IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI INC. AND ANDRX LABS, L.L.C., *Plaintiffs*, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC., *Defendants*.	)	C.A. No. 1:17-cv-00072-MSG

PLAINTIFFS' BRIEF IN SUPPORT OF ITS MOTION TO DISMISS AUROBINDO PHARMA LTD.'S AND AUROBINDO PHARMA USA INC.'S COUNTERCLAIMS

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NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs and Counterclaim-Defendants Shionogi Inc. and Andrx Labs, L.L.C. ("Shionogi" and "Andrx," collectively referred to herein as "Plaintiffs") filed a complaint for patent infringement of U.S. Patent Nos. 6,790,459 ("the '459 Patent") and 6,866,866 ("the '866 Patent") (collectively, the "Patents-in-Suit") against Defendants and Counterclaim-Plaintiffs Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively "Aurobindo" or "Defendants") on January 25, 2017. (D.I. 1 at 1.)

On July 24, 2017, Aurobindo filed its Answer and Affirmative Defenses to Plaintiffs' Complaint. (D.I. 9 at 1.) Aurobindo's Answer and Affirmative Defenses also allegedly asserted counterclaims seeking declaratory judgment of invalidity of the '459 Patent and the '866 Patent, and declaratory judgment of noninfringement of the '459 Patent. (*Id.* at 13-15.) Plaintiffs now respectfully move to dismiss Aurobindo's counterclaims, pursuant to Fed. R. Civ. P. 12(b)(6), for failure to state a claim upon which relief can be granted.

SUMMARY OF ARGUMENT

The Supreme Court has held that for a pleading to properly state a claim, it must provide more than "labels and conclusions," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and must instead provide "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face,'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). District courts have held that this pleading standard applies to counterclaims for declaratory judgment of patent invalidity and noninfringement. *See, e.g.*, *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013); *Princeton Dig. Image Corp. v. Konami Dig. Entm't Inc.*, No. 12-cv-1461-LPS-CJB, 2017 WL 239326, at *5 (D. Del. Jan. 19, 2017).

Aurobindo's counterclaims fail to satisfy the *Twombly* and *Iqbal* standard. *First*, Aurobindo's counterclaims for declaratory judgment of invalidity of the '459 and '866 Patents solely consist of legal conclusions, with no factual support, and simply cite sections of the Patent Act. *Second*, Aurobindo's counterclaim for declaratory judgment of noninfringement of the '459 patent amounts to nothing more than a denial of infringement without alleging facts to support a plausible claim of noninfringement.

STATEMENT OF FACTS

Plaintiffs and Counterclaim-Defendants Shionogi and Andrx filed a complaint for patent infringement against Defendant and Counterclaim-Plaintiff Aurobindo. (D.I. 1 at 1.) The complaint related to Abbreviated New Drug Application ("ANDA") No. 20-9694 filed by Aurobindo Pharma USA seeking approval to engage in the commercial manufacture, use or sale of Metformin Extended Release 500 mg and 1000 mg Tablets, generic versions of Shionogi's FORTAMET® Tablets, prior to the expiration of the Patents-in-Suit. (*Id.*)

On July 24, 2017, Aurobindo filed its Answer and Affirmative Defenses to Plaintiffs' Complaint. (D.I. 9 at 1.) Aurobindo admitted, *inter alia*, that it

> submitted ANDA No. 20-9694 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale of generic Metformin Extended Release oral tablets, 500 mg and 1000 mg, and that ANDA No. 20-9694 contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for U.S. Patent Nos. ("the '459 Patent") and 6,866,866 ("the '866 Patent"). Aurobindo further admits that ANDA No.20-9694 6 [sic] identifies FORTAMET® oral tablets, 500 mg and 1000 mg, as the Reference Listed Drug.

(*Id.* at 1-2.)

Aurobindo's Answer and Affirmative Defenses also asserted counterclaims seeking declaratory judgment of invalidity of the '459 Patent and the '866 Patent, and declaratory judgment of noninfringement of the '459 Patent. (*Id.* at 13-15.) In support of its First Claim for

Relief, a counterclaim seeking declaratory judgment of invalidity of the '459 Patent, Aurobindo simply alleged that "[t]he '459 patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U .S. [sic[1]] Patent Code, including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116." (*Id.* at 13.) Similarly, regarding its Third Claim for Relief, a counterclaim seeking declaratory judgment of invalidity of the '866 Patent, Aurobindo only alleged that "Counterclaim-Plaintiffs deny infringement of the '866 patent and allege that the '866 patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116." (*Id.* at 14-15.) Finally, with respect to its Second Claim for Relief, a counterclaim seeking declaratory judgment of non-infringement of the '459 Patent, Aurobindo merely alleged that "[t]he manufacture, use, sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 20-9694 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly or indirectly, any valid or enforceable claim of the '459 patent." (*Id.* at 14.)

ARGUMENT

A. *Twombly* and *Iqbal* Define the Pleading Standard for Invalidity and Non-Infringement Counterclaims

Rule 8 requires that "[a] pleading that states a claim for relief 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), so as to "give the defendant fair notice of what the . . . claim is *and the grounds upon which it rests*." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (emphasis added) (internal quotation marks and citation omitted). Thus, the Supreme Court has held that the Rule 8

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[1] Plaintiffs have corrected typographical errors present in the original in our subsequent quotations from Aurobindo's counterclaims.

pleading standard "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 557). Rather, Rule 8 calls for "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face[.]' . . . A claim has facial plausibility when [the pleaded] factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Twombly*, 550 U.S. at 570).

Multiple courts in this district have faithfully applied the Supreme Court's *Twombly* and *Iqbal* pleading standard to counterclaims for declaratory judgment of invalidity. In *Senju Pharmaceutical Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013), the court "conclude[d] that the pleading standards set forth in *Twombly* and *Iqbal* apply to counterclaims of invalidity." *Senju* rejected the oft-cited argument that the heightened pleading standard would be inequitable given Form 18's lower pleading standard, holding that, "[m]ost significantly, the fact that Form 18 (rather than *Twombly* and *Iqbal*) remains the standard for pleading infringement claims is an insufficient justification for deviating from *Twombly* and *Iqbal* for pleading other causes of action." *Id.* at 303 (citing *In re Bill of Lading Transmission*, 681 F.3d 1323, 1336 (Fed. Cir. 2012) ("Form 18 should be strictly construed as measuring only the sufficiency of allegations of direct infringement. . . .")). And given the Supreme Court's express abrogation of Form 18 as a sufficient pleading device as of December 1, 2015,[2] there is no longer any doubt that the *Twombly* and *Iqbal* plausibility standard extends to invalidity counterclaims. *See also, e.g.*, *EMC Corp. v. Zerto, Inc.*, No. 12-cv-956-GMS, 2014 WL 3809365, at *2 (D. Del.

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[2] *See* Order Amending Fed. R. Civ. P. (April 29, 2015), https://www.supremecourt.gov/orders/courtorders/frcv15(update)_1823.pdf (abrogating the Appendix of Forms for all civil cases commenced after December 1, 2015).

July 31, 2014) ("[T]he court concurs with Judge Robinson's holding in *Senju*—'the pleading standards set forth in *Twombly* and *Iqbal* apply to counterclaims of invalidity.'" (citation omitted)); *Idenix Pharm., Inc. v. Gilead Scis., Inc.*, No. 13-cv-1987-LPS-CJB, 2014 WL 4222902, at *6 (D. Del. Aug. 25, 2014) ("For the reasons set out in *Senju* . . . the Court determines that Defendants' invalidity-related counterclaims are subject to the requirements of *Twombly* and *Iqbal*."), *report and recommendation adopted*, No. 13-cv-1987-LPS-CJB, D.I. 77 (D. Del. December 3, 2014).

Furthermore, the application of *Twombly* and *Iqbal* to invalidity counterclaims filed in this district is consistent with the course taken by other district courts around the country. *See, e.g., Tyco Fire Prods. LP v. Victaulic Co.*, 777 F. Supp. 2d 893, 898 (E.D. Pa. 2011) ("In the wake of *Twombly* and *Iqbal*, it is clear that a[ ] counterclaim must set forth sufficient facts to give rise to a plausible claim for relief."); *Xilinx, Inc. v. Invention Inv. Fund I LP*, No. C-11-0671, 2011 WL 3206686, at *6 (N.D. Cal. July 27, 2011) (holding that the court "will not accept 'wholly conclusory allegations' in a claim alleging patent invalidity, and that simply 'pleading the citation' to a section of the Patent Act is not sufficient").

Similarly, courts in this district have required counterclaims of noninfringement to satisfy the *Twombly* and *Iqbal* standard. In *Princeton Digital Image Corp. v. Konami Digital Entertainment Inc.*, for example, the court held that "[t]he *Twombly/Iqbal* standard should apply here to all aspects of the Second Counterclaim" alleging "no direct infringement." No. 12-cv-1461-LPS-CJB, 2017 WL 239326, at *5 (D. Del. Jan. 19, 2017), *report and recommendation*

adopted, No. 12-cv-1461-LPS-CJB, 2017 WL 1196642 (D. Del. Mar. 30, 2017).[3] *Accord PetEdge, Inc. v. Marketfleet Sourcing, Inc.*, No. 16-cv-12562-FDS, 2017 WL 2983086, at *3 (D. Mass. July 12, 2017) (holding that "where a defendant seeks to assert a viable counterclaim for non-infringement, it must do more than deny infringement; it must also plead sufficient facts to state a plausible claim for relief").

Given that *Twombly* and *Iqbal* admit of no exception for patent claims and the Supreme Court has now conclusively eliminated any lower pleading standard for patent infringement claims by abrogating Form 18, this Court should follow precedent from courts in this district and elsewhere and hold Aurobindo's counterclaims to the plausibility standard of *Twombly* and *Iqbal*.

B. Aurobindo's Invalidity Counterclaims Fail to Satisfy *Twombly/Iqbal*

Aurobindo's First and Third Claims for Relief, counterclaims for declaratory judgment of invalidity of the '459 and '866 Patents, respectively, do not provide fair notice of "the grounds upon which [they] rest," *Twombly*, 550 U.S. at 555, and fail to "plead[] factual content that allows the court to draw the reasonable inference that the [counterclaim-]defendant is liable for the misconduct alleged," *Iqbal*, 556 U.S. at 678. Instead, the sum and substance of Aurobindo's invalidity counterclaims are that the '459 and '866 Patents are "invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Code,

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[3] To the extent that some earlier cases held that counterclaims of no direct noninfringement need not satisfy *Twombly* and *Iqbal*, they premised that conclusion on the availability of Form 18 for plaintiffs pleading claims of infringement. *See Gradient Enters., Inc. v. Skype Techs. S.A.*, 932 F. Supp. 2d 447, 451 (W.D.N.Y. 2013) (reasoning that "[i]t would make no sense to allow a plaintiff to assert a claim of infringement by pleading only what is required by Form 18, but then to require a defendant seeking a declaration of noninfringement to go beyond that and plead more detailed facts showing that it has not infringed the patent in suit" but applying *Twombly* to counterclaims of invalidity and no indirect infringement). Those earlier cases are no longer persuasive due to the Supreme Court's subsequent abrogation of Form 18. *See supra* at 4 n.1; *PetEdge*, 2017 WL 2983086, at *3 n.3 ("Until recently, claims for direct non-infringement were sufficiently pleaded if they satisfied the skeletal requirements of Form 18 of the Federal Rules of Civil Procedure. But the Supreme Court abrogated Form 18 on December 1, 2015.").

including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116." (D.I. 9 at 13, 14-15.) If a "formulaic recitation of a cause of action's elements will not do," *Twombly*, 550 U.S. at 555, then certainly Aurobindo's meager statutory "labels and conclusions," *id.*, fall far short of what is required.

Courts facing similarly bare-bones and conclusory counterclaims have uniformly held that they do not satisfy *Twombly* and *Iqbal* because they are "mere legal conclusion[s], [with] no supporting facts, and cit[ing] [] broad provisions of Title 35 of the United States Code in support," *Tyco*, 777 F. Supp. 2d at 904. Specifically, Aurobindo's counterclaims do not "provide notice of what particular type of claims of invalidity are at issue, [and] also bolster those allegations with at least enough 'supporting factual allegations' to render the claims plausible." *Idenix Pharm.*, 2014 WL 4222902, at *6 (citation omitted).

In *Senju*, the court granted a motion to dismiss counterclaims which "aver[red] that the asserted claims of the patents-at-issue 'are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112,'" and "do not recite any factual allegations, except for party background and jurisdictional statements." *Senju Pharm.*, 921 F. Supp. 2d at 300. Likewise, in *EMC Corp.*, the court found that counterclaims stating that "'[o]ne or more claims . . . is invalid for failure to comply with the conditions for patentability specified by Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 101, 102, 103 and 112,' . . . do not contain sufficient factual matter to satisfy the pleading standards set forth in *Twombly* and *Iqbal*. Indeed, they are merely bare-bones legal conclusions devoid of any supporting factual allegations." 2014 WL 3809365, at *2. *See also Idenix Pharm.*, 2014 WL 4222902, at *6 (D. Del. Aug. 25, 2014) (dismissing counterclaims asserting that the "'claims of the [patent at issue] are invalid for failure to comply with one or more provisions of Title 35 of the United States Code related to

patentability, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112. . . .'"); *Xilinx*, 2011 WL 3206686, at *6 ("simply 'pleading the citation' to a section of the Patent Act is not sufficient").

Because Aurobindo's invalidity counterclaims contain nothing more than boilerplate legal conclusions akin to those found defective by other courts, do not identify particular types of invalidity contentions, and do not present any factual allegations to render those claims plausible, this Court should grant the motion to dismiss Aurobindo's First and Third Claims for Relief.

C. Aurobindo's Non-Infringement Counterclaim Fails to Satisfy *Twombly/Iqbal*

Aurobindo's Second Claim for Relief, a counterclaim for declaratory judgment of noninfringement of the '459 Patent, likewise fails to provide fair notice of the grounds of Aurobindo's claim. Aurobindo alleges that "[t]he manufacture, use, sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 20-9694 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly or indirectly, any valid or enforceable claim of the '459 patent." (D.I. 9 at 14.) As with its invalidity counterclaims, Aurobindo's noninfringement counterclaim is merely "labels and conclusions," devoid of supporting facts. *Twombly*, 550 U.S. at 555; *see also Tyco*, 777 F. Supp. 2d at 904.

Aurobindo's noninfringement counterclaim is as factually inadequate as counterclaims adjudged deficient in prior cases. In *Princeton Digital Image Corp.*, the district court granted a motion to dismiss a counterclaim of no direct infringement, agreeing that it was "merely a formulaic recitation of the elements of the claim [of noninfringement], without any supporting facts or even any identification of the products that are alleged not to infringe." 2017 WL 239326, at *5. The dismissed counterclaim alleged:

> 28. The allegations of Paragraphs 1-27 of the Counterclaims are incorporated by reference as if fully set forth herein.
>
> 29. Harmonix and EA have not infringed and are not infringing, either directly or indirectly, nor have the[y] contributed to or induced infringement by others, of any valid claim of the '129 patent, either literally or under the doctrine of equivalents.
>
> 30. Accordingly, Harmonix and EA are entitled to a declaratory judgment that they have not infringed and do not infringe the '129 patent.

Id. The district court found that that counterclaim "contain[s] no facts of any kind, let alone sufficient facts to make out a plausible claim." *Id.*; *see also PetEdge, Inc. v. Marketfleet Sourcing, Inc.*, No. 16-cv-12562-FDS, 2017 WL 2983086, at *3 (D. Mass. July 12, 2017) (dismissing counterclaim stating that "'Marketfleet has not infringed any valid and enforceable claim of the '236 patent, either literally or under the doctrine of equivalents, willfully or otherwise,' without further support" as it was "nothing more than a denial of infringement" and "fail[ed] to allege any facts to state a plausible claim for non-infringement"). So, too, is Aurobindo's conclusory noninfringement counterclaim wholly lacking in facts to support a plausible claim of noninfringement.[4]

The Court should dismiss Aurobindo's Second Claim for Relief because, aside from partially reciting the elements of the claim and denying infringement, Aurobindo has alleged no facts supporting a plausible claim of non-infringement.

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[4] Aurobindo does state that "[t]he '459 patent, which is implicated by Aurobindo's ANDA No. 20-9694, is listed in the Orange Book for Fortamet®, and Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing the '459 patent, which Counterclaim Defendants allege cover the product that is the subject of Aurobindo's ANDA No. 20-9694." (*See* D.I. 9 at 13, 14.) However, those statements made in support of declaratory judgment jurisdiction, at most, identify the "product[] that [is] alleged not to infringe," *Princeton Dig. Image Corp.*, 2017 WL 239326, at *5, but do not allege any facts supporting noninfringement (or invalidity).

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' motion to dismiss Aurobindo's counterclaims for failure to state a claim upon which relief can be granted.

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