

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 No. IPR2018-01675¹
U.S. Patent No. 8,603,044

PATENT OWNER'S RESPONSES TO PETITIONERS' OBSERVATIONS

¹ Pfizer Inc., who filed a petition in IPR2019-00977, has been joined as petitioner in this proceeding.

1. The testimony cited by Petitioner does not concern Dr. Slocum’s pen injector experience in 2003. Regardless, whether Dr. Slocum had pen injector experience in 2003 is irrelevant. *Rowe Price Investment Servs., Inc. v. Secure Access, LLC*, Case CBM2015-00027, slip op. at 21–22 (PTAB June 13, 2016) (Paper 31). Dr. Slocum was knowledgeable about pen injectors as of 2019, when he submitted his declaration. EX2107, ¶¶ 25-61. Furthermore, both Dr. Slocum and Mr. Leinsing agree that a person having ordinary skill in the art (“POSA”) does not require pen injector experience; and, in the corresponding district court litigation where both experts applied the same definitions for the level of ordinary skill as in this IPR, the district court accepted Dr. Slocum as qualified expert. EX1011 ¶106, EX2107 ¶102.

2. Petitioners mischaracterize Dr. Slocum’s testimony. Dr. Slocum did not testify that Steinfeldt-Jensen includes an express suggestion to provide a threaded driver tube. Furthermore, Petitioners cite only a portion of Dr. Slocum’s testimony explaining Steinfeldt-Jensen at column 7, lines 44-47. Dr. Slocum also testified that a POSA would understand that having a nut element rotated by a driver tube would not be a good idea. *See* EX1115, 526:13-25. This testimony is relevant to whether a POSA would have been motivated to modify Steinfeldt-Jensen in view of itself.

3. Petitioners’ description of the cited testimony is incorrect. The cited testimony does not address what Steinfeldt-Jensen proposes or whether a POSA would have been able to accomplish a modification. Regardless, Dr. Slocum did not testify 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.

4. Petitioners cite only a portion of Dr. Slocum’s testimony comparing the first and fifth embodiments. Dr. Slocum also testified that the drive mechanisms and force chains for the *dose dialing* operation are very different, in part because friction is desirable in the drive mechanism of the first embodiment but not in the fifth embodiment. *See* EX1115, 475:5-476:20. This testimony is relevant to whether Steinfeldt-Jensen at column 7, lines 44-47, applies to the fifth embodiment, because it shows that the first and fifth embodiments significantly differ.

5. Petitioners mischaracterize the cited testimony. Dr. Slocum testified that claim 6 of Steinfeldt-Jensen describes a threaded driving *member*—not a threaded driver *tube*. Moreover, the cited testimony is not relevant, because neither the Petition nor the Reply point to or otherwise rely on Steinfeldt-Jensen’s claim 6 for any obviousness grounds. Furthermore, Dr. Slocum also testified that claim 6 does not disclose a pen injector having a dose dial sleeve with a threaded engagement to a housing, a sleeve releasably connected to a dose dial sleeve, or a clutch. *See* EX1115, 597:6-598:14. This testimony is relevant to whether the pen injector disclosed by Steinfeldt-Jensen’s claim 6 renders the challenged claims obvious, because each of the challenged claims requires at least (i) a dose indicator/dose dial sleeve with a threaded engagement to a housing and (ii) a releasably connected sleeve/clutch.

6. Petitioners mischaracterize the cited testimony. The cited testimony only reflects that Dr. Slocum obtained the dimensions of the FlexPen and the coefficient of friction from Mr. Veasey to use in his spreadsheet. *See further* EX1114, 462:4-463:12. The record does not show that Mr. Veasey’s measurements are unreliable. Petitioners further mischaracterize the relevance of this testimony. Dr. Slocum does not lack relevant knowledge of the field. Dr. Slocum researched the prior art patents, conversed with those in the industry, and he canvassed the literature on pre-critical date pen injectors, design considerations, and design standards to put himself in the shoes of a POSA working on pen injectors in early 2003. *See, e.g.*, EX2107 ¶¶ 25-61. Only then did he personally design a computational model that informed his opinions. Mr. Leinsing also created a computational model, but he deleted it and did not submit it in the district court proceeding or this proceeding. EX2227, 341:17-22.

7. Petitioners again mischaracterize the cited testimony. Dr. Slocum testified that Mr. Veasey measured a coefficient of friction of 0.15 in the commercially available product but recommended using 0.1 for “super lubricious” plastics in a pen injector. Furthermore, Petitioners cite only a portion of Dr. Slocum’s testimony discussing the measurements obtained from Mr. Veasey. Dr. Slocum also testified that 0.1 is very good for plastics. *See* EX1114, 463:1-12.

8. Petitioners mischaracterize the relevance of the cited testimony. The numbers Dr. Slocum used in his spreadsheet are not flawed, and there is no evidence in the record

showing that the numbers are flawed. Instead, these numbers came from undisputed measurements of a publicly-available product. *See* EX1114, 462:4-463:12.

9. The testimony cited by Petitioners is taken out of context. Dr. Slocum was asked about a single sentence in a document specifying a coefficient of friction range of 0.05 to 0.1 for certain sliding contact bearings. Dr. Slocum was not asked whether the bearings discussed in the single sentence were suitable for pen injectors. Nor was he asked about the portion of the document explaining that coefficients of friction between 0.05 and 0.1 are for *active* lubrication environments (*e.g.*, those requiring motorized lubrication pumps). Nor was Dr. Slocum asked about a portion of the document describing a typical coefficient of friction for sliding contact plastic bearings as being 0.2. Regardless, Dr. Slocum testified that, in his personal experience, 0.1 is a “very good” coefficient of friction for a plastic. EX1114, 463:5-12. Indeed, this is a better coefficient of friction than what was seen in the commercialized Steinfeld-Jensen product – compare 0.1 with 0.15 in the commercialized product. Furthermore, Dr. Slocum also testified that using a lower coefficient of friction (*e.g.*, .08) does not resolve the problems with the proposed modification. *See* EX1114, 463:9-21.

10. In the cited testimony, Dr. Slocum explains that taking into account the points of reduced friction would only change the 51% calculation by a few percentage points. *See* EX1115, 562:20-25.

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