

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

COSMO TECHNOLOGIES LIMITED,
Patent Owner.

Case IPR2017-01035
U.S. Patent No. 9,320,716 B2

**PATENT OWNER'S OBJECTIONS TO EXHIBITS
PURSUANT TO 37 C.F.R. § 42.64**

Mail Stop: PATENT BOARD
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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), the undersigned, on behalf of Cosmo Technologies Limited (“Patent Owner”), hereby submits the following objections to certain Exhibits filed with Mylan Pharmaceuticals Inc.’s (“Petitioner”) petition for *inter partes* review of U.S. Patent No. 9,320,716 (the “Petition”). Pursuant to 37 C.F.R. § 42.62, Patent Owner’s objections below apply the Federal Rules of Evidence (“FRE”), among other things.

II. OBJECTIONS TO EVIDENCE

A. OBJECTIONS TO EXHIBIT 1015

Patent Owner hereby objects to Ex. 1015, which Petitioner alleges is the “Amendment and Response to Office Action filed on April 29, 2013 in U.S. Patent Appl. No. 13/617,138,” as not relevant under FRE 401 and therefore inadmissible under FRE 402. Indeed, Petitioner does not even cite to this Exhibit, either in its Petition or in the expert report submitted as Exhibit 1006, let alone explain how this exhibit relates to the Petition. If relevant, Patent Owner further objects to this exhibit under FRE 403 because whatever limited probative value it may possess (and Patent Owner maintains that it has no probative value in light of Petitioner’s filings) is substantially outweighed by a danger of unfair prejudice and confusing the issues.

B. OBJECTIONS TO EXHIBIT 1022

Patent Owner hereby objects to Ex. 1022, which Petitioner alleges is “PCT International Publication No. WO 96/36318,” as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it to be.

C. OBJECTIONS TO EXHIBIT 1024

Patent Owner hereby objects to Ex. 1024, which Petitioner alleges is “PCT International Publication No. WO 99/39700,” as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it to be.

D. OBJECTIONS TO EXHIBIT 1025

Patent Owner hereby objects to Ex. 1025, which Petitioner alleges is the “FDA Inactive Ingredient Guide 1996/1997,” as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it to be. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 because Petitioner offers it to prove the truth of the matter asserted. *See, e.g.*, Pet. at 23-24, 33, 56. Patent Owner further objects to this exhibit as not relevant under FRE 401 and therefore inadmissible under FRE 402. If relevant, Patent Owner objects to this exhibit under FRE 403 because its probative value is substantially outweighed by a danger of unfair prejudice and confusing the issues.

E. OBJECTIONS TO EXHIBIT 1026

Patent Owner hereby objects to Ex. 1026, which Petitioner alleges is the “Handbook of Pharmaceutical Excipients (Wade and Weller, eds., 2d ed. 1994),” as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it to be. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 because Petitioner offers it to prove the truth of the matter asserted. *See, e.g.*, Pet. at 11-12, 14, 23-24, 27, 33-36, 41, 50, 52, 56-58, 61.

F. OBJECTIONS TO EXHIBIT 1028

Patent Owner hereby objects to Ex. 1028, which Petitioner alleges is “Remington: The Science and Practice of Pharmacy, Vol. 1 (1995),” as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it to be. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 because Petitioner offers it to prove the truth of the matter asserted. *See, e.g.*, Pet. at 12, 23-24, 26-28, 32, 58.

G. OBJECTIONS TO EXHIBIT 1030

Patent Owner hereby objects to Ex. 1030, which Petitioner alleges is “Hawley’s Condensed Chemical Dictionary (John Wiley & Sons, Inc., 13th ed. 1997),” as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it

to be. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 because Petitioner offers it to prove the truth of the matter asserted. *See, e.g.,* Pet. at 31, 54-55.

H. OBJECTIONS TO EXHIBIT 1032

Patent Owner hereby objects to Ex. 1032, which Petitioner alleges is the “Entocort® RC Highlights of Prescribing Information,” as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it to be. Patent Owner further objects to this exhibit as inadmissible hearsay under FRE 802 because Petitioner offers it to prove the truth of the matter asserted. *See, e.g.,* Pet. at 64. Patent Owner further objects to this exhibit as not relevant under FRE 401 and therefore inadmissible under FRE 402. If relevant, Patent Owner objects to this exhibit under FRE 403 because its probative value is substantially outweighed by a danger of unfair prejudice and confusing the issues.

I. OBJECTIONS TO EXHIBIT 1033

Patent Owner hereby objects to Ex. 1033, which Petitioner alleges is a copy of Svensson et al., *Hydration of an Amphiphilic Excipient Gelucire 4.14*, as not properly authenticated under FRE 901. Petitioner has produced insufficient evidence to support a finding that this exhibit is what Petitioner claims it to be. Patent Owner

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