UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

Case IPR2022-01104
Patent 9,919,024

PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE[1]

[1] This paper was authorized in the Trials email on November 9, 2022.

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Bausch's POPR (at 23-40) takes the prosecution history out of context and ignores material differences between the present challenge and the prosecution.

The petition identified material error resulting from faulty unexpected-results arguments and declarations. Pet., 65, 9-10. The examiner correctly found the unit doses result from routine optimization of prior-art ranges and maintained this finding. *E.g.*, EX1022 (a parent application), 4449, 5104; EX1021, 388-402, 726; EX1002, ¶¶57-63, 109-13, 195-98. The examiner also held formulating plecanatide tablets with a low-moisture carrier and a lubricant was *prima facie* obvious. *E.g.*, EX1022, 4449-51. The examiner only allowed the claims when Bausch amended its claims to exclude excipients other than a low-moisture carrier and lubricant, and argued that the ***storage stability*** was unexpectedly improved after 6, 9 and 12 months using low-moisture versus regular-grade carriers without additional stabilizing excipients. EX1022, 0369-86, 5079-94 ("dramatic" stability increase); 4973-77 (adding "consisting of"), 5098-5104 (allowance); EX1021, 698, 702-06, 720-27 (similar for later application); EX1002, ¶¶57-67, 72-79, 591-92.

Yet the petition and supporting testimony showed the alleged unexpected results failed to overcome the claims' *prima facie* obviousness. Pet., 60-65; EX1002, ¶¶593-602. For example, Bausch conflated multiple variables instead of evaluating the low-moisture carrier's effect in a tablet-to-tablet comparison. Pet., 60-61. Bausch also exaggerated differences between its formulations, alleging a

"dramatic" 30-34% degradation reduction after storage showed unexpected stability. Pet., 61-64 & cited exhibits. A more apt tablet-to-tablet comparison "shows essentially identical levels of change in degradants over time." *Id.* Moreover, less peptide degradation was the ***intended result*** for a low-moisture carrier. Pet., 64. Bausch's flawed data strongly indicate the claimed storage stability was the ***expected result*** when formulating plecanatide in this routine, conventional manner. Pet., 8-9, 28-29, 47-50.

The POPR rebuts none of the factual problems with the data and prosecution arguments; instead, it pivots to a new argument that the unexpected result was not storage stability, but the ***initial*** purity difference between capsules and tablets before storage. POPR, 2, 18-23. This conclusory attorney argument is unsupported and absurd. The claims recite a "storage" stability limitation, not starting purity. Moreover, prosecution focused on narrowing the claims to correspond better to Bausch's alleged unexpected results without additional stabilizing excipients. POPR, 21 ("6, 9, and 12 months"). As Dr. Buckton explained, maintaining the same ***differential*** over time indicates little or no storage advantage from using low-moisture carrier. EX1002, ¶¶593-601. Also, Bausch assumes without support that initial purity resulted from carrier-moisture difference (rather than, e.g., capsule moisture or starting plecanatide purity in the different dosage forms). Indeed, Bausch's pivot to a new, baseless "unexpected results" argument confirms trial

institution is appropriate, and refutes Bausch's assertion (POPR, 39) that unexpected results played no role in allowance.

Without contrary evidence rebutting expert testimony supporting the petition, Bausch instead asks the Board to ignore this testimony and also attacks Drs. Buckton and Christians individually. POPR, 39-40. But Bausch ignores the POSA is part of a team, Dr. Buckton's eminent qualifications as a formulator, and Dr. Christians' eminent qualifications as an M.D. with clinical-pharmacology experience specific to uroguanylin peptides and extensive experience designing and conducting clinical trials. Pet., 11-13; EX1004, ¶¶1-9, 37-40; EX1002, ¶¶1-10, 81-84. Dr. Christians testified he knows the level of skill based on his education, experience, and training. EX1004, ¶¶38; EX1002, ¶¶83-84 (Buckton). If relevant, Bausch can test these renowned experts' qualifications during the trial.

The petition also noted the examination failed to apply ***applicant admissions*** (e.g., in Shailubhai) that formulating plecanatide in a tablet and determining the amount to administer were routine matters well-within the ordinary skill. *See, e.g.*, Pet., 18, 32 (plecanatide tablets "may be made using methods well known in the art" and "selection of carrier" is "well within the level of skill in this art" (citing EX1005, 13:18-52)); EX1005, 15:10-17. These admissions prove plecanatide formulation was routine using standard formulation texts (e.g., Remington), which teach a direct-compression tablet consisting of the active ingredient, an inert

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