

September 9, 2009

The Honorable Patrick J. Leahy
Chairman
Committee on the Judiciary
U.S. Senate
Washington, D.C. 20510

The Honorable Jeff Sessions
Ranking Member
Committee on the Judiciary
U.S. Senate
Washington, D.C. 20510

Re: S. 369, the “Preserve Access to Affordable Generics Act”

Dear Chairman Leahy and Ranking Member Sessions:

On behalf of the American Intellectual Property Law Association (AIPLA), I am writing to express our deep concerns regarding S. 369, titled the “Preserve Access to Affordable Generics Act.” The bill automatically and conclusively would prohibit as *per se* antitrust violations certain patent infringement lawsuit settlements—those with so-called “reverse payments”—between brand name and generic drug manufacturers.

We are deeply concerned that the bill would ban common terms in patent infringement settlements without any consideration of their possible pro-competitive or competitively neutral justifications. This bill would automatically subject parties to potential damages claims for including such terms in their settlements, prevent pro-competitive or competition neutral settlements of patent litigation, and tie up the parties’ and courts’ resources with no justification. The proposed rule-making by the Federal Trade Commission would not meet these concerns. Contrary to the assumptions underlying the bill, the evidence indicates that so-called “reverse payment” settlements can be procompetitive or competitively neutral. Moreover, industry-specific competition rules are undesirable. Also, without justification, the bill would conflict with the trend in the courts and the federal antitrust agencies to limit, rather than expand, the types of conduct that automatically violate the competition laws.

AIPLA is a national bar association of approximately 16,000 members engaged in private and corporate practice, in government service, and in academia. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, and copyright law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property, and they have a keen interest in a strong and efficient patent system and in competition.

Provisions of Concern to AIPLA

S. 369 would declare *per se* illegal under an antitrust law, the Clayton Act, so-called “reverse-payment” settlements in patent infringement lawsuits between brand name drug manufacturers, who own or license the patents, and generic drug

manufacturers, who are alleged to infringe the patents. These lawsuits follow the generic drug manufacturers' filings of Abbreviated New Drug Applications with the Food and Drug Administration for approval to market generic versions of the brand name drug products pursuant to the Hatch-Waxman Act.¹ These lawsuits typically are filed either by the brand name manufacturer under 35 U.S.C. § 271(e)(2), or by the generic drug manufacturer as a declaratory judgment action under Section 271(e)(5), before the generic drug manufacturer begins to sell the generic version.²

Specifically, Section 3(a) of S. 369 would prohibit as an automatic, *per se* antitrust law violation a settlement of such an action where the generic drug manufacturer receives anything of value, agrees not to conduct R&D, and agrees not to manufacture, market, or sell the generic drug product for any period of time. (Proposed 15 U.S.C. § 29(a).) The sole exception would be where the brand name manufacturer gives the generic manufacturer *only* the right to market the generic version before the expiration of the patent that is the basis for the infringement claim. (Proposed 15 U.S.C. § 29(b).) In addition, the bill would permit the Federal Trade Commission to promulgate rules, under the administrative rule-making process, exempting certain agreements from *per se* illegality, if the FTC were to find that an agreement is in "furtherance of market competition and for the benefit of consumers." (S. 369 Sec. 3(b).)

AIPLA's Concerns

1. Banning Settlements Providing Other Value to the Generic Drug Manufacturer Would Ban Common Procompetitive or Competitively Neutral Settlement Terms and Strongly Inhibit Settlements

S. 369's blanket ban would prohibit numerous terms that parties commonly include in settlements of patent infringement litigation and that are procompetitive or competitively neutral. For example, including the following terms in such settlements automatically would violate the antitrust law:

- global settlement of litigations between the parties on the same drug in other countries;
- settlement of litigation between the parties relating to other drugs;
- general release of all claims regarding the drug;
- cross-licensing of other patents;
- payment of attorneys' fees of the generic drug manufacturer;
- patent licensing with a more favorable royalty rate than previously offered; and
- surrender of a claim for money damages

¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271(e), 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003).

² 35 U.S.C. §§271(e)(2), 271(e)(5).

Automatic antitrust violations also would result from terms that may be procompetitive in allowing the generic drug manufacturer more quickly to enter the marketplace for the drug in issue, or with other forms of that drug or other drugs, such as:

- the brand name drug manufacturer's supplying the active ingredient for the drug to the generic drug manufacturer, or vice versa;
- licensing the generic drug manufacturer to make the active ingredient or dosage forms of the drug under the brand name manufacturer's more efficient process patents;
- allowing the generic drug manufacturer to market an authorized generic version of a drug that is not the ANDA product; and
- allowing the generic drug manufacturer to sell other generic forms of the drug (e.g., extended release forms), or generic forms of different drugs, before the patents on those other forms or other drugs expire

Given the multitude of potential benefits in any settlement or licensing arrangement, a principle that relies on the receipt of consideration as a hallmark of *per se* illegality would prohibit a wide variety of procompetitive or competitively neutral terms.

The bill's provision allowing for the FTC to consider and promulgate regulations to exempt certain agreements from the scope of the *per se* prohibition (and presumably return them to standard antitrust analysis) would not even begin to solve the problem. (S. 369, Sec. 3(b).) Settling parties typically include a wide variety of terms in their patent infringement settlement agreements to meet the particular concerns of those parties. As a practical matter, the FTC could not feasibly consider and promulgate rules for the multitude of such terms.

Moreover, any such rule-making would require substantial time for the FTC to consider the terms and proceed through the normal rule-making process. Parties in the midst of litigation, who finally are ready and willing to settle, do not have the luxury of time to wait for that process. The finally-achieved momentum toward settlement would come to a halt and may dissipate during the indeterminate time for the rule-making process toward an uncertain result. At the same time, the parties would incur additional monetary and resource costs and tie up valuable court resources while waiting for that uncertain result, which would negate the major benefits of litigation settlements—removal of uncertainty and avoidance of very substantial additional litigation costs while heading toward trial. Furthermore, given the limited 30-month window for the automatic stay on the FDA's allowing the generic drug manufacturer to begin to sell its generic version after it challenges the patent,³ the brand name manufacturer could not reasonably afford to wait for the rule-making process and its uncertain result.

Also, the criteria for the FTC's creating exemptions would be the FTC's finding that the agreement "would be in furtherance of market competition and for the benefit of consumers." (S. 369, Sec. 3(b).) Many of the terms routinely employed in settlements

³ See 21 U.S.C. § 355(j)(5)(B)(iii).

may be competitively neutral and likely would not meet that standard, however, such as settlement of other litigation, cross-licensing of other patents, or payment of attorneys' fees. Nor would the FTC be able to consider, under the bill's language, any of the efficiency-enhancing features of patent settlements. In addition, the competitive effect of particular settlement terms necessarily depends upon the competitive conditions and effect in the particular market for the drug involved in the settlement, which would be analyzed under the rule of reason. Without fact-finding particular to each drug and settlement—i.e., conducting discovery and hearing presentations—the FTC could not validly evaluate whether a term in that settlement is “in furtherance of market competition and for the benefit of consumers.” The FTC is not equipped to undertake such fact-finding for each agreement, and certainly could not do so in a timeframe reasonable for the parties to the agreement to settle their litigation.

Significantly, as Judge Posner from the Seventh Circuit aptly observed, banning all settlements in which some value is transferred to the generic drug manufacturer (other than an early entry) would inhibit both challenges to drug patents and settlements of litigation over those patents:

A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive. . . . [A]ny settlement agreement can be characterized as involving “compensation” to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden “reverse payment,” we shall have no more patent settlements.

Asahi Glass Co. v. Pentech Pharms., Inc., 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

Settlements facilitate innovation and investment in the patented technology by eliminating litigation risks and providing certainty over patent rights, and by freeing up for more productive uses resources that would otherwise be devoted to litigation.⁴ These efficiency-enhancing benefits further the goals of the antitrust and patent laws. Settlement also serves an important public policy favoring resolution of disputes without litigation:

Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. . . . By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and the citizens whose taxes support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute.

⁴ See James Langenfeld & Wenqing Li, *Intellectual Property Agreements To Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L.J. 777, 778 (2003).

Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976).⁵

The disincentives to such settlements would be magnified under the bill, because an automatic antitrust violation would open both settling parties to treble-damage antitrust suits by federal and state governments and by private parties, typically through class actions.⁶ The violation of the antitrust law would not be in issue, because of the *per se* condemnation. Instead, the primary issues would be whether and how much in damages the settling parties owe—times three. No rational business decision-maker likely would decide to take that risk.

2. The Evidence Indicates, Contrary To the Assumptions Underlying S. 369, that “Reverse Payment” Settlements Can Be Procompetitive or Competitively Neutral

Of the patent settlements that have been challenged by the FTC and others, many have turned out to be precompetitive or competitively neutral. The first two challenged by the FTC involving Cardizem CD and Hytrin were settled by consent order. With Cardizem, the FTC conceded that “it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD.”⁷ With Hytrin, in a private action brought later, the plaintiff failed to convince a jury that the settlement had delayed the entry of a generic version of Hytrin.⁸ In the case against the K-Dur settlement, the court of appeals faulted the FTC for introducing no evidence to support its assumption that, absent the “reverse payment,” the parties would have negotiated a settlement that permitted even earlier entry than that which the settlement agreement provided.⁹

In other cases, the patent settlements appear to have resulted in earlier entry than would have occurred if the cases had not settled. Thus in cases involving Tamoxifen, Cipro, and Plavix, the patents were subsequently upheld in litigation.¹⁰ Had the

⁵ See also *E. Bement & Sons v. Nat’l Harrow Co.*, 186 U.S. 70, 93 (1902) (settlement of patent litigation through license agreements is “a legitimate and desirable result in itself”); *St. Louis Mining & Milling Co. v. Mont. Mining Co.*, 171 U.S. 650, 656 (1898) (“[S]ettlements of matters in litigation or in dispute without recourse to litigation are generally favored . . .”).

⁶ See 15 U.S.C. § 15.

⁷ Analysis To Aid Public Comment, *Hoechst Marion Roussel, Inc.*, 131 F.T.C. 924, 955 (2001).

⁸ See *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1041 (9th Cir. 2009).

⁹ See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005).

¹⁰ See *Zeneca Ltd. v. Novopharm, Ltd.*, 111 F.3d 144 (Fed. Cir. 1997) (unpublished); *Zeneca Ltd. v. Pharmachemie, B.V.*, No. CIV. A. 96-12413-RCL, 2000 WL 34335805 (D. Mass. Sept. 11, 2000); *Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1329 (Fed. Cir. 2008), *pet. for cert. filed* (No. 08-1194) (U.S. Mar. 23, 2009), available at <http://origin.www.supremecourtus.gov/docket/08-1194.htm>; *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2009).

settlements been prohibited, there is every reason to believe that the generic versions of those drugs would have met a similar fate in litigation and been held off the market until the patents had expired, rather than entering earlier, as provided in the settlements.

3. Industry-Specific Competition Rules Are Undesirable

AIPLA believes that industry-specific competition rules are generally undesirable and, as in this particular case, frequently counterproductive. The antitrust laws are broad mandates that leave to the courts the responsibility to delineate their meaning in concrete situations.¹¹ This allows the antitrust laws to achieve their goals through a process that is both flexible and evolutionary, adapting to the unique circumstances of markets and industries, to changing technologies and market conditions, and to the development and growth of legal and economic theory.

S. 369 represents a radical departure from this time-tested approach by incorporating into the Clayton Act, in unprecedented fashion, an industry-specific, narrowly focused *per se* rule against supposedly anticompetitive conduct. The proposed legislation is all the more inconsistent with the philosophy of the antitrust laws, because it runs directly contrary to the emerging consensus in the courts, which have been balancing all competing considerations under the rule of reason, about the proper treatment of this very conduct.

4. *Per Se* Illegality Is a Narrow Exception Reserved Only for Conduct Found Over Time Almost Always To Violate the Antitrust Rule of Reason—But Courts Have Upheld Such Settlement Agreements, Making *Per Se* Illegality Inappropriate

So-called “reverse payment” settlements are not appropriate for *per se* illegality, because courts have *not* found that they almost always violate the antitrust rule of reason against anticompetitive conduct. To the contrary, several appellate courts have found such settlements did not violate the rule of reason. Moreover, contrary to the bill, the trend in the Supreme Court and the federal antitrust agencies has been to narrow the categories of *per se* illegal conduct.

The *per se* rule is a court-made, narrow exception to the standard rule of reason analysis under the antitrust laws, reserved only for conduct that the courts have found, through experience over time, virtually always is anticompetitive:

Resort to *per se* rules is confined to restraints . . . that would always or almost always tend to restrict competition and decrease output. To justify a *per se* prohibition a restraint must have manifestly anticompetitive effects and lack any redeeming virtue.

¹¹ See, e.g., *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 687-88 (1978) (“Congress, however, did not intend the text of the Sherman Act to delineate the full meaning of the statute or its application in concrete situations. The legislative history makes it perfectly clear that it expected the courts to give shape to the statute’s broad mandate by drawing on common-law tradition.”).

As a consequence, the *per se* rule is appropriate only after courts have had considerable experience with the type of restraint at issue, and only if courts can predict with confidence that it would be invalidated in all or almost all instances under the rule of reason. It should come as no surprise, then, that we have expressed reluctance to adopt *per se* rules with regard to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious. And, as we have stated, a departure from the rule-of-reason standard must be based upon demonstrable economic effect rather than upon formalistic line drawing.

Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 127 S.Ct. 2705, 2712-13 (2007) (internal quotation marks, ellipses, and quoted sources omitted). S. 369’s *per se* prohibition on settlements with certain terms, however, would be “formalistic line drawing.”

The Supreme Court over the past three decades has trended toward further limiting the category of *per se* illegal conduct. See *Continental T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 59 (1977) (holding vertical territorial restraints not *per se* illegal); *State Oil Co. v. Khan*, 522 U.S. 3, 22 (1997) (holding vertical maximum price fixing not *per se* illegal); *Leegin*, 127 S.Ct. at 2725 (holding vertical price fixing not *per se* illegal). Likewise, the FTC and the Antitrust Division of the Justice Department have tended to judge conduct involving patents under a rule of reason standard rather than a *per se* illegal standard, including otherwise *per se* illegal conduct where efficiencies exist.¹²

Even the FTC’s opinion in the *Schering-Plough* “reverse payment” case recognized that so-called reverse payment settlements “can be procompetitive in limited circumstances. For example, a settlement that includes payments to a cash-starved generic might, in some circumstances, permit earlier entry than would otherwise occur.”¹³ Likewise, economists also have demonstrated that “reverse payments” can, in certain circumstances, produce procompetitive settlements.¹⁴

¹² See U.S. Dept. of Justice & Federal Trade Comm’n, *Antitrust Guidelines for the Licensing of Intellectual Property* 16 (April 6, 1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.pdf>; U.S. Dept. of Justice & Federal Trade Comm’n, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* 102 n.117, 114 (April 2007), available at <http://www.usdoj.gov/atr/public/hearings/ip/222655.pdf>.

¹³ *In re Schering-Plough Corp.*, FTC Dkt. No. 9297 at 13 (Dec. 8, 2003), available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

¹⁴ See Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, AMERICAN BAR ASSN SECTION OF ANTITRUST LAW, III ISSUES IN COMPETITION LAW AND POLICY, ch. 85, pp. 2130-32 (2008); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 677-78 (2004); Carl Shapiro, *Antitrust Limits To Patent Settlements*, 34 RAND J. ECON. 391, 407-08 (2003).

Moreover, routine patent licenses, including those that result from patent infringement litigation, often permit the accused infringer to practice the patent only within a certain scope in exchange for a contractual equivalent of an injunction for part of the patent term. Such restrictions traditionally have been evaluated under the rule of reason.¹⁵ Instead, the bill would completely prohibit such provisions as *per se* violations, unless they pertained only to the right to market the product prior to the expiration of the patent that is the basis for the patent infringement claim.

Deeming so-called “reverse payment” settlement agreements *per se* illegal not only would run directly counter to this trend by the courts and antitrust enforcement agencies, economic analysis, and case law for patent licenses generally, but also would run counter to the experience of the courts adjudicating such agreements under the antitrust laws. The appellate courts have rejected holding such settlement agreements *per se* illegal,¹⁶ with the exception only of the Sixth Circuit.¹⁷ The Solicitor General also has agreed that the rule of reason, not the *per se* rule, is the correct approach:

[I]n the context of the Hatch-Waxman Act, the mere presence of a substantial reverse payment as part of the settlement of a patent infringement claim is not sufficient to establish that the settlement is unlawful under the Sherman Act. The correct approach is to apply the rule of reason, rather than a rule of *per se* legality (or illegality).

Brief for United States as *Amicus Curiae* on Pet. for Writ of *Certiorari* in *Joblove v. Barr Labs., Inc.*, No. 06-830, 2007 WL 1511527 at *12 (May 23, 2007).¹⁸

¹⁵ See, e.g., *Brownell v. Ketcham Wire & Mfg. Co.*, 211 F.2d 121, 129 (9th Cir. 1954) (holding that an agreement that a licensee under a United States patent “will not sell or export” to any foreign country any products made under the license was “an agreement by [the licensee] to honor the territorial limits of the license granted, and was lawful” under the antitrust laws); *Miller Insituform, Inc. v. Insituform of N. Am., Inc.*, 605 F. Supp. 1125, 1130-31, 1130 n.3 (M.D. Tenn. 1985), *aff’d*, 830 F.2d 606 (6th Cir. 1987) (district court holding as a matter of law that patent licensor’s use of geographic restrictions in sublicensing its patent within the United States is immunized from antitrust liability under 35 U.S.C. § 261, but in any event is subject to analysis under the rule of reason rather than the *per se* rule; Sixth Circuit affirming and holding that patent owner did not violate Sherman Act § 2, 15 U.S.C. § 2, by exercising its patent right to exclude a former licensee from practicing the patent); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1132-35 (D.C. Cir. 1981) (upholding field of use restriction under rule of reason and rejecting *per se* rule); see also *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938) (“The practice of granting licenses for a restricted use is an old one. . . . So far as appears, its legality has never been questioned.”).

¹⁶ See *Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332-37, 1341 (Fed. Cir. 2008) (rejecting *per se* approach); *Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 206-07, 216 (2d Cir. 2006) (same); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065-66 (11th Cir. 2005) (same).

¹⁷ *Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908-09 (6th Cir. 2003) (employing *per se* approach).

¹⁸ See also Brief for United States as *Amicus Curiae* on Pet. for Writ of *Certiorari* in *Federal Trade Comm’n v. Schering-Plough Corp.*, No. 05-273, 2006 WL 1358441 at *11 (May 17, 2006) (“The mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful. Rather, an appropriate legal standard should take into account the relative likelihood of success of the parties’ claims, viewed *ex ante*.”); Brief for United States as *Amicus Curiae* on Pet. for Writ of *Certiorari* in *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779, 2004 WL 1562075 at *7 (July 9,

Indeed, the bill implicitly recognizes that a blanket *per se* approach is not appropriate by permitting the FTC to promulgate rules exempting certain agreements from the scope of the law. (S. 369, Sec. 3(b).) As discussed above, however, that rule-making is not a workable solution.

Consequently, this is not the special, limited situation appropriate for *per se* treatment where the courts have found after considerable experience that such agreements would be invalidated in almost all instances under the rule of reason.

Moreover, no other conduct is deemed by statute to be a *per se* illegal antitrust violation under the Sherman or Clayton Acts. No circumstances warrant treating such patent infringement settlements as a special circumstance and diverting from the judge-made rule for *per se* illegality that has evolved, and continues to evolve, over time for competition cases.

Conclusion

For the reasons discussed above, AIPLA strongly opposes these *per se* violation and rule-making provisions of S. 369.

Thank you for considering our views.

Respectfully Submitted,



Teresa Stanek Rea
President

2004) (“A rule treating as a *per se* violation of the antitrust laws every patent infringement settlement agreement that precludes the marketing of allegedly infringing products in exchange for payments from the patentee to the alleged infringer (so called “reverse payments”) would conflict with the well-established principle that *per se* treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect.”).