

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 8,377,903

**PATENT OWNER'S OBJECTIONS TO PETITIONER'S ORAL HEARING
DEMONSTRATIVES**

Pursuant to the Board's May 21, 2024 Order Setting Oral Argument (Paper 50), Patent Owner, Merck Serono S.A., and Petitioner, Hopewell Pharma Ventures, Inc., have met and conferred regarding objections to the demonstratives on June 20, 2024. Patent Owner hereby submits the following objections to Petitioner's demonstrative slides:

1. Slide 41: Patent Owner objects to the Petitioner's presentation of "Fed. Cir. precedent belies Merck's contentions of new arguments" and citations to *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1008 (Fed. Cir. 2023) and *Rembrandt Diagnostics, LP v. Alere, Inc.*, 76 F.4th 1376, 1385 (Fed. Cir. 2023) as improper new argument to Patent Owner's sur-reply outside of the trial record.
2. Slide 42: Patent Owner objects to Petitioner's presentation of "Hopewell did not shift to a new obviousness theory to rely on Rice" as improper new argument to Patent Owner's sur-reply outside of the trial record.
3. Slide 43: Patent Owner objects to Petitioner's presentation of "Hopewell did not introduce a new argument regarding Bodor's bioavailability" as improper new argument to Patent Owner's sur-reply outside of the trial record.

4. Slide 44: Patent Owner objects to Petitioner's presentation of "Hopewell did not 'revise' its routine optimization argument" as improper new argument to Patent Owner's sur-reply outside of the trial record.

5. Slide 47: Patent Owner objects to Petitioner's presentation of its demonstrative chart, which presents new rebuttal arguments not present in Petitioner's chart provided in its Reply at 3-4; Patent Owner identifies by highlight the objectionable portions of Petitioner's demonstrative slide 47 in Appendix A.

Dated: June 21, 2024

Respectfully Submitted,

/Emily R. Whelan/

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APPENDIX A

Step 1: Merck addresses only Bodor’s “6-line dosing regimen” and ignores other relied-upon portions of Bodor (Pet. Reply, 3-4; Pet., 3-4, 7, 21-24, 33-36, 40-51, 54-60; EX1002, ¶¶17, 35-49, 60, 78-86, 91-139)

Relied-Upon Disclosures from Bodor	Petition Citations
Cladribine has been used to treat MS (EX1022, Abstract, 1:18-2:4)	22, 44, 47
Benefits of oral cladribine (EX1022, 2:9-19, 2:22-27, 5:1-7, 11-12)	3, 21-23, 33, 35, 40, 59
Bodor’s solid oral dosage form containing “a complex cladribine-cyclodextrin complex” (EX1022, 5:17-25, 6:3-4, 26:25-33:9)	23, 43, 54
MS treatment at dosages to achieve therapeutic results (EX1022, 22:1-26)	7, 41, 43-45
Bodor’s so-called “6-line dosing regimen” (EX1022, 23:15-20)	4, 23, 34-36, 40, 42-50, 55-60
Bodor’s alternative regimen with 18-month treatment-free period (EX1022, 23:21-24)	50-51
Fine-tuning cladribine’s dose and length (EX1022, 24:1-9)	24, 41-42, 47
Cladribine formulation improved absorption (EX1022, 33:10-36:8)	23
Cladribine tablets for treating MS (EX1022, Examples 1-5)	24, 33, 43-45

CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2024, I caused a true and correct copy of the
below documents:

- Patent Owner's Objections to Petitioner's Oral Hearing
Demonstratives
- Appendix A to Patent Owner's Objections to Petitioner's Oral
Hearing Demonstratives

to be served via e-mail, as consented to by Petitioner, to:

eellison-PTAB@sternekessler.com
opartington-PTAB@sternekessler.com
cvira-PTAB@sternekessler.com
jcrozendaal-PTAB@sternekessler.com
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