

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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.

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IPR2020-00040<sup>1</sup>  
Patent 7,326,708

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**PATENT OWNER'S MOTION TO EXCLUDE**

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<sup>1</sup> 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.

## I. INTRODUCTION

Petitioner Mylan Pharmaceuticals Inc.’s (“Mylan’s”) Reply argued (for the first time) that the anticipation inquiry should focus on “methanol-based experiments” rather than other potential ways of making phosphoric acid salts of sitagliptin. Reply 1–2, 5–10.<sup>2</sup> Mylan then argued that the methanol-based experiments in Dr. Chyall’s first declaration (Exhibit 2225) “[p]roduce[d] 1:1 [s]itagliptin DHP [e]very [t]ime,” which according to Mylan means that the claimed 1:1 sitagliptin DHP salt is inherently anticipated. *E.g.*, Reply 5. In its Sur-Reply, Patent Owner Merck Sharp & Dohme Corp. (“Merck”) explained why this argument is both incorrect and untimely. Sur-Reply 6–11.

In addition to the argument’s substantive deficiencies, the evidence on which Mylan relies to support it is inadmissible. Dr. Chyall is not a witness in this proceeding, and Exhibit 2225 is not direct testimony under 37 C.F.R. § 42.53. Yet Mylan relies on Dr. Chyall’s declaration for the truth of the matters asserted and as though he were an expert in this case. Exhibit 2225 is thus inadmissible hearsay under FRE 802.

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<sup>2</sup> As in prior briefs, Merck refers collectively to Petitioners, including the various remaining Joinder Petitioners, as “Mylan.”

Independently, Exhibit 2225 also is inadmissible as expert testimony because it is not reliable under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and FRE 702. The relevant question for inherent anticipation is whether non-1:1 sitagliptin phosphate salts exist. Sur-Reply 5. Dr. Chyall's salt screen, which tested various quantities of sitagliptin freebase and phosphoric acid in methanol (and only methanol) is not a scientifically valid way of answering—and did not even purport to answer—that question.

Two additional exhibits are inadmissible to the extent that they rely on Dr. Chyall's work in ways that violate the rules of evidence. Exhibit 1030, Dr. Chyall's lab notebook, is hearsay and has not been properly authenticated. And Exhibit 1035, the reply declaration of Mylan's expert Dr. Chorghade, is (1) inadmissible hearsay to the extent it recapitulates Dr. Chyall's statements, and (2) improper expert testimony under FRE 702 when it relies on Dr. Chyall's litigation testimony, as that is not the kind of material on which an expert in his field ordinarily would rely. Mylan cannot back-door Dr. Chyall's conclusions through these other exhibits.

Accordingly, and for the reasons below, Merck hereby moves to exclude Exhibit 2225 to the extent Mylan relies on it; to exclude Exhibit 1030 in its entirety; and to exclude Exhibit 1035 to the extent it addresses Exhibit 1030 or

Exhibit 2225. Merck timely filed objections to these exhibits on November 24, 2020, Paper 68.

## **II. EXHIBIT 2225 IS INADMISSIBLE FOR THE TRUTH OF THE MATTERS IT ASSERTS AND AS EXPERT TESTIMONY**

### **A. Mylan’s Use of Exhibit 2225 Is Hearsay**

Exhibit 2225 is a declaration prepared by Dr. Chyall for a proceeding in Israel. Merck, not Mylan, submitted it in this proceeding. But Merck did not cite it for the truth of Dr. Chyall’s testimony. Rather, Merck’s expert Dr. Adam Matzger performed his *own* experimental work; he made and characterized non-1:1 phosphate salts of sitagliptin, the existence of which rebuts Mylan’s inherent anticipation case. *See* POR 15–18; EX2103 ¶¶ 123–76. Dr. Matzger merely cited Exhibit 2225 because he considered it when designing his experiments—specifically, as a model of, and motivation for, Dr. Matzger’s experimental conditions. EX2103 ¶¶ 126, 131.

Mylan’s extensive use of Exhibit 2225, in contrast, is plainly as hearsay. *See, e.g.*, Reply 1, 4, 6–7, 10, 12. Dr. Chyall is not a witness in this proceeding. No party adduced his testimony as direct testimony under 37 C.F.R. § 42.53, and Merck had no opportunity to cross-examine him. Yet Mylan quotes Exhibit 2225 for what it supposedly “establishes,” “shows,” and “demonstrates,” and even the “conclusions reached in” it—in other words, for the truth of what it says—over and over. *Id.* Mylan relies on Dr. Chyall’s description of twelve experiments in

Exhibit 2225 that, he says, resulted in a 1:1 sitagliptin DHP salt. *See* Reply at 1, 4, 10, 12. Mylan also relies on Dr. Chyall’s conclusion that “there is only one possible molecular ratio, a 1:1 ratio.” Reply 1, 6. Each of these uses relies on the truth of Dr. Chyall’s statements. Exhibit 2225 is probative of Mylan’s arguments only if Dr. Chyall’s description of his experiments and observations are true or his conclusions are accepted as correct.

Mylan’s use of Dr. Chyall’s declaration is especially inappropriate because Mylan insisted that it would *not* rely on his testimony. Dr. Chyall originally was an expert witness in one of the joined proceedings; Joinder-Petitioner Teva Pharmaceuticals, Inc. filed a declaration from Dr. Chyall. That declaration parroted the conclusions of Mylan’s expert, Dr. Chorghade; it did not disclose the experiments or conclusions in Exhibit 2225. IPR2021-01045, Exhibit 1002. But even so, Merck raised the question of whether it would have the opportunity to depose him. In response, Mylan emphasized that Dr. Chyall was not Mylan’s expert. In the words of Mylan’s counsel, **“To the extent Merck wants to depose Dr. Chyall, enter into a stipulation regarding Dr. Chyall, or do anything else with connection with Dr. Chyall, I remind you that Mylan’s expert in IPR2020-00040 is Dr. Chorghade not Dr. Chyall.”** EX2285. After Dr. Chorghade’s deposition, Teva withdrew its reliance on Dr. Chyall’s testimony, and Mylan confirmed to the Board that “Mylan is not intending to rely on Dr. Len

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