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Paper No. 8
Entered: December 7, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
Petitioner,

v.

UCB PHARMA GMBH,
Patent Owner.

Case IPR2016-01665
Patent 6,858,650 B1

Before KRISTINA M. KALAN, ROBERT A. POLLOCK, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges.*

ANKENBRAND, *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

Amerigen Pharmaceuticals Limited ("Petitioner") filed a Petition ("Pet.") requesting an *inter partes* review of claims 1–5 and 21–24 of U.S. Patent No. 6,858,650 B1 (Ex. 1001, "the '650 patent"). Paper 1. Concurrently with its Petition, Petitioner filed a Motion for Joinder (Paper 3, "Mot.") with the *inter partes* review in *Mylan Pharms., Inc. v. UCB Pharma GmbH*, Case IPR2016-00510 (the "Mylan IPR" and Petitioner "Mylan"), an ongoing *inter partes* review, which was instituted on July 20, 2016. *See* IPR2016-00510, Paper 12. UCB Pharma GmbH ("Patent Owner") did not file a Preliminary Response or a response to Petitioner's Motion for Joinder.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 42.4(a). We may not institute an *inter partes* review "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). A petitioner may be joined as a party to a previously instituted *inter partes* review if that petitioner "properly files a petition . . . that we determine[] warrants the institution of an inter partes review." 35 U.S.C. § 315(c); 37 C.F.R. § 42.4(a).

After considering the Petition and the evidence currently of record, we conclude that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. Our conclusion is consistent with our institution decision in the Mylan IPR. *See* IPR2016-00510, Paper 12. Thus, we institute an *inter partes* review of claims 1–5 and 21–24 of the '650 patent. Further, we grant Petitioner's Motion for Joinder and exercise our discretion

to join Petitioner to the Mylan IPR. We further terminate the present proceeding, IPR2016-01665.

II. PETITION FOR *INTER PARTES* REVIEW

The parties indicate that the '650 patent is the subject of several district court cases filed in the U.S. District Court for the District of Delaware and the U.S. District Court for the District of West Virginia. Pet. 9; Paper 6, 2. In addition, the '650 patent is subject to the Mylan IPR, which has been instituted, and pending *inter partes* review proceedings, IPR2016-01596 and IPR2016-01636. *See* Paper 6, 3–4.

In the Mylan IPR, we instituted *inter partes* review of claims 1–5 and 21–24 of the '650 patent on the same grounds of unpatentability asserted in the present Petition, which are reproduced below. Pet. 11; Mot. 2; IPR2016-00510, Paper 12, 29.

References	**Basis**	**Claims Challenged**
Postlind,[1] "Bundgaard publications,"[2,3,4] Detrol Label,[5] and Berge[6]	§ 103	1–5 and 21–24

[1] Postlind et al., *Tolterodine, A New Muscarinic Receptor Antagonist, is Metabolized by Cytochromes P450 2D6 and 3A in Human Liver Microsomes*, 26(4) DRUG METABOLISM & DISPOSITION 289–293 (1998) (Ex. 1010) ("Postlind").
[2] As in the Mylan IPR, we interpret Petitioner's reference to "Bundgaard publications" as referring to Exhibits 1012 and 1020. IPR2016-00510, Paper 12, 5 n.3; Pet. 5, 11–12, 27–29, 36–37, 39.
[3] Bundgaard, Design of Prodrugs Elsevier (1985) (Ex. 1012) ("Bundgaard").
[4] WO 92/08459, published May 29, 1992 (Ex. 1020) ("Bundgaard PCT").
[5] Detrol™ (tolterodine tartrate tablets) prescribing information (1998) (Ex. 1009) ("Detrol Label").
[6] Berge et al., *Pharmaceutical Salts*, 66(1) J. PHARM. SCI. 1–19 (1977) (Ex. 1013) ("Berge").

References	Basis	Claims Challenged
Brynne,[7] Bundgaard publications, and Johansson[8]	§ 103	1–5 and 21–24

Petitioner supports its assertions with the same evidence and arguments proffered in the Mylan IPR. Pet. 14–68. Petitioner asserts that its Petition "is limited to the same grounds instituted in the [Mylan IPR]," and that Petitioner "relies on the same prior art analysis and expert testimony submitted by Mylan." Mot. 6. Petitioner also represents that "no substantive differences exist between the present Petition and the [Mylan IPR] petition." *Id.*

Because the asserted grounds of unpatentability, the arguments, and the supporting evidence here are identical to those in the Mylan IPR, we adopt the analysis from our institution decision in that case. IPR2016-00510, Paper 12, 6–28. Consistent with that analysis, we determine that Petitioner has shown a reasonable likelihood that it will prevail with respect to its challenges to claims 1–5 and 21–24 of the '650 patent on the asserted grounds. Accordingly, we institute an *inter partes* review in this proceeding on the same grounds as those on which we instituted trial in the Mylan IPR. We do not institute an *inter partes* review on any other grounds.

III. MOTION FOR JOINDER

Petitioner seeks joinder with the *inter partes* review in the Mylan IPR. Mot. 2. Petitioner filed the present Motion on August 22, 2016, which is

[7] Brynne et al., *Influence of CYP2D6 polymorphism on the pharmacokinetics and pharmacodynamics of tolterodine*, 63(5) CLIN. PHARMACOL. & THERAPEUTICS 529–539 (1998) (Ex. 1011) ("Brynne").
[8] Johansson et al., WO 94/11337, published May 26, 1994 (Ex. 1005) ("Johansson").

thirty-two days after our July 20, 2016 decision instituting *inter partes* review in the Mylan IPR. The date falling one month after our institution decision, however, was Saturday, August 20, 2016, and Monday, August 22, 2016 was the next succeeding business day. Pursuant to 37 C.F.R. § 1.7, when "the last day fixed . . . by or under this part for taking any action . . . falls on Saturday, Sunday, or on a Federal holiday within the District of Columbia, the action may be taken . . . on the next succeeding business day which is not a Saturday, Sunday, or a Federal holiday." 37 C.F.R. § 1.7(a). The Motion, therefore, is timely under 37 C.F.R. § 42.122(b) ("Any request for joinder must be filed, as a motion under § 42.22, no later than one month after the institution date of any inter partes review for which joinder is requested."). Accordingly, we must consider whether to exercise our discretion to join Petitioner as a party to the Mylan IPR.

In its Motion for Joinder, Petitioner asserts that "[a]bsent termination of Mylan as a party to [the Mylan IPR], [Petitioner] anticipates participating in the proceeding in a limited capacity as an understudy." Mot. 2. In that regard, Petitioner represents that it "will not submit any separate filings unless it disagrees with Mylan's position(s) (which is not anticipated), and in the event of any disagreement it will request authorization to submit a short separate filing directed only to points of disagreement with Mylan." *Id.* at 8–9. Petitioner further states that it "will not seek to submit any new expert declarations from those entered by Mylan" unless Mylan settles with Patent Owner and that settlement contractually binds Mylan's experts from continuing to support Petitioner. *Id.* at 9. Petitioner also states that it "will endeavor to coordinate with Mylan to consolidate authorized filings, manage

questioning at depositions, ensure that briefing and discovery will occur within the time normally allotted, and avoid redundancies." *Id.*

Given Petitioner's concessions, and because Petitioner has satisfied the requirements of § 315(c), we grant Petitioner's Motion for Joinder and exercise our discretion to join Petitioner as a party to the Mylan IPR, subject to the conditions detailed below.[9] We further terminate the trial in IPR2016-01665.

Petitioner shall adhere to the existing schedule in the Mylan IPR. All filings by Petitioner in the Mylan IPR shall be consolidated with the filings of the other Mylan IPR Petitioner(s), unless the filing involves an issue unique to Petitioner or states a point of disagreement related to the consolidated filing. In such circumstances, Petitioner shall seek authorization from the Board to file a separate paper. The Board expects Petitioner and Mylan to resolve any disputes between them and to contact the Board only if such matters cannot be resolved after a meaningful meet and confer between the two parties. The page limits set forth in 37 C.F.R. § 42.24 will apply to all consolidated filings.

Petitioner is bound by any discovery agreements, including deposition arrangements between Patent Owner and Mylan, and shall not seek any discovery beyond that sought by Mylan. Patent Owner shall not be required to provide any additional discovery or deposition time as a result of joinder.

[9] We issue this decision concurrently with decisions in IPR2016-01596 and IPR2016-01636. In each case, we institute an *inter partes* review based on the same grounds as those on which we instituted trial in the Mylan IPR and grant Petitioner's motion for joinder.

IV. ORDER

Accordingly, it is

ORDERED that the Petition is granted and an *inter partes* review is instituted as to:

Claims 1–5 and 21–24 of the '650 patent under 35 U.S.C. § 103 over the combination of Postlind, Bundgaard publications, Detrol Label, and Berge; and

Claims 1–5 and 21–24 of the '650 patent under 35 U.S.C. § 103 over the combination of Brynne, Bundgaard publications, and Johansson;

FURTHER ORDERED that notice is hereby given of the institution of a trial commencing on the entry date of this decision, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4;

FURTHER ORDERED that Petitioner's Motion for Joinder is *granted*;

FURTHER ORDERED that Petitioner is joined as a party to IPR2016-00510;

FURTHER ORDERED that the trial in this case is consolidated with IPR2016-00510;

FURTHER ORDERED that the present proceeding, IPR2016-01665, is terminated under 37 C.F.R. § 42.72, and all further filings shall be made only in IPR2016-00510;

FURTHER ORDERED that the asserted grounds of unpatentability on which a trial was instituted in IPR2016-00510 are unchanged;

FURTHER ORDERED that the current Scheduling Order for IPR2016-00510 shall continue to govern the consolidated proceeding;

FURTHER ORDERED that Petitioner shall adhere to the existing schedule in IPR2016-00510;

FURTHER ORDERED that all filings by Petitioner in the Mylan IPR shall be consolidated with the filing of the other Mylan IPR Petitioner(s), unless the filing involves an issue unique to Petitioner or states a point of disagreement related to the consolidated filing. In such circumstances, Petitioner shall seek authorization from the Board to file a separate paper;

FURTHER ORDERED that Petitioner and Mylan shall resolve any disputes between them and contact the Board only if such matters cannot be resolved after a meaningful meet and confer between the two parties;

FURTHER ORDERED that Petitioner shall be bound by any discovery agreements, including deposition arrangements, between Patent Owner and Mylan, and shall not seek any discovery beyond that sought by Mylan;

FURTHER ORDERED that all page limits set forth in 37 C.F.R. § 42.24 will apply to all consolidated filings;

FURTHER ORDERED that Patent Owner shall not be required to provide any additional discovery or deposition time as a result of joinder;

FURTHER ORDERED that the case caption in IPR2016-00510 shall be changed to reflect the joinder of Petitioner as a party in accordance with the attached example; and

FURTHER ORDERED that a copy of this Decision be entered into the file of IPR2016-00510.

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and MYLAN LABORATORIES LIMITED,
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Case IPR2016-00510[1]
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[1] Petitioners Alembic Pharmaceuticals Limited from IPR2016-01596, Torrent Pharmaceuticals Limited from IPR2016-01636, and Amerigen Pharmaceuticals Limited from IPR2016-01665 have been joined as Petitioners to this proceeding.