

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 AG,

Patent Owner.

Case IPR2017-00854¹

U.S. Patent No. 9,187,405

PATENT OWNER NOVARTIS'S MOTION TO EXCLUDE

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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

TABLE OF CONTENTS

	Page
I	PRELIMINARY STATEMENT1
II	ARGUMENT1
A.	Dr. Giesser’s Opinions Are Inadmissible as Unreliable under Rule 7021
B.	Exhibits Relating to the ’283 Formulation Patent IPR And the Confidential Clinical Trial Protocol Are Irrelevant7
C.	Petitioner Marked Inadmissible Exhibits and Elicited Inadmissible Testimony at Recent Depositions10
III	CONCLUSION15

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>3d Matrix, Ltd. v. Menicon Co., Ltd.</i> , IPR2014-00398, 2014 WL 3851279 (P.T.A.B. Aug. 1, 2014).....	1
<i>Am. Med. Sys., Inc. v. Laser Peripherals, LLC</i> , 712 F. Supp. 2d 885 (D. Minn. 2010).....	5
<i>AstraZeneca AB v. Aurobindo Pharma LTD, et al.</i> , 232 F. Supp. 3d 636 (D. Del. 2017).....	4
<i>Daubert v. Merrell Dow Pharm., Inc.</i> , 509 U.S. 579 (1993).....	1, 2
<i>Huang v. Marklyn Grp., Inc.</i> , Civil Case No. 11-cv-01765-REB-BNB, 2014 WL 3559367 (D. Colo. July 18, 2014).....	5
<i>Mendenhall v. Cedarapids, Inc.</i> , 5 F.3d 1557 (Fed. Cir. 1993)	7
<i>N.V. v. Abbott Labs.</i> , 512 F.3d 1363 (Fed. Cir. 2008)	5
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> , 520 F.3d 1358 (Fed. Cir. 2008)	5
<i>Seaboard Lumber Co. v. United States</i> , 308 F.3d 1283 (Fed. Cir. 2002)	2
<i>Toshiba Corp. v. Optical Devices, LLC</i> , IPR2014-01447, Paper 34 (Mar. 9, 2016)	13
<i>United States v. Williams</i> , 506 F. 3d 151 (2d. Cir. 2007)	2
<i>Warner Chilcott Labs. Ireland Ltd. v. Impax Labs., Inc.</i> , No. 2:08-CV-06304 WJM, 2012 WL 1551709 (D.N.J. Apr. 30, 2012), <i>aff'd</i> , 478 F. App'x 672 (Fed. Cir. 2012)	4

Statutes

35 U.S.C. § 103(a)5

Rules

Fed. R. Evid. 4018, 12, 13, 15
Fed. R. Evid. 4038, 12, 15
Fed. R. Evid. 60213
Fed. R. Evid. 60814
Fed. R. Evid. 61112, 13
Fed. R. Evid. 7021, 2, 3, 5

I PRELIMINARY STATEMENT

Novartis respectfully moves to exclude (A) all, or at least the pharmacology opinions in, the declaration of Dr. Barbara Giesser and related CV (**Ex. 1002, Ex. 1003**); (B) exhibits relating to an IPR involving an unrelated Novartis formulation patent (**Ex. 1032, Ex. 1035, Ex. 1037, Ex. 1041**), and a confidential clinical trial document (**Ex. 1051**); and (C) exhibits and certain testimony from recent depositions (**Exs. 1054-59**, and parts of **1063** and **1064**).

II ARGUMENT

A. Dr. Giesser's Opinions Are Inadmissible as Unreliable under Rule 702

Novartis appreciates that the Board does not often exclude expert testimony under Fed. R. Evid. 702, preferring instead to weigh the testimony in the overall process of deciding the case. But Dr. Giesser's testimony and how it was used by Petitioners here are beyond the pale.

The Board applies Federal Rule of Evidence 702 to putative expert testimony. *3d Matrix, Ltd. v. Menicon Co., Ltd.*, IPR2014-00398, 2014 WL 3851279, at *5 (P.T.A.B. Aug. 1, 2014) (applying Rule 702). Rule 702 requires the Board to act as a "gatekeeper" to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589, 597 (1993). The proponents of expert testimony—here, Petitioners—have

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.