Trials@uspto.gov
Tel: 571-272-7822

Paper No. 15
Entered: June 18, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2018-00192
Patent 7,846,441 B1

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

YANG, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

INTRODUCTION

Samsung Bioepis Co., Ltd. ("Petitioner" or "Bioepis") filed a Petition requesting an *inter partes* review of claims 1–14 of U.S. Patent No. 7,846,441 B1 (Ex. 1001, "the '441 patent"). Paper 2 ("Pet."). Genentech, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 13 ("Prelim. Resp.").

For the following reasons, we exercise our discretion under 35 U.S.C. § 325(d) and deny the Petition.

RELATED PROCEEDINGS

On January 20, 2017, Pfizer filed a petition, challenging claims 1–14 of the '441 patent. IPR2017-00731, Paper 1. We initially denied institution, but later granted Pfizer's request for reconsideration, and instituted an *inter partes* review to determine whether claims 1–14 of the '441 patent would have been obvious over the combination of Baselga '94[1] and Baselga '96[2].[3] IPR2017-00731, Papers 19, 29.

---

[1] Baselga et al., *Anti-HER2 Humanized Monoclonal Antibody (MAb) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts*, 13 Proc. AM. SOC. CLIN. ONCOL. 63 (Abstract 53) (1994) (Ex. 1006).

[2] 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. 1005).

[3] After the Supreme Court's decision in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018), and in view of Office Guidance on the Impact of *SAS* on AIA Trial Proceedings (https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial), we also added the second ground based on Baselga '94 and another reference. IPR2017-00731, Paper 87.

On March 21, 2017, Celltrion, Inc. challenged the same claims of the '441 patent as obvious under 35 U.S.C. § 103(a) over the combination of Baselga '96 and other prior art. IPR2017-01121, Paper 1. We instituted an *inter partes* review in that case. IPR2017-01121, Paper 9.

On September 7, 2017, Pfizer filed a second petition together with a motion to join Celltrion in IPR2017-01121. IPR2017-02063, Papers 2, 3. We granted Pfizer's joinder motion and instituted an *inter partes* review in that case. IPR2017-02063, Paper 25. In a concurrently issued decision, however, we denied IPR2018-00016, a third petition filed by Pfizer, challenging the same claims of the '441 patent. IPR2018-00016, Paper 25.

Pfizer and Celltrion also challenged certain claims of U.S. Patent No. 7,892,549, a patent in the same family as the '441 patent. IPR2017-00737, Paper 1; IPR2017-01122, Paper 1. Petitioner Bioepis filed IPR2017-01960, together with a motion to join Pfizer in IPR2017-00737. Pet. 4; Paper 3, 3. We granted the joinder motion and instituted an *inter partes* review in that case. IPR2017-01960, Paper 19.

The oral hearings for IPR2017-00731, -00737, -01121, -01122, and -01960 were held on May 18, 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.), *Celltrion, Inc. v. Genentech, Inc.*, No. 3-18-cv-00274 (N.D. Cal.), and *Genentech, Inc. v. Celltrion, Inc.*, No. 1-18-cv-00095 (D. Del.). Paper 3, 4; Paper 12, 2.

ANALYSIS

Petitioner argues that claims 1–14 of the '441 patent would have been obvious over the combination of (1) Lottery[4] in view of Hayes[5] and/or Baselga '96, and Gelmon,[6] and (2) Baselga '96 in view of Baselga '94 and Gelmon.[7] Pet. 5–6. Patent Owner contends that we should deny the Petition under 35 U.S.C. § 325(d) "in view of the previously-instituted IPRs based upon Baselga '96, which are at an advanced stage." Prelim. Resp. 7. We find Patent Owner's argument persuasive.

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a), "the PTO is permitted, but never compelled, to institute an IPR proceeding"). Under 35 U.S.C. § 325(d), in determining whether to institute an *inter partes* review, we "may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office."

---

[4] *A Lottery of Life, Death—and Hope*, LA Times, published August 3, 1996 (Ex. 1008).

[5] Hayes, *Editorial: Should We Treat HER, Too?* 14 J. CLIN. ONCOL. 697–99 (1996) (Ex. 1009).

[6] Gelmon, et al., *Phase I/II Trial of Biweekly Paclitaxel and Cisplatin in the Treatment of Metastatic Breast Cancer*, 14 J. CLIN. ONCOL. 1185–91 (1996) (Ex. 1016).

[7] The two asserted grounds here are identical to the challenges in IPR2018-00016, the third petition filed by Pfizer, which we previously denied. *Compare* Paper 2 *with* IPR2018-00016, Paper 1.

Here, in both asserted grounds, Bioepis challenges claims 1–14 of the '441 patent as obvious over the combination of Baselga '96 and certain other prior art. These same claims have been challenged, and are currently under review, in IPR2017-00731, IPR2017-01121, and IPR2017-02063. And the same Baselga '96 is asserted in each of those cases. As Patent Owner correctly points out, not only does the present Petition include Baselga '96, it relies on the same disclosures of Baselga '96 as those relied on in the earlier cases. *See* Prelim. Resp. 9–10.

Lottery, Hayes, and Gelmon have not been asserted in the previously instituted cases. As Patent Owner points out, however, Bioepis "has not argued that *Lottery* or the other references cited in the proposed grounds add anything to the prior art previously considered during prosecution or that is currently at issue in the instituted IPRs." Prelim. Resp. 11. For example, according to Bioepis, Lottery "discloses that the claimed anti-ErbB2 antibody/taxoid combination in the absence of an anthracycline derivative was already in clinical trials prior to the '441 patent's priority date." Pet. 21. In IPR2017-00731, Petitioner Pfizer relied on both Baselga '96 and Baselga '94 in arguing that clinical trials of combination therapy, including the combination of rhuMAb HER2 (an anti-ErbB2 antibody) and paclitaxel (a taxoid), were in progress before the priority date of the '441 patent. *See, e.g.*, IPR2017-00731, Paper 1, 24, 44–45. Indeed, as Bioepis states, Baselga '96 "is cited and discussed in Hayes, which in turn is referenced in *Lottery*." Pet. 22. In other words, Bioepis's arguments based on the newly asserted references are substantially the same as those in the earlier cases.

Thus, after considering the totality of the circumstances, we agree with Patent Owner that it is appropriate for us to exercise our discretion to deny the Petition under 35 U.S.C. § 325(d).[8] *See* Prelim. Resp. 6–15.

ORDER

Accordingly, it is

ORDERED that Petitioner's request for *inter partes* review of claims 1–14 of the '441 patent is denied and no *inter partes* review is instituted.

[8] Patent Owner also argues that we should deny the Petition pursuant to 35 U.S.C. § 314(a) under the *General Plastic* Factors. Prelim. Resp. 14–21. Because we deny institution under § 325(d), we do not need to reach this additional argument.

PETITIONER:

Dimitrios T. Drivas
Scott T. Weingaertner
WHITE & CASE LLP
ddrivas@whitecase.com
scott.weingaertner@whitecase.com

PATENT OWNER:

David L. Cavanaugh
Lauren Blakely
Robert L. Gunther, Jr.
Rebecca A. Whitfield
Adam R. Brausa
Daralyn J. Durie
Andrew J. Danford
Lisa J. Pirozzolo
Kevin S. Prussia
WILMER CUTLER PICKERING HALE and DORR LLP
david.cavanaugh@wilmerhale.com
lauren.blakely@wilmerhale.com
robert.gunther@wilmerhale.com
rebecca.whitfield@wilmerhale.com
abrausa@durietangri.com
ddurie@durietangri.com
andrew.danford@wilmerhale.com
lisa.pirozzolo@wilmerhale.com
kevin.prussia@wilmerhale.com