PATTON BOGGS LLP

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U.S. Supreme Court Rules in Favor of Generic Drug Maker in ANDA Case

Intellectual Property Client Alert

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The U.S. Supreme Court unanimously ruled in favor of generic drug company Caraco Pharmaceutical Laboratories, finding that generic drug companies can file legal counterclaims against brand name drug companies to get generic drugs on the market faster. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844 (Apr. 17, 2012).

Novo Nordisk A/C, manufacturer of the brand-name Prandin diabetes drug, holds the patent which covers one of three uses approved by the Food and Drug Administration for the drug. Novo sued Caraco for patent infringement after it filed an abbreviated new drug application (ANDA) for its generic version of the drug, and also sought to market it for the two other uses. Novo then changed the "use code" for its patent, claiming that it covers all three of the FDA-approved methods for the drug. FDA regulations require brand manufacturers to supply a description of the scope of their patents, known as a use code, which is then published in a large volume known as the Orange Book. The FDA will not approve an ANDA if the proposed label overlaps with the brand-drug's use code.

Caraco filed a statutory counterclaim, seeking an order requiring Novo to correct its use code. Caraco argued that Novo's description was too broad, preventing Caraco from entering its generic drug into the market. The Federal Circuit held that Caraco lacked the statutory authority to assert its counterclaim. The Supreme Court overturned the appellate court, however, finding that a generic drug manufacturer may file a counterclaim to "force correction of a use code that inaccurately describes the brand's patent as covering a particular method of using a drug in question."

The decision is a victory for generic drug manufacturers, who can challenge overly-broad descriptions of patents that prevent the FDA from approving generic versions of drugs.

The *Caraco Pharmaceutical Laboratories* opinion can be found here.