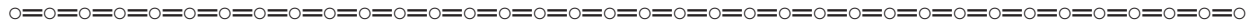


The AIPLA Antitrust News

A Publication of the AIPLA Committee on Antitrust Law

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Chairs' Corner

This issue of the Antitrust Committee's newsletter contains two articles. The first discusses the recent Federal Circuit decision in the *Ciprofloxacin* case involving antitrust standards for so-called "reverse payment" settlements in Hatch-Waxman pharmaceutical patent infringement cases. The second addresses possible antitrust implications of the Federal Circuit's *Caraco* decision on standing to sue to challenge a patent following a covenant not to sue in the Hatch-Waxman context.

This year, the Antitrust Committee has focused on antitrust/intellectual property issues in standards-setting, the pharmaceutical industry, and China, in coordination with other AIPLA committees. For the mid-Winter meeting, we presented a program on global intellectual property issues in standards-setting. For the Spring meeting, our program concerned intellectual property and the new antitrust law in China. And for the Fall meeting, our program will look at the evolving antitrust law applying to arrangements between innovator and generic pharmaceutical companies. The Antitrust Committee also has led a group with members from other AIPLA committees to prepare for possible amicus positions in expected petitions to the Supreme Court in the next several months on settlements of pharmaceutical patent cases.

We have continued to monitor the FTC's activities in the intellectual property field. In the Spring, our committee drafted comments from the AIPLA to the FTC on a proposed consent judgment in a standards-setting matter. In October, members of the Antitrust Committee and other AIPLA committees met with the FTC to discuss standards-setting issues. The Antitrust Committee also drafted proposed

comments for the AIPLA for submission to the FTC on enforcement actions in the intellectual property area under Section 5 of the FTC Act.

When important new developments have occurred, the Antitrust Committee has alerted its members through email correspondences.

The Antitrust Committee publishes this newsletter for each of the three AIPLA meetings throughout the year, and we invite you to submit articles. For more information, please contact the newsletter editor, Joyce Craig, at joyce.craig@finnegan.com.

If you are interested in participating in the Antitrust Committee's efforts, or have suggestions for future programs, please contact one of the committee's chairs, whose contact information appear below.

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The Federal Circuit Invites Supreme Court or Congressional Intervention in Balancing Patent Rights with Antitrust Law in Hatch-Waxman Cases

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In *Caraco Pharmaceutical Laboratories v. Forest Laboratories*,⁹ a three-judge panel of the Federal Circuit essentially held that the failure of a pioneer drug maker to exercise its statutory right to sue a generic drug maker for patent infringement under the Hatch-Waxman Act (“HWA”)¹⁰ amounted to a “restraint on the free exploitation of non-infringing goods.”¹¹ Senior Judge Friedman noted two major problems with this position in his dissent. First, Judge Friedman noted that in the particular context of *Caraco*, the patentee *could* delay generic competition to the patented drug, but that delay was speculative and in any event did not rise to the level of an outright restraint on trade.¹² Second, Judge Friedman pointed out that the court’s holding assumed that *Caraco* did not infringe Forest’s patent without any judicial finding to that effect.¹³ Nevertheless, the words of the majority could be interpreted as a signal that antitrust claims are available to Hatch-Waxman defendants under similar circumstances.¹⁴ Ironically, the same three-

⁹ 527 F.3d 1278 (Fed. Cir. 2008).

¹⁰ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

¹¹ *Caraco*, 527 F.3d at 1291 (citing *Red Wing Shoe v. Hockerson-Halberstadt*, 148 F.3d 1355, 1360 (Fed. Cir. 1998)).

¹² *Id.* at 1298 (Friedman, J., dissenting).

¹³ *Id.*

¹⁴ This is due to the similarity of the majority’s language with the following text from the Sherman

judge panel affirmed a denial of leave to add antitrust claims in a similar situation in *Merck & Co. v. Apotex*,¹⁵ published shortly after *Caraco* and incorporating *Caraco* by reference. However, the circumstances were different in *Merck*, and the question of whether the language in *Caraco* amounts to a judicial sanction of the availability of Sherman Act claims in like circumstances in Hatch-Waxman cases remains an open question, one that will perhaps lead to future Supreme Court or Congressional involvement.

The Hatch-Waxman Framework

The Abbreviated New Drug Application (“ANDA”) provisions of the HWA allow generic drug makers to challenge the patent rights of brand drug makers by certifying to the United States Food and Drug Administration (“FDA”) – and the patentee – that any patent(s) held by the brand drug makers and covering the same active pharmaceutical ingredient (“API”) as its sponsored generic drug is either invalid or not infringed by the generic.¹⁶ This is commonly known as “Paragraph IV” certification. A Paragraph IV certification typically invokes the filing of a patent infringement suit by the patentee within the 45 days from receipt of certification provided to it by law to do so.¹⁷ As an added incentive for generic drug makers to challenge questionable patents, the HWA provides that no generic competitor may market a drug approved via the ANDA provisions until 180 days after the first ANDA filer wins a judgment of invalidity or noninfringement, or begins commercial marketing of its generic drug.

¹⁸ In the event that a patentee fails to sue, the

Act: “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce ... is declared to be illegal.” 15 U.S.C. § 1 (2008).

¹⁵ *Merck & Co. v. Apotex, Inc.*, No. 2007-1362, 2008 WL 2753378 (Fed. Cir. Jul. 16, 2008).

¹⁶ 21 U.S.C. § 355(j)(2)(A)(7)(iv) (2008).

¹⁷ *Id.* at § 355(j)(5)(B)(iii).

¹⁸ *Id.* at § 355(j)(5)(B)(iv).

ANDA filer may seek a specific type of declaratory judgment (“DJ”) in federal court known as a “civil action to obtain patent certainty” (“CAPC”).¹⁹ Congress added the CAPC provision and others to the HWA in 2003 to address complaints of anticompetitive conduct arising from loopholes in the HWA.²⁰ On its face, the law provides automatic DJ jurisdiction for an ANDA filer that has not been sued for infringement when the 45-day period for filing suit expires.

The Factual and Legal Context of *Caraco*

Caraco was the second Paragraph IV ANDA filer challenging two patents held by Forest covering its prescription drug Lexapro[®]: U.S. Patent Nos. Re. 34,712 (“the ’712 patent”) and 6,916,941 (“the ’941 patent”). The first ANDA filer, Ivax, had lost a suit brought by Forest for infringement of the ’712 patent, but Forest never sued for infringement of the ’941 patent. Without a favorable court decision, the FDA was unable to approve Ivax’s ANDA; as a result, Ivax was left unable to trigger its 180-day market exclusivity period under the HWA, blocking subsequent ANDA filers from the market for generic versions of Lexapro[®]. Forest also sued Caraco for infringement of the ’712 patent in response to Caraco’s Paragraph IV certifications, and later granted a unilateral covenant not to sue Caraco for infringement of the ’941 patent. Caraco, however, invoked the CAPC provision of the HWA and accordingly sought a DJ of invalidity or noninfringement of the ’941 patent, which

would trigger Ivax’s market exclusivity period if successful and expedite Caraco’s entry into the market at the end of that period. The trial court, however, dismissed Caraco’s DJ action on the grounds that Caraco failed to present a justiciable case or controversy as required by Article III of the United States Constitution.

Article III Declaratory Judgment Standing

Until recently, the Federal Circuit applied the “reasonable apprehension of a lawsuit” test to determine whether an Article III case or controversy existed for the purpose of determining whether a DJ plaintiff had standing to seek a determination of patent invalidity or noninfringement.²¹ That test was abrogated, however, by the decision in *Medimmune v. Genentech*,²² where the Supreme Court held that all circumstances surrounding the dispute – not just the imminent threat of a lawsuit – must be considered in determining whether a DJ plaintiff has standing under Article III.

Having recognized this new requirement previously in *Teva v. Novartis*,²³ the *Caraco* panel employed the “all-the-circumstances” test in order to determine whether Caraco had standing to seek a DJ in federal court. In accordance with *Medimmune*, the Federal Circuit systematically considered whether (1) Caraco presented an injury-in-fact that was (2) caused by the conduct of Forest and (3) redressable by the court.²⁴ Of specific interest for the purpose of this article is the Court’s

¹⁹ *Id.* at § 355(j)(5)(C).

²⁰ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (where Congress adopted FTC recommendations by amending the Hatch-Waxman Act to deter anticompetitive settlement arrangements and related conduct); see also Federal Trade Commission, FTC Recommends Legislative Changes to Hatch-Waxman Act, Jul. 30, 2002, available at <http://www.ftc.gov/opa/2002/07/genericdrugstudy.shtm> (noting instance of anticompetitive conduct between drug manufacturers during Hatch-Waxman settlements).

²¹ See *Medimmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005) (lack of standing for licensee in good standing to challenge licensed patents); *Teva v. Pfizer*, 395 F.3d 1324 (Fed. Cir. 2005) (lack of standing for second ANDA filer blocked from market due to failure to trigger market exclusivity provision of HWA, similar to the *Caraco* situation).

²² 549 U.S. 118 (2007).

²³ 482 F.3d 1330 (Fed. Cir. 2007).

²⁴ *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008), citing *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 102-03 (1998).

characterization of Forest's conduct as "restraint on the free exploitation of non-infringing goods"²⁵ – language that reads with striking similarity to the text of Section 1 of the Sherman Act²⁶ – in considering whether an injury-in-fact existed.

The Antitrust Implications of the Caraco Injury-in-Fact Analysis

The Federal Circuit's language in *Caraco* suggests that antitrust claims may be available to generic drug companies when the conduct of their Hatch-Waxman opponents prevents them from competing for a share of the pharmaceutical market, despite the fact that such conduct amounts to what would otherwise be considered a free and legal exercise of intellectual property rights. Section 1 of the Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce ... is declared to be illegal."²⁷ Read against the backdrop of the Sherman Act, the *Caraco* opinion suggests that the Federal Circuit viewed Forest's failure to sue Caraco for infringement of the '941 patent as the cause of an antitrust injury that could be redressed by the court.²⁸ However, the same three-judge panel that heard *Caraco* quickly back-pedaled in *Merck* by relying on the background of *Caraco* in affirming the United States District Court for the District of Delaware's denial of a Hatch-Waxman

defendant's motion to add antitrust claims to its DJ pleading.²⁹ The problem, however, is that there are important differences in the factual settings of the two cases that leave open the question of whether antitrust claims are available in factual circumstances analogous to those in *Caraco*.

As discussed above, in *Caraco*, Forest won a verdict for infringement of its '712 patent against the first ANDA filer, Ivax, and declined to sue Ivax for infringement of its '941 patent. Pursuant to the provisions of the HWA, this situation prevented Ivax from having its ANDA approved absent a verdict of invalidity or noninfringement of the '941 patent. As a practical consequence, Caraco, or any subsequent ANDA filer, would need to win a verdict of invalidity against the '712 patent in order for any generic drug maker to market generic Lexapro[®].³⁰ These facts are distinguishable from those in *Merck* for two major reasons. First, while Apotex was similarly situated to Caraco inasmuch as neither was the first ANDA filer in its respective Hatch-Waxman case, the first Paragraph IV ANDA filer in *Merck* – Teva Pharmaceuticals – had already begun marketing its generic drug by the time Apotex's appeal was heard due to the expiration of Merck's API patent.³¹ Second, Merck had granted Apotex – a subsequent ANDA filer – a covenant not to sue for infringement of *any* of its active patents listed with the FDA as covering the same drug that was the subject of Teva's ANDA.³² Accordingly, Apotex was free to have its ANDA approved and begin commercial

²⁵ *Id.* at 1291 (citing *Red Wing Shoe v. Hockerson-Halberstadt*, 148 F.3d 1355, 1360 (Fed. Cir. 1998)).

²⁶ 15 U.S.C. § 1 (2008).

²⁷ *Id.*

²⁸ In addition to citing "restraint on the free exploitation of non-infringing goods" as an injury-in-fact, the Federal Circuit also found the injury traceable to the conduct of Forest, reasoning that "if Forest had not listed its '712 and '941 patents in the FDA's Orange Book ... then [the HWA] would not independently delay Caraco's ANDA from being approved by the FDA." *Caraco*, 527 F.3d at 1292. The Court also reasoned that the redressability requirement was met because a ruling in favor of Caraco in a CAPC would "clear the path to FDA approval that Forest's actions would otherwise deny Caraco." *Id.* at 1293.

²⁹ *Merck & Co. v. Apotex, Inc.*, No. 2007-1362, 2008 WL 2753378, at *1 (Fed. Cir. Jul. 16, 2008).

³⁰ Technically, if Ivax were released by Forest from enforcement of the '712 patent infringement verdict and any controversy involving the '941 patent, Ivax could have its ANDA approved and begin commercial marketing, triggering the 180-day exclusivity period. Obviously, this would be highly unlikely.

³¹ Teva had been previously found to infringe Merck's API patent covering the drug that was the subject of its ANDA, but the patent had since expired, allowing Teva's ANDA to be approved. *Merck*, 2008 WL at *3.

³² *Merck*, 2008 WL at *1.

marketing upon the passing of Teva's exclusivity period.³³ It is easy to see why this situation could not be construed as a "restraint on the free exploitation of noninfringing goods." This leaves open, however, the question of whether the type of conduct demonstrated by Forest could lead to antitrust liability.

Judge Friedman's dissent is instructive. First, the dissent implied that the delay experienced by Caraco was the product of a statutory scheme designed to provide a mechanism to get generic drugs to consumers faster, and that the delay currently experienced by Caraco was the product of the remaining term of one of Forest's patents, which was judicially determined to be valid.³⁴ Second, and more importantly, the dissent noted that "Caraco's argument assumes it will prevail in its non-infringement claim – an uncertain assumption at best."³⁵ Unfortunately, Judge Friedman's opinion is a dissenting opinion, which leaves room for a dispositive opinion on the antitrust liability associated with Forest's conduct.

Conclusion

Judge Friedman's last statement discussed above is certainly true, and undercuts the notion proffered by the majority that Forest's failure to sue for infringement of the '941 patent amounted to a "restraint on the free exploitation of noninfringing goods." Nevertheless, the language of the majority is controlling as a matter of judicial precedent for the time being. While it seems unlikely that antitrust claims made in reliance on the failure to sue someone for patent infringement as the causative act could survive a motion to dismiss for failure to

state a claim,³⁶ the language of the majority in *Caraco* may provide Hatch-Waxman defendants with additional leverage that may ultimately lead to a petition for *certiorari* to the Supreme Court on the matter, or yet another Congressional amendment to the HWA.

³³ *Id.* at *3.

³⁴ *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1298 (Fed. Cir. 2008) (Judge Friedman also noted that there was no indication that the first ANDA filer, Ivax, would delay commercial marketing beyond the expiration of the '712 patent, the date of which would then trigger Ivax's market exclusivity period.).

³⁵ *Id.*

³⁶ Provided by FED. R. CIV. P. 12(b)(6) (2008).