Pharmaceutical Patent Settlements: The Antitrust Risks

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"The [Hatch-Waxman Act] has been turned on its head. We were trying to encourage more generics and through different business arrangements, the reverse has happened."[1]

— Congressman Henry A. Waxman

"The central message of the Sherman Act is that a business entity must find new customers and higher profits through internal expansion—that is, by competing successfully rather than by arranging treaties with its competitors."[2]

— Justice Potter Stewart

I. INTRODUCTION

This article addresses the topic of settlements between innovator and generic firms and when they may pose antitrust risks. These agreements have received considerable attention in the media because of their substantial impact on consumers.[3] It begins by describing the important role of antitrust enforcement in pharmaceutical markets and, in particular, reviews recent important enforcement actions taken by the Antitrust Division of the Department of Justice (DOJ) and the Federal Trade Commission (FTC). It then addresses the significance of competition in pharmaceutical markets and the important role of the Hatch-Waxman Act.[4] It continues by discussing why patent settlements as a general matter may raise competitive concerns. These concerns are often greater in the pharmaceutical context because the first generic to challenge a patent often has an exclusive right to market the drug for a 180-day period. The FTC recently brought a case in which the incumbent brand name drug manufacturer essentially paid a potential generic entrant, with generic exclusivity, to stay out of the market pending resolution of a patent infringement action. The case against Abbott Laboratories and Geneva Pharmaceuticals, Inc., was settled with a consent agreement.[5] The article closes with a discussion of the Food and Drug Administration's (FDA's) proposed rule on generic exclusivity and comments by the FTC staff on the proposal.

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[1] Congressman Henry A. Waxman, quoted in Sheryl Stolberg & Jeff Gerth, *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A-1.

[2] United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 116 (1975).

[3] Stolberg & Gerth, *supra* note 1; David Pilling & Richard Wolfe, *Drug Abuses*, FIN. TIMES, Apr. 20, 2000; Dan Goldblatt, *Generic Drug Firms Protect Their Turf*, N.J. BUS. J., Apr. 18, 2000 (quoting Hemant K. Shah, "It's very clear that when [drug companies] are able to delay generic competition, the rewards can be enormous for both. If the prices don't drop the company can afford to give part of their profits to generic companies.").

[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. §§ 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

[5] Abbott Lab., FTC File No. 981-0395 (consent agreement accepted for public comment, Mar. 16, 2000); Geneva Pharms., Inc., FTC File No. 981-0395 (consent agreement accepted for public comment, Mar. 16, 2000). These types of agreements also have resulted in private litigation. *See* Biovail Corp. Int'l v. Hoechst Marion Roussel N. Am., Inc., 49 F. Supp. 2d 750 (D.N.J. 1999) ("A reasonable trier of fact could conclude that an agreement between two competitors to delay the applicability of an exclusivity period for the purpose of keeping another competitor out of the market is an unreasonable restraint of trade or willful attempt to maintain a monopoly."). *See*

continued

II. ANTITRUST ENFORCEMENT IN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is increasingly the subject of antitrust enforcement. In some respects, that should not be surprising. Pharmaceutical costs make up an ever-growing portion of the country's healthcare expenditures. According to the Health Care Financing Administration, prescription drug spending is rising at a rate of twelve percent annually, more than double the rise in U.S. healthcare expenditures overall.[6] FTC's Bureau of Competition receives more complaints from consumers about rising drug costs than about any other single issue.

Pharmaceutical markets are evolving rapidly, often in response to the growth in managed care. A significant merger wave continues, in response to many factors, including the increased number of patents that will expire in the next few years, increased costs of research and development, and the drive for efficiency, caused, in part, by the globalization of markets. Antitrust enforcement plays a critical role in ensuring that consumers receive the rewards of competition as these markets evolve, rather than becoming the victims of growing market power in manufacturing or distribution.

Without vigorous antitrust enforcement, competitors may heed the lure of collusion with their rivals as a means of release from the stressful life of competition. Potential colluders should be aware that the penalties can be severe when taking the cartel "off-ramp" from the competition highway. Perhaps the most dramatic illustration of this is the series of criminal actions brought by the DOJ within the last year, charging seven companies and seven individuals with raising and fixing prices, and allocating market shares for various vitamin products.[7] The companies charged included Hoffmann-La Roche Inc., BASF AG, Takeda Chemical, Eisai Company, Daiichi Pharmaceutical, Chinook Group, and Lonza AG. As of the end of September 1999, the companies had been sentenced to pay, or agreed to pay, a total of almost $880 million in criminal fines.[8] The $500 million fine for Hoffmann-La Roche was the largest in the history of federal criminal enforcement.[9]

As an aside, it should be noted that within DOJ jurisdiction—not that of the FTC—antitrust violations that show the requisite clarity of intent and result can end in extremely serious criminal liability, even including jail terms for individuals. This sort of liability generally arises from price fixing among competitors, and it is something firms must keep in mind when the temptation arises to make the markets in which they compete more "orderly." Moreover, the headaches of the vitamin conspirators did not cease at the door of the DOJ. The antitrust laws provide for treble damages, which means that for every dollar the cartel secured from consumers, it can face the prospect of repaying three times that amount to the injured purchasers.[10]

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also In re Cardizem CD Antitrust Litig., Civ. No. 99-md-1278 (E.D. Mich. June 6, 2000); Zeneca Ltd. v. Pharmachemie, B.V., Civ. No. 96-12413-RCL, 1999 U.S. Dist. LEXIS 2951 (D. Mass. Feb. 25, 1999); Aetna U.S. Healthcare, Inc. v. Hoechst AG, 54 F. Supp. 2d 1042 (D. Kan. 1999). Another recent FTC enforcement action, In re Hoechst Marion Roussel, Inc., Docket No. 9293 (Mar. 16, 2000), is not addressed in this paper.

[6] Rose Darby, *On a Roll! Baby Boomers, Advertising and Science Fuel a Pharmaceuticals Boom, but for How Long?*, INVESTMENT DEALERS DIG., Nov. 8, 1999.

[7] Former Foreign Executives of Leading European Vitamin Firms Agree to Plead Guilty to Participating in International Vitamin Cartel, DOJ Press Release No. 00-179 (Apr. 6, 2000), *available in* (last visited Aug. 11, 2000) <www.usdoj.gov/atr>.

[8] Gary Spratling, Remarks at the Seventh National Conference on Foreign Competition Practices (Dec. 9, 1999).

[9] *Id.*

[10] Clayton Act § 4, 15 U.S.C. § 15 (1996).

At the FTC, most enforcement actions concern mergers, either involving pharmaceuticals or medical devices. In the past five years alone, the Commission has brought over fifteen merger enforcement actions in these industries.[11] Many of these cases involve concerns over the potential loss of innovation, where both merger partners are developing similar products or one is developing a product that may compete against an established product of the other. In other cases, the FTC has challenged the acquisition of generic firms by innovator firms.

Outside the merger field, anticompetitive conduct such as collusion, monopolization, or unlawful restraints also is the subject of FTC enforcement. For example, in December 1998, after an investigation prompted by some extraordinary price increases for certain generic prescription drugs—on the order of 2,000 to 3,000 percent within a few months—the Commission filed an action in the U.S. District Court for the District of Columbia seeking injunctive and monetary relief against Mylan Laboratories, the nation's second largest generic pharmaceutical manufacturer; Profarmaco, S.r.l., an Italian firm that produces the essential active pharmaceutical ingredients (APIs) for the prescription drugs Lorazepam and Clorazepate; Cambrex Corporation, Profarmaco's parent; and Gyma Laboratories of America, Inc., Profarmaco's U.S. distributor.[12] The complaint alleges that these four firms conspired to raise prices by entering into exclusive license agreements for these APIs.[13] Lorazepam and Clorazepate, generic anti-anxiety drugs, are used by millions of Americans. The complaint alleges that the exclusive license agreements denied Mylan's competitors access to the main source of the APIs necessary to manufacture these drugs.[14] The Commission asked the court to compel Mylan and the other defendants to rescind their illegal agreements, and also sought "disgorgement and restitution in an amount exceeding $120 million plus interest, as the Court finds necessary to redress and prevent recurrence" of the violations alleged.[15] On July 7, 1999, in a key ruling, the district court upheld the Commission's authority to seek disgorgement in a case such as this one.[16]

The FTC plays more than a law enforcement role. It frequently acts as an advocate for competition in specific industries, filing comments before state legislatures and regulatory bodies about proposed legislation or regulation and how those proposals can best be adapted to permit competition to flourish. For example, the FTC played a critical role in the early 1980s, advocating before state legislatures for the elimination of generic antisubstitution laws.[17] Later, this article describes another example—FTC's recent comments before FDA on generic exclusivity.

The FTC also provides important studies on various industries, particularly those undergoing critical economic change. In March 1999, the FTC's Bureau of Economics issued a study on the pharmaceutical industry.[18] This study, based in part on the FTC's numerous law enforcement investigations, provided an overview of the forces

[11] For a comprehensive description of these cases, see David A. Balto & James Mongoven, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, 54 FOOD & DRUG L.J. 255 (1999).

[12] FTC v. Mylan Lab., Inc., CV-98-3115 (D.D.C. filed Dec. 22, 1998; amended complaint filed Feb. 8, 1999).

[13] *Id.* ¶¶ 27-29.

[14] *Id.* ¶¶ 21, 25.

[15] *Id.* ¶ 4.

[16] FTC v. Mylan Lab., Inc., 62 F. Supp. 2d 25 (D.D.C. 1999). It has been reported that this case was recently settled. *See* Stephen Labaton, *Generic Drug Maker Agrees to Settle Price Fixing Case*, N.Y. TIMES, July 13, 2000, at A-1 (reporting that Mylan agreed to settle the FTC lawsuit with a payment of $100 million).

[17] *See* ALISON MASSON & ROBERT STEINER, FTC, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES (1985).

[18] FTC, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE (1999) *available in* (last visited Mar. 1999) <www.ftc.gov/be/ecorrpt.htm> [hereinafter FTC STAFF REPORT].

that are changing the industry.[19] It also discussed a variety of industry practices that may raise competitive concerns, including price discrimination, bundling, volume rebates, and various types of mergers.[20]

III. THE BENEFITS OF THE HATCH-WAXMAN ACT

To understand the context of settlements between brand name and generic firms, one must begin with a discussion of the Hatch-Waxman Act, which Senator Orrin Hatch (R-UT) once called "the most important consumer bill of the decade." Many commentators have written about the impact of the Act from the perspective of innovator or generic firms. Antitrust enforcement agencies have a different perspective: that of consumers. For consumers, the Act has had an important impact on the delivery of safe, effective, and lower-priced drugs. As expressed by Alfred Engelberg, a scholar and private attorney who specializes in the representation of generic manufacturers and was involved in the negotiations that led to the Act's passage, the Act was "an unprecedented attempt to achieve two seemingly contradictory objectives, namely, 1) to make lower-costing generic copies of approved drugs more widely available and 2) to assure that there were adequate incentives to invest in the development of new drugs"[21] by extending the term of the innovator's patent-protected exclusivity.

Both of these objectives seem to have been fulfilled to a significant degree. To deal with the most fundamental point first, the added protections and exclusivity term for innovator firms have accompanied a tremendous increase both in the investment in, and the success of, pharmaceutical innovation. The United States is the leader in pharmaceutical innovation, due in large part to the protections afforded by our intellectual property laws and the spur to compete protected by our competition laws.

Recently, some industry observers have noted that the threat of generic entry upon patent expiration—a particularly straightforward avenue for competition—has been a great stimulant for innovation.[22] In response to generic competition with their older drugs, innovator companies research, develop, and market increasing numbers of new, improved drugs. Such additions to the marketplace may satisfy previously unmet medical needs, break new therapeutic ground, or compete with older drugs.

Some might suggest that providing the exclusivity incentive for innovators is a one-way street—the more exclusivity provided, the greater will be the resulting innovation. But that approach is short sighted. As Joseph Stiglitz, former Chairman of the President's Council of Economic Advisors, has explained:

> [w]e often talk about how important patents are to promote innovation, because without patents, people don't appropriate the returns to their innovation activity, and I certainly very strongly subscribe to that. . . . On the other hand, some people jump from that to the conclusion that the broader the patent rights are, the better it is for innovation, and that isn't always correct, because we have an innovation system in which one innovation builds on

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[19] *Id.* ch. II, *An Environment of Change in the Pharmaceutical Industry.*

[20] *Id.* ch. V, *Antitrust Issues and the Changing Pharmaceutical Industry.*

[21] Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389 (1999).

[22] Kim Roller, *What Will Drive Pharmacy Sales Into the New Millennium?*, DRUG STORE NEWS, Jan. 11, 1999, at 21 (Raymond Gilmartin, President and CEO of Merck, states that Merck plans to invest $2.1 billion in research and development as company faces patent expiration on five of its major drugs in 2000 and 2001.).

> another. If you get monopoly rights down at the bottom, you may stifle competition that uses those patents later on, and so . . . the breadth and utilization of patent rights can be used not only to stifle competition, but also [can] have adverse effects in the long run on innovation. We have to strike a balance.[23]

The Hatch-Waxman Act attempted to strike that balance in the pharmaceutical area by providing a clear path for generic alternatives to enter the market. In many respects, the Act has been successful in fostering the development of generics. As a recent Congressional Budget Office (CBO) study observed, since the Act was passed the generic drug share of U.S. prescription sales has grown from nineteen percent in 1983 to over forty percent in 1995.[24] The industry also has seen an increase in the percentage of branded drugs that have a generic competitor on the market. Today, nearly 100% of the top-selling drugs with expired patents have generic versions available, versus only thirty-six percent in 1983.[25] Indeed, the generic share of prescription drug volume has increased by almost 150% since enactment of the Hatch-Waxman Act in 1984.[26] Empirical research has shown that relaxation of entry impediments has given rise to significant entry and price competition in drug markets.[27]

In addition, evidence from the CBO study indicates that for many branded drugs whose patents have expired recently, generics quickly gain a large share of the market.[28] For example, for twenty-one innovator drugs where generics entered between 1991 and 1993, the CBO study determined that in the first, full calendar year of entry, generics accounted for an average of forty-four percent of prescriptions dispensed through pharmacies.[29]

Consumers have saved billions of dollars by purchasing generic drugs in place of their more expensive branded counterparts. According to the CBO study, the savings were between $8 and $10 billion for pharmaceutical sales through retail pharmacies alone in 1994.[30] In turn, insurance and pharmaceutical benefits management companies have responded positively to the increased availability of generic drugs by contracting with generic manufacturers for bulk purchases.[31] Enrollees benefit from these relationships through cost savings realized via multi-tiered drug co-payment structures.

Moreover, the Hatch-Waxman Act has served as a catalyst to expand the number of generic drug manufacturers producing the same drug.[32] This increased breadth and depth of generic drug market presence has augmented pharmaceutical competition on three levels: 1) brand-brand; 2) brand-generic; and 3) generic-generic. The benefits of this increased competition have been confirmed in FTC staff investigations of the pharmaceutical industry. Generally, the FTC has found that the more generic versions of the same drug product that are on the market, the lower the price consumers pay for a generic version, regardless of which generic company is marketing the drug prod-

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[23] *Hearings Before the FTC on Global and Innovation-Based Competition*, at 24-25 (Oct. 12, 1995) (testimony of Joseph E. Stiglitz).

[24] CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 1 (July 1998).

[25] *Id.* at 5.

[26] *Id.* ch. III, at 27.

[27] *Id.* at xii.

[28] *Id.* ch. III, at 28.

[29] *Id.*

[30] *Id.* ch. III, at 1, 20.

[31] *Id.* ch. 1, at 1.

[32] *Id.* at xiii/8.

uct.[33] For example, the entry of a second generic drug product generally doubles the price decrease introduced by the first generic product from the branded product's price. Three or more companies offering a generic version of a drug can lower the price by at least fifty percent, if not substantially more, from the branded price. These price discounts tend to show that the sooner more companies offer the same generic product, the greater the price competition and the lower the price consumers pay for a generic version of a drug product.

The entire issue of pharmaceutical competition and the effectiveness of the Hatch-Waxman Act could not be more important for our nation's efforts to control medical costs. The opportunities for competition and lower prices in the next decade cannot be overstated. Within the next four years, patents on thirty-three drugs will expire, representing over $14 billion in sales.[34]

The Hatch-Waxman Act, like any regulatory structure, is imperfect, and the issue this article addresses is settlements between innovator and generic firms that may subvert both the purposes of the Act and consumer welfare generally. As described in greater detail below, there is a significant temptation for an innovator company and a would-be generic competitor to use certain Hatch-Waxman provisions to perpetuate rather than erode whatever market power the innovator has by virtue of its patent protection for the drug in question. This can be achieved by reaching a settlement or partial settlement of patent litigation that delays generic entry and allows the innovator and generic challenger to "share the wealth"—that is, to share what antitrust lawyers and economists like to call "rents," or supracompetitive returns.

IV. THE ANTITRUST BACKGROUND

The primary concern under the antitrust laws are agreements among competitors that unreasonably restrain trade, a category made unlawful by section 1 of the Sherman Antitrust Act[35] and subsequently by section 5 of the Federal Trade Commission Act.[36] Antitrust law addresses "agreements" because, as the Supreme Court stated in *Copperweld Corp. v. Independence Tube Corp.*,

> [c]oncerted activity inherently is fraught with anticompetitive risk. It deprives the marketplace of the independent centers of decisionmaking that competition assumes and demands. In any conspiracy, two or more entities that previously pursued their interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction. Of course, such mergings of resources may well lead to efficiencies that benefit consumers, but their anticompetitive potential is sufficient to warrant scrutiny even in the absence of incipient monopoly.[37]

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[33] FTC STAFF REPORT, *supra* note 18, at 206.

[34] Amy Barrett, *Crunch Time in Pill Land*, BUS. WK. 52 (Nov. 22, 1999).

[35] In pertinent part, section 1 forbids "[e]very contract, combination . . . or conspiracy, in restraint of trade." 15 U.S.C. § 1 (1996). This language has been understood to be less inclusive than its literal terms: to be limited to the prohibition of agreements in "undue" or unreasonable restraints of trade. Standard Oil Co. v. United States, 221 U.S. 1, 59-60 (1911).

[36] Section 5 proscribes "unfair methods of competition." 15 U.S.C. § 45.

[37] 467 U.S. 752, 767-69 (1984).

There are two general categories of unreasonable agreements. First, agreements that the parties will refrain from competing in some important dimension such as price, quality, or innovation, or in some particular territory or product field, or perhaps not compete at all. Agreements between or among competitors and/or potential competitors, so-called "horizontal" restraints, are regarded as the most straightforwardly anticompetitive category in consumer welfare terms. The vitamin cartel is one example of this type of arrangement. Second, agreements that the parties will cooperate to prevent some other entity from entering or succeeding in their market, by refusing to deal with it or otherwise denying it some part of the means of competing. The *Mylan* case illustrates this situation.

Some agreements or unilateral conduct also may violate section 2 of the Sherman Antitrust Act, which prohibits conduct that constitutes monopolization of, or an attempt to monopolize, a line of commerce.[38] This can occur when one of the parties to the agreement, or both collectively, has substantial market power in the relevant market and uses the agreement either to reinforce existing monopoly power or to gain monopoly power.

V. ANTITRUST CONCERNS WITH PATENT DISPUTE SETTLEMENTS

The Supreme Court has observed that the granting of patents "is an exception to the general rule against monopolies and to the right to access to a free and open market."[39] Of course, recognition of the desirability of making this controlled exception to a regime of open competition, of allowing patent holders to earn economic rents, long pre-dates the antitrust statutes themselves, being grounded in the Constitution.[40] But as Kevin Arquit, a former Director of the Bureau of Competition, noted, patent protection that affords the opportunity to earn economic rents will encourage not only the behavior it is meant to encourage, investment in innovation, but also other behavior of greater concern to the antitrust lawyer—including the kind of collusive activity already mentioned.[41] In other words, patents, in general, provide public benefits, but they also create some tempting opportunities that antitrust enforcers must police.

As a general proposition, public policy favors settlements of disputes.[42] Court dockets are overcrowded and settlements can lower the transaction costs for resolving disputes, in terms of time and resources, for both the parties and the courts. They also can reduce risks and uncertainties for the litigants. Additionally, settlements can play a particularly positive role in the patent area by clearing the way for economic growth and innovative products. Cross-licenses and patent pools are commonly used settlement mechanisms in patent disputes, and where the patents do not compete with each other, the settlement can result in the introduction of new products or services. Joel Klein, the Assistant Attorney General for Antitrust, has observed that:

> [B]y far most cross-licenses and [patent] pools are, on balance, procompetitive. That means that, at bottom, they help sellers provide consumers with better

[38] 15 U.S.C. § 2.

[39] Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) (quoting Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 816 (1945)).

[40] U.S. CONST. art. I, § 8.

[41] Kevin J. Arquit, *Patent-Antitrust: Dead or Alive? Patent Abuse and the Antitrust Laws*, 59 ANTITRUST L.J. 739, 740 (1991).

[42] *See* ARO Corp. v. Allied Witan Co., 531 F.2d 1368, 1378 (6th Cir. 1976) ("Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is inordinately complex and time consuming. Settlement arrangements should therefore be upheld whenever equitable and policy considerations so permit.").

> products and services at lower prices because of benefits ranging from cost savings—due to more efficient production technologies—to improved product quality—resulting from combining complementary inventions.[43]

This value also is recognized in the Intellectual Property Guidelines jointly issued by the FTC and the DOJ.[44] The vast majority of patent settlements probably are procompetitive or competitively neutral. Patent settlements are procompetitive where firms combine their intellectual property to produce a product that otherwise would not exist, or where a patent holder and a new entrant compromise their dispute to allow the new entrant to come to market for compensation paid to the patent holder.[45] The latter type of settlement removes uncertainty for the parties surrounding the patent at issue, eliminates a barrier to one firm entering the market, and generally allows both parties to compete in the marketplace, albeit with one party typically paying royalties to the other.[46] These arrangements are not free of competitive concerns, but offer the promise of some additional competition in the market.

VI. ANTICOMPETITIVE SETTLEMENTS OF DISPUTES AND LITIGATION

Settlements can raise competitive concerns and the Commission has struck down various anticompetitive settlements of disputes, including patent disputes. One recent case in this category, although not involving patents, is the *Sensormatic* enforcement action.[47] Sensormatic is a major manufacturer of antishoplifting devices. During an investigation of a merger to which Sensormatic was a party, the FTC secured evidence that Sensormatic and Checkpoint, the other leading manufacturer of antishoplifting devices—the two firms had over seventy percent of the market between them—had entered into an agreement to refrain from comparative advertising that unfavorably characterized the competitor's product in comparison to one's own.[48] In 1993, both had engaged in fairly direct comparative advertising. A particular Checkpoint advertisement suggested Sensormatic's devices damaged compact discs and video cassettes.[49] Sensormatic responded with a lawsuit alleging that the advertising was false and deceptive, and the parties settled the litigation in part by agreeing to refrain from further comparative advertising without regard to whether the information conveyed was true or false.[50]

Although the parties may have benefited from the resolution of the dispute, competition did not. The settlement weakened competition between the parties by restricting truthful, nondeceptive advertising. Advertising plays a vital role in a competitive

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[43] Joel I. Klein, Remarks Before the American Intellectual Property Law Association (May 2, 1997). *See* Standard Oil Co. v. United States, 283 U.S. 163, 171 (1931) ("[W]here there are legitimately conflicting claims or threatened interferences, a settlement by agreement rather than by litigation, is not precluded by the [antitrust laws].").

[44] DOJ & FTC, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (1995) ("Settlements involving the cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements."). The guidelines advise, however, that, "[w]hen such [settlement] involves horizontal competitors, [the government] will consider whether the effect of the settlement is to diminish competition among entities that would have been actual or likely potential competitors" in the absence of the settlement.

[45] *Id.* ¶ 5.5.

[46] *Id.*

[47] Sensormatic Elec. Corp., FTC Dkt. C-3796 (consent order filed Apr. 6, 1998).

[48] *Id.* ¶ 11.

[49] *Id.* ¶ 8.

[50] *Id.* ¶¶ 8, 11, 12.

marketplace, and comparative advertising in particular can convey critical information to consumers. As the Supreme Court observed in *FTC v. Indiana Federation of Dentists*,[51] an agreement not to compete with respect to information provided to consumers "impairs the ability of the market to advance social welfare by ensuring the provision of desired goods and services to consumers at a price approximating the marginal costs of providing them," and limits consumer choice by impeding the "ordinary give and take of the marketplace."[52] Put more plainly, an agreement to refrain from advertising comparatively superior product characteristics to potential customers will reduce the rewards that accrue to attaining such superiority, which will reduce the incentive to compete in attaining it, which will reduce its attainment—and consumers will be the loser.

The leading case finding an anticompetitive settlement of patent disputes is the 1963 Supreme Court decision in *United States* v. *Singer Manufacturing Co.*,[53] directly involving issues of patent infringement. The Court found that the salient purpose of cross-licensing agreements entered into by producers of sewing machines, in which they agreed not to sue each other for infringement, was not to settle disputes among the parties but rather to exclude competition from Japanese manufacturers in violation of the antitrust laws.[54] As the *Singer* holding was characterized in the 1976 Fifth Circuit opinion, *Duplan Corp. v. Deering Milliken Inc.*, crucial to the finding of an antitrust violation in the settlement of patent litigation is "not the mere act of settlement but the intent of the parties in entering into that settlement and their actions pursuant thereto."[55]

Interestingly, however, Justice White, in a concurring opinion, expressed his willingness to go further. He asserted that, even considered apart from the "conspiracy to exclude the Japanese from the market," the "collusive termination of a Patent Office interference proceeding pursuant to an agreement between Singer and Gegauf [the Swiss corporation with the conflicting patent claim] to help one another to secure as broad a patent as possible, invalidity considerations notwithstanding,"[56] would "run afoul of the Sherman Act's prohibitions against conspiracies in restraint of trade."[57] The record indicated that Singer feared losing the interference proceeding to Gegauf, but was in a position to bring to the attention of the Patent Office prior articles that could have resulted in neither Singer nor Gegauf receiving the patent they sought. This information was suppressed by agreement between Singer and Gegauf. In Justice White's view, while "settlement of an interference in which the only interests at stake are those of the parties," as where the issue is simply priority, "may well be consistent with the general policy favoring settlement of litigation," where the settlement results in withholding information bearing on whether any patent should be granted,

> [t]here is a public interest . . . which the parties have subordinated to their private ends—the public interest in granting patent monopolies only when the progress of the useful arts and of science will be furthered because as the consideration for its grant the public is given a novel and useful invention.[58]

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[51] 476 U.S. 447, 459 (1986).

[52] *Id.* (internal quotations omitted).

[53] 374 U.S. 174 (1963).

[54] *Id.* at 192-93.

[55] 540 F.2d 1215, 1221 (5th Cir. 1976).

[56] 374 U.S. at 197. An interference is an adjudicative proceeding in the U.S. Patent and Trademark Office to determine which party was the first to invent a claimed invention and, thus, is entitled to the patent. *See* 35 U.S.C. § 135 (1996).

[57] *Id.* at 200.

[58] *Id.* at 199.

The Commission's 1967 case against American Cyanamid and Pfizer, often referred to as the *Tetracycline Case*, involved an anticompetitive settlement of patent litigation.[59] Pfizer and American Cyanamid had filed applications for patents on the antibiotic drug tetracycline. The Patent Office opened an interference. Pfizer and Cyanamid then signed a cross-licensing agreement, after which Cyanamid conceded priority to Pfizer and withdrew its application. In the course of the application process, Pfizer and Cyanamid misrepresented test results to the Patent Office and withheld information showing that tetracycline was found in laboratory samples produced under previously patented processes—that is, they suppressed the existence of prior art. The patent examiner, relying on the misinformation provided by the parties, granted a patent to Pfizer. Subsequently, three other competitors secured patent licenses from Pfizer after threatening to contest the validity of the patent—that is, they elected to collude with Pfizer and Cyanamid to share rents rather than seek to open competition to all comers.[60]

The Commission held that Pfizer's conduct in securing the tetracycline patent and subsequent exploitation of the patent violated section 5 of the Federal Trade Commission Act.[61] The Commission held alternatively that Pfizer had committed fraud before the Patent Office and was liable for attempted monopolization.[62] The Commission also held that Cyanamid deliberately withheld from the Patent Office information it knew or had reason to believe was relevant to the validity of Pfizer's patent.[63]

What are the potential competitive concerns from these types of settlements? For one, as Justice White suggests, there is a public interest in the determination of whether the patent really is valid. As he noted in *United States v. Glaxo Group Ltd.*, "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."[64] Some patents may be invalid or procured improperly. For another, the terms of the settlement actually may delay the entry of a competing product. In addition, as in *Singer*, the settling challenger may have important evidence about the validity of the patent that may be lost in the settlement. So ultimately, a settlement may serve the interests of the parties at the expense of consumers and competitors. As Assistant Attorney General Joel Klein has observed:

> Settlements are often based on considerations that lead parties to give up rights that they might well vindicate if they went to the mat. And when intellectual property rights are at stake, the consequences of those compromises can align the settlers' interests against the interests of consumers.[65]

VII. THE HATCH-WAXMAN ACT AND ANTICOMPETITIVE AGREEMENTS

So how does all this relate to the Hatch-Waxman Act in particular? In the normal patent settlement there certainly can be concerns about the diminution of competition between the settling parties. But the agreement may not restrict the ability of other

[59] American Cyanamid Co., 72 F.T.C. 623 (1967), *aff'd sub nom*, Charles Pfizer Co. v. FTC, 401 F.2d 574 (6th Cir. 1968), *cert. denied*, 394 U.S. 920 (1969).

[60] *Id.* at 657.

[61] *Id.* at 684.

[62] *Id.* at 685.

[63] *Id.* at 688.

[64] 410 U.S. 52, 58 (1973) (citing Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892)).

[65] Klein, *supra* note 43.

firms to invent around the patent, and/or to challenge the patent. Thus, the incentives for a patent holder and a challenger to use a settlement strategically—to share monopoly rents—may be limited, because the "prize" for resolving their own dispute is limited by the potential for entry or patent challenges by other firms.

But the Hatch-Waxman Act provides one critical feature that makes a world of difference: the first generic firm to challenge a patent holder is the only generic firm that can enter; until it enters, no other generic firm can enter the market.[66] Under the current provision, the first applicant submitting an ANDA that contains a paragraph IV certification[67] is protected from competition by subsequent generic versions of the same drug product for a period of 180 days after either the first marketing of the first applicant's drug, or a decision of a court holding the patent that is the subject of the paragraph IV certification invalid or not infringed.[68]

The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws and the Hatch-Waxman Act by delaying generic entry for a substantial period. As FDA has recognized, "[u]nder current regulatory provisions, the first generic applicant to file a substantially complete ANDA with a paragraph IV certification can delay generic competition by entering into certain commercial arrangements with an innovator company."[69] There are several kinds of agreements that could have that effect. To illustrate, let us call the innovator company "IC" and the generic firm with 180-day exclusivity "G1." First, G1 might enter into a settlement with the IC that results in a judgment in favor of the patent and prohibits G1 from marketing a product under its ANDA until the patent expires. This means that the 180-day exclusivity period only starts at the time of patent expiration. Second, to make the issue a little more subtle, the parties might structure a partial settlement that gives G1 sufficient incentives, i.e., cash payments, that make G1 unlikely to enter the market until IC's patent expires. Third, the settlement might involve a situation in which IC's patent position is weak and not reasonably likely to prevail in litigation, but G1 nonetheless agrees to delay its entry—probably for some compensation in return. Fourth, the settlement may contain provisions that prevent noninfringing entry by G1 through another formulation of the product, prohibit waivers of the 180-day exclusivity, or restrict marketing of other generic or bio-equivalent products. This is not intended to be an exhaustive list, but it illustrates some arrangements that may pose concerns. Settlements reflecting these characteristics are increasingly prevalent, because, as FDA explains:

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[66] A proposed new rule amending the exclusivity provisions currently is under consideration by FDA. *See* FDA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (June 1998). FDA's proposal for a new rule interpreting eligibility for 180-day exclusivity currently is pending (*See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873 (1999) (to be codified at 21 C.F.R. pt. 314.107)) and will be discussed below.

[67] Under the Hatch-Waxman ANDA process, an applicant is no longer required to submit safety and effectiveness data, but instead may rely on FDA's prior findings of safety and efficacy, so long as it can demonstrate that its generic drug is bio-equivalent to the approved drug product, also known as the reference listed drug. Apart from demonstrating bio-equivalence, the ANDA applicant must provide a certification with respect to each patent listed in the *Orange Book* for the reference drug. This certification must make one of the following statements: (I) no patent information on the drug product that is the subject of the ANDA has been submitted to FDA; (II) the patent has expired; (III) the patent will expire on a particular date; or (IV) such patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a paragraph IV certification.

[68] The proposed rules will start the 180-day exclusivity with a district court decision.

[69] 64 Fed. Reg. at 42,882.

> a successful strategy to extend market exclusivity can mean tens of millions of dollars in increased revenue for an innovator firm. Under such circumstances, it can be beneficial for the innovator and the generic company that is awarded 180 days of generic exclusivity to enter into agreements that block generic competition for extended periods.[70]

The agreements described above effectively "put the cork in the bottle," preventing other generic competition for the innovator drug for an indefinite period, and preserve rents that can be shared with the challenger to reward its acquiescence. Under current interpretations of the 180-day provision, G1 apparently retains its 180-day exclusivity, even over any subsequent noninfringing generic challenger, because the agreement between IC and G1 prevents the 180-day exclusivity period from being triggered. Such agreements should be of deeper concern to antitrust policy than a garden-variety agreement not to compete—which is bad enough—because they manipulate the statute to bar the possibility of other competitive entry. Antitrust analysis often looks to the potential for new entry as an ameliorative factor because it can limit and deter exploitation of market power by those who temporarily possess it.[71] Agreements that restrict new entry therefore are viewed with great concern.

VIII. THE FTC'S RECENT ENFORCEMENT ACTION: *ABBOTT-GENEVA*

A. *Background*

These concerns were addressed in a recent FTC enforcement action against Abbott and Geneva. Abbott is a major pharmaceutical company with 1998 net sales worldwide of approximately $12.5 billion.[72] Over twenty percent of Abbott's pharmaceutical sales in the United States are for a drug called Hytrin.[73] This medication is used to treat two chronic conditions that affect millions of Americans, particularly senior citizens: hypertension (high blood pressure) and benign prostatic hyperplasia (enlarged prostate). This is a market with large profits at stake. Abbott's sales of Hytrin in 1998 amounted to $540 million and 8.3 million prescriptions.[74]

Geneva, on the other hand, is one of the leading generic drug manufacturers in the United States. Geneva was the first company to file an ANDA for terazosin hydrochloride (terazosin HCL), the generic version of Hytrin.[75] It filed applications covering a tablet form and a capsule form of its generic terazosin HCL. Geneva filed a paragraph IV certification with FDA stating that these products did not infringe any valid patent held by Abbott covering terazosin HCL. In June 1996, Abbott sued Geneva for patent infringement by Geneva's terazosin HCL tablet product, but, due to an oversight, failed to make an infringement claim against Geneva's capsule product, although both products raised the same potential infringement issues.[76]

Abbott's lawsuit triggered a thirty-month stay of final FDA approval of Geneva's terazosin HCL tablet ANDA, until December 1998. No stay applied to the FDA approval process for Geneva's terazosin HCL capsule ANDA, however, because no in-

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[70] *Id.* at 42,882-83.

[71] DOJ & FTC, HORIZONTAL MERGER GUIDELINES § 3 (1992) (*revised in* 1997).

[72] Analysis to Aid Public Comment at 1, *Geneva*, FTC File No. 981-0395 (Mar. 16, 2000).

[73] *Id.*

[74] *Id.*

[75] *Id.* at 2.

[76] *Id.*

fringement claim was filed within the statutory time period required by the Hatch-Waxman Act.[77] FDA granted Geneva final approval to market generic terazosin HCL capsules on March 30, 1998.[78]

According to the Commission's complaint, on the day Geneva was granted approval to market its generic terazosin HCL capsules, it contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter. Two days later, on April 1, 1998, Abbott and Geneva entered into an agreement, pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of 1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court, or 2) entry of another generic terazosin HCL product.[79]

The second condition—entry of another generic terazosin HCL product—was a null set, because Geneva also agreed—at Abbott's insistence—not to transfer, assign, or relinquish its 180-day exclusivity right.[80] The effect of this provision was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement because Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire. The complaint alleges these agreements were not justified by any countervailing efficiencies.[81]

The Abbott-Geneva agreement did not settle the patent infringement suit; it simply delayed generic entry. In exchange, Abbott agreed to pay Geneva $4.5 million per month until a district court judgment in the parties' patent infringement dispute was issued and then (assuming Geneva won in the district court) to pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation, after which Geneva would receive the payments if its district court victory was upheld.[82]

Abbott's payment to Geneva of $4.5 million per month was well over Geneva's expected return from entering the market, which it estimated at $1-to-$1.5 million per month. The complaint alleges that Abbott was willing to pay Geneva a "premium" to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial situation.[83] Abbott forecasted that entry of generic terazosin HCL on April 1, 1998, would eliminate over $185 million in Hytrin sales in just six months. Accordingly, the complaint charges that Abbott sought to forestall Geneva, and all other potential generic competition to Hytrin, from entering the market because of the threat they represented to the high profits it was making from Hytrin.[84]

The complaint further charges that, in accordance with the terms of the agreement, Geneva did not enter the market with its generic terazosin HCL capsules, even after the district court and the court of appeals upheld Geneva's position that Abbott's patent was invalid.[85] In August 1999, Abbott and Geneva—aware of the Commission's investigation—terminated their agreement (which by its terms would not have ended until disposition of the litigation by the Supreme Court). Geneva finally brought its generic terazosin HCL capsule product to market on August 13, 1999.

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[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.*

[81] Complaint ¶ 39, *Geneva*, FTC File No. 981-0395.

[82] Analysis to Aid Public Comment at 2, *Geneva*, FTC File No. 981-0395.

[83] *Id.*

[84] Complaint ¶ 24, *Geneva*, FTC File No. 981-0395.

[85] Complaint ¶ 32, *Geneva*, FTC File No. 981-0395.

B. *Competitive Concerns*

Having described the allegations in some detail, what are the antitrust concerns? First, the settlement is an agreement between potential horizontal competitors that delays the entry of new products which offer substantial benefits to consumers. Even though Geneva is not a "current" competitor, it is a potential competitor since it had declared its intention and capability to enter with a bio-equivalent drug that it had certified as noninfringing. A company that currently is not active in a relevant market is a potential competitor if it has the desire, intent, and capability to enter the market. For example, in *United States v. Rochester Gas and Electric Corp.*,[86] the DOJ challenged an agreement between a university and a utility in which the university agreed not to enter the electric generation market through a cogeneration facility; the DOJ alleged that this was an illegal market division. The district court found that the university might be a potential competitor even though it had yet to receive regulatory approval. The district court rejected the argument that the university was not a competitor because its entry would be fraught with legal and regulatory obstacles, noting that it was incontrovertible that at some point during the university's planning, it considered becoming a competitor. Market allocation agreements among potential competitors are per se illegal.[87]

The agreements at issue in *Abbott* are fundamentally agreements not to compete. They are especially problematic because they delayed not only Abbott, but also other potential generic competitors from entering the market. Those kinds of agreements are sure to trigger antitrust alarms. Antitrust analysis often looks to the potential for new entry as an ameliorative factor because it can limit and deter exploitation of market power by those who temporarily possess it. Agreements that restrict new entry therefore are viewed with great concern.

Second, in *Abbott* the parties compounded the problem by prohibiting the potential entrant from marketing not only the generic version that was challenged in the infringement suit, but any generic version of the branded manufacturer's product, even those that were not claimed to be infringing. That not only bottles up products the generic manufacturer may have in the pipeline, but it also reduces incentives to invent around the incumbent's patent.[88]

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[86] 4 F. Supp. 2d 172 (W.D.N.Y. 1998). *See also* Yamaha Motor Co. v. FTC, 657 F.2d 971 (8th Cir. 1981), *cert. denied*, 456 U.S. 915 (1982); Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1 (1st Cir. 1979) (holding that a company is a potential competitor if it "had the necessary desire, intent and capability" to enter the market), *cert. denied*, 449 U.S. 890 (1980).

[87] Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990) (per curiam). Under a per se analysis, certain types of agreements are summarily condemned without exhaustive consideration of efficiencies or potential anticompetitive effects. Under a rule-of-reason analysis, a court conducts a more thorough analysis seeking to balance pro- and anticompetitive effects. In a recent case, a district court held that a private settlement agreement between Andrx and Hoechst was per se illegal. In re Cardizem CD Antitrust Litig., Civ. File No. 99-md-1278 (E.D. Mich. June 6, 2000). The court specifically observed that the firms were horizontal competitors even though Andrx had not entered the market. The agreement was per se illegal since it was not reasonably necessary for some efficiency enhancing conduct. The court, in particular, focused on the fact that the settlement was not similar to a court-ordered preliminary injunction because the generic firm received interim payments, the generic firm was barred from marketing drugs not at issue in the patent case, and the agreement barred the generic from relinquishing the right to the 180-day exclusivity period. *Id.* at 40-41. The court observed: "[r]ather than facilitating or fostering an expeditious resolution of the . . . patent infringement suit, the Agreement required Andrx to diligently prosecute its ANDA, the very act of infringement that triggered the . . . patent suit." *Id.* at 42. For an analysis of why these agreements should be treated as per se illegal, see George S. Cary & Stephen J. Kaiser, A Law of Unintended Consequences: The Hatch-Waxman Act and the Potential for Collusive Behavior in Patent Litigation in the Pharmaceutical Industry, Presentation Before the ABA Antitrust Section (Apr. 6, 2000); *see also* M. Howard Morse, *FTC Challenges Payments by Patent Holders to Alleged Infringers to Stay Out of Market*, INTELL. PROP. COMM. NEWSL., Spring 2000.

[88] Further grounds for concern would, of course, include restrictions that limit competition between innovator and generic challenger once the patent actually had expired, as these would go far beyond any valid efficiency explanation for the arrangement's other terms.

Third, the parties restrained competition even more by agreeing that the generic manufacturer would not relinquish its 180-day exclusivity. That prevented other generic manufacturers from entering as well, so it is more restrictive than a simple agreement not to compete.

Fourth, there were substantial payments from the patent holder to the alleged infringer. Typically, in patent infringement cases the payment flows from the alleged infringer to the patent holder. A payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement.[89] Moreover, it may indicate whether the generic firm has the incentive or ability to enter the market or to pursue fully the litigation. In essence, the generic firm may have chosen the "quiet life," at least temporarily, of an amicable settlement, rather than the hard life of competition. This situation would be troublesome particularly, where, as FDA observed, "the economic gains to the innovator from delaying generic competition exceed the potential economic gains to the generic applicant from 180 days of market exclusivity."[90]

The second and third restraints—the agreement not to enter with a product that is not subject to the infringement suit, and the agreement not to relinquish the 180-day exclusivity—raise the question of ancillarity. Antitrust law holds that secondary provisions that are not reasonably necessary to the fulfillment of efficiencies sought by the principal agreement—i.e., the secondary provisions are not "ancillary" to the principal agreement—can be illegal even if the principal agreement is lawful. Even if the principal agreement might achieve some efficiencies, if a secondary restraint cannot itself be justified in those terms—i.e., it is not truly ancillary to the cognizable efficiencies—it will be analyzed under the per se rule.[91] As Judge Bork stated in *Rothery Storage & Van Co. v. Atlas Van Lines:*

> [t]o be ancillary, and hence exempt from the per se rule, an agreement eliminating competition must be subordinate and collateral to a separate, legitimate transaction. . . . If [the restraint] is so broad that part of the restraint suppresses competition without creating efficiency, the restraint is, to that extent, not ancillary.[92]

The agreement not to enter with a noninfringing product and the agreement not to relinquish the 180-day exclusivity were not ancillary restraints. These types of agree-

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[89] Some commentators have noted that "if the patent owner pays the infringer, and if the infringer settles by accepting an injunction or agrees to abandon the field, scrutiny is warranted." Robert J. Hoerner, *Antitrust Pitfalls in Patent Litigation Settlement Agreements*, 8 Fed. Cir. B.J. 113, 122-23 (Summer 1998). See also Arquit, *supra* note 41, at 744 for discussion of a closely related point:

> [t]he difficulty that we face, as antitrust enforcers, lies in identifying those cases in which settlements enable parties to share economic rents through patents that the parties know to be invalid. One possible indicator of anticompetitive conduct is the royalty that a patent holder extracts from its licensee. We would expect that if a patent is legitimate, the patent holder will charge a royalty that captures most or all of the monopoly rents associated with the patent. If a patent reduces manufacturing costs, for example, the royalty should approximate the magnitude of the cost reduction relative to competing technologies. A license that provides for no royalty or a trivial royalty may be suggestive of a cartel arrangement, particularly if it is accompanied by a price floor or output limitation.

[90] FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,882-3.

[91] *See* NCAA v. Board of Regents, 468 U.S. 85 (1984) (finding that absent a reasonable procompetitive justification for a specific restraint itself, a restraint on output would be deemed a naked restraint in violation of section 1 of the Sherman Antitrust Act even in the context of a larger agreement with procompetitive justifications).

[92] 792 F.2d 210, 224 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1033 (1987).

ments typically are treated as illegal per se, regardless of how one views the principal agreement to defer the generic firm's entry.

One might ask whether an interim settlement, such as in *Abbott*, should receive relatively sympathetic antitrust treatment, because it is no more than a stipulated preliminary injunction.[93] In a recent speech, FTC Commissioner Sheila Anthony explained why these agreements are distinguishable from a stipulated preliminary injunction.[94] A private settlement agreement, unlike a preliminary injunction entered by a court, does not involve any judicial review. Judicial review serves many important purposes, including assessing the public interest and taking the likelihood of success on the merits into account. Judicial review would often prevent parties from entering into other types of agreements, such as the agreements in *Abbott* that prevented Geneva from selling even a noninfringing version of the drug. A judge is an independent arbiter representing the public interest. As Commissioner Anthony observes,

> With purely private agreements, that is, those lacking any court review, the temptation is to reach an agreement at the public's expense. The patent system, however, exists for a reason. Patent litigation, which tests and reviews the validity of a patent, should be allowed to run its course. A preliminary injunction issued under Rule 65 of the Federal Rules of Civil Procedure is the proper vehicle for maintaining the status quo while the complicated infringement issues are resolved by the court.[95]

Commissioner Anthony identified three factors that should raise antitrust questions in considering potential settlements. First, agreements containing provisions that the firms could not secure under Rule 65, such as nonrefundable payments from a patent holder to an alleged infringer. Second, the lack of court review of a settlement agreement may raise concerns because "without review weak patents may be honored in favor of a share of the monopoly rents at the expense of the public interest."[96] Third, the addition of provisions that go beyond what is reasonably necessary, such as the provisions in *Abbott* that prevented Geneva from marketing certain noninfringing versions of the drug or relinquishing the 180-day exclusivity period.

C. *Efficiency Issues*

As noted earlier, settlements of patent litigation can be procompetitive and efficiency-enhancing if they lead to the introduction of new products or services, or to new entry sooner rather than later.[97] Settlements can be of particular value in the pharmaceutical context where they can reduce risk, clarify intellectual property rights,

[93] This argument was specifically rejected by the court in In re Cardizem CD Antitrust Litig., Civ. File No. 99-md-1278, slip op. at 40-41 (E.D. Mich. June 6, 2000).

[94] Sheila F. Anthony, Prepared Remarks before the ABA Antitrust and Intellectual Property: The Crossroads Program, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implication of Certain Types of Agreements Involving Intellectual Property* (June 1, 2000), *available at* (last visited Aug. 11, 2000) <www.ftc.gov/speeches/anthony/sfip000601.htm>.

[95] *Id.*

[96] *Id.*

[97] An "efficiency" generally is something that will benefit consumers, through the introduction of new products or better services. *See, e.g.*, Clamp-All Corp. v. Cast Iron Soil Pipe Inst., 851 F.2d 478, 486 (1st Cir. 1988) (quoting Breyer, J., "[T]he law assesses both harms and benefits in light of the Act's basic objectives, the protection of a competitive process that brings to consumers the benefits of lower prices, better products, and more efficient production methods.").

and reduce the costs and burdens of litigation.[98] Efficiency has a particular meaning under the antitrust laws. An "efficiency" is something that will benefit consumers, through the introduction of new products or better services.[99] So when a settlement does not benefit consumers, as distinct from the parties themselves, it will not be saved by this argument.

To what extent can these agreements be justified by a legitimate interest in resolving patent disputes? The Commission's analysis in *Abbott-Geneva* is instructive. The Commission noted that the restraints imposed by that agreement went well beyond what likely would be available to the parties under a court-ordered preliminary injunction. For example, the agreement in *Abbott-Geneva* 1) barred Geneva's entry beyond the pendency of the district court litigation; 2) provided large up-front payments that could be expected to create disincentives for Geneva to enter (in contrast to a court-ordered bond to cover damages actually incurred as a result of the court's injunction); 3) barred Geneva from relinquishing its exclusivity rights; and 4) prohibited Geneva from developing or marketing noninfringing generic products.[100] Moreover, the restraints contained in the agreement were entered into without any judicial finding that Abbott was likely to succeed on the merits of its infringement suit, without any consideration of whether Abbott would suffer irreparable injury, and without any weighing of the equities, including any consideration of the public interest. The Commission therefore concluded that any legitimate interest in resolving patent disputes cannot justify the harm to consumers imposed by the agreement in that case.[101]

Commissioner Anthony observed, regarding these efficiency claims:

> While settlements are generally favored, we cannot overlook other interests and concerns. Settlements can reduce costs and, through licensing or other similar means, even speed and engender competition. On the other hand, settlements between monopolists and would-be entrants are ripe for collusive dealing that leave consumer and competition behind. In short, the public's interest must be represented at the settlement table. This is best left to a court.[102]

D. *Remedies*

What remedies are appropriate for these kinds of cases? Government enforcement actions seek to enjoin and prevent the recurrence of practices that are illegal, and want to "fence-in" practices that may lead to similar kinds of restraints in the future. And of course, an order should be tailored to the situation, taking into account both the seriousness of the offense and any circumstances in which similar conduct may be permissible. As the Commission stated in the Analysis to Aid Public Comment in the *Abbott-Geneva* case:

> [p]rivate agreements in which the brand name drug company (the NDA holder) pays the first generic to seek FDA approval (the first filer) not to enter the

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[98] For a thoughtful discussion of the potential procompetitive benefits from intellectual property settlement arrangements, see *Abbott*, File No. 981-0395 (Public Comments of Stephen A. Stack, Jr., Dechert, Price & Rhoads, filed Apr. 17, 2000).

[99] *See* Anthony, *supra* note 94; *see also supra* note 97.

[100] Complaint ¶ 26, *Geneva*, FTC File No. 981-0395 (Mar. 16, 2000).

[101] Analysis to Aid Public Comment at 4, *Geneva*, FTC File No. 981-0395 (Mar. 16, 2000).

[102] Anthony, *supra* note 94.

> market can substantially delay generic competition and raise serious antitrust issues. Moreover, the FDA, which has expressed concern about such private agreements, has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to the brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.[103]

Accordingly, the *Abbott-Geneva* consent agreements sharply limit the use of agreements in which the brand name drug company pays the first generic to seek FDA approval not to enter the market. The *Abbott-Geneva* consent:

(1) bars agreements between brand name drug companies and potential generic competitors that prohibit an ANDA first filer from relinquishing its Hatch-Waxman 180-day exclusivity rights;[104]
(2) bars agreements between brand name drug companies and potential generic competitors that prohibit an ANDA first filer from entering the market with a bio-equivalent product that is not challenged in an infringement suit;[105]
(3) bars agreements involving payments to the generic company to stay off the market, in the context of an interim settlement of patent litigation where the parties do not agree to dismiss the litigation, unless the agreement is approved by the court, with notice to the Commission to allow it time to present its views to the court; and[106]
(4) requires respondents to give the Commission written notice thirty days before entering into such agreements in other contexts.[107]

The consent provides that if a brand name manufacturer wants to pay a potential generic competitor to stay out of the market pending resolution of an infringement action, that should be done pursuant to a stipulated, court-ordered Rule 65 injunction, and the Commission will have an opportunity to be heard before that happens. The consent bars agreements that restrict the generic from waiving its exclusivity right. Finally, because of the seriousness of agreements not to compete, the consent requires the respondents to give the Commission notice before becoming a party to any other agreements in which an ANDA first filer agrees to refrain from entering the market. This covers other factual situations, not involving interim relief in a litigated matter, such as where the brand name manufacturer has not filed an infringement action or the agreement is part of a final settlement. These situations present a sufficiently serious risk of competitive and consumer injury that, in the absence of judicial supervision and a court-ordered remedy, the Commission should have a prior opportunity to examine the proposed agreement.

The notification and behavioral restrictions imposed in *Abbott-Geneva* are not necessarily the full range of relief that will be adopted by the Commission in future cases. Indeed, the Commission, upon issuing the *Abbott-Geneva* order, also issued a unanimous statement to put the industry on notice of the substantial competitive concerns that may be raised by these agreements. The Commission suggested that the

[103] Analysis to Aid Public Comment at 5, *Geneva*, FTC File No. 981-0395 (Mar. 16, 2000).
[104] Consent Order ¶ 2, *Geneva*, FTC File No. 981-0395 (Mar. 16, 2000).
[105] *Id.*
[106] *Id.* ¶ 3.
[107] *Id.* ¶ 4.

relief in *Abbott-Geneva* was prospective and limited in large part because this was the first government enforcement action regarding behavior in the context of the complicated provisions of the Hatch-Waxman Act. It observed that pharmaceutical firms should now be on notice that the challenged conduct can raise serious antitrust issues and that in the future the Commission may seek additional remedies, including "the disgorgement of illegally obtained profits," as the Commission did in the *Mylan Laboratories* action.

IX. FDA's PROPOSED NEW 180-DAY EXCLUSIVITY RULE

The 180-day exclusivity provision offers some opportunities for strategic conduct that can thwart the development of generics and the intent of the Act.

To respond to these concerns, FDA has proposed to amend its rules by placing a time limit (180 days) on when the first-filed ANDA applicant must trigger its rights to obtain the 180-day marketing exclusivity period and by clarifying which applicants are eligible for the 180-day marketing exclusivity.[108] FDA has proposed to implement a "use it or lose it" triggering period in which a first-filed paragraph IV ANDA applicant has 180 days to start (or trigger) the 180-day marketing exclusivity period.[109] The triggering period would begin after a second generic drug application with a paragraph IV certification has received tentative approval.[110] During the triggering period, the first-filed ANDA applicant would be required either to obtain a final court decision finding the patent to be invalid, unenforceable, or not infringed by the ANDA product or to begin commercial marketing of the generic drug. In three instances, the triggering period will start not only after a subsequent ANDA receives tentative approval but also after, depending upon the circumstance, 1) the thirty-month stay of ANDA approval has expired if the first-filed ANDA applicant is involved in patent litigation; 2) a preliminary injunction prohibiting the marketing of an ANDA product (if a court has issued one) has expired; or 3) where applicable, the statutorily described exclusivity period for the listed drug has expired.[111]

A "use-it-or-lose-it" triggering period appears to be helpful in implementing the Hatch-Waxman Act's intent to "make available more low cost generic drugs."[112] The 180-day time period appears more than adequate to permit the applicant to prepare to launch the generic product; as FDA noted in the proposed rule, generic drug products are "routinely marketed within a 2-month period following ANDA approval."[113] In practical effect, the "use-it-or-lose-it" triggering period ensures that, once there is another generic product that has received tentative approval from FDA—and, where applicable, the other relevant statutory or court-ordered time periods have expired—the first-filing ANDA applicant must "fish or cut bait," i.e., it must either move to commercial marketing or a final court order within 180 days, or lose the 180-day marketing exclusivity. Either way, FDA's proposed triggering rule ensures that the ongoing potential for generic competition is maintained so that consumers may benefit from a ready supply of generic versions of a drug product. By adding another triggering event—tentative approval for a second generic drug—that is not within the control of either the first-filing ANDA applicant or the branded company, the proposed rule would reduce the ability and incentive of generic and branded companies to enter into agreements that can forestall generic competition.

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[108] 64 Fed. Reg. at 42,873.

[109] *Id.* at 42,877.

[110] *Id.*

[111] *Id.*

[112] H.R. REP. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

[113] 64 Fed. Reg. at 42,878.

Such an approach has the potential for vitiating the perverse incentives that currently prevail, and helping to realize further the promise of Hatch-Waxman in serving consumer interests. Implementation of FDA's proposal can expand the availability of these benefits. Nonetheless, the FTC will remain active in searching for possible violations of the antitrust laws in this sector, as long as there are indications that consumers are being injured.

FTC staff filed a comment supporting the FDA's proposed rule. In its comment, the staff suggested that FDA implement a system requiring parties to file, on a confidential basis, 1) patent litigation agreements (either full or partial settlements) between branded companies and ANDA applicants, and 2) agreements related to the filing of an ANDA by a potential applicant.[114] This suggestion was similar to one proposed by Assistant Attorney General Joel Klein two years earlier with respect to patent settlements generally.[115] The FTC staff's suggestion was made in the hope of overcoming the antitrust authorities' "disadvantage in learning about a whole range of agreements involving intellectual property rights that may impede competition while affording no countervailing competitive benefits," with the added observation that the Commission's pending investigations of such agreements were initiated only when Commission staff became aware of the agreements, which had often been in effect for months, and sometimes over a year. The FTC staff suggested the filing of all agreements related to the ANDA, based on the concern that other agreements might impact the settlement of litigation. If the FTC staff does not have timely notice of such agreements and the agreements eventually are held to have violated antitrust laws, consumers will have paid millions of dollars in unlawfully high prices before such a determination is made, and the Commission will be put in the position of seeking disgorgement and restitution, which, while serving the ends of justice, are imperfect tools for making consumers whole.

X. CONCLUSION

Ultimately, neither enforcement action nor regulatory reform may wholly resolve the problems arising from the 180-day exclusivity period. The flood of litigation, the various efforts to reform the provisions, and most importantly, the ability of firms to manipulate the provisions, suggest that the Act is not meeting its objective of "get[ting] generic drugs into the hands of patients at reasonable prices—fast."[116] The 180-day exclusivity provision appears to have led to strategic conduct that has delayed and not fostered the competitive process. As one court recently observed, the Hatch-Waxman Act was "intended to provide an incentive for drug companies to explore new drugs, not a market windfall for crafty, albeit industrious market players."[117]

Some commentators have suggested that the 180-day marketing exclusivity provision has outlived its usefulness and Congress should consider its elimination. As Alfred Engelberg, one of the drafters of the Act, has observed, the authors "foolishly believed that patent challenges would only arise in cases where the validity of basic patents was at issue, that there was no realistic possibility that such cases could be

[114] BUREAU OF COMPETITION AND OFFICE OF POLICY PLANNING, FTC, IN THE MATTER OF 180-DAY GENERIC DRUG EXCLUSIVITY FOR ABBREVIATED NEW DRUG APPLICATIONS, Docket No. 85N-0214. Senators Leahy and Kohl have proposed legislation to require drug companies to file these types of settlements with the DOJ and the FTC. S. 2993 (106th Cong., 2d Sess.)(filed July 27, 2000).

[115] Klein, *supra* note 43.

[116] In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir.), *cert. denied*, 502 U.S. 906 (1991).

[117] Mylan Pharms., Inc. v. Henney, 94 F. Supp. 2d 36, 55 (D.D.C. 2000).

settled, and that litigation would be extensive. We were wrong on all counts!"[118] Engelberg concludes, "It is now reasonably clear that the 180-day rule has been abused and produces no public benefits that would not occur in its absence."[119] The *New York Times* in a recent editorial called for reform of the provision, observing that because the exclusivity provision "is being manipulated to impede competition, [it] needs to be fixed so that the production of generic drugs cannot be blocked by a single company that decides not to compete."[120]

The area of settlements between innovator and generic firms has been receiving considerable attention by the regulators, by antitrust enforcers, and by private antitrust litigation. That attention is inappropriate, especially when lead to the introduction of new products. In some cases, however, settlements can be used to subvert competition and harm consumers. Thus, prudent firms will seek careful antitrust counseling before entering into these agreements.

[118] Alfred B. Engleberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 425 (1999). *See* Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 33 (D.D.C. 2000) (some of the drafters of the Act believed that an incentive had to be provided in order to induce generic firms to challenge potentially invalid patents).

[119] Engleberg, *supra* note 119.

[120] *Driving Up Drug Prices*, N.Y. TIMES, July 26, 2000, at A-26.