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
Patent No. 8,603,044

PETITIONERS' REPLY IN SUPPORT OF PETITIONERS' MOTION TO EXCLUDE
37 CFR §42.64(c)

The petitioners (Mylan) seeks exclusion of patent owner (Sanofi) exhibits 2001-2014, 2017-2026, 2100-2102, 2104-2107, 2111-2153, 2158-2201, 2203-2212, 2214-2218, and 2225, and of the redirect testimony in Mylan exhibit 1054. Page number references are to Sanofi's opposition unless otherwise indicated.

I. ARGUMENT

A. EX2001-EX2011, EX2019-EX2026

At 1, Sanofi states these exhibits "are not cited in connection with any disputed issues raised in the post-institution briefing[so] the Board will have no further reason to refer to them." Sanofi thus concedes the papers have no relevance to any issue at trial. The institution issues to which Sanofi says the exhibits relate are not appealable so the exhibits are no longer relevant for any legitimate purpose. 35 U.S.C. 314(d). The papers should be excluded under FRE402-403 as irrelevant and likely to cause confusion. If not, their admissibility should be limited to the purpose for which they were submitted. FRE105.

B. EX2012, EX2017, EX2018, EX2117, EX2147-EX2152, EX2162, EX2167, EX2168, EX2206, EX2207, EX2211, EX2215-EX2218 – animations

At 2, 3-4, and 12-13, Sanofi does not contest that these exhibits are hearsay, but says that its expert relied on the exhibits. While an expert may rely on hearsay in forming an opinion (FRE703), that fact does not make the evidence admissible

in trial. In any case, if these exhibits are not excluded they should be limited to the purpose for which they were submitted (showing basis for expert testimony) and should not be used for any other purpose. FRE105.

C. EX1054 (redirect), EX2107 – Slocum testimony

At 4 and 6-13, Sanofi contends that Dr. Slocum's lack of experience and flawed methodology are inconsequential. Sanofi misstates Mylan's challenge and fails to rebut the key problems with the testimony. Mylan's *Daubert* challenge does not pose the subjective question of whether Dr. Slocum *could* be an expert on the involved technology;[1] instead, Mylan shows that Dr. Slocum objectively failed to act as an expert in this case regardless of whatever potential he might possess. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993) (requiring "that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand").

Sanofi also tries to turn its opposition into an unauthorized briefing opportunity to attack Mylan's expert, Karl Leinsing, an undisputed expert with

[1] Hence, whether another tribunal found Dr. Slocum qualified is irrelevant without showing that Dr. Slocum gave the same testimony with the same bases.

personal experience in the field at all relevant times. This improper briefing violates the rules requiring objections and motions to exclude, prejudices Mylan by impinging on Mylan's limited reply briefing opportunity, and is simply wrong. Sanofi's improper attacks on Mr. Leinsing should be disregarded entirely.

Sanofi argues (at 6-7) argues that Dr. Slocum need not have been an expert in the involved technology at the relevant time. Sanofi misses the point. Absence of relevant experience should be considered in weighing credibility.[2] FRE702 (listing experience as a relevant consideration). A purported expert who lacks such experience (or knowledge, skill, training, or education directly related to the involved technology) must demonstrate that "the testimony is based on sufficient facts or data; ... is the product of reliable principles and methods; and [has been] reliably applied the principles and methods to the facts of the case." *Id*.

Sanofi says Dr. Slocum considered the prior art, other literature on design considerations, and discussions with Dr. Goland (an endocrinologist) and Mr.

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[2] A ceramics appraiser need not be a Ming Dynasty potter to appraise a Ming vase, but cannot simply uncritically accept the seller's word on the vase's value and provenance.

Veasey (an unproduced inventor). Dr. Slocum himself, however, explained that he lacked any knowledge and so started with Mr. Veasey, whose data he accepted without question because he had no relevant knowledge or experience as recently as three weeks ago (EX1115, 553:20-555:12), yet Sanofi hid Mr. Veasey from cross examination on the basis he provided. Models theoretical or physical that ultimately depend on undisclosed inputs from a self-interested inventor are intrinsically unreliable. Cf. *United States v. Esquivel-Rios*, 725 F.3d 1231, 1234 & n.1 (10th Cir. 2013) (Gorsuch, J., explaining the limitations of a law-enforcement database) ("Garbage in, garbage out. Everyone knows that much about computers: you give them bad data, they give you bad results.").

Sanofi argues in a footnote that Mylan could have cross examined Mr. Veasey on an irrelevant authentication declaration or sought additional discovery (a transparent burden shift), but fails to explain why it should be absolved of its obligation to show the bases of its expert's testimony. Cross examining the expert is not sufficient if the expert does not know and can only revert to an absent inventor.

Dr. Slocum also relied on post-critical date publications regarding the importance of injection force, and on an off-record discussion with Dr. Goland

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