

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 OPPOSITION TO PETITIONERS'
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

	<u>Page</u>
I PRELIMINARY STATEMENT	1
II ARGUMENT	1
A. The Novartis Inventors’ Report and Related Testimony Is Admissible	1
1. The Report Itself Is Admissible	1
2. The Experts’ Testimony Is Independently Admissible	5
B. Dr. Lublin’s Evidence of Expectations and Skepticism is Admissible	6
1. Exhibits 2063-2066 Are Admissible.....	7
2. Dr. Lublin’s Testimony Is Independently Admissible	10
C. Novartis’s Testimony About Webb Is Admissible	11
1. Petitioners Invited This Testimony.....	12
2. Petitioners’ Attempt to Raise a Discovery Deficiency Fails	13
3. Rule 702 Does Not Preclude the Testimony.....	13
III CONCLUSION.....	15

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Lankford v. Reladyne,</i> LLC, 2016 WL 1444307 (S.D. Ohio Apr. 8, 2016)	2
<i>Monsanto Co. v. David,</i> 516 F.3d 1009 (Fed. Cir. 2008)	5
<i>U.S. E.E.O.C. v. Olsten Staffing Servs. Corp.,</i> 657 F. Supp. 2d 1029 (W.D. Wis. 2009)	2
<i>United States v. Caballero,</i> 277 F.3d 1235 (10th Cir. 2002)	13
<i>United States v. Logsdon,</i> 2013 WL 5755614 (W.D. Okla. Oct. 23, 2013)	13
<i>Weatherford Int’l, LLC,</i> IPR2016-01509, 2018 WL 1637993 (P.T.A.B. Apr. 3, 2018)	8
Rules	
Fed. R. Evid. 106	9
Fed. R. Evid. 602	1, 4, 9
Fed. R. Evid. 702	13, 14
Fed. R. Evid. 703	5, 10
Fed. R. Evid. 801	1, 3
Fed. R. Evid. 803	1, 7, 8, 9
Fed. R. Evid. 805	1
Fed. R. Evid. 807	9
Fed. R. Evid. 901	1, 2

I PRELIMINARY STATEMENT

In their motion, Petitioners nowhere dispute that Novartis's evidence satisfies every relevance criteria. Petitioners instead attack selected Exhibits with a mélange of authentication, hearsay, and personal knowledge objections, sprinkled with some complaints about discovery. None of these objections has any merit, and the Board should consider all of Novartis's concededly relevant evidence.

II ARGUMENT

A. The Novartis Inventors' Report and Related Testimony Is Admissible

Novartis submitted a report prepared by the inventors that describes the animal studies underlying the invention claimed in the '405 patent. (Ex. 2057.) Novartis experts Drs. Steinman and Jusko in turn discuss this document, which is also addressed in Novartis's Patent Owners Response. (Paper 26 at 22-25.)

Petitioners say the report and all parts of Novartis's experts' testimony about it "should be excluded under Fed. R. Evid. 602, 801-803, 805, and 901." (Paper 82 at 1-2.) None of these rules achieves what Petitioners hope for.

1. The Report Itself Is Admissible

The Novartis report is authentic. Under Fed. R. Evid. 901, a document may be authenticated by "testimony of a witness with knowledge" that the item "is what it is claimed to be." Fed. R. Evid. 901(b)(1). Novartis authenticated the report with

testimony from a co-author of the document, inventor Christian Schnell. His declaration shows the report is exactly what Novartis says it is—a report that he, co-inventor Peter Hiestand, and others prepared to describe the work that led to the '405 patent. (Ex. 2026 at ¶ 1–2, 4.) That should end the inquiry.

Petitioners' contrary arguments have no merit. Petitioners first assert that Mr. Schnell lacks substantive knowledge of parts of the document that Mr. Hiestand handled. (Paper 82 at 3–4.) That is irrelevant. Rule 901 requires only personal knowledge that the document “is what it is claimed to be.” Mr. Schnell was a co-author. He thus provided that testimony from his own recollection. Testimony from an author indeed is more than is needed under the Rule. *See, e.g., U.S. E.E.O.C. v. Olsten Staffing Servs. Corp.*, 657 F. Supp. 2d 1029, 1033–34 (W.D. Wis. 2009) (rejecting argument that author or witness with personal knowledge of contents of document is required); *Lankford v. Reladyne, LLC*, 2016 WL 1444307, at *1 (S.D. Ohio Apr. 8, 2016) (affidavit of treatment center's custodian of records sufficient to authenticate medical records under Rule 901).

Petitioners next complain that Mr. Schnell did not see Mr. Hiestand sign the final document. (Paper 82 at 3.) That's a straw man. Rule 901 does not require that Mr. Schnell serve as notary.

Petitioners note also that Mr. Schnell did not “personally” deposit the document into Novartis's electronic filing system. (*Id.*) That is another red herring.

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.