

2011

# Three Statutory Regimes at Impasse: Reverse Payments in Pay-For-Delay Settlement Agreements Between Brand-Name and Generic Drug Companies

Rudolph J.R. Peritz  
*New York Law School*

Follow this and additional works at: [https://digitalcommons.nyls.edu/fac\\_articles\\_chapters](https://digitalcommons.nyls.edu/fac_articles_chapters)

 Part of the [Food and Drug Law Commons](#), [Health Law and Policy Commons](#), and the [Intellectual Property Law Commons](#)

---

## Recommended Citation

Three Statutory Regimes at Impasse: Reverse Payments in Pay-For-Delay Settlement Agreements Between Brand-Name and Generic Drug Companies, Chapter 11 in *More Common Ground For International Competition Law?* (J. Drexler, et al, eds; Edward Elgar Publishing, Inc, 2011)

This Article is brought to you for free and open access by the Faculty Scholarship at DigitalCommons@NYLS. It has been accepted for inclusion in Articles & Chapters by an authorized administrator of DigitalCommons@NYLS.



The decision effectively delayed market entry by generics producers, who compete against brand name manufacturers not only on price but also in litigation to challenge patent validity and scope. Moreover, FDA procedures already required generics producers to go through a lengthy and expensive approval process *de novo* even though their products were chemically identical to brand-name drugs that had already been approved. Combined with the Federal Circuit decision, the requirement of full FDA re-testing effectively delayed competition by generics for years beyond the patent period for brand-name drugs.

At the same time, the lengthy FDA approval process was also affecting the branded companies whose research and development produced the vast majority of new pharmaceuticals. Indeed, the industry claimed an 'innovation crisis' starting in the 1970s, when the number of new pharmaceuticals beginning human testing fell over 80 percent after Congress amended the food and drug act to require the showing that drugs were not only safe but also effective in their intended uses. The declared crisis in pharmaceutical research and development was attributed to the increased time needed for FDA approval and, with it, a steep decline in the patent's effective life to seven years.<sup>11</sup>

Congress amended the food and drug act by passing the Hatch-Waxman Act of 1984, not only to open bottlenecks in the FDA approval process but also to overturn the Federal Circuit decision that prohibited unlicensed experimental use of patented drugs in preparation for seeking FDA approval.

The legislation intended a balancing of policies to promote competition by innovation by brand-name producers and to promote competition on price by generic makers. Experience would show the statute was a flawed attempt to promote both forms of competition in the pharmaceutical industry.

Nonetheless, the effort was well-intended. On the one hand, the 1984 legislation addressed the brand name producers' declared 'innovation crisis' by extending the drug patent term for as much as five years to take into account the lengthy FDA approval process.<sup>12</sup> On average, the period of exclusivity for drugs covered by valid patents would increase from 7 to 12 years.

On the other hand, Congress intended to hasten price competition by generics in three important ways. First, Congress overturned the Federal

<sup>11</sup> Cf. Carrier, *supra* n. 2.

<sup>12</sup> The amendment adds to the patent term half the time taken for clinical trials plus the subsequent waiting period for FDA approval, up to a maximum of 14 additional years.

Circuit decision and opened the door to unlicensed experimental use when it involved drug testing associated with FDA approval. Second, generics producers could now rely largely on branded manufacturers' prior FDA testing. This expedited approval process would permit generic producers to enter the market before patent expiration if the branded manufacturer's patent was either invalid or not infringed by the generic. It should be noted that FDA approval processes as a general matter are confidential. Third, Congress injected an incentive for generic producers to challenge drug patents and seek early entry by granting the first filer a 180-day period of exclusivity in the generics market.<sup>13</sup>

Despite best intentions, the statutory framework quickly began to break down. When the generic producer seeks early entry, the statute requires that notice be given the patent holder, notice spelling out the basis for contending invalidity or non-infringement.<sup>14</sup> If the patent holder sues the first filer for infringement within 45 days of notice, the statute calls for the FDA to halt consideration of the generic's application for 30 months, unless a court earlier finds the patent invalid or not infringed – an unlikely prospect given crowded federal court dockets. Of course such responsive infringement suits have become automatic.

This *automatic* stay is inconsistent as a matter of policy with the recent Supreme Court decision in *eBay* (2006).<sup>15</sup> Interpreting the Patent Act provision concerning the injunction remedy, the Court rejected the Federal Circuit's doctrine that injunctions were granted as a matter of course to protect presumptively valid patents: in the Federal Circuit's view, a property remedy for a property right. But the Supreme Court reminded the Federal Circuit that the Patent Act calls upon judges to issue injunctions only after balancing traditional equitable principles. There is nothing automatic about injunctions in patent cases. Moreover, automatic 30-

<sup>13</sup> In 2003, Congress amended the statute by defining a series of events that trigger forfeiture of the exclusivity bonus. 21 USC § 355(j)(5)(D)(i). The 180-day exclusivity bonus provides the first filer with two significant benefits beyond the obvious head start in the generics market. First, market studies have shown that first generics tend to price their products just below the price of brand name drugs. It is the entry of subsequent producers that brings price competition to the market. In consequence, the period of exclusivity delivers six months of high profits to the first filer. Second, firstness promises longevity because pharmacies tend to use only one generics supplier and so there is a formulary inertia that favors the incumbent generic supplier, the first filer, who must typically do no more than meet subsequent suppliers' prices to retain its exclusive place on the pharmacy's formulary list.

<sup>14</sup> While notice of the generic's FDA application is public, the substance remains secret.

<sup>15</sup> *eBay Inc. v MercExchange, LLC*, 126 S Ct 1837 (2006).

month stays under the Hatch-Waxman Act make little sense in light of an FTC study showing that pharmaceutical patent holders have lost almost 75 percent of patent infringement cases, despite the strong presumption that requires accused infringers to prove patent invalidity by clear and convincing evidence.<sup>16</sup>

It is not surprising, then, that drug patent holders pay generics – accused infringers – to settle infringement cases that statistics suggest they are likely to lose three times out of four.<sup>17</sup> The Hatch-Waxman Act was passed on the assumption that generics and consumers have a common interest in price competition. But the statute inadvertently changed the game. Now branded and generic producers have the common interest: the pay-for-delay provisions cost the branded companies far less than the profits they would lose from price competition, while generic makers gain far more than they would from competing on the market. In effect, it's the consumer who pays.<sup>18</sup>

In my view, the food and drug act requires further amendment. First, when a case is settled, the first filer's 180-day period of exclusivity should revert to the next generics filer. Restoring this incentive to file would revive the competitive pressure intended by Congress. Second, the automatic 30-month stay should be eliminated; instead, injunctive relief should be available to the drug patent holder only under the same demanding principles applied in other patent cases. Third, the reasons claimed for patent invalidity or non-infringement in a generic filer's FDA confidential application for early market entry should no longer be kept secret. Public disclosure would have two likely benefits. First, free information about a drug patent's infirmities and limitations would improve the conditions for other generics to seek early entry. Second, the size of reverse payments would decrease to the extent branded producers are paying for generics' agreement to maintain secrecy.

<sup>16</sup> <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (accessed November 2009) at p. vi.

<sup>17</sup> The settlement has a bonus for the paying patent holder: the patents remain presumptively valid.

<sup>18</sup> To make matters even worse, the Hatch-Waxman Act showed an unintended loophole that permitted the first filing generic to keep the 180-day period of exclusivity even after settlement. As a result, all other generics were blocked from entering the market until 180 days after the first filer's delayed entry – years later, if at all. And so the brand name drug-maker had another valuable reason to settle. Congress did pass an amendment in 2003 that narrowed the loop hole prospectively. The first filer would now forfeit the exclusivity bonus if it failed to market its generic drug within 75 days of FDA approval or of an appellate court determination that the patent is invalid or not infringed.

It is in this context that federal courts have heard antitrust challenges to the reverse payments in agreements settling patent infringement cases. Both the Federal Trade Commission and private plaintiffs have filed numerous lawsuits claiming that settlements with pay-for-delay provisions violate the antitrust laws as agreements in restraint of trade or conspiracies to monopolize.

The first appellate decision, handed down in 2003, concluded that the agreement was 'a classic example of a per se illegal restraint of trade.'<sup>19</sup> The FTC has taken the more moderate position that these agreements are presumptively illegal.<sup>20</sup>

But all federal appeals courts since 2003 have rejected the views that such agreements are per se or presumptively illegal under Sherman Act § 1 and its FTC § 5 equivalent. For example, the Eleventh Circuit in reversing the FTC applied a truncated rule of reason to conclude that the pay-for-delay agreement was reasonable and thus legal. The primary rationale given was that when the agreement stays within the scope of the patent, the patent holder is merely exercising its statutory right to exclude others from making, using, or selling the patented invention. Exercising patent rights cannot be a violation of the antitrust laws. The court also relied on policies in favor of settling lawsuits.<sup>21</sup>

In the past few years, these two rationales – patents as exclusionary rights and settlements as deserving deference – have been taken up by the 2nd Circuit in New York and the powerful Federal Circuit in Washington to conclude that such agreements are per se *legal* unless the patent is a sham or the infringement case is entirely baseless. This standard has a profound impact that goes beyond the antitrust injury to consumers, the higher prices for pharmaceuticals.<sup>22</sup> It spills over into patent policy. The courts, in refusing to consider the reasonableness of the agreement, have also put aside the question of patent viability. The 2nd Circuit stated explicitly that its policy of favoring settlement is so strong that it extends to 'fatally weak' patents, 'even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.' This overwhelming judicial deference to case settlements, which are, after all, just private contracts, creates the perverse incentive to litigate and settle rather than innovate and compete.<sup>23</sup>

There are two recent class action suits brought by purchasers of

<sup>19</sup> *In re Cardizem*, 332 F.3d 896 (6th Cir. 2003).

<sup>20</sup> See *supra* n. 15.

<sup>21</sup> *Schering-Plough Corp. v FTC*, 402 F.3d 1056 (11th Cir. 2006).

<sup>22</sup> *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

<sup>23</sup> *In re Tamoxifen litigation*, 466 F.3d at 211.

Cipro, the subject matter of Bayer's \$398 million reverse payment that I mentioned to open the chapter. In one, the Supreme Court refused to review the Federal Circuit's determination of per se legality<sup>24</sup> even though 54 law, economics, and business scholars filed an *amicus* brief urging the Court to overturn the decision. In the other Cipro class action, the 2nd Circuit affirmed the lower court's decision approving the settlement agreement. Many thought the Court would take a more skeptical attitude toward the agreement and depart from precedent because the Court prior to oral argument addressed an extraordinary letter to the Solicitor General of the United States inviting 'the Executive Branch to address the question.'<sup>25</sup> The invitation is highly unusual if not unprecedented in its acknowledgement of criticism – here by the Solicitor General that the 2nd Circuit's influential opinion in its prior reverse payments case was 'incorrect.' An open letter from ten large consumer rights organizations urges the government to accept the invitation and confute the view that these settlement agreements are legal under the antitrust laws.<sup>26</sup>

The 54 scholars' *amicus* brief urged the United States Supreme Court to reject the view of per se legality, arguing that the public policy in favor of settlement does not merit such weight. In light of the 73 percent failure rate of pharmaceutical patents in cases actually litigated, there is a more powerful public interest in invalidating weak patents, stopping unearned monopoly profits, and bringing to a halt the perverse incentives produced by these reverse payments.

Indeed, it was five years ago that the Supreme Court affirmed the doctrine that patents do not grant antitrust immunity.<sup>27</sup> Moreover, there is longstanding Supreme Court precedent that IP licensing cannot provide a pretext for agreements in restraint of trade.<sup>28</sup> The Second and Federal

<sup>24</sup> *Arkansas Carpenters Health and Welfare Fund v Bayer AG*, 129 S Ct 2828 (2009).

<sup>25</sup> *Arkansas Carpenters Health and Welfare Fund v Bayer AG*, 2d Cir., No. 05-2851-cv(L), reported in (BNA 1 September 2010) 80 *Patent, Tradem & Copyr J* 636. Letter re: In re Ciprofloxacin Hydrochloride Antitrust Litigation to the Office of the Solicitor General of the United States from Clerk of the Court, on behalf of a three-judge panel for the United States Court of Appeals for the Second Circuit, dated 6 April 2009.

<sup>26</sup> Letter re: Need for the Administration's Views in Pharmaceutical 'Exclusion Payments' cases written on Behalf of [10 named consumer rights organizations] to United States Attorney General Eric H Holder, Jr, US Department of Justice, dated 17 April 2009, on file with the author.

<sup>27</sup> *Illinois Tool Works Inc. v Independent Ink, Inc.*, 547 US 28 (2006).

<sup>28</sup> *Palmer v BRG of Ga., Inc.*, 498 US 46 (1990) (finding per se illegal copyright licensing agreement as pretext for territorial market allocation).

Circuits thus seem to have got it wrong in declaring that every patent holder has an absolute right to prevent competition within the 'exclusionary zone' of all patents, including the many that are weak. This approach takes the rebuttable status of patent validity and treats it as irrebuttable, even though the Supreme Court has long characterized a patent as something closer to a probable property right.<sup>29</sup> Moreover, it seems pretty clear that the generics' promises to delay entry are in consideration for the large reverse payments, not in concern for the restraining effects attributable to weak patents.

So, what is the prognosis? If the Supreme Court had granted the petition in the Federal Circuit's *Cipro* case to resolve the conflict in the circuit courts, the outcome would have been in deep doubt, in my view. Why? Because there are two powerful policies that collide, two policies each of which the Court has supported independently. For one, there is the strong support for property rights, especially intellectual property rights. And so the Court is inclined to find as reasonable an agreement whose restraints fall within the so-called 'exclusionary zone' of the patent. The second policy is procedural rather than substantive. In recent years, the Supreme Court has moved away from clear rules and toward balancing tests in both antitrust and patent cases. Per se rules have given way to more fact-intensive inquiries. In patent cases, for example, the Supreme Court has rejected bright line rules fashioned by the Federal Circuit for injunctions, prosecution history estoppel, and prior art reference materials to determine non-obviousness.<sup>30</sup> In antitrust, the Court's rejection of the century-old doctrine that resale price maintenance is per se illegal is only the most recent example of a shift toward the rule of reason.<sup>31</sup>

Does this shift make sense? In theory, a rule of reason calls for a flexible approach intended to take into account the particular commercial circumstances. And that's good. But, in practical terms, a rule of reason analysis

<sup>29</sup> A patent represents a 'legal conclusion by the Patent Office, . . . often ex parte, . . . on factors as to which reasonable men can differ widely. Consequently, it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment . . .' *Lear, Inc. v Adkins*, 395 US 653, 670 (1969).

<sup>30</sup> See, e.g. *eBay* (more flexible approach to injunctive remedy), *supra* note. 15; *KSR Int'l. Co. v Teleflex Inc.*, 127 S Ct 1727, 1742 (2007) (less rigid approach to determining prior art for nonobviousness inquiry; *Festo Corp. v Shoketsu Kogyo Kabushiki Co., Inc.*, 535 US 722 (2002) (more open approach to determining extent of prosecution history estoppel).

<sup>31</sup> See, e.g. *Leegin Creative Leather Products, Inc. v PSKS, Inc.*, 551 US 877 (2007) (applying rule of reason to minimum resale price maintenance); *State Oil Co. v Khan*, 522 US 3 (1997) (applying rule of reason to maximum resale price maintenance).

in antitrust amounts to de facto legality because it produces high cost and high risk cases, which deters litigation. This closing of the court house door in my view is inconsistent with the longstanding US policy favoring and, indeed, depending on private plaintiffs, often small firms and consumers unable to afford the expensive litigation of rule of reason cases; moreover, the standards for class action suits have become exceedingly difficult to attain. And so I am disinclined from a full-blown rule of reason.

The best solution in the antitrust cases, in my view, would be adoption of the FTC's approach of presumptive illegality, which would shift some cost and risk to the brand-name manufacturer and, as a result, improve conditions for generics to challenge weak patents and compete on price. Moreover, the approach would mitigate the perverse incentives that result from shielding weak patents from scrutiny. Indeed, a *strong* presumption of illegality would reflect judicial experience, in particular the 73 percent failure rate in cases litigated to date. Finally, the FTC would become an even more forceful arbiter of these settlement agreements.

Together with amendments to fix the food and drug act, what would be the result of an antitrust analysis that begins with a strong presumption that reverse payments in pay-for-delay settlements are illegal? The market for pharmaceuticals would sooner become price competitive, weak drug patents would be more open to challenge, and as a result consumers would save billions of dollars annually without taking from branded drug companies legitimately earned incentives to engage in research and development.

## 12. Patent ambush and reverse payments: Comments

Gustavo Ghidini

My comments are very short and address both topics jointly. I believe that, in the case of both reverse payment and patent ambush, antitrust enforcement should not take into consideration, as arguments for defence, the questions of validity and/or scope of the patent concerned, or the degree of market power it may embody or has come to embody.

In either case, indeed, on the one hand, the competitor's behaviour is not based, in a proper sense, on the exercise of her/his statutory patent rights (see below). On the other hand, symmetrically, the rationale of antitrust enforcement rests on *different and independent* legal grounds, not essentially influenced by 'strictly IP' questions. Of course, patents come into play, but in relation to the *factual*, rather than the *legal*, framework.

Take, for example, the issue of reverse payments: what has this practice to do, in a proper sense, with the exploitation of patent rights? Patent rights allow the exclusion of free riders, and not of lawful entries. In other words, contractual exclusion is not a legal exercise of patent rights. Therefore, a pay-for-delay settlement is just a *straightforward horizontal agreement* in restraint of competition, which would be equally illicit – this is a counterproof of my assumption – even if no patent existed. Wouldn't pay-for-delay settlements violate antitrust rules even if they took place between two producers of generics? As Abbott and Michel of the FTC have convincingly argued in 2006,<sup>1</sup> 'the payment and not the patent provides exclusion resulting from the agreement'.

Analogously in patent ambush cases: here, thanks to his fraudulent

<sup>1</sup> AF Abbot and ST Michel, 'The right balance of competition policy and intellectual property law: a perspective on settlement of pharmaceutical patent litigation' (2005) 46 *IDEA* 1, also available at: <http://nessiteras.piercelaw.edu/assets/pdf/idea-vol46-no1-abbott-michel.pdf> (accessed December 2010). Mr Abbott was Associate Director, and Ms Michel Chief Counsel at the Federal Trade Commission. See also *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 US 939 (2004).