S. 214's Inappropriate Interference With the Fundamental Right to Settle Litigation

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EXECUTIVE SUMMARY

Patent settlement agreements with consideration in generic drug patent litigation that is brought pursuant to the Hatch-Waxman Act have been a cause of concern to the Federal Trade Commission. The FTC has taken the position that these agreements delay the time when generic equivalents of patented drugs are able to enter the market. A bill has been introduced in Congress to address this concern. The bill -- S. 214 -- would presume that all reverse payment settlement agreements are unlawful and put an extremely heavy burden on the settling parties to prove to the FTC that the pro-competitive effects of their settlement outweigh the settlement's anti-competitive effects.

S. 214 is an incorrect and inappropriate way to deal with the perceived problem that patent settlements may, in some circumstances, pose for the availability of generic drugs. Recent history shows that most of these agreements help accelerate, not delay, the public availability of inexpensive generic equivalents of patented drugs. By presuming that all patent settlements with consideration are illegal, S. 214 would make it very difficult -- sometimes impossible -- for the parties to patent disputes to achieve such useful settlements. The enactment of S. 214 would be both wrong in principle and counterproductive in practice.

Settlements of patent infringement cases that bring a generic drug to market before the end of the patent term of the patented drug serve the public interest in accelerating the availability of inexpensive generic drugs. These agreements also serve the public's and the parties' interests in avoiding expensive, complex and time-consuming litigation. Because of these beneficial effects, the law's presumption should favor, not oppose, such agreements. Presuming that these settlement agreements are illegal also conflicts with the fundamental due process principle that private litigants are ordinarily entitled to decide, free from government interference, how to litigate their own cases. A presumption of invalidity would inappropriately free the government from the substantial burden it ought to have to justify interfering with that basic right, and instead inappropriately place that burden on the parties seeking to exercise that fundamental right. A presumption of invalidity would, in addition, be inconsistent with the long-standing statutory presumption that patents issued by the government are valid, as well as turn on its head the normal and common-sense practice in American law of requiring the plaintiff or complaining party in a case to satisfy the burden of proof, rather than requiring the defendant or respondent

to bear that burden, which will often entail the impossible task of proving the existence of a negative.

While placing the burden of proof on the wrong party, S. 214 also poses the wrong issue as the basis for deciding whether or not to permit a settlement. S. 214 would require settling parties to prove, by clear and convincing evidence, that their agreement, in addition to shortening the effective patent term, would, on balance, have pro-competitive rather than anti-competitive effects. That is an abstract and essentially meaningless speculative question where presumably valid patents are concerned, since patents are intended, if valid, to preclude competition in the patented product for the extent of the patent term. The question that should be asked, in light of the Hatch-Waxman Act's purpose to hasten the public availability of generic drugs, is whether settlement of an infringement case will give the public access to a generic drug before patent expiry. The fact that consideration is included as part of a settlement agreement does not by any means demonstrate that the public's access to a generic drug will be delayed.

For these and other reasons, courts considering the legality of reverse payment patent settlements have almost uniformly held those settlements to be lawful, so long as the agreement in question does not extend the patent's term or scope. In rejecting those thoughtful and well-reasoned decisions, S. 214 would unnecessarily interfere with the basic right of private parties to control litigation strategy free from governmental interference, reverse the ordinary burden of proof in civil cases and, as a result, prevent many settlements that, if permitted, would significantly serve the public interest. S. 214 is neither wise nor useful legislation.

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I. Introduction

Senate Bill S. 214, the Preserve Access to Favorable Generics Act, has been introduced in this session of Congress as a response to perceived problems caused by so-called "reverse payment" settlement agreements of patent infringement cases involving patented drugs. The bill contains findings that these agreements "have unduly delayed the marketing of low-cost generic drugs," and have resulted in "consumers losing the benefits that the 1984 [Hatch-Waxman] Act was intended to provide."[1] S. 214's stated purpose is to regulate "reverse payment" settlement agreements in order to "prohibit[] anticompetitive practices in the pharmaceutical industry that harm consumers."[2]

S. 214 defines a "reverse payment" settlement agreement, perhaps more accurately referred to as a "patent settlement with consideration," as an agreement settling patent infringement claims between the maker of a

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1 S. 214, § 2(a)(6)(B), (D).

2 *Id.* at (b)(2).

patented drug and the maker of a generic equivalent in which the generic manufacturer "receives anything of value" from the patent holder, while agreeing "to limit or forego research, development, manufacturing, marketing, or sales of the [generic] product for any period of time."[3]

These patent settlements with consideration can and typically do serve the public interest because a common term in these agreements is that the patent holder will permit the generic version of the drug to enter the market before the expiration of the term of the underlying patent. Such agreements result in significant cost savings to consumers. For example, Lipitor, the best-selling prescription medicine of all time, became available in generic form in November 2011 through such a settlement. If, instead of settling, the parties had proceeded with the patent infringement litigation and if the patentee had won, the generic drug would not have been available to the public until 2017.[4]

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[3] S.214 §(a)(2).

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

It is true that patent litigation settlements with consideration can, in some circumstances, be contrary to the public interest. A settlement agreement of this kind that kept a generic drug out of the market for the entire, or almost the entire, patent term and that, in doing so, excluded all other potential generic competition would presumably be against the public interest.[5]

The problem, then, is to permit the many good agreements that further the public interest while prohibiting those that do not. The Medicare Modernization Act of 2003 currently does this by requiring parties to settlements to file the agreements with the Federal Trade Commission and the Department of Justice.[6] If either the FTC or DOJ objects to the agreements, it may challenge the settlement, bearing the burden of showing the negative effects of challenged agreements on a case-by-case basis.[7]

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[5] Since the adoption of the Medicare Modernization Act of 2003, all but one federal appeals court to address the issue have held that the provision of consideration by the patent owner to the generic drug manufacturer as part of a settlement is legal so long as the agreement does not extend the scope of the patent. *See, e.g., In re Cardizem Antitrust Litigation,* 332 F. 3d 896 (6th Cir. 2003) (interim settlement that prevented or delayed approval of all other generic drug applications is unlawful); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F.Supp.2d 188, 242 (E.D.N.Y. 2003) (distinguishing cardizem case from other patent settlements containing consideration); Ken Letzler and Sonia Pfaffenroth, *Patent Settlements: Good Medicine or Wrong Prescription?* 23 Antitrust 81, 82 (Vol.2) (Spring 2009).

[6] Medicare Modernization Act of 2003, § 1112 *et seq.*, codified at 21 U.S.C. § 355 (note).

[7] *See Schering-Plough, Corp. v. Federal Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213-14 (2d Cir. 2006).

S. 214, however, would presume that all patent settlement agreements are illegal, and would place the burden on the parties to the agreement to prove to the FTC that the pro-competitive effects of the settlement outweigh its anticompetitive effects. This white paper explains why the enactment of S. 214 would be harmful, rather than helpful, to consumers and how it unnecessarily conflicts with basic principles of the American judicial system.

II. The Role of Settlements in the U.S. Justice System

It is important in considering the provisions of S. 214 to understand the historic and important role that settlements play in our justice system. The English common law recognized the importance of settlement as a valid means of resolving disputes, and had procedures in place to encourage it. [8]

[8] 3 Blackstone, Commentaries on the Laws of England 15-16 & n.53 ("ACCORD is a satisfaction agreed upon between the party injuring and the party injured; which, when performed, is a bar of all actions upon this account." As if a man contract to build a house or deliver a horse, and fail in it; this is an injury, for which the sufferer may have his remedy by action; but if the party injured accepts a sum of money, or other thing, as a satisfaction, this is a redress of that injury, and entirely takes away the actions. By several late statutes, particularly 11 Geo. II. c. 19. in case of irregularity in the method of disreining; and 24 Geo. II. c. 24. in case of mistakes committed by justices of the peace; even tender of sufficient amends to the party injured is a bar of all actions, whether he thinks proper to accept such amends or no.). *See also* J.Chitty, Esq. of the Middle Temple, Barrister, The Practice of the Law in all its Departments 58 (Vol. 2 1834) (a circuit court companion from the British judiciary indicating the deeply engrained nature of settlements) ("As to compromises, they may be made and invited by the attornies [sic]

The "plea of tender," for example, was a procedure through which a debtor could, by making an offer before commencement of suit, or paying money into court at the outset of litigation, shift the cost of litigation onto the creditor plaintiff.[9] Our justice system has always preferred people to resolve their own disputes. "Discourage litigation. Persuade your neighbors to compromise whenever you can. Point out to them how the nominal winner is often a real loser--in fees, expenses, and waste of time." The Language of Liberty: The Political Speeches and Writings of Abraham Lincoln 124 (Ed. Joseph R. Fornieri 2003) (quoting Abraham Lincoln's "Notes of July 1, 1850?(?)" law lecture).

Courts have repeatedly recognized that the ability of parties to avoid litigation through settlement results in both private benefits to the adverse parties and benefits for the public and the court system.[10] Voluntary

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on each side; . . . they cannot be taken advantage of injuriously by either party. . . . The offer of a compromise should be liberal, fair, and adequate to the circumstances[.]")

[9] 3 Blackstone, Commentaries on the Laws of England, at 304; *see also id.* n. 52 ("the plaintiff, it seems, can gain now advantage by not taking the money out of court, and it has been said that if the plaintiff shall not take any money, but take issue on the tender, then the defendant shall have it.").

[10] *See e.g.*, *St. Louis Mining & Milling Co. v. Montana Milling Co.*, 171 U.S. 650, 656 (1898) ("settlements of matters in litigation, or in dispute, without recourse to litigation, are generally favored"); *Williams v. First Nat'l Bank*, 216 U.S. 582, 595 (1910) ("compromises of disputed claims are favored by the courts"); *McCarthy v. Cahill*, 249 F. Supp. 194, 198 (D.D.C. 1966) (noting that the courts should encourage, promote, and sustain the compromise and settlement of disputed claims); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976); *American Sec. Vanlines, Inc. v. Gallagher*, 782 F.2d 1056, 1060 (D.C. Cir. 1986) ("Few public policies are as well established as the

resolution of disputes avoids the "inveterate and costly effects of litigation."[11] Voluntary settlements, by "[f]orego[ing] formal courtroom procedures, including discovery, trial, briefs and arguments, bring substantial benefits to the parties. The costs of litigation are reduced and crowded dockets are relieved."[12] Settlements eliminate uncertainty for both the litigating parties and the public at large.[13] With the potential of lengthy delays and numerous appeals, a case that is not settled can persist without a final judgment for many years. For these reasons, it is well established that courts will not ordinarily interfere with good-faith litigation settlements.[14]

Modern federal procedural rules expressly encourage settlement. For example, Rule 16 of the Federal Rules of Civil Procedure permits judges to

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principle that courts should favor voluntary settlements of litigation by the parties to a dispute."); 15B Am Jur 2d Compromise and Settlement § 3.

11 *Schering-Plough, Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1075 (11th Cir. 2005).

12 *Janneh v. GAF Corp.*, 887 F.2d 432, 435 (2d Cir. 1989).

13 *See D. H. Overmyer Co. v. Loflin*, 440 F.2d 1213, 1215 (5th Cir. 1971).

14 *See Hennessy v. Bacon*, 137 U.S. 78, 85 (1890) (finding a settlement beneficial and binding even if the court felt that a different outcome would be warranted upon review as long as the settlement was not the result of fraud); *D. H. Overmyer Co. v. Loflin*, 440 F.2d 1213, 1215 (5th Cir. 1971) ("Settlement agreements are highly favored in the law and will be upheld whenever possible because they are a means of amicably resolving doubts and uncertainties and preventing lawsuits." And a unilateral negligent mistake cannot provide a basis for avoiding a legal settlement.); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) (settlement agreements should be upheld whenever equitable and policy reasons permit); *Hemstreet v. Speigel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988) (there is a compelling public interest in enforcing voluntary settlement agreements).

order pre-trial conferences for the purpose of facilitating settlement, and requires that parties or their representative be reasonably available to consider a possible settlement during such conferences.[15] Even if the court does not order a pre-trial conference specifically for settlement purposes, the Rules direct that the parties "must consider . . . the possibilities for promptly settling or resolving the case."[16] The civil discovery process under Rule 26 is designed in part to promote the settlement of disputes, and Rule 68 creates a "cost incurred" penalty if one party rejects a formal settlement offer and fails to obtain a judgment more favorable than the rejected offer.[17] In order to encourage settlement of litigation, Rule 408 of the Federal Rules of Evidence prohibits the introduction of evidence of settlement negotiations as proof of the parties' position on the merits.[18] Congress has also both mandated that all civil litigants consider using alternative dispute resolution processes and has required federal agencies to develop policies that use alternative dispute resolution as a potential means to resolve disputes with or

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15 Fed R. Civ. P. 16(a)(5); Fed R. Civ. P. 16(c)(2)(I); Fed R. Civ. P. 16(c)(1).

16 Fed R. Civ. P. 26(f)(2).

17 *See* Fed R. Civ. P. 68(d); *Delta Air Lines, Inc. v. August*, 450 U.S. 346, 352 (1981) ("Rule 68 provides an additional inducement to settle in those cases in which there is a strong probability that the plaintiff will obtain a judgment but the amount of recovery is uncertain.").

18 *See* Fed. R. Evid. 408; H. Rep. No. 93-650, 1974 U.S.C.C.A.N. 7075, 7081; S. Rep. No. 93-1277, 1974 U.S.C.C.A.N. 7051, 7057.

before the agency.[19] The ethical canons of many states obligate attorneys to disclose any offer of settlement to their clients, no matter how unappealing that settlement may appear to counsel.[20]

These general policies encouraging litigation settlements apply with special force to patent litigation, with its high stakes, uncertainty, and inherent complexity.[21] Patent litigation is an "infamously costly and notoriously unpredictable process."[22] For these reasons, the overwhelming majority of patent litigants (95%) forego the vagaries of trial and appeal and settle their cases.[23] An examination of 370 patent infringement cases between 2000 and 2010 reveals that, when these disputes proceed to trial,

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19 *See* 28 U.S.C § 652(a); The Administrative Dispute Resolution Act of 1996, Pub. Law No. 104-320 (requiring federal agencies to have ADR policies in matters including contract disputes, administrative litigation and enforcement actions, and encouraging them to settle disputes).

20 *See* Model Rules of Prof'l Conduct R 1.2 (resting the power to settle with the client); *id*. at R 1.4(a)(1) (requiring that the attorney communicate to the client offers of settlement); *see also id*. at 1.2 cmt. 1.

21 *See, ,e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008); *See* RBC Capital Markets, Industry Comment: Pharmaceuticals 4 (Jan. 15, 2010), reprinted in Generic Pharmaceutical Association, Drug Patent Litigation Settlements: A compendium of Relative Materials (Vol. 1) (indicating the low success percentage of 48% when cases are fully litigated but 76% success when settlements are allowed); *TM Patents, L.P. v. IBM Corp.*, 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999) ("nearly 40 percent of claims constructions are changed or overturned by the Federal Circuit").

22 *Federal Trade Comm., v. Watson Pharm., Inc.*, 677 F.3d 1298, 1300 (11th Cir.); *see also TM Patents, L.P. v. IBM Corp.*, 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999) ("nearly 40 percent of claims constructions are changed or overturned by the Federal Circuit").

23 Marc G. Schildkraut, Patent-Splitting Settlements & the Reverse Payment Fallacy, 71 Antitrust L.J. 1033, 1048 (2004).

the generic challenger to a drug patent loses more often than not, so that the generic drug cannot enter the market until the conclusion of the patent term.[24] In contrast, when settlements are factored in along with cases that are won or dropped, the generic success rate jumps to 76 percent.[25] Of the 22 generic drugs that entered the marketplace in 2011, 17 of the entries resulted from the settlement of patent infringement litigation.[26] One generic manufacturer estimated that the early generic entry permitted by its settlements alone "removed 138 years of monopoly protection" and saved consumers $128 billion.[27] Indeed, despite claims by the FTC[28] that patent settlements with consideration would cripple the ability of generic drugs to enter the market, the industry estimates that amount of consumer savings due to generic drugs has hit new record highs in each of the past ten years, in

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24 *Id.*

25 RBC Capital Markets, Industry Comment: Pharmaceuticals 4 (Jan. 15, 2010), *reprinted in* Generic Pharmaceutical Association, Drug Patent Litigation Settlements: A compendium of Relative Materials (Vol. 1)

26 *Id.* at 7.

27 *See* Teva Pharms. USA, Press Release, *Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements* (June 24, 2009), http://tinyurl.com/TevaStatement.

28 Jon Liebowitz, This Pill Not to be Taken with Competition, Washington Post (Feb. 25 2008), available at http://www.washingtonpost.com/wp-dyn/content/article/2008/02/24/AR2008022401669.html.

substantial part due to the ability of parties to arrive at litigation settlements.[29]

As the current Chief Judge of the Federal Circuit, which handles all patent appeals, stated:

> The courts are not a guarantor of all resolution of all disputes; rather, in the American system of Justice we prefer to encourage private settlement. In America, the courts are not here to solve all the problems. They're not here to repair all the holes in the stairways in every department store in America, they're not here to guarantee that everyone gets the right cost for anything, whether it be intellectual property or the rent they pay on their apartment. Rather, the court is a kind of a safety net. It is the final arbiter to whom you can turn when all private resolution mechanisms fail."[30]

III. The Key Provisions of S. 214

S. 214 would presume that all settlements of ANDA litigation[31] are unlawful if the generic drug company receives "anything of value" and agrees to limit or forego "marketing or sales" of the generic drug for "any

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[29] GPha, *Savings: 1.1 Trillion over Ten Years: Generic Drug Savings in the U.S.* at 3 (2012).

[30] Judge Randall Rader, U.S. Court of Appeals for the Federal Circuit, Washington, D.C., CASRIP Symposium Keynote Address: *The Pace and Expense of Litigation in United States Courts* (No. 5 2000), *available at* http://www.law.washington.edu/casrip/symposium/Number5/pub5atcl1.pdf.

[31] ANDA litigation arises in the context of the Hatch-Waxman Act, as amended by the Medicare Modernization Act of 2003, 21 U.S.C. § 355. Hatch-Waxman permits the generic drug manufacturer to file an "Abbreviated New Drug Application" in which it relies on the patented drug's research and clinical testing. The filing of that application, combined with a particular kind of certification by the ANDA filer is an act of patent infringement and serves to commence litigation over the drug patent's validity.

period of time."[32] To overcome the presumption, the parties to the settlement would have to show by "clear and convincing evidence" that the "procompetitive benefits of the agreement outweigh the anti-competitive effects of the agreement."[33]

To make the burden on the settling parties especially onerous, the legislation would unaccountably forbid the fact-finder from presuming that an agreement is legal because it provides for "entry of the [generic] product prior to the expiration of the relevant patent term."[34] Violations of S. 214 are tried before the Federal Trade Commission, and carry the threat of millions in damage awards.

IV. S. 214 Is Harmful and Inappropriate Legislation

A. Many Settlements that S. 214 Presumes to be Invalid Accelerate the Availability to Consumers of Inexpensive Generic Drugs

S. 214's presumption would presume the illegality of many settlements that can and do enable consumers to have access to cheaper drugs that facilitate the early entry of the generic drug into the marketplace. In the language of the bill, agreements in which the generic drug

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32 S. 214, § 3(a)(2).

33 S. 214, sec. 3(2), § 2(a)(2)(B). That clear and convincing standard is the highest existing burden of proof in civil cases.

34 S. 214, sec. 3(2), § 28(c)(2).

manufacturer receives "anything of value" and delays putting the generic drug on the market for "any period" of time are presumed unlawful. For example, the drug Lamictal treats bipolar disorder and depression. In 2005, the owner of a patent in Lamictal agreed, in a settlement that S. 214 would have presumed to be illegal, to allow the generic manufacturer to sell a chewable generic version of the drug 37 months before the patent expired.[35]

Another example of a reverse payment settlement that S. 214 presumed to be illegal involved the branded drug Nolvadex (tamoxifen)—at the time of litigation, the most widely prescribed cancer drug in the world. Four generic companies challenged the validity of the drug's patent. The settlement permitted one of the companies to offer a generic version of the drug nine years before the patent expired.[36] The generic drug manufacturers that did not join the settlement litigated and lost their cases. And in the case currently being considered before the Supreme Court, a settlement that S. 214 would presume to be illegal resulted in a generic drug entering the market five years before the end of the patent term of the drug for which it

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[36] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 195 (2d Cir. 2006), cert. denied, 551 U.S. 1144 (2007); *see id.* at 190, 193-95.

was an equivalent.[37] These and other similar agreements have accelerated access to cheaper drugs.

B. Presuming that Patent Settlements With Consideration Are Illegal Is Wrong

1. Parties Have a Presumptive Right to Settle Cases Unless the Government Demonstrates that a Settlement is Harmful to the Public Interest. S. 214 Does Not Require the Government to Make that Showing.

As explained earlier in this paper, the ability of parties to settle claims is a basic feature of the American judicial system. Settlement of claims without undue government interference is an essential aspect of the due process that the Constitution guarantees. That is not to say that resolution of claims through settlement, like any litigation strategy, is completely immune from governmental regulation and limitation. Governmental interference with the presumptive and due process-related right to settle claims rather than bear the costs and uncertainties of litigation must, however, be supported by a demonstrable need for that interference. If the right to settle claims to a dispute is to have meaning and substance, government must be required to bear the burden of proving that a settlement

[37] Pet Br. at 43 n.10, *Federal Trade Comm. v. Watson Pharm., Inc.*, No. 12-416 (U.S.).

that it wants to prevent is so likely to be contrary to the public interest that the freedom of parties to choose to settle, rather than litigate their opposing claims must give way.

S. 214 flies in the face of the presumptive right of parties to settle, rather than litigate their opposing claims. It presumes, without proof, that patent settlements containing certain terms are contrary to the public interest, even when those settlements unquestionably result in accelerated public access to inexpensive generic drugs, and places upon the parties that wish to settle the heavy burden of proving, by clear and convincing evidence, that their settlement is not harmful to the public. That requirement that parties prove their entitlement to exercise a basic procedural right, as a substitute for why the right should not be exercised, is a dangerous assault on a cornerstone of procedural due process.

2. S. 214 Conflicts with the Well-Established Rule that Plaintiffs, Not Defendants, Bear the Burden of Proving their Case.

S. 214's presumption against the legality of patent settlements with consideration conflicts with the normal rule that plaintiffs, not defendants, should bear the affirmative burden of proving the elements of their case. S. 214 does not ban all patent settlements within its scope. It recognizes, as it

must, that some patent settlements with consideration promote the public interest in access to generic drugs, even if other settlements of that kind do not. In Anglo-American law, the way that issues of that kind are resolved is to place upon the complaining party—in the case of S. 214, the FTC—the burden of proving its case. By requiring the settling parties to prove that their agreement is not a harmful one, S. 214 does exactly the opposite. The proposed statute offers no justification for reversing the ordinary burden of proof in American civil litigation.

3. S. 214's Approach is Inconsistent with the Presumption of Patent Validity.

Patents issued to inventors by the U.S. Patent Office are, by statute, deemed presumptively valid – unless the contrary is shown, they give a valid legal monopoly to the inventor for the full extent of the patent term.[38] If that presumption is correct, the settlement of Hatch-Waxman Act litigation through an agreement that shortens the period of the patent monopoly will almost certainly favor the public interest, since such a settlement will make the generic version of the drug available to the public before the end of the legal monopoly that the presumptively valid patent provides. For that reason, most courts have recognized that, so long as the settlement

[38] 35 U.S.C. § 282(a).

agreement does not extend the patent's scope or lengthen its term, the settlement will not conflict with the public interest in the prompt availability of generic drugs.[39] One can presume that such settlements will be contrary to the public interest, as S. 214 does, only by ignoring the statutory presumption of patent validity.

4. Because Hatch-Waxman Encourages the Parties to Sue, It is Unfair to Remove the Primary Tool By Which they Can Resolve Their Dispute.

Congress intended the Hatch-Waxman Act to lower drug prices by making it easier for generic drugs to come to market.[40] It accomplished this goal by encouraging patent owners and the generic industry to litigate the validity of drug patent claims. Hatch-Waxman has by all accounts been successful in achieving its aims, and the Act expressly recognizes patent litigation settlements as an integral part of its statutory scheme.[41]

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[39] *Compare In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2828 (2009) (patent settlement agreement with consideration permissible so long as patent monopoly not extended); *Schering Plough Corp. et al. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S.Ct. 2929 (2006) (same); with *In re K Dur*, 686 F.3d 197 (3d Cir. 2012) (presuming consideration to be unlawful). *See also FTC v. Watson*, 677 F.3d 1298 (11th Cir.), cert. granted, 133 S.Ct. 787 (2012).

[40] *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (noting that Hatch-Waxman's purpose is "to speed the introduction of low-cost generic drugs to market").

[41] *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I), (II).

Having encouraged the parties to litigate, it would be unfair to deprive them of resolving the litigation through settlement—the way that the vast majority of patent cases have historically been resolved. S. 214's strong presumption of settlement invalidity will do just that in most cases. And given Hatch-Waxman's structure, the presence of consideration in these settlements "are particularly to be expected . . . because the Hatch-Waxman Act created an environment that encourages them."[42]

C. S. 214 Asks the Wrong Question By Focusing on Competition Rather than Quicker Access to Generic Drugs

In addition to placing the burden of proof on the wrong party, S. 214 focuses the required proof on the wrong issue. The basic purpose of the Hatch-Waxman Act is to bring generic drugs to the market as early as possible, while preserving the incentives to develop useful new products that patent law is designed to provide. As discussed above, the critical issue under that Act is not whether the settlement fosters competition. It is whether the settlement will make the generic drug available to the public sooner than it would be if the presumptively valid patent were fully enforced for its statutory term. S. 214, however, asks the finder of fact to ignore that

[42] *In re Tamoxifen*, 466 F.3d at 206 (citation omitted); *see Schering-Plough*, 402 F.3d at 1074 (observing that Hatch-Waxman shifted the relative risks of the parties in a way that explains the flows of consideration and its magnitude).

question, and focus instead on the net pro or anti competitive effect of the settlement, a factor that has no legal relevance with respect to a valid patent, which is intended to preclude competition for the duration of the patent period.

S. 214's concern over "competition" is entirely misplaced. When it enacted Hatch-Waxman, Congress's overriding concern was on enhancing consumer access to lower priced generic drugs, and the Hatch-Waxman Act recognizes that patent settlements are a successful means of ensuring that access. By addressing the presence of consideration in patent settlements entirely from the perspective of whether or not competition is increased, S.214 ignores the fact that patents are *themselves* "anti-competitive:" the inventor has a monopoly in the invention as a reward for innovation. That is why courts have generally held patent licenses immune from antitrust review. [43] Examining the settlement's effect on "competition" as a way of determining whether the settlement is in the public interest is therefore a non sequitur.

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[43] *U.S. v. General Electric Co.*, 272, 490 (1926) (noting that it was "entirely reasonable" for the patent owner to fix prices of sale of the patented invention with the licensee); *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902); *see also In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 201-02 (2d Cir.2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir.2003).

Whether or not a settlement agreement actually promotes consumer access to cheaper drugs depends on whether the patent would be held valid, an uncertainty that the settlement is intended to resolve and a reality S. 214 utterly ignores. S. 214 presumes the presence of consideration in these settlements to be fundamentally corrupt. As Judge Posner explained, however, the presence of consideration in the settlement agreement may be essential if the generic is to be given the opportunity to compete with the patented drug:

> 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. At any rate, the theory, good or bad, is inapplicable here. … Any 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. … In this case, in contrast, the settlement led to increased competition, first in Puerto Rico and now throughout the United States. Another way to put this is that in this case there is only a "payment" to the settling defendant when competition breaks out. The "payment" of Puerto Rico to [the generic] increased the competition there, and the "payment" in the form of free paroxetine occurred as a byproduct of increased competition, that is, of [the generic] selling in competition with [the patent holder].[44]

V. CONCLUSION

[44] *Asahi Glass v. Pentech*, 289 F. Supp. 2d 996, 994 (2003).

S. 214's presumptive prohibition of consideration in patent settlements is hopelessly flawed. It would interfere with the basic right of litigants to decide whether to settle their disputes, impose unusual and unfair burdens of proof on litigants, ignore the statutory presumption of patent validity, serve to frustrate the pro-litigation scheme created under the Hatch-Waxman Act, and preclude many settlements that will promote the interests of consumers. Rather than adopting that unusual and dangerous solution, the government should utilize the tools it has in hand under the Medicare Modernization Act of 2003 that requires the FTC to review and prove the illegality of settlements on a case by case basis—an approach consistent both with the benefits these settlements create for consumers, and long-standing traditions of constitutional fairness.