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December 6, 2011

The Supreme Court Hears Oral Argument in *Caraco v. Novo Nordisk*: Decision Could Curtail Ability of Brand Drug Companies to Use Broad Patent Use Codes to Block ANDAs with Section viii Carve-Outs

By Stephanie Hsieh and Scott C. Moore

Oral arguments were presented yesterday to the U.S. Supreme Court in *Caraco v. Novo Nordisk*. While the case centers "simply" on an issue of statutory interpretation, the Court's decision will define another chapter in the saga of brand versus generic pharmaceutical manufacturers under the Hatch-Waxman Act.

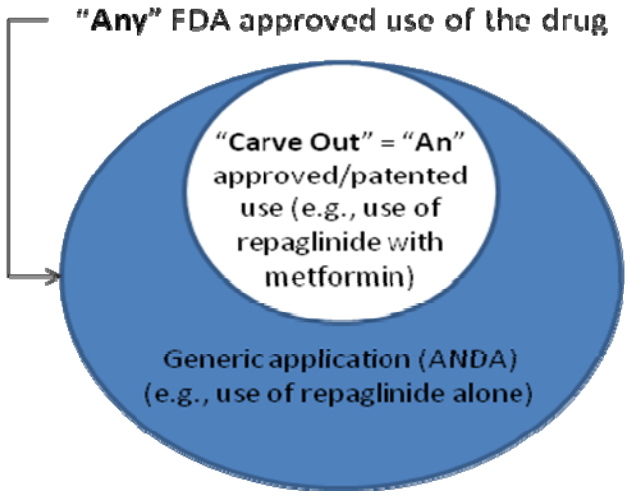
WHY TO WATCH THIS CASE

The complex regulatory framework of the Hatch-Waxman Act is designed to strike a delicate balance between innovation and competition in the pharmaceutical industry. The Supreme Court's decision in *Caraco v. Novo Nordisk* will have an important impact on that balance by either permitting patent holders to expand patent use code narratives in a manner that could impede approval of generic drug applications, or giving generic manufacturers a means by which to challenge the scope of patent use code narratives.

THE RELEVANT HATCH-WAXMAN FRAMEWORK

When a brand manufacturer files an application for a new drug (NDA) with the Food and Drug Administration (FDA), it is required to submit the patent numbers and expiration dates of any patents that claim the drug or methods of using the drug. If a patent happens to claim a method of using the drug, the FDA also requires that the brand manufacturer submit a description of those patented uses.[1] This description is referred to as the "use code narrative." The patent numbers, expiration dates, and any associated use code narratives are then published by the FDA in the "Orange Book," which serves as notice to generic manufacturers seeking approval of generic versions of the drug.

[1] 21 C.F.R. 314.53.



Where an approved brand-name drug has multiple uses, a generic manufacturer may carve-out from its drug application any of those uses that are patented, thereby avoiding exposure to a patent infringement suit. In determining whether or not the generic company's proposed carve-out is protected by a brand manufacturer's patent, the FDA compares the use of the drug that the generic proposes carving out to the use code narrative provided by the brand manufacturer—making the assumption that the narrative provided by the brand manufacturer accurately reflects the scope of the patent. If the brand manufacturer submits a use code narrative that is broader than its patent claims, such that it also encompasses unpatented uses, it could effectively block the generic manufacturer's use of the carve-out provision, forcing the generic manufacturer to either wait for the expiration of the patent or litigate a patent it never intended to infringe.

BACKGROUND OF THE CASE

Novo Nordisk markets the drug repaglinide under the brand name PRANDIN®. Repaglinide is approved for use alone or in combination with other drugs, such as metformin, to treat diabetes. The Orange Book listing for PRANDIN® includes U.S. Patent No. 6,677,358 (the '358 Patent), which claims a method of using repaglinide in combination with metformin for treating diabetes.

Caraco filed an abbreviated new drug application (ANDA) seeking approval of its generic version of PRANDIN®. In doing so, Caraco sought to carve out the use of repaglinide in combination with metformin, so that its product could be approved without running afoul of the '358 Patent. However, the use code narrative submitted by Novo, "[a] method for improving glycemic control in adults with Type 2 diabetes mellitus," did not reflect the '358 Patent's limitation to the use of the drug in combination with metformin. Because the FDA bases its carve-out decisions on the scope of the published use code narrative—and does not examine the scope of the underlying patent claims upon which it is based—the FDA did not permit Caraco to use the carve-out provision and refused to approve its ANDA.

Novo Nordisk sued Caraco, under the Hatch-Waxman Act, for infringement of the '358 Patent. Caraco counterclaimed, asking for summary judgment and an injunction that would require Novo Nordisk to correct its use code narrative to accurately reflect the '358 Patent's limitation to the use of repaglinide in combination with metformin.[2] The district court found that Caraco had a right to challenge the scope of the use code narrative submitted by Novo Nordisk and granted

[2] *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 656 F. Supp. 2d 729 (E.D. Mich 2009).

the injunction. However, the Federal Circuit reversed on appeal, holding that Caraco had no right to challenge the allegedly overbroad use code narrative in a district court action.[3]

THE HEART OF THE ISSUE

Caraco's challenge of Novo Nordisk's use code narrative was brought pursuant to the counterclaim provision of the Hatch-Waxman Act, which enables a generic manufacturer that is sued under the Act to "assert a counterclaim seeking an order requiring the [patent/NDA] holder to ***correct or delete the patent information*** submitted by the holder … 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."[4]

In reversing the district court, the Federal Court found that the counterclaim provision was not available to Caraco for challenging Novo Nordisk's use code narrative. In doing so, the Court interpreted two aspects of the provision:

i. The Court read "does not claim … an approved method" to mean does not claim *any* approved method of using the drug—such that the counterclaim provision is only available to the generic manufacturer if the patent in suit does not claim ***any*** approved method of using the drug; and

ii. "[P]atent information" that may be corrected or deleted by the counterclaim provision was interpreted as pertaining only to Orange Book-listed patent numbers and expiration dates, and not patent use code narratives.

THE ARGUMENTS PRESENTED TO THE SUPREME COURT

In its briefs, Caraco argued that "the Federal Circuit's readings of the phrases 'an approved method' and 'patent information' are foreclosed by the [Hatch-Waxman] Act's text, structure, and extensive legislative history."[5] According to Caraco, the Federal Circuit's interpretation of these two phrases "contravene[s] the broader structure and purpose of the Act and the patent laws."[6] Both Caraco and the Solicitor General posit that "[u]nder the Federal Circuit's decision, a brand-name manufacturer can effectively preclude generic competition by submitting an overbroad description of its method-of-use patent"[7]—effectively eliminating a generic manufacturer's ability to carve out the patented use. Another effect of the Federal Circuit's decision, according to Caraco, is to render moot the remedy of "correcting" patent information. If, as the Federal Circuit held, "patent information" is limited to the patent numbers and patent expiration dates listed in the Orange Book, the only correcting that remains possible would be of typographical errors.

On the other hand, Novo Nordisk took the position that "the counterclaim is a delisting provision; if a patent is properly listed in the Orange Book… then the counterclaim is not available."[8] In both its brief and yesterday's argument, Novo Nordisk focused on the FDA's express authorization of use code narratives based on "a description of each approved method of use or indication"[9] and the fact that its use code narrative, though not necessarily an accurate description of the patented use, was an accurate description of the indication for which PRANDIN® is approved.

With Justice Breyer commenting that "this is about the most technical statute I ever read," much of the questioning was

[3] *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F. 3d 1359 (Fed. Cir. 2010).
[4] 21 U.S.C. §355(j)(5)(C)(ii)(I) (emphasis added).
[5] *Brief for Petitioner*, No. 10-844, 2011 WL 3873257, at *41 (U.S. August 29, 2011).
[6] *Id.*
[7] *Brief for the United States as Amicus Curiae*, No. 10-844, at 11 (U.S. May 26, 2011) (the Solicitor General was invited by the Supreme Court to express the views of the United States).
[8] *Brief for Respondent*, No. 10-844, 2011 WL 4957382, at *19 (U.S. October 17, 2011).
[9] *Id.* (emphasis added).

directed to the "quandries" created by the statute and the interplay between patent law, the statute's provisions, and the FDA's role in executing those provisions. The issue of inadvertent expansion of patent rights via the use code narrative was addressed by several justices, with Justice Kagan summarizing the implications of Novo's position as follows:

> The statute read [Novo's] way essentially allows [Novo] to unilaterally expand the patent in areas in which it's quite clear that [the] patent ought not to go—does not go—but allows [Novo] to do that. So why should we read the statute so that it effects a purpose that is entirely antagonistic to the purpose that Congress had in passing this statute, given that the statute is at best from [Novo's] perspective ambiguous?

WILL THE SCALES TIP?

Yesterday the Justices pressed on the "parade of horribles" that could occur if the rules of the game are interpreted one way or another. The alternative of placing more onus on the FDA was explored, with the natural consequence being for a generic manufacturer in Caraco's position to sue the FDA under the Administrative Procedure Act. At the end of the day, however, the focus remained on effecting the most appropriate balance between innovation and competition consistent with the broader intent of the Hatch-Waxman Act and determining whose interpretation of the counterclaim provision keeps the reindeer games balanced.

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