NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TOLMAR THERAPEUTICS, INC., et al. Plaintiffs, v. FORESEE PHARMACEUTICALS CO., LTD., et al., Defendants.	No. 21cv15782 (EP) (CLW) **OPINION**

PADIN, District Judge.

Plaintiffs Tolmar Therapeutics, Inc. ("TTI") and Tolmar Pharmaceuticals, Inc. ("TPI") own (TTI) and sell (TPI) Eligard, an FDA-approved advanced prostate cancer drug. Defendant Foresee Pharmaceuticals Co., Ltd. ("Foresee") later developed CAMCEVI, also a prostate cancer drug. After Foresee submitted CAMCEVI for FDA approval, Co-Defendant Accord BioPharma, Inc. ("Accord") became CAMCEVI's Applicant Holder. Plaintiffs allege that CAMCEVI infringes upon TTI's U.S. Patent No. 8,470,359 ("the '359 patent"). Defendants move for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c). D.E.s 35, 40. Plaintiffs oppose. D.E. 38.

The Court cannot analyze patent infringement without determining a claim's boundaries through claim construction. Without the proper resources and procedure, it is too early for claim construction. The Court will therefore deny the motion.

I. BACKGROUND[1]

TTI own various New Drug Applications ("NDA") for Eligard, an injectable leuprolide acetate drug product treating advanced prostate cancer. FAC ¶ 3. TTI is also the owner and assignee of the '359 Patent, listed in the FDA's "Orange Book" for the Eligard NDAs. *Id.* ¶ 4. Claim 1 of the '359 patent recites:

> A flowable composition for a controlled release formulation comprising
>
> an organic solvent,
>
> a medicament
>
> and a polymer of Formula
>
> HO—(P)—C(=O)O—R^a—O(O=)C—(P)—OH
>
> wherein:
>
> R^a is an alkane diradical comprising about 4 to about 8 carbons and is a residue of an alkane diol,
>
> P is a polymeric segment of repeating units of lactide, lactic, co(lactide-glycolide) or co(lactic-glycolic) moieties,
>
> the polymer is substantially insoluble in water and body fluid, the polymer has substantially no titratable carboxylic acid groups, and the polymer has a weight average molecular weight from about 10 kD to about 50 kD, and the polymer in neat form is a solid at ambient temperature,
>
> the organic solvent is a polar, aprotic organic solvent having at least some water solubility.

Id. ¶ 28 (the "Claim").

Foresee submitted NDA 211488 to the FDA for CAMCEVI (leuprolide) injectable emulsion for the treatment of advanced prostate cancer. *Id.* ¶ 29. The FDA approved NDA No.

[1] The following draws from Plaintiff's First Amended Complaint ("FAC"), D.E. 34, disregarding any "rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements." *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012).

211488 on May 25, 2021. *Id.* at ¶ 30; D.E. 34-1. In January 2022, Accord became the NDA's Applicant Holder. FAC ¶ 31; D.E.s 34-2, 34-3.

As described in NDA No. 211488, CAMCEVI comprises a "flowable composition for a controlled release formulation and includes a polar aprotic organic solvent[2] (N-methyl-2-pyrrolidone) and a medicament[3] (leuprolide mesylate, a pharmaceutically acceptable salt of leuprolide). FAC ¶¶ 34-35. CAMCEVI also includes a poly(D,L-lactide) polymer. *Id.* ¶ 37. The poly(D,L-lactide) polymer is synthesized from D,L-lactide monomers using a lauryl alcohol initiator ($C_{12}H_{25}OH$). *Id.* Thus, the poly(D,L-lactide) polymer has no titratable carboxylic acid groups as it contains a hydroxyl end group (-OH) and an ester end group. *Id.* Each pre-filled CAMCEVI subcutaneous syringe delivers 42 mg of leuprolide over a six-month period. *Id.* ¶ 36.

Plaintiffs filed the initial Complaint on August 20, 2021, which alleged that Foresee's NDA filing infringes the '359 patent under 35 U.S.C. § 271(e)(2) and sought a declaratory judgment of infringement. D.E. 1. Specifically, the Complaint alleged that CAMCEVI "meets the limitation of Claim 1 of the '359 Patent requiring a polymer having R*a*, wherein 'R*a* is an alkane diradical comprising about 4 to about 8 carbons and is a residue of an alkane diol' under the doctrine of equivalents." D.E. 1 ¶ 32.

Foresee previously moved for judgment on the pleadings. D.E. 24. On April 1, 2022, the Court granted Plaintiffs leave to file the FAC and terminated the motion. D.E. 32. Plaintiffs filed the FAC, adding Accord as a defendant, but otherwise asserting essentially the same infringement claim. D.E. 34 ¶ 44. Foresee re-filed its motion, now joined by Accord. D.E.s 35, 40. Plaintiffs oppose, and Foresee has replied. D.E.s 38, 39.

[2] Carbon-based substances capable of dissolving or dispersing one or more other substances.
[3] A substance used in therapy (a drug).

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment "[a]fter pleadings are closed," as long as it is "early enough not to delay trial." When evaluating a defendant's motion for judgment on the pleadings, the Court must accept as true all factual allegations in the complaint, viewing them in the light most favorable to the nonmoving party. *See Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008); *see also Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000). This standard is the same one that applies to a motion to dismiss under Rule 12(b)(6). *See Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). The Court will not grant a Rule 12(c) motion "unless the movant clearly establishes that no material issue of fact remains to be resolved" and that it is "entitled to judgment as a matter of law." *Rosenau*, 539 F.3d at 221.

"The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference." *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (explaining that documents integral to pleadings may be considered on Rule 12(c) motion). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Burlington Coat Factory*, 114 F.3d at 1420. Thus, a court may grant a motion for judgment on the pleadings only if, after making all reasonable inferences in the plaintiff's favor, the "plaintiff is not entitled to relief." *Maio*, 221 F.3d at 482.

III. DISCUSSION

Defendants' arguments boil down to the following. First, Plaintiff's use of "about" in the '359 patent's "about 4 to about 8" carbon atoms means that CAMCEVI's 12 carbon chain cannot

literally infringe upon the '359 patent. Second, Plaintiff cannot employ the doctrine of equivalents to argue that CAMCEVI *functionally* infringes upon the '359 patent because: (1) the patent's use of "about" as a claim-broadening tool limits the applicability of the doctrine of equivalents; and (2) because the disclosure-dedication rule[4] also precludes the doctrine of equivalents.

Plaintiffs counter that they have plausibly pled infringement because the term "about," which modifies the '359 patent's "about 4 to about 8" carbon atoms and therefore the claim, can be construed in different ways. Opp'n at 22-23. Plaintiffs also maintain that they "have not abandoned" a theory of literal infringement *Id.*

Either theory of infringement—literal infringement or infringement pursuant to the doctrine of equivalents—requires construction of the '359 patent's "about 4 to about 8" carbons. "About" avoids a strict numerical boundary, and "must be interpreted in its technologic and stylistic context." Determining whether a patent claim using "about" has been literally infringed requires claim construction—how far, in other words, "about" extends the patent claim. *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The determination of whether the literal meaning or scope of 'about 5:1 to about 7:1' includes 4:1 is a matter of claim construction")

Likewise for Plaintiff's theory of infringement relying upon the doctrine of equivalents. The doctrine of equivalents "prevents an accused infringer from avoiding infringement by

[4] As explained below, the Court need not (and cannot) reach the disclosure-dedication issue prior to claim construction because the disclosure-dedication rule limits application of the doctrine of equivalents. *Toro Co. v. White Consol. Indus., Inc*., 383 F.3d 1326, 1331 (Fed. Cir. 2004). Briefly, however, the disclosure-dedication rule holds that when a patent drafter discloses but declines to claim subject matter, ... the unclaimed subject matter is dedicated to the public. *In re Bendamustine Consol. Cases*, No. CV 13-2046, 2015 WL 1951399, at *2 (D. Del. Apr. 29, 2015) (citing *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*,285 F.3d 1046, 1054 (Fed. Cir. 2002)). In other words, a patentee cannot omit something from a claim, then seek to "reclaim" it through the doctrine of equivalents.

changing only minor or insubstantial details of a claimed invention while retaining their essential functionality." *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997). The doctrine recognizes that the "nature of language makes it impossible to capture the essence of a thing in a patent application. … If patents were always interpreted by their literal terms, …[u]nimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731-32 (2002).

Thus, under the doctrine, 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.[5] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Or phrased another way, "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape." *Graver Tank & Mfg. Co. v. Linde Air Products Co.,* 339 U.S. 605, 608 (1950) (accused welding process using manganese infringed on claimed process using magnesium because manganese was interchangeable with the magnesium and in the accused process the manganese performed the same function, in the same way, to achieve the same result as the claimed magnesium); *and see Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1574 (Fed. Cir.) (Nies, J.,

[5] It bears emphasizing what the doctrine of equivalents does *not* do: expand the scope of a patented claim. *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1109 (Fed. Cir. 1996) (citing *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.,* 904 F.2d 677, 684 (Fed. Cir. 1990) ("To say that the doctrine of equivalents extends or enlarges *the claims* is a contradiction in terms. The claims—i.e., the scope of patent protection *as defined by* the claims—remain the same and application of the doctrine *expands the right to exclude* to "equivalents" of what is claimed.") (emphasis in original), *disapproved on other grounds by Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 92 (1993)).

dissenting) ("While a ballpoint and fountain pen may be equivalent overall, they are not equivalent in the sense of the doctrine because their components are not equivalent."), *supplemented*, 64 F.3d 675 (Fed. Cir. 1995), *and rev'd*, 520 U.S. 17 (1997), *adhered to*, 114 F.3d 1161 (Fed. Cir. 1997).

Recall Defendants' argument: that Plaintiffs cannot, as a matter of law, rely on the doctrine of equivalents to prove that the '359 patent's "about 4 to about 8" carbon structure is infringed upon by CAMCEVI's 12-carbon structure. In other words, Plaintiffs cannot, according to Defendants, claim a broad, "fuzzy" range (by definition, expanding the claim), then expand it yet further by accusing CAMCEVI of infringement using the doctrine of equivalents. Defendants correctly summarize the doctrine of equivalents, but applying it, like the theory of literal infringement, also requires claim construction.

Further examples involving the use of "about" are instructive. In *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1372 (Fed. Cir. 2008), after construing "about 30 μm" to include particles between 23.044 μm and 25 .434 μm only if the particles were large enough "to assure that a column containing the particles is capable of attaining turbulence," *id.* at 1370, the Federal Circuit said that "by electing to include the broadening word 'about' in the claim, the patentee has ... already captured what would otherwise be equivalents within the literal scope of the claim," *id.* at 1372. Accordingly, the court held that "[w]here, as here, a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim."

In *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab'ys, Ltd.*, 476 F.3d 1321, 1328 (Fed. Cir. 2007), the Federal Circuit determined that a ratio limitation of "about 1:5," construed to "encompass[ ] a range of ratios no greater than 1:3.6 to 1:7.1," was not infringed upon by a formula

with a ratio of "no less than 1:7.5" because the patentee could not use the doctrine of equivalents to encompass the 1:7.5 ratio, a ratio outside of the confidence intervals identified in the patent. *Id.*

In *Takeda Pharm. Co. v. TWi Pharms., Inc.*, the court had construed an "about 5.0 to about 5.5" pH claim limitation to mean "approximately 5.0 to about 5.5." 87 F. Supp. 3d 1263, 1281 (N.D. Cal. 2015). By using "approximately," "the claim's literal scope necessarily include[d] equivalents whose enteric coatings might be designed to release dexlansoprazole *just outside the claimed 5.0 to 5.5 pH range*." *Id.* at 1282 (emphasis added). Thus, the patentee could not rely on the doctrine of equivalents to prove that the accused product infringed upon the patent's "about 5.0 to about 5.5" pH claim limitation because "certain equivalents are already encompassed by the claim's literal [approximate] scope." *Id.*

And in *Regents of Univ. of Minnesota v. AGA Med. Corp.*, No. 07-CV-4732, 2011 WL 13943, at *13 (D. Minn. Jan. 4, 2011), the court likewise held that a patentee could not utilize the doctrine of equivalents to expand an already-fuzzy limitation. Specifically, the court rejected an attempt to expand claims stating ratios between an occluding disk and a heart defect of "between about 1.6 and about 2.5 times" and "at least about 1.6 times the diameter of the defect." *Id.* at *10. The court rejected the patentee's attempted theory of equivalence asserting that a device infringes, "regardless of the numerical ratio of the diameters of a disk and a defect, as long as the disk [occludes the defect] without negatively interfering with the…heart. In other words, … as long as an occluding device *works,* the ratio between the disks and the defect could be *anything.*" *Id.* at *13.

To illustrate by contrast, in *Pozen Inc. v. Par Pharmaceutical, Inc.,* 696 F.3d 1151, 1169-70 (Fed. Cir. 2012), the plaintiff sought to apply the doctrine of equivalents to a claim that included the limitation "substantially all." The defendant argued that this was "a 'fuzzy' quantitative

limitation not entitled to equivalents." *Id.* Nevertheless, the Federal Circuit held that the doctrine of equivalents applied because the term "substantially all" was construed to have a specific "quantitative definition"—namely, "at least 90%, and preferably greater than 95%." *Id.* at 1170. Because "at least 90%" set a 90% floor, rather than an *approximate* floor, the *Pozen* court held that the doctrine of equivalents *could* apply and that "a tablet layer with 85% of the agent can be fairly characterized as an insubstantial change from a tablet layer with 90% of the agent." *Id.* at 1170–71.

There are two lessons to extract from these cases. The first is that the use of broadening language does not automatically preclude reliance upon the doctrine of equivalents. The Federal Circuit has "never held that the doctrine of equivalents is inapplicable to broad claims[. T]he fact that a claim recites numeric ranges does not, by itself, preclude reliance on the doctrine of equivalents." *Cohesive*, 543 F.3d at 1371. The "way that the patentee has used the word 'about' in the context of the written description and the claims…requires consideration of the purpose or 'criticality' of the limitation to the invention. *Id.* at 1372. But as Plaintiffs argue, "the term 'about' is not entitled to equivalents only if it is given a *literal construction* that already encompasses equivalents." Opp'n at 18. But "'about' does not have a universal meaning in patent claims, and that the meaning depends on the technological facts of the particular case." *Pall*, 66 F.3d at 1217.

And the second lesson: the common feature of *Takeda*, *Pozen*, *Cohesive*, *Ortho-McNeil*, and *Regents* is that their "fuzzy" patent claims had already been construed to establish the claim boundaries. Construing the limitation determines the literal scope of the claim, which in turn permits analysis of whether the doctrine of equivalents is even available (and then whether the disclosure-dedication rule is applicable). Usually, and particularly when confronting more complicated subject matter, claim construction has already occurred to assist in defining the

meaning of "about." *Cohesive*, 543 F.3d at 1372 ("*As our construction makes clear*, 'about 30 μm' encompasses particle diameters that perform the same function, in the same way, with the same result as the 30 μm particles, as long as those diameters are within the range left open by the specific disclosures of the specification").

Courts hesitate to grant judgment of noninfringement on the pleadings before claim construction. *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1343 (Fed. Cir. 2012) (holding that district court's narrow construction of the patent's claims "at the pleading stage—with no claim construction processes undertaken—was inappropriate"); *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 2012 WL 2365905, *1 (D. Del. 2012) ("Given the complex technology at issue and the standard of review, the court finds these counterclaims particularly ill suited for disposition on a motion for judgment on the pleadings."); *Novartis Pharms. Corp. v. Actavis, Inc.*, No. CIV.A. 12-366-RGA, 2012 WL 6212619, at *7 (D. Del. Dec. 5, 2012) (collecting cases stating that motions requiring claim construction to perform an infringement analysis should be denied because claim construction should be illuminated by extrinsic evidence and *Markman* procedures).

Where such claims *are* granted at the pleading stage, the issues are more factually straightforward or purely legal. For example, in *PSC Computer Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1357 (Fed. Cir. 2004), cited by Defendants in reply, the district court and Federal Circuit did not construe the claims because, unlike here, the parties agreed on claim construction. Likewise, in *In re Bendamustine Consol. Cases*, the parties agreed that the doctrine of equivalents applied, and the patent in question was an *Abbreviated* New Drug Application ("ANDA"). No. CV 13-2046, 2015 WL 1951399, at *1 (D. Del. Apr. 29, 2015) (granting the motion for judgment on the pleadings based on disclosure-dedication rule because claimed product, which used solvent

TBA disclosed but did not claim other, non-TBA organic solvents used by allegedly-infringing product; *see also Amgen Inc. v. Coherus Biosciences Inc.,* No. CV 17-546, 2018 WL 1517689, at *4, n.5 (D. Del. Mar. 26, 2018), *aff'd*, 931 F.3d 1154 (Fed. Cir. 2019) (distinguishing *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337 (Fed. Cir. 2018) (claim construction was "only a legal dispute" turning on the "clear and unambiguous prosecution history"); *Anderson v. Kimberly-Clark Corp.*, Fed. Appx., 2014 WL 3361130, *2-*3 (Fed. Cir. 2014) (*nonprecedential*) (affirming a Rule 12(c) judgment of no infringement of a design patent asserted by a *pro se* plaintiff where a simple comparison of the photographs and the patent showed there could not be any infringement); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1320-21 (Fed. Cir. 2012) (the issue "is a very narrow one": where the asserted method of use patent required using the drug to simultaneously treat three symptoms, but the FDA had approved the drug for only one symptom, whether the accused infringers' label for that one approved usage created liability); *Ferring Pharmaceuticals Inc. v. Lupin Inc.*, 2020 WL 3414750, *4 (D. Del. 2020) (finding that discovery was not needed to determine that the label of the accused drug product did not instruct or otherwise encourage the drug product be taken in a timing sequence that was required by the claimed method).

The claim here is not so straightforward. Accordingly, the more prudent path is to proceed to claim construction. The Court therefore need not address Defendants' remaining arguments, which depend upon that construction.

IV. CONCLUSION

For the reasons above, Defendants' motion for judgment on the pleadings (D.E.s 35, 40) will be DENIED. An appropriate order follows.

Dated: October 24, 2022

Evelyn Padin, U.S.D.J.