

Date Filed: December 3, 2024

Filed on Behalf of:

Novartis Pharmaceuticals Corporation

By:

Nicholas N. Kallas

nkallas@venable.com

(212) 218-2243

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MICHIGAN AND
UNIVERSITY OF SOUTH FLORIDA,
Patent Owners.

Case No. IPR2023-01346
U.S. Patent No. 10,633,344

**PETITIONER'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO
EXCLUDE**

Table of Contents

I.	Patent Owners Repeatedly Ignore Their Burden of Establishing the POSA's Knowledge <i>as of the Priority Date</i> , Not Any Later Date.....	1
II.	Patent Owners Fail to Meaningfully Address the Lack of Factual Support for Dr. Ward's Opinions.....	1
III.	Patent Owners Fail to Meaningfully Address the Relevance of the Exhibits They Failed to Cite in Their Briefing	3

Table of Authorities

Cases

<i>Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.</i> , 776 F.2d 281 (Fed. Cir. 1985)	2
<i>Cisco Systems, Inc. v. C-Cation Techs., LLC</i> , IPR2014-00454, Paper 12 (P.T.A.B. Aug. 29, 2014)	3
<i>Envirotrainer AB v. Doubleday Acquisitions, LLC</i> , IPR2022-00864, Paper 66 (P.T.A.B. Feb. 1, 2024)	4
<i>Ex parte Erlich</i> , 22 USPQ 2d 1463 (B.P.A.I. 1992)	1
<i>Mylan Pharm. Inc. v. Regeneron Pharm. Inc.</i> , IPR 2021-00880, Paper 89 (P.T.A.B. Nov. 9, 2022)	4
<i>Riverbed Tech. Inc. v. Realtime Data LLC</i> , IPR2016-00978, Paper 67 (P.T.A.B. Oct. 30, 2017)	5
<i>SK Innovation Co., Ltd. v. Celgard, LLC</i> , IPR2014-00679, Paper 58 (P.T.A.B. Sep. 25, 2015)	3
<i>Upjohn Co. v. Mova Pharm. Corp.</i> , 225 F.3d 1306 (Fed. Cir. 2000)	2
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022)	2
<i>Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.</i> , IPR2013-00159, Paper 71 (P.T.A.B. Aug. 22, 2014)	5

Rules

F.R.E. 402	1, 2, 3, 5
F.R.E. 403	1, 2, 3, 5
F.R.E. 702	1, 3, 5

F.R.E. 703	1, 3, 5
------------------	---------

Regulations

37 C.F.R. § 42.65(a).....	2
---------------------------	---

Patent Owners fail to show that Petitioner has not met its burden to exclude any, let alone all, evidence identified in Petitioner's Motion to Exclude (Paper 28).

I. Patent Owners Repeatedly Ignore Their Burden of Establishing the POSA's Knowledge *as of the Priority Date*, Not Any Later Date

Although Patent Owners allege that they rely on Exhibits 1007, 1027, and 2012 to demonstrate only the level of ordinary skill in the art as of March 3, 2003, they fail to address that these references reflect a POSA's knowledge *after—not as of—the priority date*. For example, that a POSA could devise a screening strategy *after the priority date* does not say anything about whether he or she could have done so *as of the priority date*. Because these exhibits are improper evidence of only a later state of the art, they should be excluded under F.R.E. 402, 403, 702 and/or 703 to the extent they are relied on *as prior art*.

Patent Owners argue that art after the priority date can be used to show the *level* of skill in the art (Paper 29 at 2 (citing *Ex parte Erlich*, 22 USPQ 2d 1463 (B.P.A.I. 1992))), but the level of skill in the art is not in dispute here; both parties agree that the level of skill is “high.” Patent Owner Sur-Reply (Paper 25) at 13.

II. Patent Owners Fail to Meaningfully Address the Lack of Factual Support for Dr. Ward's Opinions

Patent Owners point to Dr. Ward's scientific background opinions and his experience as providing factual support for his opinions in Ex. 2014, ¶¶ 55-57, 73-75, and 81. But “[e]xpert testimony that does not disclose the underlying facts or

data on which the opinion is based is entitled to little or no weight.” *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential), *citing* 37 C.F.R. § 42.65(a); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985).

Patent Owners’ attempt to discredit *Ashland Oil* as a “pre-*Daubert* case” (Paper 29 at 2-3), ignores that *Ashland Oil* is still good law, helpfully discusses the “probative value” of evidence without factual support (a key consideration under F.R.E. 402 and 403), and is regularly cited by the Board. *See, e.g., Xerox*, IPR2022-00624, Paper 9 at 15 (citing *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000), quoting *Ashland Oil*, 776 F.2d at 294).

Dr. Ward fails to provide the appropriate factual support here:

Exhibit 2014, ¶¶ 55-57: Mentioning Dr. Etter’s work does not provide facts or data supporting the specific conclusions in these paragraphs.

Exhibit 2014, ¶¶ 73-75: Dr. Ward does not identify facts or data to support his conclusions about Exhibit 1028 (Fleischman).

Exhibit 2014, ¶ 81: Dr. Ward does not identify facts or data to support or explain why the field of pharmaceutical co-crystals is “highly sophisticated.” Patent Owners’ post hoc attempt to rely on Ex. 2014, ¶¶ 3-15, 31 as support (Paper 29 at 4) confuses the issue; according to Dr. Ward, the field of pharmaceutical co-crystals was both “emerging” and “highly sophisticated.”

As the above cited paragraphs lack factual support, they should be excluded under F.R.E. 402, 403, 702 and/or 703.

III. Patent Owners Fail to Meaningfully Address the Relevance of the Exhibits They Failed to Cite in Their Briefing

Patent Owners do not dispute that Exhibits 2006, 2009, 2010, 2011, 2012, 2013 and Exhibit 2014, ¶¶ 51-52 are not cited in their briefing.

To be clear, Petitioner does not object to Patent Owners relying on these exhibits to provide “context” to Dr. Ward’s opinions. However, Petitioner objects to the extent Patent Owners plan to rely on any of these Exhibits affirmatively at the oral hearing, or to the extent the Board relies on these Exhibits in its decision.

As explained in *Cisco Systems, Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 8-10 (P.T.A.B. Aug. 29, 2014) (informative), “[a] brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record.” *See also, SK Innovation Co., Ltd. v. Celgard, LLC*, IPR2014-00679, Paper 58 at 49 (P.T.A.B. Sep. 25, 2015) (granting motion to exclude exhibits because the patent owner did not cite them or rely on them “with any particularity during th[e] proceeding”). If all these Exhibits are only providing “context” as Patent Owners allege (Paper 29 at 5-6), they are not relied on with “any particularity.” Had Patent Owners intended to rely on them with “any particularity,” Patent Owners would have cited the exhibits in their briefing. It would be prejudicial to allow Patent Owners to now rely on with particularly any of Exhibits 2006, 2009, 2010, 2011,

2012, 2013, and Exhibit 2014, ¶¶ 51-52.

Neither *Mylan* nor *Envirotrainer*, supports Patent Owners’ assertion that providing context is sufficient to allow the reliance on uncited materials where the objecting party alleged that would be prejudicial. Paper 29 at 5 (citing *Mylan Pharm. Inc. v. Regeneron Pharm. Inc.*, IPR 2021-00880, Paper 89 at 19 (P.T.A.B. Nov. 9, 2022); *Envirotrainer AB v. Doubleday Acquisitions, LLC*, IPR2022-00864, Paper 66 at 86 (P.T.A.B. Feb. 1, 2024)). Neither of these cases involved *prejudice* to the objecting party, whereas here, Petitioner identifies specific prejudice, including the breadth of Patent Owners’ reliance on context to support the use of the above-identified Exhibits (6 of 9 Exhibits cited in Dr. Ward’s declaration are described as providing “context”). It is prejudicial to Petitioner to have to address any possible point Patent Owners could make based on these Exhibits and the “context” they are alleged to provide. Patent Owners were obligated to indicate in their briefing which portions of each exhibit they are relying on, and for what purpose. To rely on something different now at the oral hearing would be prejudicial.

This prejudice is especially salient for the post-priority Exhibits 2011 (Morissette) and 2012 (HHS Guidance 2003), particularly since the summaries of these Exhibits provided by Patent Owners, and the context they are alleged to provide, again improperly implies that these post-priority references reflect the state of the art as of March 3, 2003. Paper 29 at 6.

Patent Owners' arguments regarding incorporation by reference (Paper 29 at 7) are inapposite. Petitioner is not asking to exclude these Exhibits based on improper incorporation by reference. The rules on incorporation by reference, by analogy, lend support to why it is important for Patent Owners to cite the Exhibits they are relying on *in their briefing*, and how failing to do so can render those exhibits irrelevant. *See* Paper 28 at 6-7 (using *cf.* signal for analogous authority).

Finally, it is proper to exclude specific paragraphs of an expert's declaration that violate the rules of evidence. *Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.*, IPR2013-00159, Paper 71 at 54-55 (P.T.A.B. Aug. 22, 2014) (excluding paragraph of expert declaration relying on unfiled and/or untranslated documents); *Riverbed Tech. Inc. v. Realtime Data LLC*, IPR2016-00978, Paper 67 at 41 (P.T.A.B. Oct. 30, 2017) (excluding paragraphs of expert declaration relying on excluded exhibit).

Exhibits 2006, 2009, 2010, 2011, 2012, 2013 and Exhibit 2014, ¶¶ 51-52 should be excluded under F.R.E. 402, 403, 702 and/or 703.

Dated: December 3, 2024

Respectfully submitted,

/Nicholas N. Kallas/
Nicholas N. Kallas (Reg. No. 31,530)
VENABLE LLP
151 W. 42nd Street, 49th Floor
New York, NY 10036
Telephone: (212) 218-2243
nkallas@venable.com

Lead Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Petitioner's Reply Brief in Support of its Motion to Exclude was served on December 3, 2024 via electronic mail on the following counsel of record for the Patent Owners:

Lead Counsel

Michael Kane
Fish & Richardson P.C.
60 South Sixth Street
Minneapolis, MN 55402
Phone: 202-783-5070
Fax: 877-769-7945
kane@fr.com
IPR51957-0001IP1@fr.com

Back-up Counsel

Kelly Del Dotto
Ahmed Davis
Taylor Burgener
Jacqueline Moran
60 South Sixth Street
Minneapolis, MN 55402
Phone: 202-783-5070
Fax: 877-769-7945
allenspach.del.dotto@fr.com
adavis@fr.com
burgener@fr.com
jtmoran@fr.com
IPR51957-0001IP1@fr.com

Date: December 3, 2024

/Nicholas N. Kallas/
Nicholas N. Kallas (Reg. No. 31,530)
VENABLE LLP
151 W. 42nd Street, 49th Floor
New York, NY 10036
Telephone: (212) 218-2243
Facsimile: (212) 218-2200
nkallas@venable.com

*Lead Counsel for Petitioner, Novartis
Pharmaceuticals Corporation*