

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-874-SLR-SRF
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

**REPORT AND RECOMMENDATION**

**I. INTRODUCTION**

On July 3, 2014, plaintiff Merck Sharp & Dohme Corp. (“Merck”) filed this action against defendant Teva Pharmaceuticals USA, Inc. (“Teva”), alleging infringement of United States Patent No. 6,127,353 (“the ‘353 patent”). Pending before the court are Teva’s motion to dismiss for failure to state a claim and motion for judgment on the pleadings (D.I. 8), as well as its motion to transfer venue to the District of New Jersey (D.I. 12). For the following reasons, I recommend that the court deny Teva’s motion to transfer, grant Teva’s motion to dismiss with leave to amend Count II of the complaint, and deny Teva’s motion for judgment on the pleadings as moot.

**II. BACKGROUND**

Merck is a New Jersey corporation maintaining its principal place of business in Whitehouse Station, New Jersey. (D.I. 1 at ¶ 2) Teva is a Delaware corporation with its principal place of business in Horsham, Pennsylvania. (*Id.* at ¶ 3)

On October 3, 2000, U.S. Patent No. 6,127,353 (“the ‘353 patent”), entitled Mometasone Furoate Monohydrate, Process For Making Same And Pharmaceutical Compositions, issued to Pui-Ho Yen, Charles Eckhart, Teresa Etlinger, and Nancy Levine. (*Id.* at ¶ 9) The ‘353 patent

discloses and claims novel forms of mometasone furoate monohydrate and novel pharmaceutical compositions thereof. (*Id.*) Merck is the owner by assignment of the ‘353 patent, and owns the approved New Drug Application No. 20762, covering mometasone furoate monohydrate metered nasal spray sold under the Nasonex® trademark. (*Id.* at ¶ 10) Nasonex® nasal spray is widely used in the United States and throughout the world to treat upper respiratory diseases, including allergic and nonallergic rhinitis. (*Id.* at ¶ 11)

Prior to the expiration of the ‘353 patent, Teva filed an abbreviated new drug application (“ANDA”) with the FDA for generic mometasone furoate nasal spray (“ANDA No. 205149”), containing a certification that the ‘353 patent is “invalid, unenforceable, or will not be infringed.” (*Id.* at ¶ 13) Teva refused to make ANDA No. 205149 or samples of its proposed generic copy of Nasonex® nasal spray available to Merck. (*Id.* at ¶ 14)

On July 3, 2014, Merck initiated the present action, asserting direct and contributory infringement of the ‘353 patent. (D.I. 1) Pursuant to Merck’s conversion theory of contributory infringement, Teva would be liable for infringement even if the generic copy of Nasonex® nasal spray sold by Teva contains only anhydrous mometasone furoate, because at least some of the mometasone furoate contained in Teva’s product converts to the allegedly infringing monohydrate form during the proposed shelf life of the product. (D.I. 18 at 7-8) Paragraph 15 of the complaint states that, “[u]pon information and belief, Teva’s proposed generic copy would contain mometasone furoate in such a form that would infringe the ‘353 patent.” (D.I. 1 at ¶ 15) Paragraph 25 further alleges that,

[o]n information and belief, Teva has or will have knowledge that if it were to receive approval from the FDA to market the product described in ANDA No. 205149 and made said product available for sale and/or use during the proposed shelf life of the product, such activities would result in the sale and/or use of an infringing article that is not a staple article or commodity of commerce suitable

for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the ‘353 patent.

(*Id.* at ¶ 25)

Teva informed Merck of its intention to move to transfer the case to New Jersey, and counsel for the parties held a meet and confer on July 28, 2014. (D.I. 13 at 2) Merck previously asserted the ‘353 patent against Apotex Inc. (“Apotex”) in the United States District Court for the District of New Jersey on December 18, 2009 (the “Apotex case”). (D.N.J. C.A. No. 09-6373-PGS-TJB, D.I. 1) The district judge in the Apotex case issued a decision on June 15, 2012, holding that Merck had failed to establish that Apotex’s anhydrous mometasone furoate product infringed the asserted claims of the ‘353 patent directed to mometasone furoate monohydrate. *See Schering Corp. v. Apotex Inc.*, 2012 WL 2263292 (D.N.J. June 15, 2012). The Federal Circuit affirmed the district court’s decision on June 10, 2013. *See Merck Sharp & Dohme Corp. v. Apotex Inc.*, 517 F. App’x 939 (Fed. Cir. 2013).

### **III. DISCUSSION**

#### **A. Transfer of Venue**

##### **1. Legal Standard**

Section 1404(a) of Title 28 of the United States Code grants district courts the authority to transfer venue “[f]or the convenience of parties and witnesses, in the interests of justice . . . to any other district or division where it might have been brought.” 28 U.S.C. § 1404(a). Much has been written about the legal standard for motions to transfer under 28 U.S.C. § 1404(a). *See, e.g., In re Link\_A\_Media Devices Corp.*, 662 F.3d 1221 (Fed. Cir. 2011); *Jumara v. State Farm Ins. Co.*, 55 F.3d 873 (3d Cir. 1995); *Helicos Biosciences Corp. v. Illumina, Inc.*, 858 F. Supp. 2d 367 (D. Del. 2012).

Referring specifically to the analytical framework described in *Helicos*, the court starts with the premise that a defendant’s state of incorporation has always been “a predictable, legitimate venue for bringing suit” and that “a plaintiff, as the injured party, generally ha[s] been ‘accorded [the] privilege of bringing an action where he chooses.’” 858 F. Supp. 2d at 371 (quoting *Norwood v. Kirkpatrick*, 349 U.S. 29, 31 (1955)). The Third Circuit in *Jumara* instructs that “[t]he burden of establishing the need for transfer . . . rests with the movant” and that, “in ruling on defendants’ motion, the plaintiff’s choice of venue should not be lightly disturbed.” 55 F.3d at 879 (citation omitted).

The Third Circuit recognizes that,

[i]n ruling on § 1404(a) motions, courts have not limited their consideration to the three enumerated factors in § 1404(a) (convenience of parties, convenience of witnesses, or interests of justice), and, indeed, commentators have called on the courts to “consider all relevant factors to determine whether on balance the litigation would more conveniently proceed and the interests of justice be better served by transfer to a different forum.”

*Id.* (citation omitted). The Court describes some of the “many variants of the private and public interests protected by the language of § 1404(a).” *Id.*

The private interests have included: plaintiff’s forum of preference as manifested in the original choice; the defendant’s preference; whether the claim arose elsewhere; the convenience of the parties as indicated by their relative physical and financial condition; the convenience of the witnesses – **but only to the extent that the witnesses may actually be unavailable for trial in one of the fora**; and the location of books and records (**similarly limited to the extent that the files could not be produced in the alternative forum**).

The public interests have included: the enforceability of the judgment; practical considerations that could make the trial easy, expeditious, or inexpensive; the relative administrative difficulty in the two fora resulting from court congestion; the local interest in deciding local controversies at home; the public policies of the

fora; and the familiarity of the trial judge with the applicable state law in diversity cases.

*Id.* (citations omitted) (emphasis added).

## **2. Analysis**

In view of the “jurisdictional guideposts” described above, the court turns to the “difficult issue of federal comity” that transfer motions present. *E.E.O.C. v. Univ. of Pa.*, 850 F.2d 969, 976 (3d Cir. 1988). Merck has not challenged Teva’s assertion that the instant action could have been brought in the District of New Jersey. *See* 28 U.S.C. § 1404(a); (D.I. 20 at 3)

Turning to the *Jumara* factors, the court notes that the parties’ dispute focuses solely on the weight given to Merck’s choice of forum and considerations of judicial economy. Teva does not allege that litigating the instant action in Delaware would be inconvenient, nor does it raise arguments regarding where the claims arose, the parties’ relative physical and financial condition, the availability of witnesses, the location of books and records, the enforceability of the judgment, administrative difficulty, the local interest in deciding local controversies at home, public policies, or the familiarity of the trial judge with state law. These factors are therefore neutral.

### **(a) Parties’ Choice of Forum**

In support of its motion to transfer, Teva contends that transfer is warranted because Delaware is not Merck’s home forum. (D.I. 13 at 10-11) Teva further accuses Merck of engaging in forum shopping in contravention of the policy considerations underlying § 1404. (*Id.* at 11) In response, Merck stresses that its choice of venue should be awarded significant deference because it filed suit in Teva’s home forum. (D.I. 20 at 7-8)

“The deference afforded plaintiff’s choice of forum will apply as long as plaintiff has selected the forum for some legitimate reason.” *Cypress Semiconductor Corp. v. Integrated Circuit Sys., Inc.*, 2001 WL 1617186, at \*2 (D. Del. Nov. 28, 2001) (internal citations omitted). A party’s state of incorporation is a traditional and legitimate venue. *See Helicos*, 858 F. Supp. 2d at 371; *see also ChriMar Sys., Inc. v. Cisco Sys., Inc.*, C.A. No. 11-1050-GMS, 2013 WL 828220, at \*4 (D. Del. Mar. 6, 2013) (citing *Schubert v. OSRAM AG*, C.A. No. 12-923-GMS, 2013 WL 587890, at \*4 (D. Del. Feb. 14, 2013)). In the present matter, Teva has chosen to avail itself of the rights, benefits, and obligations afforded by Delaware law by incorporating in Delaware. Moreover, this court does not generally elevate a defendant’s choice of venue over that of a plaintiff, and “the fact that plaintiffs have historically been accorded the privilege of choosing their preferred venue for pursuing their claims remains a significant factor.” *FastVDO LLC v. Paramount Pictures Corp.*, 947 F. Supp. 2d 460, 462 (D. Del. June 4, 2013). In light of the fact that Delaware is not Merck’s home turf, but is Teva’s state of incorporation, the court awards this factor “increased weight in the *Jumara* analysis but less than the ‘substantial’ or ‘paramount’ weight” it would be given had Merck filed suit in its home forum. *ChriMar*, 2013 WL 828220, at \*4. This factor weighs against transfer.

Teva’s allegations of forum shopping do not alter the court’s analysis. This court has declined to characterize a plaintiff’s choice of venue as forum shopping when, “by moving to transfer venue, a defendant is doing the same thing—choosing a venue that it believes to be more favorable to its claims for whatever reason.” *Collectis S.A. v. Precision Biosciences, Inc.*, 858 F. Supp. 2d 376, 385 (D. Del. 2012).

**(b) Practical Considerations – Judicial Economy**

Next, Teva identifies the practical consideration of judicial economy as sufficient justification for transfer, alleging that in the Apotex case,<sup>1</sup> the District of New Jersey previously considered whether anhydrous mometasone furoate in a generic product converts over time to mometasone furoate monohydrate in the context of the '353 patent and is therefore familiar with the highly technical factual issues in the case. (D.I. 13 at 8-9)

In response, Merck alleges that considerations of judicial economy have no bearing on federal patent cases. (D.I. 20 at 5-6) Merck insists that the adverse ruling in the Apotex case<sup>2</sup> did not affect its choice of forum because the Apotex case involved an accused product that was not sufficiently similar to the accused product in the instant litigation to affect the outcome of this case. (*Id.*) Merck further alleges that the interest in judicial economy would not be served by transferring the case to New Jersey because the ruling in the Apotex case was not based on an in-depth review of the facts presented,<sup>3</sup> and the passage of time since the decision in the Apotex case was rendered more than two years ago substantially diminishes the public interest in transferring the case. (*Id.* at 8-9)

The interests in judicial economy highlighted by Teva are not sufficiently compelling to warrant transfer of the case to the District of New Jersey. As a preliminary matter, the instant

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<sup>1</sup> See *Schering Corp. v. Apotex Inc.*, 2012 WL 2263292 (D.N.J. June 15, 2012), *aff'd*, *Merck Sharp & Dohme Corp. v. Apotex Inc.*, 517 F. App'x 939 (Fed. Cir. 2013).

<sup>2</sup> *Id.*

<sup>3</sup> Specifically, Merck notes that no *Markman* hearing was held in the Apotex case in the District of New Jersey. (D.I. 20 at 8)

case involves different defendants and different accused products<sup>4</sup> than those at issue in the Apotex case. Moreover, there is no co-pending litigation before the District of New Jersey at this time. These differences distinguish the instant case from the case authorities cited by Teva. *See In re Vistaprint*, 628 F.3d 1340, 1344-45 (Fed. Cir. 2010) (holding that the district court properly denied the motion to transfer venue where a co-pending patent case regarding the same patent was before the district court); *Medicis Pharm. Corp. v. Nycomed U.S. Inc.*, C.A. No. 10-1099-SLR, 2011 WL 2457598, at \*3 (D. Del. June 16, 2011) (granting motion to transfer when parties and patents-in-suit were identical to a case that was co-pending in the Southern District of New York).

Teva bears the burden of persuading the court that transfer is appropriate, not only for its convenience but in the interests of justice. In this case, Merck chose a legitimate forum based on Teva's state of incorporation. Teva has not demonstrated that litigating in Delaware would be unduly burdensome under the *Jumara* factors. Therefore, the court is not persuaded that transfer is warranted.

**B. Motion to Dismiss Pursuant to Rule 12(b)(6) and Rule 12(c)**

Under Federal Rule of Civil Procedure 12(c), “[a]fter the pleadings are closed – but early enough not to delay trial – a party may move for judgment on the pleadings.” Fed. R. Civ. P. 12(c). When deciding a Rule 12(c) motion for judgment on the pleadings based on an allegation that the plaintiff has failed to state a claim, the motion “is analyzed under the same standards that apply to a Rule 12(b)(6) motion.” *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010), *cert.*

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<sup>4</sup> The court declines to make factual determinations at this stage of the proceedings regarding alleged similarities and differences between the accused products in the instant case and the Apotex case.



*denied*, 131 S. Ct. 995, 178 L. Ed. 2d 825 (Jan. 18, 2011). The distinction between a motion brought under Rule 12(b)(6) and a motion brought pursuant to Rule 12(c) is a distinction in form only. *See id.* (“A motion for judgment on the pleadings based on the defense that the plaintiff has failed to state a claim is analyzed under the same standards that apply to a Rule 12(b)(6) motion.”); *see also Money Suite Co. v. 21st Century Ins. & Fin. Servs., Inc.*, C.A. No. 13-984-GMS, 2015 WL 436160, at \*1 n.1 (D. Del. Jan. 27, 2015).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), 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). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

When determining whether dismissal is appropriate, the court must take three steps.<sup>5</sup> *See Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the court must identify the elements of the claim. *Iqbal*, 556 U.S. at 675. Second, the court must identify and reject conclusory allegations. *Id.* at 678. Third, the court should assume the veracity of the well-pleaded factual allegations identified under the first prong of the analysis, and determine whether

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<sup>5</sup> Although *Iqbal* describes the analysis as a “two-pronged approach,” the Supreme Court observed that it is often necessary to “begin by taking note of the elements a plaintiff must plead to state a claim.” 556 U.S. at 675, 679. For this reason, the Third Circuit has adopted a three-pronged approach. *See Santiago v. Warminster Twp.*, 629 F.3d 121, 130 n.7 (3d Cir. 2010); *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011).

they are sufficiently alleged to state a claim for relief. *Id.*; see also *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The third prong presents a context-specific inquiry that “draw[s] on [the court’s] experience and common sense.” *Id.* at 663-64; see also *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). As the Supreme Court instructed in *Iqbal*, “where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not ‘show[n]’ - ‘that the pleader is entitled to relief.’” *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

Pending before the court is Teva’s motion to dismiss for failure to state a claim and for judgment on the pleadings regarding Merck’s contributory infringement claim. Teva argues that Merck’s claim for contributory infringement must be dismissed because it is facially deficient under the *Iqbal/Twombly* pleading standard pursuant to Rule 12(b)(6), and because it is substantively deficient under Rule 12(c). For the following reasons, I recommend that the court dismiss Merck’s claim for contributory infringement as facially deficient under Rule 12(b)(6) and grant leave to amend the claim. I recommend that the court deny as moot Teva’s motion for judgment on the pleadings in light of the recommendation that Merck be given leave to amend the contributory infringement claim. Moreover, it would be improper to grant judgment on the pleadings at this stage of the proceedings because the court would have to accept as true Teva’s contentions about its proposed generic formulation prior to discovery.

To state a claim for contributory infringement, a plaintiff must plead the following: “(1) an offer to sell, sale, or import; (2) a component or material for use in a patented process constituting a material part of the invention; (3) knowledge by the defendant that the component is especially made or especially adapted for use in an infringement of such patents; and (4) the component is not a staple or article suitable for substantial noninfringing use.” See *Courtesy*

*Prods., L.L.C. v. Hamilton Beach Brands, Inc.*, C.A. No. 13-2012-SLR, --- F. Supp. 3d ----, 2014 WL 5780877, at \*3 (D. Del. Nov. 5, 2014) (citing *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010)). Applying this standard, a defendant “must know ‘that the combination for which [its] component was especially designed was both patented and infringing.’” *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067 (2011) (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964)). Moreover, the patentee must “plead facts that allow an inference that the components sold or offered for sale [by the alleged infringer] have no substantial non-infringing uses,” that is, uses that are “not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *In re Bill of Lading*, 681 F.3d 1323, 1337 (Fed. Cir. 2012) (internal citation omitted).

#### 1. Materiality

Teva first alleges that Merck’s cause of action for contributory infringement is facially deficient because it fails to specifically reference or make factual allegations regarding materiality. (D.I. 18 at 5) (“Thus, that ‘material part of the invention’ is not explicitly set out in no way renders Merck’s contributory infringement claim facially deficient.”) Merck relies on this court’s decision in *Netgear, Inc. v. Ruckus Wireless, Inc.*, which sets forth a five-pronged test for contributory infringement<sup>6</sup> that does not include a materiality requirement, in support of its argument that it sufficiently pleaded the elements of the claim. *See Netgear, Inc. v. Ruckus*

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<sup>6</sup> The test set forth in *Netgear* requires a plaintiff to plead that the defendant: “(1) had knowledge of the patent; (2) sold products especially made for infringing use; (3) had knowledge of the infringing use; (4) sold products with no substantial noninfringing use; and (5) directly infringed.” 852 F. Supp. 2d at 476-77. The requirements for a claim of contributory infringement set forth in *Netgear* differ from this court’s more recent decision in *Courtesy Products*, and do not identify the materiality requirement set forth in both the language of § 271(c) and recent case law such as *Courtesy Products*. *See Courtesy Prods.*, 2014 WL 5780877, at \*3.

*Wireless, Inc.*, 852 F. Supp. 2d 470, 476 (D. Del. 2012). However, Section 271(c) specifies that the allegedly infringing component must “constitut[e] a material part of the invention,” and recent case law from this court identifies the materiality requirement as an element of the analysis. 35 U.S.C. § 271(c); *see also Intel Corp. v. Future Link Sys., LLC*, C.A. No. 14-377-LPS, 2015 WL 649294, at \*8 (D. Del. Feb. 12, 2015); *Courtesy Prods., L.L.C. v. Hamilton Beach Brands, Inc.*, C.A. No. 13-2012-SLR, 2014 WL 5780877, at \*3 (D. Del. Nov. 5, 2014). This court requires that facts regarding all elements of a claim for contributory infringement must be pleaded. *See E.I. DuPont de Nemours & Co. v. Heraeus Holding GmbH*, C.A. No. 11-773-SLR-CJB, 2012 WL 4511258, at \*9 (D. Del. Sep. 28, 2012) (*see also Pragmatus AV, LLC v. Yahoo! Inc.*, C.A. No. 11-902-LPS-CJB, 2012 WL 6044793, at \*16 (D. Del. Nov. 13, 2012)). As a result, Merck’s cause of action for contributory infringement is facially deficient and should be dismissed on this basis.

## **2. Plausibility**

### **(a) Conversion theory**

Teva next contends that Merck’s contributory infringement allegations fail as a matter of law pursuant to *Twombly* and *Iqbal* because the complaint does not contain facts creating a plausible inference that the anhydrous mometasone furoate in Teva’s product will convert into mometasone furoate monohydrate over the course of its shelf life. (D.I. 9 at 14) Teva claims that the complaint is devoid of allegations referencing Merck’s conversion theory, showing that Teva had knowledge of such a conversion, or demonstrating that Teva’s product was made especially for use in the direct infringement of the ‘353 patent. (*Id.* at 15-16) In response, Merck argues that it is not required to plead specific factual details of its conversion theory at

this stage of the proceedings, and its claim for contributory infringement satisfies the pleading standard. (D.I. 18 at 6)

Pursuant to the Supreme Court's decision in *Iqbal*, the plausibility standard does not rise to a "probability requirement," but requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S. Ct. at 1949. Unsupported allegations, "bald assertions," and legal conclusions are rejected. *Id.*; see also *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) ("unsupported conclusions and unwarranted inferences" are insufficient); *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996) (allegations that are "self-evidently false" are rejected). Reviewing a complaint for plausibility is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 129 S. Ct. at 1950. As a result, well-pleaded facts that only infer the "mere possibility of misconduct" do not suffice under Rule 8(a)(2). *Id.*

Merck's cause of action for contributory infringement meets the plausibility requirement under *Twombly* and *Iqbal* at this stage of the proceedings. The complaint alleges that,

[o]n information and belief, Teva has or will have knowledge that if it were to receive approval from the FDA to market the product described in ANDA No. 205149 and made said product available for sale and/or use **during the proposed shelf life of the product, such activities would result in the sale and/or use of an infringing article** that is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '353 patent.

(D.I. 1 at ¶ 25) (emphasis added) Although Merck does not expressly identify in its complaint the conversion theory set forth in its briefing, the allegations of the complaint, taken as true, are plausible. To rule in favor of Teva on this issue, the court would have to credit Teva's interpretation of Merck's theory over the language of the complaint itself. The court declines to

engage in a fact finding analysis regarding the merits of Merck's theory of liability at the pleadings stage.

**(b) Substantial non-infringing use**

Additionally, Teva claims that the complaint does not state a plausible claim for contributory infringement because any use of Teva's product would constitute a substantial non-infringing use until the product allegedly converts into an infringing product. (D.I. 9 at 17) In response, Merck alleges that Teva's argument is premised on its assertion that its product does not directly infringe, which Teva improperly asks the court to accept as fact. (D.I. 18 at 9) Merck argues that it should not be required to plead a "null set" with specificity, and suggests that affirmatively pleading the absence of a substantial non-infringing use renders the claim plausible. (D.I. 18 at 10)

Taking all facts as true and drawing all inferences in favor of the non-moving party, Merck sufficiently alleges the absence of a substantial non-infringing use by affirmatively pleading the existence of no substantial non-infringing uses. The Federal Circuit has ruled that affirmatively pleading the absence of substantial non-infringing uses renders the claim plausible if the pleadings do not undermine that allegation. *See In re Bill of Lading*, 681 F.3d 1323, 1339 (Fed. Cir. 2012); *see also Driessen v. Sony Music Entm't*, 2013 WL 4501063, at \*2 (D. Utah Aug. 22, 2013) (denying motion to dismiss and concluding that a plaintiff is not required "to plead a null set under the plausibility standard of *Twombly* and *Iqbal*—that it is impossible to plead with specificity something that does not exist."). Merck alleges in its complaint that FDA approval of Teva's product "would result in the sale and/or use of an infringing article that is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '353 patent." (D.I. 1

at ¶ 25) Merck's affirmative allegation regarding the absence of substantial non-infringing uses is sufficient to properly plead a claim for contributory infringement in accordance with the Federal Circuit's ruling in *In re Bill of Lading*, and Merck need not aver a nullity.

**(c) Component**

Finally, Teva alleges that Merck's complaint does not plausibly identify a component of the invention because the facts recited by Merck in the complaint relate only to a claim of direct infringement. (D.I. 9 at 17) Specifically, Teva contends that the facts set forth in the complaint describe the sale of the invention itself, as opposed to a component of the invention. (*Id.*) In response, Merck alleges that the complaint identifies a form of mometasone furoate as the infringing component of the patented invention. (D.I. 18 at 7)

Paragraph 15 of the complaint states that, "[u]pon information and belief, Teva's proposed generic copy would contain mometasone furoate in such a form that would infringe the '353 patent." (D.I. 1 at ¶ 15) This paragraph sufficiently identifies mometasone furoate as the allegedly infringing component of the '353 invention. The court cannot appropriately make factual findings regarding whether anhydrous mometasone furoate is a component of mometasone furoate monohydrate at this stage of the proceedings.

**3. Leave to Amend**

In light of the foregoing analysis, I recommend that the court grant Merck leave to amend the complaint to remedy the deficiencies in Count II of the complaint with respect to the materiality requirement. Amendment is not futile under the facts of the present case. Teva's reliance on the District of New Jersey's decision in the Apotex case is not persuasive because the decision is not binding on this court, and it is distinguishable because it was decided on summary judgment after the conclusion of discovery. *Apotex*, 2012 WL 2263292, at \*10. Teva's

allegation that the accused product in the present matter has the same ingredient as the product in the Apotex case is factual in nature, and cannot properly be resolved by the court at the pleadings stage.

#### **4. Rule 12(c) Analysis**

A Rule 12(c) motion for judgment on the pleadings premised on the defense that the plaintiff has failed to state a claim is analyzed under the same standards as a Rule 12(b)(6) motion. *See Revell*, 598 F.3d at 134; *see also Money Suite Co.*, 2015 WL 436160 at \*1 n.1. Based on the foregoing analysis and the partial grant of its 12(b)(6) motion with leave to amend the complaint, Teva's motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) is denied as moot. At this stage of the proceedings, this court must accept Merck's allegations as true and cannot appropriately make factual findings regarding whether anhydrous mometasone furoate is a component of mometasone furoate monohydrate. Therefore, I recommend denial of Teva's Rule 12(c) motion because the court cannot appropriately make a judgment on the pleadings at this stage of the litigation.

#### **V. CONCLUSION**

For the foregoing reasons, I recommend that the court deny Teva's motion to transfer venue. (D.I. 12) I recommend that the court grant Teva's motion to dismiss, deny Teva's motion for judgment on the pleadings as moot, and grant Merck's request to amend the complaint within thirty (30) days of the date of this decision. (D.I. 8)


This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir.



2006). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The objections and responses to the objections are limited to ten (10) pages each.

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, [www.ded.uscourts.gov](http://www.ded.uscourts.gov).

Dated: July 1, 2015

  
Sherry R. Fallon  
UNITED STATES MAGISTRATE JUDGE