IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUMBERLAND PHARMACEUTICALS INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 12-618-LPS
	:	
INNOPHARMA, INC.,	:	
	:	
Defendant.	:	

MEMORANDUM ORDER

At Wilmington this 1st day of November, 2013, this matter coming before the Court upon the motion to dismiss (D.I. 7) plaintiff Cumberland Pharmaceuticals Inc.'s ("Plaintiff" or "Cumberland") Complaint (D.I. 1), filed by defendant InnoPharma, Inc. ("Defendant" or "InnoPharma"), and having considered the parties' papers submitted in connection therewith;

IT IS HEREBY ORDERED that Defendant's motion to dismiss (D.I. 7) is GRANTED for the reasons that follow.

1. This patent litigation action arises under the Hatch-Waxman Act. On April 4, 2012, InnoPharma notified Cumberland that it had filed an Abbreviated New Drug Application ("ANDA"), ANDA No. 200644, for a generic acetylcysteine formulation (for use in treatment of acetaminophen overdose patients). InnoPharma's letter contained a "Paragraph IV" certification contending that Cumberland's U.S. Patent No. 8,148,356, entitled "Acetylcysteine Composition and Uses Therefor" ("the '356 patent"), was invalid, unenforceable, or would not be infringed by InnoPharma's generic formulation. (*See* D.I. 1 ¶ 15; D.I. 8 at 5; D.I. 12 at 1)

2. On May 17, 2012, within 45 days of receipt of InnoPharma's notice letter, Cumberland filed suit for infringement, triggering an automatic 30-month stay of FDA approval

of InnoPharma's ANDA. (*See* D.I. 12 at 1-2; 21 U.S.C. § 355(j)(B)(iii)) Cumberland alleges infringement of the '356 patent (Count I) and seeks a declaratory judgment of infringement of the '356 patent (Count II).

3. On June 8, 2012, InnoPharma filed its motion to dismiss. InnoPharma moves to dismiss the Complaint under Fed. R. Civ. P. 12(b)(1) (lack of subject matter jurisdiction),[1] 12(b)(6) (failure to state a claim),[2] and 12(c) (for judgment on the pleadings).[3] According to Defendant, all claims of the patent-in-suit cover only a formulation "free from a chelating agent," yet the Complaint alleges that InnoPharma's product contains EDTA, which is "a chelating agent." (D.I. 8 at 1) Therefore, InnoPharma argues, its product "logically and legally cannot possibly infringe the asserted patent." (D.I. 8 at 1) Indeed, in InnoPharma's view, paragraph 16 of Cumberland's complaint states the opposite of a claim for patent infringement, alleging that

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[1]Rule12(b)(1) precludes actions where there is no reasonable basis to allege infringement. *See Astrazeneca Pharms. LP v. Apotex Corp.*, 2010 WL 5376310, at *1 (D. Del. Dec. 22, 2010) (dismissing Hatch-Waxman case on jurisdiction grounds where "generic manufacturer excludes from its ANDA all patented methods of use").

[2]Evaluating a motion to dismiss under Rule 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481–82 (3d Cir. 2000) (internal quotation marks omitted). However, "[t]o survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v.. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). While heightened fact pleading is not required, "enough facts to state a claim to relief that is plausible on its face" must be alleged. *Twombly*, 127 S. Ct. at 1974.

[3]The standard for deciding a Rule 12(c) motion for judgment on the pleadings is the same as the standard for reviewing a motion to dismiss brought pursuant to Rule 12(b)(6). *See Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 443 (D.N.J. 2006) (granting judgment on pleadings under Rule 12(c)).

"InnoPharma's product contains exactly the ingredient that the asserted patent forbids." (*Id.*; *see also* D.I. ¶ 16)

4. In opposing the motion, Plaintiff argues that InnoPharma improperly asks the Court to "prematurely construe terms and make factual findings that certainly are in dispute." (D.I. 12 at 10) Plaintiff contends that neither the infringement allegations contained in the Complaint, nor the patent-in-suit, are limited to an EDTA-free product. (*Id.* at 2) Cumberland cites to examples of cases in which courts have refused to construe disputed claim terms in connection with a motion to dismiss and have denied dismissal of patent infringement actions.

5. The Court agrees with InnoPharma that its "motion rests upon three facts, all drawn from the complaint and the asserted patent attached to the complaint," specifically:

> 1. All patent claims cover only formulations "free from a chelating agent."
>
> 2. EDTA is chelating agent.
>
> 3. InnoPharma's product "contains EDTA."

(D.I. 13 at 1)

a. Independent claim 1, which is representative of all of the claims of the patent-in-suit, covers only formulations that are "free from a chelating agent," as is seen below:

> A stable aqueous pharmaceutical composition comprising between 200 and 250 mg/mL acetylcysteine, wherein the composition is ***free from a chelating agent***, or pharmaceutically acceptable salts thereof, wherein said composition is in a suitable form for intravenous injection, wherein the pH of the composition is from 6 to 7, and wherein said composition is sealed in an airtight container comprising a fill volume of said composition and a headspace volume occupied by a pharmaceutically inert gas.

('356 patent at col. 9, lines 17-25) (emphasis added)[4] No formal process of claim construction is necessary in order to determine that "free from a chelating agent" means that a claimed composition may not include a chelating agent. Cumberland does not even suggest how "free from a chelating agent" could be construed to cover a composition containing a chelating agent. Indeed, to the contrary, the patent explains that the inventor developed a composition distinct from a prior art formulation in that the "old" formulation contained a chelating agent while the "new" formulation does not. (*See, e.g.,* '356 patent, Abstract ("This invention relates to novel acetylcysteine compositions in solution, comprising acetylcysteine and which are substantially free of metal chelating agents, such as EDTA."); *id.*, Summary of the Invention, col. 2, lines 45-50 ("It has been surprisingly found that an aqueous composition containing acetylcysteine, sterilized water, and a pH-adjusting agent, is stable without the addition of a chelating agent. Thus, the present invention relates to a solution containing acetylcysteine, which is substantially free of chelating agents.")) Likewise, the Complaint explains that Cumberland moved from an "old formulation" containing EDTA to a "new formulation" that does not. (*See* D.I. 1 ¶ 12 ("Contrary to the expectations and teaching in the field, Cumberland was successful in developing a new formulation that contained no EDTA or any other chelating agent yet offered surprisingly good stability."); *id.* at ¶¶ 9-14)[5]

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[4]Cumberland's claims are, obviously, based on the '356 patent, which is attached to the Complaint. It is appropriate for the Court to consider the '356 patent for purposes of evaluating the pending motion. *See, e.g.*, Fed. R. Civ. P. 10(c).

[5]Cumberland insists, in a conclusory manner, that "neither the infringement allegations in the Complaint nor the patent-in-suit is limited to an EDTA-free product." (D.I. 12 at 2) To the extent Cumberland means to suggest that its patent is not limited to products free of a chelating agent, Cumberland identifies no basis for such a contention. The Court agrees with InnoPharma that the patent contains "no claim that ***allows*** a chelating agent." (D.I. 13 at 3)

b. Plaintiff's Complaint alleges that the ingredient EDTA is an example of a "chelating agent." (*Id.* at ¶ 12) Additionally, the '356 patent identifies EDTA as an example of a class of compounds called chelating agents. ('356 patent at col. 4 lines 7-16) In fact, the patent identifies EDTA as a "widely used" example of a chelating agent. (*Id.*)

c. The Complaint alleges: "[o]n information and belief, InnoPharma's proposed acetylcysteine product contains EDTA." (D.I. 1 at ¶ 16) The Court must accept this well-pleaded factual allegation as true.

d. It follows from the foregoing that InnoPharma's ANDA does not infringe any claim of the '356 patent.

6. Cumberland's attempts to avoid this conclusion are unavailing. No claim construction is required. Nor is there anything in any of the precedents relied on by Cumberland that provides any persuasive reason for allowing this case to proceed to discovery. Infringement under the doctrine of equivalents is unavailable because a finding of infringement would vitiate the "free from a chelating agent" claim limitation. Finally, even assuming that the Complaint satisfies the notice pleading requirements discussed in *Phonometrics, Inc. v. Hospitality Franchise Sys., Inc.*, 203 F.3d 790, 794 (Fed. Cir. 2000) (per curiam) (reversing dismissal of patent infringement case where complaint met notice pleading requirements), that does not preclude dismissal, given the Complaint's failure (nonetheless) to state a claim for which relief may be granted, for the reasons already provided.

Accordingly, InnoPharma's motion (D.I. 7) is GRANTED. Cumberland's Complaint is DISMISSED. The Clerk of Court is directed to CLOSE this case.

Wilmington, Delaware

UNITED STATES DISTRICT JUDGE