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 IPR2023-00481
Patent No. 8,377,903

PETITIONER'S OBJECTIONS TO EVIDENCE

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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.

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