IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC.,	:	
Plaintiff,	:	
v.	:	Civil Action No. 18-1953-CFC
SLAYBACK PHARMA LLC,	:	
Defendant.	:	

John W. Shaw, Karen E. Keller, Nathan R. Hoeschen, SHAW KELLER LLP, Wilmington, Delaware

Counsel for Plaintiff

Neal C. Belgam, Eve H. Ormerod, SMITH, KATZENSTEIN & JENKINS, LLP, Wilmington, Delaware

Counsel for Defendant

REVISED MEMORANDUM OPINION

May 9, 2019
Wilmington, Delaware

COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Plaintiff Eagle Pharmaceuticals, Inc. has sued Defendant Slayback Pharma LLC, alleging infringement under the doctrine of equivalents of four patents: U.S. Patent Nos. 9,265,831 (the "#831 patent"), 9,572,796 (the "#796 patent"), 9,572,797 (the "#797 patent"), and 10,010,533 (the "#533 patent"). *See generally* D.I. 1. Pending before me is Slayback's motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). D.I. 14. The matter is fully briefed. D.I. 15, 20, 25. For the reasons discussed below, I will grant Slayback's motion.

I. BACKGROUND

Eagle is the holder of New Drug Application (NDA) No. 205580 for BALRAPZO®, a drug with the active ingredient bendamustine, that was approved by the Federal Drug Administration (FDA) to treat patients with chronic lymphocytic leukemia and indolent B-cell non-Hodgkin lymphoma. D.I. 1 at ¶¶ 13–14. Eagle initiated this lawsuit in response to Slayback's submission to the FDA of NDA No. 212209 for approval to manufacture and sell before the four asserted patents expire a bendamustine drug that is bioequivalent to BALRAPZO®. *Id.* at ¶ 1.

The four asserted patents share in all material respects the same written description; and all the independent claims of the patents require the presence of three limitations in the claimed pharmaceutical composition: (1) bendamustine or a pharmaceutically acceptable salt thereof; (2) a pharmaceutically acceptable fluid that contains some combination of two solvents: propylene glycol and polyethylene glycol; and (3) a stabilizing amount of an antioxidant. Claim 1 of the #796 patent, for instance, recites in relevant part:

> A non-aqueous liquid composition comprising:
> bendamustine, or a pharmaceutically acceptable salt thereof;
> a pharmaceutically acceptable fluid comprising a mixture of polyethylene glycol and propylene glycol, wherein the ratio of polyethylene glycol to propylene glycol in the pharmaceutically acceptable fluid is from about 95:5 to about 50:50; and
> a stabilizing amount of an antioxidant;
> wherein the composition has less than about 5% total impurities after 15 months of storage at about 5° C. . . .

#796 patent at claim 1.

Slayback's motion focuses on the second claim limitation—a pharmaceutically acceptable fluid that contains some combination of propylene glycol and polyethylene glycol. I will refer to this limitation as the "solvent limitation." Slayback's proposed bendamustine drug contains polyethylene glycol, but instead of propylene glycol it uses another, second solvent ("Slayback's second

solvent"). D.I. 15-1 at Ex. B (Slayback's NDA).[1] Eagle alleges that Slayback's drug infringes the solvent limitation under the doctrine of equivalents. D.I. 1 at ¶¶ 29, 36, 47, 58, 64, 71, 83, 95. Slayback has moved to dismiss on the ground that the so-called disclosure-dedication doctrine bars application of the doctrine of equivalents to the solvent limitation.

II. LEGAL STANDARDS

Pursuant to Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter pleadings are closed—but early enough not to delay trial." Regional circuit law governs a court's review of motions for judgment on the pleadings in patent cases. *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1293 (Fed. Cir. 2016). Under Third Circuit law, in ruling on a Rule 12(c) motion, the court must accept as true all well-pleaded allegations in the non-movant's pleadings and draw all reasonable inferences in the non-movant's favor. *Zimmerman v. Corbett*, 873 F.3d 414, 417–18 (3d Cir. 2017). A court may grant a Rule 12(c) motion only where "the movant clearly establishes

[1] I disagree with Eagle's argument that Slayback's NDA is not "integral" to the pleadings and therefore should not be considered in adjudicating this motion. In evaluating a motion for judgment on the pleadings, a court may consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "*integral to or explicitly relied* upon" in the pleadings. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis in the original). "[W]hat is critical is whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited." *Id.* (citations omitted).

that no material issue of fact remains to be resolved and [the movant] is entitled to judgment as a matter of law." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). Application of the disclosure-dedication doctrine presents a question of law suitable for resolution on a motion for judgment on the pleadings. *See In re Bendamustine Consol. Cases*, 2015 WL 1951399, at *3 (D. Del. Apr. 29, 2015) (granting Rule 12(c) motion after finding that the disclosure-dedication doctrine barred plaintiff's doctrine of equivalents arguments).

III. DISCUSSION

The sole issue before me is whether, under the disclosure-dedication doctrine, the asserted patents' disclosure of Slayback's second solvent as an alternative to propylene glycol bars Eagle from claiming that Slayback's drug infringes the solvent limitation under the doctrine of equivalents. If Slayback's drug does not meet this limitation, then it cannot be said to infringe the asserted patent claims. *See TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 788 (Fed. Cir. 2019) (to infringe an asserted patent claim, the accused product must meet all the limitations of the asserted claim).

A. Legal Standards

"Patent infringement occurs when a device (or composition or method), that is literally covered by the claims or is equivalent to the claimed subject matter, is made, used, or sold, without the authorization of the patent holder, during the term

of the patent." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1476 (Fed. Cir. 1998) (citing 35 U.S.C. § 271). Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner–Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950)).

"Application of the doctrine of equivalents involves a fact[-]intensive analysis to determine whether or not differences between a claim limitation of the patent and the corresponding element of the accused [product] are merely insubstantial or unimportant substitutions." *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 565 (D.N.J. 2004); *see also Warner–Jenkinson*, 520 U.S. at 39–40 (addressing the linguistic framework for determining "equivalence" and stating that "[d]ifferent linguistic frameworks may be more suitable to different cases, depending on their particular facts."). In certain circumstances, however, the law restricts application of the doctrine of equivalents without further fact finding. *Sage Products, Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997). One such restriction is the disclosure-dedication doctrine. *See Aventis*, 335 F. Supp. 2d at 565.

Under the disclosure-dedication doctrine, a patentee can disclaim an equivalent by disclosing the equivalent in the written description but not claiming it. *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1363 (Fed. Cir. 2012). The disclosure-dedication doctrine provides:

> [W]hen a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee's exclusive right.

Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc) (internal quotation marks omitted).

The doctrine "does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public." *PSC Comput. Products v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004). Rather, for the disclosure-dedication doctrine to apply, "the 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." *Id.* Furthermore, "before unclaimed subject matter is deemed to have been dedicated to the public, that 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). Thus, "[t]he proper inquiry is whether one of ordinary skill in the art could identify which subject matter has been disclosed and

which subject matter has been claimed." *Aventis*, 335 F. Supp. 2d at 577–78 (citing *PSC Comput. Products*, 355 F.3d at 1360).

B. Analysis

Slayback asserts that the disclosure-dedication doctrine bars Eagle's claims for infringement of the solvent limitation under the doctrine of equivalents because the common written description of the asserted patents discloses, but does not claim, Slayback's second solvent as a specific alternative to propylene glycol. D.I. 15 at 1–2. I agree.

The written description of the asserted patents explicitly and repeatedly identifies Slayback's second solvent as an alternative to propylene glycol in embodiments of the patented invention. *See, e.g.*, #796 patent at 1:60-64, 4:34-47, 5:27-35, 5:41-50, 6:3-14, 6:31-36, 7:14-19. 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 1:60-64.

Despite these disclosures, Eagle makes two arguments against applying the disclosure-dedication doctrine. First, it contends that the Federal Circuit's decision in *Nalco Co. v. Chem-Mod, LLC*, 883 F. 3d 1337 (Fed. Cir. 2018) prohibits

application of the disclosure-dedication doctrine at the Rule 12(c) stage. D.I. 20 at 6–8. Second, Eagle argues that it would be inappropriate to grant Slayback's motion at this time because Slayback has not shown that a person of ordinary skill in the art (a POSITA) would understand the patents' written description to teach the use of Slayback's second solvent as an alternative to propylene glycol in the claimed formulation. *See id.* at 12–16. I address these arguments in turn.

1. *Nalco* Does Not Prohibit the Court From Applying the Disclosure-Dedication Doctrine at the Rule 12(c) Stage

Eagle's reliance on *Nalco* is problematic for two reasons. First, *Nalco* did not address the disclosure-dedication doctrine. Second, contrary to Eagle's assertion, *Nalco* did not hold that all "questions over the proper interpretation of a patent's intrinsic record are 'not suitable' and 'particularly inappropriate' for resolution on a motion to dismiss." *Id.* at 1 (quoting *Nalco*, 883 F.3d at 1349).

In *Nalco*, the Federal Circuit reversed a district court's decision to dismiss a complaint for failure to state a claim for direct or indirect infringement because the motion hinged on the interpretation of certain claim terms that had not been construed by the district court. The plaintiff argued that the district court erred in dismissing its complaint because the district court, at least implicitly, construed certain claim terms and thereby improperly resolved a claim construction dispute at the motion to dismiss stage of the proceeding. *Nalco*, 883 F.3d at 1347. The Federal Circuit agreed, noting that the defendants' objections to plaintiff's

infringement theories "read like classic *Markman* arguments" such that the dispute was "not suitable for resolution on a motion to dismiss." *Id.* at 1349.

Eagle argues that *Nalco* bars at the pleadings stage all questions over the proper interpretation of a patent's intrinsic record. *See* D.I. 20 at 8. But the holding of *Nalco* is not so broad. *See Amgen, Inc. v. Coherus Biosciences Inc.*, 2018 WL 1517689, at *4 n.5 (D. Del. Mar. 26, 2018). In *Amgen,* Chief Judge Stark rejected an analogous argument to that made by Eagle here and granted a motion to dismiss based on the doctrine of prosecution history estoppel. Like Eagle, the plaintiff in *Amgen* cited *Nalco* to argue that dismissal of its claim for infringement under the doctrine of equivalents would be premature because the court did not have a developed record. *Id.* Judge Stark disagreed, distinguishing the claim construction dispute in *Nalco* from the purely legal dispute he was asked to decide that "turn[ed] on the clear and unambiguous prosecution history." *Id.*

Judge Stark's reasoning in *Amgen* is equally applicable here. The parties have not identified a claim construction dispute, and the written description of the asserted patents unambiguously and repeatedly identifies Slayback's second solvent as an alternative to propylene glycol. Like the plaintiff in *Amgen*, Eagle merely disputes the interpretation of the written description, contending that, in context, the disclosures do not support applying the disclosure-dedication doctrine. *Compare id.* at *4, *with* D.I. 20 at 10–11. The main difference between this case

and *Amgen* is that Eagle attempts to manufacture a factual dispute concerning a POSITA's understanding of the disclosures in the written description of the asserted patents by relying on an expert declaration from Dr. Amiji. *See* D.I. 21. But, as Eagle admits, "reliance on expert testimony would be improper at this preliminary stage[.]" D.I. 20 at 11.[2] Additionally, like the prosecution history estoppel issue addressed by Judge Stark, the disclosure-dedication doctrine is a legal question appropriate for resolution at the 12(c) stage of the proceedings. *See, e.g.*, *In re Bendamustine Consol. Cases*, 2015 WL 1951399, at *3 (granting Rule 12(c) motion after finding that the disclosure-dedication rule barred plaintiff's doctrine of equivalents arguments); *see also Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1331 (Fed. Cir. 2004) ("The disclosure-dedication rule limits application of the doctrine of equivalents, much in the same way as prosecution history estoppel."). Here, I have sufficient context to decide a question of law—i.e., that the disclosure-dedication doctrine applies to bar Eagle's claims for infringement under the doctrine of equivalents.

2. The Disclosure-Dedication Doctrine Applies to Claim Limitations, Not Entire Embodiments

Next, Eagle argues that the disclosure-dedication doctrine does not bar Eagle's infringement allegations under the doctrine of equivalents because the

[2] Accordingly, I have not considered the expert declaration from Dr. Amiji in reviewing the merits of this dispute.

written description of the asserted patents does not specifically disclose the use of Slayback's second solvent as an alternative to propylene glycol in the specific formulation claimed by the patents such that a POSITA would understand that Slayback's formulation was dedicated to the public. D.I. 20 at 14. More specifically, Eagle argues that a POSITA would understand from the written description of the asserted patents that Slayback's second solvent can be an alternative to propylene glycol only in embodiments that include a stabilizing amount of a chloride salt and not embodiments that require, as the patents' claims do, a stabilizing amount of an antioxidant. *See id.* at 12–16.

Eagle's attempt to confine the disclosure-dedication doctrine to cases where an alleged infringer's exact formulation is disclosed in the written description, however, is contrary to established Federal Circuit precedent. Under Federal Circuit law, the disclosure-dedication doctrine applies to unclaimed subject matter that is "identified by the patentee as an alternative to a *claim limitation*." *Pfizer*, 429 F.3d at 1379 (emphasis added). Indeed, Eagle acknowledged in its answering brief that the Federal Circuit's articulation of the disclosure-dedication doctrine requires Slayback to show that "[Slayback's second solvent]—the ingredient allegedly used in Slayback's NDA Product—was 'identified by the patentee *as an alternative to [the] claim limitation*' at issue." D.I. 20 at 12 (second alteration and emphasis in original) (citing *SanDisk*, 695 F.3d at 1364). In this case, the solvent

limitation is the claim limitation at issue, and the written description of the asserted patents repeatedly identifies Slayback's second solvent as an alternative to one of the two solvents recited in that limitation (i.e., propylene glycol).

Two district courts within the Third Circuit have addressed and rejected nearly identical arguments to those advanced by Eagle in this action. *See Aventis*, 335 F. Supp. 2d 558; *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, 2017 WL 3782782 (D. Del. Aug. 31, 2017). In *Aventis*, the asserted patents claimed pharmaceutical compositions consisting of a piperidinoalkanol compound and three specific inert ingredients. 335 F. Supp. 2d at 574–75. The written descriptions of the asserted patents identified other inert ingredients—specifically povidone, crospovidone, and sodium starch glycolate—that could be used in the composition, and these ingredients were used in the defendants' accused products as alternatives to the claimed inert ingredients. *Id.* at 563, 575. Defendants moved for summary judgment based on the disclosure-dedication doctrine, and plaintiffs countered that the disclosure-dedication doctrine did not apply because the doctrine was limited only to cases where "a patentee fails to claim an *alternative embodiment* of the patentee's invention that is disclosed in the patent specifications, not individual elements in isolation." *Id.* at 575 (emphasis in original). The court rejected plaintiffs' argument "because the dedication doctrine encompasses unclaimed subject matter, which includes not only unclaimed

embodiments, but also unclaimed elements and limitations." *Id.* at 576. The court then found that the plaintiffs could not rely on the doctrine of equivalents because the asserted patents dedicated povidone, crospovidone, and sodium starch glycolate to the public. *Id.* at 579.

Similarly, in *Reckitt Benckiser*, Judge Andrews rejected an argument that the disclosure-dedication doctrine did not apply where the written description did not disclose the exact combination of ingredients found in the defendants' ANDA product. The asserted patent in *Reckitt Benckiser* claimed a "mucosally-adhesive water-soluble film product comprising . . . at least one water-soluble polymer component consisting of polyethylene oxide ["PEO"] in combination with a hydrophilic cellulosic polymer ["HCP"][.]" *Reckitt Benckiser*, 2017 WL 3782782, at *1–2. One of the claim limitations required that the PEO component comprise specified amounts of low and high molecular weight PEOs. *Id.* at *2. The specification of the asserted patent identified but did not claim polyvinyl pyrrolidone ("PVP") as an alternative to HCP in a list of "Film-Forming Polymers." *Id.* at *3. The plaintiffs alleged that defendants' ANDA product, by substituting PVP for HCP, infringed the asserted claims under the doctrine of equivalents. *Id.* To counter the defendant's disclosure-dedication doctrine argument, the plaintiffs argued that "because there is no passage or example in the '150 patent specification that specifically discloses a combination of low and high

molecular weight PEOs with PVP, the dedication-disclosure rule does not apply." *Id.* at *4. Judge Andrews rejected this argument, holding that the disclosure-dedication doctrine applied because "[i]t would be clear to a POSA reading the patent as a whole that PVP is disclosed as an alternative to the HCP element of the asserted claims." *Id.*

In arguing that the disclosure-dedication does not apply in this case because "the specification does not specifically disclose the formulation proposed by Slayback—bendamustine, [polyethylene glycol], [Slayback's second solvent], and an antioxidant[,]" D.I. 20 at 14, Eagle not only ignores these two district court cases but also ignores the Federal Circuit's seminal disclosure-dedication doctrine decision in *Johnson & Johnston*. In *Johnson,* the Federal Circuit, sitting en banc, held that a plaintiff could not avail itself of the doctrine of equivalents to extend its claimed limitation of an aluminum substrate where the patent disclosed but did not claim steel as a substitute for aluminum. 285 F.3d at 1055. Not only did the Court apply the disclosure-dedication doctrine to a claim limitation in *Johnson*, but it also overruled *YBM Magnex Inc. v. Int'l Trade Comm'n*, 145 F.3d 1317 (Fed. Cir. 1998), a case which purported to limit the application of the disclosure-dedication doctrine "to situations where a patent disclose[d] an unclaimed alternative [embodiment] distinct from the claimed invention." *Johnson & Johnston*, 285

F.3d at 1052. By overruling *YBM Magnex*, the Federal Circuit in *Johnson* essentially rejected the same argument raised by Eagle in this action.

I understand *Johnson* to hold implicitly that the disclosure-dedication doctrine is not restricted to disclosures of embodiments and that the doctrine applies to claim limitations. Here, I find that it would be clear to a POSITA that the asserted patents disclose Slayback's second solvent as an alternative to propylene glycol, a claim limitation found in each of the independent claims. Therefore, Eagle is barred by the disclosure-dedication doctrine from alleging, based on Slayback's substitution of Slayback's second solvent for propylene glycol, that Slayback's proposed bendamustine drug product infringes the solvent claim limitation under the doctrine of equivalents.

IV. CONCLUSION

For the above-stated reasons, I will grant Slayback's motion for judgment on the pleadings.

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