UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., and SUN PHARMACEUTICALS INDUSTRIES LTD.,
Petitioners,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

IPR2020-00040[1]
Patent 7,326,708

PATENT OWNER'S REPLY IN SUPPORT OF MOTION TO EXCLUDE

[1] Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. were joined as parties to this proceeding via a Motion for Joinder in IPR2020-01060; and Sun Pharmaceuticals Industries Ltd. was joined as a party to this proceeding via Motion for Joinder in IPR2020-01072.

Mylan's Opposition (Paper 83, "Opp.") proceeds from the startling premise that if an exhibit is in evidence for one purpose, the exhibit is in evidence for all purposes. That is not how the rules of evidence work. "If the court admits evidence that is admissible against a party or for a purpose—but not against another party or for another purpose—the court . . . must restrict the evidence to its proper scope." Fed. R. Evid. 105. Just such a "restrict[ion]" is required here. Mylan undisputedly relies on Dr. Chyall's declaration, EX2225, for its truth and for Dr. Chyall's conclusions as an expert witness. It even begins its Reply with his opinion, which it claims EX2225 "establishes": that "there is only one possible molecular ratio, a 1:1 ratio . . . of . . . sitagliptin [DHP]." Reply 1. *Mylan's use* of the disputed exhibits must comply with *Daubert* and Fed. R. Evid. 702—and does not. Similarly, *Mylan's use* of EX2225 and EX1030 (including indirectly through Dr. Chorghade in EX1035) must comport with the hearsay rule—and does not.

Fed. R. Evid. 702. To begin with, the Board should limit the evidence, as Merck's motion (Paper 91, "Mot.") requests, based on Rule 702 alone. Mylan *never even attempts* to defend Dr. Chyall's statements—including his assertion about what stoichiometries are "possible" (*e.g.*, Reply 1)—as admissible expert opinions on the relevant question for inherency: whether 1:1 sitagliptin DHP is the only salt that can form upon combining sitagliptin and phosphoric acid. Sur-Reply 5–9; *see* Mot. 9. Mylan also does not dispute that Dr. Chyall never considered, let

alone opined about, WO498. Because Dr. Chyall's statements neither address the relevant legal standard, nor even Mylan's new Reply theory that the POSA would seek to replicate WO498's Example 7 (modified to use phosphoric acid), they are not admissible expert opinions under Rule 702 and must be disregarded. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994); Mot. 8.

Dr. Chorghade's hindsight-driven assertion that Dr. Chyall's experiments anticipate because they are a "reproduction" of WO498, Opp. 14, even though *they differ from anything in it,* also is unreliable and must be excluded. According to Dr. Chorghade, the POSA would modify the starting material from BOC-protected sitagliptin, the acid from hydrochloric to phosphoric, and myriad other parameters (*see* Mot. 8; Opp. 14), but *not* the solvent—no, never the solvent—and thus would arrive at Dr. Chyall's experimental methods, which he undisputedly selected for a different purpose. Because that opinion has no basis other than Dr. Chorghade's say-so and is completely disconnected from the law of inherent anticipation, it fails to meet the bar of Rule 702. Mot. 7–9. It must also be disregarded.

Mylan's Use of Hearsay. Separately, Mylan defends its blatant reliance on hearsay using a "goose/gander" argument that Merck cited EX2225 already. The elephant in the room is that *Mylan does not dispute* that Merck did not rely on EX2225 for its truth, but cited it because Dr. Chyall's work motivated Dr. Matzger's experiments. Mot. 4. Given that, it simply is not a response to say

Merck cited it first, given the hornbook principle that evidence may be admissible "only for a particular purpose" and "not generally against all parties or for all purposes." 1A Fed. Jury Prac. & Instr. § 11:09 (6th ed.); *Tennessee v. Street*, 471 U.S. 409, 413–15 (1985). That Merck cited and filed the exhibit is thus irrelevant, as are Mylan's cases (Opp. 1–2) where two parties each cited the same transcript for its truth. The Board can and should limit consideration of Dr. Chyall's declaration to non-hearsay purposes. *See Mylan Pharms. Inc. v. Sanofi -Aventis Deutschland GmbH*, IPR2018-01676, Paper 84, at 46 (P.T.A.B. May 29, 2020). What is sauce for the goose may not be sauce for the elephant.

Timeliness. The distinction between different uses of EX2225 also answers Mylan's assertion that Merck's objection is untimely. Opp. 4–5. Merck could not have foreseen Mylan's improper uses of EX2225, and it timely objected to them. Paper 68. It is no answer for Mylan to argue that Merck knew what was in the document. Mylan used Dr. Chyall's statements as though they were testimony after it *affirmatively represented* that it would not use Dr. Chyall as an expert witness in the case. Mot. 5–6. Mylan's Opposition completely ignores this point, even though it is reason alone to exclude Mylan's reliance on his work. *Id.* Merck can hardly be faulted for failing to predict that Mylan would go back on its word.

Fed. R. Evid. 801(d)(2)(B). Contrary to Mylan's suggestion, it is not true that a document becomes an "adoptive admission" under Rule 801(d)(2)(B) simply

because a party cites it. Merck's limited use of Dr. Chyall's declaration and notebook do not come close to an adoption of their entire contents. Mylan's authorities do not suggest otherwise. *Pfizer Inc. v. Teva Pharma. USA, Inc.* involved documents created by a party's own experts and submitted by that party as testimony in another forum. No. 04-cv-00754, 2006 WL 3041102, at *5 (D.N.J. Oct. 26, 2006). And *Avocent Redmond Corp. v. Rose Elecs.* involved schematics depicting a party's own devices that the party had produced. 2012 U.S. Dist. LEXIS 162177, *6–9 (W.D. Wash. Nov. 13, 2012). Neither is anything like Merck's non-hearsay citation of an *opposing* party's work.

Fed. R. Evid. 807. As to Rule 807, Mylan entirely ignores one prong of the rule, providing that it would only apply if the evidence were "more probative" than "any other evidence" Mylan could obtain with "reasonable effort." Fed. R. Evid. 807(a)(2). Mylan cannot possibly meet that standard. Rule 807 is unavailable where a party "could have retained its own expert." *N5 Tech. LLC v. Capital One N.A.*, 56 F. Supp. 3d 755, 765 (E.D. Va. Jan. 30, 2014). Mylan *did so*, but unlike Merck elected to rely on Dr. Chyall's experiments instead of performing its own. Mylan also unilaterally *resisted* offering expert testimony from Dr. Chyall, even though its co-Petitioner Teva retained him for this proceeding. Mot. 5–6.

Mylan's supposed "guarantees of trustworthiness," moreover, indicate at most that Dr. Chyall performed experiments and that some of his experimental

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