Filed on behalf of Patent Owner Genentech, Inc. by:

David L. Cavanaugh (Reg. No. 36,476)
Rebecca A. Whitfield (Reg. No. 73,756)
Robert J. Gunther, Jr. (*Pro Hac Vice To Be Filed*)
Lisa J. Pirozzolo (*Pro Hac Vice To Be Filed*)
Kevin S. Prussia (*Pro Hac Vice To Be Filed*)
Andrew J. Danford (*Pro Hac Vice To Be Filed*)
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006

Adam R. Brausa (Reg. No. 60,287)
Daralyn J. Durie (*Pro Hac Vice To Be Filed*)
DURIE TANGRI LLP
217 Leidesdorff Street
San Francisco, CA 94111

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-02063
Patent No. 7,846,441

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Federal Statutes

Regulations

Constitutional Provisions

Genentech, Inc. ("Patent Owner") submits this Preliminary Response to the Petition filed by Pfizer, Inc. ("Petitioner") (Paper 2).

I. INTRODUCTION

This is Petitioner's second 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 denied institution on July 27, 2017. (IPR2017-00731, Paper 19.) It was only after denial of institution of Petitioner's first petition that Petitioner filed this second Petition, which it seeks joinder with IPR2017-01121, filed by Celltrion, Inc., which also challenges the '441 patent. After filing the present petition, Petitioner's request for rehearing with respect to its first petition was granted and trial on the first petition has been instituted. (IPR2017-00731, Paper 29 (Oct. 26, 2017).) Petitioner has also filed a third petition challenging the '441 patent in IPR2018-00016. (IPR2018-00016, Paper 1.) In sum, Petitioner now has ***three*** petitions challenging the '441 patent pending before the Board, and each petition includes in its grounds the same primary reference as asserted in its first petition.

Petitioner's current Petition should be denied as it is precisely the type of abusive, follow-on petition that the Board discourages under its precedential opinion in *Gen. Plastic Indus. Co. Ltd. v. Canon Kabushiki Kaisha*, IPR2016-

01357, Paper 19 (Sept. 6, 2017). Petitioner could have, but did not, raise the arguments it presents in its now-instituted prior petition challenging the same claims of the '441 patent. Moreover, Petitioner's IPR strategy already demands significant resources from Patent Owner and the Board. Indeed, the present Petition is one of ***fifteen*** petitions it has filed within the last year against Patent Owner's patents covering aspects of its Herceptin® biologic.[1] The Board's finite

[1] *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).

resources should not be spent entertaining Petitioner's successive petitions against the same claims of the '441 patent.

The parties have fully briefed the issue of joinder (Papers 3, 8, 10), and in its opposition to joinder, Patent Owner explains why institution should be denied pursuant to 35 U.S.C. § 325(d). (*See* Paper 8.) In this Preliminary Response, Patent Owner presents new facts that further support denial of institution. For example, Petitioner's request for rehearing with respect to its first petition has been granted and trial has been instituted (IPR2017-00731, Paper 29 (Oct. 26, 2017)), and Petitioner has since filed yet a third petition challenging the '441 patent (IPR2018-00016, Paper 1).

Accordingly, Petitioner's Petition should be denied.

II. PROCEDURAL HISTORY

Petitioner filed its first petition challenging the '441 patent in *Hospira, Inc. v. Genentech, Inc*., IPR2017-00731, on January 20, 2017.[2] (IPR2017-00731, Paper 1.) The Board initially denied institution on July 27, 2017 (IPR2017-00731, Paper

[2] 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.)

19), but granted Petitioner's request for rehearing and instituted trial on October 26, 2017 (IPR2017-00731, Paper 29).

Celltrion, Inc. filed a petition challenging the '441 patent in *Celltrion, Inc. v. Genentech, Inc*., IPR2017-01121 (the "Celltrion IPR"), on March 21, 2017 (IPR2017-01121, Paper 1), and trial was instituted on October 4, 2017 (IPR2017-01121, Paper 9).

Petitioner filed its present Petition on September 6, 2017, two months ***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. Petitioner also filed a Motion for Joinder to join the present proceeding with the Celltrion IPR. (Paper 3.)

Since filing its present Petition, Petitioner also filed a third petition challenging the '441 patent in *Pfizer, Inc. v. Genentech, Inc*., IPR2018-00016, on October 3, 2017. (IPR2018-00016, Paper 1.)

Below is a summary of the asserted grounds in Petitioner's three petitions challenging the '441 patent. Petitioner alleges that each ground renders claims 1-14 of the '441 patent obvious under 35 U.S.C. § 103.

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. § 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). In particular, abusive follow-on petitions should be denied institution to mitigate "the potential for abuse of the [*inter partes*] review process by repeated attacks on

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

patents." *See Gen. Plastic*, IPR2016-01357, Paper 19 at 17 (Sept. 6, 2017); *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

Petitioner's current Petition, 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 petition in IPR2017-00731. 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, especially in view of the fact that Petitioner has now filed a ***third*** petition challenging the same exact claims of the '441 patent. (IPR2018-00016, Paper 1.)

To the extent Petitioner argues that a different petitioner—its subsidiary—filed the prior 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.

At the time Petitioner filed its first petition in IPR2017-00731, Petitioner knew or should have known of the prior art cited in the present proceeding. In IPR2017-00731, Petitioner argued two grounds for invalidity, one of which was Baselga 1996 (IPR2017-00731, Ex. 1004) in view of Baselga 1994 (IPR2017-00731, Ex. 1005). (IPR2017-00731, Paper 1 at 5.) In this proceeding, Petitioner argues one ground of invalidity, again based on Baselga 1996 (Ex. 1120), but this time in view of Seidman 1996 (Ex. 1111), and the 1995 Physician's Desk Reference entry for Taxol ("the 1995 Taxol PDR") (Ex. 1112). These cited references have been publicly available since the 1990s. Indeed, Pfizer's expert Dr. Lipton (who submitted a declaration both in IPR2017-00731 and in support of Pfizer's current Petition) admits that a person of ordinary skill in the art would have been aware of Seidman 1996 (Ex. 2101, IPR2017-00731 Lipton Dep. 121:3-123:18.)[4] Dr. Lipton states that Seidman 1996 was submitted for the 32nd Annual Meeting of the American Society of Clinical Oncology ("ASCO"), and that he is "very familiar with the annual ASCO meetings," and even "typically" attends

[4] Although Dr. Lipton states that a person of ordinary skill in the art "would have been aware of the Seidman 1995 report," his description of the reference makes clear that he is referring to Seidman 1996.

them. (Ex. 1102, Lipton Decl. ¶ 59.) Further, as a medical doctor with a clinical practice, Dr. Lipton was certainly aware of the 1995 Taxol PDR, which "is a periodical distributed to physicians, which contains safety, efficacy, and dosing information for drugs approved by the FDA," or in other words, information from the Taxol label. (*Id*. ¶¶ 22, 38.) In fact, Petitioner submitted a similar reference, the 1998 Taxol FDA-approved label, as an exhibit in the prior proceeding. (IPR2017-00731, Ex. 1025.)

Petitioner has not asserted that these additional secondary references were not known to it before, or could not have been discovered earlier, thus, raising "a reasonable inference that those references were known and available . . . when review was requested the first time [which] tip[s] the balance in favor of denial." *Roche Molecular Sys. Inc. v. Illumina, Inc*., IPR2015-01091, Paper 18 at 15 (Oct. 30, 2015).

3. Factor 3 Weighs In Favor Of Denying Institution.

At the time Petitioner filed its current Petition on September 6, 2017, Petitioner had already received in IPR2017-00731 both Patent Owner's Preliminary Response (filed May 2, 2017) and the Board's decision denying institution (filed July 27, 2017). The Celltrion IPR was filed on March 21, 2017 (IPR2017-01121, Paper 1), and the only apparent reason Petitioner filed the present Petition is the Board's denial of institution of Petitioner's first petition in IPR2017-

00731. But the Board has since granted Petitioner's request of rehearing and instituted trial in IPR2017-00731 (Oct. 29, 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.

The length of time that Petitioner knew of the prior art and its lack of explanation for waiting to file its current Petition weigh in favor of denial. As stated above, Baselga 1996 is the lead reference in both IPRs. Further, Petitioner's expert can hardly deny knowing of Seidman 1996 and the 1995 Taxol PDR at the time of Petitioner's first petition, and there is no reason why Petitioner could not have raised those references in IPR2017-00731. Petitioner simply sought a second opportunity to challenge the '441 patent when it filed its current Petition, but now that rehearing has been granted and trial has been instituted in IPR2017-00731, Petitioner's Petition no longer needs to continue in this current proceeding.

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 second 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. 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 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. Petitioner could have raised Baselga 1996 in view of Seidman 1996 and the 1995 Taxol PDR as an asserted ground of unpatentability in its prior petition in IPR2017-00731, but it chose not to do so. Although Petitioner filed its present Petition on the belief that its first petition had been denied, the Board has granted rehearing and instituted trial in the first proceeding; thus, Petitioner no longer needs its current Petition for Petitioner to proceed with its challenge of 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 terminate this proceeding because it 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: January 5, 2018

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

Robert J. Gunther, Jr.
Pro Hac Vice To Be Filed

Counsel for Patent Owner

WILMER CUTLER PICKERING HALE AND DORR LLP
1875 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20006
TEL: 202-663-6000
FAX: 202-663-6363
EMAIL: david.cavanaugh@wilmerhale.com

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Patent Owner's Preliminary Response contains 2,515 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: January 5, 2018

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

CERTIFICATE OF SERVICE

I hereby certify that, on January 5, 2018, I caused a true and correct copy of the following materials:

- Patent Owner's Preliminary Response
- Patent Owner's Exhibit List
- Exhibit 2101
- Certificate of Compliance

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

Amanda Hollis
KIRKLAND & ELLIS LLP
amanda.hollis@kirkland.com
300 North LaSalle, Chicago, IL 60654

Stefan M. Miller, Ph.D.
stefan.miller@kirkland.com
601 Lexington Avenue, New York, NY 10022

Karen Younkins
karen.younkins@kirkland.com
333 South Hope Street, Los Angeles, CA 90071

Benjamin A. Lasky
benjamin.lasky@kirkland.com
601 Lexington Avenue, New York, NY 10022

Sarah K. Tsou
sarah.tsou@kirkland.com
601 Lexington Avenue, New York, NY 10022

Mark C. McLennan
mark.mclennan@kirkland.com
601 Lexington Avenue, New York, NY 10022

Christopher J. Citro
christopher.citro@kirkland.com
601 Lexington Avenue, New York, NY 10022

Pfizer_Genentech_IPRs@kirkland.com

/Rebecca A. Whitfield/
Rebecca A. Whitfield
Reg. No. 73,756
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

IPR2017-02063
Patent Owner's Exhibit List

Patent Owner's Exhibit Number	Exhibit Name
2101	Deposition Transcript of Allan Lipton, Ph.D. submitted in IPR2017-00731