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Xiang Yu* & Anjan Chatterji**

I. INTRODUCTION

¶1 Pay-for-delay settlements, also known as reverse exclusionary settlements, have evoked much debate amongst the legal, economic, and political communities over the last decade. A pay-for-delay settlement arises from a patent infringement action between a brand and a generic pharmaceutical manufacturer where the settlement payment flows from the patentee brand to the alleged infringer generic. When the brand pays off the generic challenger and delays the challenger's launch of a generic product, such a settlement may appear to be collusive market division and may trigger antitrust enforcement actions.

¶2 However, the phenomenon of reverse payments cannot be viewed in isolation. To understand the deeper legal and economic underpinnings of these settlements and associated reverse payments, it is important to place antitrust law in the particular context of the pharmaceutical industry and the Hatch-Waxman Act. To understand the dynamics of reverse payments, it is critical to understand the asymmetric risks the brand and the generic bear in patent litigation. Although a brand heavily relies on its patents to ensure profits and sustain research and development (R&D), the Hatch-Waxman Act makes it particularly susceptible to patent challenges. Therefore, for a brand, to settle with or without reverse payments or to litigate is usually a conscious business decision based on risk management. A brand may choose settlement over litigation even if it has strong reasons to believe the validity of its patent will be upheld by the court.

¶3 In this Article we propose a quantitative settlement model and systematically evaluate the risks of litigation to both the brand and the generic. Evaluation of the economic benefit suggests that both parties usually prefer settlement with reverse payment over litigation. In addition, the model suggests that launch at risk¹ by a generic

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¹ Launch at risk refers to a generic manufacturer's launch of a generic product after the FDA's approval of the Abbreviated New Drug Application (ANDA) but prior to a federal district court's decision on the patent infringement dispute brought by a brand manufacturer against the generic.

is unlikely because the potential damages for which the generic may be liable lower the expected value of economic reward to the generic, a result consistent with general observations. Assessing existing United States courts of appeals cases, this Article also finds that reverse payment is consistent with risk aversion and that no collusion is necessary for a brand to make a rational decision to pay the generic. These results suggest that a clear understanding of the asymmetric risks the brand and the generic bear is important to make a correct judgment on the use of reverse payment and the legality of a pay-for-delay settlement. The results also support a “Rule of Reason”² analysis of antitrust liability because a per se illegal ruling ignores the underlying economic rationales. Since the patentee owns the default property rights, the Rule of Reason test should incorporate the scope of patent protection. Further, because the ultimate goal of antitrust law is to protect consumer welfare, a careful assessment of consumer welfare should be employed as part of the Rule of Reason analysis. The brand patentee, therefore, should be free to settle a dispute on its patent as long as there is no unreasonable impairment of consumer welfare.

II. THE HATCH-WAXMAN ACT AND PAY-FOR-DELAY SETTLEMENTS

A. Generic Challenge Under the Hatch-Waxman Act

¶4 The Drug Price and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, greatly facilitates Food and Drug Administration (FDA) approval for, and the sale of, low-cost generic drugs. The Hatch-Waxman Act only requires a generic manufacturer to demonstrate the “bioequivalence” of its generic product to the “pioneer” or brand drug as opposed to requiring lengthy and costly clinical trials.³ Also, the generic is only required to file an Abbreviated New Drug Application (ANDA) with the FDA instead of a full New Drug Application (NDA).⁴ Further, to encourage generics to enter the market earlier, before the patent on a brand drug expires, the Hatch-Waxman Act provides a strong incentive for generic manufacturers to challenge the brand’s patent validity. The Act offers generics the opportunity to earn a bounty: the first ANDA filer receives the exclusive right to sell the generic version of the brand drug for 180 days.⁵ The value of the bounty can be enormous, perhaps hundreds of millions of U.S. dollars when the brand drug being challenged is a “blockbuster” drug.⁶

¶5 Under the Hatch-Waxman Act, a typical generic challenge works as follows: before the patent on a brand drug expires, the generic files an ANDA and a Paragraph IV certification challenging the validity of the patent or claiming that the patent is not

² Rule of Reason is a doctrine the Supreme Court of the United States developed in its interpretation of the Sherman Act as an alternative to per se violation, which condemns monopoly power as inherently illegal. Chief Justice Edward White developed the Rule of Reason doctrine in his *Standard Oil* opinion and stated that only combinations and contracts that unreasonably restrain trade are subject to antitrust actions. *Standard Oil Co. of New Jersey v. United States*, 221 U.S. 1, 96 (1911).

³ 21 U.S.C. § 355(j)(2)(B)(iv)(I), (j)(8)(C) (2006).

⁴ *Id.*

⁵ *Id.* § 355(j)(5)(B)(iv).

⁶ *See, e.g.*, Pfizer Inc., Annual Report (Form 10-K) 21 (Feb. 26, 2010) (reporting the median revenue for several major Pfizer biopharmaceutical products is \$700 million).

infringed.⁷ The brand has up to forty-five days from the date it receives notice from the ANDA filer to file a patent infringement action.⁸ When the brand files suit, the FDA approval of the ANDA is stayed for thirty months unless the patent is ruled invalid,⁹ and such a stay can extend to several years.¹⁰ In light of the pending patent litigation and the high economic stakes involved, the brand may settle with the generic challenger. Sometimes the settlement provides that the brand makes payments to the generic, the alleged patent infringer, to delay the generic's entry into the market. Such a settlement is often referred to as a pay-for-delay or a reverse exclusionary settlement.

B. *Pay-for-Delay Is a By-product of the Hatch-Waxman Act*

¶6 Pay-for-delay is probably an unintended consequence of the Hatch-Waxman Act. The patent infringement action that results from an ANDA filing is an artificial one.¹¹ The generic is generally exempted from infringing the patented drug in the process of the ANDA preparation.¹² The infringement cause of action is triggered only through the ANDA filing. On one hand, there is a strong economic incentive for the generic to challenge the brand's patent despite a low economic reward even if the challenge is successful. If the generic loses the challenge, it incurs mostly litigation expenses, usually several million dollars worth. A court is likely to award only minimal damages for this patent infringement because there have not yet been any sales of the generic drug. Thus, for a small price, the potential upside for the generic challenger is enormous. This creates an incentive for the generic to adopt a risk-seeking posture and to file challenges to a brand's patent. The brand is often risk-averse and has every desire to settle the uncertainty, even if it has strong defenses for the patent's validity, because it has so much to lose and nothing to gain. If the brand loses, then most, if not all, of its patent-granted monopoly profits are lost. If it prevails, its economic position is essentially the same as it had been before the challenge because the court likely will not award it any damages or royalties. As a result, these lawsuits usually settle, and payments may be involved. Some commentators have argued that the only possible directional flow of the payment in a settlement with such exceedingly asymmetric risks would be the reverse flow—from the brand patent holder to the alleged generic infringer.¹³

⁷ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

⁸ *Id.* § 355(c)(3)(C).

⁹ *Id.* § 355(j)(5)(D)(i)(I)(BB).

¹⁰ *Id.* § 355(j)(5)(F)(ii). See generally C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006).

¹¹ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–78 (1990).

¹² See 35 U.S.C. § 271(e)(1) (“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”).

¹³ See Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 765–76 (2002) (suggesting payment can go either way in a rational settlement depending on economic stakes and negotiating power between the settling parties). But see Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent*

¶7 What appears to be highly controversial is the direction in which the settlement payments flow when those payments flow from the patentee, the brand, to the alleged infringer, the generic. Pay-for-delay settlements have caught the attention of the Federal Trade Commission (FTC) and various consumer advocacy groups. The FTC opposes such settlements as a conspiracy to divide the pie of consumer surplus between the brand and the generic, while consumers lose the benefit of lower price from generic entry.¹⁴ In a recent report, the FTC claimed that on average a generic's entry into the market is delayed for seventeen months due to such settlements and that the consumer loss amounts to \$3.5 billion annually.¹⁵ The FTC has challenged these settlements vigorously because it believes such settlements are collusive, illegal payoffs to prevent generic competition.¹⁶

C. *The Legal Dilemma on Pay-for-Delay Settlements*

¶8 The law on pay-for-delay settlements is far from settled. The FTC challenges pay-for-delay settlements as violations of Section 1 of the Sherman Act on the basis that such settlements constitute horizontal market division and unreasonable restraint of trade.¹⁷ However, the purpose of the settlements is to resolve patent disputes; thus, since patents are legal monopolies, these settlements inevitably support such legal monopolies unless the patents are invalid. The patent system has been adopted to incentivize continuing innovation, and some studies have found that society's return on investment in R&D leading to innovation is significantly larger than the return on investment to the person or organization financing the R&D.¹⁸

¶9 A patent entitles the patentee to a legal monopoly for a limited period of time, a monopoly which is exempt from antitrust law. The patent's validity is dispositive. If the patent is invalid, so are the monopoly and any agreements associated with it. This raises several questions. Is a patent not presumed to be valid unless proven otherwise?¹⁹ Before we impose any antitrust liability, should we first determine whether the patent is valid? When the two parties settle, can we claim *ex ante* that the patent is invalid, and, thus, antitrust law comes into play? When patent law and antitrust law conflict, which

Rights and False Positives, ANTITRUST, SPRING 2003, at 68, 69–70 (asserting that payment flow can only be one-way in the reverse direction because the generic has prospect of free entry while having no exposure to infringement damages).

¹⁴ *Pay To Delay: Are Patent Settlements that Delay Generic Drug Market Entry Anticompetitive?: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 17–18 (2009) (prepared statement of Richard Feinstein, Director, Bureau of Competition, Fed. Trade Comm'n).

¹⁵ FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010) [hereinafter FTC REPORT].

¹⁶ *See id.* at 7.

¹⁷ 15 U.S.C. § 1 (Section 1 of the Sherman Act purports to condemn “[e]very contract, combination . . . , or conspiracy, in restraint of trade.”).

¹⁸ *See* COUNCIL OF ECON. ADVISORS, SUPPORTING RESEARCH AND DEVELOPMENT TO PROMOTE ECONOMIC GROWTH: THE FEDERAL GOVERNMENT'S ROLE 6–7 (1995). Social economic studies have long established that the social rate of return on R&D is twice that of the private rate of return to the inventor. For a list of econometric studies and a summary of their findings, see *id.* at 7 tbl.2.

¹⁹ *See* 35 U.S.C. § 282.

one prevails? Some commentators have argued that patent validity is irrelevant in patent settlements,²⁰ while others insist that it is the most important element of pay-for-delay.²¹

¶10 The answers to these questions are not clear; the courts are split as to which legal standard should apply to pay-for-delay settlements. Rulings have ranged from per se illegal (in the Sixth Circuit)²² to almost per se legal (in the Second Circuit)²³ and have included something in between with a Rule of Reason test (in the Federal and Eleventh Circuits).²⁴ Nonetheless, the case law seems to support that a brand and a generic may choose to make a reasonable, competitive agreement. Even the Sixth Circuit's per se illegal standard should probably be read narrowly, as that case, *Cardizem*, involved an FDA approved ANDA and the retention of the 180-day exclusivity after the settlement.²⁵ Decisions from the other circuits seem to suggest that antitrust law is not undermined as long as the settlement is within the scope of patent protection.²⁶ Those decisions did not discuss whether the patents at issue were valid.²⁷

¶11 The split is not only among United States courts of appeals, but also between antitrust enforcement agencies. While the FTC is seeking per se prohibition of reverse

²⁰ Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 391–95 (2003) (proposing that patent right is “probabilistic” and a patent holder is entitled to the level of protection based on its likelihood to win a patent litigation and extent of exclusion that such a victory would permit); see also Keith Leffler & Cristofer Leffler, *The Probabilistic Nature of Patent Rights: In Response to Kevin McDonald*, 17 ANTITRUST 77 (2003).

²¹ McDonald, *supra* note 133, at 70.

²² *In re Cardizem CD Antitrust Litig. (Cardizem)*, 332 F.3d 896, 907–08 (6th Cir. 2003). The Sixth Circuit held that the agreement for HMR to pay Andrx \$10 million per quarter to refrain Andrx from selling its generic Cardizem after FDA approval is horizontal division of market because Andrx refused to relinquish its 180-day exclusivity. *Id.*

²³ *In re Tamoxifen Citrate Antitrust Litig. (Tamoxifen)*, 466 F.3d 187, 205 (2d Cir. 2006). The Second Circuit held that reverse payments, without more, do not establish a Sherman Act violation and noted that reverse payments are expected within the context of drug patent because the Hatch-Waxman Act created an environment that encourages the payment. *Id.* at 206. In *Tamoxifen*, the district court found Zeneca's patent invalid and the agreement required that Barr obtain a vacatur of the district court's finding. *Id.* at 190. In addition, Barr retained its 180-day exclusivity. *Id.* at 194. In a recent opinion, the Second Circuit upheld the *Tamoxifen* decision as dispositive and rejected a petition for en banc hearing. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 110 (2d Cir.), *reh'g denied*, 625 F.3d 779 (2d Cir. 2010).

²⁴ *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro)*, 544 F.3d 1323, 1332 (Fed. Cir. 2008) (holding that there is no restraint or “bottleneck” for future ANDA filers because the generic manufacturer Barr failed to retain its 180-day exclusivity); *Schering-Plough Corp. v. Fed. Trade Comm'n (Schering-Plough)*, 402 F.3d 1056, 1066 (11th Cir. 2005) (holding that analysis of antitrust liability requires the scope of exclusionary potential of the patent, the extent to which the agreements exceed that scope, and the resulting anticompetitive effects).

²⁵ *Cardizem*, 332 F.3d at 907.

²⁶ See, e.g., *Tamoxifen*, 466 F.3d at 208 (holding in the Second Circuit that the patent holder is entitled to seek a settlement in order to protect its lawful monopoly unless the patent litigation is sham or otherwise baseless,) at 208; *Schering-Plough*, 402 F.3d at 1065–66 (holding in the Eleventh Circuit that patents, by nature, create an environment of exclusion and consequently anticompetitive effect and that the proper analysis of antitrust liability requires a 3-step examination, which includes the scope of patent protection).

²⁷ See, e.g., *Tamoxifen*, 466 F.3d at 200 (holding in the Second Circuit that the antitrust claim brought by the plaintiff does not require the court to examine whether the district court's decision on patent invalidity should be upheld or not, or whether the patent was infringed upon or not); *Cipro*, 544 F.3d at 1336 (holding in the Federal Circuit that the validity of the patent will not be considered in its antitrust analysis in the absence of fraud at the PTO).

payments and has been actively investigating and prosecuting these settlements, the other antitrust enforcement agency, the Department of Justice, takes a different view and supports the Rule of Reason analysis.²⁸ To date, the Supreme Court has not taken a pay-for-delay case.

III. SETTLEMENT VERSUS LITIGATION

A. *The Ongoing Debate*

¶12 A great deal of debate arises from long-standing public policy and judicial preferences for settlement over litigation. In a case in which the plaintiff made an antitrust claim based on a settlement between Glaxo and Pentech regarding infringement of Glaxo's Paxil patent, Judge Richard Posner of the United States Court of Appeal for the Seventh Circuit, sitting by designation in the United States District Court for the Northern District of Illinois, stated that general policy favoring settlement extends to patent infringement suits and that the patentee enjoys the right to either enforce its patent or settle unless the patent is almost certainly invalid or non-infringed.²⁹ The *Cipro* court adopted the same rationale, holding that the Sherman Act does not preclude settling patent claims, even if the settlement may have some adverse effects on competition.³⁰

¶13 Opponents of pay-for-delay settlements equate the "reversed" flow of settlement payments to conspiracy to divide the market.³¹ They also contend that the objective of settlement, which is to save unnecessary litigation costs, has been upset by pay-for-delay settlements because the large payments involved in such settlements far exceed the litigation costs.³² Further, they argue that the savings on litigation costs do not make up the losses to the consumer.³³ Lastly, they argue that industry-specific regulation undercuts patent policy in the context of industry-specific pay-for-delay settlements.³⁴ Because brands already benefit from regulatory protection, any legal tool which artificially stretches that protection should be subject to strict antitrust scrutiny. Thus, opponents of settlements with reverse payments urge that they should be presumed anticompetitive and subject to antitrust scrutiny and that the brand should bear the burden to rebut that presumption.³⁵

¶14 However, as Judge Posner wrote in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, any claim that settlement leads to unnecessary consumer loss must be accompanied

²⁸ Brief for the United States as Amicus Curiae Supporting Respondents, *Fed. Trade Comm'n v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273). The Solicitor General opposed the FTC's petition seeking Supreme Court review of pay-for-delay and expressly disagreed with the FTC's view by filing an amicus brief supporting the Eleventh Circuit decision in *Schering-Plough*. See generally Michael Perry, *Antitrust Liability for Pharmaceutical Patent Settlements After Tamoxifen and Schering-Plough*, 12 STAN. J.L. BUS. & FIN. 166 (2006).

²⁹ *Asahi Glass Co. v. Pentech Pharm.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003). Judge Richard Posner made the statement in dictum.

³⁰ *Cipro*, 544 F.3d at 1333.

³¹ Hemphill, *supra* note 10, at 1557, 1572.

³² *Id.* at 1581.

³³ *Id.* at 1557, 1576.

³⁴ *Id.* at 1561–67.

³⁵ *Id.* at 1561, 1615.

with a strong proposition of patent invalidity.³⁶ The risks associated with litigation in a pay-for-delay settlement, however, may completely outweigh the parties' beliefs in the patent's validity when the two parties make a settlement decision. A settlement with payment flowing in either direction is economically rational as long as the net present value (NPV) of settlement exceeds that of litigation for both parties. This Article systematically examines the economics associated with settlement and litigation and shows that the asymmetric risks the two parties bear determines the direction in which the payment will flow.

B. The Settlement Model

¶15 This Section develops the settlement model for a brand and a generic in a typical Paragraph IV challenge. This Article uses p to denote the ex ante probability that the patent is held invalid in trial, R_g to denote the reward the generic gets when it prevails in trial, and L_b to denote the loss the brand suffers when the patent is held invalid. When the patent is held valid in trial, the generic pays damages D to the brand. In addition, the cost of litigation is C_g for the generic and C_b for the brand. When the two parties settle, the settlement amount is S from brand to generic (if the generic pays the brand, then S has a negative sign). Thus, this Article estimates the costs and rewards for the two parties as shown in Table 1.

TABLE 1. Costs and Rewards for the Generic and the Brand in a Patent Dispute

	COST/REWARD	
	Generic	Brand
Litigation cost	$-C_g$	$-C_b$
Patent valid (probability = $1 - p$)	$-C_g - D$	$-C_b + D$
Patent invalid (probability = p)	$-C_g + R_g$	$-C_b - L_b$
Expected value of litigation	$pR_g - (1 - p)D - C_g$	$-pL_b + (1 - p)D - C_b$
Expected value of settlement	S	$-S$

¶16 For each party, settlement is preferred when expected value of settlement exceeds expected value of litigation. For the generic, this means

$$S > pR_g - (1 - p)D - C_g$$

and for the brand, this means

$$-S > -pL_b + (1 - p)D - C_b, \text{ or } S < pL_b - (1 - p)D + C_b.$$

Therefore, settlement is preferable for both parties when

$$pR_g - (1 - p)D - C_g < S < pL_b - (1 - p)D + C_b.$$

¶17 We denote this range as the zone of reverse payment (ZORP). It should be noted that p denotes the ex ante probability that the patent will be held invalid by a court and that, for simplicity, we use a single p for both the brand and the generic. In reality, the brand and the generic may have different estimates of p . However, the general conclusion still holds that there exists a ZORP in which both parties prefer settlement and the brand would choose to pay the generic to settle.

³⁶ *Asahi Glass Co. v. Pentech Pharm.*, 289 F. Supp. 2d 986, 993 (N.D.Ill. 2003).

¶18 To examine when the payment would have flown the “usual” way, that is, from the generic to the brand, we can check the “tipping point” of the above inequality by setting the settlement amount $S = 0$. Thus, reverse payment is rational for the brand whenever

$$p > \frac{D - C_b}{L_b + D}.$$

¶19 Interestingly, when there are no damages ($D = 0$), the right hand side of the above inequality is negative, and, thus, reverse payment is never irrational for the brand. For the generic, payment to the brand is rational when

$$p < \frac{D + C_g}{R_g + D}.$$

Again, when there are no damages, the generic would choose to pay the brand and settle the case only when $p < \frac{C_g}{R_g}$. Since the cost of litigation is usually in the magnitude of

several million U.S. dollars, while the reward can be hundreds of millions of dollars (unless the probability of prevailing in a trial is close to zero for the generic), the payment is very unlikely to flow the “usual” way, from brand to generic. Even under that circumstance, the generic may still launch the challenge because (1) the ex ante estimate of the probability becomes fuzzy when it is small, and the generic is unlikely to differentiate a one percent probability of success from a five percent probability, the latter of which may make reverse payment rational; and (2) the generic may still bank on the brand’s willingness to pay because the brand’s threshold to make reverse payments is very small.

¶20 The range of ZORP depends on the parameters p , R_g , L_b , D , C_g and C_b , and we can obtain a rough estimate based on commonly available data with a few assumptions. We assume the revenue of the brand drug is R_b , the remaining patent life on the drug is n_p , the revenue grows at rate g during the remaining patent life, and the discount rate is r_b for the brand and r_g for the generic. The NPV of the patent is a reasonable proxy of the brand’s loss L_b :

$$L_b = \frac{R_b}{r_b - g} \left(1 - \left(\frac{1 + g}{1 + r_b} \right)^{n_p} \right).$$

If we further assume the revenue growth rate equals discount rate, or $r_b = g$, then L_b is reduced to $L_b = n_p R_b$.

¶21 We will use this simplified formula of L_b for the discussion that follows. For the generic, the reward can be approximated by the NPV of the revenue stream from the generic product in a commodity market plus the value of the 180-day exclusivity, if there is one. To estimate the former, we assume that in a stabilized market the generic product sells at a discount of d_s (measured as a fraction of the brand price), that the generic penetration is c_s , that there are k generic competitors, and that each one has an equal market share. Thus, we can approximate the NPV of the generic revenue as a perpetuity:

$$NPV_{rev} = \frac{R_b d_s c_s}{k r_g}.$$

¶22

To estimate the latter, we assume that, during the 180-day exclusivity period, the generic product sells at a discount of d_e , the generic penetration is c_e , and the generic expects its launch in t years (the time it takes to win the trial or ANDA approval). Thus, the value of the bounty is

$$NPV_{bty} = \frac{R_b d_e c_e}{2(1+r_g)^t}$$

Therefore, the generic's reward is

$$R_g = \begin{cases} \frac{R_b d_s c_s}{kr_g} + \frac{R_b d_e c_e}{2(1+r_g)^t}, & \text{with 180-day exclusivity} \\ \frac{R_b d_s c_s}{kr_g}, & \text{without 180-day exclusivity} \end{cases}$$

C. A Numeric Example

¶23

Here, we provide a simple numerical example to illustrate ZORP as a function of the ex ante probability p . We assume the revenue of the brand drug $R_b = \$500$ million, the remaining patent life $n_p = 9$ years,³⁷ revenue growth rate $g = r_b = r_g = 7\%$, the damages $D = 0$, and the cost of litigation $C_g = C_b = \$5$ million. In addition, we assume the generic price is 80% lower than the brand product (d_s), generic penetration is 90% (c_s), and there are 5 generic manufacturers in a stabilized market ($k = 5$). During the exclusivity period, the generic price is 25% lower than the brand ($d_e = 75\%$), and generic penetration is 40% ($c_e = 40\%$). Finally, we assume it takes three years before the generic can launch its product ($t = 3$).³⁸ Thus, we have (all numbers are U.S. dollars in millions) $L_b = 4,500$ and $R_g = 318.37$ with the 180-day exclusivity. We demonstrate ZORP as a function of p and S in Figure 1. It can be seen that there is a wide settlement range within which the brand is willing to make a reverse payment to the generic even if the probability of losing its patent in a trial is fairly small. On the other hand, the generic will choose litigation over settlement only if its ex ante probability of prevailing in a trial is very high and the settlement amount is very small. For instance, when the NPV of total reverse payment to a first-filer is \$150 million ($S = 150$),³⁹ ZORP is reached when $3.2\% < p < 47.9\%$. Thus, the brand is willing to pay the generic a significant amount and settle as long as there is a minute chance of losing the patent in a trial, whereas the generic is willing to accept the payment and settle when it does not have strong belief that it will prevail at trial. No collusion or conspiracy is necessary for a pay-for-delay settlement to happen, as both parties are making economically rational decisions. The "tipping point" for a first-filer generic to make a rational decision to settle and pay the

³⁷ The average useful patent life for a brand drug is 11.7 years. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL 30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("THE HATCH-WAXMAN ACT") 33–34 (2005). No ANDA filing will be accepted by the FDA in the first 3 years after NDA approval. *Id.* at 24. So 9 years seem to be a reasonable estimate.

³⁸ The time can be the waiting period for a court decision or the thirty-month stay for ANDA approval.

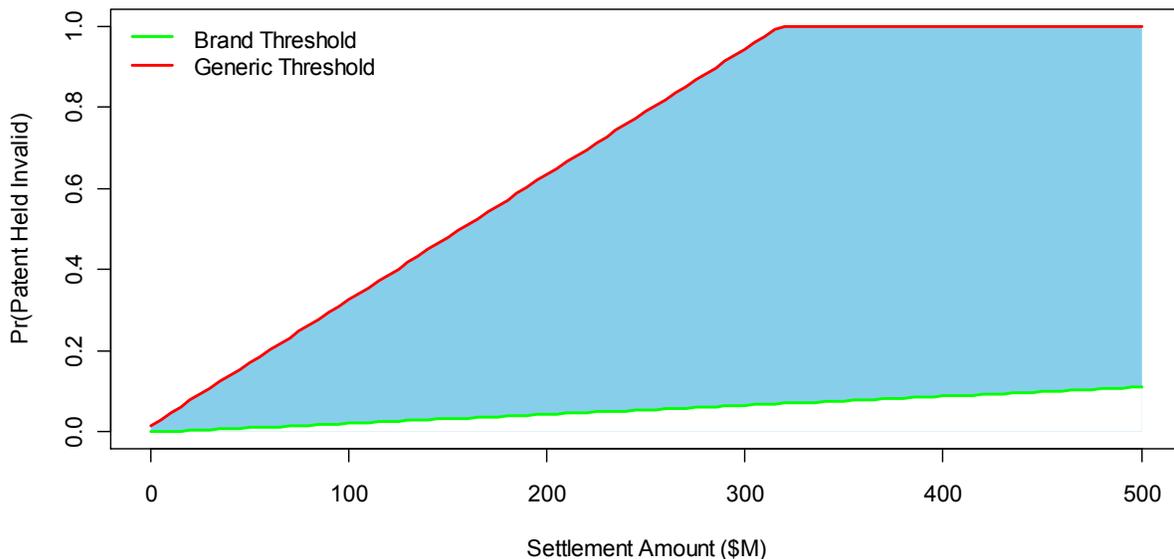
³⁹ This would be equivalent to an annual payment of \$23 million from the brand to the generic for the next nine years of the remaining patent life given the aforementioned discount rate.

brand is attained when $p < 1.6\%$. In this case, the “usual” flow of payment is unlikely to happen.

¶24

In Figure 1, the ZORP strikingly demonstrates how wide the gap is between the brand’s threshold and the generic’s threshold. Even as the amount of the reverse payment increases, a brand may still be reluctant move from settlement to litigation because its probability threshold increases very slowly. The threshold of the generic increases rapidly, however, making it much more willing to choose settlement, since the brand is willing to pay more. Even when the ex ante probability of prevailing in a trial for the generic is high and the model suggests that litigation has a higher expected value, a risk-averse generic may still choose settlement with a reverse payment; that is, a sure gain today is worth more than a larger but uncertain one tomorrow.⁴⁰ The only area in the ZORP that arguably could suggest collusion is where the generic knows ex ante that its probability to win is 100% but still chooses settlement because the brand is willing to pay more than the generic’s reward from litigation. Theoretically, this could happen in the area where the generic’s threshold is flat at 100%, as shown in Figure 1 (note the reason the threshold is flat is because that is capped at 100%, otherwise the calculation would lead to a higher threshold). Such an area, however, is of little practical significance because (1) ex ante, no one can be 100% certain they will prevail in a trial; (2) even if the generic is 100% certain, it is evidentially challenging to prove so; and (3) it is still economically reasonable for the brand to unilaterally decide to make reverse payments because its threshold is so low.

FIGURE 1. Zone of Reverse Payment as a Function of Settlement Amount and Ex Ante Probability of Patent Being Held Invalid



⁴⁰ Such risk aversion behavior has been thoroughly discussed in psychology literature. See, e.g., Daniel Kahneman & Dan Lovallo, *Timid Choices and Bold Forecasts: A Cognitive Perspective on Risk Taking*, 39 MGMT. SCI. 17, 18–19 (1993).

¶25 The green line represents the threshold of the ex ante probability that the patent is held invalid in a trial, above which the brand is willing to settle and make a reverse payment. The red line represents the threshold of the ex ante probability, below which the first-filer generic is willing to settle and accept a reverse payment. The light blue region represents the ZORP, within which both parties prefer settlement and the brand is willing to pay the generic.

D. Launch at Risk

¶26 A generic may launch its generic product while the patent dispute is still pending, a movement called launch at risk. Launch at risk can be examined using our settlement model by setting reasonable damages. When the generic is facing potential damages, the dynamics of settlement could be completely changed. Using the same example as in Section III-C, assume the generic has to pay different amounts of damages if it loses the trial and estimate the same probability thresholds for the brand and the generic, as well as ZORP. Using damage awards of \$50 million, \$150 million, \$250 million, and \$500 million—representing small, moderate, large and exceptional damages, respectively—the model estimates the probability thresholds necessary for the brand and the generic to prefer settlement as a function of settlement amount. The results are shown in Figure 2. Thus, when damages are small or moderate, a large proportion of settlements still occur within the ZORP, meaning a brand is still willing to pay. Only when the generic faces large potential losses with litigation and the brand expects a huge reward from winning the trial would the payment have gone the “usual” way.

¶27 Additionally, there is still a striking gap between the brand’s threshold and the generic’s threshold, regardless of the amount of damages. The generic can easily exploit this gap because the brand is willing to pay to settle when it has a slight chance to lose. Another factor for the generic to consider in a launch at risk is that the brand may be willing to settle, effectively reducing the amount of damages the generic would have to pay if it lost the trial, thereby reducing risks to the generic of launching. In practice, we see relatively few launches at risk, likely due to a narrower ZORP and the existence of a zone of “usual” payment. This is especially so when the potential damages the generic faces are large.

E. Evaluation of Circuit Court Decisions

¶28 This Section evaluates circuit court decisions on pay-for-delay settlements using the settlement model. Table 2 provides a summary of the cases. Table 2 shows information about the settlement amount, revenue of the brand drug, and the remaining patent life of brands, obtained from United States courts of appeals and district court opinions, case briefs, amicus briefs, and other supporting documents pertaining to the cases. All numbers are shown in present value as of the time of settlement (PV) and are rounded to first decimal point. The growth and discount rates used were $g = r_b = r_g = 7\%$. Because none of those cases were launch-at-risk cases, the model assumes there are no damages, or $D = 0$. The litigation costs used were $C_g = C_b = \$5$ million. In addition, sensitivity analysis was performed by varying the discount rate from 5% to 15% and litigation costs from \$2 million to \$10 million, giving results for a range of probability threshold for the brand and the generic. Table 3 shows the results.

¶29 The settlement model suggests that these reverse payments were indeed economically rational decisions. In all United States courts of appeals' decisions, the probability threshold for the brand to make a reverse payment was extremely low, ranging from about one percent for *Cardizem* to slightly over six percent for *Cipro*. Thus, the reverse payments were consistent with a brand's risk aversion. By paying a small premium, the brands avoided the risks of litigation and patent invalidation. Additionally, the sensitivity analysis demonstrates that the range of the brand's threshold was fairly narrow for all cases when different discount rates and litigation costs were used, suggesting that a brand will likely make a calculated decision to pay and settle even after careful risk analysis. The results for the generics were more dispersed and are analyzed on a case-by-case basis.

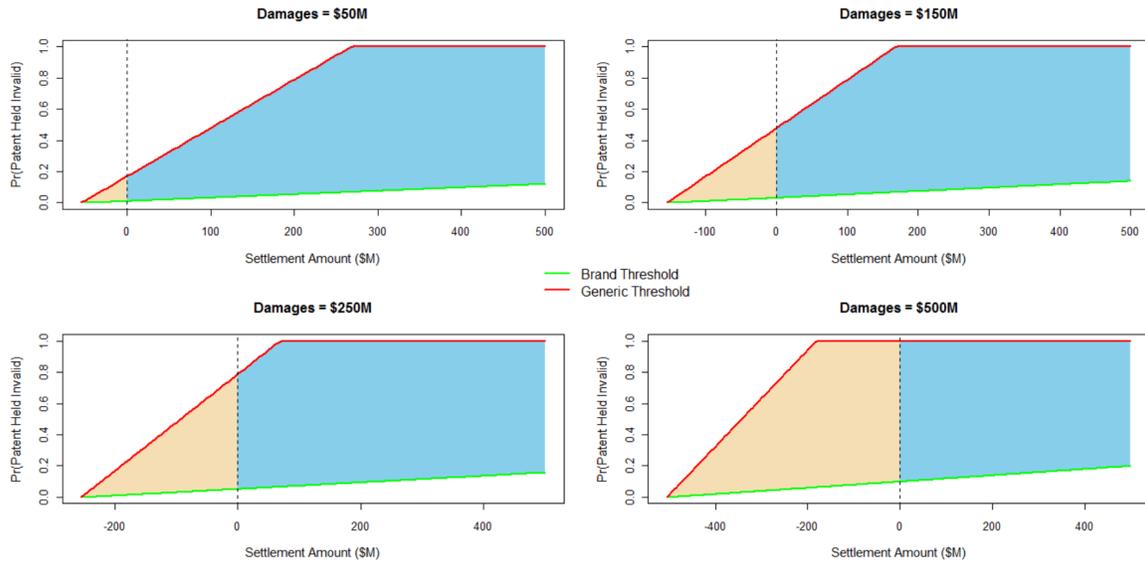
¶30 For *Cipro* and *Schering-Plough*, the generic would need a fairly strong belief in patent invalidity in order to choose litigation over reverse payment. For *Cardizem*, the economically rational decision for the generic would be litigation, as long as the generic has some moderate belief in patent invalidity, that is, a little more than twenty percent. However, several features of this case were notable. First, the payment agreement was contingent on a complicated set of events, each one of which would trigger a stop-payment.⁴¹ Second, the settlement amount of \$89.9 million was just a one-year payment, because Andrx obtained ANDA approval in July 1998 and launched its generic in June 1999.⁴² Thus, the amount of \$89.9 million does not faithfully represent the expected value of payment from HMR to Andrx, although it may serve as a lower bound.

¶31 A better estimate can be obtained by calculating the probability of each event and using the expected value of the total payment conditioned on those events. An upper bound can be roughly estimated by assuming the \$89.9 million continues annually (for 13.4 years) until patent expiration, which leads to a total payment of \$765.6 million (in 1998 present value) and a probability threshold of 9.9% for the HMR and 100% for Barr, respectively. Even considering these factors, it is still reasonable for the brand to pay, because its risk tolerance is sufficiently low and it is always better for the generic to settle. Notably, the sensitivity analysis shows that the generic's probability threshold is highly variable, meaning that a slight change in its assumptions of discount rate and litigation cost would have required a relatively strong belief in patent invalidity, as opposed to a moderate one.

⁴¹ *Cardizem*, 332 F.3d 896 at 902–03, 903 n.3 (6th Cir. 2003).

⁴² *Id.* at 903.

FIGURE 2. Settlement Payment and Threshold for the Brand and the Generic When the Generic Faces Damages



¶32 Again, the green line represents the threshold of the ex ante probability that the patent is held invalid in a trial, above which the brand is willing to settle and make a reverse payment of given settlement amount. The red line represents the threshold of the ex ante probability, below which the first-filer generic is willing to settle and accept a reverse payment. The light apricot region represents the “zone of usual payment,” within which both parties prefer settlement and the generic is willing to pay the brand. The light blue region represents the ZORP, within which both parties prefer settlement and the brand is willing to pay the generic.

¶33 Therefore, a generic may well accept a smaller reverse payment in order to hedge its litigation risk even if the expected payoff from litigation could be higher. For *Tamoxifen*, it may seem that litigation would be a better choice for Barr because it only needed a 37% or greater probability to win in order for the expected value of litigation to exceed the settlement value. However, the sensitivity analysis again revealed a very wide range for the threshold. Further, the settlement amount was relatively small, but, arguably, the non-exclusive license granted to Barr was far more valuable. If we assume Barr gets 25% of Zeneca’s revenue through the license, the total settlement amount would be \$634.5 million, and the probability threshold would be 27.2% for Zeneca and 100% for Barr, points at which it was still not unreasonable for both parties to settle.

¶34 Therefore, reverse payment alone, as demonstrated by the above assessment, is not direct evidence of collusion. In fact, it is not even a strong piece of circumstantial evidence. The reason we observe these reverse payments is that a wide gap exists between the brand’s risk tolerance and the generic’s willingness to litigate, given the economic payoff for each party. A per se prohibition of reverse payment would totally neglect the asymmetric risks the brand and the generic bear, as well as, the economic rationality. Instead, a fair analysis would be to place reverse payment in the context of the entire settlement package and apply a Rule of Reason test. Clearly, most United States courts of appeals follow this rationale, and we believe the Sixth Circuit over-emphasized the reverse payment in its *Cardizem* decision.

F. Cost of Pharmaceutical Patent Litigation

¶35 In addition to the economic rationales examined in our settlement model, a sound public policy should also consider the indirect costs of pharmaceutical patent litigation. Determining whether a patent is valid is costly, particularly in the pharmaceutical industry. Full litigation can take several years. For the brand, there are direct costs associated with litigation, including attorney fees, discovery expenses, and extensive expert testimony; there are also tremendous indirect costs, such as access to trade secrets during discovery and an inability to invest in R&D and marketing due to uncertainty about predicted revenue stream. More importantly, the possibility of losing the protection on a valid patent for a blockbuster drug in a trial, even if minute, looms large for the brand. Embracing that rationale, Daniel Crane argues that an option for settlement is like insurance to encourage innovation. Absent that insurance, risk-averse brand firms will be less likely to commit capital to R&D.⁴³

¶36 Consumers suffer losses as well. The litigation costs incurred by the brand and the generic are ultimately passed on to consumers in some form. The brand may increase price in anticipation of litigation, leading to additional, unnecessary deadweight loss. Furthermore, an economic study on market output upon generic entry that included 101 brand drugs has shown that there is a substantial short-term loss of market output as a result of precipitation of brand marketing.⁴⁴ The short-run decline will create a consumer welfare loss of approximately \$400,000 per month for each drug facing generic entry.⁴⁵ Such a loss cannot be explained by classic price competition theory but is attributed to loss of non-price competition benefits conferred via brand marketing. Those benefits include continuing professional education and patient awareness for under-diagnosed diseases as well as preventative care.⁴⁶ Because the brand cannot economically sustain its marketing activities when its revenue drops eighty percent after generic entry, those benefits are lost, resulting in inefficiency in market output.⁴⁷ It takes several years for the benefits of price-reduction to dominate the negative output caused by inefficiencies in non-price competition.⁴⁸

¶37 Uncertainty about patent litigation can lead to similar inefficiencies, as a brand often suspends certain marketing activities when the case is pending. Allowing the brand to settle will dispel those uncertainties and help restore adequate marketing activities, maximizing non-price competition benefits to consumers. Note that, although the FTC holds the position that consumers suffer a loss up to \$3.5 billion per year due to pay-for-delay settlements,⁴⁹ its estimation method has recently been challenged on legal and

⁴³ See Crane, *supra* note 13, at 762.

⁴⁴ Darius Lakdawalla, Tomas Philipson & Y. Richard Wang, *Intellectual Property and Marketing* 24–28 (AEI Brookings Joint Ctr. for Regulatory Studies, Working Paper No. 07-20, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1089045.

⁴⁵ *Id.* at 2–3.

⁴⁶ In general, marketing to healthcare providers include four major forms: detailing, continuing medical education (CME), samples, and gifting. The last technique has been largely restricted with the Physician Payment Sunshine Act.

⁴⁷ Lakdawalla et al., *supra* note 44, at 24–26. The quantity of total sales for an average drug falls 5% within five months of patent expiration and is attributed to diminishing advertising.

⁴⁸ *Id.* at 2.

⁴⁹ FTC REPORT, *supra* note 155, at 2.

economic grounds.⁵⁰ The short-term loss of consumer welfare due to alleged settlements and resulting delay in generic entry, after appropriate adjustment by several factors, is in fact minimal.⁵¹ Long-term loss is still possible, but, again, can only be substantiated via an antitrust claim when the underlying patent is *ex ante* invalid.

¶38 Finally, social costs of litigation cannot be ignored. Trial is an imperfect tool to resolve patent validity. While litigation may help reduce false positives (invalid patents otherwise thought to be valid), it may also lead to false negatives (valid patents held invalid). Those false negatives are extremely costly for pharmaceutical patents, because of huge R&D spending, leading to undesired deterrence of innovation. The Sixth Circuit has held that the constitutional interest is equally injured when an invalid patent is held valid and a valid patent is held invalid.⁵² Thus, a unilateral requirement to resolve pharmaceutical patent validity through trial may upset the very congressional intent to encourage innovation by granting patents.

G. Antitrust Law and Industry-specific Regulation

¶39 Antitrust analysis of business practices, even if derived from the Hatch-Waxman Act, should be conducted within the well-established antitrust framework. Industry-specific regulation does not by itself impose antitrust liability, although it provides context in evaluating the totality of circumstances. Professor Hemphill has argued that the intent of the bounty is to encourage litigation, rather than settlement; therefore, pay-for-delay settlements should be presumed to be illegal and placed under close scrutiny.⁵³ Our settlement model indicates that congressional intent to strike weak patents⁵⁴ has not been best attained in practice, because the generic is overtly incentivized to challenge every valuable patent due to the low risk and high reward of such a challenge. Thus, a case-by-case analysis of each settlement is fairer to the settling parties than that strong presumption of illegality. In a case study on Glaxo's patented antibiotic Augmentin, which is not subject to the Hatch-Waxman Act, the findings suggested that the bounty is not necessary to induce generics to challenge a brand's patent, but that economic reward is needed.⁵⁵ Other generic launches-at-risk that occur prior to a favorable ruling that a patent is invalid have also been documented and, not surprisingly, they have all been on blockbuster drugs.⁵⁶ Additionally, under the current incentive structure, bounty hunting

⁵⁰ See Anjan Chatterji & Xiang Yu, *Impact of Reverse Exclusionary Settlements on Consumer Welfare: A Law and Economic Analysis*, 23 A.B.A. ANTITRUST HEALTH CARE CHRON., JULY 2010, AT 1, 2—9.

⁵¹ *Id.* at 5.

⁵² *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1373 (6th Cir. 1976).

⁵³ See Hemphill, *supra* note 10, at 1596 (proposing a rebuttable presumption that reverse payment settlements are illegal and allocating to the brand the burden to prove the settlement is not anticompetitive).

⁵⁴ *Pay To Delay: Are Patent Settlements that Delay Generic Drug Market Entry Anticompetitive?: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9 (2009) (prepared statement of Richard Feinstein, Director, Bureau of Competition, Fed. Trade Comm'n).

⁵⁵ Jeremiah Helm, Comment, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. & TECH. L. REV. 175, 191 (2007).

⁵⁶ See, e.g., John Carreyrou & Joann S. Lublin, *Emergency Room: How Bristol-Myers Fumbled Defense of \$4 Billion Drug*, WALL ST. J., Sept. 2, 2006, at A1 (Aptex launched a generic version of Plavix while the district court adjudication of patent infringement was still pending.); Press Release, Barr Pharmaceuticals,

generics are more likely to challenge brand drugs with high revenue (hundreds of millions of dollars or more) rather than those with truly weak patents, even if the probability of success is lower in the former.⁵⁷

¶40

Such a viewpoint is supported by a recent Supreme Court decision *Pacific Bell Telephone Co. v. Linkline Communications Inc.*⁵⁸ In *Linkline*, the Court rejected the argument that industry-specific regulations, mandated by federal agencies, have precedence over the Sherman Act.⁵⁹ Upholding an earlier decision,⁶⁰ the Court reemphasized that industry-related public law does not create antitrust claims that go beyond existing antitrust standards. The Court did not examine the plaintiff's claim against the defendant under the specifics of the Federal Communications Commission (FCC), but under those of the Sherman Act, and found no liability.⁶¹

IV. CONCLUSION

¶41

In conclusion, our settlement model suggests that, for most pay-for-delay settlements, the reverse payment is economically rational for both the brand and the generic. Consistent with observations, our model also predicts that launch at risk is rare because the generic faces potentially large damages. Analysis of United States courts of appeals cases indicates that settlement and reverse payment are consistent with a brand's risk-aversion. Allowing settlement is not inconsistent with the congressional intent embedded in the Hatch-Waxman Act to balance innovation and promotion of consumer welfare through generic entry. Reverse payments should not constitute prima facie evidence of collusion to horizontal market division but should be analyzed in the totality of all circumstances on a case-by-case basis. Ex ante evidence of patent validity should

Inc., Barr Says Court Denies Preliminary Injunction to Halt Generic Allegra(R) Sales (Jan. 27, 2006), <http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=809655> (Barr and Teva marketed a generic version of Allegra before a district court's decision on a patent infringement action brought by Aventis.).

⁵⁷ See, e.g., Pfizer Inc., Annual Report (Form 10-K), *supra* note 6. To obtain a rough estimate in the industry, take the data from the FTC Report. The total revenue for drugs facing Paragraph IV challenge is \$90 billion per year. FTC REPORT, *supra* note 15, at 9. A rough estimate of the number of drugs challenged per year is 107. Chatterji & Yu, *supra* note 5, at 5. Thus, the average revenue for each challenged drug is about \$90 billion divided by 107, which equals \$841 million, meaning that drugs being challenged are blockbuster ones. The above estimate is very rough, and the median should be more meaningful than the mean as the revenue is likely to be skewed by huge blockbusters; at least that estimate, however, gives some idea of what the typical drugs being challenged are.

⁵⁸ Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc., 555 U.S. 438 (2009). In *Linkline*, the plaintiffs alleged that AT&T engaged in an unlawful "price squeeze" act in violation of the antitrust law. *Id.* at 449–50. The Ninth Circuit denied AT&T's motion for judgment on pleading and the Supreme Court reversed. *Id.* at 446–48. The Court reasoned that, because AT&T has no duty to sell its wholesale transport service to competitors under the Sherman Act and such a duty comes from the regulation of the Federal Communications Commission, AT&T has no obligation to provide its rivals a "sufficient" level of service. *Id.* at 450.

⁵⁹ *Id.* at 450.

⁶⁰ Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 410–11 (2004). The Supreme Court held that to state an antitrust claim, one must first allege an antitrust duty under the antitrust law rather than other federal regulations. *Id.*

⁶¹ *Linkline*, 555 U.S. at 451–55.

be carefully considered in order to determine whether consumer welfare is unreasonably impaired beyond the scope of patent protection.

TABLE 2. Summary of Circuit Cases

Case	Circuit	Product	PPIV Certification	Settlement Date	Patent Expiration	Key Settlement Terms	Ruling
<i>Cardizem</i>	6th	Diltiazem hydrochloride CR	Non-infringing	9/24/1997	2/15/2011	HMR pays Andrx \$40M/yr from date of ANDA approval to the earliest of a set of events [†] ; Andrx retains 180-day exclusivity	Illegal
<i>Tamoxifen</i>	2nd	Tamoxifen citrate	Invalid	3/5/1993	8/20/2002	Zeneca pays Barr \$21M and grants a non-exclusive license to Barr; Zeneca pays Heumann \$9.5M and \$35.9M over next 10 years	Legal
<i>Cipro</i>	Federal	Ciprofloxacin hydrochloride	Invalid	1/8/1997	6/9/2004	Bayer pays Barr \$49.1M; Bayer supplies Cipro to Barr or makes quarterly payment to Barr until 12/31/2003 [‡]	Legal
<i>Schering-Plough</i>	11th	Potassium chloride ER	Non-infringing	6/17/1997	9/5/2006	Schering makes no payment to Upsher; Schering acquires Niacor-SR from Upsher [¶] ; Schering pays ESI \$5M	Legal

[†]The set of events include: (1) a final and unappealable order or judgment in the patent infringement case; (2) the earlier date of (a) expiration of required notice period or (b) Andrx starts commercial sale if HMR notifies its intention to license to a third party; and (3) the effective date of license if Andrx exercises its option to obtain a license from HMR. Total payment was \$89.93 million from July 1998 to June 1999.

[‡]Total payment amounts to \$398.1 million, representing 6.5% of Bayer's total revenue (\$6.1 billion) during that period.

[¶]Schering pays (1) \$60 million in initial royalty fees; (2) \$10 million in milestone royalty fees; and (3) ten to fifteen percent royalty on sales.

TABLE 3. Estimates of ZORP for Circuit Cases (all numbers except patent life and probabilities in million dollar settlement year PV)

Case	BRAND					GENERIC			
	Revenue	Patent Life	Loss	Settlement	Probability Threshold (Range)	NPV of Generic Revenue	NPV of Bounty	Total Reward	Probability Threshold (Range)
<i>Cardizem</i>	571.4 ¹	13.4	7,656.9	89.3	1.1% (1.0%, 1.4%)	293.9	70.0	363.8	26.1% (17.8%, 60.2%)
<i>Tamoxifen</i>	257.2 ²	9.4	2,315.2	55.7 ⁶	2.1% (1.8%, 3.6%)	132.3	31.5	163.8	37.1% (23.5%, 99.3%)
<i>Cipro</i>	670.9 ³	7.4	4,696.4 ⁵	306.5 ⁷	6.1% (6.2%, 6.5%)	345.0	82.1	427.2	72.9% (53.9%, 100%)
<i>Schering-Plough</i>	234.3 ⁴	9.2	2,155.4	70.0 ⁸	3.0% (2.6%, 3.9%)	120.5	28.7	149.2	50.3% (33.9%, 100%)

¹Cardizem CD revenue was \$700 million. *Cardizem*, 105 F. Supp. 2d 618, 623 (E.D. Mich. 2000). We assume it to be 2000 revenue.

²Tamoxifen domestic revenue was \$442 million in 2001. *Tamoxifen*, 466 F.3d 187, 193 n.6 (2nd Cir. 2006).

³Derived as annual cash inflow from the total revenue of Cipro during a seven-year period. See *infra* note 5.

⁴K-Dur 20 domestic revenue was \$287 million in 2000. *In re Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, at s*6 (F.T.C. June 27, 2002) 27.

⁵Bayer's total revenue from Cipro was \$6.1 billion during the settlement payment period. We assume equal annual cash inflow and discount to 1997 PV.

⁶Includes \$21 million to Barr, \$9.5 million to Heumann, and ten equal annual payments of \$3.59 million.

⁷Total payments were \$398.1 million. We assume equal annual payment and discount to 1997 PV.

⁸Because there was no payment, we use the \$60 million initial royalty and \$10 million milestone royalties for acquisition of Niacor-SR.