

Paper 11, April 27, 2023

In the United States Patent and Trademark Office

Before the Patent Trial and Appeal Board

TWI PHARMACEUTICALS INC.,

Petitioner,

v.

MERCK SERONO SA,

Patent Owner.

U.S. Patent No. 7,713,947 B2

Ser. No. 11/722,018

Issue Date: May 11, 2010

Title: Cladribine Regimen for Treating Multiple Sclerosis

Case No. IPR2023-00049

Patent No. 7,713,947 B2

**PETITIONER'S REQUEST FOR REHEARING OF DENIAL OF
INSTITUTION**

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REGULATIONS

37 C.F.R. § 42.712

I. Statement Of Precise Relief Requested

Petitioner TWi Pharmaceuticals Inc. respectfully requests rehearing of the Decision Denying Institution of *Inter Partes* Review, Paper 10 (“*Decision*”) because the *Decision* overlooked or misapprehended that it allows Patent Owner to remove from the public domain use of the very treatment disclosed in Bodor (Ex. 1029) ***on a patient of average weight*** and claim an exclusive property right in that previously disclosed treatment. The *Decision* overlooked or misapprehended the scope of the prior art references (including materials incorporated by reference therein) and mistakenly applied an inherency standard (where instead the claim reads directly on the prior art disclosure) to conclude, incorrectly, that the Petitioner has not demonstrated a reasonably likelihood of showing invalidity over the prior art. Petitioner respectfully requests that the Board grant rehearing and institute *inter partes* review of claims 36, 38–39, and 41–48 (“Challenged Claims”) of U.S. Patent No. 7,713,947 B2 (“the ’947 patent”) (Ex. 1001). This Request is timely filed within 30 days of the entry of the *Decision*.

It is undisputed that the Challenged Claims do ***not*** include a limitation requiring that the total dose of Cladribine during the “maintenance period” be lower than the total dose of Cladribine during the “induction period,” which the patent repeatedly characterizes as the invention. The patent never describes “weight-based” dosing as the invention but instead admits that expressing cladribine dosage in terms

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