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

PATENT OWNER PRELIMINARY RESPONSE
UNDER 37 C.F.R. § 42.107(a)

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TABLE OF CONTENTS

I. Introduction.....1

II. The Board should deny institution under 35 U.S.C. § 314(a) because all *General Plastic* factors are met. 6

A. Factor 1 supports denial of institution because Sanofi has filed two other petitions directed to all the same claims Sanofi challenges here.8

B. Factor 2 supports denial of institution because Sanofi knew of the art asserted in the present Petition when it filed its first Petition. 10

C. Factor 3 supports denial of institution because Sanofi had already received Immunex's Patent Owner Preliminary Response in IPR2017-01129 when it filed the present Petition and used it to re-shape its arguments here. 11

D. Factor 4 supports denial of institution because Sanofi was aware of the primary reference asserted in this Petition for several months before filing. 14

E. Factor 5 supports denial of institution because Sanofi does not provide an adequate explanation for the time elapsed between filing its petitions. 15

F. Factor 6 supports denial of institution because Sanofi's Petition would strain the finite resources of the Board. 18

G. Factor 7 supports denial of institution because overlapping issues between the three petitions would have complicated obtaining a Final Written Decision less than one year from institution.....20

H. Summary: all of the *General Plastic* factors weigh against institution. 21

III. The Board should deny institution because Sanofi's Petition fails to clarify Sanofi's ambiguous position on claim construction. 23

A. Sanofi again failed to inform the Board of its §112, ¶6 claim construction in district court and failed to reconcile its inconsistent constructions of "antibody." 23

B. Sanofi has presented incompatible positions on claim scope given its indefiniteness position in district court. 28

IV. The Board should also exercise its discretion to deny the Petition under 35 U.S.C. § 325(d). 31

V. Sanofi's Petition should be denied because it fails to show that the mAb 6-2 disclosures in the '132 Publication anticipate any of the challenged claims. 35

A. The Petition fails to show that the '132 Publication is enabling to specifically make the 6-2 antibody.....35

B. Dr. Zurawski improperly relied on teachings in the '487 Patent to make mAb 6-2. 37

VI. The Board should deny institution because the relied upon portions of the '132 Publication do not disclose an invention "by another" under Section 102(e). 38

A. The relied upon portions of the '132 Publication represent the work of the '487 Patent inventors, not John Pluenneke. 41

1. The '487 Patent inventors directed Immunex's Therapeutic Antibodies Group 44

2. The '487 Patent inventors generated human anti-hIL-4R antibodies. 47

i. The '487 Patent inventors immunized transgenic mice with soluble hIL-4R. 48

ii. The '487 Patent inventors prepared hybridoma fusions from the immunized transgenic mice. 49

iii. The '487 Patent inventors screened the antibodies for hIL-4R binding activity. 49

iv. The '487 Patent inventors screened antibodies for the ability to block IL-4 binding to hIL-4R and inhibit IL-4 and IL-13 signaling through IL-4R. 50

3. The '487 Patent inventors developed the 6-2 hybridoma and 6-2 antibody 51

4. The relied upon portions of the '132 Publication are not the work of John D. Pluenneke. 52

5. Summary of relied upon portions of the '132 Publication. 55

B. Sanofi is not likely to prevail on its anticipation ground. 58

VII. Should the Supreme Court hold that *Inter Partes* Review trials are unconstitutional, the Board should vacate and terminate this proceeding 60

VIII. Conclusion 61

Patent Owner Immunex Corporation ("Immunex") provides this Preliminary Response to the Petition for *inter partes* review ("IPR") of claims 1-14, 16, and 17 of U.S. Patent No. 8,679,487 ("the '487 Patent"; EX1001) filed by Petitioners Sanofi-Aventis U.S. LLC, Genzyme Corp., and Regeneron Pharmaceuticals, Inc. (collectively, "Sanofi").

I. Introduction

Sanofi has filed three, serial IPR petitions challenging the same claims of the same patent. This Petition represents the second, improper bite at the apple – the very type of abuse the Board cautioned against in *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB, Sept. 6, 2017) (precedential). The second Petition challenges the same claims as the first Petition based on art that Sanofi was aware of when it filed the first Petition. Sanofi waited for Immunex to file its Patent Owner Preliminary Response in IPR2017-01129 and then blatantly used it as a roadmap to craft this Petition. Sanofi provides no credible reason for its staggered filings or tactic of leveraging Immunex's first Patent Owner Preliminary Response. Although the Board ultimately denied Sanofi's first IPR petition, the overlapping issues between the three petitions would have complicated obtaining a Final Written Decision less than one year

from institution. Because all of the *General Plastic* factors weigh against institution, the Board should exercise its discretion to deny this Petition under 35 U.S.C § 314(a).

Further, in its denial of Sanofi's first Petition against the '487 Patent, the Board was "troubled by Petitioner's failure to inform [the Board] of its contention before the district court that the claims should be construed under 35 U.S.C. § 112 ¶ 6." IPR2017-01129, Paper 19, at 12. And in *Facebook, Inc. v Sound View Innovations, LLC*, the Board similarly found "troubling" the Petitioner's failure to inform the Board of its §112 ¶6 claim construction position before the district court. *Facebook, Inc. v Sound View Innovations, LLC*, IPR2017-00998, Paper 13, at 17 (PTAB, Sept. 5, 2017). This Petition suffers from the same defect. In fact, the Board should find the present Petition even more troubling, because even after reading Immunex's Patent Owner Preliminary Response to the first Petition and using it as a roadmap for crafting the present Petition, Sanofi *still* fails to inform the Board of Sanofi's §112 ¶6 claim construction position before the district court. Sanofi also failed to inform the Board of its position in district court that the claims are indefinite, creating further ambiguity regarding Sanofi's claim construction

positions. Either of these defects alone warrant denying institution. *See* 35 U.S.C. § 314(a); 37 C.F.R. §42.104(b)(3).

This Petition is additionally flawed because it raises *substantially the same* prior art that was already presented to the Office, in direct contravention of 35 U.S.C. §325(d). During prosecution of the '487 Patent, the Examiner cited and made of record a publication (EX1202, the "March" reference) that provides *verbatim* the same alleged anticipatory disclosure as the '132 Publication. And yet, the Examiner deemed March insufficient to anticipate any of the '487 Patent claims. Therefore, it would be improper to institute a Petition that merely recycles art previously considered by the Office.[1]

On top of the procedural defects, this Petition is also flawed on the merits. Sanofi's sole ground for unpatentability is based entirely on its *speculation* that the '132 Publication—an Immunex patent application publication—describes an

[1] *See Cultec, Inc. v. Stormtech LLC*, IPR2017-00777, Paper 7 (PTAB, Aug. 22, 2017) (informative); *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00739, Paper 16 (PTAB, July 27, 2017) (informative); *Unified Patents Inc. v. Berman*, IPR2016-01571, Paper 10 (PTAB, Dec. 14, 2016) (informative).

invention "by another" under 35 U.S.C. §102(e). Had Sanofi bothered to investigate its theory, it would have learned that the relied upon portions of the '132 Publication are actually the work of the '487 Patent inventors—not John Pluenneke. Immunex provides overwhelming declaration testimony from *all three inventors* of the '487 Patent, explaining that the relied upon portions of the '132 Publication represent their own work.[2] Immunex also provides disclaimer testimony from John D. Pluenneke himself—the single listed inventor on the '132 Publication—testifying that he is *not* the inventor of mAb 6-2. And Immunex provides substantial corroborating evidence including testimony from the '487 Patent inventors' former Research Associates and contemporaneous documentary evidence, all showing that the portions of the '132 Publication relied upon by Sanofi as prior art represent the work of the '487 Patent inventors, not the work of

[2] Immunex directs the Board's attention to Declaration testimony from the '487 Patent inventors, Richard J. Armitage (IMX2007), José Carlos Escobar (IMX2006), and Arvia E. Morris (IMX2008); and corroborating testimony from Norman Boiani (IMX2009), Teri Aldrich (IMX2010), and John D. Pluenneke (IMX2011).

"another" under 35 U.S.C. §102(e). Measuring the speculative information presented in the Petition against the overwhelming evidence presented in this Preliminary Response shows that Sanofi is *not* reasonably likely to prevail in its challenge to the '487 Patent based on the '132 Publication. Instituting trial here, where the sole ground is based on disclosures that are *not prior art* to the '487 Patent, would be an enormous waste of time and resources. The Board can – and should – deny trial on this basis alone.

Even if the Board were to consider the substance of the '132 Publication's disclosures, Sanofi's Petition still fails to show a reasonable likelihood of prevailing on its anticipation arguments. The Petition fails to show that the '132 Publication would have enabled a skilled artisan to specifically make and use the mAb 6-2 antibody. Indeed, Sanofi's own declarant, Dr. Zurawski, relied on disclosures *in the '487 Patent*, rather than prior art knowledge, to make mAb 6-2 for his competition assay experiments. EX1200, ¶¶82-93. Sanofi's and Dr. Zurawski's reliance on the '487 Patent's disclosures underscores the insufficiency of the '132 Publication as anticipatory art.

Finally, the Board should deny the Petition because institution of IPR of the

'487 Patent would deprive Immunex of its right to a jury trial under the Seventh Amendment. IPR proceedings are a form of litigation over private property rights, and the Seventh Amendment preserves a Patent Owner's right to have litigation over its private property take place in an Article III Court, not before an administrative agency of the Executive Branch. Adjudicating the validity of the '487 Patent in this forum would violate Immunex's Seventh Amendment rights.

In sum, the Board should deny trial because the information presented in the Petition and in this Response shows that there is *not* a reasonable likelihood that the Petitioner would prevail in its challenges to claims 1-14, 16, and 17.

II. The Board should deny institution under 35 U.S.C. § 314(a) because all *General Plastic* factors are met.

The Board should exercise its discretion to deny institution under § 314(a) because Sanofi's Petition is part of an "abuse of the review process by repeated attacks on patents." *General Plastic*, Paper 19, at 16-17. In *General Plastic*, which the PTAB has designated a precedential decision, an expanded panel affirmed the previously-used list of seven non-exhaustive "factors that are considered in the exercise of the Board's discretion under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a)." *Id.* at 4-5, 15-16; *see also*, *NVIDIA Corp. v. Samsung Elec. Co., Ltd.*,

IPR2016-00134, Paper 9, at 6–7 (PTAB, May 4, 2016)[3]. Those factors are:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;

2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;

3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;

4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the

[3] The *NVIDIA* decision issued on May 4, 2016—well before Sanofi decided to file its three staggered petitions challenging the same claims of the same patent. The *General Plastic* decision simply reiterates and reinforces the factors set forth in *NVIDIA*. *See General Plastic*, Paper 19, at 8-10, 15-16.

second petition and the filing of the second petition;

5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;

6. the finite resources of the Board; and

7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

See General Plastic, Paper 19, at 9-10, 16; *see also, NVIDIA,* Paper 9, at 6–7.

As described below, each and every *General Plastic* factor weighs against institution of this Petition.

A. *Factor 1 supports denial of institution because Sanofi has filed two other petitions directed to all the same claims Sanofi challenges here.*

Before filing this Petition, Sanofi had "already previously filed a petition directed to the same claims of the same patent." *General Plastic*, Paper 19, at 16. Sanofi has filed three IPR petitions to date, each challenging the same claims of the

same patent. Sanofi filed its first petition in IPR2017-01129 (Petition #1) on March 23, 2017, challenging claims 1-17 of the '487 Patent. Over four months later, on July 28, 2017—and three weeks *after* Immunex filed its Preliminary Response to the first petition—Sanofi filed the present petition (Petition #2), challenging claims 1-14 and 16-17 (omitting only claim 15[4]); and then filed a third petition in IPR2017-01884 on July 31, 2017 (Petition #3), again challenging claims 1-17.

In *General Plastic*, the Board "noted that the same claims of the same patent were at issue in the follow-on petitions as in the first-filed petitions, where institutions were denied." *General Plastic*, Paper 19, at 10. The same applies here. As the Board explained in *Nautilus Hyosung, Inc. v. Diebold, Inc*., the petitioner already "*had an opportunity to be heard* with regard to the patentability of the claims challenged in the Second Petition" when it filed the first petition. *Nautilus Hyosung, Inc. v. Diebold, Inc*., IPR2017-00426, Paper 17, at 12 (PTAB, June 22, 2017) (emphasis added). This "weighs toward [the Board] exercising [its] discretion not to institute." *Id.*; *see also, General Plastic*, Paper 19, at 10.

[4] Sanofi's omission of claim 15 in the present Petition makes § 314 no less applicable.

That institution was denied on Sanofi's first petition is of no moment here. Sanofi had its opportunity to be heard when it challenged the same claims of the same patent in its first petition, and the Board's denial of institution in IPR2017-01129 makes *General Plastic* no less applicable here. Indeed, in both *General Plastic* and *NVIDIA*, the Board previously denied institution on the petitioners' first petitions before exercising its discretion to deny the subsequent petitions. *General Plastic*, Paper 19, at 2-3; *NVIDIA*, Paper 9, at 2.

B. *Factor 2 supports denial of institution because Sanofi knew of the art asserted in the present Petition when it filed its first Petition.*

The Board has stated that, "[o]ut of concern for fundamental fairness, in determining whether to deny institution on subsequent petitions challenging the same claims of the same patent, we look to whether a petitioner knew or should have known of the prior art asserted in its later case when it filed the earlier one…." *Apple, Inc. v. Immersion Corp*., IPR2017-00887, Paper 7, at 6-7 (PTAB, Aug. 25, 2017) ("*Apple I*"); *see also*, *General Plastic*, Paper 19, at 10.

Here, the record shows that Sanofi was well aware of the '132 Publication at the time Sanofi filed its first petition in IPR2017-01129. Indeed, Sanofi included the '132 Publication as an exhibit with its first petition. *See* IPR2017-01129,

EX1016. Even if the ’132 Publication had not been cited in Sanofi’s first petition, “a reasonably diligent search” could have found it because it is a published patent application. *General Plastic*, Paper 19, at 20. Thus, as a matter of “concern for fundamental fairness,” the Board should weigh this factor against institution. *Apple I*, Paper 7, at 6-7; *see also, General Plastic*, Paper 19, at 10.

No other references outside of the ’132 Publication were cited as part of Sanofi's grounds in the present Petition. Therefore, “because Petitioner knew or should have known of the primary reference[] it uses to support its challenges, and provided no explanation of why it could not have raised the other reference in the First Petition, this factor weighs against institution.” *Apple I*, Paper 7, at 6-7; *General Plastic*, Paper 19, at 16.

C. *Factor 3 supports denial of institution because Sanofi had already received Immunex’s Patent Owner Preliminary Response in IPR2017-01129 when it filed the present Petition and used it to re-shape its arguments here.*

Whether the petitioner has received the Patent Owner’s Preliminary Response at the time of filing a later petition is a factor that the Board considers because of the risk that Petitioner will tailor argument in a later filed petition based on information that it learned in the Patent Owner’s earlier response. *General*

Plastic, Paper 19, at 16-17. Here, the risk of such gamesmanship is not merely theoretical. Immunex filed its Patent Owner Preliminary Response in IPR2017-01129 on July 6, 2017. Three weeks later, on July 28, 2017, Sanofi filed the present Petition. Thus, Sanofi had the benefit of Immunex's Patent Owner Preliminary Response in IPR2017-01129 when it filed the present Petition. Moreover, Sanofi blatantly adjusted its arguments in the present Petition based on Immunex's Patent Owner Preliminary Response to the first petition—a practice the Board unequivocally admonished in *General Plastic*. *See* IPR2016-01357, Paper 19, at 16-17.

For example, Sanofi offered no construction of the term "antibody" in its first petition, which Immunex brought to the Board's attention in the first Patent Owner Preliminary Response. *See* IPR2017-01129, Paper 1, at 24-25; Paper 14, at 15-22. Attempting to correct the glaring deficiencies in its first petition, Sanofi's second Petition now conveniently construes the term "antibody." Pet., at 33-35. Sanofi has clearly "modified its challenges in the follow-on petitions in an attempt to cure the deficiencies" that Immunex identified in its Patent Owner Preliminary Response in IPR2017-01129. *General Plastic*, Paper 19, at 11.

Moreover, the present Petition provides *rebuttal arguments* to Immunex's Patent Owner Preliminary Response to the first petition. *See* Pet., at 33-34, n. 5. In the present Petition, Sanofi explicitly refers to Immunex's Patent Owner Preliminary Response in IPR2017-01129 and alleges that "Patent Owner incorrectly argues that institution should be denied because in litigation Petitioners assert that 'antibody' should be limited to the sequences of the Six MAbs or their equivalents." *Id*. This rebuttal argument is highly improper and prejudicial to Immunex because Sanofi is essentially filing a Reply to Immunex's Patent Owner Preliminary Response in IPR2017-01129—a request that was flatly denied by the Board in its email of July 25, 2017. *See* IMX2005. That the Board ultimately denied institution in IPR2017-01129 is of no moment because the fact remains that Sanofi deliberately waited for Immunex's Patent Owner Preliminary Response and tailored its present Petition to address Immunex's arguments. *See* IPR2017-01129, Paper 19. "[T]he opportunity to read Patent Owner's Preliminary Response [to a petition filed by the same petitioner against the same patent], prior to filing the Petition here, is unjust." *Toyota Motor Corp. v. Cellport Systems, Inc.*, IPR2015-01423, Paper 7, at 8 (PTAB, Oct. 28, 2015).

Accordingly, the third *General Plastic* factor weighs heavily against institution because "at the time of filing of the second petition the petitioner already received patent owner's preliminary response to the first petition" and used that response to craft its later petition. *General Plastic*, Paper 19, 16-17.

D. *Factor 4 supports denial of institution because Sanofi was aware of the primary reference asserted in this Petition for several months before filing.*

It is undisputed that Sanofi was aware of the sole reference asserted in this Petition—the '132 Publication—for at least four months before filing the present Petition because Sanofi submitted the '132 Publication as an exhibit with its first petition filed March 23, 2017. Further, even if Sanofi were to make the untenable argument that it was "unaware" of the '132 Publication, only a "reasonably diligent search" would have been needed to uncover the '132 Publication, which is publicly indexed, owned by Immunex, and mentions IL-4R. *General Plastic*, Paper 19, at 20.

The Board has considered knowledge of a publication "about one month prior to filing of the petition" to be a factor in why "it would be unjust to Patent Owner to institute" a follow-on petition. *NVIDIA*, Paper 9, at 11; *see also*,

Alarm.com Inc. v. Vivint, Inc., IPR2016-01091, Paper 11, at 9-10 (PTAB, Nov. 23, 2016). In the present case, over four months passed between the filing of Sanofi's first and second petitions while pursuing its serial challenges.

Accordingly, the fourth *General Plastic* factor weighs against institution because of "the length of time that elapsed between the time petitioner learned of the prior art asserted in the second petition and filing of the second petition." *General Plastic,* Paper 19, at 16.

E. *Factor 5 supports denial of institution because Sanofi does not provide an adequate explanation for the time elapsed between filing its petitions.*

The only explanation Sanofi offers with regard to its staggered, serial filings is the allegation that it "could not have filed this Petition sooner, because the testing of the prior art 6-2 antibody disclosed in the '132 Publication was only recently completed on July 19, 2017." Pet., at 12. Sanofi offers no evidence to support this bald assertion. Further, this concocted rationale fails because it does not explain why it was necessary to file multiple petitions on multiple dates; rather, the timing of the IPR petition filing is only a reflection of Sanofi's tactical decisions.

Sanofi's alleged rationale fails to explain the delay because Sanofi provides no reason why the testing to detect competition between mAb 6-2 and 12B5 (*i.e.*, the ’487 patent’s reference antibody) could not have been performed earlier. To the contrary, Sanofi could have performed testing on mAb 6-2 whenever it desired. As Dr. Zurawski acknowledges, the light chain and heavy chain variable region sequences of mAb 6-2 are disclosed in the ’487 Patent, and thus would have been available to make mAb 6-2 for testing, *e.g.*, when the application for the ’487 Patent published as US 2011/0002913 A1 on January 6, 2011. EX1200, ¶¶82-93; EX1001, at 0001. And Petitioner Regeneron Pharmaceuticals, Inc. has been performing competition assays with the 12B5 antibody for at least 10 years. For example, US 2008/0160035 to Stevens *et al.* (EX1006; “Stevens”), which was filed in October 2007 and assigned to Regeneron Pharmaceuticals, Inc., disclosed testing a range of antibodies for competition with 12B5. EX1006, Example 6. Accordingly, this testing could have been performed for at least the last six years since US 2011/0002913 A1 published. The decision of when to begin and complete testing was entirely under Sanofi's control, and does not provide an adequate explanation for Sanofi's filing its three petitions over the course of four

months, and *after* Immunex's Preliminary Response in the first IPR. The Board should "hold [Sanofi] accountable for its own actions and inactions." *NVIDIA*, Paper 9, at 12.

Even if it were not possible for Sanofi to have completed testing before July 19, 2017 (though Sanofi has provided no evidence to support that assertion), that still would not justify Sanofi's serial petitions because the staggered filings are a result of Sanofi's tactical decision to make repeated attacks on Immunex's patent. Sanofi has not provided any reason why it could not have filed all of its petitions concurrently or as a single petition. *See Apple, Inc. v. Immersion Corp.*, IPR2017-01368, Paper 8, at 13-14 (PTAB, November 7, 2017) ("*Apple II*") (applying the *General Plastic* factors to deny a follow-on petition, and noting that petitioner "does not explain why Petitioner could not have filed the petitions at the same time."). Sanofi was under no obligation to file its first petition when it did. Sanofi's petitions were not filed in view of an imminent statutory bar. And the related district court litigation relating to the '487 Patent began on March 20, 2017, when Sanofi filed a complaint seeking a declaratory judgment of non-infringement. IMX2001. Just as the Board has previously stated, Immunex should not "be made

to share a burden created exclusively by Petitioner's tactical decisions." *Hamilton Beach Brands, Inc. v. F'Real Foods, LLC*, IPR2017-00765, Paper 7, at 11 (PTAB, July 31, 2017); *see also, General Plastic*, Paper 19, at 10-11.

Accordingly, the fifth *General Plastic* factor weighs against institution. *General Plastic*, Paper 19, at 16.

F. *Factor 6 supports denial of institution because Sanofi's Petition would strain the finite resources of the Board.*

Another *General Plastic* factor is whether consideration of the petition will strain "the finite resources of the Board." *General Plastic*, Paper 19, at 16. "The Board's resources would be more fairly expended on initial petitions, rather than on follow-on petitions, such as the Petition in this case. This is especially apparent when, as here, we are confronted with the third challenge to a patent . . . ." *Alarm.com*, Paper 11, at 13-14. Rather than selecting and presenting their strongest arguments at one time, Sanofi has filed three petitions at different times during a four-month period, adding unnecessary strain to the Board's resources. As the Board has previously stated, it is more efficient to address a matter once:

> No case, rule, or procedure compels the Board to expend judicial resources on consecutive unpatentability

> challenges by the same entity/ies, against the same claims of the same patent. Indeed, it is more efficient for the parties and the Board to address a matter once rather than twice.

Aruba Networks, Inc. v. Mobile Telecomm. Tech., LLC, IPR2017-00637, Paper 27, at 12-13 (PTAB, July 27, 2017) (internal quotations omitted); *see also, Samsung Elec. Co. v. Rembrandt Wireless Techs., LP*, IPR2015-00114, Paper 14, at 6-7 (PTAB, Jan. 28, 2015) ("[i]n this proceeding, however, we are not apprised of a reason that merits a second chance. Petitioner simply presents arguments now that it could have made in IPR '518, had it merely chosen to do so.")

Sanofi had its opportunity to be heard in IPR2017-01129 and should not be afforded a second bite at the apple. "Permitting second chances in cases like this one ties up the Board's limited resources; [the Board] must be mindful not only of this proceeding, but of 'every proceeding'" *Samsung*, Paper 14, at 7. Moreover, the relied upon disclosures in the '132 Publication are not prior art to the '487 Patent. *See* Section VI, *infra*. Institution of *inter partes* review here would be an enormous waste of the Board's time and resources. Accordingly, the sixth *General Plastic* factor also weighs against institution.

G. *Factor 7 supports denial of institution because overlapping issues between the three petitions would have complicated obtaining a Final Written Decision less than one year from institution*

Sanofi's three IPR petitions all relate to the same claims of the same patent, and issues such as claim construction are shared between the three petitions. Although the Board recently denied institution in IPR2017-01129, Sanofi should not get a pass on *General Plastic* Factor 7. The premature filing of a deficient Petition should not buy Sanofi additional time to file others. The Board should still consider and weigh Sanofi's tactical decision to file three serial Petitions because at the time Sanofi filed the present Petition, no decision on institution had been reached in IPR2017-01129. Indeed, at the time Sanofi filed the present Petition, Sanofi's tactics would have increased the burden on the Board to manage three staggered IPR proceedings, including three sets of briefing, and potentially three oral hearings—all for the same Petitioner challenging the same claims of the same patent. This would frustrate the Board's efforts to reach a Final Written Decision within one year from institution. Accordingly, even in light of the Board's decision not to institute IPR2017-01129, the seventh *General Plastic* factor weighs against institution in this case. *General Plastic*, Paper 19, at 16.

H. *Summary: all of the* General Plastic *factors weigh against institution.*

Board decisions prior to *General Plastic* have similarly noted that these factors "guide [the Board's] decision to exercise discretion, but all factors need not be present, and [the Board] need not give equal weight to each factor in reaching [its] decision." *Alarm.com*, Paper 11, at 7; *see also*, *Apple I*, Paper 7, at 6. Here, *all* of the factors weigh against institution, and the weight of the combined factors justifies denying institution.

Well before *General Plastic* was designated a precedential decision, the Board previously denied institution of follow-on petitions under circumstances nearly identical to those present here. For example, in *NVIDIA*, the Board denied institution when the petitioner filed a second petition (1) that was filed "approximately two months after Patent Owner filed its preliminary response," (2) that challenged the same claims using art that the "Petitioner identified and produced" in related litigation before the first petition was filed, and (3) that was delayed "with no apparent justification." *NVIDIA*, Paper 9, at 9-12. The *NVIDIA* Panel held that "it would be unjust to Patent Owner to institute review in this proceeding" and that "we hold Petitioner accountable for its own actions and

inactions." *Id.* at 11.

Another example is *Nautilus Hyosung Inc. v Diebold, Inc.*, IPR2017-00426, in which the Board denied institution of a second petition directed to the same claims of the same patent when (1) "Petitioner has not explained why the arguments and evidence relied on in its Second Petition were not filed with the First Petition," (2) "Patent Owner provides persuasive evidence that Petitioner was aware of at least [two cited references] when Petitioner filed its First Petition," (3) "Petitioner had sufficient time to take advantage of Patent Owner's and the Board's responses to the First Petition," and (4) "Petitioner's explanation as to why it should be permitted another challenge to the same claims of the same patent under the circumstances of this case is conclusory and inaccurate," *Nautilus*, Paper 17, at 12-16.

The present case presents the epitome of what the *General Plastic* factors and §314 discretionary analysis are intended to prevent. Just as the Board's expanded Panel concluded in its precedential decision in *General Plastic*, the factors in the present case "strongly favor[] non-institution," and the Board should "exercise[] discretion and den[y] institution under 35 U.S.C. § 314(a) and 37

C.F.R. § 42.108(a).” *General Plastic*, Paper 19, at 11. Doing otherwise would unduly burden the Board, greatly prejudice Immunex, and be contrary to the interests of justice. It would also endorse such tactics and encourage future Petitioners to adopt them.

III. The Board should deny institution because Sanofi’s Petition fails to clarify Sanofi's ambiguous position on claim construction.

Sanofi’s Petition should be denied because Sanofi fails to explain how the challenged claims are to be construed, as required by 37 C.F.R. §42.104(b)(3). In particular, the Board should deny institution because Sanofi failed to adequately explain its inconsistent claim constructions in district court litigation and the present proceeding.

A. *Sanofi again failed to inform the Board of its §112, ¶6 claim construction in district court and failed to reconcile its inconsistent constructions of “antibody.”*

The Board should deny institution because Sanofi failed to adequately explain its inconsistent claim constructions in district court litigation and the present proceeding. As with Sanofi’s first petition, the Board should find this omission troubling. *See* IPR2017-01129, Paper 19, at 12. In this proceeding, Sanofi argues that the term “antibody” should be broadly construed to encompass “whole

antibodies and antigen binding fragments thereof," and "full-length antibodies of any isotype, antibody fragments, fusion proteins, and/or single chain antibodies." Pet., at 34-35. In concurrent district court litigation concerning the '487 Patent, Sanofi represented to the U.S. District Court for the District of Massachusetts *and* to the U.S. District Court for the Central District of California[5] that the term "antibody" recited in the *same claims* of the *same patent* "must be construed in accordance with 35 U.S.C. § 112 ¶6" and that, "[p]roperly construed, none of the claims of the '487 Patent cover matter beyond the structures specifically disclosed in the specification, *i.e.*, the sequences of mAbs 6-2, 12B5, 27A1, 5A1, 63, or 1B7, the only structures conceivably capable of performing the 'compet[ing]' function, or their equivalents."[6] IMX2001, at ¶¶30-31; *see also*, IMX2002, at ¶¶66-67; IMX2003, ¶¶66-67; IMX2004, at 1. Sanofi's first petition in IPR2017-01129

[5] Sanofi has now quadrupled down on its §112, ¶6 argument in federal court, pushing its §112, ¶6 construction in at least four district court filings. *See* IMX2001, at ¶¶30-31; IMX2002, at ¶¶66-67; IMX2003, ¶¶66-67; IMX2004, at 1.

[6] Immunex does not concede that any of Sanofi's conflicting statements regarding the scope of the claim term "antibody" are correct.

offered no specific construction of the term "antibody," with *no mention* of its ongoing narrow and inconsistent construction of the same term in district court. Sanofi's present Petition now conveniently offers a construction of "antibody," yet *still fails to inform the Board* of its inconsistent claim construction position in district court, with no mention of §112, ¶6 or means plus function.

The Board recently denied institution in *Facebook, Inc. v. Sound View Innovations, LLC*, based on the petitioner's seemingly inconsistent positions before the district court and the PTAB. Like Sanofi here, the petitioner in *Facebook* argued for a means-plus-function construction before the district court, while arguing before the PTAB that no claim term required an explicit construction in the IPR and failing to inform the Board of its inconsistent claim construction position in district court. *Facebook*, Paper 13, at 8, 14-15. The *Facebook* Panel admonished the petitioner for failing to inform the Board of the inconsistent construction made in district court, and for its failure to explain its reasoning for not offering the same construction in the IPR:

> Clearly, based on its arguments to the district court, Petitioner believes that claim 19 "contains a means-plus-function . . . limitation" … Nevertheless, Petitioner chose

> not to provide us with the required construction … *Perhaps even more troubling, Petitioner chose not to inform us in its Petitions that it simultaneously was arguing a different treatment of the terms of claim 19 before the district court … nor did it explain the reason for Petitioner's change of heart regarding the presence of means-plus-function terms in claim 19*…. At the very least, Petitioner's failure to inform us of its differing claim construction arguments before the district court raises the specter of lack of candor.

Facebook, Paper 13, at 16-18 (emphasis added). Here, just as in *Facebook*, the Board should consider Sanofi's "failure to inform [the Board] of [Sanofi's] seemingly inconsistent claim construction positions or to provide [the Board] with means-plus-function constructions as required by [the] Rules" more than sufficient grounds for denial. *Facebook*, Paper 13, at 18.

Though district courts apply the *Phillips* standard and the PTO applies the BRI, the differences between these standards cannot be used to selectively invoke §112 ¶6 at Sanofi's will. Indeed, "[§ 112] paragraph six applies regardless of the context in which the interpretation of means-plus-function language arises, i.e., whether as part of a patentability determination in the PTO or as part of a validity

or infringement determination in a court." *IPCOM GMbH & Co. v. HTC Corp.*, 861 F.3d 1362, 1369 (Fed. Cir. 2017) (citing *In re Donaldson Co., Inc*., 16 F.3d 1189, 1193 (Fed. Cir. 1994) (en banc); *see also, Euro-Pro Operating LLC v. Acorne Enterprises, LLC*, IPR2014-00351, Paper 19, at 6-7 (PTAB, July 10, 2014); *Facebook,* Paper 13, at 14-18. And as the Board acknowledged in its denial of Sanofi's first petition in IPR2017-01129, "[t]hat the broadest reasonable interpretation applies to construing claims in *inter partes* review proceedings does not justify taking a different position with respect to §112 ¶ 6 before the district court." IPR2017-01129, Paper 19, at 12. Thus, Sanofi's markedly different stance on construction of the term "antibody" in this proceeding cannot be excused simply because the BRI applies here.

In *Facebook*, the Board found "troubling" the petitioner's failure to inform the Board that it was arguing §112 ¶ 6 applies to the challenged claim in district court. *Facebook*, Paper 13, at 17-18. In IPR2017-01129, the Board similarly wrote that "[w]e are troubled by [Sanofi's] failure to inform us of its contention before the district court that the claims should be construed under 35 U.S.C. §112 ¶6 ." IPR2017-01129, Paper 19, at 12. Sanofi's present Petition suffers from the same

deficiencies as those in *Facebook* and IPR2017-01129 because it *still* fails to inform the Board of its § 112 ¶ 6 contentions in district court. Accordingly, the present Panel should use its discretion under §314(a) to deny institution, just as the Board did in *Facebook* and IPR2017-01129.

B. *Sanofi has presented incompatible positions on claim scope given its indefiniteness position in district court.*

In this proceeding, Sanofi "request[ed] that the claim terms be given their broadest reasonable interpretation," and stated that only the terms "human" and "antibody" "may need to be defined or further clarified." Pet., at 31-35. In contrast, Sanofi has repeatedly and consistently asserted in district court—before filing the present Petition—that "[o]ne or more of the claims of the '487 Patent are invalid as indefinite under 35 U.S.C. § 112 ¶ 2 for failing to particularly point out and distinctly claim the subject matter of the alleged invention claimed therein." IMX2002, at 13; EX1432, at 2-3. Sanofi is, in effect, requesting that the Board construe one or more claims that Sanofi is arguing to be indefinite before the district court, again creating ambiguity regarding Sanofi's position on claim

construction.[7] By failing to reconcile inconsistent positions on claim construction, Sanofi improperly "shifts the burden of advancing a claim construction from the petitioner to the Board." *Palo Alto Networks v. Finjan, Inc.*, IPR2015-02000, Paper 9, at 4 (PTAB, May 20, 2016). This defect is fatal to Sanofi's Petition, and the Board should deny the Petition on this basis.

Sanofi did not disclose its inconsistent district court indefiniteness position at all in IPR2017-01129, and Sanofi's Petition here likewise did not disclose Sanofi's district court indefiniteness position even though Sanofi had already asserted indefiniteness in district court before filing this Petition. IMX2002, at 13. Sanofi only belatedly informed the Board of its indefiniteness contentions by requesting to enter an exhibit, just three weeks prior to the due date for Immunex's Preliminary Response. IMX2100; EX1432. Such belated disclosure is inadequate to address Sanofi's claim construction failures—Sanofi has not offered any way of reconciling its two positions despite concurrently arguing for both.

[7] While Immunex has provided a construction of certain claim terms in IPR2017-01884, construction of those terms is not needed to resolve the issues in this proceeding.

Immunex does not agree with Sanofi's district court contentions regarding the alleged indefiniteness of the claims, and is not addressing the merits of those arguments here because there were no such arguments presented in the Petition. Nevertheless, it is significant that Sanofi has again created ambiguity regarding its position on claim construction because, as the PTAB has recognized, a patent may not, like a "nose of wax," be twisted "as it suits [the parties'] infringement and invalidity cases." *Google, Inc. v. Koninklijke Philips N.V.*, IPR2017-00411, Paper 11, at 13 (PTAB, May 24, 2017) (citing *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001)). Furthermore, though district courts apply the *Phillips* standard and the PTAB applies the broadest reasonable interpretation, the differences between the standards cannot be used to argue that claims are definite under one standard but not the other. *See e.g., Ex Parte McAward*, Appeal No. 2015-006416 (PTAB, Aug. 25, 2017). It is illogical for Sanofi to assert that the '487 Patent claims comply with the BRI standard of indefiniteness but not the *Phillips* standard, and Sanofi has not explained how one or more claims are somehow indefinite under the *Phillips* standard but not the BRI. Thus, Sanofi's different position in this proceeding on the definiteness of the claims

cannot be brushed aside simply because the BRI applies here.

IV. The Board should also exercise its discretion to deny the Petition under 35 U.S.C. § 325(d).

In addition to the reasons discussed above, the Board should also exercise its discretion to deny the Petition under 35 U.S.C. §325(d) because the Office already considered art containing the same alleged anticipatory disclosures in the '132 Publication, made the art of record, and knowingly deemed it unworthy of forming the basis for a rejection. EX1002, at 0051.

Section 325(d) gives the Board discretion to deny trial when "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. §325(d); *see also Hyperbranch Med. Tech. v. Incept, LLC*, IPR2016-01836, Paper 14, at 12-14 (PTAB, April 4, 2017). Indeed, the PTAB recently designated a trio of § 325(d)-based decisions as "informative," further highlighting the importance of preventing petitioners from recycling prior art or arguments already considered by the Office during prosecution. *See Cultec, Inc. v. Stormtech LLC*, IPR2017-00777, Paper 7, at 13 (PTAB, Aug. 22, 2017) (informative) (denying institution under §325(d) because "the same or substantially the same prior art or arguments as are presented in the Petition previously were

presented to the Office."); *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00739, Paper 16, at 17-19 (PTAB, July 27, 2017) (informative) (denying institution under §325(d) because the petitioner's priority challenge was already considered by the Office); *Unified Patents Inc. v. Berman*, IPR2016-01571, Paper 10 (PTAB, Dec. 14, 2016) (informative) (denying institution on certain claims because "the Petition relies on the same or substantially the same prior art and arguments presented previously to the Office," and further noting that institution "would not be an efficient use of Board resources in this matter."). Sanofi should not be allowed to recycle substantially the same prior art (the '132 Publication) that was already considered by the Office (the March reference).

The facts here are parallel to those in *Hyperbranch*. In *Hyperbranch*, the petitioner asserted that the challenged claims were anticipated by, *inter alia*, disclosures in a reference called "Rhee '587." *Hyperbranch*, Paper 14, at 6, 13. The patent owner argued that the same disclosures in Rhee '587 relied upon by the petitioner for anticipation were previously before the Office during examination in the form of a different reference, "Rhee '500." *Id.* at 13-14. The *Hyperbranch* Panel concluded that "Rhee '587 constitutes 'substantially the same prior art' as

Rhee ’500 so as to satisfy § 325(d). In this regard, Petitioner relies on the same disclosure in both Rhee ’500 and Rhee ’587 to teach the ‘visualization agent’ limitation of the challenged claims.” *Id.* at 14.

The facts here are essentially the same. As Sanofi acknowledges, the Office expressly considered U.S. Patent Application Publication US 2002/0076409 to March *et al.*, published June 20, 2002 (filed as Appl. No. 09/904,245 on July 11, 2001) (“March”) during prosecution of the ’487 Patent. *See* Pet., at 11; EX1002, at 0051. Sanofi alleges that “the disclosure regarding the mAb 6-2 antibody in March … is *similar* to that disclosed in the ’132 Publication.” Pet., at 11 (emphasis added). But the disclosures regarding mAb 6-2 in the two references are not just “similar,” as Sanofi portrays them, they are *identical*. A copy of each disclosure is shown below for comparison:

Hybridoma Cell Line

[0246] One hybridoma cell line generated by procedures described above (see example 4) is designated 6-2. The anti-IL-4R monoclonal antibody secreted by this hybridoma is a blocking antibody, as determined in a conventional plate binding assay, and thus functions as an IL-4 antagonist. The monoclonal antibody produced by 6-2 also exhibits the ability to reduce an IL-13-induced biological activity.

’132 Publication (EX1016, ¶[0246])

Hybridoma Cell Line

[0219] One hybridoma cell line generated by procedures described above (see Example 4) is designated 6-2. The anti-IL-4R monoclonal antibody secreted by this hybridoma is a blocking antibody, as determined in a conventional plate binding assay, and thus functions as an IL-4 antagonist. The monoclonal antibody produced by 6-2 also exhibits the ability to reduce an IL-13-induced biological activity.

March (EX1202, ¶[0219])

The 6-2 hybridoma disclosure in March—identical to that in the ’132

Publication—was squarely before the Examiner during prosecution of the '487 Patent, when the Examiner expressly made the March Publication of record and chose not to rely on it:

> *The art made of record and not relied upon is considered pertinent to applicant's disclosure: March et al, U.S. PG-Pub: 2002/0076409* (published on 20 June 2002, 102 (e) date: 12 July 2000, via 60/217,888;; [*sic*] post-filing reference;; [*sic*] March et al teach an isolated human antibody that binds to the human IL-4 receptor. March et al disclose that said antibody is an lgG1 antibody, as well as fragments of said antibody and wherein the antibody inhibits IL-4 mediated activities, (see paragraphs 0049, 0104, 0107, 0112, 0210-0214, 0220 and claims). March et al disclose that the antibodies bind to IL-4 receptor and inhibit IL-4 and IL-13 activities, (see paragraph 0107)).

EX1002, at 0051 (emphasis added).

The Petition assumes, *without any evidence*, that the examiner chose not to rely on March "presumably due to the absence of any competition data regarding mAbs 6-2 and 12B5." Pet., at 11-12. But the examiner made no such statement in the record nor even suggested as much. EX1002, at 0051. Sanofi's argument

should be rejected for what it is—unsubstantiated attorney argument and speculation.

Here, as in *Hyperbranch*, "[the '132 Publication] constitutes 'substantially the same prior art' as [March] so as to satisfy § 325(d)." *Hyperbranch*, Paper 14, at 14. The Board should exercise its discretion under 35 U.S.C. § 325(d) to deny institution.

V. Sanofi's Petition should be denied because it fails to show that the mAb 6-2 disclosures in the '132 Publication anticipate any of the challenged claims.

The Board should also deny institution here because the Petition fails to show how the '132 Publication is enabling to specifically make and use mAb 6-2 because Sanofi and Dr. Zurawski rely on information not in the prior art to make mAb 6-2, and the Petition makes factually flawed arguments regarding the alleged "shared" disclosures between the '132 Publication and the '487 Patent.

A. *The Petition fails to show that the '132 Publication is enabling to specifically make the 6-2 antibody.*

"To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to *make the anticipating subject matter*." *Elan Pharms. v. Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003)

(emphasis added) (quoting *PPG Indus., Inc. v. Guardian Indus. Corp*., 75 F.3d 1558, 1566 (Fed. Cir.1996)). Sanofi argues that "the '132 Publication provides at least as much 35 U.S.C. § 112 support for mAb 6-2 as the '487 Patent's original specification provides for its claimed genus of 'isolated human antibod[ies] that compete[] with a reference antibody.'" Pet., at 39. Sanofi then makes an unfounded leap to the conclusion that that "the '132 Publication … provide[s] an enabling disclosure of all the elements of claims 1-14 and 16-17 of the '487 Patent." *Id.* But the Petition fails to show how the '132 Publication's mention of a "hybridoma cell line … designated 6-2" or "monoclonal antibody produced by 6-2" would have enabled a skilled artisan to *specifically make mAb 6-2*. *Elan Pharms.*, 346 F.3d at 1054.

Apparently recognizing the weaknesses in its anticipation position, Sanofi argues that the '132 Publication discloses "how to generate and screen for anti-hIL-4R *mAbs like mAb 6-2*" and "how to assay generated *antibodies like mAb 6-2* for IL-4 and IL-13 blocking activity." Pet., at 38. Thus, at best, the Petition argues that the '132 Publication would have enabled an artisan to make antibodies *like mAb 6-2*. Even assuming, *arguendo*, that the '132 Publication would have enabled

a skilled artisan to generate antibodies "like mAb 6-2," the Petition ultimately fails to show that the same disclosures would have enabled an artisan to specifically make *the actual 6-2 antibody* without engaging in undue experimentation.

B. *Dr. Zurawski improperly relied on teachings in the '487 Patent to make mAb 6-2.*

The Petition's failure to show how the '132 Publication is enabling to specifically make the mAb 6-2 antibody is further highlighted by Dr. Zurawski's failure to address enablement entirely in his Declaration (EX1200). Moreover, Sanofi's position that the '132 Publication would have enabled an artisan to specifically make mAb 6-2 is squarely contradicted by the approach that Dr. Zurawski took to make the mAb 6-2 antibody himself. EX1200, ¶¶82-93.

Rather than relying on information in the '132 Publication and general knowledge in the art, Dr. Zurawski had to resort to using information first disclosed in the later filed '487 Patent – as though it were prior art against itself. *Id.* As Dr. Zurawski admits, he used "the identified VH and VL variable region *sequences disclosed in the '487 Patent*" to make mAb 6-2. EX1200, ¶83; *see also, id.* at ¶¶86, 92. Thus, Dr. Zurawski relied on *post-filing* knowledge—mAb 6-2 sequence information disclosed in the '487 Patent specification—to make mAb 6-

2. Sanofi and Dr. Zurawski fail to show that information in the ’132 Publication would have been sufficient to enable a skilled artisan to make the mAb 6-2 antibody.

Indeed, it is no wonder that the Petition concocts completely incorrect arguments regarding the alleged similarities between the disclosures in the ’132 Publication and the ’487 Patent specification. The Petition repeatedly asserts that “[t]he ’132 Publication shares much of the same specification with the ’487 Patent specification.” Pet., at 6; *see also, id.* at 37, 42. A closer look at Sanofi’s redline comparison of the ’132 Publication and the ’487 Patent shows that the ’487 Patent specification contains *nearly 20 pages* of subject matter *not present* in the ’132 Publication. EX1203, at 2, 3, 11, 21-30, 36, 38, 42, 45, and 47-49. And the ’487 Patent further provides SEQ ID NOs. 4-26, which were not disclosed in the ’132 Publication. Pet., at 37, n. 6; *see also,* EX1203, at 47-49. The Petition’s assertions are plainly false.

VI. The Board should deny institution because the relied upon portions of the ’132 Publication do not disclose an invention “by another” under Section 102(e).

In addition to each of the reasons set forth above, the Board should deny

institution here because the relied upon portions of the ’132 Publication do not describe an invention “by another” under 35 U.S.C. §102(e) and are therefore not prior art to the ’487 Patent. As the witness declarations and corroborating evidence demonstrate, the relied upon portions of the ’132 Publication represent the work of the ’487 Patent inventors. Thus, the Petition’s sole ground for unpatentability relies on a reference that is not prior art to the ’487 Patent, and instituting *inter partes* review here would be an enormous waste of time and resources.

Sanofi wrongly assumes that mAb 6-2 was invented by John D. Pluenneke—the listed inventor on the ’132 Publication—rather than the ’487 Patent inventors, simply because a hybridoma cell line designated 6-2 is mentioned in the ’132 Publication. But the mere mention of “6-2” in the ’132 Publication fails to demonstrate that mAb 6-2 was the invention of anyone other than the ’487 Patent inventors. After all, the 6-2 hybridoma is not—nor was it ever—claimed in the ’132 Publication.

“The fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art.” *Applied Materials Inc. v. Gemini Research Corp*., 835 F.2d 279, 281 (Fed. Cir. 1987); *see also, Robert*

Bosch Tool Corp. v. SD3, LLC, IPR2016-01750, Paper 15, at 20 (PTAB, April 3, 2017) ("The question of whether the asserted prior art is 'by another' is not, however, dependent on the inventors listed on the face page of a patent, but dependent on who the inventor of the underlying subject matter asserted as prior art is, as compared to the claimed subject matter at issue."). Indeed, the Federal Circuit has held that "[w]hat is significant is not merely the differences in the listed inventors"; rather, the test is whether "the portions of the reference relied on as prior art" are the work of a common inventive entity. *Riverwood Int'l Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1356 (Fed. Cir. 2003) (citing *In re DeBaun*, 687 F.2d 459, 462 (CCPA 1982)); *see also EmeraChem Holdings LLC v. Volkswagen Group of America, Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017) ("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.'" (quoting *Riverwood* at 1356)). "[C]ertainly *one's own invention*, whatever the form of disclosure to the public, may not be prior art against oneself, *absent a statutory bar*." *In re Katz*, 687 F.2d 450, 454 (CCPA 1982) (quoting *In re Facius*, 408 F.2d

1396, 1406 (CCPA 1969) (emphasis in original)).

A. *The relied upon portions of the '132 Publication represent the work of the '487 Patent inventors, not John Pluenneke.*

The relied upon portions of the '132 Publication are not disclosures "by another" under 35 U.S.C. § 102(e) because the relied upon portions disclose the joint work of the '487 Patent inventors: Richard J. Armitage, José Carlos Escobar, and Arvia E. Morris. *See In re Katz*, 687 F.2d at 455. In *Katz*, the prior art reference asserted by the Office during prosecution ("Chiorazzi") was a publication co-authored by the sole inventor, Dr. Katz, and two of Dr. Katz's students. *Id.* at 452-453. Dr. Katz submitted a declaration to the Office explaining that he was the sole inventor of the application and that the two co-authors on the Chiorazzi publication were not inventors. *Id.* The Office maintained the rejection and the Board of Appeals affirmed. *Id.* at 453-454. On appeal, the CCPA explained that, while disclaiming affidavits from the two non-inventor co-authors on Chiorazzi "would have ended the inquiry," disclaiming affidavits are not required. *Id.* at 455. "What is required is a reasonable showing supporting the basis for the applicant's position." *Id.*

Further, showing "diligence and/or reduction to practice [is] not required to

show [the inventor] invented the subject matter" in the reference at issue. *See In re DeBaun*, 687 F.2d at 462; *see also, Varian Medical v. William Beaumont*, IPR2016-00160, Paper 82, at 26 (PTAB, May 4, 2017) (finding that showing reduction to practice is "an unnecessary requirement on Patent Owner" for addressing the question of whether a work is by "others.").

While the burden of production in an IPR may shift between the parties, the burden of persuasion remains 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). Here, Sanofi fails to meet its burden of persuasion. Immunex provides more than a reasonable showing that the relied upon portions of the '132 Publication are not an invention "by another." *See* 35 U.S.C. § 102(e). Immunex provides declarations from each named inventor of the '487 Patent, a disclaimer declaration from Mr. Pluenneke, declarations from two corroborators, and contemporaneously-prepared documentary evidence supporting the '487 Patent inventors' testimony:

Exhibit	**Description**
IMX2006	Declaration of '487 inventor José Carlos Escobar
IMX2007	Declaration of '487 inventor Richard J. Armitage

Exhibit	Description
IMX2008	Declaration of ’487 inventor Arvia E. Morris
IMX2009	Declaration of Research Associate Norman Boiani
IMX2010	Declaration of Research Associate Teri Aldrich
IMX2011	Disclaimer Declaration of John D. Pluenneke
IMX2012	Meeting minutes from Immunex Meeting A (confidential)
IMX2013	Meeting minutes from Immunex Meeting B (confidential)
IMX2014	Meeting minutes from Immunex Meeting C (confidential)
IMX2015	Meeting minutes from Immunex Meeting D (confidential)
IMX2016	Meeting minutes from Immunex Meeting E (confidential)
IMX2017	Non-confidential summary of meeting minutes from Immunex Meeting A
IMX2018	Non-confidential summary of meeting minutes from Immunex Meeting B
IMX2019	Non-confidential summary of meeting minutes from Immunex Meeting C
IMX2020	Non-confidential summary of meeting minutes from Immunex Meeting D
IMX2021	Non-confidential summary of meeting minutes from Immunex Meeting E

In contrast to the evidence above, Sanofi offered only unsupported *speculation* that the relied upon portions of the ’132 publication represent the work of someone other than ’487 Patent inventors. Had Sanofi bothered to investigate its theory before filing this Petition, it would have learned that John Pluenneke did

not invent the 6-2 antibody. Sanofi's baseless allegations cannot withstand the great weight of evidence that Immunex has provided, and the Board should deny institution on this basis alone.

The Petition relies on the following portions of the '132 Publication as prior art for its anticipation arguments: paragraphs [0016]-[0017], [0131], [0145], [0149], [0151], [0180], [0183], [0218]-[0220] (Example 1), [0232]-[0236] (Example 3), [0237]-[0241] (Example 4), [0242]-[0245] (Example 5), and [0246]-[0247] (Example 6). *See* Pet., at 36-61. These portions of the '132 Publication (referred to herein as "the relied upon portions") relate to transgenic mice, hybridoma cells, antibody screening assays, a hybridoma cell line designated "6-2," an antibody produced by the 6-2 cell line, and disclosures related to the antibody such as pharmaceutical compositions and kits. *Id.* All of Sanofi's arguments rely on mAb 6-2 as the basis for allegedly meeting the elements of the challenged claims.

1. The '487 Patent inventors directed Immunex's Therapeutic Antibodies Group

Beginning in the late 1990s, Richard J. Armitage, José Carlos Escobar, and Arvia E. Morris—the listed inventors on the '487 Patent—developed the mAb 6-2

antibody at Immunex when they worked together as Directors of Immunex's Therapeutic Antibodies Group. As each inventor testifies, they worked together to develop antibodies directed against the human IL-4 receptor (hIL-4R), including mAb 6-2. IMX2006, ¶¶8-9; IMX2007, ¶¶8-9; IMX2008, ¶¶8-9. Together, the '487 Patent inventors developed human antibodies that bind human IL-4R (hIL-4R), block binding of IL-4 to hIL-4R, and inhibit IL-4 and IL-13 signaling through hIL-4R. IMX2006, ¶¶9-10, 13-17; IMX2007, ¶¶9-10, 13-17; IMX2008, ¶¶9-10, 13-17.

The Federal Circuit recently held that corroboration of inventor testimony is not "required in every case, but [the Court] recognize[s] that corroborating an inventor's testimony is a well-established principle in our case law." *EmeraChem Holdings*, 859 F.3d at 1345-1346. The testimony of José Carlos Escobar, Richard Armitage, and Arvia Morris is corroborated by testimony from Norman Boiani, who worked as a Research Associate under José Carlos Escobar's direction and control; and Teri Aldrich, who worked as a Research Associate under Arvia Morris's direction and control. IMX2009, ¶8; IMX2010, ¶8. Norman Boiani's and Teri Aldrich's testimony each confirms that the '487 Patent inventors developed human anti-hIL-4R antibodies that block binding of IL-4 to IL-4R and inhibit IL-4

and IL-13 signaling through IL-4R; and that one such antibody was mAb 6-2. IMX2009, ¶¶7-19; IMX2010, ¶¶7-17. Mr. Pluenneke's disclaimer testimony provides further corroboration of the '487 Patent inventors' testimony. IMX2011, ¶¶7-8.

The *Emerachem* Court also recognized "that contemporaneous documentary evidence can serve as 'the most reliable proof that the inventor's testimony has been corroborated.'" *EmeraChem*, 859 F.3d at 1347 (quoting *Sandt Tech. Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1351 (Fed. Cir. 2001). Here, the '487 Patent inventors' testimony is further corroborated by contemporaneous documentary evidence. As part of the regular business practices at Immunex, the Therapeutic Antibodies Group held monthly meetings during which members of the group presented updates on the IL-4R therapeutic antibodies project. IMX2006, ¶¶11-12; IMX2007, ¶¶11-12; IMX2008, ¶¶11-12; IMX2009, ¶¶10-11; IMX2010, ¶¶10-11. These meetings each took place before May 26, 2000—the earliest claimed priority date for the '132 Publication (the filing date of U.S. Appl. No. 09/579,808). IMX2006, ¶12; IMX2007, ¶12; IMX2008, ¶12. After each meeting, the '487 Patent inventors regularly prepared confidential written summaries of the

meeting in the form of meeting minutes. IMX2006, ¶¶11-12; IMX2007, ¶¶11-12; IMX2008, ¶¶11-12; IMX2012; IMX2013; IMX2014; IMX2015; IMX2016. The written meeting minutes were collected and maintained at Immunex as part of Immunex's regularly conducted business activities. IMX2006, ¶11; IMX2007, ¶11; IMX2008, ¶11.

The confidential meeting minutes documents IMX2012-IMX2016 are filed under seal. Non-confidential summaries of each meeting minutes document are provided for purposes of this proceeding. IMX2017; IMX2018; IMX2019; IMX2020; IMX2021; *see also,* IMX2006, ¶12; IMX2008, ¶12.

2. The '487 Patent inventors generated human anti-hIL-4R antibodies.

The Petition relies upon paragraphs [0016]-[0017], [0145], [0180], [0183], [0218]-[0220] (Example1), [0232]-[0236] (Example 3), [0237]-[0241] (Example 4), and [0242]-[0245] (Example 5) in the '132 Publication as allegedly disclosing "the generation of transgenic mice," "how to generate and screen for anti-hIL-4R mAbs like mAb 6-2," and "how to assay generated antibodies like mAb 6-2 for IL-4 and IL-13 blocking activity." *See e.g.*, Pet., at 38, 40-42, 51-53, 55, 57-61. These portions of the '132 Publication represent the joint work of Drs. Escobar,

Armitage, and Morris. IMX2006, ¶¶13-17; IMX2007, ¶¶13-17; IMX2008, ¶¶13-17; IMX2009, ¶¶12-19; IMX2010, ¶¶12-17; IMX2012; IMX2013, IMX2014, IMX2015; IMX2016; IMX2017, IMX2018; IMX2019; IMX2020; IMX2021.

i. The '487 Patent inventors immunized transgenic mice with soluble hIL-4R.

As each of the '487 Patent inventors testifies, they decided to use commercially available Medarex mice[8] to generate human anti-hIL-4R antibodies. IMX2006, ¶13; IMX2007, ¶13; IMX2008, ¶13. Norman Boiani and Teri Aldrich confirm that it was José Carlos Escobar, Richard Armitage, and Arvia Morris who decided to use transgenic mice for making human anti-hIL-4R antibodies. IMX2009, ¶12; IMX2010, ¶12. To make the anti-hIL-4R antibodies, the '487 Patent inventors and Therapeutic Antibodies Group personnel working at their behest immunized the transgenic mice with soluble human IL-4R. IMX2006, ¶13; IMX2007, ¶13; IMX2008, ¶13; IMX2009, ¶12; IMX2010, ¶12; IMX2012, at 1, ¶¶4, 6; IMX2017; IMX2014, at 2, ¶1; IMX2019. These experiments correspond to

[8] Sanofi also acknowledges that Medarex mice were commercially available research reagents. *See* Pet., at 41; EX1200, ¶120.

paragraphs [0016]-[0017], [0145], [0180], [0183], [0218]-[0220], and [0232]-[0238] of the ’132 Publication.

ii. The ’487 Patent inventors prepared hybridoma fusions from the immunized transgenic mice.

After immunizing transgenic mice, the ’487 Patent inventors and Therapeutic Antibodies Group personnel working at their behest prepared hybridoma “fusions” from the immunized mice by fusing mouse spleen cells with myeloma cells. IMX2006, ¶13; IMX2007, ¶13; IMX2008, ¶13; IMX2009, ¶12; IMX2010, ¶12; IMX2012, at 1, ¶6; IMX2017; IMX2013, at 1, ¶¶1, 3; IMX2018; IMX2016, at 2, ¶5; IMX2021. Each hybridoma cell culture secreted a monoclonal antibody into the culture supernatant. *Id.* These experiments correspond to paragraphs [0219] and [0239] of the ’132 Publication.

iii. The ’487 Patent inventors screened the antibodies for hIL-4R binding activity.

The ’487 Patent inventors and Therapeutic Antibodies Group personnel working at their behest also screened the antibodies produced by the hybridomas for the ability to bind hIL-4R using an ELISA plate binding assay. IMX2006, ¶13; IMX2007, ¶13; IMX2008, ¶13; IMX2006, ¶12; IMX2009, ¶12; IMX2012, at 1, ¶6; IMX2017; IMX2013, at 1, ¶¶1, 3; IMX2018; IMX2014, at 1, ¶2; IMX2019;

IMX2016, at 2, ¶4; IMX2021. Samples that read positive in the hIL-4R plate binding assay were subsequently tested for blocking ability (discussed in the next section below). IMX2006, ¶¶13-14; IMX2007, ¶¶13-14; IMX2008, ¶¶13-14; IMX2012, at 2, ¶1; IMX2017; IMX2013, at 1, ¶¶3-4; IMX2018; IMX2014, at 1, ¶2; IMX2019; IMX2015, at 1, ¶4; IMX2020; IMX2016, at 2, ¶4; IMX2021. These experiments correspond to paragraphs [0149], [0220], and [0240] of the ’132 Publication.

iv. The ’487 Patent inventors screened antibodies for the ability to block IL-4 binding to hIL-4R and inhibit IL-4 and IL-13 signaling through IL-4R.

As the ’487 Patent inventors explain, antibodies determined to be positive for anti-hIL-4R binding activity were subsequently screened for the ability to block IL-4 binding to IL-4R using an ELISA hIL-4R blocking assay. IMX2006, ¶¶13-14; IMX2007, ¶¶13-14; IMX2008, ¶¶13-14; IMX2009, ¶¶12-13; IMX2010, ¶¶12-13; IMX2012, at 2, ¶1; IMX2017; IMX2013, at 1, ¶¶3-4; IMX2018; IMX2014, at 1, ¶2; IMX2019; IMX2015, at 1, ¶4; IMX2020; IMX2016, at 2, ¶4; IMX2021. Antibodies that were found to block IL-4 binding were also tested in a CD23 expression assay for their ability to inhibit IL-4 and IL-13 signaling through hIL-4R. IMX2006, ¶14; IMX2007, ¶14; IMX2009, ¶14; IMX2013, at 1, ¶5; IMX2018;

IMX2014, at 1, ¶4; IMX2019; IMX2015, at 1, ¶4; IMX2020; IMX2016, at 3, ¶¶1-2; IMX2021. These experiments correspond to paragraphs [0149] and [0241]-[0245] of the ’132 Publication.

3. The ’487 Patent inventors developed the 6-2 hybridoma and 6-2 antibody

The Petition repeatedly relies on paragraphs [0246]-[0247] (Example 6) of the ’132 Publication for references to a hybridoma designated “6-2,” the antibody produced by hybridoma 6-2, and IgM and IgG1 isotypes of the antibody. Pet., at 6, 38-42, 51-53, 55, 58, 60. These portions of the ’132 Publication also represent the joint work of José Carlos Escobar, Richard Armitage, and Arvia Morris. IMX2006, ¶¶15-16; IMX2007, ¶¶15-16; IMX2008, ¶¶15-16; IMX2009, ¶¶14-19; IMX2010, ¶¶14-17.

The ’487 Patent inventors testify that they developed a hybridoma fusion designated 6-2. IMX2006, ¶15; IMX2007, ¶15; IMX2008, ¶15; IMX2013, at 1, ¶3; IMX2018; IMX2014, at 1, ¶¶2, 4-5; IMX2019; IMX2016, at 2, ¶¶4-5 and 3, ¶2; IMX2021. This testimony is corroborated by testimony from Norman Boiani and Teri Aldrich. IMX2009, ¶15; IMX2010, ¶15. The ’487 Patent inventors determined that the antibody produced by hybridoma 6-2 binds to hIL-4R and that the antibody

blocks IL-4 binding to the hIL-4 receptor and inhibits IL-4 and IL-13 signaling through hIL-4R. IMX2006, ¶15; IMX2007, ¶15; IMX2008, ¶15; IMX2009, ¶¶15-17; IMX2010, ¶¶15-16; IMX2013, at 1, ¶5; IMX2018; IMX2016, at 3, ¶2; IMX2021. The ’487 Patent inventors further explain that the original antibody produced by hybridoma 6-2 was an IgM isotype, and that the inventors decided to subsequently expressed the antibody as an IgG1 isotype. IMX2006, ¶16; IMX2007, ¶16; IMX2008, ¶16; IMX2009, ¶¶18-19; IMX2010, ¶17; IMX2012, at 2, ¶2 and 3, ¶1; IMX2017; IMX2014, at 1, ¶5; IMX2019; IMX2016, at 1, ¶5, 2, ¶4, and 3, ¶2; IMX2021. These experiments correspond to paragraphs [0246]-[0247] of the ’132 Publication.

4. The relied upon portions of the ’132 Publication are not the work of John D. Pluenneke.

Sanofi wrongly assumes that the relied upon portions of the ’132 Publication are the work of John D. Pluenneke, the sole named inventor on the ’132 Publication. It is notable that Sanofi fails to provide testimony from anyone with knowledge of the development of hybridoma 6-2 or antibody 6-2; Sanofi merely lodges this unsupported attack and hopes it sticks. But as shown above and further supported by testimony from John Pluenneke himself, the relied upon portions in

the ’132 Publication represent the work of the ’487 Patent inventors, not John D. Pluenneke. IMX2011, ¶¶7-8; IMX2006, ¶18; IMX2007, ¶18; IMX2008, ¶18; IMX2009, ¶20; IMX2010, ¶18. *See e.g., Coalition for ADROCA v. ACORDA Therapeutics*, IPR2015-01850, Paper 72, at 37-40 (PTAB, March 9, 2017) (disqualifying an accused anticipatory reference as prior art because the “pertinent portions” of the reference were “the inventors’ own work” and “not by others.”)

Mr. Pluenneke testifies that the relied upon portions of the ’132 Publication—including paragraph [0246]’s disclosure of the 6-2 hybridoma cell line and the antibody produced by it—do not represent his work. IMX2011, ¶¶7-8. Mr. Pluenneke further testifies that the ’132 Publication’s disclosure of transgenic mice (Example 3), methods of generating and screening anti-hIL-4R antibodies, including screening antibodies for their ability to block IL-4 binding to IL-4R (Examples 1 and 4), and assays for screening antibodies for their ability to inhibit IL-4 and IL-13 signaling through hIL-4R (Example 5) do not represent his work. IMX2011, ¶¶7-8.

It is of no moment that Mr. Pluenneke is named as the sole inventor on the ’132 Publication because inventorship is determined by what is *claimed*, and mAb

6-2 is not and was never claimed in the ’132 Publication – a fact Sanofi ignores. EX1016, at p. 0032 (claims 1-4); IMX2022, at 44. And naming Mr. Pluenneke as the sole inventor is consistent with his Inventor Oath submitted during prosecution of Appl. No. 09/785,934, which later published as the ’132 Publication. IMX2022, at 73; IMX2023, at 1. Mr. Pluenneke stated in his Inventor Oath that he believed himself to be “an original, first and sole inventor … *of the subject matter which is claimed* and for which a patent is sought on the invention.” *Id.* (emphasis added).

Mr. Pluenneke’s testimony further corroborates the testimony of the ’487 Patent inventors that the relied upon portions of the ’132 Publication are the work of the ’487 Patent inventors—not the work of John Pluenneke. In *Katz*, the CCPA stated that, while not required, “[s]ubmission of [disclaimer] affidavits or declarations would have ended the inquiry” as to whether the disclosures in the asserted Chiorazzi reference were “by another.” *Katz*, 687 F.2d at 455. Here, considering the inventor testimony, the corroborating testimonial and documentary evidence, and Mr. Pluenneke’s disclaimer testimony, the Board should end the inquiry. *See e.g.*, *Duncan Parking Tech., Inc. v. IPS Group, Inc.*, IPR2016-00067, Paper 29, at 8 (PTAB, March 27, 2017) (finding that a prior art reference was not

"by another" in view of inventor declaration testimony and a disclaimer declaration); *General Electric v. Univ. Virginia Patent Foundation*, IPR2016-00357, Paper 57, at 13 (PTAB, June 21, 2017) (finding that a prior art reference was not "by another" in view inventor declaration testimony and a disclaimer declaration).

5. Summary of relied upon portions of the '132 Publication.

In sum, the relied upon portions of the '132 Publication represent the joint work of José Carlos Escobar, Richard Armitage, and Arvia Morris—not John Pluenneke. For the Board's convenience, this is summarized in the table below:

Table 1: The relied upon portions of the '132 Publication represent the joint work of the '487 Patent inventors.

	Relied upon portions of '132 Publication (EX1016)	**'487 Patent inventors' work**
1.	¶¶[0016]-[0017], [0145], [0180], [0183], [0218]-[0220], [0232]-[0238]	Immunizing transgenic mice with soluble IL-4R to generate human anti-hIL-4R antibodies for therapeutic utility. *See* IMX2006, ¶¶9-10, 13-17; IMX2007, ¶¶9-10, 13-17; IMX2008; ¶¶9-10, 13-17; IMX2009, ¶¶8-9, 12; IMX2010, ¶¶8-9, 12; IMX2012, at 1, ¶¶4, 6; IMX2017; IMX2014, at 2, ¶1; IMX2019.

	Relied upon portions of '132 Publication (EX1016)	**'487 Patent inventors' work**
2.	¶¶[0219], [0239]	Preparing hybridoma "fusions" from the immunized mice. *See* IMX2006, ¶13; IMX2007, ¶13; IMX2008; ¶13; IMX2009, ¶12; IMX2010, ¶12; IMX2012, at 1, ¶6; IMX2017; IMX2013, at 1, ¶¶1, 3; IMX2018; IMX2016, at 2, ¶5; IMX2021.
3.	¶¶[0220], [0240]	ELISA screening antibodies for the ability to bind IL-4. *See* IMX2006, ¶13; IMX2007, ¶13; IMX2008; ¶13; IMX2009, ¶12; IMX2010, ¶12; IMX2012, at 1, ¶6; IMX2017; IMX2013, at 1, ¶¶1, 3; IMX2018; IMX2014, at 1, ¶2; IMX2019; IMX2016, at 2, ¶4; IMX2021.
4.	¶¶[0149], [0241]	ELISA screening antibodies for the ability to block IL-4 binding to IL-4R. *See* IMX2006, ¶13; IMX2007, ¶13; IMX2008; ¶13; IMX2009, ¶12; IMX2010, ¶12; IMX2012, at 2, ¶1; IMX2017; IMX2013, at 1, ¶¶3-4; IMX2018; IMX2014, at 1, ¶2; IMX2019; IMX2015, at 1, ¶4;

	Relied upon portions of '132 Publication (EX1016)	**'487 Patent inventors' work**
		IMX2020; IMX2016, at 2, ¶4; IMX2021.
5.	¶¶[0149], [0242]-[0245]	Screening antibodies for the ability to inhibit CD23 expression induced by IL-4 and IL-13 on human peripheral blood B cells. *See* IMX2006, ¶14; IMX2007, ¶14; IMX2008; ¶14; IMX2009, ¶13; IMX2010, ¶13; IMX2013, at 1, ¶5; IMX2018; IMX2014, at 1, ¶4; IMX2019; IMX2015, at 1, ¶4; IMX2020; IMX2016, at 3, ¶¶1-2; IMX2021.
6.	¶[0246]	Hybridoma 6-2 and the monoclonal antibody produced from hybridoma 6-2. *See* IMX2006, ¶15; IMX2007, ¶15; IMX2008; ¶15; IMX2009, ¶¶14-17; IMX2010, ¶¶14-16; IMX2013, at 1, ¶¶3, 5; IMX2018; IMX2014, at 1, ¶¶2, 4-5; IMX2019; IMX2016, at 2, ¶¶4-5 and 3, ¶2; IMX2021.
7.	¶[0247]	IgM and IgG1 isotypes of the antibody produced by hybridoma 6-2. *See* IMX2006, ¶16; IMX2007, ¶16; IMX2008; ¶16; IMX2009, ¶¶18-19;

	Relied upon portions of ’132 Publication (EX1016)	**’487 Patent inventors’ work**
		IMX2010, ¶17; IMX2012, at 2, ¶2 and 3, ¶1; IMX2017; IMX2014, at 1, ¶5; IMX2019; IMX2016, at 1, ¶5, 2, ¶4, and 3, ¶2; IMX2021.

Discussed above in Section II, institution of this IPR—based solely on a reference that is not prior art to the ’487 Patent—would be a huge waste of the Board’s time and resources. The Board should end the inquiry here and deny institution. *See Katz*, 687 F.2d at 455.

B. *Sanofi is not likely to prevail on its anticipation ground.*

It is well-established law that “the burden of persuasion [in an IPR] is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ … and *that burden never shifts to the patentee*.” *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015) (citations omitted; emphasis added). Even if, *arguendo*, Immunex had “a burden of coming forward with relevant evidence tending to support its position” that the ’487 Patent inventors were the sole inventors of the relied upon portions of the ’132 Publication, it “met any such burden” by providing substantial testimonial and

documentary evidence. *Duncan Parking Tech.*, IPR2016-00067, Paper 29, at 8-9.

Rule 108 requires that "[t]he Board's decision w*ill take into account a patent owner preliminary response* where such a response is filed, *including any testimonial evidence*, but a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an inter partes review." 37 C.F.R. §42.108(c) (emphasis added). Here, the Board should take into account the arguments in this Preliminary Response along with the great amount of testimonial and documentary evidence.

The only argument raised in the Petition is based entirely on Sanofi's erroneous *speculation* that the mAb 6-2 disclosure in the '132 Publication is the work of John Pluenneke. By comparison, Immunex provides the Board with testimonial evidence from *all three '487 Patent inventors*, corroborating contemporaneously-produced documentary evidence, corroborating testimony from as well as a disclaiming declaration from Mr. Pluenneke, the named inventor on the '132 Publication. Thus, there is no "genuine issue of material fact" regarding whether the '132 Publication is §102(e) art to the '487 Patent—it is not.

37 C.F.R. §42.108(c). Instituting IPR will not shift the balances here, especially because Sanofi had the burden *in the Petition* to make out its case, and the burden of persuasion never shifted to Immunex. In view of the overwhelming evidence provided herein, compared with Sanofi's unfounded speculation, the Board should exercise its discretion and deny institution.

VII. Should the Supreme Court hold that *Inter Partes* Review trials are unconstitutional, the Board should vacate and terminate this proceeding

The Supreme Court recently granted a certiorari petition in *Oil States Energy Services LLC v. Greene's Energy Group, LLC* to decide whether the IPR statute violates the U.S. Constitution by granting the Board the authority to extinguish private property rights in a non-Article III forum without a jury. *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 639 F. App'x 639 (Fed. Cir. 2016) (Mem.), *cert. granted*, 137 S. Ct. 2239 (2017). Immunex respectfully objects to this tribunal's exercise of jurisdiction to adjudicate the validity of the '487 Patent because it would violate Immunex's right to a jury trial under the Seventh Amendment. If the Supreme Court disturbs the Federal Circuit's precedent in this area, Immunex will advise the Board and seek dismissal of this matter.

VIII. Conclusion

The Petition should be denied under 35 U.S.C. §314(a) because all of the *General Plastic* factors weigh against institution. Moreover, Sanofi again fails to inform the Board of its §112, ¶6 position in district court, and fails to explain or reconcile its inconsistent positions on definiteness of claim scope. The Petition should also be denied under 35 U.S.C. §325(d) for asserting substantially the same prior art already presented to the Office. The Petition should also be denied on the merits because it fails to show a reasonable likelihood that any of the challenged claims is unpatentable as anticipated by the '132 Publication. Therefore, the Board should deny institution.

Respectfully submitted,
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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that Immunex Corp.'s Patent Owner Preliminary Response contains 11,823 words as counted by the word-processing program used to generate this reply. This total does not include the table of contents, the table of authorities, appendix of exhibits, certificate of service, or this certificate of word count.

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

The undersigned hereby certifies that the above-captioned "Patent Owner Preliminary Response" was served in its entirety on November 16, 2017, upon the following parties via electronic mail:

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