

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,

Petitioner,

v.

GENENTECH, INC.,

Patent Owner.

Case IPR2017-001960
Patent US 7,892,549 B2

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

POLLOCK, *Administrative Patent Judge*.

DECISION

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

I. INTRODUCTION

Samsung Bioepis Co., LTD (“Bioepis”) filed a Petition requesting an *inter partes* review of claims 1–17 of U.S. Patent No. 7,892,549 B2 (“the ’549 patent”). Paper 2 (“Pet.”). Genentech, Inc. (“Genentech”) has not filed a Preliminary Response to the Petition, and any such response is due November 27, 2017.

Along with its Petition, Bioepis filed a Motion for Joinder to join this proceeding with IPR2017-00737. Paper 1 (“Mot.”). Bioepis filed the Petition and Motion for Joinder in the present proceeding on August 25, 2017, within one month after we instituted trial in IPR2017-00737. Genentech opposes the Motion. Paper 7.

As explained further below, we institute trial on the same grounds as instituted in IPR2017-00737 and grant Bioepis’s Motion for Joinder.

II. DISCUSSION

In IPR2017-00737, Hospira, Inc., (“Hospira”) challenged claims 1–17 of the ’549 Patent on the following grounds:

Ground	Claim(s)	References	Basis
1	1–11 and 14–17	Baselga ’97 ¹ and Gelmon ²	§ 103
2	12	Baselga ’97, Gelmon, and Drebin ³	§ 103
3	13	Baselga ’97, Gelmon, and Presta ⁴	§ 103
4	1–11 and 14–17	Baselga ’96, ⁵ Baselga ’94, ⁶ and Gelmon	§ 103
5	12	Baselga ’96, Baselga ’94, Gelmon, and Drebin	§ 103
6	13	Baselga ’96, Baselga ’94, Gelmon, and Presta	§ 103

After considering the Petition and Patent Owner’s Preliminary Response, we instituted trial in IPR2017-00737 on each of the six asserted grounds. IPR2017-00737, Paper 19, 25–26.

Bioepis’s Petition is substantively identical to Hospira’s Petition, challenging the same claims based on the same art and the same grounds. *Compare* IPR2017-001960, Paper 2, *with* IPR2017-00737, Paper 1. For the same reasons stated in our Decision on Institution in IPR2017-00737, we institute trial in this proceeding on the same six grounds.

¹ Baselga et al., 11(3) (Suppl. 2) ONCOLOGY 43–48 (1997). Ex. 1007.

² Gelmon et al., 14(4) J. CLIN. ONCOL. 1185–91 (1996). Ex. 1025.

³ Drebin et al., 2(3) ONCOGENE 273–77 (1988). Ex. 1010.

⁴ Presta et al., 57(20) CANCER RES. 4593–99 (1997). Ex. 1012.

⁵ Baselga et al., 14(3) J. CLIN. ONCOL. 737–44 (1996). Ex. 1005.

⁶ Baselga et al., 13 Proc. AM. SOC. CLIN. ONCOL. 63 (Abstract 53) (1994). Ex. 1006.

Having determined that institution is appropriate, we now turn to Bioepis's Motion for Joinder. 35 U.S.C. § 315(c). Section 315(c) provides, in relevant part, that "[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." *Id.* 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 avers that joinder will "create no additional burden for the Board, Genentech, or Hospira," "have no impact on the trial schedule of IPR2017-00737," and result in no prejudice to either Genentech or Hospira." Mot. 1–3. In particular, Bioepis asserts that its Petition raises no new grounds of unpatentability from IPR2017-00737, and is "essentially a copy of the Hospira Petition," relying "on the same prior art analysis, the same expert testimony, and the same arguments that Hospira presented." *See id.* at 1, 3, 4. Bioepis further asserts that "anticipates participating in the proceeding in a limited 'understudy' capacity," unless Hospira is terminated as a party. *Id.* at 2; *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"); *id.* at 3, n1, 5 (stating that it may rely on the testimony of its own expert if Hospira's expert becomes unavailable).

In response, 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 asserts, for example, that as long as Hospira remains a party to IPR2017-000737, Bioepis should be precluded from any “right to its own briefing or oral argument,” “proceed solely on the arguments and evidence presented and maintained by Hospira,” undertake no additional discovery or ask any questions during deposition, “not attempt to alter the Hospira IRP trial schedule,” and “acknowledge[] that the estoppel provisions of 35 U.S.C. § 315(e) will be applicable to it even if remains in a circumscribed secondary role.” *Id.* at 2–3. We do not find Genentech’s arguments persuasive.

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. Counterintuitively, Genentech’s proposed conditions seem designed to discourage petitioners from seeking joinder under these circumstances and, thus, incompatible with “the just, speedy, and inexpensive resolution of every proceeding.” *See* 37 C.F.R. § 42.1(b).

For example, although Bioepis “anticipates” taking an understudy role in this proceeding, we can envision circumstances in which it “strongly disagrees” with a position that Hospira adopts (or repudiates) subsequent to the filing of Hospira Petition. *See* Mot. 6. Under these circumstances, this panel may wish to entertain requests for additional briefing, additional discovery, or an opportunity for Bioepis to ask questions at a deposition.⁷

⁷ Parties are reminded that communications regarding these and all other matters are conducted with courtesy, candor, good faith. 37 C.F.R. § 42.1(c), 42.11(a).

Strict adherence to Genentech's proposed conditions, however, would be at odds with our discretion to managing this case. *See generally*, 37 C.F.R. § 42.71(a).

We also address Genentech's proposed condition that "Bioepis acknowledges that the estoppel provisions of 35 U.S.C. § 315(e) will be applicable to it even if remains in a circumscribed secondary role." Paper 7, 3. To the extent we grant its Motion for Joinder, Bioepis becomes a "petitioner" in the IPR2017-00737 *inter partes* review pursuant to 35 U.S.C. § 315(e). Patent Owner cites (nor are we aware of) any authority suggesting that a passive role in an IPR proceeding insulates a petitioner from the estoppel provision of this section. Rather, the provision vests as a matter of law such that Bioepis's formal acknowledgement of § 315(e) is irrelevant.

In view of the foregoing, we find that joinder based upon the conditions stated in Bioepis's Motion for Joinder will have little or no impact on the timing, cost, or presentation of the trial on the instituted grounds and promote the just, speedy, and inexpensive resolution of the involved proceedings. Moreover, 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, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1–17 of U.S. Patent No. 7,892,549 B2 based on the following grounds of unpatentability:

- 1) Claims 1–11 and 14–17 under 35 U.S.C. § 103 as obvious over the combination of Baselga '97 and Gelmon;
- 2) Claim 12 under 35 U.S.C. § 103 as obvious over the combination of Baselga '97, Gelmon and Drebin;
- 3) Claim 13 under 35 U.S.C. § 103 as obvious over the combination of Baselga '97, Gelmon and Presta;
- 4) Claims 1–11 and 14–17 under 35 U.S.C. § 103 as obvious over the combination of Baselga '96, Baselga '94, and Gelmon;
- 5) Claim 12 under 35 U.S.C. § 103 as obvious over the combination of Baselga '96, Baselga '94, Gelmon, and Drebin;
- 6) Claim 13 under 35 U.S.C. § 103 as obvious over the combination of Baselga '96, Baselga '94, Gelmon, and Presta.

FURTHER ORDERED that Bioepis's Motion for Joinder with IPR2017-00737 is granted;

FURTHER ORDERED that IPR2017-01960 is terminated and joined to IPR2015-00737, pursuant to 37 C.F.R. §§ 42.72, 42.122, based on the conditions discussed above;

FURTHER ORDERED that 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;

IPR2017-001960
Patent US 7,892,549 B2

FURTHER ORDERED that the Scheduling Order in place for IPR2017-00737 (Paper 18, as amended in Paper 36) shall govern the joined proceedings;

FURTHER ORDERED that all future filings in the joined proceeding shall be made only in IPR2017-00737;

FURTHER ORDERED that the case caption in IPR2017-00737 for all further submissions shall be changed to add Bioepis as a named Petitioner after Apotex, and to indicate by footnote the joinder of IPR2017-01960 to that proceeding, as indicated in the attached sample case caption;

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2017-00737.

IPR2017-001960
Patent US 7,892,549 B2

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IPR2017-001960
Patent US 7,892,549 B2

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Sample Case Caption

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