Filed: April 22, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and
AMNEAL PHARMACEUTICALS LLC

Petitioners,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.

Patent Owner.

Case No. IPR2015-00643 (8,232,250 B2)
Case No. IPR2015-00644 (8,399,413 B2)
Case No. IPR2015-00830 (8,969,302 B2)[1,2]

PETITIONERS' RESPONSE TO PATENT OWNER'S OBSERVATIONS ON REPLY

[1] Case Nos. IPR2015-01976, IPR2015-01980 and IPR2015-01981 have been joined with these proceedings.

[2] A word-for-word identical Response is being filed in each proceeding.

TABLE OF ABBREVIATIONS

CNS ..... Central Nervous System

FDA ..... Food and Drug Administration

GA ..... Glatiramer Acetate

ISR ..... Injection Site Reaction

MBP ..... Myelin Basic Protein

MOA ..... Mechanism of Action

OOCE ..... Observation on Cross Examination

PK ..... Pharmacodynamics

POSA ..... Person of Ordinary Skill in the Art

SBOA ..... Summary Basis of Approval (Ex. 1007)

SEC ..... Securities and Exchange Commission

TIW ..... Three Injections Per Week

Yeda ..... Patent Owner Yeda Research & Development Co. Ltd.

Petitioners hereby file their response to Patent Owner's Observations on Cross Examination ("OOCE"). IPR2105-00643, Paper 71.

Response 1-6, 23-24, 26, 31-32, 35: Yeda's OOCEs misstate the record. These OOCEs are not the "testimony" of Dr. Hay or Dr. Green as asserted by Yeda. Rather, Yeda has repackaged its attorney's reading of selected passages of documents into the record as the experts' "testimony." The question and answer underlying OOCE 35 is illustrative of Yeda's approach:

> **Q.** Okay. And then the second paragraph under that section states, "Copaxone revenues in the United States in 2015 increased four percent to $3.2 billion." Do you see that?
>
> **A.** Yes.
>
> **Q.** And then I want to direct your attention about -- to the last paragraph on the page, which states: "Copaxone accounted for 20 percent of our revenues in 2015 and is significantly higher percentage contribution to our profits and cash flow from operations during such period." Do you see that?
>
> **A.** Yeah. And that's exactly the kind of misleading statement that I would never be able to rely on to look at the profits or the returns on investment associated with Copaxone.

Ex. 1141 at 98:6-25. Yeda states that Dr. Hay testified that "Copaxone revenues in the United States in 2015 increased four percent to $3.2 billion" and "Copaxone accounted for 20 percent of our revenues in 2015 and is [a] significantly higher percentage contribution to our profits and cash flow from operations during such

period." Yeda repeated this approach throughout both depositions.[3] In view of Yeda's improper use of these observations, OOCEs 1-6, 23-24, 26, 31-32, 35 should be struck.

Response 1: Yeda concludes that "testimony" attributed to Dr. Green "contradicts" Dr. Green's assertion that a POSA would not rely on Yeda's MOA theory that an increase in Th2 cells counteracted inflammation in the CNS to account for GA's therapeutic effect. But the cited testimony omits Dr. Green's testimony that "I think that should be qualified." Ex. 1142 at 224:2-3. In fact, even the question posed to Dr. Green demonstrates his express qualification:

> *And with the caveat that you stated earlier*, that we still don't know today exactly all of the details of the mechanism of action of GA in 2009, this increase in Th2 cells theory was one of the leading theories of how glatiramer acetate worked in patients; right?

Id. at 223:20-25 (emphasis added). Yeda also failed to cite to Dr. Green's qualification immediately following the quoted passage: "So I don't think people thought in 2009, or around that time, that this was exclusively the mechanism of

[3] After a series of such questions, Dr. Green pointed out in his deposition (Ex. 1142 at 285:21-286:1):

> I'm not sure if the exercise here is for you to read parts of papers and ask me if you've read them correctly. I thought it was to ask me questions about how these influenced my opinion and ask questions about my opinion. So I think it's important to provide that context.

action." *Id*. at 224:6-8. Further, Dr. Green testified that Yeda's proposed MOA theory was "not the only and perhaps even not the major mechanism of action by which the drug worked." *Id*. at 226:9-11. Moreover, the testimony cited by Yeda in no way "contradicts" Dr. Green's opinion that a POSA would rely on demonstrated clinical evidence over a hypothetical MOA theory. Dr. Green testified that a POSA would first look to the clinical literature, "which was overwhelming." *Id*. at 273:21-24 (testifying that POSA would not have "necessarily even gone to Hickey in the first place . . . . They would have gone to the existing clinical data, which was overwhelming"); *see also id*. at 295:7-10 ("So that's why the POSA relies on clinical information and doesn't rely on tenuous arguments about animal experiments that I certainly did not bring into the proceedings."). Dr. Green's testimony is entirely consistent with the opinions set forth in his reply evidence (Ex. 1085 ¶¶ 43-45, 49-71).

Response 2-4: Yeda's conclusion that the quoted "testimony" is "relevant" for the "same reasons identified above in ¶ 1" is incorrect and not supported by the cited testimony. For example, the quoted testimony in OOCE 2 is of Yeda's attorney reading into the record a sentence from an article. Ex. 1142 at 225:8-15. Dr. Green was then asked, "Do you see that?" and "Did I read that correctly, other than with that one correction?" Dr. Green answered, "Yes." *Id.* at 225:16-23. This is not "testimony" that can be attributed to Dr. Green. Yeda also omits Dr. Green's

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