Supreme Court Rules on Patent Use Codes

On Tuesday, the Supreme Court decided *Caraco Pharmaceutical Laboratories v. Novo Nordisk*. In a unanimous opinion authored by Justice Kagan, the Court construed the counterclaim provision of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C)(ii)(I), to permit generic drug manufacturers to challenge in litigation the breadth of a "use code" submitted to FDA by a brand manufacturer to describe its patent coverage for a reference listed drug.

Under FDA regulations, a brand-name drug manufacturer is required to provide a description, known as a use code, of any method-of-use patent it holds that covers the marketed drug. The use code is accepted "as is" by the FDA and published in the Orange Book.

When a generic manufacturer seeks approval, FDA looks to the use code to determine what is covered by the drug's patent(s). If the information in the label that reflects the use code cannot be "carved out" of the label without affecting the safety or efficacy of the drug, the generic manufacturer must file a paragraph IV certification, triggering notification of the innovator and a 30 month stay on approval of the generic drug while the patent is litigated. If, on the other hand, the use code is narrower and the information it refers to can be carved out, the generic files a so called "section viii" statement that its label will not violate the patent; in such cases the generic need not notify the innovator of its intention to market and there is no 30 month stay.

Allegations arose in the late 1990's that brand manufacturers were submitting inaccurate patent information to FDA to prevent or delay generic market entry. In one case, *Mylan Pharmaceuticals, Inc. v. Thompson*, a brand manufacturer listed a patent covering neither the drug nor any method of using it, which resulted in rejection of a generic manufacturer's drug application. The generic sued to delete the improper listing from the Orange Book, but the Federal Circuit held that the Hatch-Waxman Amendments did not allow such a right of action. In response, Congress created the statutory counterclaim at issue in *Caraco* which provides in relevant part that an ANDA applicant sued for patent infringement "may assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or (c) [of § 355] on the ground that the patent does not claim . . . an approved method of using the drug."

Caraco filed an ANDA with a paragraph IV certification seeking to market a generic version of Novo's drug Prandin, and Novo subsequently filed suit. At the time, Novo's method-of-use patent covered one of three FDA-approved uses of the drug. Following FDA's advice, Caraco filed a section viii statement with proposed labeling carving out Novo's single patented use. Then, in response to a change in its approved indication, Novo also amended its use code language. The amended use code encompassed all three approved methods of use, although two of them did not appear in the approved label. In response, Caraco filed the statutory counterclaim at issue to force Novo to correct its use code.

The District Court granted summary judgment for Caraco, but was reversed by the Federal Circuit on appeal. The Federal Circuit read the statutory phrase "the patent does not claim . . . an approved method of using the drug" to require the ANDA applicant to show that the patent does not claim *any* approved method of use. The Federal Circuit also found that the counterclaim provision did not apply to use codes because they were not "patent information submitted by the [brand] under subsection (b) or (c)."

The Supreme Court reversed the Federal Circuit, holding that the statute permits a counterclaim whenever the patent does not claim a *particular method of use* for which the ANDA applicant seeks to market the drug. "The availability of the counterclaim thus matches the availability of FDA approval under the statute: A

company may bring a counterclaim to show that a method of use is unpatented because establishing that fact allows the FDA to authorize a generic drug via section viii." Furthermore, the Court determined that the "submitted under" language was sufficiently broad to encompass use codes, holding that the statutory phrase "patent information submitted . . . under subsection (b) or (c)" included "everything (about patents) that the FDA requires brands to furnish in the proceedings 'subject to,' 'governed by,' or conducted 'by reason of the authority of' §§ 355(b) and (c)."

In conclusion, the Court determined that the "text and context of the [counterclaim] provision demonstrate that a generic company can employ the counterclaim to challenge a brand's overbroad use code."

In a concurring opinion, Justice Sotomayor highlighted the fact that the availability of a counterclaim does not solve the problem inherent in the statute: because there is no validation of use codes submitted to FDA by brand manufacturers, costly and time-consuming litigation is necessary to correct overly broad use codes. In her opinion, Congress or FDA should act to correct this situation. Justice Sotomayor was also sympathetic to Novo's amendment of its use code, finding "FDA's guidance as to what is required of brand manufacturers in use codes remarkably opaque."

It remains to be seen how significantly the Court's decision will impact Hatch-Waxman litigations. Generic applicants are likely to scrutinize use codes more closely and to try to reduce their scope to permit section viii statements. On the brand side, manufacturers will have to even more carefully tailor their use codes more closely to their method claims when submitting future new drug applications; however nothing in the Court's opinion requires manufacturers to reexamine use codes currently in the Orange Book.

To find out how the Supreme Court's decision in *Caraco* affects your interests, please contact your usual Ropes & Gray attorney or one of the following Ropes & Gray attorneys:

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