REVERSE PAYMENTS IN HATCH-WAXMAN CA ANTIT

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TRUST-PATENT BATTLE

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Contrary to popular myth, branded and generic pharmaceutical companies do not disagree about everything. Sometimes government action encourages such extreme partisans to become strange bedfellows. The FTC has provided that action, and though the inevitable and continuing conflict between branded and generic pharmaceutical companies over drug patents is not close to ending, developments in antitrust law over the last decade have placed some branded and generic companies on the same side of the issue: whether settlements of Hatch-Waxman "paragraph IV" litigation that include so-called "reverse" payments violate the antitrust laws. The FTC, some members of academia, consumer groups, and class-action plaintiffs' lawyers all believe that reverse-payment settlements between branded and generic pharmaceutical companies should be deemed per se or presumptively anticompetitive, while generic and branded pharmaceutical companies view the agreements as competitively neutral. This article reviews both sides of the story.

HATCH-WAXMAN BRIEFLY

Passed in 1984 and amended several times since, the Hatch-Waxman Amendments ("HW") to the Food, Drug, and Cosmetic Act established a balance between promotion of innovation and promotion of generic entry into the marketplace. This balance is advanced by allowing companies seeking FDA approval for a generic drug to rely on the extensive clinical trials performed by branded pharmaceutical companies, requiring simple bioequivalence studies instead. Additionally, HW includes a special exemption to the patent law that allows generics to manufacture and test drugs despite the existence of the branded pharmaceutical company's patent on the drug. HW also strips branded companies of their previously exclusive and perpetual rights to their data on safety and effectiveness, providing limited exclusivity of five years for new chemical entities and three years for other approvals as a substitute. These provisions have helped speed the entry of generic drugs into the market at the back end of the patent term, and as a result, generic-drug market share has risen from less than 20 percent before HW to close to 50 percent today.

In exchange for this largesse to generics, HW provides branded companies a mechanism for extending the term of a patent claiming the drug or its use; that extension partially offsets the reduction in the useful term of the patent that results from the time consumed by preapproval clinical trials required by the FDA. The maximum extension to the patent term is five years, not to exceed 14 years of remaining term for the patent. In addition, the branded company is allowed to list its patent in the FDA's Orange Book, providing notice to generic companies of the patent and providing the potential for an automatic 30-month stay of approval of a generic drug should the generic assert that the patent is invalid or not infringed by its product.

In order to enter the market under HW, a generic may file an Abbreviated New Drug Application ("ANDA") with the FDA, showing, among other things, the bioequivalence of its drug to an approved branded drug. As part of the ANDA, the generic must make one of the following four certifications with respect to each patent listed in the Orange Book for the branded drug product: (I) that no such patent information has been

HW'S CREATION OF AN ARTIFICIAL ACT OF INFRINGEMENT

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filed with the FDA and listed in the Orange Book, (II) that the listed patent has expired, (III) that the listed patent will expire on a date certain (and is not challenged by the generic), or (IV) that the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. The last certification (called a "paragraph IV certification") is the only one in which the generic seeks FDA approval prior to the expiration of a listed patent. HW provides that filing a paragraph IV certification is an act of patent infringement and requires the generic to provide written notice to the patent holder of the factual and legal basis for its claim that the patent is invalid or will not be infringed.

The patent holder has 45 days to sue the generic and activate an automatic 30-month stay of approval of the generic's ANDA. After 45 days, if not sued by the branded company, the generic may seek a declaratory judgment that the patent is invalid or not infringed. To provide an incentive for generic applicants to seek entry before the patent expires, HW makes the first generic applicant file a paragraph IV certification eligible for 180 days of exclusivity, during which time the FDA cannot approve another generic's ANDA. The 180-day exclusivity period begins to run after the first filer commences marketing unless the first filer has forfeited its exclusivity. Under the 2003 Medicare Modernization Act Amendments, exclusivity is forfeited if the first applicant fails to market the drug by the later of: 1) either the earlier of 75 days after the date that approval of the first applicant's application is effective or 30 months after the ANDA submission date, or 2) 75 days after the patent for each listed drug is found invalid or not infringed in a final decision, the court signs a settlement order that includes a finding that the patent is invalid or not infringed, or the NDA holder removes the patent from the Orange Book.

WHAT ARE REVERSE PAYMENTS?

Branded pharmaceutical companies face an almost unique situation when confronted with a paragraph IV certification. HW's creation of an artificial act of infringement as a result of a paragraph IV certification results in the generic being the defendant in a patent-infringement action from which the branded company can receive no damages award, because there have been no infringing sales. There are no infringing sales because the generic cannot legally sell the drug prior to receiving FDA approval. Thus, the generic is in a no-lose situation by litigating the issue. Either the generic wins the litigation by proving noninfringement or invalidity of the patent and can sell the drug immediately, or the generic loses the litigation and then must wait no longer

to sell the drug than it would have had to in the absence of the legal challenge due to the patent. In effect, HW provides generic companies with an opportunity to set aside the patent without having to risk the cost of entry into the market or damages from infringing sales, thus altering the assessment of risk of the litigation for both the branded and generic company.

As a result of this no-lose situation for generics and the enormous risk to patentees posed by HW litigation, branded pharmaceutical companies in the 1990s began entering into settlement agreements with generics that included cash payments by the branded companies to the generics in exchange for delayed entry by the generics. Because these payments flow from the patent holder to the alleged infringer rather than from the alleged infringer to the patent holder, some have deemed these payments "reverse payments" and the settlements "reverse-payment settlements."

Some commentators and several courts have identified the limitations and inaccuracies endemic to this definition. Specifically, all litigation settlements that do not result in full value being given to the patentee could be considered reverse payments, whether or not cash actually changes hands from the patentee to the infringer. By way of example, consider infringement litigation where the defendant's sales have reduced the patent holder's profits by $100 million. A settlement where the infringer pays the patentee $80 million may be considered a "reverse payment" of $20 million to the infringer. As the vast majority of all settlements involve some discount from the full actual value of the patent rights, all of these settlements may be considered reverse payments.

ANTITRUST ATTACK ON REVERSE-PAYMENT SETTLEMENTS

The Opponents of Reverse-Payment Settlements. The Federal Trade Commission, some academics, consumer groups, and class-action plaintiffs have attacked these agreements as per se or presumptively illegal under the antitrust laws. Initially, these attacks flow from two general beliefs. The first views the branded and generic companies as competitors or potential competitors, and any settlement where the generic receives money in exchange for staying out of the market appears to be a market-division agreement (although the branded's patent makes this argument more complicated). The second belief arises from a comparison of reverse-payment agreements with what has been called a traditional patent settlement. Specifically, opponents argue that payments in traditional settlements flow in the other direction, from the alleged infringer to the patent holder, in exchange for a license agreement, and payments that flow in the other direction reflect an anticompetitive intent because they necessarily delay generic entry into the market.

Since the FTC's first enforcement efforts in 1999 and 2000, the theories for why reverse-payment settlements should be per se or presumptively illegal have evolved into the two basic premises presented by the FTC in its petition for writ of *certiorari* in *Schering-Plough Corporation v. FTC.* The first premise may be called the "better settlement" premise. The Commission's opinion in *Schering-Plough* stated that its analysis turned on "whether [the settlement's] unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates *that would have been agreed upon in the absence of the payments*." *In re Schering-Plough Corporation, et al*., 2003 WL 22989651 (F.T.C.) at 7 (emphasis added). The FTC considers a reverse payment anticompetitive if it "delay[s] generic entry beyond the date that would have been provided in a differently crafted settlement." *Id.* at 16. The second theory advanced in the FTC's *cert.* petition has been called the "probabilistic property" theory. That theory claims, first, that patents are not real property and represent only a right *to try* to exclude entry of an infringer in court. Accordingly, because there is a chance in every patent case that the patentee will lose, consumers have a "property right" in the patentee's risk of loss. As a result, so the theory goes, the settlement must provide the value of this risk to consumers through reduced drug prices, that is, by allowing the generic an entry date prior to the expiration date of the patent. Under the probabilistic-property theory, any settlement that fails to do so is anticompetitive.

The Other View of Reverse-Payment Settlements. Defenders of reverse payments view them as, at worst, competitively neutral. They note that all settlements are "payoffs" to avoid risk, that all patent litigation seeks to "delay" entry, and that all patent agreements are market-division agreements if you ignore the patent, so the rhetorical attacks on these settlements do not advance the analysis. Because antitrust law does not, and should not, protect infringing rivalry, the controlling issue is whether the settlement excludes more competition than the patent itself. If the generic product would

have been excluded by the patent, no amount of cash payment can be anticompetitive.

To date, the FTC's theories against reverse payments have been unpersuasive to a clear majority of judges, including the Eleventh Circuit (twice), the Second Circuit, and Judge Richard Posner (sitting as a district judge), for some or all of the following reasons:

1) The theories ignore the exclusionary effect of duly issued patents.
2) They are not limited to "payments."
3) They fail to acknowledge the benefits of settlement.
4) They are contrary to other, established legal principles.
5) They are not judicially workable.

IGNORING THE EXCLUSIONARY EFFECT OF PATENTS

A number of courts have noted that both FTC theories ignore the situation where the settlement negotiations fall through and the patentee wins; in that case, competition would be prevented to the same extent as the reverse-payment settlement delaying generic entry until the patent expires. Judge Posner made this point expressly in *Asahi Glass Co. Ltd. v. Pentech Pharmaceuticals, Inc., et al.*

These courts have concluded that the first question in any antitrust analysis of a patent settlement is whether the settlement goes beyond the scope of the patent. And that may happen in one of two ways: first, the settlement may exclude not only infringing products but also noninfringing products that the patent does not even cover; and second, the patent may be so weak that it is "objectively baseless" and hence has no exclusionary scope at all.

NOT LIMITED TO PAYMENTS

The courts have also noted that the FTC's theory of harm to competition does not actually depend on the presence of payments as a consideration for the settlement. The FTC argues, for example, that instead of reverse or exclusion payments, a better result is settlements involving early-entry licenses, as these would necessarily result in a public benefit. But precisely the same "anticompetitive" price reduction could be obtained through the use of a license with certain terms, as noted by the District Court for the Eastern District of New York in *In re Ciprofloxacin Hydrochloride Antitrust Litigation,* 363 F. Supp. 2d 514, 537 (E.D.N.Y. 2005):

> The parties to a Hatch-Waxman patent litigation could settle on an early entry date with a license calibrated to achieve a similar financial result to the parties as an exclusion payment. [P]laintiffs . . . agreed that some sort of license, such as an exclusive license for a limited geographic area, "theoretically" could have been negotiated that would, as between the parties, approximate the effect of an exclusion payment.

As a result, the court observed that banning reverse payments is not a guarantee of public benefit and would not necessarily achieve the FTC's goal "unless royalty rates are also constrained." *Id.* at 538. In response, the FTC has stated that it is the type of consideration exchanged that matters and that some types of consideration, like royalties to the patentee, an early entry date, or compromising on a damage claim, "generally" do not involve sharing the benefits of eliminating potential competition. Defenders assert that this premise is simply incorrect, as it fails to grasp that the value of each of these types of consideration derives from the same elimination of short-term "competition" inherent in every patent.

NO PLACE FOR THE BENEFITS OF SETTLEMENT

Neither of the FTC's theories includes the pro-competitive benefits of such settlements. Specifically, defenders believe that the FTC fails to take the longer view by not addressing the *competitive* benefits that result from enforcing valid patents. Fundamental to patent law is the social bargain providing a limited right to exclude rivals in the short term in exchange for the long-term benefits of the dedication of the invention to the public at the end of the patent term. In the absence of the profits resulting from the right to exclude, there would be less incentive for innovation and less actual innovation. It has been estimated by economists that the societal benefit of invention significantly exceeds the private benefit given to the inventor. In other words, defenders assert, the patent system represents a very good *pro-competitive* bargain for society, and the probabilistic-property theory assumes these benefits away.

CONTRARY TO ESTABLISHED LAW AND PRINCIPLES

The courts have also rejected the FTC's theories on the ground that there is no legal requirement that private parties enter into settlements that yield "better" competition or benefits for consumers and that judges do not have carte

continued on page 38

continued from page 27

blanche to force parties into the best competitive fit for consumers. Thus, the "concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation and there is no support in the law for such a right." *Ciprofloxacin* at 531. Additionally, they say, there is no legal justification to force private litigants to bear the costs and risks of litigation for society.

JUDICIALLY UNWORKABLE

In the minds of reverse-payment defenders, both FTC theories suffer from being impossible to implement in a judicial setting. Specifically, they ask, how can a "better" settlement be identified, especially if royalties, geographic restrictions, use restrictions, and other common licensing terms are considered? What value should be given to each? How can a settlement agreement ever be considered complete if there is always the possibility of someone identifying a better one that must be implemented? The probabilistic-property theory is believed to suffer from the impossibility of quantifying the true consumer interest, that is, the probability that the patent is invalid or not infringed. In addition, how do differing risk aversion and differing evaluations of success in the litigation by the participants get factored into the theory?

THE COMING WAVE: SENATE BILL S. 316

All of this conflict may become moot if S. 316 becomes law. Introduced in January of 2007, this bill is intended to "prohibit brand name drug companies from compensating generic drug companies to delay entry of a generic drug into the market." The bill proposes amendments to the Clayton Act that make it unlawful to be a party to an agreement resolving or settling a patent infringement claim in which an ANDA filer receives "anything of value" *and* agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time. By using the phrase "anything of value," this bill will go beyond preventing "cash payments" to include any form of consideration flowing from the branded company to the generic company (except for a license in which the only negotiable term is the date of the generic's early entry). The apparent effect would be to vastly reduce the number of achievable settlements, and to skew the advantages in litigation settlement negotiations even further toward generic companies in the remainder. In addition, the definition of the term "patent infringement claim" within the bill is so broad that it may include license negotiations between branded and generic companies outside the context of litigation. The bill explicitly allows agreements where the settlement to the generic includes no more than the right to market the ANDA product prior to expiration of the patent. The bill also amends HW by providing for forfeiture of the 180-day exclusivity period by violating the amended Clayton Act. The likely effect of this bill, if it is passed into law as it currently stands, will be to eliminate reverse-payment settlements, decrease license agreements, and increase litigation.

Since the Supreme Court refused to grant the FTC's petition for *certiorari* from the Eleventh Circuit's decision in *Schering-Plough v. FTC*, it appears that for now reverse-payment settlements in HW cases are not illegal under the antitrust laws. But the introduction of S. 316, which was placed on the Senate Legislative Calendar under general orders on February 27, 2007, should be carefully watched by both the generic and branded pharmaceutical industries as it passes through the legislative process. ⏭

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