

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

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

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

**PATENT OWNERS' OPPOSITION TO PETITIONER'S
MOTION TO EXCLUDE**

Petitioner’s Motion to Exclude (Paper 28, the “Motion”), which seeks to exclude large swaths of Patent Owners’ evidence, should be denied. The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence (“FRE”). *See* 37 C.F.R. §§ 42.20(c), 42.62(a). Petitioner failed to meet its burden.

First, Petitioner misapprehends the way Patent Owners rely on the challenged exhibits and expert opinions. For example, rather than asserting that certain references were prior art, Patent Owners rely on challenged exhibits to show the level of knowledge of skill in the art.

Second, Petitioner relies on dated caselaw to suggest that Dr. Ward cannot rely on his extensive experience, knowledge, education, skill, and training in the field to support his opinions.

Finally, Petitioner incorrectly asserts that exhibits or paragraphs from an expert declaration should be stricken if not cited in the Patent Owners’ papers. The caselaw and rules do not support this theory, nor is it appropriately raised as an evidentiary challenge.

- I. Exhibits 1007 (Ueto), 1027 (Reddy), and 2012 (HHS Guidance 2003) Should Not be Excluded.

Petitioner challenges EX1007, EX1027, and EX2012 as improper prior art. Mot. at 2. Petitioner cites MPEP § 2124 – the same MPEP section which recognizes “References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the relevant time. *See Ex parte Erlich*, 22 USPQ2d 1463 (Bd. Pat. App. & Inter. 1992).” That is exactly how Petitioner uses the challenged exhibits:

- EX1007 and EX1027: Ueto and Reddy are used to show that a POSA would be able to use the Etter rules to devise a manual or high-throughput screening strategy for co-crystallization. *See* EX2014 at ¶¶46, 74.
- EX2012: HHS Guidance 2003 is used to show how a POSA would use exemplary guidance documents to inform its decision on how to develop a pharmaceutical formulation. *See* EX2014 at ¶45.

II. Paragraphs 55-57, 73-75, and 82 of Dr. Ward’s Declaration (Exhibit 2014) Should Not be Excluded.

Petitioner cites caselaw that pre-dates *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) to suggest that an expert’s opinion requires external validation of some sort. Mot., 5. Not so. As the Advisory Committee Notes to the post-*Daubert* amendments to Federal Rule of Evidence 702 make clear, “Nothing in this amendment is intended to suggest that experience alone—or experience in

conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience.” *See* Adv. Comm. Notes to FRE 702 (2000).

Dr. Ward detailed his experience in the field as well as his knowledge, skill, training and education (EX2014 at ¶¶3-15). He also provided background to his opinions, detailing what a person of ordinary skill in the art would know about co-crystals, the principles of hydrogen bonding, pharmaceutical formulation, and high-throughput screening. *See* EX2014 at ¶¶30-49. As shown below, these earlier sections provide support for the opinions and conclusions Dr. Ward draws in the challenged paragraphs:

- EX2014 at ¶¶ 55-57: These paragraphs repeatedly refer to Dr. Etter’s work, which was summarized in Dr. Ward’s declaration at ¶¶38-43. Petitioner’s suggestion, therefore, that these paragraphs are “unsupported” is inaccurate.
- EX 2014 at ¶¶73-75: These paragraphs reflect Dr. Ward’s, ergo a person of ordinary skill in the art’s, understanding of the disclosures of Fleischman 2003 (EX1028). Given his detailed synopsis of his

experience, knowledge, skill, training, and education earlier in his report, these paragraphs are not unsupported.

- EX2014 at ¶81: This paragraph reflects Dr. Ward’s opinion that the field of pharmaceutical co-crystals is “highly sophisticated” with a high level of skill in the art for a POSITA. His explanation of the high level of skill in the art – which is not disputed by Petitioner – was described earlier in his report at ¶¶3-15. His opinions regarding the sophistication of the field are further supported by his earlier background on the field of co-crystals (EX2014 at ¶31 (referring to co-crystals being known the art, “but knowledge of pharmaceutical co-crystals was emerging” and citing references)).

III. Exhibits 2006 (Peterson), 2009 (Yusov), 2010 (Etter 1990), 2011 (Morisette), 2012 (HHS Guidance 2003), and 2013 (HHS Guidance 1997), and Paragraphs 51-52 of Dr. Ward’s Declaration Should Not be Excluded

Petitioner moves to exclude EX2006, EX2009, EX2010, EX2011, EX2012, and paragraphs 51-52 for lack of relevance under FRE 402/403 and FRE 702/703. Citing two non-precedential Board decisions from 2015 and 2016, Petitioner argues that these exhibits are irrelevant because they were “neither cited nor relied on in the POR or Sur-reply.” Mot., 9. The Board should deny and/or dismiss Petitioner’s motion to exclude these exhibits.

First, no rule or binding authority requires an exhibit to have been cited in a POR or Sur-reply to meet the relevance requirement of FRE 401. Uncited paragraphs may provide context and/or make cited facts more or less probable. *Mylan Pharm. Inc. v. Regeneron*, IPR2021-00880, Paper 89, at 19, 26 (P.T.A.B. Nov. 9, 2022); *Envirotrainer AB v. Doubleday Acquisitions, LLC*, IPR2022-00864, Paper 66, at 86 (denying motion to exclude evidence because uncited evidence may provide “helpful context to the cited material” and Petitioner showed no prejudice from the existence of the material in the record). As shown below, the challenged exhibits and paragraphs provide helpful context:

- EX2006: Peterson provides helpful context to show that high-throughput screening was used in the pharmaceutical context as of 2002/2003. *See* EX2014 at ¶48.
- EX2009: Yusov provides helpful context to show that the Etter rules of hydrogen bonding were widely accepted in the pharmaceutical context as of 2002/20023. *See* EX2014 at ¶¶38-39.
- EX2010: Etter 1990 provides helpful context to show that the Etter rules of hydrogen bonding were well-known in the art as of 2002/2003. *See* EX2014 at ¶38.

- EX2011: Morisette provides helpful context to show that high-throughput screening was used in the pharmaceutical context as of 2002/2003. *See* EX2014 at ¶¶47-48.
- EX2012: The HHS Guidance 2003 provides helpful context to show how a person of ordinary skill in the art would have been aware of guidance that listed available solvents as of 2002/2003. *See* EX2015 at ¶45.
- EX2013: Like the HHS Guidance 2003, the HHS Guidance 1997 provides helpful context to show how a person of ordinary skill in the art would have been aware of guidance that listed available solvents as of 2002/2003. *Id.*
- ¶¶51-52 of (EX2014): These referenced paragraphs of Dr. Ward’s declaration provide important context to and clarification of Dr. Rogers’ opinions concerning the proper construction of the term “permits formation of” as well as the disclosure of the ’344 patent.

Second, Petitioner overreads *SK Innovation*, Mot., 9-10. In *SK Innovation*, the excluded exhibit was not relied on anywhere in the *proceeding*. Paper 58 at 49. Here, the challenged exhibits are cited throughout Dr. Ward’s declaration. *See* EX2014 at ¶¶38-39, 47-48.

Third, Petitioner argues that the challenged exhibits and paragraphs amount to improper incorporation by reference. Mot., 6 (citing 37 C.F.R. § 42.6(a)(3) and *Cisco Systems, Inc. v. C-Cation Techs., LLC*, IPR2014-00454 Paper 12 at 8-10 (P.T.A.B. Aug. 29, 2014) (informative)). A motion to exclude, however, is properly to challenge the admissibility of evidence under the Federal Rules of Evidence, not briefing rules. *See Apple Inc. v. Masimo Corp.*, IPR2022-01291 Paper 75 at 134-135 (“Motions to exclude concern admissibility of evidence under the Federal Rules of Evidence, not improper briefing. *See* 37 C.F.R. §§ 42.61–42.64.”)

Fourth, an expert’s declaration should not be excluded in piecemeal fashion as the Petitioner contends. *See Sony Computer Entm’t Am. LLC v. Game Controller Tech. LLC*, IPR2013-00634, Paper 32, at 32 (P.T.A.B. Apr. 14, 2015) (“we regard it as the better course to have a complete record of the evidence to facilitate public access, as well as appellate review”); *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66, at 19 (PTAB May 1, 2014); *Gnosis S.p.A. v. S. Alab. Med. Sci. Found.*, IPR2013- 00118, Paper 64, at 43 (P.T.A.B. June 20, 2014); *Flir Sys. v. Leak Surveys, Inc.*, IPR2014-00411, Paper 113, at 4, 11–12.

Finally, the challenged exhibits and paragraphs are relevant to the background knowledge of the POSITA and the general knowledge in the art. As

the Board has explained, “even if the exhibit is not discussed in a brief, we find that it gives context to the testimony of record.” *Medtronic Vascular, Inc. v. TMT Sys., Inc.*, IPR2021-01532, Paper 56 at 48 (PTAB Mar. 7, 2023). And if the Board does not rely on EX2006, EX2009, EX2010, EX2011, EX2012, and paragraphs 51-52 in making its Final Written Decision, then the Board may dismiss as moot this portion of Petitioner’s motion. *See, e.g., TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, IPR2022-01400, Paper 41 at 46 (PTAB Jan. 26, 2024); *Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, IPR2022-00796, Paper 45 at 102 (PTAB Oct. 11, 2023).

Respectfully submitted,

Date: November 27, 2024

/Kelly Del Dotto/
Kelly Del Dotto, Reg. No. 74,120
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
T: 202-783-5070
F: 877-769-7945

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), the undersigned certifies that on November 27, 2024, a complete and entire copy of this Patent Owners' Opposition to Petitioner's Motion to Exclude were provided via email, to the Petitioner by serving the email correspondence addresses of record as follows:

Nicholas N. Kallas, Reg. No. 31,530
Christina Schwarz, Reg. No. 78,484
Laura Fishwick, Reg. No. 69,907
VENABLE LLP
151 W. 42nd Street, 49th Floor
New York, NY 10036
Telephone: (212) 218-2243
Facsimile: (212) 218-2200
nkallas@venable.com
cschwarz@venable.com
lfishwick@venable.com

/Crena Pacheco/
Crena Pacheco
Fish & Richardson P.C.
60 South Sixth Street
Minneapolis, MN 55402
pacheco@fr.com