Trials@uspto.gov
571-272-7822

Paper No. 9
December 1, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01959
Patent 7,371,379 B1

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

PAULRAJ, *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, 16–28, and 30–40 of U.S. Patent No. 7,371,379 B1 (Ex. 1001, "the '379 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 IPR2017-00805. Paper 1 ("Mot."). Patent Owner opposes the Motion. Paper 7.

As explained further below, we institute trial on the same grounds as instituted in IPR2017-00805 and grant Petitioner's Motion for Joinder.

II. DISCUSSION

In IPR2017-00805, Hospira, Inc. ("Hospira") challenged claims 1–3, 5, 7, 9–11, 16–28, and 30–40 of the '379 patent as obvious under 35 U.S.C. § 103(a) over the combination of the Herceptin Label,[1] Baselga '96,[2] Pegram '98,[3] and the Knowledge of a Person of Ordinary Skill in the Art. On July 27, 2017, we instituted trial to review the patentability of those claims. *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00805, Paper 13.

---

[1] Genentech, Inc, Herceptin® Trastuzumab, Sept. 1998 (hereinafter "Herceptin Label" (Ex. 1008).

[2] Jose Baselga, *Phase ll Study of Weekly Intravenous Recombinant Humanized Anti-p185^{HER2} Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer*, 14 JOURNAL OF CLINICAL ONCOLOGY 737–744 (1996) (hereinafter "Baselga '96") (Ex. 1013).

[3] Mark D. Pegram, *Phase ll Study of Receptor-Enhanced Chemosensitivity Using Recombinant Humanized Anti-p185^{HER21neu} Monoclonal Antibody Plus Cisplatin in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer Refractory to Chemotherapy Treatment*, 16 JOURNAL OF CLINICAL ONCOLOGY 2659–71 (1998) (hereinafter "Pegram '98") (Ex. 1014).

The Petition in this case is substantively identical to the one in IPR2017-00805. *Compare* IPR2017-00805, Paper 1 *with* IPR2017-01959, Paper 2. For the same reasons stated in our Decision on Institution in IPR2017-00805, we institute trial in this proceeding on the same ground. *See* IPR2017-00805, 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 IPR2017-00805. *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 IPR2017-00805." 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 IPR2017-00805," 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 IPR2017-00805, 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 IPR2017-00805 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 IPR2017-01959 to determine whether claims 1–3, 5, 7, 9–11, 16–28, and 30–40 of the '379 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 IPR2017-01959 is terminated and joined to IPR2017-00805, pursuant to 37 C.F.R. §§ 42.72, 42.122, based on the

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.