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FDA Requires Reformulation and Recertification by Generic - Results in Dismissal of Declaratory Judgment Action

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On January 18, 2011, the United States District Court for the District of New Jersey, in *Paddock Laboratories, Inc. v. Ethypharm, S.A.*, an unpublished opinion, dismissed a declaratory judgment claim brought by an ANDA applicant because the FDA had required the ANDA applicant to reformulate its product and recertify to an Orange Book-listed patent.

Paddock submitted an ANDA seeking approval to market a generic version of Antara® (fenofibrate) capsules. *Paddock Labs., Inc. v. Ethypharm, S.A.*, Civ. No. 09-3799, 2010 WL 149860 at *3. Paddock's ANDA had initially contained a Paragraph IV certification to Orange Book-listed Patent No. 7,101,574 ("the '574 patent"). *Id.* Paddock then provided notice of its Paragraph IV certification to Ethypharm, which did not sue for patent infringement within the statutory 45-day period and obtain a 30-month stay of FDA approval of Paddock's ANDA. *Id.* Following expiration of the 45-day period, Paddock filed a declaratory judgment action against Ethypharm seeking a ruling that Paddock's proposed generic product did not infringe the '574 patent. *Id.* Ethypharm moved to dismiss. *Id.* at 1.

Paddock's ANDA product had the fenofibrate active ingredient coated on the exterior surface of Paddock's proposed capsule. *Id.* As a result, FDA found Paddock's product was not a "capsule" and thus not the same as Antara® capsules to which Paddock claimed bioequivalence. *Id.* Accordingly, FDA suspended review of Paddock's ANDA and recommended Paddock reformulate its product. *Id.* To comply with the definition of a capsule, Paddock placed its initial formulation inside an outer capsule and filed a Major Amendment to its ANDA describing this change. *Id.* Following Paddock's reformulation, FDA informed Paddock that it was now required to recertify to the '574 patent. *Id.*

In dismissing Paddock's declaratory judgment action, the New Jersey District Court reasoned that Paddock's recertification would be the only "active" certification at issue in the case. The Court stated that "[t]he Hatch-Waxman Act clearly contemplated that owners of pharmaceutical patents would have the opportunity to file suit in response to a new Paragraph IV certification." *Id.* at *4. Accordingly, Paddock's declaratory judgment action was contrary to the intent of the Hatch-Waxman Act because it would require the declaratory judgment defendants "to defend a lawsuit before they have even had the opportunity to bring a suit of their own in response to the new Paragraph IV certification and may ultimately require Defendants to participate in two cases when there is only one active Paragraph IV certification." *Id.*

This decision appears to be the first in which a court has declined declaratory judgment jurisdiction based on an FDA requirement that an ANDA applicant recertify to an Orange Book-listed patent. The FDA's requirement that Paddock reformulate its proposed ANDA product and recertify to an Orange Book-listed patent appears to be consistent with FDA's response to a recent Citizen's Petition concerning an ANDA applicant for generic Hectorol®, in which FDA required a different generic company to recertify to an Orange Book-listed patent following a formulation change.

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We welcome the opportunity to answer any questions you may have about this decision. Please do not hesitate to contact any of the following Paul Hastings New York lawyers:

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