UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
and PFIZER INC.,
Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01676[1]
Patent No. 8,603,044

PETITIONERS' OBSERVATIONS REGARDING THE TESTIMONY OF ALEXANDER SLOCUM, Ph.D.

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[1] To maintain uniformity and to simplify the Board's review of Petitioners' observations across nine related IPRs, all nine papers present the same set of observations.

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1. Dr. Slocum testified that he had no personal experience designing injector pens as of March 2003 (EX1115, 518:17-23), which is relevant to Petitioners' position that his testimony should be excluded or at least given little to no weight. Paper 64 ("Motion to Exclude"), 5-8. It is also relevant to Petitioners' position that a person of ordinary skill in the art ("POSA") would have been motivated to modify the injector-pen references, because it shows that Dr. Slocum, who disputes that motivation, lacks familiarity with the relevant aspects of injector-pen design. Paper 2 ("Petition"), 40-42, 76-79; Paper 46 ("Reply"), 11-18.

2. Dr. Slocum testified that he had no evidence to support his assertion that Steenfeldt-Jensen's express suggestion to provide a threaded driver tube was added by lawyers rather than the inventors. EX1115, 526:6-12. This is relevant to Petitioners' position that a POSA would have been motivated to modify Steenfeldt-Jensen as proposed within the reference itself, and would have had no reason to ignore the reference's express suggestion, because it shows that Dr. Slocum's justification that this suggestion was merely a "lawyer add-on" is not supported by any evidence. Petition, 40-42; Reply, 9-10.

3. Dr. Slocum testified that Steenfeldt-Jensen expressly proposes an embodiment where the driver tube has an internal thread instead of a slot, and wall 4 has a slot instead of a thread, and that a POSA would have been able to accomplish this modification. EX1115, 526:6-12. This is relevant to Petitioners'

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position that a POSA would have been motivated to modify the reference as proposed with a reasonable expectation of success. Petition, 40-42; Reply, 2-8.

4. Dr. Slocum testified that Steenfeldt-Jensen's first and fifth embodiments have very similar drive mechanisms and force chains for injection. EX1115, 531:12-22. This is relevant to Petitioners' position that Steenfeldt-Jensen's suggestion of alternative embodiments (with a threaded driver tube and a wall with flats) equally applies to the fifth embodiment, because it shows that the aspects of the drive mechanism implicated by the proposed modification are the same in the first and fifth embodiments. Petition, 40-42; Reply, 2-8.

5. Dr. Slocum testified that Steenfeldt-Jensen includes a claim describing a threaded driver tube that rotates relative to a threaded piston rod to drive the piston rod distally during injection. EX1115, 534:16-542:21. This is relevant to Petitioners' position that Steenfeldt-Jensen does suggest a threaded driver tube satisfying the recited drive sleeve. Petition, 40-42; Reply, 2-3.

6. Dr. Slocum testified that Robert Veasey, an inventor of the challenged patent, provided key bases for Dr. Slocum's opinions. EX1115, 546:18-552:23. This is relevant to Petitioners' position that Dr. Slocum's testimony should be excluded or at least given little to no weight. Reply, 11-14; Motion to Exclude, 5-8. It is relevant because it shows that Dr. Slocum lacked the relevant knowledge of the field and instead relied on an interested party to provide numerous, critical

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bases for his opinions.

7. Dr. Slocum testified that, despite knowing that lubricious plastics could have coefficients of friction of 0.08 or lower, he followed Mr. Veasey's instructions to use 0.1 because of Dr. Slocum's own lack of experience with pen injectors. EX1115, 552:24-555:12. This is relevant to Petitioners' position that Dr. Slocum is not qualified as an expert in this proceeding and that the underlying bases for his testimony were not his own. Motion to Exclude, 5-8. It is also relevant to Petitioners' position that Dr. Slocum's assessment of Steenfeldt-Jensen is unreliable, because it shows that a key variable for the injection-force calculation was controlled by an inventor of the challenged patent. Reply, 11-14.

8. Dr. Slocum testified that, in his spreadsheet purporting to calculate injection force in Steenfeldt-Jensen's fifth embodiment, using a lower coefficient of friction or a smaller collar diameter would lower the injection force. EX1115, 555:13-557:19, 559:24-561:14. This is relevant to Petitioners' position that Dr. Slocum's assessment of Steenfeldt-Jensen is flawed, because it shows why the flawed assumptions of the model provided by Mr. Veasey skew the results. Reply, 15-16.

9. Dr. Slocum testified that he disagreed that 0.05 was a reasonable coefficient of friction for his calculations. EX1114, 463:13-16. Yet he also testified that in an earlier book, he wrote that sliding contact bearings (the type of interface addressed in his "collar friction" testimony) have coefficients of friction between **0.05** and

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0.1 (EX1115, 557:22-559:19) and that he would have used 0.05 if Mr. Veasey had suggested it (*Id.*, 555:5-12). This is relevant to Petitioners' position that Dr. Slocum's Steenfeldt-Jensen analysis is unreliable and flawed, because it shows that he chose the *highest* coefficient of friction from his previously published range, and because it shows that his present-day view regarding coefficients of friction contradicts his previously published views. Reply, 15-16. It is also relevant to Petitioners' position that Dr. Slocum did not provide critical bases for his testimony, because it shows that he adopted Mr. Veasey's suggestions over his own previously published views. Reply, 11-14; Motion to Exclude, 5-8.

10. Dr. Slocum testified that his assertion of a 51% increase in injection force was based on calculations that only factored in points of added friction without considering points of reduced friction elsewhere in the mechanism. EX1115, 561:19-563:6. This is relevant to Petitioners' position that Dr. Slocum's assessment is flawed, because it shows that his calculation skewed the result by omitting any points of reduced friction. Reply, 14.

11. Dr. Slocum testified that the specification has only one embodiment (EX1115, 576:21-577:16), that this embodiment does not have an internally threaded piston rod (*Id.*, 586:2-7), that none of the purported examples of internally threaded piston rods he identified were injector pens (*Id.*, 586:8-587:1), and that he did not search injector-pen art to see whether internally-threaded piston rods were

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