

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PFIZER, INC.  
Petitioner,

v.

BIOGEN, INC. and GENENTECH, INC.,  
Patent Owner.

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Case IPR2017-01115  
Patent 7,820,161 B1

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Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and  
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION

Institution of *Inter Partes* Review, Grant of Motion for Joinder, and Grant of  
Joint Motion to Dismiss Certain Challenges in the Petition  
*37 C.F.R. §§ 42.71 (a), 42.108, 42.122(b)*

## I. INTRODUCTION

Pfizer, Inc. (“Petitioner”) timely filed a Petition (“Pfizer Petition”) requesting an *inter partes* review of claims 1–12 of U.S. Patent No. 7,820,161 B1 (Ex. 1001, “the ’161 patent”). Paper 2 (“Pet.”). Petitioner also timely filed a Motion for Joinder to join this proceeding with *Celltrion Inc. v. Biogen, Inc. and Genentech, Inc.*, Case IPR2016-01614 (the “Celltrion IPR”) which was instituted on February 24, 2017. Paper 3 (“Joinder Mot.”). Biogen, Inc. and Genentech, Inc.<sup>1</sup> (collectively, “Patent Owner”) did not file a Preliminary Response to the Petition. With our authorization, Petitioner and Patent Owner filed a Joint Motion to Dismiss the claim challenges not instituted in the Celltrion IPR. Paper 11.

For the reasons set forth below, we (1) *grant* the Joint Motion to Dismiss certain challenges raised in the Petition; (2) institute an *inter partes* review based on the same grounds as instituted in the Celltrion IPR, and (3) *grant* Petitioner’s Motion for Joinder, subject to the conditions detailed herein.

## II. JOINT MOTION TO DISMISS

In the Pfizer Petition, Petitioner raises the identical grounds raised in the Celltrion IPR. Those grounds include challenges to claims that were not instituted in the Celltrion IPR. In the Joint Motion to Dismiss, Petitioner and Patent Owner jointly move to dismiss the challenges of those claims not instituted in the Celltrion IPR. Specifically, the motion seeks to dismiss “the challenge of claims 1–12 as set forth in Ground 1 and the challenge of

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<sup>1</sup> In its Mandatory Notices, Patent Owner explains that the real party-in-interest are Genentech, Inc. and Biogen, Inc. Paper 7, 2.

claims 4, 8, and 12 as set forth in Grounds 2 and 3.” Paper 11, 1. In other words, the Petitioner seeks to modify the challenges in the Petition from:

Claims	Basis	References
1–12	§ 103(a)	Edwards, <sup>2</sup> FDA Conversation, <sup>3</sup> and the Rituxan <sup>®</sup> Label <sup>4</sup>
1–12	§ 103(a)	Edwards, O’Dell, <sup>5</sup> and the Rituxan <sup>®</sup> Label
1–12	§ 103(a)	Edwards, Kalden, <sup>6</sup> and the Rituxan <sup>®</sup> Label

to:

Claims	Basis	References
1–3, 5–7, and 9–11	§ 103(a)	Edwards, O’Dell, and the Rituxan <sup>®</sup> Label
1–3, 5–7, and 9–11	§ 103(a)	Edwards, Kalden, and the Rituxan <sup>®</sup> Label

The parties explain that the motion seeks to “clarify that Pfizer seeks institution of the same claims and ground for which the Board instituted in the Celltrion IPR.” Paper 11, 1.

Upon consideration of the agreement of the parties and the circumstances involved, including an unopposed joinder motion, Paper 3,

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<sup>2</sup> Edwards et al., *Rheumatoid Arthritis: The Predictable Effect of Small Immune Complexes in Which Antibody is Also Antigen*, 37 BRITISH J. RHEUMATOLOGY 126–130 (1998) (Ex. 1030).

<sup>3</sup> Schwieterman, *Immunosuppression in Combination with Monoclonal Antibodies*, BIOLOGIC AGENTS IN AUTOIMMUNE DISEASE 291–298 (1995) (Ex. 1030).

<sup>4</sup> IDEC Pharmaceuticals Corporation and Genentech, Inc., Product label for Rituxan<sup>®</sup> (1997) (Ex. 1037).

<sup>5</sup> O’Dell, *Methotrexate Use In Rheumatoid Arthritis*, 23 RHEUMATIC DISEASE CLINICS OF NORTH AMERICA 779–796 (1997) (Ex. 1015).

<sup>6</sup> Kalden et al., *Rescue of DMARD failures by means of monoclonal antibodies or biological agents*, 15 J. CLINICAL AND EXPERIMENTAL RHEUMATOLOGY S91–S98 (1997) (Ex. 1051).

the joint motion to dismiss certain claim challenges is *granted*. See 37 C.F.R. § 42.71 (a) (“The Board may . . . enter any appropriate order.”).

### III. INSTITUTION OF *INTER PARTES* REVIEW

In the Celltrion IPR, we instituted trial on the following ground: Claims 1–3, 5–7, and 9–11 of the ’161 patent under 35 U.S.C. § 103(a) as obvious over Edwards, the Rituxan<sup>®</sup> Label, O’Dell, and Kalden. Celltrion IPR, Paper 12, 12. Pfizer’s Petition is substantially identical to Celltrion’s Petition, challenging the same claims based on the same art and the same grounds. Pfizer’s Petition relies on its own declarant, Elena Massarotti, M.D. (Ex. 1002). Her declaration testimony, however, supports the Pfizer Petition in a similar manner as the declarants relied upon by Celltrion in the Celltrion IPR. Indeed, Petitioner confirms in the Motion for Joinder that “[t]he opinions set forth in Dr. Massaratti’s declaration are nearly identical to the opinions set forth in the declaration of Dr. Maarten Boers filed in the Celltrion IPR.” Paper 3, 3. As discussed in our Decision granting the Joint Motion to Dismiss, Section II above, Petitioner seeks only institution of the same claims and ground for which the Board instituted in the Celltrion IPR.

Patent Owner has not filed a Preliminary Response in this proceeding. Thus, at this stage of the proceeding, Patent Owner has not raised any arguments in response to the substantive grounds of the Pfizer Petition. In view of that, and our dismissal of the claim challenges in the Petition that differ from those instituted in the Celltrion IPR, we determine that, under the current circumstances, it is appropriate to exercise our discretion to institute an *inter partes* review of the remaining challenged claims based upon the same ground authorized and for the same reasons discussed in our Institution Decision in the Celltrion IPR. See Celltrion IPR, Paper 12.

#### IV. JOINDER OF *INTER PARTES* REVIEWS

An *inter partes* review may be joined with another *inter partes* review, subject to the provisions 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 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, Petitioner 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: set forth the reasons joinder is appropriate; identify any new grounds of unpatentability asserted in the petition; and explain what impact (if any) joinder would have on the trial schedule for the existing review. *See Kyocera Corp. v. Softview, LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15); *see also*, “Frequently Asked Questions H5,” <http://www.uspto.gov/ip/boards/bpai/prps.jsp>.

Petitioner timely filed its Joinder Motion within one month of the institution of the Celltrion IPR, as required by 37 C.F.R. § 42.122(b). In the motion, Petitioner explains that it will “maintain a secondary role in the proceeding, if joined [with the Celltrion IPR proceeding]. Petitioner will assume a primary role only if the Celltrion IPR petitioner ceases to participate in the IPR.” Paper 3, 3. As discussed in the Institution Decision, Section III above, the instituted ground in this proceeding is the same as that instituted in the Celltrion IPR.

Having considered the unopposed motion for joinder, and our decisions to institute the same ground in the Celltrion IPR and the Pfizer IPR, we determine that Petitioner Pfizer has established persuasively that joinder is appropriate and will have little to no impact on the timing, cost, or presentation of the trial on the instituted ground. Thus, in consideration of the foregoing, and in the manner set forth in the following Order, the Motion for Joinder is *granted*.

#### V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Joint Motion to Dismiss the challenge of claims 1–12 as set forth in Ground 1, and the challenge of claims 4, 8, and 12 as set forth in Grounds 2 and 3, of the Pfizer Petition, Paper 2, is *granted*;

FURTHER ORDERED that trial is instituted in IPR2017-01115 on the following ground:

Claims 1–3, 5–7, and 9–11 of the '161 patent under 35 U.S.C. § 103(a) as obvious over Edwards, the Rituxan<sup>®</sup> Label, O'Dell, and Kalden;

FURTHER ORDERED that Petitioner's Unopposed Motion for Joinder with IPR2016-01614 is *granted*;

FURTHER ORDERED that IPR2017-01115 is terminated and joined with IPR2016-01614, pursuant to 37 C.F.R. §§ 42.72, 42.122, wherein Pfizer will maintain a secondary role in the proceeding, unless and until Celltrion ceases to participate as a petitioner in the *inter partes* review;

FURTHER ORDERED that the Scheduling Order in place for IPR2016-01614, along with modifications appropriately stipulated to by the parties, shall govern the joined proceeding;

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FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2016-01614;

FURTHER ORDERED that the case caption in IPR2016-01614 for all further submissions shall be changed to add Pfizer, Inc. as a named Petitioner after the Celltrion Petitioner, and a footnote shall be added to indicate the joinder of IPR2017-01115 to that proceeding, as shown in the attached sample case caption; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2016-01614.

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Joined Case Caption

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<sup>1</sup> Case IPR2017-01115 has been joined with this proceeding.