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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

IMMUNEX CORPORATION,

Plaintiff,

v.

SANOFI et al.,

Defendants.

Case No. 2:17-CV-2613-SJO (PLA)

IMMUNEX'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT

The Hon. S. James Otero
Hearing: June 26, 2017
Time: 10:00 am
Place: Courtroom 10C

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I. INTRODUCTION

The allegations in Immunex's Complaint are more than sufficient to state a claim of direct infringement. Defendants' arguments to the contrary seek to impose pleading requirements that go well beyond those articulated by the Supreme Court in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). The standard set forth in those cases requires a plaintiff to provide a defendant fair notice of its claim; in patent cases, that means including "allegations sufficient to permit the court to infer that the accused product infringes each element of at least one claim." *TeleSign Corp. v. Twilio, Inc.*, No. 16-cv-2106 PSG, 2016 WL 4703873, at *3 (C.D. Cal. Aug. 3, 2016) ("*TeleSign II*") (alterations omitted).[1] The Complaint does that and more. It specifically identifies Defendants' human anti-interleukin-4 receptor ("IL-4R") antibody, dupilumab,[2] as the accused product and alleges that dupilumab satisfies each of the limitations of claim 1 of U.S. Patent No. 8,679,487 (the "'487 Patent"). *See* Compl. ¶ 42. Nothing more is required under *Iqbal* and *Twombly*.

Although Defendants pretend to be surprised by Immunex's allegations, Defendants have long been preparing for this infringement dispute—first by initiating opposition proceedings involving the European counterpart to the '487 Patent in April 2016, then by filing a revocation action in the United Kingdom in September 2016, then by initiating a declaratory judgment complaint for non-infringement of the '487 Patent in March 2017, and finally by filing a petition for *inter partes* review of the '487 Patent at the U.S. Patent and Trademark Office ("PTO") about a week before launching dupilumab in the United States.[3] Equally

[1] Internal citations and quotation marks omitted unless otherwise specified.

[2] Immunex will refer to Dupixent® and its active ingredient dupilumab collectively as "dupilumab."

[3] Defendants voluntarily dismissed their complaint. *See Sanofi-Aventis U.S. LLC v. Amgen Inc.*, No. 1:17-cv-10465-NMG (D. Mass. May 1, 2017) (D.I. 36).

significantly, Defendants' statements in their motion to dismiss confirm that they fully understand Immunex's allegations. *See* Br. 1 ("Immunex contends that Defendants' breakthrough therapy Dupixent® falls within the scope of the '487 Patent. *That contention cannot be correct unless Dupixent® 'competes' with [12B5].*") (emphasis added). As these statements make clear, Defendants have "fair notice of what the claim [against them] is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. For that reason, the motion should be denied.

Defendants also argue that the Complaint does not set forth a factual basis for the assertion that dupilumab competes with 12B5, as required by claim 1.[4] But that argument is flawed. Although the *Iqbal/Twombly* standard requires a plaintiff to allege the "grounds upon which [its claim] rests," *id.*, a plaintiff need not prove the merits of its infringement claim in its Complaint, as Defendants appear to contend (Br. 10-11), *see Rosen v. Amazon.com, Inc.*, No. CV 14-2115 ABC, 2014 WL 12597073, at *1 (C.D. Cal. May 28, 2014) ("A motion under Rule 12(b)(6) is not the proper vehicle for seeking a ruling on the merits of claims."). Consistent with *Iqbal* and *Twombly*, Immunex has alleged that dupilumab meets all of the elements of at least one patent claim. The Court should thus permit the case to proceed to discovery. In any event, the Complaint goes above and beyond the *Iqbal*/*Twombly* standard by alleging additional factual matter to support Immunex's assertion that dupilumab competes with 12B5 for binding to IL-4R, *see* Compl. ¶¶ 35-41, an assertion that must be accepted as true at this stage. *Iqbal*, 556 U.S. at 679-80.

For these reasons, Immunex's patent infringement allegations readily satisfy the *Iqbal/Twombly* standard and Defendants' motion should be denied.

[4] As discussed below, Immunex's 12B5 antibody is a "reference antibody" recited in claim 1 of the '487 Patent. *See* Compl. ¶¶ 28-29; *see also* Br. 5.

II. FACTUAL BACKGROUND

Immunex is a biopharmaceutical company committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing, and delivering innovative human therapeutics. Compl. ¶ 3. Immunex is a pioneer in elucidating the complex signaling systems that regulate the human immune system and in developing strategies and therapeutics for treating inflammatory diseases. *Id.* Immunex was the first major biotechnology company to focus on the IL-4R signaling pathway and its role in such grievous illnesses as asthma and atopic dermatitis. Immunex's groundbreaking research in this area resulted in an intellectual property portfolio that includes the '487 Patent. *Id.* ¶¶ 24-27.

The '487 Patent discloses human monoclonal antibodies that bind to human IL-4R and inhibit the activity of interleukins-4 and -13 (IL-4 and IL-13). *Id.* ¶ 27. One of those antibodies is 12B5. *Id.* ¶ 28. Claim 1 of the '487 Patent recites "[a]n isolated human antibody that competes with a reference antibody for binding to human [IL-4R], wherein the light chain of said reference antibody comprises the amino acid sequences of SEQ ID NO:10 and the heavy chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:12." *Id.* ¶ 29. The '487 Patent discloses 12B5, an antibody with these sequences. *Id.* ¶ 28; *see also id.* Ex. B, col.43 ll.26-54 and cols.61-65. In other words, Claim 1 describes "[a]n isolated human antibody that competes with [12B5] for binding to human [IL-4R]." *See id.* ¶ 29.

On April 5, 2017, Immunex filed a complaint against Defendants alleging that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of its Dupixent® product (the active ingredient of which is dupilumab) infringes the '487 Patent. *See, e.g., id.* ¶¶ 1, 58; *see also supra* n.2. The Complaint alleges that "dupilumab is an isolated human antibody that competes with Immunex's 12B5 antibody for binding to human IL-4R, as claimed in Immunex's '487 Patent."

Compl. ¶ 42. Immunex further alleges that "dupilumab is an isolated human antibody that is reported to specifically block the IL-4/IL-13 signaling pathway by binding to IL-4R," thereby infringing additional claims of the '487 Patent. *Id.* ¶ 35.

Defendants' infringement of the '487 Patent has been willful as evidenced by Defendants' awareness of the '487 Patent. For example, the Complaint alleges that Defendant Regeneron relied on Immunex's 12B5 antibody during its own attempts to identify therapeutic anti-IL-4R antibodies. *Id.* ¶ 55. In addition, the Complaint alleges that Defendants Regeneron and Sanofi filed opposition proceedings at the European Patent Office ("EPO") in connection with the European counterpart of the '487 patent and a declaratory judgment action in the District of Massachusetts (which they have since dismissed). *See id.* ¶¶ 54-55; Lee Decl. Ex. 3 at 19; *Sanofi-Aventis U.S. LLC v. Amgen Inc.*, No. 1:17-cv-10465-NMG (D. Mass. May 1, 2017) (D.I. 36) (voluntary dismissal). Defendants also filed a petition for *inter partes* review challenging the validity of the '487 Patent in the PTO. *See* Declaration of Heather E. Takahashi in Support of Immunex's Motion to Dismiss Plaintiff's Complaint (hereinafter, "Takahashi Decl."), Decl. Ex. 1. Immunex seeks damages and attorney fees for Defendants' unlawful infringement of its patent.

III. DEFENDANTS' MOTION TO DISMISS SHOULD BE DENIED.

A. Legal Standard

"[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 677-78. A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. This pleading standard arises from two core principles: First, a complaint should "contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). Second, "the factual allegations . . . must plausibly suggest an entitlement to relief, such that it is not unfair to require the

opposing party to be subjected to the expense of discovery and continued litigation." *Id.* In assessing plausibility, the Court must accept "all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Rowe v. Educ. Credit Mgmt. Corp.*, 559 F.3d 1028, 1029-30 (9th Cir. 2009).

In evaluating a motion to dismiss in a patent action, the Court must look to the law of the regional circuit. *TeleSign Corp. v. Twilio, Inc.*, No. CV 154-3240 PSG, 2015 WL 12765482, at *2 (C.D. Cal. Oct. 16, 2015) ("*TeleSign I*") ("Although patent claims are normally governed by the law of the Federal Circuit, the rules for purely procedural matters, such as the Federal Rules of Civil Procedure, are governed by the law of the Ninth Circuit."). In patent infringement cases, it is well established that, to satisfy the *Iqbal/Twombly* standard, a plaintiff must specifically identify the accused product and then "include allegations sufficient to permit the court to infer that the accused product infringes each element of at least one claim." *Id.* at *3 (alterations omitted); *see also e.Digital Corp. v. iBaby Labs, Inc.*, No. 15-cv-05790 JST, 2016 WL 4427209, at *4 (N.D. Cal. Aug. 22, 2016) (explaining that a plaintiff can survive a motion to dismiss by "plausibly alleg[ing] that the accused products practice each of the limitations found in at least one asserted claim").[5] So long as the complaint includes those allegations, the defendant has "fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555.

[5] Before December 1, 2015, courts evaluated whether a patent infringement complaint "sufficiently pleaded a claim by comparing the allegations in the complaint with Form 18 of the Federal Rules of Civil Procedure." *e.Digital*, 2016 WL 4427209, at *2. Because a rule change removing Rule 18 took effect on December 1, 2015, most district courts—including the Central District of California—now apply the pleading standards set forth in *Iqbal* and *Twombly* in patent infringement cases. *See TeleSign*, 2016 WL 4703873, at *2. Accordingly, Immunex relies in this brief on case law that applies the *Iqbal/Twombly* standard.

B. Immunex Has Properly Alleged a Claim for Patent Infringement.

1. *The Complaint Alleges that Dupilumab Infringes Every Element of Claim 1 of the '487 Patent.*

The allegations in Immunex's Complaint are plainly sufficient to survive Defendants' motion to dismiss. Immunex has specifically identified Defendants' allegedly infringing product: dupilumab, "an isolated human antibody that is reported to specifically block the IL-4/IL-13 signaling pathway by binding to IL-4R." Compl. ¶ 35; *see TeleSign II*, 2016 WL 4703873, at *3. The Complaint then alleges that the "accused product infringes each element of at least one claim"—namely, claim 1—because "dupilumab is an isolated human antibody that competes with Immunex's 12B5 antibody for binding to human IL-4R, as claimed in Immunex's '487 Patent." Compl. ¶ 42; *see TeleSign II*, 2016 WL 4703873, at *3. These allegations, taken as true, readily satisfy the *Iqbal* and *Twombly* standard.

Immunex's allegations are analogous to patent infringement allegations the court found to be sufficient in *McAfee Enterprises, Inc. v. Yamaha Corp. of America*, No. CV 2:16-2562 BRO, 2016 WL 6920675, at *3 (C.D. Cal. June 24, 2016). There, the patent-in-suit "relate[d] generally to drum beat counters" and included one independent claim "requir[ing] a strike sensor, a strike counter, and a presenter that displays the number of drum strikes." *Id.* The plaintiff's amended complaint alleged that the defendant's accused product contained each of the elements recited in the independent claim; in other words, the defendant made, used, or sold drum kits comprising a strike sensor, a strike counter, and an audio count information presenter. *Id.* The amended complaint also identified the "accused product model numbers and the specific features of [those] products." *Id.* Taken together, the court said, "[t]hese factual allegations are sufficient to support a reasonable inference that [the defendant] is liable for infringement of the asserted claims." *Id.* The court accordingly denied the defendant's motion to dismiss.

Furthermore, Immunex's allegations go well beyond the allegations Defendant Regeneron recently pled in a patent infringement complaint in *Regeneron Pharmaceuticals, Inc. v. Merus B.V.*, No. 14-CV-1650 KBF, 2014 WL 2795461 (S.D.N.Y. June 19, 2014). There, Regeneron merely paraphrased the patent claim and stated, upon information and belief, that the defendant had made the claimed product. *See id.* at *4; Complaint, *Regeneron Pharm., Inc. v. Merus B.V.*, 1:14-cv-01650 KBF, 2014 WL 1315361, D.I. 1 at ¶¶ 22, 24 (S.D.N.Y. Mar. 11, 2014). Regeneron's complaint included no additional allegations to support Regeneron's infringement claim. *Id.* Nevertheless, on the strength of this allegation, Regeneron argued to the district court that it had adequately pleaded a claim for infringement. *See* Takahashi Decl. Ex. 2 (Regeneron's Opposition to Defendant Merus B.V.'s Motion To Dismiss) at 11-19.

The district court agreed. Applying the pleading standards set forth in *Iqbal* and *Twombly*, the court held that Regeneron had adequately alleged infringement, even though Regeneron did little more than allege that "Merus's conduct falls within the scope of [a] claim of its patent." *Regeneron Pharm.*, 2014 WL 2795461, at *3-4. Citing *Twombly*, the court noted that:

> [I]t is true, plaintiff has alleged relatively little about its claim. But, it has said enough. *It has alleged a specific patent and a specific product that allegedly infringes that patent by virtue of certain specific characteristics. . . . At this stage of the case, this allegation pleads a plausible claim for infringement.* Whether developments in the evidence will show non-infringement or some other defense is not a matter for this Court to consider at this preliminary stage.

Id. at 4 (emphasis added).

Despite Defendants' best efforts to obfuscate, the Complaint provides straightforward infringement allegations that give Defendants fair notice of Immunex's claims. *See Twombly*, 550 U.S. at 555. Defendants know precisely which of their products they will need to defend (dupilumab), and they know how dupilumab infringes independent claim 1 of the '487 Patent (it competes with 12B5 for binding to IL-4R). *See* Br. 1. That is all that is required.

2. *The Complaint Contains Sufficient Factual Matter to Support Its Allegation that Dupilumab Infringes the '487 Patent.*

Notwithstanding the clarity of Immunex's allegations, Defendants insist that the Complaint is deficient because "Immunex never alleges a factual basis for claiming that Dupixent® competes with the '487 Patent's reference antibody." *Id.* at 10. This argument is nothing more than a thinly veiled attempt to prematurely litigate the merits of this case at the pleading stage. Immunex need not prove its infringement case before discovery even begins. *See Rosen*, 2014 WL 12597073, at *1. To the extent Defendants contend that the Complaint must include sufficient "factual content [for the Court] to draw the reasonable inference that [Defendants are] liable" for infringement, *Iqbal*, 556 U.S. at 678, Immunex has easily carried that burden. The Complaint provides numerous allegations that, when taken as true, provide strong factual support for Immunex's infringement claim.

First, Immunex alleges that dupilumab "is reported to specifically block the IL-4/IL-13 signaling pathway by binding to IL-4R." Compl. ¶ 35. The Complaint states that "Defendants have taken the position [before the EPO] that *any* antibody that blocks binding of IL-4 to IL-4R also will compete with Immunex's 12B5 antibody for binding to IL-4R." *Id.* ¶ 41 (emphasis added). While Immunex does not agree with this blanket statement (and does not allege it as being true), Defendants' position before the EPO suggests that Defendants know that dupilumab competes with 12B5. Unless Defendants believed dupilumab would compete with 12B5 for binding to IL-4R, they could not have truthfully taken the position that all

anti-IL-4R antibodies that block binding of IL-4 to IL-4R also compete with 12B5. Defendants' actions—including filing opposition proceedings to the '487 Patent's European counterpart, a revocation action in the United Kingdom, a declaratory judgment action in Massachusetts, and a petition for *inter partes* review in the PTO—are further proof of Defendants' belief that dupilumab competes with 12B5 and infringes Immunex's patent claims. *Id.* ¶¶ 54-55.

Second, Immunex further provided a factual basis for infringement by including allegations addressing competition testing that Defendant Regeneron has done on its other anti-IL-4R antibodies. *Id.* ¶ 37. According to Regeneron's own patent,[6] Regeneron has tested 23 other antibodies it made against IL-4R, the same target as dupilumab, and *all 23 of those antibodies* compete with 12B5 for binding to IL-4R. *Id.* ¶¶ 37, 42; *see also* Takahashi Decl. Ex. 1 at 57 (conceding that Regeneron's '237 Patent "teaches that each of the 23 disclosed antibodies competes with MAb 12B5").

It is more than reasonable to infer from the facts set forth above that Regeneron has confirmed that dupilumab also competes with 12B5. Actual proof of infringement is not necessary at the pleading stage of litigation. *See Twombly*, 550 U.S. at 555-56. For now, all that Immunex was required to do was plausibly allege that Defendants' accused product dupilumab infringes at least one patent claim. *See Iqbal*, 556 U.S. at 678. There is no credible argument to the contrary.

[6] U.S. Patent No. 7,605,237 provides Regeneron's account of its competition experiment. The '237 Patent is part of the same family as and is wholly incorporated by reference in U.S. Patent No. 8,337,839, the patent that discloses dupilumab. *See* Compl. ¶¶ 34, 36-38.

3. *Immunex's Position in Its Complaint Is Consistent with Its Position Before the EPO and PTO.*

Defendants accuse Immunex of taking a position in this Court that is inconsistent with the positions it has taken at the EPO and the PTO. Br. 12-14. But Immunex's reference to Defendants' statements before the EPO does not in any way endorse the correctness of Defendants' position regarding the antibody science underlying their statements. Immunex stands by its position that it would be "error" to assume that all anti-IL-4R antibodies "necessarily compete for binding with the reference antibody." Lee Decl. Ex. 1 at 7. Immunex has previously stated and still believes that Defendants' "view that claim 1 covers all inhibitory human anti-human IL-4R antibodies" is "speculation and guesswork." Lee Decl. Ex. 3 at 22 ¶¶ 4.3-4.4.

The Complaint relies on Defendants' statements to the EPO for an entirely different purpose: to show that *Defendants* believe their antibody infringes the '487 Patent. Specifically, the Complaint alleges that dupilumab blocks binding of IL-4 to IL-4R—an allegation that Defendants have not contested in their motion—and alleges that "Defendants have taken the position . . . that any antibody that blocks binding of IL-4 to IL-4R also will compete with Immunex's 12B5 antibody for binding to IL-4R." Compl. ¶¶ 35, 41.

Defendants' judicial estoppel argument (Br. 12) therefore misses the mark because Immunex has not taken inconsistent positions. Immunex has simply drawn the logical conclusion that, based upon the publicly available information about dupilumab and the positions taken by the Defendants in the EPO, Defendants' anti-IL-4R antibody (dupilumab) competes for binding with 12B5. Immunex's position in this litigation therefore is entirely consistent with its positions in other fora.

If anyone should be estopped from asserting an inconsistent position, it is Defendants. Despite telling the EPO that all anti-IL-4R antibodies necessarily compete with 12B5 for binding, they now resist the conclusion that their anti-IL-4R

antibody competes with 12B5 for binding to IL-4R. It is thus Defendants, not Immunex, who "seek[] to have it both ways." *Id.*

C. Immunex Has Also Adequately Alleged Indirect Infringement, Willful Infringement, and Exceptionality.

Defendants claim that the allegations of indirect infringement, willful infringement, and exceptionality in the Complaint are also deficient because they lack the predicate allegation of direct infringement. *Id.* at 15-16. But this argument fails because Immunex has sufficiently pled its direct infringement claim. *See supra* III.B. Because Immunex has alleged the necessary predicate for the related claims, Defendants have provided no sound reason for their dismissal.

IV. CONCLUSION

Because Immunex's patent infringement allegations are proper under *Iqbal/Twombly*, Defendants' motion to dismiss should be denied.

Respectfully submitted,

DATED: June 5, 2017

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CERTIFICATE OF SERVICE

Pursuant to Rule 5-3 of the Local Civil Rules of the United States District Court for the Central District of California, I declare under penalty of perjury under the laws of the United States of America that on June 5, 2017, a true and correct copy of the above document was filed through the Court's Electronic Case Filing system and served by that system upon all counsel of record registered for the system and deemed to have consented to electronic service in the above-captioned case.

Executed on June 5, 2017, at Los Angeles, California.

/s/ Heather E. Takahashi
Heather E. Takahashi