

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
WOCKHARDT BIO AG, TEVA PHARMACEUTICALS USA, INC.,
AUROBINDO PHARMA U.S.A. INC., and SUN PHARMACEUTICAL
INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE and
AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

IPR2015-01340
Patent RE44,186¹

**PETITIONERS' RESPONSE TO MOTION FOR OBSERVATIONS
REGARDING THE CROSS-EXAMINATION OF DEFOREST MCDUFF**

¹ Petitioner Wockhardt from IPR2016-01209, Petitioner Teva from IPR2016-01122, Petitioner Aurobindo from IPR2016-01117, and Petitioner Sun/Amneal from IPR2016-01104 have each been joined as Petitioner to this proceeding.

Petitioners file this Response to Patent Owner’s Motion for Observations on Cross-examination of DeForest McDuff (Paper 61) in accordance with Due Date 5 (Papers 17, 35, 57).

Observation #1:

Patent Owner complains that Dr. McDuff did not review the entirety of the district court record, but Patent Owner did not produce the entirety of the district court record in this IPR proceeding. On October 13, 2016, Patent Owner and Petitioner entered a stipulation agreeing that “Petitioner Mylan will rely on the transcript of Dr. Christine Meyer’s September 21, 2016 cross-examination testimony from District Court Case ...and the documents referenced therein” in lieu of deposing Dr. Meyer in the IPR regarding her declarations. Paper 35, ¶4. The parties also stipulated regarding the scope of district court materials for submission: “The entirety of the District Court Meyer cross-examination...and any documents referenced therein...” Paper 35, ¶5. Contrary to Patent Owner’s suggestion in Observation #1, Patent Owner did not produce in this IPR “the entirety of the record generated in the parallel district court proceeding involving the RE’ 186 patent on the issue of commercial success.” In EX2220 at 9:5-7, 14-19, Dr. McDuff testified that he reviewed all pertinent information in reaching his conclusions to the extent the information was available. Specifically, Dr. McDuff testified that he reviewed the Meyer declaration (EX2059A) and the underlying

sources cited in the Meyer declaration and that he was provided with “all or nearly all of the exhibits” put forth by the patent holder. EX2220 at 11:8-12:10. Dr. McDuff also testified that he “reviewed a wide range of academic literature relating to pharmaceuticals” and information “generally about the subject matter of the case.” EX2220 at 12:11-22. Dr. McDuff testified that he “gathered information to the extent [he] thought it was relevant” and that “if [he] asked for information from counsel and they had access to that information, [he] was provided that as well.” EX2220 at 15:1-12. Dr. McDuff also testified at 16:4-7 that he did not restrict his review to material favorable to Petitioners. Dr. McDuff testified that he was not aware of Patent Owner producing Dr. Meyer’s expert report from the district court proceeding (EX2220 at 17:4-7, 19:9-16), and no such report appears on Patent Owner’s Exhibit List (Paper 64). Dr. McDuff also testified that he understood that Dr. Meyer’s IPR declaration provides the totality of “her opinions here” in the IPR proceeding. EX2220 at 17:19-18:2, 19:9-16, 20:4-14. Dr. McDuff testified that he reviewed the Hofmann expert report that was deemed produced in this IPR by Patent Owner pursuant to the parties’ stipulation (Paper 35) “to obtain information that was not available elsewhere.” EX2220 at 19:17-22. Dr. McDuff also testified that he reviewed Patent Owner’s cross-examination of Mr. Hofmann’s testimony from the trial in the district court litigation (EX2220 at 18:20-23) and Dr. Meyer’s trial demonstratives (EX2220 at

20:15-20), thereby ensuring that he was aware of any deficiencies in Mr.

Hofmann's testimony that Patent Owner had purported to identify. Dr. McDuff testified that he would have liked to review information that AstraZeneca failed to provide in this case, such as information about "discounts and information on early prescriptions and sales in the market." EX2220 at 14:13-25. Dr. McDuff testified that he was "surprised to see in Dr. Meyer's declaration given that she makes a claim on pricing that she did not provide information on discounts for Onglyza or Kombiglyze, nor did she provide information for other DPP-4 competitors, nor did AstraZeneca provide any business documents to my knowledge that provide such price comparison." EX2220 at 139:7-14.

Observation #2:

As explained above in Petitioners' response to Observation #1, Patent Owner complains that Dr. McDuff did not review the entirety of the district court record, but Patent Owner did not produce the entirety of the district court record in this IPR proceeding. The parties stipulated regarding the scope of district court materials for submission and to the use of Dr. Meyer's cross-examination in lieu of a separate deposition in the IPR. Paper 35, ¶¶45. Moreover, Dr. McDuff testified at length regarding the information he reviewed in reaching his conclusions, including the totality of Dr. Meyer's opinions in this case and the supporting materials thereto. EX2220 at 9:5-7, 9:14-19, 11:8-12:10, 12:11-22, 15:1-12,16:4-

7. Dr. McDuff testified that he was not aware of Patent Owner producing Dr. Meyer's expert report from the district court proceeding (EX2220 at 17:4-7, 19:9-16), and no such report appears on Patent Owner's Exhibit List (Paper 64). Dr. McDuff also testified that he understood that Dr. Meyer's IPR declaration provides the totality of "her opinions here" in the IPR proceeding. EX2220 at 17:19-18:2, 19:9-16, 20:4-14. Dr. McDuff testified that he reviewed the Hofmann expert report that was deemed produced in this IPR by Patent Owner pursuant to the parties' stipulation (Paper 35) "to obtain information that was not available elsewhere." EX2220 at 19:17-22. Dr. McDuff also testified that he reviewed Patent Owner's cross-examination of Mr. Hofmann's testimony from the trial in the district court litigation (EX2220 at 18:20-23) and Dr. Meyer's trial demonstratives (EX2220 at 20:15-20), thereby ensuring that he was aware of any deficiencies in Mr. Hofmann's testimony that Patent Owner had purported to identify.

Observation #3:

In EX2220 at 53:3-54:7, Dr. McDuff testified, that "[t]here are situations where I do have a finding or opinion of commercial success," and that "I have had that finding in my work," but simply that in none of these cases has he served as the testifying expert where the case proceeded to a point where he testified regarding that opinion. In EX2220 at 159:23:160:11, Dr. McDuff testified that

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