Paper 9, 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. 8,377,903
Ser. No. 12/766,173
Issue Date: Feb. 19, 2013
Title: Cladribine Regimen for Treating Multiple Sclerosis

Case No. IPR2023-00050

Patent No. 8,377,903 B2

PETITIONER'S REQUEST FOR REHEARING OF DENIAL OF INSTITUTION

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TABLE OF AUTHORITIES

CASES

REGULATIONS

I. Statement Of Precise Relief Requested

Petitioner TWi Pharmaceuticals Inc. respectfully requests rehearing of the Decision Denying Institution of *Inter Partes* Review, Paper 8 ("*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 17, 19–20, and 22–29 ("Challenged Claims") of U.S. Patent No. 8,377,903 ("the '903 patent") (Ex. 1002). 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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