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**April 19, 2012**

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# Hatch-Waxman Counterclaim Provision Allows Generic Drug Maker to Force Correction of Brand's Orange Book-Listed Use Code, Supreme Court Rules

***By Andrew J. Kozusko, III and Lauren J. Grous***

On April 17, 2012, the Supreme Court resolved an important, long-standing question under the Hatch-Waxman Act. While the Act provides that an ANDA applicant sued for patent infringement may bring a counterclaim seeking an order requiring the brand manufacturer to "correct or delete the patent information [it] submitted... on the ground that the patent does not claim… an approved method of the drug," 21 U.S.C. § 355(j)(5)(C)(ii)(I), the Federal Circuit had never breathed life into this section. In the unanimous *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk, A/S* decision, the Supreme Court held that an ANDA applicant may employ this provision to force correction of a use code that inaccurately describes the brand manufacturer's patent as covering a particular method of using the drug in question.

## The Underlying Dispute and Proceedings Below

The Supreme Court's decision arose from the Prandin® (repaglinide) ANDA litigation between Novo Nordisk, A/S ("Novo"), the NDA holder, and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), the first generic to file an ANDA. FDA had approved Prandin® to treat diabetes with: (i) repaglinide alone; (ii) repaglinide in combination with metformin; and (iii) repaglinide in combination with thiazolidinediones such as pioglitazone (TZDs). Novo's patent for the repaglinide compound itself expired in 2009 (the "'035 patent"), leaving Novo with a method-of-use patent claiming a "method for treating [diabetes by] administering… repaglinide in combination with metformin" (the "'358 patent"), which expires in 2018. No patents have issued for the use of repaglinide alone or in combination with TZDs.

In 2005, Caraco filed its ANDA, which sought approval to sell repaglinide for its unpatented methods of uses. Indeed, at the time Caraco filed its ANDA, Novo's use code for the '358 patent limited the patent to "[u]se of repaglinide in combination with metformin to lower blood glucose." At FDA's direction, Caraco filed a "section (viii) statement," instead of a patent certification, to the '358 patent, with proposed labeling carving out Novo's patented metformin combination therapy.

Later, Novo changed its Orange Book-listed use code for the '358 patent, expanding its scope to include all three FDA-approved methods of using repaglinide to treat diabetes, thereby rendering Caraco's proposed carve-out insufficient, and requiring the filing of a Paragraph IV patent certification instead of a "section (viii)" statement. In response, Caraco filed a counterclaim under § 355(j)(5)(C)(ii)(I), seeking an order requiring Novo to "correct" its use code on grounds that the '358 patent does not claim two approved methods of using repaglinide (alone and in combination with TZDs).

While the district court ordered Novo to correct its use code, the Federal Circuit reversed, holding that Caraco lacked "a statutory basis to assert a counterclaim" and, further, determining that the counterclaim provision did not reach use codes because they are not "patent information submitted by the [brand] under subsection (b) or (c) [of § 355]." The Supreme Court granted certiorari and, in a decision authored by Justice Elena Kagan, reversed the Federal Circuit's decision on both grounds.

## The Statutory Context Supports Use Correction

The Court first addressed Caraco's ability to pursue a counterclaim pursuant to Section 355(j)(5)(C)(ii)(I), which permits an ANDA applicant to file such a claim "on the ground that the patent does not claim… an approved method of using the drug." Based on the statutory context, the Court concluded that the phrase "not an" means "not a particular one," the interpretation urged by Caraco, as opposed to "not any," the interpretation espoused by Novo and the Federal Circuit. According to the Court, the Hatch-Waxman Act[1] contemplates that one patented use will not foreclose marketing a generic drug for other unpatented uses; the counterclaim "naturally functions" to challenge the brand manufacturer's assertion of rights over whichever discrete use or uses the generic company desires to pursue. Thus, generic manufacturers may now reinforce their carve outs with counterclaims showing that unpatented uses have been improperly listed in the Orange Book.

## Patent Information "Submitted Under" Subsections (b) or (c) Includes Use Codes

The Court also addressed Novo's contention that the counterclaim does not provide a mechanism to correct use codes because such codes are not "patent information submitted by the [brand] under subsection (b) or (c)" of § 355. Acknowledging that the statute does not define "patent information," the court nevertheless held that information "submitted under" is not limited to patent numbers and expiration dates, the information required by subsections (b) and (c). Rather, the Court held that use codes are among the information "submitted under" as part of the "comprehensive scheme of regulation" premised on those subsections. In the Court's view, such information encompasses everything about patents, including, as is relevant here, use codes. Indeed, limiting the information to patent numbers and expiration dates would effectively delete "correct" out of the counterclaim's statutory text and, by extension, would foreclose that statutorily provided-for remedy from being pursued.

## The Purpose of the Counterclaim

Finally, the Court affirmed the purpose of the counterclaim and its importance in bringing a generic drug to market. Significantly, where, as in the case before it, a brand files an overbroad use code, a generic manufacturer cannot use the "section (viii)" statement to obtain FDA approval of a non-infringing product. Any label proposed by the generic manufacturer will necessarily infringe the brand's patent, as defined by the overly broad use code, and require a Paragraph IV certification. As illustrated by Caraco's dispute with Novo, the counterclaim, therefore, is the generic manufacturer's only route to market for non-infringing uses, and, further, enables FDA to fulfill its statutory duty to approve generic drugs that do not infringe patent rights.

[1] Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, amending the Federal Food, Drug, and Cosmetic Act of 1938.

## Conclusion

The Court's decision will undoubtedly have important ramifications in the pharmaceutical industry. Namely, it will affect lifecycle management for proprietary products and will influence product development and certification strategies for generics. If you have any questions regarding the Court's opinion, or its impact, please contact Andrew J. Kozusko, III listed below.

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