

July 16, 2010

The Honorable Harry Reid
Majority Leader
United States Senate
The Capitol, Room 221
Washington, DC 20510-7010

The Honorable Mitch McConnell
Minority Leader
United States Senate
The Capitol, Room 231
Washington, DC 20510-7020

**Re: Opposition to Pharmaceutical Patent Settlement Agreement Provisions
in H.R. 4899, 2010 Supplemental Appropriations Bill**

Dear Majority Leader Reid and Minority Leader McConnell:

On behalf of the American Intellectual Property Law Association (AIPLA), I am writing to express our deep concerns regarding the Pharmaceutical Patent Settlement Agreement Provisions in H.R. 4899, the 2010 Supplemental Appropriations Bill that passed in the House of Representatives on July 1, 2010. H.R. 4899 was amended to include language nearly identical to S. 369, titled the “Preserve Access to Affordable Generics Act,” which seeks to prohibit certain patent infringement lawsuit settlements—those with so-called “reverse payments”—between brand name and generic drug manufacturers.

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.

We are deeply concerned that the bill effectively would ban common terms in patent infringement settlements by prohibiting agreements that are potentially procompetitive or competitively neutral. The bill would do this by imposing a presumption of illegality and erecting a particularly demanding legal standard that will make it exceedingly difficult for parties to demonstrate that patent infringement settlements are procompetitive. This bill would chill the use of patent settlement agreements by subjecting parties to potential monetary penalties for including such terms in their settlements, prevent procompetitive or competition-neutral settlements of patent litigation, and tie up the parties’ and courts’ resources with no justification. The proposed rulemaking by the Federal Trade Commission (“FTC”) would not meet these concerns.

Contrary to the assumptions underlying the bill, evidence indicates that so-called “reverse-payment” settlements can be procompetitive or competitively neutral. Moreover, industry-specific competition rules are undesirable, particularly in antitrust law, where more than a century of judicial decision-making provides clear standards for the types of competitive concerns that this legislation attempts to address. Also, the quasi *per se* rule for reviewing these agreements would conflict with the trend in the courts and federal antitrust agencies to limit, rather than expand, the types of conduct that automatically violate the competition laws.

Provisions of Concern to AIPLA

The Patent Settlement Agreement Provisions in H.R. 4899 would establish a rebuttable presumption that certain patent settlement agreements—so-called “reverse-payment” settlements in patent infringement lawsuits between brand name drug manufacturers, who own or license the patents, and generic drug manufacturers—are illegal under the Federal Trade Commission Act (“FTC Act”). These settlements arise in the lawsuits that follow the generic drug manufacturers’ filings of Abbreviated New Drug Applications (“ANDA”) with the Food and Drug Administration (“FDA”) for approval to market generic versions of 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 4202(a)(2)(A) of H.R. 4899 would establish a presumption that a settlement of such an action where the generic drug manufacturer receives anything of value, agrees to limit or not to conduct R&D, or agrees to limit or not to manufacture, market, or sell the generic drug product for any period of time, violates the FTC Act. (Proposed 15 U.S.C. § 44(a).) The only exceptions 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 or before the expiration of any other patent or exclusivity that would prevent the marketing of the generic drug. (Proposed 15 U.S.C. § 44(b).) The presumption is rebuttable, but only if the parties to the agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh its anticompetitive effect.³

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).

³ The bill provides that, in determining whether the pro-competitive benefits of the agreement outweigh its anti-competitive effects, the fact finder should consider the following factors: 1) the remaining time on the patent relative to the agreed upon entry date for the generic product; 2) the value to consumers of competition from the generic product allowed under the agreement; 3) the form and amount of consideration received

In addition to the clear and convincing standard, the bill also would proscribe courts from presuming that generic entry would not have occurred prior to patent expiration absent the settlement, or presuming that an agreement for generic entry prior to patent expiration is procompetitive. (H.R. 4899, Sec. 28(c)(1), (c)(2).) In addition, the bill would permit the Federal Trade Commission to promulgate rules, under the administrative rulemaking process, exempting certain agreements from the presumption of illegality, if the FTC were to find that an agreement “will further market competition and benefit consumers.” (*Id.*, Sec. 28(e)(1).)

The bill would provide civil penalties where agreements are held illegal. Where the brand manufacturer receives value from the violation, the civil penalty may be up to three times the value received by the brand manufacturer reasonably attributable to the violation of the legislation. Where the brand manufacturer does not receive value, the penalty to the brand manufacturer would be no larger than three times the value given to the generic filer. (*Id.*, Sec. 28(g)(1).) In addition, the bill (with the exception of the monetary penalty provisions) would apply to agreements entered into after November 15, 2009, covering agreements that were forged well before the enactment of the legislation. (*Id.*, Sec. 4202(b).)

AIPLA’s Concerns

1. Presumed Antitrust Illegality of Patent Settlements Providing Other Value to the Generic Drug Manufacturer Effectively Would Ban Common Procompetitive or Competitively Neutral Settlement Terms and Strongly Inhibit Settlements

The Patent Settlement Provisions of H.R. 4899 would have a chilling effect on the usage of 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 be presumed illegal:

- 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;
- patent licensing with a more favorable royalty rate than previously offered; and
- surrender of a claim for money damages.

by the generic filer in the patent settlement agreement; 4) the revenue the generic filer would have received by winning the patent litigation; 5) the reduction in the brand manufacturer’s revenues if it had lost the patent litigation; 6) the time period between the date of the agreement conveying value to the generic filer and the date of the settlement of the patent infringement claim; and 7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection. (H.R. 4899, Sec. 28(b).)

The presumption of illegality, and resulting monetary penalty risk and legal costs, would result from terms that may be procompetitive by allowing the generic drug manufacturer to more quickly 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;
- 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; and
- the brand name manufacturer investing in other drugs being developed by the generic manufacturer.

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 a presumption of illegality effectively 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 rebuttable presumption of illegality (and presumably return them to standard antitrust analysis) would not even begin to solve the problem. (H.R. 4899, Sec. 28(e).) Settling parties typically include a wide variety of (often novel) terms in their patent 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 rulemaking would require substantial time for the FTC to consider the terms and proceed through the normal rulemaking 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 rulemaking 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 pre-trial litigation costs.

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,⁴ the brand name manufacturer could not reasonably afford to wait for the rulemaking process and its uncertain result.

Also, the criteria for the FTC exemptions would be the FTC's finding that the agreement "will further market competition and benefit consumers." (H.R. 4899, Sec. 28(e)(1).) Many of the terms routinely employed in settlements may be competitively neutral and likely would not meet that standard, however, such as settlement of other litigation or cross-licensing of other patents. In addition, the competitive effect of particular settlement terms necessarily depends upon the competitive conditions and effects 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 "will further market competition and benefit 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, effectively rendering illegal 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 resources for more productive uses than litigation.⁵ 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:

⁴ See 21 U.S.C. § 355(j)(5)(B)(iii).

⁵ 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).

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.

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

As has been pointed out in testimony before Congress, restricting such settlements would have the effect of furthering litigation which does not benefit anyone. “As a result, it would force companies to engage in patent disputes that might otherwise be settled reasonably, quickly, and in the public interest. The parties involved could be forced to spend significant resources on litigation, diverting those resources from valuable investment in future innovation.” (*Pay to Delay: Are Patent Settlements that Delay Generic Drug Market Entry Anticompetitive?: Hearing Before the Subcommittee on Courts and Competition Policy, House Judiciary Committee*, 111th Cong. 4 (2009) (statement of Guy Donatiello, Vice President for Intellectual Property for Endo Pharmaceuticals Inc.) <http://judiciary.house.gov/hearings/pdf/Donatiello090603.pdf>).

The disincentives to such settlements would be magnified under the bill, because under the clear and convincing standard that would apply in initial FTC litigation under the bill, defendants would bear a heavy burden to prove that the procompetitive benefits of settlements outweigh any anticompetitive effect, a burden that would be unique (and reverse of the normal burden) under antitrust law.⁷ Given the difficulty of meeting this burden, no rational business decision-maker likely would decide to take the enormous risk of settling patent litigation as a result of the high likelihood of substantial monetary penalty and potential costly follow-on private litigation.

⁶ 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”).

⁷ Traditional rule of reason analysis involves no presumption of illegality and places the burden on the challenging party to show by a preponderance of the evidence that the anticompetitive effects of the challenged activity outweigh its procompetitive benefits. See e.g., *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007); *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679 (1978).

2. The Evidence Indicates, Contrary To the Presumption in the Patent Settlement Agreement Provisions of H.R. 4899, that “Reverse-Payment” Settlements Often Are Procompetitive or Competitively Neutral

Of the patent settlements that have been challenged by the FTC and others, many have turned out to be procompetitive 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.”⁸

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.⁹ 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.¹⁰

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.¹¹ Had the settlements been prohibited, or had defendants been required to rebut a presumption of illegality by clear and convincing evidence, there is every reason to believe that the generic versions of those drugs would have been held off the market until the patents had expired, rather than entering earlier, as provided in the settlements.

⁸ Analysis To Aid Public Comment, *Hoechst Marion Roussel, Inc.*, 131 F.T.C. 924, 955 (2001).

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

¹⁰ *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005).

¹¹ *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), *cert. denied*, 129 S.Ct. 2828 (2009); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2009).

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.¹² 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.

The Patent Settlement Agreement Provisions of H.R. 4899 represent a radical departure from this time-tested approach by incorporating into the FTC Act, in unprecedented fashion, an industry-specific, narrowly focused, radically heightened rule-of-reason standard 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, without any presumption of illegality, about the proper treatment of this very conduct.

4. Courts Have Upheld Patent Settlement Agreements Under the Traditional Rule of Reason, Making the Heightened Standards in the Patent Settlement Agreement Provisions of H.R. 4899, Which Effectively Establishes *Per Se* Illegality, Inappropriate

So-called “reverse-payment” settlements are not appropriate for a heightened rule-of-reason analysis or effective *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 conduct presumed to be illegal and expand the usage of traditional rule-of-reason analysis. Courts have appropriately handled this matter, making legislation unnecessary.

The rule of reason is the standard approach for reviewing the legality of competitive actions under antitrust law. Heightened standards, including the *per se* rule and the quick look rule of reason, are appropriate only where there is substantial evidence that the challenged behavior is almost always anticompetitive.

¹² See, e.g., *National Society of Professional Engineers 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.”).

The Patent Settlement Agreement Provisions of H.R. 4899 impose a rebuttable presumption of illegality and a heightened evidentiary standard to institute a novel antitrust standard that functionally amounts to a *per se* ban. Like a *per se* ban, the presumption of illegality assumes that settlement agreements are almost always anticompetitive. The demanding clear and convincing evidence standard imposed on the proponents of an agreement would make it extremely difficult for parties to overcome the presumption of illegality, such that, coupled with substantial monetary penalties, the practical effect would be equivalent to a *per se* ban.¹³

There is simply no evidence to support the claim that these agreements are almost always anticompetitive, as is demonstrated clearly by the overwhelming majority of cases that have found settlement agreements legal using a standard rule-of-reason approach.

The *per se* rule, which creates—like H.R. 4899—a presumption of illegality, is a court-made, narrow exception to standard rule-of-reason analysis, 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.

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, 886-87 (2007) (internal quotation marks, ellipses, and quoted sources omitted). The bill’s presumption of illegality and effective *per se* prohibition on settlements with certain terms, however, clearly would be “formalistic line drawing.”

¹³ In the patent field “clear and convincing evidence” requires that the inference must be “the single most reasonable inference able to be drawn from the evidence.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357,1366 (Fed.Cir. 2008).

The Supreme Court over the past three decades has trended toward further limiting the category of *per se* illegal conduct and expanding the use of traditional rule-of-reason analysis. *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*, 551 U.S. at 907 (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.¹⁴

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 and declined to apply a *per se* rule for that reason. For example, a settlement that includes payments to a cash-starved generic might, in some circumstances, permit earlier entry than would otherwise occur."¹⁵ Likewise, economists also have demonstrated that "reverse payments" can, in certain circumstances, produce procompetitive settlements.¹⁶

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.¹⁷

¹⁴ *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>.

¹⁵ *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>.

¹⁶ *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).

¹⁷ *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

Moreover, courts have traditionally held that restrictions within the scope of the exclusivity granted by the patent are lawful under rule-of-reason analysis.¹⁸ The bill would depart from this approach, applied to every other type of patent licensing agreement, by effectively prohibiting such provisions in patent settlement agreements, 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. No other type of patent licensing agreement is subject to such a stringent standard, which would allow restrictions that are within the scope of the patent to be deemed unlawful.

Presuming so-called “reverse-payment” settlement agreements are 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,¹⁹ with the exception only of the Sixth Circuit.²⁰ The Solicitor General also has agreed that the rule of reason, not the *per se* rule, is the correct approach:

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.”).

¹⁸ *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303 (11th Cir. 2003) (employing scope of the patent test to determine legality of patent settlement agreements); *Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332-37, 1341 (Fed. Cir. 2008) (same); *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); *In re Androgel Litigation (II)*, 687 F.Supp.2d 1371 (N.D. Ga. 2010) (same).

¹⁹ *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).

²⁰ *Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908-09 (6th Cir. 2003) (employing *per se* 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).²¹

Indeed, the bill implicitly recognizes that a blanket presumption is not appropriate by permitting the FTC to promulgate rules exempting certain agreements from the scope of the law. (H.R. 4899, Sec. 28(e)) As discussed above, however, that rulemaking is not a workable solution.

Consequently, this is not the special, limited situation appropriate for a presumption of illegality, i.e., where the courts have found after considerable experience that such agreements would be invalidated in almost all instances under the rule of reason. To the contrary, courts routinely have upheld these agreements.

Moreover, no other conduct is singled out by statute to be presumptively unlawful under the Sherman or Clayton Acts. There are no special market factors or circumstances related to pharmaceutical patent settlement agreements that justify creating a unique, ad hoc antitrust standard, or using the legislative process to address competition law that has evolved, and continues to evolve, through jurisprudence.

²¹ 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, 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.”).

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5. The Patent Settlement Provisions of H.R. 4899 Are Retro-Active, Prohibiting and Providing Liability for Agreements Entered Into Before It Was Enacted

The bill would impose retro-active prohibitions on agreements entered into November 15, 2009. This post-hoc condemnation of agreements entered into before the change in the law unfairly imposes risks, including potential litigation costs, on parties that were not on notice of potential illegality. This runs counter to the well-established principle that parties should be given the opportunity to conform their conduct to the law, and should not be subject to ex post facto condemnation.

Conclusion

For the reasons discussed above, AIPLA strongly opposes the presumption of illegality, and heavy legal burden for rebutting this presumption of illegality, and rulemaking provisions of the Patent Settlement Provisions of H.R. 4899.

Thank you for considering our views.

Respectfully submitted,



Alan J. Kasper
President