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.,
SUN PHARMACEUTICAL INDUSTRIES, LTD.,
SUN PHARMA GLOBAL FZE and
AMNEAL PHARMACEUTICALS LLC
Petitioners,

v.

ASTRAZENECA AB,
Patent Owner.

Case: IPR2015-01340[1]
U.S. Patent No. RE44,186

PATENT OWNER'S MOTION FOR OBSERVATIONS REGARDING THE CROSS-EXAMINATION OF DEFOREST MCDUFF

[1] Petitioner Wockhardt from IPR2016-01029, Petitioner Teva from IPR2016-01122, Petitioner Aurobindo from IPR2016-01117, and Petitioners Sun/Amneal from IPR2016-01104 have been added as Petitioners to this proceeding.

Patent Owner AstraZeneca AB submits this Motion for Observations Regarding Cross-Examination of DeForest McDuff pursuant to the Scheduling Order (Paper No. 17) and the Joint Notice of Stipulation (Paper No. 57).

Observation #1 - In Ex. 2220 at 15:14-16:3, Dr. McDuff testified that he did not review the entirety of the record generated in the parallel district court proceeding involving the RE'186 patent on the issue of commercial success. This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060, 1060A; Reply at 24-27), specifically, to the weight and understanding to be given to his statements and conclusions because it raises concerns that he has not considered all relevant information on the issue of commercial success.

Observation #2 - In Ex. 2220 at 16:8-20:20, Dr. McDuff testified that he reviewed Dr. Meyer's cross-examination but not her direct examination; he also testified that he reviewed Dr. Hofmann's expert report but not Dr. Meyer's expert report. This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060, 1060A; Reply at 24-27), specifically, to the weight and understanding to be given to his statements and conclusions because it raises concerns that he selectively considered information on the issue of commercial success.

Observation #3 - In Ex. 2220 at 53:3-54:7, Dr. McDuff testified that he has never testified that a branded pharmaceutical product is commercially successful. This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060, 1060A; Reply at 24-27), specifically, to the weight and understanding to be given to his statements and conclusions because it raises concerns regarding his impartiality and credibility.

Observation #4 - In Ex. 2220 at 161:1-2 and 161:18-162:3, Dr. McDuff testified that he obtained his Ph.D. in 2009 and has never authored any publications of the issue of commercial success or presented on the issue of commercial success in any of his speaking engagements. This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060, 1060A; Reply at 24-27), specifically, to the weight and understanding to be given to his statements and conclusions because it raises concerns regarding his credibility and the level of his expertise on the issue of commercial success.

Observation #5 - In Ex. 2220 at 52:4-13 and 69:4-14, Dr. McDuff testified that he understood that the patent owner has the burden of proof on commercial success. This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060,

1060A; Reply at 24-27), specifically, to the weight and understanding to be given to his statements and conclusions because it raises concerns that he applied the wrong burdens of proof in his opinions.

Observation #6 - In Ex. 2220 at 47:24-50:25, Dr. McDuff testified that he understood that commercial success must be attributed to the novel parts of the invention and not to factors unrelated or already known. In Ex. 2220 at 117:24-118:5, Dr. McDuff also testified that saxagliptin's status as the first-invented, FDA-approved DPP-4 inhibitor was not a primary consideration. This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060, 1060A ¶¶ 29-34; Reply at 26), specifically, because it raises concerns that his assertions that Onglyza and Kombiglyze are not particularly differentiated or unique products does not take into account saxagliptin's status as the first-invented, FDA-approved DPP-4 inhibitor.

Observation #7 - In Ex. 2220 at 21:6-13, 22:17-25:25, 28:6-31:15, and 35:16-36:5, Dr. McDuff testified that he did not dispute any of the calculations in Tables 2(a), 3, 4, 5, 6(a), 6(b), 7, and 8 of Dr. Meyer's declaration (Ex. 2059, 2059A). This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060,

1060A; Reply at 24-27), specifically, because it establishes that he does not dispute any of the data on which Dr. Meyer bases her opinions.

Observation #8 - In Ex. 2220 at 62:2-66:14, Dr. McDuff testified that it did not make sense to him to characterize $2.5 billion in net revenue as substantial without drawing any comparisons. In Ex. 2220 at 69:15:70:14, Dr. McDuff also testified that he did not seek to provide a "complete guidance or set of opinions on what one could compare saxagliptin revenues to." This testimony is relevant to statements and conclusions in Dr. McDuff's declaration and Petitioners' Reply brief regarding commercial success (Exs. 1060, 1060A; Reply at 24-27), specifically, because it raises concerns that he has not offered an opinion on what is the relevant market in his opinions on commercial success.

Observation #9 - In Ex. 2220 at 42:15-17, Dr. McDuff testified that he was not providing opinions in rebuttal to Dr. Lenhard's declaration. This testimony is relevant to statements and conclusions in Dr. McDuff's declaration regarding Dr. Lenhard's opinion that vildagliptin is a failure because it was not approved by the FDA and is approved in Europe with a twice-daily dosing regimen and significant safety precautions due to liver toxicity (Exs. 1060, 1060A ¶ 18), specifically, to the weight and understanding to be given to his statements and conclusions because it establishes that his opinions on the issue of commercial success do not address Dr. Lenhard's opinions on the issue of failures of others.

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