U.S. Supreme Court Unanimously Upholds Generic Drug Makers’ Right to Correct Inaccurate Brand Patent Descriptions

In its first-ever case construing the Hatch-Waxman Act’s provisions governing competition between generic and brand-name drug makers, the United States Supreme Court on Tuesday handed a major victory to the generic drug industry. By a vote of 9-0, the Court reversed the Federal Circuit and held that generic drug makers such as Winston clients Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd., may “force correction” when “the brand submits misleading patent information to the FDA.” The case, *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, was closely watched in the $300 billion pharmaceutical industry because manipulating patent descriptions—known as “use codes”—had become a favored method for “exploiting” the Act to “prevent or delay the marketing of generic drugs.”

The case began with the brand (here, Novo Nordisk A/S) seeking to extend the life of an expired compound patent by relying on a lingering method patent—here, one protecting a method of administering the diabetes drug repaglinide. After Novo sued, claiming infringement, Caraco filed with the FDA what is known as a “Section viii” statement “carving out” from its label the infringing use—which prompted FDA to tentatively approve the marketing of Caraco’s product. But Novo frustrated that result by suddenly broadening its description of the patent to cover Caraco’s non-infringing uses, leading FDA to reject Caraco’s attempted “carve-out.”

In response, Winston invoked the Hatch-Waxman counterclaim, which provides a remedy for fixing incorrect patent information, and obtained an injunction commanding Novo to correct its patent description. On appeal to the Federal Circuit, the question was whether the Act’s counterclaim authorizes such corrections. A fractured panel of that Court said it does not.

Winston then succeeded in convincing the Supreme Court to hear the case. And, in a unanimous opinion by Justice Elena Kagan, the Supreme Court reversed. As the Court noted, the statute provides that a generic “may assert a counterclaim seeking an order requiring the [brand manufacturer] to correct or delete the patent information [it] submitted … under [two statutory subsections] 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). According to Novo, Caraco could not invoke this provision for two reasons—both of which the Court rejected.

First, Novo argued that “the counterclaim is available only if the listed patent does not claim any (or, equivalently, claims no) approved method of using the drug.” And because its patent technically claimed an approved method of using the drug—albeit not a method Caraco sought to market—Novo argued that the counterclaim was not available. Relying on multiple examples of usage provided by Winston, the Court held that this usage was too hidebound, because “[w]hen it comes to the meaning of ‘not an,’ context matters.” And with the Hatch-Waxman counterclaim, context showed that Congress intended that “one patented use will not foreclose marketing a generic drug for other unpatented ones.” (Emphasis added.)
Second, Novo asserted that the counterclaim would not work for Caraco, because a use code is not “patent information submitted under” the governing subsections of Hatch-Waxman. Here again, the Court rejected Novo’s position. For one thing, the Court noted that a use code “describes a method of use claimed in a patent” and thus is patent information “under any ordinary understanding of the language.” And the use code was “submitted under” the listed subsections, because “submitted under” “most naturally refers to patent information provided as part of the comprehensive scheme of regulation premised on those subsections.” Use codes fit that bill, the Court held, because they “are pivotal to FDA’s implementation of the Hatch-Waxman Amendments.”

Concurring, Justice Sonia Sotomayor agreed that the Court had adopted the “most sensible reading in light of the existing regulatory scheme,” but cautioned that “the counterclaim can only lessen the difficulties created by an overly broad use code; it cannot fix them.” Accordingly, Justice Sotomayor urged that Congress and FDA further streamline and clarify the Hatch-Waxman process, so that “expensive and time-consuming” litigation would prove increasingly unnecessary.

Today’s forceful unanimous opinion provides a major check on the practice of filing overbroad or misleading descriptions of drug patents. Moreover, it ensures that generics will not be thwarted in their efforts to obtain “carve-out” labels from FDA—paving the way for the marketing of generic drugs for uses not covered by any patent. The result is likely to save consumers billions of dollars. Drugs covered only by method patents are prevalent. As the United States Solicitor General explained in the government’s brief supporting Caraco’s position, for example, three of the five top-selling drugs that went generic in 2010—each with sales of more than $2.5 billion—went to market as a result of “carve outs” from method patents.

The case was argued by Winston partner James Hurst. He was joined on the brief by partners Steffen Johnson, Charles Klein, and David Bloch, and associates Andrew Nichols, Bill Ferranti, and Christopher Bruno. Partners Scott Blackman and Matthew Campbell and Counsel John Hsu provided assistance in the proceedings below, and partners Gene Schaerr and Linda Coberly provided assistance in argument preparation. (Caraco’s Opening Brief and Caraco’s Reply Brief)

If you have any questions regarding any matters discussed in this briefing, please contact any of the Winston & Strawn attorneys listed below or your usual Winston & Strawn contact.

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