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Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S Supreme Court Holds Generic Company Can Bring Counterclaim to Challenge Use Code

The U.S. Supreme Court, in a unanimous decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, No. 10-844 (U.S. Apr. 17, 2012), held that generic drug companies may counterclaim to challenge "use code" listings asserted against them by branded drug manufacturers. The Court reversed the Federal Circuit's ruling that generic drug companies had no litigation-based means to challenge incorrect or overbroad use code listings.

Case Background

Novo markets and distributes the drug repaglinide under the brand name Prandin. Repaglinide has been approved by the FDA for three uses related to diabetes. Prandin has two patents listed in the Orange Book: (1) a patent for the chemical composition of repaglinide, which expired on March 14, 2009; and (2) a use patent for the drug covering one of the three approved uses — repaglinide in combination with metformin — which expires on June 12, 2018. An Orange Book entry generally contains a patent number, a patent expiration date and a use code narrative describing the scope of the patented method. The FDA relies on the patent owner to accurately describe the Orange Book entry, including the scope of the patented method. Petition for Writ of Certiorari, *Caraco v. Novo*, __ U.S. __ (2011) (No. 10-844) ("The FDA lacks the authority and expertise needed to verify the patent information submitted by name-brand drug companies, however, so it defers to their descriptions of the scope of their patents.").

Caraco filed an abbreviated new drug application (ANDA) on February 9, 2005, for repaglinide. Novo, seeking to protect its use patent, initiated an infringement action against Caraco. Caraco stipulated that it was not seeking approval for repaglinide in combination with metformin and submitted a label to the FDA reflecting this. But, on May 6, 2009, Novo updated their use code narrative in the Orange Book from "U-546-Use of repaglinide in combination with metformin to lower blood glucose" to "U-968-A method for improving glycemic control in adults with type 2 diabetes mellitus." The FDA then disallowed Caraco's ANDA because the new use code narrative overlapped with the submitted label.

Caraco viewed this new use code narrative as overbroad because it suggested that the use patent covered all uses of repaglinide instead of only repaglinide in combination with metformin. On June 11, 2009, Caraco filed a counterclaim against Novo under 21 U.S.C. § 355(j)(5)(C)(ii), requesting an order requiring Novo to change the use code for the use patent back to U-546. Caraco then moved for summary judgment. The Hatch-Waxman Act enables a generic manufacturer to assert a counterclaim challenging the accuracy of the patent information in the Orange Book. 21 U.S.C. § 355(j)(5)(C)(ii)(I) ("[The ANDA] applicant may assert a counterclaim seeking an order … to correct or delete the patent information … on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug.").

The district court granted the motion finding that Novo had improperly filed an overbroad use code narrative and directing Novo to request the FDA to reinstate the original use code narrative.

The Federal Circuit reversed and vacated the district court judgment. Chief Judge Rader found that the statute only allows a counterclaim if the "listed patent does not claim any approved methods of using the listed drug." Because the patent covered one of the three approved methods, the court concluded a counterclaim was not available. The court further found that "patent information" as used in the act meant "the patent number and expiration date." Because the problem with the Orange Book entry was the use code narrative — not the patent number or expiration date — the court reversed and vacated the district court judgment.

The Court's Decision and Practical Guidance

A unanimous Court held that a generic manufacturer may employ 21 U.S.C. § 355(j)(5)(C)(ii) to "force correction of a use code that inaccurately describes the brand's patent as covering a particular method of using the drug in question." *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, No. 10-844, slip op. at 2 (U.S. Apr. 17, 2012). The Court found that the Hatch-Waxman Amendments authorize the FDA to approve generic drugs for unpatented uses, and section viii provides the ability for generics to identify those uses and provide a label that will allow them to quickly come to market. *Id.* at 13. The Court found that this statutory context contemplated one patented use not foreclosing the introduction of a generic, and the counterclaim "naturally functions to challenge the brand's assertion of rights over whichever discrete use (or uses) the generic company wishes to pursue." *Id.* As such, generic drug makers can utilize the counterclaim to correct brand use codes that are asserted against them while seeking FDA approval.

The Court further held that "patent information" in the statute — though not explicitly defined — must include the use codes. *Id.* at 15. The Court found that "patent information submitted under sections 355(b) or (c)" includes "everything (about patents) that the FDA requires brands to furnish in [those] proceedings." *Id.* at 17. The Court held that use codes are pivotal to the FDA's implementation of Hatch-Waxman and the overall regulatory scheme and "[a]n overbroad use code therefore throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates." *Id.* at 18. This interpretation gives content to the remedies of the counterclaim — correcting or deleting the erroneous patent information — and "enables courts to resolve patent disputes so that the FDA can fulfill its statutory duty to approve generic drugs that do not infringe patent rights." *Id.* at 18, 24.

Caraco allows generics an avenue for challenging what they perceive as overbroad or inappropriate use codes. Branded pharmaceutical companies may want to take additional steps to ensure that their entries are accurate to avoid the risk of counterclaim litigation for wrong or overly broad use code entries.

Attorney contacts appear on the next page.

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