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Caraco V. Novo Nordisk: Antitrust Implications

Law360, New York (May 30, 2012, 1:03 PM ET) -- The United States Supreme Court recently took up the issue of overbroad patent leverage in Caraco v. Novo Nordisk.

The case addressed the specific context of the U.S. Food and Drug Administration's Orange Book and its "use codes," primarily focusing on statutory construction and semantics, as explained below.[1] Perhaps more interesting to practitioners who spend their time at the intersection of antitrust and intellectual property, however, is that the Supreme Court's decision upheld a generic's right to challenge a name-brand manufacturer's overbroad designation of the scope of its patent coverage, delaying the entrance of generic competitors.

While specific to the statutory right to counterclaim for amendment of the Orange Book entry, the ruling contains dicta that may provide ammunition to a generic pursuing a misuse defense or antitrust counterclaim, or to others harmed by the delay in a generic's entry to the competitive market.

An ANDA Primer in Eight Paragraphs

The Orange Book, Paragraph IV Certifications, Section VIII Carve-Outs, and the Dreaded 30-Month Stay

Caraco comes to us courtesy of the Hatch-Waxman Act, which sets forth abbreviated new drug application procedures. These allow a generic drug manufacturer to pursue a shortened FDA approval process in bringing its bioequivalent versions of pharmaceuticals to market, and further provides the generic manufacturer with a limited (180-day) exclusivity period before another generic can gain ANDA approval.[2]

To determine bioequivalence, the FDA maintains the "Orange Book," which lists all approved drugs and their approved uses (categorized by "use codes"), along with their proprietary names and relevant patent information as submitted by the name-brand applicant. The Orange Book is important, because as part of its ANDA submission to the FDA, the generic must certify that the name brand has not submitted a patent to the Orange Book, or that if it has, that the patent has expired, will expire, is unenforceable, or that the generic will not infringe.[3] ANDAs that rely on a certification that the patent is invalid, unenforceable, or will not be infringed are called "paragraph iv certifications," after the relevant paragraph in the Hatch-Waxman Act.

This is where litigation comes into play, because a paragraph IV certification creates standing to sue for patent infringement; its filing is considered the infringing act, albeit one that limits the patentee's remedy to an injunction.[4]

A generic manufacturer can attempt to avoid litigation by limiting the scope of its ANDA submission, called a "carve out." This mechanism is available because there is typically more than one patent on any particular drug — one or more that covers the compound(s) and others that cover particular methods of use. The Orange Book may list a number of FDA-approved uses, only some of which are subject to patent protection.

Ordinarily, a generic's label must provide the same instructions as the name-brand label (i.e., listing instructions for all approved uses, even those that infringe). But a carve-out can be used to "carve" the patent-protected uses out of the label, leaving only those uses that are not subject to patent protection.[5] Since a carved-out label does not provide any instructions on a patented use, it does not infringe or induce infringement.

If a name-brand patentee sues the generic manufacturer within 45 days of the paragraph IV certification, a 30-month stay provision is automatically put into effect.[6] (Carve-out labeling is a different creature, but the practical effect of litigation is the same.[7]) The 30-month stay is a powerful tool, because it is triggered regardless of the merits of any claim of infringement. Patentees have therefore utilized the Orange Book and the 30-month stay to their tactical advantage.[8] Indeed, and as the Supreme Court acknowledged, paragraph IV certifications tend to "provoke" litigation.[9]

For example, in the late 1990s, name-brand manufacturers would submit patents to the Orange Book, even when the patents did not actually cover the drug or its method of use. The FDA simply had to take their submissions at their word. And, at the time, generics did not have the right to seek correction or deletion of the Orange Book entries.[10] Generics were therefore forced into filing a paragraph IV certification, triggering an infringement suit, and then simply waiting out the 30-month period without recourse.[11]

In 2003, Congress acted to prevent "these anticompetitive practices."[12] It provided a right to counterclaim for an order requiring the name-brand to "correct or delete the patent information" on the ground that the patent does not claim either (1) the FDA-approved compound, or (2) "an approved method of using the drug."[13]

The Caraco Dispute

In Caraco, the name-brand drug had three FDA-approved uses listed in the Orange Book; Novo Nordisk's patent covered only one of the approved uses. Caraco pursued a carve-out for the other two uses (i.e., its ANDA sought approval for only those uses that were not covered by Novo's patent).[14]

In response, Novo Nordisk submitted a new "use code" that covered all three approved uses in the Orange Book. The FDA could not, therefore, grant Caraco's ADNA because Novo Nordisk's use codes prevented a "carve out."[15] There were simply no approved uses left that were not subject to the patent's use code, making a carve-out impossible.

Caraco filed counterclaims, the first seeking "correction or deletion" in accordance with the counterclaim statute. It won at the district court level, but the court of appeals reversed. It also filed a misuse counterclaim. The district court denied Novo Nordisk's motion to strike, but the misuse counterclaim was never adjudicated, nor was the district court's decision on the motion to strike reviewed by the Federal Circuit or the Supreme Court.[16]

By the time the Supreme Court took up the case, the main dispute had been distilled to the interpretation of the generic's statutory right to counterclaim for correction or deletion where the patent does not claim an approved use.[17] Specifically, the parties fought over the statute's use of the phrase "not ... an approved method of using the drug."[18]

The first section of the Supreme Court's decision interprets whether "an" meant "any" in which case Novo Nordisk would prevail. It did, after all, have a patent claiming at least one FDA-approved use of the drug — "an" approved method. The Supreme Court, after lengthy discussion of how to interpret "not ... an," concluded that Novo's reading must be incorrect, in terms of both the English language and in order to fulfill the statutory goal of allowing generics to compete. It was intended to remedy a situation in which a patent does not claim an approved use of the drug, but that use is submitted to the Orange Book nonetheless, preventing competition.[19]

The second section deals with the scope of "patent information" subject to an order requiring correction or deletion. The statute says that the right to correct or delete relates to "patent information submitted" by the name brand, and Novo Nordisk argued that this relates to such information as the patent number and expiration date, but not information like the Orange Book's use codes. The Supreme Court disagreed. The codes must necessarily qualify as "patent information" because they relate to the method of use as claimed in the patent:

The statute does not define "patent information," but a use code must qualify. It describes the method of use claimed in a patent. That fits under any ordinary understanding of the language.[20]

The Supreme Court further noted that the patent information "submitted under" clause should be read as broadly as possible to give effect to the overall comprehensive scheme of regulation.[21] In short, the court focuses on what the statute as a whole was designed to accomplish, and read the specific provisions and subprovisions in that light.

Competitive Implications in a Post-Caraco Setting

The Supreme Court did not address the anti-competitive effect of overbroad use codes in the Orange Book, although it did note that the brand names' use of overbroad codes in the 1990s was "anticompetitive," triggering an investigation by the FTC and prompting Congress to enact the statutory right of a counterclaim.[22] It also classified the Orange Book entries as "patent information," solidifying a direct link between FDA use code submissions and the patent itself and reasoning that the phrase should be read in the greater context of the statute and regulatory scheme.

This is an interesting development for potential misuse challenges based on either antitrust violations or improper expansion of scope. While the Supreme Court did not address the misuse issue, the competitive issues surrounding the statutory counterclaim appear to have factored into its consideration of how to give effect to congressional intent. It did describe the submission of overbroad use codes as "anticompetitive practices," and described the practice as an abuse that the statutory counterclaim was designed to cure.[23]

And the Supreme Court did solicit input from the US. Department of Justice before rendering its opinion. The DOJ sided with Caraco; its amicus brief details a strong position on the competitive impact of Novo's position.[24] It argued that the practice, if allowed, would engender the precise sort of competitive harm that the counterclaim statute was designed to prevent in the first place: "unjustified delay or obstruction of a generic drug's entry into the market."[25]

The Department of Justice wrote that it could quantify the competitive harm to "an important path to market entry for generic drugs." In fiscal year 2010, the FDA approved 11 sets of ANDAs with carve-out labeling. Out of five of the top-selling brand-name drugs that went generic during that period alone, three of the ANDAs relied on a carve out. The top two had annual sales of approximately $2.5 billion each.

The DOJ concluded that because "the use of carve-out labeling depends on the accuracy and precision of NDA holders' use codes, an important aspect of the Hatch-Waxman balance [between competition and innovation] would be subverted if the counterclaim provision were unavailable in this context."[26]

The Supreme Court's opinion does not recite these figures, nor does it go out of its way to detail any anti-competitive effects or mention a misuse defense. It stated only that its decision was consistent with a congressional intent to facilitate "the approval of non-infringing generic drugs" – i.e., to facilitate the entry of market competitors.[27] It was clearly persuaded to avoid the competitive harm of Novo Nordisk's position.

Conclusion and Implications

The Supreme Court's decision is limited to a generic manufacturer's right to avail itself of the statutory right to counterclaim in a carve-out setting, and holds only that the counterclaim may be brought, even where the name-brand manufacturer does have a patent that reads on at least one of the drug's approved uses.

Nonetheless, Caraco may contain dicta that could be leveraged in the antitrust and misuse arena, particularly given its focus on (1) the competitive market for generic drugs, and (2) how FDA approval is a necessary prerequisite to entry. The DOJ's amicus brief is also illustrative of the competitive ills associated with overbroad use codes.

The Caraco decision clearly reaffirms the competitive harms that the Hatch-Waxman Act was designed to remedy, and takes a broad view of reading the statutory provisions in order to address those harms. This dicta provides potential weight to an argument that affected parties should be able to bring a patent misuse or antitrust claim, perhaps more so given the Federal Circuit and Supreme Court's silence on the appropriateness of the district court's denial of Novo Nordisk's motion to strike.

The competitive effect is the same: Name-brand drug manufacturers delay or prevent a generic's market entry by use of an overbroad Orange Book use code. Such claims could be brought not only by generic challengers, but perhaps also by purchasers, payors, or consumers of pharmaceutical products who overpaid as a result of the wrongful exclusion of a generic's entry.

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[1] See Caraco Pharmaceutical Laboratories Ltd. v. Novo Nordisk A/S, No. 10-844, 566 U.S. __ (2012).

[2] 21 U.S.C. § 355(j) et seq.; 355(j)(2)(A)(iv) (bioequivalence); 355(j)(5)(B)(iv) (180-day period).

[3] 21 C.F.R. § 314.94(a)(12)(i)(A); 21 U.S.C. § 355(j)(2)(A)(I)-(IV) (emphasis added).

[4] 35 U.S.C.(e)(2)(A). Further details regarding ANDAs can be found by visiting the FDA's website. See http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/default.htm

[5] §355(j)(2)(A)(viii) ("Carve-out" is a colloquialism for the eponymous "Section VIII Statement" under this provision.); see also 21 C.F.R. §314.94(a)(8)(iv), §314.127(a)(7); 21 U.S.C. §§355(j)(2)(A)(v), 355(j)(4)(G).

[6] See 21 C.F.R. § 314.107(b)(3)(i)(A) (noting that the stay is automatic, and the application will not be approved for 30 months (unless the case is resolved sooner)).

[7] Cf. 59 Fed. Reg. 50,347 (1994) (paragraph IV certification cannot be based on a carve-out label). For paragraph iv certifications, the ANDA applicant must use an identical label, whereas for carve-outs, the label must not contain the patented use.

[8] See generally, Brian Range, The ANDA Patent Certification Requirement and Thirty-Month Stay Provision: Is it Necessary?, 3L paper, available at http://leda.law.harvard.edu/leda/data/355/Range.html#fn30.

[9] See Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S, No. 10-844, 566 U.S. __, Slip Op. at *4 (April 17, 2012).

[10] Id. at *6 (citing Mylan Pharms, Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001)).

[11] Id.

[12] Id

[13] 21 U.S.C. §355(j)(5)(C)(ii)(I).

[14] See Caraco, 566 U.S. at *4, *7-*8.

[15] Id. at 9

[16] Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd., 649 F.Supp.2d 661 (E.D. Mich. 2009) (denying motion to strike misuse defense for improper Orange Book listing); Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd., No. 2010-1001, Slip. Op. at *7-8, *15 (Fed. Cir. April 14, 2010) (noting that district court declined to address misuse defense). There is currently a split among courts—some have determined that because the Federal Food, Drug, and Cosmetic Act does not provide for a private right of action, there is no counterclaim for misuse; only for delisting. E.g., Takeda Pharm. Co. v. Zydus Pharms USA, Inc., 2011 U.S. Dist. LEXIS 56328 (D.N.J. May 25, 2011). Others have allowed a misuse counterclaim to stand. Id. (collecting several authorities that allowed a misuse counterclaim to go forward, including cases decided even after Mylan Pharmaceuticals, Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001), held that there was no private right of action under the FFDCA).

[17] Id. at *7, *9-*10.

[18] 21 U.S.C. §355(j)(5)(C)(ii)(I) (emphasis added).

[19] Id. at *11-*15.

[20] Id. at *15 (citations omitted).

[21] Id. at *16-*17.

[22] Id. at *6.

[23] Id.

[24] U.S. Supreme Court, Docket No. 10-844, Brief of Amicus Curiae of United States , available at http://www.justice.gov/osg/briefs/2011/2pet/6invit/2010-0844.pet.ami.inv.pdf\

[25] Id. at *29.

[26] Id. at *33.

[27] Caraco, 566 U.S. at *15.