No. 12-416

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF APOTEX, INC. AS *AMICUS CURIAE* SUPPORTING PETITIONER

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INTEREST OF *AMICUS CURIAE*

Apotex, Inc. is a leading generic pharmaceutical manufacturer with customers in the United States, as well as 115 other countries, and annual sales in excess of $1 billion. As a major market participant, Apotex has a significant interest in the proper application of federal competition law to the American pharmaceutical market. This market features unique barriers to entry regulated, in part, by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585—a law directed at the intersection of the patent laws and the federal Food, Drug and Cosmetic Act (FDCA). In addition, Apotex is a party to patent litigation that includes antitrust claims against Cephalon, Inc., the brand manufacturer of the drug modafinil. *See Apotex, Inc.* v. *Cephalon, Inc.*, No. 2:06-cv-2768 (E.D. Pa.) (antitrust claims stayed), *patent appeal filed*, No. 12-1417 (Fed. Cir.). The resolution of the present case could have a profound effect on the relative merits of Apotex's claims in that litigation. As a result, Apotex's interests in this case are substantial.[1]

Apotex also is unique among generic manufacturers in arguing that the courts should apply heightened antitrust scrutiny to settlements between

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[1] Counsel for all parties have consented to the filing of this brief, and those consents are on file with the Clerk of the Court. No counsel for a party in this case authored this brief in whole or in part. No person or entity—other than Apotex or its counsel—made a monetary contribution specifically for the preparation or submission of this brief.

brand-name and generic drug manufacturers that include any form of reverse payment. For this reason, Apotex does not support the position that its trade association has taken in cases like this one, because that organization has advocated for a test that would essentially insulate these types of settlement agreements from antitrust scrutiny—the so-called "scope-of-the-patent" test. *See* Br. for Generic Pharm. Ass'n as *Amicus Curiae* at 21-22, *Upsher-Smith Labs., Inc.* v. *Louisiana Wholesale Drug Co.*, No. 12-265 (U.S.) (filed Oct 1, 2012). In addition, Apotex's Chief Executive Officer, Dr. Bernard Sherman, has testified before Congress about the current ability of brand-name and generic drug manufacturers to structure their settlement agreements in a way that effectively blocks other generic manufacturers from challenging weak drug patents. *See The Protecting Consumer Access to Generic Drugs Act of 2009*: *Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade and Consumer Protection of the H. Comm. on Energy and Commerce*, 111th Cong. 214-29 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.). Accordingly, Apotex has repeatedly demonstrated its commitment to a fair playing field—one that reasonably rewards and protects innovation, while ensuring that erroneously-issued patents are not exploited to the detriment of American consumers.

Apotex submits this brief as an *amicus curiae* to draw the Court's attention to several errors in a critical assumption underlying the scope-of-the-patent test. The courts that have adopted this test (including the one below) have candidly acknowledged that it would insulate reverse-payment settlements from

any form of meaningful antitrust scrutiny, allowing brand-name drug manufacturers to share monopoly profits with their generic rivals even in situations where the underlying patent has no "*actual* exclusionary power." *E.g.*, *FTC* v. *Watson Pharms., Inc.*, 677 F.3d 1298, 1308, 1315 (11th Cir. 2012). But these courts have reasoned that, "[i]f the patent actually is vulnerable, then presumably other generic companies . . . will attempt to enter the market and make their own challenges to the patent." *Id.* at 1315. A proper understanding of the pharmaceutical market—including the unique legal setting in which it operates—reveals the errors in this critical assumption.

SUMMARY OF THE ARGUMENT

In this case, the parties have focused on the potential anticompetitive nature of patent-infringement settlements among brand-name and generic drug manufacturers that include a reverse payment—and rightly so. Such a payment allows a brand-name drug manufacturer to share monopoly profits with a generic rival, in the hope of staving off generic competition, even where the underlying patent would not survive judicial scrutiny. In these circumstances, the settlement agreement operates as a naked restraint of trade—an agreement not to compete—and it should be subject to heightened antitrust scrutiny under a "quick look" rule-of-reason approach.

A number of courts (including the one below) have rejected this straightforward approach and, instead, have insulated virtually all reverse-payment settlements from any form of meaningful antitrust scruti-

ny—even in situations where the underlying patent would not survive judicial review. The courts that have adopted this approach have acknowledged as much. *See, e.g.*, *Watson Pharms.*, 686 F.3d at 1315.

These courts, however, have discounted the concern that such a test would allow weak drug patents to go completely untested, based on the assumption that non-settling generic manufacturers are equally motivated to come forward to challenge the patent at issue. For instance, the court below reasoned that "there usually are many potential challengers to a patent, at least to drug patents," and that, "[i]f the patent actually is vulnerable, then presumably other generic companies . . . will attempt to enter the market and make their own challenges to the patent." *Id.*

This foundational assumption is based on an erroneous understanding of the pharmaceutical market. That market does not provide non-settling generic manufacturers with the same incentives as the initial generic challenger.

To begin with, "the initial generic challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv)." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 215 (3d Cir. 2012), *petitions for cert. pending*, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012). In passing the Hatch-Waxman Act, Congress recognized that, following complete generic market entry, the profit margins are not necessarily sufficient to encourage any single generic manufacturer to undertake the risk of launching a

lengthy and costly legal challenge against a brand manufacturer's patent. As a result, Congress provided a 180-day period of generic market exclusivity as a reward to encourage at least one generic manufacturer to undertake such a challenge. This period of generic exclusivity is triggered on the day that the first filer begins to commercially market its drug. *See id.* "Notably," however, "the 180-day exclusivity window is only available to the first filer," which means that "even if the first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or withdraws [from] litigation, that potential benefit will not pass to subsequent filers." *K-Dur*, 686 F.3d at 204. Stated simply, subsequent generic challengers are not eligible to avail themselves of the carrot afforded to their first-filing brethren.

It might be one thing if non-settling generics were merely deprived the exclusive carrot established by the Hatch-Waxman Act, but they also face a stick, a so-called poison-pill clause, wielded by their settling rivals to affirmatively beat back challenges to weak drug patents. The typical poison-pill clause—including the one at issue in this case—provides that the settling generic manufacturer agrees not to market a generic version of the patented drug until a specific date, but it may immediately market such a version, and still reap the benefit of its 180-day period of generic market exclusivity, if another generic company is successful in challenging the drug's patent. *See* Compl. ¶¶ 65, 76, J.A. 46, 49; *see also* Br. for Pet. at 52 (describing the operation of these clauses and noting that their inclusion is "typical" in Hatch-Waxman settlements). As a result, a poison-pill clause renders it economically irrational for non-

settling generic manufacturers to continue their challenges to the patent at issue, because the clause ensures that, even if they are successful in challenging the patent, they will be deprived of the benefit of their labors and forced to enter the market 180 days after the settling first filer has entered.

The combination of no carrot and an affirmative stick helps to explain why non-settling generic manufacturers have not stepped forward to challenge weak drug patents covered by a settlement agreement between a brand-name manufacturer and an initial challenger. The carrot itself is a thing of immense value. By some estimates, an eligible generic manufacturer stands to gain several hundred million dollars during its 180-day period of generic market exclusivity. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1560 (2006). Because subsequent challengers are not eligible to receive this valuable reward, they lack the same incentive to challenge the patent at issue. What is more, a non-settling generic manufacturer faces a stick as well: the immense cost of litigating a patent challenge—"$10 million or more," *see* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 952 (2011)—coupled with the certainty that the subsequent challenger will not reap the rewards of its labors.

The fact that non-settling generic manufacturers are outright discouraged from maintaining their own challenges to a drug patent further demonstrates why this Court should apply quick-look scrutiny to

any form of reverse-payment settlement between brand-name and generic pharmaceutical manufacturers. The alternative approach—the scope-of-the-patent test—would essentially insulate these highly anticompetitive settlement agreements from judicial review, while allowing the settling parties to structure their agreements in a manner that discourages non-settling parties from maintaining their own challenges to the patent at issue. In short, the scope-of-the-patent test would allow the weakest drug patents to go completely untested—permitting the settling parties to divvy up ill-deserved monopoly profits—at an enormous cost to American consumers.

ARGUMENT

BECAUSE NON-SETTLING GENERIC MANUFACTURERS ARE DISCOURAGED FROM CHALLENGING PATENTS COVERED BY A REVERSE-PAYMENT SETTLEMENT, THE SCOPE-OF-THE-PATENT TEST WOULD EFFECTIVELY INSULATE WEAK DRUG PATENTS FROM ANY FORM OF JUDICIAL SCRUTINY.

A number of courts (including the one below) have held that, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Watson Pharms.*, 677 F.3d at 1312; *accord In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213-14 (2d Cir. 2005), *cert. denied sub nom.*, *Joblove* v. *Barr Labs, Inc.*, 551 U.S. 1144 (2007). Under this approach, "a

patent's *actual* exclusionary power" is irrelevant. *Watson Pharms.*, 677 F.3d at 1308. Rather, what matters is the patent's "*potential* exclusionary" power, which the Eleventh Circuit describes as "the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim," *id.* at 1311 n.8 (emphasis added).

In practice, the scope-of-the-patent test "does not subject reverse payment agreements to any antitrust scrutiny," *K-Dur*, 686 F.3d at 214—even in situations where the underlying patent would not survive judicial review. The courts that have adopted this test have acknowledged as much. For instance, the Eleventh Circuit did not dispute that, under the scope-of-the-patent test, potential drug rivals might be able to "'forgo litigation over patent infringement and split up an ongoing stream of monopoly profits, even in situations in which it is evident that it is more likely than not that the patent would be found invalid or not infringed.'" *Watson Pharms.*, 677 F.3d at 1315. Similarly, the Second Circuit acknowledged the possibility that, through these settlements, colluding pharmaceutical manufacturers could extend an "ill-gotten patent monopoly." *Tamoxifen*, 466 F.3d at 212.

The courts that have adopted the scope-of-the-patent test have discounted this serious concern—that parties might agree to forgo challenges to even weak drug patents and split ill-deserved monopoly profits—based on the assumption that non-settling generic manufacturers are equally motivated to come forward to challenge the patent at issue. The Eleventh Circuit presumed that other potential challeng-

ers have the same incentive to "enter the waters by filing their own paragraph IV certifications attacking the patent." *Watson Pharms.*, 677 F.3d at 1315. Similarly, the Second Circuit believed that "other potential generic manufacturers" would be able to avail themselves of the Hatch-Waxman Act's 180-day period of generic market exclusivity, even after the initial generic challenger had agreed to settle and drop its challenge to the patent at issue. *See Tamoxifen*, 466 F.3d at 214.

The assumption that others will come along to challenge weak drug patents is critical to the operation of the scope-of-the-patent test, because it presumes that the market will limit the reach of otherwise anticompetitive settlements between brand-name and generic pharmaceutical manufacturers. For this reason, the Second Circuit further assumed that the holder of a weak patent could not "'stave off *all* possible challengers with exclusion payments because the economics simply would not justify it.'" *Id.* at 212 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005)).

But these underlying assumptions are easily proved false. Non-settling generic manufacturers do not have the same incentives to challenge a patent in the face of a settlement agreement between a brand-name manufacturer and the initial generic challenger. In fact, non-settling generic manufacturers are actively *discouraged* from continuing to maintain their own challenges to the patent at issue. Moreover, in many situations, the underlying economics

would allow brand-name manufacturers to essentially "buy off" all possible challengers.

As a result, even aside from the many legal flaws that undermine the scope-of-the-patent test's deferential treatment of reverse-payment settlements—flaws that are recounted at length by the Federal Trade Commission, *see* Br. for Pet. at 19-51—the scope-of-the-patent does not properly "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). This misapprehension of the economic and legal landscape further demonstrates why this Court should reject the scope-of-the-patent test in favor of the "quick look," truncated rule-of-reason analysis adopted by the Third Circuit in *K-Dur*.

A. The Scope-of-the-Patent Test is Premised, in Large Part, on the Erroneous Assumption that Non-Settling Generic Manufacturers Will Come Forward to Challenge Weak Drug Patents.

Because the scope-of-the-patent test would, in practice, shield reverse-payment settlements from any form of antitrust scrutiny, *see K-Dur*, 686 F.3d at 214; *see also Watson Pharms.*, 677 F.3d at 1315 (acknowledging the same), there is a risk that a brand-name manufacturer could stave off challenges by each of its generic rivals even when a patent would not withstand judicial scrutiny—protecting undeserved monopoly profits—at an enormous cost to American consumers. The courts that have adopted the scope-of-the-patent test have assumed that this

risk is mitigated, because other generic manufacturers will come forward to challenge weak drug patents, and because a brand-name manufacturer cannot afford to "buy off" all generic challengers. Both assumptions are unsound.

1. Non-Settling Generic Manufacturers Do Not Have the Same Incentives to Challenge Drug Patents Covered by Settlements Between a Brand-Name Manufacturer and the Initial Generic Challenger.

Non-settling generic manufacturers lack sufficient incentives to challenge a drug patent covered by a settlement between a brand-name manufacturer and the initial generic challenger. For one thing, although the Hatch-Waxman Act included a provision intended to encourage at least one generic manufacturer to challenge a drug patent, that provision has been interpreted such that it is available only to the initial challenger of a drug patent. For another, settling drug manufacturers have included within their agreements a so-called "poison-pill" clause to actively discourage non-settling generic manufacturers from continuing to maintain their own challenges to the patent at issue.

a. Only the initial generic challenger may avail itself of a provision of the Hatch-Waxman Act designed to encourage generic manufacturers to challenge weak drug patents.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585, "which amended the FDCA

and the patent laws in several important respects." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 665 (1990). As its formal name implies, the Hatch-Waxman Act "struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to the market." *Andrx Pharms., Inc.* v. *Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002); *accord* H.R. Rep. No. 98-857, pt. 2, at 7 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2691 (discussing this legislation as "the best possible compromise between two competing economic interests").

Within the balance struck by Congress, the Hatch-Waxman Act provides an incentive for generic manufacturers to challenge a drug patent's validity or to invent around its reach: The first generic manufacturer to file a paragraph IV certification (certifying that the patent is invalid or not infringed) is granted a 180-day period during which the FDA will not make effective any other application to market a generic version of that drug. *See* 21 U.S.C. § 505(j)(5)(B)(iv); *K-Dur*, 686 F.3d at 204 (describing the 180-day provision as a form of encouragement); *accord* FDA, *Effective Date of Approval of an Abbreviated New Drug Application*, 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998) (stating that the 180-day period was "created as an incentive to generic manufacturers to challenge patents that may be invalid, not infringed, or unenforceable"); *see also* H.R. Rep. No. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661 (discussing the operation of this period of generic market exclusivity).

Good intentions aside, Congress left the 180-day provision susceptible to an interpretation that grants the reward of exclusivity even to first filers who do not succeed in proving that the patent is invalid or not infringed. Under this interpretation of the 180-day provision, as long as the generic manufacturer does not lose in litigation, it may retain this exclusivity—even if it does nothing else.

The FDA initially resisted this interpretation, insisting that the first-to-file generic had to mount a "successful defense" to a brand manufacturer's infringement action. *See* FDA, *Policy on 180-Day Marketing Exclusivity for Drugs Marketed Under Abbreviated New Drug Applications; Clarification*, 62 Fed. Reg. 63,268, 63,268 (Nov. 28, 1997). But the FDA ultimately abandoned this position after it was invalidated by a handful of courts. *See, e.g.*, *Mova Pharm. Corp.* v. *Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997) ("The language of the statute . . . is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation."), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998); *see also* Ctr. for Drug Evaluation & Research, FDA, *Guidance for Industry: 180-Day Generic Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act* 4 (1998) (stating that the "FDA will not enforce the 'successful defense' provisions" and would "formally remove" them from the Code of Federal Regulations) (available at: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079342.pdf) (last viewed Jan. 28, 2013).

Importantly, rather than find a middle ground following the invalidation of its "successful defense" approach, the FDA abandoned altogether any requirement that the first filer do anything beyond being the first to file a paragraph IV certification. *See* 21 C.F.R. § 314.107(c)(1). Moreover, the FDA has maintained this position, even though the Hatch-Waxman Act defines a "first applicant" as one who first "submits a substantially complete application that contains *and lawfully maintains*" a certification that the patent is invalid or otherwise not infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (emphasis added); *see also Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 969-71 (arguing that the "first applicant" provision should be interpreted to require the first filer to earn its period of generic exclusivity by maintaining a legal challenge to the patent at issue). As a result, the 180-day exclusivity period is available only to the first generic manufacturer to file a paragraph IV certification, "even if the first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or withdraws [from] litigation." *K-Dur*, 686 F.3d at 204 (citing 21 U.S.C. § 355(j)(5)(D)(iii)).

Regardless of the propriety of this interpretation, it has a profound—and, perhaps, underappreciated—effect on settlements between brand and first-to-file generic manufacturers. As an initial matter, it provides the first-to-file generic manufacturer with a unique incentive unmatched by its generic rivals. *See Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1583 (noting "a sharp difference in incentives . . . between [the first paragraph IV] filer and all other generic firms"). Indeed, one scholar estimated that

such exclusivity can be "worth several hundred million dollars to a generic firm that successfully challenges the patents on a major drug." *Id.* at 1579 & n.110 (citing as an example litigation in which Apotex prevailed). Moreover, the Second and Eleventh Circuits have assumed, erroneously, that "other potential generic manufacturers" would be able to avail themselves of this period of generic exclusivity, even after the first filer had agreed to settle and drop its challenge to the patent at issue. *Tamoxifen*, 466 F.3d at 214; *see Watson Pharms.*, 677 F.3d at 1315 (assuming that non-settling generic companies are equally motivated to "enter the waters by filing their own paragraph IV certifications attacking the patent"); *see also K-Dur*, 686 F.3d at 215 (discussing this misapprehension); *Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1584-85 (same).

As it turns out, the incentive provided by the 180-day period is often necessary to ensure that at least one generic manufacturer has an incentive sufficient to lead it to undertake the risk of challenging the validity of a drug patent. Such challenges are expensive. *See Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 952 (estimating that litigation can cost a generic manufacturer "$10 million or more"). And once there is complete generic market entry, the profit margins might be too slim to justify the risk and expense for any one manufacturer to mount a legal challenge to the patent. *See id.* at 948 n.3 (explaining that up to 80% of a generic drug company's estimated profit on a drug is made during this period of exclusivity) (citing Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective*, 25 Biotech. L. Rep. 525,

525-26 (2006), and Martin A. Voet, The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management 61 (2005)); *see also id.* at 952 ("Once multiple generic firms enter the market, prices fall, often dramatically."). The exclusivity period therefore serves as a bounty to overcome a "collective action problem." *Id.* at 953.

To summarize, the 180-day period is an important "carrot, encouraging generic firms to challenge and invalidate bad patents (or invent around them) early and often, and accordingly get generic drugs on the market earlier." *See id.* at 947; *see also* S. Rep. No. 107-167, at 4 (2002) (explaining that the original Hatch-Waxman Act included the 180-day provision to encourage generic manufacturers to "challenge weak or invalid patents . . . so consumers can enjoy lower drug prices"). But it also is important to understand that this carrot is available only to the first generic manufacturer to file a paragraph IV certification. *K-Dur*, 686 F.3d at 204 (citing 21 U.S.C. § 355(j)(5)(D)(iii)). As a result, the statute has been allowed to create a "mismatch between the rights accorded to the first applicants and the first successful challenger," contributing to "an atmosphere in which anticompetitive agreements [a]re entered into between certain pioneer and generic drug firms." 149 Cong. Rec. S16,104, S16,105 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

b. Settling drug manufacturers also have structured their settlement agreements, using a so-called poison-pill clause, to actively discourage challenges by non-settling generic manufacturers.

As a further disincentive to challenges by their non-settling rivals, settling drug manufacturers have included within their settlement agreements a clause designed to create a "collective outcome problem" similar to the one that the 180-day exclusivity provision was intended to prevent. Through the typical poison-pill clause, the settling parties agree that the first-to-file generic manufacturer will delay market entry until a specific time, but it may immediately enter the market if another generic manufacturer is successful in challenging the patent at issue as invalid or not infringed. *See, e.g.*, Compl. ¶ 65, J.A. 46 (alleging that the first-to-file generic manufacturer "agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date"); *see also* Br. for Pet. at 52 (explaining that the use of these clauses is "typical" in Hatch-Waxman settlements).

The upshot of such a clause is that it serves as a stick—effectively discouraging *non-settling* generic manufacturers from continuing to maintain challenges to the patent at issue. This is so because, even if a non-settling manufacturer is successful in challenging the patent, the settling first filer can swoop in at the last minute and obtain the benefit of the subsequent challenger's hard work. "As a result,

the patentee can 'buy off' the first generic entrant, paying it to delay entry into the market. Meanwhile, the generic firm retains [in its pocket] the valuable period of exclusivity," effectively scaring off other would-be challengers. *Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 948.

In the end, the use of poison-pill clauses further undermines a key assumption of the scope-of-the-patent test—that non-settling generic manufacturers are still sufficiently motivated to challenge a patent covered by a reverse-payment settlement. *See Watson Pharms.*, 677 F.3d at 1315 (assuming that non-settling generics are equally motivated); *Tamoxifen*, 466 F. 3d at 212-14 (same). These clauses make it economically irrational for non-settling generic manufacturers to continue their own challenges, because they face the immense cost of litigating a patent challenge, along with the certainty that they will not reap the rewards of their labors.

2. Non-Settling Generic Manufacturers Generally Have Not Stepped Forward to Challenge Weak Drug Patents that Are Covered by a Settlement.

Together, the 180-day provision and poison-pill clauses have allowed brand-name manufacturers to successfully discourage subsequent generic manufacturers from challenging the patent, because a later challenger has much less to gain if it litigates its own challenge to judgment. Even assuming that it prevails in the trial court and on appeal, a subsequent challenger is in for a disturbing reward: After shelling out up "$10 million or more" to litigate the case to judgment, *Earning Exclusivity*, 77 Antitrust

L.J., *supra*, at 952, the persistent non-settling generic manufacturer must sit on the sidelines for 180-days, while the settling first-to-file generic manufacturer reaps a period of generic market exclusivity "worth several hundred million dollars." *Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1579. What is more, the settling generic manufacturer can use this period as a head start to negotiate commercial arrangements with large purchasers, locking up sales even after other generic manufacturers enter the market. *Earning Exclusivity*, 77 Antitrust L.J., *supra*, at 953 & n.26. Finally, even after entering the market, the persistent challenger is rewarded with smaller profit margins brought about by the market entry of every other rival generic. *See id.* at 952 n.20 (explaining that, after complete generic market entry, the price of a drug can drop to less than 5% of its original value). For these reasons, a first-to-file generic manufacturer might earn up to 80% of its total profits during the period of generic market exclusivity, *id.* at 948 n.3—profits that are not available to a non-settling generic manufacturer that decides, against economic reason, to persist in its challenge.

Given the wide disparity between monopoly profits and those following complete generic market entry, brand manufacturers are often in a position to literally "pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation." *K-Dur*, 686 F.3d at 215. In addition, because the initial challenger has more to gain than its generic rivals should it pursue its challenge to judgment, *id.*, the brand-name manufacturer pays far less to settle with each subsequent generic challenger, because each subsequent challenger has a dimin-

ished incentive to pursue its case to judgment and, hence, less leverage to command a higher settlement demand, *see Paying for Delay*, 81 N.Y.U. L. Rev., *supra*, at 1586.

It also should come as no surprise that later generic filers have been reluctant to maintain patent challenges in the face of a settlement between the brand-name manufacturer and the first-to-file generic. *See id.* Apotex has provided a rare exception. After the brand manufacturer of the drug modafinil entered into reverse-payment settlements with *four* generic manufacturers that were considered simultaneous first filers challenging the patent, Apotex filed suit under the antitrust laws and stood alone as the only generic manufacturer to challenge the patent to a judgment of non-infringement and invalidity. *See Apotex, Inc.* v. *Celphalon, Inc.*, No. 2:06-cv-2768, 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011), *patent appeal filed*, No. 12-1417 (Fed. Cir.). The modafinil case included unique enticements to a subsequent filer, because: (1) agreements had been reached with *four* "first filers" within a few months, suggesting collusive conduct, and (2) there was evidence (and the district court subsequently found) that the brand-name manufacturer had engaged in a deliberate fraud on the Patent and Trademark Office. This provided additional incentives for Apotex to challenge the patent, because if Apotex proved the patent had been procured by fraud, then it could obtain damages under its antitrust claims, even though the Hatch-Waxman Act provisions gave Apotex no additional reward. But for Apotex's proof of fraud on the Patent and Trademark Office (among other theories of antitrust liability), Apotex would have stood to

gain little to nothing for its efforts in challenging the patent covering modafinil. That is why Apotex's challenge in the modafinil case is the exception, rather than the rule.

B. Heightened Antitrust Scrutiny is Superior to an Approach that Would Effectively Shield Weak Drug Patents From Any Form of Judicial Scrutiny.

The Federal Trade Commission presents a powerful case for why this Court should hold that reverse-payment settlements are presumptively anticompetitive. *See* Br. for Pet. at 19-40. Such a settlement would allow a brand-name drug manufacturer to share monopoly profits with a generic rival, even where the underlying patent would not survive judicial scrutiny. In these circumstances, the settlement agreement operates as a naked restraint of trade—an agreement not to compete. Given the substantial likelihood that these circumstances will actually play out, *see id.* at 6 (explaining that "would-be generic competitors have prevailed nearly three questers of the time in paragraph IV litigation against brand-name manufacturers" and citing authorities), a reverse-payment settlement should be subject to heightened antitrust scrutiny.

But even putting to one side the legal justifications favoring "quick look" scrutiny over the scope-of-the-patent test, the fact remains that non-settling generic companies are *not* equally motivated to challenge patents covered by reverse-payment settlements—as the court below erroneously assumed. *See Watson Pharms.*, 677 F.3d at 1315; *see also Tamoxifen*, 466 F.3d at 214 (similar). As a result, the scope-

of-the-patent test would not only effectively insulate *reverse-payment settlements* from any form of meaningful antitrust scrutiny, *K-Dur*, 686 F.3d 214, but it also would effectively shield the underlying *patent* from further judicial scrutiny as well. For this reason, the Third Circuit correctly observed that the scope-of-the-patent test "improperly restricts the application of antitrust law *and is contrary to the policies underlying the Hatch-Waxman Act*." *K-Dur*, 686 F.3d at 214 (emphasis added).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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