UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC.,

Plaintiffs and Counter-Defendants,

-against-

No. 17 Civ. 9922 (CM)

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, AVADEL SPECIALTY PHARMACEUTICALS, LLC

Defendants and Counterclaimants.

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MEMORANDUM DECISION AND ORDER DENYING PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

McMahon, C.J.

Following the FDA's approval of its NOCDURNA product and the construction of the asserted claims in this case, Plaintiffs Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. ("Ferring," the "Plaintiffs," or the "Counter-Defendants") have twice moved for summary judgment. The motions are denied.

I. Prior Proceedings

Familiarity with the facts of this case and the case of *Ferring B.V. v. Allergan, Inc.*, No. 12 Civ. 2650 (RWS), (the "2012 Action") is assumed. The following summary is provided only as necessary to resolve the pending motions.

On April 28, 2017, Ferring commenced this action in the District of Delaware against Defendants Serenity Pharmaceuticals, LLC ("Serenity") and Reprise Biopharmaceutics LLC

("Reprise") (together, "Defendants," and, with Avadel Specialty Pharmaceuticals LLC ("Avadel"), "Counterclaim Plaintiffs") seeking a declaratory judgment of patent invalidity, unenforceability, and non-infringement with respect to United States Patent No. 7,405,203 (the "203 Patent"), United States Patent No. 7,579,321 (the "321 Patent"), and United States Patent No. 7,799,761 ("the 761 Patent") (together, the "Patents in Suit"). *See generally* Pl. Compl., ECF No. 1.

Ferring amended its complaint on June 30, 2017. ECF No. 18.

After briefing from the parties on the issue of jurisdiction in Delaware and transferability, the case was transferred to this District, where the Hon. Robert W. Sweet, who presided over this case before his passing, agreed to take it because of his familiarity with the 2012 Action. *See* ECF Nos. 25-27, 58. Around the same time, Allergan was voluntarily dismissed from the case. ECF No. 35.

Following much dispute over whether Ferring's NOCDURNA drug would be approved, and with Serenity's motion to dismiss for lack of jurisdiction pending, Ferring received FDA approval of its New Drug Application ("NDA") on June 21, 2018. *See* ECF No. 99.

On June 28, 2018 Serenity and Reprise, together with newly-joined patent licensee Avadel Specialty Pharmaceuticals LLC ("Avadel"), answered Ferring's Amended Complaint and asserted various counterclaims, including patent infringement and willful patent infringement by NOCDURNA over the 203 Patent and the 321 Patent. ECF No. 101.

On July 19, 2018, Ferring moved to strike certain of Serenity's defenses and to dismiss certain of its counterclaims, including those alleging patent infringement under 35 U.S.C. § 271(a). ECF No. 114 at 13-14.

On July 23, 2018, Serenity moved for a preliminary injunction to block the commercial release of NOCDURNA. ECF No. 117.

On August 2, 2018, Serenity filed a cross-motion to strike certain of Ferring's affirmative defenses asserted in its July 19 motion to strike and dismiss. ECF No. 136.

On August 14, 2018, Serenity filed a motion for judgment on the pleadings. ECF No. 148.

On August 20, 2018, Ferring withdrew its July 19, 2018 motion to strike and dismiss certain of Serenity's affirmative defenses. ECF No. 160.

On September 10, 2018, Ferring moved for summary judgment on the issue of invalidity under 35 U.S.C. § 112 for lack of enablement, ECF No. 178, and for non-infringement or, alternatively, invalidity due to lack of written description. ECF No. 182.

On September 21, 2018, Serenity moved for judgment on the pleadings on the issue of collateral estoppel. ECF No. 206.

On October 16, 2018, Judge Sweet commenced a hearing on Serenity's motion for a preliminary injunction to block the commercial release of NOCDURNA. ECF No. 117.

On October 29, 2018, Judge Sweet heard argument on Ferring's motions for summary judgment on invalidity for lack of enablement, ECF No. 178, and for non-infringement or, alternatively, invalidity due to lack of written description. ECF No. 182. Also on that date, he heard argument on Serenity's motion for judgment on the pleadings on collateral estoppel. ECF No. 206.

On November 8, 2018, Defendant's motion for a preliminary injunction was denied with leave to renew. ECF No. 300.

On November 13, 2018, a claim construction hearing was held where both parties proposed constructions for the 203 and 321 Patents. On January 22, 2019, the Court issued its opinion on claim construction ("Claim Construction Opinion"), which adopted, in large part, Serenity's proposed constructions. That Opinion is discussed more fully below.

II. The Patents in Suit

On May 7, 2002, Ferring filed a Great Britain Patent Application No. GB0210397.6 (the "GB Application"), for a "pharmaceutical dosage form of desmopressin adapted for sublingual absorption," with no inventor named. 166 F. Supp. 3d at 417. In the following months and years, Dr. Fein and Ferring filed several patents involving this subject matter. *See Ferring B.V. v. Allergan, Inc.*, No. 12 Civ. 2650 (RWS), 2015 WL 5671799, at *2-*3 (S.D.N.Y. Sept. 22, 2015) (detailing the many Fein and Ferring patents).

On September 20, 2002, Ferring filed PCT Application IB02/04036, claiming the same subject matter as the GB Application and naming Fein as one of its inventors. *Ferring v. Allergan*, 253 F. Supp. 3d 708, 711 (S.D.N.Y. 2015).

On May 7, 2003, Ferring filed a modified PCT Application IB03/02368 (the "PCT Application") that claimed priority to the GB Application, but did not include low dose and sublingual claims. *Ferring*, 166 F. Supp. 3d at 418. Nor did it name Fein as an inventor. *Id.*

On November 12, 2003, Dr. Fein, through counsel, filed continuation-in-part U.S. patent application 10/706,100 based off his PCT application US2003/014463. *Ferring v. Allergan*, 253 F. Supp. 3d 708, 713 (S.D.N.Y. 2015). U.S. patent application 10/706,100 issued as U.S. Patent Application 2004/0138098 A1 on July 15, 2004. *Id.*

On May 4, 2007, Dr. Fein, through counsel, filed U.S. patent application 11/744,615 as a division of his previously filed U.S. patent application 10/706,100. *Id.*

On July 15, 2008, Dr. Fein, through counsel, filed U.S. patent application 12/173,074 as a continuation of his previously filed U.S. patent application 11/744,615. *Id.*

On July 29, 2008, Dr. Fein's U.S. patent application 11/744,615 issued as U.S. Patent No. 7,405,203, *i.e.*, the 203 Patent. *Id.*

On June 18, 2009, Ferring filed U.S. patent application 12/487,116 as a continuation of its previously filed U.S. patent application 10/513,437. *Id.* at 712.

On August 25, 2009, Dr. Fein's patent application 12/173/074 issued as U.S. Patent No. 7,579,321, *i.e.*, the 321 Patent. *Id.*

On October 12, 2010, Adriana Burgy of Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., counsel of record for Ferring, filed a request for reexamination of Fein's 203 Patent before the United States Patent and Trademark Office ("PTO"). *Id.*

On January 19, 2011, the PTO denied Ferring's request for reexamination of the 203 Patent. *Id.*

On May 24, 2011, Ferring's U.S. patent application 12/487,116 issued as U.S. Patent No. 7,947,654 (the "654 Patent"). Lloyd Decl. Ex. 10 at 2. *Id.*

A. Claim Construction

This Opinion incorporates the findings of law from the Court's Claim Construction Opinion of January 22, 2019. ECF No. 421. In the Claim Construction Opinion, the Court first concluded that a shared preamble from claims 1 and 19 of the 321 Patent ("Shared Preamble") was to be given its plain and ordinary meaning as a statement of dual purposes: "to (1) postpone urination in a patient; while (2) reducing the risk that the patient develops hyponatremia." *Id.* at 14.

As for the claims themselves, the Court resolved two primary disagreements between the parties. The first was directed at Dr. Fein's use of the term "transmucosal" to describe the delivery of his desmopressin invention. *See id.* at 20. The Court rejected Ferring's proposed dose limitation construction, and instead concluded that the portions of the 203 and 321 Patents that claim a blood/ plasma concentration of desmopressin was "well-understood [] to a person of ordinary skill in the art," and therefore "require[d] no further construction." Claim Construction Opinion.

III. The Applicable Standards

A. Summary Judgment

Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The relevant inquiry on application for summary judgment is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52. A court is not charged with weighing the evidence and determining its truth, but with determining whether there is a genuine issue for trial. *Westinghouse Elec. Corp. v. N.Y.C. Transit Auth.*, 735 F. Supp. 1205, 1212 (S.D.N.Y. 1990) (quoting *Anderson*, 477 U.S. at 249). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine issue of material fact*." *Anderson*, 477 U.S. at 247-48 (emphasis in original).

B. Patent Invalidity

To establish patent invalidity, the movant must marshal "such clear and convincing evidence of invalidity . . . that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001); *see also Alloc, Inc. v. Norman D. Lifton Co.*, 653 F. Supp. 2d 469, 477 (S.D.N.Y. 2009).

When an invalidity challenge is not based on prior art, the movant "has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (quoting *Hoist v. Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)). When this is the case, there must be a showing "that the PTO was wrong in its decision to grant the patent." *See PowerOasis*, 522 F.3d at 1304.

The Federal Circuit has indicated that summary judgment is not appropriate in patent cases where factual disputes are manifested in conflicting expert opinions. *See Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986) ("The fact issues herein must be resolved by trial in which the conflicting views of the experts will be subject to the refining fire of cross examination").

C. Written Requirement

With respect to the written description requirement, 35 U.S.C. § 112 requires a patent's specification to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use [it]." 35 U.S.C.A. § 112 (West).

Importantly, "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability

of the relevant technology." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

D. Enablement under 35 U.S.C. § 112

"The enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Strick v. Dreamworks*, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008) (quoting *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)). In determining whether an invention can be practiced without undue experimentation, "the key word is undue, not experimentation." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1336 (Fed. Cir. 2005) (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)); *see also Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984) ("That some experimentation is necessary does not preclude enablement; the *amount* of experimentation, however, must not be unduly extensive.) (emphasis added).

E. Non-Infringement

"Patent infringement suits are typically inappropriate for summary disposition." *See Alloc, Inc. v. Norman D. Lifton Co.*, 653 F.Supp.2d 469, 474 (S.D.N.Y. 2009) (denying summary judgment for non-infringement, because "[t]his case involves numerous disputes over complex issues of material fact that go to the heart of [non-movant's] infringement claims and [movant's] defenses.") (citing *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 1571 (Fed. Cir. 1984)).

IV. Ferring's Motions are Denied

A. Ferring's Motion for Summary Judgment on Invalidity Due to Lack of Written Description

A patent's specification "shall contain a written description of the invention" sufficient to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]" 35 U.S.C. § 112. The test for sufficiency under the written description requirement "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). In determining whether a patent's written description requirement is met, courts consider "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *See ScriptPro LLC v. Innovation Associates, Inc.*, 833 F.3d 1336, 1340 (Fed. Cir. 2016) (citing *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

"A district court must base its analysis of written description under Section 112 on proper claim construction." *See Koninklijke v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1336 (Fed. Cir. 2010). Ferring's contentions regarding invalidity were directed at the possibility that, at claim construction, the Court would not read a dose limitation into the asserted claims of the 203 and 321 Patents. The crux of Ferring's invalidity motion is that, without a dose limitation, "there is no way to distinguish the present invention from the prior art," and, therefore, "the written description requirement renders every asserted claim invalid as matter of law." Pl.'s Memo. in Supp. at 27. Ferring contends, "Counterclaimants' asserted claims are classic examples of what the written description requirement prohibits." *Id.*

Ferring cites in its opening brief *Atl. Research v. Troy*, where the Federal Circuit affirmed a grant of summary judgment on the invalidity of a design patent because "the specification did not disclose such a design." 659 F.3d 1345, 1353 (Fed. Cir. 2011). There, the patentee's

invention—a handguard accessory for a rifle—was "supported solely by clamping to the barrel nut." *Id.* at 1353-54. The patent's specification, however, "did not disclose an invention where the barrel nut attachment point provides *complete* support for the handguard." *Id.* at 1354. In other words, the specification was narrower in definitional scope than the claimed invention. Moreover, the inventor in that case, "[A]greed wholly with the judge's conclusion that the specification does not disclose [the claim's limitation]." *Id.* The patent was deemed invalid because the claims at issue "exceed[ed] in scope the subject matter the inventor chose to disclose to the public in the written description." *Id.* at 1355.

That is simply not the case here. As discussed in the Claim Construction Opinion, Dr. Fein's 203 and 321 Patents, which share a specification ("Common Specification"), include extensive pharmacokinetic teachings designed to enable a person skilled in the art to practice the invention. For example, the Common Specification teaches:

> After oral administration of desmopressin maximum plasma concentrations were observed at 0.5-2.0 hours after dosing. The maximum plasma concentration was 14.25, 30.21 and 65.25 pg/ml after an oral dose of 200, 400 and 800 ug, respectively. After reaching the maximum value desmopressin was elimination with a mean elimination half-life in the range of 2.8-3.0 hours. The bioavailability was determined to be 0.30% with a 95% confidence interval of 0.23-0.38%

Common Specification, 203 and 321 Patents.

After review of the Common Specification, the Patent Examiner explicitly found it sufficiently detailed to support its teaching. *Notice of Allowance* ¶ 49, ECF No. 211-6. Specifically, with respect to the 203 Patent, the Examiner recognized the "linear manner" of desmopressin and the specification's "discuss[ion]" of achieving the claimed plasma concentration ("Cmax") based on the specification's dose examples, or embodiments. For example, the Examiner noted:

> The specification discusses producing Cmax in a linear manner for doses p.o. of 200, 400 and 800 ug and discusses Cmax values for i.v. administration. Taken together with these examples, along with the discussion of the necessity for 'low dosages', one would reasonably find support . . . for a Cmax no greater than 10 pg/ml.

Id.

The Patent Examiner's conclusion, that "one would reasonably find support [in the Common Specification] for a Cmax no greater than 10pg/ml" based on the desmopressin dose embodiments, militates against a finding of invalidity for lack of written description. *Id.* As noted in the Court's Claim Construction Opinion, the Examiner also recognized that Fein's "claims are distinguished over the art, as the art did not recognize achieving a Cmax of 10 pg/ml or less." *See* ECF 421 at 28. Far from *Atl. Research v. Troy*, where the claims were broader than what was described in the specification, Fein's Specification is detailed and broad, with examples and teachings to allow a skilled person to practice the invention. 659 F.3d at 1353; Notice of Allowance, ECF 211-6 ("it would not pose an undue burden to determine what dosage/dosage form would be necessary to achieve the requisite desmopressin Cmax as in the claims, particularly since the examples show a linear correlation between dose and Cmax.").

Fein's written description of his invention is consistent with the purpose of the written description requirement, which is that a patent's claims "not overreach the scope of its contribution to the field of art as described in the patent specification." *See Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000). As discussed in both the Claim Construction Opinion and in this opinion, the Common Specification describes in detail the relationship between dose amount, plasma concentration, and bioavailability profiles. *See* ECF 421 at 31 ("The linear relationship between dosage of desmopressin and blood/plasma concentration of the drug—based on various routes of administration and

associated bioavailabilities—allows a person of ordinary skill in the art to practice Dr. Fein's low dose discovery.").

The Common Specification includes examples, such as Example 7, that discloses, among other things: the dose linearity of desmopressin, with detailed Cmax read-outs associated with tiered desmopressin doses; and average half-life readouts for desmopressin based on various routes of administration. With this information, Serenity contends, "a skilled artisan would know that the dose of desmopressin needed to achieve the plasma/ serum concentration within the claimed range can be greater than 20 ug." Def. Opp. at 13. The Court agrees. *See ScriptPro LLC*, 833 F.3d at 1340 (denying summary judgment motion on invalidity for lack of written description because "the specification does not limit the claimed invention," but instead "discloses multiple problems that the invention solves").

Despite Ferring's contentions otherwise, there is no indication that Fein's claims in the 203 and 321 Patents are "unlimited in dose amount," and therefore "overreach [their] contribution to the field of art as described in the patent specification." *See* Pl.'s Memo in Supp. at 27-28 (citing *Centocor Ortho Biotech, Inc. v. Abbott Labs*, 636 F.3d 1341, 1353 (Fed. Cir. 2011)). Nor does Serenity claim the patents are unlimited in scope. Instead, as recognized by the Patent Examiner, the claims are limited, in part, by the Cmax levels recited by Fein: "Taken together with these examples, along with the discussion of the necessity for 'low dosages', one would reasonably find support under 112 1st paragraph for a Cmax no greater than 10 pg/ml." Pl.'s Opp. at 24 (with respect to the 203 Patent).

Accordingly, Fein's detailed description of his invention in the Common Specification, along with the Patent Examiner's analysis of the invention, strongly suggests that Fein's written description was adequate. That is, the description teaches a person skilled in the art how to deliver desmopressin in the method, manner, and dose required to treat patients. Notice of Allowance, ECF 211-6 ("with regards to the enablement/ written description rejections, the examiner finds the current amended claims [] supported by the disclosure sufficient to withdraw the rejections."). The written description describes Fein's invention in "full, clear, concise, and exact terms enable any person skilled in the art to which it pertains . . . to make and use [it]." 35 U.S.C. § 112.

Ferring's motion for summary judgment on invalidity for lack of written description is denied.

B. Ferring's Motion for Summary Judgment on Invalidity Due to Lack of Enablement

Ferring's motion for summary judgment on invalidity due to lack of enablement ("Enablement Motion") is based primarily on Dr. Fein's purported admission to the USPTO "that the common specification does not teach how to make and use the claimed invention." Pl.'s Memo in Supp. at 5, ECF No. 179.

"Once issued by the PTO, a patent is presumed valid and the burden of proving otherwise rests solely on the challenger." *Greenwood v. Hattori Seiko Co.*, 900 F.2d 238, 240–41 (Fed. Cir. 1990). Where a patent's validity is being challenged for lack of enablement, courts ask "whether the patent's specification taught one of skill in the art how to make such a device without undue experimentation as of the patent's effective filing date." *Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1362 (Fed. Cir. 2018).

However, a finding of "enablement is not precluded by the necessity for some experimentation such as routine screening." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1336-37 (Fed. Cir. 2005). When assessing whether "undue experimentation" is required to enable an invention, "the key word is undue, not experimentation." *Id.* (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)).

Here, the enablement question has already been addressed by the Patent Examiner, who opined: "[W]ith regards to [] enablement . . . the current amended claims are supported by the disclosure sufficient to withdraw the rejections . . . it would not pose an undue burden to determine what dosage/ dosage form would be necessary to achieve the requisite desmopressin Cmax as in the claims, particularly since the examples show a linear correlation between dose and Cmax." *Notice of Allowance* ¶ 49, ECF No. 211-6. The Examiner went on to note, "Achieving the Cmax would amount to nothing more than routine optimization." *Id.* The Patent Examiner's opinion, while not dispositive on the issue of enablement, "is, however, evidence the court must consider in determining whether the party asserting invalidity has met its statutory burden by clear and convincing evidence." *See, e.g.*, *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (citing *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984)).

"The enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Strick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Particularly relevant here is the principle that "the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation." *Warner-Labert*, 418 F.3d at 1337. The law does not require a specification to teach every detail of a claimed invention; otherwise, "patent

specifications would turn into product specifications, which they were never intended to be." *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004).

Despite a lengthy recitation of Dr. Fein's long history before the PTO and his many representations from patent prosecution here and in Europe, Ferring omits from its opening brief the Patent Examiner's findings on enablement. *See* Pl.'s Memo. in Supp. In reply, Ferring attempts to minimize the Examiner's specific finding of enablement. *See* Pl.'s Reply at 12 ("[T]he narrow analysis quoted by Counterclaimants themselves reveals the irrelevancy of [their] entire position.").

Ferring contends that the Examiner's opinion to withdraw previous rejections to the 203 Patent's issuing was "specific to what dosage/ dosage form would be necessary to achieve the requisite desmopressin Cmax as in the claims[.]" *Id.* at 12 (citing Notice of Allowance at 16). But the Examiner's finding—that "it would not pose an undue burden" to determine a dose of desmopressin sufficient to achieve the claimed Cmax—goes to the heart of Ferring's position. "*At the very least*," Ferring contends, "the common specification fails to enable one of ordinary skill in the art, absent undue experimentation, to make and administer all dosage forms and all routes of administration to use in the claimed methods to [] achieve the claimed plasma/ serum concentrations[.]" Pl.'s Memo in Supp. at 5. Contrast that with the Allowance, in which the Examiner concluded, "[I]t would not pose an undue burden to determine what dosage/ dosage form would be necessary to achieve the requisite desmopressin Cmax as in the claims, particularly since the examples show a linear correlation between dose and Cmax." *Notice of Allowance* ¶ 49, ECF No. 211-6.

Ferring then makes the unfounded claim that "what the Examiner said at the time of allowance of the patents in suit is fully undermined by Fein's later admission." Pl.'s Memo in

Supp. at 5. But nothing in the factual record "fully undermine[s]" the findings of the Patent Examiner.

To support its position, Ferring first points to Dr. Fein's statements to the European Patent Office ("EPO"), where, when referencing a table from the common specification of the 203 Patent, he noted that its teaching "is not enabled, *i.e.*, there is no examples of demonstrating that any of the suggested dose ranges are effective to establish a steady plasma/ serum desmopressin concentration . . . ." Pl.'s Memo. in Supp. at 10. As Serenity notes, however, this statement was made in connection with the prosecution of Dr. Fein's European patent, and specifically during the "inventive step" analysis, which asked whether Fein's *European* patent was enabled by the 203 Patent's specification. Def.'s Memo. in Opp. at 20-21. This statement is of little value to the present issue—whether the 203 and 321 Patents, taken at face value, enable a person of ordinary skill to make and use the invention.

Next, Ferring cites Dr. Fein's counsel's statement to the EPO recognizing the need to narrow the range of dosages identified in the 203 Patent's specification "to arrive at the dose range of claim 1 (1-5 mcg or 0.75 mcg)" and that such a narrowing would "amount to a research program." *Id.* at 21, ECF No. 179. In Ferring's view, this statement "unequivocally show[s] that the common specification [] does not enable the asserted claims . . . [and] summary judgment is warranted on this basis alone." Pl.'s Memo in Supp. at 14. But that narrow dose range is from Dr. Fein's European dosage form/ metered dose spray device claim—and has little to do with the Patents in Suit, which are not directed at a particular dose range. ECF 179, Claim Construction Opinion.

While a patentee's statements in a foreign proceeding can constitute "admissions against interest," and so are some evidence that a finder of fact may weigh, Ferring has not carried its

burden of establishing that the Patent Examiner was wrong on validity or enablement. *Sarazin v. Wright Aeronautical Corp.*, 54 F. Supp. 244, 251 (S.D.N.Y. 1944), *aff'd sub nom. Clark v. Wright Aeronautical Corp.*, 162 F.2d 960 (2d Cir. 1967); *Greenwood v. Hattori Seiko Co.*, 900 F.2d 238, 240–41 (Fed. Cir. 1990) ("Once issued by the PTO, a patent is presumed valid and the burden of proving otherwise rests solely on the challenger.").

As discussed above and in Judge Sweet's Claim Construction Opinion, the Common Specification refers specifically to the linear relationship between dose and blood/ plasma concentration, and lists bioavailability profiles for different routes of administration, which are also listed. *See* 203 and 321 Patents. In full, the specification teaches a person of ordinary skill how to practice Dr. Fein's claimed invention, and specifically how to determine dose form and dose amount, without undue experimentation. *See* Claim Construction Opinion ("The linear relationship between dosage of desmopressin and blood/plasma concentration of the drug—based on various routes of administration and associated bioavailabilities—allows a person of ordinary skill in the art to practice Dr. Fein's low dose discovery.").

Because Ferring has not presented "clear and convincing evidence of invalidity" sufficient to disturb the Patent Examiner's explicit findings of validity and enablement, the motion for summary judgment on invalidity due to lack of enablement is denied.

C. Ferring's Motion for Summary Judgment of Non-Infringement is Denied

Ferring's summary judgment motion on non-infringement is directed at its proposed, but rejected, claim construction, which called for a specific dose limitation to be read into certain of the asserted claims. Other than to argue in the alternative that, "if the Court chooses not to construe the asserted claims as limited to a dose of desmopressin in the range of 0.5 ng to no greater than 20 ug, the asserted claims lack written description," Ferring does not direct its non-

infringement contentions to the plain language of the asserted claims, which the Court adopted at claim construction.

Ferring does not appear to take the position that there is no dispute of material fact with respect to whether the asserted claims, as construed, are not infringed by Ferring's NOCDURNA product. And the Court finds no reason to suggest that is the case. The motion for summary judgment on non-infringement is therefore denied.

CONCLUSION

Based on the conclusions set forth above, Plaintiffs' motions for summary judgment are denied. The Clerk of Court is respectfully directed to close ECF Nos. 178 and 182.

It is so ordered.

Dated: April 22, 2019

Chief Judge

BY ECF TO ALL COUNSEL