No. 12-416

In The
Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC. ET AL.,

Respondents.

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

BRIEF OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF RESPONDENTS

RICHARD F. PHILLIPS, *PRESIDENT*
KEVIN H. RHODES, *CHAIR*
AMICUS BRIEF COMMITTEE
INTELLECTUAL PROPERTY
OWNERS ASSOCIATION
1501 M Street, N.W.
Suite 1150
Washington, D.C. 20005
(202) 507-4500

ROBERT P. TAYLOR
COUNSEL OF RECORD
JONATHAN I. GLEKLEN
DIANE E. BIERI
ARNOLD & PORTER LLP
555 12th Street, NW
Washington, DC 20004
(202) 263-3000
robert.taylor@aporter.com

Counsel for Amicus Curiae

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INTEREST OF *AMICUS CURIAE*

Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO's membership includes more than 200 companies and a total of over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[1]

IPO submits this brief in support of Respondents in light of the importance of strong patent protection and the special role that patents play in encouraging pharmaceutical research and development.[2] IPO believes the presumption of illegality that Petitioner would attach to so-called reverse payment patent settlements would have a substantial negative

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[1] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

[2] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. The parties have consented in writing to the filing of this brief.

impact on innovation in the pharmaceutical industry and beyond.

SUMMARY OF ARGUMENT

Contrary to the position advanced by Petitioner and its *amici*, the issues in this case are fundamentally different from those in classic market division cases (*e.g.*, *Palmer v. BRG of Georgia*, *Inc.*, 498 U.S. 46 (1990)), where naked agreements among competitors are properly held to be *per se* violations of Section 1 of the Sherman Act. In such cases, the parties allocate markets without even an arguable basis for challenging each other's entry in the absence of a collusive agreement. Here, by contrast, a lawfully issued and presumptively valid patent would, until its expiration, bar generic firms from entering the market and competing with AndroGel® unless the patent were ruled either not valid or not infringed.

Central to this case—and to evaluating the agreements at issue—are the unique dynamics involved in the parties' efforts to settle expensive and time-consuming patent litigation on commercially reasonable terms that compromise the risk of unpredictable, erratic, or erroneous outcomes. Efforts to settle litigation of any kind usually involve mutuality of risk. Each party tries to assess a variety of factors that might affect that party's interests if the case should proceed to trial; both parties then try to find an agreeable exchange of increments of value that can offset one another and resolve the case without a trial.

The same is true of a patent infringement case, except that the opportunities for both misaligned risk assessments in settlement negotiations and erroneous outcomes at trial are often greater because

of the technical subject matter. Nonetheless, both sides in a typical patent case have something significant at risk if the case goes to trial. The infringer faces the possibility of substantial damages, maybe an injunction, and sometimes attorneys fees. The patent owner faces the risk of having a valuable property right being held invalid or substantially narrowed in scope, and often the further prospect of counterclaim liability. The settlement of such a case thus reflects the composite interaction of separate parties, each trying to predict and evaluate highly uncertain future events, and the mutual resolution of risk factors.

With Hatch-Waxman cases, however, this mutuality of risk is either missing entirely or is heavily shifted to favor the challenger of the patent. The Hatch-Waxman Act was designed to facilitate the entry of generic drugs into the market by giving a generic manufacturer a low-risk path for challenging the validity or coverage of an innovator's patent. The Act allows generic drug makers to trigger patent disputes without actually placing their products on the market, thus eliminating the likelihood of a damage award. The Act also rewards the first generic firm to challenge a patent associated with a particular drug by awarding 180 days of exclusivity following FDA approval and a successful patent challenge.

Data collected by the Federal Trade Commission show that generic drug makers have raced one another to challenge innovators' patents, and that they have compelling incentives to do so with little or no regard for the merits of those challenges. The heavily skewed risk profile of a Hatch-Waxman patent challenge essentially eliminates the normal

incidents of value that facilitate the settlement of other types of patent cases. In this judicial and regulatory construct, a transfer of value from the innovator to the generic manufacturer should not automatically—or even presumptively—trigger antitrust liability. Numerous courts and economists have found that, far from being "inherently suspect" as Petitioner would have it, such transfers of value are essential to facilitate settlement.

Simply put, there is no basis in law or logic to require the settling parties in a Hatch-Waxman case to overcome a presumption of illegality in order to justify a reverse payment settlement. To create such a requirement would negate the well-established statutory presumption of a patent's validity. Instead, the Court should hold that the objectives of the antitrust laws are met by asking whether the settlement unreasonably restrains trade outside the scope of the patent in question and allowing the parties to reach an arm's-length bargain where no such impact is apparent.

ARGUMENT

I. CONSUMERS BENEFIT FROM LEGAL STANDARDS THAT GIVE FULL FORCE TO PATENTS AND FACILITATE NEGOTIATED RESOLUTION OF PATENT LITIGATION

As a recent report published by the Department of Commerce acknowledges, "[t]he granting and protection of intellectual property rights is vital to promoting innovation and creativity and is an essential element of our free-enterprise, market-based system." Economics and Statistics Administration & United States Patent and

Trademark Office, United States Department of Commerce, *Intellectual Property and the U.S. Economy: Industries in Focus*, v (March 2012) (hereinafter *Commerce Department Report*), *available at* http://1.usa.gov/IkztGg. Clearly, innovation drives our national economy, and strong IP protection fuels that innovation.

A. Strong Patent Protection Serves As The Cornerstone For Innovation

Patents provide essential incentives for companies to invest in research and development and to assure the capital necessary to bring new products to market. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."). As the government has explained:

> The investments necessary to develop IP are often quite substantial. Firms and individuals, in order to invest the necessary resources, need some assurance that they will benefit from and recover the costs of the creation of intellectual property.

Commerce Department Report at 1. The fundamental mechanisms of the patent system have worked effectively for over two centuries to foster new technologies and new industries on an unparalleled scale.

B. Patent Protection And A Strong Patent System Are Essential Predicates To Bringing New Medicines To Market

In terms of their impact on personal and public health, pharmaceutical innovations surely stand among the most important advances in recent history. According to two University of Chicago economists, "[o]ver the last half century, improvements in health have been as valuable as all other sources of economic growth combined." Kevin Murphy & Robert Topel, *Measuring the Gains from Medical Research: An Economic Approach*, 4 (2003).

Patent protection is particularly critical to pharmaceutical innovation, given the immense investments and significant time required to discover and obtain regulatory approval for new drugs and the comparative ease of copying after an innovator has made those investments. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616-17 (2003) ("The ratio of inventor cost to imitator cost, therefore, is quite large in the absence of effective patent protection. As a result, it is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."); *see also* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 851 (2002) ("Absent patent protection, . . . imitators could free ride on the innovator's FDA approval and duplicate the compound for a small fraction of the originator's costs.").

Winning FDA approval for a new drug takes, on average, 15 years and costs more than $1 billion. *See* Peter Hutt et al., *Food and Drug Law* 764 (3d ed. 2007); PhRMA, *Drug Discovery and Development,*

available at http://onphr.ma/fTUYTc (last visited Feb. 22, 2013).[3] This figure includes the costs of working with thousands of compounds that enter the drug development pipeline but ultimately never make it to market. For every 5,000 to 10,000 compounds that enter the pipeline, only five will ever progress to clinical studies in humans and only one will ultimately receive FDA approval. PhRMA, *Drug Discovery and Development: Understanding the R&D Process*, 2 (February 2007), *available at* http://bit.ly/12gRzn1. One economist has noted that "[w]ithout a well-structured system of patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, as the rate of new product introductions and patent expirations would decline significantly." Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. at 853. Indeed, without patent protection, an estimated 65 percent of pharmaceutical products would never have been brought to market. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci., 173, 175 (1986).

C. The Ability To Settle Patent Litigation On Terms Acceptable To Both Parties Is A Crucial Component of Patent Enforcement

Pharmaceutical companies, like all patent owners, are entitled to assert their patents in court.

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[3] This figure likely underestimates the actual cost. A comparison of R&D budgets to the number of drugs major pharmaceutical companies launched over the last fifteen years yields average costs/successful launch of $3.6 billion to $11.8 billion. Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, Forbes, (Feb. 10, 2012), *available at* http://onforb.es/zxOm33.

Just as the right to litigate is vital to realizing fully a patent's protective purpose, so too is the right to resolve that litigation through a negotiated settlement. "The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits." *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005) (citations omitted).[4] Settlements resolve disputes with far less risk, time and expense than litigation imposes on the parties. They ease the burden on scarce judicial resources. And they provide certainty for all parties, allowing companies to focus on business interests rather than litigation disputes.

Petitioner pays lip service to the long-standing "public policy favoring settlement", yet gives virtually no weight to this policy in its analysis. Pet'r. Br. at 47. Instead, Petitioner asks the Court to adopt a rule that would raise substantial obstacles to settlement. Rather than enhancing competition from generic drugs, limiting settlement options could result in fewer patent challenges because generics will face greater risks challenging patents. Likewise, a rule that favors litigation to final judgment over settlement will also mean less generic competition because in recent years generic drug makers have lost more Hatch-Waxman trials than they have won.

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[4] *See also McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) ("public policy wisely encourages settlements"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 544 F.3d 1323, 1333 (Fed. Cir. 2008) ("there is a long-standing policy in the law in favor of settlements"); Brett Dickey, et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry,* 19 Annals Health L. 367, 375-76 (2010) (describing benefits of patent settlements compared to litigation).

Petitioner's dismissive attitude toward settlements appears to be driven by a belief that patent owners are willing to settle litigation primarily because the patents in question are weak. *See* Pet'r. Br. at 44 (pointing to purported "empirical evidence concerning actual outcomes in litigated patent cases"); Brief of *Amicus Curiae* Knowledge Ecology International in Support of Petitioner at 17; Brief of Apotex, Inc. as *Amicus Curiae* Supporting Petitioner at 4. In reality, data gathered by PricewaterhouseCoopers shows that branded pharmaceutical companies won 50% of Hatch-Waxman cases, on average, between 2006 and 2011 (and won 56% and 53% of cases in 2010 and 2011 respectively). PricewaterhouseCoopers, 2012 Patent Litigation Study 28 (2012), *available at* http://pwc.to/SHzquB. Faced with the uncertainties inherent in litigation and a 50% probability of winning, it is no surprise that both parties often prefer to settle rather than litigate to final judgment. Petitioner's claim that generics win 75% of the cases that go to trial is based on old data that looks only to the 1992 to 2000 time period. *See* Pet'r. Br. at 6-7.

More fundamentally, differentiating a weak patent from a strong one is not something readily accomplished by looking retrospectively at litigation outcomes in other cases. The fundamental reality of patent litigation is that the process is highly unpredictable, even to experts, and is error prone. This means that the strongest of patents has a substantial chance of losing after a trial and appeal, just as the weakest of patents has a substantial chance of winning. This reality nullifies any

conclusions that one might discern from a summary of outcomes in a small number of cases.[5]

Finally, Petitioner's reasoning ignores the statutory directive that patents "shall be presumed valid." 35 U.S.C. § 282. This presumption of validity does not permit the classification of patents as either weak or strong. An issued patent is presumed valid until it is adjudicated otherwise. As this Court recently recognized, in the face of similar arguments in a different context, neither allegations of "bad" or "weak" patents nor purported flaws in the patent system justify adoption of a legal standard that ignores the Congressional intent of Section 282. *See Microsoft Corp. v. i4i Limited Partnership,* 131 S. Ct. 2238, 2251-52 (2011) (policy arguments concerning "bad" patents cannot override Congress' intent that the presumption of a patent's validity can be overcome only by clear and convincing evidence).

When the parties to a patent case can find common ground on which to settle the case, a rule forcing the case to trial will be counterproductive. The Hatch-Waxman Act was intended to give generic drug makers the incentive to challenge patents, which it clearly does. The Act was not intended as a surrogate for the reexamination of every patent subjected to its procedures.

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[5] In 2011, the FTC lost two out of three of its litigated merger challenges. *See* Federal Trade Commission and Department of Justice, *Hart-Scott-Rodino Annual Report Fiscal Year 2011*, at 16-17, available at http://1.usa.gov/YEHivl. But Petitioner would presumably agree that its 33% win rate in litigated cases does not suggest that it likewise had "weak" arguments in the nine merger cases it settled that year via consent decree.

II. THE HATCH-WAXMAN ACT CREATES INCENTIVES THAT FUEL WEAK CHALLENGES AND INVITE REVERSE PAYMENT SETTLEMENTS

Innovators who bring a new pharmaceutical product to market go through a time consuming and expensive process to secure FDA approval of a New Drug Application, or "NDA." In contrast, the Hatch-Waxman Act allows generic drug makers to use a radically less expensive and faster process, the Abbreviated New Drug Application, or "ANDA," essentially "piggy-backing on the brand's NDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).[6] Firms pursuing this approach must show only that their generic product has the same active ingredients and is bioequivalent to a reference drug that previously has been approved. *Id.* Further, a company can seek approval from the FDA to market the generic drug before the expiration of a patent relating to the brand name drug by certifying that the patent in question is invalid or not infringed by the generic product (a "Paragraph IV certification"). 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

From the standpoint of the generic company, one of the most attractive features of the Hatch-Waxman Act is the ability to initiate a challenge to the patent without incurring any liability in doing so. Filing a Paragraph IV certification, in and of itself,

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[6] In contrast to the huge sums spent on bringing an innovator drug to market, the cost of preparing and filing an ANDA is about $1 million. Emily Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 Fordham Intell. Prop. Media & Ent. L.J. 245, 262 (2012).

constitutes an act of patent infringement, but in name only. 35 U.S.C. § 271(e)(2)(A). The patent holder does not sustain any damages, and the generic challenger is not required to bring products to market as a prerequisite to the challenge.[7] Normally, the generic drug maker's only risk in challenging a patent is that it will spend money on legal fees and FDA filings that it may not recover (or may recover only after patent expiration) if it loses the litigation. Further, the Hatch-Waxman Act grants 180 days of exclusivity to the first generic company to succeed in challenging an innovator's patents and win FDA approval for its product. 21 U.S.C. 355(j)(5)(B)(iv). Because the innovator's brand product rapidly loses substantial market share to the first generic that enters the market, a successful patent challenge often means enormous profits for the generic company.[8]

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[7] *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 51 (2010) ("Unlike the usual patent case, there are ordinarily no damages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic. As a result, no sales or profits are lost by the patentee to the generic. While patent infringement suits are often settled by compromise of a damages claim, that vehicle is typically not available in Hatch-Waxman cases.").

[8] Data collected by the FTC show a generic drug maker predicting gross profits of $170 million in the first ten months following the launch of a generic version of a drug with $500 million in annual brand sales. Fed. Trade Comm'n, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact at 91 n.57 (Aug. 2011), *available at* http://1.usa.gov/oGSiIg (hereinafter *FTC Report*).

The result of this combination of factors is that the Hatch-Waxman Act creates a powerful incentive for generic drug makers to challenge patents even where the patent holder is highly likely to prevail in court. Under these circumstances, as explained in more detail below, it is no wonder that "reverse-payment" settlements are the "natural by-product of the Hatch-Waxman process." *Schering-Plough*, 402 F.3d at 1074 (internal quotation marks omitted).

A. Hatch-Waxman Creates An Incentive For Generic Drug Makers To Challenge Patents Even Where They Have Almost No Chance Of Success

The actual result of these "skewed" incentives under the Hatch-Waxman framework is stunning. Petitioner itself recently concluded that "for a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has ***at least a 4 percent chance of winning . . . .***"[9] FTC Report at iii n.7 (emphasis added). If there is an authorized generic, the challenger "would need [only] a 10 percent chance of winning to expect a patent challenge to be profitable." *Id.*

Even the eye-catching statistics in the FTC Report understate the magnitude of generic drug makers' skewed incentives. Only about three percent of dollar sales of branded drugs facing a first

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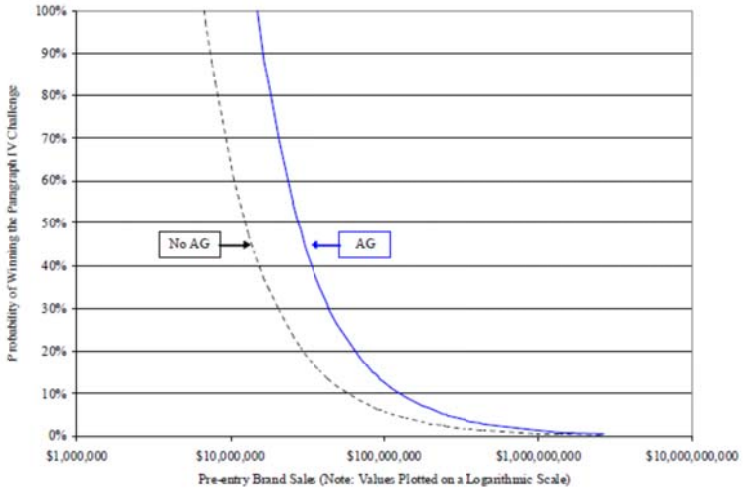
[9] "Authorized generic" or "AG" refers to a drug that is marketed by either the branded drug company or its licensee as a generic product under the innovator's NDA rather than under an ANDA. *See Mylan Pharm. v. FDA*, 454 F.3d 270, 273 (4th Cir. 2006).

generic challenge involve drugs whose annual sales are at or below $130 million. *Id.* at 115. The "break-even" likelihood of success required for a generic challenge falls dramatically as the level of sales increases. The following chart, taken from the FTC Report, shows that the likelihood of success required to justify a challenge to the patent covering a blockbuster drug is—literally—vanishingly small.

Figure 6-6: Break-Even Market Sizes for Varying Probabilities of Successful Paragraph IV Challenge



Id. at 118.

Specifically, for more than 90% of branded drug sales (measured in dollars), a generic challenger balancing upside gain under Hatch-Waxman against downside risk limited to litigation costs can justify the challenge if it believes it has at least a 1.3% chance of success. Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI Antitrust Chronicle, 2 (Sept. 2012), *available at* http://bit.ly/VMMTTS.

The FTC's own analysis thus shows that there are more likely to be challenges to drug patents than to other kinds of patents and that, when a blockbuster drug is involved, it is economically rational to challenge the patent even in the absence of grounds to believe the patent is infirm.[10] Indeed, in one case, the decision to pursue a generic version of a patented drug was made by the generic company's CEO based on historic sales levels, without consulting a patent lawyer and without review of the file history of the patents at issue. *Glaxo Grp. Ltd. v. Apotex, Inc.*, 268 F. Supp. 2d 1013, 1022-23 (N.D. Ill. 2003), *aff'd in part, rev'd in part*, 376 F. 3d 1339 (Fed. Cir. 2004). Moreover, incentives to challenge patents extend beyond the first generic filer; it is not unusual for blockbuster drugs to attract multiple generic challengers. *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 Santa Clara Computer & High Tech. L.J. 489, 520-21 & n.177 ("Highly profitable drugs with tremendous therapeutic utility should and do generally attract multiple generic challengers."); Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. at 377 & n.59.

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[10] *See* Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 Fordham Intell. Prop. Media & Ent. L.J. at 262 ("In effect, the Hatch-Waxman Act actually makes pharmaceutical patents weaker than any other type of patent by making challenges to pharmaceutical patents easier and more attractive than for any other type of patent.").

B. Reverse Payments Are A Natural Response To The Hatch-Waxman Framework

Numerous courts and commentators have attributed the prevalence of "reverse payment" settlements in Hatch-Waxman litigation to this distorted litigation dynamic. *See, e.g., Schering-Plough*, 402 F.3d at 1074; *In re Ciprofloxacin*, 544 F.3d at 1333 n.11; Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. at 388-89; Kevin McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, Antitrust 68, 69-70 (2003). As one court explained:

> [T]he Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude.

Schering-Plough, 402 F.3d at 1074 (citations omitted). In other words, reverse payments from the brand to the generic—even sizeable ones—should not be treated as unusual or inherently suspect.

Petitioner argues that there is nothing about the structure of the Hatch-Waxman Act that mandates "reverse-payment agreements as a natural response to the incentives that the Amendments create." Pet'r. Br. at 49. That argument is directly contrary to what the United States told this Court in its brief in an earlier case recommending against certiorari,

where the United States acknowledged that "[t]he resulting disparity in the litigants' respective risks may tend to increase the cost of settlement for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong." Brief for the United States as *Amicus Curiae* at 10, *Joblove v. Barr Labs.Inc.*, 551 U.S. 1144 (2007) (No. 06-830), *available at* http://1.usa.gov/XXiyhj. *See generally Schering-Plough Corp. v. FTC*, 402 F.3d at 1074-75 ("The Commission's inflexible compromise-without-payment theory neglects to understand that '[r]everse payments are a natural by-product of the Hatch-Waxman process.'") (quoting *In re Ciprofloxacin*, 261 F. Supp. 2d at 252 (E.D.N.Y. 2003)).

Petitioner argues that the increased leverage a generic manufacturer holds over the innovator in the Hatch-Waxman context need not result in a reverse payment, but could instead lead the generic manufacturer to negotiate for an earlier entry date. Pet'r. Br. at 50. This assertion fails to account for the difficulty encountered in settling many patent cases. Of course there may be situations where early entry might be sufficient to satisfy the generic challenger and secure a settlement in a specific case. On the other hand, the parties often have disparate views of the merits of a case, different risk profiles, and different priorities in terms of the litigation and settlement negotiations. In those situations, settlements can be difficult to achieve. *E.g., Schering-Plough*, 402 F.3d at 1073 ("Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts agreed that ancillary agreements may be the only avenue to settlement.");

Steven W. Day, *Leaving Room for Innovation: Rejecting the FTC's Stance Against Reverse Payments in Schering-Plough v. FTC*, 57 Case W. Res. L. Rev. 223, 250-55 (2006) (discussing "practical reasons" why an innovator and a generic firm may not be able to reach a settlement by agreeing solely on an earlier generic entry date).[11]

The fact is that a reverse payment (or other transfer of value) may facilitate a settlement in the Hatch-Waxman context when nothing else will, thus avoiding litigation costs and still providing for generic entry prior to patent expiration.

[11] In 2007, the CEO of generic manufacturer Barr Pharmaceuticals testified before the Senate Judiciary Committee that the ability of parties to reach a settlement agreement that provides for some consideration in addition to generic entry prior to patent expiration can assist parties "to narrow the gap" that may exist based on the parties' evaluations of the case on its merits. Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited? Hearing before S. Comm. On the Judiciary, 110th Cong. 28 (2007) (Statement of Bruce L. Downey, Chairman and CEO, Barr Pharm., Inc.).

III. REVERSE PAYMENT SETTLEMENTS SHOULD NOT BE CONSIDERED PRESUMPTIVELY UNLAWFUL AND ARE NOT PROPERLY SUBJECT TO A "QUICK LOOK" ANALYSIS

A. Applying A Presumption Of Illegality To Settlements That Fall Within The Scope Of The Patent Claims Would Contravene Precedent And Petitioner's Previous Statements To The Court

Petitioner acknowledges that "it is well established that" patent settlement agreements "generally do not violate the antitrust laws." Pet'r. Br. at 26 (citing *Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163, 171 (1931). This principle flows from the nature of the patent right itself and the fact that "the essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm and Haas Co.,* 448 U.S. 176, 215 (1980). If the patent owner has the statutory right to exclude others from activities within the scope of its claimed invention, there can be no adverse effect on competition in settling patent cases on terms that simply honor such proper exclusion. *E.g.*, *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918) ("[T]he right to exclude others from the use of the invention . . . . is not an offense against the Anti-Trust Act."); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997) (referencing "this Court's numerous holdings that it is the claim [of the patent] that defines the invention and . . . the limits of the patent monopoly").

Notwithstanding this right of a patent owner to exclude competitors from activities that would

infringe the claims of a patent, a right reaffirmed in multiple decisions of this Court over more than a century, Petitioner urges adoption of a rule under which *every* patent litigation settlement that does not permit immediate entry by the alleged infringer becomes suspect and subject to "antitrust analysis requir[ing] a nuanced examination of the specific terms" of the settlement. Pet'r. Br. at 27. This argument, as with much of Petitioner's position in this case, ignores the statutory presumption of validity and effectively assumes that any infringer that asserts the invalidity of a patent is likely to prevail, thereby benefiting consumers with lower prices. Petitioner does not explain how one would conduct the "nuanced examination" ostensibly required, except to say that the "likelihood that the patent holder would have prevailed" is irrelevant to that analysis. *Id.* at 54.

Petitioner would apply a particularly harsh rule to settlements involving a "reverse payment," arguing that such settlements should be viewed as "presumptively unlawful." *Id.* at 19. In so doing, the United States has abandoned the view, thrice-stated in briefs filed with this Court, that reverse payments are not presumptively unlawful. *See* Brief for the United States as *Amicus Curiae* at 9, *Andrx Pharms. Inc. v. Kroger*, *Co.*, 543 U.S. 939 (2004) (No. 03-779), *available at* http://1.usa.gov/Xf3qhd ("Reverse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare."); Brief for the United States as *Amicus Curiae* at 11, *Joblove v. Barr Labs. Inc.*, 551 U.S. 1144 (2007) (No. 06-830), *available at* http://1.usa.gov/XXiyhj ("[T]he public policy favoring settlements, and the right of a patent holder to exclude competition within the scope of its valid

patent, would be frustrated by adoption of a legal standard that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation."); Brief for the United States as *Amicus Curiae* at 11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No 05-273), *available at* http://1.usa.gov/12zorad ("[T]he mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."). Petitioner has not offered any explanation for its change of heart, and its new approach is incorrect as a matter of economics and common sense.

B. The Proposed "Presumption Of Illegality" Would Constrain Settlement Options In A Wide Variety Of Circumstances

Every settlement of patent litigation involves consideration of some kind flowing to the alleged infringer; otherwise there would be no reason to settle. *See generally Asahi Glass Co. v. Pentech Pharm. Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.), *appeal dismissed*, 104 Fed. Appx. 178 (7th Cir. 2004). With no bright lines, under Petitioner's proposed approach, every intellectual property owner that settles an infringement claim without authorizing immediate entry by the alleged infringer faces the prospect of lengthy and expensive antitrust litigation, for disputed issues of fact mean that neither dismissal on the pleadings nor dismissal at the summary judgment stage is likely to be available. But Petitioner's brief does not grapple with that issue.

Petitioner's effort to distinguish the "reverse payment" in this case from consideration that flows

in every other type of settlement is unavailing. In fact, there was no mere "direct payment of money" in this case; Solvay paid Watson for marketing AndroGel® to urologists, paid Paddock to act as a back-up manufacturer, and paid Par to market the drug to primary care physicians. Pet'r. Br. at 11. Petitioner alleges, however, that these agreements "made economic sense" only as payments for delayed generic entry because the services provided "had little value to Solvay." *Id.* at 12.

Even if these ancillary agreements, however, did involve "overpayments" (and how that might be determined is far from clear), the flow of consideration in these "reverse payments" cases is economically indistinguishable from the consideration that is commonly found in many litigation settlements. Endorsing Petitioner's proposed rule risks opening every patent settlement that does not result in immediate entry to antitrust challenge. Petitioner's proposed rule of law would mean that thousands of patent settlements outside the pharmaceutical context must be treated as "presumptively unlawful" and subject to "quick look" condemnation. The unprecedented overreach of Petitioner's proposed rule of law demonstrates its fundamental flaws.

The most common form of consideration in a patent settlement is a release of the patent owner's claim for damages. While, as we discuss above, a pharmaceutical patent holder will often have no damages claim against the alleged infringer because of the artificial act of infringement created by the Hatch-Waxman Act, that is not uniformly the case. Some generic drug makers launch "at risk" (after the expiration of the automatic 30-month stay), leading

to a damages claim for lost profits or a reasonable royalty. And, outside the pharmaceutical settlement context, it is common to settle infringement cases with an agreement by the infringer to withdraw its product from the market for some period of time while the patent holder compromises its damages claims by settling for less than the full damages it claims to be owed. If the patent holder has a risk adjusted expected damages recovery of $100 million and agrees to settle for $50 million, it has agreed to a "reverse payment" that is indistinguishable in effect from a $50 million cash payment. Either case involves a transfer of value worth $50 million from the patent holder to the alleged infringer.

In other cases the alleged infringer receives consideration that is less transparent, but consideration nonetheless. Imagine, for example, that the infringer expects to sell $200 million worth of infringing goods. If the patent owner agrees to a 25% royalty rather than a 50% royalty, it has transferred $50 million of value to the infringer. Would Petitioner second-guess every settlement with a running royalty to determine whether the royalty rate is a disguised reverse payment?

Petitioner suggests that this conundrum can be avoided if one looks only to consideration that the infringer would not receive even if it prevailed in the litigation, which Petitioner suggests "implies the other terms of the settlement are disconnected from any justification they might otherwise have had in the Patent Act." Pet'r. Br. at 30. But this is nothing more than *ipse dixit;* Petitioner does not explain *why* consideration only matters if the infringer would not receive it, even if it prevailed. Release of $50 million in damages claims or a $50 million reduction in

royalty payments is real consideration, even if the infringer would not have to pay either damages or royalties if it prevailed. Patent litigation is an uncertain business, and because we are speaking here only of non-sham litigation, alleged infringers are by definition facing exposure. Petitioner does not and cannot explain why a $50 million reduction in an accused infringer's exposure is less "presumptively unlawful" than, for example, the $2 million payment to Paddock to act as a backup manufacturer in this case.

Regardless, many settlements involve consideration to the alleged infringer that the infringer would not receive if it prevailed in the litigation—consideration that Petitioner acknowledges constitutes a "reverse payment" under its proposed test. For example, it is common for infringement litigation to settle with a broad release (including potential infringement claims under patents not asserted in the litigation). Some infringement litigation settles with the infringer receiving an exclusive or quasi-exclusive license in a field of use or territory. Other infringement litigation settles with a know-how license coupled with the patent license or with a license to patents not asserted in the lawsuit. All of these settlements give the alleged infringer something it would not get if it simply litigated through trial and appeal (a broad release, exclusive rights, or a know-how license or license to additional patents). But all would be "presumptively unlawful" under Petitioner's proposed rule.

C. There Is No Basis In This Court's Precedents To Apply The "Quick Look" Standard In This Case

This Court has held that conduct may be condemned using a "quick look" when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999). In *California Dental*, the Court held that "quick look" treatment was inappropriate because the challenged restrictions "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition." *Id.* at 771.

There is no basis to believe that "reverse payment" settlements, however defined, inevitably have an anticompetitive effect. Patent holders often prevail in infringement litigation, and any settlement that allows early entry by an infringer that would otherwise be off the market for the life of the patent has a net procompetitive effect regardless of the presence of a reverse payment.[12]

This is not a hypothetical argument. The cases reveal concrete examples of pharmaceutical patent owners that settled with some generics with a reverse payment and early entry and then litigated with other generics and prevailed, keeping these later infringers off the market. For example, after the settlement at issue in the Second Circuit's *Cipro* case, the patent was repeatedly upheld as valid in other Hatch-Waxman litigation, meaning that absent

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[12] It goes without saying that a "rudimentary understanding of economics" is of no assistance in determining the strength of a patent or the likely outcome of infringement litigation.

the settlement there likely would have been no early entry by any generic at all. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519-520 (E.D.N.Y. 2005) (summarizing results of litigation where Bayer defeated two generic companies' validity challenges on summary judgment and overcame another generic's validity challenge after a nine-day bench trial).

The same outcome occurred after the settlements at issue in *In re Tamoxifen Citrate Antitrust Litigation* were reached, 466 F.3d 187 (2d Cir. 2006), where the patent was repeatedly upheld as valid. *See Zeneca Ltd. v. Novopharm Ltd.*, No. 9601364, 1997 WL 168318 (Fed. Cir. Apr. 10, 1997); *Zeneca Ltd. v. Pharmachemie B.V.*, No. CIV.A.96-12413-RCL, 2000 WL 34335805 (D. Mass. Sept. 11, 2000).

Similarly, after Petitioner blocked a "reverse payment" settlement between Bristol-Myers Squibb and Apotex involving the drug, Plavix, BMS took the patent case to trial and won. *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007). These examples demonstrate that reverse payment settlements can have procompetitive effects by permitting entry that would not have occurred in the absence of the settlement.

Under *California Dental*, an agreement cannot be analyzed under the "quick look" approach unless someone with a "rudimentary understanding of economics" would conclude that the agreement is inevitably anticompetitive. Presumably the United States would concede that the Antitrust Division of the Department of Justice and the Office of the Solicitor General possess such a "rudimentary understanding of economics." The United States, over the signatures of both of those agencies, has

three times told this Court that "reverse payment" agreements are *not* inevitably anticompetitive and may in fact have *procompetitive* effects. The United States was obviously right in those three briefs; anyone possessing such a "rudimentary understanding" would instantly recognize that the settlements in *Cipro* and *Tamoxifen* did *not* have anticompetitive effects and that, as the United States previously told this Court, "[r]everse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare." Brief for the United States as *Amicus Curiae* at 9, *Andrx Pharms. v. Kroger*, *Co.*, 543 U.S. 939 (2004) N(o. 03-779), *available at* http://1.usa.gov/Xf3qhd.

Petitioner calls its version of the "quick look" doctrine the "inherently suspect" test. *See generally In re Polygram Holding*, *Inc.*, 136 F.T.C. 310 (2003), *aff'd sub nom. Polygram Holding v. FTC*, 416 F.3d 29, 35-36 (D.C. Cir. 2005). According to Petitioner, the inherently suspect test is reserved for conduct that "past judicial experience and current economic learning have shown to warrant summary condemnation." *Id.* at 344-45. Here, of course, with the exception of the Third Circuit's aberrant decision in *K-Dur*, "judicial experience" with "reverse payments"—six appellate decisions from three circuit courts—shows that summary condemnation is *not* warranted.

Indeed, Petitioner is itself a relatively recent convert to the application of the "inherently suspect" or "quick look" doctrine to these cases. In its 2003 decision challenging Schering's "reverse payment" settlements, Petitioner concluded that "[i]n cases like this one, where the conduct is not inherently suspect,

the prosecutor has the burden of demonstrating actual or likely market effects by reference to facts specific to the case." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 969 (2003), *vacated by Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

There have been no significant developments in economic or judicial thinking since the United States filed its briefs in *Joblove*, *Andrx* and *Schering*, or since Petitioner's own decision in *Schering*. This Court's "quick look" precedents and Petitioner's analogous "inherently suspect" precedents make plain that patent settlements cannot be condemned with a "quick look."

CONCLUSION

As explained in detail in Respondents' brief, the so-called "scope of the patent test" adopted by the Eleventh, Second and Federal Circuit Courts of Appeal in evaluating Hatch-Waxman settlements is firmly grounded in well-established precedents.

The Court should affirm the judgment of the Court of Appeals for the Eleventh Circuit and hold that reverse payment settlements should be reviewed under the scope of the patent test.

Respectfully submitted,

Richard F. Phillips,
President
Kevin H. Rhodes, *Chair*
Amicus Brief
Committee
Intellectual Property
Owners Association
1501 M Street, N.W.
Suite 1150
Washington, D.C.
20005
(202) 507-4500

Robert P. Taylor
Counsel of Record
Jonathan Gleklen
Diane E. Bieri
Arnold & Porter LLP
555 12th Street, NW
Washington, DC 20004
(202) 263-3000
robert.taylor@aporter.com

APPENDIX

APPENDIX

Members of the Board of Directors Intellectual Property Owners Association[1]

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