

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWI PHARMACEUTICALS, INC.,
Petitioner,

v.

MERCK SERONO S.A.,
Patent Owner.

Case IPR2023-00050
U.S. Patent 8,377,903

**PATENT OWNER'S OPPOSITION TO PETITIONER'S
MOTION FOR ADDITIONAL DISCOVERY**

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Petitioner improperly requests privileged communications between Drs. Bodor and Dandiker and their counsel, WilmerHale, including protected work product. Petitioner's request should be denied on this basis alone. Even if Petitioner were permitted to pierce both the declarants' privilege and related work product protections, Petitioner makes no attempt to demonstrate how its requested discovery would serve the interests of justice. On the contrary, Petitioner's requests should be denied as nothing more than a speculative fishing expedition.

I. Statement of Material Facts

Each of Petitioner's grounds in these IPRs relies on a single passage of the Bodor PCT. Pet. (Paper 1) 45-48. This passage of the Bodor PCT does not qualify as prior art, however, because the dosing regimen disclosed therein was made by the inventors of the challenged patents, not by Dr. Bodor or Dr. Dandiker.

Drs. Bodor and Dandiker are former employees of IVAX who partnered with Patent Owner's predecessor, Serono, to develop cladribine for treating MS. Ex. 2054, ¶18; Ex. 2055, ¶¶14-18. Drs. Bodor and Dandiker developed an oral formulation of cladribine. *Id.* Serono designed and ran clinical studies for treating MS with cladribine, including developing the regimens which Serono later patented. Ex. 2048, 2, 17-20; Ex. 2054, ¶13; Ex. 2055, ¶14. Even though "they

have no interest in the outcome of this matter whatsoever,”¹ Mot. (Paper 52) 6-7, Drs. Bodor and Dandiker each submitted a declaration confirming that they did not invent the cited dosing regimen; the Serono inventors did. Ex. 2054, ¶¶27-28; Ex. 2055, ¶¶25-29.

Each declarant sought WilmerHale’s legal advice regarding both preparation of their declarations, attesting that they did not invent any dosing regimen, and preparation for and representation at their depositions in these proceedings and related proceedings, *Hopewell Pharma Ventures, Inc. v. Merck Serono S.A.*, IPR2023-00480, IPR2023-00481, *Merck KGaA v. Hopewell Pharma Ventures, Inc.*, No. 22-1365 (Consolidated) (D. Del.). Dr. Bodor established an attorney-client relationship with WilmerHale as of October 18, 2023, and Dr. Dandiker

¹ Although Petitioner does not request them, communications between IVAX’s and Serono’s counsel regarding prosecution of the Bodor PCT, exchanged under a joint research agreement including developing a patent portfolio protecting cladribine for treating MS, Ex. 2048, are protected by common interest privilege. *In re Regents of Univ. of California*, 101 F.3d 1386, 1389 (Fed. Cir. 1996).

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