

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-02140
Patent 6,407,213 B1

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, 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 September 29, 2017, 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 also filed a Motion for Joinder to join this proceeding with IPR2017-01489. 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 IPR2017-01489 and grant Petitioner’s Motion for Joinder.

II. DISCUSSION

In IPR2017-01489, Pfizer, Inc. challenged claims 1, 2, 4, 12, 25, 29–31, 33, 42, 60, 62–67, 69, and 71–81 of the ’213 patent based on the following grounds:

| Claim(s) | Basis | Reference(s) |
|---|--------------|--|
| 1, 2, 12, 25, 29, 63, 64, 66, 67, and 71–81 | § 103 | Queen 1989 ¹ and Protein Data Bank (PDB database) |
| 1, 2, 4, 12, 25, 29, 62–64, 66, 67, 69, and 71–81 | § 103 | Queen 1990 ² and PDB database |
| 65, 75–77, and 79 | § 103 | Queen 1989, PDB database, and Tramontano ³ |

¹ Queen et al., *A Humanized Antibody that Binds to the Interleukin 2 Receptor*, 86 PRO. NAT’L ACAD. SCI. 10029–33 (1989) (Ex. 1534).

² Queen, et al., International Publication No. WO 1990/07861 A1, published July 26, 1990 (Ex. 1550).

³ Tramontano, A. et al., *Framework Residue 71 is a Major Determinant of the Position and Conformation of the Second Hypervariable Region in the*

| Claim(s) | Basis | Reference(s) |
|------------------------|-------|---|
| 65, 75–77, and 79 | § 103 | Queen 1990, PDB database, and Tramontano |
| 4, 62, 64, and 69 | § 103 | Queen 1989, PDB database, and Kabat 1987 ⁴ |
| 30, 31, 42, and 60 | § 103 | Queen 1989, PDB database, and Hudziak ⁵ |
| 30, 31, 33, 42, and 60 | § 103 | Queen 1990, PDB database, and Hudziak |

On December 1, 2017, we instituted an *inter partes* review to review the patentability of those claims. *Pfizer, Inc. v. Genentech, Inc.*, IPR2017-01489, Paper 27.

The Petition in this case is substantively identical to the one in IPR2017-01489. *Compare* IPR2017-01489, Paper 1 *with* IPR2017-02140, Paper 1. For the same reasons stated in our Decision on Institution in IPR2017-01489, we institute an *inter partes* review in this proceeding on the same grounds. *See* IPR2017-01489, 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

VH Domains of Immunoglobulins, 215 J. MOL. BIOL. 175–82 (1990) (Ex. 1551).

⁴ Kabat, et al., *Sequences of Proteins of Immunological Interest* 4th Ed., Tabulation and Analysis of Amino Acid and Nucleic Acid Sequences of Precursors, V-Regions, C-Regions, J-Chain, T-Cell Receptor for Antigen, T-Cell Surface Antigens (National Institutes of Health, Bethesda, Md.) (1987) (Ex. 1552).

⁵ 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. 1521).

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 IPR2017-01489, 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 IPR2017-01489,” 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.*, IPR2017-01958, Paper 9, 6. Those requirements, although not verbatim, appear to be substantially the same as Genentech requests. *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 IPR2017-02140 on the following grounds:

1. claims 1, 2, 12, 25, 29, 63, 66, 67, and 71–81 as obvious over the combination of Queen 1989 and PDB database;
2. claims 1, 2, 4, 12, 25, 29, 62–64, 66, 67, 69, and 71–81 as obvious over the combination of Queen 1990 and PDB database;
3. claims 65, 75–77, and 79 as obvious over the combination of Queen 1989, PDB database, and Tramontano;
4. claims 65, 75–77, and 79 as obvious over the combination of Queen 1990, PDB database, and Tramontano;
5. claims 4, 62, 64, and 69 as obvious over the combination of Queen 1989, PDB database, and Kabat 1987;
6. claims 30, 31, 42, and 60 as obvious over the combination of Queen 1989, PDB database, and Hudziak; and
7. claims 30, 31, 33, 42, and 60 as obvious over the combination of Queen 1990, PDB database, and Hudziak;

FURTHER ORDERED that Bioepis's Motion for Joinder with IPR2017-01489 is granted;

FURTHER ORDERED that IPR2017-02140 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

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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 IPR2017-01489;

FURTHER ORDERED that the case caption in IPR2017-01489 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 IPR2017-01489.

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FOR PETITIONER BIOEPIS:

Dimitrios Drivas

ddrivas@whitecase.com

Scott Weingaertner

sweingaertner@whitecase.com

FOR PATENT OWNER:

David Cavanaugh

david.cavanaugh@wilmerhale.com

Owen Allen

owen.allen@wilmerhale.com

Adam Brausa

abrausa@durietangri.com

FOR PETITIONER PFIZER (IPR2017-01489):

Amanda Hollis

amanda.hollis@kirkland.com

Stefan Miller

Stefan.Miller@kirkland.com

Karen Younkins

karen.younkins@kirkland.com

Mark McLennan

mark.mclennan@kirkland.com

Christopher Citro

christopher.citro@kirkland.com

Benjamin A. Lasky

blasky@kirkland.com

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Sample Case Caption

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⁶ Case IPR2017-02140 has been joined with this proceeding.