Patent Litigation Alert

Supreme Court Allows Generic Manufacturers To Challenge Overbroad Use Codes

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The United States Supreme Court has again reversed the Federal Circuit, ruling unanimously that a generic drug manufacturer may file a counterclaim to force correction of an overbroad use code that encompasses unclaimed methods of using the drug at issue. In interpreting the text of 21 U.S.C. § 355(j)(5)(C)(ii)(I), the Court in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, No. 10-844, 566 U.S. __ (2012), gave substantial weight to ensuring that the FDA fulfill its statutory duty to approve non-infringing generics in accord with Congressional intent. Brand manufacturers are advised to review active use codes to ensure that they reasonably reflect the scope of any claimed methods of use.

STATUTORY AND REGULATORY FRAMEWORK

When a brand manufacturer seeks to market a new drug, it must file a New Drug Application ("NDA") with the FDA detailing clinical studies of the drug's safety and efficacy. As part of this process, the brand manufacturer must identify by number and expiration date all patents that claim the drug or any methods of using that drug. 21 U.S.C. § 355(b)(1), (c)(2). For any patent claiming a method of use, the FDA also requires that the brand manufacturer describe the claimed methods, a description commonly referred to as the "use code." 21 C.F.R. § 314.53(c)(2)(ii)(P)(3), (e). The FDA does not verify the accuracy of use codes, instead viewing its role as purely ministerial.

In order to facilitate the approval of generic pharmaceuticals, and thus speed the availability of less expensive prescription drugs to the public, the Hatch-Waxman Amendments allow generic manufacturers to bypass clinical testing by relying, in an Abbreviated New Drug Application ("ANDA"), on the safety and efficacy studies originally submitted by the brand manufacturer. An ANDA filer seeking to market a generic equivalent prior to the expiration of a patent covering either the brand-name drug or a method of use for that drug then has two choices.

First, the generic manufacturer can make a "Paragraph IV certification," thereby asserting that any such patents are invalid or will not be infringed. A Paragraph IV certification is considered an act of infringement, and the brand manufacturer has 45 days from its filing to initiate litigation against the generic manufacturer. If the brand manufacturer fails to file suit, the FDA may approve the ANDA (although this would still allow the brand manufacturer to later file a typical patent infringement lawsuit based on sales of the generic manufacturer's drug). If the brand manufacturer sues based on the ANDA filing, then the FDA may not approve the ANDA until whichever of the following occurs first — expiration of the patent, resolution of the litigation, or thirty months.

Alternatively, the generic manufacturer can seek FDA approval for a use not covered by the patents by making a "section viii statement" and submitting a proposed label to the FDA omitting the patented method of use. This alternative route is typically used when the brand manufacturer's patent on the drug itself has expired, but patents claiming methods of using the drug remain. The FDA can only approve a section viii statement, however, if there is no overlap between the proposed carve-out label and the use code for the brand-name drug.

Following reports that brand manufacturers were exploiting the framework established by the Hatch-Waxman Amendments in order to prevent or delay competition from generic drugs, Congress created a mechanism for generic manufacturers engaged in Paragraph IV litigation to challenge the accuracy of the patent information submitted by brand manufacturers to the FDA:

> [The ANDA] applicant may assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the holder under

> subsection (b) or (c) of this section 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.

21 U.S.C. § 355(j)(5)(C)(ii)(I). At issue in this case was whether a generic manufacturer has the right to bring such a counterclaim to correct an overbroad use code.

BACKGROUND OF THE CASE

Novo Nordisk filed suit against Caraco in 2005 alleging infringement of U.S. Patent No. 6,677,358 ("the '358 patent") after Caraco filed an ANDA for generic repaglinide with a Paragraph IV certification. Repaglinide, which is marketed by Novo Nordisk under the brand name PRANDIN®, has been approved by the FDA for three uses with respect to improvement of glycemic control in adults with type 2 diabetes: (1) repaglinide by itself; (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones. The '358 patent is the sole unexpired Novo Nordisk patent relating to repaglinide, and claims only the second use, i.e., repaglinide-metformin combination therapy.

In 2008, Caraco stipulated that its ANDA would infringe the '358 patent if it included a label for repaglinide administered in combination with metformin, and sought FDA approval for a label omitting such combination therapy. As explained above, however, the FDA can only approve such a "carve-out" label if it does not overlap with the use code submitted by the brand manufacturer. Although the original use code for the '358 patent was limited to the claimed repaglinide-metformin combination therapy, Novo Nordisk subsequently amended the use code to broadly encompass "[a] method for improving glycemic control in adults with type 2 diabetes mellitus." This new use code thus encompassed all three FDA-approved uses. As a result, although the FDA initially indicated that it would approve Caraco's proposed carve-out label, it declined to do so following Novo Nordisk's amendment of the use code.

Caraco sought to force Novo Nordisk to reinstate the original use code by filing a counterclaim pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I) in the ongoing Paragraph IV litigation. The district court entered an injunction ordering Novo Nordisk to request that the FDA reinstate the original use code. On appeal, however, the Federal Circuit vacated the injunction, finding that Caraco did not have a statutory basis to request such relief. The U.S. Supreme Court granted *certiorari*, and oral argument was held on December 5, 2011.

THE SUPREME COURT'S DECISION

In adopting a sweeping construction of the counterclaim provision to encompass challenges to overbroad use codes, the Court considered three key phrases in the governing statute.

First, the Court interpreted "on the ground that the patent does not claim . . . *an* approved method of making the drug" to mean "on the ground that the patent does not claim . . . *a particular* method of making the drug." In so doing, the Court rejected the primary basis on which the Federal Circuit rested its opinion — that this phrase should be interpreted to mean "on the ground that the patent does not claim . . . *any* approved method of making the drug." The Court noted that the meaning of "not an" depends on its context and provided several examples, including the following:

> [I]f a sports-fan friend bemoans that "the New York Mets do not have a chance of winning the World Series," you will gather that the team has no chance whatsoever (because they have no hitting).[1] But now stop a moment. Suppose your spouse tells you that he got lost because he "did not make a turn." You would understand that he failed to make a particular turn, not that he drove from the outset in a straight line.

1 Mets fans would note that the Mets are off to a 7-3 start this year.

The Court further observed that its broad reading ensured that the scope of the counterclaim right would match the availability of FDA approval under the statute, which "contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."

Second, the Court interpreted "patent information submitted by the holder under [21 U.S.C. § 355(b) or (c)]" to include not only the information specified in those statutory subsections — namely, the patent number and expiration date of any patent claiming the drug or its method of use — but also any patent information required by regulations implemented pursuant to § 355. As these implementing regulations require submission of use codes, the counterclaim provision encompasses this descriptive information also:

> Use codes are pivotal to the FDA's implementation of the Hatch-Waxman Amendments — and no less so because a regulation, rather than the statute itself, requires their submission. Recall that those Amendments instruct the FDA (assuming other requirements are met) to approve an ANDA filed with a section viii statement when it proposes to market a drug for only unpatented methods of use. To fulfill that charge, the FDA must determine whether any patent covers a particular method of use; and to do that, the agency (which views itself as lacking expertise in patent matters) relies on the use codes submitted in the regulatory process. An overbroad use code therefore throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates.

The Court thus again turned to Congressional intent to defend its broad interpretation of the "patent information" subject to deletion or correction via the counterclaim provision.

Third, the Court observed that the counterclaim provision provides two independent remedies — deletion and correction — and that its reading gives effect to both. By contrast, if the counterclaim only applied to patent numbers and expiration dates, the term "correct" would be effectively read out of the statute. For example, where the brand manufacturer owns a patent claiming a relevant method of use, the brand manufacturer will have every incentive to correct the patent number if it is provided incorrectly to the FDA. On the other hand, a manufacturer seeking to market a generic version of the same drug would have no incentive to bring the mistake to a court's attention via the counterclaim provision.

Having dispensed with textual interpretation, the Court also rejected the contention that a narrow construction of the counterclaim provision was mandated by its drafting history. Admittedly, Congress had previously considered but failed to enact a bill that would have required brand manufacturers to submit a description of claimed methods of use, and would have furthermore created an independent cause of action allowing a generic manufacturer to challenge overbroad descriptions of a patent. But even setting aside the fact that the proposed legislation could have been rejected for any number of untold reasons, the drafters of the counterclaim provision later enacted were aware that the FDA had in the meantime issued a rule requiring brand manufacturers to supply such descriptions in the form of use codes. Accordingly, there was no need to statutorily duplicate what was already required by regulation. Moreover, Congress was aware when enacting the counterclaim provision "that generic companies generally had no avenue to challenge the accuracy of brands' patent listings, and that the FDA therefore could not approve proper applications to bring inexpensive drugs to market." The evolution of the statutory framework ultimately adopted by Congress thus supports an intent to enforce the use-code requirement through the counterclaim provision.

Not until the end of its opinion does the Court touch on what likely motivated its sweeping interpretation of the counterclaim — the lack of an effective forum for addressing overbroad use codes were it to reach a contrary holding. Because a Paragraph IV certification requires that the generic drug be labeled in the same way as the brand drug, no carve-out label can be devised in light of an overbroad use code, and infringement would be unavoidable. The Court thus concludes that "the counterclaim offers the *only* route to bring the generic drug to market for non-infringing uses."

JUSTICE SOTOMAYOR'S CONCURRENCE

Perhaps most interesting is the concurrence filed by Justice Sotomayor emphasizing the deficiencies of the current statutory and regulatory framework. In effect, Justice Sotomayor asks Congress and the FDA to strengthen and clarify the mechanism by which generic manufacturers challenge overbroad use codes.

With respect to the counterclaim provision, Justice Sotomayor notes that a generic manufacturer can only file a counterclaim challenging an overbroad use code if the brand manufacturer first initiates Paragraph IV litigation. Even setting aside the expense and length of such litigation, a loophole exists — the brand manufacturer may decline to file suit in response to a Paragraph IV certification. If so, the FDA may approve the ANDA with a label materially identical to that of the brand-name drug, and without prejudice to any infringement claims that the brand manufacturer might bring upon production or marketing of the generic drug. This situation thus sets the stage for the generic manufacturer to induce infringement of the method-of-use patent, which, as Justice Sotomayor dryly notes, "is not a position I imagine a generic manufacturer wants to be in."

Justice Sotomayor also criticizes the FDA's regulatory guidance as "remarkably opaque." In particular, Justice Sotomayor faults the FDA for limiting use codes to no more than 240 words, and for promulgating regulations that suggest that use codes may describe either a claimed method of use or an approved indication.

IMPLICATIONS

It remains to be seen whether Congress and the FDA will accept Justice Sotomayor's challenge. In the meantime, it seems likely that counterclaims alleging overbroad use codes will be raised in Paragraph IV litigations where the use code does not precisely reflect the claimed method of use. Such situations may be more common than expected given the FDA's 240-word limit. In addition, buried within a footnote in today's opinion is an explicit rejection of Novo Nordisk's contention that a use code may describe either an approved method of use *or indication*. Brand manufacturers are thus advised to review active use codes to ensure that they reasonably reflect the scope of any claimed methods of use.

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