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 ROBERT J. TANENBERG

[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 Patent Owner's Motion for Observations Regarding Cross-Examination of Petitioners' Reply Witness, Robert J. Tanenberg, pursuant to the Scheduling Order (Paper No. 17) and the Joint Notice of Stipulation (Paper No. 57).

Observation #1 - In Ex. 2222 at 22:13-23:16, Dr. Tanenberg testified that he did not focus on claims 25 and 26 of the RE'186 patent for the purpose of his analysis of secondary considerations, despite also testifying that he understood claims 25 and 26 to saxagliptin include the chemical and biological properties that are associated with the compound saxagliptin. This testimony is relevant to statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding failure of others, long-felt need, and unexpected results (Ex. 1041 at ¶34, 43, 51-53; Reply at 18-24), specifically, to whether Dr. Tanenberg failed to consider the full scope of properties associated with the chemical compound saxagliptin for the purpose of his analysis of secondary considerations, and raises concerns that his opinions are non-responsive to Dr. Lenhard. Ex. 2057 at ¶16 (Dr. Lenhard stating that: "[m]y consideration of the objective evidence of non-obviousness is in connection with the chemical compound saxagliptin.").

Observation #2 - In Ex. 2222 at 25:1-16, Dr. Tanenberg testified that he did not dispute that a nexus exists between the evidence of secondary considerations and claims 25 and 26 of the RE'186 patent. This testimony is relevant to

statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding failure of others, long-felt need, and unexpected results (Ex. 1041 at ¶¶30, 43, 53; Reply at 18-24), specifically, to whether Dr. Lenhard's opinion that the properties and advantages of saxagliptin are directly tied to the active pharmaceutical ingredient saxagliptin is undisputed. Ex. 2057 at ¶ 54.

Observation #3 - In Ex. 2222 at 27:22-28:6, Dr. Tanenberg testified that the majority of drugs that go into clinical testing will not succeed in becoming an FDA-approved drug, and that many fail for safety or efficacy reasons. This testimony is relevant to statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding unpredictability, failure of others, long-felt need, and unexpected results (Ex. 1041 at ¶¶31-33, 36-41, 52, 55; Reply at 18-24), specifically, to the weight given to Petitioner's argument that a gliptin investigator may forgo FDA approval for non-clinical reasons and to Patent Owner's argument that achieving a DPP-4 inhibitor compound with the necessary drug-like properties for FDA-approval was unpredictable.

Observation #4 - In Ex. 2222 at 35:16-21, Dr. Tanenberg testified that he did not look at the invention dates of any of the class of FDA-approved DPP-4 inhibitors, rather he only looked at the dates those drugs were approved by the FDA. This testimony is relevant to statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding long-felt need (Ex. 1041 at ¶¶32-

37; Reply at 22-24), specifically, to whether Dr. Tanenberg failed to apply the legal standard of evaluating long-felt need as of the patent's filing date and not when the patented product first entered the market.

Observation #5 - In Ex. 2222 at 35:22-24, Dr. Tanenberg testified that he did not consider evidence of failure of others after the 2001 timeframe. This testimony is relevant to statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding failure of others (Ex. 1041 at ¶¶38-50; Reply at 18-20), specifically, to whether Dr. Tanenberg failed to consider Dr. Lenhard's evidence that many other companies attempted to develop a safe and effective DPP-4 inhibitor and failed to do so even after the invention of saxagliptin. Ex. 2057 at ¶66 and Table 4.

Observation #6 - In Ex. 2222 at 37:2-5, Dr. Tanenberg testified that vildagliptin is not approved by the FDA for the treatment of type 2 diabetes. This testimony is relevant to statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding failure of others (Ex. 1041 at ¶¶39-41; Reply at 18-20), specifically, to whether vildagliptin is a failure.

Observation #7 - In Ex. 2222 at 38:16-39:20, Dr. Tanenberg testified that the approved dosing for vildagliptin in Europe is twice daily when used as a monotherapy or with metformin and is administered once daily only when used in combination with a sulfonylurea. This testimony is relevant to statements and

conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding unexpected results (Ex. 1041 at ¶53; Reply at 22), specifically, to whether saxagliptin's property of once-daily dosing is unexpected as compared to vildagliptin.

Observation #8 - In Ex. 2222 at 40:22-41:12, Dr. Tanenberg testified that each of the available oral treatments for type 2 diabetes in the prior art had "shortcomings" and that each patient with type 2 diabetes will eventually need two or more oral agents and/or insulin to maintain good control. This testimony is relevant to statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding long-felt need (Ex. 1041 at ¶¶18-21, 31-37; Reply at 22-24), specifically, to whether there was a long-felt need in the prior art for a new alternative treatment option for treating type 2 diabetes.

Observation #9 - In Ex. 2222 at 44:1-5, Dr. Tanenberg testified that for the purpose of his analysis of unexpected results, he only compared the properties of saxagliptin to the later-invented FDA-approved DPP-4 inhibitors: sitagliptin, linagliptin, and alogliptin. This testimony is relevant to statements and conclusions in Dr. Tanenberg's declaration and Petitioner's Reply brief regarding unexpected results (Ex. 1041 at ¶¶28-30, 51-55; Reply at 20-22), specifically, to whether Dr. Tanenberg failed to apply the legal standard of comparing the unexpected

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