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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENZYME CORPORATION, Petitioner,

v.

GENENTECH, INC. AND CITY OF HOPE, Patent Owner.

Case IPR2016-00460 Patent 6,331,415 B1

Before LORA M. GREEN, ERICA A. FRANKLIN, and SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

GREEN, 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

Genzyme Corporation ("Petitioner" or "Genzyme") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–4, 9, 11, 12, 14–20, and 33 of U.S. Patent No. 6,331,415 B1 (Ex. 1001, "the '415 patent"). On February 26, 2016, Petitioner filed a Motion for Joinder (Paper 10, "Mot."). The Motion for Joinder seeks to join this proceeding with *Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. v. Genentech, Inc. and City of Hope*, Case IPR2015-01624 ("the '1624 IPR"). Mot. 1. In response, Genentech Inc. and City of Hope (collectively "Patent Owner" or "Genentech") filed a Notice of Non-Opposition to Motion for Joinder and Waiver of Preliminary Response. Paper 11.

For the reasons described below, we institute an *inter partes* review of challenged claims 1–4, 11, 12, 14, 18–20, and 33, and grant Petitioner's Motion for Joinder.

II. INSTITUION OF INTER PARTES REVIEW

The Petition in this proceeding asserts the same grounds as those on which we instituted review in the '1624 IPR. Specifically, based on the Petition filed by Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. (collectively "Sanofi-Aventis"), on February 5, 2016, we instituted a trial in the '1624 IPR on the following grounds:

References	Basis	Claims Challenged
Bujard ¹ and Riggs & Itakura ²	§ 103(a)	1, 3, 4, 11, 12, 14, 19, and 33
Bujard and Southern ³	§ 103(a)	1, 2, 18, 20, and 33

Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. v. Genentech, Inc. and City of Hope, Case IPR2015-01624, slip. op. at 26 (PTAB February 5, 2016) (Paper 15).

Petitioner proposes an order in its Motion for Joinder in which the instant *inter partes* review is instituted only on the grounds for which *inter partes* review was instituted in the '1624 IPR. Mot. 8. In view of the fact that the challenges presented by the instant Petition and in the petition in the '1624 IPR are identical, *see* Mot. 3, we institute an *inter partes* review in this proceeding on the same grounds and for the same reasons as those on which we instituted the '1624 IPR. We do not institute *inter partes* review on any other grounds or as to any additional claims.

III. GRANT OF MOTION FOR JOINDER

An *inter partes* review may be joined with another *inter partes* review, subject to the provisions of 35 U.S.C. § 315(c), which governs joinder of inter partes review proceedings:

¹ Bujard et al., US 4,495,280, issued Jan. 22, 1985 ("Bujard") (Ex. 1002).

² Arthur D. Riggs and Keiichi Itakura, *Synthetic DNA and Medicine*, 31 AM. J. Hum. Genet., 531–538 (1979) ("Riggs & Itakura") (Ex. 1003).

³ P.J. Southern and P. Berg, *Transformation of Mammalian Cells to Antibiotic Resistance with a Bacterial Gene Under Control of the SV40 Early Region Promoter*, 1 J. MOLECULAR AND APPLIED GENETICS 327–341 (1982) ("Southern") (Ex. 1004).

(c) JOINDER.—If 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 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

As the moving party, Genzyme bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should: (1) set forth the reasons joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; and (3) explain what impact (if any) joinder would have on the trial schedule for the existing review. *See* Frequently Asked Question H5, http://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/patent-review-processing-system-prps-0 (last visited June 2, 2016).

The Petition in this proceeding has been accorded a filing date of January 15, 2016 (Paper 3), which is before the date of institution in the '1624 IPR, which was instituted on February 5, 2016 ('1624 IPR, Paper 15). The Petition, therefore, satisfies the joinder requirement of being filed within one month of our instituting a trial in the '1624 IPR. 37 C.F.R. § 42.122(b).

In its Motion for Joinder, Genzyme contends that the grounds asserted in the instant Petition are the same grounds of unpatentability asserted in the '1624 IPR. Mot. 1, 3, 8. Genzyme contends further that joinder is appropriate as it will promote efficient resolution of the challenges to the claims of the '415 patent. *Id.* at 1. Genzyme represents that "joinder would not affect the pending schedule in the Sanofi-Aventis IPR nor increase the complexity of that proceeding, thereby minimizing costs," stating that it agrees to consolidated filings with Sanofi-Aventis. *Id.* at 1–2. Patent Owner

does not oppose joinder, but lists several conditions that should be included in the decision ordering joinder to which Genzyme has agreed, such as the necessity for consolidated filing to avoid lengthy and duplicative briefing. Paper 11, 1–3.

As discussed above, joinder is discretionary. In the instant proceeding, we agree with Genzyme that joinder of the instant proceeding with the '1624 IPR would promote the efficient resolution of the proceedings. Genzyme has brought the same challenges as presented by the '1624 IPR, thus, the substantive issues in the '1624 IPR would not be unduly complicated by joining with the instant IPR. In particular, joinder merely introduces the same grounds presented originally in the '1624 IPR, where all of the prior art asserted in this Petition is of record. In addition, Genzyme agrees to be limited to the grounds on which trial was instituted in the '1624 IPR. Mot. 8. Moreover, the instant proceeding was filed timely before we instituted trial in the '1624 IPR. Finally, Patent Owner will be able to address the challenges in a single proceeding, promoting efficiency.

IV. ORDER

In view of the foregoing, it is

ORDERED that IPR2016-00460 is *instituted and joined* with IPR2015-01624;

FURTHER ORDERED that the grounds on which IPR2015-01624 was instituted are unchanged and no other grounds are instituted in the joined proceeding;

FURTHER ORDERED that the Scheduling Order entered in IPR2015-01624 shall govern the schedule of the joined proceedings;

FURTHER ORDERED that, throughout the joined proceeding, Sanofi-Aventis or Genzyme will file papers, except for motions that do not involve the other party, as a single, consolidated filing; that the filing party (either Sanofi-Aventis or Genzyme) will identify each such filing as a consolidated filing;

FURTHER ORDERED that, throughout the joined proceeding, Sanofi and Genzyme will designate an attorney to conduct the cross-examination of any witness produced by Patent Owner, as well as the redirect of any witness produced by Sanofi-Aventis and Genzyme within the time provided by 37 C.F.R. § 42.53, and Genzyme will not receive any cross-examination or redirect time separate from that of Sanofi-Aventis;

FURTHER ORDERED that IPR2016-00460 is terminated under 37 C.F.R. § 42.72, and all further filings in the joined proceedings are to be made in IPR2015-01624;

FURTHER ORDERED that a copy of this Decision will be entered into the record of IPR2015-01624; and

FURTHER ORDERED that the case caption in IPR2015-01624 shall be changed to reflect joinder with this proceeding in accordance with the attached example.

IPR2016-00460 Patent No. 6,331,415 B1

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Example Case Caption for Joined Proceeding

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SANOFI-AVENTIS U.S. LLC, REGENERON PHARMACEUTICALS, INC., AND, GENZYME CORPORATION, Petitioners,

v.

GENENTECH, INC. AND CITY OF HOPE, Patent Owners.

Case IPR2015-01624¹ Patent 6,331,415 B1

¹ Case IPR2016-00460 has been joined with this proceeding.