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16 *Genzyme Corporation; Aventisub LLC;*
17 *and Regeneron Pharmaceuticals, Inc.*

18 **UNITED STATES DISTRICT COURT**
19 **CENTRAL DISTRICT OF CALIFORNIA**

20 IMMUNEX CORPORATION,
21 Plaintiff,
22 v.
23 SANOFI; SANOFI-AVENTIS U.S.
24 LLC; GENZYME CORPORATION;
25 AVENTISUB LLC; and REGENERON
26 PHARMACEUTICALS, INC.,
27 Defendants.

Case No. 2:17-cv-2613-SJO-PLA

**DEFENDANTS' NOTICE OF
MOTION AND MOTION TO DISMISS
PLAINTIFF'S COMPLAINT UNDER
FED. R. CIV. P. 12(b)(6);
MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT
THEREOF**

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

1 **TO ALL PARTIES AND THEIR RESPECTIVE ATTORNEYS OF**
2 **RECORDS:**

3 **PLEASE TAKE NOTICE** that on June 26, 2017 at 10:00 a.m., or as soon
4 thereafter as the matter may be heard, in this Court, located at First Street Courthouse,
5 350 W. First Street, Courtroom 10C, Los Angeles, CA 90012, Defendants, Sanofi,
6 Sanofi-Aventis U.S. LLC, Genzyme Corporation and Aventisub LLC (collectively,
7 “Sanofi”), and Regeneron Pharmaceuticals, Inc. (“Regeneron”), will and hereby do
8 move, pursuant to Federal Rule of Civil Procedure 12(b)(6), to dismiss the Complaint
9 for failure to state a plausible claim for relief. This motion is based upon this notice of
10 motion and motion, the attached memorandum, the request for judicial notice filed
11 concurrently herewith, the declaration of Phillip Lee filed concurrently herewith, and
12 upon such other and further matters, papers, and arguments as may be submitted to the
13 Court at or before the hearing on this motion.

14 This motion is made following the conference of counsel pursuant to Local
15 Rule 7-3 that took place on May 19, 2017.

16 Dated: May 26, 2017

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1 Defendants Sanofi, Sanofi-Aventis U.S. LLC, Genzyme Corporation and
2 Aventisub LLC (collectively, “Sanofi”), and Regeneron Pharmaceuticals, Inc.
3 (“Regeneron”) (collectively, “Defendants”), hereby move pursuant to Rule 12(b)(6) of
4 the Federal Rules of Civil Procedure to dismiss Plaintiff Immunex Corporation’s
5 (“Immunex”) Complaint (Dkt. No. 1) (“Compl.”).

6 **I. INTRODUCTION**

7 All of the claims of the patent-in-suit, U.S. Patent No. 8,679,487 (the “’487
8 Patent”), cover “[a]n isolated human antibody that **competes** with a reference
9 antibody for binding to human IL-4 interleukin-4 (IL-4) receptor.” Compl. Ex. B,
10 Claims (emphasis added). Immunex contends that Defendants’ breakthrough therapy
11 Dupixent® falls within the scope of the ’487 Patent. That contention cannot be correct
12 unless Dupixent® “competes” with a reference antibody that the ’487 Patent allegedly
13 teaches. This motion should be granted because Immunex’s Complaint fails to
14 properly allege that Dupixent® “competes” with a reference antibody and Immunex is
15 estopped from arguing, by inference, to the contrary.

16 Rather than pleading facts supporting Immunex’s assertion that Dupixent®
17 “competes” with a reference antibody, the Complaint asks the Court to infer
18 “compet[ition]” from two allegations: (1) Dupixent® blocks interleukin-4 (“IL-4”)
19 from binding to its receptor (“IL-4R”), Compl. ¶ 35; and (2) in a European Opposition
20 Proceeding (“EOP”) challenging the validity of a foreign counterpart to the ’487
21 Patent, Defendants argued that Immunex’s patent is invalid because, under Immunex’s
22 sweeping claims, “any antibody that blocks binding of IL-4 to IL-4R also will
23 compete with Immunex’s [reference antibody].” Compl. ¶ 41.

24 But Immunex cannot allege facts by inference that it has expressly disclaimed.
25 Immunex previously disclaimed the very inference it now asks the Court to draw—
26 that all IL-4 blocking antibodies compete with the ’487 Patent’s reference antibody—
27 as “factual error,” “legal error,” “mere conjecture,” “speculation,” and “guesswork”
28 before the United States Patent and Trademark Office (“USPTO”) and the European

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1 Patent Office. To persuade the USPTO to grant the '487 Patent, Immunex expressly
 2 argued that it was “factual error,” “legal error,” and “mere conjecture” for the
 3 examiner to infer that prior art antibodies that block IL-4 from binding to IL-4R meet
 4 the '487 Patent’s “competes” limitation. Decl. of Phillip Lee ISO Defs.’ Mot. to
 5 Dismiss and Req. for Judicial Notice (“Lee Decl.”) Ex. 1 at 5, 7. And Immunex
 6 repeated this argument in the EOP, where it expressly argued that inferring
 7 “compet[ition]” from IL-4 blocking is mere “speculation and guesswork [that] cannot
 8 lead to a finding of a direct and unambiguous disclosure of the antibody of the
 9 claims.” Lee Decl. Ex. 3 ¶ 4.4. In a complete about-face, Immunex now asks the Court
 10 to infer that Dupixent® satisfies the “competes” limitation because it blocks IL-4 from
 11 binding to IL-4R. But this is the very inference Immunex dismissed before the
 12 USPTO and in the EOP as “factual error,” “legal error,” “mere conjecture,”
 13 “speculation,” and “guesswork.”

14 Judicial estoppel forecloses Immunex’s gamesmanship. *Rissetto v. Plumbers &*
 15 *Steamfitters Local 343*, 94 F.3d 597, 600 (9th Cir. 1996) (holding that judicial
 16 estoppel “precludes [litigants] from gaining an advantage by taking one position, and
 17 then seeking a second advantage by taking an incompatible position.”). Immunex has
 18 called, and continues to call, the very inference it is now asking the Court to draw here
 19 unreasonable. Thus, by Immunex’s own admission, the Complaint fails to provide
 20 “factual content that allows the court to draw the reasonable inference that the
 21 defendant[s] [are] liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662,
 22 678 (2009). Defendants’ motion should be granted.

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1 **II. BACKGROUND¹**

2 Defendants Sanofi and Regeneron discover, develop, and commercialize novel
3 medicines. Dupixent® (dupilumab), the product at issue in this action, is a
4 monoclonal antibody that was developed using Regeneron’s revolutionary
5 VelocImmune® mouse technology. Defendants invested many years of research
6 efforts and hundreds of millions of dollars in developing both VelocImmune® and
7 Dupixent®.

8 Dupixent® is a game-changer in the fight against atopic dermatitis, a life-long,
9 debilitating, disfiguring disease characterized by chronically inflamed lesions that
10 cover the affected person’s skin. After receiving a “Breakthrough Therapy”
11 designation from the U.S. Food and Drug Administration (“FDA”) in 2014,
12 Dupixent® underwent extensive clinical trials in patients suffering from uncontrolled,
13 moderate-to-severe forms of atopic dermatitis. Within two weeks of beginning
14 treatment, most patients reported relief of their symptoms. By the end of the treatment
15 cycle, nearly 40 percent of participants saw all or almost all of their skin lesions
16 disappear. As the New York Times reported, because “[t]here has never been a safe
17 and effective treatment” for atopic dermatitis, Dupixent® now “offer[s] hope to the
18 estimated 1.6 million adult Americans” that are affected by the condition. On March
19 28, 2017, Dupixent® became the first and only antibody approved by the FDA for the
20 treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is
21 not adequately controlled with topical prescription therapies or when those therapies
22 are not advisable.

23 _____
24 ¹ Immunex’s Complaint references a complaint for declaratory relief that certain of the
25 Defendants filed in the U.S. District Court for the District of Massachusetts. Compl.
26 ¶ 54. While, in the interest of judicial efficiency, the Defendants have since dismissed
27 the Massachusetts action, the Court may take judicial notice of indisputable
28 allegations the Defendants made in the Massachusetts complaint. *Davis v. HSBC
Bank*, 691 F.3d 1152, 1160 (9th Cir. 2012) (quoting *Knievel v. ESPN*, 393 F.3d 1068,
1076 (9th Cir. 2005)).

1 Immunex and its parent Amgen Inc. (“Amgen”) also attempted to develop an
2 antibody that could be used to treat certain atopic disorders.² But those efforts failed.
3 Specifically, Immunex and Amgen’s antibody—known under the code name AMG-
4 317—“did not demonstrate clinical efficacy across the overall group of patients.” *See*
5 Corren, et al., “A Randomized, Controlled, Phase 2 Study of AMG 317, an IL-4 α
6 Antagonist, in Patients with Asthma,” *Am. J. Respir. Crit. Care Med.* (181):788–96
7 (2010).³

8 Despite Immunex and Amgen’s failure to develop an effective antibody,
9 Immunex managed to obtain several patents directed to antibodies to IL-4R, including
10 the ’487 Patent. The ’487 Patent is one member of an extended patent family sharing a
11 specification that dates back to May 1, 2001. Each member of the family discloses six
12 antibodies that interact with IL-4R—none of which is Dupixent®. The initial patents
13 in this family claimed the various antibodies disclosed in Immunex’s specification,
14 such as an antibody referred to as 12B5. But toward the end of 2008, Immunex
15 changed tactics.⁴ Rather than tailor its claims to the antibodies described in its
16 specification, Immunex began to file new continuing applications that attempt to claim
17 the antibodies of Immunex and Amgen’s competitors instead of those that Immunex
18 invented. Immunex did this by attempting to claim a genus of antibodies by virtue of
19 their functional relationship to one of the antibodies disclosed in its specification.
20 Thus, in the ’487 Patent, which was filed after the failure of Immunex and Amgen’s
21
22

23 ² In July 2002, Immunex became a wholly-owned subsidiary of Amgen. Compl. ¶ 3.

24 ³ The Corren article is publically available at
25 <http://www.atsjournals.org/doi/full/10.1164/rccm.200909-1448OC>.

26 ⁴ By 2008, Immunex had relinquished control of prosecution to Amgen, and Amgen—
27 not Immunex—is listed as the party to which correspondence concerning the ’487
28 Patent should be addressed on the USPTO’s website.

1 AMG-317 antibody, Immunex sought to cover competitors' antibodies by claiming
2 any antibody "that competes" with a "reference antibody" such as 12B5. Compl. ¶ 29.

3 The Complaint, however, does not plead any facts to substantiate Immunex's
4 contention that Dupixent® meets the "competes" limitation of the '487 Patent's only
5 independent claim and all dependent claims. Instead, Immunex claims to satisfy this
6 limitation by making two allegations: (1) Dupixent® blocks IL-4 from binding to its
7 receptor IL-4R; and (2) in the EOP, Defendants supposedly argued that Immunex's
8 sweeping claims are invalid because any blocking antibody to IL-4R necessarily
9 "competes" with a reference antibody. Compl. ¶¶ 35, 41–42.

10 In the same EOP, however, Immunex defended validity of its patent by
11 expressly contending that the "competes" limitation is not inherently present in all
12 antibodies to IL-4R.⁵ Immunex characterized Defendants' position as "speculation
13 and guesswork [that] cannot lead to a finding of a direct and unambiguous disclosure
14 of the antibody of the claims." Lee Decl. Ex. 3 ¶ 4.4. Immunex also contended that
15 Defendants' invalidity argument was "not backed up by any evidence whatsoever"
16 and "that the antibody of the claim is not merely inhibitory. It must also compete for
17 binding with a reference IgG1 antibody." Lee Decl. Ex. 3 ¶¶ 5.2, 5.5.

18 Immunex's contentions in the EOP mirror Immunex's arguments to the USPTO
19 during prosecution of the '487 Patent.⁶ To overcome prior art that was asserted by the

20 _____
21 ⁵ The Court should consider Immunex's statements from the EOP in ruling on this
22 Motion to Dismiss because Immunex expressly references the EOP in the Complaint.
23 Compl. ¶¶ 41, 55; *Davis*, 691 F.3d at 1160 (holding that a court may treat documents
24 incorporated by reference in the complaint "as part of the complaint, and thus may
25 assume that [their] contents are true for purposes of a motion to dismiss under Rule
26 12(b)(6).") (internal quotations omitted). In addition, the Court may take judicial
27 notice of Immunex's filing in the EOP. *See* Defs. Req. for Judicial Notice at 1-2;
28 *Mack v. South Bay Beer Distrib., Inc.*, 798 F.2d 1279, 1282 (9th Cir. 1986), *abrogated*
on other grounds by Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 111
(1991).

⁶ The Court may take judicial notice of Immunex's representations to the USPTO in

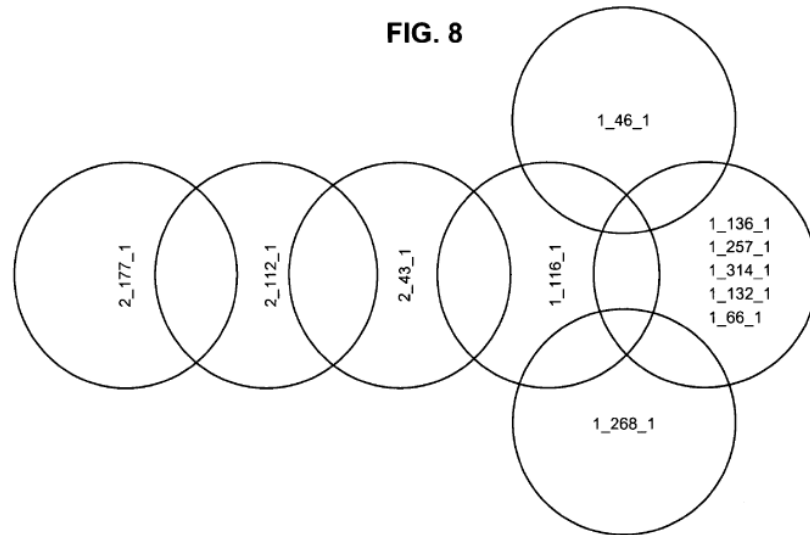
1 examiner, Immunex specifically distinguished antibodies that “compete” from those
 2 that merely block IL-4 from binding to IL-4R. For example, Immunex argued, “[i]n
 3 particular, [the rejection] assumes that the ligand-blocking anti-human IL-4 receptor
 4 antibody⁷ of [the prior art] will necessarily compete for binding with the reference
 5 antibody recited in the rejected claims. As explained above, **it is legal error to make
 6 such an assumption without evidence; it is a factual error as well because there
 7 are examples of antibodies that bind to the same small target without competing
 8 with each other.**” Lee Decl. Ex. 1 at 7 (emphasis added). In fact, Immunex argued
 9 that it was “mere conjecture” for the examiner to infer that an antibody that blocks
 10 IL-4 from binding to IL-4R would also compete with the ’487 Patent’s reference
 11 antibody. Lee Decl. Ex. 1 at 5. Taking issue with the examiner’s inference that prior
 12 art IL-4 blocking antibodies would practice the ’487 Patent’s “competes” limitation,
 13 Immunex also repeatedly demanded evidence from the examiner proving that the prior
 14 art IL-4 blocking antibodies actually compete with the ’487 Patent’s reference
 15 antibody. *See* Lee Decl. Ex. 1 at 5 (requesting “documentary evidence” that the prior
 16 art IL-4 blocking antibodies compete); Lee Decl. Ex. 4 at 35 (“If it is a fact that any
 17 two antibodies . . . must *necessarily* compete for binding to [IL-4R], then let the
 18 evidence show it.”) (emphasis in original).

19 To further refute the examiner’s inference that prior art IL-4 blocking
 20 antibodies satisfy the ’487 Patent’s “competes” limitation, Immunex cited Figure 8
 21 from U.S. Patent No. 7,807,159 (the “159 Patent”), which according to Immunex,
 22 depicts results from a “competition binding assay.” Lee Decl. Ex. 1 at 6. Immunex
 23

24 prosecuting the ’487 Patent and consider them in ruling on this Motion to Dismiss.
 25 *See* Defs. Req. for Judicial Notice at 1-2; *Mack*, 798 F.2d at 1282; *U.S. Rubber*
 26 *Recycling, Inc. v. ECORE Int’l*, No. 09-09516 SJO (OPx), 2011 WL 13127548, at *2
 (C.D. Cal. July 8, 2011) (taking judicial notice of a reissue patent’s file history).

27 ⁷ In context, “ligand-blocking anti-human IL-4 receptor antibody” means an antibody
 28 that blocks IL-4 from binding to IL-4R, such as Dupixent®.

1 noted that in Figure 8 of the '159 Patent, shown below, competition between
 2 antibodies to the same target is signified by overlapping circles—*i.e.*, 1_46_1
 3 competes with 1_136_1, but not with 1_268_1.



13 Lee Decl. Ex. 1 at 6 (citing '159 Patent). Using Figure 8 as an example, Immunex
 14 argued that antibodies to a common target will not necessarily compete for binding to
 15 that target because they may bind to slightly different locations on the target.
 16 Immunex explained that “the '159 patent demonstrates that even two antibodies raised
 17 against a homodimerized 109 amino acid polypeptide⁸ **do not necessarily compete**
 18 for binding to the polypeptide.” *Id.* (emphasis added). Immunex accordingly argued
 19 that it “cannot be concluded that the [prior art IL-4 blocking antibodies] compete for
 20 binding with the reference antibody recited in the rejected claims.” *Id.*

21 Ultimately, Immunex’s arguments persuaded the examiner to allow the '487
 22 Patent. In the Notice of Allowance, the examiner expressly noted that the claims were
 23 allowed based on Immunex’s arguments:

24 **Applicants’ argument that a set of antibodies that bind to a common**
 25 **target, do not all necessarily compete for binding with each other for**
 26 **binding to the target, is persuasive.** Applicants submit that United

27 ⁸ The '159 Patent concerns antibodies to myostatin (*i.e.*, a homodimerized 109 amino
 28 acid polypeptide), which is a small protein that mediates muscle growth.

1 States Patent Number 7,807,159 discloses antibodies that bind to
 2 myostatin and demonstrates that even two antibodies raised against a
 3 homodimerized 109 amino acid polypeptide do not necessarily compete
 4 for binding to the polypeptide. **Applicants’ argument that it cannot be**
 5 **concluded that the [prior art blocking antibodies] compete for**
 6 **binding with the reference antibody recited in the rejected claims, is**
 7 **found persuasive.**

8 Lee Decl. Ex. 2 at 16–17 (emphasis added).

9 III. LEGAL STANDARD

10 Federal Rule of Civil Procedure 12(b)(6) requires dismissal when a complaint
 11 fails to state a claim upon which relief can be granted. “To survive a motion to
 12 dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a
 13 claim to relief that is plausible on its face.’” *Ashcroft*, 556 U.S. at 678 (quoting *Bell*
 14 *Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility
 15 when the plaintiff pleads factual content that allows the court to draw the reasonable
 16 inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*,
 17 550 U.S. at 556). The plausibility requirement is meant to “give the defendant fair
 18 notice of what the . . . claim is and the grounds upon which it rests.” *Twombly*, 550
 19 U.S. at 555 (quoting *Conley v. Gibson*, 355 U.S. 41, 47, (1957) (alterations in
 20 original)). “Factual allegations must be enough to raise a right to relief above the
 21 speculative level.” *Id.*

22 To plead a plausible claim for patent infringement, “a plaintiff must include
 23 allegations sufficient to ‘permit [the] court to infer that the accused product infringes
 24 each element of at least one claim.’” *TeleSign Corp. v. Twilio, Inc.*, No. CV 16-2106
 25 PSG, 2016 WL 4703873, at *3 (C.D. Cal. Aug. 3, 2016) (quoting *Atlas IP, LLC v.*
 26 *Exelon Corp.*, 189 F. Supp. 3d 768, 775 (N.D. Ill. 2016)). “[S]imply reciting some of
 27 the elements of a representative claim and then describing generally how an accused
 28 product operates, without specifically tying the operation to any asserted claim or
 addressing all of the claim requirements, is insufficient.” *Atlas IP LLC v. Pacific Gas*

1 *and Electric Co.*, No. 15-cv-05469-EDL, 2016 WL 1719545, at *2 (N.D. Cal. Mar. 9,
2 2016). “This is because ‘the failure to meet a single limitation is sufficient to negate
3 infringement of [a] claim.’” *E.Digital Corp., v. iBaby Labs, Inc.*, No. 15-cv-05790-
4 JST, 2016 WL 4427209 at *3 (N.D. Cal. Aug. 22, 2016) (quoting *Laitram Corp. v.*
5 *Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991)). If a plaintiff fails to plausibly
6 allege that the accused product practices every element of at least one claim, then the
7 “Plaintiff has failed to give Defendant[s] sufficient notice to state a claim in the world
8 of *Twombly* and *Iqbal*.” *TeleSign Corp.*, 2016 WL 4703873, at *3.

9 In ruling on a motion to dismiss, the Court “may properly look beyond the
10 complaint to matters of public record and doing so does not convert a Rule 12(b)(6)
11 motion to one for summary judgment.” *Mack*, 798 F.2d at 1282. For example, the
12 Court may consider records of administrative bodies in ruling on a Rule 12(b)(6)
13 motion. *Id.* The Court also may “take into account ‘documents whose contents are
14 alleged in a complaint and whose authenticity no party questions, but which are not
15 physically attached to the [plaintiff’s] pleading.’” *Davis*, 691 F.3d at 1160. “When
16 documents contain statements that contradict allegations in a complaint, the
17 documents control and a court need not ‘[a]ccept as true allegations that contradict
18 matters properly subject to judicial notice or by exhibit.’” *Green v. Boggust*, No.
19 EDCV 15-2578-JGB, 2016 WL 3267712, at *2 (C.D. Cal. Apr. 25, 2016) (quoting
20 *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001)). “Contradictory
21 allegations . . . are inherently implausible, and fail to comply with Rule 8, *Twombly*,
22 and *Iqbal*.” *Hernandez v. Select Portfolio, Inc.*, No. CV 15-01896 MMM (AJWx),
23 2015 WL 3914741, at *10 (C.D. Cal. June 25, 2015).

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1 **IV. ARGUMENT**

2 **A. Immunex Fails to State a Plausible Claim that Dupixent® Directly**
 3 **Infringes the '487 Patent.**

4 **1. Immunex Fails to Allege Its Basis for Contending that**
 5 **Dupixent® Competes with the '487 Patent's Reference**
 6 **Antibody.**

7 The Complaint fails to satisfy the pleading obligations imposed by Federal Rule
 8 of Civil Procedure 8(a), *Twombly*, and *Iqbal* because Immunex never alleges a factual
 9 basis for claiming that Dupixent® competes with the '487 Patent's reference antibody.
 10 Immunex must "give the defendant[s] fair notice of what the . . . claim is and the
 11 grounds upon which it rests." *Twombly*, 550 U.S. at 555. Here, Immunex attempts to
 12 circumvent its obligation to plead the grounds upon which it claims that Dupixent®
 13 competes (if such grounds exist) by pleading Defendants' alleged position in the EOP
 14 that "any antibody that blocks binding of IL-4 to IL-4R also will compete with
 15 Immunex's 12B5 antibody." Compl. ¶ 41. But even if accepted as true, Immunex's
 16 characterization of Defendants' position in Europe fails to save the Complaint in this
 17 action. To satisfy Rule 8(a), *Twombly*, and *Iqbal*, a plaintiff must ensure that a
 18 complaint "contain[s] sufficient allegations of underlying facts to give fair notice and
 19 to enable [the defendants] to defend [themselves] effectively." *Levitt v. Yelp! Inc.*, 765
 20 F.3d 1123, 1135 (9th Cir. 2014) (internal citations and quotations omitted).
 21 Immunex's attempts to use Defendants' invalidity arguments to short-circuit the
 22 pleading requirements here are unavailing. If Immunex's position before this Court
 23 was that the "competes" limitation is satisfied merely because Dupixent® blocks
 24 binding of IL-4 to IL-4R, then Immunex should have stated so. But Immunex cannot
 25 circumvent the pleading standards by referencing Defendants' invalidity arguments
 26 made in another proceeding—arguments that Immunex has expressly disputed.

27 Immunex's failure to plead the factual basis underlying its claim that
 28 Dupixent® "competes" with the '487 Patent's reference antibody is material and fatal.
 As explained above, the '487 Patent recites only one independent claim, and that

1 independent claim hinges on the functional limitation that the claimed genus of
2 antibodies “compete[.]” with a reference antibody. Compl. ¶ 29. Notwithstanding that
3 Immunex relied almost exclusively on the functional “competes” limitation to
4 convince the USPTO to award the ’487 Patent, the concept of competition between
5 two antibodies is barely described in the specification. In fact, the word “competes” is
6 used only six times, each time in the same *pro forma* sentence for each of six
7 antibodies disclosed in the specification: “Particular monoclonal antibodies of the
8 invention are selected from the group consisting of . . . a MAb that **competes** with
9 [one of the disclosed antibodies] for binding to a cell that expresses human
10 IL-4R” *See, e.g.*, Compl. Ex. B at 22:4–10 (emphasis added). But the
11 specification is devoid of any examples of experiments showing antibody competition,
12 much less any proof that an antibody competes with the ’487 Patent’s reference
13 antibody. Because every claim in the ’487 Patent hinges on antibody competition, and
14 further because the specification provides no guidance on the scope of this term, it is
15 paramount that Immunex plead its factual basis for contending that Dupixent®
16 “competes” with the ’487 Patent’s reference antibody so that Defendants can
17 effectively prepare a defense to Immunex’s claim.

18 Immunex’s exercise in artful pleading does not entitle it to forgo the obligations
19 imposed by Rule 8(a), *Twombly*, and *Iqbal*—namely, “[P]laintiff’s obligation to
20 provide the grounds of [its] entitlement to relief.” *Twombly*, 550 U.S. at 555 (internal
21 quotations omitted). As applied to this case, Immunex must identify what it alleges is
22 required to practice the ’487 Patent’s “competes” limitation and plead its basis for
23 asserting that Dupixent® practices the “competes” limitation. Because Immunex has
24 failed to do so, “Plaintiff has failed to give [Defendants] sufficient notice to state a
25 claim in the world of *Twombly* and *Iqbal*.” *TeleSign*, 2016 WL 4703873, at *3.
26 Accordingly, the Complaint should be dismissed for failing to allege sufficient facts to
27 show a plausible claim that Dupixent® practices every limitation of at least one claim
28 of the ’487 Patent.

1 **2. Immunex Should Be Estopped from Asking the Court to Draw**
 2 **an Inference that Immunex Expressly Contradicts and**
 3 **Disavows.**

4 Immunex’s focus on Defendants’ alleged arguments that “any antibody that
 5 blocks binding of IL-4 to IL-4R also will compete,” Compl. ¶ 41, is unavailing. This
 6 is because in the EOP and the USPTO, Immunex unequivocally **denies** that any
 7 antibody that blocks binding of IL-4 to IL-4R also will compete. Immunex now seeks
 8 to have it both ways, taking whichever position suits the exigencies of the moment, by
 9 asking the Court to draw from its Complaint the very inference that Immunex has
 10 contradicted in two separate patent office proceedings. But Immunex can’t have its
 11 cake and eat it too. Judicial estoppel “precludes a party from gaining an advantage by
 12 taking one position, and then seeking a second advantage by taking an incompatible
 13 position.” *Rissetto*, 94 F.3d at 600.

14 In the Ninth Circuit, judicial estoppel is invoked “not only to prevent a party
 15 from gaining an advantage by taking inconsistent positions, but also because of
 16 general considerations of the orderly administration of justice and regard for the
 17 dignity of judicial proceedings, and to protect against a litigant playing fast and loose
 18 with the courts.” *Hamilton v. State Farm Fire & Casualty Co.*, 270 F.3d 778, 782 (9th
 19 Cir. 2001) (internal quotation and citation omitted). Judicial estoppel is appropriate
 20 where a court or administrative agency “relied on, or ‘accepted,’ the party’s previous
 21 inconsistent position.” *Id.* at 783. It applies to statements made in prior administrative
 22 proceedings—such as to the USPTO—because “the truth is no less important to an
 23 administrative body acting in a quasi-judicial capacity than it is to a court of law.”
 24 *Rissetto*, 94 F.3d at 604 (quoting *Muellner v. Mars, Inc.*, 714 F. Supp. 351, 357 (N.D.
 25 Ill. 1989)); *see also MobileMedia Ideas, LLC v. Apple Inc.*, 907 F. Supp. 2d 570, 623
 26 (D. Del. 2012) (recognizing that deferring to the patentee’s statements before the
 27 patent office “preserves the integrity of the PTO and the Courts and, therefore, judicial
 28 estoppel is appropriate”) *vacated in part on other grounds*, 780 F.3d 1159 (Fed. Cir.
 2015); *Synopsys, Inc. v. Magma Design Automation*, No. C-04-3923 MMC, 2007 WL

1 322353, *26 (N.D. Cal. Jan. 31, 2007) (“[T]he Court finds the doctrine of judicial
2 estoppel is applicable to cases in which the prior statements at issue were made to the
3 PTO.”).

4 Judicial estoppel applies here because Immunex persuaded the USPTO to grant
5 the '487 Patent by arguing that it was “legal error,” “factual error,” and “mere
6 conjecture” for the examiner to assume that prior art antibodies that block IL-4 from
7 binding to IL-4R would also practice the '487 Patent’s “competes” limitation. Lee
8 Decl. Ex. 1 at 5, 7. The Notice of Allowance specifically states that the examiner
9 found these arguments “persuasive.” *See* Lee Decl. Ex. 2 at 17. Notwithstanding its
10 position before the USPTO, Immunex now asks the Court to draw the very inference
11 that Immunex refuted in order to obtain the '487 Patent. Having obtained the '487
12 Patent by disavowing the examiner’s inference that antibodies that block IL-4 would
13 compete with the '487 Patent’s reference antibody, Immunex should be estopped from
14 asking this Court to draw the opposite conclusion.

15 Judicial estoppel also applies in light of Immunex’s EOP statements. There,
16 Immunex explicitly argued that inferring competition from blocking is “speculation
17 and guesswork [that] cannot lead to a finding of a direct and unambiguous disclosure
18 of the antibody of the claims.” Lee Decl. Ex. 3 ¶ 4.4. Immunex stressed “that the
19 antibody of the claim is not merely inhibitory” but instead “[i]t must also compete.”
20 Lee Decl. Ex. 3 ¶ 5.2 (emphasis added). Immunex thus asks the Court to infer that
21 Dupixent® infringes the '487 Patent on grounds that Immunex explicitly contends
22 “cannot lead to a finding . . . of the antibody of the claims.” Lee Decl. Ex. 3 ¶ 4.4.
23 Although there has not been a final decision on the merits of Immunex’s arguments in
24 the EOP, Immunex’s arguments in the EOP further demonstrate that Immunex is
25 playing fast and loose with the Court. *See New Hampshire v. Maine*, 532 U.S. 742,
26 751 (2001) (emphasizing that judicial estoppel is not subject to “inflexible
27 prerequisites or an exhaustive formula Additional considerations may inform the
28 doctrine’s application in specific factual contexts.”). Regardless of whether

1 Immunex’s arguments in the EOP would be sufficient on their own to trigger judicial
2 estoppel, they should be considered in conjunction with Immunex’s success in
3 asserting the same arguments during prosecution before the USPTO, and accordingly
4 Immunex’s arguments in the EOP further demonstrate that judicial estoppel is
5 appropriate in this case.

6 **3. Immunex’s Complaint Is Inherently Implausible.**

7 As an alternative to judicial estoppel, Immunex’s arguments in the EOP show
8 that Immunex’s Complaint is inherently implausible. *See Sprewell*, 266 F.3d at 988
9 (“The court need not . . . accept as true allegations that contradict matters properly
10 subject to judicial notice or by exhibit.”); *Hernandez*, 2015 WL 3914741, at *10
11 (“Contradictory allegations . . . are inherently implausible, and fail to comply with
12 Rule 8, *Twombly*, and *Iqbal*.”). As explained above, Immunex specifically bases its
13 claim that Dupixent® competes with the ’487 Patent’s reference antibody on
14 statements that Defendants allegedly made in the EOP. Compl. ¶ 41. Thus, the Court
15 has discretion to incorporate Immunex’s own filings from the EOP into the Complaint
16 and may assume that the contents of those filings are true for purposes of this Motion
17 to Dismiss. *Davis*, 691 F.3d at 1160.

18 As shown by Immunex’s own statements in the EOP, Immunex fails to plead a
19 plausible claim that Dupixent® “competes” with the ’487 Patent’s reference antibody.
20 On the one hand, in the EOP, Immunex alleges that it is “speculation and guesswork”
21 to infer that IL-4 blocking antibodies necessarily compete with the ’487 Patent’s
22 reference antibody. Lee Decl. Ex. 3 ¶ 4.4. On the other hand, in the Complaint,
23 Immunex asks the Court to infer that Dupixent® competes with the ’487 Patent’s
24 reference antibody because Dupixent® is an IL-4 blocking antibody. Compl. ¶ 41.
25 Thus, by Immunex’s own words, its Complaint requires an unreasonable inference
26 and fails to provide sufficient “[f]actual allegations . . . to raise a right to relief above
27 the speculative level.” *Twombly*, 550 U.S. at 555; *see also Weisbuch v. County of Los*
28 *Angeles*, 119 F.3d 778, 783 n.1 (9th Cir. 1997) (“A plaintiff may plead [itself] out of

1 court. If the pleadings establish facts compelling a decision one way, that is as good as
 2 if depositions and other expensively obtained evidence on summary judgment
 3 establishes the identical facts.”) (internal citation and quotation omitted).

4 Accordingly, Immunex fails to satisfy the pleading requirements of *Twombly*,
 5 *Iqbal*, and Rule 8. In the Complaint, Immunex never actually pleads its factual basis
 6 for asserting that Dupixent® practices the ’487 Patent’s “competes” limitation.
 7 Instead, it asks the Court to infer that Dupixent® competes with the ’487 Patent’s
 8 reference antibody because Dupixent® blocks IL-4 from binding to IL-4R, and
 9 because Defendants allegedly stated that all such blocking antibodies compete with
 10 the ’487 Patent’s reference antibody.⁹ *See* Compl. ¶¶ 35, 41–42. However, Immunex
 11 unequivocally contradicts this inference in the ’487 Patent’s prosecution history and in
 12 the EOP proceedings referenced in the Complaint. Thus, Immunex fails to plead a
 13 plausible claim that Dupixent® practices every limitation of at least one claim in the
 14 ’487 Patent, and accordingly its claim that Dupixent® directly infringes the ’487
 15 Patent should be dismissed.

16 **B. Immunex’s Allegations of Indirect Infringement and Willfulness**
 17 **Should Also Be Dismissed.**

18 Immunex’s remaining claims should be dismissed because each requires a
 19 plausible allegation that Dupixent® **directly** infringes the ’487 Patent. As shown
 20 above, Immunex has not plausibly pled that Dupixent® practices every limitation of at

21 _____
 22 ⁹ To the extent Immunex argues otherwise, its allegations regarding Regeneron’s
 23 alleged use of Immunex’s 12B5 antibody in Regeneron’s U.S. Patent Nos. 7,605,237
 24 (“’237 Patent”) and 8,337,839 (“’839 Patent”), *see* Compl. ¶¶ 36–38, even if taken as
 25 true, do not cure Immunex’s failure to state a plausible claim for relief. Regeneron’s
 26 ’237 Patent and ’839 Patent are directed to Regeneron’s invention of novel, high
 27 affinity human antibodies to human IL-4 receptor. Immunex does not allege that either
 28 of these patents discloses competition between Dupixent® and the ’487 Patent’s
 reference antibody—nor could it. Thus, Immunex cannot use Paragraphs 36–38 of
 Complaint as its factual basis for alleging that Dupixent® competes with the ’487
 Patent’s reference antibody.

1 least one claim of the '487 Patent. Immunex's remaining claims—indirect
2 infringement, willful infringement, and exceptionality—each necessitate a plausible
3 allegation of direct infringement. *TeleSign*, 2016 WL 4703873, at *3. Thus,
4 Immunex's failure to adequately plead direct infringement dooms Immunex's claims
5 of indirect infringement, willful infringement, and exceptionality as well. *Id.*

6 **V. CONCLUSION**

7 For the foregoing reasons, Defendants respectfully request that Immunex's
8 Complaint (Dkt. No. 1) be dismissed.

9 Dated: May 26, 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 hereby certify under penalty of perjury under the laws of the United States of America that on May 26, 2017, a true 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.

Dated: May 26, 2017

/s/ Phillip J. Lee

Phillip J. Lee

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