UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2022-01105
Patent 9,925,231 B2

REQUEST FOR REHEARING
37 C.F.R. §42.71(d)(2)

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I. INTRODUCTION

Petitioner (Mylan) respectfully requests rehearing of the decision (Paper 15, Dec.) denying institution. The decision misapprehends both law and fact, imposing a limitless obligation on Mylan to prove a negative when *no* contrary contention is even alleged, much less shown, and where all evidence of record, including the evidence of Patent Owner (Bausch), shows Mylan is correct on the very point—peptide moisture sensitivity—the decision considered lacking. Where, as here, Mylan's showing is exactly the same as the Office's earlier uncontroverted holding on the same point, only powerful evidence of a previous error could justify an inconsistent Board decision. The decision provides no reason for the agency's shifting position, and Mylan had no warning of this shift.

The decision also arbitrarily imposes an unlawfully heightened burden on Mylan—far beyond of the likelihood standard required for institution—without providing Mylan an opportunity to reply. Mylan asked to brief Bausch's unreasonably high standard, yet the Board denied this request without a hearing. The Federal Circuit en banc rejected this heightened requirement, and the Supreme Court has similarly rejected any specific-motivation requirement. To the extent Bausch raised any colorable issue at all, it justifies a trial rather than dismissal. The Board should withdraw its decision in Paper 15 and institute review. This request is timely. 37 C.F.R. §42.71(d)(2).

II. INCORRECT OBVIOUSNESS ANALYSIS

A. Background

Mylan filed a petition (Paper 2, Pet.) supported in relevant part by an expert declaration from Dr. Graham Buckton (EX1002). The petition points to Dr. Buckton's testimony, a background survey article (EX1016, Lai), and an art handbook (EX1006, Remington) as support for the mundane, uncontroverted technical fact that peptides (like the claimed peptide) are moisture sensitive. Pet., 17, 25, 37, 47, 66-67; EX1002, ¶¶104, 140, 144; EX1016, 489 (Introduction: many protein and peptide drugs "are formulated as lyophilized or freeze-dried products to prolong their shelf life" because of their "susceptibility to chemical degradation in solution," but "residual moisture" can still impact their chemical stability). Indeed, Dr. Buckton noted that the Office, citing Lai generally, had already made the same finding regarding peptides, leaving no reason to believe the issue was seriously in question. EX1002, ¶62, citing EX1022 (prosecution history), 4136-48.

In response, Bausch miscited a nonprecedential decision as authority for a legally-erroneous heightened-obviousness standard. Paper 8 (POPR), 50 ("But Mylan has failed to identify any teaching or suggestion in the prior art that plecanatide is moisture sensitive."), citing *Novartis Pharm. Corp. v. Watson Labs., Inc.,* 611 F. App'x 988, 995-96 (Fed. Cir. 2015) . As will be explained below, controlling precedent establishes a general teaching is sufficient. Bausch conceded

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