

For the Petitioner

Paper No. __

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Coalition for Affordable Drugs V LLC,

Petitioner,

v.

BIOGEN MA, INC.,

Patent Owner.

Case IPR2015-01993

Patent 8,399,514

**REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE
IN SUPPORT OF PETITION FOR INTER PARTES REVIEW
OF U.S. PATENT 8,399,514 UNDER 35 U.S.C §§ 311-319**

I. INTRODUCTION

Pursuant to the Patent Trial and Appeal Board's (PTAB's) Order of 8 January 2016 (Paper 13), Petitioner respectfully submits this Reply to Patent Owner's Preliminary Response in IPR2015-01993 for U.S. Patent 8,399,514 (the "514 patent"). Petitioner respectfully submits institution is proper in light of the new grounds of unpatentability set forth in the petition and the new arguments and evidence introduced by the Patent Owner in its Preliminary Response (see e.g., **Exs. 2005-2008** and **2013**).

II. RESPONSE

On page 1 of the Preliminary Response, Patent Owner argues this petition (hereafter "the second petition" or "Pet.") "repackaged" the same arguments as those in petition in IPR2015-01136 (hereafter "the first petition") (**Ex. 2002**). The response is the second petition did not repackage the same arguments as the first petition. Critical differences include the second petition's reliance on the PTAB's intervening decision in Interference No. 106,023, use of new and distinctive prior art, and assertion of new and distinguishing arguments. The PTAB's intervening decision held the '514 patent was not entitled to the filing date of its provisional application and was accorded an effective filing date of only February 7, 2008. *See* Pet. at 14 and 19-21; **Ex. 1010**. As a result of this intervening decision, *Kappos 2006* became available under 35 U.S.C. § 102(b) for the first time,

enabling the unpatentability arguments in the second petition to be presented for the first time. The second petition includes fundamentally new arguments based, *inter alia*, on actual results of a Phase II study shown in *Kappos 2006*, which was neither relied upon in the first petition nor available as 102(b) art at the time the first petition was filed.

On pages 2-3 and 6 of the Preliminary Response, Patent Owner argues the interference decision concerning the priority date of the '514 patent is irrelevant because Petitioner asserted the same alleged effective filing date in both petitions. The response is a) the priority date is highly relevant since it determines under which section of 35 U.S.C. 102 a prior art reference qualifies and b) that the assertion the same effective filing date was relied upon in both petitions is incorrect. First, to the extent an obviousness rejection relies on prior art qualifying under 35 U.S.C. § 102(a) such prior art may be removed with a Rule 131 declaration, whereas prior art qualifying under §102(b) cannot. Second, the first petition relied on printed publications published on dates repeatedly said to be “more than one year prior to February 8, 2007, the earliest effective filing date of the '514 patent” (**Ex. 2002** at 5) (underlining added). In contrast, the second petition repeatedly identifies February 7, 2008 as “the earliest effective filing date for the claims of the '514 patent,” based on the PTAB’s holding in the related interference (Pet. at 5-6, 14, 19-21).

On pages 3-5 of the Preliminary Response, Patent Owner argues the Board, relying on 35 U.S.C. § 325(d), should decline to institute an IPR based on the second petition to the extent it raises the same or substantially the same prior art and arguments as previously presented. The response is even if the second petition raised the same or substantially the same arguments as previously presented (which it did not), the Board is not required to reject such a petition. The statute includes permissive language, *e.g.*, “may,” rather than mandatory language, *e.g.*, “must.” 35 U.S.C. § 325(d); *see also Rackspace v. PersonalWeb Tech.*, IPR2014-00057, Paper 9 at 24-25 (PTAB Apr. 15, 2014). In the second petition, Petitioner relied on prior art qualifying under § 102(b), to reject the ‘514 patent claims as obvious over the appropriate known and available prior art. Indeed, once the Board held on August 19, 2015 that the ‘514 patent claims had an effective filing date of February 7, 2008 (not February 8, 2007) (**Ex. 1010**), Petitioner promptly filed its second petition on September 28, 2015 in order to present its best challenges to the ‘514 patent. Further, none of the prior art used to challenge the ‘514 patent in the first petition teaches “excipients,” an element in claims 1-10 and 15-19 of the ‘514 patent. In the second petition, *Joshi* teaches treating an oral preparation containing DMF and excipients. (Pet. at 26 citing **Ex. 1030**, col. 4:39–42.) *Joshi 2002* teaches oral preparations containing MMF and excipients. (Pet. at 54 citing **Ex. 1036**, col. 11:21–25.) Even further, none of the prior art used to challenge the ‘514 patent in

the first petition teaches pharmaceutical compositions containing MMF.

Pharmaceutical compositions containing MMF are recited in claim 7 of the '514 patent. In the second petition, *Joshi 2002* teaches pharmaceutical compositions containing MMF. Petition at 54 citing **Ex. 1036**, col. 11:21–25. Further still, none of the prior art used in the first petition teaches DMF or MMF as a “tablet, a suspension or a capsule,” as recited in claim 2 of the '514 patent. In the second petition, *Kappos 2006* teaches capsules containing DMF (referred to as BG00012). (Pet. at 30 citing **Ex. 1003**, at 27, col. 2:32–33.) On the other hand, *Kappos 2005*, cited in the first petition, does not teach any particular form of pharmaceutical composition. In the second petition *Joshi* teaches tablets. (Pet. at 30 citing **Ex. 1030**, col. 4:31–33.) Therefore, the Board should institute an IPR based on the second petition because it does not raise the same or substantially the same prior art and arguments as previously presented.

On pages 4-5 of the Preliminary Response, Patent Owner argues the petitions abuse the system and unwarrantedly burden the Board because Petitioner “markets no product and is not using IPRs as an alternative to litigation.” The response is Article III standing is not a requirement to appear before the USPTO. The America Invents Act (“AIA”) was designed to encourage the filing of meritorious patentability challenges, by any person who is not the patent owner, in order to further improve patent quality. The second petition is such a filing. *See*

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