26, 56) The Court will address this line of argument first.

Although the term "disorders" is not used in any of the claims, both it and the term "diseases" are separately found in the specification. Ordinarily, when different words are used in a patent, it is presumed that they carry different meanings. *See, e.g.*, *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008); *Va. Innovation Scis., Inc. v. Samsung Elecs. Co., Ltd.*, No. 2:12cv548, 2013 WL 5410013, at *15 (E.D. Va. Sept. 25, 2013); *comScore, Inc. v. Moat, Inc.*, Civil Action No. 2:12cv351, 2013 WL 3874548, at *4 (E.D. Va. July 25, 2013). Yet courts have also noted that, particularly where the terms at issue lack discernibly different meanings, "different words [may] be used to express similar concepts, even though it may be poor drafting practice[.]" *Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373 (Fed. Cir. 2004); *see also Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1120 (Fed. Cir. 2004); *Va. Innovation Scis.*, 2013 WL 5410013, at *15.

Here, the Court finds that the patent's usage of the terms "disorders" and "diseases" do not signal that they mean the same thing; instead their use suggests that while there is a relationship between the terms, the former carries a broader meaning than the latter. By way of example, the specification begins by explaining that: "[v]arious *disorders* of warm-blooded animals are linked with an excess of metals . . . in the body tissues. For example, aluminum in . . . Alzheimer's *disease* is representative." ('750 Patent, col. 1:11-15 (emphasis added)) The

manner of usage of the terms "disorders" and "disease" here is the first suggestion that the patentees did not intend them to mean exactly the same thing. Instead, as Defendants note, the patentees "particularly refer to Alzheimer's as a disease" in a manner suggesting that "disorders is a broad category" while "disease" is a term that is "more particular and more precise." (Tr. at 46-47 (Defendants' counsel noting that "[t]here would be no need to say Alzheimer's is a disease if people already knew it because the introductory phrase sa[ys] in various disorders . . . "))

The specification again utilizes the term "disorders" at the beginning of column 2 of the patent, when introducing the general concept that it "has now been found that certain [compounds] have valuable pharmacological properties when used in the treatment of *disorders* which cause an excess of metal in the human or animal body or are caused by it[.]" ('750 Patent, col. 2:4-18 (emphasis added)) Thereafter, the specification goes on to focus more particularly on the present invention, explaining in two other places that the invention "relates to the use of [deferasirox] . . . for the treatment of *diseases* which cause an excess of iron in the human or animal body or are caused by it[.]" (*Id.*, col. 4:53-56 (emphasis added); *see also id.*, col. 2:19-57 (noting that the present invention "relates to the use of [deferasirox] . . . in the treatment of *diseases* which cause an excess of metal in the human or animal body or are caused by it") (emphasis added)) Plaintiffs seize on the similarity of these references to "disorders" and "diseases" in arguing that the patent uses the terms interchangeably.

However, a closer look at the context of these references counsels against that conclusion. Column 2's opening sentence (that which uses "disorders") is a broad, general sentence, one not directly tied to the present invention, and refers to a group of "disorders" which cause or are caused by an excess of "metal." In contrast, the other two sentences at issue are couched in more

narrow terms—in that they summarize the present invention—and they refer to certain "iron" or "metal"-related "diseases," not "disorders."[5] This juxtaposition provides some indication that even when the terms "disorders" and "diseases" were being used in sentences with similar phraseology, the term "diseases" was used in a more precise context, suggesting that it carries a narrower meaning than does "disorders."

In the end, it is clear that the patentees knew how to use the term "disorders," and did so at various points in the specification. However, in summarizing the invention, and in setting out the patent's claims, they chose to use a distinctly different word—"diseases." It is well-settled that "a patent applicant defines his invention in the claims, not in the specification[,]" for it is the "claims, not the specification, [that] provide the measure of the patentee's right to exclude." *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (citing cases).[6] Taken together, all of the above indicates that "disorders" is a broader term than "diseases," and that the patentees were claiming something narrower in referencing the treatment of the latter, not the former.

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[5] Even Plaintiffs acknowledged that the opening sentence in column 2 uses "broader language" than does at least one of the other two "narrowing" references (although in using these descriptors, Plaintiffs were focused on the use of the broader term "metal" in the opening sentence versus the later use of the narrower term "iron"). (Tr. at 24-25)

[6] In contrast, in the cases cited by Plaintiffs in support of their argument that the terms are used interchangeably, (D.I. 81 at 3), the patentees used clear and unambiguous signals to demonstrate the interchangeability of terms to the person of ordinary skill in the art. *See Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009) (finding that "graft" and "intraluminal graft" were used interchangeably, where they were clearly used to refer to the same device, at times in the same sentence); *St. Clair Intellectual Prop. Consultants, Inc. v. Acer, Inc.*, No. 09-354-LPS, 2012 WL 3536454, at *9 (D. Del. Aug. 7, 2012) (finding terms "mode" and "state" were used interchangeably, including via the repeated interchangeable use of the terms in the same sentences in the patent).

Before leaving the specification, it is worth noting that it uses the term "diseases" in one other notable instance—in a manner that does not conflict with the Defendants' original proposed construction. In explaining the need for the present invention, the specification describes the problematic treatment for iron overload that preceded deferasirox, known as desferrioxamine B. ('750 Patent, col. 1:43-65) It explains that certain difficulties with administration of this therapy severely hampered the ability to use it to comprehensively treat "thalassaemias . . . malaria . . . and sickle-cell anemia[,]" which are thereafter described as "widespread *diseases*[.]" (*Id.*, col. 1:45-61 (emphasis added)) This use of "diseases" signals that the proper construction of the term must account for and include these three maladies.[7] And it is not disputed that each of these three listed diseases would be recognized by a person of ordinary skill in the art to fall within the remaining portion of Defendants' proposed construction: "disorders of body function, system, or organ." (D.I. 76 at 8; D.I. 81 at 3)

The Court lastly turns to extrinsic evidence presented by the parties. Here, both parties provided citations to dictionary definitions, though Plaintiffs cite to no dictionary that defines "diseases" as being referred to interchangeably with "disorders." (Tr. at 48) Defendants put forward multiple dictionary definitions, but the one the Court finds most persuasive is Defendants' citation to *Stedman's Medical Dictionary* ("Stedman's"). (D.I. 76 at 10 & n.7) It is the only one of Defendants' referenced dictionaries that is not outside the relevant field of art, and the only one that Plaintiffs do not take issue with. (D.I. 81 at 5) In fact, Plaintiffs

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[7] Of course, this usage of "diseases" in the specification is far from an explicit statement that *only* these three diseases (or certain of their characteristics) should be represented in the appropriate construction. *See Phillips*, 415 F.3d at 1320 (explaining that "one of the cardinal sins of patent law" is reading a limitation from the specification into the claims) (internal quotation marks and citation omitted).

affirmatively cite to this very source in support of their construction for another disputed term, "iron overload." (*Id.* at 8) Stedman's defines "disease" as "an interruption, cessation, or disorder of body function, system, or organ"—tracking the substance of Defendants' original proposed construction (but not the second, newly-added portion relating to causation). (D.I. 84, ex. 14 at JA000284) This definition supports Defendants' position that the plain and ordinary meaning of "diseases" is that they are a subgroup of "disorders," and affect particular portions or aspects of the body. (Tr. at 47-48)

For the foregoing reasons, the Court recommends that "diseases" be construed to mean "disorders of body function, system, or organ."

B. "iron overload"

The parties next dispute the construction of the term "iron overload." The term appears in or relates to claims 8, 16, and 17 of the patent. Defendants propose that the term be construed to mean "an excess of iron in various tissues of a subject." (D.I. 76 at 13; D.I. 83 at 8) Plaintiffs argue that the term should be construed to mean "an excess of iron." (D.I. 70 at 15; D.I. 81 at 7) For the following reasons, the Court concludes that Defendants' proposal for "iron overload" should be adopted.

While the claim language itself does not shed light on whether "iron overload" must occur "in various tissues" of a subject, Defendants argue that the specification "expressly defines" the term. (D.I. 76 at 13; D.I. 83 at 8; Tr. at 79-80) The relevant portion of the specification states:

> *In other illnesses, in particular of man, an excess of iron occurs in the various tissues. This is designated as iron overload (formerly haemosiderosis).* It occurs, e.g., after

> parenteral administration of iron (especially repeated blood transfusions) or after increased uptake of iron from the gastrointestinal tract.

('750 Patent, col. 1:15-20 (emphasis added))

The Court agrees with Defendants that the highlighted language above conveys the patentees' definition of "iron overload" to the person of ordinary skill in the art (and indeed, as will be discussed further below, a definition that is consistent with the term's plain and ordinary meaning). It is well-settled that "[t]he specification acts as a dictionary when it expressly defines terms used in the claims[.]" *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). And when the specification does so, "without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998). The highlighted language is the first reference to "iron overload" made after the patent's Abstract, and sets out the meaning of that term in a very precise, specific way. The Court is thus persuaded that the phrase "[t]his is designated as" is being used as definitional language here, and that it provides clear indication that the preceding language—"an excess of iron occurr[ing] in the various tissues"—is meant to define what "iron overload" is. *See, e.g.*, *Mars, Inc. v. JCM Am. Corp.*, Civil No. 05-3165 (RBK), 2008 WL 2684118, at *12 (D.N.J. July 2, 2008) (finding that patent provided a definition of term "document" where the specification stated that "[t]hroughout the following, the term document *will designate* a rectangular sheet of paper or other material of suitable dimensions . . . .") (emphasis added).[8] Thus, this portion of the specification indicates that the patentees defined

[8] The Court is not otherwise convinced by Plaintiffs' contention that in *Mars, Inc.*, the phrase "[t]hroughout the following" is "arguably" the language that signaled to the person of ordinary skill in the art that the patentees were defining the term. (D.I. 81 at 7 n.6) Perhaps the

"iron overload" to mean an excess of iron in various tissues.[9]

Indeed, additional intrinsic evidence further supports Defendants' proposed construction. For instance, in the next paragraph, the specification recites that "[i]ron chelators are able to mobilize and excrete the iron deposited in the organs[.]" ('750 Patent, col. 1:31-32) Additionally, the Kontoghiorges reference, cited in the '750 Patent specification and acknowledged to be intrinsic evidence by both parties, (D.I. 76 at 14; Tr. at 87), states that "[t]he

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use of that term further strengthened the argument that the specification offered a definition of "document" that applied "throughout" the patent. But the use of the phrase "will designate" amounted to clear definitional language there—it is the phrase that introduced the definition of the term at issue, which followed immediately thereafter. The use of similar phraseology here ("[t]his is designated as iron overload")—at least the way it is used in this particular patent—too provides strong indication that the patentees were explicitly defining the term. *Cf. Wyeth, LLC v. Intervet, Inc.*, 771 F. Supp. 2d 334, 340 (D. Del. 2011) (where patent specification stated "[i]n the present description, PWD circovirus will be understood *as designating* . . . [,]" relying in part on "designating" language to explain how undisputed term "PWD circovirus" was "described" by the patent) (emphasis added).

[9] The Court is not persuaded to the contrary by Plaintiffs' statement that this passage of the specification does not constitute lexicography. (D.I. 81 at 7 n.6) Plaintiffs' claim construction briefing failed to meaningfully confront the issue. (*See* D.I. 70 at 16-17 (excluding reference to the specification's use of the phrase "[t]his is designated as iron overload . . . " in making argument as to why Defendants' proposed construction was flawed); D.I. 81 at 7 & n.6 (addressing the issue exclusively in a footnote, and reserving the remainder of the argument as to this term as to the meaning of "in tissues") During the *Markman* hearing, Plaintiffs asserted a new argument with respect to this issue—that the definitional language is in a "paragraph of examples" and so "to say that [the patentees] were now defining what iron overload means in the context of this paragraph . . . is [] pushing that too far." (Tr. at 68-69; *see also id.* at 73) The Court disagrees. The passage at issue appears in the second paragraph of the specification and is the first substantive paragraph therein, as the opening paragraph simply provides details relating to the patent's application history. ('750 Patent, col. 1:5-17) It is true, as Plaintiffs state, that the sentence following the definitional language "is basically saying there are examples of the way you can get iron overload, either through a transfusion through parenteral administration of the iron . . . or increased uptake from the gastrointestinal tract." (Tr. at 69) But the definitional language defines what iron overload *is*, and there is nothing exemplary about that definition. The examples cited go to a different, though related issue—they provide various reasons why and/or how iron overload *occurs*. ('750 Patent, col. 1:17-28 ("[Iron overload] occurs, e.g., ...))

presence of *excess iron in tissues* leads to the saturation of the metabolic, antioxidant and other controls, usually protecting the body from such toxicity and as a result molecular and tissue damage could occur which, in the case of transfusional *iron overload*, may be irreversible." (D.I. 84, ex. 9 at JA000074 (emphasis added)) And the Prescribing Information for EXJADE® explains that in two clinical studies involving patients undergoing transfusion, iron overload was measured by liver biopsies. (*Id.*, ex. 11 at JA000132-33)

Indeed, in this case, the specification's definition of "iron overload" actually comports with the ordinary meaning of the term as understood by a person of skill in the art—further underscoring that Defendants' proposal should be adopted. (D.I. 76 at 15; Tr. at 77, 88) For example, a food and nutrition encyclopedia cited by Defendants describes iron overload as "[a]n increase in nontoxic tissue storage of iron [] called hemosiderosis [iron overload.]" (D.I. 84, ex. 17 at JA000310) And a *New Scientist and Science Journal* article, also cited by Defendants, explains that "iron overload can be of several types. Excess tissue iron may be acquired orally, by high environmental levels of iron or through high alcohol intake, or by repeated blood transfusions. The term used to describe the high level of tissue iron in these circumstances is haemosiderosis [iron overload]." (*Id.*, ex. 18 at JA000315) Plaintiffs failed to address these extrinsic sources, instead simply asserting in conclusory fashion that "[t]he plain meaning of iron overload, i.e., excess of iron, does not so limit the term [to iron deposited in tissues]." (D.I. 81 at 7)

Tellingly, even Plaintiffs "agree[] that iron overload includes iron deposited in the tissues." (*Id.*) Plaintiffs' briefing and argument at the *Markman* hearing reveals that their primary disagreement is not so much with the substance of Defendants' proposed construction,

but instead with any argument by Defendants that "an excess of iron in various tissues of a subject" cannot refer to an excess of iron found in blood plasma. (*See, e.g.*, D.I. 70 at 15-17; D.I. 81 at 7) Indeed, the section of Plaintiffs' reply claim construction brief regarding "iron overload" is almost entirely devoted to arguing that blood plasma is a tissue. (D.I. 81 at 7-8)[10]

Thus, the Court recommends that "iron overload" be construed to mean "an excess of iron in various tissues of a subject."

C. "treating"

The final term-at-issue is "treating." The term appears in or relates to claims 1-13 and 15-18 of the patent.[11] Defendants propose that "treating" be construed to mean "causing a therapeutic improvement in," (D.I. 76 at 12-13; D.I. 83 at 7-8), a definition that they contend is the term's plain and ordinary meaning in the context of this patent, (Tr. at 109). For their part,

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[10] The patent infringement analysis is conducted in two steps; first is construction of the claims, and second is comparison of the construed claim to the accused product. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed. Cir. 2003). When asked during the *Markman* hearing if the issue of whether blood plasma is a tissue is a matter of claim construction for the Court to decide in advance of trial or a matter of infringement for the trier of fact, Defendants' counsel asserted that it was the latter, while Plaintiffs' counsel conceded that it is a "close[] question in terms of what side of the line it falls on." (Tr. at 70-71, 83-84) The issue *is* a close one, and the Court is not inclined to resolve it here, where (1) neither party has addressed how the instant circumstances relate to the caselaw in this area (*see, e.g.*, *Every Penny Counts, Inc. v. Am. Express Co.*, 563 F.3d 1378, 1381-83 (Fed. Cir. 2009); *Genentech, Inc. v. Trustees of Univ. of Pa.*, 871 F. Supp. 2d 963, 969-971 (N.D. Cal. 2012)) and (2) where Defendants have not provided any substantive argument as to whether blood plasma is or is not a tissue. The Court will instead address this issue separately with the parties.

[11] The term "treating" appears in three contexts in the claims: (1) "*treating* diseases which cause an excess of metal in a human or animal body" ('750 Patent, claims 1-13, 15-18 (emphasis added)); (2) "*treating* diseases which . . . are caused by an excess of metal in a human or animal body" (*id.* (emphasis added)); and (3) "*treating* iron overload" (*id.*, claims 8 and 16 (emphasis added)). The parties agree that "treating" has the same meaning in each of these contexts. (D.I. 65; D.I. 81 at 5 n.5)

Plaintiffs argue that no construction is necessary for this "well-understood" term. (D.I. 70 at 13-15; D.I. 81 at 5-7) Alternatively, Plaintiffs assert that the term could correctly be construed to mean "attempting to cause a therapeutic improvement[,]" as such a construction would be consistent with the term's plain meaning. (D.I. 93 at 5; Tr. at 110) As is evident from these competing proposals, there is a real dispute here between the parties as to the term's ordinary meaning, one that is capable of resolution and should be resolved by the Court. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). The crux of that dispute is whether the patent requires that "treating" *must* cause a particular result—therapeutic improvement—or instead whether such an outcome "is possible, and even hoped for, but not required by the claim language." (D.I. 93 at 5; *see also* Tr. at 89) For the following reasons, the Court recommends that Plaintiffs' proposed construction of "attempting to cause a therapeutic improvement" be adopted.

In resolving this dispute, the Court turns first to the language of the claims. The use of the term "treating" in claim 3, set out above at the beginning of this Section, is representative. While the claim language does not explicitly define the term "treating[,]" it is also true that nothing in that language imposes a requirement that "treating" bring about a particular result (i.e., the therapeutic improvement of diseases or iron overload). (*See, e.g.*, '750 Patent, col. 27:63-67) The claims do not recite methods of "therapeutically treating" or "effectively treating" diseases or iron overload with the claimed compounds. (D.I. 70 at 14) As such, the Court agrees with Plaintiffs that Defendants' proposed construction improperly "injects a non-existent functional requirement into the claims, *i.e.*, that the 'treatment' result in a 'therapeutic improvement.'" (*Id.* at 13; *see also* Tr. at 107-108)

In arguing to the contrary, Defendants rely heavily on the fact that the claims at issue state that "treating" diseases or iron overload involves administering a "therapeutically effective amount" of the relevant compound. (D.I. 76 at 12; D.I. 83 at 8; Tr. at 102-103, 109) In light of this, they argue that it is "abundantly clear that the '750 Patent claims 'causing a therapeutic improvement in' the disease." (D.I. 76 at 12)

The Court is not persuaded by this argument. Instead, the Court agrees with Plaintiffs that while the claims require administering a dose of the claimed compound that is a "therapeutically effective amount[,]" such a requirement does not qualify the method of "treating" or otherwise require that "treating" cause a specific *outcome*. (D.I. 70 at 14; *see also* D.I. 81 at 6 ("[A] patient may be treated with a 'therapeutically effective amount' of a drug without that drug necessarily 'causing a therapeutic improvement' in the disease of the patient."); Tr. at 93 (Plaintiffs' counsel asserting that "what the doctor is doing in the course of [the treatment required by the claims] is giving that person that which has been found in others to be a therapeutically effective amount and hop[ing] that it will work in the course of this one person.")) It is obvious that the patentees knew how to use the word "therapeutically," and their choice to not use the word (or a variation of it) to modify the term "treating" is meaningful. The patentees could have, but did not, claim "a method of *therapeutically treating*" diseases or iron overload. That choice must be given meaning here.

The patent's specification does not counsel a different conclusion. In support of their argument, Defendants primarily point to two sections of the specification. The first section states that "[t]he present invention relates to the use of compounds . . . preferably in the form of pharmaceutically acceptable preparations, in particular in a method for the *therapeutic treatment*

of the human body, and to a treatment method of this type." ('750 Patent, col. 2:19-60 (emphasis added)) The second section similarly states that "[i]n particular, the invention relates to the use of a compound . . . for the treatment of diseases . . . preferably in the form of pharmaceutically acceptable preparations, in particular a method for the *therapeutic treatment* of the human body, and to a treatment method of this type." (*Id.*, col. 4:53-59 (emphasis added))

However, as Plaintiffs note, (D.I. 93 at 4), given the use of the term "preferably" in these statements, this language appears to be "merely expressing a non-limiting preferred embodiment of a broader invention." *See Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1357 (Fed. Cir. 2003) (explaining that "use of the term 'preferably' makes clear that the language describes a preferred embodiment, not the invention as a whole"); *see also Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1250-51 (Fed. Cir. 2008). The Federal Circuit has repeatedly warned against confining the claims of a patent to specific embodiments described in the specification. *Phillips*, 415 F.3d at 1323. To the extent that "therapeutic treatment" as used in the specification suggests that "treating" must cause therapeutic improvement, it is significant that the patentees did not choose to modify "treating" in the claims themselves, and the Court will not here import such a limitation from the specification into the claim. Thus, the intrinsic evidence does not support construing "treating" to mean "causing a therapeutic improvement in."[12]

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[12] During the *Markman* hearing, Defendants introduced for the first time a case involving similar claim language to that at issue here, in which this Court construed "method of treating" to mean "[a] method of alleviating the symptoms or deferring the decline associated with [relevant diseases.]" (Tr. at 103-105 (citing *In re '318 Patent Infringement Litig.*, 578 F. Supp. 2d 711, 725 (D. Del. 2008)) However, in contrast to the specification here, in which the prospect of therapeutically effective treatment is described in language expressing a non-limiting preferred embodiment, in *In re '318 Patent Infringement Litig.*, the patent's specification clearly and explicitly stated that it was an "object" of the present invention "to improve the cognitive function of patients with [the relevant disease]." *In re '318 Patent Infringement Litig.*, 578 F.

However, in ascertaining the plain and ordinary meaning of "treating" in the context of the '750 Patent, the Court agrees with Defendants that the term must connote something other than the physical act of "administering the claimed compounds." (D.I. 76 at 13; *see also* D.I. 83 at 7-8; D.I. 92 at 1) The '750 Patent includes the step of "administering" the claimed compound as part of the claimed method for "treating" diseases or iron overload, and it is well-settled that claim terms must be construed "such that words in a claim are not rendered superfluous." *Digital-Vending Servs. Int'l, LLC v. Univ. of Phx., Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012); *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (citation omitted).

Ultimately, though, the Court agrees with Plaintiffs that the plain and ordinary meaning of "treating" diseases or iron overload (as reflected by the term's use in the patent) is to *attempt* to cause a therapeutic improvement, without necessarily having assurance of what the outcome will be. This conclusion is in line with the decisions of other courts as to the plain and ordinary meaning of "treating," in cases where the term was used alongside very similar claim language to that at issue here. *Cf. Schering Corp. v. Mylan Pharms., Inc.*, Civil Action No. 09-6383 (JLL), 2011 WL 2446563, at *2, *5 (D.N.J. June 15, 2011) (in construing term "treating" that appeared in, *inter alia*, a claim requiring "[a] method of treating . . . atherosclerosis . . . comprising administering to a mammal . . . an effective amount" of the claimed compound, noting that "the plain meaning of 'treatment' does imply a goal of [stopping, slowing, or reversing the progression of a disease]" but "does not necessarily imply success"); *Pfizer Inc. v. Teva Pharms. USA, Inc*, 803 F. Supp. 2d 397, 401, 406 (E.D. Va. 2011) (noting that construing

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Supp. 2d at 725 (internal quotation marks and citation omitted).

"treating erectile dysfunction" to mean "keeping [erectile dysfunction] from returning, or preventing it" would not be in line with the ordinary or customary meaning of "treating," and ultimately rejecting such a construction, where the method of "treating" in the claim was "comprising orally administering . . . an effective amount of a compound"). None of these courts found that such a meaning was redundant to or rendered superfluous a claim's subsequent reference to "administering" the claimed compound at issue. *Schering Corp.*, 2011 WL 2446563, at *5; *Pfizer*, 803 F. Supp. 2d at 406. Nor does the Court here.

Indeed, even the dictionary definition that Defendants introduced during the *Markman* hearing as "basically [their]" construction for "treating," underscores that the plain meaning of the term does not absolutely require an improvement in the condition at issue. (Tr. at 98-99 (quoting *Random House College Dictionary* 1399 (rev. ed. 1984) ("to deal with (a disease, patient, etc.) in order to relieve or cure, as a physician does"))) As set out in that definition, "treating" a disease amounts to "deal[ing]" with the disease "*in order to* relieve or cure" it—wording that, to the Court, suggests intention that the disease be relieved or cured, but not certainty that success will be achieved.

Therefore, the Court recommends that "treating" be construed to mean "attempting to cause a therapeutic improvement in."

D. Claims 8 and 16

Finally, the parties dispute whether claims 8 and 16 of the '750 Patent are independent or dependent claims. Claim 8 is set out above in this Section (as is claim 3, referenced in claim 8). The language of claim 16 is similar to that of claim 8:

> 16. A method of treating iron overload comprising administering

> to a subject in need of such treatment a therapeutically effective amount of a compound of formula II, as claimed in claim **9**, or a pharmaceutically acceptable salt thereof.

('750 Patent, col. 32:57-61).

And the language of claim 9, referenced in claim 16, is similar in nature to that of claim 3:

> 9. A method of treating diseases which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body comprising administering to a subject in need of such treatment a therapeutically effective amount of a compound of formula (II) wherein . . . or a pharmaceutically acceptable salt thereof.

(*Id.*, col. 30:40-31:26)

While an independent claim stands on its own as described in a single claim, a dependent claim refers to and adds further limitations to an independent claim. 35 U.S.C. § 112(d) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."); *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1357 (Fed. Cir. 2007) ("To establish whether a claim is dependent upon another, this court examines if the new claim both refers to an earlier claim and further limits that referent."). "A claim's status as dependent or independent depends on the substance of the claim in light of the language of [Section 112(d)], and not the form alone." *Monsanto*, 503 F.3d at 1357-58 (citing Manual of Patent Examining Procedure ("MPEP") §§ 608.01(m), (n) (August 2006); 37 C.F.R. § 1.75 (2007) (setting forth proper drafts for independent and dependent claims)).

Defendants argue that the dependency of claims 8 and 16 is demonstrated by the plain language of the claims as well as by the prosecution history of the '750 Patent. (D.I. 76 at 16; D.I. 83 at 9) As to the language of the claims, Defendants point out that claims 8 and 16 refer to earlier claims (claims 3 and 9, respectively), and "further limit the scope of the claims from which they depend by specifying that the method at issue is narrower than treating the universe of diseases encompassed in the subject independent claim[s]." (D.I. 76 at 16-17) That is, according to Defendants, independent claims 3 and 9 sweep in two sets of diseases ((1) those "which cause an excess of metal" and (2) those which "are caused by an excess of metal"), while "[p]roperly construed, 'iron overload' [in claims 8 and 16] refers to only *one* of those two types of diseases"—the second type. (*Id.; see also* Tr. at 126) Thus, Defendants argue, the language of claims 8 and 16 follows the dictates of Section 112(d).

Beyond the claim language itself, Defendants note that during the prosecution history of the '750 Patent, the applicants made "two definitive statements" that issued claims 8 and 16 are narrower than those directed to methods of treating diseases which cause or are caused by an excess of metal. (Tr. at 128; *see also* D.I. 76 at 17-20; Tr. at 135) After the filing of the relevant patent application, the United States Patent & Trademark Office ("PTO") required that the application be restricted to either claims reciting methods of treatment (Group I, then-claims 1-4) or claims reciting compounds (Group II, then-claims 10-16). (D.I. 84, ex. 12 at JA000200-205; Tr. at 117) Predecessor claim 11 contained language similar in nature to the language of claims 8 and 16, reciting "[a] method of treating iron overload comprising administering to a subject . . . a therapeutically effective amount of a compound of claim 12[,]" with predecessor claim 12 reciting a compound. (D.I. 84, ex. 12 at JA000191) In response to the restriction requirement,

Plaintiffs elected to prosecute the method-of-treatment claims. (*Id.* at JA000220) However, they also argued that the Examiner's inclusion of claim 11 among Group II (i.e., claims reciting compounds) was due to inadvertence; they noted that "[i]f not, [] Applicants traverse this portion of the restriction requirement because 'the method of treating iron overload' is not patentably distinct from 'the method of treating various diseases which cause an excess of metal or are caused by it' *since the scope of the former is embraced by the latter*." (*Id.* (emphasis added)) Defendants argue that with this statement, the Applicants made clear that "'treating iron overload' is merely a subset of the scope of the pertinent independent claims." (D.I. 76 at 17)

The applicants next cancelled certain claims and added new claims. (D.I. 84, ex. 12 at JA000211-221) Claims 17 and 23, like issued claims 3 and 9, recited a "method of treating diseases which cause an excess of metal . . . or are caused by it . . . ." (*Id.* at JA000211-214) Claims 22 and 30 recited a "method of treating iron overload comprising administering . . . a therapeutically effective amount of a compound of [claim 17 and 23, respectively], or a pharmaceutically acceptable salt thereof." (*Id.* at JA000214-217) The applicants told the Examiner that claim 22 (issued claim 8) is "directed to [a] preferred embodiment[] of" claim 17 (issued, in essence, as claim 3), and that claim 30 (issued claim 16) is "directed to [a] preferred embodiment[] of" claim 23 (issued, in essence, as claim 9). (*Id.* at JA000220)[13]

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[13] In addition to these statements, Defendants point to the fee payments that the applicants made to the PTO as further proof in the prosecution history that claims 8 and 16 are dependent claims. (D.I. 76 at 18-19; D.I. 83 at 9-10; Tr. at 129) Despite their present assertion that the '750 Patent contains seven independent claims (including claims 8 and 16), Plaintiffs only paid for a total of five independent claims during prosecution. (D.I. 84, ex. 12 at JA000143-144, JA000221) In other words, Plaintiffs never paid for what issued as claims 8 and 16 as if those were independent claims. (D.I. 76 at 19) In response, Plaintiffs assert that "[t]he applicant's fee payment has no bearing on the claims' status as independent or dependent," citing the difference between the criteria for determining whether a claim is determined to be

In view of the claim language—and particularly the prosecution history—the Court is persuaded that claims 8 and 16 are dependent claims. With the statements referenced above, Plaintiffs clearly presented claims 8 and 16 to the PTO as claims of dependency, strongly informing the Court's decision here. *Monsanto*, 503 F.3d at 1358 (in concluding that claim was dependent, considering prosecution history as it "provide[d] additional insight into the scope of [the] claim"); *Maury Microwave, Inc. v. Focus Microwaves, Inc.*, No. CV 10-03902 MMM (JCGx), 2012 WL 9161988, at *31, *33 (C.D. Cal. July 30, 2012) (same).

The Court's conclusion is strengthened by the fact that Plaintiffs have no real answer for how to square that prosecution history with their current position that the claims are independent. Their opening brief failed to address the prosecution history, despite the fact that Defendants cited to that history in the Joint Claim Construction Chart that preceded briefing. (D.I. 65 at 4-5) Plaintiffs' reply brief simply stated in conclusory fashion that the portions of the prosecution history that Defendants rely upon are not dispositive of the claims' status as independent or dependent (without explaining *why* that is so). (D.I. 81 at 9) And although Plaintiffs asserted at the *Markman* hearing that the file history does not support Defendants' arguments in this regard, they never really addressed the substance of that argument—that during the prosecution history,

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independent for fee payment purposes as compared to the legal criteria used by a Court in making such a determination. (D.I. 81 at 9 n.9) Even acknowledging such differences, the Court is not persuaded that this evidence is irrelevant to the current dispute. Indeed, at least one court has considered the applicant's fee payment in determining the dependency of claims in dispute. *See, e.g.*, *Maury Microwave, Inc. v. Focus Microwaves, Inc.*, No. CV 10-03902 MMM (JCGx), 2012 WL 9161988, at *33 (C.D. Cal. July 30, 2012) (where parties disputed whether claims were independent or dependent, concluding the latter and considering fee payments in support thereof). And here, the fact that Plaintiffs did not consider the claims at issue as independent when making payment to the PTO is at least *some* evidence suggesting that Plaintiffs themselves recognized that the claims are dependent claims.

Plaintiffs stated that identical claim language to that at issue in claims 8 and 16 was language of dependency. (Tr. at 115-17)[14]

For these reasons, the Court recommends that claims 8 and 16 be construed as dependent claims.

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. "diseases" means "disorders of body function, system, or organ";

2. "iron overload" means "an excess of iron in various tissues of a subject";

3. "treating" means "attempting to cause a therapeutic improvement in"; and

4. Claims 8 and 16 are dependent claims.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R.

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[14] Indeed, Plaintiffs' counsel ultimately conceded during the *Markman* hearing that, "in view of the prosecution history[,]" the issue "is a relatively close question in terms of which way it comes out." (*Id.* at 134) It is true that if the Court were considering the language of the claims alone, divorced from the prosecution history, it is a closer call. For one, as Plaintiffs note, the preambles of the other undisputably dependent claims in the patent are written differently than those of claims 8 and 16 (i.e., "The method of claim X wherein . . . ." or "The method according to claim X wherein . . . ."). (*See, e.g.*, '750 Patent, col. 31:27, 32:47) Moreover, in a vacuum, it could be possible that claims 8 and 16, though themselves referring back to "a compound of" Claims 3 and 9 respectively, were drafted in a type of short-hand—simply to avoid re-writing 35 lines of formula (and thus, could be said to incorporate only the compounds recited in claims 3 and 9, rather than all of the limitations of those independent claims). (D.I. 70 at 18-20) On the other hand, were the Court to focus only on claim language, in addition to "contain[ing] a reference to a claim previously set forth[,]" claims 8 and 16 also "specify a further limitation of the subject matter claimed." 35 U.S.C. § 112(d). The method recited in claims 8 and 16 (treating iron overload) is explicitly narrower than that recited in claims 3 and 9 (treating diseases which cause or are caused by an excess of metal). In any event, what might have been a close question is clearly answered in Defendants' favor when the prosecution history is taken into account.

Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: November 21, 2013

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE