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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2018-00331
Patent No. 9,249,218

PATENT OWNER'S PRELIMINARY RESPONSE

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Patent Owner Genentech, Inc. ("Genentech") respectfully submits this Preliminary Response to the second petition for *inter partes* review of U.S. Patent No. 9,249,218 ("the '218 patent") filed by Petitioner Pfizer, Inc. ("Pfizer") (Paper 1).

I. INTRODUCTION

Pfizer's new petition for *inter partes* review of the '218 patent is a transparent and improper attempt to remedy deficiencies in its first petition. Pfizer filed this second petition four days after receiving Genentech's preliminary response to its prior petition. While Pfizer's second petition challenges the very same claims based on exactly the same prior art, Pfizer presents new arguments and evidence directed to the deficiencies that Genentech identified in its preliminary response. Pfizer also filed a joinder motion that effectively seeks to add its new arguments and evidence to its initial, placeholder petition, while retaining the benefit of that petition's earlier filing date. Notably, Pfizer does not even attempt to explain why it previously chose to omit these new arguments and evidence—all of which were available to Pfizer and could have been included in its first petition.

The Board has repeatedly held that such abusive tactics are not consistent with the *inter partes* review system and should be rejected. The Board has identified seven factors—the so-called *General Plastic* factors—that should be considered in assessing whether a follow-on petition should be denied under Section 314(a), and

all seven factors weigh heavily in favor of denying Pfizer's new petition. The Board has explained further that a petition like Pfizer's, which presents prior art previously considered by the Board, also should be rejected under Section 325(d). Moreover, Pfizer would suffer no prejudice from the denial of its new petition because the Board already has instituted trial with respect to Pfizer's first petition.

Accordingly, Genentech respectfully requests that the Board exercise its discretion to deny Pfizer's second petition challenging the '218 patent pursuant to 35 U.S.C. §§ 314(a) and/or 325(d).

II. PROCEDURAL HISTORY

A. Pfizer's First Petitions Challenging The '142 And '218 Patents

On August 29, 2017, Pfizer filed petitions for *inter partes* review of two of Genentech's patents related to Genentech's groundbreaking antibody trastuzumab, which is approved as HERCEPTIN® for treating a particularly virulent form of breast cancer known as HER2-positive breast cancer. In IPR2017-02019 Pfizer challenged claims 1-3 of U.S. Patent No. 6,339,142 ("the '142 patent"), and in IPR2017-02020 Pfizer challenged claims 1 and 5-7 of U.S. Patent No. 9,249,218 ("the '218 patent," *i.e.*, the same claims of the same patent challenged in the present action). The '142 patent and '218 patent relate to improved anti-HER2 compositions in which certain kinds of byproducts formed by the degradation of anti-HER2

antibodies (so called "acidic variants") are minimized, resulting in a drug composition with improved purity and effectiveness.

In each petition, Pfizer asserted that the challenged claims were invalid as anticipated and/or obvious over three references: Andya (Ex. 1004), Waterside (Ex. 1005), and Harris (Ex. 1007), *i.e.*, the same three references asserted in the present petition. All three references relate to work performed by Genentech scientists, but none discloses the compositions claimed in the '142 and '218 patents. Andya is an International PCT Application (WO 97/04801) assigned to Genentech and directed to a method of lyophilizing (*i.e.*, freeze-drying) and reconstituting antibody formulations such as anti-HER2 antibody compositions. Ex. 1004 at 3. Harris is an article by Genentech analytical chemist Reed Harris describing techniques for evaluating the characteristics of anti-HER2 antibodies referred to as "rhuMAb HER2" antibodies. Ex. 1007 at 4-5. Waterside is a slide presentation by Mr. Harris that also describes techniques for evaluating rhuMAb HER2 antibodies. Ex. 1005 at 3. Pfizer contends that Waterside discloses essentially the same information as the Harris reference and corresponds to a slide presentation delivered by Mr. Harris at the 1996 Waterside Monoclonal Conference. Paper 1 at 21, 61.

Pfizer supported each of its initial petitions with affidavits from three declarants: Dr. Carl Scandella, Dr. Richard Buick, and Mr. Keith Carson. Dr. Scandella, a purported expert in protein analysis, opined that Andya, Waterside, and

Harris anticipated the challenged claims and/or rendered them obvious. Dr. Buick, a purported expert in preparing recombinant antibodies, described certain experiments in which he attempted to manufacture the product of the prior art (which, according to Pfizer, supported Pfizer's contention that the prior art was enabling). Mr. Carson, the director of the organization that hosted the 1996 Waterside Monoclonal Conference, purported to describe certain procedures related to how documents were distributed at the conference. With respect to Dr. Buick and Mr. Carson, the declarations that Pfizer submitted in IPR2017-02019 and IPR2017-02020 were identical.

B. Genentech's Preliminary Responses To Pfizer's First Petitions

On December 14, 2017, Genentech submitted its preliminary responses to Pfizer's first petitions. In its responses, Genentech identified numerous deficiencies in each petition and explained why Pfizer had failed to satisfy the required legal standards.

Genentech explained, for example, that Pfizer's obviousness challenge based on Andya was legally deficient because Pfizer had failed to articulate the reasons it contended that a person of ordinary skill in the art would have been motivated to modify Andya to achieve the claimed invention. *E.g.*, IPR2017-02019, Paper 10 at 28-29; IPR2017-02020, Paper 10 at 31-32. Similarly, Genentech explained that Pfizer had failed to meet its burden of showing that Waterside qualified as a printed

publication because Mr. Carson had failed to explain how interested members of the public could have learned about the Waterside conference and also failed to authenticate Pfizer's copy of the Waterside reference. *E.g.*, IPR2017-02019, Paper 10 at 40-41; IPR2017-02020, Paper 10 at 43-44. Genentech likewise explained that Pfizer's assertions that various claim elements were inherently disclosed in the prior art were all legally insufficient because Pfizer had failed to apply the correct legal standard. *E.g.*, IPR2017-02019, Paper 10 at 2; IPR2017-02020, Paper 10 at 2.

Genentech also explained that Dr. Buick's experiments failed to show that the prior art was enabling. Among other things, Dr. Buick failed to actually practice the prior art's teachings that he attempted to follow. For example, Dr. Buick purported to demonstrate the prior art was enabling because (according to Dr. Buick) his experiments followed the teachings of a particular prior art reference ("Carter") described in Andya. IPR2017-02019, Paper 10 at 33-34; IPR2017-02020, Paper 10 at 36-37. But as Genentech explained, Carter teaches that its antibody was produced using human embryonic kidney ("HEK") cells, whereas Dr. Buick chose to deviate from that teaching and instead use Chinese hamster ovary ("CHO") cells. IPR2017-02019, Paper 10 at 33-34; IPR2017-02020, Paper 10 at 36-37. Genentech further explained that the use of different cell lines impacts the post-translational modification and the chemical degradation of a protein, and thus the formation of acidic variants as recited in the challenged claims. IPR2017-02019, Paper 10 at 34;

IPR2017-02020, Paper 10 at 37. Therefore, Dr. Buick's failure to use HEK cells meant that even if his experiments were otherwise successful (though they were not), they still would not show that the prior art was enabling.

C. Pfizer's Second Petitions Challenging The Same Claims Based On The Same Prior Art

On December 18, 2017, Pfizer filed two follow-on petitions for *inter partes* review of the '142 and '218 patents—the present petition and IPR2018-00330. In the present petition, Pfizer is challenging the same claims (1 and 5-7) based on the same prior art references (Andya, Waterside and Harris) as its prior petition directed to the '218 patent, and in IPR2018-00330, Pfizer is similarly challenging the same claims (1-3) based on two of the same prior art references (Andya and Waterside) as its prior petition directed to the '142 patent.

Each of Pfizer's follow-on petitions includes new evidence and arguments that were not included in Pfizer's first petitions, including evidence and arguments directed to (although not overcoming) the deficiencies that Genentech identified in its preliminary responses to Pfizer's first petitions. For example, as discussed above, Genentech's preliminary responses demonstrated that Pfizer's original petitions included obviousness challenges based on Andya that were legally deficient because Pfizer had failed to present reasons why a person of ordinary skill would have been motivated to modify Andya to achieve the claimed invention. In each of its follow-

on petitions, Pfizer included a declaration from a new purported expert, Dr. Drew Kelner, who opined on the issue of a motivation to modify Andya. *E.g.*, Paper 1, Ex. 1002, ¶¶ 188-219.

Each of Pfizer's follow-on petitions also includes a new declaration from Mr. Carson. As Genentech explained in its preliminary responses, Pfizer's first petitions failed to demonstrate that Waterside qualified as a printed publication because Mr. Carson failed to authenticate Pfizer's copy of Waterside and further failed to explain how interested members of the public could have learned about the Waterside conference. In his new declaration, Mr. Carson purports to authenticate Pfizer's copy of Waterside and purports to demonstrate how the Waterside conference was advertised. Paper 1, Ex. 1020, ¶¶ 4, 11.

Pfizer's new petitions also include a new declaration from Dr. Buick. Paper 1, Ex. 1015. As discussed above, Genentech's preliminary responses explained that Dr. Buick had failed to demonstrate that the prior art was enabling because he deviated from the prior art teachings that he purported to follow, for example by conducting his experiments using CHO cells rather than HEK cells. In his new declaration, Dr. Buick describes additional experiments using HEK cells. Paper 1, Ex. 1015, ¶¶ 23-24. Notably, Dr. Buick completed these HEK cell experiments in July 2017, *i.e.*, ***before*** he completed the CHO cell experiments that he described in his August 29, 2017 declaration in support of Pfizer's first petitions. *Id.* at 61-62

(showing HEK cell experiments completed in July 2017 and CHO cell experiments completed in August 2017); *see also id.*, ¶ 1 ("This declaration describes the experimental protocols and analyses that I have personally conducted from December 2016 to August 2017."). Dr. Buick does not explain why he chose to omit the HEK cell experiments from his first declaration. However, Dr. Buick's new declaration explains that his original HEK cell experiments failed due to supposed "pressure issues," and that he conducted additional HEK cell experiments that deviated from the prior art teachings, and it is the result of these experiments that he reports in his new declaration. *Id.*, ¶¶ 23-24, 40-41.

Despite the fact that the Board had previously established the factors to be considered in assessing whether a petitioner's follow-on petition should be instituted, *see Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (P.T.A.B. Sept. 6, 2017) (precedential), Pfizer's new petitions do not even attempt to address these factors or otherwise attempt to explain why Pfizer's new evidence and arguments were not included in its first petitions.

D. Pfizer's Joinder Motion

On December 22, 2017, Pfizer filed concurrent motions to join each of its new IPR petitions to its earlier petitions. *E.g.*, Paper 3. Pfizer asserted that joinder was appropriate because each new petition was "substantively identical" to its prior petition challenging the same claims of the same patent. *Id.* at 5.

On January 22, 2018, Genentech filed its oppositions to Pfizer's joinder motions. *E.g.*, Paper 7. Genentech explained that Pfizer's position was nonsensical, *i.e.*, if the new petitions were "substantively identical" to the first petitions as Pfizer contended, there would have been no need for Pfizer to file them. *Id.* at 4. Genentech further explained that (as discussed above) Pfizer's new petitions contain new evidence and arguments, including new evidence and arguments directed to (although not overcoming) the deficiencies that Genentech identified in its preliminary responses. *Id.* at 4-10. Genentech also demonstrated that joinder would be unfair and prejudicial to Genentech, as it would simply allow Pfizer to get the benefit of its original filing date by filing placeholder petitions while significantly expanding the scope of the arguments and evidence that Genentech would need to address within the narrow time frame and page limits allowed under the Board's rules. *Id.* at 10-12.

On February 22, 2018, Pfizer filed its replies in support of its joinder motions. *E.g.*, Paper 9. Pfizer asserted that it would have been "virtually impossible" to create its new petitions from scratch in the four days between the filing of Genentech's preliminary responses to the first petitions and the filing of Pfizer's second petitions. *Id.* at 3. Pfizer also asserted that its first petitions were not legally deficient, but Pfizer did not dispute that its new petitions contain additional evidence and argument attempting to address deficiencies Genentech identified in its preliminary responses.

Id. at 2-3. Pfizer failed to put forth any reason why its new evidence and arguments could not have been included in its first petitions. And Pfizer did not dispute that joinder would expand the scope of the proceedings while cutting short Genentech's time to respond to Pfizer's new arguments and evidence.

E. The Board's Decision On Institution Regarding Pfizer's First Petitions

On March 12, 2018, the Board issued its decisions on institution with respect to Pfizer's first petitions. Paper 16. The Board instituted review of all challenged claims based on Pfizer's proposed grounds that the claims were anticipated by Andya and that the claims were obvious over Harris. *Id.* at 32. The Board did not address Dr. Buick's experiments purportedly demonstrating that the prior art is enabling, but instead found that the prior art was entitled to an initial presumption of enablement. *Id.* at 21 (citing *In re Antor Media Corp.*, 689 F.3d 1282, 1287 (Fed. Cir. 2012)).

The Board denied Pfizer's obviousness challenge based on Andya on the same basis set forth in Genentech's preliminary response, *i.e.*, because Pfizer had failed to articulate its obviousness rationale. Paper 16 at 17. The Board further exercised its discretion to deny Pfizer's challenges based on Waterside. *Id.* at 31.

III. ARGUMENT

A. The Board Should Deny Institution Pursuant To 35 U.S.C. § 314(a) Under The *General Plastic* Factors.

The Board repeatedly has explained that serial petitions challenging the same patent claims are disfavored in light of "the potential for abuse of the review process by repeated attacks." *Gen. Plastic*, IPR2016-01357, Paper 19 at 17. Such petitions are particularly disfavored in circumstances like the present case, where the petitioner files a placeholder petition and then, after reviewing the patent owner's preliminary response, files a new petition asserting the same prior art references while attempting to address deficiencies that the patent owner identified. *Id.*

To evaluate whether a follow-on petition should be denied under Section 314(a), the Board should consider seven non-exclusive factors that address the potential "undue inequities and prejudices to Patent Owner" caused by follow-on petitions. *Gen. Plastic*, IPR2016-01357, Paper 19 at 16-17. These 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 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 requirements 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.

Id. at 16 (citing *NVIDIA Corp. v. Samsung Elec. Co.*, IPR2016-00134, Paper 9 at 6-7 (P.T.A.B. May 4, 2016)). These factors all weigh heavily in favor of denying institution of Pfizer's second petition challenging the '218 patent, and the Board therefore should find that Pfizer's follow-on petition does not warrant the institution of an *inter partes* review.

1. Factor 1: Pfizer Is Challenging The Same Claims As Its Prior Petition.

The first factor that the Board should consider is whether the same petitioner previously filed a petition directed to the same claims of the same patent. *Gen. Plastic*, IPR2016-01357, Paper 19 at 16. Here, Pfizer's new petition seeks review of the same exact claims (*i.e.*, claims 1 and 5-7) of the '218 patent that it challenged in its prior petition. Thus, Factor 1 weighs heavily in favor of denying institution.

2. Factor 2: Pfizer Is Asserting The Same Prior Art References As Its Prior Petition, As Well As Additional Evidence That It Knew Of But Withheld From Its Prior Petition.

The second factor—whether the petitioner knew or should have known of the prior art asserted in the second petition at the time it filed its first petition—likewise weighs heavily in favor of denying institution. *Gen. Plastic*, IPR2016-01357, Paper 19 at 16.

Pfizer's new petition relies on the same exact references—Andya, Waterside, and Harris—as its prior petition in IPR2017-02020. The current petition thus is based entirely on prior art that was known to Pfizer at the time it filed its first petition. On this basis alone, the Board should deny institution of Pfizer's new petition. *See, e.g.*, *Reloaded Games, Inc. v. Parallel Networks LLC*, IPR2014-00950, Paper 12 at 4-5 (P.T.A.B. Oct. 22, 2014) (denying institution of follow-on petition raising new arguments based on same prior art asserted in first petition).

Pfizer's new petition also relies on certain experiments performed by Dr. Buick that were completed ***before*** Pfizer's first petition and thus could have been included in that petition as well. Paper 1, Ex. 1015. Dr. Buick's current declaration presents two sets of experiments in which he attempts to recreate the product of the prior art. *Id.*, ¶¶ 37-42. The first set of experiments involves a composition derived from CHO cells, and the second set involves a composition derived from HEK cells. *Id*. Dr. Buick presented only the first set of experiments (involving CHO cells) in

the declaration that Pfizer submitted in support of its first petition (with both the petition and declaration dated August 29, 2017). IPR2017-02020, Paper 1, Ex. 1042, ¶ 8. However, Dr. Buick's new declaration explains that he performed ***all*** of his experiments and analyses between December 2016 and August 2017. Paper 1, Ex. 1015, ¶ 1. And in fact, the timestamps on the HEK cell experiments (*i.e.*, the experiments omitted from Dr. Buick's first declaration) demonstrate that they were completed in July 2017 (*id*. at 62, Fig. A8), while the CHO cell experiments were not completed until August 2017 (*id*. at 61, Fig. A7).[1] Thus, Pfizer could have presented all of Dr. Buick's experiments in its first petition, rather than electing to hold back the HEK cell experiments until after it received Genentech's preliminary response to its first petition.

Pfizer's current Petition also relies on eight technical "background" references that it failed to include in its first petition. Paper 1, Exs. 1009, 1010, 1011, 1012, 1016, 1021, 1023, 1024. These new references are books and journal articles published between 1987 and 2009. Pfizer does not assert that it was unaware of any

[1] Dr. Buick is based in the United Kingdom and uses the European day-month-year format for his timestamps. The last HEK cell experiment is dated "25.07.17" and the last CHO cell experiment is dated "01.08.17." Paper 1, Ex. 1015, at 61-62.

of these references before filing its first petition, nor does Pfizer provide any reason why these references could not have been included in its first petition.

Thus, all of the materials presented in Pfizer's new petition—the asserted prior art, Dr. Buick's experiments, and the background references—were available to Pfizer well before it filed its first petition, and therefore Factor 2 weighs heavily in favor of denying institution.[2]

3. Factor 3: Pfizer's New Petition Used Genentech's Preliminary Response As A Roadmap To Deficiencies In Its First Petition.

The third factor—whether Pfizer filed its second petition after receiving Genentech's preliminary response—also weighs strongly in favor of denying institution. *Gen. Plastic*, IPR2016-01357, Paper 19 at 16.

Pfizer filed its new petition on December 18, 2017, four days ***after*** Genentech filed its preliminary response to Pfizer's first petition (IPR2017-02020, Paper 10, filed December 14, 2017). Pfizer's new petition, moreover, attempts (albeit unsuccessfully) to remedy specific deficiencies that Genentech identified in its

[2] As discussed above, Pfizer's petition also includes a new declaration from Mr. Carson as well as a declaration from its new purported expert Dr. Kelner, but Pfizer likewise has not provided any reason why the materials contained in these new declarations could not have been included in its original petition.

preliminary response, as set forth in the examples below. The Board has held that this weighs strongly against instituting review. *See, e.g.*, *Aruba Networks, Inc. v. Mobile Telecomms. Techs., LLC*, IPR2017-00637, Paper 27 at 12 (P.T.A.B. July 27, 2017) (holding that review should be denied when a petitioner files a new petition that attempts to correct deficiencies identified in a patent owner's preliminary response).

a) Pfizer improperly attempts to address the deficiencies Genentech identified regarding Dr. Buick's experiments.

Genentech explained in its preliminary response that Dr. Buick's experiments were deficient, *inter alia*, because he failed to use HEK cells. IPR2017-02020, Paper 10 at 36-37. Dr. Buick purported to demonstrate through a series of experiments that the prior art enabled one of skill in the art to obtain the claimed composition. *Id.*, Paper 1, Ex. 1042 ¶ 6. Among other things, Dr. Buick opined that his experiments demonstrated that the prior art was enabling because he followed the teachings of the Carter reference described in Andya. *Id.*, ¶¶ 10, 15-16. But Dr. Buick elected to use CHO cells for his experiments, even though Carter teaches that its antibody was produced using HEK cells. *Id.*, Paper 10 at 36-37. This is a significant deviation because the use of different cell lines impacts the post-translational modification and the chemical degradation of a protein, and thus the formation of acidic variants—which is relevant to whether a composition falls within

the scope of the challenged claims. *Id.* at 37. Thus, as Genentech explained in its preliminary response, Dr. Buick's failure to use HEK cells meant that his experiments could not show that the prior art was enabling. *Id*.

Pfizer's new petition attempts to address this deficiency by relying on previously-undisclosed experiments performed by Dr. Buick using HEK cells. *E.g.*, Paper 1 at 32. As discussed above, these HEK cell experiments were all completed well before Pfizer filed its first petition, yet Pfizer elected to hold them back until after it received Genentech's preliminary response. *See* Section III.A.2. This is not surprising, as the HEK cell results were less favorable to Pfizer than the CHO cell results. For example, Dr. Buick was unable to obtain a composition from HEK cells using Protein A purification as disclosed in Carter (due to supposed "pressure issues"). Paper 1, Ex. 1015, ¶ 40. Thus, instead of following Carter, Dr. Buick instead modified the prior art procedure by combining Protein A purification with a different purification method (so-called "batch purification") and then making further deviations from the prior art (*e.g.*, adding a slurry into the culture mixture and incubating it overnight). *Id.*, ¶ 41; *see also id.*, ¶¶ 23-24 (describing additional deviations from the prior art in Dr. Buick's HEK cell experiments).

Dr. Buick's inability to obtain the supposedly anticipatory composition following the prior art teachings demonstrates that the prior art is not enabling. But regardless, the fact that Pfizer withheld Dr. Buick's HEK cell experiments until after

Genentech criticized Dr. Buick for failing to perform experiments with HEK cells demonstrates that Pfizer improperly used Genentech's preliminary response as a roadmap to attempt to correct deficiencies in its first petition.

b) Pfizer improperly attempts to address the deficiencies Genentech identified regarding Pfizer's obviousness challenge based on Andya.

Genentech demonstrated in its preliminary response that Pfizer's obviousness arguments based on Andya in its first Petition were legally insufficient. Indeed, Pfizer's arguments generally consisted of only a single, conclusory sentence that failed to explain why a person of ordinary skill would have been motivated to modify the prior art to achieve the claimed invention with reasonable expectation of success. *See, e.g.*, IPR2017-02020, Paper 10 at 31-32; *cf. In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("Because … conclusory statements [regarding a motivation to combine prior art] cannot satisfy the petitioner's burden of demonstrating obviousness, the Board did not have sufficient evidence on which to base its legal conclusion of obviousness."); *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 995-97 (Fed. Cir. 2009) (rejecting obviousness argument where challenger had not established a reasonable expectation of success).

The Board ultimately agreed with Genentech, and denied Pfizer's obviousness challenge based on Andya. IPR2017-02020, Paper 16, at 17 ("[W]e determine that the Petitioner has not presented those arguments sufficiently, as it has not explained

an obviousness rationale. We decline to speculate as to Petitioner's obviousness rationale … and determine that Petitioner has not set forth a reasonable likelihood of prevailing in showing the unpatentability of [the challenged] claims as obvious over Andya.").

Pfizer's second petition includes new arguments and evidence that attempt to address these clear failings of the first petition. For example, Pfizer's new petition relies on a declaration from a new purported expert, Dr. Kelner, who opined on a supposed motivation to modify Andya. *E.g.*, Paper 1 at 36-46; *see also id.*, Ex. 1002 at ¶¶ 188-219. While Pfizer's new arguments are still legally insufficient, that is beside the point. As the Board has explained, it is fundamentally unfair—and contrary to the *inter partes* review scheme—for a petitioner to attempt to "recast and enhance unpatentability challenges lodged in the Previous IPRs against the same claims of the same patent with the insight provided by the Preliminary Response." *Aruba Networks*, IPR2017-00637, Paper 27 at 12.

c) Pfizer improperly attempts to address the deficiencies Genentech identified regarding Pfizer's challenge based on Waterside.

Genentech explained in its preliminary response that Pfizer had failed to meet the legal standard for establishing that the Waterside reference constituted a prior art printed publication. *See, e.g.*, IPR2017-02020, Paper 10 at 43-44. In its first petition, Pfizer relied on a declaration by Keith Carson, who helped to organize the

1996 Waterside Monoclonal Conference where Pfizer contends the Waterside reference was distributed. Genentech's preliminary response demonstrated that Mr. Carson's declaration was insufficient to meet Pfizer's burden of establishing that Waterside was a printed publication because, *inter alia*, Mr. Carson failed to address how interested members of the public could have learned about the Waterside conference and also failed to authenticate Pfizer's copy of Waterside in a manner consistent with Federal Rule of Evidence 901. *Id*. As Genentech explained, Mr. Carson failed to even state that Pfizer's version of Waterside was a "true and correct" copy of the document. *Id.* at 43; *cf. GoPro, Inc. v. Contour IP Holding LLC*, IPR2015-01080, Paper 55 at 11 (P.T.A.B. Oct. 26, 2016) (explaining that Rule 901 is satisfied when a declarant with personal knowledge testifies that a document is a "true and correct copy of the [document] that was distributed").

Pfizer's second petition contains a new declaration from Mr. Carson, dated one day ***after*** Genentech's preliminary response. Paper 1, Ex. 1020. Mr. Carson purports to address several of the clear deficiencies that Genentech identified, for example by discussing how the Waterside conference was advertised and by opining that Pfizer's copy of Waterside is a "true and correct" copy. *Id.*, ¶¶ 4, 11. Mr. Carson's new declaration is still insufficient to show that Waterside constitutes a printed publication—for example, Mr. Carson states that Waterside is "in a format that is consistent with the format that [Mr. Carson's organization] used when

distributing printed slides" at various conferences (*id.*, ¶ 10), but the slides are merely in a standard printing format and Mr. Carson does not state that the document comes from his organization's records or otherwise identify any source for verifying that the version of Waterside that Pfizer relies on matches a document distributed at the Waterside conference. But once again, the inadequacies in Mr. Carson's new declaration are beside the point—Pfizer's attempt to remedy the deficiencies in its first petition and in Mr. Carson's declaration through the filing of a new petition and a new declaration is improper.

d) Pfizer improperly attempts to address the deficiencies Genentech identified regarding Pfizer's inherency arguments.

Genentech demonstrated in its preliminary response that Pfizer's anticipation arguments were legally insufficient because (among other reasons) Pfizer relied on allegedly "inherent" disclosures in the prior art yet failed to apply the correct legal standard for establishing inherency, *i.e.*, "that the prior art's teachings ***'necessarily' and 'inevitably'*** result in the claimed invention." IPR2017-02020, Paper 10 at 2 (emphasis added); *cf. In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012) (explaining that inherency requires that a missing claim element "must inevitably result" from a reference's disclosure). Pfizer's second petition includes new arguments that attempt to meet this standard. *See, e.g.*, Paper 1 at 5 (asserting that

Dr. Buick's new experiments demonstrate that certain elements "are ***necessarily and inevitably*** formed when practicing the prior art" (emphasis added)).

Pfizer's new petition still fails to demonstrate that various claim elements are inherently present in the prior art, but that remains beside the point. Once again, Pfizer improperly has attempted to remedy deficiencies identified in Genentech's preliminary response, and for that reason its follow-on petition should be denied.

e) Pfizer's contrary argument is without merit.

In response to Pfizer's joinder motion, Genentech explained that it would be improper to join Pfizer's follow-on petition to its original petition for reasons similar to those discussed above, *i.e.*, because Pfizer attempted to use Genentech's preliminary response to identify deficiencies in its first petition. Paper 7 at 6-10. In its reply regarding joinder, Pfizer asserted that it would have been "virtually impossible" for Pfizer to have "drafted and finalized its petition, including three declarations … that together encompass over 220 pages of arguments" in the four days between the filing of Genentech's preliminary response and the filing of Pfizer's follow-on petition. Paper 9 at 3.

Pfizer's resort to attacking a strawman is telling. There is no dispute that at least some of the work underlying Pfizer's new petition was conducted well before Pfizer filed it. As explained in Section III.A.2 above, Pfizer was long aware of the asserted prior art, and Dr. Buick completed all of his experiments before Pfizer filed

its first petition. But it is irrelevant whether Pfizer composed its new petitions over the course of four days or whether it had complete drafts ready and waiting so that it could pick and choose which arguments to include and which to omit based on the arguments raised in Genentech's preliminary response. Either way, Pfizer's new petition demonstrates that it did precisely what the Board has said is forbidden—using Genentech's preliminary response as a roadmap for a follow-on petition that attempts to remedy failings identified in its earlier petition.

4. Factors 4 And 5: Pfizer Provides No Explanation For Its Decision To Wait Until After It Reviewed Genentech's Preliminary Response Before Filing Its New Petition.

Factor 4 is the length of time that elapsed between the time that Pfizer learned of the prior art asserted in the second petition and the filing of the second petition, and Factor 5 is whether Pfizer has provided an adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent. *Gen. Plastic*, IPR2016-01357, Paper 19 at 16. Both of these factors weigh strongly in favor of denying institution.

As discussed above with respect to Factor 2, Pfizer has long known of all of the asserted prior art references—it asserted the same exact references in its first petition. Similarly, Pfizer knew of all of Dr. Buick's experiments before filing its first petition, though it elected to withhold the less-favorable results of Dr. Buick's HEK cell experiments until after Genentech criticized Dr. Buick for failing to use

HEK cells. And Pfizer has not asserted any alleged reason why it failed to timely identify the new "background" references cited in its second petition (books and journal articles published between 1987 and 2009). *See* Section III.A.2.

In sum, Pfizer has provided ***no explanation*** as to why its new evidence and arguments could not have been included in its first petition—even though the Board's *General Plastic* opinion was decided and designated precedential well-before Pfizer filed its new petition, and made clear that such information was necessary to the Board's consideration of whether to institute a follow-on petition. *See Gen. Plastic*, IPR2016-01357, Paper 19 at 16. Rather than address the *General Plastic* factors, Pfizer's only attempt to justify its follow-on petition is its assertion that the new petition is "substantively identical" to the first petition. Paper 3 at 5. As Genentech explained in response to Pfizer's motion for joinder, that is nonsensical because Pfizer is the petitioner in both proceedings—if the two petitions were substantively identical, there would be no need for Pfizer to file the second one. Paper 7 at 4. Tellingly, Pfizer's reply in support of its joinder motion did not respond to this point, nor did Pfizer otherwise attempt to provide any justification for its decision to omit its "new" (but previously-known) evidence and arguments from its first petition. *See* Paper 9. Thus, Factors 4 and 5 weigh heavily in favor of denying institution.

5. Factor 6: Instituting Pfizer's New Petition Would Waste The Board's Resources And Encourage Abusive Serial Petitions.

Factor 6—the Board's finite resources—also weighs strongly in favor of denying institution. The Board's resources are significantly taxed by Pfizer's current petition and by Pfizer's overall strategy of filing multiple petitions with respect to each of Genentech's patents that it challenges. The present petition is Pfizer's second petition challenging the '218 patent, and one of ***fifteen*** petitions that Pfizer has filed challenging Genentech's patents related to its anti-HER2 breast cancer antibody trastuzumab.[3] The Board's finite resources should not be spent entertaining

[3] IPR2017-00731; IPR2017-00737; IPR2017-00739; IPR2017-00804; IPR2017-00805; IPR2017-01488; IPR2017-01489; IPR2017-01726; IPR2017-01727; IPR2017-02019; IPR2017-02020; IPR2017-02063; IPR2018-00016; IPR2018-00330; IPR2018-00331. In addition to the two petitions challenging the '218 patent (IPR2017-02020 and IPR2018-00331), Pfizer has filed multiple petitions against each of the patents it has challenged: three petitions against U.S. Patent No. 7,846,441 (IPR2017-00731, IPR2017-02063, and IPR2018-00016); two petitions against U.S. Patent No. 7,892,549 (IPR2017-00737 and IPR2017-00739); two petitions against U.S. Patent No. 6,407,213 (IPR2017-01488 and IPR2017-01489); two petitions against U.S. Patent No. 8,591,897 (IPR2017-01726 and IPR2017-01727); and two petitions against U.S. Patent No. 6,339,142 (IPR2017-

Pfizer's follow-on petitions—particularly here, where Pfizer could have included its evidence and argument in its first petition, yet chose to hold them back until after receiving Genentech's preliminary response. *Aruba Networks*, IPR2017-00637, Paper 27 at 12.

Furthermore, instituting review of Pfizer's follow-on petition would further burden the Board by encouraging petitioners to file serial petitions that waste the Board's resources. As the Board has explained, "[i]t is more efficient for the parties and the Board to address a matter once rather than twice. The Board is concerned about encouraging, unnecessarily, the filing of petitions which are partially inadequate." *Apple Inc. v. Immersion Corp.*, IPR2017-00896, Paper 10 at 10 (P.T.A.B. Aug. 17, 2017) (internal citations and quotation marks omitted). Thus, Factor 6 likewise weighs in favor of rejecting Pfizer's attempt to correct deficiencies in its first petition by filing a second petition.

6. Factor 7: Pfizer's Follow-On Petition Is Inconsistent With The Statutory Requirement That The Board Resolve A Petitioner's Challenge To A Patent Claim's Validity Within One Year Of Institution.

The seventh factor is the statutory requirement that the Board resolve a petitioner's challenge to a patent claim's validity within one year of its decision to institute *inter partes* review of that claim. This factor weighs in favor of denying

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02019 and IPR2018-00330).

institution in cases such as this where the petitioner files "multiple, staggered" petitions challenging the same claim of the same patent, particularly where the petitioner fails to provide "sufficient justification for bringing its follow-on Petition." *FedEx Corp. v. Intellectual Ventures II LLC*, IPR2017-02028, Paper 9 at 11-12 (P.T.A.B. Feb. 21, 2018).

Here, as discussed above, Pfizer has provided ***no explanation whatsoever*** for its follow-on petition. Pfizer's mere desire to prolong its challenge to the same claims of the '218 patent by asserting additional arguments and evidence does not outweigh Genentech's interest in "avoid[ing] harassment and enjoy[ing] quiet title to [its] rights." *Neil Ziegman, N.P.Z., Inc. v. Stephens*, IPR2015-01860, Paper 11 at 12-13 (P.T.A.B. Feb. 24, 2016).

* * *

In sum, all seven *General Plastic* factors weigh strongly against allowing Pfizer's follow-on petition. Moreover, Pfizer would suffer no prejudice from the denial of its current petition because the Board has instituted review of all claims challenged in Pfizer's first petition. Indeed, Pfizer itself asserts that the follow-on petition is "substantively identical" to the one that already has been instituted. Paper 3 at 5. Accordingly, Pfizer should not be allowed to burden the Board and Genentech with yet another petition challenging the '218 patent.

B. The Board Should Deny Institution Under 35 U.S.C. § 325(d).

The Board also should exercise its discretion to deny institution under Section 325(d) because it already has considered the same prior art references—during prosecution and in Pfizer's first petition—and it would waste the Board's resources to institute yet another petition filed by the same party challenging the same claims based upon the same prior art. *See* 35 U.S.C. § 325(d) (providing that a petition may be rejected when the "same or substantially the same prior art or arguments previously were presented to the Office"); *see also Harmonic, Inc. v. Avid Tech., Inc*., 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding."); *Unified Patents, Inc. v. Berman*, IPR2016-01571, Paper 10 at 9, 11 (P.T.A.B. Dec. 14, 2016) (informative).

First, the asserted references—Andya, Waterside and Harris—were considered and overcome during prosecution of the '218 patent. All three are listed on the face of the patent (Paper 1, Ex. 1001, 1-3), and Andya is further described in the specification and incorporated by reference (*id.*, 19:54-57). Pfizer's new petition should be denied on that basis alone. *See Cultec, Inc. v. Stormtech LLC*, IPR2017-00777, Paper 7 at 8 (P.T.A.B. Aug. 22, 2017) (informative) (denying institution because "[i]t is beyond reasonable dispute that [the two asserted prior art references] were presented to, and considered by, the Office").

Second, Pfizer previously presented the same prior art references to the Board in its first petition. The Board considered Pfizer's arguments and instituted review of all challenged claims on the grounds of anticipation by Andya and obviousness over Harris, while rejecting Pfizer's challenge based on Waterside as well as Pfizer's obviousness challenge based on Andya. IPR2017-02020, Paper 16. Because the Board already has considered Pfizer's challenge to the same claims based on the same prior art, Pfizer's new petition should be denied under Section 325(d)—particularly under the present circumstances, where (as discussed in Section III.A.3 above) Pfizer has used Genentech's preliminary response as a roadmap to attempt to address deficiencies in the first petition. *See T-Mobile U.S., Inc. v. Tracbeam, LLC*, IPR2016-00728, Paper 11 at 10-11, 14 (P.T.A.B. May 25, 2016) (denying under 35 U.S.C. § 325(d) a follow-on petition that used a prior decision "as a roadmap to remedy [the first petition's] prior, deficient challenge") (citing *Butamax Advanced Biofuels LLC v. Gevo, Inc*., IPR2014-00581, Paper 8 at 12-13 (P.T.A.B. Oct. 14, 2014)).

Thus, in addition to the numerous deficiencies detailed above, Pfizer's petition also should be denied pursuant to Section 325(d).

C. *Inter Partes* Review Proceedings Violate The Constitution.

The Board should also deny institution because *inter partes* review violates Genentech's constitutional rights. Patents are private property rights and disputes

concerning their validity were traditionally decided by courts; patent validity therefore must be litigated in an Article III court, not before an executive branch agency. *McCormick Harvesting Mach. Co. v. C. Aultman & Co.*, 169 U.S. 606, 609 (1898). Adversarial challenges to an issued patent—like *inter partes* reviews—are also "Suits at common law" for which the Seventh Amendment guarantees a jury trial. U.S. Const. amend. VII; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 376-77 (1996). Moreover, even if *inter partes* review is constitutional in other circumstances, it is unconstitutional for patents—like the '218 patent—that claim priority to a parent application that issued before passage of the America Invents Act.

The Supreme Court is currently considering the constitutionality of *inter partes* reviews in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, No. 16-712. Genentech presents this constitutional challenge to preserve the issue pending the Supreme Court's decision.

IV. CONCLUSION

The Board should deny institution of Pfizer's second petition for *inter partes* review of the '218 patent.

Respectfully submitted,

Date: April 18, 2018

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Patent Owner's Preliminary Response contains 6,834 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. § 42.24(d).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on April 18, 2018, I caused a true and correct copy of the following materials:

- Patent Owner's Preliminary Response
- Certificate of Compliance

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