Patent Settlement Legislation: Good Medicine or Wrong Prescription?

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WE'VE ALL BEEN THERE. The Great Idea. Great, that is, until you think about it for a few minutes. Exhibit A in the antitrust world is the idea that all competing purchasers should get the same price, which has been made into law in the form of the Robinson-Patman Act. Exhibit B, we fear, is the bill pushed by the Federal Trade Commission to make per se illegal the settlement of Hatch-Waxman patent cases brought by research-oriented drug companies against their generic rivals when "anything of value" moves from the company that invented the drug (the Brand) to a maker of generic drugs (the Generic) that seeks to enter the market before the Brand's patent(s) expire.

There is a beguiling sense of fairness about this, much like the sense of fairness that puts a Teflon coating on the Robinson-Patman Act. A "reverse payment" moving from the patent holder to the alleged infringer, combined with an agreement to defer entry, looks on the surface like a naked agreement not to compete. Thus, one might ask, doesn't the proposed bill work just the way the per se rule is supposed to work? Doesn't the bill describe something that is never (or almost never) pro-competitive?

Once you think about it a few minutes, the answers are "no" and "no."

Some Background: The Hatch-Waxman Act

You can sell pharmaceuticals in this country only with government approval, and there are a couple of ways to get that approval. The pioneer company that discovers the drug gets to market by filing a new drug application (NDA).[1] This route requires time consuming and expensive clinical studies to establish the safety and efficacy of the drug. The Hatch-Waxman Act[2] provides generic companies with a couple of shortcuts. One is an abbreviated new drug application (ANDA) that requires only a showing that the generic works the same as a previously approved pioneer drug.[3] The second is a "Paper NDA" (also known as a "505(b)(2) application"), which allows the use of data developed by others in lieu of doing your own (expensive) clinical studies.[4] This route can be used, for example, to get approval for a drug with the same active ingredient as the pioneer drug but with a different dosage form, e.g., approval of a 100 mg capsule when the pioneer drug is a 100 mg tablet. The final shortcut is as an "authorized generic," which is typically a plain white pill version of the branded drug made by the Brand but usually sold as a generic product by a third party that buys it from the Brand.

Importantly for this article, the Hatch-Waxman Act balances the advantages of the ANDA and Paper NDA routes with a provision that says that if the Brand thinks the ANDA or paper NDA product violates its patent, it can immediately sue for infringement. A timely filed patent suit means the Food and Drug Administration cannot approve the application for thirty months,[5] which, if the court moves quickly, allows the court to decide the patent dispute before the Generic gets on the market. The Hatch-Waxman Act also incentivizes the "first filer" by disabling FDA from approving any subsequently filed ANDA until 180 days after a triggering event (typically the marketing of the generic product or a court of appeals decision that finds the patent invalid or not infringed).[6]

This regulatory framework changes patent settlement dynamics significantly. Outside of the Hatch-Waxman context, the typical patent case arises after infringement, and settlement often involves the patent holder waiving some or all of the infringement damages claimed. In a Hatch-Waxman case, however, suit is brought thirty months before entry, so there are typically no infringement damages. Thus a practice evolved of compromise favoring the Generic, either allowing the Generic entry before the patent expired, or a cash payment from the Brand to the Generic (a "reverse payment"), or both.

The FTC Challenges Brand-Generic Settlements

The FTC took a long and hard look before it challenged these settlements. It picked as its starting point cases with favorable facts, and the respondents all accepted consent decrees. After these initial successes, however, the FTC and private plaintiffs broadened their attacks and have been met with a string of adverse decisions.

The FTC's original foray into this area came in the context of two "settlements" that did not actually settle the underlying patent litigation. Rather, they involved interim, not final deals—agreements by the Brand to pay cash to first-filing Generics and agreements by the Generics to hold

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off entry until the patent case was over, combined with an agreement not to withdraw the ANDA or relinquish the first filer's 180-day exclusivity.[7] The latter provisions created what the FTC termed a "cork in the bottle" effect that kept other generic manufacturers off the market. To sum up, these cases had five attributes favorable to the FTC's challenge: (1) cash moved "the wrong way," from the patent holder to the alleged infringer; (2) the Generic agreed to delay entry (and the Brand did not yield any of the disputed patent term); (3) the parties, it was alleged, manipulated the regulatory structure (the 180 days exclusivity afforded the first filer) to block entry by non-parties to the settlement; (4) the structure of the challenged arrangements created an incentive to continue to litigate, not settle, the patent case, because the Generic made more money by taking the cash from the Brand and litigating than it would make by entry; and (5) when the cases were litigated to a judgment, the patents were found invalid or not infringed.

The FTC resolved its initial cases by consent decrees. The Sixth Circuit, the first court of appeals to address an interim settlement agreement—in the context of private litigation that followed the FTC consent—concluded that the deal was a per se unlawful agreement not to compete.[8] And by and large, the antitrust community applauded the Commission's efforts.

Perhaps emboldened by these developments, the FTC and private plaintiffs pushed the envelope. It did not go well for them. The Eleventh Circuit rejected the view of the Sixth Circuit that an interim settlement was per se unlawful, reasoning that the lower court's analysis failed to take into account the exclusionary power of the patent.[9] This was not necessarily a repudiation of the Commission's views, since it had not, to that point, argued that such settlements were per se unlawful, but it was an ominous sign.

Moreover, it was a sign that the FTC did not heed. Rather, it and the private bar brought cases that had only the first element of the five listed above—a "reverse" payment moving from the Brand to the Generic. They went after settlements that had intrinsic competitive benefits (guaranteed entry by a generic competitor before patent expiration), that did not involve "cork in the bottle" restraints on third parties, that actually settled patent cases, and that (in some cases) involved patents which subsequent litigation showed to be valid.

In support of these subsequent cases, the FTC made two points. First, the FTC characterized generic entry as ending monopoly pricing. According to the FTC, it is profitable to both the Brand and the Generic for the incumbent monopolist (the Brand) to pay off the potential entrant (the Generic) to preserve monopoly pricing and profits. Both parties can make more by delaying entry. Second, the FTC said, if the case would settle by the Brand granting the Generic early entry and cash, then it would settle for earlier entry and no cash.

The courts found these new cases less compelling. The theories in these cases paid only lip service to the public interest in settlement and ignored both the special circumstances created by the Hatch-Waxman Act (i.e., infringement suits brought before any damages accrue) and the fact that patents by their nature exclude competitors. Moreover, in many of the subsequent cases, the settlement enhanced competition relative to the alternative—litigation to a judgment upholding the patent. The FTC and private plaintiffs started to lose, consistently.[10] To add insult to injury, the Solicitor General's Office has refused to back the FTC approach in the Supreme Court, and the Court has followed the SG's advice to deny certiorari, rather than the FTC's, and has declined to review any reverse payment cases.[11] As matters now stand, the Eleventh, Second, and Federal Circuits have all concluded pretty much that, so long as the settlement involves no greater restraint on the Generic than could be obtained if the Brand won the patent case, the settlement is lawful.

Realizing that it would lose any administrative case against a company that could appeal to the Second or the Eleventh Circuits, the FTC has brought two cases in federal court, hoping to create a circuit split.[12] And, opening a second front, the FTC asked Congress to give by statute what the FTC, so far, has not been able to get by litigation. While the bills did not move forward under President Bush, the FTC may expect a more receptive climate in the new Congress.

The Proposed Legislation

The FTC has supported bills that would make unlawful a Hatch-Waxman patent settlement in which "anything of value" is given by the patent holder (i.e., the Brand) to the ANDA filer and the ANDA filer agrees to delay entry by any amount of time. A new Senate bill was introduced on February 3, 2009. Although no bill has, as yet, been introduced in the the House, in the current Congress we anticipate that a new bill similar to the 2007 bill will soon be forthcoming. The previous House version of the bill provides:

> It shall be unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which—(1) an ANDA filer receives anything of value; and (2) the ANDA filer agrees not to research, develop, manufacture, market, or sell, for any period of time, the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim.[13]

The Senate version of the bill has similar language.[14]

The House bill allows only two exceptions to this per se rule; the Senate bill includes one. Both bills provide that a settlement is acceptable if the "thing of value" is the right to enter before patent expiration, i.e., the right to market the ANDA drug "before the expiration of—(A) the patent that is the basis for the patent infringement claim; or (B) any other statutory exclusivity that would prevent the marketing of such drug."[15] The House bill also provides that a settlement is acceptable if the thing of value is a "waiver of a patent infringement claim for damages based on prior marketing of such drug."[16] Any other thing of value moving from the

Brand to the Generic makes the settlement unlawful. There is no inquiry into whether the settlement as a whole is normal, reasonable, even procompetitive.

The Senate bill would make any such settlement a violation of the Clayton Act and thus enforceable by the government and by private plaintiffs. The House bill says such conduct is a violation of the Federal Trade Commission Act, enforceable by the FTC but not the Antitrust Division. There is no implied right of private action under the FTC Act, but it is likely that a private party would argue that the fact that a patent settlement agreement violates the FTC Act supports a conclusion that it is an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, which does have a private right of action. In addition, private rights of actions are created under many state unfair and deceptive practices acts, and it is likely that private parties would argue that a settlement that is unlawful under the FTC Act should be unlawful under the analogous state laws, which often carry treble damage remedies.

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This Is a Straightforward Application of the Per Se Rule, Right?

The proposed legislation takes the form of a per se rule. In a settlement in which the Generic agrees to stay out of the market for two years and then enter two years before patent expiration, the only inquiry is whether something of value moves to the Generic (other than the right to early entry and waiver of infringement damages). The supporters would argue that this is a routine application of the per se rule to an agreement not to compete.[17]

We believe it is not. Courts apply a per se rule when considerable judicial experience identifies a category of conduct that almost invariably reduces output and raises price. At that point, concern for judicial economy kicks in. The conduct is per se illegal—there is no need to look at whether this particular deal is bad. It is not worth years of litigation to see if this is the one price-fixing agreement in a million that does not hurt consumers. We have seen this movie before, and we know how it ends.

That is not this case. The FTC is not pushing this legislation because it wants to codify an emerging judicial consensus. It is pushing this legislation because there is a judicial consensus that a lot of these deals are just fine. Indeed, the Solicitor General has said that treating reverse payments as per se unlawful "would conflict with the well-established principle that per se treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect."[18] Even the FTC claimed to pursue a rule of reason approach in each of its earlier cases, including *Schering-Plough*.[19] Thus, the proposed legislation would enact a rule more sweeping than the position the FTC has taken in any of its cases to date. And even while encouraging enactment of the proposed legislation, then-Chairman of the Federal Trade Commission Deborah Platt Majoras acknowledged that "Undoubtedly, there can be significant procompetitive benefits of settling patent litigation between brand and generic manufacturers. Further, we recognize the importance of settlements generally to the judicial system."[20] Neither these "significant procompetitive benefits" nor the understanding that the per se standard is inappropriate is reflected in the FTC's support of proposed legislation that condemns settlements under a per se approach, without regard to their competitive effect. Thus, whatever one could fairly say about the merits of the decisions and the merits of these bills, this is not a routine application of the per se rule.

But Haven't All These Reverse Payment Settlements Been Bad Things?

In the antitrust world, a Bad Thing is something that reduces output and raises price.[21] Have the patent settlements that the FTC has investigated—and that would be thrown under the bus by this bill—routinely had that result? If the FTC competition folks were pressed on this point, we believe the answer would necessarily be, "Well, no."

Even in the cases that the FTC successfully challenged, the settlement did not delay entry of a generic or otherwise cause harm to consumers. For example, in the Cardizem case, the FTC itself noted 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."[22] Nor is there reason to conclude there was a delay in entry in the other early FTC case, involving Hytrin. For while Abbott and Geneva settled with the FTC, Kaiser pursued a private treble damages action against Abbott and Geneva and failed to prove that the settlement delayed entry.[23]

In other cases, hindsight being 20/20, the settlements look procompetitive compared to the likely outcome of the litigation. We say that because the settlements produced earlier entry than the patents—which were subsequently upheld as valid—would have allowed. For example, after the Barr tamoxifen case settled for early entry plus cash, the patent was repeatedly upheld as valid.[24] The same was true in the case of Cipro, where four later challengers all failed.[25] As the CEO of Barr Laboratories, which was seeking to enter with a generic in the cases of both tamoxifen and Cipro, explained:

> My company, Barr, was able to settle our litigation over the Cipro patent and secure early generic entry when four challengers all lost their cases. Thus, with the benefit of hindsight, if Barr had not settled, it is pretty clear there would have been no benefit to consumers—we would have lost. Allowing us

> to settle on terms to which Barr and the patent holder could agree thus secured a pro-competitive result. Similarly, we settled our patent litigation regarding tamoxifen to introduce a competing product years before patent expiration, despite the fact that the patent was later upheld in subsequent litigation. In short, these settlements all provided value to the consumer that would not have been achieved if the generics had proceeded to litigate and lose.[26]

Similarly, while Bristol-Myers Squibb was willing to settle its case on Plavix with early entry and something of value, when the FTC blocked the settlement, BMS went to trial and won.[27]

The current regulatory framework—where a generic can mount a patent challenge on thin evidence, see what turns up in discovery, and settle if the case goes south—encourages patent challenges. Making settlements harder will reduce the incentive to challenge a patent. As the CEO of Barr Laboratories testified, "In rendering settlement less likely, this proposal would inevitably raise the costs and risks of bringing patent challenges, thereby reducing the number of patent challenges a generic company can effectively mount."[28] Judge Richard A. Posner echoed that thought in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*: "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."[29]

Does the Bill's Language Sweep Too Broadly?

We assume the bills mean exactly what they say. They make unlawful under the Sherman Act or the Federal Trade Commission Act a settlement where anything of value moves from Brand to Generic.[30] It does not matter if the thing of value is small or if it is competitively neutral and ancillary to an overall procompetitive settlement. It does not matter if the thing of value is in fact procompetitive. It is illegal if it is "of value," moves the "wrong way," and is not on the short list of permitted exceptions. The following examples show the problem with the sweep of the bills' per se approach.

Supply Agreements. In a case with a seven-year disputed patent term, Brand agrees that Generic can sell the ANDA drug five years before patent expiration. In addition, Generic can be the sole supplier of the bulk active ingredient to Brand for the pioneer drug a year before Generic enters with its ANDA drug. The agreement would benefit Brand by allowing it to shift manufacturing capacity from the pioneer drug to new products in the lead-up to generic entry while continuing to supply the market with the pioneer drug. It would benefit Generic by allowing it to start up a production line prior to entering the market with its own product. But it would be per se unlawful because the supply contract is something of value. This is clearly an intended result. The FTC has a similar claim pending in the Cephalon (Plavix) case.[31] Although, in that case, the FTC does not contend that the settlement would be unlawful if the side deals stood on their own merits, the FTC appears frustrated by its failure to prevail in such cases and wants to outlaw all such settlements through legislation.

Multi-Deal Settlement. In a case with a seven-year disputed patent term, Brand agrees that Generic can sell the ANDA drug five years before patent expiration. In addition, Brand pays Generic for the right to sell a different product owned by Generic. It is often easier to reach settlement where circumstances outside the four corners of the litigation are considered. There is no reason to assume that a second deal included in the patent settlement, a deal which might not otherwise have been undertaken, would not have procompetitive benefits to consumers. Under the legislation, however, there would be no analysis of the independent merits of the second transaction; the settlement would be per se unlawful. This, too, is an intended result. The FTC unsuccessfully challenged such arrangements in the Schering (K-Dur) matter, arguing that the side deal was a sham. The FTC Staff lost that argument before the Administrative Law Judge, the Commission reversed him on appeal, and the Eleventh Circuit reversed on other grounds without deciding the question of whether the side deal was a sham.[32] The intent here is to make such proof unnecessary.

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Different Forms of the ANDA Drug. In a case with a seven-year disputed patent term, Brand agrees that five years before patent expiration Generic can sell both the ANDA product and an authorized generic of a different dosage form, for which there are no ANDAs pending and which is protected by the same patent. This settlement is procompetitive in that the settlement "payoff" consists only of early entry that benefits consumers. There are no ANDAs pending on the second dosage form, so there can be no question that launching an authorized generic will increase competition. But because the right to market the second dosage form does not involve "the drug that is to be manufactured under the ANDA involved," the settlement would be per se unlawful. The FTC has seen such deals and has not objected to them, but under the statute, they would be unlawful.

505(b)(2) Application. In a case with a seven-year disputed patent term, Generic files a 505(b)(2) "Paper NDA" application on the capsule form of a pioneer drug sold only in tablet form.[33] Brand settles by agreeing that Generic can, five years before patent expiration, sell an authorized generic version of the tablet product. No cash moves to the Generic. In essence, this is a pure early entry settlement, but

it is illegal under the proposed statute because entry is on the tablet product, not the capsule product that was the subject of the Hatch-Waxman patent suit. FTC Staff has seen such deals and has not objected to them.

Settling Other Claims. Brand sues Generic A, the first ANDA filer, and settles. Brand sues Generic B. Generic B asserts by way of antitrust counterclaim that it is blocked from the market by the unlawful settlement agreement with Generic A. Brand settles with Generic B, allowing it to enter three years before patent expiry and providing a cash payment. In exchange, Generic B releases antitrust claims. The agreement with Generic B is unlawful under the proposed law, even if the FTC agrees the original settlement with Generic A was anticompetitive and the payment to the generic constituted antitrust damages. It is, after all, something of value.

Using a Broad Release. Generic files an ANDA on the 100mg version of Drug A. Brand files a patent suit, triggering a thirty-month stay. The thirty-month stay expires, but the litigation is ongoing. Generic launches the ANDA drug at risk. Thereafter, the case settles. Under the settlement Generic will stop selling for two years, but re-enter five years before patent expiration. Brand waives damage claims for patent infringement and for inducing direct buying retailers to breach their partial exclusive supply contracts with Brand. The release of breach of contract claims is prohibited under the proposed legislation. The settlement is thus unlawful even though it is difficult to see how such a settlement term would harm competition. Indeed, it is hard to see how the case settles at all without a release of the breach of contract claims.

It is conceivable that even boilerplate settlement language could render a settlement unlawful. Assume the Generic asks for standard language that says Brand is releasing "all claims, known and unknown, relating to the marketing of the product." Today, such a release would raise no issue under the antitrust laws, for it has no competitive significance. But the whole purpose of this bill is to change the law so that the question is not whether on balance the settlement is procompetitive or anticompetitive but whether anything of value (other than time to enter on the ANDA drug or release of infringement damages claims) moves to the Generic. A broad release is surely "of value" to the Generic. Similarly, if Generic wants Brand to explicitly agree that the settlement releases any right Brand has to recover costs of suit or claims for fees incident to, e.g., unsuccessful discovery motions or where infringement is willful, that is also "something of value." Lawyers typically seek broad releases even where they are not really worried about cost-shifting, but under the proposed legislation to do so would be per se unlawful.

Authorized Generics. In a case with a seven-year disputed patent term, Brand agrees that Generic can sell the ANDA drug five years before patent expiration and further agrees not to enter into an authorized generic relationship with another generic company permitting it to enter until at least six months after Generic enters. The FTC has underway a study of the competitive effects of authorized generics, which demonstrates the FTC's concern that authorized generic agreements may be anticompetitive.[34] Yet the proposed legislation would make it unlawful for the Brand to agree to forgo such an agreement.

Won't the FTC Solve Any Problems with the Bill by Rule Making?

Both the House and the Senate bills contain a provision permitting the FTC to exercise rule-making authority to exempt additional types of agreements from the Act "if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers."[35] Then-Chairman Majoras recognized that "[t]he challenge for the antitrust enforcement agencies, the courts, and the pharmaceutical industry at large is to devise a workable rule, or set of rules, to distinguish those patent settlements that restrain competition from those that do not."[36] The FTC could thus promulgate rules that would exempt categories of settlements from per se condemnation. But could they do enough and would they if they could?

Recall that the bill would permit exceptions only where the provision is "in furtherance of market competition and for the benefit of consumers." How, one might ask, is a provision permitting the Brand to accede to the Generic's demand for, e.g., a broad release, something that is "in furtherance of competition" and "for the benefit of consumers"? Since the thrust of the proposed statute is that only a very narrow kind of settlement in the brand-generic setting is not inimical to competition, and given that the bill gives literally no weight to the public interest in settlement, it is hard to see how the FTC could take a broad rule of reason, ancillary restraint approach in its rule making. And even if the FTC could, would it? The FTC does not do a lot of rule making.

Finally, one may ask whether it makes sense to pass a bill that is unworkable unless an agency guts it with rule making. It seems akin to reinstating the rule of *Schwinn*[37] that vertically imposed restraints on customers and territories are per se unlawful, with the caveat that the FTC could exempt listed categories of vertical restraints. It is one thing to pass a statute that generally gets it right and let the agency use its rule-making authority to fill gaps in the law, but to ask the FTC to take a statute that as written gets it wrong and try to fix it by carving out exceptions that are at odds with the premise of the bill looks fundamentally inconsistent with the appropriate division of responsibility between the legislative branch and the executive branch.

Conclusion

A lot of ink has been spilled debating how to balance the public interest in settlement and the public interest in competition. Beyond the torrent of speeches and law review articles, four courts of appeals have opined on the underlying issue, and more cases are pending. We express no view on that

issue in this article other than to say that the proposed legislation is not the solution. The proposed legislation would apply a per se standard to settlement agreements that, under a more thoughtful analysis, might in many cases turn out both to be procompetitive and to serve the public interest in settlement. We do not suggest that letting the matter work its way out in the courts is inherently preferable to legislation, but it is surely preferable to this legislation. ■

[1] 21 U.S.C. § 355(b)(1).

[2] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[3] 21 U.S.C. § 355(j).

[4] *Id.* § 355(b)(2).

[5] *Id.* § 355(j)(5)(B)(iii).

[6] *Id.* § 355(j)(5)(B)(iv).

[7] *See* Abbott Labs., FTC No. C-3946, 2000 WL 681849 (May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/c3946omplaint.htm; Hoechst Marion Roussel, Inc., 131 F.T.C. 924 (2001), *available at* http://www.ftc.gov/os/adjpro/d9293/010404acco.pdf.

[8] Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

[9] Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304–06 (11th Cir. 2003).

[10] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1059–60 (11th Cir. 2005); Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 389, 390–91, 400 (2d Cir. 2005); Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1341 (Fed. Cir. 2008).

[11] Brief of the United States as Amicus Curiae, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441. Certiorari was denied. The SG's brief suggested that a rule of reason analysis was appropriate, noting that "[i]n determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anticompetitive, a court at a minimum should take into account the relative likelihood of success of the parties' [patent] claims view ex ante." *Id.* at *12.

[12] FTC v. Watson Pharm., Inc., No. 09cv0598 (C.D. Cal.); FTC v. Cephalon, Inc., No. 08cv2141 (E.D. Pa.). The FTC originally filed the *Cephalon* case in the U.S. District Court for the District of Columbia, but it was transferred to the U.S. District Court for the Eastern District of Pennsylvania.

[13] H.R. 1902, 110th Cong. § 2 (2007).

[14] S. 369, 111th Cong. § 3 (2009).

[15] H.R. 1902, 110th Cong. § 2. The Senate bill is similar, though it does not include the exception relating to "any other statutory exclusivity." S. 369, 111th Cong. § 3.

[16] H.R. 1902, 110th Cong. § 2.

[17] Even the sponsors of this legislation clearly have some unease over per se treatment. The Senate sponsors, responding to criticisms from the generic drug industry that some patent settlements do not harm competition, included a rule-making provision similar to that found in the previous House version that allows the FTC to create exemptions from the amendment's general ban on reverse payment settlements. S.369, 111th Congress (2009) (statement of Sen. Kohl).

[18] Brief for the United States as Amicus Curiae, 2004 WL 1562075 at *7, Andrx Pharms., Inc. v. Kroger Co., 543 U.S. 939 (2004) (No. 03-779); Brief for the United States as Amicus Curiae, 2007 WL 1511527, at *12, Joblove v. Barr Labs., Inc., 127 S. Ct. 3001 (2007) (No. 06-830) ("The correct approach is to apply the rule of reason, rather than a rule of per se legality (or illegality).").

[19] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1064 (11th Cir. 2005).

[20] Deborah Platt Majoras, Chairman, Fed. Trade Comm'n, ACI Conference on Pharmaceutical Antitrust Issues 12 (May 16, 2007), *available at* http://www.ftc.gov/speeches/majoras/051607ACI_Pharma.pdf.

[21] In the judicial world, a Bad Thing is something that discourages settlement and clogs the courts. An Especially Bad Thing is something that forces judges to try patent cases, where reversal rates are high and which often involve math. While the FTC acknowledges that settlement is in the public interest, none of the tests it has advanced gives any weight to that public interest.

[22] Hoechst Marion Roussel, Inc., 131 F.T.C. 924, 955 (2001).

[23] Kaiser Found. Health Plan, Inc. v. Abbott Labs, Inc., Nos. 06-55687, 06-55748, 2009 WL 69269 at *7 (9th Cir. Jan. 13, 2009).

[24] Zeneca Ltd. v. Novopharm Ltd., 111 F.3d 144 (Fed. Cir. 1997); Zeneca Ltd. v. Pharmachemie B.V., No. CIV. A.96-12413-RCL, 2000 WL 34335805 (D. Mass. Sept. 11, 2000).

[25] Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1329 (Fed. Cir. 2008).

[26] *Paying Off Generics to Prevent Competition with Brand Name Drugs, Hearing Before the Senate Committee on the Judiciary*, 110th Cong. (Jan. 17, 2007) (testimony of Bruce Downey, Chairman and CEO of Barr Pharmaceuticals, Inc.) [hereinafter Downey testimony].

[27] Sanofi-Synthelabo v. Apotex, Inc., 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007). There is a considerable back story to this settlement—one senior BMS executive was indicted and another fired. The point is simply that a settlement acceptable to the parties but unlawful under the proposed bill was competitively superior to trying the case to a verdict upholding the patent.

[28] Downey testimony, *supra* note 25.

[29] 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

[30] The sponsors of S. 369 suggest that "our bill will not ban any settlement which does not involve an exchange of money." S.369, 111th Congress (2009) (statement of Sen. Kohl). This reassurance, however, stands in stark contrast to the language of the bill. Courts would look to the legislative history only where the language of the bill is ambiguous, Oklahoma v. New Mexico, 501 U.S. 221, 236 n.5 (1991), and "anything of value" does not look ambiguous. If the bill really means to limit the prohibition to "exchanges of money," this creates an extremely broad loophole. For example, Brand and Generic could agree that Generic will never enter the market and, in exchange, Generic receives the rights to an old Brand product which is projected to generate a net present value of $20 million in profits over its life. Under the "exchange of money" view of the bill, this settlement would be legal even though its effect is no different than a settlement involving a cash payment of $20 million.

[31] Complaint, FTC v. Cephalon, Inc., No. 08cv2141 (E.D. Pa. Feb. 13, 2008), *available at* http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf.

[32] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1061–62 (11th Cir. 2005).

[33] The same thirty-month stay provision under Hatch-Waxman applies to paper NDAs.

[34] Press Release, Fed. Trade Comm'n, FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs (Mar. 29, 2006), *available at* http://www.ftc.gov/opa/2006/03/authgenerics.shtm. Although information requests have been issued, no report has been published. Press Release, Fed. Trade Comm'n, Commission Announces Issuance of Information Requests to Generic and Authorized Generic Drug Companies (Dec. 21, 2007), *available at* http://www.ftc.gov/opa/2007/12/fyi07268.shtm.

[35] H.R. 1902, 110th Cong. § 3; S. 369, 111th Cong. § 3.

[36] Majoras, *supra* note 20, at 14.

[37] United States v. Arnold, Schwinn & Co., 388 U.S. 365 (1967).