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The Supreme Court Reverses the Federal Circuit's Decision in *Caraco v. Novo Nordisk*

Finding A Permissible Cause of Action for Challenging Brand Drug Companies' Tailoring of Use Codes to Block ANDAs with Section viii Carve-Outs

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The U.S. Supreme Court issued its decision in *Caraco v. Novo Nordisk*, holding that Hatch-Waxman permits generic drug companies to counterclaim to force correction of a use code that inaccurately describes the brand company's patent as covering a particular method of using the drug in question. While the case centered on an issue of statutory wording, the Court's decision depended upon the broader context of the Hatch-Waxman Act. In supporting its decision, the Court emphasized that "[t]he statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."¹

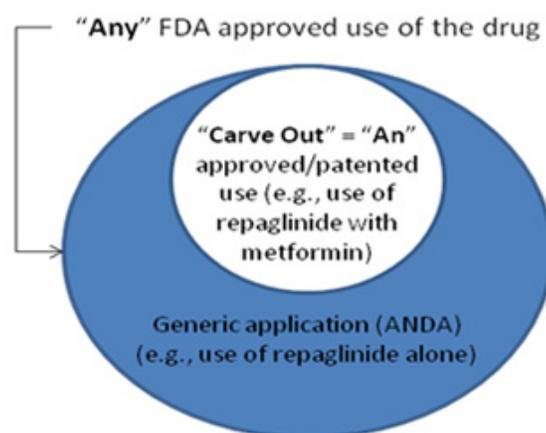
BACKGROUND

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 giving generic manufacturers a means by which to challenge the scope of a brand company's broadly drafted patent use code narrative designed to impede approval of generic drug applications.

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, FDA also requires that the brand manufacturer submit a description of those patented uses.² 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 FDA in the "Orange Book," which serves as notice to generic manufacturers seeking approval of generic versions of the drug.

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 avoids a brand



¹ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, No. 10-844, 566 U.S. ___, slip op. at 13 (U.S. Apr. 17, 2012).

² 21 C.F.R. 314.53.

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manufacturer's patent, 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 planned to challenge.

BACKGROUND OF THE CASE

Novo Nordisk ("Novo") 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®. The ANDA was filed with a so-called "paragraph IV certification"³ stating that the '358 Patent "was invalid or [would] not be infringed" by the generic.⁴ As permitted by the patent statute, Novo treated the ANDA filing as an act of infringement and sued. At the time, Novo's use code narrative indicated that the '358 Patent covered "[u]se of repaglinide in combination with metformin to lower blood glucose."⁵ The FDA thus suggested that Caraco file a "section viii statement,"⁶ carving out the patented use and seeking approval to market the generic only for approved, non-patented methods.⁷ After Caraco did so, however, Novo amended its use code narrative to describe "[a] method for improving glycemic control in adults with Type 2 diabetes."⁸ Because FDA bases carve-out decisions on the scope of published use code narratives without examining the underlying patent and Novo's new use code did not reflect the '358 Patent's limitation to the use in combination with metformin, FDA did not permit Caraco to use the carve-out provision.

In the pending infringement suit, Caraco then 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.⁹ The district court found that Caraco had a right to challenge the scope of the use code narrative submitted by Novo Nordisk and granted the injunction. 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.¹⁰

THE FEDERAL CIRCUIT'S DECISION

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

³ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

⁴ *Caraco Pharm. Labs.*, slip op. at 8.

⁵ *Id.*

⁶ See 21 U.S.C. § 355(j)(2)(A)(viii).

⁷ *Id.*

⁸ *Caraco Pharm. Labs.*, slip op. at 8, note 3. While Novo asserted that this change was made to correspond to a change in the drug's labeling required by the FDA, the Court noted that this request did not request or require amending the use code. *Id.* In a concurring opinion, Justice Sotomayor observed that due to ambiguity in regulations, "the company can hardly be faulted for" thinking that its amended use code complied with regulations, given the change in labeling. *Caraco Pharm. Labs.*, slip op. at Concurrence, page 4.

⁹ *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 656 F. Supp. 2d 729 (E.D. Mich 2009).

¹⁰ *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010).

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an order requiring the [patent/NDA] holder to *correct or delete* the *patent information* submitted by the holder *under subsection (b) or (c)* [of 21 U.S.C. § 355] 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.”¹¹

In reversing the district court, the Federal Circuit 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 phrases 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.
- (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 SUPREME COURT REVERSES THE FEDERAL CIRCUIT’S DECISION, HOLDING THAT CONGRESS MEANT TO FACILITATE THE APPROVAL OF NON-INFRINGEMENT GENERIC DRUGS

The Supreme Court reversed, interpreting the counterclaim provision more broadly and holding that it may be used to force a correction of a use code. The decision emphasized that the counterclaim provision was enacted to facilitate approval of non-infringing generic drugs, and thus should be available to challenge use codes that extend beyond patented methods of use.¹²

“An approved method” means “a particular approved method” and “patent information” includes use codes.

Calling the counterclaim provision not “altogether free of ambiguity,” the Supreme Court looked to the statutory context to interpret the phrases construed by the Federal Circuit.¹³ As to the first phrase, the Court noted that “not an” *can* mean “not any” as Novo had argued, but in other contexts means “not a particular one.”¹⁴ The Court said that certain portions of the Hatch-Waxman Act showed Congress’ understanding that a given patent may cover only certain method(s) of a drug’s use.¹⁵ The Court emphasized that the Act itself permits carve-outs and approval of generic drugs for unpatented uses.¹⁶ It reasoned that in this context, the counterclaim provision naturally allows a generic company pursuing a particular use to challenge a brand company’s assertion of rights over that use, which “after all, is the thing blocking . . . entry on the market.”¹⁷ The Court could not accept that Congress meant to allow a counterclaim in a case where the brand has *no* patent, but not where the brand has only “a patent for a method of use in which neither [the generic] nor the FDA is interested at all.”¹⁸ Thus, the Court held that in this context, “an approved method” meant “a particular approved method,” consistent with the application of this provision to use code challenges.

¹¹ 21 U.S.C. § 355(j)(5)(C)(ii)(I) (emphasis added).

¹² *Caraco Pharm. Labs.*, slip op. at 24.

¹³ *Id.* at 10.

¹⁴ *Id.* at 11–12.

¹⁵ *Id.* at 13 (citing 21 U.S.C. § 355(b)(1) (requiring an NDA applicant to file information about “any patent which claims the drug . . . or which claims a method of using such drug).

¹⁶ *Id.* at 13.

¹⁷ *Id.* at 13.

¹⁸ *Id.* at 14.

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On the question of whether use codes qualify as “patent information submitted by the [brand] under subsection (b) or (c)” of § 355, the Court again sided with Caraco. Quickly concluding that use codes qualified as “patent information,”¹⁹ the Court focused on whether they were the type of information “submitted under subsection (b) or (c).” The Court rejected Novo’s argument that this phrase encompassed only information expressly required by subsections (b) and (c)—namely patent numbers and expiration dates.²⁰ The Court cited its own prior decisions and narrower phrasing in adjacent subsections to support a broader interpretation.²¹ In the Court’s view, this phrase covers not only information required by the subsections, but also information required by regulations designed to implement them, including those requiring submission of use codes.²²

The Court pointed to remedies provided by the counterclaim provision as further support for its statutory interpretation. The counterclaim provision allows the claimant to seek an order forcing the brand to “correct or delete” the offending patent information.²³ In the Court’s view, interpreting “not . . . an” as “not any” or restricting “patent information” to patent numbers and expiration dates “would all but read the term ‘correct’ out of the statute.”²⁴

The Court rejects Novo’s drafting history arguments and finds a greater need for a counterclaim in the case of an overbroad use code.

The Court also rejected two arguments by Novo that drafting history supported a more narrow interpretation. Novo had cited Congress’ failure to pass earlier legislation, which would have required brands to submit descriptions of method-of-use patents and allowed generic companies to file suit challenging those descriptions.²⁵ The Court was not persuaded that failure to pass this bill foreclosed a broad interpretation of the counterclaim provision.²⁶ In the Court’s view, the bill could have been rejected for any number of reasons and would have carried “stronger medicine” than the current counterclaim provision by allowing generic companies to bring independent causes of action.²⁷ Finally, the Court pointed out that between failure of the first bill and enactment of the counterclaim provision, FDA had adopted its use code requirements.²⁸ The Court reasoned that if anything, this historical observation suggested that Congress intended the provision to enforce this new use code requirement.²⁹

The Court also was not convinced that Congress meant the counterclaim provision to address only the result of *Mylan Pharmaceuticals, Inc. v. Thompson*.³⁰ *Mylan* had held that no action was available to force delisting of a patent not

¹⁹ *Id.* at 15, note 7 (rejecting Novo’s argument that a use code may sweep more broadly than a patent based on the FDA’s express authorization of use code narratives based on “a description of each approved method of use or indication”).

²⁰ *Id.* at 16.

²¹ *Id.* at 17 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 667 (1990); *Ardestani v. INS*, 502 U.S. 129, 135 (1991); 21 U.S.C. §§ 355(c)(2) (“patent information described in subsection (b)”), 355(d)(6) (“patent information prescribed by subsection (b)”).

²² *Caraco Pharm. Labs.*, slip op. at 17.

²³ 21 U.S.C. § 355(j)(5)(C)(ii)(I).

²⁴ *Caraco Pharm. Labs.*, slip op. at 18–19 (noting that such narrow interpretations would leave correction of typographical errors in numbers or expiration dates as the only possible type of “correction”).

²⁵ *Caraco Pharm. Labs.*, slip op. at 20.

²⁶ *Id.* 21–22.

²⁷ *Id.* at 21–22.

²⁸ *Id.* at 21–22.

²⁹ *Id.* at 21–22.

³⁰ 268 F.3d 1323 (Fed. Cir. 2001)

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covering an approved drug or a method of its use.³¹ In the Court's view, even if *Mylan* had prompted the counterclaim provision, it simply had "alerted Congress to a broader problem—that generic companies generally had no avenue to challenge the accuracy of brands' patent listings, and that FDA therefore could not approve proper applications to bring inexpensive drugs to market."³² The Court saw this problem as applicable to overbroad use codes and refused to restrict the provision to the situation in *Mylan*.

In fact, the Court reasoned that the need for the counterclaim is even greater in the case of an overbroad use code. The Court noted that unlike in the situation in *Mylan*, a Paragraph IV certification does not provide an avenue to approval of a generic drug for a non-patented use. The Court explained that where a patent does not cover any use of the drug, the generic manufacturer can simply file its ANDA with a Paragraph IV certification, stating that the listed patent "is invalid or will not be infringed."³³ A Paragraph IV certification requires labeling of the generic that is identical to that of the brand, meaning that it cannot carve out a patented use. Thus, the Court reasoned that a Paragraph IV certification would not be a viable option in this situation, leaving the counterclaim as the only available route to bring a generic drug to market for noninfringing uses.³⁴

Justice Sotomayor's concurrence

In a concurring opinion, Justice Sotomayor agreed that the counterclaim provision should be available to challenge use codes, but noted that this interpretation would not completely remove various "difficulties created by an overly broad use code."³⁵ The concurring opinion notes the delay and expense involved in obtaining approval of a generic drug for a non-patented use in this context and urges FDA and/or Congress to provide some guidance as to what exactly is required in a use code.³⁶

To view the Court's opinion, click [here](#).

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³¹ *Caraco Pharm. Labs.*, slip op. at 22–24.

³² *Id.* at 23–24 (noting that the statutory language and context discussed in the opinion supports this conclusion).

³³ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

³⁴ *Caraco Pharm. Labs.*, slip op. at 24.

³⁵ *Caraco Pharm. Labs.*, slip op. at Concurrence, page 1.

³⁶ *Caraco Pharm. Labs.*, slip op. at Concurrence, page 4–5.

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