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IN THE MEDIA

Caraco Asks for Rehearing from Federal Circuit on Injunction

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Steffen Johnson, a litigation partner in Winston & Strawn's Washington, D.C. office and a founding member of the firm's nationwide appellate and critical motions practice, was quoted in the *Law360* article titled "Groups Urge Fed. Circ. To Rethink Novo Nordisk Win," published June 3, 2010.

Mr. Johnson represents Caraco in *Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories Ltd., et al*. In an effort to introduce a generic version of Prandin, a diabetes drug manufactured by Novo, for two non-patented uses, Caraco asked the U.S. Food and Drug Administration (FDA) to approve its generic product. Due to Novo's broad patent description, implying that the Novo patent covers these two approved uses, the FDA rejected Caraco's application on the ground that Caraco was seeking approval for patented uses. This was not true, as Novo has conceded. The question before the court was whether Caraco could obtain an injunction requiring Novo to correct its patent description. The district court granted such an injunction, but the Federal Circuit, in a split-decision, disagreed. As per the Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act, the majority ruled that they correctly applied the law and Novo is not required to amend misleading patent descriptions submitted to the FDA.

Caraco has asked for a rehearing and various consumers and generics makers, such as Teva, Mylan, The Generic Pharmaceutical Association, Apotex, and Impax have filed amicus briefs urging for the Federal Circuit to review its ruling for Novo Nordisk. In response to these filings, Mr. Johnson stated that the high number of amicus filings in support of appellee Caraco Pharmaceutical Laboratories Ltd.'s request for a rehearing by the court underscores the importance of the case for both consumers and generics makers.

All five briefs focus on slightly different aspects of the court's decision.

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