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Filed on Behalf of:

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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 MOTION TO EXCLUDE

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I. INTRODUCTION

Pursuant to the March 19, 2024 Scheduling Order (Paper 9) in this proceeding, 37 C.F.R. § 42.64(c), and the Federal Rules of Evidence (“F.R.E.”), Petitioner Novartis Pharmaceuticals Corporation (“Novartis”) moves to exclude the following evidence under F.R.E. 402, 403, 702 and/or 703:

1. Exhibits 1007, 1027, and 2012, dated after March 2003, to the extent they are cited in Patent Owners’ Response (“POR”) and Dr. Ward’s Declaration *as prior art* and the paragraphs and/or statements in Dr. Ward’s declaration that rely on these exhibits, *i.e.*, Exhibit 2014 ¶¶ 45-46, 61, 65.

2. Paragraphs and/or statements in Dr. Ward’s declaration that do not cite any support, and/or fail to identify with particularity the underlying facts and data on which the opinion is based, *i.e.*, Exhibit 2014, ¶¶ 55-57, 73-75, 81.

3. Exhibits and paragraphs of Dr. Ward’s declaration that are not cited in Patent Owners’ Response or Sur-reply, *i.e.*, Exhibits 2006, 2009, 2010, 2011, 2012, 2013, and Exhibit 2014, ¶¶ 51-52.

Petitioner timely filed and served its objections to the above identified exhibits. Paper 20 at 2-9.

II. ARGUMENT

A. Non-Prior Art Exhibits 1007 (Ueto), 1027 (Reddy), and 2012 (HHS Guidance 2003) Should Be Excluded to the Extent They Are Relied on *as Prior Art*, as Well as the Paragraphs and/or Statements in Exhibit 2014 That Rely on Them as *Prior Art*

The parties dispute in the present proceeding whether the priority date for U.S. Patent No. 10,633,344 (Ex. 1001, “the ’344 patent”) is (i) no earlier than February 13, 2014, the filing date of U.S. Application No. 14/179,862 (Petitioner’s position) or (ii) March 3, 2003, the filing date of U.S. Application No. 10/378,956 (“the ’956 priority application”) (Patent Owner’s position). Patent Owners allege a March 3, 2003 priority date and bear the burden of production to establish written description and enablement support in the ’956 application as of that date. *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011). In doing so, Patent Owners and Dr. Ward improperly rely on several references (Exs. 1007, 1027, and 2012) dated after March 3, 2003 *as prior art*. Dr. Ward’s (and Patent Owners’) reliance on these exhibits as prior art should be excluded under F.R.E. 402, 403, 702, and/or 703. *Cf. K-Tec, Inc. v. Vita-Mix Corp.*, 696 F.3d 1364, 1372-73, 1377 (Fed. Cir. 2012) (affirming jury instruction confining invalidity analysis to prior art evidence); MPEP § 2124 (“[I]t is impermissible to use a later factual reference showing the state of the art existing after the effective filing date of the claimed invention to determine whether the application is enabled or described as required under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph” citing *In re*

Koller, 613 F.2d 819, 823 n. 5 (C.C.P.A. 1980).) None of the limited exceptions to this principle applies here.

For the avoidance of doubt, Novartis does not seek to exclude these exhibits for all purposes. Novartis's objection is limited to the improper use of these post-March 2003 publications *as prior art*, *i.e.*, use of these publications, which discuss a post-March 2003 state of the art, to supply art-related facts that were not available to a person of ordinary skill in the art as of March 2003. *Id.* Petitioner does not object to other, proper, uses of art dated after March 2003.

Exhibits 1007 and 1027 (cited in POR at 24; Ex. 2014, ¶ 46): On their face, Exhibits 1007 and 1027, indicate that they were published on November 29, 2011 (Ex. 1007), and September 11, 2003 (Ex. 1027), *after* the alleged March 3, 2003 priority date. Patent Owners cite Exhibits 1007 and 1027 improperly implying that their teachings were known “in the field” as of the priority date. POR at 24 (“Dr. Rogers fails to note the successes in the field....,” citing Exs. 1007 and 1027).

Exhibit 2012 (cited in Ex. 2014, ¶ 45): On its face, Exhibit 2012 indicates it was published in November 2003, *after* the alleged March 3, 2003 priority date. Dr. Ward relies on Exhibit 2012's disclosures *as prior art* to demonstrate the number of solvents available as of the priority date. Ex. 2014, ¶ 45 (citing Ex. 2012 to support the statement that “a POSA would be aware of guidance available from

the U.S. Department of Health and Human Services in 2002/2003 that listed solvents available at the time based on their assigned classes.”); *see also* POR at 9 (citing Ex. 2014, ¶ 45). Of note, the prior version of this guidance document (Ex. 2013), that was available as of the priority date, did not list any solvents.

Exhibit 2014: In instances where the Ward Declaration relies on the above-referenced exhibits (Exhibits 1007, 1027, and 2012) as prior art, these portions of the Ward Declaration should also be excluded. Exhibit 2014, ¶¶ 45-46, 61, 65; *Wi-Lan Inc. v. Sharp Elecs. Corp.*, 992 F.3d 1366, 1374-76 (Fed. Cir. 2021) (“[Proponent of expert testimony] attempts to do exactly what is impermissible under Rule 703 by using its expert ... to circumvent the rules of evidence to admit otherwise inadmissible evidence.”).

Patent Owners and Dr. Ward could have searched for and identified art dated prior to March 2003 to support their written description and enablement arguments if any such art existed. Patent Owners’ attempts to establish the state of the art as of March 2003 by using later-dated references should be rejected by excluding the above-identified exhibits to the extent they are relied on as prior art and excluding Dr. Ward’s statements relying on them. MPEP § 2124; *In re Koller*, 613 F.2d at 823 n. 5; *K-Tec, Inc.*, 696 F.3d at 1372-73, 1377.

B. Unsupported Statements in Exhibit 2014 Should Be Excluded

Dr. Ward includes several paragraphs in his declaration that do not cite any support, and/or fail to identify with particularity the underlying facts and data on which the opinion is based, *i.e.*, Exhibit 2014, ¶¶ 55-57, 73-75, 81. These paragraphs should be excluded under F.R.E. 402, 403, 702 and/or 703. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (“Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination.”).

Exhibit 2014, ¶¶ 55-57 does not cite any references supporting Dr. Ward’s written description opinions. Dr. Ward’s unsupported opinions should be excluded.

Exhibit 2014, ¶¶ 73-75 includes unsupported statements regarding how a POSA would interpret the disclosures in Fleischman (Exhibit 1028). Again, Dr. Ward provides no evidence of the underlying facts or data that support his assertions. Dr. Ward’s unsupported opinions should be excluded.

Finally, Exhibit 2014, ¶ 81 includes an unsupported statement regarding the nature of the field of the invention. Dr. Ward provides no evidence of the underlying facts or data that support his assertion that the nature of the field is

“highly sophisticated[,]” nor does he explain what he means by this term. Dr. Ward’s unsupported opinions should be excluded.

C. Exhibits 2006 (Peterson), 2009 (Yusov), 2010 (Etter 1990), 2011 (Morissette), 2012 (HHS Guidance 2003) and 2013 (HHS Guidance 1997) and Paragraphs of Exhibit 2014 Not Cited in Patent Owners’ Response or Sur-Reply Should be Excluded

Exhibits 2006, 2009, 2010, 2011, 2012 and 2013 are not cited in Patent Owners’ Response or Sur-Reply. Likewise, several paragraphs of Dr. Ward’s declaration, *i.e.*, Exhibit 2014, ¶¶ 51-52 are nowhere cited in Patent Owners’ Response or Sur-Reply. These Exhibits and paragraphs should be excluded under F.R.E. 402, 403, 702 and/or 703 because they are not discussed in Patent Owners’ Response or Sur-Reply. *See 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 patent owner did not cite them or rely on them “with any particularity during this proceeding”); *cf.* 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”); *Cisco Systems, Inc. v. C-Cation Techs., LLC*, IPR2014-00454 Paper 12 at 8-10 (P.T.A.B. Aug. 29, 2014) (informative) (“This practice of citing the Declaration to support conclusory statements that are not otherwise supported in the Petition ... amounts to incorporation by reference. ... A brief must make all arguments

accessible to the judges, rather than ask them to play archeologist with the record.”).

III. CONCLUSION

For the foregoing reasons, the evidence identified herein should be excluded.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Petitioner's Motion to Exclude was served on November 20, 2024 via electronic mail on the following counsel of record for the Patent Owners:

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