IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,

Petitioner

v.

GENENTECH, INC.

Patent Owner

U.S. Patent No. No. 7,976,838 B2 to Benyunes
Issue Date: July 12, 2011
Title: Therapy of Autoimmune Disease in a Patient
With an Inadequate Response to a TNF-a Inhibitor

Inter Partes Review No. 2015-01733

MOTION FOR JOINDER
Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22 and 42.122(b)

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Celltrion, Inc. respectfully submits this Motion for Joinder, together with a Petition for *Inter Partes* Review of U.S. Patent No. 7,976,838. Pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b), Celltrion requests institution of *inter partes* review (IPR) and joinder with the IPR concerning the same patent in *Boehringer Ingelheim Int'l GmbH and Boehringer Ingelheim Pharm., Inc. v. Genentech, Inc.*, Case IPR2015-00417 (the "Boehringer IPR"), which was instituted on July 14, 2015. Joinder is appropriate because it will promote the efficient and consistent resolution of the validity of a single patent, and will not delay the Boehringer IPR trial schedule or prejudice the parties to that IPR. Boehringer Ingelheim has advised Celltrion that it does not oppose Celltrion's motion for joinder.

Celltrion's request for joinder is timely, as it is submitted within one month of the July 14, 2015 institution of the Boehringer IPR. 37 C.F.R. §§ 42.22, 42.122(b).

II. STATEMENT OF MATERIAL FACTS

Genentech, Inc. ("Patent Owner") owns U.S. Patent 7,976,838 ("the '838 patent"). On July 14, 2015, the Board instituted Boehringer's IPR on the '838 patent on the following two grounds of unpatentability:

(1) obviousness of claims 1-5 and 7-14 over Edwards et al., *Efficacy and Safety of Rituximab, a B-Cell Targeted Chimeric Monoclonal Antibody: A Randomized, Placebo-Controlled Trial in Patients with Rheumatoid Arthritis*, Abstracts of the American College of Rheumatology 66th Annual Meeting, Oct. 24 29, 2002 (New Orleans, LA) ("Edwards VI," Ex. 1003), and Tuscano, *Successful Treatment of Infliximab-Refractory Rheumatoid Arthritis with Rituximab*, Arthritis Rheum 46: 3420, LB 11 (2002) (Ex. 1008); and

(2) obviousness of claim 6 over PCT Application WO 00/67796 (Curd et al.) (Ex. 1005), De Vita et al., *Ruolo Patogentico Dei Linfociti B Nella Sinovite Reumatoide: Il Blocco Selettivo B Cellulare Puo Indurre Risposta Clinica In Pazienti con Artrite Reumatoid Refrattaria*, Official Journal of the Italian Society of Rheumatology, Vol. 53, No. 3 (Suppl. No. 4) (2001) [ENGLISH TRANSLATION] (Ex. 1006), and Edwards et al., *Sustained improvement in rheumatoid arthritis following a protocol designed to deplete B lymphocytes*, Rheumatology 40:205-211 (2001) ("Edwards IV," Ex. 1022).

See Institution of *Inter Partes* Review, Boehringer IPR Paper No. 11, July 14, 2015.

Other than the Boehringer IPR, Celltrion is not a party to, or aware of, any prior or pending litigation or administrative proceedings regarding the ’838 patent.

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Legal Standard

The Leahy-Smith America Invents Act (AIA) permits joinder of like review proceedings, *e.g.* an IPR may be joined with another IPR. 37 C.F.R. § 42.122(a). The Board has discretion to join parties to an existing IPR. 35 U.S.C. § 315(c). In deciding whether to exercise its discretion, the Board considers factors including: (1) the movant’s reasons why joinder is appropriate; (2) whether the new petition presents any new grounds of unpatentability; (3) what impact (if any) joinder would have on the trial schedule for the existing review; and (4) how briefing and discovery may be simplified. *Dell Inc. v. Network-1 Security Solutions, Inc*., Decision on Motion for Joinder, IPR2013-00385, Paper No. 17 at 4 (July 29, 2013). The Board should consider “the policy preference for joining a party that does not present new issues that might complicate or delay an existing proceeding.” *Id.* at 10. Under this framework, joinder of the present Celltrion Petition for IPR with the Boehringer IPR is appropriate.

B. Joinder is Appropriate Because Celltrion's Petition Contains No New Grounds of Unpatentability and Joinder Will Not Impact the Trial Schedule

Joinder will not impact the Board's ability to complete its review of the '838 patent in a timely manner, as Celltrion raises no issues that are not already before the Board in the Boehringer IPR. Celltrion's Petition seeks review of the same claims at issue in the Boehringer IPR (claims 1-14 of the '838 patent), based on the same grounds and combinations of prior art. Indeed, Celltrion's Petition is substantively identical to Boehringer's petition (Boehringer IPR, Paper No. 1), except that Celltrion omitted grounds of unpatentability not instituted by the Board in the Boehringer IPR, and on pages 5-6 of the Petition, clarified the grounds for which Petitioner is seeking IPR.[1] There are no other substantive differences. Further, Celltrion relies on the same exhibits and same expert declaration of Dr. Kalden. Boehringer Ingelheim has advised Celltrion that it does not oppose Celltrion's relying on Dr. Kalden's opinions, including his declaration(s) and any oral testimony.

In such circumstances, the PTO anticipated that joinder would be granted as a matter of right. *See* CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) ("The Office anticipates that joinder will be allowed as of right – if an inter partes review is instituted on the basis of a petition, for example, a party that

1 Celltrion also updated the Mandatory Notices.

files an identical petition will be joined to that proceeding, and thus allowed to file its own briefs and make its own arguments.").

Because joinder will not introduce any new prior art, expert declarations, or grounds of unpatentability into the Boehringer IPR, joining Celltrion's proceeding will not complicate the substantive issues already pending in the Boehringer IPR. Celltrion respectfully submits that the Patent Owner would thus not be prejudiced by the joinder, and would not need a substantial amount of time to complete a Preliminary Patent Owner's Response, should it choose to file one.

In contrast, Celltrion would be prejudiced if joinder is denied. It is noted that Celltrion would not be time-barred from filing the present Petition without a corresponding motion for joinder. However, joinder is warranted to permit Celltrion to protect its interests. If Boehringer and the Patent Owner settle their disputes, the Boehringer IPR could terminate without a final written decision, forcing Celltrion to re-start IPR proceedings, having lost valuable time to pursue expeditious and timely review of the '838 patent. *See* 35 U.S.C. § 317(a) (providing that an *inter partes* review "shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner" unless the Board has already reached its decision on the merits, and if no petitioner remains after settlement, "the Office may terminate the review").

Moreover, joinder is the most expedient way to secure just and efficient resolution of two related proceedings in a single IPR. *See* 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b). Determining the same validity questions in separate proceedings would duplicate efforts and create a risk of inconsistent results and piecemeal review, whereas joining Celltrion to Boehringer's IPR would ensure protection of the parties' interests and would not negatively impact the Boehringer IPR schedule.

C. How Briefing and Discovery May be Simplified

Given that Boehringer and Celltrion would be addressing the same prior art and grounds of unpatentability and relying on the same expert, Celltrion envisions few, if any, differences in the petitioners' positions. Consequently, Celltrion respectfully submits that briefing and discovery in the joined proceeding could be simplified to minimize any impact to the schedule or volume of materials to be submitted to the Board. And because Boehringer and Celltrion rely on the same expert, no additional depositions would be needed. Further, Celltrion will cooperate with Boehringer to simplify briefing and discovery, and agrees to consolidated filings. As noted above, Boehringer Ingelheim has advised Celltrion that it does not oppose Celltrion's motion for joinder.

Celltrion respectfully submits that the Board could adopt procedural safeguards similar to those in Dell, IPR2013-00385 and Motorola Mobility,

IPR2013-00256, where the Board ordered the petitioners to file consolidated filings (for which the first petitioner was responsible), and allowed the new petitioner to file seven additional pages directed to points of disagreement with points asserted in the consolidated filing, with corresponding additional responsive pages allowed to the Patent Owner. IPR2013-00385, Paper 17 at 8; IPR2013-00256, Paper 10 at 8-9. The Board recognized that these procedures would minimize any complication or delay caused by joinder.

IV. CONCLUSION

For the foregoing reasons, Celltrion respectfully requests that the Board institute its Petition for *Inter Partes* Review of U.S. Patent 7,976,838 and join this proceeding with *Boehringer Ingelheim Int'l GmbH and Boehringer Ingelheim Pharm., Inc. v. Genentech, Inc.*, IPR2015-00417.

Although Petitioner believes that no fee is required for this Motion, the Commissioner may charge any additional fees which may be required for this Motion to Deposit Account No. 50-4494.

Respectfully submitted,

Date: August 14, 2015

/Elizabeth J. Holland/
Elizabeth J. Holland (Reg. No. 47,657)
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Counsel for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 14th day of August 2015, I caused to be served a true and correct copy of the foregoing "MOTION FOR JOINDER PURSUANT TO 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22, AND 42.122(b)" by Federal Express Next Business Day Delivery on the Patent Owner and its representatives at the below addresses:

Genentech, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.

Petitioner

v.

GENENTECH, INC. AND
BIOGEN IDEC, INC.

Patent Owners

U.S. Patent No. 7,820,161 B1 to Curd *et al.*
Issue Date: October 26, 2010
Title: Treatment of Autoimmune Diseases

Inter Partes Review No. IPR2015-01744

MOTION FOR JOINDER
Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22 and 42.122(b)

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Alexandria, VA 22313-1450

I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Celltrion, Inc. respectfully submits this Motion for Joinder, together with a Petition for *Inter Partes* Review of U.S. Patent No. 7,820,161. Pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b), Celltrion requests institution of *inter partes* review (IPR) and joinder with the IPR concerning the same patent in *Boehringer Ingelheim Int'l GmbH and Boehringer Ingelheim Pharm., Inc. v. Genentech, Inc. and Biogen IDEC, Inc.*, Case IPR2015-00415 (the "Boehringer IPR"), which was instituted on July 17, 2015. Joinder is appropriate because it will promote the efficient and consistent resolution of the validity of a single patent, and will not delay the Boehringer IPR trial schedule or prejudice the parties to that IPR. Boehringer Ingelheim has advised Celltrion that it does not oppose Celltrion's motion for joinder.

Celltrion's request for joinder is timely, as it is submitted within one month of the July 17, 2015 institution of the Boehringer IPR. 37 C.F.R. §§ 42.22, 42.122(b).

II. STATEMENT OF MATERIAL FACTS

Genentech, Inc. and Biogen IDEC, Inc. ("Patent Owners") own U.S. Patent 7,820,161 ("the '161 patent"). On July 17, 2015, the Board instituted Boehringer's IPR on the '161 patent on the following two grounds of unpatentability:

(1) obviousness of claims 1, 2, 5, 6, 9, and 10 over Edwards et al., *Rheumatoid Arthritis: the Predictable Effect of Small Immune Complexes in which Antibody Is Also Antigen*, British Journal of Rheumatology, 37: 126-130 (1998), the 1997 Product Label for Rituxan®, and O'Dell, *Methotrexate Use in Rheumatoid Arthritis*, Rheumatic Disease Clinics of North America, Vol. 23, No. 4, pp 779-796 (1997); and

(2) obviousness of claims 1, 2, 5, 6, 9, and 10 over Edwards et al., *Rheumatoid Arthritis: the Predictable Effect of Small Immune Complexes in which Antibody Is Also Antigen*, British Journal of Rheumatology, 37: 126-130 (1998), the 1997 Product Label for Rituxan®, and Kalden, *Rescue of DMARD failures by means of monoclonal antibodies or biological agents*, Clinical and Experimental Rheumatology, 15 (Suppl. 17): S91-S98 (1997).

See Institution of *Inter Partes* Review, Boehringer IPR Paper No. 13, July 17, 2015.

Other than the Boehringer IPR, Celltrion is not a party to, or aware of, any prior or pending litigation or administrative proceedings regarding the '161 patent.

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Legal Standard

The Leahy-Smith America Invents Act (AIA) permits joinder of like review proceedings, *e.g.* an IPR may be joined with another IPR. 37 C.F.R. § 42.122(a). The Board has discretion to join parties to an existing IPR. 35 U.S.C. § 315(c). In deciding whether to exercise its discretion, the Board considers factors including: (1) the movant's reasons why joinder is appropriate; (2) whether the new petition presents any new grounds of unpatentability; (3) what impact (if any) joinder would have on the trial schedule for the existing review; and (4) how briefing and discovery may be simplified. *Dell Inc. v. Network-1 Security Solutions, Inc*., Decision on Motion for Joinder, IPR2013-00385, Paper No. 17 at 4 (July 29, 2013). The Board should consider "the policy preference for joining a party that does not present new issues that might complicate or delay an existing proceeding." *Id.* at 10. Under this framework, joinder of the present Celltrion Petition for IPR with the Boehringer IPR is appropriate.

B. Joinder is Appropriate Because Celltrion's Petition Contains No New Grounds of Unpatentability and Joinder Will Not Impact the Trial Schedule

Joinder will not impact the Board's ability to complete its review of the '161 patent in a timely manner, as Celltrion raises no issues that are not already before

the Board in the Boehringer IPR. Celltrion's Petition seeks review of the same claims at issue in the Boehringer IPR (claims 1, 2, 5, 6, 9, and 10 of the '161 patent), based on the same grounds and combinations of prior art. Indeed, Celltrion's Petition is substantively identical to Boehringer's petition (Boehringer IPR, Paper No. 1), except that Celltrion (1) omitted prior art combinations not instituted by the Board in the Boehringer IPR; (2) on pages 5-6 of the Petition, limited the list of challenged claims to only those on which the Board instituted trial in the Boehringer IPR and clarified the grounds for which Petitioner is seeking IPR; (3) omitted argument that related specifically to claims 3, 4, 7, 8, 11, and 12; and (4) conformed the claim charts to only the claims for which the Board instituted trial in the Boehringer IPR.[1] There are no other substantive differences. Further, Celltrion relies on the same exhibits and same expert declaration of Dr. Kalden. Boehringer Ingelheim has advised Celltrion that it does not oppose Celltrion's reliance on Dr. Kalden, including his declaration(s) and any oral testimony.

In such circumstances, the PTO anticipated that joinder would be granted as a matter of right. *See* CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) ("The Office anticipates that joinder will be allowed as of right – if an

[1] Celltrion also updated the Mandatory Notices.

inter partes review is instituted on the basis of a petition, for example, a party that files an identical petition will be joined to that proceeding, and thus allowed to file its own briefs and make its own arguments.").

Because joinder will not introduce any new prior art, expert declarations, or grounds of unpatentability into the Boehringer IPR, joining Celltrion's proceeding will not complicate the substantive issues already pending in the Boehringer IPR. Celltrion respectfully submits that the Patent Owners would thus not be prejudiced by the joinder, and would not need a substantial amount of time to complete a Preliminary Patent Owners' Response, should they choose to file one.

In contrast, Celltrion would be prejudiced if joinder is denied. It is noted that Celltrion would not be time-barred from filing the present Petition without a corresponding motion for joinder. However, joinder is warranted to permit Celltrion to protect its interests. If Boehringer and the Patent Owners settle their disputes, the Boehringer IPR could terminate without a final written decision, forcing Celltrion to re-start IPR proceedings, having lost valuable time to pursue expeditious and timely review of the '161 patent. *See* 35 U.S.C. § 317(a) (providing that an *inter partes* review "shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner" unless the

Board has already reached its decision on the merits, and if no petitioner remains after settlement, "the Office may terminate the review").

Moreover, joinder is the most expedient way to secure just and efficient resolution of two related proceedings in a single IPR. *See* 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b). Determining the same validity questions in separate proceedings would duplicate efforts, and create a risk of inconsistent results and piecemeal review, whereas joining Celltrion to Boehringer's IPR would ensure protection of the parties' interests and would not negatively impact the Boehringer IPR schedule.

C. How Briefing and Discovery May be Simplified

Given that Boehringer and Celltrion would be addressing the same prior art and grounds of unpatentability and relying on the same expert, Celltrion envisions few, if any, differences in the petitioners' positions. Consequently, Celltrion respectfully submits that briefing and discovery in the joined proceeding could be simplified to minimize any impact to the schedule or volume of materials to be submitted to the Board. And because Boehringer and Celltrion rely on the same expert, no additional depositions would be needed. Further, Celltrion will cooperate with Boehringer to simplify briefing and discovery and agrees to

consolidated filings. As noted above, Boehringer Ingelheim has advised Celltrion that it does not oppose Celltrion's motion for joinder.

Celltrion respectfully submits that the Board could adopt procedural safeguards similar to those in *Dell*, IPR2013-00385 and *Motorola Mobility LLC v. SoftView LLC*, IPR2013-00256, where the Board ordered the petitioners to file consolidated filings (for which the first petitioner was responsible), and allowed the new petitioner to file seven additional pages directed to points of disagreement with points asserted in the consolidated filing, with corresponding additional responsive pages allowed to the Patent Owner. IPR2013-00385, Paper No. 17 at 8; IPR2013-00256, Paper No. 10 at 8-9. The Board recognized that these procedures would minimize any complication or delay caused by joinder.

IV. CONCLUSION

For the foregoing reasons, Celltrion respectfully requests that the Board institute its Petition for *Inter Partes* Review of U.S. Patent 7,820,161 and join this proceeding with *Boehringer Ingelheim Int'l GmbH and Boehringer Ingelheim Pharm., Inc. v. Genentech, Inc. and Biogen IDEC, Inc.*, IPR2015-00415.

Although Petitioner believes that no fee is required for this Motion, the Commissioner may charge any additional fees which may be required for this Motion to Deposit Account No. 06-0923.

Date: August 17, 2015

Respectfully submitted,
/s/ Elizabeth J. Holland

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Counsel for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 17th day of August, 2015, I caused to be served a true and correct copy of the foregoing "MOTION FOR JOINDER PURSUANT TO 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22 AND 42.122(b)" by Federal Express Next Business Day Delivery on the Patent Owners and their representative at the below addresses:

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