Paper No. ____
Filed: June 26, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ICOS CORPORATION,
Patent Owner.

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Case No. IPR2017-00323
Patent No. 6,943,166

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PETITIONER MYLAN PHARMACEUTICALS INC.'S OBJECTIONS TO EVIDENCE

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Mylan Pharmaceuticals Inc. ("Petitioner") submits the following objections to ICOS Corporation's ("Patent Owner") Exhibits 2001-2003 and 2005-2007, as listed on the List of Exhibits filed by Patent Owner with the Patent Owner's Preliminary Response ("Preliminary Response") on March 13, 2017, and any reference to or reliance on the foregoing Exhibits in the Preliminary Response or future filings by Patent Owner. As required by 37 C.F.R. § 42.62, Petitioner's objections below apply the Federal Rules of Evidence ("F.R.E.").

II. OBJECTIONS

i. Objections to Ex. 2001, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 602 (Foundation); F.R.E. 801, 802, 803, 805 (Inadmissible Hearsay); F.R.E. 901 (Authenticating Evidence).

Patent Owner describes Ex. 2001 as "Eli Lilly & Co., Heritage" printed from the website www.lilly.com. Ex. 2001 contains no print date. Neither the Patent Owner nor the exhibit provides adequate foundation for the document itself or its authenticity. F.R.E. 602, 901. Further, the document itself appears to be inadmissible hearsay. F.R.E. 801, 802, 803. To the extent that Patent Owner relies on any statements in this exhibit for the truth of the matter asserted, such

statements are inadmissible hearsay when relied upon by Patent Owner. F.R.E. 801, 802, 803, 805.

ii. Objections to Ex. 2002, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 602 (Foundation); F.R.E. 801, 802, 803, 805 (Inadmissible Hearsay); F.R.E. 901 (Authenticating Evidence).

Patent Owner describes Ex. 2002 as "Bloomberg: Company Overview of Mylan Pharmaceuticals, Inc.," printed from the website Bloomberg.com. Neither the Patent Owner nor the exhibit provides adequate foundation for the document itself or its authenticity. F.R.E. 602, 901. Further, the document itself appears to be inadmissible hearsay. F.R.E. 801, 802, 803. To the extent that Patent Owner relies on any statements in this exhibit for the truth of the matter asserted, such statements are inadmissible hearsay. F.R.E. 801, 802, 803, 805.

iii. Objections to Ex. 2003, and any Reference to/Reliance Thereon

Ground Grounds for Objection: F.R.E. 602 (Foundation); F.R.E. 801, 802, 803, 805 (Inadmissible Hearsay); F.R.E. 901 (Authenticating Evidence).

Patent Owner describes Ex. 2003 as a Mylan N.V. Annual Report (Form 10K) dated February 15, 2016, downloaded from "shareholder.com." Patent Owner has failed to establish any foundation for "shareholder.com" as an authentic source of Mylan N.V. SEC filings, and the document is hundreds of pages long, making a comparison with the authentic document to confirm its authenticity

unwieldly and burdensome. F.R.E. 602, 901. To the extent that Patent Owner relies on any unauthenticated statements in Ex. 2003 for the truth of the matter asserted, such statements are inadmissible hearsay. F.R.E. 801, 802, 803, 805.

iv. Objections to Ex. 2005, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 602 (Foundation); F.R.E. 801, 802, 803, 805 (Inadmissible Hearsay); F.R.E. 901 (Authenticating Evidence).

Patent Owner describes Ex. 2005 as "FDA's Review Process for New Drug Applications: A Management Review, Office of Inspector General, OEI-01-01-00590 (March 2003)." Neither the Patent Owner nor the exhibit provides adequate foundation for the document itself, its authenticity, or how it was obtained. F.R.E. 602, 901. Further, Exhibit 2005 appears to contain inadmissible hearsay. F.R.E. 801, 802, 803, 805.

v. Objections to Ex. 2006, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 602 (Foundation); F.R.E. 801, 802, 803, 805 (Inadmissible Hearsay); F.R.E. 901 (Authenticating Evidence).

Patent Owner describes Ex. 2006 as "Manual of Policies and Procedure, Center for Drug Evaluation and Research, Office of Communications, Communicating Drug Approval Information, MAPP 4520.1, Rev. 1 (Effective 8/20/14)." Neither the Patent Owner nor the exhibit provides adequate foundation for the document itself, its authenticity, or how it was obtained. F.R.E. 602, 901.

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