SETTLEMENT OF INTELLECTUAL PROPERTY DISPUTES IN THE PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRIES: ANTITRUST RULES

M. Howard Morse

In recent years, the Federal Trade Commission (FTC) has devoted substantial antitrust enforcement resources to the pharmaceutical and medical device industries in order to protect consumers from high prices charged by companies unlawfully exercising market power. The FTC’s latest enforcement initiative targets pioneer or branded drug manufacturers and generic drug manufacturers for violating the antitrust laws by entering into agreements during the course of pending patent infringement litigation allegedly to delay generic market entry.

These actions have attracted substantial attention from commentators. They have been characterized as cases of “first impression,” “novel,” “difficult,” and “complex” by the FTC Commissioners challenged to “sort through the thicket that often is found at the intersection of the intellectual property and antitrust laws.” They are, however, best understood as the
latest in a series of FTC challenges to steps taken by pharmaceutical and medical device manufacturers to resolve intellectual property disputes in a manner that may limit or eliminate competition. The analyses in the earlier cases ought to provide guidance for the latest enforcement initiative, as well as inform judicial analyses of similar issues in private litigation.

Two principal precedents are relevant. In 1995, the FTC filed suit to block a proposed acquisition of Cardiovascular Imaging Systems, Inc. by Boston Scientific Corporation (Boston Scientific). That acquisition resolved patent litigation between the established medical device manufacturer and the innovative start-up. The FTC alleged, however, that the acquisition would substantially lessen competition and allowed the acquisition to proceed only after Boston Scientific agreed to grant a broad license to its own intellectual property, as well as acquired intellectual property, in order to preserve competition.  

In 1998, the FTC challenged a patent pooling agreement between Summit Technology, Inc. (Summit) and VISX, Inc. (VISX) that resolved patent disputes over laser technology for vision-correcting eye surgery. The FTC alleged that the Summit-VISX agreement constituted price-fixing and ordered royalty-free cross licensing.  

In the last two years, the FTC has brought three enforcement actions against pioneer and generic pharmaceutical companies, alleging that agreements they entered into during the course of patent infringement litigation constituted “unfair methods of competition” in violation of section 5 of the FTC Act.  

In May 2000, the FTC charged Abbott Laboratories (Abbott) with paying Geneva Pharmaceuticals, Inc. (Geneva) to delay bringing its generic alternative to an Abbott drug to market while patent litigation was pending. Abbott and Geneva settled the FTC claim by agreeing to cease and desist from entering into similar agreements in the future and agreeing to waive statutory rights to exclusivity so other generic drugs could immediately enter the market.  

The FTC simultaneously filed an administrative complaint against Hoechst Marion Roussel, Inc. (Hoechst, now Aventis Pharmaceuticals, Inc. or Aventis) and Andrx Corp. (Andrx), alleging that Hoechst paid Andrx to stay out of the market during patent infringement litigation, preventing Andrx and others from marketing generic drugs in competition with Hoechst. That matter settled before trial, with

---


Hoechst and Andrx agreeing not to enter into similar agreements and agreeing to provide notice to the FTC of future agreements. The same day that the FTC accepted the settlement of the *Hoechst-Andrx* litigation, it filed administrative litigation against Schering-Plough Corporation (Schering), Upsher-Smith Laboratories (Upsher), and American Home Products Corporation (AHP, now Wyeth), alleging that Schering illegally paid Upsher and AHP to induce them to delay launching their generic versions of a Schering drug. This latest action is different from the earlier cases in important respects. Most notably, Schering, Upsher, and AHP reached settlements terminating litigation in a manner that allowed the generics to enter the market before the pioneer’s patents would have otherwise expired. In contrast, the *Abbott-Geneva* and *Hoechst-Andrx* cases challenged agreements that restricted marketing during the pendency of ongoing patent litigation left unresolved by the challenged agreements.

Some have argued that all of these pioneer-generic agreements should be condemned as *per se* illegal naked market division agreements in restraint of trade whenever a patent holder pays an alleged infringer, on the theory that it is a payment to delay entry. It is true, of course, that antitrust law usually condemns “naked” agreements not to compete through price fixing, market allocation, or other arrangements as *per se* illegal. On the other hand, courts generally, and often strongly, encourage settlement of intellectual property litigation.

Balancing these conflicting legal principles, it seems appropriate to apply a rule of reason approach to any agreement that settles bona fide (non-sham) litigation. Rule of reason analysis—at least for permanent settlements—should provide sufficient incentive for businesses to resolve their intellectual property disputes in a manner that does not unduly restrict competition. Ancillary restraints that are not reasonably necessary to achieve procompetitive efficiencies may be condemned if it is clear that practical and significantly less restrictive alternatives would have achieved similar efficiencies.

---


10 See discussion *infra* Part II.
While courts have sometimes focused on parties’ subjective intent, the trend is to focus on objective evidence, and examine whether the effect of a settlement is to diminish competition that would likely have existed absent the settlement. In *Boston Scientific* and *Summit-VISX*, the FTC considered the loss of interim competition during protracted litigation, the ability of the firms to invent around patents, objective evidence that the parties expected to compete, and the likelihood that the parties would have resolved their dispute in a manner substantially less restrictive of competition. The strength of the underlying patent case may also be relevant to the question whether a settlement agreement impaired competition, at least if the government cannot demonstrate that the parties would likely have settled on terms that would have allowed earlier competition.

Two additional critical issues arise in the permanent settlement cases. First, if there was other consideration for the payment from the pioneer to the generic, such as a license to another product, illegality may depend on the government showing that such consideration was a sham, since “side deals” are often used to resolve disputes. Second, the *Noerr-Pennington* doctrine may provide immunity if a settlement is entered into with court involvement.

This Article examines judicial precedents relating to antitrust challenges to settlement agreements, explores the earlier *Boston Scientific* and *Summit-VISX* enforcement actions, and applies the teaching from those cases to the recent pioneer-generic pharmaceutical agreement challenges.

I. THE FTC’S FOCUS ON THE PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRIES

The pharmaceutical and medical device industries have become a prime target of the popular press in recent years as a leading cause of rising health care costs. At the same time, these industries have increasingly become the subject of FTC antitrust enforcement actions.

---

11 Id.
12 See discussion infra Parts III, IV.
14 The FTC shares civil antitrust enforcement authority with the Department of Justice (DOJ) Antitrust Division. The two agencies have, however, agreed to allocate enforcement, based on industry expertise, and the FTC has handled nearly every civil matter involving pharmaceutical and medical device manufacturers and distributors in recent years. Indeed, a recent failed effort by the FTC and DOJ to formally allocate industries between the agencies would have assigned pharmaceuticals, medical equipment and medical devices to the FTC. See Memorandum of Agreement Between the Federal Trade Commission and the Antitrust Division of the United States Department of Justice Concerning Clearance Procedures for Investigations (Mar. 5, 2002), available at http://www.ftc.gov/opa/2002/02/clearance/ftcdojagree.pdf; Press Release, DOJ, Statement by Charles A. James Regarding DOJ/FTC Clearance Agreement (May 20, 2002), available at
The FTC views its mission as one of protecting consumers from high prices. FTC officials explain their focus on the pharmaceutical and medical device industries by highlighting increasing costs of health care generally and drugs in particular, noting that pharmaceutical costs make up an “ever-growing portion” of the country’s healthcare expenditures. They have cited Health Care Financing Administration data showing that prescription drug spending has risen at rates of 12-19% annually as evidence of “the need to ensure competition in pharmaceutical markets,” and have said that the FTC’s Bureau of Competition receives more complaints from consumers about rising drug costs than about any other single issue.

Much of the FTC’s enforcement in the pharmaceutical and medical device industries has involved mergers and acquisitions requiring government reporting under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Over the last ten years, the Commission has brought over two dozen merger enforcement actions in these industries, nearly all of which were resolved by consent agreements requiring divestitures or other relief as a condition of merger approval.  


The DOJ has exclusive jurisdiction over criminal matters. DOJ has collected over $900 million in criminal fines from eleven companies charged with fixing prices and allocating market shares in the vitamin industry. See Press Release, DOJ, Two German Firms and Two U.S. Corporations Agree to Plead Guilty to Participating in International Vitamin Cartels (May 5, 2000), available at http://www.usdoj.gov/opa/pr/2000/May/249at.htm; Press Release, DOJ, Four Foreign Executives of Leading European Vitamin Firms Agree to Plead Guilty to Participating in International Vitamin Cartel (Apr. 6, 2000), available at http://www.usdoj.gov/opa/pr/2000/April/179at.htm.


These investigations exposed the pharmaceutical and medical device industries to the FTC and merger investigations revealed conduct that has led to subsequent non-merger investigations. The investigations also uncovered contacts between agency staff and manufacturers, customers, and third-party payers in the industry that have led to complaints about conduct, and further investigations. Most recently, during 2002, the FTC challenged the acquisition and listing of a patent in the Food & Drug Administration’s (FDA’s) Orange Book, allegedly to delay generic entry, and a distribution agreement among generic manufacturers that allegedly deterred additional generic entry. Settlement of patent disputes remains a focus of enforcement, but the agency is broadly interested in any action by pioneer or generic manufacturers that may delay entry beyond lawful exclusivity periods.

Beyond its law enforcement role, the FTC has filed amicus briefs in private litigation, claiming “significant expertise concerning competition in the pharmaceutical industry.” FTC staff have filed comments before the FDA, advising the agency on proposed rules implementing the Hatch-Waxman Act, and have even filed an FDA Citizen Petition seeking clari-
fication of issues relating to patent listings with the FDA. Agency economists recently published a detailed report analyzing competitive dynamics in, and trends impacting, the pharmaceutical industry. That study discussed industry practices that may raise competitive concerns, including price discrimination, bundling, volume rebates, and various types of mergers.

Among the key characteristics of the pharmaceutical and medical device industries is the importance of patents to companies in these industries. Innovation leading to the development of new products is critical to the success of companies in these industries, which invest over five times more per sales dollar in research and development efforts than companies in a composite of all industries. The FTC recognizes that pharmaceutical companies rely especially heavily on intellectual property rights in the form of patents and trademarks. In fact, empirical research indicates that new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries.

Justifying increased antitrust enforcement in the pharmaceutical industry, FTC officials have suggested that “[w]ithout vigorous antitrust enforcement, competitors may heed the lure of collusion with their rivals as a means of release from the stressful life of competition.” Senior agency officials have characterized patents as “an exception to the general rule against monopolies,” and while recognizing that patents may encourage investment in innovation, have suggested patents also “create some tempting opportunities that antitrust enforcers must police.” Agency officials available at http://www.ftc.gov/be/v000005.pdf; Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, FDA Docket No. 85N-0214 (Nov. 4, 1999).

24 The Bureau of Competition and Policy Planning Staff of the Federal Trade Commission’s Citizen Petition to the Commissioner of Food and Drugs pursuant to 21 C.F.R. §§ 10.25(a), 10.30 concerning certain issues relating to patent listings in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) and requesting that the FDA clarify these issues via industry guidance or other means that the FDA considers appropriate (May 16, 2001), available at http://www.fda.gov/ohrms/dockets/dailys/01/May01/052901/c000005.pdf (on file with the George Mason Law Review).


26 See Levy, supra note 25, at 174-75.
27 Id. at 180.
29 Balto, supra note 1, at 322.
30 Balto, supra note 1, at 327 citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965)). The historical view is that there is an inherent conflict between the intellectual property laws which grant a “monopoly” to the intellectual property owner and the antitrust laws which seek to prevent the creation or enhancement of monopoly power:

While the antitrust laws proscribe unreasonable restraints of competition, the patent laws reward the inventor with a temporary monopoly that insulates him from competitive exploitation of his patented art…. [T]he patent and antitrust laws necessarily clash…. [T]he primary
have also noted the large numbers of drugs coming off patent over the next few years, expressing the view that “consumers can expect major savings from generics if the incumbents do not block competition with illegal agreements.”

The FTC observes that the benefits to consumers from generic competition are often dramatic. The agency noted that (a) the first generic manufacturer to enter a market typically charges 70% to 80% of the brand manufacturer’s price; and (b) as additional generic versions of the same drug enter the market, the price typically continues to drop, sometimes to a level of 50% or less of the brand price. When enforcing the antitrust laws in these industries, such savings must of course be balanced against maintaining incentives for firms to invest in innovation as societal benefits from technological progress quickly swamp short-term price effects.

II. THE LEGAL FRAMEWORK

While there may be some facial appeal to the argument that settlement agreements that keep a firm off the market for some period of time should be analyzed like market division agreements and condemned as per se illegal, the issue is not so simple. The Supreme Court has made it clear that lower courts should analyze most agreements under the rule of reason, particularly when dealing with unfamiliar species of agreements, and a per se rule is only to be adopted once the courts have sufficient experience with a

SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1203 (2d Cir. 1981). The modern view, however, is that intellectual property laws authorize owners of intellectual property to exclude others from using that property, and do not necessarily create market power. See U.S. Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property §§ 2.0, 2.2 (Apr. 6, 1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132, at 20,734-35 [hereinafter 1995 Intellectual Property Guidelines] (“The Agencies will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner . . . .” The Agencies regard intellectual property as being essentially comparable to any other form of property.”). Antitrust and intellectual property laws, in fact, have similar goals, and need not conflict:

When the patented product is so successful that it creates its own economic market or consumes a large section of an existing market, the 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.


type of restraint that they can conclude it has a pernicious effect of competition and lacks any redeeming virtue. The Court more recently instructed that where the “anticompetitive effects of a given restraint are far from intuitively obvious, the rule of reason demands a more thorough inquiry into the consequences of those restraints.”

The issue of appropriate antitrust analysis of settlements of intellectual property disputes has found its way to the Supreme Court twice. The Court’s decisions, however, leave a lot of room for continued debate as intellectual property becomes even more significant to many firms than their brick and mortar properties in the New Economy. The first important case, Standard Oil Co. v. United States, involved patents for “cracking” oil to produce gasoline. In an opinion by Justice Brandeis, the Court held that “[w]here there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather than by litigation, is not precluded by the [Sherman] Act.” As the Court explained, “[a]n interchange of patent rights and a division of royalties according to the value attributed by the parties to their respective patent claims is frequently necessary if technical advancement is not to be blocked by threatened litigation.”

The seminal case—30 years later—addressing settlement of patent

---

35 See, e.g., State Oil Co. v. Kahn, 522 U.S. 3, 10 (1997) (“most antitrust claims are analyzed under a ‘rule of reason.’”); Ind. Fed’n of Dentists v. FTC, 476 U.S. 447, 458-59 (1986) (“[W]e have been slow . . . to extend per se analysis to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious.”); Ariz. v. Maricopa County Med. Soc’y, 457 U.S. 332, 334 (1982) (“Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, it has applied a conclusive presumption that the restraint is unreasonable.”); Broad. Music, Inc. v. CBS, Inc., 441 U.S. 1, 9, 19 (1979) (citing United States v. Topco Assocs., Inc., 405 U.S. 596, 607-08 (1972)) (“[I]t is only after considerable experience with certain business relationships that courts classify them as per se violations.”); Cont’l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49-50 (1977) (citing N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958)) (holding that the per se rule should only apply to agreements that are shown to have a “pernicious effect on competition and lack of any redeeming virtue.”); Standard Oil v. United States, 221 U.S. 1, 59-61 (1911) (“[T]he criteria to be resorted to in any given case for the purpose of ascertaining whether violations of the section have been committed is the rule of reason.”).


37 See Lawrence H. Summers, The New Wealth of Nations, Remarks Before the Hambrecht & Quist Technology Conference (May 10, 2000) (transcript available at http://www.ustreas.gov/press/releases/ls617.htm) (“It used to be that value resided in the mass of what was produced—as with an ingot of iron or a barrel of oil or a bushel of wheat. But increasingly today the canonical product is a gene sequence, a line of computer code or a logo.”).

38 283 U.S. 163 (1931).

39 Id. at 171. The Court in Standard Oil acknowledged “[a]ny agreement between competitors may be illegal if part of a larger plan to control interstate markets” and reasoned that “an agreement for cross-licensing and division of royalties violates the Act only when used to effect a monopoly, or to fix prices, or to impose an otherwise unreasonable restraint.” Id. at 170, 175. See also Duplan Corp. v. Deering Milliken, Inc., 540 F. 2d 1215, 1220 (4th Cir. 1976), aff’d 540 F.2d 1215 (D.S.C. 1976) (denying the release of attorney work product to subsequent litigants because settlement of patent litigation by the patent holders does not violate antitrust laws unless made in bad faith or intended to restrain competition); Boston Scientific Corp. v. Schneider (Europe) AG, 983 F. Supp. 245, 269-71 (D. Mass. 1997) (upholding settlement agreement based on the “general rule that settlements and cross-licensing agreements do not without something more, violate the antitrust laws”).
litigation is United States v. Singer Manufacturing Co. In Singer, the government contended that the U.S. sewing machine manufacturer and Swiss and Italian competitors conspired to restrain trade in zig-zag sewing machines. Singer, after purchasing a patent covering such machines, entered into a cross-licensing agreement with the Swiss and Italian firms and abandoned an interference that had been declared. Singer thereafter acquired the application of one of the firms. Following issuance of that patent, Singer instituted infringement actions against distributors and sought to exclude importation of Japanese sewing machines. The Supreme Court concluded that the patent had been placed in Singer’s hands to exclude the Japanese machines. The Supreme Court rejected the district court’s conclusion that the “dominant and sole purpose” of Singer was to protect its own commercial interests by settling the priority dispute. The Court thus condemned the settlement as part of a conspiracy to monopolize in violation of Section 2 of the Sherman Act.

Justice White, concurring in Singer, asserted that even apart from the “conspiracy to exclude the Japanese from the market,” the “collusive termination of a Patent Office interference proceeding between Singer and [its competitor with a conflicting patent claim] to help one another to secure as broad a patent monopoly as possible” violated the Sherman Act. Justice White reasoned that “the settlement of an interference in which the only interests at stake are those of the adversaries . . . may well be consistent with the general policy favoring settlement of litigation.” But, he added:

the present case involves a less innocuous setting . . . [in 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.

Singer is now cited for the proposition that settlement agreements among horizontal competitors will be scrutinized for anticompetitive purpose or effect and condemned when the dominant purpose is to exclude a mutual competitor of the parties. Indeed, one court of appeals analysis of a settlement agreement to determine if it violates the antitrust laws followed Singer reasoning to find the “critical factor” lying in “the anticompetitive intent or purpose of the parties.” According to the court, settlement

41 Id. at 177-78.
42 Id. at 178.
43 Id. at 187-88.
44 Id. at 194-95.
45 Id. at 192.
47 Singer, 374 U.S. at 199.
48 Id. at 197-99.
50 Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1221 (4th Cir. 1976).
agreements that violate antitrust laws must “be entered into in bad faith and utilized as part of a scheme to restrain or monopolize trade.”

The FTC’s tetracycline patent litigation during the 1960s is also worth noting. While generally characterized as a *Walker Process* case involving fraud on the U.S. Patent and Trademark Office (USPTO), the case involved settlement of an interference dispute between American Cyanamid and Pfizer over the priority of their respective patent applications. American Cyanamid entered a cross-license with Pfizer and then conceded the priority of Pfizer’s application. The Commission found that the firms’ withholding of prior art from the USPTO combined with the cross license constituted an attempt to share in an unlawful monopoly, and required the firms to license tetracycline at a reasonable royalty.

The 1995 DOJ and FTC *Antitrust Guidelines for the Licensing of Intellectual Property* (1995 Intellectual Property Guidelines) also recognize that “[s]ettlements involving the cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements.” On the other hand, the 1995 Intellectual Property Guidelines recognize that settlement agreements may be subject to antitrust scrutiny. Citing *Singer*, the guidelines advise that “[i]n the absence of offsetting efficiencies, such settlements may be challenged as unlawful restraints of trade.” The guidelines conclude that “[w]hen such cross-licensing 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 cross-license.

While *Singer* arguably suggests that the test of legality is a subjective one—focusing on the parties’ purpose—this language suggests an objective test—focusing on the agreement’s effect. While evidence of intent may sometimes inform effects evidence, reliance on intent evidence is often misleading. Thus, the trend in antitrust law is to focus primarily on effects of conduct. Exclusionary purpose, which is inherent in the patent right, would otherwise be found in nearly every antitrust case involving patents. Put simply, it appears that while the efficiency of settling litigation is a relevant consideration, settlement agreements that eliminate preexisting

---

53 American Cyanamid Co., 72 F.T.C. 623, 625 (1967), aff’d sub nom Charles Pfizer & Co. v. FTC, 401 F.2d 574, 579, 582-83 (6th Cir. 1968); Cf. Boston Scientific Corp. v. Schneider (Europe) AG, 983 F. Supp. 245, 271 (“anti-competitive effects cannot be adequately alleged when they require a presumption that the PTO is unable to do its job without the assistance of outside parties.”).
54 1995 Intellectual Property Guidelines, supra note 30, § 5.5.
55 Id.
56 Id.
57 See, e.g., Ocean State Physicians Health Plan v. Blue Cross & Blue Shield, 883 F.2d 1101, 1113 (1st Cir. 1989) (“[D]esire to crush a competitor, standing alone, is insufficient to make out a violation of the antitrust laws.”); A.A. Poultry Farms v. Rose Acre Farms, 881 F.2d 1396 (7th Cir. 1989).
competition between the settling parties or exclude potential rivals may be condemned under existing precedent applying the rule of reason.

Public policy strongly favors settlement of disputes without litigation, or at least without a full trial and appeal.\(^{58}\) Such agreements enable faster resolutions and spare the parties from what can be enormous litigation costs and the burdens of trial, allow other litigants to obtain speedier justice by reducing congestion in the court system, and reduce costs of operating the judicial system. Settlement agreements are therefore generally upheld whenever equity and policy considerations permit.\(^{59}\) In fact, as one appellate court has explained, “*[t]hese agreements are of particular value in patent litigation, the nature of which is often inordinately complex and time consuming.*”\(^{60}\) In today’s litigious society, “the need for settlement is greater than ever before”; “without them our system of civil adjudication would quickly break down.”\(^{61}\)

The line between agreements to settle intellectual property disputes and other agreements, however, is not always clear. Many, if not most, agreements to settle intellectual property disputes include licenses of intellectual property rights. At the same time, many ordinary license agreements anticipate potential disputes, and many disputes are settled in the face of threatened litigation. Indeed, public benefits from avoiding litigation altogether argue for encouraging resolution of intellectual property disputes before litigation is commenced.

There are, on the other hand, important differences between settlement agreements and other agreements that are relevant to the antitrust analysis. Once litigation is commenced, the parties are undoubtedly forced to take positions on key issues; it may well be difficult to walk away from pleadings attested to under Federal Rule of Civil Procedure 11\(^{62}\) in the face of an

---

\(^{58}\) See infra note 59 and accompanying text.


\(^{60}\) Aro Corp., 531 F.2d at 1372. See also Schlegal Mfg. Co. v. U.S.M. Corp., 525 F.2d 775, 783 (6th Cir. 1975) (“The importance of encouraging settlement of patent infringement litigation...cannot be overstated.”); Procter & Gamble, 61 F. Supp. 2d at 108.

\(^{61}\) Chiron Corp., 136 F.3d at 1322 (quoting Neary v. Regents of Univ. of Cal., 834 P.2d 119, 121 (Cal. 1992)).

\(^{62}\) Rule 11 provides: “[b]y presenting to the court (whether by signing, filing, submitting, or later advocating) a pleading, written motion, or other paper, an attorney or unrepresented party is certifying
antitrust challenge to the settlement. A record and the parties’ state of
testimony on issues such as prior art, obviousness, and infringement will 
be developed through discovery, motions, and trial. To the extent that anti-
trust analysis considers the strength of the intellectual property claims in an 
uncertain world and the parties’ state of knowledge about those claims, 
litigation can make a significant difference. Liability, for instance, has histor-
ically been based on actual knowledge by the patent owner of patent 
invalidity or fraud on the USPTO.

Another significant difference between ordinary agreements and set-
ttlement agreements is that the latter provide an opportunity for judicial 
supervision. While judges may not always be sensitive to the impact of set-
ttlement agreements on competition or third parties, their involvement is 
often significant. At least one court has viewed the original trial court’s 
approval of a settlement agreement as a trump card in rejecting an antitrust 
claim based on that settlement.

Thus, it seems appropriate to adopt a bright line at the filing of litiga-
tion and apply a rule of reason analysis at least to agreements that settle 
litigation, absent a finding that the underlying litigation was a sham. In-
deed, courts have generally been reluctant to find that settlements are mere 
pretexts for anticompetitive agreements.

that to the best of the person’s knowledge, information, and belief, formed after an inquiry reasonable 
under the circumstances . . . it is not being presented for any improper purpose . . . [and] the allegations and 
other factual contentions have evidentiary support . . ." Fed. R. Civ. P. 11(b)(1)(3).

Handgards Inc. v. Ethicon, Inc., 743 F.2d 1282 (9th Cir. 1984); Walker Process Equip., Inc. v. 

Speed Shore Corp. v. Denda, 197 U.S.P.Q. 526 (C.D. Cal. 1977), aff’d on other grounds, 605 
F.2d 469 (9th Cir. 1979).

See N.C. v. Chas. Pfizer & Co., 537 F.2d 67, 75 (4th Cir. 1975) (holding that settlement justified 
to avoid delay in granting patent); Hutzler Bros. Co. v. Sales Affiliates, Inc., 164 F.2d 260, 267 (4th 
Cir. 1947). See also Herbert Hovenkamp et al., XII ANTITRUST LAW: AN ANALYSIS OF ANTITRUST 
PRINCIPLES AND THEIR APPLICATION ¶ 2046 at 263-67 (1999) ("[A]ssuming a genuine dispute, the 
outcome of even a settlement agreement producing a per se antitrust violation might be no more anti-
competitive than the outcome of the litigation…As a result, some agreements that would be unlawful if 
undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide dispute. 
… [O]nce a sufficient conflict is found, full analysis under the rule of reason is usually called for, 
including an inquiry into power and anticompetitive effects.").

The antitrust analysis of a settlement agreement thus should be basically the same as for other 
agreements subject to a rule of reason. Both the DOJ/FTC 1995 Intellectual Property Guidelines and the 
more recent Antitrust Guidelines for Collaborations Among Competitors focus on the following factors: 
the competitive relationship of the parties; their positions in and competitive conditions of relevant 
matters; the effect of the agreement on competition that would exist in the absence of the agreement; 
and the availability of significantly less restrictive alternatives. 1995 Intellectual Property Guidelines, 
supra note 30; U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for 
Collaborations Among Competitors (Apr. 7, 2000), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,161 
[hereinafter 2000 Competitor Collaboration Guidelines].

The FTC staff has relied principally upon United States v. Masonite Corp., 316 U.S. 265 (1942), 
as standing for the proposition that the Supreme Court finds anticompetitive agreements settling patent 
disputes to be per se unlawful. See Complaint Counsel’s Trial Brief, Schering-Plough Corp., No. 9297 
involved agreements in settlement of litigation. In that case, however, the Supreme Court assumed 
arguendo that the patents at issue were valid and infringed. Even under those circumstances, the parties’ 
conduct—whereby competing manufacturers entered into agreements to distribute Masonite’s products
III. RESOLVING PATENT DISPUTES THROUGH MERGER

Settlements of intellectual property disputes that result in an acquisition are subject to section 7 of the Clayton Act, whether the agreement results in the acquisition of a company as a whole, an acquisition of intellectual property assets, or an exclusive license. In fact, while the accumulation of patents from the USPTO is not in itself an antitrust violation, patents have been held to be “assets” and assignments of patent rights have been held to be “acquisitions” subject to the Clayton Act. Grants of exclusive licenses have also been held acquisitions subject to the Act, although non-exclusive licenses should not raise similar concerns.

A merger or acquisition eliminates all competition between the merged businesses. Mergers, however, even absent a claim that they resolve patent litigation, are analyzed under the rule of reason, as the integration of the firms is generally recognized to generate efficiencies.

The FTC addressed a merger aimed at resolving patent litigation when Boston Scientific proposed to acquire Cardiovascular Imaging Systems, Inc. (“CVIS”). In January 1995, the FTC filed suit to block that acquisition, alleging the two firms both produced intravascular ultrasound imaging (“IVUS”) catheters used in the diagnosis and treatment of cardiovascular disease, and that the effect of the proposed acquisition, if consummated, at prices set by Masonite—constituted unlawful price fixing. Masonite, 316 U.S. at 282-83. In other words, the outcome there was more anticompetitive than any possible outcome of the litigation. See also United States v. New Wrinkle, Inc., 342 U.S. 371, 380 (1952) (finding licensing agreement a means for patent owner to set prices per se unlawful); United States v. Line Material Co., 333 U.S. 287, 314-15 (1948) (determining cross-license agreement that fixed the price of patented device per se unlawful).

Section 7 of the Clayton Act prohibits transactions where “the effect…may be substantially to lessen competition, or to tend to create a monopoly.” 15 U.S.C. § 18 (1997). A merger can also be challenged under the Sherman Act, as a “restraint of trade” or an “attempt to monopolize.” 15 U.S.C. §§ 1, 2 (1997). Additionally, the FTC may challenge a merger or acquisition under Section 5 of the FTC Act as an “unfair trade practice.” 15 U.S.C. § 45 (1997). The standards for challenging mergers under all three statutes are virtually identical.

The DOJ/FTC Horizontal Merger Guidelines set forth the analysis to determine if a merger is likely to have anticompetitive effects, such as higher prices, reduced output or reduced innovation. That analysis requires consideration of market shares, the likelihood of unilateral anticompetitive effects or coordinated interaction, an assessment of entry conditions, and consideration of efficiencies. U.S. Department of Justice and Federal Trade Commission, Horizontal Merger Guidelines (Apr. 8, 1997), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,104 [hereinafter 1997 Horizontal Merger Guidelines].
“may be substantially to lessen competition or tend to create a monopoly.” 71 IVUS catheters are medical devices used to generate an ultrasound image from the inside of arteries, providing detailed information that, according to the FTC, was not obtainable using other imaging techniques such as angiography. 72 The catheters are used with therapeutic procedures such as balloon angioplasty, atherectomy, and stent implantation, to diagnose and treat cardiovascular disease. 73 The FTC alleged—and two courts have subsequently held in related matters—that the acquisition would combine the market leaders in the development, manufacture, and sale of IVUS catheters; result in a firm with a share of over 80% of the U.S. IVUS catheter market; eliminate a key competitor; and increase the likelihood of diminished product innovation and increased prices. 74

The fact that the Boston Scientific-CVIS merger was in settlement of patent litigation is not clear from the FTC’s complaint seeking to block the transaction. But the FTC’s memorandum in support of its motion for a preliminary injunction anticipated Boston Scientific’s defense to the merger enforcement action. That memorandum noted that in discussions with the Commission, Boston Scientific argued “the acquisition should be allowed because . . . it would resolve ongoing patent disputes between the companies.” 75 The Commission argued that this so-called “patent defense” should be rejected. It characterized Boston Scientific’s arguments as: (1) asserting that the firm may not be able to continue to compete in the IVUS market absent the proposed acquisition because CVIS had alleged Boston Scientific was infringing its patents; and (2) arguing that the transaction should be allowed because it settles the patent litigation. 76

A firm’s historic market share may be irrelevant to predicting its competitive significance if it lacks required capacity to compete in the future. Thus, in United States v. General Dynamics Corp., 77 the Supreme Court held that a coal company that lacked coal reserves had little competitive significance despite a large current market share based on

---

73 Id.
75 Complaint ¶ 11, Boston Scientific (No. C-3573).
sales. Similarly, one might argue that a firm likely to lose an infringement suit may have no ability to compete in the future.

In Boston Scientific, the FTC rejected this argument, noting that while Boston Scientific made that argument to the Commission, the company had argued in the patent litigation that CVIS’ patents were invalid and that CVIS was infringing one of its own patents. The Commission argued that “[t]he patent litigation [was] in its early stages and the ultimate outcome [was] far from certain.” It then concluded that “there [was] no reason that the litigation must end in an adjudicated decision that would require Boston Scientific to exit the market.” Rather than forcing Boston Scientific to exit, the court hearing the patent suit could have found CVIS’ patents invalid, or the parties might have reached a negotiated cross-license. The FTC’s economic expert testified that while the merger might resolve the parties’ patent dispute and reduce litigation costs and uncertainty, the same benefits could have been achieved by alternative means, such as licensing, rather than by a means that would result in the complete elimination of competition between the two firms.

The FTC argued as a legal matter that even where agreements settle patent litigation, “[w]hen these agreements involve horizontal competitors, they are carefully scrutinized for anticompetitive purpose or effect.” Knocking down a straw man, the Commission suggested that immunizing a transaction merely because it settles patent litigation would create “a new, broad, unwarranted exception to the antitrust laws.” The FTC characterized Boston Scientific’s argument that the transaction should be allowed because it settled patent litigation as “curious” in light of the fact that the litigation was actually commenced in the middle of acquisition negotiations.

Boston Scientific argued that the proposed acquisition settled pending litigation and that this was an efficiency, rather than an absolute defense to the Commission’s action. The company asserted that development of IVUS was significantly impeded by intellectual property disputes between Boston Scientific and CVIS and planned to present evidence at trial that the uncertainty created by those disputes held back development of the technology. Anticipating that argument, the FTC’s motion for a

---

78 Id. at 498, 502, 510-11 (focusing on probable future of the relevant market).
79 FTC Memorandum, supra note 75, at 40.
80 Id.
81 Id.
82 Id.
84 FTC Memorandum, supra note 75, at 41 (quoting ABA, ANTITRUST LAW DEVELOPMENTS, 854 n.400 (3d ed. 1992)).
85 Id.
87 BSC Memorandum, supra note 86, at 6.
preliminary injunction argued that Boston Scientific had “not proffered
evidence to the Commission of efficiencies sufficient to offset the likely
harm to competition, nor [had] it demonstrated that claimed efficiencies
could not be achieved by other means.”

In Boston Scientific, the FTC thus rejected the “patent defense” by
focusing on: (1) inconsistencies between Boston Scientific’s patent and
antitrust litigation arguments; (2) the benefits of current competition while
the litigation was pending; and (3) less restrictive means of resolving the
dispute. Rather than litigate with the FTC, Boston Scientific entered into a consent agreement. That agreement allowed Boston Scientific to acquire CVIS and another firm, SCIMED Life Systems, Inc. (SCIMED). The FTC alleged that SCIMED had conducted research and development on IVUS catheters, had developed a prototype, was perceived as a potential entrant by Boston Scientific, and was likely to enter the market within two to three years. Boston Scientific agreed to grant a broad non-exclusive license to Hewlett-Packard Company, a manufacturer of consoles used with the catheters, to Boston Scientific’s own IVUS patents and the patents of CVIS and SCIMED, as well as non-patented technology relating to IVUS catheters. According to the FTC, the consent agreement was “designed to launch a strong independent competitor in the U.S. IVUS catheter market, thus restoring the competition lost in the acquisitions and eliminating any patent uncertainty that may exist in the market.”

The FTC thus allowed Boston Scientific to acquire CVIS, the firm with which it was in patent litigation, but required Boston Scientific to grant a license to a well-qualified new entrant with complementary products of its own, CVIS’, and SCIMED’s patents and technology. A new competitor with clear rights to compete was created, potentially enhancing pre-merger competition which existed under a patent cloud and could have forced one firm to exit the market.

88 FTC Memorandum, supra note 75, at 43.
89 Boston Scientific Corp., 119 F.T.C. 549, 564-71, No. C-3573 (Apr. 28, 1995) (consent agree-
ment).
90 Complaint ¶ 5, Boston Scientific, No. C-3573.
91 Id. The FTC also required Boston Scientific to provide technical assistance and advice to Hew-
lett-Packard (HP) or the alternative licensee for three years to effect the transfer of the IVUS technology and enable the licensee to obtain all necessary FDA approvals to enable it to manufacture IVUS catheters, and in the interim, required Boston Scientific to supply IVUS catheters at cost to the licensee to enable it to compete immediately. The FTC also prohibited Boston Scientific from entering into any arrangement that would make its catheters compatible with only certain consoles. Id. ¶ 15.
92 Press Release, FTC, Boston Scientific To Help Launch New Maker of Cardiac Catheter, To
93 In October 2000, the DOJ sued Boston Scientific for civil penalties and injunctive relief under the Trade Commission Act, 15 U.S.C. § 45(l) (2000), for violating the FTC Order. A federal court in Boston granted summary judgment in favor of the government in September 2001 for Boston Scientific’s failure to license certain intellectual property and refusal to supply HP with certain catheters pursuant to the interim supply agreement mandated by the order. Boston Scientific, 167 F. Supp. 2d at
IV. ARRANGEMENTS TO FIX PRICES

Price fixing agreements have long been condemned as illegal per se, without elaborate inquiry, under section 1 of the Sherman Act which literally makes unlawful every “contract, combination . . . or conspiracy in restraint of trade.” Other agreements that have been held per se illegal include agreements among competitors to fix output, rig bids, or share or divide markets by allocating customers, suppliers, territories, or lines of commerce.

Despite its expansive language, the Sherman Act has long been interpreted to prohibit only unreasonable restraints, and even agreements between competitors on price are judged under the rule of reason if ancillary to efficient joint activity or “necessary to market [a] product at all.” The federal antitrust enforcement agencies advise that if “participants in an efficiency-enhancing integration of economic activity enter into an agreement that is reasonably related to the integration and reasonably necessary to achieve its procompetitive benefits, the agencies analyze the agreement under the rule of reason, even if it is of a type that might otherwise be considered per se illegal.” While a restraint need not be essential, if the participants could achieve “comparable efficiency-enhancing integration through practical, significantly less restrictive means,” then the agencies will conclude that the restraint is not “reasonably necessary.”

440. HP also sued Boston Scientific for breach of contract, monopolization, and attempted monopolization. That case settled after HP prevailed on a motion to dismiss. See Hewlett-Packard, 77 F. Supp. 2d at 198 (“[T]he allegation of a bad faith violation of the licensing agreement, specifically designed to promote a viable, independent competitor in the catheter market, permits an inference of exclusionary conduct.”).

96 See Chicago Bd. of Trade v. United States, 246 U.S. 231, 238 (1918); Standard Oil Co. v. United States, 221 U.S. 1, 58 (1911) (holding that Congress did not intend to prohibit contracts that cause insignificant or attenuated restraints of trade, but only those agreements “which were unreasonably restrictive of competitive conditions”).
97 Broad. Music, Inc. v. CBS, 441 U.S. 1, 23 (1979) (reviewing a joint venture among copyright owners to offer blanket license). See also NCAA v. Bd. of Regents, 468 U.S. 85, 100 (1984) (holding that restriction on college football television broadcast rights is a restraint on output which ordinarily is deemed illegal per se, but such treatment is inappropriate where the restraint is “essential if the product is to be available at all”).
98 2000 Competitor Collaboration Guidelines, supra note 65, § 3.2 (citing Arizona v. Maricopa County Med. Soc’y, 457 U.S. 332, 339 n.7, 356-57 (1982)). The federal agencies advise that in an efficiency-enhancing integration, participants collaborate to perform or cause to be performed one or more business functions, such as production, distribution, marketing, purchasing or research and development, and thereby benefit, or potentially benefit, consumers by expanding output, reducing price, or enhancing quality, service, or innovation. They explain further that participants, in an efficiency-enhancing integration typically combine, by contract or otherwise, significant capital, technology, or other complementary assets to achieve procompetitive benefits that the participants could not achieve separately. Id.
99 2000 Competitor Collaboration Guidelines, supra note 65, § 3.2. See also SCFC ILC, Inc. v. Visa USA, Inc., 36 F.3d 958, 970 (10th Cir. 1994) (to be found lawful, a restraint must be “reasonably related to…and no broader than necessary to effectuate” the venture’s procompetitive business pur-
Price fixing was the core allegation in the FTC’s 1998 challenge to Summit Technology and VISX’s patent pool involving patents for photo refractive keratectomy (PRK) vision correcting eye surgery.\textsuperscript{100} PRK uses specialized, computer-guided lasers to reshape the cornea.\textsuperscript{101} According to the FTC complaint, Summit and VISX were the only two firms with FDA approval to market laser equipment for performing PRK in the United States.\textsuperscript{102} The FTC alleged that each firm had developed technology for performing laser eye surgery and each owned or controlled numerous patents related to PRK.\textsuperscript{103}

Summit and VISX pooled most of their existing, as well as certain future, patents related to PRK in a partnership to license third parties. Summit and VISX each “relinquished the right to unilaterally license” any PRK equipment manufacturer. At the same time, each partner was given the right and power to prevent the pool from licensing any of the pooled patents to any PRK equipment manufacturer.\textsuperscript{104} Moreover, according to the FTC, Summit and VISX agreed each would pay a per procedure fee to the partnership pool, the level of which would be set within a predetermined range at the “higher of the amounts separately proposed” by either firm.\textsuperscript{105} The result, the Commission charged, was a $250 licensing fee every time a laser was used to perform PRK, the proceeds of which were split between the two firms according to a predetermined formula.\textsuperscript{106} The FTC explained that “this was price fixing under the guise of a patent cross-licensing arrangement.”\textsuperscript{107}

In a key allegation, the FTC asserted Summit and VISX “could have and would have competed” with one another in the sale or lease of PRK equipment by using their respective patents, licensing them, or both, even “in the absence of” the pooling agreement.\textsuperscript{108} In addition, the complaint alleges, Summit and VISX “would have engaged in competition” with each other in connection with the licensing of technology related to PRK.\textsuperscript{109} That is, the complaint alleges that Summit and VISX were horizontal competitors because they could and would have competed in the sale or lease of

\textsuperscript{101} Id. ¶ 4, Summit Tech., Inc., No. 9286.
\textsuperscript{102} Id. ¶ 6.
\textsuperscript{103} Id. ¶¶ 4-6.
\textsuperscript{104} Id. ¶ 10.
\textsuperscript{106} Id.
\textsuperscript{108} FTC Complaint ¶ 8, Summit Tech., Inc., No. 9286.
\textsuperscript{109} Id.
equipment using their own technology and in licensing PRK technology.\footnote{110}

These allegations bring the Summit/VISX patent pool within the DOJ and FTC 1995 Intellectual Property Guidelines.\footnote{111} Those guidelines recognize that intellectual property licensing is “typically welfare-enhancing and procompetitive.”\footnote{112} However, they clarify antitrust concerns as those that “may arise when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors in a relevant market in the absence of the license.”\footnote{113} The 1995 Intellectual Property Guidelines repeat the same principles with respect to pooling arrangements. They explain pooling arrangements “may provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation.”\footnote{114} However, where pooling arrangements “are mechanisms to accomplish naked price fixing or market division,” or where they “diminish competition among entities that would have been actual or likely potential competitors in a relevant market” in the absence of the pool, they are subject to challenge.\footnote{115}

The FTC complaint does not mention any patent dispute between Summit and VISX. The Commission’s Analysis to Aid Public Comment, issued with its proposed consent decree resolving the patent pooling charges, however, reveals that the Summit-VISX pool was created to resolve a patent dispute.\footnote{116} There, the FTC explained, Summit and VISX contended the pool “reduced the uncertainty and expense associated with the patent litigation that would have inevitably ensued” without the partnership pool, and allowed both parties “to be in the market, when patent infringement might have precluded one or both from coming to market.”\footnote{117}

The FTC rejected this argument, reasoning Summit and VISX could have achieved these efficiencies through “any number of significantly less restrictive means.”\footnote{118} According to the FTC, the companies could have entered “simple licenses or cross-licenses that did not dictate prices to users or restrict entry,”\footnote{119} and, significantly, “patent infringement would not have
precluded either firm from coming to market.\textsuperscript{121}

A subsequent speech by the Director of the FTC Bureau of Competition confirms that despite the price fixing allegations against Summit and VISX, the agency applied a rule of reason analysis in these circumstances:

Now, it is true that the parties could argue that, notwithstanding the underlying merits, they really were afraid of litigation, and the pool was a way to avoid that litigation. But that argument goes too far. Once it is shown that the patents are not completely blocking and the parties could have competed with each other, there is an anti-competitive effect to be weighed in the rule of reason balance. Concerns about avoiding litigation, however real, are an efficiency to be weighed against that effect.\textsuperscript{122}

Summit and VISX abandoned their pool in the face of the FTC challenge and entered into consent decrees.\textsuperscript{123} The FTC prohibited Summit and VISX from fixing prices or agreeing to restrict each other’s sales or licensing of PRK lasers and patents.\textsuperscript{124} Interestingly, the FTC mandated royalty-free cross licensing despite the claim that the firms could have competed absent the pool.\textsuperscript{125} The FTC reasoned that “subsequent sunk-cost investments” by each firm in reliance on the pool made a cross-license desirable and approximated competitive conditions that would have been achieved had the pool not been formed.\textsuperscript{126}

The Summit-VISX agreement was similar in certain respects to the oil cracking pool addressed in Standard Oil.\textsuperscript{127} There, the parties issued licenses to each other’s patents and shared royalties. Applying the rule of reason, Justice Brandeis reasoned that “[i]f combining patent owners effectively dominate an industry, the power to fix and maintain royalties is tantamount to the power to fix prices.”\textsuperscript{128} In fact, the defendants there had only an estimated 55% share of cracking capacity, the cracking processes only accounted for about 26% of gasoline produced, and other gasoline was sold

\textsuperscript{121} Id. at 46,453-54 (FTC Sept. 1, 1998) (analysis to aid public comment).


\textsuperscript{124} Decision and Order, Summit Tech., No. 9286. Id.


\textsuperscript{126} Standard Oil v. United States, 283 U.S. 163 (1931).

\textsuperscript{127} Id. at 174.
interchangeably, so the defendants could not in fact control the supply or fix the price of cracked gasoline. On the other hand, the Summit-VISX pool involved the only two firms in the market, and the FTC condemned the pool because the firms “could have and would have competed” in the absence of the agreement. 129

V. PAYMENTS FROM PATENT HOLDERS TO ALLEGED INFRINGERS TO STAY OUT OF THE MARKET

Most recently, the FTC brought three enforcement actions challenging agreements between a patent-protected “pioneer” or “innovator” pharmaceutical company, 130 and potential generic competitor alleging that an agreement has had the effect of both keeping the generic out of the market and forestalling other generic competition. 131 Like the Boston Scientific and Summit-VISX matters, these cases involve litigation settlements, though there are important distinctions between the Abbott-Geneva and Hoechst-Andrx cases, which involve agreements to delay marketing during the pendency of litigation, and the Schering-Ploughagreements, which compromised litigation allowing entry before the disputed patent otherwise would have expired.

A. The Regulatory Framework

These antitrust actions can only be fully understood in the context of the unique regulatory structure governing the pharmaceutical industry. 132 Under the Federal Food, Drug and Cosmetic Act (FDCA), 133 any person

---

129 63 Fed. Reg. at 46,453. It is instructive to distinguish these facts from those in an unsuccessful challenge to a settlement agreement between Procter & Gamble and Kimberly Clark over disposable diapers by the leading private label disposable diaper producer. After years of expensive patent litigation, the two leading disposable diaper manufacturers settled, granting each other worldwide immunity from suit regarding specified patents. Despite allegations of price fixing, Kimberly Clark and Procter & Gamble each maintained the right to license its own patents, and not the other party’s patents, and they did not share royalties. Moreover, they did not explicitly agree to royalty rates. An agreement to fix the rate could not be inferred from subsequent conduct, since the actions were as consistent with legitimate self-interest as with illegal activity. Procter & Gamble v. Paragon Trade Brands, Inc., 61 F. Supp. 2d 102, 108 n.7 (D. Del. 1996).

130 The FTC consistently refers to such firms as “branded” manufacturers, emphasizing the fact that such firms trademark their products in contrast to most generic manufacturers, and ignoring the research and development such firms undertake before introducing such drugs.


132 See generally Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001); Andrx Pharmns., Inc. v. Biovail Corp., 256 F.3d 799, 801-02 (D.C. Cir. 2001).

seeking to market a new drug, a so-called “pioneer” applicant, must first obtain FDA approval by filing a New Drug Application (NDA). Preparing such an application is a time-consuming and expensive process as one must provide, among other things, data from clinical studies showing that the drug is safe and effective for its intended use.

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, amended the FDCA, to establish a streamlined approval process for generic versions of approved drugs. Prior to the passage of the Hatch-Waxman Act, manufacturers of generic drugs were required to file a new NDA and duplicate the safety and efficacy studies already conducted by the original applicant. Hatch-Waxman created an Abbreviated New Drug Application (ANDA) process, by which an applicant can rely on the safety and effectiveness tests conducted by a pioneer drug manufacturer, so long as the generic applicant can demonstrate that its drug is bio-equivalent to the approved, reference listed drug.

The Hatch-Waxman Act represented a political compromise that balanced the competing interests of pioneer drug manufacturers and generic producers. The Act streamlined approval of generic drugs in order to “make available more low cost generic drugs,” while at the same time protecting the interests of patent-holding pioneer drug manufacturers and “creating a new incentive for increased expenditures for research and development.” The relevant provisions of the statute are complex. Various courts have termed them “cumbersome,” “very confusing and ambiguous,” and far “from a model of legislative draftsmanship.”

In order to achieve its goals, the Hatch-Waxman Act requires, among

135 Id. § 355(b)(1).
137 Generic drugs are versions of pioneer prescription drugs that are generally sold without a brand name and that contain the same active ingredients, but not necessarily the same inactive ingredients as the original. See United States v. Generix Drug Corp., 460 U.S. 453, 454-55 (1983).
141 Id. at 14-18. See generally Gerald J. Mossinghoff, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, 54 FOOD & DRUG L.J. 187 (1999); James J. Wheaton, Generic Competition and Pharmaceutical Innovation: the Drug Price Competition and Patent Term Restoration Act of 1984, 35 CATH. U. L. REV. 433 (1986). The patent term restoration provisions of the Act generally provide for extensions of one-half the time required to conduct safety tests and all of the time required for the FDA to approve marketing, up to five years, so long as the remaining patent life plus the extension does not exceed 14 years. 35 U.S.C. § 156 (2000). Congress expressly recognized the importance of patents, noting they are “designed to promote innovation by providing the right to exclude others from making using or selling an invention,” enabling innovators to obtain greater profits than if direct competition existed, providing “incentives for innovative activities.” H.R. REP. NO. 98-857, at 17, reprinted in U.S.C.C.A.N. at 2650.
143 Id. at 1069.
other things, that all NDA applicants submit to the FDA information on any patent covering the drug, its active ingredient, formulation or composition, any method of delivery of the drug, or any method of using the drug for treatment of disease, for which a claim of patent infringement could reasonably be asserted against an unauthorized party. The FDA then lists the approved drug and related patents in a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the “Orange Book.”

An ANDA applicant must provide a certification with respect to each patent listed in the Orange Book, which claims the reference drug or a method of using it for which the applicant is seeking approval. The certification must make one of four statements: (1) that no patent information has been submitted to the FDA; (2) that the patent has expired; (3) that the patent will expire on a particular date; or (4) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA is submitted. Thus, for each patent applicable to a pioneer drug, the ANDA applicant must certify whether the proposed generic drug would infringe that patent, and if it would not, then why not.

ANDA filers certifying under the fourth statement, or “Paragraph IV,” must provide notice to the owner of each patent and to the NDA holder for the listed drug. The notice must include a detailed statement of the factual and legal basis for the ANDA applicant’s opinion that “the patent for the pioneer drug is either invalid or will not be infringed by the marketing of the generic drug.” If the patent holder, upon receiving notice of a Paragraph IV certification, files a patent infringement suit within 45 days, the FDA may not approve the ANDA until the earliest of: (1) the date the patents expire; (2) a final non-appealable determination that the patent is invalid or not infringed by the marketing of the generic drug; or (3) 30-

---


147 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). If the applicant makes a certification under Paragraphs I or II (i.e., if no patents are in force on the approved drug), the statute provides that the FDA may approve the ANDA immediately. If the applicant makes a certification under Paragraph III (i.e., if a valid patent is in force and would be infringed), the FDA may approve the ANDA effective on the date that the applicant certifies that the patent will expire. § 355(j)(5)(B)(i)-(ii). The Hatch-Waxman Act overruled Roche Prods., Inc. v. Boler Pharm., Co., 733 F.2d 858 (Fed. Cir. 1984), and authorizes use of patented drugs to develop and submit information to the FDA to obtain premarketing approval, without infringing patents, to ensure generic drugs are ready for market as soon as relevant patents expire. See 35 U.S.C. § 271(e)(1) (2000). When an applicant makes a certification under Paragraph IV, things become more complicated, as explained infra.


months from the patent holder’s receipt of the notice. The statute thus provides for an automatic 30-month stay of FDA approval based on the mere filing of a patent infringement action. That stay may be extended or shortened by the court if it finds that either party has failed to “reasonably cooperate in expediting the action.” These provisions are intended to give the patent-holder “time to vindicate its patent in court before the generic competitor is allowed entry into the market.”

The Hatch-Waxman Act provides an incentive for generic drug manufacturers to challenge patents that may be invalid or not infringed by generic drugs. Under the Act, the first applicant to submit an ANDA which contains a Paragraph IV certification gets 180 days of marketing exclusivity. That is, the first applicant is protected from competition from other generic versions of the same drug for approximately six months. The statute provides that subsequent ANDA applications cannot be approved for a period of 180 days from the earlier of (i) the date of a court decision holding the patent invalid or not infringed (the so-called “court decision trigger”); or (ii) the date the generic manufacturer begins commercial marketing of the drug (the so-called “commercial marketing trigger”). These provisions give the first applicant a period of exclusivity, which one court characterized as an “[e]denic moment of freedom from the pressures of the marketplace.”

153 Id.
155 21 U.S.C. § 355(j)(5)(B)(iv). The statute actually says the exclusivity period applies whenever there is a “previous” application, thus the statute might conceivably be read to confer a 180-day period on a second or third applicant.
156 Mova Pharm., Inc. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998). If no infringement suit is filed within 45 days, FDA review and approval may proceed according to the FDA’s expedited schedule. A patent owner may file an infringement action at any time, but does not gain the benefit of the 30-month automatic stay unless the suit is filed within 45 days.
158 Mova Pharm., 140 F.3d at 1064. The D.C. Circuit in Mova held that the statute did not allow the FDA to condition the 180-day exclusivity period on a requirement that the first filer had successfully defended against a patent infringement suit. Id. at 1076. The FDA, which had required the first filer to successfully defend against a patent infringement suit to obtain exclusivity, thereafter formally withdrew the challenged portion of its regulations, issued a guidance document, and is undertaking a rule-making process to reinterpret the Act in a way that balances encouraging innovation and getting generic competition in the market quickly. Effective Date of Approval of an Abbreviated New Drug Application, 63 Fed. Reg. 59,710 (Nov. 5, 1998) (to be codified at 21 C.F.R. pt. 314); Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 63 Fed. Reg. 37,890 (July 14, 1998), available at http://www.fda.gov/cder/guidance/2576finl.pdf; 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed Reg. 42,873, 42,874 (Aug. 6, 1999) (to be codified at 21 C.F.R. pt. 314). Pioneer-generic agreements entered into when the governing FDA regulations required that an ANDA applicant successfully defend the patent holder’s infringement suit in order to be entitled to exclusivity and before those regulations were struck down may not be subject to antitrust challenge on the grounds that they created a “bottleneck” to subsequent generic competition as are later agreements.
Under the current statutory and regulatory scheme, an ANDA filer may incur liability if it enters the market and is ultimately found to have infringed the pioneer’s patent. Thus, the ANDA applicant may decide on its own to stay off the market even after the 30 months stay expires, until the litigation is resolved, in order to minimize potential damages. Indeed, currently, the first ANDA filer may do so without triggering the 180-day exclusivity period. A second filer may, however, obtain a declaratory judgment of non-infringement or invalidity to trigger the first-filer’s exclusivity period. The statute thus gives the pioneer drug manufacturer an automatic preliminary injunction for two-and-a-half years to pursue an infringement action. At the same time, the statute gives prospective generic competitors an expedited FDA approval process and gives the first generic a six-month jump on additional generic competitors.

By granting an automatic stay on competition by the mere filing of a patent infringement suit, the Act appears to give pioneer firms a huge incentive to list patents in the Orange Book, irrespective of whether they are a significant barrier to legitimate competition, and to file unfounded lawsuits against ANDA applicants based on invalid and uninfringed patents. One commentator has suggested that the Act enables a patent owner to prevent competition “irrespective of the merits of the patent being asserted and without any meaningful penalty . . . as compared to the hundreds of millions of dollars in monopoly profits that can be earned during the thirty months a competitor is held off the market.” Businesses filing baseless lawsuits, however, may in fact find themselves subject to Rule 11 sanctions, and also to treble damages liability under the antitrust laws for sham petitioning.

---

159 See 35 U.S.C. § 284 (2000); King Instruments Corp. v. Perego, 65 F.3d 941, 948 (Fed. Cir. 1995); FTC Initial Decision at 106, Schering-Plough Corp., 2002 WL 1488085, No. 9287 (F.T.C. June 27, 2002), available at http://www.ftc.gov/os/2002/07/scheringinitial (“The prudent practice, then, is for generic manufacturers to await the conclusion of patent litigation before marketing a product and risking financial ruin.”). The FDA, in one Federal Register notice, similarly characterized such delay as “prudent” and in “the public interest.” Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,894 (July 10, 1989). The FDA has, however, more recently proposed a “use it or lose it” trigger under which the first generic to file a Paragraph IV certification would have 180 days in which to trigger the 180-day exclusivity period after a second filer receives tentative FDA marketing approval. 64 Fed. Reg. at 42,878.

160 Teva Pharms., USA, Inc. v. FDA, 182 F.3d 1003, 1005 n.3 (D.C. Cir. 1999).


162 Federal Rule of Civil Procedure 11 provides for sanctions upon attorneys, law firms, and parties that make allegations (1) presented for an improper purpose, such as to harass or to cause unnecessary delay, (2) are not warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law, or (3) the allegations and other factual contentions lack evidentiary support and are not likely to have evidentiary support after a reasonable opportunity for further investigation or discovery. Fed. R. Civ. P. 11(b)-(c).

163 See Pro’l Real Estate Investors, Inc. v. Columbia Pictures, Inc., 508 U.S. 49, 60-61 (1993) (finding unlawful sham litigation that is ‘objectively baseless’ and constitutes ‘an attempt to interfere
B. The Abbott-Geneva and Hoechst-Andrx Facts and Anticompetitive Theory

The FTC brought two actions in March 2000 challenging payments by pioneer drug manufacturers to prospective generic competitors on the verge of commencing marketing in exchange for the generic manufacturers staying off the market pending the conclusion of the patent litigation. The principal anticompetitive theory in these cases is that the challenged agreements raise barriers to the entry of follow-on generic competitors by delaying the entry of the first generic to seek marketing approval. The FTC specifically alleges that, because of the Hatch-Waxman 180-day exclusivity provisions, the challenged agreements “created a bottleneck” that prevented other potential generic competitors from entering the market.

1. Abbott-Geneva

The Abbott-Geneva facts are relatively straightforward. Abbott marketed and sold the prescription drug Hytrin, the brand name for terazosin HCl, used to treat hypertension and enlarged prostates. Geneva filed an ANDA application in 1993 for approval to market generic terazosin HCl tablets, and in 1995, Geneva filed another ANDA for approval to market generic terazosin HCl capsules. In early 1996, Abbott notified the FDA of a new patent and listed it in the Orange Book. In April 1996, Geneva certified that its entry would not infringe that patent, and according to the FTC, was “confident that it ultimately it would prevail.” Abbott sued in June 1996, claiming patent infringement against Geneva’s tablets. According to the FTC, Abbott mistakenly failed to file suit against Geneva’s capsules, even though they raised the same potential infringement issues as the tablets. Thus, while the 30-month stay delayed FDA approval of Geneva’s
tablets, FDA review and approval of Geneva’s capsules continued, and Geneva made preparations to launch its capsules.

According to the FTC, the very day it was granted FDA approval, Geneva contacted Abbott and announced that it would launch “unless it was paid by Abbott not to enter the market.”169 Two days later, Geneva agreed not to bring its generic capsules or tablets to market until final resolution of the patent infringement lawsuit, including possible review by the Supreme Court, or entry of another generic terazosin HCl, in exchange for $4.5 million per month until the district court ruled. At Abbott’s insistence, Geneva also agreed not to transfer, assign, or relinquish its 180-day exclusivity right.170

2. Hoechst-Andrx

In September 1995, Andrx sought FDA approval to manufacture a generic version of Cardizem CD, a widely prescribed drug for the treatment of hypertension, or high blood pressure, and angina. In December 1995, Andrx made a Paragraph IV certification with regard to all unexpired patents for Cardizem CD, certifying that its generic did not infringe the patents. Hoechst promptly sued Andrx for infringement, which stayed FDA approval for 30-months, until July 1998.

Hoechst reached an agreement with Andrx before expiration of the 30-month stay, purporting to maintain the status quo pending the outcome of the patent infringement litigation. In exchange for $10 million per quarter from Hoechst, Andrx agreed to refrain from marketing its generic until the end of the suit and all appeals. According to the FTC, Andrx also agreed, at Hoechst’s request, to refrain from selling any other generic version of Cardizem “regardless of whether such product would infringe” and agreed not to withdraw its pending ANDA or to relinquish its 180-day exclusivity rights.171

3. The Anticompetitive Theories

The Abbott-Geneva and Hoechst-Andrx cases, alleging violations of section 5 of the FTC Act, were based on both Sherman Act section 1 and

---


170 Complaint ¶ 26, Abbott Labs., No. C-3945; Complaint ¶ 26, Abbott Labs., No. C-3946. Geneva prevailed on a motion for summary judgment in the patent litigation, but did not commence marketing until the challenged agreement with Abbott was canceled in the face of the FTC investigation. Complaint ¶¶ 31, 33, Abbott Labs., No. C-3945; Complaint ¶¶ 31, 33, Abbott Labs., No. C-3946.

section 2 principles. The FTC alleged that the challenged agreements constituted unreasonable restraints of trade, that the pioneer drug firms monopolized or attempted to monopolize, and that all of the firms conspired to monopolize narrowly defined drug markets. The FTC specifically alleged that the acts and practices of the respondents “had the purpose or effect, or the tendency or capacity to restrain competition unreasonably and to injure competition [and consumers] by preventing or discouraging the entry of competition in the form of generic versions” of branded drugs.

The FTC allegations are based on two distinct theories of competitive harm. First, the FTC asserted that the Abbott-Geneva and Hoechst-Andrx agreements were illegal agreements not to compete between potential horizontal competitors. Second, the FTC asserted that those agreements created a “bottleneck” that prevented other potential generic competitors from entering the relevant markets by delaying the trigger of the 180-day exclusivity period. In the words of one FTC Commissioner, “at base, we have an agreement between competitors whereby one is paying the other to stay out of the market . . . [and] to block any other potential entrants.”

The FTC specifically asserted in its papers that the challenged agreements were “not justified by any countervailing efficiency” that may have resulted in benefits to competition and consumer welfare. The government professes to have considered whether the agreements “could be considered a procompetitive effort to effectuate a temporary settlement of a patent dispute, akin to a court-ordered preliminary injunction.” Explaining the Abbott and Geneva charges in some detail in its Analysis to Aid Public Comment on the consent agreements, the Commission asserted that the challenged agreement imposed restraints beyond “what likely would [have been] available to the parties under a court-ordered preliminary in-

---

174 Complaint ¶ 34, Abbott Labs., No. C-3945; Complaint ¶ 34, Abbott Labs., No. C-3946; Complaint ¶ 29, Hoechst Marion Roussel, No. 9293.
175 Complaint ¶ 40, Abbott Labs., No. C-3945; Complaint ¶ 40, Abbott Labs., No. C-3946; Complaint ¶ 36, Hoechst Marion Roussel, No. 9293.
177 Anthony, Riddles and Lessons, supra note 2.
178 Complaint ¶ 39, Abbott Labs., No. C-3945; Complaint ¶ 39, Abbott Labs., No. C-3946; Complaint ¶ 34, Hoechst Marion Roussel, No. 9293.
suggestion, suggesting a possible standard for future acceptable agreements akin to stipulated preliminary injunctions. The FTC specifically noted that the parties agreed to: (1) bar Geneva’s entry beyond the pendency of the district court proceeding; (2) make payments in excess of a court-ordered bond to cover damages; (3) prevent Geneva from relinquishing its exclusivity rights; and (4) prohibit Geneva from marketing even non-infringing products. To be analogous to a stipulated preliminary injunction bond, payments would have to be refundable to the pioneer, in the event that it prevails in the litigation, and limited to the anticipated profits of the generic. 

While Abbott and Geneva agreed immediately to settle the FTC’s allegations, Hoechst and Andrx litigated with Commission staff for six months. The case was removed from adjudication in November 2000 when the staff reached agreement with Hoechst and Andrx on the terms of a consent agreement. The FTC, however, did not accept the consent for more than four months, making it public on the same day it brought suit against Schering. In accepting the consent for public comment, the FTC issued a statement that casts doubt on the actual impact of the Hoechst-Andrx agreement in the market. The Commission stated:

Based on the FTC’s investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD.

If there was no delay in entry by either Andrx or any other potential manufacturer, it is difficult to understand how the agreement diminished competition.

4. The Consent Orders

The FTC consent orders with Abbott and Geneva required Geneva to waive its 180-day marketing exclusivity, which the FTC said would allow other generic terazosin HCl tablet producers to immediately enter the market. In this respect, the order was similar to those with Boston Scientific

---

180 Id.
181 Id.
182 Id. at 17,504-05.
183 See Leary, Antitrust Issues, Part II, supra note 2; Anthony, Riddles and Lessons, supra note 2.
and Summit/VISX, where the respondents were forced to license intellectual property to others to create competition to resolve the antitrust allegations.\textsuperscript{187}

In prohibiting future conduct, the Abbott-Geneva and Hoechst-Andrx orders were narrowly tailored, providing guidance as to what conduct may be considered permissible and impermissible. The orders:

- bar agreements between brand name drug companies and potential generic competitors that restrict the generic from giving up Hatch-Waxman exclusivity rights or from entering the market with non-infringing drugs;
- require that agreements involving payments to a generic company to stay off the market be approved by the court when undertaken in the context of an interim settlement of patent litigation, with notice to the FTC to allow it to present its views to the court; and
- require 30 days notice to the FTC before entering such agreements in other contexts.\textsuperscript{188}

It is noteworthy that these FTC decrees do not ban all payments from pioneer drug companies to generics, but rather only ban restrictions on generics giving up their 180-day exclusivity rights and entering the market with non-infringing products. These decrees also only require notice to the FTC of other agreements with first filers that have the potential to create a bottleneck. The outright bans on waiving exclusivity and restricting entry with a non-infringing product clearly signal that the Commission views these provisions as not reasonably necessary to achieve any efficiency.\textsuperscript{189}

C. The FTC’s Latest Challenge to Permanent Settlements Raises Additional Issues

The same day that the FTC accepted the settlement of the Hoechst-Andrx suit, it instituted administrative litigation against Schering, Upsher-Smith, and AHP, challenging a permanent settlement agreement.\textsuperscript{190} The


\textsuperscript{189} A subsequent speech by one commissioner suggests that even restrictions on 180-day exclusivity waivers may not be “always pernicious.” Companies are also advised that settlements with reverse payments—from patent holders to alleged infringers—“should raise a flag but does not signal that barriers are down.” Leary, Antitrust Issues, supra note 2.

FTC alleged that Schering illegally paid Upsher-Smith and AHP to induce them to delay launching generic K-Dur 20, a potassium chloride supplement used to treat patients with low blood-potassium levels. According to the FTC complaint, Upsher-Smith filed an ANDA to market a generic potassium chloride supplement, submitted a Paragraph IV certification, and Schering promptly sued it for patent infringement. On the eve of their patent trial and well in advance of the expiration of the 30-month stay, Schering and Upsher-Smith agreed to a permanent settlement dismissing the infringement litigation. According to the FTC complaint, Schering agreed to pay Upsher-Smith $60 million in exchange for licenses to market five Upsher-Smith products and Upsher-Smith agreed not to enter the market until September 2001. If Schering had prevailed in the patent litigation, Upsher-Smith would have been prohibited from entering until September 2006, when the relevant patent would expire.

The FTC complaint further alleges that AHP submitted an ANDA after Upsher-Smith, intending to launch a generic potassium chloride supplement after Upsher-Smith’s 180-day exclusivity period expired. According to the FTC, Schering sued AHP for infringement, then agreed to settle, paying AHP up to $15 million, depending upon when AHP obtained FDA approval, and paying an additional $15 million for licenses to two other drugs. In exchange, AHP agreed not to introduce its generic drug until January 2004.

Notably, Schering, Upsher-Smith, and AHP reached settlements terminating their litigation in a manner that allowed the generics to enter the market years before the challenged patent otherwise would have expired, rather than continue costly, distracting litigation. In contrast, the Abbott-Geneva and Hoechst-Andrx cases challenged agreements that restricted marketing during the pendency of litigation. Whatever the analysis of those earlier cases, absent sham, these permanent settlements ought to be evaluated under the rule of reason for the reasons discussed in Part II of this Article.

Also in contrast to Abbott-Geneva and Hoechst-Andrx, there is no allegation that Schering restricted waiver or transfer of the 180-day exclusivity. Thus, another firm with a non-infringing generic could have acquired...
the 180-day exclusivity from Upsher-Smith and entered the market immediately. Indeed, if Upsher-Smith had another non-infringing product, it could have transferred that product as well as the 180-day exclusivity to another firm.

The FTC did allege that Schering prohibited AHP from entering with a generic drug “regardless of whether such product would infringe Schering’s patents.” At first glance, settlement agreements that prohibit a potential entrant from marketing not only an allegedly infringing generic product but also any other generic version—whether or not claimed to be infringing—seems offensive. Certainly, an agreement that on its face prohibits introduction of any non-infringing product may be condemned as extending a firm’s monopoly beyond the “scope of the patent.” On the other hand, the innovator forced to prosecute expensive infringement litigation may be entitled to some respite from retrying a nearly identical case by a firm modifying its product only slightly. Thus the pioneer firm may be entitled to some reasonable “fencing in” around a patent when settling litigation. An “ancillary restraint” that specifies the products covered by the agreement providing an objective description of what can and cannot be marketed seems reasonable.

1. The “But For” World

The most difficult issue confronting the antitrust plaintiff in cases of this sort is demonstrating that the effect of a settlement is to “diminish competition among entities that would have been actual or likely potential competitors” in the absence of the challenged settlement. That is, the government must establish that the challenged agreement lessened competition as compared to the “‘but for’ world that would have existed in the absence of the agreement” tested by the facts “as they appeared when the contract was made.” Alternatively, the leading antitrust law treatise instructs that a settlement is not anticompetitive if the parties had a “bona fide dispute,” the settlement is “a reasonable accommodation,” and the settlement is “not more anti-competitive than a likely outcome of the litigation.”

---

201 FTC Initial Decision at 113, Schering-Plough, No. 9297 (“It is not enough just to identify the subject of the agreement as ‘infringing products,’ as the parties involved in patent litigation necessarily disagree over what does or does not infringe the patent . . . . Such a specification would likely lead to renewed litigation, with its attendant costs and inefficiency.”); Rothery Storage & Van Co. v. Atlas Van Lines, 792 F.2d 210, 224 (D.C. Cir. 1986) (“The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose.”).
203 2002 FTC ANTITRUST Guidelines, supra note 65, ¶ 2046. See also CARL SHAPIRO, ANTITRUST LIMITS TO PATENT SETTLEMENTS (Berkeley Center for Law and Technology Working Paper 5-01, May 2001) (proposing a rule that would require proposed settlements generate at least as much surplus for consumers as they would have enjoyed had the settlement not been reached), available at http://www.berkeley.edu/institutes/bclt/pubs/wp/501.pdf.
The suggestion that the generic is a “potential competitor” merely because it has declared its intention to enter the market with a bio-equivalent drug that it certified as non-infringing is misleading. A firm must have the capability, as well as desire and intent, to enter the market. If the generic would have been found to infringe and would have been enjoined from competing, it was not a “likely potential competitor.”

The FTC appears to want to condemn all “reverse payments” from patent holders to alleged infringers on the theory that, absent such payments, the alleged infringer would have entered earlier. It is argued that “[i]f the settlement agreement . . . includes reverse payments, they must have been traded for something—and the most likely ‘something’ is further deferral of the generic entry date.”\(^\text{205}\) Indeed, FTC officials have argued that the presence of reverse payments “may provide an objective test for finding likely consumer harm.”\(^\text{206}\) On the other hand, absent the payment, there may well have been no settlement at all. It is not enough simply to assert that a settlement without such a payment and earlier entry would have been a less restrictive alternative. The government should have to show that a settlement without such a payment would have been practical in the circumstances based upon evidence of the firms’ willingness to compromise on such terms.

Alternatively, in order to prove the agreement had anticompetitive effects, the government could prove that the relevant patent was either invalid or not infringed, and that therefore the generic would have prevailed in the patent litigation. Even if the government does not introduce evidence regarding the likely outcome of the patent litigation in its case in chief, the ultimate burden of proof remains on the government.\(^\text{207}\) Thus, it should have to rebut defendants’ evidence that the pioneer firm would likely have prevailed in the patent case and the generic was thus unlikely to have become a competitor until after the patent expired.\(^\text{208}\) While the FTC has limited patent expertise, and inquiring into the likely outcome of the patent litigation may be burdensome and complicate an already complex antitrust trial, this is no excuse for ignoring the issue.

The government may also rely on subjective evidence of the parties’ views on the strength of the patent case, but such evidence is usually privi-
leged\textsuperscript{209} and likely to be equivocal. If one knew that the firms thought the pioneer or the generic had a 60\%, 70\%, or even 80\% chance of succeeding, it is not clear that such information would be dispositive of the antitrust litigation. While some might argue that a firm’s subjective or objective likelihood of success ought to impact the split of the patent life, in fact, the only possible outcomes of litigation are all or nothing, issuance of an injunction or denial of an injunction, allowing entry either only at the end of the patent life or immediately upon the conclusion of trial and all appeals. A settlement splitting the patent life in any manner ought therefore to be a reasonable compromise eliminating uncertainty for both firms. If anything, the fact that each firm had at least a reasonable probability of prevailing in the patent litigation should underscore the efficiency of settlement. Particularly where the pioneer firm has a very high expectation of prevailing, and the generic has little expectation of prevailing, but there is some gap in their views, agreement on a future entry date, with a payment that bridges the gap in expectations and reduces the pioneer firm’s uncertainty would seem to be procompetitive.

While the generic may have pleadings in the patent litigation asserting invalidity that can be used against it, such evidence will not go far against the pioneer firm. Objective evidence that the parties were in the market competing, had taken concrete steps to enter, or were willing to license on other terms, as in \textit{Boston Scientific} and \textit{Summit/VISX}, may also be informative.

2. Future Entry, Royalties and Reverse Payments

A straightforward settlement of a patent dispute that provides for generic royalty-free entry at some future date before the expiration of the patent with no payment between pioneer and generic firms seems presumptively benign.\textsuperscript{210} So might a similar settlement with a small royalty after entry. It would be bizarre if antitrust law were to condemn settlements of intellectual property litigation that provide for payments of royalties by alleged infringers to patent holders, just as it would be to condemn settlements that allow for entry after some future date. Presumably settlement agreements that combine these two features are also lawful.

Once one recognizes the possibility of royalties after entry, however, the analysis becomes much more complex as pioneer and generic firms may agree to delay entry in exchange for a lower royalty. The difference between such a scenario and “reverse payments” would seem to be primarily the time value of money. A royalty, however, likely impacts a firm’s marginal costs, and may substantially affect its incentives to compete.

\textsuperscript{209} While it may sometimes be in a firm’s interest to waive privilege, no inference should be made from a firm’s refusal to do so.

\textsuperscript{210} See FTC Initial Decision at 107, \textit{Schering-Plough}, No. 9297 (quoting Complaint Counsel Post-Trial Brief at 43, “This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone”).
Higher royalties generally make a firm a less effective competitor once it does enter. It is not clear \textit{a priori} whether society is better off with later entry and a lower royalty or earlier entry at a higher royalty rate. Similarly, it is not clear that society is better off prohibiting “reverse payments” that may put cash into the hands of generic competitors, where such payments may facilitate reaching terms of agreement rather than continuing to litigate patent disputes. At a minimum, payments less than the cost of litigation should be permitted. For all these reasons, the government’s single-minded focus on “reverse payments” seems misdirected.

3. Sham Side Payments

It may not even be obvious whether reverse payments are present in a transaction. As noted above, Schering obtained rights to five products from Upsher-Smith at the same time they resolved their patent litigation. FTC officials have recognized that “side deals” on issues not directly related to a dispute are a very common way to resolve otherwise irreconcilable differences.\footnote{Leary, Anitrust Issues, Part II, supra note 2.} That is, if a seller thinks a particular product is worth a lot more than a buyer does, the gap may be bridged if the buyer makes a reciprocal offer to sell a different product at a price the first seller finds favorable.\footnote{Id.}

The FTC alleges that the Schering payment to Upsher-Smith “was unrelated to the value of the products licensed.”\footnote{FTC Complaint ¶ 45, Schering-Plough Corp., No. 9297 (Apr. 2, 2001), available at http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf.} If that allegation were proven either by subjective evidence of Schering’s and Upsher’s intent or by objective evidence available to Schering and Upsher at the time of the agreement on the value of the intellectual property, this point would be probative. If the payment were a sham, it ought to be condemned. On the other hand, if the pioneer firm had a good faith belief that it paid fair value for the licensed intellectual property, the payment should be competitively neutral.\footnote{See FTC Initial Decision at 107, Schering-Plough Corp., No. 9297 (June 27, 2002), available at http://www.ftc.gov/os/adjppts/02927/020627id.pdf. (“The fact testimony at trial was unrebutted and credible that the licensing agreement was a bona-fide arms-length transaction . . . [and was corroborated by] contemporaneous documentary evidence.”).}

The further FTC allegations that the licensed products proved post-hoc to be “of little value” to Schering as Schering made “minimal sales” of one licensed product and “never sold” the other products,\footnote{Complaint ¶ 46, Schering-Plough, No. 9297.} should be of little relevance. The legality of the settlement agreement should be tested by the facts as they appeared when the agreement was made and not by subsequent events. Indeed, only a small percentage of pharmaceutical products are ever successful, and bad business judgment should not lead to antitrust liability. The fact that the history of negotiations shows that there was an initial demand for a reverse payment that matches the amount paid should not be surprising where the side deal is intended to
create value in order to bridge the gap between the firms’ expectations regarding likelihood of success in the patent litigation in order to reach an acceptable settlement.

D. The Private Litigation

Several lower courts have addressed the conduct at issue in *Abbott-Geneva* and *Hoechst-Andrx*. Like the FTC, these courts upheld Commission claims and condemned the conduct. Some have applied the *per se* label to their analysis, but those cases should not be overread. The decisions generally provide support for the proposition that it is appropriate to consider the “but for” world before condemning a settlement agreement. They also distinguish between interim settlements and those that fully resolve pending litigation.

In the first judicial decision, in *Biovail Corp. Int’l v. Hoechst Aktiengesellschaft*, a federal district court in New Jersey denied a motion to dismiss antitrust claims brought by Biovail, which was seeking approval to market a generic Cardizem CD allegedly blocked by the Hoechst-Andrx agreement. The court held that 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 a willful attempt to maintain or obtain a monopoly.” The court specifically rejected Hoechst’s argument that Biovail’s claims were “nothing more than a frustration with the statutory exclusivity period” granted by the Hatch-Waxman Act. The court reasoned that Biovail’s claims instead were that the defendants were “taking advantage of the exclusivity period in an anticompetitive manner.”

A federal district court in Michigan is hearing *In re Cardizem CD Antitrust Litigation*—consolidated cases brought by purchasers of Cardizem CD. That court granted partial summary judgment for the plaintiff purchasers, concluding that the Hoechst-Andrx agreement was “unlawful on its face and is a *per se* violation of Section 1 of the Sherman Act.” The court held that the agreement was between horizontal competitors to minimize generic competition and to allocate the entire U.S. market for Cardizem CD.

---


218 *Id.* at 767.

219 *Id.* at 768.

220 *Id.*


222 *Id.* at 699.
to Hoechst.  

The Michigan court, however, carefully analyzed the “but for” world in the absence of the agreement and it is far from clear that its reasoning would apply to a case permanently settling litigation. The court reasoned that Hoechst and Andrx were potential rivals, specifically rejecting arguments that Andrx was not a potential competitor since if it had attempted to compete it might have been found liable for infringing Hoechst’s patents. The court reasoned that “but for” the agreement: (1) Andrx would have marketed its generic after the 30 month stay expired as it had represented to the court presiding over the patent case; (2) Hoechst would not have paid Andrx millions of dollars to stay off the market if it was not reasonably probable that Andrx would enter the market; and (3) other generics would not have been delayed as long as they were as a result of the Hoechst-Andrx agreement.

The court concluded as a matter of law that the agreement was not reasonably ancillary to procompetitive activity rather than a “naked” restraint of trade. Like the FTC, the court rejected arguments that the Hoechst-Andrx agreement: (1) maintained the status quo like a preliminary injunction and fostered the expeditious resolution of the patent infringement dispute; (2) provided Andrx with capital to invent around Hoechst’s patent and enter the market sooner; and (3) provided Andrx with an opportunity to obtain a license to enter the market. The court reasoned that the plain terms of the agreement “belie the argument” that it was designed to enhance competition and thus ought to be analyzed under the rule of reason. In particular, the court noted that the Hoechst-Andrx agreement did not resolve pending litigation, and “[r]ather than facilitating or fostering an expeditious resolution” of the patent infringement suit, the agreement created the incentive to pursue the litigation beyond the district court and through the appellate courts.

A federal district court in Florida hearing In re Terazosin Hydrochloride Antitrust Litigation, similarly concluded that the Abbott-Geneva interim settlement agreement was per se illegal but reached that conclusion only after examining the defendants’ chief mitigating arguments. The court was “mindful that ‘the probability that anticompetitive consequences will result from a practice . . . must be balanced against its pro-competitive consequences.’” The court rejected the argument that the agreement was “reasonably ancillary to procompetitive activity,” reasoning that it did not resolve pending litigation but instead “tended to prolong the dispute.”

223 Id.
224 Id. at 677-79, 700 (denying motion to dismiss).
225 Id. at 703.
228 Id. at 1350.
229 Id.
In the only appellate decision to date, Andrx Pharmaceuticals, Inc. v. Biovail Corp., the D.C. Circuit Court of Appeals reversed a district court decision dismissing with prejudice—on standing grounds—Biovail’s antitrust claim against Andrx based on the Hoechst-Andrx agreement. The decision provides direction on the analysis of the merits in several respects. For instance, the D.C. Circuit reasoned that “a reasonable juror” could conclude that Andrx’s argument that any rational actor would not market its generic until the patent infringement suit was resolved was contradicted by the payments not to enter the market. The Court reasoned: “[o]ne can fairly infer from these facts . . . that but for the [a]greement, Andrx would have entered the market.”

The decision also advises that anticompetitive provisions in the Hoechst-Andrx agreement “were not necessarily ancillary restraints but rather could reasonably be viewed as an attempt to allocate market share and preserve monopolistic competition.”

At first glance, recent judicial precedent may seem to provide some support for proponents of per se treatment of settlement agreements. But the cases only address interim settlement agreements and their very reasoning suggests application of the rule of reason analysis where a party challenges a permanent settlement agreement that allows entry before a patent otherwise expires.

VI. THE NOERR-PENNINGTON DOCTRINE MAY IMMUNIZE SOME AGREEMENTS

A potentially dispositive defense in these cases is the claim that Noerr-Pennington immunity protects any settlement of litigation unless the underlying lawsuit is objectively baseless and the litigants attempt to interfere directly with a competitor’s business by using the legal process, rather than its outcome, as an anticompetitive weapon. That judicial doctrine limits antitrust laws by immunizing private action aimed at influencing the government, in order to preserve the Constitutional right to petition, even when such actions may restrain trade.

Just as courts have extended Noerr protection to prelitigation

---

231 Id.
232 Id. at 809.
233 Id. See also In re Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740, 749-50 (E.D.N.Y. 2001) (relying on this language in rejecting the argument that federal patent law is a necessary element of a well pleaded state antitrust complaint, concluding one can state a claim for antitrust injury without first demonstrating that the pioneer drug company’s patent is invalid).
234 Andrx Pharm., 256 F.3d at 811.
235 See infra notes 237-43 and accompanying text.
threats, they could extend it to out-of-court settlements of litigation "incidental" to a valid effort to influence government action. Where the competitive harm flows from a private settlement of which the court is not aware, however, it may be difficult to justify applying the doctrine. Where a settlement is reached without judicial involvement and the litigation is dismissed pursuant to stipulation under Federal Rule of Civil Procedure 41(a)(1), it would appear to be more akin to a private contract for which part of the consideration is dismissal of the lawsuit, rather than conduct incidental to petitioning. On the other hand, absent sham litigation, if a settlement agreement is entered at the direction of, or under the supervision of, the court, or the agreement is only effective if approved by the court or entered as an order by the court in which the infringement litigation is pending, the restraint should be seen as "the result of valid governmental action" and the Noerr doctrine should protect the conduct.

In the Abbott-Geneva and Hoechst-Andrx actions, the FTC appears to have been significantly influenced by the fact that the agreements were not approved by or even disclosed to the court. In Abbott, the Commission specifically alleged that "[t]he court hearing the patent litigation was not made aware of the respondent’s Agreement." As one commissioner subse-

---

237 See, e.g., Cardtoon v. Major League Baseball Players Ass’n, 182 F.3d 1132 (10th Cir. 1999); McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1560 n.11 (11th Cir. 1992); Coastal States Mkts., Inc. v. Hunt, 694 F.2d 1358, 1366-67 (5th Cir. 1983). Cf. Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988) ("where, independent of any government action, the anticompetitive restraint results directly from private action, the restraint cannot form the basis for antitrust liability if it is "incidental" to a valid effort to influence governmental action.").


239 Rule 41(a)(1) provides for dismissal “without order of the court … by filing of a stipulation by all parties who have appeared in the action.” Id.


241 See In re New Mexico Natural Gas Antitrust Litig., 1982-1 Trade Cas. (CCH) ¶ 64,685 (D.N.M. 1982) (reasoning that "[i]n this case if the defendants had settled their litigation by agreement among themselves and merely filed a notice of dismissal with the Court, there would be no issue of Noerr-Pennington protection. However, the settlement was submitted to the Court and approved in an order of dismissal of the case."). See also Speed Shore Corp. v. Denda, 197 U.S.P.Q. 526 (C.D. Cal. 1977), aff’d on other grounds, 605 F.2d 469 (9th Cir. 1979) (upholding a settlement agreement against a claim of misuse on the ground that the settlement had been approved by the trial judge). See also Wilson, supra note 1, at 1250 (“If a court orders or approves of such an agreement . . . , then the agreement is probably immune from antitrust liability.”).

242 FTC Complaint, Abbott Labs., 2000 WL 681849, No. C-3945 (F.T.C. May 22, 2000), avail-
quently explained: “[a] judge’s review, which among other things, takes the public interest . . . into account, distinguishes this private agreement. . . . [W]ith purely private agreements, that is, those lacking any court review, the temptation is to reach an agreement at the public’s expense.” The commissioner advised: “proceed with caution when considering private preliminary or permanent settlements of patent litigation that are not reviewed by a Court.” In reality, of course, judicial review may be little more than a rubber stamp when lawyers take a potential dispute off a harried court’s crowded docket. But antitrust enforcement should no more question the thoroughness of judicial review in approving a settlement agreement than it should question any other judicial action.

VII. CONTINUED GOVERNMENT SCRUTINY IS LIKELY

It is evident that the government is extremely interested in this area, and is likely to continue to scrutinize patent settlements as well as unilateral conduct by drug manufacturers allegedly designed to forestall competition. Bush Administration FTC Chair Timothy Muris praised the Clinton Administration for its efforts in looking at potential abuses of the Hatch-Waxman Act and said publicly that the Bush Administration will continue those efforts.

In written testimony before Congress, the FTC has argued that the benefits to consumers from generic competition are “dramatic.” The FTC has also argued that with patents on brand-name drugs accounting for nearly $20 billion in sales expiring over the next five years, there is an enormous opportunity for the generic drug industry. The Commission has suggested the patent settlement issues are “a tremendously important area, with high stakes to consumers and our Nation’s efforts to control medical costs.”

The FTC is currently conducting a comprehensive study to examine whether pioneer and generic drug manufacturers have entered into agreements, or have used other strategies, to delay competition from generic versions of patent-protected drugs. Among the issues the FTC is explor-

---

244 Anthony, Riddles and Lessons, supra note 2.
245 Id.
248 Id.
ing in that study is whether drug companies have “manipulated” provisions of the Hatch-Waxman Act to delay the marketing of generic drugs. The FTC characterizes this study as a targeted evaluation of the effectiveness of the Hatch-Waxman Act in order to provide a more complete picture of how generic competition has developed under the Act, and whether the Act has unintentionally enabled anticompetitive strategies that delay or deter market entry by generic drugs. But the Commission’s announcement makes clear that the documents and information obtained may “help the FTC determine whether agreements or other strategies are being used to delay generic drug competition and thus . . . merit law enforcement action.”

Legislation is also under consideration to facilitate federal antitrust enforcement by giving federal antitrust authorities early access to agreements between pioneer manufacturers and potential generic competitors. A Senate bill reported favorably by the Senate Judiciary Committee, in 2001, would require notification of agreements between a company that owns or controls a listed patent for a drug or holds the NDA and any company seeking to manufacture the generic version of that drug where the agreement concerns the manufacture, marketing, or sale of either the brand name or generic versions of the drug, or where the agreement relates to the 180-day exclusivity period. The stated purpose of the notification is to ensure that enforcement agencies have an early opportunity to consider whether such agreements may violate existing antitrust laws.

The government already has means to learn about competitively significant patent settlements. Exclusive licenses that meet the Hart-Scott-Rodino Act’s statutory size-of-person and size-of-transaction thresholds already require pre-consummation notification. Moreover, patent inter-
ference settlements must be filed with the USPTO, from which the government may obtain them for review.

In light of the tremendous scrutiny being applied to patent litigation settlements, sensible firms—particularly in the pharmaceutical and medical device industries—are well advised to seek antitrust advice before entering into any settlement that might arguably lessen competition, whether through merger or acquisition, patent pool, or agreement not to compete for some period of time.

35 U.S.C. § 135(c) (1995) (detailing “any agreement or understanding between parties to an interference, including any collateral agreements referred to therein, made in connection with or in contemplation of the termination of the interference” must be filed with the USPTO, and failure to file renders the agreement and related patents unenforceable). See CTS Corp. v. Piher Int’l Corp., 727 F.2d 1550, 1555 (Fed. Cir. 1984) (suggesting that § 135(c) was designed to prevent the use of anticompetitive settlement agreements); accord United States v. FMC Corp., 717 F.2d 775, 777-78 (3d Cir. 1983).