

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS GENE THERAPIES, INC. & NOVARTIS PHARMACEUTICALS
CORPORATION,
Petitioners,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2023-01044
Patent No. 10,429,288

PETITIONERS' OBJECTIONS TO PATENT OWNER'S EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (“FRE”), Petitioners Novartis Gene Therapies, Inc. and Novartis Pharmaceuticals Corporation (collectively, “Novartis”) submit the following objections to certain exhibits submitted with Patent Owner’s Preliminary Response to the Petition for *Inter Partes* Review of U.S. Patent No. 10,429,288 (“POPR,” Paper 9). Novartis’s objections apply equally to Patent Owner’s reliance on these exhibits in any subsequently filed documents. These objections are timely filed and served within ten business days of the Board’s decision to institute trial in this proceeding.

Exhibit 2001

Novartis objects to Exhibit 2001 (Declaration of Jeffrey C. Hansen) as a declaration by a witness that contains unreliable testimony under FRE 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), including at least because Dr. Hansen lacks sufficient skill in the art, and his opinions lack the requisite scientific, technical, or other specialized knowledge sufficient to help the trier of fact understand the evidence or determine a fact in issue, do not sufficiently disclose underlying facts or data in support, are conclusory, and do not reflect a reliable application of the principles and methods to the facts of the case. Novartis objects to Exhibit 2001 to the extent the opinions described therein are not relevant and not helpful to the trier of fact, and Exhibit 2001 is thus unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time under FRE 401, 402, and

403. Novartis also objects to Exhibit 2001 to the extent it relies on unauthenticated evidence (e.g., Exhibits 2003-2009).

Exhibit 2003

Novartis objects to Exhibit 2003, which is not self-authenticating, as lacking authentication under FRE 901. To the extent Patent Owner relies on the contents of Exhibit 2003 for the truth of the matter asserted (*see* POPR, 2, 6, 7), Novartis objects to Exhibit 2003 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Novartis also objects to Exhibit 2003, which appears to be dated after the priority date of the '288 patent, as not relevant and not helpful to the trier of fact, and is thus unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time under FRE 401, 402, and 403. Novartis also objects to the POPR and Exhibit 2001 to the extent they rely on Exhibit 2003.

Exhibit 2004

Novartis objects to Exhibit 2004, which is not self-authenticating, as lacking authentication under FRE 901. To the extent Patent Owner relies on the contents of Exhibit 2004 for the truth of the matter asserted (*see* POPR, 7), Novartis objects to Exhibit 2004 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Novartis also objects to Exhibit 2004, which appears to be dated after the priority date of the '288 patent, as

not relevant and not helpful to the trier of fact, and is thus unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time under FRE 401, 402, and 403. Novartis also objects to the POPR and Exhibit 2001 to the extent they rely on Exhibit 2004.

Exhibit 2005

Novartis objects to Exhibit 2005, which is not self-authenticating, as lacking authentication under FRE 901. To the extent Patent Owner relies on the contents of Exhibit 2005 for the truth of the matter asserted (*see* POPR, 7, 8), Novartis objects to Exhibit 2005 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Novartis also objects to Exhibit 2005, which appears to be dated after the priority date of the '288 patent, as not relevant and not helpful to the trier of fact, and is thus unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time under FRE 401, 402, and 403. Novartis also objects to the POPR and Exhibit 2001 to the extent they rely on Exhibit 2005.

Exhibit 2006

Novartis objects to Exhibit 2006, which is not self-authenticating, as lacking authentication under FRE 901. To the extent Patent Owner relies on the contents of Exhibit 2006 for the truth of the matter asserted (*see* POPR, 63), Novartis objects to Exhibit 2006 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under

any exceptions, including FRE 803, 804, 805, and 807. Novartis also objects to the POPR and Exhibit 2001 to the extent they rely on Exhibit 2006.

Exhibit 2007

Novartis objects to Exhibit 2007, which is not self-authenticating, as lacking authentication under FRE 901. To the extent Patent Owner relies on the contents of Exhibit 2007 for the truth of the matter asserted (*see* POPR, 10), Novartis objects to Exhibit 2007 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Novartis also objects to the POPR and Exhibit 2001 to the extent they rely on Exhibit 2007.

Exhibit 2008

Novartis objects to Exhibit 2008, which is not self-authenticating, as lacking authentication under FRE 901. To the extent Patent Owner relies on the contents of Exhibit 2008 for the truth of the matter asserted, Novartis objects to Exhibit 2008 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Novartis also objects to Exhibit 2008 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403, because it is not cited in the Patent Owner's Preliminary Response. Novartis also objects to the POPR and Exhibit 2001 to the extent they rely on Exhibit 2008.

Exhibit 2009

Novartis objects to Exhibit 2009, which is not self-authenticating, as lacking authentication under FRE 901. To the extent Patent Owner relies on the contents of Exhibit 2009 for the truth of the matter asserted (*see* POPR, 2), Novartis objects to Exhibit 2009 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Novartis also objects to the POPR and Exhibit 2001 to the extent they rely on Exhibit 2009.

Respectfully submitted,

Dated: January 24, 2024

By: /John D. Livingstone/
John D. Livingstone, Lead Counsel
Registration No. 59,613

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Petitioners' Objections to Patent Owner's Evidence** was served electronically via email on January 24, 2024, in its entirety on the following:

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Patent Owner has consented to electronic service by email.

Date: January 24, 2024

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