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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

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