

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>RAYNER SURGICAL INC. and RAYNER INTRAOCULAR LENSES LTD.,</p> <p>Plaintiffs,</p> <p>v.</p> <p>SOMERSET THERAPEUTICS, LLC,</p> <p>Defendant.</p>	<p>Civil Action No. 24-09017 (GC) (JBD)</p> <p><u>MEMORANDUM OPINION</u></p>
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CASTNER, District Judge

THIS MATTER comes before the Court upon Defendant Somerset Therapeutics, LLC's Motion for Judgment on the Pleadings pursuant to Federal Rule of Civil Procedure (Rule) 12(c). (ECF No. 99.) Plaintiffs Rayner Surgical Inc. and Rayner Intraocular Lenses, Ltd. opposed, and Defendant replied. (ECF Nos. 104, 112.) The parties also submitted supplemental briefing regarding the extent to which the Court's ruling regarding claim construction impacted Defendant's Motion for Judgment on the Pleadings. (ECF Nos. 175, 178, 179.) The Court has carefully reviewed the parties' submissions and decides the matter without oral argument pursuant to Rule 78(b) and Local Civil Rule 78.1(b). For the reasons set forth below, and other good cause shown, Defendant's Motion is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY¹

The Court writes exclusively for the parties, who are familiar with the procedural and factual history of this case, and will set forth only those facts necessary to this Court’s analysis. This case arises out of a patent infringement dispute under the Hatch-Waxman Act. Plaintiffs “make[] and sell[] OMIDRIA®, a combination product used during cataract surgery or intraocular lens replacement to maintain pupil size by preventing miosis and to reduce postoperative pain.” (ECF No. 1 ¶ 18.) Plaintiffs are the assignees and owners of United States Patent Nos. 9,066,856, 9,486,406, and 9,855,246, which are associated with OMIDRIA®. (*Id.* ¶¶ 1, 22, 23.) Defendant filed an Abbreviated New Drug Application (ANDA) No. 219384 seeking approval to market a generic version of OMIDRIA® prior to the expiration of Plaintiffs’ patents. (*Id.* ¶¶ 1, 27.)

The asserted patents indicate that Plaintiffs’ product OMIDRIA® is formulated with three components: ketorolac, phenylephrine, and a buffer system. (*Id.* ¶¶ 38, 57, 76.) Ketorolac and phenylephrine are active pharmaceutical ingredients (APIs), (*id.* ¶¶ 18), and the parties have since stipulated that a “buffer system” is “a solution including a mixture of a weak acid and its conjugate base, or a weak base and its conjugate acid.” (ECF No. 157 at 2.)² On September 6, 2024, Plaintiffs filed the Complaint in this case asserting Defendant’s ANDA infringes upon the ’856, ’406, and ’246 patents. (ECF No. 1 ¶¶ 1, 34-90.) Plaintiffs allege that Defendant’s product infringes upon the asserted patents because it is a “liquid pharmaceutical formulation” containing “phenylephrine,

¹ On a motion for judgment on the pleadings under Rule 12(c), “the court must accept as true all factual allegations in the plaintiff’s complaint.” *Zebrowski v. Wells Fargo Bank, N.A.*, 657 F. Supp. 2d 511, 514 (D.N.J. 2009).

² Page numbers for record cites (*i.e.*, “ECF Nos.”) refer to the page numbers stamped by the Court’s e-filing system and not the internal pagination of the parties.

ketorolac, and a buffer system.” (*See id.* ¶¶ 39, 58, 77.) On November 4, 2024, Defendant filed its Answer and Separate Defenses. (ECF No. 9.)

On July 11, 2025, Defendant filed the present Motion for Judgment on the Pleadings pursuant to Rule 12(c), (ECF No. 99), arguing that Plaintiff’s allegations of infringement fail as a matter of law and must therefore be dismissed (*see* ECF No. 100). Concurrently, the parties were briefing disputes regarding claim construction in preparation for a *Markman* hearing.³ (*See* ECF Nos. 76, 95, 96, 118, 119.) On November 20, 2025, the Court held a *Markman* hearing for three disputed terms in the asserted patents: “ketorolac,” “phenylephrine,” and “phenylephrine, ketorolac, and a buffer system.” (ECF No. 171 at 1.) On January 21, 2026, the Court issued an Order construing those terms, including construing “phenylephrine, ketorolac, and a buffer system” to mean “a formulation with at least three separate components: (1) phenylephrine, (2) ketorolac, and (3) a buffer system.” (*Id.* at 2.) On that same day, the Court directed the parties to file supplemental briefing regarding the extent to which the Court’s ruling regarding claim construction impacted Defendant’s Motion for Judgment on the Pleadings, (ECF No. 172), and the parties filed such briefing. (ECF Nos. 175, 178, 179.) Defendant’s Motion is now ripe for decision.

II. LEGAL STANDARD

“The standard under which the Court must analyze the plaintiff’s complaint and the defendant[’s] arguments in a Rule 12(c) motion for judgment on the pleadings is the same as the standard in a motion to dismiss under [Rule] 12(b)(6).” *Wyeth v. Ranbaxy Lab’ys Ltd.*, 448 F. Supp. 2d 607, 609 (D.N.J. 2006). On a Rule 12(b)(6) and Rule 12(c) motion, courts “accept the factual allegations in the complaint as true, draw all reasonable inferences in favor of the plaintiff,

³ *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

and assess whether the complaint and the exhibits attached to it contain enough facts to state a claim to relief that is plausible on its face[.]” *Wilson v. USI Ins. Serv. LLC*, 57 F.4th 131, 140 (3d Cir. 2023) (internal quotations omitted).

After claim construction, “the second step of an infringement analysis is to determine how the claims, as construed, compare to the allegedly infringing device. This inquiry is factual.” *Int’l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1374 (Fed. Cir. 2004) (citation omitted); *see also Baxter Healthcare Corp. v. Nevakar Injectables, Inc.*, Civ. No. 21-1184, 2025 WL 823224, at *3 (D. Del. Mar. 14, 2025). “A plaintiff can survive a Rule 12(c) motion if her complaint contains ‘sufficient factual matter to show that the claim is facially plausible, thus enabling the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged.’” *Bibbs v. Trans Union LLC*, 43 F.4th 331, 339 (3d Cir. 2022) (alteration in original) (quoting *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 84 (3d Cir. 2011)). However, “[a] court may grant a Rule 12(c) motion ‘if, on the basis of the pleadings, the movant is entitled to judgment as a matter of law’” and there are no material issues of fact to be resolved. *Id.* (quoting *Fed Cetera, LLC v. Nat’l Credit Servs., Inc.*, 938 F.3d 466, 469 n.7 (3d Cir. 2019)); *see also KOM Software Inc. v. NetApp, Inc.*, 697 F. Supp. 3d 203, 209 (D. Del. 2023). On a Rule 12(c) motion, the issue for the court “is not whether a plaintiff eventually will prevail, but whether the plaintiff is entitled to offer evidence in support of his or her claims.” *Huggard v. Crown Bank*, Civ. No. 11-6194, 2012 WL 529548, at *2 (D.N.J. Feb. 17, 2012) (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

III. DISCUSSION

Defendant argues that its Motion for Judgment on the Pleadings must be granted because the Plaintiffs’ factual allegations and theories of infringement are inconsistent with the Court’s construction that the asserted patents require formulations with a buffer system that is a separate and distinct component from the active ingredients. (*See* ECF No. 175 at 6, 12.) Plaintiffs reply

that Defendant’s Motion must be denied because Plaintiffs have identified components of Defendant’s product that satisfy the limitations specified in the asserted patents as construed by the Court, and “infringement by [Defendant’s] ANDA Product, literally or under the doctrine of equivalents, presents factual questions that cannot be resolved on a Rule 12(c) motion.” (ECF No. 178 at 6, 14-15.) Plaintiffs assert two theories of infringement: literal infringement, and infringement under the doctrine of equivalents. (ECF No. 1 ¶¶ 47, 66, 85; *see also* ECF No. 178 at 8.) Defendant argues that judgment on the pleadings must be granted as to both theories; and the Court will consider each in turn.

A. Pleading Standard for Complaints under the Hatch-Waxman Act

Defendant first argues that Plaintiff’s Complaint is deficient, as it is based on “unsupported allegations” and “[s]imply reciting claim limitations in a pleading is not enough to create a material issue of fact.” (ECF No. 175 at 10; ECF No. 179 at 6-7.) Plaintiffs respond that courts have recognized Hatch-Waxman plaintiffs can plead with lower levels of specificity, and they have satisfied this pleading standard. (ECF No. 178 at 10-11.)

The purpose of the Hatch-Waxman Act is “‘to facilitate the speedy and cost-effective entrance of generic drug[s] to the market,’ and that such ‘purpose is advanced by allowing plaintiffs in this type of case to rely on the sufficiency of pleading the artificial act of infringement, allowing the particularized theory of infringement to be developed through discovery and other phases of the case.’” *Bristol-Myers Squibb Co. v. Xspray Pharma AB*, Civ. No. 22-964, 2023 WL 3354261, at *4 (D.N.J. Apr. 25, 2023) (quoting *Belcher Pharms., LLC v. Int’l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 331 (D. Del. 2019)). As such, “[c]ourts have recognized a relaxed standard of pleading in situations where ‘essential information lies uniquely within another party’s control’” and “similarly recognized [that] a Hatch-Waxman plaintiff could plead with a lower level of specificity than required in other infringement suits and still comply with the *Twombly* and *Iqbal*

pleading requirements.”⁴ *Novartis Pharms. Corp. v. Alembic Pharms. Ltd.*, Civ. No. 22-1395, 2023 WL 6387975, at *2 (D. Del. Sept. 29, 2023) (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330-31 (Fed. Cir. 2009)). Generally, when bringing patent infringement claims, “[a] plaintiff is not required to plead infringement on an element-by-element basis.” *Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1352 (Fed. Cir. 2021); and

The Court finds that Plaintiffs have sufficiently pled their claims. Plaintiffs’ Complaint sufficiently pleads Plaintiffs’ interest in the asserted patents, the filing of Defendant’s ANDA, and Plaintiffs’ contentions that Defendant’s product will infringe Plaintiffs’ patents. (ECF No. 1 ¶¶ 21-23, 27-29, 36, 47, 55, 66, 74, 85.) *See Novartis Pharms. Corp.*, 2023 WL 6387975, at *3-4 (finding the plaintiff sufficiently pled claims under “relaxed pleading standard” where complaint alleged “that [the defendant] committed acts of infringement by filing their ANDAs, and that the challenged drug products will infringe one or more claims of [plaintiff’s asserted patent]” and “essential information lies uniquely within another party’s control”) (internal quotations omitted).

B. Literal Infringement

Defendant argues that judgment on the pleadings must be granted because Plaintiffs’ theory of literal infringement fails, as Defendant’s product has no separate and distinct buffer system as per the Court’s claim construction. (ECF No. 175 at 8-12.) Plaintiffs contend that factual disputes remain, and proffers that the evidence will show that components in Defendant’s product create “a buffer system that exists separately from ‘phenylephrine’ and ‘ketorolac’ in the liquid formulation of [Defendant’s] ANDA Product and that there is therefore literal infringement when accounting for the Court’s claim construction.” (ECF No. 178 at 15.)

⁴ Citing to *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

Under the theory of literal infringement, “[t]o prove an accused product literally infringes the patent in suit, the product must contain each and every limitation of the asserted claim(s).” *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1166 (Fed. Cir. 2014). Accepting all factual allegations in the Complaint as true, as it must on a motion for judgment on the pleadings, *Syndicate 1245 at Lloyd’s v. Walnut Advisory Corp.*, 721 F. Supp. 2d 307, 314-15 (D.N.J. 2010), the Court finds there is a factual dispute regarding whether Defendant’s product contains a separate and distinct buffer system. *See, e.g., Allergan, Inc. v. Mankind Pharma Ltd.*, Civ. No. 23-272, 2024 WL 1931969, at *2-3 (D. Del. Jan. 4, 2024), *report and recommendation adopted*, 2024 WL 1931756 (D. Del. Jan. 29, 2024) (internal quotations omitted) (recommending denial of judgment on the pleadings where there was a factual dispute because the absence of a component from the ANDA “does not conclusively establish judgment as a matter of law of no literal infringement”); *Novartis Pharms. Corp.*, 2023 WL 6387975, at *4-5 (denying judgment on the pleadings where ANDA product claimed a certain form of a compound while the asserted patent required a different form of that compound, holding that “[a]n infringement adjudication cannot be completed merely by reviewing the ANDA, and without taking into account any other evidence—including, most notably, expert testimony”) (quoting *Par Pharma., Inc. v. Hospira Inc.*, 2018 WL 3343238, at *3 (D. Del. May 11, 2018)); *cf. Baxter Healthcare Corp.*, 2025 WL 823224, at *4-5 (granting summary judgment of non-infringement on plaintiff’s claims of literal infringement because (1) the court construed the claims at issue as requiring “a separate chemical compound, added to the composition,” and (2) during a hearing, the plaintiff’s counsel conceded that “in light of the construction for [the term at issue]—[the plaintiff] cannot make a viable argument of literal direct infringement”).

C. Doctrine of Equivalents

Defendant argues judgment on the pleadings must be granted because Plaintiffs' alternative theory of infringement under the doctrine of equivalents also fails. Defendant contends this doctrine is not a license to ignore claim limitations, and Plaintiffs' contention that the "tromethamine counterion" meets the "'ketorolac' limitation *and* as an equivalent of the buffer system" would render the "buffer system" limitation meaningless. (ECF No. 175 at 12-13 (emphasis in original).) Plaintiffs respond again that there is a factual dispute, and evidence will show infringement under this theory because components in Defendant's product are "equivalent to a separately added buffer system because it has substantially the same function, acts in substantially in the same way, and achieves substantially the same result as compared to a separately added buffer system, and the differences between [Defendant's] ANDA Product and the claim limitation are insubstantial." (ECF No. 178 at 15-16.)

Under the theory of 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). While "there need not be a one-to-one correspondence between elements of the accused device and the claimed invention, that does not condone ignoring a claimed limitation in assessing infringement under the doctrine of equivalents." *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1377 (Fed. Cir. 2008).

The Federal Circuit has held that whether "the accused product 'performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product' . . . is a question of fact." *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013) (quoting *Crown Packaging Tech., Inc. v.*

Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009)); *see also Aventis Pharms., Inc. v. Barr Lab'ys, Inc.*, 335 F. Supp. 2d 558, 565 (D.N.J. 2004) (“Application of the doctrine of equivalents requires a fact intensive analysis to determine whether or not differences between a claim limitation of the patent, and the corresponding element of the accused device, are merely insubstantial or unimportant substitutions.”). The question of whether a theory of equivalence vitiates, or renders ineffective, a particular claim element is fact-specific, and “the vitiation test cannot be satisfied by simply noting that an element is missing from the claimed structure or process because the doctrine of equivalents, by definition, recognizes that an element is missing that must be supplied by the equivalent substitute.” *Brilliant Instruments, Inc.*, 707 F.3d at 1347 (quotation omitted). The Federal Circuit has also explained that “[c]haracterizing an element of an accused product as the ‘antithesis’ of a claimed element is also a conclusion that should not be used to overlook the factual analysis required to establish whether the differences between a claimed limitation and an accused structure or step are substantial *vel non*.” *Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1372 (Fed. Cir. 2015).

Furthermore, the Court notes that in issuing its claim construction Opinion, it found that “the specification does not suggest that phenylephrine or ketorolac can also serve as a buffer system or vice versa and [Plaintiffs have] not identified any such disclosure.” (ECF No. 173 at 12:13-16.) Defendant argues that this statement means Plaintiffs cannot assert that the tromethamine in Defendant’s product, originally added into the solution as “ketorolac tromethamine,” is substantially equivalent to a separately added buffer system under the doctrine of equivalents. (*See* ECF No. 179 at 12-13.) But the Court’s finding on claim construction does not necessarily foreclose the applicability of infringement under the doctrine of equivalents, such a determination is a question of fact. *See Baxter Healthcare Corp.*, 2025 WL 823224, at *10

(holding that “it could well be said (as [the plaintiff] argues) that the [c]ourt’s construction of ‘chelating agent’ to mean a ‘separate chemical compound, added to the overall composition’ sounds like the antithesis of, or the opposite of, the way that the chelating agent is present in [the plaintiff’s] products. After all, the bitartrate anions in [the plaintiff’s] products are *not* separately added to the solution vis-à-vis other claimed components like norepinephrine—they started out as part of the norepinephrine substance in the first place. But in line with the Federal Circuit’s guidance in cases like *Cadence*, that type of ‘antithesis’ or ‘opposite’ argument is not the end of the [‘vitiation’ inquiry”).

As a result, the Court finds there is a genuine factual dispute as to whether the components of Defendant’s product are equivalent to the components identified in the asserted patents as to infringe upon them. *See, e.g., id.*, at *6-12 (denying summary judgment on doctrine of equivalents claim as there was a genuine dispute of material fact regarding whether a component in the plaintiff’s product was equivalent to a claim limitation in the asserted patent); *cf. Eagle Pharms., Inc. v. Slayback Pharma LLC*, 382 F. Supp. 3d 341, 346-48 (D. Del. 2019), *aff’d*, 958 F.3d 1171 (Fed. Cir. 2020) (granting defendant’s motion for judgment on the pleadings in case involving application of the disclosure-dedication doctrine because there was no factual dispute as to the patent disclosures and the court could decide the question of law regarding application of the disclosure-dedication doctrine).

IV. CONCLUSION

For the foregoing reasons, and other good cause shown, Defendant's Motion for Judgment on the Pleadings (ECF No. 99) is **DENIED**. An appropriate Order follows.

Dated: April 2 2026



GEORGETTE CASTNER
UNITED STATES DISTRICT JUDGE