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. JEROLD CHUN

[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. Jerold Chun given on April 9, 2018 (EX1063).

1. In EX1063 at 61:10-63:17, 67:18-25, 70:13-22, 134:18-137:12, 138:17-139:8, 141:5-145:6, 146:2-18, Dr. Chun testified that he has consulted for Novartis since 2003, that his 16-year relationship with Novartis is his longest, that Novartis paid him to participate in post-marketing and commercial activities for fingolimod, and that three of his post-docs were funded by a Novartis fellowship. This is relevant to Dr. Chun's credibility because it shows he has a deep and long-standing financial relationship with Novartis and its fingolimod product. EX2098 (Chun Decl), ¶¶1, 10-16; Paper 63 (PO Sur-Reply), 2, 6-7.

2. In EX1063 at 77:23-84:22, 87:10-88:7, 90:5-91:10, 92:3-93:6, 94:4-16, 150:14-151:16, 153:12-16, Dr. Chun testified that he believed Drs. Webb and Rao were the primary drafters and lead authors of the Webb paper, that he did not have firsthand knowledge about who did most of the writing, that he did not know which co-author wrote which portion of the Webb paper, that he did not remember which co-authors did which experiments, that co-author Hale was not part of his team. This is relevant to Dr. Chun's assertion that his declaration speaks for the "collective judgment" of all nine authors of the Webb paper. EX2098, ¶¶7-8; Paper 63, 6-7; *see also* EX2096 (3rd Steinman Decl), ¶40.

3. In EX1063 at 148:19-24, Dr. Chun testified that Webb was the first

reference he co-authored that discussed an EAE experiment, and that his EAE experience "was limited" when he began at Merck in 2001. *Id.*, 150:7-13, 13:8-10. This is relevant to Dr. Chun's assertions that his testimony regarding Webb should be relied upon over Dr. Benet's. EX2098, ¶¶7-8, 17, 36-44; Paper 63, 2, 6-7.

4. In EX1063 at 96:8-19, 97:5-22, 159:21-160:13, Dr. Chun testified that the key and primary conclusion of the Webb paper was a "proof of concept" for using fingolimod therapeutically to treat a model of MS in Swiss Jim Lambert (SJL) mice with EAE. He testified that the abstract sets forth the key conclusions, basic conclusions, and overall conclusions of the Webb paper, and the abstract makes no mention of any 70% lymphopenia threshold for efficacy. *Id.*, 153:22-155:23. This is relevant to Dr. Chun's assertions that an about 70% lymphopenia threshold for efficacy was a "basic" or "overall" conclusion of the Webb paper. EX2098, ¶34; Paper 63, 5-7; *see also*, Paper 27 (POR), 16-19; EX2003 (1st Lublin Decl), ¶33; EX2024 (2nd Jusko Decl), ¶¶70-75; EX2096, ¶26; Paper 56 (Pet. Reply), 11-12; EX2039 (Giesser Depo), 74:1-86:8; EX1047 (Benet Decl), ¶¶38-48.

5. Dr. Chun agreed that Webb Figure 5A demonstrates rapid improvement in clinical score during administration of each of the tested doses of FTY720. EX1063, 160:23-161:9. When asked whether he agreed the lower clinical scores demonstrates an alleviation of the relapse and a deeper depression in clinical score than what was observed in the control group, Dr. Chun agreed that there appeared

to be "reductions in the clinical score" in the fingolimod doses. *Id.*, 162:7-25. This is relevant to Novartis's assertion that the 0.03 mg/kg dose lacked any efficacy and that Dr. Giesser's recognition of an efficacy trend in Figure 5 indicated she lacked expertise. EX2098, ¶¶28-29; Paper 63, 1, 5-8; *see also* EX2039, 70:18-86:8; Paper 27, 16-17; EX2022 (1st Steinman Decl), ¶¶130-36; EX2024, ¶¶76-77.

6. In EX1063 at 155:24-156:14, 159:8-20, Dr. Chun testified that one of Webb's key conclusions is that when phosphorylated fingolimod interacts with the S1P receptors on lymphocytes and thereby causes lymphocyte sequestration, that this is not the only mechanism by which fingolimod is providing therapeutic treatment against EAE. This is relevant to Novartis's arguments that proof of persistently achieving at least 70% lymphopenia without variation was required to see any efficacy against RRMS. EX2098, ¶¶5-8, 36, 43-44; Paper 63, 5-7; *see also* Paper 27, 34-38; EX2096, ¶¶48-52; Paper 56, 11-12; EX1047, ¶¶38-65.

7. In EX1063 at 101:14-20, 103:13-107:18, 125:17-25, Dr. Chun testified that he does not have the data underlying the Webb paper, does not have access to it, has not had access to it since he left Merck, has not reviewed it for ~16-years, has never asked Merck for access to it, left any Webb-related materials describing the data at Merck when he left Merck, did not review any summaries or descriptions of it in preparing his declaration, and left Merck sometime around June 2003. This is relevant to Dr. Chun's reliance on the underlying data in contravention of 37 C.F.R.

§ 42.65. EX2098, ¶¶1-8, 16-17, 21-44; Paper 63, 2, 6-7.

8. In EX1063 at 126:2-127:8, 181:7-13, Dr. Chun testified that he did not personally submit Webb for publication, did not know who did, and did not know when any of the co-authors gave final approval for publication. *Id.*, 181:14-182:15. Dr. Chun testified that he did not know how many peer reviewers provided comments on the Webb paper and did not know what revisions were made before publication. *Id.*, 271:23-272:13. This is relevant to Dr. Chun's assertion the "about" 70% sentence reflected the collective judgment of all nine authors of Webb. EX2098, ¶¶1-8, 16-17, 21-44; Paper 63, 5-7.

9. In EX1063 at 182:16-183:15, Dr. Chun testified that, prior to the submission of the Webb manuscript for publication, he never discussed with any of co-authors Hale, Tham, Lin, Lariosa-Willingham, Yu, or Mandala any correlation between lymphopenia and cumulative clinical score. This is relevant to Dr. Chun's assertion the "about" 70% sentence reflected the collective judgment of all nine authors of Webb. EX2098, ¶¶1-8, 16-17, 21-44; Paper 63, 5-7.

10. In EX1063 at 169:14-172:25, 173:14-175:8, 176:19-178:12, 179:23-181:6, Dr. Chun testified that Webb Figure 6C correlated nadir lymphopenia at day 25 to cumulative clinical score at day 25 and could not identify any graph or table in Webb correlating lymphopenia to clinical efficacy not at the lymphopenia nadir. This is relevant to Novartis's and Dr. Chun's arguments that correlation of

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