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Bruce R. Genderson

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SETTLEMENTS IN HATCH-WAXMAN ACT PATENT LITIGATION: RESOLVING CONFLICTING INTELLECTUAL PROPERTY AND ANTITRUST CONCERNS

*Bruce R. Genderson**
Williams & Connolly L.L.P
Washington, D.C.

The policies underlying the patent and antitrust laws often are in conflict. Over the years, this conflict has spawned a broad range of litigation. Recently, much of this litigation has involved antitrust challenges to settlements or other agreements in litigation under the Hatch-Waxman Act. This is an area in which the interplay between intellectual property and antitrust laws is particularly complex and the law is still unsettled. This paper will examine recent antitrust cases challenging these agreements and will explore practical considerations for future settlements under the Hatch-Waxman Act.

I. BACKGROUND

A. Antitrust and Patent Laws—Conflicting Policies

The antitrust and patent laws in the United States advance very different public policies. The antitrust laws promote competition in open markets by prohibiting unreasonable restraints of trade. Section One of the Sherman Anti-Trust Act prohibits "[e]very contract, combination . . . or conspiracy, in restraint of trade . . . ." 15 U.S.C. § 1 (1994). Section Two prohibits acts of monopolization and attempted monopolization. Because, as Justice Brandeis recognized, "[e]very agreement concerning trade, every regulation of trade, restrains," only *unreasonable* restraints are prohibited: "The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918); *see Standard Oil Co. v. United States*, 221 U.S. 1, 60 (1911). While some practices, such as agreements to fix prices, allocate markets or rig bids, are so incompatible with competition policy that they are viewed as *per se* illegal, most conduct is subject to the "rule of reason" standard, in which courts "must determine whether the restraints in the agreement are reasonable in light of their actual effects on the market and their pro-competitive justifications." *Clorox Co. v. Sterling Winthrop, Inc.,* 117 F.3d 50, 56 (2d Cir. 1997). In short, the basic goal of antitrust policy is to prevent the use of market power or monopoly power to limit competition to the detriment of consumers.

* The views expressed herein are those of the author and do not necessarily reflect the views of Williams & Connolly LLP or any of its clients.

The patent laws, on the other hand, grant the patent owner the right to exclude others from infringing its patent by making, using or selling the patented invention—in effect granting a limited monopoly.[1] 35 U.S.C. § 271 (1994 & Supp. V 1999). One purpose of the patent statutes is to encourage investment in research and innovation. Absent this right to exclude, others who did not make such investments could copy the invention and thereby appropriate much of its economic value. The patent grant eliminates the deterrent to innovation caused by the potential for such copying and increases the potential value of the invention to the inventor. The patent laws thus foster innovation and investment in the discovery of new technologies; but they do so at the expense of limiting competition within the scope of the patented invention.

Courts sometimes have claimed that there is no real conflict between the policies of the patent and antitrust laws:

> [T]he aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.

Atari Games Corp. v. Nintendo of America, Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990). Likewise, the Department of Justice and Federal Trade Commission have commented that "[t]he intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare." DOJ & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* § 1.0 (April 6, 1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132.

Whatever one thinks of the ability to harmonize these policies in theory, in practice they often come into conflict. Within certain limits, this conflict has been resolved. Thus, it is settled that a restraint that results from a patent, without more, is not a violation of the antitrust laws. *See United States v. Westinghouse Elec. Corp.,* 648 F.2d 642 (9th Cir. 1981); *Intergraph Corp. v. Intel Corp.,* 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("the antitrust laws do not negate the patentee's right to exclude others from patent property"); *Miller Insituform, Inc. v. Insituform of North America, Inc.,* 830 F.2d 606, 608 (6th Cir. 1987) (competition is unaffected by exclusion that derives from a patent). On the other hand, the patent laws do not protect the patent owner from antitrust enforcement against restraints that are outside the scope of the patent grant. Thus, tying, royalty agreements with payments for sales made after the expiration of a patent, and other attempts to extend the right to exclude beyond the scope of the patent generally are prohibited. *See Brulotte v. Thys Co.,* 379 U.S. 29, 32 (1964) (royalty agreement beyond expiration of patent unlawful *per se*). Likewise, a patent may not protect against antitrust liability for enforcement attempts if the patent is acquired through fraud on the PTO, *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), or if objectively baseless sham litigation is filed for the purpose of burdening a rival by virtue of the litigation process itself, rather than its result. *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993).

Among the areas in which no such bright line rules yet exists, however, is the settlement of Hatch-Waxman Act litigation.

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1 The "monopoly" over the patented invention may or may not result in a monopoly in antitrust terms, because the patented product may have to compete with alternative products. Richard A. Posner, *Antitrust Law: An Economic Perspective* 172 n.3 (1976) ("most patents confer too little monopoly power to be a proper subject of antitrust concern.")

B. The Hatch-Waxman Act[2]

Most patent practitioners are familiar with this statute, which was designed to encourage competition between brand-name and generic prescription drug manufacturers. The Act allows generic drug manufactures to obtain FDA approval for a drug by filing an Abbreviated New Drug Application ("ANDA") demonstrating that the product is bioequivalent to a previously approved brand-name or pioneer drug. 21 U.S.C. § 355(j)(2)(A) (1994 & Supp. V 1999) (requiring certification of same "active ingredient"). An ANDA certification allows the generic manufacturer to rely on the data of the brand-named manufacturer submitted in connection with the original New Drug Application ("NDA") to establish safety and effectiveness of the active ingredient, thus saving substantial time and money.

Most importantly for our purposes, the Act allows generic manufacturers to challenge the validity of patents underlying brand-name drugs, which patents would otherwise prevent the generic from marketing its drug, by certifying under "paragraph IV" that the patent is invalid or that the generic product will not infringe the patent. 21 U.S.C. § 355(j).[3] Once the patent holder is given notice of the filing of such an ANDA IV certification, it has 45 days to file suit for patent infringement. The statute treats the filing of the ANDA-IV certification as a technical act of infringement, thereby creating jurisdiction. Under this statutory scheme, a generic manufacturer can challenge a patent the patent holder asserts covers the generic product without risking damages for actual infringement. If suit is filed, the Act imposes an automatic thirty-month stay barring final FDA approval of the generic drug until the suit is resolved or the stay is lifted. The Court in the litigation can shorten or extend the stay.

In addition, the first generic manufacturer to file an ANDA-IV challenging a patent for a specific drug is entitled to a 180-day period of exclusive generic marketing rights during which the FDA cannot approve an ANDA-IV of another generic for the same drug as to the same patent. 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period begins to run from the earlier of the date that the first-filer begins commercial marketing of its drug or the date of a court decision finding that the patent at issue is invalid or not infringed. *Id.*

These economic incentives have resulted in generic manufacturers filing many ANDA-IV certifications, which almost always lead to the filing of a lawsuit by the patent holder.

II. SETTLEMENT OF PATENT CASES

A. Incentives to Settlement Generally

For a variety of reasons, a high percentage of all patent cases are resolved by settlement. The stakes involved in patent litigation outside the Hatch-Waxman context often are too great for either party to risk the uncertainty of a jury verdict. Even in judge trials, the issues often are so complex and the law sufficiently unsettled that the risk of error is great. Indeed, as discussed below, reversal rates in patent cases are extremely high. The defendant who is accused of infringement often risks damages and treble damages in the tens or even hundreds of millions of dollars. The patent holder almost always risks an equally costly finding that its patent is invalid or unenforceable.

2 Codified as the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, amending the Federal Food Drug & Cosmetic Act.

3 With respect to each listed patent, the applicant must either make an ANDA-IV certification or certify that no patent data on the referenced drug was submitted to the FDA (ANDA-I); that the relevant patent has expired (ANDA-II); or that the applicant seeks approval only upon the expiration date of the patent (ANDA-III). 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

Because patent cases generally involve complex technology and difficult legal concepts, there is always be some uncertainty about the outcome. One commentator has noted that "a technology case in the hands of a lay judge or jury" is a "gamble," Seymour E. Hollander, *Why ADR May be Superior in Patent Disputes*, 2 No. 1 Intell. Prop. Strategist, Oct. 1995, at 6, and another that "[t]he chances of prevailing in [patent] litigation rarely exceed seventy percent and for all practical purposes never exceeded eighty or ninety percent. Thus, there are risks involved even in that rare case with great prospects." Steven Z. Szczepanski, *Licensing or Settlement: Deferring the Fight to Another Day,* 15 AIPLA Q.J. 298, 300-01 (1987). And even when we are confident that we will prevail at trial—as most of us litigators generally are—reversal rates reported for the Federal Circuit in patent cases are high. See, e.g., *Cybor Corp. v. FAS Techs., Inc.,* 138 F.3d 1448, 1475 (Fed. Cir. 1998)(Rader, concurring)("The Federal Circuit, according to its own official 1997 statistics, reversed in whole or in part 53% of the cases from district courts"); Donald R. Dunner et al., *A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994*, 5 Fed. Circuit B. J. 151, 154 (1995) (reporting a reversal rate for findings of non-infringement of about 23% and for findings of invalidity of about 39%).

Our legal system generally encourages settlement, *see McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) ("public policy wisely encourages settlements"), as do the Federal Rules of Civil Procedure. *Merak v. Chesny*, 473 U.S. 1, 5 (1985) ("The plain purpose of Rule 68 is to encourage settlement and avoid litigation.") Judges often require mandatory settlement conferences or mediation. Such judicial encouragement of settlement is perhaps even greater in the context of patent litigation: "Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time-consuming." *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976).

Because both parties in a typical patent case are at risk, settlements outside of Hatch-Waxman litigation often involve some combination of a current payment or future royalty payments from the defendant accused of infringement to the patent holder and a full or partial license from the patent holder to the defendant.

B. Settlement of Cases Under the Hatch-Waxman Act

The peculiar nature of Hatch-Waxman litigation creates an even greater incentive for settlement than in the normal patent case. In litigation under the Hatch-Waxman Act, the generic manufacturer has everything to gain while the patent holder has everything to lose. The generic manufacturer risks only its own legal fees and the costs involved in filing its ANDA, because no damages for infringement can be recovered.[4] The patent holder, by contrast, can gain nothing from continuing the litigation and its risk is enormous—the potential loss of its patent exclusivity.

In the context of a brand-name pharmaceutical drug for which the patent holder is earning large profits and already has expended hundreds of millions of dollars in obtaining FDA approval, the value of even a small risk of losing the patent can be millions of dollars. But, unlike the non-Hatch-Waxman patent suit in which settlement payments typically flow from the accused infringer to the patent holder, here a monetary settlement is possible only if payment flows in the opposite direction—from the patent holder to the generic manufacturer. A settlement based on a license from the patent holder to the generic manufacturer will usually cost the patent holder much more than a monetary settlement that gives the generic the same economic value. This is because, depending on its terms, generic

4 A prevailing party may be able to recover legal fees under § 285 in "exceptional cases."

sales resulting from the license will reduce the profit to which the holder of a valid patent is entitled by much more than the generic manufacturer can earn, due to the fact that the generic price—and thus the profit to the generic—is always less than the price charged by the patent holder.[5] Thus, parties to Hatch-Waxman Act litigation almost always have an incentive to settle on monetary terms. And, in fact, many settlements or agreements under the Act have involved large payments from the patent holder to the generic manufacturer. A number of these agreements have resulted in the filing of enforcement actions by the FTC and private antitrust class actions.

III. FTC ENFORCEMENT ACTIONS AND COURT CASES ASSERTING ANTITRUST VIOLATIONS FROM AGREEMENTS REACHED IN ANDA SUITS

A. Terazosin Litigation—Abbott and Geneva

1. FTC Investigation

Abbott Laboratories, Inc. markets Hytrin, the brand name of the drug terazosin hydrochloride, which is used to treat hypertension and related conditions.[6] Geneva Pharmaceuticals, Inc. filed ANDAs requesting approval to market generic versions of terazosin in both tablet and capsule forms, and later amended the ANDAs to include paragraph IV certifications asserting that the generic products would not infringe any valid Abbott patent. Abbott then filed suit, alleging infringement by Geneva's tablet formulation, but (apparently inadvertently) failed to assert infringement by the capsule formulation. After the 45-day statutory period for filing suit expired, Geneva was in position to obtain final FDA approval for the capsule product and it began taking steps to introduce a generic version of terazosin capsules.

The day after obtaining final FDA approval, Geneva and Abbott entered into an agreement with the following terms:

1. Geneva would not market capsules or tablets until the earlier of the resolution of the tablet litigation or the launch of another generic version of terazosin;

2. Geneva would not transfer or waive its right to the 180-day exclusivity period;

3. Abbott would pay Geneva $4.5 million a month during the district court litigation, and if Geneva succeeded on appeal, Abbott would pay an additional amount equal to $4.5 million times the number of months the case was on appeal.

The FTC began an investigation and, allegedly as a result, Abbott and Geneva abandoned the agreement. The district court in the ANDA patent litigation then granted summary judgment in favor of Geneva, holding that the relevant patent was invalid, and the judgment was affirmed. *See Abbott Labs. v. Geneva Pharms., Inc.*, 51 U.S.P.Q.2d 1301 (N.D. Ill. Sept. 1, 1998), *aff'd* 182 F.3d 1315 (Fed. Cir. 1999), *cert. denied*, 528 U.S. 1078 (2000).

5 As the Federal Circuit has observed, for many patented products, "[t]he value of exercising the right to exclude is greater than the value of any economically feasible royalty. [Thus,] the patent owner benefits more by excluding others than by licensing." *King Instruments Corp. v. Perego*, 65 F.3d 941, 951 (Fed. Cir. 1995).

6 The facts relevant to the Terazosin and other litigations described herein are based on the allegations contained in FTC or private class-action complaints and in court opinions. As none of these cases has gone to trial, the actual facts may differ from these allegations.

Abbott and Geneva subsequently entered into Consent Orders with the FTC. *In re Abbott Labs., Inc. & Geneva Pharms., Inc.*, No. 981-0395 (F.T.C. May 26, 2000) (Decision & Order), available at <http://www.ftc.gov/os/2000/03/abbott.do.htm>; *In re Geneva Pharmaceuticals, Inc.*, No. 981-0395 (F.T.C. May 26, 2000) (Decision & Order), available at <http://www.ftc.gov/os/2000/03/generad&o.htm>. The Consent Orders prohibited future agreements containing terms 1 or 2, and Geneva waived its 180-day exclusivity for generic tarazosin tablets. As to the third term, the Order prohibited agreements in which payments are made not to dismiss litigation, but to refrain during litigation from marketing a product, unless, among other things, the parties stipulated to a preliminary injunction with notice to the FTC and an opportunity for the FTC to object.

2. Private Class Action Lawsuit

In addition, private class-action lawsuits were brought against Abbott and Geneva. *In re Terazosin Hydrochloride Antitrust Litig.,* No. 99MDL1317, 2000 WL 33534279 (S.D. Fla. Dec. 13, 2000).[7] In an opinion dated December 13, 2000, the court granted plaintiffs' motion for partial summary judgment, finding that the agreement between Abbott and Geneva constituted a *per se* violation of Section I of the Sherman Act. The court rejected the argument that the agreement allowed Geneva to avoid the substantial risks of marketing its generic product before the litigation was resolved. The court noted that Geneva could have unilaterally refrained from marketing its generic product, so that no agreement was necessary.[8] The court also pointed out that the agreement was not a settlement and did not resolve any of the litigation issues, and that the monthly payments gave Geneva an incentive to drag out the litigation and stay off the market. The court also stressed that Geneva agreed to oppose any attempts by other ANDA applicants to enter the market early. The court appeared to disapprove of the fact that payments flowed from the patent holder to the alleged infringer, viewing the payments as part of an anti-competitive agreement to keep Geneva off the market.

B. Cardizem litigation—HMR and Andrx

1. Facts

Heochst Marion Roussel ("HMR," now a subsidiary of Aventis SA) is the brand-name manufacturer of Cardizem CD, the brand name of a drug whose active ingredient, diltiazem hydrochloride, is used to treat hypertension, angina and for the prevention of heart attacks and strokes. Andrx Pharmaceuticals, Inc. developed a generic version of Cardizem CD and provided samples to HMR in an effort to demonstrate that its formulation did not infringe the HMR formulation patents. Andrx then filed an ANDA-IV for its generic product, claiming non-infringement of HMR's patents, and HMR responded by suing Andrx for infringement. While the litigation was pending, Andrx amended its ANDA to specify a dissolution profile that allegedly was even more clearly distinct from that claimed by the HMR patents. This reformulated version was not subject to the pending lawsuit. Andrx then received tentative approval from the FDA for its first proposed generic version. Because the 30-month automatic stay was set to expire in July 1998, absent court action extending the stay, Andrx would have been free of any FDA restriction to marketing its product at that time. In September 1997, the parties entered into the following agreement:

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7 Also named as a defendant was Zenith Goldline Pharmaceuticals.

8 As discussed above, profits that a generic manufacturer can anticipate from the sale of its product generally are significantly less than the anticipated lost profits to the brand-name manufacturer resulting from the introduction of generic competition. This is because (1) the price for a generic product is less than the brand-name price and (2) the existence of a generic product may require the brand-name manufacturer to reduce the price for the sales it retains. As a result, a generic that markets its product before litigation is resolved risks potential damages in an infringement action that often will far exceed its profits from the generic sales. Indeed, the FDA has recognized that after the expiration of the 30-month litigation stay, generally "a prudent ANDA holder . . . [will] stay off the market until the litigation is resolved, thereby minimizing potential damages." Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,894 (July 10, 1989).

1. Andrx agreed not to sell its generic product until the earlier of the conclusion of the lawsuit, HMR's granting of a license to Andrx pursuant to terms specified in the Agreement, or HMR's agreement to license a third-party;

2. Andrx agreed not to sell *any* generic version of Cardizem CD, including its reformulated version submitted in the supplement to its ANDA that was not subject to the lawsuit, whether or not the product would infringe any HMR patent;

3. Andrx, as the first ANDA-IV filer, agreed not to transfer or relinquish its 180-day exclusivity;

4. HMR agreed to pay Andrx $10 million per quarter from the time it received preliminary FDA approval until the occurrence of an event in 1 above, and if HMR lost the lawsuit, an additional $60 million.

The FTC began an investigation of the agreement while the litigation was still pending. In June 1999, HMR and Andrx terminated their Agreement, settled the patent infringement suit and Andrx began to market the reformulated generic version of Cardizem CD. On March 16, 2000, the FTC filed an administrative complaint alleging that the agreement constituted an unreasonable restraint of trade, monopolization, conspiracy to monopolize and unfair competition. *In re Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Pharmaceuticals, Inc.*, No. 9293 (F.T.C. Mar. 16, 2000), available at <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>. On November 28, 2000 the complaint was withdrawn to consider a proposed consent agreement.

2. Private Class Action Litigation in the Eastern District of Michigan

Private antitrust class actions were then brought against HMR and Andrx. The district court first denied defendants' motion to dismiss, *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2000), and later granted plaintiffs' motion for partial summary judgment, holding that the HMR-Andrx agreement was a *per se* violation of Section I of the Sherman Act. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000). Both decisions were certified for interlocutory appeal on August 15, 2000 and the appeal is currently pending in the Sixth Circuit.

In ruling on the motion to dismiss, the court first rejected defendants' *Noerr-Pennington* defense. The court then rejected the defense that plaintiffs had failed to allege antitrust injury. Plaintiffs' had alleged that but for defendants' anticompetative agreement, a generic version of Cardizem CD would have been marketed by Andrx starting in July 1998 and that plaintiffs therefore would have had the benefit of generic pricing. Because the agreement prevented Andrx from marketing its product, they suffered antitrust injury. Defendants responded that the complaints failed to establish causation because there were two other plausible explanations for why Andrx may have delayed going to the market after July 1998—HMR might have been able to obtain a preliminary injunction preventing the sale or Andrx might have unilaterally refrained from entering the market because of the risk of patent damages. Thus, plaintiffs would have suffered the same injury—delayed entry of generic competition—even without any antitrust violation.

The court rejected this argument. First, it relied on plaintiffs' allegation that Andrx had represented to the court in the underlying patent litigation that it intended to enter the

market once it received final FDA approval. For purposes of a motion to dismiss, the court noted that it must accept as true the allegation that Andrx would have done so.[9] The court further noted that the fact that the parties could have engaged in the same conduct unilaterally without antitrust consequences does not prevent the imposition of liability for collusive conduct.

The next month, the court granted plaintiffs' motion for partial summary judgment, holding that the agreement was a *per se* violation of Section 1 of the Sherman Act. *Cardizem*, 105 F. Supp. 2d at 699. The court concluded that the agreement (a) restrained Andrx from marketing its generic product when FDA approval was obtained, (b) restrained it from marketing other generic versions of Cardizem CD, including non-infringing or potentially non-infringing versions that were not even at issue in the lawsuit, and (3) restrained Andrx from relinquishing its 180-day exclusivity. *Id.* It further found that the payments restrained competition by creating an incentive for Andrx to stay off the market after it received FDA approval and for Andrx to retain its 180-day exclusivity period. *Id.*

The court rejected the argument that the agreement was reasonably ancillary to a pro-competitive purpose and thus must be analyzed under a rule of reason. First, the court found that the agreement did not maintain the status quo because, among other reasons, it barred Andrx's entry into the market for (possibly) non-infringing formulations not at issue in the suit and created an incentive for Andrx to retain its 180-day exclusivity. Presumably, the court believed that the later restraint was intended to discourage other generic challengers. The court also relied on the facts that the agreement did not resolve the pending patent claims and that rather than fostering an expeditious resolution of the infringement suit, the agreement created an incentive for the parties to drag out the litigation. *Id.* at 703-5.

3. Andrx v. Biovail

The HMR-Andrx agreement also was the basis for an antitrust lawsuit between Andrx and another generic manufacturer, Biovail Corporation International. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001). In June 1997, during the pendency of the HMR-Andrx litigation, Biovail filed an ANDA-IV for its generic version of Cardizem CD. HMR declined to sue for infringement and in September 1997 entered into its agreement with Andrx. In early 1998, Andrx filed suit against the FDA and Biovail to enforce its right as the first to file an ANDA to the 180-day exclusivity period and requested an injunction prohibiting the FDA from approving Boivail's ANDA until 180-days after Andrx marketed its generic product. Biovail filed a counterclaim alleging an antitrust violation, which the district court dismissed with prejudice. The D.C. Circuit affirmed the dismissal, but reversed to allow Biovail to replead.

On the issue of causation, the Court disagreed that Biovail's injury was caused by the statutory scheme rather than the HMR-Andrx agreement. *Id.* at 808-9. The Court noted that a jury could reasonably conclude that but for the agreement, Andrx would have entered the market. *Id.* The Court also noted that "[a]lthough it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period." *Id.* at 809. The Court found that by accepting

9 The court's focus on evidence indicating that Andrx did not infringe the HMR patents suggests that the court may have believed that, unlike the normal ANDA case where it is risky to market a generic product while the infringement case is still pending, Andrx did not consider the risk of marketing its product to be significant.

payments from HMR, Andrx received the benefit of the exclusivity period "without starting the clock" and that by agreeing with HMR to share HMR's profits from the sale of Cardizem CD, it was able to exclude other competitors from entering the market. *Id.* at 809-10. The Court also found that the requirement that Andrx continue to pursue its ANDA was anti-competitive. As long as Andrx did so, Biovail could not use 21 C.F.R. § 314.107(c)(3) of the Hatch-Waxman Act to revoke the exclusivity period, and thus the agreement could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions. *Andrx Pharms.* 256 F.3d at 812.

IV. SORTING OUT THE PITFALLS

Several generalizations concerning settlements and litigation agreements under the Hatch-Waxman Act emerge from these cases and from the recent FTC enforcement actions. First, although often unstated, any settlement involving payment from the patent holder to the generic defendant will be carefully scrutinized. As discussed below, however, this factor alone should not be the basis for imposing antitrust liability. Rather, consistent with more traditional antitrust analysis, the courts have focused on certain specific provisions in these agreements in finding a basis for imposing antitrust liability. The issues presented by these cases are highly fact specific, and it is impossible at this early stage in the development of the law to provide clear guidelines about what is permissible. Nonetheless, it is useful to examine specific provisions in a settlement agreement that may give rise to antitrust problems or that may help avoid them. Bear in mind, however, that the outcome of an antitrust challenge often will depend on the totality of the circumstances rather than on any one individual factor.

A. Payments to the Generic Defendant

As discussed in section II.B above, the parties to an infringement suit brought under the Hatch-Waxman Act almost always have an economic incentive to settle with the payment of money flowing from the patent holder to the generic challenger. In many cases, this is the only realistic way for the case to settle.

There are risks involved in even the strongest case (see discussion in section II.A above), and these risks can increase during the course of litigation due to a myriad of factors unrelated to the merits of the case. For example, a key expert may become ill or develop an unforeseen credibility problem that damages the case even though an objective assessment of the merits remains the same. A patent holder whose patent is valid and infringed should be free to settle its case with payments flowing to the generic challenger whenever it perceives that the cost of settling is less than the risk of continuing to litigate. As FTC Commissioner Thomas Leary has noted:

> *If the patent is valid*, the pioneer manufacturer is entitled to its monopoly profit, and a settlement that merely transfers a portion of that profit to a potential generic manufacturer *causes no harm*.[10]

This conclusion follows from the policy of encouraging patent settlements and the fundamental principle that the "heart of [the patentee's] legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) (quotation omitted & alteration in original). For this reason, "the antitrust laws do not negate the patentee's right

10 Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes* (Nov. 3, 2000) (emphases added), available at <http://www.ftc.gov/speeches/leary/learypharma.htm>.

to exclude others from the patent property," *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999).

Thus, where the patent is valid, the patent holder should be free to enter into a settlement agreement without risk of antitrust liability so long as the agreement does not expand its rights beyond the original patent grant. Does this mean that if the patent is later found to be invalid or unenforceable, settlement payments from the patent holder necessarily create antitrust liability? Under proper antitrust analysis, the answer is no. Where the patent holder has a good faith belief that its patent is valid, antitrust liability should not turn on whether it later turns out to have been wrong. As the court recognized in *Duplan Corp. v. Deering Milliken, Inc.,* 540 F.2d 1215, 1217-18 (4th Cir. 1976):

> [I]t is not the mere act of settlement but the intent of the parties in entering into that settlement and their actions pursuant thereto that, in law, constitute [an antitrust] violation. It is . . . the anti-competitive intent or purpose of the parties which is the critical factor.

Thus, it is not an antitrust violation to bring an action to enforce a patent that later is found to be invalid. "A patentee's infringement suit is presumptively in good faith," *Handgards, Inc. v. Ethicon, Inc.,* 601 F.2d 996, 998 (9th Cir. 1979). As Justice Harlan recognized,

> to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble damage suits.

Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 180 (1965) (Harlan, J., concurring); *accord SSP Agric. Equip., Inc. v. Orchard-Rite, Ltd.*, 592 F.2d 1096, 1103-04 (9th Cir. 1979) ("patent fraud is required . . . [to attack] the use of an *invalid* patent to monopolize . . . a segment of the market") (emphasis added). Thus, to prevail in an antitrust claim based on enforcement of an invalid or unenforceable patent, the patentee must have "acted in *bad faith* in enforcing the patent because he *knew* that the patent was invalid." *Argus Chem. Corp. v. Fibre Glass-Evercoat Co.,* 812 F.2d 1381, 1386 (Fed. Cir. 1987) (emphases supplied).

Several arguments have been advanced in support of the contrary view that such settlement payments in and of themselves can create antitrust liability. The most common is that such settlements, particularly with the first generic filer, thwart the pro-competitive purpose of the Hatch-Waxman Act. Only the first filer can benefit from the 180-day exclusivity period, and other generics, therefore, have less incentive to file additional challenges after a settlement. In practice, however, just the opposite is often true. As discussed in section IV.C below, a successful second generic always will be able to go to market, and if the first generic does not maintain its ANDA-IV application, the second generic may be able to do so without waiting 180 days. While the second generic will not have benefit from the exclusivity period, often it will have the benefits of a roadmap created in the first litigation. The availability of pleadings, depositions, document discovery and contentions from the first case can greatly reduce the time and expense for a second generic challenger. As a result, past settlements of ANDA-IV cases have resulted in the filing of additional ANDA-IV certifications.

Equally unpersuasive is the argument that, regardless of the validity of plaintiff's patent, but for the settlement payments, the patent holder would have licensed the generic challenger, thereby creating generic competition. Accordingly, so the argument goes, the payments constitute unreasonable restraints of trade by stifling such competition. But the fact that some believe that consumers would be better off (at least in the short-run) if a patent holder did not exercise its patent rights to exclude other competitors begs the question of whether a monetary settlement agreement is a legitimate exercise of those rights. As shown above, where the patent is valid, or if not, where the patent holder has a good faith belief in the validity of its patent, such payments constitute a reasonable exercise of rights within the scope of the patent grant.

B. Agreement To Make Payments During Pendency of Litigation

According to the courts that analyzed them, neither the Abbott-Geneva agreement nor the HMR-Andrx agreement settled the respective litigations. Rather, both involved payments made to keep the generic challenger from entering the market during the pendency of ongoing litigation. Assuming that those courts were correct (a point currently in contention before the Sixth Circuit in *Cardizem*), the policy of encouraging settlements does not apply with equal force to an agreement that is not, in fact, a settlement. And as the court emphasized in *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000), rather than fostering an expeditious resolution of the infringement suit, such an agreement may create an incentive to drag out the litigation. *Id.* at 703-05. Thus, settlement payments from the patent holder to the generic challenger are much more likely to avoid antitrust problems in the context of a complete litigation settlement.

C. Requirement that Generic Challenger Maintain ANDA-IV

An important factor in most of the court decisions discussed above is that the agreements required the generic challenger to maintain their 180-day exclusivity period and/or to oppose attempts by other applicants to enter the market. In each of the cases, the generic challenger was the first to file an ANDA-IV certification. As discussed above, the statute entitles the first filer with respect to a specific drug an exclusive 180-day period during which the FDA cannot approve an ANDA-IV of another generic manufacturer to market the same drug. 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period for the first ANDA-IV filer begins to run from the earlier of the date it begins commercial marketing of its drug or the date of a court decision finding that the patent at issue is invalid or not infringed. *Id.* The court in *Andrx v. Biovail Corp. Int'l,* was bothered by the parties' agreement not to pull the first of those exclusivity triggers: "Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period." 256 F.3d at 809. Whether the ability of other applicants to obtain a court decision against the patent rendered any such "delay" academic was not addressed by the *Biovail* court.

An additional concern expressed by some commentators is that an agreement that the generic challenger will stay off the market while retaining its 180-day exclusivity will prevent another generic from entering the market before the patent expires. *See, e.g,* David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L.J. 321, 331 (2000). This concern is overstated. If a second generic manufacturer files an ANDA-IV and successfully challenges the validity of the patent, the exclusivity period would, at the latest, begin to run from the court decision in favor of the second generic, and all other

generic manufactures that filed ANDAs (whether or not an ANDA-IV) could enter the market at the expiration of the exclusivity period. *See Teva Pharms., USA, Inc. v. U.S. FDA,* 182 F.3d 1003, 1004 (D.C. Cir. 1999). It is true that the possession of the exclusivity period by the first filer creates some practical disincentive for other generic manufacturers to file ANDA-IV patent challenges, because of the risk that even if successful, they will have to wait an additional 180-days to enter the market, but that is a choice made by the statute, not the settlements in question. In any event, the empirical experience suggests that many generic manufacturers are not deterred by prior ANDA-IV filings.

In light of these cases, parties to future settlements under the Hatch-Waxman Act should avoid any agreements that require the first ANDA-IV filer to maintain its ANDA or to challenge other generics. Because antitrust plaintiffs may still argue that even without such a requirement, the settlement creates an economic incentive to do the same thing anyway, the parties should also consider taking the additional step of agreeing that the first filer *must* amend its ANDA-IV certification to an ANDA-III (approval only upon the expiration of the patent), in effect abandoning the ANDA-IV certification altogether. This pro-competitive step would minimize as much as possible, and perhaps eliminate, any deterrent effect of the first filed ANDA-IV on other generic filers.[11]

D. Agreement to Keep Non-infringing Products Off the Market

In the HMR-Andrx litigation, the court relied heavily on the fact that the agreement kept what appeared to be non-infringing products off the market. It is settled that restraints outside the limits of the patent rights granted by a patent are not protected from the antitrust laws. A contrary rule would allow "the patent owner, under the guise of his patent monopoly, not merely to secure a reward for his invention but to secure protection from competition which the patent law, unaided by restrictive agreements, does not afford." *United States v. Masonite Corp.*, 316 U.S. 265 278-79 (1942). Thus, for example, a royalty agreement with payments for sales extending beyond the expiration date of the patent is unlawful *per se. Brulotte v. Thys Co.*, 379 U.S. 29, 32 (1964).

An agreement to keep off the market products that the parties know do not infringe the patent in suit clearly is not protected by the patent grant. The difficulty is that in some cases, particularly those involving formulation patents as in the HMR-Andrx litigation, it may be uncertain whether infringement exists. One of the benefits of a settlement is the certainty it provides to the parties. For the same reasons discussed in section IV.C above, the parties should be protected from antitrust liability if they believe in good faith that the products subject to the agreement were within the scope of the patent grant. On the other hand, the antitrust laws clearly prohibit the parties from intentionally extending the patent monopoly to cover products that they do not believe infringe (and in fact do not infringe) the patent in suit, as the court suggested was the case with the HMR-Andrx agreement.

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11 The rules governing the exclusivity period in the context of multiple ANDA-IV challenges are in flux and have been the subject of much litigation. FDA regulations provide that "[o]nce an amendment or letter for the change [from ANDA-IV to ANDA- III] has been submitted, the application will no longer be considered to be one containing a certification under paragraph (a)(12)(i)(A)(4) of this section." 21 C.F.R. § 314.94(a)(12)(viii)(A) (2001). The meaning of this regulation has been hotly disputed, but an amendment from ANDA-IV to ANDA-III may render the first-filer ineligible for exclusivity. When the FDA determined that an amendment to an ANDA-III did *not* deprive the first-filer of exclusivity, its decision was held to be contrary to the statute. *Mylan Pharm. Inc. v. Henney*, 94 F. Supp. 2d 36, 42 (D.D.C. 2000), *appeal pending sub nom.*, *Pharmachemie B.V. v. Henney*, Nos. 00-5204, 00-5205, 00-5206 and 00-5207 (D.C. Cir.).
In 1999, the FDA proposed new regulations providing that, if the first-filer withdraws or changes its ANDA-IV status, *no party* will have the 180-day exclusivity period. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,875 (Aug. 6, 1999) (explaining proposed amendment to 21 C.F.R. § 314.107: "If the first applicant subsequently withdraws its application or changes or withdraws its [P]aragraph IV certification, either voluntarily or as a result of a settlement or defeat in patent litigation, no ANDA applicant will be eligible for 180-day exclusivity"). If adopted, this would mean that once the first ANDA-IV filer withdrew its certification, subsequent filers would be able to immediately market their product upon successfully invalidating or proving non-infringement of the patent of the brand-name manufacturer.

E. Products That Were Not at Issue in the Suit

Both the Abbott-Geneva and the HMR-Andrx agreements had the effect of keeping off the market products that were not subject to suit. In the Abbott-Geneva case, because Abbott inadvertently had failed to sue on the capsule formulation, Geneva was free to market that product and had evidenced an intent to do so. In HMR-Andrx, Andrx had reformulated its generic product, and the reformulation was not part of the suit. The court in both cases relied on this as one of several factors that resulted in a finding of an unreasonable restraint of trade. While it may be difficult to isolate this single factor in the context of either of those cases, as a general matter, whether the antitrust laws prohibit a settlement agreement from including a product that infringes the plaintiffs' patent (see discussion in section IV.D above) should not turn on whether the product is subject to the suit. For example, the fact that Andrx was free under the FDA regulations to market its capsules because no stay was in place covering that product does not mean that the product was not part of the controversy. Abbott had the right to sue Geneva for infringement once it began its marketing efforts, and the policy of encouraging settlements apply with equal force before and after a lawsuit occurs. Likewise, antitrust liability in the HMR-Andrx case should not depend on the technicality of whether HMR first amended its complaint to include the new formulation before entering into the settlement.

F. Other Terms To Avoid Antitrust Liability

In addition to the factors that were identified in the cases discussed above, parties contemplating settlement of Hatch-Waxman Act patent litigation should consider other terms in their agreement or other actions that might help protect their agreement from antitrust attack.

1. Entry of Judgment of Validity and Infringement

Given the relevance of the patent's validity (see discusssion in section IV.A above) and of infringement by the generic challenger (see discussion in section IV.D above), it may be helpful in establishing that a settlement does not violate the antitrust laws to obtain a consent order entering judgement of validity and infringement in favor of the patent holder.

Because of the current hostility to settlements of ANDA-IV patent cases, litigant's should also consider whether to request court approval of the settlement agreement itself.

2. Including Licensing Terms

It may well be easier to defend a settlement if the generic challenger is provided with some meaningful license that commences before the patent expiration, even if only shortly before. Through limitations on territory and commencement date and by setting an appropriate royalty rate, it may be possible to limit the economic impact of the license while still creating a significant competitive benefit.

3. Reexamination

Where some or all of the issues raised in the settled litigation are properly subject to reexamination before the PTO, the patent holder should consider filing for reexamination on the basis of the issues raised in the litigation. A successful reexamination based on the same evidence and arguments used by the generic challenger should strengthen greatly the patent holder's antitrust position. First, it serves as compelling evidence of validity. See discussion in section IV.A above. It also constitutes powerful evidence of the patent holder's

good faith belief in the validity of its patent and that the settlement was entered into simply to avoid litigation risk. Finally, by placing the generic challenger's arguments and evidence before the PTO and thereby making these materials publicly available, it eliminates the argument that the purpose of the settlement was to hide evidence or to make it more difficult for another generic company to challenge the patent.

V. CONCLUSION

While some components of the Hatch-Waxman litigation settlements discussed above do raise legitimate antitrust concerns, underlying much of the criticism of these settlements is the often unstated view that the public interest is almost *never* served by such settlements. But private parties to litigation are entitled to act in their own self-interest. Where the patent holder has a valid patent or has a good faith belief that the patent is valid, it should be allowed to eliminate the risk inherent in any litigation by settling the case, even if the settlement involves a payment to the generic challenger.