UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Priority	____
Send	____
Enter	____
Closed	____
JS-5/JS-6	____
Scan Only	____

CASE NO.: **CV 17-02613 SJO (PLAx)** **DATE:** **June 21, 2017**

TITLE: **Immunex Corp. v. Sanofi et al.**

==========

PRESENT: THE HONORABLE S. JAMES OTERO, UNITED STATES DISTRICT JUDGE

Victor Paul Cruz Courtroom Clerk	Not Present Court Reporter
COUNSEL PRESENT FOR PLAINTIFF:	**COUNSEL PRESENT FOR DEFENDANTS:**
Not Present	Not Present

==========

PROCEEDINGS (in chambers): ORDER DENYING DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT UNDER FED. R. CIV. P. 12(b)(6) [Docket No. 33]

This matter is before the Court on Defendants Sanofi, Sanofi-Aventis U.S. LLC, Genzyme Corporation and Aventisub LLC (together, "Sanofi Group") and Regeneron Pharmaceuticals, Inc.'s ("Regeneron") (collectively, "Defendants") Motion to Dismiss Plaintiff's Complaint Under Fed. R. Civ. P. 12(b)(6) ("Motion"), filed May 26, 2017. Plaintiff Immunex Corporation ("Immunex" or "Plaintiff") opposed the Motion ("Opposition") on June 5, 2017, and Defendants replied ("Reply") on June 12, 2017. The Court found this matter suitable for disposition without oral argument and vacated the hearing set for June 26, 2017. *See* Fed. R. Civ. P. 78(b). For the following reasons, the Court **DENIES** Defendants' Motion.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Allegations and Causes of Action

Immunex initiated the instant patent infringement action on April 5, 2017 by filing a Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement ("Complaint") against Defendants, in which it alleges the following. (*See* Compl., ECF No. 1.) Immunex, which became a wholly owned subsidiary of Amgen Inc. in July 2002, is a biopharmaceutical company "committed to developing immune system science to protect human health." (Compl. ¶¶ 2-3.) Sanofi, its three wholly owned subsidiaries, Sanofi-Aventis U.S. LLC, Genzyme Corporation, and Aventisub LLC, and Regeneron are each in the business of developing, formulating, manufacturing, marketing, and selling pharmaceutical drug products and/or biologic products, including antibody products. (Compl. ¶¶ 4-11, 16, 20.)

On March 25, 2014, United States Patent No. 8,679,487 (the "'487 Patent"), entitled "Anti-Interleukin-4 Receptor Antibodies," issued to Immunex as assignee of the named inventors Richard J. Armitage, Jose Carlos Escobar, and Arvia E. Morris. (Compl. ¶ 24.) The '487 is a member of a family of related patents directed to antibodies to IL-4R that date back to May 1,

2001. (*See generally* Compl., Ex. B ("'487 Patent").) The claims of the '487 Patent are directed to human antibodies that bind to human anti-interleukin-4-receptor-alpha ("IL-4R"), thereby blocking the actions of the interleukin-4 ("IL-4") and interleukin-13 ("IL-13") signaling molecules, which play a role in inflammatory conditions such as allergy, asthma, and dermatitis. (Compl. ¶¶ 1, 26, Ex. B ("'487 Patent") col. 2:19-33.) Thus, the '487 Patent discloses human monoclonal antibodies that bind to human IL-4R and inhibit the activity of IL-4 and IL-13, one of which is the human monoclonal antibody designated **12B5**. (Compl. ¶¶ 27-28.) The '487 Patent discloses that the amino acid sequences for the light chain variable region and the heavy chain variable region of the 12B5 antibody are "SEQ ID NO:10" and "SEQ ID NO:12," respectively, and presents these sequences in columns 61 through 65. (Compl. ¶ 28; '487 Patent cols. 45-54.) Claim 1, the sole independent claim of the '487 Patent, recites, in full, with certain words bolded for emphasis:

> An **isolated human antibody** that **competes** with a reference antibody **for binding** to human IL-4 interleukin-4 **(IL-4) receptor**, wherein the light chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:10 and the heavy chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:12.

('487 Patent col. 71:25-31 [emphasis added].)

Since at least November 2007, Sanofi Group and Regeneron have collaborated on the research and development for antibody product candidates for commercial use in the United States upon FDA licensure, with the various parties entering into joint development agreements in 2007 and 2009. (Compl. ¶¶ 30-33.) Pursuant to these agreements, and subsequent to the research efforts that led to Immunex's '487 Patent, Sanofi Group and Regeneron initiated development of a fully human monoclonal antibody product candidate against IL-4R called **dupilumab** (also called "H4H098P") as a treatment for atopic dermatitis and other atopic or allergic disorders, with the goal of launching it for ale in the United States and worldwide marketplace. (Compl. ¶¶ 34, 43.) More particularly, dupilumab is an isolated human antibody that is reported to specifically block the IL-4/IL-13 signaling pathway by binding to IL-4R. (Compl. ¶ 34.)

On or about September 26, 2016, Defendants submitted a Biologics License Application ("BLA") for dupilumab to the United States Food and Drug Administration ("FDA"), a necessary prerequisite to offering dupilumab for asle in the United States, for Priority Review. (Compl. ¶ 44.) On March 28, 2017, the FDA approved Defendants' BLA for the use of dupilumab for the treatment of moderate-to-severe atopic dermatitis, and Defendants thereafter began marketing and selling dupilumab in the United States under the trade name **Dupixent**. (Compl. ¶¶ 45-46.)
Based on these and other allegations detailed below, Immunex asserts causes of action for infringement of the '487 Patent and declaratory judgment of infringement of the '487 Patent based on Defendants' use, offering for sale, sale, or importation of Dupixent in the United States. (*See* Compl. ¶¶ 57-65.) Immunex, "[u]pon information and belief," alleges Regeneron, in its attempts to identify therapeutic anti-IL-4R antibodies, employed Immunex's patented 12B5 antibody.

(Compl. ¶ 36.) In support of this contention, Immunex cites first to the alleged fact that U.S. Patent Nos. 7,605,237 (the "'237 Patent") and 8,337,839 (the "'839 Patent"), both assigned to Regeneron, which state that a control antibody used to test the binding of its antibodies was the "fully human anti-IL-4R antibody" with sequences "SEQ ID NOs: 10 and 12" from Immunex's U.S. Patent No. 8,186,809. (Compl. ¶ 36.) Immunex further alleges that Example 2 of each of these patents "discloses a real-time biosensor surface plasmon resonance assay (BIAcore™ 2000) to assess the binding affinity of selected human antibodies to human IL-4R that were generated by Regeneron." (Compl. ¶¶ 37-38.) "In that assay, a fully human anti-IL-4R antibody with the same heavy chain and light chain variable region sequences associated with Immunex's 12B5 antibody was used as the control antibody." (Compl. ¶¶ 37-38.) "In addition, Example 6 and Figure 1A of Regeneron's '237 [P]atent disclose a sequential binding assay in which a control antibody with the same heavy chain and light chain variable region sequences associated with Immunex's 12B5 antibody was shown to block binding to human IL-4R by selected human antibodies to human IL-4R." (Compl. ¶ 37.) Moreover, Sanofi, directly or indirectly through its affiliates and agents, directed an outside contractor, Evitria AG, located in Switzerland, "to synthesize and purify Immunex's 12B5 antibody" and directed a second outside contractor, Syd Labs, Inc., located in Massachusetts, "to test Immunex's 12B5 antibody for binding to a cell that expresses human IL-4R." (Compl. ¶¶ 38-39.) Finally, and most relevant to the instant Motion, Immunex alleges "Defendants have taken the position in opposition proceedings to Immunex's European Patent 2292665 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. ¶ 41 [emphasis added].) Based on these allegations, Immunex alleges dupilumab is an isolated human antibody that competes with 12B5 for binding to human IL-4R, as claimed in the '487 Patent. (Compl. ¶ 42.)

B. Requests for Judicial Notice

Both sides ask the Court to take judicial notice of certain publicly available documents related to the '487 Patent and its European counterpart, European Patent No. 2,292,665 (the "European counterpart"). (*See* Defs.' Req. for Judicial Notice in Supp. Mot. ("RJN"), ECF No. 34; Decl. Heather E. Takahashi in Supp. Opp'n ("Takahashi Decl."), ECF No. 45-1.) Specifically, Defendants ask the Court to consider (1) Immunex's November 11, 2011 and August 13, 2013 Responses to Office Action from the prosecution history of the '487 Patent; (2) the USPTO's November 5, 2013 Notice of Allowance for the '487 Patent; and (3) Immunex's November 23, 2016 submission to the European Patent Office in the Opposition Proceedings of the European Counterpart entitled "Reply of the patent proprietor to the notice(s) of opposition." (Decl. Phillip Lee in Supp. Mot. and RJN ("Lee Decl."), Exs. 1-4.) Immunex, meanwhile, asks the Court to the consider (1) excerpts of *Inter Partes* Review Petition No. IPR2017-01129, filed by Defendants before the Patent Trial and Appeal Board ("PTAB") at the USPTO; and (2) a copy of "Plaintiff Regeneron Pharmaceuticals, Inc.'s Opposition to Defendant Merus B.V.'s Motion To Dismiss," obtained from the docket in *Regeneron Pharm. Inc. v. Merus B.V.*, 1:14-cv-01650-KBF (S.D.N.Y. Mar. 11, 2014) as document number 48. (Takahashi Decl., Exs. 1-2.)

Neither side opposes the other's request, and the Court finds it appropriate to consider these documents either pursuant to Rule 201 of the Federal Rules of Evidence in light of the judicial, quasi-judicial, or administrative nature of the documents or under the doctrine of incorporation by reference. The Court accordingly **GRANTS** both sides' requests.

II. DISCUSSION

In their Motion, Defendants ask the Court to dismiss Immunex's Complaint with leave to amend, arguing it fails to properly allege that Dupixent "competes" with a reference antibody and further submitting that Immunex is "estopped from arguing, by inference, to the contrary" in light of previous positions it took before both the United States Patent and Trademark Office ("USPTO") and its European counterpart, the European Patent Office. (Mot. 1-2, ECF No. 33.) According to Defendants, Immunex claims to satisfy the "competes" limitation by making two allegations: (1) Dupixent blocks IL-4 from binding to its receptor IL-4R; and (2) in an European Office Proceeding ("EOP"), Defendants "supposedly argued that Immunex's sweeping claims are invalid because any blocking antibody to IL-4R necessarily 'competes' with a reference antibody." (Mot. 5 [citing Compl. ¶¶ 35, 41-42].)

In raising these arguments, Defendants point to several pieces of evidence. First, they note that Immunex, in the same EOP, (1) "defended validity of its patent by expressly contending that the 'competes' limitation is not inherently present in all antibodies to IL-4R," characterizing Defendants' position as "speculation and guesswork [that] cannot lead to a finding of direct and unambiguous disclosure of the antibody of the claims;" (2) contended that Defendants' invalidity argument was "not backed up by any evidence whatsoever;" and (3) submitted "that the antibody of the claim is not merely inhibitory[, but] must also compete for binding with a reference IgG1 antibody." (Mot. 5 [citing Lee Decl., Ex. 3].) They next point to Immunex's similar submission to the USPTO during prosecution of the '487 Patent that antibodies can block the same receptor without "competing" with one another, stating "it is legal error to make such an assumption without evidence; it is a factual error as well because there are examples of antibodies that bind to the same small target without competing with each other." (Mot. 5-6 [citing Lee Decl., Ex. 1 at 7].) Finally, they note the examiner of the '487 Patent was persuaded by Immunex's argument raised in response to an invalidity challenge that not all antibodies to a common target will necessarily compete for binding to that target because the antibodies might bind to different physical locations on the target by citing to certain examples in U.S. Patent No. 7,807,159. (Mot. 6-7 [citing Lee Decl., Ex. 1 at 6; Ex. 2 at 16-17].)

Immunex responds by arguing that Defendants 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). (Opp'n 1, ECF No. 45.) According to Immunex, the allegations in the Complaint pass muster under these authorities because the Complaint "specifically identifies Defendants' [IL-4R] antibody, dupilumab[ ], as the accused product and

alleges that dupilumab satisfies each of the limitations of claim 1 of the ['487 Patent]." (Mot. 1.) Immunex also asks the Court to reject Defendants implied submission that the Compalint fails to provide them with "fair notice of what the claim [against them] is and the grounds upon which it rests" in light of their own litigation efforts. (Opp'n 1-2.) Finally, Immunex argues that because it "has alleged that dupilumab meets all of the elements of at least one patent claim," the Court should deny Defendants' request that Immunex "prove the merits of its infringement claim in its Complaint." (Opp'n 2.)

A. Legal Standard Governing Motions to Dismiss

Federal Rule of Civil Procedure 12 ("Rule 12"), which provides for dismissal of a plaintiff's cause of action for "failure to state a claim on which relief can be granted," *see* Fed. R. Civ. P. 12(b)(6), must be read in conjunction with Rules 8(a) and 9(b), which impose pleading standards. *See Ileto v. Glock Inc.*, 349 F.3d 1191, 1199-1200 (9th Cir. 2003). Rule 8(a) 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). Although the pleader is not required to plead "detailed factual allegations" under Rule 8, this standard demands "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Pleadings that contain nothing more than legal conclusions or "a formulaic recitation of the elements of a cause of action" are insufficient. *Id.* (citation and quotation marks omitted). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Where a complaint pleads sufficient facts "to raise a right to relief above the speculative level," a court may not dismiss the complaint under Rule 12(b)(6). *Twombly*, 550 U.S. at 555.

Since December 1, 2015, "allegations of direct infringement are now subject to the pleading standards established by *Twombly* and *Iqbal* requiring plaintiffs to demonstrate a 'plausible claim for relief.'"[1] *Atlas IP LLC v. Pac. Gas & Elec. Co.*, No. 15-cv-05469-EDL, 2016 WL 1719545, at *2 (N.D. Cal. Mar. 9, 2016). Thus, "[i]n patent cases, 'with regard to [a] direct infringement claim, [a] court need not accept as true conclusory legal allegations cast in the form of factual allegations.'" *Apollo Fin., LLC v. Cisco Sys., Inc.*, — F. Supp. 3d —, 2016 WL 3234518, at *2 (C.D. Cal. June 7, 2016) (quoting *Medsquire LLC v. Spring Med. Sys. Inc.*, No. 2:11-cv-04504-JHN-PLA, 2011 WL 4101093, at *2 (C.D. Cal. Aug. 31, 2011)).

[1] December 1, 2015 is the effective date of the Judicial Conference's abrogation of Rule 84, which provided that "[t]he forms in the Appendix," including Form 18, "suffice under these rules and illustrate the simplicity and brevity that these rules contemplate." *See* Fed. R. Civ. P. 84; *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1334 (Fed. Cir. 2012).

Finally, in reviewing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court only considers the complaint, documents incorporated by reference in the complaint, and matters of judicial notice. *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). A court may deny leave to amend where amendment would be futile or if the claim is legally insufficient. *Miller v. Rykoff-Sexton, Inc.*, 845 F.2d 209, 214 (9th Cir. 1988).

B. Analysis

As noted above, Defendants challenge the sufficiency of Immunex's allegations concerning whether Dupixent "competes" with the "reference antibody" 12B5. (*See generally* Mot.) In essence, Defendants' arguments boil down to the following: Immunex should be precluded from arguing the word "competes" is equivalent to the word "blocks" in light of positions it took both during prosecution of the '487 Patent and in other judicial and administrative proceedings, and the Complaint should therefore be dismissed with leave to amend because it lacks any factual allegations plausibly supporting a theory that Dupixent "competes" with 12B5 other than under such an impermissible definition.

These arguments do not persuade, both because they fail to take into account all of the allegations in the Complaint and because they misunderstand the role that claim construction plays in patent infringement actions. First, the Complaint alleges facts that demonstrate why Immunex's infringement theory is plausible, even under Defendants' apparently preferred construction of the term "competes." For example, Immunex alleges that Regeneron relied on the 12B5 antibody during its own attempts to identify therapeutic anti-IL-4R antibodies, from which the Court can plausibly infer that dupilumab and 12B5 bind to overlapping physical locations on IL-4R. (Compl. ¶ 55; *see also* Lee Decl., Ex. 1 at 6 [depicting, at Figure 8, one understanding of the word "competes" in the antibody context, wherein antibodies to a common target "compete" when they bind to at least some of the same molecules of the surface of the target].) Nothing in the Complaint or any of the documents submitted by the parties contradicts such a possibility.

Moreover, the Complaint alleges that Defendants themselves have taken the position in other proceedings "that any antibody that blocks binding of IL-4 to IL-4R will also compete with Immunex's 12B5 antibody for binding to IL-4R." (Compl. ¶ 41.) Because the Court must accept this allegation as true at this stage in the litigation and because the Complaint alleges facts suggesting dupilumab blocks binding of IL-4 to IL-4R, the Court cannot say that Immunex's direct infringement theory is implausible.

In their Reply, Defendants confirm they take primary issue with the breadth of the functional term "competes," arguing first that "Immunex's '487 Patent attempts to cover a nearly infinite genus of

antibodies that Immunex itself did not invent" and second that "Immunex's patent does not provide the information its Complaint lacks because competition is barely described in the '487 Patent." (Reply 4-5, ECF No. 58.) These might ultimately prove to be strong claim construction and invalidity arguments—indeed, the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), recently clarified the standard for "indefiniteness"—which Defendants can pursue at the appropriate stage in the litigation. This Court's Initial Standing Order, however, notes that the Court may hold a claim construction hearing and states that "[d]uring the scheduling conference, the Court will impose rules limiting . . . the content of [infringement and invalidity contentions]." (Inital Standing Order ¶ 21(a), (b), ECF No. 15.) Defendants will therefore have ample opportunity to ascertain the particulars of Immunex's direct infringement theory, including through (1) Immunex's disclosure of its initial infringement contentions; (2) the exchange of preliminary claim constructions and extrinsic evidence; (3) Immunex's *Markman* briefs; and (4) the parties' continuing meet-and-confer efforts, as guided by their obligations under Rule 11 of the Federal Rules of Civil Procedure. *Accord Avago Techs. Gen. IP (Singapore) PTE Ltd. v. Asustek Computer, Inc.*, No. 15-cv-04525-EMC, 2016 WL 1623920, at *4 (N.D. Cal. Apr. 25, 2016) (denying defendants' motion to dismiss in part because "this District generally has not required detailed infringement theories until the time that infringement contentions are served, which is typically several months after a complaint has been filed"). So long as "the allegations are not as conclusory as that formerly permitted under Form 18 and ha[ve] sufficient specificity to provide at least some notice to [defendants]," the pleading will withstand a motion to dismiss for failure to state a claim. *Id.* At this stage, the Court concludes the Complaint contains "a short and plain statement of the [direct infringement] claim showing that [Immunex] is entitled to relief" such that Defendants have been given "fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (quoting Fed. R. Civ. P. 8(a)(2); *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

In conclusion, a little over a decade ago, the Supreme Court instructed that where a complaint pleads sufficient facts "to raise a right to relief above the speculative level," a court may not dismiss the complaint under Rule 12(b)(6). *Twombly*, 550 U.S. at 555. Immunex accomplishes this task by alleging in its Complaint facts that plausibly demonstrate how Defendants' drug Dupixent and its active ingredient dupilumab practice each element of at least one patent claim. *See TeleSign Corp. v. Twilio, Inc.*, No. CV 16-2106 PSG, 2016 WL 4703873, at *3 (C.D. Cal. Aug. 3, 2016) (stating that to plead a plausible claim for patent infringement, "a plaintiff must include allegations sufficient to 'permit [the] court to infer that the accused product infringes each element of at least one claim'" (quoting *Atlas IP, LLC v. Exelon Corp.*, 189 F. Supp. 3d 768, 775 (N.D. Ill. 2016)). The Court declines Defendants' invitation to issue a *Markman* order at this premature stage without the benefit of full briefing.

IV. RULING

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

CASE NO.: CV 17-02613 SJO (PLAx) **DATE: June 21, 2017**

For the foregoing reasons, the Court **DENIES** Defendants Sanofi, Sanofi-Aventis U.S. LLC, Genzyme Corporation and Aventisub LLC and Regeneron Pharmaceuticals, Inc.'s Motion to Dismiss Plaintiff's Complaint Under Fed. R. Civ. P. 12(b)(6). Defendants shall file their answers the Complaint within **seven (7) days** of the issuance of this Order.

The Court **SETS** a scheduling conference for **Thursday, August 3, 2017 at 9:00am** and **ORDERS** the parties to file their Joint Rule 26(f) Report on or before **Monday, July 17, 2017**. During the scheduling conference, the Court wishes to have the parties provide a technology tutorial and overview of likely contested and potentially dispositive issues. The parties will have 30 minutes each to present their tutorials, and welcomes the use of PowerPoint presentations and slides that it and its staff can use as aids. The Court is particularly interested in hearing from Immunex (1) why it believes that dupilumab "competes" with 12B5 and how it formed this belief; (2) how the '487 Patent relates to other members of the same family; (3) the nature of other litigation(s) between it and any of the Defendants concerning the '487 Patent or any similar patents; and (4) its own efforts to commercialize drugs aimed at inhibiting IL-4 and IL-13. The Court is interested in hearing from Defendants (1) how dupilumab functions; (2) a preview of their noninfringement and invalidity arguments; and (3) whether they intend to move for *inter-partes* or other post-grant review. The Court is also interested in hearing from both parties which claim term(s) are most likely to be disputed and an overview of the parties' prior efforts to settle their disputes concerning not only the asserted patent, but other patents directed toward the treatment of inflammatory conditions.

IT IS SO ORDERED.