"Promoting the Progress" or Paying for Delay? Balancing Patent and Antitrust Law in the Age of Health Care Reform

*By Robert G. Pluta**

In patent litigation valued between $1 million and $25 million, a patent owner should expect to spend more than $2 million litigating the patent through trial and appeal. Costs can climb above $4 million where more than $25 million is at stake.[1] While the rewards for successfully enforcing a patent may be large and beneficial, the risks are large as well: loss of the patent through invalidation means a loss in, among other things, current or potential licensing revenue enjoyed by the patent holder. Sunk costs for research, development, and bringing to market a product or process that may be the subject of the claims of the patent also raise the stakes of litigation. The risks and rewards involving pharmaceutical patent litigation are no exception, and may be higher in many respects.

Costs to bring a drug to market are substantial.[2] A new drug is essentially an information good—once its formula is understood, it is generally easy and inexpensive for others to manufacture it without incurring similar research and development costs.[3] Empirical evidence suggests that higher drug profits are positively correlated with greater research and development efforts.[4] Pharmaceuticals have been associated with the case for strong patents because of the substantial research and development costs.[5]

Things are more complicated than they seem. Congress has established an elaborate regulatory scheme to test the validity and scope of the pharmaceutical patent such that, if the patent holder's patent is found invalid or not infringed, a generic competitor may enter the market prior to the scheduled expiration of the patent.[6] For reasons explained below, this scheme spawns patent infringement lawsuits between a pharmaceutical patent holder and a generic drug manufacturer aspiring to enter the market. Oftentimes such lawsuits, as with most patent litigations, end in settlement.

Sometimes, settlement results in payments made to the accused infringer.[7] Individuals and organizations that are suspicious of such payments often derogate them as "reverse payments" or "pay-for-delay" because they believe the natural direction in which payments should flow in settling a patent litigation is from the alleged infringer to the patentee-plaintiff, rather than the other way around. Critics primarily cite concerns for competition and consumer cost as reasons such payments should explicitly be ruled antitrust violations.[8] However, most courts that have considered the issue find "reverse payment" settlements in line with the antitrust laws.[9] Yet, even with a fairly consistent pronouncement from the circuit courts on the issue, controversy remains.

The current White House Administration has indicated that eliminating such payments is one of the ways to achieve savings to help pay for health care reform.[10] The FTC chairman has indicated that eliminating these deals is one of the FTC's highest priorities,[11] and the DOJ is following suit.[12] Congress is currently wrangling over legislation that would do away with "reverse payments."[13]

Are these payments good or bad for competition? Are these settlements consistent with the patent system's goal of "promoting progress"?[14] The answer, as with most in law, is: "It depends." This paper highlights some concerns of the proposed legislation and suggests that per se treatment of so-called "reverse payments" under the antitrust laws would upset the delicate balance between patent and antitrust law, and likely be harmful to competition and to consumers in the long run.

I. Brief History of The Hatch-Waxman Framework

The genesis of "reverse payments" is the Hatch-Waxman Act (the "Act"). The Act incentivizes innovator companies to develop and market new drugs and treatments and incentivizes generic firms to introduce low cost versions of branded drugs.[15] The Act sets forth procedures for securing early determination of whether a generic drug infringes patent rights.

Once a New Drug Application ("NDA") has been approved, the Act allows a generic firm to market a competing version of the drug without repeating the process endured by the NDA applicant, provided the generic firm adheres to tenets of the Act. The filing of an Abbreviated New Drug Application ("ANDA") by a generic rival is less complicated and time-consuming than seeking an NDA. The ANDA applicant need not independently demonstrate safety and efficacy of the drug, but rather must show that the proposed generic is bioequivalent to an approved branded drug.[16]

As part of the ANDA process, the ANDA applicant must, for each unexpired patent included in the branded drug's listing with the government, either identify the patent and its expiration date (a "Paragraph III certification") or certify that each patent listed is either invalid or not infringed by the proposed generic (a "Paragraph IV certification").[17] A Paragraph IV certification is an act of infringement under the patent statute, thereby implicating the branded drug's right to enforce its patent immediately and enabling the generic applicant to challenge the patent without making potentially infringing sales that exposes it to damages.[18] Upon Paragraph IV certification, the generic must provide notice to the holders of the applicable patent.[19] If the patent holder does not file an infringement lawsuit within forty-five days of receiving notification of Paragraph IV certification, the FDA may approve the ANDA.[20] If the patent holder files suit within the prescribed time, FDA approval for the ANDA is automatically stayed for thirty months with certain exceptions or until the court hearing the infringement case determines that the patent is invalid, not infringed, or unenforceable, whichever is earlier.[21]

The Act incentivizes generic firms to challenge patents by granting the first ANDA holder to file a Paragraph IV

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certification a 180-day generic exclusivity period, during which time the FDA will not approve any other ANDAs containing Paragraph IV certifications that list the same branded drug and patent.[22] The 180-day exclusivity does not begin to run until one of the first filers markets the drug or until any generic applicant obtains a final, non-appealable judgment against the patent, whichever is earlier.[23] A first filer retains its 180-day exclusivity if it is sued by a patentee and the parties subsequently settle and agree that the generic can begin marketing on a date certain. This exclusivity period stokes the controversy of so-called reverse payment settlements because when the patentee settles with the first filer, it prolongs the time during which newcomers cannot enter the market other than the party that enjoys the Act's exclusivity period.

II. Hatch-Waxman Litigation

Significant litigation has occurred addressing the issues surrounding reverse payments in pharmaceutical litigation. Nearly every circuit court that has addressed the issue has ruled that reverse payments do not necessarily run afoul of the antitrust laws.[24] Certain cases often cited by the FTC and opponents of "reverse payments" are distinguishable because those cases involved interim agreements in which a branded drug company paid a generic challenger to stay off the market while the patent litigation continued.[25] Such agreements neither settle litigation nor foster innovation, and therefore courts have recognized that they are not subject to the same analysis as reverse payment situations.[26]

The majority of courts that have considered the issue have adopted a "scope of the patent" test, which states that settlements are lawful, even if they contain reverse payments, so long as competition is not restricted beyond the scope of the patent's claims or beyond its term. These courts recognize that "a delicate balance must be drawn between [antitrust law and patent law]."[27] As Michael Friedland has noted in these pages,

> If the interests of antitrust law were ignored, patent law could be used as a pretext for collusion. A company could use an invalid patent for, among other things, cover for a price-fixing scheme . . . . Ignoring the interests of patent law would lead to an equally undesirable result. Under patent law, and the Constitution, patent owners are granted the exclusive right to exploit their inventions. A patent owner wanting to exercise that right would not have the option of obtaining a settlement that includes an agreement by its competitor to withdraw from the market. Because such a settlement would be too vulnerable to antitrust challenge, the patent owner would be forced to litigate his patent suit to final judgment or give up on his exclusive right.[28]

This reasoning was bluntly expressed by the Second Circuit in *Tamoxifen*, stating:

> Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.[29]

The key part of this holding is the latter portion: so long as any agreement restraining competition does not extend beyond the life of the patent, the interests of patent law and antitrust law are balanced. The *Schering-Plough* court recognized that a rule encouraging patent litigation could obstruct innovation: "[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around [an inventor's] ability to research, develop, and market the patented product or allegedly infringing product."[30]

Prior to the Hatch-Waxman Act, a generic manufacturer would need to enter the market and begin producing its product in order to challenge an incumbent's patent.[31] Under the Act, a challenge is easier. The *Schering-Plough* court noted this change altered the balance of bargaining power in favor of patent challengers, and it was more likely that settlements would involve payments to the generic challenger.[32] The court found that in this setting treating all settlements with reverse payments as antitrust violations would discourage settlements.[33] And, without the availability of the Act to permit challenges to patents prior to a challenger entering the market, challenges to patents would not be as prevalent.

Notwithstanding the consensus among the circuit courts that have considered the issue, the current FTC chairman has forthrightly acknowledged the FTC's aim to create a circuit split in the hopes of persuading the Supreme Court to accept review.[34] The present White House Administration has—through the Department of Justice—filed briefs that clearly have the same aim.

III. Current Issues and Policy Considerations Involving Reverse Payments

Critics of reverse payments charge that the settlement arrangements violate antitrust laws and are anti-competitive because they can delay a generic drug's entry into the market. This delay can be manifested in the Act's 180-day exclusivity period because the first-filer retains its exclusivity if it is sued and the parties subsequently settle and agree that the first-filer can begin marketing on a date in the future. The Department of Justice, the FTC, the current White House Administration, and certain members of Congress are poised to eliminate the option for patent litigants. Jon Leibowitz, the current Chairman of the FTC, sees eliminating reverse payments as a way to pay for health care reform and a "highest priority" for the FTC.[35] Members of Congress also have proposed legislation aimed at eliminating such payments.[36]

In its brief in the *Cipro* case, the Department of Justice argues that reverse payment settlements must be scrutinized under the antitrust laws and that the Second Circuit's *Tamoxifen* standard inappropriately permits patent holders to contract their way out of what the DOJ characterizes as a statutorily-imposed risk that patent litigation could lead to invalidation of the patent while the parties claim antitrust immunity for that private contract.[37] The DOJ further states that the *Tamoxifen* standard treats a private settlement agreement excluding competition as the equivalent of a litigated judgment affirming the validity of the patent. This, the DOJ argues, is a bad thing. However, all patent litigation settlements—whether they contain a "reverse payment" or

not—are private settlement agreements excluding competition in one way or another. Similarly, all patent litigations contain the risk of loss of patent through invalidation. Taking this reasoning to its logical conclusion, the DOJ would advocate a policy that forbids patent litigation settlements absent the FTC's blessing on the transaction. This policy is embodied in the legislation pending before Congress.

The proposed Senate bill bans reverse payments by forbidding the following:

> any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving a patent infringement claim in which (1) the [generic firm] receives anything of value; and (2) the [generic firm] agrees not to research, develop, manufacture, market or sell the [generic] product for any period of time.[38]

The House bill is similar. Both Acts give the FTC power to exempt and authorize any reverse payment agreements which act "in furtherance of market competition and for the benefit of consumers."[39] Notwithstanding this provision, the bills propose a per se rule against reverse payments.

The goal of preserving access to affordable generic drugs is laudable, but a rigid per se application to reverse payment patent settlements should be resisted. Courts apply a per se rule only where an agreement always or almost always reduces output to a product market and increases prices to consumers. Further, the language of the bills unnecessarily hamstrings litigants. For example, a proscription against a generic company receiving anything of value is so vague as to be meaningless. Settling any litigation, even for no money whatsoever, can be viewed as value received by the exiting litigant. In the case of a putative patent infringer, exiting the litigation by agreeing not to research, develop, manufacture, market, or sell the infringing product for a period of time (generally while the patent is not expired) is a necessary precursor to effective enforcement of intellectual property rights. Thus, putting aside for the moment the concept of per se treatment of reverse payments, the current language of the bills appears to forbid the settlement of patent litigation generally where two pharmaceutical companies are the litigants.

Opponents of the bills, including several antitrust scholars, warn against a per se rule in the context of generic drugs due to the lack of empirical evidence supporting the per se approach.[40] It is only after considerable experience with certain business relationships that courts should consider classifying those business relationships as per se violations.[41] The Eleventh Circuit in *Schering-Plough* approached the issue prudently when it declined to find reverse payments per se illegal and declined to apply a rule of reason analysis to those payments.[42]

To be sure, anticompetitive effect is necessarily present in these situations because patents are, by their nature, exclusionary. However, the focus instead should be on whether the challenged conduct of a particular settlement extends beyond the reach of the patent. Specifically, as the Eleventh Circuit concluded, an analysis of antitrust liability should include "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[43]

The ex post review proposed by the bills only injects uncertainty for parties contemplating patent settlement. Indeed, in contrast to the recent statements of the FTC's chairman, the FTC in the past has acknowledged the "serious uncertainties that would confront parties who seek to settle patent litigation if the Commission undertook to examine the underlying merits itself later on, and gave them conclusive weight."[44]

Those focusing on reverse payments as antitrust violations face a challenge, in that the social effects or costs of anticompetitive patent settlements are only tenuously correlated with the direction in which payment flows in the settlement. Professor Dan Crane argues that the social cost of patent settlements involving cessation of competition between the branded and generic firm equals the social cost of the continuing monopoly multiplied by the probability that, but for the settlement, the generic would have won the patent infringement action and entered the market in competition with the branded firm.[45]

There is, however, no relationship between the social cost of cessation of competition between the branded and generic and the fact that the settlement payment flows from the branded to the generic, unless of course the fact that payment flows from the patentee-plaintiff to the infringer-defendant necessarily evidences that the plaintiff's claim is weak, which in turn means that the branded's probability of success in the infringement action is low and the social cost of the settlement is therefore high. Thus, as Professor Crane posits, antitrust rules that focus on reverse payment settlements as a category not only run the risk of creating false positives, but they also run the risk of creating false negatives to the extent that they focus the inquiry on the direction in which consideration flows.

The parties to a patent dispute generally will have incentives to settle in order to avoid costly and risky litigation, and these incentives are more aligned than not with social benefits.[46] Further, employing reverse payments may be necessary for socially beneficial and pro-competitive settlements to be reached due to, for example, asymmetric information, excess optimism, and differential cash needs between the parties to a patent dispute.[47] Finally, and most likely, reliable judgments about the likelihoods of litigation outcomes of a patent dispute are not feasible if those judgments would be part of any antitrust inquiry because such inquiry may disturb the normal behavior of the litigants, who would otherwise be balancing risks and rewards of settlement absent the uncertainty of the possibility of settlement vitiation due to antitrust inquiry.

From a policy standpoint, more experience by antitrust agencies and courts, along with more economic research, is needed to determine whether—as a general matter—settlement is likely to benefit or harm competition. An informed determination of whether terms of a given settlement will likely benefit or harm competition will be more probative when the fact-finder is aware of the timing of the settlement (e.g., before or after the date of entry of a successfully-

challenging generic), the facts underlying the character of a settlement, and the basis for and size of compensation in the form of "reverse payments." This probative knowledge will never be ascertained if a per se rule is adopted.

IV. Conclusion

The central goal of the patent system is to provide an economic tool for promoting public access to new technologies.[48] The foregoing illustrates that, at least at this point in our understanding of how reverse payment situations work, a rigid per se rule against reverse payments would be overly restrictive of settlements and may actually stifle innovation by disallowing a generic an income stream through settlement as a reward for posturing itself to bring a generic drug to market. It remains to be seen what, if anything, Congress will do and what any final bill regarding reverse payments will look like. Interested people of both political parties have reasons for supporting or for attacking reverse payments. However, taking a calm view and applying what we know about reverse payments in practice, along with a recognition of the delicate balance between patent law and antitrust law, it is likely most prudent to allow parties to patent suits to continue to settle the matters in the ways the parties best see fit.

Endnotes

1 American Intellectual Property Law Association, *Report of the Economic Survey*

2 Studies estimate it may cost a drug company $802 million to bring a drug to market. Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151 (2003). Under the Food, Drug, and Cosmetic Act, a drug company must demonstrate that a drug is safe and effective before the FDA will approve it for marketing. 21 U.S.C. § 355(d) (2009). That demonstration is made through a New Drug Application (NDA), which is a lengthy, expensive, time-consuming process that costs millions of dollars to the drug company, much of which is spent conducting necessary clinical trials. *Id.* § 355(b). Therefore, drug makers rely heavily on patent protection because a patent is generally considered necessary to recoup the costs of an initial investment in the drug. *See* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 Brookings Papers On Econ. Activity (Special Issue) 783, 795-96, 819 (illustrating that pharmaceutical manufacturers value patents highly as appropriation means); *see also* Eli Lilly & Co. v. Teva Pharms. USA, Inc., 609 F. Supp. 2d 786, 811 n.23 (S.D. Ind. 2009) (providing examples of steep erosion of brand sales upon generic entry (loss of approximately 80% of sales within three weeks)).

3 *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006). Drug companies, compared to innovators in other industries, cannot as easily rely upon a head start, complementary assets, and scale of production as means to preserve profits.

4 Carmello Giacotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & Econ. 195, 195 (2005).

5 *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1615-17 (2003).

6 *See* 21 U.S.C. § 355 et seq.

7 A good general consideration of the issue has been presented in these pages before. *See* Michael K. Friedland, *Antitrust Implications of Patent Settlements: Balancing Patent Policy, Antitrust Law, and the Practical Limits of Litigation*, 9 Engage 89 (June 2008); *see also* Geoffrey A. Manne & Joshua D. Wright, The Federalist Society for Law and Public Policy Studies, Reverse Payment Settlements and Upcoming Congressional Action (Aug. 20, 2009), http://www.fed-soc.org/doclib/20090820_ReversePayments.pdf.

8 *See generally* Bigelow & Willig, *"Reverse Payments" in Settlements of Patent Litigation: Schering-Plough, K-Dur, and the FTC*, *in* The Antitrust Revolution 248 (Kwoka, Jr. & White eds., 2005). The term "reverse payment" is a misnomer because any patent settlement involves compensation to the alleged infringer in the form of, for example, reduced damages or lower royalty payments.

9 *See* In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied sub nom*, Ark. Carpenters Health & Welfare Fund v. Bayer, AG, 129 S. Ct. 2828 (2009) ("*Cipro*"); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) ("*Schering-Plough*"); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004) ("*Valley Drug*"); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), *amending* 429 F.3d 370 (2d Cir. 2005), *cert. denied*, 127 S. Ct. 3001 (2007) ("*Tamoxifen*").

10 Office of Mgmt. & Budget, Executive Office of the President, Budget of the United States Government, Fiscal Year 2010, at 28 (2009) (proposed), *available at* http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

11 Jon Leibowitz, Chairman, Fed. Trade Comm'n, Address at the Center for American Progress: "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf.

12 *See* Brief for the United States in Response to the Court's Invitation, Ark. Carpenters Health & Welfare Fund v. Bayer, AG, No. 05-2852-cv (CON) (2d Cir. 2009).

13 *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009).

14 The Constitution of the United States expressly provides Congress with the power to "promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. James Madison wrote in Federalist #43 that "[t]he utility of [this provision] will scarcely be questioned . . . . The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals." The Federalist No. 43 (James Madison).

15 *See* Mead Johnson Pharm. Group v. Bowen, 838 F.2d 1332, 1333 (D.C. Cir. 1988).

16 *See* 21 U.S.C. § 355(j)(2)(A), (8)(B). The requirements additionally require demonstrations that the generic drug contains the same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling. While costs for establishing these requirements, including bioequivalence, are not trivial, the process is much less expensive than NDA clinical trials. *See* Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003) (highlighting estimates of ANDA preparation and filing costs ranging between $300,000 and $1 million).

17 21 U.S.C. § 355(j)(2)(A)(vii)(III)-(IV).

18 35 U.S.C. § 271(e)(2).

19 21 U.S.C. § 355(j)(2)(B).

20 *Id.* at § 355(j)(5)(B)(iii).

21 *Id.*

22 *Id.* at § 355(j)(5)(B)(iv)(I).

23 *Id.* at § 355(j)(5)(B)(iv)(I), 355(j)(5)(D).

24 *See Cipro*, 544 F.3d 1323 (Fed. Cir. 2008) ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."); *Schering-Plough*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug*, 344 F.3d 1294 (11th Cir. 2003) (holding that a "reverse payment" settlement is subject to antitrust scrutiny only if "found to have effects beyond

the exclusionary effects of [defendant's] patent"); *Tamoxifen*, 466 F.3d 187 (2d Cir. 2006) (upholding dismissal of private challenges to a Hatch-Waxman settlement and stating that "[w]e generally agree . . . that 'simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'")

25 *See* In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Andrx Pharms. Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001); In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279 (S.D. Fla. 2005) ("*Valley Drug remand*").

26 *See, e.g.*, *Schering Plough*, 402 F.3d at 1066 n.14 ("We noted that the case at bar is wholly different from [*Valley Drug remand*]. The critical difference is that the agreements at issue in *Valley Drug* did not involve final settlements of patent litigation, and, moreover, the *Valley Drug* agreements did not permit the generic company to market its product before patent expiration . . . . Given these material distinctions, the same analysis cannot apply.")

27 *Schering-Plough*, 402 F.3d at 1067.

28 Friedland, *supra* note 7.

29 *Tamoxifen*, 466 F.3d at 213.

30 *Schering-Plough*, 402 F.3d at 1075.

31 *Id.*

32 *Id.* at 1074.

33 *Id.*

34 *Hearing Before the S. Comm. on the Judiciary* 3 (Jan. 17, 2007) (statement of Commissioner Jon Leibowitz), *available at* http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf.

35 In a June 23, 2009 speech given at the Center for American Progress, Mr. Leibowitz stated that eliminating "reverse payment" settlements is one of the FTC's highest priorities. Leibowitz, *supra* note 11. Mr. Leibowitz summarizes the court decisions allowing such payments as concluding that, because a drug company's patent might block the generic's product, a drug company can pay to eliminate the possibility of competition until its patent expires. *Id.*

36 *See* Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009).

37 *See supra* note 12.

38 S. 369.

39 *Id.* § 3; H.R. 1706. As recently as December 3, 2009, Senator Kohl submitted S. 369 as a bipartisan amendment to the U.S. Senate health care legislation package.

40 *See* Bigelow & Willig, *supra* note 8; *see also supra* note 7.

41 Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1 (1979) (quoting United States v. Topco Assocs., Inc., 405 U.S. 596, 607-08 (1972)).

42 "We think that neither the rule of reason nor the per se analysis is appropriate in this context." *Schering-Plough*, 402 F.3d at 1065.

43 *Id.* at 1066.

44 *See* Supplemental Brief for the Petitioner, *Fed. Trade Comm'n v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2009) (No. 05-273), 2006 WL 1647529, at *4 ("A key drawback to [an ex post review] is that it places parties contemplating settlement in the predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal."); Reply Brief for the Petitioner Federal Trade Commission in support of its Peitition for Writ of Certiorari, *Fed. Trade Comm'n v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2009) (No. 05-273), 2005 WL 2652617, at *5 n.4 (stating the view that an "ex post inquiry into the patent merits was neither necessary nor helpful" and "ultimately [would] have a chilling effect on the efficient settlement of patent litigation").

45 Posting of Dan Crane to Truth on the Market, Crane on Carrier's Innovation in the 21st Century, http:www.truthonthemarket.com/2009/03/30/ (Mar. 30, 2009, 19:57 ET).

46 *See* Bigelow & Willig, *supra*, note 8.

47 *Id.*

48 F. Scott Kief, *Coordination, Property & Intellectual Property: An Unconventional Approach to Anticompetitive Effects & Downstream Access*, 56 Emory L.J. 327 (2006).