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BY MESSENGER AND ELECTRONIC MAIL

United States Senate
Committee of the Judiciary
Washington, D.C. 20510-6275

Attn: Ms. Nikole Burroughs
Hearing Clerk
224 Dirksen Senate Office Building

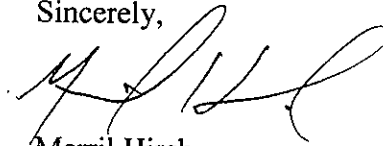
Re: **Answers to Written Questions**

Dear Ms. Burroughs:

As Chairman Leahy requested in his January 25, 2007 letter, attached are answers to the written questions submitted by Committee Members. Please call me if you have questions.

Thanks again for your assistance.

Sincerely,



Merril Hirsh

Enclosure
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Senator Kohl's Follow-Up Questions from Hearing on "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?"

1. Do you have an estimate of how much consumers are paying as a result of these "reverse payment" patent settlements which have the effect of keeping generic competition off the market?

RESPONSE: I believe that the answer would be in the billions of dollars each year. In your opening statement, you noted that savings from three years of early entry of generic competition for Prozac and Paxil alone saved consumers respectively about \$2.5 billion and \$2 billion. During his testimony, Commissioner Leibowitz added the examples of Zantac and Platinol and reported that the early entry for just these four products "is established to have saved consumers more than \$9 billion alone." I have no reason to dispute these figures. Had entry been delayed by reverse payment, that money would have been lost to consumers.

There is every reason to believe that the losses currently to consumers are at least as large and probably larger. As the FTC recently reported, in FY 2006, there were 14 agreements in which brand and generic companies settled patent litigation with reverse payment settlements on 8 different branded pharmaceutical products. "Each of these agreements involved a product with 2005 U.S. annual sales exceeding \$125 million; eight of the agreements involved products with 2005 U.S. annual sales of more than \$450 million." Bureau of Competition, FTC, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements filed in FY 2006, at 4 (2007) (available <http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>).

Beyond this general estimate, it is difficult to be more precise about how much consumers have lost to date. To conduct this analysis, you would need to know, first, the amount of revenue the brand company can be expected to obtain from the drugs, and then, the lower amount consumers would be expected to pay after competition. It is possible to estimate the

second of these figures (the lower prices after competition). As Commissioner Leibowitz noted during his testimony, although the price reduction might vary somewhat from drug to drug, “[w]hen the first generic enters the market, it generally does so at a 20- to 30- percent discount off the brand price. Prices drop even further – by 80 percent or more – after other generic competitors go to market, usually 6 months later.”

The first figure (the expected sales of the drug) would probably also be obtainable, but (for confidentiality reasons) the FTC’s report does not actually identify the drugs, the specific amount of sales of each or the extent to which generic entry has been delayed. Accordingly, I do not have access to that specific information.

Once this analysis has been conducted, there are at least two ways of looking at the effect of reverse payments. One would be to compare the results of the reverse payment settlement to what would be expected had cases gone to judgment in litigation. Another would be to compare those results to what would be expected had the parties instead settled by having the generic company enter the market earlier, without the inducement of a payment to stay out of the market.

Each of these approaches would require some additional information. A comparison with the expected result in litigation would require an assessment of the likelihood of success in the litigation. A comparison with the expected result in settlement would require assessing what expected settlement would be in a world in which the reverse payment portion was outlawed. It is fair to say that we would expect the generic company, without the reverse payment, to insist on entering the market sooner – and where the reverse payments are currently large, we would expect that entry to occur significantly sooner. However, it would require more data to determine the precise effect.

In one important way, however, the problem is much larger than any of these figures suggest. As you have noted in your third question (below), given the current state of the law, there is every reason to think that brand and generic companies will routinely use reverse payment settlements to resolve patent disputes – and, in particular, use them in situations when the brand company most expects to lose its case. If this remains the law, the use of reverse payment settlements threatens to eliminate, going forward, all of the gains derived from the ANDA-IV process under Hatch-Waxman. Obviously, that loss to consumers would be staggering.

2. In your view, are there any circumstances in which consumers are benefited by a patent settlement in which a generic firm agrees to keep its drug off the market in return for a cash payment from a brand name manufacturer?

RESPONSE: I do not believe that there are genuine circumstances in which consumers are benefited by the component of the settlement in which cash is being paid for the generic company's agreement to stay out of the market. I also believe that, in any event, this component of an agreement is, like any other agreement among competitors not to compete, so inherently unlikely to benefit consumers that it is better to bar it through a bright-line rule.

During his testimony at the hearing, Mr. Downey noted that some settlements may involve *other* components that help consumers. He gave examples of settlements that, in his view, allowed Barr to enter the market before the expiration of patents that Barr had concluded ultimately would have been upheld on appeal.

I would not second-guess Mr. Downey's statements about how Barr assessed the merits of these cases. And it is certainly possible that these settlements, in *some* ways, benefit consumers. But the assertion that a settlement benefited consumers in *some* ways, does not show that it was good for consumers to have – *as a component of the settlement* – a provision in which

the brand company paid the generic *not* to compete. In those settlements, the brand company was willing to forego a benefit in order to avoid an adjudication of the patent dispute; and Barr was willing to accept some benefit in exchange for dropping its challenge. Because the brand company was able to make some of that settlement in cash, Barr did not have to insist on as early an entry date in order to receive the benefit that it did. Consumers were not made better off because this was possible. They were made worse off.

In my written testimony and in the article I attached to it, I talked about the main argument people have made in the literature in response to this argument. People have attempted to argue that, in theory, there could be situations in which the only way to settle a case is to have the brand company make a payoff. As the attached article explains in more detail, there are a number of responses to this argument. Merril Hirsh and Dan Zoloth Dorfman, "I Didn't Say Orphan Often: The Benefits of a Bright-Line Rule Banning Brand to Generic Payments in Hatch-Waxman Patent Settlements," ABA ANTITRUST HEALTH CARE CHRONICLE, Vol. 19, No. 2 (Summer 2005). (Available at <http://www.rdbl原因.com/files/News/b2383914-25ae-41ca-8785-0bd69e9e07dd/Preview/NewsAttachment/72fbb496-9eb9-48bf-a618-12c4e5152e1c/Health%20Care%20Chronicle%20Summer%202005.pdf>). I would respectfully ask that this article be made part of the record.

But the most basic response is that this discussion really is theoretical. As you note in your final question, we went almost overnight from a situation in which brand and generics managed to settle cases with *no* reverse payments, to a situation in which now they use reverse payments frequently.

This huge shift did not happen because something made it suddenly impossible in 2006 to settle cases without reverse payments. It happened because court cases suggested that brand and

generic companies might be able to get away with these settlements. In 2005 and 2006, coinciding with the decision against the FTC's position by the Eleventh Circuit in *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006), and the decisions upholding a reverse-payment settlement in *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D. N.Y. 2003), *aff'd* 429 F.2d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), brand and generic companies reversed course and entered into fourteen new reverse payment settlements. See Bureau of Competition, FTC, Agreements filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006 (2007) (available <http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>).

If several years of cases can be resolved without reverse payments only to have reverse payment settlements return after the legal winds change, reverse payments must not be "essential." Brand and generic companies will enter them if they can. As history has demonstrated, if they cannot, they will resolve their disputes in a different way.

3. The FTC reports that in the year after the two court decisions allowing these "reverse payment" patent settlements half of all patent settlements contained terms in which the brand name company paid the generic money in return for the generic's agreement to keep its drug off the market. The year before the court decision, no patent settlement contained such terms. Doesn't this data show that such "reverse payment" settlements are likely to become increasingly common unless our legislation is enacted?

RESPONSE: I think that it is near certain that "reverse payment" settlements will become common in the absence of legislation or a Supreme Court decision rejecting the reasoning of the *Tamoxifen* and *Schering-Plough* decisions. For the companies involved, the economics is very simple. Drug sales tend to be very inelastic – the amount of a prescription drug sold does not increase very much when the price goes down. If a drug has sales of \$1

billion a year, and the price would be reduced by even 50 percent by the advent of full competition, full competition reduces total revenues by about \$500 million a year, and creates a market in which the brand is vying with the generic companies to share that revenue. If, for example, the brand company expects to retain $\frac{2}{3}$ of the market, its own revenue goes from \$1 billion a year to about \$333 million a year ($\frac{2}{3}$ of \$500 million). That is a loss of almost \$2 million in revenue each *day* competition is delayed.

If the brand and generic companies believe that there is any reasonable possibility of fighting off an antitrust challenge to this arrangement, they have an enormous incentive to try to do so. The FTC's experience with *Schering-Plough* shows that the agency can be entirely vigilant; it can scrutinize the settlements; it can enforce its view of the law; but it still may not be able to protect consumers when the companies agreeing to the reverse payment settlements take the obvious course of challenging the FTC's decision in a friendly United States Circuit Court of Appeals. The weaker the brand company's patent position, the more likely the brand company is to want to use a "reverse payment" settlement to preserve this extraordinary amount of revenue.

There is no certainty that the Supreme Court will solve this problem, or that it will do so soon. The Supreme Court takes a very small percentage of the cases presented to it. And because there is nothing currently in the Hatch-Waxman Act that expressly prohibits reverse payment settlements, any request for Supreme Court review would have to be based upon the argument that, in general, as a matter of antitrust law, these settlements are illegal. Although I would hope that the Supreme Court would take the case and so find, it is possible for the Court to conclude that although these settlements may be bad as a matter of policy, it is for Congress (and not the courts) to decide what the policy should be. In the meantime, customers are paying the enormous price.

Questions Submitted by Dianne Feinstein
Following the January 17, 2007 Senate Judiciary Committee Hearing
“Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?”

The Eleventh Circuit held in the *Schering-Plough* case that there was no antitrust violation when a settlement between a name-brand pharmaceutical company and a generic manufacturer prevented the generic company from marketing the competing generic product – because the settlement did not stifle any competition beyond what the patent already prohibited. To reach this conclusion, the court relied on a presumption that patents are valid.

- *To reach a conclusion that such a settlement is inherently anticompetitive, do we have to assume that the patent is **not** valid?*
- *If yes, why should we start from an assumption that the patent in question is not valid?*

RESPONSE: This question, I believe, helps to clarify an important issue that has led to a lot of confusion: Condemning reverse payment settlements does *not* require assuming that the patent is invalid. There is no conflict between, on the one hand, assuming that patents are valid and, on the other hand, preventing brand and generic companies from *settling* patent disputes by paying the generic company not to compete.

All litigation involves issues on which one side or the other has a burden of proof. In most litigation, there is something to be said for both side’s positions and certainly parties are entitled to rely on legal presumptions. But it is not true that just because a party may benefit from a presumption, or, more generally, have a legitimate position in litigation, it is empowered to settle the lawsuit by an agreement to eliminate competition.

Whatever the respective merits of their cases, the parties that enter into reverse payment settlements have decided that they want to settle. They can settle in two basic ways: One way is that the brand company can pay the generic to drop the lawsuit. This works to its benefit because it funds the settlement using the monopoly rent being paid by consumers. But it ensures that consumers receive no benefit at all. Another way is that the brand company and generic can

negotiate over *when* the generic company will enter the market. This settles the dispute by affording the generic the benefit of being able to market the product. But it benefits consumers by resulting in competition. Telling the parties that they can only settle in the second way does not affect the presumption of validity of the patent.

Reverse-payment settlements dramatically change the results this litigation would be expected to achieve. The fact that a patent is presumed to be valid does not mean that the patentholder has more than a 50 percent chance of success at any given point. It just means that the burden falls on the challenger to show that the patent is not valid. The evidence of invalidity could be anywhere from non-existent to overwhelming. (In addition, many patent disputes do not involve, or do not involve only, the question of whether a patent is valid. The major or even exclusive issue is often whether the generic company is *infringing* the patent. There is no presumption that a product *infringes* a patent).

Assume, however, you have ten cases, and in each of them the patentholder has a 60 percent chance of success. That means that we would expect – even *with* the presumption of validity – that, if all ten went to resolution, the patentholder would lose four of them. If you allow reverse payment settlements, you allow a result in which there is *no* competition in *any* of these cases. If you eliminate reverse payment settlements, you either have the cases going to resolution (in which case you get the competition in the four cases), or you have settlements in which your expected resolution is that the generic company will be allowed to compete on each drug 40 percent sooner than the generic company would otherwise. Both of those results avoid allowing the parties to use a payoff to afford patents more exclusive power than they actually have – even with the presumption. And reverse payments allow the patentholder to maintain the monopoly even when its position had only a 30 percent chance of success, or less.

In the real world, negotiations are more complicated. Parties may be risk averse; some may press better bargains than others. But the point is that, when the generic company is not being paid off, it has no incentive to stay out of the market. It has the incentive to compete as much as possible. The parties determine the actual date on which the generic company enters, not by a collusive negotiation designed to preserve a monopoly, but at arm's-length.

In fact, even if we agreed that, in a significant percentage of these cases, the brand company was destined to win the patent case, that still would not mean that, as a matter of policy, we should allow the brand company to pay off the generic for dropping the challenge. Companies cannot usually defend agreements not to compete by arguing "no harm, no foul." In *United States v. Reicher*, 983 F.2d 168 (10th Cir. 1992), for example, the court found that a defendant was properly convicted of criminal bid rigging even though the ostensible "competitor" with whom it rigged the bid would have been unable to perform the contract. As the court explained "[d]espite its ultimate inability to perform the contract, [the competitor] held itself out as a competitor for the purposes of rigging what was supposed to be a competitive bidding process. This is exactly the sort of 'threat to the central nervous system of the economy,' that the antitrust laws are meant to address." 983 F.2d at 170 (*quoting United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 226 n.59 (1940)). In *United States v. MMR Corp.*, 907 F.2d 489 (5th Cir. 1990), *cert. denied*, 499 U.S. 936 (1991), the court upheld a criminal price fixing conviction in a case where a company agreed not to bid on a prime contract in exchange for a subcontract from the bid winner. There, as in *Reicher*, it did not matter that the company that agreed not to bid had never handled such a large project on its own, or that the job greatly exceeded its bonding capacity. 907 F.2d at 492, 497. *See also United States v. Finis P. Ernest, Inc.*, 509 F.2d 1256, 1262 (7th Cir.), *cert. denied*, 423 U.S. 893 (1975) (to similar effect).

Similarly, it is not a defense to price fixing to argue that the price set was “reasonable.” “The aim and result of every price-fixing agreement, if effective, is the elimination of one form of competition. The power to fix prices, whether reasonably exercised or not, involves power to control the market and to fix arbitrary and unreasonable prices.... Agreements which create such potential power may well be held to be in themselves unreasonable or unlawful restraints, without the necessity of minute inquiry whether a particular price is reasonable or unreasonable as fixed...” *United States v. Trenton Potteries*, 273 U.S. 392, 397 (1927). *Accord Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 986 (9th Cir. 2000) (citing *Trenton Potteries* as reflecting the “long-established rule” that “[f]oremost in the category of *per se* violations is horizontal price-fixing among competitors”). *See also NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133 (1998); *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (price fixing and divisions of markets are illegal *per se* “without elaborate inquiry as to the precise harm they have caused or the business excuse for their use”).

Accordingly, even as we recognize that patents are presumed to be valid, we should not want to have a system in which parties can be paid off not to challenge them. Agreements not to challenge patents, just like “[p]rice-fixing of any kind[,] distorts in a basic way the competitive process the antitrust laws were meant to protect.” *USA Petroleum Co. v. Atl. Richfield Co.*, 859 F.2d 687, 692 (9th Cir. 1988), *rev'd on other grounds*, 495 U.S. 328 (1990). If we allow reverse payments, we are preventing the market from operating to solve the problem. That is wrong, by itself, even if our best guess is that the market might have happened to have reached the same result without the agreement.

Attached is a copy of an article that provides some additional detail that I hope might be helpful in addressing these issues. Merril Hirsh and Dan Zoloth Dorfman, “I Didn’t Say Orphan

Often: The Benefits of a Bright-Line Rule Banning Brand to Generic Payments in Hatch-Waxman Patent Settlements," ABA ANTITRUST HEALTH CARE CHRONICLE, Vol. 19, No. 2 (Summer 2005). (Available at <http://www.rdbl.com/files/News/b2383914-25ac-41ca-8785-0bd69e9e07dd/Preview/NewsAttachment/72fbb496-9eb9-48bf-a618-12c4e5152e1c/Health%20Care%20Chronicle%20Summer%202005.pdf>). I would respectfully ask that this article be made part of the record.

I DIDN'T SAY ORPHAN OFTEN: THE BENEFITS OF A BRIGHT-LINE RULE BARRING BRAND TO GENERIC PAYMENTS IN HATCH-WAXMAN PATENT SETTLEMENTS

by Merril Hirsh and Dan Zoloth Dorfman¹

The debate over the potential anticompetitive aspects of settlements of patent litigation between branded and generic drugs continues to rage, Schering-Plough notwithstanding. In this issue of the Chronicle we present a paper by Merril Hirsch and Dan Dorfman, arguing for a brighter line in the tests determining whether the settlement is merely a contrivance to share monopoly profits, and responsive comments by Karen Bokar and George Gordon, highlighting other ways to look at the issue.

GENERAL: I ask you, have you ever known what it is to be an orphan?

KING: Often!

GENERAL: Yes, orphan. Have you ever known what it is to be one?

KING: I say, often.

ALL: (disgusted) Often, often, often. (Turning away)

GENERAL: I don't think we quite understand one another. I ask you, have you ever known what it is to be an orphan, and you say "orphan." As I understand you, you are merely repeating the word "orphan" to show that you understand me.

KING: I didn't repeat the word often.

GENERAL: Pardon me, you did indeed.

KING: I only repeated it once.

GENERAL: True, but you repeated it.

KING: But not often.

GENERAL: Stop! I think I see where we are getting confused. When you said "orphan," did you mean "orphan," a person who has lost his parents, or "often," frequently?

KING: Ah! I beg pardon - I see what you mean - frequently.

GENERAL: Ah! you said "often," frequently.

KING: No, only once.

GENERAL: (irritated) Exactly - you said "often," frequently, only once.

— W.S. Gilbert, *The Pirates of Penzance*

INTRODUCTION

Everyone pretty much agrees on the basic situation: A brand-name drug company, claiming patent protection for one of its popular products, settles an infringement lawsuit against a drug company that has asserted a right to compete against the brand with its generic version of the drug. Among other things, the brand-name company agrees to pay money to the generic and the generic agrees not to bring its product to market and compete with the brand for some period of time.² Beyond that, the contentious discussions of the antitrust implications of these settlements – the subject of so much court time³ and law journal pages⁴ – often [frequently] seem the equivalent of this colloquy between the Pirate King and the Major General.⁵ Much of the heat and controversy on the issue comes from courts, scholars, and plaintiffs' and defense antitrust bars talking past each other – asking two fundamentally different questions and getting fundamentally different answers.⁶ The question favored by the antitrust defense bar, some scholars,⁷ and some courts including, most notably, the Eleventh Circuit,⁸ focuses on comparing the settlement with the alternative of litigation. This side essentially asks, "Is it bad for pharmaceutical competitors to agree to a mutually satisfactory arrangement including 'reverse payments' to resolve the uncertainty and cost of patent litigation?" "No," some courts answer.⁹ "No" or at least "probably not," answer commentators like Kevin McDonald and Marc Schildkraut.¹⁰ A payment from the patent holder to the generic company in settlement of patent claims, this side argues, is only uncharitably called a "reverse payment." In

Continued on page 5

¹ Merril Hirsh and Dan Zoloth Dorfman are attorneys in, respectively, the Washington, D.C. and Chicago offices of Ross, Dixon & Bell, LLP. They represent both plaintiffs and defendants in commercial and insurance litigation, including plaintiff purchasers in antitrust litigation arising out of Hatch-Waxman patent settlements. The views (and musical tastes) expressed in this article are their own and do not necessarily reflect those of Ross, Dixon & Bell, LLP or any of its clients. The authors drafted this article in connection with the ABA Antitrust Section's May 12-13 Conference on Antitrust in Health Care and invite comments and questions from those who are interested. All rights reserved, but re-publication may be permitted upon request.

Continued on page 2

fact, they maintain, such a payment merely reflects the same type of adjustment to consideration that takes place in other patent settlements in which the patent holder has a damage claim from defendant's prior sales, and accepts less than he might have received if successful in the litigation.¹¹ Accordingly, these settlements do not necessarily raise antitrust concerns, at least as long as the settlement terms are reasonable and, perhaps, as long as the patent position was not so frivolous in the first place as to constitute "sham patent" litigation.¹²

Hence, the Eleventh Circuit's three-part test: When faced with an antitrust challenge to a Hatch-Waxman settlement between pioneer and generic drug manufacturers, a court should first examine "the scope of the exclusionary potential of the patent." Then, the court should look at "the extent to which the agreements exceed that scope," and, lastly, at "the resulting anticompetitive effects."¹³ If the brand-name company is going to win the patent case more than half the time, as the presumption of patent validity suggests, there is no harm in having it pay money to delay entry that would not have occurred in any event and may actually occur sooner by virtue of the settlement.

But, respond the plaintiffs' bar, the FTC,¹⁴ some scholars,¹⁵ and some courts¹⁶ – most prominently the 6th Circuit,¹⁷ the question is not whether the generic would have won the patent case or *why* it might settle. Instead, the question is what do we think about the payments being made as part of the *terms* of settlement? To put it another way: "Is it bad to have settlements in which brand-name companies pay generics large amounts of money in exchange for an agreement not to compete as opposed to settling on a time for market entry?"

By asking this different question, this side comes to the different answer that these settlements are bad. Moreover, even within the confines of the Eleventh Circuit's approach, there is room for a "yes" answer to this question, a federal district court judge recently found in granting summary judgment to plaintiffs on remand from the Eleventh Circuit's *Valley Drug* decision¹⁸: "While [Abbott and Geneva] could have structured their Agreement in a *less restrictive way* that reasonably implemented Abbott's patent protections, they instead agreed to a restraint that *surpassed that which the patent would have allowed*."¹⁹

In a particular version of this view, a patent settlement could be anticompetitive regardless of whether the brand-name company was more likely than not to win the patent case. This could be true because we call the unadjudicated patent

right "probabilistic," i.e., until the brand-name company wins, it only has a chance of winning and, therefore, also has a chance of losing that it resolves by buying off a competitor.²⁰ Or it could be true because we do not care, i.e., given that the case is settling, buying off a competitor is either inherently or empirically an anticompetitive way of settling because it shares monopoly profits between the participants without resulting in competition.²¹

Although we would not agree with all the analysis on this side, the second question is the correct one in our view, and we favor *per se* treatment of these settlements or, at least, a bright-line rule presuming the anticompetitive nature of settlements in which the pioneer pays the generic to stay out of the market. Still, we believe that understanding the miscommunication may offer both sides of the debate a way out of the impasse.

I. HOW DO "REVERSE-PAYMENT" SETTLEMENTS COME ABOUT? ²²

A. The Hatch-Waxman Act and the Marketing of Generic Drugs

A brief synopsis of the Hatch-Waxman Act and its procedures is in order. No drug company may sell a prescription drug in the United States until it has applied for and received approval from the Food and Drug Administration ("FDA").²³ To secure FDA approval, a drug company must file a New Drug Application ("NDA"), including reports and information that demonstrate the drug is safe and effective for its proposed use(s).²⁴ New drugs that are approved and marketed through the NDA-approval process are called "pioneer" or "brand-name" drugs.²⁵ In 1984, concerned that the NDA process was cumbersome and delayed entry of relatively inexpensive generic drugs into the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act ("Hatch-Waxman").²⁶

The Act established an abbreviated process to obtain FDA approval for generic versions of previously approved pioneer drugs.²⁷ Five years after the FDA has approved a new drug, a generic pharmaceutical company may seek approval to market a generic version of the drug by filing an Abbreviated New Drug Application ("ANDA"). To secure FDA approval of an ANDA, the generic must demonstrate that the proposed drug is the bioequivalent of the corresponding brand-name drug.²⁸ Hatch-Waxman, in order to protect the patent rights of the pioneer

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manufacturer, also requires the ANDA filer to make one of four certifications concerning patents listed with the FDA for the brand-name drug. Most pertinently for our issue, in a Paragraph IV Certification, the generic manufacturer attests that the listed patent "is invalid . . . or will not be infringed" by the generic drug.²⁹

Moreover, if the generic files an ANDA IV, it must provide notice to the patent holder of the certification, including a statement of the factual and legal basis for its opinion that the patent is invalid or will not be infringed.³⁰ If the pioneer company brings a patent infringement suit against the generic within 45 days of receiving notice of the Paragraph IV Certification, the FDA delays approval of the ANDA until the earlier of (1) 30 months after the pioneer's receipt of the notice or (2) issuance of a court decision relating to the ANDA holding the patent invalid or unenforced.³¹

The first ANDA filer enjoys a 180-day exclusivity period during which other generic drug makers are barred from competing in the market for the drug at issue; the exclusivity period commences when the first filer begins selling its product or the pioneer's patent is held to be invalid or unenforced.³² Accordingly, prior to the enactment of the Medicare Reform Act, any agreement between the pioneer and the first generic to delay the latter's entry into the market served to keep other generic competitors out as well, as long as the generic agreed to defend and/or not to waive its exclusivity rights.

B. "Reverse-Payment" Settlements

Not all Hatch-Waxman settlements are controversial. The attention of the FTC and private antitrust litigators – and the focus of this article, much case law, and the voluminous commentary noted earlier – has been drawn to settlements that (1) include a "reverse-payment" and (2) either condition the payment upon the generic company not competing, or bar the generic company from competing, for some period.

In setting forth this scenario, we need to stress two points. *First*, it is not the settlements themselves that raise antitrust concerns, but the combination of these two provisions. It is theoretically possible that there could be other settlements that violate the antitrust laws.³³ But, as a practical matter, it makes sense to have a working assumption that, if the brand-name company is *not* making a substantial payment to the generic in exchange for the generic's agreement not to compete for a period of time, the two are actually bargaining at arm's-length over the terms of competition.

Similarly, if the brand-name company wants, for some reason, to pay the generic *without* restricting the generic's entry into the market, that may be a management problem but it is not especially an antitrust problem. The concern in Hatch-Waxman settlements is not that generic companies receive funding; it is that they are agreeing not to compete in exchange for the funding. The combination of the "reverse-payment" element and the foreclosed competition raises a point of discussion because of the potential for the brand-name company's inducing the generic not to bargain at arm's-length over the terms of competition, but instead to bargain over how to divide up the monopoly rent that the brand-name company obtains from the lack of competition.

Second, in the real world, the fact scenario in which a Hatch-Waxman settlement is likely to give rise to private antitrust litigation is somewhat extreme. The cases that arise, at least in private antitrust litigation, usually involve blockbuster drugs with hundreds of millions of dollars of annual sales. If the brand-name drug is only marginally successful, it is not likely that the generic will want to pick the patent fight in the first place. Even if the generic goes ahead with the ANDA IV filing in such a case, the brand-name company has little reason to pay substantial money to generics to preserve the right to sell marginal product. And if the monopoly rent is small, the private plaintiffs' bar does not have much incentive to bring an antitrust case in an effort to disgorge it.³⁴

Moreover, the cases that give rise to antitrust litigation are more likely to involve some fair grounds for dispute over the patent's validity or applicability. Granted, Hatch-Waxman established a system in which generic companies appear to have an incentive to challenge patents because they can do so without risking damages or incurring the costs and uncertainties associated with marketing the drug. The system, then, may be expected (inappropriately, we argue, when reverse payments can be sought) to encourage ANDA IV filings that might not otherwise be made. Nevertheless, generic companies who file ANDA IV applications cannot be assumed to be picking frivolous patent fights.³⁵ By applying to the FDA for permission to market their drugs, they invite a lawsuit for patent infringement.³⁶ They risk substantial litigation costs, the costs and effort of preparing their drugs for market, and potentially extensive delays until they can market their products, if the courts fail to vindicate their patent positions. Moreover, weak patent challenges are less likely to lead to a reverse-payment settlement. The weaker the case, the more likely it is to fail on early motion and the

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less likely to exact a premium in settlement from the pioneer.³⁷

In short, although in theory you might have a case involving a marginal product and a brand-name company that has a 99.9 percent chance of winning the patent case, in practice, the cases can be expected to involve far more dollars and significantly closer patent disputes.

C. Recent Illustrations from the Case Law

Two recent "reverse-payment" Hatch-Waxman patent cases respectively involve somewhat weaker and somewhat stronger facts for analyzing the antitrust claim.

1. *K-Dur 20*

At issue in the *Schering-Plough* litigation was Schering-Plough Corporation's brand-name drug "K-Dur 20," an extended-release potassium chloride medicine, used in the treatment of high blood pressure and congestive heart disease.³⁸ Schering-Plough's patent, due to expire in September 2006, claimed the pills' extended-release coating; the active ingredient, potassium chloride, was commonly used and unpatentable.³⁹

In August 1995, Upsher-Smith Laboratories filed an ANDA IV to market a generic version of K-Dur 20. Schering-Plough sued Upsher for patent infringement in December 1995; the earliest that Upsher could market its drug, upon FDA approval, was December 1998. In June 1997, on the eve of trial, Schering-Plough and Upsher settled and agreed that the earliest entry date for Upsher's generic would be September 1, 2001. Schering-Plough also agreed to pay Upsher \$60 million plus other consideration to license three Upsher products.⁴⁰

In March 2001, the FTC filed an administrative complaint against Schering-Plough, Upsher, and a third generic company⁴¹; the FTC's Administrative Law Judge ("ALJ") found that the agreements were lawful settlements of patent lawsuits and dismissed the complaint.⁴² In December 2003, the full Commission reversed the ALJ's decision, concluding that the payments in the settlements were a *quid pro quo* for delayed entry of the generics and thus harmful to competition and consumers in violation of the antitrust laws. Schering-Plough and Upsher timely petitioned the Eleventh Circuit for review.⁴³ In addition to the proceedings before the FTC, reviewed by the Eleventh Circuit, private antitrust litigation arising from the Schering-Plough's agreements with Upsher and ESI has been consolidated in the New Jersey District Court.⁴⁴

2. *Hytrin*

Abbott Laboratories manufactures Hytrin, a "very successful" brand-name drug used to treat hypertension and enlarged prostate.⁴⁵ The active ingredient in Hytrin is a form of terazosin hydrochloride, for which Abbott holds a number of patents.⁴⁶ In 1996, Geneva Pharmaceuticals filed several ANDA IVs based on Hytrin⁴⁷ and Abbott filed a patent infringement suit, asserting that Geneva's proposed product infringed one of its patents.⁴⁸ In April 1998, the companies entered into an agreement, in which Geneva agreed not to market a generic terazosin hydrochloride drug until either Abbott's '532 patent expired in 2000, another company introduced a generic terazosin hydrochloride drug, or Geneva obtained a final court judgment, from which no appeal could be taken, that Geneva's terazosin products did not infringe the '207 patent or the patent was invalid. Geneva also agreed not to transfer or sell its rights to the 180-exclusivity period under its ANDAs and to support Abbott in any efforts to extend the 30-month stay of FDA approval of Geneva's ANDA. In return, Abbott agreed to pay Geneva \$4.5 million/month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim.⁴⁹

In September 1998, the Northern District of Illinois held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent; the decision was affirmed by the Federal Circuit Court of Appeals in July 1999.⁵⁰ In December 2000, the Southern District of Florida granted summary judgment to class action and individual antitrust plaintiffs in their suit against Abbott, Geneva, and Zenith, finding that the agreements at issue constituted geographic market allocation agreements between horizontal competitors and hence were per se unlawful under Section 1 of the Sherman Act.⁵¹ In *Valley Drug*, the Eleventh Circuit reversed and remanded for consideration of the agreements under its three-part test. On remand, the district court held that the "appellate-stay" provision⁵² of the agreement exceeded the scope of the '207 patent and was per se a violation of federal antitrust law.⁵³

II. WHAT ARE THE PROBLEMS WITH "REVERSE-PAYMENT" SETTLEMENTS?

There are two questions discussed at the outset of this article: (1) the "*settlement vs. litigation*" question,

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concerning whether the parties should be settling as opposed to litigating; and (2) the "*what settlement*" question, concerning how they are settling compared to other settlements. Both questions raise potential antitrust problems. The problems involved, however, are often [frequently] confused. The first – whether the settlement is worse than litigation – is a closer one; the second – whether this particular settlement is worse than others that might have happened – is really pretty clear in theory, even if there are arguments for why it is trickier in practice.

A. The Settlement vs. Litigation Question

The closer question is the one that the Eleventh Circuit focuses on: When, if ever, do reverse-payment Hatch-Waxman patent settlements violate the antitrust laws?⁵⁴ On this issue, there are some strong competing considerations. It is indisputable that patents accord certain rights, both temporal and practical, and confer legal and economic advantages on the nation. It is also indisputable that, in general, settlements of litigated disputes provide advantages to litigants, the courts, and society in general.⁵⁵

If, as the side asking this question argues, some settlements would not happen but for the reverse-payment,⁵⁶ society loses this benefit. And when you are comparing a world with patent rights that are being litigated to one in which patent rights are settled, it is not easy to sort out the extent to which the lack of competition is a function of the settlement (and therefore infirm) as opposed to the patent itself (a lack of competition we tolerate or even encourage for other reasons).

Some commentators suggest that, because of risk aversion, there are circumstances in which a settlement, even with reverse payments, might be better than the expected result in litigation.⁵⁷ The Eleventh Circuit even goes so far as to suggest that "[b]y restricting settlement options, which would effectively increase the cost of patent enforcement," a *per se* rule barring reverse payment settlements "would impair the incentives for disclosure and innovation."⁵⁸ Others maintain that reverse-payment settlements might actually further competition by providing cash-strapped generics with the money to launch more-effective competition when the period of exclusion ends.⁵⁹

Various commentators, Judge Posner,⁶⁰ and the Eleventh Circuit⁶¹ have also challenged the premise that reverse-payment settlements are a big deal. They argue that the awkward appearance of having a patent holder pay the generic it is suing is merely a function of the artificial Hatch-

Waxman setting in which a generic is able to pick a patent fight without already having infringed and run up damages. In this argument, there is no difference between having a brand-name company with a \$0 potential recovery agree to pay the generic \$500 million than there is having a patent holder in another case with a \$1 billion potential recovery agree to accept "only" \$500 million in settlement.

We believe these arguments are, to varying degrees, overstated or misapplied.

1. Reverse-payment settlements protect weak patent positions.

Society's interest in protecting patents does not connote an equally strong interest in protecting weaknesses in patent positions. Patent holders may need some room to be mistaken about patent positions without automatically facing antitrust liability, as some argue.⁶² But it seems to go overboard to grant brand-name companies the right to use patent disputes as an occasion to pay a competitor not to compete whenever the brand-name company has a patent argument that is "merely" a losing one and not completely frivolous.⁶³

You do not have to agree that patent rights are "probabilistic" to recognize the risk in allowing litigation settlements to overstate the strength of a patent position. Suppose a brand-name company has ten patents, each with a 50/50 chance of being upheld and enforced. All right, in light of the presumption of validity, make it 60/40, make it 70/30. No one would contend that it is frivolous or a "sham" for a patent holder to assert an infringement claim with a 50, 60 or 70 percent chance of success. Yet, it is only in five cases, or six or seven, that the brand should win; in five, four or three, it should lose. If the law permits the brand-name company to settle all ten of these cases by paying the generic company some of its monopoly rent to stave off a patent challenge, there is no competition in *any* of the ten cases. This seems wrong.

The Eleventh Circuit's standard, requiring the trial court to look at "the extent to which the agreements exceed" the scope of the patent,⁶⁴ seems to recognize the problem, but not to address this form of it. Taken literally, this standard deals with a situation in which brand-name and generic companies use the occasion of a patent dispute to eliminate competition in a way that is *broader* than the patent does. But it does not seem to address the problem that a settlement may eliminate competition in a way that is *stronger* than the patent justifies. This is an especial risk in the real world with large monopoly rents attending

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blockbuster drugs and some presumed merit in the generic company's patent position. Getting three to five out of ten cases wrong can mean that those who purchase drugs are paying hundreds of millions or even billions of dollars more than they would if the drug companies either litigated the cases to conclusion or settled on terms that traded at arm's-length on competition rather than dollars.

Perhaps we are reading the opinion too literally. The Eleventh Circuit recognizes the possibility of "circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure."⁶⁵ Indeed, when *Valley Drug* came back for remand in *Terazosin II*, Judge Seitz focused on the concern that the settlement agreement there barred Geneva's entry into the market beyond resolution of the patent suit in the district court "without any determination of whether Abbott was likely to succeed on the merits of any appeal," i.e., without any assessment of the strength or weakness of Abbott's patent position.⁶⁶ The *Valley Drug* court also cited to case law extending the sham patent principles of *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.*⁶⁷ to circumstances where the patentee knew the patent was invalid,⁶⁸ and limits its holding to circumstances in which the antitrust plaintiff had "demonstrated nothing more than subsequent invalidity."⁶⁹

Nonetheless, the Eleventh Circuit's conclusion – that a payment from the brand-name to the generic company not to compete is not *per se* anticompetitive, even in a case in which the patent is subsequently determined to be invalid – seems to add a kind of supra-anticompetitive property to the patent. If even an invalid or unenforceable patent affords antitrust immunity for paying a competitor not to compete, we are accepting error in more than five cases out of ten.

2. *Reverse-payment settlements cannot be expected to encourage innovation.*

The premise that drives this willingness to accept a high rate of error is unproven and seems counterintuitive. The Eleventh Circuit is concerned that preventing patent holders from settling Hatch-Waxman cases by paying their competitors will "impair the incentives for disclosure and innovation."⁷⁰ But this seems remote. There is no reason to believe that a brand-name company that is willing to go to all the expense and risk of developing and testing a drug (and then enjoy at least a five to seven-and-a-half year period of monopoly sales before the first generic can hit the market) is not going to do so based upon the fear that *if* the

drug is approved by the FDA, and *if* the brand-name company obtains a patent, and *if* it is challenged by a generic someday, and *if* the brand-name company decides to settle the litigation by paying the generic not to compete, and *if* the generic is interested in that settlement, and *if* the brand-name pays so much as to reflect a genuine weakness in the patent position, it might then face antitrust liability. Moreover, as discussed in more detail in Section IV below, the long-run effect of barring reverse-payment settlement is more likely to support disclosure and innovation by reducing the risk of extortion through litigation.

3. *Reverse-payment settlements do not seem to be "necessary" to settle patent litigation, or necessarily desirable even if they were.*

The contention that reverse-payment settlements are "necessary" in Hatch-Waxman litigation is a more sophisticated, and potentially troubling, argument. But it has several weaknesses. To explain this point requires a brief explanation of the argument itself.

Marc Schildkraut, for example, argues that reverse payments can close the gap in a situation where the benefits to the brand-name company of exclusivity are greater than the benefits of entry to the generic company. He uses the example of a situation where the patent holder and the generic are a year apart in their negotiations over the time when the generic can enter the market and "[t]o the patent holder, [a] year is worth, say, \$120 million in monopoly profits beyond the competitive profits available after entry. To the alleged infringer, it is worth \$10 million (in competitive profits)."⁷¹ Schildkraut then posits situations in which the parties, therefore, would never reach an agreement on time without money because each day of movement costs the patent holder more than the generic gains.⁷² He similarly uses examples of situations in which the brand-name company is risk-averse, but the generic overly-optimistic; in these circumstances, he argues, the time-of-entry numbers do not overlap and the pioneer's and the generic's differing expectations about money may allow them to reach agreement.⁷³

This analysis is intriguing, but seems overstated. Even assuming that these particular situations occur in the real world, it is not clear that they would exist in a world in which reverse-payment settlements were illegal. A change in the rules may well change the result. If, for example, the rule were that reverse-payment settlements (or those involving a certain level of such payments) were *per se* illegal, generics whose primary interest was in the reverse

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Continued from page 9

payment rather than in competition would likely not file ANDAs for their products in the first place. Accordingly, those cases that were brought would be ones in which the ability to compete would have significant value to the generic.

Moreover, because a high proportion of civil cases settle and patent litigation involves some of the most imaginative professionals in our legal firmament, it is not clear that eliminating one avenue for agreement would lead to despair of all others. As a practical matter, commercial litigators often face this dilemma in settlement negotiations. Litigation — be it trademark disputes, tortious interference, or breach of contract claims — can always be settled on anticompetitive terms. How often in negotiations do we approach that moment when we say, out loud or to ourselves, “We could do this, it would settle the case and serve our client’s interests, but . . . we really can’t?” Agreements not to compete are quite frequently “win-win” agreements for those who agree to them and, therefore, could close many gaps in settlement negotiations. Yet, somehow, cases settle without them.

Indeed, Hatch-Waxman patent disputes do settle without reverse-payments. An FTC Report published in early 2005 concluded that “[s]ettlements after 1999 do not appear to include a payment from the brand-name company to the generic manufacturer in exchange for the generic’s agreement not to market its product.”⁷⁴ If several years of cases can be resolved without reverse payments, how “essential” can they be?

Moreover, even if reverse payments were somehow “necessary” to settle these cases, the benefits of having them settle may still not outweigh the detriment of agreements not to compete. In *Valley Drug*, for example, the Eleventh Circuit recognized that settlements that go beyond the scope of patent protection may be *per se* illegal, even if they do help close the gap between the parties.⁷⁵ It may be readily apparent that a patent settlement overreaches when the agreement not to compete extends beyond the four corners of the patent,⁷⁶ but it is difficult to see why, in principle, “closing the gap” is any better excuse for permitting settlements that alter the strength of the patent position in a way that litigation would not. Regardless of the terms that are restricting competition more than litigation would, it would not be surprising to see the parties swear after the fact on a stack of F3d’s that these terms were the *only* ones on which they could possibly have agreed given the circumstances.

However, most problematically, Schildkraut’s example illustrates the very problem it purports to solve. Why is it that a year to the patent holder is worth \$120 million in monopoly profits beyond the competitive profits available after entry but only \$10 million (in competitive profits) to the alleged infringer? It is probably not simply because the generic is going to sell less product. Probably, it is, in part, because generic drugs have lower margins *from which consumers benefit when the generic company enters the market*. Clearly, consumers do not benefit from these lower margins when the pioneer and the generic agree to use the monopoly rent to pay for a year less of competition. Reverse-payment agreements are such “win-win” settlements for Hatch-Waxman litigants and are so useful for closing gaps because it is the rest of us who pay for them.

The interests of the private parties to these settlements simply do not conform to the interest that society has in competitive balance. Patents may be socially and economically beneficial; settlements may be good; competition may be good, but the parties with the greatest interest in the patents and the settlement do not necessarily share the same fervent interest in competition as they do in the other two.⁷⁷

4. *Reverse-payment settlements are an inefficient way to fund competition.*

The argument that we should allow reverse-payment settlements so that generic companies can use brand-name companies to fund the generic’s eventual competition seems especially strained. Even if we assumed that generic drug companies are all cash-strapped (which is, of course, untrue), companies generally do not look to their competitors as essential sources of funding for their operations. If generics have a product to sell and need cash to do it, they ought to take their business plans to venture capitalists, stockholders, bondholders or private lenders, like other businesses do. In any event, it is difficult to see why we would want to encourage generics to pick patent fights in order to pursue the sales of drugs that they cannot afford to market and/or demonstrate are worth funding. And, in the case of the type of blockbuster drugs that give rise to these issues, the inability to fund competition seems like a very remote concern.

5. *Reverse-payment settlements are not a benign “oddy” of Hatch-Waxman.*

The argument that the “reverse-payment” feature of “reverse-payment” settlements is merely an oddity of Hatch-Waxman is more misleading than it is helpful. Yes, when

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people compromise, they generally accept less than their highest hopes; and if the highest hope is zero, the compromise becomes negative. But, as noted above,⁷⁸ what makes these Hatch-Waxman settlements a concern is not merely that the payment goes in an apparently odd direction, but *also* the fact that the generic who receives the money is being paid not to compete. Although it would be difficult to demonstrate empirically, most patent settlements probably do not have as their tag line – “I will accept only X, if you agree never to compete.” They usually say, “I will accept X amount of dollars for now, and then you will pay Y dollars to license.”

Even if the tag line were that the generic is agreeing not to compete, the issue is more complex than it might appear. If the conventional patent plaintiff with a guaranteed \$1 billion patent claim agreed to accept a mere \$500 million in exchange for an agreement to have the alleged infringer agree not to compete, that would be a pay off. However, if the patent claim were *guaranteed* to be worth \$1 billion, the case is not one with a weak patent position; the alleged infringer never had the right to compete in the first place and, thus, objectively, was *not* being paid not to compete. This is different than the Hatch-Waxman situation, because there we know that the patent holder is entitled to receive \$0 *win or lose*.

Accordingly, to have a situation in which the patent holder is not guaranteed to win, requires adding a level of uncertainty to the hypothetical. It would involve a decision-tree situation something like this: Suppose the patent holder has, say, a 50 percent chance of success that would produce \$1 billion, but nonetheless agreed to accept significantly less than \$500 million (\$1 billion x .5 probability of it occurring) (say \$250 million) in exchange for an agreement that barred the alleged infringer from competing for some period of time.

The problem in this analysis is that, although we can *say* all this for purposes of a hypothetical, in the real world of non-Hatch-Waxman settlements, there is so much uncertainty that, absent very extreme facts, what we say is probably not worth the paper it is printed on. Not only is the 50 percent chance of success (a) objectively uncertain; (b) not necessarily equal to the honest, but subjective, perceptions of the parties; and (c) subject to the parties' (potentially unequal) level of risk-aversion, the \$1 billion in *damages* is usually even more difficult to pin down on all of these scales. Moreover, large sums of money like this may also be subject to a diminishing marginal return to money. Even a reasonably large company might prefer to guarantee

\$250 million rather than incur even a mathematically justified risk in order to obtain \$500 million, not merely because it is averse to the risk, but because it cares more about the first \$250 million it receives than the next \$250 million. Thus, although in theory, you could ask the same question in the non-Hatch-Waxman settlement – what is (the reduction in) money paying for? – in practice, the non-Hatch-Waxman setting is far more likely to present non-competition-related answers to that question.

When we are examining whether to have a *per se* rule, the issue of “how sure we are that this is anticompetitive” is not merely a footnote to a pristine theoretical analysis – it is the central question. A *per se* rule is warranted when “the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output.”⁷⁹ In the case of reverse payments in exchange for delayed (or non-) entry of generic competition into pharmaceutical markets, the commentators are straining to come up with circumstances in which the settlement would *not* be anticompetitive. In the case of reductions in amounts potentially recovered from non-Hatch-Waxman patent claims, we have to strain to figure out when we can be sure the settlement *would be* anticompetitive.

In short, although there are certainly arguments to be made on both sides of the question of whether reverse-payment settlements are better or worse than litigation, on the whole, they are weaker than they might appear.

B. The “What Settlement?” Question.

Although the anti-reverse payment settlement side of this debate has made a number of these points at various times, the main focus of the competing analysis is not on explaining why it would be better to continue the litigation rather than settle on these terms. Instead, the approach is, in varying degrees, to take the fact of settlement as a given, and then to focus on its terms. This makes the answer to the question easier: If we assume that the case is going to settle and then focus on why the settlement included reverse payments, paying money to the generic company seems to do a lot less for competition than agreeing to the generic company's obtaining its consideration by entering the market sooner. As one judge, considering the same agreements at issue in *Schering-Plough*, explained: “Plaintiffs can sustain a claim of anticompetitive conduct simply by alleging facts which show that the outcome of the settlement agreements would have been more pro-competitive absent the cash payments from Schering to Upsher and ESI.”⁸⁰

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The problem becomes more glaring if the amount of the payment is large. Judge Seitz, for example, was troubled by the size of the reverse-payments, which, she observed, "exceeded Geneva's [the generic's] total revenues for 1997," the year before the settlement agreement.⁸¹ This, in turn, raised a red flag as to whether Abbott and Geneva could have reasonably implemented Abbott's patent protections in a "less restrictive way."⁸²

In *Schering-Plough*, the Eleventh Circuit's reaction to the FTC's decision was scathing on the facts, and especially frustrating to antitrust writers because, in significant measure, it rests on a factual determination that just ruins a good hypothetical. In the settlement, Schering-Plough, the brand-name company, received additional consideration in the form of cross-licenses for several of the generic company's drugs, principally Upsher's cholesterol drug, Niacor. The FTC's ALJ concluded that the cross-licenses had value. However, as noted above, the full Commission reversed, concluding that they did not. The Eleventh Circuit held that the FTC was wrong to reject the ALJ's findings.⁸³ If Schering-Plough actually did obtain independent value for its payment, this was not a "reverse-payment" settlement at all; it was a settlement that included a purchase agreement, and the compromise on when the generic would enter the market was presumably reached at arm's-length.

But the Eleventh Circuit did not stop with the facts. And when it turned to the theory, its discussion was mostly "often" to the FTC's "orphan." To the FTC, a reverse payment was a red-flag, presumed to be bad because parties could always be expected to trade money for time of competition. To the Eleventh Circuit, the reason for the reverse payment was not a theoretical question, but a factual one — the court critiqued the FTC for relying on an expert's "rather amorphous 'incentive' theory despite its purported lack of empirical foundation."⁸⁴

Although the Eleventh Circuit cited to "facts" (mainly the *post hoc* explanations of those who settled about why they could not settle in any other way), the court largely relied on theories of its own. First, it declared that "[w]ithout any evidence to the contrary, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product."⁸⁵ Then, it explained that, "[r]everse payments are a natural by-product of the Hatch-Waxman process."⁸⁶ And in a theoretical discussion about what might happen, it reasoned that, under Hatch-Waxman, generics have significant settlement leverage that alleged infringers do not normally have in patent litigation. They risk litigation costs,⁸⁷ but not

the multiple damages normally at stake in a patent infringement actions.⁸⁸ Moreover, litigation costs "pale[] in comparison to the immense volume of generic sales and profits."⁸⁹ On the other hand, the litigation could cost the patent holder its patent,⁹⁰ with substantial losses in revenue and profits, especially in the face of competition from the victorious generic and possibly other manufacturers.

"Ultimately," the Eleventh Circuit concluded, "the consideration paid to Schering by Upsher and ESI was arguably less than if Schering's patent had been invalidated, which would have resulted in the generic entry of potassium chloride supplements."⁹¹ That is why "[a] conceivable compromise . . . directs the consideration from the patent owner to the challengers."⁹²

The problem is that none of this theory really answers the facts. True, Hatch-Waxman settlements are different. True, they involve different plusses and minuses on the parties' respective sides. And this explains why a generic may, in a Hatch-Waxman situation, be able to command a better settlement than would an alleged infringer in a non-Hatch-Waxman situation facing large potential damages. But it does not explain why the settlement needs to take the form of money, or refute the FTC's point — that the payment of money raises a red flag pointing to the likelihood that, without the money, the settlement would have resulted in the generic's competing sooner. Nor does it deal with the more basic problem — that the focus of the antitrust laws is not on the benefits that agreements confer on the potential competitors who enter them, but on the effect their obtaining these benefits has on consumers who are supposed to benefit from competition.⁹³

III. A *PER SE* OR BRIGHT-LINE RULE BARRING REVERSE-PAYMENT HATCH-WAXMAN SETTLEMENTS WOULD BENEFIT ALL SIDES OF THE ISSUE

As noted above, a *per se* rule is warranted when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output."⁹⁴ When this is the case, no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition.⁹⁵ The classic examples that the Supreme Court has identified as subject to the *per se* rule include naked, horizontal restraints pertaining to prices or the allocation of territories.⁹⁶

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Bright-line rules are similar.⁹⁷ Although bright-line rules may be over- or under-inclusive, they have the great advantage of clarity and simplicity. As Judge Posner explains in a different context, "[a] rule singles out one or a few facts and makes it or them legally determinative" as distinct from a "standard" which "allows a more open-ended inquiry."⁹⁸ The problem with confusing the two, Judge Posner warns, is that we are liable to fall into the fallacy of "confusing a rule with its rationale," which leads us often into "potentially costly, time-consuming and uncertain inquiry" into a dispute whose resolution ought really to be straightforward.⁹⁹

Whether we are talking *per se* or bright-line rule, a rule barring significantly large reverse payments responds effectively to both the "litigation versus settlement" problem and the "what settlement" problem. As noted above, it is easy to see how a non-payment settlement including an agreement on time of market entry helps with the "what settlement" concern. The significant risk in Hatch-Waxman settlements is that the powerful force of patent-infringement settlement-bargaining will be directed to finding a solution that is very good for the parties themselves, but not at all good for the rest of us. Not only is there a temptation to agree on the "win-win" of sharing the consumer's money; the transfer of the money – especially a lot of money – is a pretty good indication *ex post facto* that the parties have yielded to it.

A system in which these settlements cannot take the form of money beyond cost of defense aligns the interests of generic companies with those of consumers. Barred from sharing in the brand-name company's monopoly profits, the generic's interests and incentives shift to forcing more competition and gaining revenues by selling product. The agreement is truly at arm's-length and, therefore, can be presumed to have fairly balanced the patent holder's interests in protection and the concerns of competition, with weakness in the patent position genuinely resulting in competition rather than mere payment.

Perhaps more tellingly, however, a bright-line rule against reverse-payment Hatch-Waxman settlements also seems to do a much better job of dealing with the "litigation versus settlement" problem than does the Eleventh Circuit's rule. We believe that the effects of a *per se* rule on disclosure, innovation, the ability to reach the best results in settling litigation and the need to clear dockets of patent cases would be positive, not negative. Under the current system, generic companies have an incentive to file ANDA IVs announcing an intention to challenge the patents for

blockbuster drugs in order to receive money in reverse-payment settlements. If such settlements were barred, generic companies would be more likely to challenge patents when they genuinely were willing and able to compete. Surely, brand-name companies, given the option, would opt not to get involved in the patent litigation in the first place rather than have the privilege of settling the litigation by paying off a potential competitor.

Moreover, a *per se* rule strengthens the self-selection that already exists in some measure when generic companies decide to file ANDA IVs. Assume that the two major motivations that animate the decision to file an ANDA IV are: (1) weakness in the brand-name company's patent position; and (2) the amount of money the pioneer drug makes. In a system where the generic company can hope to be paid off rather than to compete, the relevant number for the amount of money the drug makes is, logically, the amount it makes *for the brand-name company*, who may now share some of this monopoly rent in settlement. In a system where that option is gone, the relevant figure would seem to be the (lower) amount of money the drug makes *for the generic* after competition has brought down price. The less money available to drive the decision to file an ANDA IV, the more the decision can be expected to be driven by weakness in the patent position, and the more closely we approach the situation where the brand-name company, with ten 50/50 patent positions, is sued on the five losing ones and not on the five winning ones.

Obviously, this is theoretical and imperfect. But it is, ironically, a "free-market" solution that, as many such solutions do, better approaches the result we should want than do arrays of uncertain judge-made standards.

² In Section II below, we discuss briefly but in more detail the basic Hatch-Waxman scheme and describe some of the settlements that have attracted the attention of the FTC and the courts.

³ Recent published decisions include: *Schering-Plough Corp. v. FTC*, No. 04-10688, 2005 WL 528439 (11th Cir. Mar. 8, 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re: Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003); *In re: Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279 (S.D. Fla. 2005) ("*Terazosin I*"); *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517 (D. N.J. 2004); *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp.2d 986 (N.D. Ill. 2003); *In re Tamoxifen Citrate Antitrust Litigation*, 277 F.Supp.2d 121 (E.D. N.Y. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F.Supp.2d 188, 250 (E.D. N.Y. 2003) ("*Cipro I*"); *In re: Terazosin Hydrochloride Antitrust Litigation*, 164 F.Supp.2d 1340 (S.D. Fla. 2000) ("*Terazosin I*"), *rev'd sub nom.*, *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

Continued on next page

- 4 Some recent articles on this issue include: Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004); Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069 (2004); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004); Keith Leffler and Christofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33 (2004); Merrill Hirsh, *Are False Positives Really So Negative? A Response to Kevin McDonald*, ANTITRUST, Summer 2003, at 83; Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68; Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).
- 5 As one scholar recently observed, "Much ink has been spilled on the topic of reverse-payment settlement agreements and their antitrust implications . . . and yet the legality of reverse payments remains very much a live, and hotly contested, issue." Cotter, *Antitrust Implications of Patent Settlements*, 71 ANTITRUST L.J. at 1069-70.
- 6 This should surprise no one. These cases arise at the intersection of intellectual property and antitrust law, as courts and commentators have observed, and what you ask and what answer you find satisfactory depends, in part, on where you are standing. See, e.g., *In the Matter of Schering-Plough Corp., Upsder-Smith Laboratories, Inc., and American Home Products Corp.*, Docket No. 9297, Final Order and Opinion of the Commission (Dec. 8, 2003) ("*Schering-Plough [FTC]*"), *overturned on appeal*, *Schering-Plough v. FTC*, No. 04-106588, 2005 WL 528439 (11th Cir. Mar. 8, 2005), available on the FTC website at <http://www.ftc.gov/os/adiprod/09297/031218finalorder.pdf> and <http://www.ftc.gov/os/adiprod/09297/031218commissionopinion.pdf>, respectively (noting that this "challenging case raises important issues at the intersection of patent law and antitrust law"); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68 (same).
- 7 See, e.g., Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004); McDonald, *Hatch-Waxman Patent Settlements and Antitrust*, ANTITRUST, Spring 2003, at 68.
- 8 See *Schering-Plough Corp. v. FTC*, No. 04-10688, 2005 WL 528439, *17 (11th Cir. Mar. 8, 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 1:00-MDL-1383 (DGT) (E.D. N.Y. Mar. 31, 2005) ("*Cipro III*"). As this article went to press, only the slip opinion was available.
- 9 See *Schering-Plough*, 2005 WL 528439 at *17 (rejecting *per se* treatment of "reverse-payment" Hatch-Waxman settlements "[g]iven the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements"); *Valley Drug*, 344 F.3d at 1309 (reasoning that "[t]o hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally"); *Cipro III*, slip op. at 49 (rejecting "plaintiffs' assertion that [brand-name] Bayer's payment [of \$398 million] to [generic] Barr is anti-competitive because, without it, Bayer and Barr would have agreed on an earlier entry date for Barr or would have otherwise fashioned a more pro-competitive agreement" because it "ignores the fact that, if defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable").
- 10 See Kevin D. McDonald, *Patent Settlements and Payments That Flow The "Wrong" Way: The Early History of a Bad Idea*, ANTITRUST HEALTH CARE CHRONICLE, Winter 2002, at 12 (explaining that "if the settlement precludes no more generic competition than the patent itself, then the *direction* of payment flow tells us nothing about reduced competition"); Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L.J. at 1034 (arguing that "reverse payments are not necessarily anticompetitive" because there are "many circumstance where a reverse payment is necessary to resolve a patent litigation and that resolution is better for consumers than continued litigation").
- 11 See Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L.J. at 1033 (concluding that "there really is no such thing as a 'reverse payment' in the context of a settlement of a patent case . . . [because] it is likely that consideration is moving from the patent holder to the alleged infringer in most settlements of patent disputes," based on the difference between the money payments by the alleged infringer to the patent holder and the value of the patent in the market).
- 12 In *Valley Drug*, the Eleventh Circuit suggested that antitrust liability might attach to a Hatch-Waxman settlement "when the antitrust claimant proves that the patentee knew that the patent was invalid." See *Valley Drug*, 344 F.3d at 1308-09. Liability in that circumstance, the court reasoned, "would not undermine the encouragement of genuine invention and disclosure" in the way the court concluded a *per se* rule would. *Id.*
- 13 See *Schering-Plough*, at 20, citing *Valley Drug*, 344 F.3d at 1312.
- 14 See *In the Matter of Schering-Plough Corp., Upsder-Smith Laboratories, Inc., and American Home Products Corp.*, Docket No. 9297, Final Order and Opinion of the Commission (Dec. 8, 2003) ("*Schering-Plough [FTC]*"), *overturned on appeal*, *Schering-Plough v. FTC*, No. 04-106588, 2005 WL 528439 (11th Cir. Mar. 8, 2005), available on the FTC website at <http://www.ftc.gov/os/adiprod/09297/031218finalorder.pdf> and <http://www.ftc.gov/os/adiprod/09297/031218commissionopinion.pdf>, respectively.
- 15 See, *inter alia*, Keith Leffler and Christofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33 (2004); Merrill Hirsh, *Are False Positives Really So Negative? A Response to Kevin McDonald*, ANTITRUST, Summer 2003, at 83; Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).
- 16 See, e.g., *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 531-532 (D.N.J. 2004) (the question to be resolved is not patent invalidity or infringement, but "whether the settlement agreements . . . constitute anti-competitive conduct").
- 17 See *In re: Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003) ("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").
- 18 See *In re: Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279, 1318-19 (S.D. Fla. 2005) ("*Terazosin II*") (holding that the disputed "appellate-stay provision evidences a 'naked restraint of trade' subject to *per se* treatment"). Although not ruling on Judge Seitz's decision, the Eleventh Circuit noted her application of *per se* analysis and distinguished the agreements in *Valley Drug* on their facts from the agreements at issue in *Schering-Plough*. See *Schering-Plough*, at 19, n.14.
- 19 *Terazosin II*, 352 F.Supp.2d at 1317, emphasis added. (For a discussion of the facts in the *Terazosin* litigation, see Section II.C.2 below.) Earlier in her opinion, Judge Seitz discussed the "guidance" she found in Hovenkamp's three-part analysis of Hatch-Waxman settlements (as well as the "absence of an articulated analytic framework from the Eleventh Circuit"). *Id.* at 1295, citing Hovenkamp, *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. at 1727 (urging courts examining such settlements to determine "(1) that the parties did have a bona fide [intellectual property] dispute; (2) that the settlement is a reasonable accommodation; and (3) that the settlement is

- not more anticompetitive than a likely outcome of the litigation"). Keeping in mind the Eleventh Circuit's *Valley Drug* test and relying on Hovenkamp's analytical approach, Judge Seitz articulated her own three-part test to evaluate whether the Abbott-Geneva agreement "was a reasonable implementation of the exclusionary potential of the '207 patent." *Id.*, citing *Valley Drug*, 344 F.3d at 1312. First, "the exclusionary scope of the '207 patent" must be examined in order to determine "the extent of the protections afforded to Abbott." Second, the court must evaluate "the likely outcomes" of the underlying patent litigation, including the likelihood of Abbott's obtaining injunctive relief barring Geneva from the market pending appeal of the patent validity issue. Lastly, the court must determine whether the settlement represented "a reasonable implementation of the protections afforded by the '207 patent, in light of the applicable law, the then-pending litigation, and the general policy justifications supporting settlements of intellectual property disputes." *Id.* at 1295-96. Although Judge Seitz could not adopt the FTC's and Sixth Circuit's analysis, it seems clear that she was sympathetic to it, relying as she did on Hovenkamp's approach, which closely parallels that analysis.
- ²⁰ See, e.g., Keith Leffler and Christofer Leffler, *In Response to Kevin McDonald: The Probabilistic Nature of Patent Rights*, 17 ANTITRUST, Summer 2003, at 77. Although we clearly differ with Kevin McDonald's approach to Hatch-Waxman settlements, we do not entirely disagree with his critique of the "probabilistic" theory of patent rights. See Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 71 (critiquing the notion of "probabilistic" patent rights as a "semantic game" that could be played to "redefine any other form of property," for example, considering a deed to land as "only a 'right to ask a court to bar trespassers'" or title to a car as "only a right to ask a court for a judgment in conversion").
- ²¹ See *Cardizem CD*, 332 F.3d at 907-908 (noting that pioneer Hoechst Marion Roussel ("HMR") paid generic Andrx almost \$90 million to stay off the market for 11 months and explaining that there was "simply no escaping the conclusion that the Agreement [between pioneer and generic] . . . was, at its core, a horizontal agreement to eliminate competition in the market for [HMR's] Cardizem CD throughout the United States, a classic example of a *per se* illegal restraint of trade"); *Schering-Plough [FTC]*, at 26 (reasoning that "[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").
- ²² We take the point that the term "reverse payments," is viewed by some as loaded. It is, however, less pejorative than other terms, e.g., "exit" or "exclusion payments." More importantly, as explained below, our point is that they do *not* work out the same way as situations in which the alleged infringer pays the patent holder plaintiff, albeit less than what the plaintiff might have hoped to achieve in damages.
- ²³ See, generally, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et. seq.*
- ²⁴ See *Valley Drug*, 344 F.3d at 1296, citing 21 U.S.C. § 355(a); see also *Terazosin II*, 352 F.Supp.2d at 1287.
- ²⁵ See *Terazosin II*, 352 F.Supp.2d at 1287.
- ²⁶ *Id.*, citing 21 U.S.C. § 355; see also *Cipro II*, 261 F.Supp.2d at 191-92.
- ²⁷ Hatch-Waxman also permitted the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was awaiting FDA approval. See *Valley Drug*, 344 F.3d at 1296, citing 35 U.S.C. § 156.
- ²⁸ See *Terazosin II*, 352 F.Supp.2d at 1288; *Cipro II*, 261 F.Supp.2d at 192-93, citing 21 U.S.C. § 355(j)(2)(A)(iv).
- ²⁹ See *Terazosin II*, 352 F.Supp.2d at 1288; *Cipro II*, 261 F.Supp.2d at 192-93, citing 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.94(a)(12)(A)(4). In this article, we refer to an ANDA that is filed with a Paragraph IV certification as an "ANDA IV."

³⁰ See *Terazosin II*, 352 F.Supp.2d at 1288; *Cipro II*, 261 F.Supp.2d at 192-93, citing 21 U.S.C. § 355(j)(2)(B).

³¹ See *Valley Drug*, 344 F.3d at 1297, citing 21 U.S.C. § 355(j)(5)(B)(iii), 21 U.S.C. § 355(j)(5)(B)(iii)(I); see also *Terazosin II*, 352 F.Supp.2d at 1288-89. If, on the other hand, the court finds the patent valid and infringing, the approval date is set for a date on or after the patent's expiration. See *Valley Drug*, 344 F.3d at 1297, citing 21 U.S.C. § 355(j)(5)(B)(iii)(II) and 35 U.S.C. § 271(e)(4)(A).

³² Approval of an ANDA IV is automatically delayed if another ANDA IV was previously filed based on the same brand-name drug. See *Valley Drug*, 344 F.3d at 1297, citing 21 U.S.C. § 355(j)(5)(B)(iv). Prior to January 1, 2004, the effective date of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Reform Act"), the delay lasted until 180 days after the earlier of (1) the first commercial marketing of a generic under the previous ANDA or (2) the date a court hearing the infringement action brought against the previous filer held the patent invalid or unenforced. *Id.* at 1297-98, citing 21 U.S.C. § 355(j)(5)(B)(iv). The Medicare Reform Act makes the 180-day exclusivity period contingent on the first ANDA filer marketing its drug by the earlier of 75 days after FDA approval or 30 months after the date of the ANDA filing. See 21 U.S.C. § 355(j)(5)(D)(i)(I). Accordingly, there is now less incentive for a pioneer to condition settlement with a first ANDA filer on the generic's agreeing not to waive and/or to defend its 180-exclusivity period. On the other hand, there is greater incentive to settle individually and *seriatim* with subsequent generic ANDA filers.

³³ For example, imagine a situation where a clearly invalid or unenforceable patent is used as the excuse for a settlement that bars the generic from entering until the day before the patent would have expired any way; or a license deal made under such onerous royalty terms that it constitutes a ruse to bar competition. Such settlements obviously could benefit the brand company by avoiding competition it would otherwise face, but unless there are special circumstances (such as logrolling in which one company benefits from one deal while another benefits from a second), it is not obvious what the generic company's incentive is to agree to them without money changing hands.

³⁴ In July 2002, the FTC issued a study of Hatch-Waxman patent litigation and settlements from 1992-2002 entitled *Generic Drug Entry Prior to Patent Expiration: An FTC Study* ("2002 FTC Study"). [The 2002 FTC Study may be found on the Commission's website at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.] The study noted the prominence in the Hatch-Waxman process of "blockbuster" drugs, which it defined as drugs that appeared in the top 20 ranked by annual gross sales during one of the years covered in the study. Mentioned by name were such widely-prescribed drugs as Cardizem CD, Cipro, Claritin, Neurontin, Paxil, Pepcid, Prozac, Xanax, Zantac, Zocor, and Zolof. See 2002 FTC Study at ii.

³⁵ Judge Trager concedes in *Cipro III* that "the patents most likely to be the subject of exclusion [or reverse] payments would be precisely those patents that have the most questionable validity," but then discounts this admittedly "well-taken . . . point" by suggesting that the strategy of buying off generic competitors only works for the first competitor but not to ward off subsequent challenges. See *Cipro III*, *slip op.* at 45-46. Judge Trager's confidence seems ill-founded. The published case law and the logic we discuss here suggest that brand-name companies have ample incentive, resources and will to reach reverse-payment with several generics at the same time, particularly when high-margin, blockbuster drugs are at stake and their patent position is suspect. See, e.g., *Schering-Plough*, 2005 WL 528439 at *1-3 (discussing successive settlements reached in 1997 between pioneer Schering-Plough and generic challengers Upsher and ESI); *Valley Drug*, 344 F.3d at 1298-1300 (describing nearly simultaneous settlements between brand-name Abbott and generics Zenith and Geneva).

³⁶ To some extent, brand-name companies can be expected to refrain from wholly-frivolous patent defenses. But they are almost certain to take up the invitation to file lawsuits in the types of cases that give rise to reverse-payment disputes. Few companies can be expected to concede without a fight that their patents on blockbuster drugs afford no protection. And

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Hatch-Waxman provides brand-name companies the powerful incentive of a potential 30-month delay in competition for filing a complaint. The 2002 FTC Study involving all drugs (even those that are not blockbuster) found that brand-name companies sued the first generic applicant 72 percent of the time, i.e. regarding 75 out of 104 possible drugs. See 2002 FTC Study at 14-15.

³⁷ The relative strength of the generics' patent positions and the weakness of the pioneers' is suggested by the fact that generics prevailed in 73 percent of the cases in which a court resolved the patent dispute, while the brand-name companies prevailed 27 percent of the time. *Id.* at 16.

³⁸ See *Schering-Plough*, 2005 WL 528439 at *1.

³⁹ *Id.*

⁴⁰ Most prominently, an Upsher drug called Niacor, a sustained-release niacin product used to reduce cholesterol. *Id.* at *1-2.

⁴¹ In its complaint, the FTC also named ESI Lederle Inc. ("ESI"), a division of American Home Products, another generic manufacturer with which Schering-Plough had settled patent litigation involving K-Dur 20. Before the trial by the ALJ or subsequent proceedings, American Home Products settled with the FTC and was not a party to the petition for review to the Eleventh Circuit. *Id.* at *3, n.9.

⁴² *Id.* at *3.

⁴³ *Id.* at *4.

⁴⁴ On September 29, 2004, the court denied Schering-Plough, Upsher, and ESI's motions to dismiss the complaint and for judgment on the pleadings as to most of the claims, including plaintiffs' federal antitrust claims. See *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 551-552 (D. N.J. 2004).

⁴⁵ See *Valley Drug*, 344 F.3d at 1298. In 1998, according to the FTC, Hytrin generated \$540 million in sales, accounting for more than 20 percent of Abbott's net sales of pharmaceutical products in the United States. See *Terazosin I*, 164 F.Supp.2d at 1343.

⁴⁶ See *Valley Drug*, 344 F.3d at 1298.

⁴⁷ Another company, Zenith Goldline Pharmaceuticals ("Zenith"), filed an ANDA in 1994 for a terazosin hydrochloride drug subject to Abbott's Patent No. 4,215,532 (the "532" patent) and was subsequently involved in litigation with Abbott. In 1998, Abbott reached a settlement agreement with Zenith, under which Zenith agreed not to sell any generic terazosin hydrochloride product unless another generic came into the market first or until the '432 patent expired in 2000. In return, Abbott agreed to pay Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months thereafter until March 1, 2000. *Id.* at 1300 and n.13. After the district court granted partial summary judgment to plaintiffs in *Terazosin I*, Zenith came to a tentative settlement of the antitrust litigation and was not a party to the appeal of that decision to the Eleventh Circuit. *Id.* at 1296, n.1.

⁴⁸ *Id.* at 1299. Abbott's Patent, No. 5,504,207 (the "'207 patent'"), claimed a method of preparing anhydrous terazosin hydrochloride and was due to expire in October 2014. *Id.* at 1299, n.10.

⁴⁹ *Id.* at 1300.

⁵⁰ *Id.* at 1301. Abbott's petition for certiorari was denied in January 2000. However, these events did not terminate Abbott's agreement with Geneva; the companies apparently terminated the agreement in August 1999 on their own in response to an FTC investigation. *Id.*

⁵¹ *Id.* at 1301-02.

⁵² On remand from the *Valley Drug* decision, plaintiffs focused their challenge to the Abbott-Geneva settlement agreement on the prohibition of Geneva's marketing its generic terazosin hydrochloride products until the conclusion of the appeals in the patent infringement litigation. See *Terazosin II*, 352 F.Supp.2d at 1294-95.

⁵³ *Id.* at 1307-10, 1312-15.

⁵⁴ See *Schering-Plough*, 2005 WL 528439 at *6 (explaining that "[i]n the context of patent litigation, . . . the anticompetitive effect [of a pioneer-generic settlement agreement] may be no more broad than the patent's own exclusionary power"); *Valley Drug*, 344 F.3d at 1305 (stating that "[t]o the extent that [the generic drug companies] agreed not to market admittedly infringing products before the [pioneer's] patent expired or was held invalid, the market allocation characterization [by which the district court held the agreement a *per se* antitrust violation] is inappropriate").

⁵⁵ See, e.g., *Schering-Plough*, 2005 WL 528439 at *14.

⁵⁶ See, e.g., Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L. J. at 1061-65.

⁵⁷ *Id.* at 1061-62. Schildkraut poses the hypothetical of two companies which, in the year 2000, negotiate the resolution of a dispute over a patent that expires in 2010. He posits that, if the patentholder has a 50 percent chance of prevailing, the mean expected outcome of litigation is that the alleged infringer will enter the market in 2005. However, a risk-averse patent holder might permit entry in 2004 rather than risking losing more years of exclusivity and then, in exchange for making a reverse payment, might still get to a settlement of entry somewhere between 2004 and 2005 that represents a better result than the one expected in litigation.

⁵⁸ See *Valley Drug*, 344 F.3d at 1308.

⁵⁹ This argument tends to be asserted a fair amount on ABA panels. Schildkraut makes the more sophisticated points that a "cash-strapped" patent infringer or generic may be specially motivated to litigate and to demand reverse payments in patent litigation settlements and that settlement with such a generic "is impossible without a reverse payment." See Schildkraut, *Patent-Splitting Settlements*, 71 ANTITRUST L.J. at 1063.

⁶⁰ See *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (opinion by Seventh Circuit Judge Posner sitting by designation, arguing, in *dicta*, that a prohibition on reverse payments would "reduce the incentive to challenge patents by reducing the challengers' settlement options should he be sued for infringement, so might well be thought anticompetitive").

⁶¹ See *Valley Drug*, 344 F.3d at 1309 (stating that the court "cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements").

⁶² See, e.g., *Asahi*, 289 F.Supp.2d at 992 (cautioning against the inhibiting effect on patent settlements of third parties' "haul[ing] the parties to the settlement over the hot coals of antitrust litigation").

⁶³ Even the Eleventh Circuit acknowledges this point: "It may be that the size of the payment to refrain from competing . . . raises the suspicion that the parties lacked faith in the validity of the patent, particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim . . ." *Valley Drug*, 344 F.3d at 1309-10.

⁶⁴ See *Schering-Plough*, 2005 WL 528439 at *7; *Valley Drug*, 344 F.3d at 1312.

⁶⁵ See *Valley Drug*, 344 F.3d at 1308.

⁶⁶ See *Terazosin II*, 352 F.Supp.2d at 1317. Moreover, Judge Seitz was plainly skeptical that Abbott and Geneva were not well aware of the weakness of Abbott's patent position. *Id.* at 1306 (explaining that the "focus of analysis . . . is not whether the [patent] litigation was frivolous and baseless, but rather on whether, upon Geneva's assertion of 'substantial questions' regarding the validity of the '207 patent, Abbott was able to demonstrate that Geneva's arguments were substantially without merit" and concluding that "Abbott's challenge to Geneva's 'on-sale bar' argument was weak and unlikely to result in a District Court finding that the '207 patent was valid").

⁶⁷ 382 U.S. 172 (1965).

⁶⁸ See *Valley Drug*, 344 F.3d at 1308-09, citing *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 994-96 (9th Cir. 1979); *Locite Corp. v. Ultraseal, Ltd.*,

<http://www.ftc.gov/os/2004/01/040106pharmrules.pdf>. In early 2005, the FTC's Bureau of Competition published a report on the Commission's website summarizing the number and type of agreements received during Fiscal Year 2004, ending September 30, 2004. That report may be found at <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>. The FTC's statistics are concededly limited. The Bureau of Competition indicates that it does not have settlements of litigation that were entered into between June 2002 and January 2004. Nevertheless, its report gives some indication that reverse-payment settlements do not occur all that frequently.

⁷⁵ See *Valley Drug*, 344 F.3d at 1312 (holding that, on remand, provisions of the settlement agreements "found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probably anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act"); *id.* at 1313 (noting that some provisions may be "so obviously anticompetitive that they can be condemned as illegal on the evidence so far adduced . . .").

⁷⁶ This may not always be true. The scope of a patent is itself an issue potentially subject to dispute.

As Judge Seitz commented in *Terazosin II*, "It is well known that 'parties to an intellectual property dispute have a strong incentive to enter into agreements that maximize their own interests but disserve the public's interest with respect to either competition or innovation.'" *Terazosin II*, 352 F.Supp.2d at 1308-09, quoting Hovenkamp, *et. al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. at 1722.

⁷⁸ *Supra*, Section III.

⁷⁹ See *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 19-20 (1979).

⁸⁰ *In re K-Dur Antitrust Litigation*, 338 F.Supp.2d 517, 532 (D. N.J. 2004). This question is also at the heart of the FTC's Final Order and Opinion in *Schering-Plough [FTC]*: "The issue is whether these unconditional payments [by Schering-Plough to Upsher] were likely to have anticompetitive effects because they delayed entry beyond the dates that would have been agreed upon in the absence of the payments." *Schering-Plough [FTC]*, Opinion at 7.

⁸¹ See *Terazosin II*, 352 F.Supp.2d at 1317.

⁸² *Id.*

⁸³ *Id.* at *11 ("To borrow from the Commission's own words, we think its conclusion that Niacor was not worth \$60 million, and that settlement payment was to keep Upsher off the market is 'not supported by law or logic'"); *id.* at *12 ("We think that this record [of the proceedings by the FTC's ALJ] consistently demonstrates the factors that Schering considered, and there is nothing to undermine the clear findings of the ALJ that this evidence was reliable").

⁸⁴ *Id.* at *11.

⁸⁵ *Id.* at *9.

⁸⁶ *Id.* at *16 (quoting *Cipro II*, 261 F.Supp.2d at 251).

⁸⁷ *Id.* at *15.

⁸⁸ See *Cipro II*, 261 F.Supp.2d at 208 ("the new Hatch-Waxman scheme . . . allows a generic manufacturer to seek entry into a market without incurring damages for infringement").

⁸⁹ See *Schering-Plough*, 2005 WL 528439 at *15.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Nor is it entirely fair. As noted in Section II.A.2 above, in *Valley Drug*, the Eleventh Circuit relied on an assumption that preventing reverse-payment settlements would impede research and development. This assumption was no more based in empirical evidence, and probably even more difficult to test, than the FTC's assumption that parties inclined to settle would find a different way to do it. The truth is that all of these discussions – our own included – rely a fair amount on armchair theorizing.

⁹⁴ See *BMI*, 441 U.S. at 19-20.

⁹⁵ See *NCAA v. Board of Regents*, 468 U.S. 85, 100 (1984).

⁹⁶ See *Cardizem CD*, 332 F.3d at 907 (citing *NCAA*, 468 U.S. at 100) ("[h]orizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal per se' approach because the probability that these practices are anticompetitive is so high").

⁹⁷ Actually, Judge Posner considers all rules to be bright-line and the term "per se rule" therefore redundant. See Richard A. Posner, *ANTITRUST LAW* 39 (2d ed. 2001).

⁹⁸ *Id.*

⁹⁹ See *Level 3 Communications, Inc. v. Federal Ins. Co.*, 168 F.3d 956, 958 (7th Cir. 1999) (applying this logic in interpreting an insurance policy). ■