IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS INTERNATIONAL GMBH, AND CEPHALON, INC.	:	
Plaintiffs,	:	
v.	:	Civil Action No. 18-1074-CFC
HOSPIRA, INC.	:	
Defendant.	:	

John Shaw, Karen Keller, Nathan Hoeschen, SHAW KELLER LLP, Wilmington, Delaware; Daniel Brown, Michelle Ernst, LATHAM & WATKINS LLP, New York, New York; Kenneth Schuler, Marc Zubick, LATHAM & WATKINS LLP, Chicago, Illinois; Elise Baumgarten, David Berl, Adam Harber, Shaun Mahaffy, Ben Picozzi, WILLIAMS & CONNOLLY LLP, Washington, District of Columbia

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Counsel for Defendant

REVISED MEMORANDUM OPINION[1]

December 18, 2019
Wilmington, Delaware

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[1] The original, sealed Memorandum Opinion (D.I. 35) has been revised to remove references to information that might reasonably be deemed proprietary.

COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Plaintiffs Eagle Pharmaceuticals, Inc., Teva Pharmaceuticals International GMBH, and Cephalon, Inc. have sued Defendant Hospira, Inc., alleging infringement of nine patents listed in the Orange Book maintained by the Food and Drug Administration (FDA). The nine patents cover liquid formulations of the cancer drug bendamustine. Plaintiffs allege that Hospira's submission to the FDA of a New Drug Application (NDA) for a liquid bendamustine drug product constituted an artificial act of infringement of the nine patents pursuant to 21 U.S.C. § 355(b)(2) and 35 U.S.C. § 271(e)(2).

Pending before me is Hospira's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). D.I. 13. The matter is fully briefed. D.I. 14; D.I. 15; D.I. 27.

I. BACKGROUND

The claims of eight of the asserted patents[1] literally require some combination of two solvents in the claimed liquid bendamustine formulation: propylene glycol and polyethylene glycol. Following the parties' lead, I will refer

[1] U.S. Patent Nos. 10,010,533 (the "#533 patent"), 9,034,908 (the "#908 patent"), 9,155,568 (the "#568 patent"), 9,597,397 (the "#397 patent"), 9,597,398 (the "#398 patent"), 9,597,399 (the "#399 patent"), 9,000,021 (the "#021 patent"), and 9,579,384 (the "#384 patent").

to these patents as the "PG patents." In Counts II through IX and XI through XVIII of the Complaint, Plaintiffs allege that Hospira's NDA product, which contains polyethylene glycol but uses another, second solvent ("Hospira's second solvent") instead of propylene glycol,[2] infringes the PG patents under the doctrine of equivalents. D.I. 1 ¶¶ 55, 61, 72, 83, 94, 105, 116, 127, 149, 156, 168, 180, 192, 204, 216, 228.

The ninth asserted patent, U.S. Patent No. 9,572,887 (the "#887 patent"), requires a "non-aqueous" bendamustine formulation. In Counts I and X of the Complaint, Plaintiffs allege that Hospira's NDA product, which contains a small amount of water,[3] infringes the claims of the #887 patent both literally and under the doctrine of equivalents. *Id.* ¶¶ 44–47, 140.

II. LEGAL STANDARDS

To state a claim on which relief can be granted, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Detailed factual allegations are not required, but the complaint must include more than mere "labels and conclusions" or "a formulaic

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[2] D.I. 15, Ex. 2C, Hospira NDA No. 211530 § 2.3 at 21. Hospira's NDA is integral to and explicitly relied upon by Plaintiffs in the Complaint and therefore may be considered in addressing Hospira's Rule 12(b)(6) motion. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). I am intentionally not identifying Hospira's second solvent because of its proprietary nature.

[3] D.I. 15, Ex. 2C, Hospira NDA No. 211530 § 2.3 at 21; D.I. 25 at 13.

recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). The complaint must set forth enough facts, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* at 570. A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Deciding whether a claim is plausible is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679 (citation omitted).

III. DISCUSSION

A. The #887 Patent

Hospira argues that the Complaint fails to state a claim of infringement of the #887 patent because Hospira's NDA product is not "non-aqueous" and because Plaintiffs are barred by the doctrine of claim vitiation and prosecution history estoppel from alleging equivalence infringement.

The premise of Hospira's arguments is that "non-aqueous" means the complete absence of water. Hospira contends that its NDA product does not literally infringe the #887 patent because it contains some amount of water. D.I. 14 at 9. It similarly contends that claim vitiation bars application of the doctrine of equivalents to its NDA product because "[t]he term 'non-aqueous' presents a

black-or-white proposition: either a composition is non-aqueous [i.e. completely lacking in water] or, if it is not, it is the complete opposite (i.e., aqueous)." *Id.* at 18. And, finally, Hospira contends that prosecution history estoppel applies because the patentee amended the claims to specify that the claimed formulations are "non-aqueous" in order to overcome prior art that referenced "aqueous" solutions. *Id.* at 19.

Plaintiffs, however, argue that "non-aqueous" to a person of ordinary skill in the art (POSITA) does not require the complete absence of water, and they point to the fact that Hospira represented to the FDA that its NDA product is "predominantly *a non-aqueous formulation*." D.I. 25 at 7 (emphasis in original) (citing D.I. 15, Ex. 2C, Hospira NDA No. 211530 § 2.3 at 22). Thus, Hospira's arguments boil down to a claim construction dispute that is not suitable for resolution in the context of a motion to dismiss. *See Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1349–50 (Fed. Cir. 2018). Accordingly, I will deny Hospira's motion to dismiss Plaintiffs' claim of infringement of the #887 patent.

B. The PG Patents

Hospira argues that Plaintiffs' claims of equivalence infringement of the PG patents fail as a matter of law because they are barred by the disclosure-dedication rule and prosecution history estoppel. D.I. 27 at 1. As explained below, I agree that the disclosure-dedication rule bars these claims. I therefore need not, and do

not, address the argument that the claims are barred by prosecution history estoppel.

1. Legal Standards

Section 112(b) of Title 35 provides that a patent's "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." This requirement codifies the "bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks and citations omitted); *see also Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1325 (Fed. Cir. 2004) ("Surely there is no principle more firmly established in patent law than the primacy of the claims in establishing the bounds of the right to exclude." (citations omitted)); *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc) ("Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent." (citation omitted)). It is the claims—not the patent's written description—that define the invention and provide the measure of the patentee's right to exclude others from using it. *Milcor Steel Co. v. George A. Fuller Co.*, 316 U.S. 143, 146 (1942) ("Out of all the possible permutations of elements which can be made from the specifications, he reserves for himself only those contained

in the claims." (citation omitted)). "Claims define and circumscribe, the written description discloses and teaches." *Ariad Pharm.*, 598 F.3d at 1347; *see also Univ. of Rochester*, 375 F.3d at 1326 ("The primary role of the written description is to support the claims, assuring that persons skilled in the art can make and use the claimed invention.").

A corollary to the principle that only the claims define the scope of a patented invention is the disclosure-dedication rule. That rule precludes a finding of infringement that is based on subject matter disclosed in the written description but not claimed. As the Federal Circuit held in *Johnson & Johnston Associates Inc. v. R.E. Service Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc), "when a patent drafter discloses but declines to claim subject matter . . . [she] dedicates that unclaimed subject matter to the public."

The rule was first articulated by the Supreme Court in 1881 in *Miller v. Bridgeport Brass Co.*, 104 U.S. 350, 352 (1881) ("[T]he claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the patent, are, in law, a dedication to the public of that which is not claimed."). Three years later, in *Mahn v. Harwood*, 112 U.S. 354 (1884), the Court offered this explanation of the rule:

> Of course, what is not claimed is public property. The presumption is, and such is generally the fact, that what is not claimed was not invented by the patentee, but was known and used before he made his invention. But,

> whether so or not, his own act has made it public property, if it was not so before. The patent itself, as soon as it is issued, is the evidence of this. The public has the undoubted right to use, and it is to be presumed does us[e], what is not specifically claimed in the patent.

Id. at 361.

The disclosure-dedication rule "applies equally" to literal and equivalence infringement claims. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1107 (Fed. Cir. 1996). As the Federal Circuit noted in *Johnson*, the claims provide notice of an invention's scope not only to the public (and thus potential competitors), but also to the examiner at the U.S. Patent and Trademark Office (PTO). 285 F.3d at 1052. Thus, application of the disclosure-dedication rule helps to prevent a patentee from narrowly claiming an invention to avoid prosecution scrutiny by the PTO, and then, after the patent issues, using the doctrine of equivalents to "extend[] the coverage of an exclusive right to encompass more than that properly examined by the PTO." *Id.* at 1055 (citation omitted).

For the disclosure-dedication rule to apply, "[t]he disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed[,]" *PSC Comput. Prods. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004), and the "unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation," *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005).

Whether the disclosure-dedication rule bars an infringement claim is a question of law. *Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1333 (Fed. Cir. 2004). Accordingly, when the construction of a patent's claims is not in dispute and the patent's written description is clear and unambiguous, it may be appropriate to apply the disclosure-dedication rule in the context of a motion to dismiss equivalence infringement claims. *See Eagle Pharm., Inc. v. Slayback Pharma LLC*, 382 F. Supp. 3d 341, 345–48 (D. Del. 2019) (applying disclosure-dedication rule in context of Rule 12(c) motion where patent's written description was clear and unambiguous and parties did not dispute construction of claim limitation in question).

2. Analysis

The written description of the #533 patent explicitly and repeatedly identifies Hospira's second solvent as an alternative to propylene glycol in embodiments of the patented invention. *See, e.g.*, #533 patent at 1:62–67, 4:35–48, 5:32–41, 5:45–57. The first sentence in the "Summary of the Invention" section of the written description, for example, reads as follows:

> In other aspects of the invention, the bendamustine-containing compositions include a) a pharmaceutically acceptable fluid which contains one or more of propylene glycol, ethanol, polyethylene glycol, benzyl alcohol and glycofurol, and b) a stabilizing amount of a chloride salt.

Id. at 1:62–67.

The remaining PG patents have a different written description than the #533 patent, but they incorporate by reference U.S. Patent Application No. 13/016,473, which has the same written description as the #533 patent. *See* D.I. 15, Ex. 1H, U.S. Patent Application No. 2011/0184036. Plaintiffs concede that incorporated documents can be used to show disclosure for disclosure-dedication rule purposes. D.I. 25 at 19.

In light of the clear and unambiguous disclosure of Hospira's second solvent as a substitute for propylene glycol in the #533 patent's written description and the fact that the PG patents do not claim Hospira's second solvent as the second solvent in the claimed liquid bendamustine formulation, the disclosure-dedication rule bars Plaintiffs from alleging that Hospira's NDA product infringes the PG patents under the doctrine of equivalents.

Plaintiffs offer four reasons why I should not apply the disclosure-dedication rule at this juncture. First, they contend that Hospira's second solvent is not identified in the #533 patent as an alternative to propylene glycol. *Id.* at 14–15. But this is incorrect. The #533 patent's written description explicitly treats Hospira's second solvent as an alternative to propylene glycol. *See* #533 patent at 1:62–67, 4:35–48, 5:32–41, 5:45–57. Second, they point to an embodiment in the written description that does not disclose Hospira's second solvent as the second solvent. D.I. 25 at 15. There is, however, no requirement that every embodiment

in the written description have the equivalent element in question for the discourse-dedication rule to apply; the rule is triggered by any disclosure in the written description that is not claimed. Once a single disclosure is made, the subject matter in question is dedicated to the public. There is no way to unring a bell that has already rung.

Third, Plaintiffs argue that Hospira does not assert that the complete formulation of its NDA product is disclosed in any single embodiment in the written description. *Id.* But the disclosure of the entire accused product is not a prerequisite for application of the disclosure-dedication rule. "[T]he doctrine of equivalents must be applied to individual elements of the claim, not the invention as a whole." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). Thus, the issue for the court is whether the patent discloses the element of the invention that is alleged to be the equivalent of a claim limitation, not whether the entire accused product or process is disclosed.

Finally, Plaintiffs contend that they should be afforded an opportunity to present expert evidence about whether the disclosure of Hospira's second solvent is specific enough to trigger the disclosure-dedication rule. But Plaintiffs do not explain why expert testimony is necessary to decide the question of law presented to me. It is undisputed that Hospira's second solvent is one of the solvents disclosed in the #533 written description and it cannot be reasonably disputed that

the patent discloses Hospira's second solvent as a substitute for propylene glycol. Accordingly, the disclosure-dedication rule bars Plaintiffs' claims of equivalence infringement of the PG patents, and I will grant Hospira's motion to dismiss Plaintiffs' claims of infringement of those patents.

IV. CONCLUSION

For the above-stated reasons, I will deny Hospira's motion to dismiss insofar as it seeks to dismiss the Complaint's claims of infringement of the #887 patent (Counts I and X) and I will grant the motion insofar as it seeks to dismiss the equivalence claims of infringement of the PG patents (Counts II through IX and XI through XVIII).

The Court will issue an order consistent with this Memorandum Opinion.