

CLIENT ALERT

PTAB Petitioner Permitted to Add a Real Party in Interest After One-Year Time Bar Due to "Interests of Justice"

JUNE 21, 2019

Mayne Pharma International PTY v. Merck Sharp & Dohme Corporation, No. 2018-1593 (Fed. Cir. June 21, 2019) The patent owner appealed a final written decision of the Patent Trial and Appeal Board (PTAB) in an *inter partes* review (IPR). The PTAB concluded that several claims of a patent directed to a pharmaceutical composition were unpatentable as anticipated or obvious. On appeal, the patent owner argued that the PTAB erred in two ways: (1) by instituting review instead of applying a time bar under 35 U.S.C. § 315(b) because the petitioner did not include its parent company as a real party in interest in its original mandatory notice; and (2) by declining to accept the patent owner's narrow constructions limiting the claims to nontoxic compositions that produce the claimed pharmacokinetic profile in humans. The Federal Circuit concluded that the PTAB did not err and affirmed the PTAB's decision invalidating the patent.

On the issue of a time bar, the PTAB allowed the petitioner to update its mandatory notice to include its parent company, without affecting the petition's filing date. The patent owner argued that the petitioner should not have been allowed to make such an amendment more than one year after the parallel district court litigation was filed. The Federal Circuit, like the PTAB, concluded that this amendment was permissible under the "interests of justice" provision in 37 C.F.R. § 42.5(c)(3) because both the petitioner and its parent company agreed to be bound by the effects of statutory estoppel and because the PTAB was properly apprised of conflicts. Further, neither the Federal Circuit nor the PTAB found any evidence of intentional concealment by the petitioner.

The Federal Circuit also agreed with the PTAB's broad claim constructions. Specifically, the Federal Circuit concluded that the term "pharmaceutical composition" was not limited to nontoxic compositions because the specification was silent as to this restriction, and that the term "in vivo" was not limited to humans because the specification explicitly defined the term to mean "in the living body of a plant or animal." A copy of the opinion can be found here.

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