No. 12-416

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

ACTAVIS, INC., ET AL.,
Respondents.

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

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE SUPPORTING RESPONDENTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Rules and Regulations:

Legislative History:

Other Authorities:

INTEREST OF THE AMICUS CURIAE

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. GPhA members' products account for roughly 80% of all prescriptions dispensed in the United States but only 27% of the money spent on prescriptions. In this way, the products sold by GPhA members save consumers nearly $200 billion each year. GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. GPhA regularly participates in litigation as *amicus curiae*, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844; *PLIVA, Inc. v. Mensing*, No. 09-993.[1]

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[1] All parties have consented to the filing of this brief. A letter reflecting petitioner's consent is on file with the Clerk, and letters reflecting respondents' consent are being lodged with this brief. No counsel for a party authored this brief in whole or in part. No party, no counsel for a party, and no person other than *amicus*, its members, and its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

Consumers benefit when a brand-name drug company that is seeking to exclude a generic competitor for the full term of a patent agrees to halt its litigation and allow early entry of a generic drug. This Court should reject the FTC's argument that whenever such settlements should be declared presumptively unlawful under the "quick look" doctrine whenever they include a so-called "reverse payment." As the court below properly recognized, the inclusion of some form of payment does not change the fact that the settlements did not restrain any trade beyond the scope of the patent, and therefore was permissible under both the patent laws and the antitrust laws.

The FTC's arguments for reversal fail for both legal and factual reasons. "[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-12 (2004) (quoting *Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.)). The FTC acknowledges that principle (Br. 30), but the FTC's effort to apply it here is fundamentally flawed. Indeed, the linchpin of its entire argument—the assertion that these settlements are analogous to naked price-fixing agreements (Br. 20, 34)—is a staggering oversimplification that ignores the economic, legal, and regulatory context in which these settlements occur.

The issues presented in this case involve the complex interplay of numerous factors, including: (1) a patent-holder's exclusionary rights, which threaten to delay generic entry to a date far later than the

early entry afforded by the settlement being challenged; (2) the intricate regulatory structure of the Hatch-Waxman Act (formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585), which influences almost every aspect of competition in the pharmaceutical industry; and (3) the economics of the generic drug industry, including the need to preserve adequate incentives for generic companies to invest in future patent challenges to continue their work in speeding the entry of generic drugs to market. Given the complexities involved, it is hard to imagine a situation *less* suited to presumptive condemnation under the "quick look" doctrine.

Hatch-Waxman is designed not to foment litigation for its own sake, but "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). Under Hatch-Waxman, a patent claim generally blocks FDA from approving a generic drug. When a generic challenges such a patent claim, what matters is that the challenge succeeds in facilitating early entry, not whether that result was achieved by litigation to judgment or by settlement. Hatch-Waxman explicitly recognizes settlement as a valid basis for a court to lift the patent-based restrictions that bar FDA from approving a generic drug application. Allowing the generic product to come to market before the patent expires is a pro-competitive result, even if the settlement includes some form of compensation to the generic company in addition to a compromise entry date.

In this brief, GPhA addresses several key aspects of the industry—and the economic and legal consid-

erations unique to it—that are overlooked or mischaracterized by the FTC and its *amici*. A correct understanding of these industry factors makes it even more clear that the FTC's reliance on the "quick look" doctrine is entirely unfounded and should be rejected.

A. Settlement agreements promote competition by allowing a generic product to come to market before the end of the patent term. Generic competition reduces drug prices dramatically: on average, a generic drug costs about one-third as much as its brand-name equivalent. But a brand-name company that prevails in patent litigation can exclude generic competition and continue to charge higher prices for the term of the patent. A settlement brings about generic entry during the patent term—providing dramatic savings to consumers. Settlements also ensure that generic drug manufacturers earn a return on their investment in challenging a brand's patent in the first place. That return on investment, in turn, enables generic manufacturers to continue bringing new generic drugs to market, including by challenging new brand-name drug patents.

B. The FTC dismisses these pro-competitive benefits based on a flawed assessment of the risks that patent litigation entails. The FTC's basic point is that, although a settlement may allow the generic defendant to enter the market before the end of the patent term, the generic might have been able to enter the market even sooner, *if* it had won the litigation. But under real-world conditions, generic defendants cannot count on the lopsided chance of winning that the FTC portrays. While generic drug companies have won many important victories,

speeding up the entry of lower-cost generic medicines, brand-name companies also have won a significant number of cases, successfully asserting their patents to block generic entry until the patents expire. The FTC's assertion that generics win three-quarters of the cases litigated to conclusion (Br. 6-7) is based on outdated information; current data show that the generic "win" rate is slightly less than 50%.

Settlements replace substantial litigation risk with certainty: the generic manufacturer can obtain guaranteed entry before the patents expire. And that certainty confers a concrete, pro-competitive benefit. The FTC acknowledges (Br. 40) that under its proposed treatment of "reverse payment" settlements, some cases that would otherwise have settled will instead be litigated to judgment. And as the statistics suggest, in a significant number of those cases the generic challenger would lose and, as a result, would be barred from entering the market until the relevant patents had expired. *See* 35 U.S.C. § 271(e)(4)(A). In other words, in those cases, the FTC's rule will cause generic entry—competition—to occur *later* than a settlement entry date, not sooner. No principle of antitrust law supports that result.

C. Nor does a single settlement protect a patent from additional challenges. The generic market is competitive, and other generics are free to file their own ANDAs challenging the patent. Even when one company settles, other generic companies have significant incentives to challenge the same patent so that they can bring their own products to market. And the incentives work: experience shows that generic companies, including those who do not qualify for the special incentive that Hatch-Waxman be-

stows on "first filers," continue to litigate patent challenges even after the brand-name company has settled with a first filer. If those challenges succeed, the regulatory structure ensures that generic entry can occur within days and will not be blocked by a prior settlement agreement, accelerating entry for everyone. The court below properly recognized this dynamic and correctly understood that it mitigates any competitive concerns about "reverse payment" settlement agreements. Pet. App. 35a-36a.

D. A proper understanding of the risks involved in the patent litigations being settled, of the operation of the relevant FDA laws, and of the actual experience of the industry thoroughly dispels any suggestion that "reverse payment" settlements can properly be branded as presumptively anticompetitive under a "quick look" analysis. *See Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 771 (1999) ("quick look" review is reserved for cases where anticompetitive effect is "obvious"). To the contrary, all the relevant regulatory, legal, and economic evidence demonstrates that these agreements are *procompetitive* and should be sustained. Adopting the FTC's rule will delay generic entry and deter future patent challenges by generic companies who have fewer options to settle costly patent litigation on terms that will justify investing in the patent challenge to begin with. That result hurts both competition and consumers.

ARGUMENT

A full understanding of the generic drug industry, and the legal and economic incentives that govern it, dispels the FTC's arguments. The FTC asserts that settlements of patent litigation containing a "reverse payment" are so obviously analogous to naked re-

straints of trade that they deserve no more than a "quick look" before condemnation. As we explain below, in the context of settlements of Hatch-Waxman litigation, the FTC's analogy does not hold true at all (much less obviously so). Patent claims are an obstacle to competition that is inherent in every Paragraph IV case. Settlements remove that obstacle and bring competition to the market even while patents are still in force. Eliminating reverse payments means precluding some cases from settling—resulting in needless litigation, delayed competition, and higher prices.

I. Generic Drugs Create Competition And Benefit Consumer Welfare Every Time They Enter The Pharmaceutical Market

The nearly 30 years of experience with Hatch-Waxman can only be called a success. A vibrant generic drug industry makes available high quality, safe, and less expensive medicines to patients and providers in the United States. As the FTC acknowledges (Br. 45), the generic drug industry also is fulfilling the intent of Hatch-Waxman in challenging patents on brand-name drug products when it is appropriate to do so. As with all types of civil litigation, many of the patent cases between brand and generic companies result in settlements, which invariably permit generic drugs to come to market sooner than they would have if the patent case had proceeded to judgment and the generic company had lost. These settlements have contributed importantly to the enormous savings generated by the availability of generic drugs.

A. The Availability Of Generic Drugs Saves Consumers Money And Increases Consumer Access To Lifesaving Therapies

Generic drugs are therapeutically equivalent to their brand-name counterparts. To be approved by FDA, a generic drug must contain the same active ingredients as a brand-name drug, in the same dosage strength and form, and the drug must be absorbed by the body in the same ways. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv). Upon approval, FDA certifies that a generic drug is safe and effective for its intended uses, just as FDA does for brand-name drugs. Because the generic drug is therapeutically equivalent to its counterpart in every relevant sense, it does not need to undergo the same clinical testing before approval. *See, e.g.*, *Caraco*, 132 S. Ct. at 1676; FDA, *Generic Drugs: Questions and Answers*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last updated Aug. 24, 2011).

A generic drug manufacturer starts the approval process for a new drug by filing an Abbreviated New Drug Application ("ANDA") with FDA. The application demonstrates that the new drug is identical in the relevant respects to a drug that FDA has already approved. 21 U.S.C. § 355(j)(2)(A). FDA may disapprove the application only on grounds specified in the statute. *Id.* § 355(j)(4).

Generic drugs are substantially less expensive than brand-name drugs, in part because of the efficiencies generated by this streamlined approval pathway. The average generic drug costs only about one-third as much as the average brand-name drug. GPhA, *Economic Analysis: Generic Pharmaceuticals*

1999-2008: $734 Billion in Health Care Savings 5 (May 2009). That cost saving was precisely why Congress, in adopting the Hatch-Waxman Act, sought to encourage generic-drug applications. *See, e.g.*, *Caraco*, 132 S. Ct. at 1676. Today, when the rising cost of health care remains one of the most pressing national issues, the ability to develop and market cost-effective generic drugs is all the more important.

Consumers have responded overwhelmingly to the ready availability of low-cost generic drugs. About 4 billion prescriptions were written in 2011; more than 3.2 billion of them—roughly 80%—were dispensed with generics. GPhA, *Generic Drug Savings in the U.S.* 2 (4th ed. 2012). Indeed, when equivalent branded and generic drugs were both available, the generic was purchased 94% of the time. *Id.* at 3. All told, the availability of generic drugs saved the U.S. health care system more than $1 trillion over the course of the last decade—nearly $200 billion in 2011 alone. *Id.* at 1; *see also, e.g.*, Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 31 (July 1998).

B. Patents Are A Substantial Obstacle To Generic Competition

None of these benefits can be realized, however, until the brand-name manufacturer's patent claims are resolved. Under Hatch-Waxman, even if FDA is prepared to approve a generic drug as safe and effective, a brand-name manufacturer's patent claims put the approval on hold for a period of time while the brand-name and generic manufacturers litigate. *Caraco*, 132 S. Ct. at 1676. And if the generic manufacturer loses, it cannot win approval of its drug un-

til after the patent expires. Settlements provide a certain resolution to that problem: they bring the costly litigation to a close, and they guarantee that consumers will reap the benefits of generic competition as of a date certain, before the patent expires.

When a brand-name manufacturer submits a new drug application, it must include a listing of patents: every patent that claims the drug or a method of using it and that the patentee could reasonably assert would be infringed by the manufacture, offer for sale, or sale of a generic version of the drug. 21 U.S.C. § 355(b)(1). FDA maintains an electronic compilation known as the Orange Book (formally, "Approved Drug Products with Therapeutic Equivalence Evaluations"), which contains the number, expiration date, and certain other information for each listed patent. Listing patents in the Orange Book creates a substantial hurdle to generic competition on the claimed product.

When a generic drug manufacturer submits an ANDA for a generic that is bioequivalent to a drug with patents listed in the Orange Book, the manufacturer must advise FDA of how it plans to deal with the listed patents. If a patent is still in force, then the manufacturer must either agree to wait for FDA approval until the patents expire, *id.* § 355(j)(2)(A)(vii)(III), or must certify that the patent is invalid or will not be infringed by the proposed generic, *id.* § 355(j)(2)(A)(vii)(IV). The latter option is known as a "Paragraph IV certification." The patentee must be notified of any such filing, and it may—and usually does—file a patent-infringement action without further ado. *Id.* § 355(j)(2)(B); 35 U.S.C. § 271(e)(2)(A) (providing that merely filing the

ANDA constitutes patent infringement, without the need to wait until the ANDA is approved or the generic drug is made or sold). If the patentee files suit, then the ANDA may not be approved—even if FDA is ready to declare the drug safe and effective—until 30 months go by[2] or a court rejects either the patent itself or the claim of infringement. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee wins, then the generic manufacturer's ANDA cannot be approved until the patent expires. *Id.* § 355(j)(5)(B)(iii)(II)(bb); 35 U.S.C. § 271(e)(4)(A).

If the parties reach a settlement, however, the obstacle is removed and generic competition may begin. Hatch-Waxman expressly recognizes two circumstances under which FDA may approve the generic immediately: if the generic wins a court decision (a "judgment" of a district court, or a decision of a court of appeals), *or* the parties reach a settlement (a "settlement order or consent decree") that permits the generic to go forward. 21 U.S.C. § 355(j)(5)(B)(iii)(I), (II). Thus, Hatch-Waxman's explicit terms recognize settlements as a valid basis for terminating the patent challenge and authorizing FDA approval of a generic drug prior to patent expiration.

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[2] If the litigation is still pending 30 months after the Paragraph IV certification, FDA may approve the ANDA, at least pending any court decision that the patent is valid and infringed. But the generic manufacturer still faces substantial disincentives to actually begin selling the approved drug in that posture (known as "launching at risk"): if it loses the patent litigation before it begins selling its product on the market, it is subject only to injunctive relief, but if it loses *after* it begins selling, it is also subject to substantial damages liability. 35 U.S.C. § 271(e)(4)(C).

C. Settlements That Permit Early Entry Improve Consumer Welfare

When settlements lock in generic entry before a patent expires, the benefit to competition and to consumers is often quite dramatic. For example, generic equivalents of Lipitor, the best-selling prescription medicine of all time, became available in November 2011 due to patent settlements. If, instead of settling, the parties had proceeded with the patent litigation and the brand had won, generic entry would not have occurred until early 2017.[3] Introducing a lower-cost alternative, more than five years early, to the world's best-selling drug is projected to save consumers as much as $4.5 billion per year by 2014.[4]

GPhA's members have obtained similar results for a growing volume of drugs. One GPhA member estimated in 2009 that in total, its settlements had "removed 138 years of monopoly protection" and thereby provided $128 billion in savings to consumers through early generic entry. *See* Teva Pharms. USA, Press Release, *Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements* (June 24, 2009), http://tinyurl.com/TevaStatement.

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[3] *See* Pfizer Inc., Press Release, *Pfizer and Ranbaxy Settle Patent Litigation Worldwide* (June 18, 2008), http://www.pfizer.com/news/press_releases/pfizer_press_release_archive.jsp?guid=20080618005386en&source=2008&page=6; FDA, *Patent and Exclusivity Search Results*, http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=020702&Product_No=001&table1=OB_Rx (last updated Feb. 26, 2013).

[4] *See* Cynthia A. Jackevicius et al., *Generic Atorvastatin and Health Care Costs*, 366 New Eng. J. Med. 201 (2012).

In fact, when one generic manufacturer settles and the others litigate, it is frequently the case that the settlement, not the litigation, will produce the better result for consumers. For example, four different generic manufacturers filed Paragraph IV certifications seeking to manufacture generic tamoxifen citrate, a breast-cancer treatment that was then the world's most widely prescribed anticancer medication. The brand-name manufacturer sued all four to enforce its patent. The first generic manufacturer to file its certification, Barr Laboratories, ultimately reached a settlement allowing it to market tamoxifen under its own label, nine years before the patent expired. The three other generic manufacturers litigated their cases to conclusion, but were unsuccessful. "In each case, the court . . . upheld the validity of [the brand-name manufacturer's] tamoxifen patent." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 195 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *see id.* at 190, 193-95.

The unsuccessful court challenges to the tamoxifen patent illustrate the tangible consumer benefit from Barr's settlement. Nine years before the patent expired, Barr was able to bring a cheaper version of tamoxifen to market. *See id.* at 194-95 & n.9. If Barr had instead litigated to final judgment and lost as the other companies did, the brand-name manufacturer would have faced no generic competition for nine more years.

II. Patents Pose Significant Risks That Can Delay Generic Entry, And Settlements Mitigate Those Risks To The Benefit Of Consumers

The settlements at issue in this case undeniably bring the very real benefits of generic-drug competition to consumers sooner than the pharmaceutical patent would allow. To call that pro-competitive effect anticompetitive, the FTC treats as a solid baseline what is really an uncertain bet: *if* a generic manufacturer could persuade a district court and the Federal Circuit that none of the relevant patents allows the brand-name manufacturer to exclude the generic from the marketplace, then the generic would come to market even sooner—perhaps immediately. But that *if* represents an enormous risk for generic manufacturers. It will not necessarily come to pass; it will not even presumptively come to pass. As we show in detail below, current data demonstrate that generic manufacturers lose as many challenges to drug patents as they win. And with each loss, consumers are deprived of the benefit of generic-drug competition until the full expiration of the patent's term. Settlements like those at issue here avoid that risk and bring consumers a definite benefit: the *certainty* of greater competition and lower prices before the patents expire. The antitrust laws should encourage that result, not condemn it.

A. Generic Manufacturers Face Substantial Litigation Risk, Losing As Often As They Win

The FTC dismisses the hastening of competition by five years as "irrelevant" to the question of competi-

tion law presented here. Br. 43 n.10.[5] That position is premised on the FTC's assumption that a generic applicant likely would have won in the litigation and been able to enter the market on an earlier date than the settlement permits. *See* FTC Br. 4, 6-7, 44. Any such assumption is belied by the empirical data and should be rejected.

GPhA's members have achieved important successes by challenging patents in court and bringing generic drugs to market sooner than the patents would allow. *See, e.g.*, *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (Prozac). It is equally true, however, that brand-name drug manufacturers have prevailed in a large number of patent cases arising under Hatch-Waxman, successfully enforcing their patents to prevent generic entry until after the full term of their patents had expired.

In suggesting that generics' patent challenges are mostly successful, the FTC relies principally on data that is more than a decade old. *See* FTC Br. 4, 6-7, 44. In particular, the FTC relies on its own 2002 *Generic Drug Study*—which examined only 40 drug products—to assert that generic drug manufacturers have won "nearly three quarters of the time" in litigated patent cases. *Id.* at 6. More recent and comprehensive data paint a very different picture.

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[5] The FTC contends that because the scope-of-the-patent test might hypothetically allow a settlement to provide for generic entry only at the end of the patent term, the law instead should presumptively condemn *real* agreements, like those in this case, that provide for competition *before* the end of the patent term. As we show in this brief, agreements providing for early entry are the norm, particularly because of the incentives created by competition from multiple ANDA filers and the potential to forfeit exclusivity. *See infra* pp. 27-32.

According to a study from 2010, which analyzed cases that had been litigated over the prior decade, generics prevailed in 82 cases and lost in 89 cases, for a generic "win" rate in litigated cases of 48%. RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf. These data do not support any presumption that continuing to litigate patent cases, rather than permitting the parties to settle with an agreement that permits generic entry prior to patent expiration, would benefit competition.

Moreover, generic challengers face substantial risks without regard to the type of patent at issue or the nature of the challenge. The FTC describes certain types of patents—such as those claiming a formulation or a method of using a drug, as opposed to those claiming the chemical compound itself—as "secondary patents" and asserts that such patents "may be particularly susceptible to being avoided, in whole or in part, by generic competitors." FTC Br. 7. Once again, the FTC's assertion is overstated. A review of Federal Circuit decisions in Hatch-Waxman cases between 2010 and 2012 shows that: (1) generics did not win any validity challenges[6] to patents covering the chemical compound of the medicine; (2) generics won 7 challenges[7] to the validity of formula-

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[6] *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511 (Fed. Cir. 2012); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368 (Fed. Cir. 2012); *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280 (Fed. Cir. 2012); *Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010).

[7] *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 642 F.3d 1370 (Fed. Cir. 2011); *Duramed Pharm., Inc. v. Watson Labs., Inc.*, 413 F. App'x 289 (Fed. Cir. 2011); *AstraZeneca LP v. Apotex,*

tion or method-of-use patents but lost 5 challenges[8] to such patents; and (3) generics won 4 non-infringement defenses[9] to formulation or method-of-use patents but lost 3 non-infringement defenses[10] to such patents. These examples show that, even as to these so-called "secondary patents," generic drug manufacturers still face real and substantial litigation risk.

Experience also shows that generic drug challengers face significant risks even if they prevail in district court, which permits the FDA to approve an ANDA so the generic can commence sales. The Federal Circuit's willingness and propensity to disagree with district courts has been well documented. For example, one recent study compared the Federal Circuit (limited to patent cases) and representative re-

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Inc., 633 F.3d 1042 (Fed. Cir. 2010); *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010); *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010); *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935 (Fed. Cir. 2010); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 377 F. App'x 978 (Fed. Cir. 2010).

[8] *Pozen Inc. v. Par Pharm.*, 696 F.3d 1151 (Fed. Cir. 2012); *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litig.*, 676 F.3d 1063 (Fed. Cir. 2012); *Unigene Labs, Inc. v. Apotex, Inc.*, 655 F.3d 1352 (Fed. Cir. 2011); *Eli Lilly v. Actavis Elizabeth LLC*, 435 F. App'x 917 (Fed. Cir. 2011); *Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 435 F. App'x 927 (Fed. Cir. 2011).

[9] *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012); *Duramed Pharm., Inc. v. Paddock Labs., Inc.*, 644 F.3d 1376 (Fed. Cir. 2011); *Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 430 F. App'x 871 (Fed. Cir. 2011); *In re Brimonidine Patent Litig.*, 643 F.3d 1366 (Fed. Cir. 2011).

[10] *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283 (Fed. Cir. 2010); *Eli Lilly*, 435 F. App'x at 926-27; *Pozen*, 696 F.3d at 1167-72.

gional circuits and found that the Federal Circuit was more than twice as likely to reverse a district court decision. Ted L. Field, *"Judicial Hyperactivity" in the Federal Circuit: An Empirical Study*, 46 U.S.F. L. Rev. 721, 757, 758, 760 (2012).

Even an appellate decision does not resolve the litigation risk. In 2004, for example, an ANDA applicant won a ruling in the district court that certain patents claimed to cover the blockbuster pain medication Oxycontin were unenforceable. *See Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1128 (Fed. Cir. 2006). Several generic manufacturers started selling their products; others followed after a panel of the Federal Circuit affirmed the judgment of unenforceability in 2005. But a year later, on the brand company's petition for rehearing, the Federal Circuit panel vacated its decision and reversed the finding of unenforceability. *See id.* at 1126. On remand, moreover, the district court held that the patents at issue were valid, enforceable, and infringed. As a result, the generic drug manufacturers suddenly faced exposure to potentially enormous damages claims.[11] Many other similar situations have occurred over the past several years.

Until a patent case is litigated through the court of appeals, therefore, a generic applicant continues to face significant litigation risks. Success in the dis-

[11] The potential damages exposure to a generic drug company in this type of situation could exceed the company's entire profits from selling its product, even in the absence of a claim for enhanced damages. As the FTC notes (Br. 21), the profits that a brand company loses upon generic entry often exceed the profits earned by the generic company.

trict court provides little security, especially on matters reviewed *de novo* on appeal.

B. Restricting The Ability To Settle Threatens To Disrupt The Overall Generic Marketplace

Generic manufacturers enter this risky terrain only after careful analysis of the potential gains if they prevail and the potential exposure if they lose. The cost, length, and uncertainty of litigation represent the chief obstacles to entering the market with a Paragraph IV certification. Settlements are a key way of overcoming those obstacles and bringing competing pharmaceuticals to market sooner—the goal of Hatch-Waxman. In some instances, generic manufacturers can and do settle cases solely by agreeing on a compromise entry date. But even the FTC concedes (Br. 40) that sometimes no such agreement is possible—and thus no settlement is possible—without some additional consideration. By taking consideration off the table through the threat of antitrust liability for anything that even resembles a payment, the FTC's proposed rule would make settlements more difficult and, in some cases, impossible to achieve. Adopting such a rule would drive up the expected cost of Paragraph IV litigation. It would delay generic entry in every case that leads to judgment for the brand-name plaintiff instead of a settlement. And it would decrease the number of challenges generic companies will be willing to make.

When a generic manufacturer is deciding whether to file a Paragraph IV certification to seek approval for a new generic drug that is claimed by a patent, the manufacturer must consider the cost of defending the all-but-inevitable patent-infringement action.

See, e.g., *Protecting Consumer Access to Generic Drugs Act of 2007: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 110th Cong. 136 (2007) (statement of Theodore Whitehouse). That price can be extremely high, particularly given the high stakes for the brand-name patentee seeking to protect blockbuster profits from generic competitors. One estimate puts the average cost of a single ANDA litigation at about $10 million.[12]

The availability of settlements is indispensable to managing these costs, because the possibility of settling decreases the chances that the generic will end up incurring the litigation costs but gaining nothing—which is what happens if the patentee prevails at the end of the litigation. And the ability to include valuable consideration in the negotiation increases the chances that a settlement can be worked out. That is particularly important in the context of a dispute between brand-name and generic pharmaceuticals, because their very different business models causes them to value potential entry quite differently. If, as the FTC suggests, the only permissible settlement tool is a calendar—the parties may bargain over a compromise entry date, but neither party may offer additional consideration as a way to bridge the gap between the parties' differing views of the strength of the patent—the parties in many cases simply will be too far apart to reach agreement.

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[12] Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 Colum. L. Rev. 1788, 1795 n.41 (2011) (citing Marc Goodman et al., Morgan Stanley Equity Research, *Quantifying the Impact from Authorized Generics* 9 (2004)).

The FTC's own statistics bear out this point. Many settlement agreements in Paragraph IV cases do not contain any term that the FTC would characterize as a reverse payment. That does not mean that reverse payments are unnecessary to secure agreement. To the contrary, it is evidence that such payments are used when they *are* necessary and the alternatives, such as simply bargaining over the entry date, have failed.

Depriving manufacturers of the ability to settle would raise the cost of Paragraph IV litigation. If each case must be litigated all the way to trial, and likely through a Federal Circuit appeal as well, the price of entry will go up substantially. That, in turn, will decrease the number of such cases generic drug companies will be willing to undertake. Pharmaceutical companies need to know *before* they file their ANDAs whether they can settle Paragraph IV cases, and if so, on what sort of terms. If the ability to bargain for settlement becomes so restricted that, in many cases, there will be no ability to settle at all, generic drug companies will bring fewer patent challenges and consumers will have to wait longer to obtain lower-cost medicines.

III. Patent Settlements Under Hatch-Waxman Do Not Impede Competition Among Generics

Hatch-Waxman's goal is promoting consumer access to affordable generic drugs—not merely promoting litigation to challenge drug patents, as the FTC believes (Br. 30-33). *Caraco*, 132 S. Ct. at 1676. Evaluating whether settlements serve the statutory purpose cannot focus narrowly on whether a single Paragraph IV case settles or proceeds to trial, be-

cause Paragraph IV litigation involves multiple players and vibrant competition on the generic side. If one company settles, consumers are guaranteed early access to a low-cost generic drug. And if that company's generic competitors continue to litigate, as they often do, consumers stand to benefit even further. Definite early entry by a settling generic, on the one hand, and the possibility of *immediate* entry by a litigating generic, on the other, are both positives.

The FTC and its *amicus* Apotex discount the effect of competition on the generic side, based on a misconception about the legal significance of filing the first Paragraph IV certification. Although Hatch-Waxman gives "first filers" a period of exclusive marketing as an incentive to file a Paragraph IV challenge, the FTC and Apotex are demonstrably incorrect in suggesting that *only* one first filer will challenge the patent in litigation—and that the brand-name company can insulate its patent simply by settling with the first generic challenger. That simplistic assumption is not consistent with either the statute or the facts. Even if one generic manufacturer reaches a settlement in order to manage the risk and uncertainty associated with Paragraph IV litigation, there are numerous reasons to expect that other generics will fight on. That single settlement does not insulate the patent from challenge; indeed, more challenges may be filed *after* the settlement.

A. Multiple Generic Companies May Claim The First-Applicant Bounty

More than one company can claim the reward of a 180-day exclusivity period and, consequently, have an incentive to litigate. Under current law, FDA

awards exclusivity based on the first day that a Paragraph IV certification is filed: all manufacturers who file ANDAs with Paragraph IV certifications on that day are "first applicants" who share the exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day* (July 2003).[13] That type of simultaneous filing occurs with some frequency. It is particularly common when the brand-name drug is granted "New Chemical Entity" exclusivity, which means that FDA cannot even begin *accepting* applications for generic equivalents until a specified date. *See* 21 U.S.C. § 355(j)(5)(F)(ii); *infra* note 18. Thus, when there are multiple first filers, Hatch-Waxman gives every one of them equal incentives to pursue a patent challenge. Apotex and the FTC—relying on pre-2003 law—do not mention that broadened incentive. *See* Apotex Br. 11 (referring to exclusivity as "available only to *the* initial challenger of a drug patent") (emphasis added); *see also id.* at 4-5, 14, 16; FTC Br. 2 n.1.

The FTC suggests (Br. 52) that a brand-name company could enter into settlements with every ANDA filer. The FTC's own data show, however, that some drugs "have been subject to as many as *sixteen* first-day ANDAs with [Paragraph IV] certifications." FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 136 (Aug. 2011), http://www.

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[13] The statute was amended to adopt this rule in 2003. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(1), 117 Stat. 2066, 2457. The new statutory rule does not apply to any drug for which a Paragraph IV certification was made before the 2003 amendment. *See id.* § 1102(b), 117 Stat. at 2460.

ftc.gov/os/2011/08/2011genericdrugreport.pdf (emphasis added). In 2005, the average was *eleven* such ANDAs for each drug, and between 2002 and 2008, the yearly average never dropped below three such ANDAs per drug. *Id.* at 136 tbl.7-5.

As the number of first filers sharing the 180-day exclusivity grows, the idea that the brand-name manufacturer could simply settle with all of them becomes increasingly unlikely. As the court below recognized, even "monopoly profits . . . will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent," Pet. App. 36a, and allowing multiple first filers broadens the incentive to enter.

B. Subsequent Filers Continue To Press Patent Challenges

Even if a brand-name company were to settle with all first filers, those settlements would not make a vulnerable patent safe from challenge. The structure of Hatch-Waxman creates many reasons why generic drug companies who are not first filers for a particular product will nonetheless pursue Paragraph IV challenges to the brand's patents, and actual experience shows that these challenges do occur—exactly as the court below posited they would. Therefore, while the FTC tries to discount the possibility that challenges by subsequent filers will continue after a settlement (Br. 52), and Apotex baldly asserts that when a generic manufacturer does not achieve first-filer status, it "lack[s] sufficient incentives to challenge a drug patent covered by a settlement between a brand-name manufacturer and the initial generic challenger" (Br. 11), the facts are otherwise.

Apotex's own experience refutes its argument. Apotex acknowledges that it is currently litigating its ability to bring generic modafinil to market, despite not being first to file. It seeks to explain away its own conduct by claiming that it was motivated by the "unique enticement" of antitrust damages. Apotex Br. 20-21. "But for" these antitrust theories, Apotex contends, it "would have stood to gain little to nothing for its efforts in challenging the patent covering modafinil." *Id.* But modafinil is hardly the only example.

Apotex itself is currently litigating at least two other cases challenging patents for which it did not file the first Paragraph IV certification. In both cases, the first filer reached a settlement with the brand-name manufacturer. One of the settling defendants has used its period of exclusivity;[14] the other has not yet brought the drug to market.[15] But

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[14] IVAX Pharmaceuticals filed the first ANDA and Paragraph IV certification challenging the two key patents listed for budesonide inhalation suspension, an asthma treatment. *See* Am. Compl. ¶¶ 9, 12, *AstraZeneca LP v. IVAX Pharms., Inc.*, No. 1:05-cv-5142 (D.N.J. Jan. 19, 2006) (Dkt. No. 7). Apotex later filed its own ANDA, although not a Paragraph IV certification; its co-defendant has filed an ANDA as well. *See AstraZeneca*, 633 F.3d at 1046, 1047. IVAX reached a settlement with the brand-name manufacturer more than four years ago and brought the generic product to market more than three years ago. *See* Consent Judgment, *IVAX, supra* (D.N.J. Nov. 25, 2008) (Dkt. No. 171). All exclusivity has long since expired. Apotex has been preliminarily enjoined from marketing its product, 633 F.3d at 1042, but continues to challenge the validity of the two patents. The case is currently in trial. *See AstraZeneca LP v. Breath Ltd.*, No. 1:08-cv-1512 (D.N.J.).

[15] Mylan Pharmaceuticals filed the first ANDA and Paragraph IV certification challenging the key patent for armodafinil, a wakefulness drug. Mylan reached a settlement with the brand-

Apotex continues to litigate for the right to launch its generics. So do several other companies; Apotex has three co-defendants in one case, one in the other. It is hard to imagine clearer evidence refuting the proposition that subsequent filers will not continue to challenge patents after the first filers have settled.

Apotex's behavior is hardly unique. In fact, it is common for generic manufacturers to pursue a challenge despite the possibility of having to wait out the first filer's 180-day period of exclusivity. In the tamoxifen cases discussed above, for example, three manufacturers filed ANDAs and Paragraph IV certifications not only after Barr had become the first filer, but also *after Barr had settled* the resulting litigation and begun selling an authorized generic version of tamoxifen. *See In re Tamoxifen*, 466 F.3d at 193-95.[16] Similarly, in the litigation over ciproflaxin, four generic manufacturers filed ANDAs after Barr, the first filer, settled its Paragraph IV litigation. In both cases, the later companies lost their cases—highlighting again that settlement often will lead to earlier entry than litigating a case to the bitter end—

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name manufacturer in April 2012. *See* Mylan Inc., Press Release, *Mylan Announces Settlement Agreement for its First-to-File Generic Version of Nuvigil®* (Apr. 30, 2012), http://investor.mylan.com/releasedetail.cfm?releaseid=668495. Apotex has filed its own Paragraph IV certification, as have three other generic manufacturers. *E.g.*, Compl. ¶ 27, *Cephalon, Inc. v. Apotex Corp.*, No. 1:10-cv-695 (D. Del. Aug. 18, 2010) (Dkt. No. 1). Apotex and the three companies have continued to press their claims of patent invalidity. The trial on the parties' consolidated litigation concluded in July 2012, and the District Court's decision is pending. *In re Armodafinil Patent Litig.*, No. 10-md-2200 (D. Del.).

[16] Under the law at the time, Barr retained its 180-day exclusivity. That is no longer the case. *See infra* pp. 30-31.

but the key point here is that those companies filed their ANDAs and continued to litigate their patent challenges even though the first filer retained its 180-day exclusivity and could have invoked it if the patents had been invalidated. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 102 & n.9 (2d Cir. 2010).

Many more examples exist.[17] The foregoing few, however, suffice to demonstrate that the FTC and Apotex are simply incorrect in asserting that settlements with first filers will effectively end any challenge to a brand company's patents by other generic companies.

The fact that these challenges actually do continue—despite Apotex's talk about subsequent filers' supposed lack of incentives—should come as no surprise. There are several reasons why generic companies continue to litigate even when they are not first filers, and that this Court can be confident they will continue to do so.

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[17] To offer just one more: Barr Labs filed the first ANDA and Paragraph IV certification challenging the key patent for budesonide capsules, a treatment for irritable bowel syndrome. *See* Compl. ¶ 18, *AstraZeneca LP v. Barr Laboratories, Inc.*, No. 1:08-cv-00305 (D. Del. May 22, 2008) (Dkt. No. 1). Barr reached a settlement with AstraZeneca in May 2010. *See* Consent Order & Judgment, *AstraZeneca v. Barr*, *supra* (D. Del. May 20, 2010) (Dkt. No. 168). Mylan filed its own ANDA and Paragraph IV certification. See Compl. ¶ 15, *AstraZeneca LP v. Mylan Pharms., Inc.*, No. 08-cv-453 (D. Del. July 22, 2008) (Dkt. No. 1). Mylan continued to litigate infringement issues and ultimately won a decision of non-infringement. *AstraZeneca LP v. Mylan Pharms. Inc.*, No. 08-cv-453, 2011 WL 2516381 (D. Del. June 23, 2011), *aff'd*, 467 F. App'x 885 (Fed. Cir. 2012).

First, at the time the generic manufacturer decides to file an ANDA, it often will not know with any certainty whether it will be first to file. Yet much of the expense of developing a new generic drug—both the formulation work to develop the product, and the legal work to develop defenses to the brand's patents—occurs *before* the ANDA is filed.

Most ANDAs can be submitted at any time, even during a period of exclusivity when they can only be tentatively approved; only certain types of ANDAs have a designated first day for submissions.[18] And FDA generally does not disclose the existence or status of an ANDA that has not yet been approved, much less confirm whether a rival ANDA was filed on the same date or earlier. *See* 21 C.F.R. § 314.430(b).

Therefore, generic manufacturers frequently make the business decision to pursue an ANDA, and make substantial investments in developing that ANDA, without knowing whether the ANDA will qualify for first-filer status. Those investments are sunk costs, and there are substantial reasons for the generic company to continue pursuing the ANDA to recoup those investments, even if it learns that it will not be the first filer.

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[18] If none of a drug's active ingredients has ever been approved before, then the manufacturer reaps a five-year period of exclusivity after the drug is approved. During that time, "no [ANDA] may be submitted," except during the last year an ANDA with a Paragraph IV certification may be filed. 21 U.S.C. § 355(j)(5)(F)(ii). In most other cases, an ANDA may be submitted at any time, even if FDA is temporarily precluded from approving it. *See* 21 U.S.C. § 355(j)(5)(F)(iii)-(v) (exclusivity precludes FDA from "mak[ing] the approval of an [ANDA] . . . effective").

The manufacturer often will learn that it is a first filer only once litigation is triggered. A generic drug manufacturer that files a Paragraph IV certification can expect to be sued within 45 days. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (providing that the brand-name manufacturer may stay the approval of an ANDA by filing suit within 45 days after receiving a Paragraph IV certification). Accordingly, a decision to file is a decision to litigate, and that decision—assessing the validity and scope of the brand-name drug's patents, the potential profit from launching a new generic product, and the probability of success in patent litigation—must be made without counting on first-filer status.

Second, in 2003 Congress prescribed a number of ways in which a company that files the first ANDA may nonetheless lose its exclusivity. Thus, any subsequent filer has reason to carry on with its Paragraph IV challenge even if it does not receive the bounty of 180-day exclusivity, because the first filer ultimately may not receive it either. *See id.* § 355(j)(5)(D)(iii); *see also supra* note 13 (effective date).

For example, if the company that submits the first ANDA makes sufficient changes to its application, FDA may decline to treat the amended application as relating back to the original filing date, causing that company to lose any first-filer exclusivity. Similarly, Congress has carefully written into the statute several conditions that can be grounds for revoking (or denying) a first filer's period of exclusivity. *See* 21 U.S.C. § 355(j)(5)(D). For instance, if the first filer does not obtain approval of its ANDA during the first 30 months after applying (subject to an exception

that applies when the rules are changed during the 30 months), its exclusivity is forfeited. *See id.* § 355(j)(5)(D)(i)(IV). Rival generics can sue to enforce these "forfeiture events." *See, e.g.*, *Mylan Labs. Ltd. v. FDA*, No. 12-cv-1637, 2012 WL 6705957 (D.D.C. Dec. 27, 2012).

Third, a subsequent filer's victory in patent litigation might accelerate the entry date of a first filer who has settled, and thus the subsequent filer's entry as well. What Apotex colorfully calls a "poison-pill clause" (Br. 5, 17, 18) is in fact just an agreement that a settling party does not give up the right to enter earlier *if* the patent is actually invalidated. The result is more competition, sooner: if the settling first filer launches earlier because of the patent ruling, then the subsequent filer can do so as well, because the 180-day exclusivity will lapse sooner.[19] That hardly qualifies as an anticompetitive result, nor does it discourage subsequent filers from litigating.

Following the 2003 amendments to the statute, if the first filer does not start selling its product within 75 days after a final court decision finding the patent(s) at issue invalid or not infringed, the first filer forfeits its exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Therefore, a win by a

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[19] If Apotex's real complaint is that the subsequent filer does not itself earn the 180-day exclusivity, then Apotex's quarrel is with Congress's decision to award incentives to first filers, not with reverse payments at all. Indeed, a subsequent filer that prevails in patent litigation must wait out the first filer's 180-day exclusivity whether or not the first filer has entered into a settlement agreement containing a so-called "reverse payment." As discussed below, that brief 180-day period does not discourage subsequent filers from entering the market.

subsequent filer can lead a settling first filer to launch sooner than its settlement agreement otherwise might provide, triggering the 180-day exclusivity and removing it as a regulatory barrier to approval of the subsequent filer's ANDA. Alternatively, if the first filer does not launch its product in time, the forfeiture provisions will allow the subsequent filer's ANDA to be approved immediately. Either way, the subsequent filer's win in the patent litigation can speed up its own entry, notwithstanding a settlement by the first filer.

Fourth, and finally, focusing narrowly on the six-month exclusivity period is incorrect in any event. A patent is issued for 20 years, and because some patents are actually issued *after* the brand-name drug is approved,[20] successfully invalidating a patent could result in well over a decade of profitable participation in the generic market. The FTC argues that the majority of a first filer's profits will come from sales of a product made during the 180-day exclusivity (Br. 6), but this observation obviously has no bearing for all of the *other* generic companies that sell a product without sharing in the first filer's exclusivity. For everyone but the first filer, the profit opportunity comes from getting to market and staying in for an extended period. One of the first generic drugs approved in the wake of Hatch-Waxman was diazepam, the generic equivalent of Valium®. Barr Laboratories' ANDA was approved November 1,

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[20] *See, e.g.*, 21 C.F.R. § 314.50(i)(1)(i)(A), (4) (providing that after a new drug is approved, the brand-name manufacturer must submit any new patents within 30 days, or they will not be taken into account in considering ANDAs with respect to that drug).

1985, and several diazepam ANDAs are still active today, more than 27 years later. *See, e.g.*, FDA, *Drugs@FDA*, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (last updated Feb. 27, 2013) (search for diazepam). A generic manufacturer that is in it for the long haul is unlikely to be dissuaded from mounting a Paragraph IV challenge purely because another company might get a six-month "head start."

IV. Settlements' Pro-Competitive Effects Preclude Any Presumption Of Illegality

The FTC asks this Court to declare that the Sherman Act presumptively forbids *any* settlement agreement containing a "reverse payment" (whatever that may include). But as this Court has repeatedly said, the sort of "quick-look review" the FTC seeks is reserved for cases in which "the likelihood of anticompetitive effects is . . . obvious." *Cal. Dental*, 526 U.S. at 771. Quick-look review is not appropriate for cases in which the challenge conduct "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all." *Id.* That is the case here.

This case arises in a highly complex and specialized regulatory context, in which a patent claim keeps the generic equivalent drug off the market while the case is litigated. The patent claim alone makes the FTC's blanket claim of anticompetitive effect dubious. But even more significantly, there is a strong—indeed, undeniable—countervailing boost to competition every time a settlement shaves years off of a patent term. In at least some cases, the FTC's rule would forestall a settlement and leave the Paragraph IV case to be litigated to judgment—potentially a judgment that blocks competition from

lower-priced generic products for the patent's full term.

This Court need not calculate for itself the net positives and net negatives of settlements like those at issue here in order to reject the FTC's position. Once it concludes that both competing claims meet the standard of "plausibility," *Cal. Dental*, 526 U.S. at 778, then under this Court's cases, that is enough to reject "quick look" review.

As the parties have explained in detail in their briefs, settlements that restrain no trade beyond the scope of the patent are not presumptively unlawful; they are not unlawful at all. GPhA agrees that the scope of the patent sets the appropriate bounds for assessing the competitive effects of the settlements at issue here: taking proper account of the role patent rights play in the competitive dynamic of Hatch-Waxman litigation, while also properly ensuring that settlements do not restrain trade outside the scope of the patent. As the court below correctly recognized, under that standard the FTC's claim in this case cannot proceed.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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