IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANOFI-AVENTIS U.S. LLC,
GENZYME CORP. AND
REGENERON PHARMACEUTICALS, INC.,
Petitioners

v.

IMMUNEX CORPORATION,
Patent Owner

Case IPR2017-01879
Patent 8,679,487

SURREPLY IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE

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Patent Owner Immunex Corporation files this Surreply in accordance with the Board's instructions. EX1433, 27-28. The Reply from Petitioners (collectively, "Sanofi") does nothing to remedy Sanofi's flawed Petition.

I. Nothing in Sanofi's Reply justifies its serial petitions challenging the same claims; the Board should deny trial under §314(a).

The *General Plastic* ("*GP*") factors were previously established in *NVIDIA Corp. v. Samsung Elec. Co., Ltd.*—a case decided well before Sanofi filed this serial Petition. *See* IPR2016-00134, Paper 9:6-7. All factors weigh against institution. Sanofi's Reply fails to identify any new information from *GP* that would excuse Sanofi's repeated, staggered attacks on the '487 patent, or its use of Immunex's first POPR in crafting the present Petition.

Sanofi's assertion that it could not test for "competition" until it learned of the "Perez" publication is belied by the fact that Sanofi has been using 12B5 in competition assays since at least 2007—a fact shown in the POPR and undisputed in the Reply. POPR, 15-18. Further, Sanofi's Reply *admits* it was aware of Immunex's citation to Perez since at least Nov. 23, 2016—*i.e.*, four months before filing its *first* petition. Rep., 5. Accordingly, Sanofi's Reply fails to provide an adequate explanation for the time elapsed between petitions. Sanofi's staggered petitions result solely from its tactical decisions on *when* to conduct testing and *when* to begin filing serial petitions; nothing in its Reply negates this fact.

Notably, the Reply fails to dispute Sanofi's blatant use of Immunex's first

POPR to craft the present Petition. Rep., 5; POPR, 11-14. Thus, Factors 1, 3, and 5 all weigh against institution. Factors 2 and 4 remain unrefuted by Sanofi's Reply (Sanofi knew of the asserted art for more than a year before filing its first petition). POPR, 10-15. And Sanofi's bald assertion that Factors 6-7 are irrelevant is squarely contradicted by the case law. *See, e.g.*, *General Plastic*, Paper 19:8-10 (listing relevant factors for analysis after denying institution of earlier IPRs); IPR2016-01091, Paper 11:2, 13-14 (Nov. 23, 2016) (holding that "resources would be more fairly expended on initial petitions" after denying institution in two earlier IPRs); IPR2017-00637, Paper 27: 7, 12-13 (July 27, 2017) (holding that the "finite resources of the Board" weighed against institution of a third IPR after two earlier petitions were denied). As the POPR explains, the present case presents the epitome of what §314(a), *NVIDIA*, and *GP* were intended to prevent. POPR, 6-23.

II. Recent §325(d) cases weigh in favor of denying institution here.

Sanofi fails to identify any new information that would excuse its reuse of substantially the same prior art considered during prosecution. Rep., 3-4. Sanofi's reliance on *Intel Corp. v. Alacritech, Inc.* fails. IPR2017-01392, Paper 11; Rep., 4. In *Intel*, the asserted references were previously before the Office only in the form of *IDS submissions*. *Intel*, 25. In contrast, the Examiner here not only considered March, but expressly noted it was "pertinent to applicant's disclosure" and indisputably chose not to rely on it. POPR, 34; EX1002, 0051.

III. Sanofi's Reply does not remedy its failure to prove that the relied-upon portions of the '132 publication are §102(e) art.

Nothing in the Reply cures Sanofi's mere speculation that the relied-upon disclosures in the '132 publication are work "by another." The only evidence Sanofi offers to support its theory is that the '132 publication lists a different inventor than the '487 patent inventors. But "the relevant question is not whether the references list different inventors, but whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity." *EmeraChem Holdings LLC v. Volkswagen Group of Am., Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017). Even with the full benefit of Immunex's extensive evidence, Sanofi fails to meet its burden to demonstrate that the disclosures in the '132 publication constitute prior art.

Sanofi's Reply simply repeats the Petition's approach: throw theory and conjecture at the wall—with no supporting evidence —and hope something will stick. But the burden to establish that the relied-upon disclosures are prior art rests with the petitioner – and that burden never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015). In reaching its decision on institution ("DOI"), the Board should weigh Sanofi's unsupported theories against the extensive record evidence submitted by Immunex as provided by 37 C.F.R. §42.108(c). Doing so reveals that Sanofi has failed to establish a reasonable likelihood of prevailing on the merits. And Sanofi's mere

attorney arguments —which are not grounded in *evidence* —fail to create any "genuine issue of material fact." Sanofi cannot create a genuine issue – let alone meet its evidentiary burden – simply by having its lawyers vocalize unsubstantiated disagreement with the *evidence of record*.

Sanofi wrongly implies that a "fully developed record" is required. Rep., 1. The entire statutory scheme for issuing a DOI is premised on the notion that the Board will *not* have a fully developed record at the DOI stage. Sanofi provides no authority precluding denial at DOI, and no authority relieves Sanofi of its burdens to (i) show that the '132 publication qualifies as prior art and (ii) establish a reasonable likelihood of prevailing. The Board should deny institution here, just as it has done in other cases where the petitioner failed to show a reference qualified as prior art. IPR2013-00551, Paper 6:32 (Feb. 28, 2014); IPR2014-00914, Paper 11:21 (Jan. 2, 2015); IPR2016-00017, Paper 7:9-10 (April 6, 2016).

Offering no substantiating evidence, Sanofi's Reply resorts to inapposite case law. Rep., 1-2. In *Coalition*, *MaxLinear*, and *Nelson Prods.*, the patent owners did not submit *any inventor testimony* with their POPRs. *See* IPR2015-01850, Paper 10:8-15; IPR2015-00594, Paper 9:3-17; IPR2014-00572, Paper 10:12. It is no wonder the Board instituted IPRs in those cases—the patent owners provided scant record evidence, if any, to consider before institution. Here, the record is ripe with evidence in Immunex's favor. Immunex provided declarations from *all three*

inventors, two non-inventor corroborators, and disclaimer testimony from John Pluenneke, all of which is further corroborated by contemporaneous documentary evidence. POPR, 42-43.

Meanwhile, Sanofi's Reply belatedly attempts to cast hollow theories about "inventorship" inconsistencies, but these theories all fail. Rep., 2-3. First, Sanofi could have raised these theories in its Petition, but did not. Sanofi did not need any of the POPR evidence to analyze the '132 publication (EX1016), '816 application (EX1008), or March application (EX1202), as Sanofi filed these documents *with its Petition*. Second, Sanofi conflates *what is claimed* in the applications with *what is disclosed*. Rep., 2-3. None of the applications claims "an antibody," as asserted by Sanofi, let alone mAb 6-2. Rep., 2. All three applications clearly claim *methods of treatment*. EX1008, 0056; EX1016, 0032; EX1202, 0032-0033. Thus, none of Sanofi's new inventorship theories establishes even a reasonable likelihood that the relied upon disclosures in the '132 publication are the work of John Pluenneke.

Finally, the Reply's argument about inventor "conception" fails because "establish[ing] conception and reduction to practice…imposes an *unnecessary requirement* on Patent Owner" to address whether a disclosure is "by others." *Varian Med. Sys. v. Wm. Beaumont Hosp.*, IPR2016-00160, Paper 82:26; Rep., 3. Weighed against Sanofi's mere conjecture, the extensive POPR evidence shows that the Petition failed to meet its burden and the Board should deny institution.

Respectfully submitted,
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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that the above-captioned "Surreply to Patent Owner Preliminary Response" was served in its entirety on December 22, 2017, upon the following parties via electronic mail:

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