IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Mylan Laboratories Ltd.
Petitioner,

v.

Janssen Pharmaceutica NV
Patent Owner.

U.S. Patent No. 9,439,906 to Vermeulen et al.
Issue Date: September 13, 2016
Title: Dosing Regimen Associated with Long Acting Injectable Paliperidone Esters

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Inter Partes Review No.: IPR2020-00440

AUTHORIZED REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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1. The *Apple* Factors Favor Institution

***Apple* Factor 1:** When the record lacks any evidence of a stay or whether it may or may not be granted, Factor #1 is neutral. *Apple Inc. v. Fintiv, Inc.*, Case IPR2020-00019, Paper 15 at 12 (May 13, 2020) (informative) ("*Apple II*"); *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 7 (June 16, 2020) (informative).

***Apple* Factor 2:** The FWD is due approximately September 2021. POPR at 11. Trial in the district court is not scheduled. While in the Joint Proposed Discovery Plan **the parties** proposed a trial date of "June 2021 *or at the Court's convenience*" (EX2004, p. 5 of 12), the District Court declined to set a trial date. EX2003; *Sand*, IPR2019-01393 at 9 (qualifiers like "or as available" evidences uncertainty around trial schedule); *Apple II*, IPR2020-00019 at 13 (District Court schedules generally taken at "face value."). "Patent Owner has not provided the Board with any procedural schedule **from the District Court** showing a trial date." *Oticon Medical AB et al. v. Cochlear Ltd.*, IPR2019-00975, Paper 15 at 22-24 (PTAB Oct. 16, 2019) (precedential). Under precedential PTAB authority, the parties' intentions are irrelevant. To prevail on this factor, Janssen must provide concrete evidence "from the District Court showing a trial date" (*id.*), which Janssen cannot do because the District Court expressly declined to set a trial date. Like *Oticon*, Factor #2 favors Petitioner and trial should be instituted. *Id.* at 24.

***Apple* Factor 3:** Factor #3 addresses prior investment by the Court and the parties "at the time of the institution." *Apple*, 9. At best, Janssen argues that "[i]n *Mylan*, the parties have exchanged binding validity contentions (nearly 400 pages worth), and fact discovery is ongoing." POPR at 13. Not a single deposition has occurred and Janssen points to no activity by the District Court in *Mylan*. Further, the Petition was filed prior to receiving Janssen's responsive contentions. POPR at 4-5. And, little will have occurred "at the time of the institution." (EX2004). Under similar facts, the PTAB has instituted the review. *Oticon*, IPR2019-00975 at 23 ("Patent Owner simply informs us that 'discovery is well underway.'"); *Apple*, 9-10 (lack of activity by District Court weighs against denial); *Mylan Pharms. Inc. v. Merck Sharpe & Dohme Corp*., IPR2020-00040, Paper 21 at 33-34 (PTAB May 11, 2020) ("*Merck*"); *Sand*, IPR2019-01393 at 11. Instead, Janssen focuses on an unrelated defendant in another proceeding. POPR at 13. "Mylan should not, however, be foreclosed from petitioning the Board to hear its challenge based on choices of the other drug manufacturers." *Merck*, IPR2020-00040 at 29.

Apple does state that when a petitioner is unrelated to a defendant (*i.e.*, Teva), a Petitioner should still explain "why addressing the same or substantially the same issues would not be duplicative of the prior case." *Apple*, 14. Janssen provided an excerpt of Teva's invalidity contentions. EX2007 at 40-41; POPR at 16. Other than stating in a conclusory manner that "all claims are challenged as

obvious for reasons overlapping with Mylan's Grounds here" (POPR at 12), Janssen offers no further explanation. Each of Teva's positions rely on Cleton 2008 as the primary reference. EX2007, p.41. "Cleton 2008 refers collectively to PI-74 and PI-75." POPR at fn. 9. Thus, Teva's entire case is premised on the same §102(a) art that Janssen is seeking to antedate in this IPR. POPR at 20-24. But Mylan is not using Cleton 2008 as its primary reference; Citrome is Mylan's primary reference—*a reference not even used by Teva*. Petition at 14-15; EX2007 at 40-41. Citrome is §102(b) art that cannot be antedated, and no antedation challenge has been made against Ground 3 or 4 because they only rely on §102(b) art. The Cleton 2008 threshold issue will presumably cut across Teva's entire case whereas it will not cut across all Grounds in this IPR. Citrome's unchallenged prior art status makes Mylan's challenge substantially different.

There is more. *Apple* Factor 3 also considers the timing of the Petition. *Apple*, 11. Janssen admits Mylan filed its Petition six months before the statutory deadline and without the benefit of Janssen's responsive validity contentions (POPR at 7, 8) which, as explained by *Oticon*, avoids any prejudice to Janssen. IPR2019-00975 at 22-23; *Apple Inc. v. Seven Networks LLC*, IPR2020-00156, Paper 10 at 11 (PTAB Jun. 15, 2020) (declining to exercise §314(a) discretion when the Petition was filed four months in advance of bar). Janssen complains that Mylan had on hand its positions at the time it served its notice letter as required by

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