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Subject:	IPR2023-00049; IPR2023-00050; Request for Precedential Opinion Panel Review
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Attachments:	IPR2023-00050_Paper 09 2023.04.27 Petitioner"s Request for Rehearing ("903 Pat).pdf IPR2023-00049_Paper 11 2023.04.27 Petitioner"s Request for Rehearing ("947 Pat).pdf

IPR2023-0049, U.S. Patent No. 7,713,947 B2
IPR2023-0050, U.S. Patent No. 8,377,903 B2

April 27, 2023

Sent on Behalf of Philip D. Segrest, Jr.

Based on my professional judgment, I believe the panel decisions (*TWi Pharmaceuticals, Inc. v. Merck Serono S.A.*, No. IPR2023-00049 (P.T.A.B Mar. 28, 2023), Paper 10; *TWi Pharmaceuticals, Inc. v. Merck Serono S.A.*, No. IPR2023-00049 (P.T.A.B Mar. 28, 2023), Paper 8) are contrary to the following decision(s) of the Supreme Court of the United States, the United States Court of Appeals for the Federal Circuit, or the precedent(s) of the Board concerning the standard of anticipation:

- *Hewlett-Packard Co. v. Mustek Systems, Inc*., 340 F.3d 1314 (Fed. Cir. 2003),
- *UCB, Inc. v. Actavis Lab'ys UT, Inc.*, No. 2021-1924, 2021-2336, 2023 WL 2904757, *4 [65 F.4th 679] (Fed. Cir. 2023).

Petitioner for the above-referenced petitions for *Inter Partes* Review ("IPR") respectfully submits this request for Precedential Opinion Panel review of the panel Decisions in these two IPRs denying institution. The two patents are in the same family, and Petitioner relied on the same grounds in each petition for the respective challenged claims.

In particular, the Board's decision is contrary to controlling precedent that "a prior art product that sometimes, but not always, embodies a claimed method nonetheless teaches that aspect of the invention," *Hewlett-Packard*, 340 F.3d at 1326, and that "If the prior art discloses a point within the claimed range, the prior art anticipates the claim," *UCB*, 2023 WL 2904757, *4. Here, the panel erred by applying an inapplicable inherency standard to conclude that a prior art disclosure of a dosage that would meet or embody the claimed method for a person of average weight did not anticipate because it did not always embody the method for every disclosed dosage for all possible weights.

The pertinent limitation here in the Challenged Claims (claims 17, 19–20, and 22–29 of U.S. Patent No. 8,377,903 B2 and claims 36, 38, 39, and 41–48 of U.S. Patent No. 7,713,947 B2) recited "total dose of cladribine reached" during a certain period "is about 1.7 mg/kg." Petitioner's primary reference (Bodor, US 7,888,328 B2) disclosed, for an equivalent period, administering two courses of 5, 6, or 7 tablets of 10 mg each, resulting in a total dose of 100, 110, 120, 130, or 140 mg, depending on the exact combination administered, which could be selected based on various factors. A person of ordinary skill would recognize 70 kg (about 155 lbs) as an average weight of a patient, which for the 120 mg dosage would be about 1.71 mg/kg. Other prior art doses are also around 1.71 mg/kg for a person above or below that average (whether due to differences in gender, body type, or other), but of course not all doses for weights would result in a dose 1.71 mg/kg. In fact, the Examiner performed the exact same exercise during prosecution, using a hypothetical patient weight to demonstrate that Bodor taught these limitations. The patent was then allowed to issue because of a misunderstanding that all the claims required a lower total dose for a "maintenance period" than for an "induction period," but the challenged claims here at issue did not include that limitation.

Thus, just as in *Hewlett-Packard*, the method disclosed in Bodor sometimes, but not always, embodies the claimed method. Because these instances exist, Bodor anticipates the claims for the same reasoning as *Hewlett-Packard*. And because the prior art discloses a data point in the claimed range (in fact, multiple data points in the claimed range), it is anticipatory as explained in *UCB*.

The Board departed from this controlling precedent, reasoning as follows:

> To the extent that Petitioner provides examples to show that under certain very specific circumstances, Bodor's total dose of cladribine could reach an amount that equals about 1.7 mg/kg at the end of a treatment period for a particular patient, we do not find that showing persuasive in terms of establishing a reasonable likelihood of prevailing on an anticipation challenge. It is apparent to us that Petitioner's examples involve a strategic selection of patient weight and treatment duration that support a calculation that yields a 1.7 mg/kg total dosage for the treatment period. We agree with Patent Owner that such a strategy is insufficient to establish inherency as it demonstrates only the total dose that is possible for some patients. It is a long-standing principle that inherent anticipation requires the missing descriptive element to be "necessarily present," and not merely possibly present. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

No. IPR2023-00049, Paper 10, at 13; No. IPR2023-00050, Paper 8, at 13.

The Board's approach was legal error, contrary to controlling precedent. This case represented no issue of inherency. Instead, the prior art here expressly disclosed a dosage point that met the claim limitation for a person of average weight. That fact that other dosage points Bodor disclosed, and other weights of individuals, might or might not also meet that claim limitation does not matter, because "a prior art product that sometimes, but not always, embodies a claimed method nonetheless teaches that aspect of the invention," *Hewlett-Packard*, 340 F.3d at 1326.

Because the Board erred as described above, Petitioner respectfully requests the Precedential Opinion Panel review the panel decision, grant rehearing, and render a decision instituting *inter partes* review of the two Challenged Patents.

Respectfully submitted,

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