Paper No. ___
Filed: April 16, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC, ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN PHARMACEUTICAL INDUSTIRES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,
Petitioners,

v.

NOVARTIS A.G.,
Patent Owner.

IPR2017-00854[1]
Patent No. 9,187,405

PETITIONERS' MOTION FOR OBSERVATIONS REGARDING THE CROSS-EXAMINATION OF DR. FRED LUBLIN

[1] Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

Petitioners hereby submit observations on the deposition testimony of Novartis's declarant Dr. Fred Lublin given on April 6, 2018 (EX1062).

1. In EX1062 at 31:12-33:12, 35:12-36:8, Dr. Lublin testified that Novartis paid him to make presentations at the company as far back as 2010 or 2011, that they paid him to make presentations at conferences sponsored by Novartis, and that he has "a long history" of consultation and presentations related to Novartis. This is relevant to establishing that Dr. Lublin's testimony is influenced by his long-term association with Novartis. EX2097 (4th Lublin Decl), ¶¶1, 20; Paper 63 (PO Sur-Reply), 9-11; *see also, e.g.*, EX2003 (1st Lublin Decl), ¶¶17-18; EX2025 (2nd Lublin Decl), ¶¶2, 10; Paper 27 (POR), 6-7.

2. In EX1062 at 106:24-107:15, 108:20-109:3, Dr. Lublin testified that the percentage of his income coming from consulting for pharmaceutical companies has increased over time and that he receives a larger proportion of his income from consulting for pharmaceutical companies than the time he spends working for them. This is relevant to establishing that Dr. Lublin's testimony is influenced by his financial ties to Novartis and the pharmaceutical industry. EX2097, ¶¶1, 20; Paper 63, 9-11; *see also, e.g.*, EX2003, ¶¶17-18; EX2025, ¶¶2, 10; Paper 27 (POR), 6-7.

3. In EX1062 at 44:22-46:5, Dr. Lublin testified that Novartis agreed to include the 0.5 mg dose of fingolimod in its Phase III trials because there was

some chance of efficacy based on studies showing the dose could suppress lymphocyte levels in circulating blood to some degree. This is relevant to Dr. Lublin's assertion that a person of ordinary skill in the art would have ignored the 0.5 mg dose of fingolimod unless it had been shown to achieve at least 70% lymphopenia. EX2097, ¶¶2, 6, 12-17; Paper 63, 5-7, 9-11; *see also, e.g.*, Paper 27, 1-3, 11-12; EX2025, ¶62; EX2003, ¶¶33, 39; EX1042 (12/15/2017 Lublin Depo), 171:21-175:6, 209:2-215:25; EX2024 (2nd Jusko Decl), ¶¶70-75; EX2096, ¶26; Paper 56 (Pet. Reply), 11-12; EX1047 (Benet Decl), ¶¶38-48.

4. In EX1062 at 46:6-16, 49:10-55:19, Dr. Lublin testified that he was unaware of any other hospital other than Mt. Sinai that declined to participate in any of the Phase III clinical trials of fingolimod because of the 0.5 mg dose, that 138 centers in 22 countries cooperated in enrolling 1,272 patients in the FREEDOMS I trial that included 0.5 mg fingolimod, that 172 centers in 18 countries agreed to enroll 1,292 patients in the TRANSFORMS trial in which 0.5 mg fingolimod was administered, and that 117 centers agreed to enroll 1,083 patients in the FREEDOMS II trial in which 0.5 mg fingolimod was administered. This is relevant to Dr. Lublin's testimony that there was industry skepticism of the 0.5 mg dose of fingolimod. EX2097, ¶¶3, 14-16; Paper 63, 9-12; *see also, e.g.*, Paper 27, 2-3, 25-27, 40-41; EX2025, ¶¶50-57; Paper 56, 20-23; EX1047, ¶84.

5. In EX1062 at 58:8-61:13, 63:19-65:11, Dr. Lublin testified that, in the

second-to-last sentence of paragraph 8 of his declaration (EX2097), he was providing his opinion of what he believed the expectation of a person of skill in the art would have been for the results of the Phase III trials of fingolimod before the results came out, that he was not suggesting that were the trial repeated today the drug would fail, that the trials provided evidence that established that the dose was efficacious, that it would be his expectation that testing the same dose in an equivalent group of patients today would still find a result of efficacy, that fingolimod's mechanism of action did not change because of the publication of the Phase III results, and that fingolimod's mechanism of action is just the way the drug works and is just something intrinsic in the drug for the people that you're giving it to. This is relevant to Novartis's argument in its sur-reply that efficacy in treating RRMS is not inherent to the 0.5 mg dose of fingolimod. EX2097, ¶¶2, 8; Paper 63, 4-5, 9-11; *see also, e.g.*, EX1042, 43:21-46:5, 94:9-15; EX2024, ¶¶46-47; EX2003, ¶36; Paper 56, 17-20; EX1047, ¶¶28-29.

6. In EX1062 at 65:12-67:20, Dr. Lublin testified that prior art publications, including Budde (EX1008), Kahan 2003 (EX1031) and Park (EX1019) showed that 0.5 mg daily of fingolimod would suppress lymphocytes to some extent and that this was enough to justify testing the dose. This is relevant to Dr. Lublin's assertion that a person of ordinary skill in the art would ignore the 0.5 mg dose of fingolimod unless it had been shown to achieve at least 70%

lymphopenia. EX2097, ¶¶2, 6, 12-17; Paper 63, 5-7, 9-11; *see also*, *e.g.*, Paper 27, 1-3, 11-12; EX2025, ¶62; EX2003, ¶¶33, 39; EX1042, 171:21-175:6, 209:2-215:25; EX2024, ¶¶70-75; EX2096, ¶26; Paper 56, 11-12; EX1047, ¶¶38-48.

7. In EX1062 at 67:21-73:3, Dr. Lublin testified that Budde (EX1008) provides baseline lymphocyte counts for the placebo and each of the six fingolimod doses ranging from 2,284 to 3,002 cells per microliter, that Budde teaches that 2,590 cells per microliter was the average baseline count for all treatment groups and was "very near" the normal average lymphocyte count of 2,500 cells per microliter, that the normal average lymphocyte count "depends on the laboratory" because "different laboratories have different normal values" because of the way they do the assessments, and that Budde (EX1008) excluded patients from the study if they had lymphocyte counts below 1,500, and that Budde (EX1008) reports nadir average lymphocyte counts for the placebo and each of the fingolimod treatment groups. This is relevant to Dr. Lublin's assertion that a person of ordinary skill in the art would ignore the 0.5 mg dose of fingolimod unless it had been shown to achieve at least 70% lymphopenia. It is relevant because Budde reported that 0.5 mg suppressed lymphocyte levels in circulating blood to some degree and below normal levels. EX2097, ¶¶2, 6, 12-17; Paper 63, 5-7, 9-11; *see also*, *e.g.*, Paper 27, 1-3, 11-12; EX2025, ¶62; EX2003, ¶¶33, 39; EX2024, ¶¶70-

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