IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.
Petitioner,

v.

MERCK SERONO S.A.,
Patent Owner.

Case IPR2023-00480
Patent No. 7,713,947

PETITIONER'S OBJECTIONS TO EVIDENCE

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Petitioner, Hopewell Pharma Ventures, Inc., objects under the Federal Rules of Evidence (FRE) and 37 C.F.R. § 42.64(b)(1) to the admissibility of Exhibits 2013, 2030–2043, 2048–2052, 2054–2058, 2060–2063, and 2070 (the "Challenged Evidence"), filed by Patent Owner Merck Serono S.A., on December 21, 2023, with its Patent Owner's Response ("Response"). Petitioner timely files its Objections within five business days of the date of service. 37 C.F.R. § 42.64(b)(1). Petitioner files these Objections to provide notice to Patent Owner that Petitioner may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c), unless cured by Patent Owner.

I. IDENTIFICATION OF GROUNDS FOR OBJECTIONS

A. Exhibit 2013

Exhibit 2013 purports to be an article by D. S. Goodin et al., "Disease Modifying Therapies in Multiple Sclerosis," in *American Academy of Neurology* 58 (2002). Petitioner objects to Exhibit 2013 under FRE 901 because Patent Owner fails to provide sufficient evidence indicating the origin or publication of the document, and accordingly fails to provide sufficient information regarding its authenticity. Petitioner also objects to Exhibit 2013 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.,* Response, at 28, 53. Petitioner also objects to Exhibit 2013 because it is incomplete. Petitioner did not submit the "Supplementary

Material" referred to on page 1 of Exhibit 2013. Therefore, Exhibit 2013 is not a "duplicate" as defined by FRE 1001(e) insofar as the exhibit is not "a counterpart … that accurately reproduces the original."

B. Exhibit 2030

Exhibit 2030 is an article by J. C. Sipe et al., "Development of Cladribine Treatment in Multiple Sclerosis," in *Multiple Sclerosis* 1 (1996). Petitioner objects to Exhibit 2030 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 50.

C. Exhibit 2031

Exhibit 2031 is an excerpt from a chapter by John Noseworthy et al., "Disease-Modifying Treatments in Multiple Sclerosis," in *McCalpine's Multiple Sclerosis* (4th ed. 2005). Petitioner objects to Exhibit 2031 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 1, 41, 47, 59.

D. Exhibit 2032

Exhibit 2032 is an article by K. Rammohan et al., "The Development of Cladribine Tablets for the Treatment of Multiple Sclerosis," in *Drugs* 80 (2020). Petitioner objects to Exhibit 2032 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 4, 62, 63.

E. Exhibit 2033

Exhibit 2033 is an article by G. Giovannoni et al., "A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis," in *New England Journal of Medicine* 362 (2010). Petitioner objects to Exhibit 2033 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 8, 59, 64, 65.

F. Exhibit 2034

Exhibit 2034 is a supplementary index to an article by G. Giovannoni et al., "A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis," in *New England Journal of Medicine* 362 (2010). Petitioner objects to Exhibit 2034 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 64–65.

G. Exhibit 2035

Exhibit 2035 is an article by G. Giovannoni et al., "Safety and Efficacy of Cladribine Tablets in Patients with Relapsing-Remitting Multiple Sclerosis: Results from the Randomized Extension Trial of the CLARITY Study," in *Multiple Sclerosis Journal* 24 (2018). Petitioner objects to Exhibit 2035 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 8, 60–62, 64.

H. Exhibit 2036

Exhibit 2036 is an article by G. Giovannoni et al., "Long-Term Follow-Up

of Patients with Relapsing Multiple Sclerosis from the CLARITY/CLARITY Extension Cohort of CLASSIC-MS: An Ambispective Study," in *Multiple Sclerosis Journal* 29 (2023). Petitioner objects to Exhibit 2036 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.,* Response, at 1, 61.

I. Exhibit 2037

Exhibit 2037 is an article by A. Miller et al., "Current and Investigational Therapies Used to Alter the Course of Disease in Multiple Sclerosis," in *Southern Medicine Journal* 90 (1997). Petitioner objects to Exhibit 2037 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 29.

J. Exhibit 2038

Exhibit 2038 is a website publication by Fierce Biotech. Petitioner objects to Exhibit 2038 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 60.

K. Exhibit 2040

Exhibit 2040 is a press release by the U.S. Food and Drug Administration. Petitioner objects to Exhibit 2040 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 64–65.

L. Exhibit 2041

Exhibit 2041 is a website publication by ClinicalTrials.gov. Petitioner objects to Exhibit 2041 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 64–65.

M. Exhibit 2042

Exhibit 2042 is a website publication by Neurology Live. Petitioner objects to Exhibit 2042 as inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 60, 62, 63.

N. Exhibit 2043

Exhibit 2043 is an article by J. Liliemark et al., "On the Bioavailability of Oral and Subcutaneous 2-Chloro-2'-Deoxydenosine in Humans: Alternative Routes of Administration," in *Journal of Clinical Oncology* 10 (1992). Petitioner objects to Exhibit 2043 as inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 49.

O. Exhibit 2048

Exhibit 2048 is a 2002 Product Development and License Agreement between IVAX International GMBH and Ares Trading S.A. Petitioner objects to Exhibit 2048 because it contains redacted portions and is incomplete. Therefore, Exhibit 2048 is not a "duplicate" as defined by FRE 1001(e) insofar as the exhibit is not "a counterpart … that accurately reproduces the original."

P. Exhibit 2049

Exhibit 2049 purports to be an email dated December 17, 2003 titled Cladribine Briefing Document. Petitioner objects to Exhibit 2049 as inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 60, 62, 63.

Q. Exhibit 2050

Exhibit 2050 purports to be meeting minutes dated August 27, 2003 for the Oral Cladribine for MS Project Joint Meeting. Petitioner objects to Exhibit 2050 as inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 14, 15.

R. Exhibit 2051

Exhibit 2051 is the declaration of Fred D. Lublin, M.D. Petitioner objects to ¶¶18–28 and 185 of this declaration because they are not relevant. Patent Owner does not rely upon or even cite to these substantive paragraphs in the Response, rendering Dr. Lublin's testimony in these paragraphs irrelevant under FRE 401. Petitioner therefore objects to these paragraphs under FRE 402. Petitioner also objects to this testimony under FRE 403 because it has no probative value, creates unfair prejudice to Petitioner, and will confuse the issues and waste the Board's time.

S. Exhibit 2052

Exhibit 2052 is the declaration of Bernd Meibohm, Dr. rer. nat. Petitioner

objects to ¶¶21–34, 36–45, 47–56, 58–63, 70–72, 74, 76–80, 91–92, and 94 of this declaration because they are not relevant. Patent Owner does not rely upon or even cite to these substantive paragraphs in the Response, rendering Dr. Meibohm's testimony in these paragraphs irrelevant under FRE 401. Petitioner therefore objects to these paragraphs under FRE 402. Petitioner also objects to this testimony under FRE 403 because it has no probative value, creates unfair prejudice to Petitioner, and will confuse the issues and waste the Board's time.

T. Exhibit 2054

Exhibit 2054 is the declaration of Nicholas Bodor, Ph.D. Petitioner objects to ¶¶11–17, 19–21, and 23–25 of this declaration because they are not relevant. Patent Owner does not rely upon or even cite to these substantive paragraphs in the Response, rendering Dr. Bodor's testimony in these paragraphs irrelevant under FRE 401. Petitioner therefore objects to these paragraphs under FRE 402. Petitioner also objects to this testimony under FRE 403 because it has no probative value, creates unfair prejudice to Petitioner, and will confuse the issues and waste the Board's time.

U. Exhibit 2055

Exhibit 2055 is the declaration of Yogesh Dandiker, Ph.D. Petitioner objects to ¶¶12–13, 19, and 21–22 of this declaration because they are not relevant. Patent Owner does not rely upon or even cite to these substantive paragraphs in the

Response, rendering Dr. Dandiker's testimony in these paragraphs irrelevant under FRE 401. Petitioner therefore objects to these paragraphs under FRE 402. Petitioner also objects to this testimony under FRE 403 because it has no probative value, creates unfair prejudice to Petitioner, and will confuse the issues and waste the Board's time.

V. Exhibit 2056

Exhibit 2056 purports to be a press release issued by Serono S.A. Petitioner objects to Exhibit 2056 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 13. Petitioner also objects to Exhibit 2056 under FRE 901 because Patent Owner fails to provide sufficient evidence indicating the origin or publication of the document, and accordingly fails to provide sufficient information regarding its authenticity.

W. Exhibit 2057

Exhibit 2057 purports to be a S.E.C. Form 20-F, filed by Serono S.A. Petitioner objects to Exhibit 2057 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 13. Petitioner also objects to Exhibit 2057 under FRE 901 because Patent Owner fails to provide sufficient evidence indicating the origin or publication of the document, and accordingly fails to provide sufficient

information regarding its authenticity.

X. Exhibit 2058

Exhibit 2058 purports to be an article published by the Wall Street Journal. Petitioner objects to Exhibit 2058 as containing inadmissible hearsay under FRE 801 and 802. Patent Owner relies upon it for the truth of the matter asserted. *See e.g.*, Response, at 13. Petitioner also objects to Exhibit 2058 under FRE 901 because Patent Owner fails to provide sufficient evidence indicating the origin or publication of the document, and accordingly fails to provide sufficient information regarding its authenticity.

Y. Exhibit 2060

Exhibit 2060 is a website publication by Fierce Pharma. Petitioner objects to Exhibit 2060 because it is not relevant. Patent Owner does not rely on or even cite this publication in the Response, rendering the publication irrelevant under FRE 401. Petitioner therefore objects to this publication under FRE 402. Petitioner also objects to this testimony under FRE 403 because it has no probative value, creates unfair prejudice to Petitioner, and will confuse the issues and waste the Board's time.

Z. Exhibit 2061

Exhibit 2061 is an article by the Canadian Cooperative Multiple Sclerosis Study Group, "The Canadian Cooperative Trial of Cyclophosphamide and Plasma Exchange in Progressive Multiple Sclerosis," in *The Lancet* 337 (1991). Petitioner

objects to Exhibit 2061 because it is not relevant. Patent Owner does not rely on or even cite this publication in the Response, rendering the publication irrelevant under FRE 401. Petitioner therefore objects to this publication under FRE 402. Petitioner also objects to this testimony under FRE 403 because it has no probative value, creates unfair prejudice to Petitioner, and will confuse the issues and waste the Board's time.

AA. Exhibit 2062

Exhibit 2062 is an excerpt from an article by J. W. Hainer et al., "Dosing in Heavy-Weight/Obese Patients with the LMWH, Tinzaparin: A Pharmacodynamic Study," in *Thromb Haemost* 817 (2002). Petitioner objects to Exhibit 2062 because it is not relevant. Patent Owner does not rely on or even cite this publication in the Response, rendering the publication irrelevant under FRE 401. Petitioner therefore objects to this publication under FRE 402.

BB. Exhibit 2063

Exhibit 2063 is an excerpt from the chapter "Clinical Pharmacodynamics & Pharmacokinetics," in *Textbook of Therapeutics: Drug and Disease Management* (8th Ed. 2006). Petitioner objects to Exhibit 2063 because it is not relevant. Patent Owner does not rely on or even cite this publication in the Response, rendering the publication irrelevant under FRE 401. Petitioner therefore objects to this publication under FRE 402.

CC. Exhibit 2070

Exhibit 2070 is a website publication from Mavenclad. Petitioner objects to Exhibit 2070 because it is not relevant. Patent Owner does not rely on or even cite this publication in the Response, rendering the publication irrelevant under FRE 401. Petitioner therefore objects to this publication under FRE 402. Petitioner also objects to Exhibit 2070 under FRE 901 because Patent Owner fails to provide sufficient evidence indicating the origin or publication of the document, and accordingly fails to provide sufficient information regarding its authenticity.

II. CONCLUSION

To the extent Patent Owner fails to correct the defects associated with the Challenged Evidence in view of Petitioner's objections herein, Petitioner may file a motion to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Eldora L. Ellison/

Eldora L. Ellison, Ph.D., Esq.
Registration No. 39,967
Lead Attorney for Petitioner

Date: 12/29/2023
1101 K Street, NW
10th Floor
Washington, DC 20005
(202) 371-2600

CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that the above-captioned **PETITIONER'S OBJECTIONS TO EVIDENCE** was served in its entirety on December 29, 2023, upon the following parties via email:

Emily R. Whelan (Lead Counsel)
Deric Geng (Back-up Counsel)
Cindy Kan (Back-up Counsel)
David Bassett (Back-up Counsel)
Vinita Ferrera (Back-up Counsel)
WILMER CUTLER PICKERING HALE AND DORR LLP
emily.whelan@wilmerhale.com
deric.geng@wilmerhale.com
cindy.kan@wilmerhale.com
David.Bassett@wilmerhale.com
Vinita.Ferrera@wilmerhale.com
WHMerckMavencladIPRs@wilmerhale.com

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Eldora L. Ellison/

Dated: December 29, 2023
1101 K Street, NW
10th Floor
Washington, DC 20005
(202) 371-2600

Eldora L. Ellison, Ph.D., Esq.
Registration No. 39,967
Lead Attorney for Petitioner