Reverse Payments: Hard Cases Even Under Good Law

BY KENNETH GLAZER AND JENÉE DESMOND-HARRIS

THE SO-CALLED REVERSE PAYMENT, or pay-for-delay, cases have attracted an enormous amount of attention from the antitrust community. The current Federal Trade Commission Chairman calls them the agency's top priority. The agency has two such cases pending in federal court right now, and is continuing to investigate with an eye toward bringing more cases, despite high-profile appellate losses. The Justice Department has recently joined the FTC's position after distancing itself under the Bush Administration. It has received substantial attention from Congress: a legislative fix favorable to the FTC's position made it into the landmark House health-care reform legislation and is being seriously considered by the Senate. Antitrust heavyweights like Carl Shapiro, Herbert Hovenkamp, and Robert Willig have written at length on the subject.

Reverse payments remain one of the most contentious areas of antitrust. Both courts and commentators hold widely divergent views, with some holding that, absent a fraudulent patent, reverse payments in a patent settlement should be per se lawful, while at the other extreme some argue that any reverse payment should be given almost summary condemnation. The debate over the appropriate legal framework for analyzing reverse payments is heated and seemingly intractable; the FTC's latest loss in February of this year in the Androgel litigation will certainly not be the last word on the subject.

The purpose of this article is not to revisit this debate or offer a new proposed framework.[1] This article has a more modest goal: to make the point, largely overlooked in the debate, that even if the tough legal issues are eventually resolved, the reverse-payment cases will still be complicated.[2] The reason is straightforward: it may be hard to prove a pay for delay when a pay for delay deal has not been enshrined in an express agreement, and other than in some of the FTC's early cases, the pay-for-delay cases have not involved clear agreements in which a payment is made in return for delay. Instead, the existence of such an agreement must be inferred from a complicated set of commercial arrangements entered into between the branded company and the generic company. Proving a pay for delay when there is no express agreement is like trying to prove a conspiracy from circumstantial evidence: it's possible to do but it's never easy. This difficulty will exist even if all payments by branded to generic providers are banned, as more indirect means of payment will inevitably be devised to circumvent this prohibition. And therefore these cases, regardless of which direction the law moves in, will continue to be a challenge for the FTC and private plaintiffs.

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The Basics of Reverse Payment Cases

Hatch-Waxman Framework. The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act (the Act),[3] was designed to promote the availability of generic drugs, while still allowing for legitimate patent claims and maintaining financial incentives for research and development for new pharmaceuticals. The emergence of a successful generic drug industry is often

attributed to the Act, in large part as a the result of its simplification of the process by which manufacturers of generic pharmaceuticals obtain U.S. Food and Drug Administration marketing approval under the federal Food, Drug and Cosmetic Act.[4]

Prior to its amendment, the Act required that a company seeking to market a new drug product obtain FDA approval by undertaking a lengthy New Drug Application (NDA) providing clinical data proving the drug's safety and effectiveness. Under the amended Act, the approval process was significantly streamlined and simplified. It allows generic manufacturers to circumvent the lengthy and expensive NDA filing by filing instead an Abbreviated New Drug Application (ANDA). ANDAs reference the data on safety and efficacy developed and submitted by the original drug manufacturer. The generic drug manufacturer filing an ANDA need only supplement the NDA with studies showing that its drugs are the "bioequivalent" of already-approved brand-name drugs approved by the FDA.[5]

Patent Litigation and Settlements. Generic drug manufacturers filing ANDAs are required to certify with respect to each patent belonging to the brand-name drug manufacturer that (1) no patent was listed for the drug, (2) the patent has expired, (3) the ANDA drug will not be marketed until the patent expires, or (4) the patent is invalid or would not be infringed by the generic version.[6] This certification is commonly called "Paragraph IV certification." Under the Act, the first generic drug manufacturer to file an ANDA containing a Paragraph IV certification—the so-called first filer—is allowed a 180-day period of exclusivity during which no other ANDA with a Paragraph IV certification for the same drug may be approved. This period of exclusivity is extremely valuable, giving generic manufacturers strong incentives to challenge the patented products of the branded drug manufacturers. The branded drug manufacturer can challenge the claims in the generic's Paragraph IV certification with a lawsuit within forty-five days of the ANDA filing.[7] If suit is filed, ANDA approval is automatically stayed for thirty months.[8]

Studies have shown that generic competitor drugs normally enter the market at prices 20 to 30 percent lower than the prices of brand-name counterparts, and that they quickly gain substantial market share.[9] Subsequent generics often enter the market at prices as much as 80 percent or more below that of the branded drug, providing significant savings to consumers. As a result of these lower prices in combination with health plan policies and state laws encouraging the use of generic drugs, generic drug manufacturers typically capture an average of 44 percent of the sales of branded drugs within the first year in which they are offered to the public.[10]

Incentives to Settle and Share Profits. Although the 180-day period of exclusivity was meant to encourage the entry of generic drugs, it ultimately created an incentive for the branded and generic pharmaceutical manufacturers to limit competition between each other. They accomplished this through arrangements called "reverse payments," also known as "pay for delay settlements," or "exclusion payments." These terms describe an arrangement whereby the branded drug manufacturer sues a generics manufacturer for patent infringement with respect to a particular drug and the former pays the latter to delay the sale of a generic version of the drug, even if there was not in fact any real infringement.

Reverse payment settlements make business sense for both generic and branded manufacturers. When the entry of a generic drug into the marketplace is a possibility, the generic stands to make less profit than the branded manufacturer stands to lose from its entry. The difference between the two represents the amount consumers would save as a result of the entrance of the generic into the market, a pool of money the two can share if they can keep the generic off the market for some period of time. So, for example, when announcing settlements with four generic drug makers that kept the generic versions of Provigil off the market until 2012 (in return for compensation of roughly $200 million collectively to the generics), the CEO of Cephalon stated: "We were able to get six more years of patent protection. *That's $4 billion in sales that no one expected.*"[11]

The statutory 180-day exclusivity enjoyed by the first filer plays into this. Because of that exclusivity, the first filer presents a bottleneck to the other potential generic entrants, which incentivizes the branded drug manufacturer and the first filer to cut their deal. This is not to say, however, that the incentive for a branded company to pay off generics would disappear if the statutory exclusivity period were eliminated. As Michael Kades has explained, even without that exclusivity, there could still be circumstances in which a branded drug manufacurer will pay off multiple generic companies, and it may be cheaper on the whole to pay off multiple parties than to pay off just one.[12]

Early FTC Consent Decrees

Because of the harm to consumers that results from reverse payment settlements, the FTC has made it a priority to stop these agreements, calling them "at odds with both market realities and established antitrust principles."[13] The Commission began investigating these cases in the late 1990s and bringing complaints at the beginning of the last decade. In the two earliest cases, in which the parties made no effort to disguise the purpose of the payments to generics, these actions resulted in consent decrees.

In *Abbott Labs*, the Commission alleged that Abbott Lab - oratories and Geneva Pharmaceuticals entered into an anticompetitive agreement in which Abbott paid Geneva to delay marketing a generic alternative version of Abbott's hypertension and prostate drug, Hytrin.[14] According to the complaint, Abbott paid Geneva $4.5 million per month to keep Geneva's generic version of Hytrin off the U.S. market.[15] This agreement also resulted in a significant delay in the introduction of other generic versions of Hytrin because

Geneva was the first filer with the FDA and therefore was a bottleneck preventing other generic firms from marketing their generics until Geneva's 180-day exclusivity period was up. The FTC stated that the money paid to the generic was "well over the $1 to $1.5 million per month that Abbott believed Geneva would forgo by staying off the market."[16] As it further explained:

> The complaint alleges that Abbott was willing to pay Geneva a "premium" to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial situation. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would eliminate over $185 million in Hytrin sales in just six months. Accordingly, the complaint charges, Abbott sought to forestall Geneva—and all other potential generic competition to Hytrin—from entering the market because of the threat they represented to the high profits it was making from Hytrin.[17]

The next case involved Hoechst Marion Roussel (now Aventis Pharmaceuticals, Inc.), Carderm Capital L.P., and Andrx Corporation. The FTC challenged an agreement between the companies affecting the $750 million-a-year market for Cardizem CD, a widely prescribed drug for treatment of hypertension and angina.[18] In September 1997, the FTC's complaint alleges, Hoechst and Andrx entered into an agreement in which Andrx was paid to stay off the market. Under the agreement, Andrx would not market its product when it received FDA approval and would not give up or transfer its 180-day exclusivity right. Hoechst paid Andrx $10 million per quarter, beginning in July 1998, when Andrx gained FDA approval for its product. The agreement also stipulated that Hoechst would pay Andrx an additional $60 million per year from July 1998 to the conclusion of the lawsuit if Andrx prevailed.

The 2002 FTC Study and Passage of the MMA

Following these early cases, the FTC issued subpoenas to more than seventy pharmaceutical companies seeking information about patent settlements. The results of this investigation are set forth in a study published by the Commission in July 2002.[19] The study found, among other things, that the questionable patent settlements had ceased to a large extent after the FTC's position had become generally known in the industry—in other words, when pharma companies realized that the FTC was going to come after them for entering into pay-for-delay agreements.[20]

The study made several recommendations for changes to the law, one of which was a statutory requirement that such settlements be reported to the FTC and DOJ. Congress accepted that recommendation in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).[21] That Act provides that settlements of the kind the FTC has been pursuing must be filed with the FTC within ten days of the settlement being agreed upon. Failure to comply with this filing requirement can result in civil penalties.[22]

Schering

Following passage of the MMA, the FTC's first case challenging reverse payment settlements and leading to full litigation rather than a consent decree was against Schering-Plough Corporation.[23] In contrast with the earlier FTC cases, this case involved payments made not explicitly for delay but rather for a related license from Schering to the generic providers, which the FTC alleged was a hidden payment for delay. The Commission found an illegal agreement, and on appeal the Eleventh Circuit disagreed, finding that the terms of the settlement were within the patent's exclusionary power and "reflect a reasonable implementation of the protections afforded by patent law."[24]

The FTC filed a petition for certiorari in *Schering* in September 2005, which the DOJ opposed.[25] The FTC argued that the decision conflicted with a Sixth Circuit decision holding that an interim reverse payment settlement was a per se antitrust violation,[26] and that the economic consequences of the reverse payments were significant for consumers. The Supreme Court denied certiorari.

Appellate Decisions in Private Actions

Private plaintiffs have mostly lost court challenges to reverse payments. Aside from the Eleventh Circuit's decision in *Schering*, the leading appellate pro-reverse-payment decisions are *In re Tamoxifen Citrate Antitrust Litigation*[27] and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, in which the Second Circuit and the Federal Circuit, respectively, upheld reverse payments on the grounds that a patent holder has the right to exclude competition anytime during the life of the patent.[28]

In a 2003 decision in the opposite direction, the Sixth Circuit ruled in a private case, *In re Cardizem CD Antitrust Litigation*, that reverse payments were per se violations of antitrust law, holding that "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."[29] A few months later, however, Judge Posner, sitting as district court judge, rejected this view in dicta in his *Asahi Glass* decision, reasoning that "[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 [of as] anticompetitive."[30]

FTC's Post-*Schering* Actions

Despite the string of unfavorable appellate decisions, the FTC has continued to press forward in this area, investigating settlements of which it has become aware through MMA filings. Chairman Leibowitz had made clear that he considers this a major agenda item. As he stated in a speech last June, "No matter what you call them, eliminating these deals is one of the Federal Trade Commission's highest pri-

orities."[31] That same speech also announced the results of a Bureau of Economics study finding that pay-for-delay settlements are expected to cost the American consumer $35 billion over the next ten years. That report was released to the public in January of this year.

In the last two years the FTC has brought two new cases. Instead of handling these cases administratively as with the earlier *Schering* case, the agency has chosen in these two cases to file in federal court, thereby giving the agency greater control over which circuit ultimately hears the case (though as will be seen, that has not worked out for the agency quite as planned).

In February 2008, the FTC sued the pharmaceutical company Cephalon, Inc., for reverse payments in connection with Provigil, a drug used to treat excessive sleepiness in patients with sleep apnea, narcolepsy, and shift-work sleep disorder.[32] According to the Commission's complaint, filed initially in the D.C. District Court and later transferred on motion of the defendant to Philadelphia, Cephalon entered into illegal agreements with four generic pharmaceutical firms (Teva, Ranbaxy, Mylan, and Barr), all of which had filed simultaneously with the FDA and therefore all of which were "first filers" with which Cephalon had to deal to prevent generic entry. Specifically, Cephalon paid (in the form of various complex commercial agreements) the four first filers to delay their entry for several years, until 2012, three years before the patent's expiration.

The case was cast as a monopolization claim against Cephalon—i.e., the sole count in the complaint was a claim that Cephalon had unlawfully maintained its monopoly with respect to Provigil. The Commission chose not to name the four generic companies as defendants, triggering a separate statement by then-Commissioner Leibowitz explaining why he would have done precisely that.

Upon transfer of the complaint to Philadelphia, Cephalon moved to dismiss based on the appellate decisions described above.[33] New briefing on that motion was called for when the original assigned judge was replaced by a new judge. Cephalon's motion is still pending.

In January 2009, the FTC filed suit against a branded drug company, Solvay, and three makers of generic drugs, Watson, Par, and Paddock.[34] Watson and Par were both first filers in connection with Androgel, a hormone replacement therapy drug made by Solvay. The relevant patent on Androgel was due to expire in 2020. The FTC's theory in this case is that, as in the Provigil case, the branded company entered into a series of complex arrangements with the first filers designed to induce the generics to delay their entry until 2015.[35] Unlike the Provigil case, this lawsuit contains both monopolization and restraint-of-trade claims, and the generics are named parties.

The California State Attorney General joined the FTC suit, which was originally filed in district court in California, the site of one of the parties' operations. The defendants moved to transfer to federal court in Georgia, the site of the patent lawsuit and settlement negotiation and, not incidentally, the circuit of the *Schering* decision. The FTC fought to keep the case in California but lost. After being transferred to Georgia, the defendants moved to dismiss.[36] On February 23, the district court granted the defendants' motion to dismiss the FTC's claim.[37]

We know from recent court activity that the FTC has at least one other pending investigation of reverse payments. In October 2009 the Commission petitioned the D.C. District Court to enforce a subpoena against two drug companies in connection with a reverse-payment investigation.[38] The Commission's petition explains that the investigation concerns two drugs made by Boehringer Ingelheim: Aggrenox, a medication for stroke victims, and Mirapex, used for Parkinson's disease and Restless Legs Syndrome. Boehringer settled patent litigation with Barr, a generic manufacturer working on generic versions of both drugs. The settlement with Barr specifies the dates before which Barr cannot enter the respective markets. The FTC is awaiting a ruling on that petition.

Changing Political Winds

In the last year, much attention has been focused on the possibility of congressional action. In November 2009, the House of Representatives passed legislation entitled the Protecting Consumer Access to Generic Drugs Act of 2009, which would ban pay for delay patent settlements. It was accepted in the Energy and Commerce markup of the House health care reform bill and the provision was contained in the health care bill passed by the House in November 2009, but was ultimately dropped from the health care bill passed on March 21, 2010. The Senate came close to passing similar legislation but the Senate version of anti-reverse-payment legislation failed to make it into the health care reform bill passed by the Senate in December.[39] The ban could presumably be revised as stand-alone legislation at a later point.

Meanwhile, the DOJ has shifted its stance to a completely supportive role for the FTC. In a brief filed in response to the Second Circuit's request in the private *Cipro* litigation, DOJ, reflecting its new AAG's previously stated views, took a position very close to that taken by the FTC in its various public filings.[40]

The Challenges Ahead

The FTC is hoping for a reversal of fortune. It has been pursuing the so-called reverse-payment, or pay-for-delay, pharmaceutical-industry cases for a number of years but so far it has been unsuccessful in getting the courts to accept its point of view. It suffered a major defeat in 2005 in the *Schering* case, and then both the Second and Federal Circuits rejected the FTC's position in private cases. For a while it could not even get its own sister agency, the DOJ, to agree on the proper approach to these cases.

The tide may have started to turn in recent months. The DOJ, with the arrival of the new Obama appointees, has now largely endorsed the FTC's view. Congress (at least until the

Democrats lost their filibuster-proof majority) had been moving toward enshrining the FTC's approach in health-care-related legislation, and the House bill actually contained a provision that would have made reverse payments presumptively unlawful. And even the Second Circuit now may be rethinking its stance: in the pending *Cipro* litigation, it recently asked the DOJ for its views, suggesting the possibility that the court might be rethinking the lenient position it outlined in its earlier *Tamoxifen* decision. It is possible, therefore, that in the foreseeable future, the law will move in a much more favorable direction for the FTC, either through appellate jurisprudence or legislation, or a combination of the two.

But there is still a challenge for the FTC which no change in law will erase: even if the law becomes more favorable to the Commission, these will still be hard cases to litigate and win because of the difficulty in proving that the payments were made for the purpose of delay.

The Road from Simple to Complex. The earliest cases —*Abbott* and *Hoechst*, both of which settled without a full administrative proceeding—were relatively simple. In both cases, the generic company agreed to delay its entry, and in return received a sum of money. There was a clear quo and a clear quid. But then it became apparent to pharma companies that the FTC would continue to pursue these kinds of cases. The Commission even issued a statement in the *Abbott* matter putting pharma firms on notice that they might be subject to stronger remedies than the mere cease-and-desist orders used in the two pioneer cases:

> Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits.[41]

What happened evidently is that the pharma companies received the notice and started disguising the payments. The payments went underground, in line with Herbert Hovenkamp's observation that "[i]f exclusion payments are illegal, the parties will have an incentive to conceal those payments, perhaps by turning them into non-cash compensation . . . ."[42] The parties began a game of hide the *quid*. This makes the cases much tougher for the FTC and private plaintiffs, a fact acknowledged by the head of the FTC's own health care division: "A lot of people learned from [the FTC's cases] . . . . The agreements have become more complex, making the litigation more complicated."[43]

This can be seen quite clearly in the *Schering* case. The payment there was not expressly made to delay the generic entry, as in *Abbott* and *Hoechst*. Instead, the FTC claimed that a separate licensing transaction between the branded and the generic firms was really a disguised pay for delay. But there was nothing directly linking the two—no smoking gun (and no amnesty regime encouraging one or the other to expose the conspiracy). The FTC's case was entirely circumstantial, being based on evidence about the branded company's assessment of the background of the negotiations, value of the license, its post-agreement conduct, and many other factors. The Commission's discussion of this circumstantial evidence spans almost forty pages, constituting the bulk of the entire decision. The Eleventh Circuit characterized the evidence on which the Commission relied as "forced," "unconvincing," "meretricious," and "questionable."[44] The point is not that the Commission was wrong but that at best the kind of analysis engaged in by the Commission is open to intense dispute, just as in cases involving proof of conspiracy from circumstantial evidence.[45] Of course, the FTC can always prove some agreement in these cases, because these cases involve agreements to settle patent litigation and to enter into other commercial arrangements. But the clear presence of such agreements does not establish the precise agreement the FTC is after: a payment of money in return for delayed entry.

The FTC's two pending cases are also marked by this kind of factual complexity. When the cases were filed, there was a general understanding that the FTC faced an uphill battle because of the unfavorable appellate climate. What was not generally understood at the time was that, even apart from the legal difficulties faced by the FTC—the difficulties arising from the pro-patent and pro-settlement sentiment of the courts—these cases are extremely hard and complicated from a factual point of view.

In *Cephalon*, the FTC's claim is that the pay for delay was in the form of a combination of various complex commercial arrangements, such as IP licenses, supply agreements, and co-development agreements. The Commission claimed that these side agreements were just that—side agreements, not independent business arrangements—and that they had a collective value to the generics of more than $200 million. Their real purpose, in other words, was to compensate the generics for their delayed entry.

In the case against Solvay, Watson, Par, and Paddock, the side deals included, as in *Cephalon*, a co-promotion agreement and also a back-up supply agreement. Though the public version of the complaint redacts much of the evidence, the complaint clearly goes into great detail about the specific facts suggesting that the side deals were pretextual, or at least that the amount paid by Solvay to the generics was far in excess of the real values of the services being furnished in return. For example, the complaint quotes one email from a company executive saying that a "backup manufacturer strategy [was] a partial way to compensate [Par, one of the generics] for not entering the market."[46] One thing is clear, though: there was no express pay-for-delay agreement; otherwise, the complaint surely would have said so.

Coping with Complexity. To be illegal, a patent settlement must be more than just that—a patent settlement—for in itself such settlements are perfectly legal. That has been clear in the law for a long time. Something of value must flow

from the branded company to the generic. Otherwise, there is nothing more than the settlement itself. As the FTC itself put it in *Schering*:

> A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent. In light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations.[47]

To be sure, when a generic company agrees to delay entry of an allegedly infringing product, it is agreeing to limit competition between itself and the branded company. But that limitation by itself is not of antitrust concern absent any payment from the branded to the generic. If there is no *quid* (beyond the dropping of the lawsuit) for the *quo* of agreeing to delay, then there is no reason to doubt the bona fides of the generic company's decision—no reason to question that it did so in legitimate settlement of the patent litigation. And that is why it is necessary to find a *quid*. Once it becomes clear a *quid* has to be found, then parties inevitably are going to make it hard to find that *quid*.

To be precise, there are two levels of difficulty. One is in determining whether a payment, or overpayment, to a generic company is in return for the generic company's agreement to delay entry (or limit competition in some other way). This is a question of proving a nexus between the two transactions. Was the payment really for the generic company's agreement to defer entry, or was it for something else?[48]

The other level of difficulty concerns the nature of the payment itself. If, say, a branded company pays a generic company $10 million for a license to another product, the question arises as to whether that payment is fair market value or something above it. If it is merely fair market value—if the generic is getting for the license no more than what it could get in the open market from other companies—then the FTC faces the not obviously absurd argument that the payment is not really a pay-for-delay, because the branded company is merely getting what the license is worth. If that is the correct standard—if the FTC must prove that the payment is greater than fair market value—then the case becomes even more complex, and in fact that will be an extremely important issue in *Cephalon* and *Androgel* if they survive the motion to dismiss.

Of course, this latter problem could be cured by a rule—in the form of legislation or judicial pronouncement—that anything of value should be considered a payment without any need to show its relationship to fair market value (just as we treat any payment for services as "income" for federal tax purposes even if the payment was fair market value for services rendered). That was apparently the intention behind the House bill, which prohibited agreements in which "an ANDA filer receives anything of value." Such a rule could eliminate that one level of difficulty.

But the first level of difficulty would remain. Just because a thing of value was given to the generic company does not necessarily mean that that thing of value was in return for an agreement to delay. The nexus would still need to be shown. Even under the House version, the law would have been broken only when that thing of value was part of "an agreement resolving or settling a patent infringement claim." Whether the side deals are part of the patent-settlement agreement is precisely what is at issue in the FTC's pending cases, just as in a traditional conspiracy case the nexus between B's raising its prices and A's raising prices has to be established. This problem is recognized in the FTC's own decision in *Schering*. The Commission there stated:

> If there has been a payment from the patent holder to the generic challenger . . . *[then] [a]bsent proof of other offsetting consideration,* it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.[49]

The phrase "absent proof of other offsetting consideration" is the locus of the problem: the drug companies in these cases argue the existence of "other offsetting consideration."

It may seem obvious that two transactions (a settlement and a separate payment from the branded drug manufacturer to the generic) reached on the same day or within days of each other are related, making it easy to conclude that they are part of the same settlement and thus illegal. However, it is not implausible that the two agreements took place at or near the same time because of the opportunity presented by ongoing litigation-settlement discussions. As Scott Hemphill puts it, while some side agreements are obviously pretextual, "not all such settlements are facially absurd. In some cases, the generic firm has plausible expertise in the subject of the side deal. It is very difficult to be certain that a deal is collusive without a deep and complex inquiry into the business judgment of the two drug makers"[50]—precisely what makes these cases so challenging.

This problem too can be cured by a rule that prohibits a branded company from giving the generic company anything of value at any time within some period of time—say, three months or six months—before or after a patent settlement. Indeed, that is the rule urged by the Justice Department in its *Cipro* amicus brief:

> If the plaintiff shows that the generic manufacturer withdrew its challenge to the patent's validity; that money (or other consideration serving the same purpose) flowed from the patent holder to the generic drug firm; and that the payment accompanied the agreement to withdraw the validity challenge, it has established a prima facie case.[51]

This would shift the burden to the pharma companies to prove that there was no nexus between the payment and the patent settlement. But it is unlikely that many courts will rule that favorably to the FTC in the foreseeable future, so it will continue to bear the difficult burden of proving a nexus.

Does that mean the FTC should stop pursuing these cases? Not necessarily. As the FTC has argued strenuously, these pay-for-delay deals can cost consumers hundreds of millions

if not billions of dollars. In fact, in January of this year the agency released a study by the Bureau of Economics finding that pay-for-delay deals cost consumers $3.5 billion a year—a total of $35 billion over the next ten years.[52] If there is consumer injury, then the cases should be pursued, and there does appear to be significant consumer harm.

The complexity of these cases is not necessarily a reason to drop this key agency initiative, any more than the complexity of some conspiracy cases under Section 1 is a reason not to proceed with conspiracy cases. For one thing, it is possible that in some cases the parties can be attacked for limiting competition outside the scope of the patent based on delaying not just the allegedly infringing product but any bioequivalent product regardless of whether it infringes the claimed patents. (Interestingly, the class plaintiffs in the *Cephalon* litigation recently amended their complaint to add such an allegation.)[53] In other cases, it may be relatively easy to prove a nexus. At the same time, however, the complexity of these cases will almost certainly mean that due to resource constraints the FTC will bring fewer cases than it would if these cases involved express payments for delay. ■

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1 For a good recent review of the debate, and a clear statement of the FTC's perspective by the Chairman's Attorney Advisor, see generally Michael Kades, *Whistling Past the Graveyard: The Problem with Per Se Legality Treatment of Pay-for-Delay Settlements*, 5 COMPETITION POL'Y INT'L, Autumn 2009, at 143.

2 A notable exception is C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 632 (2009) (discussing at length the "evolution in the terms of settlement. Whereas early settlements simply traded cash for delay, modern settlements show sophistication in the means by which payment and delay are provided.").

3 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b–68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282).

4 21 U.S.C. § 355. The Hatch-Waxman Amendments created section 505(j) of the Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

5 *Id.* § 355(b)(1), (j)(4)(D)(i)(f).

6 *Id.* § 355(j)(2)(A)(vii).

7 *Id.* § 355(j)(5)(B)(iii).

8 *Id.*

9 *See* CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (July 1998), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0 [hereinafter CBO Study]; *see generally* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics* (Feb. 20, 2002), *available at* http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf.

10 CBO Study, *supra* note 9, at xiii.

11 Jon Leibowitz, Chairman, Fed. Trade Comm'n, "Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Antitcompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution), Remarks at the Center for American Progress 5 (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf (citing John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUS. J., Mar. 17, 2006 (quoting Cephalon CEO Frank Baldino)).

12 Kades, *supra* note 1, at 158–59.

13 Leibowitz, *supra* note 11, at 4.

14 *See* Decision and Order, Abbott Labs., FTC Docket No. C-3945 (May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/abbott.do.htm.

15 Complaint at ¶ 27, Abbott Labs., FTC Docket No. C-3945 (May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/c3945complaint.htm.

16 Attachment to Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, Analysis to Aid Public Comment, *available at* http://www.ftc.gov/os/2000/03/genevaabbpttanalysis.htm.

17 *Id.*

18 Complaint at ¶ 23, Hoechst Marion Roussel, Inc., FTC Docket No. 9293 (May 8, 2001), *available at* http://www.ftc.gov/os/2000/03/hoechstdrxcomplaint.htm.

19 FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstud.pdf.

20 *See id.* at vii–viii ("Between April 1999 (shortly after FTC investigations in this area became public) and the end of the period covered by this study, brand-name companies and first generic applicants have not entered agreements similar to the interim agreements challenged by the FTC.").

21 Pub. L. No. 108-173, 117 Stat. 2066 (codified as 42 U.S.C.A. § 1395w-101 et seq.).

22 For example, in 2009 Bristol-Myers Squibb agreed to pay a penalty of $2.1 million under the MMA for failing to file agreements reached with the generic company Apotex in connection with the anti-clotting medication, Plavix. According to the FTC complaint, BMS and Apotex had entered into an oral patent settlement agreement under which BMS would refrain from introducing a generic version of Plavix in return for Apotex's agreement to delay the entry of *its* generic version. Complaint, Bristol-Myers Squibb Co., FTC Docket No. C-4076 (Apr. 14, 2003), *available at* http://www.ftc.gov/os/2003/04/bristolmyerssquibbcmp.pdf. The FTC also referred the matter to DOJ for criminal action based on BMS's certification that there were no side agreements. BMS paid a large fine to settle the DOJ's criminal action, and its senior vice president pled guilty for his role in the conduct and was ordered to write a book about his misconduct. *See* Plea Agreement, United States v. Bristol-Myers Squibb Co, No. 07-140 (D.D.C. June 11, 2007); *see also* Natasha Singer, *Judge Orders Former Bristol-Meyers Executive to Write a Book*, N.Y. TIMES, June 8, 2009, at B3, *available at* http://www.nytimes.com/2009/06/09/business/09bristol.html.

23 Opinion of the Commission, Schering-Plough Corp., FTC Docket No. 9297 (Dec. 18, 2003), *available at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf., *vacated*, 402 F.3d 1056 (11th Cir. 2005).

24 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1072 (11th Cir. 2005).

25 A history of the DOJ's evolving views on this topic is described in this issue of ANTITRUST. *See generally* James J. O'Connell, *Second Bites and the Search for a Standard: The DOJ's Cipro Brief*, ANTITRUST, Spring 2010, at __.

26 Petition for Writ of Certiorari, FTC v. Schering-Plough Corp., No. 05-273, 2005 WL 2105243, at *23 (U.S. Aug. 29, 2005).

27 466 F.3d 187 (2d Cir. 2006).

28 *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1334–35 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009). *See also* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304–06 (11th Cir. 2003) (holding that two separate agreements between Abbott Laboratories, the manufacturer of a brand-name drug for hypertension, and generic drug manufacturers Zurich Goldline and Geneva Pharmaceuticals that involved payments to the generic manufacturers in exchange for their agreements not to enter the market were not per se illegal, in part because Abbott had a lawful right as a patent owner to exclude potential infringers from practicing its patents)

29 *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

30 Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

[31] Leibowitz, *supra* note 11, at 1.

[32] Complaint, FTC v. Cephalon, Inc., No. 08CV00244, 2008 WL 446785 (D.D.C. Feb. 13, 2008).

[33] Defendants' Brief in Support of Motion to Dismiss, FTC v. Cephalon, No. 08-cv-00244 JDB, 2008 WL 2047585 (D.D.C. May 2, 2008).

[34] Complaint, FTC v. Watson Pharm., Inc., No. CV 09-00598 AHM, PLAx, 2009 WL 761167 (C.D. Cal. Jan. 27, 2009).

[35] *Id.* ¶¶ 61–67.

[36] Defendants' Brief in Support of Motion to Dismiss, FTC v. Watson Pharm., Inc., No. 209CV00598, 2009 WL 1427177 (C.D. Cal. Apr. 6, 2009).

[37] *In re* Androgel Antitrust Litig. (No. II), No. 1:09-MD-2084 (N.D. Ga. Feb. 23, 2010) (order) (granting motion to dismiss on the standard reverse-payment claim but denying motion to dismiss the Direct Purchasers' sham-litigation claim).

[38] Petition of the FTC for an Order Enforcing a Subpoena Duces Tecum, FTC v. Boehringer Ingelheim Pharm., Inc., FTC File No. 091-0023 (Oct. 27, 2009).

[39] H.R. Res. 3962 (2009) (enacted).

[40] *See* Brief for the U.S. in Response to the Court's Invitation, Ark. Carpenters Health & Welfare Fund v. Bayer, AG, Nos. 05-2851-cv (L), 05-2852-cv (CON), 05-2863-cv (CON), 2009 WL 2429249 (2d Cir. July 6, 2009). In response to a question in her recent confirmation hearing before the Senate Judiciary Committee, Ms. Varney testified that she supported opposition to "reverse payments" and would work to "align" the positions of the DOJ and the FTC. *Hearing on the Nomination of Christine Anne Varney to be Assistant Attorney General in the Antitrust Div.*, 111th Cong. at 38–39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Anne Varney, Nominee, Assistant Att'y Gen., Antitrust Division, DOJ).

[41] Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, *available at* http://www.ftc.gov/os/2000/05/abbottgenevastatement.htm.

[42] Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1760 (2003). This is not to suggest that naked payments completely disappeared from the scene. *See* Hemphill, *supra* note 2, at 657 (noting a possible resurgence of cash payments following the appellate losses).

[43] Joe Mullin, *Reversal of Fortune?* IP L. & BUS., Sept. 2, 2009, at 38 (quoting Markus Meier of the FTC).

[44] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1070 (11th Cir. 2005).

[45] *See, e.g.*, Kenneth Glazer, *Easy Facts Make Good Law: A Response to David Meyer's Article on the* High Fructose Corn Syrup *Decision*, ANTITRUST, Summer 2003, at 90 (debating Judge Posner's decision reversing summary judgment in *In re* High Fructose Corn Syrup Antitrust Litig., 295 F.3d 651 (7th Cir. 2002)); David L. Meyer, *The Seventh Circuit's High Fructose Corn Syrup Decision—Sweet for Plaintiffs, Sticky for Defendants*, ANTITRUST, Fall 2002, at 67 (same).

[46] Complaint at ¶ 74, *Watson Pharm.*, *supra* note 34.

[47] Opinion of the Commission at 25–26, *Schering-Plough*, *supra* note 23.

[48] While companies probably are careful to file under the MMA any agreement that is arguably "related" to a settlement agreement, thereby bringing such agreements to the FTC's attention, the mere filing of such an agreement does not constitute an admission that the agreement is in fact a *quid* for the delayed entry. Indeed, reportedly some filings expressly reserve that position.

[49] *Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003) (citations omitted) (emphasis added).

[50] Hemphill, *supra* note 2, at 665; *see also id.* at 641 ("If settlement and delay occur as part of a larger set of transactions between the two firms, how do we know that the payment was made in exchange for delay, rather than for some other valuable consideration? Often, this is a difficult question.").

[51] Brief for the U.S. in Response to the Court's Invitation, *supra* note 40, at 23. In a footnote, the Justice Department quotes Professor Hemphill's article to the effect that, "because of 'the absence of brand-generic deals outside of settlement . . . a presumption that the side deal provides disguised payment to the generic firm' for delayed entry is justified.'" *Id.* at 23 n.7 (quoting Hemphill, *supra* note 2, at 668–69)).

[52] Leibowitz, *supra* note 11, at 1–2.

[53] *See* Second Amended Consolidated Class Action Complaint, King Drug Comp of Florida Inc. et al v. Cephalon Inc., No. 06-1797 (E.D. Pa. Nov. 27, 2009).