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Paper 39
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

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Case IPR2017-02063
Patent 7,846,441 B1

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Before ZHENYU YANG, CHRISTOPHER G. PAULRAJ, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

# DECISION

Institution of *Inter Partes* Review and Grant of Motion for Joinder
*37 C.F.R. § 42.108; 37 C.F.R. § 42.122(b)*

## INTRODUCTION

Pfizer, Inc. filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 1–14 of U.S. Patent No. 7,846,441 B1 (Ex. 1001, "the '441 patent"). Along with the Petition, Pfizer also filed a Motion for Joinder seeking to join this proceeding to IPR2017-01121. Paper 3 ("Mot."). Genentech, Inc. ("Patent Owner") filed a Preliminary response to the Petition (Paper 21 ("Prelim. Resp.")) and an Opposition to the joinder Motion (Paper 8 ("Opp.")).

As explained further below, we institute trial on the same ground as instituted in IPR2017-01121 and grant Pfizer's Motion for Joinder.

## RELATED PROCEEDINGS

As set forth below, Pfizer filed the instant Petition and the Motion for Joinder after we had declined to institute an *inter partes* review of the '441 patent based on an earlier petition, but before we granted its Request for Reconsideration and instituted an *inter partes* review with respect to that earlier petition:

On January 20, 2017, Pfizer challenged claims 1–14 of the '441 patent on two asserted grounds of unpatentability. *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731 ("Pfizer IPR 1"), Papers 1, 13.

On March 21, 2017, Celltrion, Inc. challenged claims 1–14 of the '441 patent as obvious under 35 U.S.C. § 103(a) over the combination of Baselga

1996,[1] Seidman 1996,[2] and the 1995 TAXOL PDR entry,[3] in view of the knowledge of a person of ordinary skill in the art. *Celltrion, Inc. v. Genentech, Inc.*, IPR2017-01121 ("Celltrion IPR"), Paper 1.[4]

On July 27, 2017, we denied institution in Pfizer IPR 1. IPR2017-00731, Paper 19. On August 25, Pfizer filed a request for reconsideration of the decision denying institution. IPR2017-00731, Paper 21.

On September 7, 2017, Pfizer filed the instant Petition together with the Motion to join Celltrion IPR. Papers 2, 3.

On October 4, 2017, we instituted *inter partes* review of claims 1–14 of the '411 patent in Celltrion IPR. IPR2017-01121, Paper 9.

On October 26, 2017, we granted Pfizer's request for reconsideration, and instituted *inter partes* review to determine whether claims 1–14 of the '441 patent would have been obvious over the combination of Baselga 1994[5] and Baselga 1996. IPR2017-00731, Paper 21.

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[1] Baselga et al., *Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185$^{HER2}$ Monoclonal Antibody in Patients with HER2/neu-Overexpressing Metastatic Breast Cancer*, 14 J. CLIN. ONCOL. 737–44 (1996) (Ex. 1120).

[2] Seidman et al., *Over-Expression and Clinical Taxane Sensitivity: A Multivariate Analysis in Patients with Metastatic Breast Cancer (MBC)*, 15 PROC. AM. SOC. CLIN. ONCOL. 104, Abstract 80 (Mar. 1996) (Ex. 1111).

[3] Taxol® (Paclitaxel) for Injection Concentrate, PHYSICIANS' DESK REFERENCE, 682–85 (49th ed. 1995) (Ex. 1112).

[4] Celltrion filed its petition before Patent Owner filed its Preliminary Response in Pfizer IPR 1 on May 2, 2017. In other words, Celltrion did not use either Patent Owner's arguments or our decisions in Pfizer IPR 1 as a roadmap.

[5] Baselga et al., *Anti-HER2 Humanized Monoclonal Antibody (MAb) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma*

On October 3, 2017, Pfizer also filed IPR2018-00016, challenging the same claims of the '441 patent as obvious. In a concurrently issued decision, we deny that petition. *Pfizer, Inc. v. Genentech, Inc.*, IPR2018-00016 ("Pfizer IPR 3"), Paper 25 (PTAB February 21, 2018).

According to the parties, the '441 patent is also the subject of *Genentech, Inc. v. Pfizer, Inc.*, No. 1:17-cv-01672 (D. Del.) (Paper 13, 3); *Celltrion, Inc. v. Genentech, Inc.*, No. 3-18-cv-00274 (N.D. Cal.) (Paper 23, 3; Paper 24, 2); and *Genentech, Inc. v. Celltrion, Inc.*, No. 1-18-cv-00095 (D. Del.) (Paper 23, 3; Paper 24, 2).

## DISCUSSION

Under 35 U.S.C. § 315(c), the Director may join a later party to an earlier instituted *inter partes* review. When determining whether to grant a motion for joinder we consider factors such as timing and impact of joinder on the trial schedule, cost, discovery, and potential simplification of briefing. *Kyocera Corp. v. SoftView, LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15).

In this case, Pfizer has satisfied the joinder factors. Pfizer timely filed the Petition and the Motion for Joinder in the present proceeding. *See* 37 C.F.R. § 42.122(b). Pfizer represents that the Petition in this case is "essentially a copy of the Celltrion Petition," including "the identical grounds presented in Celltrion's Petition." Mot. 1. Pfizer agrees that it will participate in the proceeding "only in a secondary 'understudy' role," unless Celltrion is terminated as a party. *Id.* at 8; *see also id.* at 7–8 (agreeing that, as long as Celltrion remains a party to the IPR, Pfizer will not produce its

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*Xenografts*, 13 Proc. AM. SOC. CLIN. ONCOL. 63 (Abstract 53) (1994) (Ex. 1119).

own testifying witnesses or file substantive papers); Paper 7. As a result, Pfizer avers that joinder will "create no additional burden for the Board, Celltrion or Genentech," "will not impact on the trial schedule" of Celltrion IPR, and will result in no prejudice to either Genentech or Celltrion. *Id.* at 1, 4–5. Patent Owner does not dispute any of these assertions.

Where, as in the present case, a party seeks to take a secondary role in an on-going IPR, joinder promotes economy and efficiency, thereby reducing the burden on the Patent Owner and on the limited resources of the Board, as compared to distinct, parallel proceedings. *See* 37 C.F.R. § 42.1(b) (instructing that an *inter partes* review must be conducted to "secure the just, speedy, and inexpensive resolution").

In view of the foregoing, we find that joinder based upon the conditions stated by Pfizer in its Motion for Joinder will have little or no impact on the timing, cost, or presentation of the trial on the instituted ground in Celltion IPR.

But our inquiry does not end here. This is the second petition filed by Pfizer, challenging claims 1–14 of the '441. Patent Owner, in its Preliminary Response and the Opposition to the joinder Motion, argues that we should deny the Petition and the Motion because this is "precisely the type of abusive, serial petition" that should be discouraged. Prelim. Resp. 5; Opp. 2 (citing *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (precedential)).

We "recognize the potential for abuse of the review process by repeated attacks on patents." *Gen. Plastic*, Paper 19, 17. Nevertheless, "[t]here is no *per se* rule precluding the filing of follow-on petitions after the Board's denial of one or more first-filed petitions on the same patent." *Id.* at

15. Indeed, "there may be circumstances where multiple petitions by the same petitioner against the same claims of a patent should be permitted, and . . . such a determination is dependent on the facts at issue in the case." *Id.* at 18. In our view, the unusual procedural posture and other facts of this case justify granting the instant petition.

Even though this is the second petition challenging claims 1–14 of the '411 patent filed by Pfizer, instituting *inter partes* review in this case would not result in undue prejudice to Patent Owner. Indeed, Patent Owner does not dispute this. *See* Paper 8, 2 (Patent Owner stating that lack of prejudice is "beside the point"). We have instituted trial in Celltrion IPR on the same ground, and Patent Owner has filed its Response in Celltrion IPR addressing the same patentability challenge. Pfizer agrees that, once joined to Celltrion IPR, "Celltrion will make all final decisions and will retain responsibility for all filings and oral argument (including telephone hearings and appeals)." Paper 7, 2. Thus, instituting trial here does not impose additional burden on Patent Owner.

We are mindful of the possibility that Patent Owner may settle with Celltrion. Even under that circumstance, however, instituting trial here does not result in undue prejudice against Patent Owner. First, the statute explicitly states that even "[i]f no petitioner remains in the inter partes review, the Office may . . . proceed to a final written decision." 37 U.S.C. § 317(a). The Federal Circuit also recognizes that the "Board may enter decision even after petitioner settles and drops out of the proceeding." *Progressive Cas. Ins. Co. v. Liberty Mut. Ins. Co.*, 625 Fed. Appx. 552, 556 (Fed. Cir. 2015). Second, in granting Pfizer's request for rehearing, we instituted trial in Pfizer IPR 1. Thus, the '441 patent remains challenged by

Pfizer even if Celltrion settles out. Moreover, we have consolidated the deadlines for Pfizer IPR 1 and Celltrion IPR. *See* Pfizer IPR 1, Papers 30, 52, 57; Celltrion IPR, Papers 10, 32, 37. Once joined to Celltrion IPR, this case will be on the same schedule as Pfizer IPR 1 for all the filings and for the oral hearing. As a result, Pfizer cannot "strategically stage their prior art and arguments in multiple petitions, using our decisions [in Pfizer IPR 1] as a roadmap." *See Gen. Plastic*, Paper 19, 17. In sum, under the totality of the circumstances in this case, we conclude that there is no due prejudice against Patent Owner.[6]

Of course, Pfizer can only be joined to Celltion IPR if we determine the present Petition warrants institution on its merits. 35 U.S.C. § 315(c). The Petition in this case is substantively identical to the one in Celltion IPR. *Compare* Paper 2 *with* IPR2017-01121, Paper 1; *see also* Mot. 1 (representing that the Petition is "essentially a copy of the Celltrion Petition"). Thus, substantively, we would institute trial in this proceeding on the same ground for the same reasons stated in our Decision on Institution in Celltion IPR. *See* IPR2017-01121, Paper 9.

Finally, we are mindful that Patent Owner requests that we deny the instant Petition "Pursuant To 35 U.S.C. § 325(d) Under The *General Plastic* Factors." Prelim. Resp. 5. We are of the opinion that *General Plastic*

[6] The facts in this case are distinguishable from those in Pfizer IPR 3, in which we decline to institute trial to review claims 1–14 of the '441 patent. *See* Pfizer IPR 3, Paper 25. There, Petitioner relies on prior art not previously asserted by either this or any other petitioner. Granting that petition would require Patent Owner to respond separately to yet another challenge from the same Petitioner. That, would result in due prejudice against Patent Owner.

factors are limited to the analysis under 35 U.S.C. § 314(a). *See General Plastic*, Paper 19, 15 ("Applying Factors to Evaluate the Equities of Permitting Follow-on Petitions is a Proper Exercise of Discretion Under 35 U.S.C. § 314(a)"). Nevertheless, the outcome remains the same if those factors apply to the analysis under 35 U.S.C. § 325(d). Accordingly, we decline to exercise our discretion to deny the Petition under 325(d).

For the reasons set forth above, we institute an *inter partes* review and grant Petitioner's Motion for Joinder.

ORDER

Accordingly, it is

ORDERED that trial is instituted in IPR2017-02063 to determine whether claims 1–14 of the '441 patent would have been obvious over the combination of Baselga 1996, Seidman 1996, and the 1995 TAXOL PDR entry, and the knowledge of a person of ordinary skill in the art;

FURTHER ORDERED that Pfizer's Motion for Joinder with is granted;

FURTHER ORDERED that IPR2017-02063 is terminated and joined to IPR2017-01121, pursuant to 37 C.F.R. §§ 42.72, 42.122, under the condition that absent leave of the Board, Pfizer shall maintain an understudy role with respect to Celltrion, coordinate filings with Celltrion, not submit separate substantive filings, not participate substantively in oral argument, and not actively participate in deposition questioning except with the assent of all parties;

FURTHER ORDERED that the Scheduling Order in place for IPR2017-01121 shall govern the joined proceedings;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2017-01121;

FURTHER ORDERED that the case caption in IPR2017-01121 for all further submissions shall be changed to add Pfizer as a named Petitioner after Celltrion, and to indicate by footnote the joinder of IPR2017-02063 to that proceeding, as indicated in the attached form of caption;

FURTHER ORDERED that the parties shall file an updated Protective Order to reflect the addition of Pfizer as a named Petitioner; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2017-01121.

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Sample Case Caption

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CELLTRION, INC. and PFIZER, INC.,
Petitioners,

v.

GENENTECH, INC,
Patent Owner.

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Case IPR2017-01121[1]
Patent 7,846,441 B1

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[1] Case IPR2017-02063 has been joined with this proceeding.