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NEWSLETTER

# Generic-Branded Battle Divides Supreme Court During Oral Arguments in *Caraco v. Novo Nordisk*

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On December 5, 2011, the Supreme Court held oral argument in the first patent-related case of the 2011-2012 term-*Caraco Pharmaceuticals Laboratories Ltd. v. Novo Nordisk A/S*, Case No. 10-844. Although some commentators predicted an easy win for Caraco, the oral argument painted a picture of a Court genuinely split over when a generic drug maker can file a counterclaim under Section 355 of the Hatch-Waxman Act to force the Food and Drug Administration (FDA) or a New Drug Application (NDA) holder to correct the accuracy of patent use codes listed by the FDA in the Orange Book.

**Background of Case**

Novo Nordisk markets the anti-diabetes drug Prandin™ (repaglinide). Prandin has been approved by the FDA for three uses in the treatment of Type II diabetes: (1) repaglinide by itself; (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones. The Orange Book currently lists one unexpired patent for Prandin, U.S. Patent No. 6,677,358, which claims only the second approved use. The original use code listed in the Orange Book for Prandin confirmed that only the second method of use was covered by the '358 patent.

Caraco filed an Abbreviated New Drug Application (ANDA) to market a generic version of Prandin. Caraco sought to label its product as only approved for the first and third approved uses, *i.e.*, the non-patented uses, and accordingly filed a Paragraph IV certification that its proposed product would not infringe any existing patents. Patent litigation ensued, but Caraco was close to receiving tentative approval for its proposed generic drug when Novo submitted an amended use code description. Based on this amendment, the FDA issued a new use code for Prandin stating that Novo's patents covered all three approved methods of treatment. Caraco's proposed carve-out label was accordingly denied FDA approval on the assumption that its proposed product would infringe the '358 patent.

In response to the new use code, Caraco amended its counterclaims in the still pending patent litigation to seek an injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(I) requiring the FDA to correct the use code. That injunction was granted by Judge Avern Cohn of the U.S. District Court for the Eastern District of Michigan but was then

stayed pending appeal to the Federal Circuit. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.,* Case 2:05-cv-40188, 2009 U.S. Dist. LEXIS 88551, *2 (E.D. Mich. Sept. 25, 2009).

On April 14, 2010, the Federal Circuit reversed the district court in a 2-1 decision authored by Judge Rader and joined in part by Judge Clevenger. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010). Section 355(j)(5)(C)(ii)(I)(bb) of the Hatch-Waxman Act authorizes a counterclaim to correct a use code when "the patent does not claim . . . an approved method of using the drug." There was no dispute that the '358 patent claims only one of the three approved methods of using Prandin. Thus, the decision turned on whether "an approved method" in the counterclaim statute means "any approved method" as Novo asserted or "all approved methods" as Caraco asserted.

The Federal Circuit sided with Novo, stating that "[w]hen an indefinite article is preceded and qualified by a negative, standard grammar generally provides that 'a' means 'any.'" *Id.* at 1364. Further, "the statutory language 'an approved method of using the drug' refers to the approved methods of using the listed drug, Prandin . . . . Therefore, the Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any approved methods of using the listed drug." *Id.* at 1365.

A dissenting opinion submitted by Judge Dyk sided with Caraco, arguing that "the statute requires the NDA applicant to list patents claiming a drug or method of use 'with respect to which a claim of patent infringement could reasonably be asserted.' In other words, the statute on its face contemplates that the scope of the patent must be accurately described and that the patent must be related to the drug or method of use for which the NDA application is submitted." *Id.* at 1371.

Caraco sought Supreme Court review, and on May 26, 2011 the Court granted certiorari.

**Oral Argument at the Supreme Court**

This case drew a flood of attention from consumer groups, the Solicitor General, the FDA and Rep. Henry Waxman (the namesake of the Hatch-Waxman Act), all submitting *amicus* briefs arguing for reversal of the Federal Circuit decision. Some Court watchers expected an easy victory for Caraco, arguing that the Federal Circuit erred in its statutory interpretation of Section 355 because "an approved method of using the drug" can connote multiple methods in the context of the Hatch-Waxman Act. Thus, when all approved methods are not covered by a patent but the use code states otherwise, the Act allows filing a counterclaim to correct the use code, as Caraco asserted.

During oral argument, Justices Ginsburg and Sotomayor, and to a lesser extent, Justices Breyer and Kagan, appeared to be leaning in favor of Caraco. For example, in response to Novo's argument that the counterclaim provision of Section 355 was limited to correcting incorrectly transcribed patent numbers and expiration dates, Justice Ginsburg retorted that "I can't imagine that . . . if it's a transposition of numbers, that there would have to be a proceeding to get it changed" because "the minute it was noticed . . . the brand manufacturer would correct it." Dec. 5, 2011 Oral Argument Tr. at 40:14-18. Justice Sotomayor likewise doubted "the parade of horribles that [Novo] imagine[s] if we were to read the counterclaim provision in the way [Caraco] is promoting and the government is promoting." Tr. 46:20-23.

Justice Scalia's questions appeared most skeptical of Caraco's position, questioning whether Caraco's interpretation of the statute required adding language not found in the statute (Tr. 5:16-23). Justice Scalia further told Caraco's attorney that "if you have alternate remedies, I am not terribly shocked by the fact that you don't have a remedy under this statute." Tr. 9:6-9.

Chief Justice Roberts and Justices Alito and Kennedy seemed interested in whether the FDA's process for regulating use codes could or should be modified. Justice Kennedy asked "[w]hy does the FDA rely on use codes in the Orange Book to make the carve-outs if it doesn't do anything to ensure the accuracy of the code. " Tr. 18:8-11. Justice Alito similarly asked "if the patent holder writes a use code that is ridiculously, totally, unreasonably broad, is there anything the FDA can do about that." Tr. 19:12-15. Chief Justice Roberts echoed Justice Scalia's comments about alternative remedies, asking whether "an APA action against the FDA for relying on the use code . . . as arbitrary and capricious" was possible. Tr. 20:20-22. Chief Justice Roberts, however, also expressed concerns about placing greater burdens on the FDA to substantively review use codes, stating "the alternative is that the FDA is going to have to hire an awful lot of patent lawyers to review the use codes and their correspondence to the actual patents." Tr. 28:23-29:1.

**Case May End in Divided Opinions**

At this point it appears possible that the Court's decision may be decided on narrow grounds given the complex issues raised during oral argument. Such an outcome would seem to favor Novo. However, if the Court rejects Caraco's arguments regarding the availability of Section 355 to correct use codes, it is possible that this case will cause the FDA to adopt new use codes regulations.