

Date Filed: June 10, 2024

Filed on Behalf of:

Novartis Pharmaceuticals Corporation

By:

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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 OBJECTIONS UNDER 37 C.F.R. § 42.64 TO EVIDENCE
SUBMITTED BY PATENT OWNERS WITH THEIR RESPONSE**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Novartis Pharmaceuticals Corporation (“Petitioner”) objects to the admissibility of the following exhibits filed with Patent Owners’ Regents of the University of Michigan and University of South Florida (“Patent Owners”) Response (Paper 19) on the grounds set forth below.

In this paper, a reference to “F.R.E.” means the Federal Rules of Evidence and a reference to “C.F.R.” means the Code of Federal Regulations. All objections under F.R.E. 802 (hearsay) apply to the extent Patent Owners rely on the exhibits identified in connection with that objection for the truth of the matters asserted therein. Petitioner’s objections to Patent Owners’ exhibits are without prejudice to Petitioner’s reliance on or discussion of those exhibits in Petitioner’s papers in this proceeding.

Petitioner’s objections are as follows:

Exhibit 2005 – Etter Rules

Petitioner objects to Exhibit 2005 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 2006 – Peterson

Petitioner objects to Exhibit 2006 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time), as it is not relevant to any issue in this IPR proceeding and is not the type of document upon which a person of

ordinary skill in the art as of March 3, 2003 (“2003”), the priority date to which Patent Owners allege the challenged claims are entitled, would rely.

Petitioner also objects to Exhibit 2006 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(b), and 42.6(a)(3), as this document is not cited in Patent Owners’ Response, and therefore any later attempt by Patent Owners to rely on this Exhibit (*e.g.*, either directly by citing this Exhibit or indirectly by citing paragraphs of Patent Owners’ expert declaration that discusses this Exhibit) is improper and untimely.

Exhibit 2007 – Walsh

Petitioner objects to Exhibit 2007 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Exhibit 2008 – Remenar

Petitioner objects to Exhibit 2008 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time), as Patent Owners have not cited any evidence that Exhibit 2008 was publicly available as of the priority date to which Patent Owners allege the challenged claims are entitled and therefore is not relevant to any issue in this IPR proceeding and is not the type of document upon which a person of ordinary skill in the art as of 2003 would rely.

Exhibit 2009 – Yusov

Petitioner objects to Exhibit 2009 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time), as Patent Owners have not cited any evidence that Exhibit 2009 was publicly available as of the priority date to which Patent Owners allege the challenged claims are entitled and therefore is not relevant to any issue in this IPR proceeding and is not the type of document upon which a person of ordinary skill in the art as of 2003 would rely.

Petitioner also objects to Exhibit 2009 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(b), and 42.6(a)(3), as this document is not cited in Patent Owners' Response, and therefore any later attempt by Patent Owners to rely on this Exhibit (*e.g.*, either directly by citing this Exhibit or indirectly by citing paragraphs of Patent Owners' expert declaration that discusses this Exhibit) is improper and untimely.

Exhibit 2010 – Etter 1990

Petitioner objects to Exhibit 2010 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time).

Petitioner also objects to Exhibit 2010 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(b), and 42.6(a)(3), as this document is not cited in Patent Owners' Response, and therefore any later attempt by Patent Owners to rely on this Exhibit (*e.g.*, either directly by citing this Exhibit or indirectly by citing paragraphs of

Patent Owners' expert declaration that discusses this Exhibit) is improper and untimely.

Exhibit 2011 – Morissette

Petitioner objects to Exhibit 2011 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time), as Patent Owners have not cited any evidence that Exhibit 2011 was publicly available as of the priority date to which Patent Owners allege the challenged claims are entitled and therefore is not relevant to any issue in this IPR proceeding and is not the type of document upon which a person of ordinary skill in the art as of 2003 would rely.

Petitioner also objects to Exhibit 2011 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(b), and 42.6(a)(3), as this document is not cited in Patent Owners' Response, and therefore any later attempt by Patent Owners to rely on this Exhibit (*e.g.*, either directly by citing this Exhibit or indirectly by citing paragraphs of Patent Owners' expert declaration that discusses this Exhibit) is improper and untimely.

Exhibit 2012 – HHS Guidance

Petitioner objects to Exhibit 2012 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time), as Patent Owners have not cited any evidence that Exhibit 2012 was publicly available as of the priority date to which Patent Owners allege the challenged claims are entitled, it is not relevant to

any issue in this IPR proceeding, and it is not the type of document upon which a person of ordinary skill in the art as of 2003 would rely.

Petitioner also objects to Exhibit 2012 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(b), and 42.6(a)(3), as this document is not cited in Patent Owners' Response, and therefore any later attempt by Patent Owners to rely on this Exhibit (*e.g.*, either directly by citing this Exhibit or indirectly by citing paragraphs of Patent Owners' expert declaration that discusses this Exhibit) is improper and untimely.

Exhibit 2013 – HHS Guidance

Petitioner objects to Exhibit 2013 under F.R.E. 802 (hearsay), 402 (relevance), and 403 (confusing, waste of time), as Patent Owners have not cited any evidence that Exhibit 2013 was publicly available as of the priority date to which Patent Owners allege the challenged claims are entitled, it is not relevant to any issue in this IPR proceeding, and it is not the type of document upon which a person of ordinary skill in the art as of 2003 would rely.

Petitioner also objects to Exhibit 2013 under 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(b), and 42.6(a)(3), as this document is not cited in Patent Owners' Response, and therefore any later attempt by Patent Owners to rely on this Exhibit (*e.g.*, either directly by citing this Exhibit or indirectly by citing paragraphs of

Patent Owners' expert declaration that discusses this Exhibit) is improper and untimely.

Exhibit 2014 – Declaration of Michael D. Ward, Ph.D.

Petitioner objects to Exhibit 2014 under F.R.E. 802 (hearsay), 402 (relevance), 403 (confusing, waste of time), 702 (improper expert testimony), and 703 (bases for expert opinion), as the testimony is not based on scientific, technical, or other specialized knowledge that will help the Board to understand the evidence or to determine a fact in issue, is not based on sufficient facts or data, is not the product of reliable principles and methods, is not based on expert knowledge, and the principles and methods have not been reliably applied to the facts of the case. In particular, Exhibit 2014 ¶¶ 32, 34-36, 39, 44, 46-49, 51-67, 69-71, 73-79, and 81-82 fail to cite any support at all, include statements that do not cite any support, and/or fail to identify with particularity the underlying facts and data on which the opinion is based; Exhibit 2014 ¶ 45 is not relevant to any issue in this IPR proceeding; Exhibit 2014 ¶¶ 31, 38-39, 44-49, 59-62, 64-65, and 73-75 include expert opinion based on documents for which Patent Owners have not cited any evidence of public availability as of the 2003 priority date (*i.e.*, Exhibits 1007, 1027, 1028, 2008, 2009, and 2011-2013) to which Patent Owners allege the challenged claims are entitled and therefore such opinions are not relevant to any issue in this IPR proceeding.

Petitioner objects to Exhibit 2014 ¶¶ 25, 30, 33, 50-52, and 58 under F.R.E. 402 (relevance), 403 (confusing, waste of time), and 37 C.F.R. §§ 42.22(a)(2), 42.23, 42.24(b), and 37 C.F.R. § 42.6(a)(3), as these paragraphs are not cited in Patent Owners' Response, and therefore any later attempt by Patent Owners to rely on these paragraphs or the arguments therein to respond to Petitioner's grounds of unpatentability (including priority) is improper and untimely.

Petitioner also objects to Exhibit 2014 ¶¶ 31, 38-49, 54-66, 71, 73-77, 79, and 82 under F.R.E. 702 (improper expert testimony), 703 (bases for expert opinion), 402 (relevance), and 403 (confusing, waste of time), as these paragraphs include expert opinion based on documents that are inadmissible for Patent Owners to rely on (*i.e.*, Exhibits 1007, 1027, 1028, and 2005-2013) under at least F.R.E. 802 (hearsay), 402 (relevance), or 403 (confusing, waste of time).

Petitioner further objects to Exhibit 2014 ¶¶ 59 and 67-75 under F.R.E. 106 (completeness) because these paragraphs quote only portions of testimony from Exhibit 1002 and omit portions of testimony set forth in the cited paragraphs of the declaration of Dr. Rogers that in fairness ought to be considered in connection with Exhibit 1002.

Petitioner also objects to Exhibit 2014 under F.R.E. 702 (improper expert testimony), 703 (bases for expert opinion), 402 (relevance), and 403 (confusing,

waste of time), as the declarant is not stated to have expertise with respect to co-crystals.

Dated: June 10, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Petitioner's Objections Under 37 C.F.R. § 42.64 To Evidence Submitted By Patent Owners With Their Response was served on June 10, 2024 via electronic mail on the following counsel of record for the Patent Owners:

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