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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 IPR2018-00016
Patent No. 7,846,441

PATENT OWNER'S PRELIMINARY RESPONSE

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Genentech, Inc. ("Patent Owner") submits this Preliminary Response to the Petition filed by Pfizer, Inc. ("Petitioner") (Paper 1).

I. INTRODUCTION

The Board recently reaffirmed its authority to deny institution of petitions to avoid "the potential for abuse of the review process by repeated attacks on patents." *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 17 (Sept. 6, 2017) (precedential). If there ever were a case where the petitioner's pattern of abusive, serial petitions attacking the same patent with the same prior art warranted denial of institution, it is this.

This is Petitioner's third of three separate, follow-on petitions seeking *inter partes* review of U.S. Patent No. 7,846,441 ("the '441 patent"). Petitioner already challenged the '441 patent in *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731 (IPR2017-00731, Paper 1 (petition filed Jan. 20, 2017)), and the Board initially denied institution on July 27, 2017. (IPR2017-00731, Paper 19.) Petitioner then filed a second petition on September 7, 2017 (IPR2017-02063), challenging the same claims of the '441 patent and relying on the same primary reference (Baselga '96) as one of the proposed grounds in its first petition. Petitioner sought to join its second petition with IPR2017-01121, filed by Celltrion, Inc., and its motion for joinder is currently pending before the Board. (IPR2017-02063, Paper 3.)

Petitioner then filed this third Petition on October 3, 2017, which again challenges

the same claims of the '441 patent and relies upon the same Baselga '96 reference at issue in Petitioner's two prior petitions. Petitioner has framed this third Petition as a response to Patent Owner's arguments presented in opposition to Petitioner's first petition and the Board's initial decision denying institution in that proceeding.

But the Board has repeatedly cautioned that *inter partes* review is not an iterative process, wherein a petitioner may file successive petitions adjusted in light of the patent owner's arguments and the Board's decisions on institution. And, as explained below, the circumstances here present nearly all the factors that the Board identified as weighing in favor of the discretionary denial of follow-on petitions in *General Plastic*. Moreover, Petitioner would suffer no prejudice from the denial of this third petition challenging the '441 patent because the Board has now granted rehearing and instituted trial with respect to Petitioner's first petition.

Accordingly, Patent Owner respectfully requests that the Board exercise its discretion to deny this third petition pursuant to 35 U.S.C. §§ 314(a) and/or 325(d).

II. PROCEDURAL HISTORY

Petitioner filed its first petition challenging the '441 patent in *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731, on January 20, 2017.¹ (IPR2017-00731, Paper 1.) The Board initially denied institution on July 27, 2017 (IPR2017-00731, Paper 19), but granted Petitioner's request for rehearing and instituted trial on October 26, 2017 (IPR2017-00731, Paper 29).

Petitioner filed its second petition challenging the '441 patent on September 6, 2017, more than a month *after* institution was denied in its first petition in IPR2017-00731, but *before* the Board granted its request for rehearing and instituted trial in the same proceeding. (IPR2017-02063, Paper 2.) Petitioner sought joinder of its second petition with a petition challenging the '441 patent on the same grounds previously filed by Celltrion, Inc. in *Celltrion, Inc. v. Genentech, Inc.*, IPR2017-01121, on March 21, 2017 (IPR2017-01121, Paper 1). (IPR2017-02063, Paper 3.) Trial was instituted with respect to Celltrion's petition on

¹ The petition in IPR2017-00731 initially identified the petitioner as Hospira, Inc. (a Pfizer subsidiary). Pfizer subsequently filed Updated Mandatory Notices Pursuant to 37 C.F.R. §§ 42.8(a)(3), (b)(1), and (b)(4)(i) stating that Pfizer is the real party-in-interest for Petitioner Hospira. (IPR2017-00731, Paper 13.)

October 4, 2017 (IPR2017-01121, Paper 9), and Petitioner's motion for joinder with respect to that proceeding is currently pending before the Board.²

Petitioner filed this third Petition challenging the '441 patent on October 3, 2017 (Paper 1), which was also filed before the Board granted rehearing and instituted Pfizer's first petition against the '441 patent in IPR2017-00731.

Petitioner casts the present Petition as a response both to Patent Owner's arguments offered in opposition to Petitioner's first petition and to the Board's initial decision denying institution of the first petition. (*See* Paper 1 at 61-67.)

Each of Petitioner's three petitions challenges all claims of the '441 patent as obvious under 35 U.S.C. § 103, and each relies upon the same Baselga '96 reference. Below is a summary of the asserted grounds in Petitioner's three petitions challenging the '441 patent.

² Patent Owner has opposed joinder and submitted a Preliminary Response in IPR2017-02063 requesting that the Board deny institution on the grounds that it is an improper follow-on petition under the *General Plastic* factors. (IPR2017-02063, Papers 8, 21.)

Ground	Proposed Statutory Rejections
IPR2017-00731	
1	Baselga 1997 in view of Baselga 1994 ³
2	Baselga 1996 in view of Baselga 1994
IPR2017-02063	
1	Baselga 1996, Seidman 1996, and the 1995 Taxol PDR, in view of the knowledge of a person of ordinary skill in the art
IPR2018-00016	
1	Lottery in view of Hayes and/or Baselga 1996 and Gelmon
2	Baselga 1996 in view of Baselga 1994 and Gelmon

III. ARGUMENT

A. The Board Should Deny Institution Pursuant To 35 U.S.C. §§ 314(a) And 325(d) Under The *General Plastic* Factors.

The Board should exercise its discretion to deny institution where, as here, the “same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d); *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 (Dec. 14, 2016) (informative). And the reasons for discretionary denial of review are particularly strong where there is

³ The Board denied institution of this ground. (IPR2017-00731, Paper 19 at 11.)

“the potential for abuse of the [*inter partes*] review process by repeated attacks on patents.” *Gen. Plastic*, IPR2016-01357, Paper 19 at 17; *see also id.* at 16-18.

To evaluate whether a follow-on petition should be denied, the Board considers seven non-exclusive factors, which consider the “undue inequities and prejudices to Patent Owner” caused by follow-on petitions. *Id.* at 16-17. These factors include:

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 (May 4, 2016)). These factors weigh heavily in favor of denying institution of

this third petition challenging the '441 patent, and the Board should therefore find that the Petition does not warrant the institution of an *inter partes* review.

1. Factor 1 Weighs In Favor Of Denying Institution.

Petitioner's current Petition challenges the same exact claims (*i.e.*, claims 1-14) of the '441 patent as its prior petitions in IPR2017-00731 and IPR2017-02063. At the time Petitioner filed its present Petition, Petitioner believed that its first petition had been denied institution (IPR2017-00731, Paper 19) and sought another way to continue its challenge of the '441 patent. Because the Board has since granted rehearing and instituted trial in IPR2017-00731, allowing the present petition to proceed would be redundant.

To the extent Petitioner argues that a different petitioner—its subsidiary—filed the first petition, this argument fails as Petitioner was named as a real-party-in-interest in that proceeding. (IPR2017-00731, Paper 13.) And in any event, the Board has denied institution where multiple petitions have been filed in different IPRs by overlapping entities. *See, e.g., Aruba Networks, Inc. v. Mobile Telecomm. Techs., LLC*, IPR2017-00637, Paper 27 at 11-12 (July 27, 2017).

2. Factor 2 Weighs In Favor Of Denying Institution.

Each of Petitioner's three petitions challenging the '441 patent rest at least in part on the same Baselga '96 reference. This current Petition is thus based at least

in part on prior art that was known to Petitioner at the time that it filed its first petition.

Petitioner argues that its first proposed ground in its present petition “raises prior art and arguments not presented in any prior petition, including art Petitioner reasonably was not aware of at the time of its first petition.” (Paper 1 at 60.) But Petitioner’s explanation for why it was supposedly unaware of the *Lottery* newspaper article (Ex. 1008) at the time of its prior petition calls into question whether that reference is even properly considered analogous art:

Lottery is a newspaper article. Earlier prior art searching was reasonably focused on scientific literature, which was the nature of the art disclosed on the face of the ’441 patent and successful in invalidating its European counterpart. *Lottery* is ***not the type of reference typically identified by a routine prior art search.*** As such, it had not been identified by Petitioner.

(Paper 1 at 61) (emphasis added.) If Petitioner, with the benefit of hindsight, did not think to look at newspaper articles—which it admits is different from “the nature of the art disclosed on the face of the ’441 patent” (*id.*)—it is difficult to

fathom how a person of ordinary skill at the time of the invention would have considered a feature story in a lay newspaper to be analogous art.⁴

Nor can Petitioner reasonably purport to have been unaware of the Hayes reference (Ex. 1009). Indeed, Hayes was published in the *same* issue of the *Journal of Clinical Oncology* as Baselga '96. The table of contents included with the version of Baselga '96 that Petitioner filed even lists the Hayes reference. (Ex. 1005 at 3.) At the very least, Petitioner should have been aware of Hayes at the time that it filed its earlier petition.

⁴ Petitioner's supposed justification that its search for newspaper articles "was spurred by Patent Owner's unexpected denial that the clinical trials referenced in Baselga '96 were ongoing as of the date of that reference" (Paper 1 at 61) makes no sense. The *Lottery* newspaper article (published *after* Baselga '96) does not address what clinical trials were ongoing when Baselga '96 was submitted and accepted for publication many months earlier. Instead, Petitioner appears to rely upon the *Lottery* article as a substitute for the Baselga '97 reference. But the shortcomings of Baselga '97 should have come as no surprise. That reference was successfully antedated during prosecution, and the Board declined to institute review of Petitioner's proposed ground based upon Baselga '97 under 35 U.S.C. § 325(d). (IPR2017-00731, Paper 19 at 8.)

Finally, Petitioner admits that it was aware of Gelmon (Ex. 1016) at the time that it filed its first petition. Indeed, Petitioner filed a petition challenging a different patent in the same family based in part upon the Gelmon reference at the same time that it filed its original petition challenging the '441 patent. (*See* IPR2017-00737, Paper 1.) Petitioner argues that its failure to rely upon Gelmon in its original petition was based upon an unexpected interpretation of the limitation “in the absence of an anthracycline derivative” as requiring the “*avoidance*” of anthracyclines, rather than simply their *absence* in a treatment regimen.” (Paper 1 at 64.) But that claim interpretation could not have been unexpected; indeed, it was invited by Petitioner's own arguments. (*See* IPR2017-00731, Paper 1 at 13 (“It is unsurprising that researchers were using several rhuMAb HER2 combination regimens that avoided using anthracyclines.”); Ex. 2006, IPR2017-00731, Lipton Decl. ¶ 33 (“Largely for this reason, also during the mid to late-1990s, researchers in the area of chemotherapeutics were interested in finding chemotherapeutic regimens that avoided the use of anthracyclines.”).) And in any case, Petitioner's argument is moot because the Board granted rehearing in IPR2017-00731 and interpreted “in the absence of an anthracycline derivative” as merely requiring the absence of anthracyclines, not affirmative avoidance. (IPR2017-00731, Paper 29 at 17-18.)

Accordingly, Petitioner has provided no legitimate explanation why it did not know or could not have known of any of the references underlying this third petition.

3. Factor 3 Weighs In Favor Of Denying Institution.

At the time Petitioner filed its current Petition on October 3, 2017, Petitioner had already received in IPR2017-00731 both Patent Owner's Preliminary Response (Paper 9, filed May 2, 2017) and the Board's decision denying institution (Paper 19, filed July 27, 2017). Indeed, the current Petition purports to respond to arguments presented in Patent's Owner's Preliminary Response and the Board's decision denying institution with respect to Petitioner's first petition. (*See, e.g.*, Paper 1 at 67-68 ("Petitioner is appropriately responding to [Patent Owner's] newly-minted claim construction on the one hand, and unexpected denial regarding the public broadcasting of clinical trials of its claimed combination on the other, while also recognizing the Board's institution decision in IPR2017-00737 is necessarily applicable to the '441 patent."); *see generally* Paper 1 at 61-68.) The reasons for denying discretionary review under 35 U.S.C. § 325(d) are especially strong where, as here, brings a follow-on petition to address the shortcomings of its prior petition. *See Aruba Networks*, IPR2017-00637, Paper 27 at 12 (denying under 35 U.S.C. § 314(a) a follow-on petition that was "an 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 and the Board's decision regarding the Previous IPRs"); *T-Mobile U.S., Inc. v. Tracbeam, LLC*, IPR2016-00728, Paper 11 at 10-11, 14 (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 (Oct. 14, 2014)).

And in any case, the Board has since granted Petitioner's request of rehearing and instituted trial in IPR2017-00731 (Oct. 26, 2017), obviating the need for yet another challenge by Petitioner against the '441 patent.

4. Factors 4 and 5 Weigh In Favor Of Denying Institution.

As discussed above with respect to Factor 2, Petitioner admittedly has long been aware of all but two of the references asserted in the current Petition, and Petitioner's attempts to justify its failure to identify the *Lottery* newspaper article and Hayes reference earlier are unavailing.

Petitioner argues that "[a]fter the institution decisions in IPR2017-00731 and IPR2017-00737, and Petitioner's subsequent identification of *Lottery*, Petitioner worked diligently to prepare and submit this petition within weeks." (Paper 1 at 68.) But that explanation only underscores the problem with the timing of this Petition, which is plainly just a reaction to the initial denial of Petitioner's first petition.

Petitioner's alleged diligence in preparing its Petition *after* the Board issued its institution decision with respect to the first petition does nothing to mitigate the prejudice of the fact that Petitioner prepared this Petition with the benefit of seeing Patent Owner's arguments, as well as the Board's initial decision on institution.

5. Factor 6 Weighs In Favor Of Denying Institution.

The Board's finite resources are significantly taxed by Petitioner's current Petition and overall IPR strategy. Indeed, the current Petition is Petitioner's third of *three* petitions challenging the '441 patent alone, and one of *fifteen* of Petitioner's petitions filed within the last year challenging Patent Owner's patents

covering aspects of its Herceptin® biologic.⁵ The Board's finite resources should not be spent entertaining Petitioner's follow-on petitions. *See Hospira, Inc. v. Genentech, Inc.*, IPR2017-00739, Paper 16 at 18 (July 27, 2017) ("While petitioners may have sound reasons for raising art or arguments similar to those previously considered by the Office, the Board weighs petitioners' desires to be heard against the interests of patent owners, who seek to avoid harassment and

⁵ *See* IPR2017-00731; IPR2017-00737; IPR2017-00739; IPR2017-00804; IPR2017-00805; IPR2017-01488; IPR2017-01489; IPR2017-01726; IPR2017-01727; IPR2017-02019; IPR2017-02020; IPR2018-00016; IPR2018-00330; IPR2018-00331. Petitioner has filed multiple petitions against the same patents all owned by Patent Owner and covering aspects of its Herceptin® biologic. Three petitions have been filed 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. 6,339,142 (IPR2017-02019 and IPR2018-00330); two petitions against U.S. Patent No. 9,249,218 (IPR2017-02020 and IPR2018-00331); and two petitions against U.S. Patent No. 8,591,897 (IPR2017-01726 and IPR2017-01727).

enjoy quiet title to their rights.” (quoting *Neil Ziegman, N.P.Z., Inc. v. Stephens*, IPR2015-01860, Paper 11 at 12-13)).

6. Factor 7 Is Neutral.

The seventh factor—*i.e.*, the statutory requirement to issue a final written decision within 1 year of institution—is neutral.

* * *

In sum, six of the seven factors weigh against allowing Petitioner's follow-on petition. Moreover, Petitioner would suffer no prejudice from the denial of its current Petition because the Board has granted rehearing and instituted Petitioner's first petition challenging the '441 patent. Accordingly, Petitioner should not be allowed to burden the Board or Patent Owner with yet another petition challenging the '441 patent.

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

The Board should also deny institution because *inter partes* review violates Patent Owner's constitutional rights. Because patents are private property rights and disputes concerning their validity were traditionally decided by courts, patent validity 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, 377 (1996). Moreover, even if *inter partes* review is constitutional in other circumstances, it is unconstitutional for patents—like the '441 patent—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. Patent Owner presents this constitutional challenge now to preserve the issue pending the Supreme Court's decision.

IV. CONCLUSION

The Board should reject Petitioner's challenge to the patentability of the challenged claims.

Respectfully submitted,

Date: February 2, 2018

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Patent Owner's Preliminary Response contains 3,124 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,

Dated: February 2, 2018

/David L. Cavanaugh/
David L. Cavanaugh
Registration No. 36,476

CERTIFICATE OF SERVICE

I hereby certify that, on February 2, 2018, I caused a true and correct copy of the following materials:

- Patent Owner's Preliminary Response
- Exhibit 2006
- Exhibit List
- Certificate of Compliance

to be served electronically via email, as previously agreed by the parties, on the following attorneys of record:

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IPR2017-02063
Patent Owner's Exhibit List

<u>Patent Owner's Exhibit Number</u>	<u>Exhibit Name</u>
2001	Declaration of Robert J. Gunther in support of Motion for Admission Pro Hac Vice
2002	Declaration of Daralyn J. Durie in support of Motion for Admission Pro Hac Vice
2003	Declaration of Lisa J. Pirozzolo in support of Motion for Admission Pro Hac Vice
2004	Declaration of Kevin S. Prussia in support of Motion for Admission Pro Hac Vice
2005	Declaration of Andrew J. Danford in support of Motion for Admission Pro Hac Vice
2006	Declaration of Allan Lipton, M.D. in IPR2017-00731