

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., APOTEX PHARMACEUTICALS
HOLDINGS INC., and APOTEX HOLDINGS, INC.,

Petitioners,

v.

OSI PHARMACEUTICALS, INC.,

Patent Owner.

U.S. Patent No. 6,900,221

Case No.: IPR2016-01284

**PETITIONERS' OBJECTIONS TO EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64**

Pursuant to 37 C.F.R. § 42.64, Petitioners Apotex Inc., Apotex Corp., Apotex Pharmaceuticals Holdings Inc., and Apotex Holdings, Inc. (collectively “Apotex” or “Petitioners”) submit the following objections to evidence served with the Response of Patent Owner OSI Pharmaceuticals, Inc. (“OSI” or “Patent Owner”).

I. Exhibit 2020

Apotex objects to Exhibit 2020, Patent Owner’s Deposition of Dr. Giuseppe Giaccone. Specifically, Apotex objects to the relevance and probative value of page and line 8:11-11:1, 14:4-22:4, 22:18-23:22, 24:5-31:5, 33:5-43:19, 49:9-50:3, 55:15-57:14, 59:4-63:10, 63:18-66:2, 66:13-66:18, 70:4-71:22, 74:1-74:20, 80:17-81:20, 84:12-88:13, 92:10-103:1, 106:10-108:3, 112:18-114:22, 118:18-118:20, 122:4-122:6, 123:11-147:12, and 151:14-164:1, in light of the potential for undue prejudice and confusion of the issues. *See* Fed. R. Evid. 401, 402, and 403.

Apotex objects to page and line 132:19-135:22, 137:3-138:18, 148:20-150:6, and 150:22-151:7, as not based on sufficient facts or data. *See* Fed. R. Evid. 702, 705; 77 Fed. Reg. at 48,763; 37 C.F.R. § 42.65.

II. Exhibit 2021

Apotex objects to Exhibit 2021, Declaration of Dr. Jackson Gibbs. Specifically, Apotex objects to the relevance and probative value of ¶13, in light of

the potential for undue prejudice and confusion of the issues. *See* Fed. R. Evid. 401, 402, and 403.

III. Exhibit 2022

Apotex objects to Exhibit 2022, Declaration of Dr. Paul Bunn. Specifically, Apotex objects to the relevance and probative value of ¶¶25-27, 34-41, 43, 49, 51-65, 70-90, 92-101, 105, and 107-109, in light of the potential for undue prejudice and confusion of the issues. *See* Fed. R. Evid. 401, 402, and 403.

Apotex objects to ¶¶27, 34-37, 39-41, 49, 52, 66-71, 73, 80, and 107, as not based on sufficient facts or data, the product of reliable principles and methods, and/or a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702, 703, 705; 77 Fed. Reg. at 48,763; 37 C.F.R. § 42.65.

IV. Exhibit 2023

Apotex objects to Exhibit 2023, Declaration of Mark L. Reisenauer. Specifically, Apotex objects to the relevance and probative value of ¶¶5-17, in light of the potential for undue prejudice and confusion of the issues. *See* Fed. R. Evid. 401, 402, and 403.

Apotex objects to ¶¶5-17, as not based on sufficient facts or data, the product of reliable principles and methods, and/or a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702, 703, 705; 77 Fed. Reg. at 48,763; 37 C.F.R. § 42.65.

Apotex objects to ¶11, as being judicially estopped in view of OSI's assertion that Tarceva's commercial success was attributed to claims from a different patent (Reissue Patent RE41,065) in prior litigation before the Court of the District of Delaware.¹ *New Hampshire v. Maine*, 532 U.S. 742, 749-50 (2001).

Apotex objects to Exhibit 2023, Declaration of Mark L. Reisenauer, in its entirety, as Apotex is prejudiced by Mr. Reisenauer's biases arising from his present and past financial and fiduciary relationship with OSI Pharmaceuticals, Inc. *See* Fed. R. Evid. 607; *U.S. v. Abel*, 469 U.S. 45, 49 (1984).

V. Exhibits 2031, 2032, and 2034-2041

Apotex objects to the relevance and probative value of exhibits 2031, 2032, and 2034-2041, in light of the potential for undue prejudice and confusion of the issues. *See* Fed. R. Evid. 401, 402, and 403.

Respectfully Submitted,

Date: May 1, 2017

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¹ *See* Ex. 1028 at 33.

CERTIFICATE OF SERVICE

I hereby certify that, on May 1, 2017, I caused a true and accurate copy of

Petitioners' Objections to Evidence to be served via electronic mail on the following attorneys of record:

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