IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,	)	
Plaintiffs,	)	C.A. No. 14-113-RGA
v.	)	
ELI LILLY AND COMPANY,	)	
Defendant.	)	

OPENING BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS DEFENDANT'S PATENT MISUSE AND INVALIDITY COUNTERCLAIMS

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Plaintiffs Sanofi-Aventis U.S. LLC ("Sanofi U.S.") and Sanofi-Aventis Deutschland GmbH ("Sanofi GmbH") (together, "Sanofi") submit this opening brief in support of their motion pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) to dismiss the patent misuse and invalidity declaratory judgment counterclaims of defendant Eli Lilly and Company ("Lilly").

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Sanofi brought this Hatch-Waxman action upon receiving notice that Lilly filed a 505(b)(2) New Drug Application ("NDA") seeking FDA approval to market a follow-on to Sanofi's insulin glargine product for the treatment of diabetes. Lilly's Answer includes five counterclaims, two of which fail as a matter of law and are the subject of this motion.

For its patent misuse counterclaim, Lilly simply asserts that Sanofi initiated a "baseless litigation" with "consequent harm to Lilly and other members of the public." That counterclaim fails under both Rule 12(b)(1) and Rule 12(b)(6). Because Lilly has agreed not to market its proposed follow-on product until at least February 2015, any current allegations of future anticompetitive effect are necessarily speculative, and there can be no declaratory judgment jurisdiction over such claim. It therefore should be dismissed for lack of subject matter jurisdiction under Rule 12(b)(1). In the alternative, Lilly's patent misuse counterclaim should be dismissed for failure to state a claim under Rule 12(b)(6) because Lilly's allegations are wholly conclusory, and utterly devoid of any supporting facts.

Lilly's invalidity counterclaim fails under Rule 12(b)(6). Lilly simply asserts that the patents-in-suit are invalid, without identifying any particular theory of invalidity, or alleging any supporting facts. Such a sweeping, conclusory allegation of invalidity falls far short of this Court's pleading requirements under *Twombly* and *Iqbal*, and the counterclaim should be dismissed.

II. STATEMENT OF FACTS

A. Sanofi's Lantus® and Lantus® SoloSTAR® Products

Sanofi U.S. is the holder of NDA No. 21-081 for an insulin glargine product, a long-acting insulin diabetes drug marketed under the trade names Lantus® and Lantus® SoloSTAR®. *See* Lilly's Answer and Counterclaims (D.I. 8), Counterclaims ¶ 9. The patented Lantus® SoloSTAR® product uses a pen device to provide for controlled administration of Sanofi's medication. *See generally*, D.I. 8, Ex. B.

Sanofi has listed seven patents in the Orange Book against Lantus® and Lantus® SoloSTAR®. U.S. Patent No. 5,656,722 ("'722 patent") relates to the active ingredient in Lantus®, insulin glargine; U.S. Patent Nos. 7,713,930 ("'930 patent") and 7,476,652 ("'652 patent") relate to the Lantus® formulation; and U.S. Patent Nos. 8,603,044 ("'044 patent"), 8,556,864 ("'864 patent"), 8,512,297 ("'297 patent"), and 7,918,833 ("'833 patent") relate to the Lantus® SoloSTAR® delivery device.[1]

B. Lilly's 505(b)(2) Filing and Patent Certifications

On or around December 18, 2013, FDA accepted for filing Lilly's 505(b)(2) NDA No. 205-692. Pursuant to that submission, Lilly seeks approval under section 505(b)(2) of the Food, Drug & Cosmetic Act ("FDCA")[2] to engage in the commercial manufacture, use, and sale of a

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[1] *See* Orange Book, "Lantus," *available at* https://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021081&TABLE1=OB_Rx (hereinafter "Orange Book Entry").

[2] Section 505(b)(2) NDA submissions are similar to ANDA (*i.e.*, § 505(j)) submissions in that both may rely on FDA findings of safety and effectiveness for approved drugs, and applicants for both types of submissions are required to certify to any patents listed for a reference drug in the Orange Book. *See* 21 U.S.C. § 355(b)(2). Unlike ANDA submissions, section 505(b)(2) NDA submissions must contain complete clinical showings of safety and effectiveness. They can, however, reference some studies that were not conducted by the applicant (in contrast to section 505(b)(1) NDA submissions). *Id.*

follow-on insulin glargine product (Lilly's "Proposed Product").[3] *See* D.I. 8, Answer ¶¶ 18-19.

Sanofi received Lilly's Paragraph IV Notice Letter on December 20, 2013, and an amended Notice Letter on January 27, 2014 (collectively, the "Notice Letters"). *See* D.I. 8, Answer ¶¶ 20-21, 23-24. Lilly's Notice Letters contain Paragraph IV certifications, asserting that six of Sanofi's seven Orange Book-listed patents—the '930, '652, '044, '864, '297, and '833 patents—are invalid, unenforceable, and would not be infringed by Lilly's Proposed Product. Notwithstanding the statutory requirement that a Paragraph IV Notice Letter must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent[s are] invalid," (21 U.S.C. § 355(b)(3)(D)), Lilly's Notice Letters and accompanying Detailed Statements do not contain bases for the alleged invalidity. Rather, Lilly simply states that it reserves its right to raise invalidity defenses.

Lilly did not make a Paragraph IV certification to the remaining Orange Book patent (the '722 patent), and instead, made a Paragraph III certification with respect to that patent. As a result of its Paragraph III certification, Lilly is prevented from entering the market with its Proposed Product until the pediatric exclusivity relating to the '722 patent concludes, in February 2015.[4] *See* 21 U.S.C. § 355(b)(2)(A)(iii); *id.* § 355a(b)(1)(B)(i).

Sanofi's receipt of Lilly's first Notice Letter triggered a 45-day window for Sanofi to commence a patent infringement suit or forfeit its statutory right to a stay, up to 30 months in duration, of any FDA approval of Lilly's Proposed Product. *See* 21 U.S.C. § 355(c)(3)(C).

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[3] Insulin is considered a "biologic" (biological product) rather than a small molecule drug. Most biologics are regulated under the Public Health Service Act, with follow-on biologics (*i.e.*, "biosimilars") subject to the terms of the Biologics Price Competition and Innovation Act. A handful of biologics, including insulin, are regulated under the FDCA. Accordingly, follow-on applications for insulin products are not submitted as "biosimilars."

[4] The '722 patent expires on August 12, 2014. The FDA has, however, granted pediatric exclusivity to Lantus®, which precludes FDA from approving Lilly's NDA for an additional six months. *See* Orange Book Entry.

The Notice Letters included an "Offer of Confidential Access" to Lilly's 505(b)(2) NDA. D.I. 8, Answer ¶ 25. On Friday, January 24, 2014, after numerous discussions and communications concerning the terms that should govern any such access, Lilly mailed Sanofi's counsel a 66-page excerpt from its NDA. *See* D.I. 8, Answer ¶¶ 26-27.

C. Sanofi's Patent Infringement Complaint

On January 30, 2014, approximately one week before the expiration of the 45-day period for bringing such suit, Sanofi commenced this action against Lilly pursuant to 21 U.S.C. § 355(c)(3)(C). Sanofi's Complaint alleges that Lilly's Proposed Product infringes four of the six Orange Book patents that were the subject of Lilly's Paragraph IV Certification: the '864, '044, '652, and '930 patents ("the patents-in-suit"). Complaint (D.I. 1), ¶¶ 30-45.

D. Lilly's Answer and Counterclaims

In addition to its Answer and Affirmative Defenses, Lilly served five counterclaims. One counterclaim seeks a declaration that Sanofi engaged in patent misuse:

> By reason of Sanofi's baseless litigation and/or attempt to expand the scope of the patents-in-suit, with consequent harm to Lilly and other members of the public, the patents-in-suit are unenforceable due to misuse.

D.I. 8, Counterclaims ¶ 63. Lilly does not make a single factual allegation with respect to an anticompetitive effect or economic harm relating to this suit.

Another counterclaim seeks a declaration that the patents-in-suit are invalid. Lilly baldly alleges:

> The claims of the '864, '044, '652, and '930 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including without limitation §§ 101, 102, 103, and/or 112, and/or under judicially-created doctrines of invalidity and unenforceability.

D.I. 8, Counterclaims ¶ 61. Neither this nor any of Lilly's other allegations specify which section or sections of Title 35 purportedly render the patents-in-suit invalid, or otherwise provide a substantive basis for Lilly's invalidity counterclaim.

III. APPLICABLE LEGAL STANDARDS

A. Dismissal Pursuant to Rule 12(b)(1) For Lack of Declaratory Judgment Jurisdiction

This Court can exercise declaratory judgment jurisdiction when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of *sufficient immediacy and reality* to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (emphasis added) (quotation marks and citation omitted); *see also Verance Corp. v. Digimarc Corp.*, No. 10-cv-831, 2011 WL 2182119, at *3 (D. Del. June 2, 2011). Moreover, a "justiciable Article III controversy requires the party instituting the action to have *standing* and the issue presented to the court *to be ripe*." *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1337 (Fed. Cir. 2007) (emphasis added); *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008). Standing to assert a claim for declaratory judgment requires allegations of an injury-in-fact that is "personal, concrete and particularized, and actual or imminent" and is "fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Teva*, 482 F.3d at 1337 (quotation marks and citation omitted); *see also Penn Mut. Life Ins. Co. v Barbara Glasser 2007 Ins. Trust*, No. 09-cv-677, 2010 WL 3023420, *3 (D. Del. July 30, 2010). A case or controversy is "ripe" for resolution if the issue "is entirely or substantially a question of law and postponing a decision would work a substantial hardship on the challenging party." *Teva*, 482 F.3d at 1337; *see also*

Penn Mut. Life Ins., 2010 WL 3023420, at *3 (a "controversy must be ripe for judicial adjudication, meaning that it cannot be 'nebulous or contingent'") (citation omitted).

B. Dismissal Pursuant to Rule 12(b)(6) For Failure to State a Claim

A pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order 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, 545 (2007) (quotation marks omitted); Fed. R. Civ. P. 8(a)(2); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009).

A claim should be dismissed under Federal Rule 12(b)(6) if, accepting all of the facts as true, the plaintiff has failed to state a plausible claim for relief. This involves a two-part analysis. "First, the factual and legal elements of a claim are separated," with the court accepting all well-pleaded facts as true, but disregarding any legal conclusions. *Bishop v. J.P. Morgan Chase & Co.*, No. 13-cv-001, 2013 WL 4007508, *2 (D. Del. Aug. 5, 2013) (Andrews, J.) (citing *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009)). Second, the court determines "whether the facts alleged in the [pleading] are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* (citing *Fowler*, 578 F.3d at 211); *see also Twombly*, 550 U.S. at 545 ("Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the [pleading's] allegations are true."). These principles apply to counterclaims as well as claims. *Internet Media Corp. v. Hearst Newspaper, LLC*, No. 10-cv-690, 2012 WL 3867165, at *2 (D. Del. Sept. 6, 2012) (Robinson, J.) (A "counterclaim must set forth sufficient facts to give rise to a plausible claim for relief.") (quotation marks and citation omitted). And this Court has specifically held that counterclaims for patent invalidity must meet this heightened pleading standard. *See Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297 (D. Del. 2013) (Robinson, J.).

Lilly's counterclaim for patent misuse must also meet the heightened pleading standards articulated in *Twombly* and *Iqbal*. *See, e.g., Gemcor II, LLC v. Electroimpact Inc.*, No. 11-cv-2520, 2012 WL 628199 (D. Kan. Feb. 27, 2012) (finding that the accused infringer "has provided no basis for this court to disregard the pleading standard" described in *Twombly* and *Iqbal* "for the patent misuse counterclaim"); *Rego-Fix AG v. Techniks, Inc.*, No. 10-cv-1188, 2011 WL 471370 (S.D. Ind. Feb. 2, 2011) (dismissing a patent misuse counterclaim alleging that the patent holder brought the present lawsuit in "bad faith" with "no proper claim for infringement" because, as confirmed by the Court in *Iqbal*, "[t]hreadbare recitals of the elements of a claim or defense do not suffice").

One unpublished decision that relaxed the pleading standards for a patent misuse counterclaim relied on reasoning that this Court has subsequently rejected. *See Bayer Cropscience AG v. Dow Agrosciences LLC*, No. 10-cv-1045, 2011 WL 6934557 (D. Del. Dec. 2011) (Bumb, J., sitting by designation). First, Judge Bumb found that *Twombly* and *Iqbal* "would unfairly impose a higher pleading requirement on patent defendants than on patent plaintiffs," *Bayer*, 2011 WL 6934557, at *5. However, in this Court's later *Senju Pharmaceutical* decision, Judge Robinson dismissed such concerns, clarifying that the lower pleading standards reflected in Form 18 accompanying the Federal Rules apply only to claims of direct infringement, and that otherwise, *Twombly* and *Iqbal* apply. *Senju Pharm.*, 921 F.Supp. 2d at 303 ("'Form 18 should be strictly construed as measuring only the sufficiency of allegations of direct infringement.'") (quoting *In re Bill of Lading Transmission*, 681 F.3d 1323, 1336 (Fed. Cir. 2012)); *see also Internet Media*, 2012 WL 3867165, at *2 (*Twombly* and *Iqbal* apply to counterclaims in Delaware actions). Second, *Senju Pharmaceutical* also dismissed any

concerns raised by Judge Bumb in the *Bayer* decision that the heightened pleading standard would bypass this Court's disclosure process. *See Senju Pharm.*, 921 F.Supp. 2d at 302-03.

IV. ARGUMENT

A. Lilly's Counterclaim of Patent Misuse Should be Dismissed Under Rule 12(b)(1), or in the Alternative, Rule 12(b)(6)

Lilly's patent misuse counterclaim fails as a matter of law because Lilly cannot establish (and did not even plead) one element of the claim—an anticompetitive effect. The doctrine of patent misuse precludes a patentee from "impermissibly broaden[ing] the physical or temporal scope of the patent grant . . . in a manner that has anticompetitive effects." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010). A claim for patent misuse requires (1) "a patentee's bad faith in alleging infringement," **and** (2) "an anticompetitive effect or purpose behind the allegation." *McKesson Info. Sol'ns, LLC v. Trizetto Group, Inc.*, No. 04-cv-1258, 2005 WL 914776, at *2 n.2 (D. Del. Apr. 20, 2005); *see also Princo*, 616 F.3d at 1328; *Eurand Inc. v. Mylan Pharm. Inc.*, No. 08-cv-889, 2009 WL 3172197 (D. Del. Oct. 1, 2009). Lilly has not pled, and cannot plead, the requisite anticompetitive effect for its misuse *counterclaim*.

1. Lilly's Counterclaim for Patent Misuse Should be Dismissed Under Rule 12(b)(1) Because There is no Anticompetitive Effect

Lilly's counterclaim for patent misuse simply alleges that "Sanofi's baseless litigation[5] and/or attempt to expand the scope of the patents-in-suit, with consequent harm to Lilly and other members of the public," renders "the patents-in-suit [] unenforceable due to misuse." D.I.

[5] Although the litigation is not "baseless," and was properly brought pursuant to the Hatch-Waxman Act, the allegation must be accepted for purposes of this motion. Significantly, however, even initiating a purportedly "baseless litigation" does not support a claim for patent misuse. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998) ("It is not patent misuse to bring suit to enforce patent rights not fraudulently obtained, nor is otherwise legal competition such behavior as to warrant creation of a new class of prohibited commercial conduct when patents are involved.").

8, Counterclaims ¶ 63. These allegations are wholly conclusory. Moreover, because Lilly filed a Paragraph III certification with respect to the '722 patent—precluding it from entering the market until February 2015 at the earliest—there can be no present anticompetitive effect. Even if Lilly is ultimately able to secure FDA approval for its Proposed Product, any future anticompetitive effect is still purely speculative. As a consequence, the Court does not have subject matter jurisdiction over this counterclaim. It is not ripe for review, and Lilly lacks standing to bring it. *MedImmune*, 549 U.S. at 128 n.8 ("The justiciability problem that arises, when the party seeking declaratory relief is himself preventing the complained-of-injury from occurring, can be described in terms of standing . . . or in terms of ripeness . . ."); *see also Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008).

Other courts have dismissed similar patent misuse counterclaims for these very reasons. *See Internet Pipeline, Inc. v. Aplifi, Inc.*, No. 10-cv-6089, 2011 WL 4528340, at *3 (E.D. Pa. Sept. 29, 2011) (finding no declaratory judgment jurisdiction where the possibility of a future controversy was "hypothetical and speculative"); *Broadcom Corp. v. Qualcomm Inc.*, No. 08-cv-1829, 2009 WL 684835, at *6 (S.D. Cal. Mar. 12, 2009) (dismissing declaratory judgment action of patent misuse where "the alleged injuries for which [declaratory judgment plaintiff] seeks relief are speculative"); *cf. Seaboard Int'l, Inc. v. Cameron Int'l Corp.*, No. 1:13-cv-00281-MLH-SKO, 2013 WL 3936889 (E.D. Cal. July 30, 2013) (dismissing counterclaim of patent misuse under Rule 12(b)(6) because the alleged anticompetitive effects were "too speculative"). Lilly's counterclaim of patent misuse is therefore premature at best and should be dismissed under Rule 12(b)(1).

2. In the Alternative, Lilly's Allegations of Patent Misuse Fail to State a Plausible Claim for Relief under *Twombly* and *Iqbal* and Should be Dismissed Under Rule 12(b)(6)

Even if the Court finds that it has subject matter jurisdiction over Lilly's counterclaim of patent misuse, Lilly nevertheless fails to satisfy the applicable pleading requirements and its counterclaim should be dismissed under Rule12(b)(6). The closest Lilly ever comes to referencing an anticompetitive effect is when it states that Sanofi's "baseless litigation and/or attempt to expand the scope of the patents-in-suit" have resulted in "consequent harm to Lilly and other members of the public." *See* D.I. 8, Counterclaims ¶ 63. However, such "[t]hreadbare recitals of the elements of the cause of action, supported by mere conclusory statements" are insufficient to satisfy the required pleading standards. *See Iqbal*, 556 U.S. at 663 (quotation marks and citation omitted).

Courts have dismissed pleadings with strikingly similar deficiencies. In *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, No. 04-cv-1966, 2004 WL 1872707 (S.D.N.Y. Aug. 14, 2004), the accused infringer—an ANDA applicant—asserted a counterclaim for patent misuse, alleging that the "Plaintiffs' action in asserting the[se] [] patents against [defendants] have had, and will have, an anti-competitive effect and in addition imposes an improper restraint on competition." 2004 WL 1872707, at *1 (quotation marks omitted). The court found that these allegations "fail[ed] to meet even the minimal requirements of notice pleading," as "[t]he defendants merely parrot the elements of a claim for patent misuse, without alleging general facts to support that claim." Because "[c]onclusory references to an 'anti-competitive effect' and 'improper restraint on competition'" fail to satisfy Rule 8(a), the counterclaim was dismissed. *Id*. at *1-2; *see also Seaboard*, 2013 WL 3936889, at *3 (dismissing accused infringer's counterclaim of patent misuse for "fail[ing] to sufficiently allege

that [the patentee's] actions have had an anticompetitive effect" because, *inter alia*, "the injury alleged . . . is too speculative").

B. Lilly's Allegation of Patent Invalidity Fails to Meet the Minimum Pleading Requirements of *Twombly* and *Iqbal* and the Invalidity Counterclaim Should be Dismissed Under Rule 12(b)(6)

Lilly's counterclaim of invalidity provides nothing more than unsubstantiated legal conclusions, and it, too, should be dismissed under Rule 12(b)(6). The sole allegation relating to invalidity is the sweeping assertion that the patents-in-suit:

> are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including without limitation §§ 101, 102, 103, and/or 112, and/or under judicially-created doctrines of invalidity and unenforceability.

D.I. 8, Counterclaims ¶ 61. Lilly's invalidity counterclaim does not provide *any* notice to Sanofi of which invalidity theories Lilly intends to assert, what prior art it intends to rely on, or what deficiencies it believes exist.

Citing *Twombly* and *Iqbal*, this Court routinely dismisses such bald counterclaims of invalidity. For example, the defendant in *Senju Pharmaceutical* counterclaimed in a Hatch-Waxman suit "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.'" 921 F. Supp. at 300. The court rejected defendant Apotex's argument that its invalidity defense was "not subject to the heightened pleading standard of *Twombly* and *Iqbal*," and dismissed the counterclaim, refusing to excuse the undeniably "insufficient pleadings." *Id*. at 302-03; *see also Internet Media*, 2012 WL 3867165, at *1 (dismissing counterclaim for invalidity, which alleged that "[t]he claims of the '835 patent are invalid for failing to comply with one or more of the requirements for patentability set forth

in Title 35 of the U.S. Code, including, but not limited to, §§ 101, 102, 103, and 112") (quotation marks omitted).

Lilly has twice failed to meet its obligations to divulge the bases of its assertion that the patents-in-suit are invalid. Its Paragraph IV Notice Letters are utterly silent, a far cry from the "detailed statement of the factual and legal basis" required by the Hatch-Waxman Act (21 U.S.C. § 355(b)(3)(C)). And Lilly's counterclaim merely lists a string of statutory section numbers, falling woefully short of the pleading standards dictated by *Twombly* and *Iqbal*. Neither the governing statute nor the governing case law permits Lilly to hide its theory. The counterclaim should be dismissed.

V. CONCLUSION

For the foregoing reasons, Sanofi respectfully requests that the Court dismiss Lilly's counterclaims of patent misuse and invalidity.

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