

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MERCK SHARP & DOHME CORP.,  
Petitioner,

v.

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

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Case IPR2017-00047  
Patent 6,331,415 B1

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Before TONI R. SCHEINER, LORA M. GREEN, 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

Merck Sharp & Dohme Corp. (“Petitioner” or “Merck”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–4, 11, 12, 14, 18–20, and 33 of U.S. Patent No. 6,331,415 B1 (Ex. 1001, “the ’415 patent”). Petitioner filed also a Motion for Joinder (Paper 3, “Mot.”). The Motion for Joinder seeks to join this proceeding with *Mylan Pharmaceuticals, Inc. v. Genentech, Inc. and City of Hope*, Case IPR2016-00710 (“the ’710 IPR”). Mot. 1. Genentech Inc. and City of Hope (collectively, “Patent Owner” or “Genentech”) filed a Response to Petitioner’s Motion for Joinder. Paper 10.

For the reasons explained 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. INSTITUTION OF *INTER PARTES* REVIEW

The Petition in this proceeding asserts the same grounds as those on which we instituted review in the ’710 IPR. Specifically, based on the Petition filed by Mylan Pharmaceuticals, Inc. (“Mylan”), on March 3, 2016, we instituted a trial in the ’710 IPR on the following grounds:

References	Basis	Claims Challenged
Bujard <sup>1</sup> and Riggs & Itakura <sup>2</sup>	§ 103(a)	1, 3, 4, 11, 12, 14, 19, and 33

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<sup>1</sup> Bujard et al., US 4,495,280, issued Jan. 22, 1985 (“Bujard”) (Ex. 1002).

<sup>2</sup> Arthur D. Riggs and Keiichi Itakura, *Synthetic DNA and Medicine*, 31 AM. J. HUM. GENET., 531–538 (1979) (“Riggs & Itakura”) (Ex. 1003).

References	Basis	Claims Challenged
Bujard and Southern <sup>3</sup>	§ 103(a)	1, 2, 18, 20, and 33

*Mylan Pharmaceuticals, Inc. v. Genentech, Inc.*, Case IPR2016-00710, slip. op. at 15 (PTAB September 8, 2016) (Paper 13).

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 '710 IPR. Mot. 12–13. In view of the fact that the challenges presented by the instant Petition and the Petition in the '710 IPR are identical, and the evidence supporting the challenges is nearly so, *see* Mot. 1; Paper 10, 1 (noting that the Petition “raises the exact same art and arguments as in the petition in recently instituted IPR2016-00710”), 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 '710 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:

(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

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<sup>3</sup> 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).

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, Merck 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, <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-e2e-frequently-asked-questions> (last visited December 7, 2016).

The Petition in this proceeding has been accorded a filing date of October 11, 2016 (Paper 4), and the '710 IPR was instituted on September 8, 2016 ('710 IPR, Paper 13). Petitioner contends that the Motion for Joinder “is submitted within one month of September 8, 2016, the date on which the [’710 IPR] was instituted.” Mot. 2. The Petition, therefore, satisfies the joinder requirement of being filed within one month of our instituting a trial in the ’710 IPR. 37 C.F.R. § 42.122(b).<sup>4</sup>

In its Motion for Joinder, Merck contends that the grounds asserted in the instant Petition are the same grounds of unpatentability asserted in the ’710 IPR. Mot. 1, 5, 6–7. Merck contends further that joinder is appropriate as it will promote efficient resolution of the challenges to the claims of the ’710 patent. *Id.* at 1. Merck represents that joinder will not impact the schedule of the ’710 IPR, as it “agrees that the Scheduling Order issued in

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<sup>4</sup> In that regard, we note that October 8, 2016, was a Saturday, and October 10, 2016, was a Federal Holiday.

the [’710 IPR] will apply to the joined proceeding.” *Id.* at 9. Merck agrees also to consolidated filings and discovery. *Id.* at 10–12. Moreover, Merck states that “Mylan consents to Merck’s request for joinder.” *Id.* at 1.

Patent Owner states that it does “not object to Merck’s motion to join the present petition to IPR2016-00710, provided that, as a condition to joinder, Merck should not be permitted to proceed with its already-pending petition in IPR2016-01373.” Paper 10, 1. Inasmuch as we decline to institute trial in IPR2016-01373 under 35 U.S.C. § 325(d) concurrently with this decision, we understand Patent Owner to have no residual objection to Merck’s motion for joinder.

As discussed above, joinder is discretionary. In the instant proceeding, we agree with Merck that joinder of the instant proceeding with the ’710 IPR would promote the efficient resolution of the proceedings. Merck has brought the same challenges as presented by the ’710 IPR, thus, the substantive issues in the ’710 IPR would not be unduly complicated by joining with the instant IPR. In particular, joinder merely introduces the same grounds presented originally in the ’710 IPR, where all of the prior art asserted in this Petition is of record. In addition, Merck agrees to be limited to the grounds on which trial was instituted in the ’710 IPR. Mot. 6–9. Moreover, the instant proceeding was filed timely. 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 IPR2017-00047 is *instituted and joined* with  
IPR2016-00710;

FURTHER ORDERED that the grounds on which IPR2016-00710 was instituted are unchanged and no other grounds are instituted in the joined proceeding;

FURTHER ORDERED that the Scheduling Order entered in IPR2016-00710 shall govern the schedule of the joined proceedings;

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

FURTHER ORDERED that, throughout the joined proceeding, Mylan and Merck 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 Mylan and Merck within the time provided by 37 C.F.R. § 42.53, and Merck will not receive any cross-examination or redirect time separate from that of Mylan;

FURTHER ORDERED that IPR2017-00047 is terminated under 37 C.F.R. § 42.72, and all further filings in the joined proceedings are to be made in IPR2016-00710;

FURTHER ORDERED that a copy of this Decision will be entered into the record of IPR2016-00710; and

FURTHER ORDERED that the case caption in IPR2016-00710 shall be changed to reflect joinder with this proceeding in accordance with the attached example.

IPR2017-00047  
Patent No. 6,331,415 B1

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Example Case Caption for Joined Proceeding

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<sup>1</sup> Case IPR2017-00047 has been joined with this proceeding.