

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APOTEX, INC. and MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

NOVARTIS AG AND MITSUBISHI PHARMA CORP.,  
Patent Owners.

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Case IPR2015-00518  
Patent 8,324,283 B2

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Before LORA M. GREEN, MICHELLE R. OSINSKI, and  
CHRISTOPHER M. KAISER, *Administrative Patent Judges*.

OSINSKI, *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

Apotex, Inc. and Mylan Pharmaceuticals Inc. (collectively, “Apotex-Mylan”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–32 (“the challenged claims”) of U.S. Patent No. 8,324,283 B2 (Ex. 1001, “the ’283 patent”) and concurrently filed a Motion for Joinder (Paper 2, “Mot.”). The Motion for Joinder seeks to join this proceeding with *Torrent Pharmaceuticals Limited v. Novartis AG and Mitsubishi Pharma Corp.*, Case IPR2014-00784 (“the Torrent IPR” or “the ’784 IPR”). Mot. 1. In a teleconference on February 3, 2015, Patent Owner and Torrent Pharmaceuticals Limited (“Torrent”) indicated they did not oppose Apotex-Mylan’s Motion for Joinder, and Patent Owner waived the Preliminary Response to the Petition.

For the reasons described below, we institute an *inter partes* review of all the challenged claims and grant Apotex-Mylan’s Motion for Joinder.

## II. INSTITUTION OF *INTER PARTES* REVIEW

The Petition in this proceeding asserts the same grounds as those on which we instituted review in the Torrent IPR. On December 1, 2014, we instituted a trial in the Torrent IPR on the following ground: Claims 1–32 of the ’283 patent as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,004,565, issued Dec. 21, 1999 (“Chiba”), and PHARMACEUTICS: *THE SCIENCE OF DOSAGE FORM DESIGN* 223–321 (M.E. Aulton ed., 1988) (“Aulton”).

In view of the identity of the challenge in the instant Petition and in the petition in the Torrent IPR, we institute an *inter partes* review in this

proceeding on the same ground as that on which we instituted the Torrent IPR. We do not institute *inter partes* review on any other grounds.

### III. GRANT OF MOTION FOR JOINDER

The Petition in this proceeding has been accorded a filing date of December 31, 2014, and therefore, satisfies the joinder requirement of being filed within one month of our instituting a trial in the Torrent IPR.

37 C.F.R. § 42.122(b); Paper 7 (Notice of Filing Date Accorded to Petition),  
1.

In the teleconference on February 3, 2015, counsel for (i) Apotex-Mylan, (ii) Torrent, and (iii) Patent Owner, indicated that the parties had conferred regarding joinder and had a proposal in which this proceeding could be joined with the Torrent IPR with minimal impact on the current schedule for the Torrent IPR.

Apotex-Mylan represents that the only ground Apotex-Mylan seeks to pursue in this proceeding is that on which we instituted the Torrent IPR. Mot. 2, 4. Apotex-Mylan acknowledges that it relies upon testimony from a different expert than Torrent, but indicates that the analysis and rationale of its expert is similar to that of Torrent's expert and would have minimal impact on the proceeding. *See id.* at 5. Apotex-Mylan represents that it and Torrent "can work together to manage the questioning at depositions and presentations at the hearing to avoid redundancy." *Id.* Apotex-Mylan further represents that it would not be time-barred from filing the instant Petition without joinder, but that joinder "would avoid inefficiency and potential inconsistency and would result in a final written decision without delay." *Id.* at 5–6.

The parties agreed that Torrent and Apotex-Mylan would file papers as consolidated filings. *See* Mot. 5. The parties also agreed that the page limit for the Patent Owner Response would be extended by up to seven (7) pages, with the page limit for Petitioner's Reply to the Patent Owner Response to be extended by a corresponding number of additional responsive pages.

The parties agreed that joinder of this proceeding with the Torrent IPR would not unduly delay the resolution of either proceeding and proposed that each current due date in the Torrent IPR be extended by one month, with the oral argument to be heard on or around August 3, 2015 (subject to the availability of Hearing Room A due to the number of Petitioners involved in the joined proceedings). In that regard, a revised Scheduling Order for the joined proceedings is being entered concurrently with this decision. The parties agreed that there is no prejudice to Patent Owner, Torrent, or Apotex-Mylan from joining this proceeding with the Torrent IPR.

In consideration of the above, we institute an *inter partes* review in IPR2015-00518 and grant Apotex-Mylan's motion to join this proceeding to IPR2014-00784.

#### IV. ORDER

In view of the foregoing, it is  
ORDERED that IPR2015-00518 is instituted and joined with  
IPR2014-00784;

FURTHER ORDERED that the ground on which IPR2014-00784 was instituted is unchanged and no other grounds are instituted in the joined proceeding;

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FURTHER ORDERED that the Revised Scheduling Order entered concurrently with this Decision shall hereafter govern the schedule of the joined proceedings;

FURTHER ORDERED that, throughout the joined proceeding, Torrent and Apotex-Mylan will file papers, except for motions that do not involve the other party, as a single, consolidated filing on behalf of Petitioner; that the filing party (either Torrent or Apotex-Mylan) will identify each such filing as a Consolidated Filing;

FURTHER ORDERED that the page limit for the Patent Owner Response is extended by seven (7) pages;

FURTHER ORDERED that if the Patent Owner Response is extended by any number of pages (not to exceed seven (7) pages), the page limit for Petitioner's Reply to the Patent Owner Response may also be extended by the same number of pages (not to exceed seven (7) pages);

FURTHER ORDERED that IPR2015-00518 is terminated under 37 C.F.R. § 42.72 and all further filings in the joined proceedings are to be made in IPR2014-00784;

FURTHER ORDERED that a copy of this Decision, as well as the revised Scheduling Order, will be entered into the record of IPR2014-00784; and

FURTHER ORDERED that the case caption in IPR2014-00784 shall be changed to reflect joinder with this proceeding in accordance with the attached example.

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