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Two bills seeking to ban reverse-payment agreements are currently pending in Congress, and the European Commission has declared that such agreements, depending on the circumstances, may violate European competition laws. Meanwhile, several U.S. Courts of Appeals have upheld reverse-payment settlements as lawful if the restrictions in the settlement are within the scope of the patent. This article provides an overview of the treatment of reverse-payment agreements by the agencies, the appellate courts, Congress, and the European Commission, without advocating a view on the legality of such agreements or the merits of court decisions, proposed legislation, or investigations relating to them.

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I. Introduction

Over the last decade, branded and generic pharmaceutical companies, the federal antitrust agencies, antitrust practitioners, federal courts, legislators, and the European Commission have grappled with the legality of patent settlements and other agreements that involve "reverse payments." Reverse payments are so-termed because, in contrast to circumstances in which the alleged infringer pays the patent holder for a license to enter the market, the patent holder pays the alleged infringer supposedly not to enter the market during some or all of the term of the allegedly infringed patent. Such agreements have been challenged as antitrust violations by the Federal Trade Commission ("FTC") and the plaintiffs' bar, but have been upheld in the settlement context by most appellate courts. Two bills seeking to ban reverse-payment agreements are currently pending in Congress, and the European Commission has declared that such agreements, depending on the circumstances, may violate European competition laws.

This article provides an overview of the treatment of reverse-payment agreements by the agencies, the appellate courts, Congress, and the European Commission without advocating a view on the legality of such agreements or the merits of court decisions, proposed legislation, or investigations relating to them. We begin by briefly describing the Hatch-Waxman statutory framework within which reverse-payment agreements have arisen.

II. Statutory Framework for Reverse-Payment Agreements: The Hatch-Waxman Act

Reverse-payment agreements originated in response to patent infringement litigation that arose out of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act.[1] The Hatch-Waxman Act was designed to increase competition and lower prices for consumers by accelerating the entry of generic drugs while, at the same time, maintaining the incentives to develop new drugs. The Hatch-Waxman Act permits companies to file with the Food and Drug Administration ("FDA") an abbreviated new drug application ("ANDA") for generic products that are shown to be bioequivalent to FDA-approved branded products. The ANDA procedure permits generic manufacturers to bypass the costly and lengthy new drug application ("NDA") process and to receive faster FDA approval to market the generic products.[2]

Every ANDA filing must include one of four certifications addressing the potential of the generic product to infringe a patent covering the reference-branded drug as to which the generic drug is bioequivalent. The certifications claim that:

(I) no patent was filed for the reference drug;

(II) the patent has expired;

(III) the patent expires before the ANDA filer will begin marketing the product; or

(IV) the patent is invalid or would not be infringed by the generic product.[3]

The last is referred to as a "Paragraph IV" certification. Paragraph IV filings are a means by which generic companies police brand-company assertions of patent protection and may expedite the entry of generic competition before the asserted patent expires.

For the purpose of describing the context in which reverse-payment agreements arise, a brief summary of the relevant rules surrounding Paragraph IV certifications and patent infringement litigation follows.[4] The Hatch-Waxman Act encourages Paragraph IV filings by rewarding the first generic manufacturer to file a Paragraph IV certification on a given drug with a 180-day exclusivity period during which the first-filer can market the drug without competition from other ANDA-approved generic drugs.[5] Should the patent holder initiate patent infringement litigation, however, the first-filer cannot enter the market for 30 months after the date that the patent holder receives notice of the Paragraph IV certification, a provision commonly referred to as the "30-month stay."[6]

THE LITIGATION THAT FOLLOWS PARAGRAPH IV CERTIFICATIONS HAS PROVIDED THE CONTEXT IN WHICH REVERSE-PAYMENT AGREEMENTS HAVE EVOLVED.

The ANDA filer must notify a patent-holder within 20 days of making such a certification, and the patent-holder then has 45 days to initiate suit.[7] Brand companies frequently initiate patent-infringement litigation on the basis of the Paragraph IV certification—that is, the brand company disputes the generic company's statement that the brand company's allegedly applicable patent is invalid or will not be infringed by the imminent generic entrant. The litigation that follows Paragraph IV certifications has provided the context in which reverse-payment agreements have evolved.

III. The FTC's Initial Response to Reverse-Payment Agreements

A. THE EARLY CONSENT AGREEMENTS—HYTRIN AND CARDIZEM CD

In the mid- and late-1990s, Paragraph IV certifications increased significantly, as did the FTC's focus on competition in the healthcare sector. The FTC began to investigate reverse-payment agreements in the Paragraph IV patent-litigation context and expressed skepticism as to the legality of the practice. FTC officials described the practice as "gaming" the Hatch-Waxman Act—claiming that such agreements were designed to eliminate competition and share the resulting monopoly profits.[8] The antitrust bar watched the progress of the reverse-payment

investigations with interest, as the agreements presented challenging antitrust issues in the increasingly important pharmaceutical context.

In 2000, the FTC announced a settlement with Abbott Laboratories and Geneva Pharmaceuticals with respect to their "interim agreement" pending the conclusion of the then-current infringement litigation over Abbott's blood-pressure drug, Hytrin.[9] During the course of the Hytrin infringement litigation, Abbott had agreed to pay $4.5 million per month in exchange for first-filer Geneva's promise not to release its generic Hytrin until the earlier of the resolution of the parties' patent litigation or the entry of another generic competitor. Geneva had also agreed not to transfer or relinquish its 180-day right of exclusivity. The Geneva-Abbott agreement was entered three days after Geneva was granted FDA approval of its generic drug.[10]

Under the terms of the settlement with the FTC, Abbott and Geneva agreed not to enter into future agreements involving restrictions on relinquishing exclusivity or involving restrictions on entering the market with a non-infringing product.[11] They also agreed to submit for court approval, along with notice to the FTC, any future interim agreement involving payments to generic companies to stay off the market.[12] The Hytrin agreement reflected the FTC's skepticism of reverse payments in the Hatch-Waxman litigation context.

Following the Hytrin and Cardizem consent decrees, some concluded that reverse payments in the Hatch-Waxman context were risky.

Within a year, the FTC also announced a settlement with Hoechst Marion Roussel, Inc. ("HMR") and Andrx Corporation regarding their agreement in the context of patent-infringement litigation over HMR's angina drug, Cardizem CD.[13] That settlement followed the FTC's challenge of HMR and Andrx's interim agreement in which Andrx had agreed that, while the patent litigation remained unresolved, Andrx would neither market its generic Cardizem CD following FDA approval nor relinquish its 180-day right of exclusivity.[14] In return, HMR would give Andrx quarterly payments of $10 million with payment to begin following FDA approval. At the time the parties entered the agreement, HMR's 30-month stay on Andrx's entry was scheduled to expire within a year. The agreement further stipulated that HMR would make an additional payment to Andrx if Andrx eventually prevailed in the patent litigation.[15] The restrictions imposed on HMR and Andrx by the settlement with the FTC were largely the same as those contained in the FTC's settlement with Abbot and Geneva.[16]

Following the Hytrin and Cardizem consent decrees, some concluded that reverse payments in the Hatch-Waxman context were risky. The story, however, was just beginning to unfold.

B. ADMINISTRATIVE CHALLENGES—IN THE MATTER OF SCHERING-PLOUGH CORPORATION

Furthering the enforcement gains obtained in the Hytrin and Cardizem matters, the FTC pursued an investigation of an allegedly disguised reverse payment in connection with infringement litigation over Schering-Plough's prescription potassium deficiency drug, K-Dur 20. Schering-Plough, Upsher-Smith Laboratories, and American Home Products Corporation had entered into settlements resolving Paragraph IV patent litigation instead of interim agreements during the pendency of the infringement litigation that were used in the Hytrin and Cardizem matters. In the Schering-Plough settlements, Schering-Plough paid cash amounts to the generic companies, but did so in return for licenses to certain intellectual property that the generic companies had developed or were in the process of developing. The FTC questioned the *bona fides* of the payments, suspecting that the payments were, in fact, reverse payments.

American Home Products settled with the FTC in a consent decree with relief similar to that obtained in the Hytrin and Cardizem decrees.[17] Schering-Plough and Upsher, however, chose to litigate the case with the FTC in an action before an Administrative Law Judge.[18]

The Administrative Law Judge found that the challenged license agreements were *bona fide* and lawful and dismissed the complaint.[19] The FTC staff appealed that decision to the full Commission, which reversed in a lengthy opinion that described the Commission's view on the lawfulness of reverse payments under the antitrust laws. As an initial matter, the Commission found that the Schering-Plough payment was disproportionate to the value of the Upsher licenses and that the payment was, in fact, tantamount to a "reverse payment."[20] The FTC found 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."[21]

An appeal to the Eleventh Circuit Court of Appeals followed, the result of which is discussed below. Reverse-payment cases brought by private plaintiffs were also making their way through the federal courts during the same time period.

IV. The Federal Courts' Treatment of Reverse-Payment Agreements

A. SIXTH CIRCUIT: IN RE CARDIZEM CD ANTITRUST LITIGATION (2003)

The first appellate court to address reverse payments was the Sixth Circuit in a private action that arose from the Cardizem interim agreement between Andrx and HMR that was the subject of the FTC-Cardizem consent decree.[22] As noted above, the Cardizem agreement did not settle the underlying patent litigation but provided that the generic manufacturer would neither enter before a speci-

fied period nor relinquish its 180-day exclusivity period, thus precluding entry of other generic competitors under then-applicable Hatch-Waxman rules. The district court further observed that the agreement also prohibited Andrx from marketing "non-infringing or potentially non-infringing" drugs.[23]

The Sixth Circuit in *Cardizem*, in an opinion by Judge Oberdorfer,[24] sitting as an appellate judge by designation, treated the interim agreement as a *per se* unlawful horizontal market allocation. The Sixth Circuit noted that the agreement did not settle the litigation, contained a clause that precluded Andrx from "relinquish[ing] or otherwise compromis[ing]" its 180-day period of exclusivity, and restrained Andrx from marketing "noninfringing and/or potentially noninfringing" drugs.[25] *Per se* treatment is typically reserved for limited categories of restraints of trade so familiar to the courts that a conclusive presumption of illegality is appropriate. The opinion stated that:

> "[T]he Agreement … [is] a classic example of a per se illegal restraint of trade.… [I]t 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.… [T]he fact that this is a 'novel' area of law [does not] preclude per se treatment"[26]

DIFFERENT JUDICIAL PERSPECTIVES ON REVERSE PAYMENTS WERE ABOUT TO EMERGE—PARTICULARLY WITH RESPECT TO SETTLEMENT AGREEMENTS THAT DO NOT LIMIT EXCLUSIVITY RELINQUISHMENT AND ARE WITHIN THE SCOPE OF THE PATENT.

Thus, the court found the agreement akin to classic examples of restraints that the Supreme Court has subjected to the *per se* rule, including "naked, horizontal restraints pertaining to prices or territories."[27] Different judicial perspectives on reverse payments were about to emerge—particularly with respect to settlement agreements that do not limit exclusivity relinquishment and are within the scope of the patent.

B. ELEVENTH CIRCUIT: VALLEY DRUG CO. V. GENEVA PHARMACEUTICALS, INC. (2003) AND SCHERING-PLOUGH V. FTC (2005)

In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,[28] the Eleventh Circuit reviewed a district court decision holding the interim agreement between Abbott and Geneva over Hytrin (the same interim agreement that was challenged by the FTC and the subject of the 2000 consent agreement with the FTC), as well as a final settlement between Abbott and Zenith Goldline Pharmaceuticals, to be *per se* unlawful.[29] The Eleventh Circuit's reversal of the

district court's decision was issued while the Schering-Plough matter was under consideration by the FTC Commissioners and led some to re-examine the FTC's theories on reverse payments.

In addressing the issue of reverse payments, the Eleventh Circuit in *Valley Drug* started with the observation that a patent was at issue and that patents grant a lawful right of exclusion. As such, the court held that, "[b]ecause the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed."[30] It further held that an agreement that involves restrictions on competition no greater than "the exclusionary potential of the patent" does not violate the Sherman Act.[31] The Eleventh Circuit referred to patent-immunity law,[32] which the Federal Circuit would later address in *In re Ciprofloxacin Hydrochloride* Antitrust Litigation.[33]

The Eleventh Circuit thus started its analysis from patent law, not antitrust law, and outlined a test that it later summarized in *Schering-Plough* as follows: "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[34] The court also explained that, on the record before it, the presence or size of a reverse payment from the patent holder to the alleged infringer did "not alone demonstrate that the Agreements had obvious anticompetitive tendencies above and beyond Abott's potential exclusionary rights under the [relevant] patent."[35] The Eleventh Circuit later clarified in *Schering-Plough* that the patent infringement action may be susceptible to an antitrust suit "[i]f the challenged activity simply serves as a device to circumvent antitrust law."[36]

Although the decision in *Valley Drug* preceded the FTC's decision in Schering-Plough, the FTC did not follow *Valley Drug* or devote considerable resources to discussing the opinion, except to acknowledge *Valley Drug*'s rejection of the *per se* standard.[37] The analytical perspective of the FTC was significantly different from that of the Eleventh Circuit, as the FTC focused its assessment with the antitrust laws first in mind. From the FTC's antitrust perspective, the reverse payment was centrally relevant as it appeared to be the consideration (or the sharing of monopoly rents) for an anticompetitive agreement that was facilitated by the claimed misuse of the provisions of the Hatch-Waxman Act.[38] Although the FTC did not declare reverse-payment settlements *per se* unlawful, the circumstances in which the reverse payment would not be anticompetitive were narrowly confined.

ALTHOUGH THE FTC DID NOT DECLARE REVERSE-PAYMENT SETTLEMENTS *PER SE* UNLAWFUL, THE CIRCUMSTANCES IN WHICH THE REVERSE PAYMENT WOULD NOT BE ANTICOMPETITIVE WERE NARROWLY CONFINED.

Not surprisingly, Schering-Plough appealed the FTC's decision in its case to the Eleventh Circuit, as was its right under the FTC Act.[39] Schering-Plough thus

pitted the FTC's view that reverse payments are fundamentally anticompetitive against the different and more patent-oriented view presented in *Valley Drug*. Although the FTC tried to reconcile the two, the Eleventh Circuit's decision in *Schering-Plough* confirmed that, in the Eleventh Circuit, the *Valley Drug* patent-oriented framework prevailed. The Eleventh Circuit thus reversed the FTC decision in *Schering-Plough* and held that the K-Dur settlement was lawful under the *Valley Drug* analytical framework.[40]

The FTC sought certiorari, which prompted the Solicitor General (with the Antitrust Division of the Department of Justice ("DOJ")) to argue that the issues had not been sufficiently developed in the lower courts and to suggest that certiorari not be granted.[41] The Supreme Court denied certiorari,[42] thereby ending the first FTC-litigated reverse-payment matter with a victory for the pharmaceutical companies. Meanwhile, other cases involving reverse payments were making their way to other appellate courts.

C. SECOND CIRCUIT: IN RE TAMOXIFEN CITRATE ANTITRUST LITIGATION (2005, AMENDED 2006)

The Second Circuit in *In re Tamoxifen Citrate* Antitrust Litigation affirmed the dismissal under Federal Rule of Civil Procedure 12(b)(6) of a reverse-payment challenge involving a metastatic breast-cancer drug, tamoxifen citrate.[43] The Second Circuit held that a reverse payment to settle an appeal from a judgment of patent invalidity did not violate antitrust law where the exclusionary effects of the settlement did not exceed the scope of the patent grant.[44] The court joined the Eleventh Circuit in rejecting a "categorical[ ] condemn[ation of] reverse payments," [45] and declined to base the lawfulness of a settlement following a judgment of patent invalidity upon predictions of an appellate court's future assessment of the patent's validity.[46]

Plaintiffs in Tamoxifen, rather than arguing for *per se* unlawfulness, instead claimed that the reverse payment was unlawful because "[t]he value of the consideration provided to keep [the generic manufacturer's] product off the market . . . greatly exceeded the value [the generic manufacturer] could have realized by . . . entering the market with its own competitive generic product."[47] The court rejected that approach as failing to consider sufficiently the incentives of a patent holder, even one that is relatively confident of the validity of its patent.[48] Instead, the court opted for the *Schering-Plough* and *Valley Drug* analysis that considers "whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'"[49] The Second Circuit noted in its discussion that plaintiffs did not allege that the underlying patent was obtained through fraud or that the underlying infringement lawsuit was "objectively baseless."[50]

D. FEDERAL CIRCUIT: IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION (2008)

In re Ciprofloxacin Hydrochloride Antitrust Litigation involved the settlement of Paragraph IV litigation between Bayer and generic manufacturer Barr Laboratories, Inc. over Barr's 1991 ANDA filing for generic ciprofloxacin hydrochloride (ciprofloxacin), a synthetic antibiotic.[51] Under the terms of the settlement, Bayer agreed to pay Barr $49.1 million and either to supply Barr with ciprofloxacin for resale or to make quarterly payments through December 31, 2003. Barr also agreed to convert its Paragraph IV certification to Paragraph III and not to market generic ciprofloxacin until after Bayer's patent expired. In addition, Barr agreed to affirm the validity and enforceability of the patent and admit infringement.[52] Advocacy groups and direct and indirect purchasers of ciprofloxacin filed a complaint against Bayer and Barr, alleging that the settlement agreement was an illegal market allocation.[53]

The Eastern District of New York granted summary judgment for defendants and plaintiffs appealed.[54] Prior to the Second Circuit's approval of the reverse-payment settlement in *Tamoxifen*, defendants in *Cipro* sought to transfer the appeal from the Second Circuit to the Federal Circuit. Because the *Cipro* indirect-purchaser plaintiffs included in their complaint a state-law claim similar to a federal Walker-Process claim that involved a substantial question of patent law, the Second Circuit found that the Federal Circuit had jurisdiction over the indirect-purchaser appeal. The Second Circuit, however, denied the motion to transfer with respect to claims by the direct-purchaser plaintiffs.[55]

THE FEDERAL CIRCUIT FOUND THAT THE DISTRICT COURT HAD PROPERLY APPLIED A RULE OF REASON ANALYSIS BY PLACING THE INITIAL BURDEN ON THE PLAINTIFF TO SHOW THAT THE SETTLEMENT HAD AN ADVERSE EFFECT ON COMPETITION IN THE RELEVANT MARKET.

The Federal Circuit affirmed the district court's grant of Bayer's and Barr's motion for summary judgment against the indirect-purchaser plaintiffs. The district court reasoned that all anticompetitive effects caused by the settlement agreement were within the exclusionary zone of the patent and thus could not be redressed by antitrust law.[56] The Federal Circuit found that the district court had properly applied a rule of reason analysis by placing the initial burden on the plaintiff to show that the settlement had an adverse effect on competition in the relevant market, in this case the market for ciprofloxacin.[57]

In addition, the Federal Circuit held that, in the absence of fraud in procuring the patent or sham litigation, a court "need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."[58] That is, under the Federal Circuit's holding in *Cipro*, a *bona fide* litigation as to a patent's validity or application can be settled within the scope of the exclusionary zone of the patent.[59]

The Federal Circuit observed that the same result is reached by starting from the doctrine of patent immunity.[60] The court cited authorities indicating that, where the patent holder does not extend the exclusionary power obtained from the patent beyond the scope of the patent, the patent holder is generally immune from the application of the antitrust laws.[61] The Federal Circuit indicated that, while the district court conducted its analysis under the antitrust laws, it was implicitly respecting and affirming the traditional doctrine of patent immunity, which displaces the antitrust laws within the exclusionary zone of a patent:

> "[T]he [district] court simply recognized that any adverse anti-competitive effects within the scope of the . . . patent could not be redressed by antitrust law. This is because a patent by its very nature is anticompetitive; it is a grant to the inventor of the right to exclude others from making, using, offering for sale, or selling the invention. . . . Thus, a patent is an exception to the general rule against monopolies and to the right of access to a free and open market. The district court appreciated this underlying tension between the antitrust laws and the patent laws when it compared the anti-competitive effects of the Agreements with the zone of exclusion provided by the claims of the patent.
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> [T]he essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee."[62]

The Federal Circuit also observed that the Eleventh Circuit in *Valley Drug* "did not advocate application of [an antitrust] analysis, finding such an analysis to be inappropriate given that the anticompetitive effects of the exclusionary zone of a patent are not subject to debate."[63] The Federal Circuit pointed to the Second Circuit's analysis in *Tamoxifen* in which the Second Circuit had concluded that the presence or size of a reverse payment "is not enough to render an agreement violative of the antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent's protection."[64]

In summary, the Federal Circuit concluded that the outcome of the case was the same under both antitrust law and patent law:

> "[I]n cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is

> the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent."[65]

Plaintiffs' petition for certiorari in the United States Supreme Court seeking review of the Federal Circuit's decision was denied on June 22, 2009.[66]

V. Recent Agency Positions—*FTC v. Cephalon, Inc.*, *FTC v. Watson Pharmaceuticals, Inc.*, and the DOJ's Amicus Brief in *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*

The FTC is apparently seeking to produce a split in the circuit courts on the lawfulness of reverse payments to encourage Supreme Court review.[67] To that end, in February 2008, the FTC filed a complaint in the United States District Court for the District of Columbia against Cephalon, Inc.[68] The FTC alleged that Cephalon willfully maintained its monopoly power with respect to its branded prescription narcolepsy drug, Provigil (modafinil), through a course of allegedly anticompetitive conduct that included entering into settlement agreements with potential generic competitors that, the FTC claims, included reverse payments.[69]

THE FTC IS APPARENTLY SEEKING TO PRODUCE A SPLIT IN THE CIRCUIT COURTS ON THE LAWFULNESS OF REVERSE PAYMENTS TO ENCOURAGE SUPREME COURT REVIEW.

The FTC filed suit in federal court rather than pursuing the conduct through the FTC's administrative process (as was done in Schering-Plough) perhaps to avoid an appeal to a circuit in which the law on reverse payments appears to be largely settled (e.g., the Eleventh or Second Circuit). The FTC is seeking a permanent injunction barring Cephalon from enforcing the terms of the agreements with the four generic companies that prevent those companies from marketing generic versions of Provigil before 2012.[70] The *Cephalon* case was transferred to the Eastern District of Pennsylvania in the Third Circuit. Motions to dismiss in the cases are pending. The FTC action is accompanied by private actions also challenging the *Cephalon* settlements.[71]

More recently, the FTC challenged payments by Solvay Pharmaceuticals, Inc. to generic manufacturers of its testosterone-replacement drug AndroGel—Watson Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc—in connection with a co-marketing arrangement and a patent-infringement settlement agreement that defers generic entry until 2015. The FTC filed a complaint in the United States District Court for the Central District of California, alleging violations of the FTC Act, Sherman Act, and California unfair competition laws.[72]

According to the FTC, while Solvay's patent for AndroGel expires in 2020, ANDA first-filer Watson received FDA approval to market its generic AndroGel in 2006.[73] As alleged in the Commission's complaint, Solvay had estimated that a generic launch in mid-2006 would result in a loss of 90 percent of its sales within the year and in a decline in annual profits by about $125 million.[74] The FTC claims that Solvay agreed to pay Watson $19 million for the first year and an estimated $30 million annually for the next five years,[75] and also agreed to pay Par $12 million annually for six years, purportedly in connection with co-marketing or back-up manufacturing arrangements.[76]

The Commission relied on arguments by Watson and Par in their Paragraph IV litigation with Solvay to allege that Solvay's patent was unlikely to exclude generic competition and that the settlement agreement was an anticompetitive agreement to share monopoly profits.[77] In a statement released with the filing of the Solvay complaint, then-Commissioner Leibowitz indicated that the Commission will continue to challenge such patent settlements as anticompetitive.[78] The district court in the Central District of California in April granted defendants' motion to transfer the case to the Northern District of Georgia in the Eleventh Circuit, where the underlying patent-infringement suit was litigated.[79]

WHILE STILL A "RULE OF REASON" ANALYSIS, THIS "PRESUMPTIVELY UNLAWFUL" APPROACH PLACES A HEAVIER BURDEN ON THE DEFENDANTS THAN THE DOJ HAD PREVIOUSLY ADVOCATED.

Finally, in July 2009, in response to an invitation from the Second Circuit to address the challenge to the *Cipro* settlement in *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, the DOJ advocated that reverse-payment settlements be treated as "presumptively unlawful."[80] The DOJ argued that, if the settlement allows no generic competition until patent expiration, defendants generally will be unable to rebut the presumption with a reasonable explanation for the payment. Even if both parties believe the patentee is likely to win the validity litigation, the DOJ would view the settlement as anticompetitive because "it eliminates the possibility of competition from the generic" before the patent's expiration.[81]

While still a "rule of reason" analysis, this "presumptively unlawful" approach places a heavier burden on the defendants than the DOJ had previously advocated. In 2008, arguing against a *per se* approach, the DOJ expressed caution in impeding Hatch Waxman settlements:

> "In [the context of Hatch-Waxman settlements], per se illegality could increase investment risk and litigation costs to all parties. These factors run the risk of deterring generic challenges to patents, delaying entry of competition from generic drugs, and undermining incentives to create new and better drug treatments or studying additional uses for existing drugs."[82]

Then, the DOJ also emphasized the government's strong policy of encouraging the settlement of litigation to explain its reservations with a *per se* illegality rule.[83] The DOJ, through the Solicitor General, even confronted the FTC position by submitting an amicus brief to the Supreme Court in *Schering-Plough* that recommended that the Court deny the FTC's petition for certiorari.[84] In its brief, the DOJ highlighted competing policy considerations between patent rights and antitrust laws and asserted that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."[85]

In contrast, in its more recent amicus brief to the Second Circuit in *Arkansas Carpenters*, the DOJ argued that the *Tamoxifen* standard "inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract."[86] The DOJ also cautioned against embedding a patent trial within an antitrust trial, acknowledging that its current views are in tension with its previous call for an examination of the patent infringement claim's merits.[87] The DOJ argued that it is "neither necessary nor appropriate to determine whether the patent holder would likely have prevailed in the patent infringement litigation."[88] Instead, the DOJ advocated that the court base liability "on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the parties have by contract obtained more exclusion than warranted in light of that prospect."[89]

VI. Pending Legislation Seeks to Prohibit Reverse-Payment Agreements

Some in Congress do not believe that the appellate courts have been properly analyzing reverse-payment agreements and have proposed legislation to limit or prohibit such agreements. For example, Senator Herbert Kohl (D-WI) and Representative Bobby Rush (D-IL) introduced in the Senate and House, respectively, legislation that would specify the legal treatment of reverse-payment agreements. The Kohl bill (S. 369), which is entitled the "Preserve Access to Affordable Generics Act,"[90] was initially drafted to ban reverse-payment agreements and has since been modified to treat reverse-payment agreements as presumptively unlawful.[91]

The Kohl bill would amend the FTC Act to declare presumptively unlawful any agreement "resolving or settling, on a final or interim basis, a patent infringement claim" in which a generic drug company (1) "receives anything of value" from the brand company, and (2) "agrees to limit or forego research, development, manufacturing, marketing, or sales of the [generic] product for any period of time."[92] The Kohl bill would allow the presumption of unlawfulness to be overcome by "clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects."[93]

Excluded from prohibition under the Kohl bill are agreements in which (1) the value that the generic company receives is no more than the right to market its product prior to the expiration of the allegedly infringed patent or other statutory exclusivity; (2) the payment is for reasonable litigation expenses not exceeding $7.5 million; or (3) the brand company covenants not to sue for patent infringement by the generic product.[94] The Kohl bill would also authorize the FTC to exempt, by rule, certain agreements that it finds will further competition and benefit consumers.[95] The Senate Judiciary Committee on October 15, 2009, voted to place the Kohl bill on the legislative calendar for consideration by the full Senate.[96]

The Rush bill in the House (H.R. 1706 entitled the "Protecting Consumer Access to Generic Drugs Act") would treat violations as an unfair method of competition under section 5 of the FTC Act.[97] The Rush bill would prohibit agreements in which an ANDA filer "receives anything of value" and "agrees not to research, develop, manufacture, market, or sell, for any period of time, the [generic] drug."[98] An exception is made for generic companies receiving no more than the right to market the drug and a waiver of the patent holder's claim for damages based on prior marketing of the drug. The Rush bill also authorizes the FTC to exempt, by rule, certain agreements that it finds will further competition and benefit consumers.[99]

As anticipated, the Obama Administration seems to support the legislative restriction of reverse payments.

As anticipated, the Obama Administration seems to support the legislative restriction of reverse payments. The FTC has been a vocal advocate for legislation addressing the reverse payments issue for some time. FTC Chairman Leibowitz has indicated that he views the elimination of reverse payments a top priority in antitrust enforcement under the new administration:[100] "The new administration does seem to recognize that [pay-for-delay settlements are] a real problem for consumers, [and] fixing it … would actually help pay for healthcare reform."[101] Indeed, then-Senator Obama (along with nine other Democratic senators) co-sponsored a previous version of the Kohl bill in 2007.[102]

The fact and form of any legislative response to reverse payments, however, remain the subject of debate.

VII. The European Commission Examines Settlement Practices in the Pharmaceutical Industry

In an inquiry into competitive practices in the European pharmaceutical sector, the European Commission ("EC") investigated over 200 brand and generic companies for the period from 2000 through 2008. On July 8, 2009, the EC issued a final report of its inquiry[103] that examined (among a variety of other subjects) settlements and other agreements between patent holders and generic companies, their effect on generic entry, and the cost of pharmaceutical products. The EC found that just under half of the 207 total settlement agreements concluded between patent holders and generic companies during the time studied imposed a restriction on the generic company's ability to market its medicine.[104] Of those restrictive settlements, 45 percent included a value transfer from the patent holder to the generic company in the form of a direct payment, license, or distribution agreement.[105]

Twenty-three settlement agreements, or approximately 10 percent of all settlements and 23 percent of settlements that restricted entry, included cash payments totaling over 200 million euros.[106] In six of the 23 agreements, the generic company agreed not to enter the market until a court judgment on patent infringement had been decided. In the remaining 17 cases, the generic company agreed either to exit or not enter the market until after the brand company's patent expired.[107] The report also provided a brief overview of the U.S. assessments of such settlement agreements, discussing the FTC enforcement measures in the *Cephalon* and *Solvay* cases and the Eleventh Circuit's decision in *Schering-Plough*.[108]

While the report encourages EU member states to pass legislation to create a unified patent and litigation system, no EU legislation to ban reverse-payment settlements has been proposed.

The EC report identified for further scrutiny "[s]ettlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies [as] potentially anticompetitive agreements."[109] In a statement issued with the release of the report, the European Commissioner for Competition, Neelie Kroes, said that "[t]he first antitrust investigations are already underway, and regulatory adjustments are expected to follow dealing with a range of problems in the sector."[110]

While the report encourages EU member states to pass legislation to create a unified patent and litigation system,[111] no EU legislation to ban reverse-payment settlements has been proposed.

VIII. Conclusion

The Federal Circuit decision in *Cipro*, the most recent appellate judicial analysis of reverse-payment settlements, has synthesized the approaches in the Second and Eleventh Circuits in finding that reverse payments within the exclusionary scope of the patent do not violate the antitrust laws. The Federal Circuit employed both rule of reason and patent-immunity principles in reaching that conclusion. The FTC continues to challenge reverse-payment settlements, with the apparent goal of producing a circuit split and attracting Supreme Court review.

Congress continues to consider various responses to reverse-payment agreements. The EC is beginning to review the settlement of patent litigation in the context of its competition laws, and its pharmaceutical sector report has shown the EC's interest in the treatment of such settlement agreements by the U.S. courts and enforcement agencies.

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1 Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2003)). The Hatch-Waxman Act was originally passed in 1984 and sponsored by Senator Orrin Hatch (R-UT) and Representative Henry Waxman (D-CA).

2 21 U.S.C. § 355(j) (2003).

3 *Id*. § 355(j)(2)(A)(vii)(I)-(IV).

4 For a thorough discussion of the numerous and complex rules relating to Paragraph IV certification *see, e.g.*, In re Tamoxifen Antitrust Litig., 466 F.3d 187, 190-93 (2d Cir. 2006).

5 21 U.S.C. § 355(j)(5)(B)(iv).

6 *See Id*. § 355(j)(5)(B)(iii). A court may also shorten or lengthen the thirty-month period pursuant to this section.

7 *Id*. §§ 355(j)(2)(B)(ii)(I), (j)(5)(B)(iii); 21 C.F.R. § 314.95(f) (2007).

8 *See, e.g.*, Jon Leibowitz, Commissioner, FTC, Prepared Remarks at the Antitrust in HealthCare Conference: Health Care and the FTC: The Agency as Prosecutor and Policy Wonk (May 12, 2005), 6, available at http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf; Deborah Platt Majoras, Chairman, FTC, Prepared remarks at the World Congress Leadership Summit, New York: The Federal Trade Commission: Fostering a Competitive Health Care Environment that Benefits Patients (Feb. 28, 2005), 10, *available at* http://www.ftc.gov/speeches/majoras/050301healthcare.pdf; Timothy J. Muris, Chairman, FTC, Prepared Statement of the FTC before the Committee on Energy and Commerce Subcommittee on Health (Oct. 9, 2002), 2, *available at* http://ftc.gov/os/testimony/107hearings.shtm.

9 In re Abbott Labs., No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000). "Interim agreements" do not purport to resolve the underlying patent litigation, but rather typically have specified the generic company's competitive conduct during the pendency of the patent litigation.

10 *Id*. at 4-5.

11 *Id*. at 7.

12 *Id*. at 8.

13 In re Hoechst Marion Roussel, Inc, No. 9293 (decision and order) (May 8, 2001), *available at* http://www.ftc.gov/os/caselist/d9293.shtm.

14 The FTC alleged in its complaint that accompanied its consent order that the HMR-Andrx agreement also had the purpose and intended effect of deterring Andrx from selling "non-infringing or potentially non-infringing" drugs. In the Matter of Hoecht Marion Roussel, Inc., No. 9293 (Complaint), 6, (Mar. 16, 2000) *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm.

15 *Id.* at 4-5.

16 *See* In re Hoechst Marion Roussel, Inc, No. 9293 (decision and order) at 5.

17 *See* In re Schering-Plough Corp. (Consent Order as to American Home Products Corporation) (Apr. 2, 2002), *available at* http://www.ftc.gov/os/caselist/d9297.shtm.

18 *See* In re Schering-Plough Corp., No. 9297 (Initial Decision) (July 2, 2002), *available at* http://www.ftc.gov/os/adjpro/d9297/index.shtm; In re Schering-Plough Corp., 136 F.T.C. 96, No. 9297 (Opinion of the Commission) (Dec. 18, 2003), *available at* http://www.ftc.gov/os/adjpro/d9297/index.shtm, rev'd sub nom. Schering Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), cert denied, 548 U.S. 919 (2006).

19 In re Schering-Plough Corp., No. 9297 (Initial Decision).

20 In re Schering-Plough Corp., 136 F.T.C. 956, No. 9297 (Opinion of the Commission) at 1052.

21 *Id*. at 988.

22 In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), cert. denied sub nom, Andrx Pharmaceuticals, Inc. v. Kroger Co., 543 U.S. 939 (2004).

23 In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682, 699 (E.D. Mich. 2000); *see also* Cardizem, 332 F.3d at 908 n.13.

24 The Honorable Louis F. Oberdorfer is a Senior Judge for the U.S. District Court for the District of Columbia.

25 Cardizem, 332 F.3d at 902-03, 907-08 & n. 13 (citation and internal quotations omitted).

26 *Id.* at 908.

27 *Id*. at 907-8.

28 344 F.3d 1294 (11th Cir. 2003), cert. denied, 548 U.S. 919 (2006).

29 *See* In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1348-54 (S.D. Fla. 2000), rev'd, 344 F.3d 1294 (11th Cir. 2003).

30 Valley Drug, 344 F.3d at 1306.

31 *Id*. at 1311.

32 *Id*. at 1306-9.

33 544 F.3d 1323 (Fed. Cir. 2008).

34 Schering-Plough, 402 F.3d 1056, 1066 (11th Cir. 2005) (citing Valley Drug, 344 F.3d at 1312), cert. denied, 548 U.S. 919 (2006).

35 Valley Drug, 344 F.3d at 1310-11.

36 Schering-Plough, 402 F.3d at 1067-68 (citing Asahi Glass Co. v. Pentech Pharmaceuticals, Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003)).

37 In re Schering-Plough Corp., No. 9297 (Opinion of the Commission) at 971-72.

38 *See Id*. at 987-88.

39 15 U.S.C. § 45(c) (2007) (permitting an appeal of FTC decisions to any circuit where the respondent resides or where the challenged conduct was used).

40 Schering-Plough, 402 F.3d 1056, 1075-76 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006).

41 *See* Brief for the United States as Amicus Curiae in FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273), at *16-20, available at http://www.usdoj.gov/atr/cases/f216300/216358.pdf.

42 FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273).

43 In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190 (2d Cir. 2006).

44 *Id*. at 213-16.

45 *Id*. at 207.

46 *Id*. at 203-04.

47 *Id*. at 208.

48 *Id*. at 210 (citing Valley Drug, 344 F.3d at 1310 ("Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.")).

49 *Id*. at 212 (citing Schering-Plough, 402 F.3d at 1076).

50 *See Id*. at 208-09, 212-13, 217; *see also* Schering-Plough, 402 F.3d at 1066-68 (citing Asahi, 289 F. Supp. 2d at 991). The appellate courts have not stated that liability would attach to generic defendants for settling a matter where the branded company had filed baseless litigation or obtained the patent through fraud.

51 544 F.3d 1323, 1327-28 (2008).

52 *Id*. at 1328-29.

53 *Id*. at 1329.

54 In re Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); Cipro, 544 F.3d at 1330.

55 In re Ciprofloxacin Hydrochloride Antitrust Litigation, No. 05-2863-CV (2d Cir. Nov. 7, 2007) (unpublished order).

56 *Id*. at 1330 (citing Cipro, 363 F. Supp. 2d at 523-40).

57 *Id*. at 1332.

58 *Id*. at 1336.

59 *Id*. at 1337.

60 *Id*. at 1336 ("[T]he outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach . . . or under patent law by analyzing the right to exclude afforded by the patent").

61 *Id*. at 1333 (citing United States v. Gen. Elec. Co., 272 U.S. 476, 485 (1926), which states: "It is only when [the patent owner] . . . steps out of the scope of his patent rights . . . that he comes within the operation of the Anti-Trust Act"; E. Bement & Sons v. Nat'l Harrow Co., 186 U.S. 70, 91 (1902), which states: "The very object of [the patent] laws is monopoly, and the rule is, with few exceptions, that any conditions [imposed by the patentee] which are not in their very nature illegal . . . will be upheld by the courts"; In re Tamoxifen, 466 F.3d at 201-02; Valley Drug, 344 F.3d at 1312; United States v. Studiengesellschaft Kohle, m.b.H, 670 F.2d 1122, 1127 (D.C. Cir. 1981)).

62 Cipro, 554 F.3d at 1333 (internal quotations and citations omitted).

63 *Id*. at 1335 (citing Valley Drug, 344 F.3d at 1312 n.27).

64 *Id*. at 1336 (citing Tamoxifen, 466 F.3d at 212-13).

65 *Id*. (citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 175-77 (1965) for the proposition that "there may be a violation of the Sherman Act when a patent is procured by fraud, but [that otherwise] a patent is an exception to the general rule against monopolies").

66 Ark. Carpenters Health and Welfare Fund v. Bayer AG, __ U.S. __, 104 S.Ct. 3587 (2009).

67 *See* Statement of Commissioner Jon Leibowitz before the Subcommittee on Commerce, Trade, and Consumer Protection (May 2, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070502reversepayments.pdf (stating that "[i]t's public knowledge that [the FTC is] looking to bring a case that will create a clearer split in the circuits").

68 FTC v. Cephalon, Inc., No. 08-0244 (D.D.C. Feb. 13, 2008) (Complaint), available at http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf.

69 *Id*. at 25.

70 *Id*. at 27.

71 *See*, *e.g.*, In re Modafinil Antitrust Litigation, 06-01797 (E.D. Pa.); Apotex, Inc. v. Cephalon, Inc., 06 CV 02 768 (E.D. Pa.).

72 *See* Complaint, FTC v. Watson Pharmaceuticals, Inc., 09-00598 (C.D.Cal., Feb. 12, 2009).

73 *Id*. at ¶¶ 2, 44.

74 *Id*. at ¶ 50.

75 *Id*. at ¶ 66.

76 *Id*. at ¶ 73.

77 *Id*. at ¶¶ 58-92.

78 Jon Leibowitz, Concurring Statement of Commissioner Jon Leibowitz, Feb. 2, 2009, available at http://www.ftc.gov/os/caselist/0710060/index.shtm ("I strongly support our two-pronged approach to eliminating these unconscionable deals. First, we will continue to challenge patent settlements that are anticompetitive and force consumers to pay more for much needed drugs. Second, we will advocate for legislation along the lines of the bipartisan measure (introduced last Congress by Senators Kohl, Obama, Grassley, Durbin, and Schumer as well as Representatives Waxman, Dingell, and Rush), which would offer a simple, effective and straightforward solution to the problem by banning payments from the brand to the generic while permitting legitimate settlements.").

79 *See* Order Transferring Cases, FTC v. Watson Pharmaceuticals, Inc, No. 09-00955 (C.D.Cal. Apr. 8, 2009). Defendants' motions to dismiss are pending as of September 2009, with discovery scheduled to close in January 2010.

80 *See* Brief for the United States in Response to the Court's Invitation in Arkansas Carpenters Health and Welfare Fund v. Bayer AG, (2d Cir. 2009) (No. 05-2852), at 21-32, *available at* http://www.usdoj.gov/atr/cases/f247700/247708.pdf.

81 *Id*. at 29-30.

82 Cong. Rec. S1195 (Feb. 26, 2008).

83 *Id*.

84 Brief for the United States as Amicus Curiae in FTC v. Schering-Plough Corporation (No. 05-273) (2006).

85 *Id*. at 11.

86 *Id*. at 14.

87 *Id*. at 26, n.9.

88 *Id*. at 24.

89 *Id*. at 25.

90 S. 369, 111th Cong. § 3 (2009). The bill was formerly S. 316, 110th Cong. § 3 (2007), which expired in committee. The former Kohl bill was co-sponsored by Senator Leahy and eight other Democratic Senators. Senator Leahy is no longer a co-sponsor. Current co-sponsors include Senators Grassley (R-IA), Brown (D-OH), Feingold (D-WI), Durbin (D-IL), Collins (R-ME), Franken (D-MN), and Klobuchar (D-MN).

91 Jessica Dye, "Senate Panel Plans Looser Rules On Pay-For-Delay," Law360 (September 24, 2009).

92 S. 369 § 3 (2009). The bill reflects changes adopted unanimously by the Senate Judiciary Committee on September 24, 2009. As originally introduced, the Kohl bill would have amended the Clayton Act to

declare such agreements *per se* unlawful, excluding agreements in which the value that the generic company receives is no more than the right to market its product prior to the expiration of the allegedly infringed patent. S. 369, 111th Cong. § 3 (Feb. 3, 2009).

93 S. 369 § 3.

94 *Id*.

95 S. 369 § 3.

96 S. 369—111th Congress: Preserve Access to Affordable Generics Act. (2009). In *GovTrack.us (database of federal legislation)*. Retrieved Oct 27, 2009, from http://www.govtrack.us/congress/bill.xpd?bill=s111-369 (Oct. 26, 2009).

97 H.R. 1706 § 2(c).

98 H.R. 1706, 111th Cong. § 2 (2009). The Rush bill was formerly H.R. 1902, 110th Cong. (2007), which expired upon the conclusion of the 110th Congress.

99 H.R. 1706, 111th Cong. § 3 (2009).

100 Jon Leibowitz, Concurring Statement of Commissioner Jon Leibowitz, Feb. 2, 2009, *available at* http://www.ftc.gov/os/caselist/0710060/index.shtm. ("Eliminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today.").

101 Anna Edney, Congress Daily, "FTC Eyes Aggressive Action On Generic Drugs," Feb. 19, 2009, *available at* http://lostintransition.nationaljournal.com/2009/02/ftc-eyes-aggressive.php.

102 Cong. Rec. S11505 (Sept. 12, 2007); *see also* Barack Obama, A New Era of Responsibility: Renewing America's Promise, Feb. 26, 2009, at p. 28, *available at* http://www.whitehouse.gov/omb/assets/fy2010_new_era/a_new_era_of_responsibility2.pdf.

103 European Commission, Pharmaceutical Sector Inquiry: Final Report, Competition DG (July 8, 2009) ("EC report").

104 *Id*. at 270 ¶ 743.

105 *Id*. at 270 Figure 106.

106 *Id*. at 279 ¶ 768.

107 *Id.* at 278 ¶ 767.

108 *Id*. at 287-89.

109 *Id*. at 524 ¶¶ 1573.

110 Press Release, Antitrust: shortcomings in pharmaceutical sector require further action, July 8, 2009, *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1098&format=HTML&aged=0&language=EN&guiLanguage=en.

111 EC report at 525 ¶ 1578.