NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

VIFOR (INTERNATIONAL) AG and AMERICAN REGENT, INC.,

Plaintiffs,

Civil Action No. 19-13955 (FLW) OPINION

v.

MYLAN LABORATORIES LTD. and SANDOZ INC.,

Defendants.

WOLFSON, Chief Judge:

Plaintiffs Vifor (International) AG ("Vifor") and American Regent, Inc. ("American Regent") (collectively, "Plaintiffs") seek judicial correction of claim 1 (the "Claim") of United States Patent No. 10,519,252 ("the '252 patent") to correct an alleged error. However, because I find that any alleged error in the Claim is not clear and obvious from the face of the Patent, it would be improper for the Court to exercise judicial correction. Accordingly, Plaintiffs' Motion is **DENIED**.

I. <u>BACKGROUND</u>

This litigation arises out of Defendants Mylan Laboratories Ltd. ("Mylan") and Sandoz Inc.'s ("Sandoz") (collectively "Defendants") filing of an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration to market generic versions of Injectafer (ferric carboxymaltose injection), an iron replacement product suggested for the treatment of iron deficiency anemia ("IDA") in adult patients. IDA is a condition that develops when stores of iron in the body drop too low to support normal red blood cell production. Thereafter, Plaintiffs brought the instant patent infringement suit against Defendants, through Complaints filed on June 18, 2019 and August 2, 2019.¹

On October 9, 2020, Plaintiffs filed this Motion for Judicial Correction related to claim 1 of the '252 patent, which discloses and claims iron (III) carboxymaltodextrin complexes and the use of these complexes to treat IDA. (ECF No. 107.) As presently configured, claim 1 of the '252 patent states:

1. An iron (III) carboxymaltodextrin complex wherein said iron (III) carboxymaltodextrin complex comprises polynuclear iron (III) hydroxide 4(R)-(poly-(1-4)-O- α -D-glucopyranosyl)-oxy 2(R),**3(S)**,5(R),6-tetrahydroxy-hexanoate and has a weight average molecular weight in the range of from 80 kDa to 400 kDa, and wherein said 4(R)-(poly-(1-4)-O- α -D-glucopyranosyl)-oxy-2(R),**3(S)**,5(R),6-tetrahydroxy-hexanoate is derived from the oxidation of maltodextrin

(Declaration of William P. Deni, Jr., Esq. in Support of Motion for Judicial Correction ("Deni Decl.") Ex. 1, Claim 1) (emphasis added). Plaintiffs contend that claim 1 of the '252 patent should be corrected, because claim 1 contains an obvious error and the prosecution history supports judicial correction. Specifically, Plaintiffs explain that the "obvious" error relates to the stereochemistry at carbon-3 of the hexinaoate unit, which is incorrectly written as "3(S)," rather than "3(R)." (Pl. Moving Br., at 5.) Plaintiffs further explain that the "(R)" notation refers to the "spatial arrangement of the substituents around carbons 2, 3, and 5 of the hexanoate, *i.e.*, the 'stereochemistry' of those carbons." (Pl. Moving Br., at 2) (citing Declaration of Brian M. Stoltz, Ph.D. in Support of Motion for Judicial Correction ("Stoltz Decl.") at ¶¶ 22-28.) According to Plaintiffs, a person of ordinary skill in the art ("POSA") would understand that the '252 patent

¹ On February 6, 2020, the Court entered an Order consolidating the matters for discovery purposes. Thereafter, on April 22, 2020 and April 23, 2020, Plaintiffs filed Amended Complaints against Defendants.

"repeatedly and consistently describes a synthetic reaction that results in the formation of a ligand, poly- $(1\rightarrow 4)$ -O- α -Dglucopyranosyl)-oxy-2(R),3(R),5(R),6-tetrahydroxyhexanoate, and a related complex, polynuclear iron (III)-hydroxide 4(R)-(poly- $(1\rightarrow 4)$ -O- α -D-glucopyranosyl)-oxy-2(R),3(R),5(R),6-tetrahydroxyhexanoate." (*Id.* at 5-6) (citing Stoltz Decl. at ¶¶ 40-46, 55; Deni Decl. Ex. 1 at 5:27-9:9.) Moreover, Plaintiffs argue that the prosecution history supports judicial correction, because the stereochemistry of the hexanoate unit in the complex and its ligand was never specifically questioned or directly addressed during prosecution. (*Id.* at 9.) Accordingly, Plaintiffs argue that when corrected, claim 1 of the '252 patent would read:

1. An iron (III) carboxymaltodextrin complex wherein said iron (III) carboxymaltodextrin complex comprises polynuclear iron (III)-hydroxide 4(R)-(poly- $(1\rightarrow 4)$ -O- α -D-glucopyranosyl)-oxy-2(R),**3(R)**,5(R),6-tetrahydroxy-hexanoate and has a weight average molecular weight in the range of from 80 kDa to 400 kDa, and wherein said 4(R)-(poly- $(1\rightarrow 4)$ -O- α -D-glucopyranosyl)-oxy-2(R),**3(R)**,5(R),6-tetrahydroxy-hexanoate is derived from the oxidation of maltodextrin

(Pl. Moving Br., at 3-4) (emphasis added.)

In their opposition, Defendants argue that judicial correction is inappropriate because the Claim, as written, makes sense, and the error is neither apparent nor obvious. (Def. Opp. Br., at 6.) Defendants argue that a POSA would understand that the Claim, including the 3(S) stereochemistry, is a compound that could exist and could be produced using the processes disclosed in the patents. (*Id.*) (citing Declaration of Alexei Demchenko, Ph.D., in Opposition to Plaintiffs' Motion for Judicial Correction ("Demchenko Decl.") at ¶¶ 46-64.) Further, Defendants argue that even if the Court considers the prosecution history in this case, Plaintiffs' actions and conduct "demonstrate that that the alleged error is not facially apparent." (*Id.* at 8.)

Plaintiffs filed a reply on November 13, 2020 (ECF No. 125), and in addition, the Court considered numerous submissions filed by the parties, including letters filed by Plaintiffs on

February 8, 2021 (ECF No. 153) and March 10, 2021 (ECF No. 164), and letters filed by Defendants on February 10, 2021 (ECF No. 156) and March 2, 2021 (ECF No. 160.)

II. <u>LEGAL STANDARD</u>

In a patent infringement suit, a court may properly interpret a patent to correct an obvious error. *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 441-42 (1926). Judicial correction is not meant to be "in any real sense, a re-making of the claim; but is merely giving to it the meaning which was intended by the applicant and understood by the examiner." *Id.* at 442.

Judicial correction is proper "only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Industries, L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354 (Fed. Cir. 2003). The error to be corrected "must be evident on the face of the patent." *Fargo Elecs. v. Iris, Ltd.*, 287 Fed. Appx. 96, 102 (Fed Cir. 2008) (citing *Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1303 (Fed. Cir. 2005)). The court should also consult the prosecution history, however, to determine whether only a single reasonable correction exists. *Id.* Furthermore, in determining whether it has authority to correct the disputed claims, the court "must consider any proposed correction 'from the point of view of one skilled in the art." *CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353, 1358 (Fed. Cir. 2011) (quoting *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009)).

On a motion for judicial correction, courts "may not rewrite claims to correct material or substantive errors." *Gilead Scis., Inc. v. Watson Lab'ys, Inc.*, No. 15-2350, 2016 WL 1690306, at *2 (D.N.J. Apr. 26, 2016) (citing *Ultimax*, 587 F.3d at 1353 and *Novo Industries*, 350 F.3d at 1358). Similarly, "courts may not redraft claims, whether to make them operable or to sustain

their validity." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). Indeed, the Federal Circuit has advised that judicial correction is a "narrow remedy to be used sparingly." *Gilead Scis., Inc.*, 2016 WL 1690306, at *2. Therefore, "[judicial correction] is the exception, not the rule, and should be employed only to correct an error that is so obvious that there is no question as to the proper correction." *Id.* (citing *Novo Industries*, 350 F.3d at 1358).

In accordance with Novo Industries, the Court must first determine whether the Claim makes sense as written. Id. If the answer to that question is "no," then the error is obvious on the face of the patent and the inquiry continues. In that regard, the Court will then consider whether there is a reasonable debate as to the proper correction and if the prosecution history supports correction. See, e.g., CBT Flint, 654 F.3d at 1358 (where "district court was not required to guess which meaning was intended in order to make sense of the patent claim," the district court should have corrected "detect analyze" to "detect and analyze") (emphasis added); Ultimax, 587 F.3d at 1353 (correcting what the Federal Circuit called "an obvious typographical error" by inserting comma between "f" and "cl" in chemical formula where it was undisputed that a person of ordinary skill in the art knew that "(f cl)" "corresponds to no known mineral"); Lemelson v. Gen. Mills, Inc., 968 F.2d 1202, 1203 (Fed. Cir. 1992) (adding "toy" in claim where patent was clearly directed a toy trackway, rather than an actual trackway); ISCO Int'l, Inc. v. Conductus, Inc., 2003 WL 276250, at *4 (D. Del. Feb. 10, 2003) (deleting "planar" from term "planar amplifiers" where parties agreed that term "planar amplifiers" is "senseless to any person skilled in the relevant art") (emphasis added).

On the other hand, if the Court determines that the Claim makes sense as written, then the error is not obvious and judicial correction is inappropriate. *See Grp. One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1303 (Fed. Cir. 2005) ("The error here is not evident on the face of the patent.

The prosecution history discloses that the missing language was required to be added by the examiner as a condition for issuance, but one cannot discern what language is missing simply by reading the patent. The district court does not have authority to correct the patent in such circumstances.").

III. <u>DISCUSSION</u>

The Court first must ascertain whether the error claimed by Plaintiffs is even one that it has the authority to correct, *i.e.*, whether the correction Plaintiffs suggest is an "obvious minor typographical and clerical error" in the scope of the Court's authority or whether it is a "major error." Generally, both district courts and the United States Patent and Trademark Office ("USPTO") have the ability to correct errors in patents, but the scope of that power differs. Pursuant to 35 U.S.C. § 255, the USPTO may correct through issuance of a certificate of correction, "a mistake of a clerical or typographical nature, or of minor character ... if the correction does not involve such changes in the patent as would constitute new matter or would require reexamination." This authority "is not limited to obvious errors," but in fact "extends even to broadening corrections, so long as it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected." Novo Indus., L.P., 350 F.3d at 1356–57. The USPTO's correction, however, applies only prospectively. See 35 U.S.C. § 255 ("Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form."); see also Novo Indus., 350 F.3d at 1356 (noting that Section 255 "deal[s] only with the authority of the PTO to make prospectively effective corrections, and the PTO was given no authority to correct the claims retroactively").

District courts, on the other hand, may apply corrections retroactively, but their authority is limited to situations where (1) "the correction is not subject to reasonable debate based on consideration of the claim language and the specification" and (2) "the prosecution history does not suggest a different interpretation of the claims." *Novo Indus.*, 350 F.3d at 1357. Courts are further limited to correcting "an obvious error in a patent claim," *CBT Flint Partners, LLC*, 654 F.3d at 1358 (citing *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 442 (1926)), that involves only "minor typographical and clerical errors in patents." *Novo Indus.*, 350 F.3d at 1357. "[M]ajor errors" on the other hand "are subject only to correction by the PTO." *Id.* The court must make the determination of the presence of an error—and any correction—"from the point of view of one skilled in the art." *Id.* (quoting *Ultimax*, 587 F.3d at 1353). Accordingly, "post-issuance judicial corrections which have a retroactive effect must be carefully scrutinized." *Fujitsu Limited v. Tellabs Operations, Inc.*, No. 08-3379, 2011 WL 1303358, at *12 (N.D.III. Mar. 31, 2011).

In order to grasp and conceptualize the potential error in claim 1 of the '252 patent as it relates to the stereochemistry at carbon-3 of the hexinaoate unit, it is necessary to understand some of the fundamental rules and principles associated with stereochemistry. At its core, stereochemistry is a subdiscipline of chemistry that involves the study of the relative spatial arrangement of atoms that form the structure of molecules. Plaintiffs' expert, Brian M. Stoltz, Ph.D., has provided the Court with the technical background to assess Plaintiffs' claims of error in the stereochemistry, and Defendants' expert, Alexei Demchenko, Ph.D., has accepted Dr. Stoltz's explanation of the basics of stereochemistry. (Stoltz Decl. at ¶¶ 21-28; Demchenko Decl. at ¶ 31.)

Put simply, a carbon atom can bind to four different atoms. (Stoltz Decl. at ¶ 21.) In this scenario, the four single bonds are not all within the same plane, and therefore, a chemist envisions the carbon atom and its bonds in three dimensions. (Id.) It is the Court's understanding, based on Dr. Stoltz's explanation, that chemists have developed unique nomenclature for designating the spatial arrangement of atoms, called "stereochemistry," around these asymmetrical carbons. (Id. at ¶ 22.) One such nomenclature system, called the "Cahn-Ingold-Prelog rules," assigns the descriptors "(R)" or "(S)" to each asymmetrical carbon according to whether its configuration is right- or left-handed. (Id.) Applying the Cahn-Ingold-Prelog rules, a person can determine whether an asymmetrical carbon has (R) or (S) stereochemistry. (Id. at ¶ 23.) First, "the substituents attached to the carbon are assigned a priority from 1 to 4." (Id.) "A substituent with a higher atomic number has priority over substituents with lower atomic numbers." (Id.) An atom's "atomic number," which can be found in the periodic table of elements, is the number of protons in the atom. (Id. at \P 24.) For illustration, Dr. Stoltz explains that carbon has an atomic number of 6; oxygen has an atomic number of 8; and hydrogen has an atomic number of 1. (Id.) So it follows, when bonded to carbon, hydrogen has the lowest priority, since its atomic number is 1, while oxygen has priority over carbon, because the atomic number of oxygen, which is 8, is higher than that of carbon, which is 6. (Id. at ¶ 25.) Once the priorities are assigned, the molecules are envisioned with the lowest priority substituent (e.g., hydrogen) behind the carbon. (Id. at \P 27.) The other substituents are then numbered 1, 2, and 3 to reflect their priorities. (Id.) If the priorities appear in order when rotating clockwise around the carbon, Cahn-Ingold-Prelog rules dictate that the carbon has right-handed (R) stereochemistry. (Id.) If the substituents appear in order when rotating counterclockwise, however, the carbon has left-handed (S) stereochemistry.

(*Id.*) The parties agree that a POSA would be familiar with these rules for assigning priority and determining R/S stereochemistry. (*Id.* at \P 28; Demchenko Decl. at \P 31.)

Applying the Cahn-Ingold-Prelog rules, Plaintiffs contend that a POSA would recognize that the chemical name of the carbohydrate derived from the oxidation of maltodextrin recited in claim 1 of the '252 patent contains an obvious error in stereochemical nomenclature. (Stoltz Decl. at ¶ 45.) In that regard, Plaintiffs argue that a POSA would clearly recognize that the stereochemistry designation at carbon-3 of the hexanoate was mistakenly written as (S), when it should be (R) based on the bonds. (Id.) According to Dr. Stoltz, he was asked by Plaintiffs to analyze the stereochemistry of the oxidized maltodextrin ligand of the '252 patent, specifically wherein "oxidation (a chemical process) occurs at the terminal aldehyde (-CHO)." (Id. at ¶ 41.) According to Dr. Stoltz, "[w]hen glucose is oxidized at this position, the α-D-glucose ring opens, and the carbon numbered as 1 is oxidized to form a carboxylic acid (-COOH). (Id.) Similarly, when maltodextrin is oxidized at this position, the terminal α -D-glucose ring opens, and carbon-1 of the terminal α -D-glucose ring is oxidized to form a carboxylic acid." (*Id.*) Applying the Cahn-Ingold-Prelog rules for assigning priority, Dr. Stoltz opined that the asymmetric carbons of this terminal hexanoic acid group, including the carbon-3 of the hexanoate, all have (R) stereochemistry. (Id. at ¶¶ 42-43.) Therefore, while the name presently refers to "4(R)-(poly-(1-4)-O- α -D-glucopyranosyl)-oxy 2(R),3(S),5(R),6-tetrahydroxy-hexanoate," one of ordinary skill in the art would have understood it as: "4(R)-(poly-(1 \rightarrow 4)-O- α -D-glucopyranosyl)-oxy-2(R), 3(R), 5(R), 6-tetrahydroxy-hexanoate." (Id. at ¶ 45.) In addition, a POSA would also recognize that the chemical name of the iron (III) carboxymaltodextrin complex recited in claim 1 of the '252 patent contains this same obvious error in stereochemical nomenclature. (Id. at \P 46.)

While Defendants agree with the fundamental principles of stereochemistry recited by Dr. Stoltz, they primarily take issue with Plaintiffs' contention that a POSA reviewing claim 1 of the '252 patent would recognize an obvious or apparent error. (Demchenko Decl. at \P 45.) According to Dr. Demchenko, nothing in the language of the Claim, *i.e.*, the chemical name itself, would signal to a POSA that there was an error. (*Id.* at \P 46.) Therefore, Defendants contend that absent "any red flag in the claimed chemical name or surrounding claim language, the POSA would have no reason to draw the chemical structure or perform a detailed stereochemistry analysis," like the one performed by Dr. Stoltz. (*Id.* at \P 49.) In addition, Defendants clam that even if a POSA were to investigate the stereochemistry of the recited compound in the Claim, there is no obvious error, because the POSA would still need to draw the correct three-dimensional chemical structure to start the stereochemistry analysis. (*Id.* at \P 65-67.)

In determining whether the Court can correct this potential error, I find it instructive to compare the instant circumstances to similarly situated cases in which other courts found it appropriate to exercise judicial correction. First, in *Ultimax*, the Federal Circuit corrected "a possible drafting error in the ... patent [at issue], namely, that there should be a comma between the symbols for fluorine and chlorine [in the patent]." 587 F.3d at 1352-53. The court explained, "the claimed formula C9S3S3Ca(f cl)2 'corresponds to no known mineral,' and ... one of ordinary skill in the art would know that the formula should contain a comma." *Id.* at 1353.

The Federal Circuit also corrected a similar typographical error in *CBT Flint Partner*, where the claim at issue read, "the computer being programmed to <u>detect analyze</u> the electronic mail communication sent by the sending party to determine whether or not the sending party is an authorized sending party or an unauthorized sending party." 654 F.3d at 1356. The district court declined to correct the "detect analyze" mistake because it found there to be multiple possible

solutions—deleting the word "detect," deleting the word "analyze," or adding the word "and." *Id.* at 1358. On appeal, the Federal Circuit, however, emphasized that "[a]lthough the district court found that there are at least three alternatives that appear to be equally reasonable," it "failed to consider those alternatives from the point of view of one skilled in the art." *Id.* Specifically, the Federal Circuit noted the logical necessity of "analyzing" in conjunction with "detecting," and therefore, it held that the only reasonable solution to this grammatical mistake was to add the word "and." *Id.* at 1361. The court noted that the specification confirmed this to be a proper reading of the claim. *Id.* at 1359. Therefore, correction was appropriate because the error was obvious as a simple matter of grammar and common English construction, and there was only one logical solution to correct the mistake.

Finally, in *Senju Pharmaceuticals Co. v. Lupin Ltd.*, 162 F. Supp. 3d 405 (D.N.J. 2015), the court corrected an erroneous citation to the wrong standard. In that case, the patent at issue read "satisfies the preservative efficacy standard of US Pharmacopoeia as follows [various bacteria strains and cell counts]." *Id.* at 421. Although the patent's reference to "US Pharmacopoeia" made sense in context to a lay person, the court found that the standards recited in fact reflected the similar-but-distinct "preservative efficacy standard of EP-criteria B of the European Pharmacopoeia." *Id.* at 422. Thus, the court found this was an obvious error in light of other patents at issue in the case and the prosecution history. *Id.* Indeed, the court noted that the other patents referred to the European Pharmacopoeia standard was the standard actually recited in the patent, which was obvious to one of ordinary skill in the art, the court found the error obvious, and appropriate for judicial correction. *Id.*

Here, the circumstances in *Ultimax, CBT Flint Partners*, and *Senju Pharmaceuticals* are conspicuously distinguishable from the instant patent. Unlike those cases, which involved typographical errors of such an obvious nature that the claim at issue was either unintelligible, or the meaning was unknown to a POSA, the Claim, here, does not contain such an obvious error on its face. *See also Roche Diagnostics GMBH v. Enzo Biochem, Inc.*, No. 04-4046, 2017 WL 6988709, at *16 (S.D.N.Y. Oct. 2, 2017) (exercising judicial correction where the claim, as written, was "nonsensical[]"); *Pavo Solutions., LLC v. Kingston Tech. Co.*, No. 14-1352, 2018 WL 5099486, at *4 (C.D. Cal. Sept. 10, 2018) (granting correction where the "claim as written is not simply nonsensical, but that it is contradicted when read in the context of the patent as a whole"). Indeed, I am convinced by the fact that in order to uncover the error claimed by Plaintiffs, a POSA cannot merely look at the Claim language, or the specification, and recognize an error. Rather, to discover the potential error at issue, a POSA would have to engage in the stereochemistry analysis referenced above, which effectively includes a tedious, multi-step analysis requiring the manipulation of three dimensional molecular structures.

However, that is not to say that an error does not exist. I note my skepticism with Defendants' argument that a POSA would "recognize that the 3(S) stereoisomer could be produced, albeit indirectly, when using the processes disclosed in the patents." (Def. Opp. Br., at 5) (citing Demchenko Decl. at ¶¶ 61-62.) According to Defendants, "while a POSA would understand that the claimed processes would result in the (R) stereoisomer, the POSA would also understand that the particular chemicals disclosed in the '252 patent specification could cause the (R) stereoisomer to convert to the (S) stereoisomer via a process called epimerization." (*Id.*) (Emphasis added). Defendants' insertion of the epimerization process, however, seemingly contradicts the claim language, which makes no mention of epimerization. Nonetheless, because

I find that the error is not clear and obvious (either to the Court or a POSA), this Court should not be called on to provide the requested correction.

As the Federal Circuit highlighted in Novo Industries, L.P., 350 F.3d at 1356, "district courts are authorized to correct patents for the purpose of giving effect to the claim language and assuring that the patentee may protect the same scope of the claim as she intended to preserve." Guzik Tech. Enterprises, Inc. v. W. Digital Corp., No. 11-03786, 2013 WL 3934892, at *27 (N.D. Cal. July 19, 2013) (denying a motion to correct based on a finding that the alleged error was more akin to a major error rather than an "obvious minor typographical and clerical error"). "But where the error is not obvious, where the clerical error in fact can or should broaden the scope of the claim, the USPTO has the requisite expertise to engage in consideration of the correction." Id. Unlike the Court, the USPTO has the experience to examine the patent and to ascertain whether the change that Plaintiffs propose conflicts with earlier or later granted patents or whether scientifically, Plaintiffs' proposed change is sound. Id. Thus, an error in fact may have occurred, but that error and its proper substitute is not so obvious that a POSA easily could recognize it and more importantly replace it. Because the Court cannot ascertain whether the correction Plaintiffs offer maintains the proper scope of the claim, the USPTO is the proper entity to make this determination. Id.

Based on the Court's finding that any error proposed by Plaintiffs is not clear and obvious, the Court need not consider the prosecution history in determining whether to exercise judicial correction.

IV. <u>CONCLUSION</u>

Accordingly, based on the foregoing reasons, Plaintiffs' Motion for Judicial Correction is **DENIED**.

Dated: April 26, 2021

<u>/s/ Freda L. Wolfson</u> Freda L. Wolfson U.S. Chief District Judge