UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and AMNEAL PHARMACEUTICALS LLC

Petitioners

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Patent Owner

Case IPR2015-00643 (Patent 8,232,250 B2)
Case IPR2015-00644 (Patent 8,399,413 B2)
Case IPR2015-00830 (Patent 8,969,302 B2)[1,2]

PATENT OWNER'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE EVIDENCE

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[1] The word-for-word identical paper is filed in each proceeding identified in the caption.

[2] Cases IPR2015-01976, IPR2015-01980, and IPR2015-01981 have been joined with IPR2015-00643, IPR2015-00644, and IPR2015-00830, respectively.

I. Khan 2009 (Exs. 1068 And 1089) Is Not Prior Art And Should Be Excluded

Petitioners admit the Khan 2009 abstracts (Exs. 1068 And 1089) are not prior art. As such, they cannot be relied upon to show the state of the art as of the priority date as Petitioners suggest. Petitioners have made no showing that ***any*** of the information contained in the Khan 2009 abstracts would have been available to a POSA before the priority date. Therefore, the abstracts are irrelevant to the obviousness inquiry in this case as they are neither prior art nor evidence of the "state of the art" available to a POSA in 2009.

Petitioners' reliance on *Syntex (U.S.A.) LLC v. Apotex, Inc.* is misplaced. In *Syntex*, the inventors authored a Pharmaceutical Report, published five days after the priority date, that clearly states that octoxynol 40 was a well-known ingredient in pharmaceutical products. 407 F.3d 1371, 1379 (Fed. Cir. 2005). The Federal Circuit determined that the District Court erred by concluding that octoxynol 40 was not used in pharmaceuticals prior to its use in the patented invention. *Id.* *Syntex* is distinguishable for at least 2 reasons. Here, unlike the Pharmaceutical Report in *Syntex*, the Khan 2009 abstracts were not authored by the inventors and make no statements about what was "well-known" in the art prior to the filing of the patent. In fact, the Khan 2009 abstracts describe a clinical trial that had yet to be presented to the field, and the Khan 2009 abstracts make no comments about the

state of the art before the priority date. Therefore, the Board should exclude the Khan 2009 abstracts (Exs. 1068 And 1089).

II. The Board Should Exclude Teva's Shared Solutions Website (Ex. 1086)

Once again, Petitioners' admission that the Shared Solutions website is dated after the priority date should end the inquiry as the website is not prior art. *See* Paper 75 [Petitioners' Opposition] at p. 6. Instead, Petitioners state that the Board should consider the website because it "corroborate[s] Dr. Green's testimony." *Id.* Yet Petitioners do not even attempt to explain how information from 2016 can legitimately corroborate Dr. Green's opinion about the state of the art in 2009. Instead, Petitioners argue that the Board can rely on this after-the-fact information by claiming it is Yeda's burden to show that no "intervening clinical trial changed the known state of the art" between 2009 and 2016. *Id.* at p. 6, n. 4. This kind of post-hoc evidence is exactly the type of evidence the Board typically excludes in order to prevent the type of hindsight analysis the Petitioners have offered. It is Petitioners' burden, not Yeda's, to establish the state of the art as of the priority date with information available to a POSA ***at the time of the priority date***. Therefore, the Board should exclude the Shared Solutions website.

III. The Board Should Exclude The Lebano Article (Ex. 1098)

Petitioners also improperly rely on the post-priority date 2012 Lebano Article as purported evidence of the state of the prior art in 2009. Petitioners

incorrectly point to a passage in the Lebano Article which states "gray matter lesions are still difficult to measure and not discernable using traditional MRI" in order to argue that detecting gray matter lesions with MRI was "expensive and difficult to deploy in a multicenter clinical trial" as of the priority date. *Id.* at p. 7-8. But there is nothing in this statement pertinent to the state of the art in 2009 and, in fact, that gray matter lesions were "difficult" to measure is irrelevant to whether or not a POSA would expect the claimed invention to reduce gray matter lesions. Therefore, the Lebano Article is irrelevant and should be excluded.

IV. The Wolinsky Transcript (Ex. 1140) is Irrelevant And Should Be Excluded

The Wolinsky Transcript was never cited in any of Petitioners' filings in this proceeding or cited by any of Petitioners' experts and, therefore, is not of record. Petitioners' attempt to introduce the exhibit through improper re-direct examination of its own witness during the reply round of depositions is in flagrant disregard of the Board's rules regarding the supplementation of evidence.[3] *See* 37

[3] Petitioners' argument that Yeda waived its objections under 37 CFR § 42.123 is baseless. Counsel for Yeda specifically states that "I want to object to this document being offered. It's not part of the record in this proceeding. So I just object to any testimony on the document." This objection clearly includes an objection under 37 CFR § 42.123.

CFR § 42.123(b). Rather than seek leave to move to supplement the record, as was required[4], Petitioners attempted to have Dr. Green ostensibly read portions of the Wolinsky Transcript into the record at his deposition despite objections made by Yeda's counsel that it was improper to do so.[5] Dr. Green even admitted that he had not seen the Wolinsky Transcript until the week before his deposition and that it played no part in the opinions that he set forth in this IPR. (Ex. 1142, 404:10-12, 404: 22-24). The Wolinsky Transcript is also irrelevant to these proceedings because it is not prior art and therefore cannot be the basis of any finding by the Board. The prescribing practices and rationales of a single physician are irrelevant if those practices were not known and available to a POSA as of the priority date.

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[4] Petitioners' argument that Yeda improperly maintained confidentiality over the Wolinsky Transcript is similarly baseless. In district court litigation, it is regular practice, as Petitioners' themselves have done, to mark an entire deposition transcript confidential to protect client confidential information, and there was no undue delay in addressing Petitioners' request in the district court litigation.

[5] Yeda objected to the Wolinsky Transcript at Dr. Green's deposition as improper IPR evidence and as outside the scope of Dr. Green's direct examination. (Ex. 1142, 396:3-10, 397:1-10, 398:3-4, 398:10, 399:5-8, 398:22-23).

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