

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SAMSUNG BIOEPIS CO., LTD.,  
Petitioner,

v.

GENENTECH, INC.,  
Patent Owner.

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Case IPR2017-01958  
Patent 6,627,196 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)*

## I. INTRODUCTION

On August 25, 2017, Samsung Bioepis Co., LTD (“Bioepis”) filed a Petition, seeking an *inter partes* review of claims 1–3, 5, 7, 9–11, and 17–33 of U.S. Patent No. 6,627,196 B1 (Ex. 1001, “the ’196 patent”). Paper 2 (“Pet.”). Genentech, Inc. (“Patent Owner”) has waived its right to file a Preliminary response to the Petition. Ex. 3001. Along with the Petition, Bioepis also filed a Motion for Joinder to join this proceeding with IPR2017-00804. Paper 1 (“Mot.”). Patent Owner opposes the Motion. Paper 7.

As explained further below, we institute trial on the same grounds as instituted in IPR2017-00804 and grant Petitioner’s Motion for Joinder.

## II. DISCUSSION

In IPR2017-00804, Hospira, Inc. (“Hospira”) challenged claims 1–3, 5, 7, 9–11, and 17–33 of the ’196 patent as obvious under 35 U.S.C. § 103(a) over the combination of the Herceptin Label,<sup>1</sup> Baselga ’96,<sup>2</sup> Pegram ’98,<sup>3</sup> and the Knowledge of a Person of Ordinary Skill in the Art. On July 27, 2017, we instituted trial to

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<sup>1</sup> 1998 FDA Approved Label for Herceptin® (Ex. 1008).

<sup>2</sup> Baselga et al., *Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185<sup>HER2</sup> Monoclonal Antibody in Patients with HER2/neu-Overexpressing Metastatic Breast Cancer*, 14 J. CLIN. ONCOL. 737–44 (1996) (Ex. 1013).

<sup>3</sup> Pegram, et al., *Phase II Study of Receptor-Enhanced Chemosensitivity Using Recombinant Humanized Anti-p185<sup>HER2/neu</sup> Monoclonal Antibody Plus Cisplatin in Patients with HER2/neu-Overexpressing Metastatic Breast Cancer Refractory to Chemotherapy Treatment*, 16 J. CLIN. ONCOL. 2659–71 (1998) (Ex. 1014).

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review the patentability of those claims. *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00804, Paper 13.

The Petition in this case is substantively identical to the one in IPR2017-00804. *Compare* IPR2017-00804, Paper 1 *with* IPR2017-01958, Paper 2. For the same reasons stated in our Decision on Institution in IPR2017-00804, we institute trial in this proceeding on the same ground. *See* IPR2017-00804, Paper 13.

Having determined that institution is appropriate, we now turn to Bioepis's Motion for Joinder. Under the statute, “[i]f the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311.” 35 U.S.C. § 315(c). 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).

Under the circumstances of this case, we determine that joinder is appropriate. Bioepis filed the Petition and Motion for Joinder in the present proceeding within one month after we instituted trial in IPR2017-00804. *See* 37 C.F.R. § 42.122(b). Bioepis represents that the Petition in this case is “essentially a copy of the Hospira Petition, including a ground that is substantially identical to that presented in the Hospira Petition in IPR2017-00804.” Mot. 1. According to Bioepis, the Petition “relies solely on the same prior art analysis and expert testimony submitted by Hospira.” *Id.* at 3. Bioepis asserts that

it “anticipates participating in the proceeding in a limited ‘understudy’ capacity,” unless Hospira is terminated as a party. *Id.* at 2, 5; *see also id.* at 6 (agreeing that, “as long as Hospira remains a party . . . the Board may order petitioners to consolidate filings, and limit Bioepis to . . . [an] understudy role”). As a result, Bioepis avers that joinder will “create no additional burden for the Board, Genentech, or Hospira,” “have no impact on the trial schedule of IPR2017-00804,” and result in no prejudice to either Genentech or Hospira. *Id.* at 1–3.

Genentech argues that “Bioepis offers no real assurances that its role will be so limited as to prevent prejudice to Patent Owner.” Paper 7, 1. Genentech asks us to impose certain conditions on Bioepis, including: (1) as long as Hospira remains a party to IPR2017-00804, Bioepis “has no right to its own briefing or oral argument;” (2) Bioepis may “proceed based solely on the arguments and evidence presented and maintained by Hospira;” (3) no additional discovery is permitted by Bioepis, and Bioepis may not ask any questions during deposition; (4) Bioepis may not alter the Hospira IRP trial schedule, and (5) “Bioepis acknowledges that the estoppel provisions of 35 U.S.C. § 315(e) will be applicable to it even if it remains in a circumscribed secondary role.” *Id.* at 2–3.

We find certain conditions Genentech proposes overly restrictive. For example, although Bioepis anticipates taking an understudy role in this proceeding, it may unexpectedly “strongly disagrees” with a position adopted (or repudiated) by Hospira after the filing of Hospira Petition. *See* Mot. 6. Under those circumstances, this panel may wish to entertain requests for additional briefing,

additional discovery, or an opportunity for Bioepis to ask questions at a deposition. *See* 37 C.F.R. § 42.5 (authorizing the panel “may determine a proper course of conduct in a proceeding”). In addition, to the extent we grant its Motion for Joinder, Bioepis becomes a “petitioner” in the IPR2017-00804 proceeding. Patent Owner does not cite to, nor are we aware of, any authority suggesting that a passive role in an IPR proceeding insulates a petitioner from the estoppel provision of § 315(e). Rather, the provision vests as a matter of law such that Bioepis’s formal acknowledgement of § 315(e) is irrelevant.

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 Bioepis’s in its Motion for Joinder will have little or no impact on the timing, cost, or presentation of the trial on the instituted ground. Discovery and briefing will be simplified if the proceedings are joined. Having considered Bioepis’s Motion in light of Genentech’s response, the Motion is granted.

### III. ORDER

Accordingly, it is

ORDERED that trial is instituted in IPR2017-01958 to determine whether claims 1–3, 5, 7, 9–11, and 17–33 of the ’196

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patent would have been obvious over the combination of the Herceptin Label, Baselga '96, Pegram '98, and the knowledge of a person of ordinary skill in the art;

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

FURTHER ORDERED that IPR2017-01958 is terminated and joined to IPR2017-00804, pursuant to 37 C.F.R. §§ 42.72, 42.122, based on the conditions discussed above, specifically, absent leave of the Board, Bioepis shall maintain an understudy role with respect Hospira, coordinate filings with Hospira, 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 IPR2017-00804 shall govern the joined proceedings;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2017-00804;

FURTHER ORDERED that the case caption in IPR2017-00804 for all further submissions shall be changed to add Bioepis as a named Petitioner after Hospira, and to indicate by footnote the joinder of IPR2017-01958 to that proceeding, as indicated in the attached form of caption;

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2017-00804.

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Sample Case Caption

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<sup>1</sup> Case IPR2017-01958 has been joined with this proceeding.