

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC,
ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN
PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL
INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,
Petitioners,

v.

NOVARTIS A.G.,
Patent Owner.

IPR2017-00854¹
Patent No. 9,187,405

**PETITIONERS' NOTICE OF OBJECTIONS TO
NOVARTIS'S MARCH 23, 2018 SUBMISSIONS**

¹ Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	OBJECTIONS	1
	1. Objections to EX2095-EX2099 and EX2101-EX2106, and any Reference to/Reliance Thereon	1
	2. Objections to EX2095, and any Reference to/Reliance Thereon.....	1
	3. Objections to EX2096, and any Reference to/Reliance Thereon.....	2
	4. Objections to EX2097 and any Reference to/Reliance Thereon.....	3
	5. Objections to EX2098 and any Reference to/Reliance Thereon.....	4
	6. Objections to EX2103 and any Reference to/Reliance Thereon.....	4
	7. Objections to EX2104 and any Reference to/Reliance Thereon.....	5
III.	CONCLUSION	6

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Apotex Inc. and Apotex Corp. (“Petitioner”) submits the following objections to Novartis A.G. (“Patent Owner”)’s Exhibits 2095, 2096, 2097, 2098, 2099, 2101, 2102, 2103, 2104, 2105, and 2106, as listed on Patent Owner’s Updated Exhibit List filed on March 23, 2018, and any reference to or reliance on the foregoing Exhibits in Patent Owner’s Sur-Reply, Reply In Support of Contingent Motion to Amend, its expert declarations, 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

1. Objections to EX2095-EX2099 and EX2101-EX2106, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible); F.R.E. 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or Other Reasons). Petitioners object to Exhibits 2095-2099 and 2101-2106 as improper sur-reply or reply evidence that should have been submitted in November 2017 with Patent Owner’s Response.

2. Objections to EX2095, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible); F.R.E. 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time,

Case IPR2017-00854
Patent 9,187,405

Duplication, or Other Reasons); F.R.E. 701, 702, 703 (Expert Foundation and Opinions); F.R.E. 802, 803, 805 (Inadmissible Hearsay); 37 C.F.R. § 42.65.

EX2095 is duplicative of expert testimony offered previously by this witness and by Patent Owner's other witnesses, and offers testimony that is irrelevant, misleading, and a waste of time. F.R.E. 401-403. Petitioners object to Dr. Jusko's speculative reliance on documents or information not published before June 2006, including in paragraphs 31-40. F.R.E. 401-403, 802-805, including in paragraphs 11-12, 14-15, 23, 31, and 32, and including EX2103 and EX2104. F.R.E. 401-403, 802-805. Petitioners object to Dr. Jusko's testimony based on his analysis in paragraphs 11-12 under F.R.E. 701-703 and 37 C.F.R. § 42.65. Petitioners object to EX2095 for relying on hearsay statements for truth of the matters asserted. F.R.E. 802-805.

3. Objections to EX2096, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible); F.R.E. 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or Other Reasons); F.R.E. 701, 702, 703 (Expert Foundation and Opinions); F.R.E. 802, 803, 805 (Inadmissible Hearsay); 37 C.F.R. § 42.65.

EX2096 is duplicative of expert testimony offered previously by this witness and by Patent Owner's other witnesses, and offers testimony that is irrelevant, misleading, and a waste of time. F.R.E. 401-403. Petitioners object to Dr.

Steinman's speculative discussion of documents or information not published before June 2006, including in paragraphs 31-40. F.R.E. 401-403, 802-805.

Petitioners object to Dr. Steinman's testimony as outside his expertise, including paragraphs 9-24 and 31-40, and for failure to apply reliable methodology and disclose the data purportedly underlying his interpretation of the Webb reference. F.R.E. 701-703 and 37 C.F.R. § 42.65. Petitioners object to EX2096 for relying on hearsay statements for truth of the matters asserted. F.R.E. 802-805.

4. Objections to EX2097 and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible); F.R.E. 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or Other Reasons); F.R.E. 701, 702, 703 (Expert Foundation and Opinions); F.R.E. 802, 803, 805 (Inadmissible Hearsay); 37 C.F.R. § 42.65.

EX2097 is duplicative of expert testimony offered previously by this witness and by Patent Owner's other witnesses, and offers testimony that is irrelevant, misleading, and a waste of time. F.R.E. 401-403. Petitioners object to Dr. Lublin's speculative discussion of documents or information not published before June 2006, including in paragraphs 2, 6, 10, 16, 18, and 20. F.R.E. 401-403, 802-805. Petitioners object to Dr. Lublin's testimony as lacking adequate foundation and the requisite reliability for expert opinion. F.R.E. 701-703 and 37 C.F.R. § 42.65.

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