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IPR2017-01603, Paper No. 11
IPR2017-01078, Paper No. 9
Entered: September 25, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2017-01063
Patent 9,006,224 B2

WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

Cases IPR2017-01078
Patent 9,006,224 B2

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

DECISION
Granting Motions for Joinder
35 U.S.C. § 315(c); 37 C.F.R. § 42.122(b)

I. INTRODUCTION

On February 15, 2017, the Board instituted an *inter partes* review trial of claims 1–3 of U.S. Patent No. 9,006,224 B2 (Ex. 1001,[1] "the '224 patent"). *Par Pharm. v. Novartis AG*, Case IPR2016-01479 (PTAB Feb. 15, 2017) (Paper 8) ("the Par IPR"). Trial in that matter is pending on the following grounds of unpatentability:

1. Whether claims 1–3 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Öberg 2004,[2] Boulay 2004,[3] and O'Donnell;[4]

[1] Unless otherwise indicated, when substantively identical documents have been filed in both cases we will cite only to the docket of IPR2017-01063.

[2] K. Öberg, *Treatment of neuroendocrine tumors of the gastrointestinal tract*, 27(4) ONCOLOGÍA 57–61 (2004) (Ex. 1027).

[3] A. Boulay et al., *Antitumor efficacy of intermittent treatment schedules with the rapamycin derivative RAD001 correlates with Prolonged Inactivation of Ribosomal Protein S6 Kinase 1 in Peripheral Blood Mononuclear Cells*, 64 CANCER RES. 252–261 (2004) (Ex. 1005).

[4] A. O'Donnell et al., *A phase I study of the oral mTOR inhibitor RAD001 as a monotherapy to identify the optimal biologically effective dose using toxicity, pharmacokinetic (PK) and pharmacodynamics (PD) endpoints in patients with solid tumors*, 22 PROC. AM. SOC'Y OF CLINICAL ONCOLOGY 200(803 ab.) (2003) (Ex. 1029).

2. Whether claim 2 is unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Öberg 2004, Boulay 2004, O'Donnell, and Tabernero;[5]

3. Whether claims 1–3 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Boulay 2004, O'Donnell, and Duran;[6] and

4. Whether claim 2 is unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Boulay 2004, O'Donnell, Duran, and Tabernero.

Two additional petitions have now been filed with the Board, each seeking joinder with the Par IPR. In IPR2017-01063, Argentum Pharmaceuticals LLC filed a Petition requesting *inter partes* review of claims 1–3 of the '224 patent. IPR2017-01063, Paper 1. Concurrently with its Petition, Argentum filed a Motion for Joinder (Paper 3), seeking joinder with the Par IPR. The owner of the '224 patent, Novartis AG, filed a Response to the Motion for Joinder (Paper 9) but waived the filing of a preliminary response (Paper 10).

In IPR2017-01078, West-Ward Pharmaceuticals International Limited filed a Petition requesting *inter partes* review of claims 1–3 of the '224 patent. IPR2017-01078, Paper 1. Concurrently with its Petition, West-Ward filed a Motion for Joinder (Paper 3), seeking joinder with the Par IPR. Novartis filed

[5] J. Tabernero et al., *A phase I study with tumor molecular pharmacodynamics (MPD) evaluation of dose and schedule of the oral mTOR-inhibitor Everolimus (RAD001) in patients (pts) with advanced solid tumors,* 23(16S) J. CLINICAL ONCOLOGY 3007 (2005) (Ex. 1038).

[6] I. Duran et al., *A phase II trial of temsirolimus in metastatic Neuroendocrine Carcinomas (NECs),* 23(16S) SUPPLEMENT TO J. CLINICAL ONCOLOGY 3096 (ab.) (2005) (Ex. 1011).

a Response to the Motion for Joinder (Paper 6) but waived the filing of a preliminary response (Paper 8).

Both newly-filed Petitions assert the same grounds of unpatentability as those on which trial was instituted in the Par IPR. IPR2017-01063, Paper 1, 1; IPR2017-01078, Paper 1, 1.

As a threshold matter, we determine that the Motions for Joinder were timely. Our Rules provide that a request for joinder must be filed "no later than one month after the institution date of any *inter partes* review for which joinder is requested." 37 C.F.R. § 42.122(b). The Motions were filed on or before March 15, 2017, less than one month after the February 15, 2017 institution date of the Par I *inter partes* review, and are thus timely.

For the reasons explained below, we grant both Motions.

II. THE PETITIONS WARRANT INSTITUTION

The controlling statute regarding joinder of a party to an *inter partes* review is 35 U.S.C. § 315(c), which reads as follows:

> (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.

The statute makes clear that joinder of a party to an instituted *inter partes* review is within the Board's[7] discretion. That discretion may only be

[7] By regulation, the Director's discretion has been delegated to the Board. 37 C.F.R. § 42.4(a).

exercised, however, if the party seeking joinder "files a petition . . . that the Director . . . determines warrants the institution of an inter partes review." 35 U.S.C. § 315(c). As a threshold issue, therefore, we must first determine whether the instant Petitions warrant institution of an *inter partes* review.

The grounds of unpatentability asserted in the instant Petitions are identical to those instituted in the Par IPR. Argentum and West-Ward state that their Petitions include the same grounds and arguments as those in the Par IPR, and note that the parties rely on the same expert witness, Mark J. Ratain, M.D., as Par does. IPR2017-01063, Paper 3, 4; IPR2017-01078, Paper 3, 7–8.

We previously determined, upon consideration of the Petition and Novartis' Preliminary Response in the Par IPR, that the record in that proceeding established a reasonable likelihood that Par would prevail with respect to claims 1–3. IPR2016-01479, Paper 8, 18. Furthermore, Novartis waived any preliminary response to the Petitions, so we are not presented with any arguments against institution of trial that were not previously considered in the Par IPR. Given the identical grounds and evidence presented in the present proceedings, we likewise determine that the instant Petitions warrant institution on all presented grounds. We rely on, and hereby incorporate by reference, the reasoning set forth in our Decision on Institution in the Par IPR. *See id.* at 5–18.

III. DISCRETION TO GRANT JOINDER

Having determined that the instant Petitions warrant institution, we must determine whether to exercise our discretion to join Argentum and West-Ward as parties to the Par IPR. As the moving parties, Argentum and West-Ward bear the burden of showing that joinder is appropriate. 37 C.F.R. §§

42.20(c), 42.122(b). A motion for joinder should: (1) set forth the reasons why joinder is appropriate; (2) identify any new grounds of unpatentability; (3) explain what impact (if any) joinder would have on the trial schedule; and (4) address specifically how briefing and discovery may be simplified. *See* Frequently Asked Question ("FAQ") H5 on the Board's website at https://go.usa.gov/xRHCf.

As discussed above, the instant Petitions assert the same grounds of unpatentability as those instituted in the Par IPR and do not present any argument beyond those already at issue in the Par IPR. Furthermore, if joinder is granted, both Argentum and West-Ward propose to take an "understudy" role in the joined proceeding so long as Par remains an active party, and will consolidate filings and discovery. IPR2017-01063, Paper 3, 5; IPR2017-01078, Paper 3, 8. In its Response to the Motions, Novartis states that it does not oppose joinder, but asks that the Board order Argentum and West-Ward:

> (i) to rely solely on the petition and the evidence filed by Par in IPR2016-01479; (ii) to consolidate all briefing under the page limits of 37 C.F.R. § 42.24 and to share the pages that are allotted for written work product to Par in IPR2016-01479; and (iii) to share with Par the time that is or will be allotted for cross and redirect examination to Par in the IPR2016-01479.

IPR2017-01063, Paper 9, 1 (citing *Bungie, Inc. v. Acceleration Bay, LLC*, IPR2016-00934 at 13–14 (PTAB Jul. 8, 2016) (Paper 11); *ZTE USA, Inc. v. Evolved Wireless LLC*, IPR2016-01280 at 4 (PTAB Dec. 21, 2016) (Paper 8).

Upon review, the Motions for Joinder demonstrate that joinder of Argentum and West-Ward as parties to the Par IPR is appropriate, and will lead to the more efficient resolution of the proceedings. The instant Petitions

do not assert any new ground of unpatentability that is not already being considered in the Par IPR, rely on the same arguments and evidence, and do not require any modification to the existing schedule. We, therefore, determine that joinder will not unduly complicate or delay the proceedings, and exercise our discretion to join Argentum and West-Ward as parties to the Par IPR.

With respect to Novartis' proposed requirements that the Petitioners act in concert, we consider them appropriate and in keeping with procedures followed by the Board in other cases of joinder where the joining parties filed identical Petitions with identical evidence. We do not consider it necessary at this time to permit Argentum and West-Ward additional briefing beyond that already permitted Par. The Petitioners should work together to present consolidated briefing in the Par IPR, with Par as the lead Petitioner. If some disagreement arises which prevents a unified position, the Petitioners may request a conference call with the Board.

IV. ORDER

Accordingly, it is:

ORDERED that Argentum's Motion for Joinder (IPR2017-01063, Paper 3) is *granted*;

FURTHER ORDERED that West-Ward's Motion for Joinder (IPR2017-01078, Paper 3) is *granted*;

FURTHER ORDERED that Argentum and West-Ward are joined as Petitioners to IPR2016-01479;

FURTHER ORDERED that the grounds on which IPR2016-01479 was instituted are unchanged;

FURTHER ORDERED that, within one week of this Decision, any party may request a conference call with the Board to discuss changes to the Scheduling Order; in the absence of such changes, the Scheduling Order in place for IPR2016-01479, as modified by any stipulation agreed to by the parties, shall continue to govern the joined proceeding;

FURTHER ORDERED that, throughout IPR2016-01479, any paper, except for a motion that does not involve the other Petitioners, shall be filed by Par as a single, consolidated filing on behalf of Par, Argentum, and West-Ward, pursuant to the page limits set forth in 37 C.F.R. § 42.24, and Par will identify each such filing as a consolidated filing;

FURTHER ORDERED that except as otherwise agreed by the Petitioners, counsel for Par will conduct cross-examination and other discovery on behalf of Par, Argentum, and West-Ward, and that Novartis is not required to provide separate discovery responses or additional deposition time as a result of the joinder;

FURTHER ORDERED that Par, Argentum, and West-Ward collectively will designate attorneys to present at the oral hearing (if requested and granted) as a consolidated presentation;

FURTHER ORDERED that IPR2017-01063 and IPR2017-01078 are terminated under 37 C.F.R. § 42.72, and all further filings for these proceedings are to be made in IPR2016-01479;

FURTHER ORDERED that a copy of this Decision will be entered into the record of IPR2016-01479; and

FURTHER ORDERED that the case caption in IPR2016-01479 shall be changed to reflect the joinder, in accordance with the attached example.

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC.,
ARGENTUM PHARMACEUTICAL LLC, AND
WEST-WARD PHARMACEUTICALS
INTERNATIONAL LIMITED,
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v.

NOVARTIS AG,
Patent Owner.

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Case IPR2016-01479[1]
Patent 9,006,224 B2

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[1] Argentum Pharmaceutical LLC was joined as a party to this proceeding via a Motion for Joinder in IPR2017-01063; West-Ward Pharmaceuticals International Limited was joined as a party via a Motion for Joinder in IPR2017-01078.