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Intellectual Property Alert

The U.S. Supreme Court Allows Generic Drug Manufacturers to Use Counterclaims to Force Corrections of Overbroad Patent Use Codes

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On April 17, 2012, in *Caraco v. Novo Nordisk*, the U.S. Supreme Court overturned the Federal Circuit and ruled that a generic manufacturer may employ the Counterclaim Provision of the Medicare Modernization Act of 2003 ("MMA") to force a brand-name manufacturer to correct an overbroad use code that inaccurately describes the brand's patent. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844, 566 U.S. ___, slip op. at 2 (2012).

Background

Novo Nordisk A/S ("Novo") is the approval holder for Prandin® (repaglinide), a drug that was originally approved by the FDA for three uses to treat diabetes, including 1) by itself; 2) in combination with metformin; and 3) in combination with thiazolidinediones ("TZDs"). Novo has a patent with claims covering the use of repaglinide in combination with metformin, but does not have patent claims directed to its use either alone or in combination with TZDs.

Caraco Pharmaceutical Laboratories, Inc. ("Caraco"), a manufacturer of generic drugs, submitted an ANDA to the FDA to market a generic version of Prandin®. Caraco included a section viii statement asserting that it will market the drug for the two methods not covered by Novo's patent. At the time Caraco filed its section viii statement, Novo's use code for repaglinide stated "[u]se of repaglinide in combination with metformin to lower blood glucose." Novo subsequently changed its use code to "[a] method for improving glycemic control in adults with type 2 diabetes." Because Caraco's proposed label overlapped with Novo's broader use code, the FDA would not approve Caraco's ANDA to market a generic version of Prandin® for the two unclaimed methods of treating diabetes.

In the infringement lawsuit brought by Novo, Caraco asserted the Counterclaim Provision of the MMA, which allows a generic to "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or (c) on the ground that the patent does not claim ... an approved method of using the drug." The district court granted Caraco's request to force Novo to correct its use code — however, the Federal Circuit reversed, and found, on a narrow reading of the statute, that Caraco lacked a statutory basis to assert a counterclaim.

The Supreme Court's Decision

In the unanimous opinion authored by Justice Kagan, the Court examined the statutory language of the Counterclaim Provision. First, the Court examined the meaning of the phrase "patent does not claim ... an approved method of using." Novo argued that "not an" meant "not any," while Caraco stated that it meant "not a particular one." The Court found that the meaning depends upon the context of the sentence – and the statutory context supported Caraco's position. The Court stated "the statutory scheme ... contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."

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Second, the Court examined whether use codes are "patent information submitted by the brand under subsection (b) or (c)." Although the statute does not define "patent information," the Court found that use codes fit under the ordinary understanding of "patent information," in part because subsections (b) and (c) in the statute provide the basis for the FDA regulation requiring brands to submit use codes. Further, the Court interpreted the word "under" to be broad – it "reaches beyond that most barebones information to other patent materials the FDA demands in the regulatory process."

Justice Sotomayor wrote a separate concurring opinion to point out that the Counterclaim Provision "cannot restore the smooth working of a statutory scheme thrown off kilter by an overly broad use code." In these situations, a generic would have to submit an ANDA with a paragraph IV certification [infringe the patent], wait for the brand to initiate suit, file a counterclaim, litigate the counterclaim, and, if successful in securing the correction of the use code, return to the start of the process and ... file an ANDA with a section viii statement and a carve-out label. This route results in a huge delay and expense for the generic manufacturer, and further, there is no guarantee that the brand-name manufacturer will file suit. Justice Sotomayor stated "[a] fix is in order, but it must come from Congress or FDA."

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