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 *AMICUS CURIAE* KNOWLEDGE ECOLOGY INTERNATIONAL IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE[1]

Knowledge Ecology International ("KEI") is an international non-profit, non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. In particular, KEI is focused on the management of these resources in the context of social justice. KEI is drawn to areas where current business models and practices by businesses, governments or other actors fail to adequately address social needs or where there are opportunities for substantial improvements. Among other areas, KEI has expertise in access to medical technologies and access to knowledge issues. KEI has extensive experience in analyzing the costs of drug development and the role of generic competition in driving down prices so that consumers can purchase affordable medicines.

KEI is concerned about the impacts the Eleventh Circuit opinion immunizing reverse payment settlement agreements, also known as "pay-for-delay," from antitrust scrutiny will have on the availability of affordable generic medicines. If allowed to stand, the opinion below is likely to permit pharmaceutical companies to preserve improper monopolies over weak patents and greatly delay the entry of generics into the market, thereby adversely impacting patients.

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[1] Counsel for petitioner has filed consent to the filing of all *amici curiae* briefs. Consent from each of the Respondents' counsel have been filed with the Clerk of Court. No counsel representing any party to the case authored this brief, in whole or in part, and no counsel or party made any monetary contribution to the preparation or submission of the brief.

SUMMARY OF THE ARGUMENT

The present case involves pay-for-delay settlement agreements, also known as reverse payment agreements, where a branded pharmaceutical company pays a generic firm in order to delay the entry of the generic company into the market. Branded pharmaceutical companies have a clear incentive to preserve their monopolies, particularly over weak patents that are likely to be found invalid if patent litigation continues on the merits, and therefore enter into the pay-for-delay agreements where they offer generic challengers an opportunity to directly share in the monopoly profits of the sales of a drug. The Eleventh Circuit improperly applied the "scope-of-the-patent" test to pay-for-delay agreements finding such settlements valid because their exclusionary effect falls within the exclusive right of a patent, effectively immunizing pay-for-delay from antitrust scrutiny and ignoring the merits of the actual patent-at-issue. By contrast, the Third Circuit applied a more flexible rule that preserves important incentives to challenge weak patents by holding that pay-for-delay agreements are presumptively anticompetitive.

Proponents of heightened protection of patented products such as pharmaceuticals often fail to acknowledge the many other rewards those investing into research and development receive. A wide range of incentive mechanisms exist to induce investment in pharmaceutical drug development and such investors are well-compensated through non-patent mechanisms. Such rewards include, among

others, exclusive rights over clinical test data used to register drugs, tax credits, or vouchers for accelerated consideration of new drug approvals. The federal government also provides funding through grants and contracts to support research and development of pharmaceutical products.

In addition to receiving compensation outside of the patent system, the costs of developing new drugs are often not as high as claimed by the pharmaceutical industry. Proponents of heightened patent protection cite high costs of research and development, but the figures relied on by the pharmaceutical industry are often inflated and rely on faulty studies.

Pay-for-delay settlement agreements impede one of the intended purposes of the Hatch-Waxman Act to encourage generic firms to challenge weak patents and should be considered presumptively anticompetitive. A compelling public policy exists to promote the challenging of weak patents so that generic entry into the market occurs at an earlier date and consumers can purchase pharmaceutical drugs at a more affordable price. Immunizing pay-for-delay settlements from antitrust scrutiny, as the Eleventh Circuit opinion does, removes these incentives and harms the public interest by permitting branded pharmaceutical companies to buy off generic competitors. This Court should instead adopt the more flexible and pro-competitive, pro-consumer approach adopted by the Third Circuit.

ARGUMENT

I. JUSTIFICATIONS FOR HEIGHTENED PATENT PROTECTION AND IMMUNIZATION FROM ANTITRUST SCRUTINY FAIL TO TAKE INTO ACCOUNT OTHER REWARDS AVAILABLE TO THE PATENT HOLDER

Among the common justifications for strong protection of patents in the area of pharmaceuticals are those that point to high costs of research and development and the assertion, without evidence, that patents are necessary to protect and reward investments in the development of new products. Indeed, the Eleventh Circuit, in the opening paragraph of its opinion in the present case, pointed to the high costs of drug development. As will be discussed further in Part II.C, *infra*, the putative high costs cited by the Eleventh Circuit and other proponents for high protection of patented products are supported by industry consultant studies that rely upon facts highly distinguishable from the present case and cannot be considered relevant to or supportive of its conclusions.

These justifications also fail to take into account the numerous non-patent mechanisms that exist in the United States to reward research and development in the pharmaceutical industry.[2]

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[2] Amicus curiae does not necessarily endorse the use of each of the alternative mechanisms discussed herein, particularly the manner in which some have been implemented. This discussion of reward mechanisms serves as examples of the wide range of incentives that are currently used in the United

Patents as incentives have known deficiencies and are not the sole reward mechanism to stimulate investments in research and development for new drugs.

One common *sui generis* protection that is used in parallel to the patent system is the application of a limited time exclusive right to rely on clinical test data used to register new drugs or vaccines. Food, Drug and Cosmetics Act, New Drugs, 21 U.S.C. §355. These exclusive rights over test data include five years of protection for new chemical entity pharmaceutical products, an additional three years of protection where the pharmaceutical applies to treat a new indication, and twelve years of protection for new biologic drugs. *Id.* During this period, the originator of the test data can exclude others from relying on the data even if the patent on the pharmaceutical product has already expired. While exclusive rights over test data have their own shortcomings, it represents one way in which the originator of the test data, usually the holder of the patent, receives compensation outside the patent system.

Another existing non-patent incentive provided in the area of pharmaceutical drugs is the receipt of a fifty-percent tax credit for companies investing in the clinical trials for development of new "orphan" drug indications, that is a drug used to treat a rare medical condition. Internal Revenue Code, Clinical testing expenses for certain drugs for rare diseases or conditions, 26 U.S.C. §45C. Notably,

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States to reward research and development in the pharmaceutical industry.

in the present case, on February 5, 1996, the product-at-issue, AndroGel, received an orphan drug designation for the treatment of weight loss in AIDS patients.

Pharmaceutical companies can also benefit from a pediatric exclusivity extension. Food and Drug Administration Modernization Act of 1997, Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355(a). The pediatric extension permits certain new drug applications to obtain an additional six months of marketing exclusivity where the applicant submits information to the FDA relating to the use of the product to treat a condition afflicting the pediatric population. *Id*. The pediatric extension is an add on period of exclusive to existing marketing exclusivity or patent protection. Indeed, in the present case, AndroGel has received such a six month extension of its marketing exclusivity under this law.

Congress has also created a "Priority Review Voucher" designed to stimulate research and development in treatments for rare tropical diseases. This transferable voucher permits accelerated consideration of new drug approvals as a reward for a company that registers a drug for a category of rare disease, such as cholera or leprosy. Food, Drug and Cosmetic Act, Priority Review to Encourage Treatments for Tropical Diseases, 21 U.S.C. §360n.

In addition to various incentive and reward programs, governments support medical research and development through a number of grant and contract programs. For example, among the trials included in the National Institutes of Health (NIH) ClinicalTrials.Gov database, the U.S. government

has funded 169 clinical studies involving testosterone beginning in 1985, including eleven studies that began before the Federal Drug Administration (FDA) approval of AndroGel. Similarly, a search of the NIH RePorter database using the search term testosterone identifies 7,655 NIH-funded projects. These grants and contracts are associated with 230 clinical studies. There were 1,964 NIH funded projects in the periods including and between fiscal years 1989 to 1999, and more than $1.2 billion in project funding from fiscal year 2000 to the present. In 2012 alone, 3,944 scientific articles were published citing funding from these grants. The volume of clinical studies and projects funded by the NIH on testosterone alone demonstrates that the costs of pharmaceutical drug development are supported by the federal government and do not fall solely on branded pharmaceutical companies.

The above incentive mechanisms and rewards, in addition to the federal funding of medical research, highlight the fact that patent holders often receive numerous benefits that fall outside the patent system and are greatly supported by federal grants. These mechanisms and federal funding all serve to support and induce investments into the research and development of pharmaceutical products apart from the reward of a patent. The Eleventh Circuit opinion fails to take into account the wide range of ways pharmaceutical companies are compensated or rewarded outside of the patent system.

II. JUSTIFICATIONS FOR HIGH PATENT PROTECTION DUE TO COST OF PHARMACEUTICAL DRUG DEVELOPMENT OFTEN RELY ON INFLATED DATA AND DO NOT PROVIDE A PERSUASIVE REASON TO IMMUNIZE PAY-FOR-DELAY FROM ANTITRUST SCRUTINY

Proponents of the scope-of-the-patent test justify pay-for-delay, in part, because of the putative high costs of research and development. The Eleventh Circuit in its opening paragraph of the opinion below justified its decision in part on the high costs of developing new drugs and cited a 2010 article by Dickey, Orszag, and Tyson as support. *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1300 & n.1 (11th Cir. 2012) (*citing* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 369 & n.10 (2010)).

The Dickey, Orszag and Tyson article, which "was supported by funding from the Pharmaceutical Research and Manufacturers of America (PhRMA)" essentially reports on research regarding drug development costs that have been published by pharmaceutical industry consultants and industry funded institutions. The pharmaceutical industry funded authors cite a two page backgrounder by the Tufts Center for the Study of Drug Development, also supported by the pharmaceutical industry, which it turn reports, without evidence, an industry claim that "only 1 of every 5,000 medicines tested is eventually approved." Dickey, Orszag and Tyson at

n. 8. While it is undoubtedly true that academic researchers and companies involved in drug development research screen many different compounds for each approved drugs, the 1 in 5,000 number gives the illusion these risks have actually been quantified by experts when, in fact they have not. Even as a stylized fact, the 1 in 5,000 figure does not provide context regarding the expense of screening substances at early stages of development, which can include a variety of highly mechanized screening processes and computer simulations.

Dickey, Orszag and Tyson also cite three papers co-authored by Tufts researcher and pharmaceutical company consultant Joseph DiMasi, that make a number of assertions about the costs of drug development and the number of new drugs that recoup R&D investments. In particular, they present DiMasi's arguments that, "Recent studies estimate that the average new drug took 10 to 15 years and cost over $1.3 billion (including both direct costs and opportunity costs) to develop and . . . only 20 to 30 percent of those approved eventually recoup their R&D." Dickey, Orszag and Tyson at n.11 (citing Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL AND DECISION ECONOMICS 469-79 (2007).

While it is true that the three DiMasi studies cited by Dickey, Orszag and Tyson do make these claims, several reasons exist to call into question the specific claims and the relevance in the context of this case. Certainly the Eleventh Circuit should have avoided citing the $1.3 drug development estimate to reach the conclusion that "no rational

actor would take that kind of risk . . . without the prospect of a big reward," which is reduced where generics are able to compete in the market.

The true costs of drug development have been largely secretive. In examining various estimates of drug development costs, Morgan, Grootendorst, Lexchin, Cunningham and Greyson note:

> Despite three decades of research in this area, no published estimate of the cost of developing a new drug can be considered a gold standard. Existing studies vary in their methods, data sources, samples, and therefore estimates. While some methods are methodologically strong and some findings have been widely cited, the fact that the data and even the subjects of investigation are kept secret make it impossible to assess validity and reliability. Steve Morgan, Paul Grootendorst, Joel Lexchin, Colleen Cunningham, and Devon Greyson, *The Cost of Drug Development: A systematic review*, 100 HEALTH POL'Y 1 (2011).

The continued secrecy of the data of various industry estimates of drug development costs make it challenging to evaluate such estimates, particularly when there is so much variance in drug development costs and the samples in the DiMasi and other studies are acknowledged to be selective. Even if the estimates were reasonable, within the bounds and

context for the products being considered, they do not make sense in the present case.

In a 2012 Astrazeneca funded study of drug development costs, Mestre-Ferrandiz, Sussex and Towse note that "mean estimates of R&D costs per successful drug should be treated with caution. While useful to provide an overall picture, cost differences around the mean are important." Jorge Mestre-Ferrandiz, Jon Sussex & Adrian Towse, *The R&D Cost of A New Medicine* at 72 (2012), available at http://www.ohe.org/publications/article/the-rd-cost-of-a-new-medicine-124.cfm. Furthermore, the authors suggest that caution should be taken "because of important differences in the studies, particularly in the use of different databases of drugs. Moreover, important differences exist across subgroups of drugs—for instance, by therapeutic area, by firm size and by compound origin."

Here, it is useful to return to another DiMasi assertion including in the article by Dickey, Orszag and Tyson. Based upon the vast differences in development costs from one compound to another, as illustrated vividly by the facts in the AndroGel case, one cannot conclude that only twenty to thirty percent of those drugs approved eventually recoup their research and development investment. Dickey, Orszag and Tyson at 7. Instead, it is more likely that the highly variable research and development outlays for products provides opportunities for companies to register products with smaller market sales potential, because the drug development costs for that particular compound are lower, due to the feasibility of registering a drug with smaller trials, or benefitting from lower per-patient

outlays on trials, shorter development time, or registering products that have benefited from various federal subsidies and specialized tax credits.

In the present case, it is notable that the drug AndroGel was a new formulation of an older drug than had been used to treat patients for more than fifty years. The product was not self originated, but instead "licensed-in" from another company. The product began clinical testing in 1996, and was approved for marketing by the FDA on February 28, 2000. AndroGel received an 1996 Orphan drug designation for the treatment of AIDS related wasting. And as noted above, testosterone was the subject of thousands of grants and 169 federal government funded clinical trials, including 11 clinical studies that were started before AndroGel was approved for marketing in 2000.

The FDA approval of AndroGel was based upon a single Phase III trial (UMD-96-017) which involved just 227 patients, and all of the company's trials, including an observational trial of 106 patients, totaled 471 patients in all.[3]

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[3] The clinical trials of AndroGel consisted of seven trials with a total of 471 patients:

Trial	**Patients**	**Phase**
UMD-96-017	227	Phase III
UMD 96-012	10	Phase I
UMD 98-035	106	Observational
UMD 98-037	45	
UMD 98-038	35	
UMD-98-039	30	
UMD-98-044	18	Phase II
Total	471	

These above facts must be taken into account in estimating the costs of drug developments, but the DiMasi papers in 2003 and 2007 do not do so. While AndroGel's approval was based upon trials involving 471 patients, DiMasi reported a mean of 5,303 patients in clinical studies. *See* DiMasi at n. 41. The DiMasi figure therefore uses a figure several orders of a magnitude larger than the actual number of patients in the present case.

Furthermore, while the time between initial clinical testing of AndroGel and FDA approval took less than four years, the time from initial testing to marketing approval in the DiMasi's sample took 90.3 months on average, or 7.525 years. The shorter period of testing for AndroGel means the cost of capital adjusted figures would be much lower.

Additionally, DiMasi's study excluded licensed-in products and included only self generated products. AndroGel, by contrast, was a licensed in product. Elsewhere DiMasi has estimated that the overall clinical approval success rate for licensed-in products is much higher than for self-originated drugs (27% compared to 16%). Mestre-Ferrandiz at 53. The difference in overall success rates lowers the costs, when compared to the products in the DiMasi study.

Another important consideration is that in DiMasi's 2003 study, he dismissed the importance of orphan products and government funded research. As noted in the preceding section, *supra*, AndroGel received an Orphan Designation in 1996, and the

active ingredient in AndroGel was the subject of thousands of NIH funded studies.

The Eleventh Circuit relied upon inflated estimates of the average cost of drug development put forth by consultants that are advocates for the pharmaceutical industry. Further, this average was based upon secret data sets which were described by the industry consultants as having completely different characteristics than the characteristics of the research and development associated with AndroGel. These differences suggest that AndroGel was in fact a far less expensive product to bring to market.

Furthermore, regardless of the costs of drug development, it is important to keep in mind the Constitutional rationale for the patent system, to "promote the Progress of Science and useful Arts," U.S. CONST., Art. 1, §8, cl. 8. The patents-at-issue in most pay-for-delay cases are weak ones that do not meet the statutory standards for patent protection, often failing the "non-obvious" or "novelty" requirements. Immunizing pay-for-delay from antitrust scrutiny gives parties an incentive to settle rather than litigate the patents and permits branded pharmaceutical companies to protect unwarranted monopolies over products that do not promote the progress of science and do not represent true innovation. Additionally, even absent any patent protection, the costs of development for AndroGel would have been fully recouped by the company given the period of exclusive rights over clinical test data it was granted and discussed in Part II, *supra*, and the low outlays required for the small clinical trials used to register the product.

Pharmaceutical companies should be spending research and development dollars on treatments that represent true innovation that improve the therapeutic benefit or treat new conditions rather than merely creating new forms of old drugs. Permitting pay-for-delay reduces incentives to invest in truly new, innovative products and instead encourages reliance on preserving or creating new monopolies for old products.

III. PAY-FOR DELAY SETTLEMENT AGREEMENTS IMPEDE THE INTENDED PURPOSE OF THE HATCH-WAXMAN ACT PROVISIONS DESIGNED TO PROVIDE INCENTIVES TO PROMOTE GENERIC ENTRY INTO THE MARKET

A. The Hatch-Waxman Act Included Incentives for Generic Pharmaceutical Companies to Challenge Weak Pharmaceutical Patents Thereby Promoting Generic Competition

In 1984, Congress passed what became known as the Hatch-Waxman Act. 21 U.S.C. §355. A portion of the Hatch-Waxman Act served to provide an incentive to generic manufacturers to challenge weak patents in order to hasten generic pharmaceutical entry into the market and promote generic competition. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, H.R. REP. NO. 98–857, at 4 (1984), H.R. REP. NO. 98–857, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688. The Hatch-Waxman act created the abbreviated new drug application, known

as "ANDA," to allow generic manufacturers to rely on the previously approved NDA information, that is the clinical trial data, by demonstrating bioequivalence. 21 U.S.C. §355(j). A generic firm can file what is known as a "Paragraph IV" certification that its drug does not infringe on the existing patents, or that such patents are invalid. 21 U.S.C. §355(j)(2)(A). The first generic manufacturer to file its application can obtain an 180-day exclusivity period where it essentially enters into a duopoly with the brand name manufacturer and no other generic competitors can enter the market during this 180-day period. 21 U.S.C. §355(j)(5)(B)(iv). As confirmed by federal courts, only the first generic company to apply, not the first to successfully defend its case, is eligible for the 180-day exclusivity period. *Mova Pharm. Corp. v. Shalala*, 955 F.Supp. 138 (D.D.C. 1997), *aff'd by*, 1040 F.3d 1060, 1074 (D.C. Cir. 1998).

Once a generic company has filed an ANDA with a "Paragraph IV" certification, the brand name pharmaceutical company can file a patent infringement claim against the generic company. Instead of litigating the case on the merits, though, the branded pharmaceutical firm and the generic company may choose to settle. These settlements often result in pay-for-delay agreements, also known as reverse payment settlements, where the branded firm will pay the generic firm and, as part of the agreement, the generic firm will agree to delay entry into the market until a specified date.

Rather than continue with litigation, the generic firm may instead accept the payment offered by the pharmaceutical company. In essence, many of

these agreements result in branded manufacturers to pay to exclude generic competition from the market by offering competitors a share of the monopoly profits. The weaker the patent held by the branded company, the greater its incentive to offer a reverse payment to the generic firm.

Significantly, branded pharmaceutical companies have a clear incentive to settle in many cases. Generic companies that have used the "Paragraph IV" certification target weak patents and these challenges have been largely successful when the cases are fully litigated on the merits. A study conducted by the FTC found that in seventh-three percent of patent litigation that was ultimately resolved by a court decision, the generic challenger prevailed. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf

Although the settlement agreements generally claim that the branded company is paying for services of the generic company, such as for marketing work or backup production capacity, evidence suggests that the agreements are solely to preserve the monopoly. A 2009 survey found that outside of pay-for-delay settlement agreements, branded pharmaceuticals rarely contract generic firms for assistance in such activities and there are "no significant examples" of such work. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 666-68 (2009). That branded pharmaceuticals rarely engage in such contracts with generic companies is unsurprising because generic firms "do not have substantial

promotion teams, for they seldom have major branded drugs to promote." *Id.*

By paying off the first generic filer, the branded firm removes the most motivated challenger and is therefore more likely to preserve its monopoly. The first generic filer has the greatest incentive to challenge the validity of the patent because of the 180-day marketing exclusivity period it receives if successful. Even with the amendments to the Hatch-Waxman Act that provide for forfeiture of the 180-day exclusivity period where there is "failure to market," it is possible that forfeiture does not apply to settlement cases. Hemphill at 660 (*citing* Letter from Gary J. Buehler, Dir., Office of Generic Drugs, FDA to Marc A. Goshko, Executive Dir., Teva N. Am. 5 N. 6 (Jan 17, 2008), available at http://www.fda.gov/ohrms/DOCKETS/dockets/07n0389/07n-0389-let0003.pdf which notes that without a court entering a final judgment of invalidity or non-infringement, subsequent generic applicants cannot initiate forfeiture proceedings) (*but* noting other possible interpretations). Thus, a subsequent generic filer that challenges the validity of the branded patent may find upon conclusion of patent infringement litigation that he cannot benefit from the 180-day marketing exclusivity; the day the subsequent generic filer is able to enter the market, so too other generic firms may also market their products. As a result, the branded firm has a large incentive to settle with the first generic filer.

The outcome of the case will have an enormous impact on the availability of affordable generic medicines and, therefore, the cost of treatment. A 2009 survey demonstrated that pay-

for-delay settlements are on the rise. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 657 (2009). This survey tracks the rise, fall, and rise again of such settlement agreements noting that when the FTC initiated antitrust actions, the reverse-payment agreements diminished. *Id*. After the FTC lost these suits, however, firms began to enter into pay-for-delay settlements again and such agreements appear to be on the rise once again. *Id*. This Court's ruling will therefore likely have a significant impact on whether challenges to the patents of pharmaceutical products reach the actual merits and, subsequently, whether affordable generic medicines reach patients and consumers at an earlier date.

Congress passed the "Paragraph IV" portion of the Hatch-Waxman Act in order to promote challenges to invalid drug patents and promote earlier generic entry into the market. Where the incentives to such challenges are minimized or eliminated, such as is the case for pay-for-delay settlement agreements, the public interest in attaining lower cost drugs through the availability of generic competition is disserved. Pay-for-delay settlements are likely to result in a frustration of one of the key objectives of the Hatch-Waxman Act. Rather than promoting challenges to weak patents, pay-for-delay agreements instead promote settlement agreements that preserve monopoly power and keep prices high for consumers.

B. The Eleventh Circuit Decision Immunizes Pay-For-Delay Agreements from Antitrust Scrutiny and Reduces the Likelihood of Faster Entry of Generic Medicines Into the Market, Impeding a Key Objective of the Hatch-Waxman Act.

The rule adopted by the Eleventh Circuit in the present case immunizes pay-for-delay settlement agreements from antitrust scrutiny as long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent. *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012). In this *per se* rule of legality, the only exception applies where sham litigation or fraud occurred. *Id.* at 1312. This rule, also known as the "scope-of-the-patent" test, effectively exempts reverse payment agreements from antitrust scrutiny despite the fact that in other contexts, reverse payments have often been found to be anti-competitive. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (per curiam) (holding that payment by one bar review provider to a competitor to withdraw from the market violated antitrust law).

The "scope-of-the-patent" test is based on the erroneous assumption that the patent is legitimate and would be upheld if litigation concluded on the merits. However, as noted in the previous section, the majority of Paragraph IV challengers that follow through to the final judgment win and the challenged patent is found to be invalid. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf

Where the patent is weak, the branded pharmaceutical company has an obvious incentive to settle the case and pay the generic firm some portion of its monopoly profits rather than having a court rule that its patent is invalid and invite generic competition.

In applying the "scope-of-the-patent" test, courts completely ignore the inquiry of whether the patent is valid or not. Certainly, if the patent is a valid one, the patent-holder can exercise its exclusionary rights. However, in ignoring the strength of the patent and assuming its validity, the "scope-of-the-patent" rule results in an absurdity. If a patent is actually invalid then it does not have any scope; permitting the reverse-payment settlement goes well beyond what would be the scope of an invalid patent.

As a result, a finding of *per se* lawfulness of pay-for-delay agreements permits the patent holder to continue to exercise its monopolies over potentially weak patents. By maintaining monopoly control, the prices remain higher for a longer period than warranted in many cases and consumers are harmed because they are forced to pay high, sometimes unaffordable prices. Kaiser Family Foundation, *Healthcare Costs: A Primer, Key Information on Healthcare Costs and Their Impact* 23 (2012) (reporting that twenty-five percent of families did not fill a medical prescription and seventeen percent cut pills or skipped doses due to the high costs).

The branded pharmaceutical company has an incentive to pay off the first generic challenger

because in doing so, the company removes the firm that would benefit from the 180-day exclusivity and, thus, the most motivated challenger. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NEW YORK UNIV. L. REV. 1553, 1585 (2006). Removing the most motivated challenger clearly impedes the Congressional intent of the provisions of the Hatch-Waxman Act that provide an incentive for generic firms to challenge weak patents.

C. The Third Circuit Rule that Pay-For-Delay is Presumptively Anticompetitive Strikes the Appropriate Balance Between Promoting Progress and Protecting the Public Interest

The Third Circuit, in contrast to the Eleventh Circuit, found that pay-for-delay settlement agreements are presumptively anticompetitive and unlawful in violation of antitrust laws and "contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition." *In re K-Dur*, 686 F.3d 197, 214 (3d Cir. 2012). The Third Circuit correctly noted that the "scope-of-the-patent" test assumes validity in the underlying patent. *Id.* In essence, pay-for-delay "permit[s] the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid." *Id.* at 216 (*citing U.S. v. Studiengeselschaft Kohle, m.b.H.*, 670 F.2d 1122, 1136 (D.C. Cir. 1981)).

Although public policy generally favors settlements over full litigation, it "should not

displace countervailing public policy objectives or, in this case, Congress's determination—which is evident from the structure of the Hatch-Waxman Act and statements in the legislative record—that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers." *In re K-Dur* at 217.

Furthermore, as this Court has noted, public policy also favors promotion of innovation and progress, including rejecting invalid patents in order to allow innovators to rely on the public domain. *Cardinal Chem. Co. v. Mortion Int'l, Inc.*, 508 U.S. 83, 101 (1993) (noting that while the purpose of the patent system is to promote the progress of science and innovation, the patent system also has an "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.").

Unlike the Eleventh Circuit which applied a hardfast rule that reverse payments fall within the scope-of-the-patent regardless of the actual strength of the patent, the Third Circuit rule is a more flexible one, creating a rebuttable presumption that such settlement agreements are anticompetitive. The parties to the pay-for-delay settlement may rebut the presumption that the reverse payment is unlawful by showing either that the agreed payment was for a purpose other than delaying entry or offers a pro-competitive benefit. *In re K-Dur* at 218. This pro-competitive rule promotes the goals and objectives of the Hatch-Waxman Act and protects the public interest by preserving the incentive to challenge weak patents, rather than providing an incentive to immunize weak patents from antitrust scrutiny by

allowing branded pharmaceutical companies to buy off its generic competitors. By making this rule a presumption only, the Third Circuit opinion leaves open the possibilities that a pro-competitive reason for the reverse-payment exists or that the payment was done for a reason other than delayed generic entry. Furthermore, the Third Circuit rule is more appropriate because it does not make false assumptions about the validity or invalidity of the underlying patents-at-issue in the litigation.

A rule that pay-for-delay agreements are presumptively anticompetitive preserves the Congressionally created incentives contained in the Hatch-Waxman Act to challenge weak patents and promote generic competition. If generic applicants cannot share in the monopoly profits of the branded pharmaceutical company, they are less likely to enter into settlement agreements and more likely to continue litigating against weak patents in order to earn the 180-day marketing exclusivity if the patent is found to be invalid. The Third Circuit approach is therefore not only more pro-consumer, but also supports the purpose of the Hatch-Waxman Act.

CONCLUSION

For the reasons discussed above, this Court should reverse the decision below, reject the "scope-of-the-patent" test and instead adopt a presumption that pay-for-delay settlement agreements are anti-competitive and violate antitrust laws.

Respectfully submitted,

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