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14 Attorneys for Defendants
15 *Sanofi; Sanofi-Aventis U.S. LLC;*
16 *Genzyme Corporation; Aventisub LLC;*
and Regeneron Pharmaceuticals, Inc.

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

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

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

**DEFENDANTS' REPLY
MEMORANDUM IN SUPPORT OF
MOTION TO DISMISS PLAINTIFF'S
COMPLAINT UNDER FED. R. CIV. P.
12(b)(6)**

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

1 Immunex’s claim that Dupixent® infringes the ’487 Patent® cannot stand
 2 unless the Court accepts as true an inference that “any antibody that blocks binding of
 3 IL-4 to IL-4R also will compete with Immunex’s [reference antibody].” Compl. ¶ 41.
 4 But in its Opposition, Immunex contends this inference is **not** true. Opp. 8-10. This
 5 Court should therefore decline Immunex’s invitation to endorse an inference that
 6 Immunex itself refuses to “in any way endorse.” *Id.* Without this inference, no
 7 plausible claim is stated, as there is no support for Immunex’s bare legal conclusion
 8 that Dupixent® “competes with Immunex’s [reference] antibody for binding to human
 9 IL-4R, as claimed in Immunex’s ’487 patent.” Compl. ¶ 42. Immunex’s Complaint
 10 should be dismissed with leave to amend to allow Immunex to allege, if it can, **how**
 11 Dupixent® competes with the ’487 Patent’s reference antibody.

12 **I. Immunex Does Not Allege a Reasonable Basis to Believe That Dupixent®**
 13 **“Competes.”**

14 To infringe the ’487 Patent, an accused antibody must not only block binding of
 15 IL-4 to IL-4R, but also “compete[] with a reference antibody” for doing so. Compl.
 16 ¶ 29. But Immunex’s Opposition confirms that Immunex’s only basis for asserting
 17 that Dupixent® “competes” with the ’487 Patent’s reference antibody is the very
 18 inference Immunex expressly disclaimed as “factual error,” “legal error,” “mere
 19 conjecture,” “speculation,” and “guesswork” in prior proceedings—that “any antibody
 20 that blocks binding of IL-4 to IL-4R also will compete with Immunex’s [reference]
 21 antibody.” Opp. 8-10 (quoting Compl. ¶ 41); Mot. 1-2.¹ In its Opposition, Immunex
 22 reiterates its previous rejection of this same inference that it continues to press before
 23 this Court as a supposed “logical conclusion.” Opp. 10. Immunex emphasizes that it
 24 **“does not in any way endorse the correctness”** of this inference or “the antibody
 25

26 ¹ Immunex does not deny that it is proper for the Court to consider its prior
 27 disclaimers in ruling on this Motion. Immunex also does not oppose Defendants’
 28 Request for Judicial Notice (Dkt. 34), which should therefore be granted. *U.S. Rubber
 Recycling, Inc. v. ECOPE Int’l*, 2011 U.S. Dist. LEXIS 161433, at *6-7 (C.D. Cal.
 Aug. 8, 2011) (Otero, J.).

1 science underlying” it. *Id.* Immunex “stands by its position that it would be
 2 ‘error’” to accept this inference. *Id.* And Immunex “still believes” that this inference
 3 is “speculation and guesswork.” *Id.* Immunex’s Opposition, therefore, does not
 4 rebut that it should be estopped from asking this Court to draw from its Complaint the
 5 very inference it “has previously stated and still believes” is “error.” Opp. 10; *Rissetto*
 6 *v. Plumbers & Steamfitters Local 343*, 94 F.3d 597, 600 (9th Cir. 1996).

7 Defendants’ alleged invalidity “position [before the EPO] that any antibody that
 8 blocks binding of IL-4 to IL-4R also will compete” provides the only possible support
 9 for Immunex’s claim that Dupixent® “competes.” Opp. 8 (quoting Compl. ¶ 41). But
 10 “Immunex does not agree with this blanket statement (and does not allege it as being
 11 true).” *Id.* And the Court need not accept as true “contradictory allegations,” which
 12 “are inherently implausible, and fail to comply with Rule 8, *Twombly*, and *Iqbal*.”
 13 *Hernandez v. Select Portfolio, Inc.*, 2015 U.S. Dist. LEXIS 82922, at *24 (C.D. Cal.
 14 June 25, 2015). Thus, using Immunex’s own admission, the Complaint fails because it
 15 does not provide “factual content that allows the court to draw the *reasonable*
 16 inference” that Dupixent® “competes.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)
 17 (emphasis added) (Courts are not required to “accept as true” a Complaint’s “legal
 18 conclusions.”); *Reese v. Verizon Cal., Inc.*, 2011 U.S. Dist. LEXIS 156748, at *4
 19 (C.D. Cal. Aug. 11, 2011) (Otero, J.) (“[T]he court may dismiss a complaint . . . where
 20 the factual contentions are clearly baseless.”).

21 **II. Defendants’ Purported Beliefs Are Irrelevant to This Motion.**

22 Immunex argues that its Complaint is sufficient because “*Defendants* believe
 23 their antibody infringes the ’487 Patent.” Opp. 8-10. That is absurd. Defendants filed
 24 this Motion and a complaint for declaratory judgment of *non-infringement* precisely
 25 because they do *not* believe Dupixent® infringes the ’487 Patent. Defendants’
 26 Massachusetts complaint explained that because “Dupixent® does not in fact infringe
 27 the ’487 Patent, [Defendants] wish to eliminate any potential obstacle [Amgen and
 28 Immunex] might seek to raise against” Dupixent®. *Sanofi-Aventis U.S. LLC v. Amgen*

1 *Inc.*, No. 17-cv-10465 (D. Mass.), Dkt. 1 at 5. Defendants’ validity challenges in the
 2 EPO and PTO further evidence their belief that they do not infringe, and belie
 3 Immunex’s claim that infringement “has been willful.” Opp. 4.

4 Immunex’s attempts to rely on Defendants’ alleged positions in the EPO are
 5 unavailing. Opp. 8; Compl. ¶ 41. In the EPO, Defendants challenged the validity of a
 6 foreign counterpart to the ’487 Patent—a different patent with different claim
 7 limitations. Defendants reasoned that, if Immunex’s patent claims are construed as
 8 broadly as Immunex contends, then they are invalid because they cover any antibody
 9 that blocks binding of IL-4 to IL-4R. But an accused infringer is permitted to argue
 10 invalidity, and at the same time deny infringement, as Defendants do in this action.
 11 Immunex, however, cannot have it both ways: it cannot argue that its claims are valid
 12 because they do not cover all IL-4 antibodies, and at the same time take the position
 13 that all IL-4 antibodies infringe because they necessarily “compete[]” for binding with
 14 the reference antibody.

15 Moreover, Defendants’ purported subjective beliefs are irrelevant to direct
 16 infringement, which is an objective inquiry. *Global-Tech Appliances, Inc. v. SEB S.A.*,
 17 563 U.S. 754, 761 n.2 (2011). Immunex—not Defendants—filed the Complaint, and
 18 thus Immunex—not Defendants—was required to properly plead its basis for claiming
 19 that Dupixent® infringes. *See View Eng’g, Inc. v. Robotic Vision Sys.*, 208 F.3d 981,
 20 985-86 (Fed. Cir. 2000) (noting Rule 11 requires patentees to “apply the claims of
 21 each [asserted] patent . . . to an accused device and conclude that there is a reasonable
 22 basis for a finding of infringement,” and finding insufficient patentee’s “belief” that
 23 “devices probably infringed” based on accused infringer’s “statements”).

24 **III. Immunex Must Allege How Dupixent® Allegedly “Competes.”**

25 Contrary to Immunex’s suggestion, Defendants do not “seek to impose pleading
 26 requirements that go [] beyond” *Iqbal/Twombly* or require Immunex to “prove the
 27 merits of its infringement claim in its Complaint.” Opp. 1-2. But to satisfy
 28 *Iqbal/Twombly*, Immunex must do more than simply identify Dupixent® and state that

1 “it competes with [the reference antibody].” Opp. 8. As Immunex admits, it must also
 2 “allege the ‘grounds upon which [its claim] rests.’” Opp. 2 (quoting *Twombly*, 550
 3 U.S. at 555). But Immunex’s current Complaint does not provide Defendants with any
 4 notice of *how* Immunex contends Dupixent® “competes.” See *Atlas IP LLC v. Pacific*
 5 *Gas & Elec. Co.*, 2016 U.S. Dist. LEXIS 60211, at *7 (N.D. Cal. Mar. 9, 2016)
 6 (“[D]escribing generally how an accused product operates, without specifically tying
 7 the operation to any asserted claim or addressing all of the claim requirements, is
 8 insufficient.”); *Jenkins v. LogicMark, LLC*, 2017 U.S. Dist. LEXIS 10975, at *6-8
 9 (E.D. Va. Jan. 25, 2017) (dismissing claim that “does not identify with any
 10 particularity *how* each allegedly infringing feature [] infringes”).

11 Immunex’s ’487 Patent attempts to cover a nearly infinite genus of antibodies
 12 that Immunex itself did not invent, by claiming the antibodies “by what [they] do”
 13 rather than by what they are—by their function (“competing” with a reference
 14 antibody) rather than by their structure (amino acid sequence). *Ariad Pharms., Inc. v.*
 15 *Eli Lilly & Co.*, 598 F.3d 1336, 1349-50 (Fed. Cir. 2010). Due to Immunex’s decision
 16 to functionally claim its purported invention, to satisfy *Iqbal/Twombly*, any claim of
 17 infringement requires Immunex to identify how the accused product satisfies the
 18 required functionality—*i.e.*, how it “competes.” Immunex has not yet done that for
 19 Dupixent®. While Immunex now complains that it should not be required to allege
 20 how its functional “competes” limitation is satisfied, that is precisely what Immunex
 21 required of the PTO and Defendants. In response to the PTO’s concern about the
 22 patentability of what became the ’487 Patent, Immunex demanded “evidence” from
 23 the PTO, like “competition binding assay” results, to support the PTO’s view (rejected
 24 by Immunex) that prior art IL-4 antibodies “*necessarily* compete.” Dkt. 34-3 at 5-6;
 25 Dkt. 34-6 at 35. Because the PTO, as a government agency, could not provide the
 26 demanded evidence, Immunex’s patent was granted. Immunex also contested
 27 Defendants’ invalidity arguments in the EPO on the basis that they were “not backed
 28 up by any evidence whatsoever” showing “compet[ition].” Dkt. 34-5 ¶¶ 5.2, 5.5. But,

1 again, Immunex’s Complaint alleges no such evidence.

2 Immunex’s patent does not provide the information its Complaint lacks because
3 competition is barely described in the ’487 Patent. Mot. 11. The ’487 Patent fails to
4 describe any assay for determining whether an antibody competes. As explained in
5 Defendants’ *inter partes* review (Opp. 1, 9; Takahashi Decl. Ex. 1), determining
6 whether two antibodies compete depends on the experimental protocol used. For the
7 same two antibodies, the results of one competition assay may signify competition,
8 while the results of another may not. Decl. of Phillip Lee ISO of Defs.’ Reply, Ex. A.
9 Thus, for Defendants to effectively defend against Immunex’s claims, Immunex must
10 allege its basis for contending that Dupixent® “competes,” for example by alleging
11 the competition testing and conditions that purportedly support this contention.
12 Immunex’s argument that Regeneron’s ’237 Patent includes “competition testing” on
13 Regeneron’s “other anti-IL-4R antibodies”—not Dupixent®—does not, and cannot,
14 supply Immunex’s factual basis for Dupixent®. Opp. 9.

15 Immunex’s reliance on other cases also lacks merit. Opp. 6. In *McAfee*, the
16 claims recited structures and their “capability, [] not actual operation,” and thus it was
17 sufficient to identify the accused products’ “specific features” that satisfy the
18 structural limitations and allege that they “can” perform the capabilities. 2016 U.S.
19 Dist. LEXIS 173699, at *4-8. The ’487 Patent claims, in contrast, recite actual
20 functionality, not capability. And mere identification of Dupixent®’s structural
21 features that allegedly satisfy the functionality (which Immunex has not even
22 provided) would be insufficient to allege *how* those features actually perform the
23 functionality. Immunex’s reliance on Regeneron’s prior complaint in *Merus* is also
24 unavailing. Opp. 7. There, Regeneron argued that its infringement allegations satisfied
25 Form 18, under which “the standard for factual specificity ‘[was] not an
26 extraordinarily high one.’” Takahashi Decl. Ex. 2 at 3, 16. But as Immunex
27 acknowledges, Form 18 is no longer the appropriate standard. Opp. 5 n.5. Immunex
28 has failed to meet the more stringent pleading standards of *Iqbal/Twombly*.

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1 Dated: June 12, 2017

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/s/ Roderick G. Dorman

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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 June 12, 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: June 12, 2017

/s/ Phillip J. Lee

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