

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
MSN LABORATORIES PRIVATE LTD.,  
and MSN PHARMACEUTICALS INC.,  
Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,  
Patent Owner.

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Case IPR2022-00722<sup>1</sup>  
Patent 7,041,786

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**PETITIONERS' OBJECTIONS  
TO PATENT OWNER'S RESPONSE EVIDENCE**

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<sup>1</sup> IPR2023-00016 has been joined with this proceeding.

## **I. INTRODUCTION**

Petitioner (Mylan) objects to Patent Owner (Bausch) exhibits EX2023-EX2025, EX2027, EX2028, EX2031-EX2046, EX2048-EX2062, EX2064, and EX2065 for failure to comply with the Federal Rules of Evidence (FRE). 37 C.F.R. §42.62(a). These objections are filed under §42.64(b)(1).

## **II. OBJECTIONS**

### **A. EX2023 – Shailubhai Declaration**

EX2023 should be excluded as irrelevant because it is only passingly mentioned in EX2024 and EX2025, and otherwise uncited; moreover, likelihood of confusion and undue prejudice outweigh any probative value it might have as inventor testimony without independent corroboration. FRE 402; FRE 403.

EX2023 should be excluded as presenting opinion testimony from a fact witness without qualification or proper basis. FRE 701-FRE 703; FRE 705.

EX2023 should be excluded as hearsay without exception, including hearsay within hearsay. FRE 802.

EX2023 should be excluded for lacking authenticity and proper affirmation. FRE 603; FRE 901.

### **B. EX2024, EX2025 – Davies and Waldman Declarations**

EX2024, ¶¶44-46, 76, 83-85, 87-98, 109-113, 127-133, 135-146, 157, 158, 187-203, and 216-243, should be excluded because its likelihood to cause confusion and undue prejudice outweighs any possible probative value it might

have. FRE 402; FRE 403.

EX2025, ¶¶22-38, 49-53, 55, 59-62, 64-67, 68-82, 89-111, should be excluded because its likelihood to cause confusion and undue prejudice outweighs any possible probative value it might have. FRE 402; FRE 403.

EX2024 and EX2025 should be excluded as presenting opinion testimony, including on an ultimate issue, from witnesses without qualification or proper basis. FRE 701-FRE 705.

EX2024 and EX2025 should be excluded as hearsay without exception, including hearsay within hearsay. FRE 802.

EX2024 and EX2025 should be excluded for lacking authenticity and proper affirmation. FRE 603; FRE 901.

### **C. EX2027, EX2028 – Shailubhai Reports**

EX2027 and EX2028 are hearsay without exception, and lack independent authentication, and are likely to cause confusion and undue prejudice outweighing any possible probative value they might have. FRE 403; FRE 802; FRE 901.

### **D. EX2031-EX2046, EX2048-EX2062, EX2064, and EX2065**

EX2031-EX2046, EX2048-EX2062, EX2064, and EX2065 are each hearsay without exception and the likelihood of confusion and undue prejudice outweigh any possible probative value they might have. FRE 403; FRE 802.

Further, the relevance of EX2031, EX2034, EX2039, EX2042, EX2049,

EX2052, EX2054-EX2059, EX2061, and EX2064 is not apparent from Bausch's response. FRE 402.

EX2040, EX2044-EX2046, and EX2054 lack sufficient evidence of authenticity. FRE 901.

**E. Each Bausch exhibit should be restricted to the purpose for which Bausch offered the exhibit**

Each Bausch exhibit should be restricted to the purpose for which Bausch offered the exhibit. FRE 105. Should Bausch rely on an exhibit for a different purpose than the one for which it has been offered, Mylan reserves the right to make additional objections.

**III. CONCLUSION**

Bausch EX2023-EX2025, EX2027, EX2028, EX2031-EX2046, EX2048-EX2062, EX2064, and EX2065 should be excluded; if not excluded, they should be given no weight.

Respectfully submitted,

Dated: December 21, 2022

/Jad Mills/  
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Counsel for Mylan Pharmaceuticals Inc.

## CERTIFICATE OF SERVICE

I certify that today this paper was served by email on Bausch's counsel at:

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Dated: December 21, 2022

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