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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., Petitioner,

v.

GENENTECH, INC., Patent Owner.

Case IPR2017-02139 Patent 6,407,213 B1

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, 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

Samsung Bioepis Co., LTD ("Bioepis") filed a Petition, seeking an *inter partes* review of claims 1, 2, 4, 12, 25, 29–31, 33, 42, 60, 62–67, 69, 71–81 of U.S. Patent No. 6,407,213 B1 (Ex. 1001, "the '213 patent"). Paper 1 ("Pet."). Genentech, Inc. ("Patent Owner") did not file a Preliminary response to the Petition. Along with the Petition, Bioepis filed a Motion for Joinder to join this proceeding with IPR2017-01488. Paper 3 ("Mot."). Patent Owner opposes the Motion. Paper 7 ("Opp.").

As explained further below, we institute an *inter partes* review on the same grounds as instituted in IPR2017-01488 and grant Petitioner's Motion for Joinder.

II. DISCUSSION

In IPR2017-01488, Pfizer, Inc. challenged claims 1, 2, 4, 12, 25, 29–31, 33, 42, 60, 62–67, 69, and 71–81 of the '213 patent on the following grounds:

Ground	Claim(s)	Basis	Reference(s)
1	1, 2, 25, 29, 63, 66,	§ 102	Kurrle ¹
	67, 71, 72, 75, 76, 80,		
	and 81		
2	1, 2, 4, 29, 62–64, 80,	§ 102	Queen 1990 ²
	and 81		
3	1, 2, 4, 25, 29, 62–64,	§ 103	Kurrle and Queen 1990
	66, 67, 69, 71, 72, 75,		
	76, 78, 80, and 81		

¹ Kurrle, et al., European Patent Application Publication No. 0 403 156, published December 19, 1990. Ex. 1071.8

² Queen, et al., International Publication No. WO 1990/07861, published July 26, 1990. Ex. 1050.

Ground	Claim(s)	Basis	Reference(s)
4	12	§ 103	Kurrle, Queen 1990, and
			Furey ³
5	73 and 77	§ 103	Kurrle, Queen 1990, and
			Chothia & Lesk ⁴
6	74	§ 103	Kurrle, Queen 1990, and
			Chothia 1985 ⁵
7	79 and 65	§ 103	Kurrle, Queen 1990, Chothia
			& Lesk, and Chothia 1985
8	30, 31, 33, and 42	§ 103	Queen 1990 and Hudziak ⁶
9	42	§ 103	Queen 1990, Hudziak and
			Furey
10	60	§ 103	Queen 1990, Hudziak, and
			Chothia & Lesk

On December 1, 2017, we instituted an *inter partes* review to review the patentability of those claims. *Pfizer, Inc. v. Genentech, Inc.*, IPR2017-01488, Paper 27.

The Petition in this case is substantively identical to the one in IPR2017-01488. *Compare* IPR2017-01488, Paper 1 *with* IPR2017-02139, Paper 1; *see* Mot. 3–4 (admitting that "the Petition and evidence offered by Bioepis is nearly identical to that in IPR2017—01488"). For the reasons stated in our Decision on Institution in

³ Furey et al., Structure of a Novel Bence-Jones Protein (Rhe) Fragment at 1.6 Å Resolution, 167 J. Mol. Biol. 661–92 (1983). Ex. 1125.

⁴ Chothia and Lesk, *Canonical Structures for the Hypervariable Regions of Immunoglobulins*, 196 J. Mol. Biol. 901–17 (1987). Ex. 1062.

⁵ Chothia et al., *Domain Association in Immunoglobulin Molecules: The Packing of Variable Domains*, 186 J. Mol. Biol. 651–63 (1985). Ex. 1063.

⁶ Hudziak et al., p185^{HER2} Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor, 9 Mol. Cell Biol. 1165–72 (1989). Ex. 1021.

IPR2017-01488, we institute an *inter partes* review in this proceeding on the same grounds. *See* IPR2017-01488, Paper 27.

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 before we instituted an *inter partes* review in IPR2017-01488, and thus, satisfies the requirement of 37 C.F.R. § 42.122(b). Bioepis represents that the Petition in this case is "essentially a copy of the Pfizer Petition." Mot. 1. According to Bioepis, the Petition "relies solely on the same prior art analysis and expert testimony submitted by Pfizer." *Id.* at 3. Bioepis asserts that it "anticipates participating in the proceeding in a limited 'understudy' capacity," unless Pfizer is terminated as a party. *Id.* at 2, 5; *see also id.* at 6 (agreeing that, "as long as Pfizer 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 Pfizer,"

"have no impact on the trial schedule of IPR2017-01488," and result in no prejudice to either Genentech or Pfizer. *Id.* at 1–3.

In its Opposition, Genentech does not challenge Bioepis's arguments. Instead, Genentech urges that we impose certain conditions on Bioepis. Opp. 4–5. According to Genentech, previously, when Bioepis filed petitions to challenge three patents other than the '213 patent and sought to join three other IPRs, we instituted *inter partes* reviews and "granted joinder without any conditions." *Id.* at 2. This representation is inaccurate.

In IPR2017-01958, -01959, and -01960, Bioepis sought to join IPR2017-00804, -00805, and -00737 (all filed by Hospira, Inc.), respectively. IPR2017-01958, Paper 1; IPR2017-01959, Paper 1; IPR2017-01960, Paper 1. We instituted an *inter partes* review and granted joinder in each case. IPR2017-01958, Paper 9; IPR2017-01959, Paper 9; IPR2017-01960, Paper 11. When doing so, we specifically ordered that "absent leave of the Board, Bioepis shall maintain an understudy role with respect to 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." *See*, *e.g.*, IPR2017-01960, Paper 11, 7. Those requirements, although not verbatim, appear to be substantially the same as Genentech requests here. *See* Opp. 4–5.

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 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 Opposition, the Motion is granted.

III. ORDER

Accordingly, it is

ORDERED that trial is instituted in IPR2017-02139 on the following grounds:

- 1. claims 1, 2, 25, 29, 63, 66, 67, 71, 72, 75, 76, 80, and 81, as anticipated by Kurrle;
- 2. claims 1, 2, 4, 29, 62–64, 80, and 81 as anticipated by Queen 1990;
- 3. claims 1, 2, 4, 25, 29, 62–64, 66, 67, 69, 71, 72, 75, 76, 78, 80, and 81, as obvious over the combination of Kurrle and Queen 1990;
- 4. claim 12 as obvious over the combination of Kurrle, Queen 1990, and Furey;
- 5. claims 73 and 77 as obvious over the combination of Kurrle, Queen 1990, and Chothia & Lesk;
- 6. claim 74 as obvious over the combination of Kurrle, Queen 1990 and Chothia 1985;
- 7. claims 79 and 65 as obvious over the combination of Kurrle, Queen 1990, Chothia & Lesk, and Chothia 1985;
- 8. claims 30, 31, 33, and 42 as obvious over the combination of Queen 1990, and Hudziak;

- 9. claim 42 as obvious over the combination of Queen 1990, Hudziak, and Furey; and
- 10. claim 60 as obvious over the combination of Queen 1990, Chothia & Lesk, and Hudziak.

FURTHER ORDERED that Bioepis's Motion for Joinder with IPR2017-01488 is granted.

FURTHER ORDERED that IPR2017-02139 is terminated and joined to IPR2017-01489, 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 Pfizer, coordinate filings with Pfizer, 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 IPR2017-01489 shall govern the joined proceedings.

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2017-01488.

FURTHER ORDERED that the case caption in IPR2017-01488 for all further submissions shall be changed to add Bioepis as a named Petitioner after Pfizer, and to indicate by footnote the joinder of IPR2017-02140 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 IPR2017-01488.

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Sample Case Caption

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¹ Case IPR2017-02139 has been joined with this proceeding.