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 IPR2017-01884
Patent 8,679,487

SURREPLY IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE

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TABLE OF CONTENTS

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* factors were previously established in *NVIDIA Corp. v. Samsung Elec. Co., Ltd.*—a case decided long before Sanofi filed this serial Petition—and as explained in the POPR, all of the factors weigh against institution. *See* IPR2016-00134, Paper 9 (May 4, 2016); POPR, 6-23. Despite Sanofi's assertion to the Board that the precedential *General Plastic* decision necessitated a Reply, Sanofi's Reply does not identify or rely upon any new information from *General Plastic* that would justify Sanofi's repeated and staggered attacks on the '487 patent. EX1433, 13; Reply, 4-5. Nor does it justify Sanofi's 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 running competition experiments with 12B5 since at least 2007—a fact presented in the POPR and undisputed in Sanofi's Reply. POPR, 16-19; EX1006, ¶¶[0065]-[0066]. Further, as Sanofi's Reply *admits*, it has been aware of Immunex's citation to the Perez publication since at least Nov. 23, 2016—*i.e.*, four months before filing its *first* petition. Reply, 5. Accordingly, Sanofi's Reply does not provide an adequate

explanation for the time elapsed between filing its petitions. Sanofi's staggered petitions are a result of its own tactical decision of when to conduct testing and when to file its multiple petitions, and nothing in Sanofi's Reply negates this fact. Immunex should not "be made to share a burden created exclusively by Petitioner's tactical decisions." IPR2017-00765, Paper 7, at 11 (July 31, 2017).

Sanofi deliberately chose to file three serial petitions challenging the same claims, and as previously demonstrated, sought to take advantage of that timing by using information that it learned in the first case to craft the later petitions. POPR, 6-23. Notably, the Reply fails to dispute Sanofi's blatant use of Immunex's first POPR to craft the present Petition. Reply, 5; POPR, 12-14. Given the above, factors 1, 3, and 5 all weigh against institution.

Factors 2 and 4 also remain unrefuted by Sanofi's Reply – Sanofi plainly knew of the asserted art before it filed its first two petitions, and for more than a year before filing the present petition. POPR, 9-16. Sanofi's assertion that it was "not aware" whether the claims were obvious until the testing was complete does not relate to any *General Plastic* factor—Sanofi was demonstrably aware of the asserted references before it filed the first petition, and it even had already developed obviousness theories as evidenced by the fact that it pursued the testing in the first place. And even if Sanofi's "not aware" excuse were true, it does not justify the staggered filings. Moreover, Sanofi's bald assertion that factors six and

seven are irrelevant because the initial petition was denied is squarely contradicted by the case law. *See, e.g.*, *General Plastic*, Paper 19, at 8-10 (listing factors for analysis after denying institution of earlier IPRs); IPR2016-01091, Paper 11, at 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, at 7, 12-13 (July 27, 2017) (holding that the "finite resources of the Board" weighed against institution of an IPR after earlier petitions were not instituted). For the reasons identified in the POPR, the present case presents the epitome of what §314(a), *NVIDIA*, and *General Plastic* were intended to prevent.

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

Despite Sanofi's assertion to the Board that the newly-designated informative decisions relating to §325(d) necessitated a Reply, none of Sanofi's Reply arguments identify or rely upon new information from those decisions that excuse the Petition's reliance on substantially the same art or arguments as in prosecution. Reply, 3-4. Sanofi's Reply does not—and cannot—dispute that the Examiner considered substantially the same arguments during prosecution. Instead, Sanofi's §325(d) Reply merely restates the Petition's incorrect characterization of the prosecution history. *Compare* Reply, 3-4; *and* Pet., 1-2, 17-19. The arguments in Immunex's preliminary response remain fully applicable under recent §325(d) decisions, and the Board should deny institution.

III. Sanofi's alleged new evidence does not relate to the motivation or knowledge of a person of ordinary skill in the art

Sanofi's reply arguments are based on a fundamental misunderstanding of patent law: it seeks to use the inventors' non-public actions as though they were prior art against the patent. But the motivation to combine art must be found *in the prior art* – not by looking with hindsight at the actions of the inventors. *See, e.g.*, *Takeda Chemical Industries v. Alphapharm Pty.*, 492 F. 3d 1350, 1356 (Fed. Cir. 2007) (holding that "a prima facie case of obviousness also requires a showing of 'adequate support in the prior art' for the change"); *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F. 3d 1324, 1329 (Fed. Cir. 2009). Sanofi's so-called new "evidence" does not relate to the motivation or knowledge of a person of *ordinary* skill *in the art* ("POSA"), because it relates to *non-public* experiments performed by the *inventors* of the '487 patent.[1] Reply, 1-3.

As stated in 35 U.S.C. §103, "[p]atentability shall not be negated by the

[1] Even by Sanofi's own admissions, the additional "evidence" it relies upon is *not prior art*. The new exhibits are merely portions of untested *pleadings* from the related district court case. As Sanofi admits, new exhibits EX1435 and EX1434 were "not available" until they "were produced on August 17, 2017" and "filed on September 25 of 2017," respectively. EX1433, 8. Therefore, these new exhibits would not have informed a POSA of the state of the art before May 1, 2001.

manner in which the invention was made." And as the Federal Circuit has explained, "[p]atentability does not turn on how the invention was made, but on whether it would have been obvious to a person of ordinary skill in the field." *Sanofi-Aventis Deutschland Gmbh v. Glenmark Pharms. Inc., USA*, 748 F.3d 1354, 1360 (Fed. Cir. 2014) (rejecting the argument that the "inventors' selection" of a combination "is of itself evidence that it was obvious to try this combination"). The inventors' actions are not probative of the motivation of a POSA because "the inventor may be of a higher level of skill than someone of ordinary skill in the art, and what would have been obvious to her would not necessarily have been obvious to one of ordinary skill in the art." *Loctite Corp. v. Ultraseal Ltd.*, 781 F. 2d 861, 874 (Fed. Cir. 1985).

Moreover, Sanofi's so-called new evidence relates only to experiments confidentially performed by the inventors, using MAb230 as a research tool (*i.e.*, not as a candidate therapeutic). Such confidential experiments performed by the inventors are not evidence of how a person of *ordinary* skill would have viewed *prior art* patents and publications—the sole bases for IPR. 35 U.S.C. §311(b). Sanofi carries the burden to demonstrate that a person of *ordinary* skill would have had a reason to combine the teachings of the *prior art.* Nothing in Sanofi's Reply establishes that Sanofi has met its burden. 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 In Support of Patent Owner's Preliminary Response" was served in its entirety on December 22, 2017, upon the following parties via electronic mail:

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