

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

Case IPR2022-00722¹
U.S. Patent No. 7,041,786

**PATENT OWNER'S OBJECTIONS TO
PETITIONER'S EVIDENCE**

¹ IPR2023-00016 has been joined with this proceeding.

I. INTRODUCTION

Patent Owner Bausch Health Ireland Limited objects to Petitioner Mylan Pharmaceuticals Inc.'s Exhibits for failure to comply with the Federal Rules of Evidence (FRE). 37 C.F.R. §§ 42.62(a), 42.64(b)(1).

II. OBJECTIONS

A. Mylan's Technical Exhibits (EX1065, EX1066, EX1070) are hearsay without exception and unauthenticated.

Mylan offers EX1065, EX1066, and EX1070 as non-testimony evidence to prove the truth of the matter Mylan asserts, without identifying any exception to support such use, in violation of FRE 802. Mylan's reliance on statements Patent Owner cannot cross examine is prejudicial. Additionally, Mylan makes no attempt to establish the authenticity of EX1065, EX1066, and EX1070, in violation of FRE 901.

B. Mylan's File History Excerpt of European Patent (EX1067) is incomplete, hearsay without exception, and not in accordance with 37 CFR § 42.65(b).

Mylan offers an incomplete and selective excerpt of file history of European Patent No. 1 379 224 (EX1067), and EX1067 should be excluded for that reason alone. *See* FRE 106. Mylan offers EX1067 as non-testimony evidence to prove the truth of the matter Mylan asserts, without identifying any exception to support such use, in violation of FRE 802. Mylan's reliance on statements Patent Owner cannot cross examine is prejudicial. Mylan relies on a technical test or data included in

EX1067 without providing an affidavit as required by 37 CFR § 42.65(b), and EX1067 should be excluded for that additional reason.

C. The Peterson Reply Declaration (EX1063) is hearsay without exception and not in accordance with 37 CFR § 42.65(a).

EX1063 ¶¶ 34, 149, 152-57, 160, 162-64, 166-67 should be excluded because it relies on EX1067, which does not sufficiently disclose underlying facts or data. 37 CFR § 42.65(a). Also, EX1063 ¶¶ 34, 149, 152-57, 160, 162-64, 166-67 should be excluded because its likelihood to cause confusion and undue prejudice outweighs any possible probative value it might have. FRE 402; FRE 403. EX1063 should be excluded as presenting opinion testimony, including on an ultimate issue, from witnesses without qualification or proper basis. FRE 701-FRE 705. EX1063 should be excluded as hearsay without exception, including hearsay within hearsay. FRE 802.

D. Mylan's Technical Exhibit (EX1066) and highlights of prescribing Information of Linzess[®] (EX1072) are not prior art.

Mylan offers a technical exhibit (EX1066) and highlights of prescribing Information (EX1072) for Linzess[®], which Mylan has not established are prior art. Thus, Patent Owner objects to Mylan's reliance on EX1066 and EX1072 for any prior art purpose.

E. Each Mylan’s exhibit must be restricted to the purpose for which Mylan offered the exhibit.

Each Mylan exhibit must be restricted to the purpose for which Mylan offered the exhibit. *See* FRE 105. Should Mylan rely on an exhibit for a different purpose than that for which it has been offered, Patent Owner reserves the right to make additional objections.

III. CONCLUSION

Patent Owner submits these objections as authorized by Board rules.

Respectfully submitted,

Date: March 31, 2023

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of this paper was served electronically via email on March 31, 2023, in their entirety on the following:

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