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Vol. IV, No.4 JULY 2012

KEY IDEAS:

ANOTHER DOMINO? THE CONUNDRUM OF ANTITRUST POLICY V. PATENT RIGHTS

Are we on the brink of another domino falling in the battle to protect patent rights? It might seem so, considering a recent Third Circuit Court of Appeals' ruling that appears to elevate commercial antitrust law above the interests of patent holders.

On July 16, 2012, in the *K-Dur* case, the Third Circuit Court of Appeals ruled that a "finder of fact must treat any payment from a [pharmaceutical] patent holder to a generic patent challenger who agrees to delay entry into the market, as *prima facie* evidence of an unreasonable restraint of trade."[1] The opinion was the latest salvo in the heated debate between the Federal Trade Commission (FTC) and pharmaceutical companies regarding so-called "reverse payments." Not only did the opinion reverse a long string of circuit court opinions upholding such payments as a proper exercise of patent rights, it supported the FTC's view that such payments are inherently anti-competitive.

Remarkably, the Third Circuit's opinion contradicts an Eleventh Circuit opinion reviewing the same conduct by the same parties. Reversing the FTC, the Eleventh Circuit wrote, "Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money [to delay market entry] cannot be the sole basis for a violation of antitrust law."[2]

U.S. Supreme Court review of this obvious split opinion seems inevitable. Even if your practice doesn't involve "reverse payments," the growing tension between antitrust law and patent rights is definitely worth a "quick look."

The FDA, the FTC and "Reverse Payments"

For those unfamiliar with the Food and Drug Administration (FDA) and its regulation of pharmaceutical products, here's a bit of background:

- The FDA approves new prescription drugs before they can be marketed or sold in the United States.[3] The approval process for new (pioneer) drugs requires a New Drug Application (NDA) that requires such things as expensive safety and efficacy studies and a complete list of patents issued on the drug's composition or method of use.[4]

- In 1984, the Hatch-Waxman Act[5] created an Abbreviated New Drug Application (ANDA)

1 *In re K-Dur Antitrust Litig.,* No. 10-2077, 2012 WL 2877662, at *16 (3d Cir. July 16, 2012).

2 *Schering-Plough Corp. v. FTC,* 402 F.3d 1056 (11th Cir. 2005), *rev'g In re Schering-Plough Corp.,* 136 F.T.C. 956 (2003), *cert. denied,* 548 U.S. 919 (2006).

3 21 U.S.C. § 355(a).

4 21 U.S.C. § 355(b)(1). The FDA publishes information about patents submitted in NDAs in what is popularly known as the "Orange Book." ("Approved Products with Therapeutic Equivalence Evaluations"; *See* FDA Electronic Orange Book, http://www.fda.gov/cder/ob/).

5 The "Drug Price Competition and Patent Term Restoration Act" (Hatch-Waxman Act) which amended the Food, Drug, and Cosmetic Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984); *see, e.g.,* 21 U.S.C. § 355(j).

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designed to accelerate market delivery of less expensive generic versions of NDA-approved brand-name drugs.[6] For example, under certain circumstances, expensive safety and efficacy studies required by the NDA process are waived.[7]

- Filing an ANDA is a technical act of infringement.[8] However, generic drugs submitted for ANDA approval may not infringe patents on the brand-name drug.[9] One way to meet that requirement is for the generic manufacturer to certify that the brand-name patent is either invalid or is not infringed by the generic product.[10] A generic manufacturer making such a certification must notify the patent holder. If the patent holder brings an infringement suit promptly after receiving notice, the FDA automatically stays the approval of the ANDA for 30 months, or until the court finds the patent is either invalid or not infringed.[11]
- As an incentive to generic manufacturers, Hatch-Waxman awards the first generic manufacturer that files an ANDA and makes the requisite certification a 180-day period of exclusivity from generic competition.[12] The 180-day period begins to run on the date the first ANDA filer begins marketing its drug commercially.[13] Importantly, the exclusivity period does not pass to subsequent ANDA filers.[14]

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Given the significant incentives for generics to challenge patents on branded drugs, some patent holder plaintiffs settled ANDA cases against defendant generic manufacturers by paying the defendant generic ANDA filer to drop its patent challenge and refrain from producing a drug for a specific period—for example, until the originating patent expired.[15] With this "reverse payment," the branded manufacturer could avoid generic competition for a prescribed period, because the first generic ANDA filer never triggered the 180-day exclusivity period.[16]

These agreements, which became known in the press as "reverse payments" or "pay for delay," quickly became an FTC target.[17] Congress subsequently amended Hatch-Waxman,[18] but the basic framework remains unchanged.

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The Courts' Conundrum

While the U.S. Supreme Court has yet to address the issue, five circuit courts of appeals have ruled on the legality of reverse payment settlements.[19] The first two decisions approached the question as an antitrust issue, while the latter three focused on the strength of patent protection. The differences in outcomes are stark.

- ***Andrx Pharm., Inc. v. Biovail Corp. Int'l***[20] (2001)—A branded manufacturer agreed to pay a generic producer to delay marketing a generic product while allowing the ANDA patent litigation to continue.[21] The agreement created a "bottleneck" by not triggering the generic's

6 *Schering-Plough Corp. v. F.T.C.,* 402 F.3d at 1058 n.2.
7 *Id.; see* 21 U.S.C. § 355(j)(2)(A).
8 35 U.S.C. § 271(e)(2)(A).
9 *See* 21 U.S.C. § 355(j)(2)(A)(vii).
10 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as a "Paragraph IV certification").
11 21 U.S.C. § 355(j)(5)(B)(iii). The patent owner has 45 days to bring suit.
12 21 U.S.C. § 355(j)(5)(B)(iv).
13 21 U.S.C. § 355(j)(5)(B)(iv).
14 21 U.S.C. § 355(j)(5)(D)(iii).
15 *In re K-Dur Antitrust Litig.,* No. 10-2077, 2012 WL 2877662, at *3 (3d Cir. July 16, 2012).
16 *See id.* at *8.
17 *See, e.g.,* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.
18 Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.
19 *In re K-Dur Antitrust Litig.,* No. 10-2077, 2012 WL 2877662, at *8 (3d Cir. July 16, 2012).
20 256 F.3d 799 (D.C. Cir. 2001), *cert. denied,* 535 U.S. 931 (2002).
21 *Id.* at 803.

Applying an antitrust analysis, the Sixth Circuit held that the agreement was a "horizontal agreement to eliminate competition in the market for [the branded drug] . . . , a classic example of a per se illegal restraint of trade."

The Second Circuit formulated what is commonly referred to as the "scope of the patent test." The court relied on the presumption of patent validity and reasoned that no injury is cognizable under antitrust law, "as long as competition is restrained only within the scope of the patent.

180-day period of exclusivity, thus precluding all generic competition.[22] Reviewing the case from an antitrust law perspective, the D.C. Circuit decided that the agreement could "reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions."[23] The court treated the payment as "*prima facie* evidence of an illegal agreement not to compete."[24]

- ***In re Cardizem CD Antitrust Litig.***[25] (2003)—In a case concerning the same agreement before the court in *Andrx*, a class of direct and indirect purchasers of the branded product brought antitrust claims.[26] Applying an antitrust analysis, the Sixth Circuit held that the agreement was a "horizontal agreement to eliminate competition in the market for [the branded drug] . . . , a classic example of a *per se* illegal restraint of trade."[27]
- ***Valley Drug Co. v. Geneva Pharm., Inc.***[28] (2003)—The Eleventh Circuit reviewed two agreements where a branded manufacturer paid generic manufacturers to refrain from marketing a generic product until the end of the manufacturer's patent term.[29] Analyzing the agreements from a patent law perspective, the court reasoned that the branded manufacturer's patent gave it the exclusive right to exclude competitors.[30] The court noted that the branded manufacturer might have prevailed in the underlying litigation[31] and that policy considerations strongly favor settlement of patent infringement cases.[32] Declining to apply an antitrust analysis to the agreements, the court fashioned a rule requiring the district court to (1) determine whether any part of the settlement agreement went beyond the protections offered by the branded manufacturer's patent, and (2) if so, to apply antitrust scrutiny only to those portions of the agreement. [33]
- ***Schering-Plough Corp. v. FTC***[34] (2005)—The Eleventh Circuit analyzed the same settlement agreements that the Third Circuit addressed in *K-Dur*.[35] Applying the test from *Valley Drug Co.*, the court concluded that the agreements did not violate antitrust laws.[36]
- ***In re Tamoxifen Citrate Antitrust Litig.***[37] (2006)—The Second Circuit formulated what is commonly referred to as the "scope of the patent test."[38] The court relied on the presumption of patent validity[39] and reasoned that no injury is cognizable under antitrust law, "as long as competition is restrained only within the scope of the patent."[40] The only exception to the rule is in the case of "sham" litigation or where the patent was procured by fraud.[41] In a subsequent case, a Second Circuit panel applied the rule in *Tamoxifen* to reject an antitrust challenge to a reverse payment agreement.[42]

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22 *Id.* at 804.
23 *Id.* at 811.
24 *Id.* at 813.
25 332 F.3d 896 (6th Cir. 2003), *cert. denied,* 543 U.S. 939 (2004).
26 *Id.* at 903-04.
27 *Id.* at 908.
28 344 F.3d 1294 (11th Cir. 2003), *cert. denied,* 543 U.S. 939 (2004).
29 *Id.* at 1300.
30 *Id.* at 1301.
31 *Id.* at 1309.
32 *Id.* at 1308 n.20.
33 Neither a "*per se*" analysis nor a "rule of reason" analysis. *Id.* at 1311-12.
34 402 F.3d 1056 (11th Cir. 2005), *cert. denied,* 548 U.S. 919 (2006).
35 *In re K-Dur Antitrust Litig.,* No. 10-2077, 2012 WL 2877662, at *10 (3d Cir. July 16, 2012).
36 *Schering-Plough Corp. v. FTC,* 402 F.3d at 1069-71.
37 466 F.3d 187 (2d Cir. 2006), *cert. denied,* 551 U.S. 1144 (2007).
38 *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d at 213; *In re K-Dur Antitrust Litig.,* No. 10-2077, 2012 WL 2877662, at *11 (3d Cir. July 16, 2012).
39 35 U.S.C. § 282.
40 *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d at 213.
41 *Id.*
42 *Ark. Carpenters Health & Welfare Fund v. Bayer AG,* 604 F.3d 98 (2d Cir. 2010), *cert. denied,* __ U.S. __, 131 S. Ct. 1606 (2011).

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Vol. IV, No.4 JULY 2012

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- ***In re Ciprofloxacin Hydrochloride Antitrust Litig.***[43] (2008)—The Federal Circuit applied the "scope of the patent" test from *Tamoxifen* to overcome an antitrust challenge to a settlement agreement.[44]

K-Dur: A Game Changer?

In *K-Dur*, a potential game changer, a class of plaintiffs lodged antitrust challenges to an agreement by two generic manufacturers to drop patent challenges and refrain from entering the market in exchange for a payment from the patent holder for the branded drug.[45] The suit involved the same two agreements that had survived antitrust scrutiny in the Eleventh Circuit.[46]

Rejecting the "scope of the patent test" as improperly restricting antitrust law and contrary to policies underlying Hatch-Waxman,[47] the Third Circuit directed the district court on remand to apply a "quick look" of the "rule of reason" analysis based on the "economic realities" of the reverse payment settlement.[48] The court then adopted the presumption of illegality and held that the presumption can be rebutted only by a showing that the payment was (1) for a purpose other than to delay entry, or (2) offers a pro-competitive benefit.[49]

What is most intriguing about *K-Dur* is how two courts can take radically different views of the same law and evidence. Consider the following:

In re K-Dur Antitrust Litigation[1]	***Schering-Plough Corp. v. FTC***[2]
'[W]e take issue with the almost unrebuttable presumption of patent validity."[3]	"A patent shall be presumed valid."[4]
"This practical analysis is supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas."[5]	"Engrafted into patent laws [by Supreme Court precedent] is the notion that a patent graft bestows 'the right to exclude others from profiting by the patent invention."[6]
" . . . [R]everse payment permits the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid."[7]	"By their nature, patents create an environment of exclusion, and consequently, cripple competition."[8]
". . . [T]he judicial preference for settlement . . . should not displace countervailing public policy objectives . . . [such as] that litigated patent challenges are necessary to protect consumers from unjustified monopolies by brand-name drug manufacturers."[9]	"The efficiency-enhancing objectives of a patent settlement are clear, and public policy strongly favors settlement of disputes without litigation."[10]

Conclusions and Takeaways

K-Dur drives some compelling—and thought-provoking—conclusions:

1. Look for the U.S. Supreme Court to resolve this Circuit split. When that happens, remember that the Court denied review in each of the circuit court cases mentioned above. It is hard to predict which way this one will be resolved.

2. For now, approach reverse payment settlements in the Third Circuit with extreme caution. Such settlements might guarantee judicial review, and the likelihood of established facts to rebut the presumption that the agreement is anticompetitive seems remote.

3. Consider the unhappy intersection of antitrust law and patent rights. Are patent rights about to take another hit, or can the tension between these two competing areas of the law be constructively reconciled?

43 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied,* __ U.S. __, 131 U.S. 1606 (2011).
44 *Id.* at 1336.
45 *In re K-Dur Antitrust Litig.,* No. 10-2077, 2012 WL 2877662, at *6, *1 (3d Cir. July 16, 2012).
46 *Id.* at *10.
47 *Id.* at *12.
48 *Id.* at *16.
49 *Id.*