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A Client Alert from Paul Hastings

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## *Patent Owner Protected by Safe Harbor Provision*

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The Federal Circuit issued a decision in *Boehringer Ingelheim International GmbH v. Barr Laboratories, Inc.*, reversing the district court's judgment of invalidity of U.S. Patent No. 4,886,812 ("the '812 patent") for obviousness-type double patenting. Appeal No. 2009-1032 (Fed Cir. Jan. 25, 2010). [View a copy of the decision here](http://www.cafc.uscourts.gov/opinions/09-1032.pdf) (http://www.cafc.uscourts.gov/opinions/09-1032.pdf).

The patent in suit (the '812 patent) covered the active ingredient in drug products sold by Boehringer Ingelheim under the trademark MIRAPEX® (pramipexole dihydrochloride). The appeal was from a decision by the District of Delaware finding Boehringer Ingelheim's patent invalid for obviousness-type double patenting.

On appeal, the Federal Circuit reversed the finding of invalidity. Although the Court found that a terminal disclaimer filed after expiration of the underlying reference patent was ineffective, the Court confirmed more generally that "a patentee may file a [terminal] disclaimer after issuance of the challenged patent or during litigation, even after a finding that the challenged patent is invalid for obviousness-type double patenting." (Slip Op. at 11.) The patent in suit was subject to a § 156 patent term extension, which resulted in the existence of patent term after the expiration of the underlying reference patent even with the filing of a terminal disclaimer.

The Federal Circuit further determined that the patent in suit was protected from obviousness-type double patenting under 35 U.S.C. § 121. The court held that "divisionals of divisionals" may be protected by § 121. (Id. at 20.) The Court further found that the divisional was filed "as a result of" a restriction requirement, and that the divisional was consonant with that requirement, discussing the PTO's definition of the independent and distinct invention groups in the restriction requirement.

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