

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.  
and PFIZER INC.,  
Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,  
Patent Owner.

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Case IPR2018-01676  
Patent No. 8,603,044

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**PETITIONERS' RESPONSE TO PATENT OWNER'S OBSERVATIONS  
ON TESTIMONY OF MR. KARL LEINSING**

During his December 3, 2019, testimony, Mr. Leinsing explained numerous flaws in arguments presented by Patent Owner Sanofi-Aventis Deutschland GmbH (“PO”). PO’s Observations (Paper 68; “Obs.”) omit key portions of that testimony and other relevant context in an attempt to resuscitate those arguments.

Observation no. 1 – PO inaccurately characterizes Mr. Leinsing’s statements on injection force by omitting portions of his testimony. PO quotes Mr. Leinsing as stating “I wouldn’t say there’s a lot of focus on [reducing injection force]” and that “it is a factor, but it’s not an important factor.” Obs., 1 (citing EX2227, 336:25-337:14). However, Mr. Leinsing noted that injection force was “one of many considerations” and that “as we saw” (referencing evidence from PO’s own pen designers) “it doesn't rank as high as some others, but it's definitely a consideration.” EX2227, 336:25-337:5. Pressed again, he explained:

I wouldn't say there's a lot of focus *on that one thing* or that it's important *because it didn't rank, even by Sanofi or the developers of the -- you know, of the device, that it was even ranked a three versus a five. So it's not a very important factor*. It is a factor, but it's not an important factor.

*Id.*, 337:6-14 (emphasis added). His complete testimony thus makes clear that he was making the unassailable point, backed up by documents from PO’s own pen designers, that injection force was just one of many factors considered by pen designers, including PO’s own engineers.

PO also incorrectly characterizes Mr. Leinsing's testimony as contradictory by again ignoring context. Obs., 1. In his allegedly contradictory IPR testimony, Mr. Leinsing responded to questions specifically addressing the importance of acceptable injection force for insulin pens, not the relative importance of injection force compared to other factors. EX2163, 80:10-81. The importance of avoiding excessive injection force is entirely consistent with his subsequent testimony that injection force was one of many design considerations. Regardless, neither the claims nor the applied references are limited to insulin injectors or a particular injection force, and obviousness does not require proof that a modification optimizes a single, cherry-picked design factor. PO's first observation is thus inaccurate and, in the context of a proper obviousness inquiry, irrelevant.

Observation no. 2 – PO's focus on the original FlexPen's injection force is a red herring. The FlexPen product is not a reference in any ground in this IPR, and design flaws in the FlexPen's button have nothing to do with the ability of a person of ordinary skill in the art ("POSA") to apply ordinary creativity—including common-sense solutions like lubricant or adjusting collar size—to reduce friction on a driver tube's collar. PO thus continues to focus exclusively on injection force, ignoring other design considerations, the reference's express motivation, and its own expert's admissions regarding expectations of success. *See* EX1115, 526:6-12.

Additionally, PO incorrectly characterizes Mr. Leinsing's testimony as

contradictory. PO accuses Mr. Leinsing of contradicting himself by noting that a POSA could use ordinary creativity to mitigate any added collar friction on the driver tube. Obs., 2-3. However, in testimony omitted by PO, Mr. Leinsing explained that FlexPen's "huge" redesign involved the *button*, not the driver:

Q: ...So they did, in fact, go through a huge design process, right?

A. Yes. As I said, ***on the button. It wasn't on the whole device, it was just on the button.***

EX2227, 339:11-14 (emphasis added). Mr. Leinsing's testimony is thus entirely consistent with his IPR testimony, since the scope of Novo Nordisk's efforts to redesign the *FlexPen's button* has nothing to do with a POSA's ability to address collar friction in the context of *Steenfeldt-Jensen's driver tube*.

Observation no. 3 – PO attacks Mr. Leinsing's credibility by again omitting portions of his testimony. PO quotes the first portion of Mr. Leinsing's testimony stating that he first encountered the original FlexPen in 2002. Obs., 3 (citing EX2227, 328:25-329:9). PO then selectively quotes from his IPR testimony to create the incorrect impression that Mr. Leinsing only became aware of the original FlexPen about two years ago. Obs., 3 (citing EX2227, 329:6-330:18). To achieve this, PO removes the portion of Mr. Leinsing's testimony where he clarified that the pen he was referencing from two years ago was the *Next Generation FlexPen*, not the original:

That was my testimony, understanding what the difference was

between we were talking about original and Next Generation. So when you are asking me that question, I didn't understand what you were talking about original. And I didn't even know when I was looking at that pen back then whether that one was original or not with the name. So that's what I was talking about.

EX2227, 330:6-12.

Indeed, Mr. Leinsing had already clarified this misunderstanding during his IPR testimony. *See* EX2163, 120:13-121:25. Following the portion of his IPR testimony read in district court and quoted in Observation No. 3, Mr. Leinsing immediately clarified that, in his project from two years ago, he was “just looking at the new pen”. *Id.*, 120:20-121:9. He then further clarified that he was already aware of a previous Novo Nordisk pen as of 2003:

Q. [I]n 2003, at that time, what pen injectors were you aware of?

A. I was mostly just aware of what Eli Lilly had. ***I believe Novo Nordisk.*** There might have been some other ones. That's all I can remember since 2003. It was a long time ago.

*Id.*, 121:17-25 (emphasis added). These clarifications make it clear that Mr.

Leinsing’s description of his work with old and new FlexPens has been consistent.

Observation no. 4 – Contrary to PO’s suggestion, the Court did not confirm that Mr. Leinsing was successfully impeached by the attacks now presented by PO in observations nos. 1-3. The Court was addressing a dispute regarding whether PO’s prior attempt to hire Mr. Leinsing as an expert witness was relevant to PO’s

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