PART THREE

2003 ANTITRUST DEVELOPMENTS IN REGULATED INDUSTRIES

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I. INTRODUCTION

Professor Hovenkamp's article identifies certain fundamental economic rationales for industry-specific regulation of competition by legislative bodies. For example, regulation is necessary in order for free markets to function properly by correcting for market failures such as free-riding

and information asymmetries.[221] The need for governmental forces to intervene when market forces have failed likewise justifies the twin pillars of U.S. antitrust law. First, Section 1 of the Sherman Act condemns contracts, combinations, and conspiracies in restraint of trade, responding to the breakdown of normal competitive conditions when firms act in concert rather than independently out of rational economic self-interest (*e.g.*, price-fixing cartels). Second, Section 2 of the Sherman Act condemns unlawful monopolization, which occurs when a single firm is able, through anticompetitive conduct, to set prices without regard to market forces. Regulation also reflects policy choices made by elected representatives of the citizenry, a tenet of western civilization even more venerable than antitrust.[222]

Regulation thus exists alongside antitrust in free markets. The extent to which regulation should be allowed to *displace* antitrust as the primary means of furthering competition policy objectives has varied from industry to industry. This article focuses on three industries subject to legislative regulation of competition: pharmaceuticals, telecommunications, and securities. The proper role of antitrust in each of these industries recently has been the subject of judicial, administrative, and political commentary. Part II of this article discusses antitrust claims arising out of the exclusion of generic pharmaceutical competition, in part through the mechanism of a statute commonly known as the Hatch-Waxman Act. Part III discusses recent antitrust cases involving the telecommunications industry, including cases regarding the so-called filed-rate doctrine, and the Supreme Court's decision in *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*.[223] Finally, Part IV discusses recent cases granting implied antitrust immunity to conduct governed by the U.S. Securities and Exchange Commission.

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[221] Herbert Hovenkamp, *Antitrust and the Regulatory Enterprise*, 2004 COLUM. BUS. L. REV. 335, 336.

[222] *See id.* at 105.

[223] 124 S. Ct. 872 (2004).

II. PHARMACEUTICALS

Under the Federal Food, Drug and Cosmetic Act ("FDCA"), the U.S. Food and Drug Administration ("FDA") must approve all drugs before they can be marketed.[224] The Hatch-Waxman Act (the "Act")[225] amended the FDCA and governs, inter alia, the FDA's approval of generic drugs for marketing. Under the Act, a company seeking to market a generic copy of an approved brand name drug may submit an "Abbreviated New Drug Application" ("ANDA") to the FDA.[226] If the FDA approves an ANDA and rates the generic drug "AB", pharmacists are allowed to substitute the generic version of the drug for the brand name product where permitted or required by state law.[227] In order to demonstrate the generic drug's safety and efficacy, the ANDA is entitled to rely on the clinical studies performed by the brand name manufacturer.[228] Thus, the Act grants generic manufacturers free access to their brand name competitors' proprietary data, which in turn enables the generic manufacturers to market lower-priced drugs.[229]

The Act, however, does not disregard the patent rights of brand name manufacturers. Those manufacturers are required to list in the FDA's "Orange Book"[230] all patents, if any, that cover a particular brand name drug and its uses.[231] Once a patent is listed as covering a drug for which an

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[224] 21 U.S.C.A. § 355(a) (West Supp. 2003).

[225] The official name of the Act is the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A § 355(j) (West Supp. 2003).

[226] 21 U.S.C.A. § 355(j) (West Supp. 2003).

[227] Bristol-Myers Squibb Co. v. Shalala, 892 F. Supp. 295, 296 (D.D.C. 1995).

[228] FED TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, *at* http://www.ftc.gov/os/2003/10/innovationrptsummary.pdf (last visited Mar. 9, 2004).

[229] *Id.* at 9 & n.38.

[230] Formally entitled "Approved Drug Products with Therapeutic Equivalence Evaluations."

[231] 21 U.S.C.A § 355 (b)(1) (West Supp. 2003).

ANDA filer seeks generic approval, the ANDA filer has the option to certify that the filer will not market its product until the listed patent has expired (a "Paragraph III certification"[232]); if it does so, the FDA will not approve the ANDA until the listed patent expires.[233] Alternatively, if the ANDA applicant wishes to market its product *prior* to patent expiration, it must submit a "Paragraph IV certification" that the brand name manufacturer's patent is invalid or will not be infringed by the marketing of the ANDA product.[234] The Act provides that a Paragraph IV certification is by itself an artificial act of patent infringement that gives the patentee a right to sue under federal patent law.[235] If the patentee then sues the ANDA applicant for patent infringement within forty-five days, the FDA by law cannot give final approval to market the generic product until a "substantive determination that there is no cause of action for patent infringement," or until thirty months have elapsed (a so-called thirty month stay), whichever occurs first.[236]

Not surprisingly, some of the patent infringement lawsuits brought under the Hatch-Waxman Act have resulted in settlement. In some instances, these settlements have included the generic manufacturer's agreement not to market its allegedly infringing generic product either for the full term of the patent, or for a lesser period followed by a license under the patent (a "delayed license"). The settlements sometimes have included "reverse payments" from the patentee to the generic, so-called because in a typical patent litigation settlement the alleged infringer pays the patentee.

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[232] 21 U.S.C.A. § 355(j)(2)(A)(iii) (West Supp. 2003).

[233] 21 U.S.C.A. § 355(j)(5)(B)(ii) (West Supp. 2003).

[234] 21 U.S.C.A. § 355(j)(2)(A)(vii)(IV) (West Supp. 2003).

[235] 35 U.S.C. § 271(e)(2)(A) (2000). It is "artificial" because it is purely a creature of statute; because the generic manufacturer has yet to receive marketing approval from the FDA, there are no infringing sales of the drug.

[236] 21 U.S.C. § 355(j)(5)(B)(iii) (West Supp. 2003). Such a determination could be made by a district court or by an appellate court. *Id.*

If pharmaceutical manufacturers are merely doing what the Act allows, can they be acting in violation of federal antitrust law? As shown below, recent judicial and administrative agency decisions have indicated that there is indeed a potential for antitrust liability under these circumstances, although there are differing views as to how the antitrust laws should be applied.

A. Orange Book Listings

To date, courts that have addressed the issue have held that Orange Book listings are not immunized as governmental petitioning activity under the doctrine of *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*[237] because the FDA is required to accept a patentee's listing without making any independent assessment as to the validity of the patentee's representations as to the scope of the patent.[238] For a complete discussion of this issue, and of *Noerr* immunity in general, see the 2002 Milton Handler Annual Antitrust Review.[239]

If an Orange Book listing is not immune from antitrust scrutiny, then the next question is when such a listing will be deemed anticompetitive conduct under the antitrust laws. In that regard, it is noteworthy that the Hatch-Waxman Act *requires* the patentee to list "any patent which claims the [brand name] drug . . . or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted."[240] In the past year, the U.S. Federal Trade Commission ("FTC") has indicated that it will not challenge the listing where the

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[237] 365 U.S. 127 (1961).

[238] *In re* Buspirone Antitrust Litig., 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002); Organon Inc. v. Mylan Pharms., Inc., 293 F. Supp. 2d 453 (D.N.J. 2003).

[239] Timothy J. Muris, *Looking Forward: The Federal Trade Commission and the Future Development of U.S. Competition Policy*, 2003 COLUM. BUS. L. REV. 371, 371-73; David S. Copeland et al., *Part Four: Antitrust Immunities at the Crossroads: The Current Status of the* Noerr *and State Action Doctrines*, 2003 COLUM. BUS. L. REV. 547.

[240] 21 U.S.C.A. § 355(b)(1) (West Supp. 2003).

patentee has a "reasonable belief" that the patent meets the Hatch-Waxman Act's listing requirements.[241] A similar standard of antitrust liability governs the filing of the patent infringement suit. Bringing a lawsuit can be held to constitute exclusionary conduct in violation of the Sherman Act only if the suit is "objectively baseless," i.e., "no reasonable litigant could realistically expect success on the merits."[242]

At the end of 2003, one district c7ourt dismissed an antitrust claim where the patentee had a reasonable basis both for listing the patent and for bringing the infringement suit.[243] Thus, so long as the patentee reasonably believes, assessed objectively, that the patent should be listed, the listing will not violate the antitrust laws.

1. *In re Bristol-Myers Squibb*

In *In re Bristol-Myers Squibb Co.*,[244] the FTC alleged that BMS improperly listed patents in the Orange Book with respect to three of its products: BuSpar (buspirone), Taxol (paclitaxel) and Platinol (cisplatin). In its Complaint, the

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[241] Analysis to Aid Public Comment at 9, *In re* Bristol-Myers Squibb Co., FTC File Nos. 001-0221, 011-0046 and 021-0181 (filed Mar. 7, 2003), *at* http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm.

[242] Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56, 60 (1993) ("*PRE*"); *see also Buspirone*, 185 F. Supp. 2d at 375 (noting the similarity of the *PRE* standard to the listing requirements of the Hatch-Waxman Act); *but cf.* USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Council, 31 F.3d 800, 810-11 (9th Cir. 1994) (declining to apply *PRE* to a series of suits against competitors, and asking instead whether the evidence demonstrates a "pattern or practice of successive filings undertaken essentially for purposes of harassment"); Prime Time 24 Joint Venture v. NBC, 219 F.3d 92, 101 (2d Cir. 2000). In addition, *PRE* has a second, subjective prong. The lawsuit also must be brought for an improper motive, i.e., "to interfere directly with the business relationships of a competitor through the use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." 508 U.S. at 60-61 (citations omitted).

[243] *Organon*, 293 F. Supp.2d 453.

[244] *In re* Bristol-Myers Squibb Co., FTC Docket Nos. 001-0221, 011-0046 and 021-0181 (filed March 7, 2003).

FTC alleged that, "[o]ver the course of the past decade, Bristol-Myers Squibb ("BMS") engaged in a series of anticompetitive acts" including, inter alia, "misle[ading] the FDA about the scope, validity, and enforceability of its patents" when listing them in the Orange Book, "abus[ing] FDA regulations to block generic entry," and "fil[ing] objectively baseless patent infringement lawsuits in federal court against would-be generic competitors."[245]

With respect to buspirone, the complaint alleged that BMS submitted directly contradictory statements to the United States Patent and Trademark Office ("PTO") on the one hand (to obtain a patent), and the FDA on the other (to have the patent listed in the Orange Book), regarding whether its patent covered buspirone.[246] The complaint alleged that BMS's subsequent patent infringement suits must have been objectively baseless because, based on the position BMS had already taken with the FDA in its Orange Book listing, "the patent could not be both valid and infringed."[247] The FTC claimed that if the patent was infringed, i.e., if it covered a use of buspirone as asserted by BMS in its Orange Book listing, then it had to be invalid because the PTO had held that the use of buspirone to treat anxiety was no longer patentable.[248] According to the PTO, the only way for the patent to be valid was if it covered only a use of a "metabolite" of buspirone,[249] in which case it could not reasonably be said to cover generic versions of buspirone.[250]

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[245] Complaint, *In re* Bristol Myers Squibb Co., ¶ 2 *at* http://www.ftc.gov/os/2003/03/bristolmyerssquibbcmp.pdf (last visited Mar. 10, 2004).

[246] *Id.* ¶¶ 37-43, 45, 47, 53, 56, 58.

[247] *Id.* ¶ 59.

[248] *Id.*

[249] A metabolite is a substance produced by the human body's metabolizing the "prodrug", buspirone in this case. The metabolite may have therapeutic properties in addition to those of the prodrug, and thus may be an FDA-approved drug product separate and distinct from the prodrug.

[250] *See* Complaint ¶ 51.

With respect to paclitaxel, the Complaint alleged that BMS obtained two patents, relating to methods of administering paclitaxel, through inequitable conduct.[251] The FTC asserted that BMS knew that its patents were unenforceable due to inequitable conduct and therefore "BMS could not reasonably believe that the patents were listable under the FDA's Orange Book regulations."[252] Finally, the Complaint asserted that BMS's subsequent listing of its cisplatin patent in the Orange Book was "wrongful" because "BMS submitted the patent for listing "without a reasonable good faith belief" that the patent was "valid."[253]

The FTC's Analysis to Aid Public Comment regarding the Consent Decree in *In re BMS* suggests that the FTC will not scrutinize an Orange Book listing merely because the listed patent ultimately is found invalid or unenforceable. The FTC recognizes that "the Hatch-Waxman certification process contemplates that some patents that are listed ultimately may be found invalid or unenforceable."[254] Rather, the FTC's scrutiny will focus on whether the NDA holder that lists the patent does so "without a reasonable belief that the patent meets the listing requirements in order to use the thirty-month stay provision as a weapon against generic rivals."[255] To determine whether the patentee had the appropriate reasonable belief, the FTC is likely to focus on the extent to which information submitted by the patentee to the PTO during patent prosecution contradicts or

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[251] *Id.* ¶¶ 81-89.

[252] *Id.* ¶ 90.

[253] *Id.* ¶¶ 122, 149. The FTC alleged that, when obtaining the patent, BMS made an argument to the PTO regarding patentability that BMS could not itself have believed, claiming that the patent's acknowledgment of the drug's light sensitivity "patently distinguished" its claims from those of BMS's previous patents, even though the sensitivity of cisplatin compounds to light had been known for 30 years. *Id.* ¶ 114.

[254] Analysis to Aid Public Comment at 9, *In re* Bristol-Myers Squibb Co., FTC Docket Nos. 001-0221, 011-0046 and 021-0181 (filed Mar. 7, 2003), *at* http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm.

[255] *Id.*

conflicts with information provided to the FDA for its Orange Book listing.

2. *Organon*

In *Organon Inc. v. Mylan Pharms., Inc.*,[256] defendants, the antitrust counterclaimants, alleged that Organon had improperly listed its patent knowingly and in bad faith.[257] Defendants alleged that Organon knew that the patent covered only an "off-label use," which is a use not approved by the FDA and for which listing allegedly was improper under the Hatch-Waxman Act and FDA regulations.

The Court dismissed defendants' antitrust counterclaims pursuant to Fed. R. Civ. P. 12(b)(6) because Organon had a "reasonable basis" for listing the patent.[258] Organon reasonably read the statute and regulations to require listing a patent that claimed an off-label, unapproved use.[259] First, the plain language of the statute required listing: "The applicant shall file with the [New Drug Application ("NDA")] . . . any patent which claims the drug for which the applicant submitted the [NDA] [an approved use] *or* which claims a method of using such drug [an unapproved use]."[260] Second, the FDA regulations implementing the Hatch-Waxman listing provisions were ambiguous as to whether listing was proper for off-label uses.[261] The regulations required listing "only [for] those patents that claim indications or other conditions of use of a pending or approved application."[262] The court held the phrase "or other conditions of use" as being capable of two interpretations. On the one hand, it could be interpreted to mean off-label uses. On the other, it could be read as modified by the phrase "of a pending or approved application," and thus be

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[256] 293 F. Supp.2d 453 (D.N.J. 2003).

[257] *Id.* at 459.

[258] *Id.*

[259] *Id.* at 459-60.

[260] 21 U.S.C.A. § 355(b)(1) (West Supp. 2003) (emphasis added).

[261] *Organon*, 293 F. Supp. 2d at 460.

[262] 21 C.F.R. § 314.53(b) (2004).

limited to FDA-approved uses.[263] The court noted that the FDA itself had "tacitly acknowledged" the regulation's ambiguity when it proposed an amendment clarifying the rule.[264]

It is important to note that, although the court resolved the issue of whether Organon had a reasonable basis for listing on a motion to dismiss, it could do so because the off-label use issue presented a pure question of statutory interpretation.[265] In general, unless the motion to dismiss can be decided based on a pure question of law, or on the public record, courts may be reluctant to resolve the reasonableness of an Orange Book listing on a Rule 12(b)(6) motion to dismiss, at least absent prior adjudications of the patent's scope or validity.

The court also held that Organon had an objective basis for bringing the patent infringement suit because at the time it did so, "three district courts had denied pre-trial motions in similar cases."[266] In addition, the Court of Appeals for the Federal Circuit did not rule whether allegations mirroring those in *Organon* stated a claim for infringement until one month after the *Organon* court granted summary judgment of noninfringement. Thus, "[i]n light of the uncertain state of the law at the time with regard to induced infringement claims, this Court cannot conclude that Organon lacked an objectively reasonable basis to proceed with its claims against the generic manufacturers."[267]

B. Agreements Not to Market

Settlements of Hatch-Waxman patent litigation may unlawfully exclude generic competition where they contain an agreement by the generic that it will not market its product(s). Although agreements not to market between horizontal competitors are per se unlawful under the

[263] *Organon*, 293 F. Supp.2d at 460.

[264] *Id.*

[265] *Id.* at 459-60.

[266] *Id.* at 461.

[267] *Id.* at 462.

antitrust laws,[268] patent-holders are entitled to exclude competition within the scope of their patent.[269] In 2003, a flurry of judicial and administrative decisions elaborated on the circumstances under which such exclusion gives rise to an antitrust violation.

In *In re Cardizem CD Antitrust Litig.*, ("*Cardizem*"),[270] the Court of Appeals for the Sixth Circuit held the settlement agreement at issue to be per se unlawful because it was an agreement by the generic not to market (1) made in exchange for millions of dollars in "reverse payments", which (2) foreclosed competition not only from products that potentially infringed the brand name manufacturer's patents, but also from potentially non-infringing products as well.[271] However, in *Valley Drug Co. v. Geneva Pharms., Inc. (In re Terazosin Hydrochloride Antitrust Litig.)*

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[268] United States v. Topco Assocs., 405 U.S. 596, 608 (1972).

[269] SCM v. Xerox, 645 F.2d 1195 (2d Cir. 1981).

[270] 332 F.3d 896 (6th Cir. 2003).

[271] *Id.* at 907-08. Foreclosure of competition from potentially non-infringing products resulted from a provision in the Hatch-Waxman Act that grants 180 days of exclusive marketing rights to the first generic manufacturer to file a Paragraph IV ANDA, such as the generic in *Cardizem*. While this provision is in effect, the FDA by law is not permitted to approve any other competing generic drugs. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998). Under the provisions governing the start of the 180-day period in effect at the time of the *Cardizem* settlement, the 180-day period would have begun to run upon "first commercial marketing" of the generic product, or upon a court decision "holding the patent . . . invalid or not infringed," whichever came first. 21 U.S.C.A. § 355 (j)(5)(B)(iv) (West Supp. 2003). A patent litigation settlement that is dismissed without prejudice does not mean that the patent is invalid or not infringed. Coupled with an agreement not to market and an agreement not to waive or otherwise transfer the exclusivity rights, the settlement avoids triggering the 180-day exclusivity period. The longer it takes for the 180-day period to be triggered, the longer generic competition is kept out of the market, possibly as long as until patent expiration. *See* 21 U.S.C. § 355(j)(5)(D)(i)(VI)(2003) (eliminating the 180-day exclusivity period on the date of patent expiration). Additionally, the generic in *Cardizem* agreed not to market *any* generic product, regardless of whether it was subject to a claim of patent infringement. *See* 332 F.3d 896, 908 n.13.

("Terazosin"),[272] the Eleventh Circuit reversed the district court's holding that a similar agreement was per se unlawful because the district court failed to consider whether the allegedly excluded generic drugs would have been lawfully excluded anyway by the patent. Similarly, in *In re Ciprofloxacin Hydrochloride Antitrust Litig. ("Cipro")*,[273] the court declined to extend per se illegality to an agreement not to market where the plaintiff failed to produce evidence that the agreement exceeded the patent's lawful scope.

The FTC has taken a different approach than the courts, declining to extend per se illegality to patent litigation settlements under Hatch-Waxman, but also warning that it would scrutinize any settlement involving reverse payments in exchange for an agreement not to market, and that it would do so without consideration of the patent's lawful ability to exclude competition.[274] Thus, the FTC has indicated that, under appropriate circumstances, it is prepared to find that agreements to settle Hatch-Waxman patent litigation may violate Section 1 of the Sherman Act and Section 5 of the FTC Act.[275] In addition, according to the recently passed "Medicare Prescription Drug, Improvement and Modernization Act of 2003,"[276] agreements settling Hatch-Waxman patent litigation must be submitted to the FTC by the parties, a requirement that will facilitate the FTC's ability to bring prompt challenges to such agreements.

1. *Cardizem*

The *Cardizem* litigation arose from an agreement settling claims in patent infringement litigation brought by Hoechst Marion Roussel ("HMR") against Andrx Pharmaceuticals, the first paragraph IV ANDA-filer for a generic version of HMR's Cardizem CD, used in the treatment of hypertension

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[272] 344 F.3d 1294 (11th Cir. 2003).

[273] 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

[274] *In re* Schering-Plough Corp., FTC Docket No. 9297 (Dec. 8, 2003), *at* http://www.ftc.gov/os/adjpro/d9297 (last visited Mar. 10, 2003).

[275] *Id.* at 86.

[276] Pub. L. No. 108-173, 117 Stat. 2066 (2003).

and angina. During the patent litigation, Andrx agreed not to market its generic version of Cardizem CD until the earliest of: (1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; or (3) HMR entering into a license agreement with a third party. Andrx also agreed to dismiss its antitrust and unfair competition counter-claims, to diligently prosecute its ANDA, and to not "'relinquish or otherwise compromise any right accruing thereunder or pertaining thereto,' including its 180-day period of exclusivity."[277] In exchange, HMR agreed to make quarterly "interim" payments of $10 million to Andrx beginning on the date Andrx received final FDA approval. HMR also agreed to pay Andrx $100 million per year in the event that the patent litigation was decided in favor of Andrx, so long as Andrx abided by its agreement not to market any generic version of Cardizem CD.[278]

The 30-month stay of FDA approval expired on July 8, 1998, and the FDA granted final approval to Andrx's generic product the following day. Pursuant to their agreement, HMR began making the interim payments to Andrx, and Andrx refrained from marketing its product.[279] On September 11, 1998, Andrx supplemented its ANDA, seeking approval for a reformulated version. The FDA granted final approval to the reformulated version nine months later. On June 23, 1999, Andrx began selling a generic version of Cardizem CD for the first time.[280]

Andrx and HMR were sued by direct and indirect purchasers of Cardizem CD. The "foundation" of the various antitrust plaintiffs' claims was the allegation that, "but for the Agreement, specifically the payment of $40 million per year, Andrx would have brought its generic product to

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[277] 332 F.3d at 902. For a discussion of the exclusionary effect of an agreement not to transfer the 180-day exclusivity rights see *supra* note 271.

[278] *Id.* at 902-03.

[279] *Id.* at 903.

[280] *Id.*

market once it received FDA approval and at a lower price than the patented Cardizem CD sold by HMR."[281] Plaintiffs also alleged that the consequent delay in the triggering of Andrx's 180 days of exclusivity, which Andrx agreed not to relinquish or transfer, prevented the entry of other generic competitors.[282] "The district court concluded that the Agreement, specifically the fact that HMR paid Andrx $10 million per quarter not to enter the market with its generic version of Cardizem CD, was a naked, horizontal restraint of trade and, as such, per se illegal."[283]

On appeal, the Sixth Circuit held that the agreement was, "at its core, a horizontal agreement to eliminate competition . . . a classic example of a per se illegal restraint of trade."[284] The court found dispositive that (1) HMR paid its only competitor to stay off the market, and (2) the provision preventing Andrx from relinquishing or transferring its right to 180 days of marketing exclusivity foreclosed competition from other manufacturers.[285] The court rejected the argument that it should not apply per se treatment to a novel area of law like Hatch-Waxman, citing *Arizona v. Maricopa Cty. Med. Soc.*,[286] in which the Supreme Court stated that "[w]e are . . . unpersuaded by the argument that we should not apply the per se rule in this case because the judiciary has little antitrust experience in the health care industry." It also refused to consider any alleged procompetitive benefits of the agreements, holding that "the law is clear that once it is decided that a restraint is subject to per se analysis, the claimed lack of any actual anticompetitive effects or presence of procompetitive effects is irrelevant."[287]

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[281] *Id.* at 904.

[282] *Id.*

[283] *Id.* at 905.

[284] *Id.* at 908.

[285] *Id.* at 907-08.

[286] 457 U.S. 332 (1982).

[287] 332 F.3d at 909.

The Sixth Circuit also was not persuaded by defendants' argument that the per se rule should not be applied to patent settlements or attempts to enforce patent rights. The court agreed with the plaintiffs that:

> [I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.[288]

Here, moreover, "the agreements' restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem."[289] The Court of Appeals also held that the plaintiffs had adequately alleged antitrust injury. First, it found that deprivation of a less expensive competing product by way of a per se unlawful restraint of trade was precisely the kind of injury that the Sherman Act was meant to redress.[290] Second, the court found adequate the plaintiffs' allegation that "but for the Agreement . . . the plaintiffs would not have suffered their injury."[291] The court rejected the defendants' argument that Andrx unilaterally could have decided not to market its generic product for fear of damages for patent infringement because it only "create[d] a disputed issue of fact, not appropriately resolved on a [Rule 12(b)(6)] motion to dismiss."[292]

2. *Terazosin*

This litigation arose from the settlement of patent litigation brought by Abbott Pharmaceuticals against two generic manufacturers, Geneva Pharmaceuticals (the ANDA first-filer) and Zenith Goldline Pharmaceuticals, relating to

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[288] *Id.* at 908.

[289] *Id.* at 908 n.13 (quoting *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 242 (E.D.N.Y. 2003)).

[290] *See id.* at 910-11.

[291] *Id.* at 911.

[292] *Id.*

Abbott's formulation patents for Hytrin, a drug for the treatment of hypertension and enlarged prostate.[293] Each agreement: (1) prevented the generic from marketing *any* product containing terazosin hydrochloride, not just the product at issue in the infringement suit, until expiration of Abbott's patents (one of which was subsequently invalidated) or until another manufacturer introduced a generic terazosin product;[294] and (2) prevented the generic from waiving or transferring any rights under its ANDAs, which, in the Geneva agreement, explicitly included Geneva's 180-day exclusivity rights.[295] In return, the generics received $2-4.5 million every month—payments that would terminate or lessen if certain events came to pass, one of which was another manufacturer's marketing of a generic terazosin product.[296]

The district court granted partial summary judgment for plaintiffs, finding that these agreements constituted per se unlawful horizontal market allocations.[297] In finding that the challenged agreements were per se unlawful and exclusionary, the district court had relied solely on the existence of reverse payments in exchange for the generics' agreements not to market. The Eleventh Circuit held that this was error because it failed to account for the lawful exclusionary effect of Abbott's patents:

> If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent.

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[293] 344 F.3d. at 1298-99.

[294] Or, in the Geneva agreement, until Geneva obtained a non-appealable court judgment that its product did not infringe Abbott's patents. *Id.* at 1300. Notably, Zenith had declared that it was ready to enter the market with its generic product. *Id.* at 1301.

[295] *Id.* at 1300.

[296] *Id.*

[297] *In re* Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340 (S.D. Fla. 2000).

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> '[W]hen patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal.' *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003). Because the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these Agreements constitute per se violations of the antitrust laws must be reversed.[298]

The court found that the challenged agreements did not go beyond the lawful scope of Abbott's patents because the generics had agreed not to market only until patent expiration or until another generic terazosin product came to market (or, in Geneva's case, until a final, non-appealable judgment of patent invalidity).[299]

Regarding the existence of reverse payments, the Eleventh Circuit declined to find anything inherently suspect or warranting per se treatment, given the asymmetrical risks created by the Hatch-Waxman Act (the absence of monetary damages for the patentee) and the procompetitive effects of settling patent litigation.[300] Rather, the focus of the inquiry should be on the lawful scope of the patent grant—only then can any meaningful determination be made as to whether the reverse payments "bolstered" the patent's exclusionary scope.[301] The Eleventh Circuit expressly disagreed with the Sixth Circuit's opinion in *Cardizem* to the extent that it stands for the proposition that

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[298] 344 F.3d at 1304, 1306.

[299] *Id.* at 1305-06.

[300] *Id.* at 1309-10 (citing *Cipro*, 261 F. Supp. 2d at 251-52).

[301] *Id.* at 1310-11 ("nor do we think that the evidence regarding the exit payments in this case allows a confident conclusion to be drawn at this stage of the litigation that the exclusionary effect of the Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent").

reverse payments are simply per se unlawful.[302] The Eleventh Circuit agreed with the result in *Cardizem* to the extent it was based on an agreement not to market products not covered by the patent at issue.[303]

Nor was the Eleventh Circuit swayed by the subsequent invalidation of one of Abbott's patents, because the patent had not been adjudicated invalid at the time Abbott and the generics entered into the agreements.[304] The court reasoned that: (1) "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into[;]"[305] and (2) "exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid . . . would effectively increase the cost of patent enforcement [and] . . . impair the incentives for disclosure and innovation" because "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages."[306]

The Court of Appeals remanded the case to the district court for reevaluation of its per se ruling in accordance with the Eleventh Circuit's requirement to consider the patent's lawful scope. The Court of Appeals suggested that the district court consider on remand: (1) the exclusionary scope of the generics' agreement not to market other products not at issue in the infringement suit (referring to the possibility that this provision covered generic formulations not covered by the patents), and (2) Geneva's agreement not to waive or transfer its 180-day exclusivity rights.[307] If the district court should find that the challenged agreements *do* exceed the

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[302] *Id.* at 1310-11, 1311 n.26.

[303] *Id.*

[304] *Id.* at 1306-07.

[305] *Id.* at 1306.

[306] *Id.* at 1308.

[307] *Id.* at 1311-12. For a discussion of the exclusionary effect of such an agreement, see *supra* note 262.

lawful exclusionary power of Abbott's patents, then the district court should find those provisions of the settlements' agreements per se unlawful, i.e., not merely subject to the rule of reason, because "the anticompetitive effects of exclusion cannot seriously be debated."[308]

3. *In re Schering-Plough Corp.*

On December 18, 2003, the Federal Trade Commission ("FTC") announced a unanimous reversal of the Administrative Law Judge's ("ALJ") dismissal, after a full administrative trial on the merits, of the FTC's Complaint against Schering-Plough Corp. ("Schering"), Upsher-Smith Labs., Inc. ("Upsher"), and American Home Products ("AHP").[309] The Commission held that "the charges in the complaint that are grounded in Section 1 of the Sherman Act (Paragraphs 68-69) have been proven" under the rule of reason based on *de novo* review of the factual record.[310]

The FTC's Complaint alleged that Schering, which manufactures K-Dur 20 (a prescription drug for treatment of low potassium), entered into unlawful patent litigation settlement agreements with generic manufacturers Upsher and AHP not to market their generic versions of K-Dur 20. According to the Complaint, the settlement provided for a delayed license, under which Upsher and AHP agreed not to market any generic version of K-Dur 20 for four and five years, respectively.[311] In addition, Upsher purportedly agreed to grant Schering exclusive licenses under six products; in exchange for the licenses, Schering agreed to pay Upsher $60 million over two years.[312] Similarly, the AHP agreement provided for payments from Schering to AHP of $15 million, $10 million of which was conditioned on

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[308] *Id.* at 1311 n.27.

[309] *In re* Schering-Plough Corp., FTC Docket No. 9297 (filed Dec. 18, 2003), *at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf.

[310] Id. at 2, 86-87.

[311] *Id.* at 4-5.

[312] *Id.* at 4.

AHP's ANDA product receiving FDA approval.[313] AHP also agreed to license Schering to distribute two products in Europe, in exchange for an upfront royalty of $15 million.[314]

According to the FTC Press Release, the Commission's opinion "focuse[s] on the significance of payments from Schering, the pioneer, to the generic manufacturers."[315] The Commission announced their standard for further investigation of patent settlement agreements: "A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent. In light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations."[316] However, the Commission also stated that "[w]e . . . believe that the possible existence of a so-called 'reverse payment' raises a red flag that distinguishes [the Schering settlement] from most other patent settlements, and mandates a further inquiry."[317] "[I]f the parties simply compromise on the entry date, standing alone [*i.e.*, without reverse payments], they do not need to worry about a later antitrust attack."[318] "[W]e do not challenge agreements on entry dates, standing alone."[319]

As to what constitutes a reverse payment, the Commission offered little guidance beyond the statement that, "Absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation

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[313] *Id.* at 80 n.101.

[314] *Id.*

[315] Press Release, Federal Trade Commission, Commission Rules Schering-Plough, Upsher, and AHP Illegally Delayed Entry of Lower Cost Generic Drug (Dec. 18, 2003), *at* http://www.ftc.gov/opa/2003/12/schering.htm.

[316] *In re* Schering-Plough Corp., 25-26, FTC Docket No. 9297 (Dec. 18, 2003), *at* http://www.ftc.gov/os/adjpro/d9297.

[317] *Id.* at 29.

[318] *Id.* at 35

[319] *Id.* at 86.

compromise."[320] Whether the payments were in consideration for the licenses or for the generics' agreements not to market was a factual question. "After an exhaustive review of the facts – including the background of the settlement negotiations and the conduct of the parties after the settlement – the Commission held that 'the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses. We therefore conclude that Schering did in fact pay Upsher for delayed entry, which, in the circumstances of this case, was an agreement that unreasonably restrains commerce.'"[321]

The Commission declined to hold the agreements per se unlawful. Although the agreements contained what could be characterized as a "naked agreement to pay a potential competitor to delay its entry," the Commission acknowledged the trend in the courts was to employ the rule of reason in the Hatch-Waxman context.[322] The Commission then proceeded to find the agreements unlawful under the rule of

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[320] *Id.* at 26.

[321] FTC Press Release, *supra* note 310 (quoting *In re* Schering-Plough Corp., 79, FTC Docket No. 9297 (Dec. 18, 2003), *at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf.). The Commission's Order ("Order") did, however, prohibit litigation settlements pursuant to which either Schering or Upsher "receives anything of value" in consideration for its agreement to defer any research and development, production, or sales activities with respect to an ANDA product. *In re* Schering-Plough Corp., 2, FTC Docket No. 9297 (Dec. 18, 2003) (Order) *at* http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf. There is an exception limited to: the lesser of $2 million or the brand name manufacturer's expected future litigation costs, plus the right to market the ANDA product prior to patent expiration. *Id.* AHP settled with the Commission by entering into a consent decree prior to the Commission's decision. *Id.* at 5. Thus, the Order applies only to Schering and Upsher.

[322] *Id.* at 12-13 (citing Valley Drug Co. v. Geneva Pharmaceuticals Inc. ("Terazosin"), 344 F.3d 1294 (11th Cir. 2003); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188 (E.D.N.Y. 2003); and *In re* Tamoxifen Citrate Antitrust Litig., 262 F. Supp. 2d 17 (E.D.N.Y. 2003).) The FTC, however, refused to foreclose the possibility that reverse payment settlements would, in the future, receive per se treatment. *In re* Schering-Plough Corp., 29, FTC Docket No. 9297 (Dec. 18, 2003), *at* http://www.ftc.gov/os/adjpro/d9297.

reason, finding direct evidence of anticompetitive effects and consumer harm. For example, the Commission noted that average prices dropped significantly upon generic entry, which was consistent with the parties' predictions. This absolved FTC Complaint Counsel from proving the relevant market to establish violations of Section 1 of the Sherman Act and Section 5 of the FTC Act.[323] Although the Commission recognized that settlement of litigation is a procompetitive objective, it stated, "This does not mean, however, that all settlements are procompetitive, and we find that there is insufficient evidence to support the defense in this case."[324]

The Commission rejected the ALJ's position that proof of the merits of the underlying patent dispute was required to ascertain whether the agreement had any exclusionary effect not attributable to the lawful exclusionary power of the patent. First, even though Schering's patent must be presumed valid, it "did not necessarily confer a right to exclude generic entry in the circumstances of this case" because the issue was infringement, not validity.[325] Schering, not Complaint Counsel, had the burden of proof on this issue.[326] The Commission distinguished the contrary holdings of *Tamoxifen* and *Cipro* on this ground; both cases involved disputes as to patent validity, not infringement.[327]

Second, the Commission questioned "the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case," given the uncertainties of patent litigation.[328] The Commission

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[323] *In re* Schering-Plough Corp., 20-23, FTC Docket No. 9297 (Dec. 18, 2003), *at* http://www.ftc.gov/os/adjpro/d9297/03128commissionopinion.pdf. The Commission found it unnecessary to decide whether the agreements violated section 2 of the Sherman Act. *Id.* at 83-84. Thus, the Commission "neither endorse[d] nor rejecte[d]" the ALJ's conclusions on, inter alia, the Commission's proof of the relevant market. *Id.* at 84 & 84 n.108.

[324] *Id.* at 9.

[325] *Id.* at 30.

[326] *Id.*

[327] *Id.* at 31.

[328] *Id.* at 33-35.

addressed the flip-side of this coin by noting that "such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition, by guaranteeing that the new product will not be introduced."[329]

Finally, the Commission reasoned that the test it was announcing would create certainty for – and thereby promote—the settlement of patent disputes. The Commission stated, "Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone [*i.e.*, without reverse payments], they do not need to worry about a later antitrust attack."[330] A standard based on the merits of the underlying patent dispute would chill the settlement of litigation because of the risk of subsequent rulings on validity or infringement.[331]

4. *Cipro*

This litigation arose out of Bayer's settlement of patent litigation with Barr over Bayer's '444 patent and Barr's generic version of Cipro, a broad spectrum antibiotic. Barr acknowledged the validity of the '444 patent and other U.S. patents held by Bayer, and agreed to amend its ANDA to include a Paragraph III certification, in effect agreeing not to market until patent expiration. Bayer agreed to pay Barr $49.1 million immediately, and the parties entered a supply agreement which provided that Bayer would either: (1) supply Bayer-manufactured Cipro to Barr for distribution in the United States, or (2) make quarterly payments to Barr until expiration of the '444 patent.[332] Bayer chose to make the quarterly payments, which had amounted to $398

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[329] *Id.* at 32 n.62.

[330] *Id.* at 35.

[331] *Id.* The Commission also noted that proof of the underlying merits of the patent dispute went to damages, not liability. *Id.* at 32. The case before the Commission was the latter, as the Commission did not seek monetary damages, only prospective relief.

[332] *In re* Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F. Supp. 2d 188, 195-96 (E.D.N.Y. 2003).

million.[333] Following the settlement, Bayer and Barr were sued by direct and indirect purchasers of Cipro.

Plaintiffs sought summary judgment that Bayer's payment in exchange for Barr's agreement not to enter the market constituted a per se unlawful horizontal market allocation under § 1 of the Sherman Act.[334] However, the court found "significant obstacles to per se treatment," namely: (1) the patent at issue had been "scrutinized on reexamination by the PTO and repeatedly challenged in court, but . . . never . . . found invalid[,]" (2) the litigation's relationship to "the Hatch-Waxman Amendments—a new statutory scheme creating a novel, low-cost method for challenging the validity of drug patents[,]" and (3) the policy consideration that "settlement agreements [are] generally speaking, encouraged by the legal system and entered into with great frequency."[335]

The court held that "the proper analysis in this case is whether the plaintiffs have proven as a matter of law that the challenged agreements restrict competition beyond the exclusionary effects of the 444 [p]atent."[336] Plaintiffs failed to do so for two reasons. First, the formulation patents at issue in *Cardizem* and *Terazosin* did not cover other, non-infringing formulations containing the same active ingredient as the brand-name drug. Thus, the generics' agreements in those cases not to market *any* drug with that active ingredient exceeded the scope of the patents at issue.[337] The court noted that, "[b]y contrast [the Cipro compound patent] precludes all use of the active ingredient ciprofloxacin hydrochloride—no matter what form or

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[333] *Id.* at 196.

[334] *Id.* at 230.

[335] *Id.* at 233.

[336] *Id.* at 248-49 (citing United States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963) (patent holder does not run afoul of Sherman Act unless he acts beyond the confines of the patent monopoly) and United States v. Studiengesellschaft Kohle, 670 F.2d 1122, 1128 (D.C. Cir. 1981)).

[337] *In re* Cirpofloxacin Hydrochloride Antitrust Litigation, 261 F. Supp. 2d 188, 241-42 (E.D.N.Y. 2003).

delivery method used."[338] Thus, there was no possibility that the settlement could operate to exclude generic versions of Cipro that were outside the scope of Bayer's patent.

Second, the court determined that "probably the most significant difference" from the *Cardizem* and *Terazosin* litigations was that the Bayer/Barr settlement did not manipulate the Hatch-Waxman 180-day exclusivity period in a manner that made entry by other generics impossible, since Barr lost its right to a 180-day exclusivity period "by settling the patent litigation and withdrawing its [paragraph IV certification]."[339]

Neither did the court did find anything inherently suspect about reverse payments because reverse payments are "a natural by-product of Hatch-Waxman's shift of the litigation risk from the generic manufacturer to the patent holder."[340] Whereas non-Hatch-Waxman patent litigation is settled by a payment from the infringer to the patentee, the artificial

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[338] *Id.* at 242.

[339] *Id.* at 242, 244. Plaintiffs' failure to prove that the settlement excluded generic competition beyond the scope of Bayer's lawful patent monopoly seems to warrant dismissal of plaintiffs' claim for failure to allege antitrust injury. *See In re* Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 137-38 (E.D.N.Y. 2003), *appeal docketed*, No. 03-7641 (2d Cir. Jan. 16, 2004) (dismissing claim pursuant to Fed. R. Civ. P. 12(b)(6)). However, the *Cipro* court accepted plaintiffs' theory of injury that, absent the challenged conduct and agreements, Bayer would have settled the patent litigation by granting Barr a license to its '444 Patent, permitting entry by Barr and, potentially, other generics. 261 F. Supp. 2d at 207. The court distinguished between a unilateral refusal to license a patent, which would not violate the antitrust laws, and plaintiffs' allegation that Bayer would have granted a license "if it had not instead agreed to pay Barr . . . hundreds of millions of dollars." *Id.* at 209. The court found credible plaintiffs' allegations that Bayer would have licensed the '444 patent but for the allegedly unlawful agreements because: (1) Bayer had engaged in "serious" licensing discussions with Barr; and (2) Bayer—in the supply agreement itself—had given Barr a license to distribute Bayer-manufactured Cipro beginning in 1998. *Id.* at 208. Thus, the court found that plaintiffs had adequately alleged injury-in-fact despite the lawful exclusionary power of the '444 patent.

[340] 261 F. Supp. 2d at 250-51.

cause of action for infringement under the Hatch-Waxman Act creates a risk/reward structure resulting in the opposite:

> By contrast, in creating an artificial act of infringement (the ANDA IV filing), the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from infringing commercial sales. This statutory scheme affects the parties' relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, Barr's exposure in the patent litigation was limited to litigation costs, but its upside—exclusive generic sales—was immense. The patent holder, however, has no corresponding upside, as there are no infringement damages to collect, but has an enormous downside—losing its patent. Moreover, patent holders realize that it is a 'gamble' to place 'a technology case in the hands of a lay judge or jury.'[341]

The FTC in *Schering* expressly disagreed with this reasoning:

> We agree with the court that Hatch-Waxman may have altered the litigation incentives of pioneer and generic manufacturers. The statute was intended to do just that . . . Congress specifically decided that it wanted to encourage patent challenges for pharmaceutical products. (An offsetting concession for patent holders is the automatic 30-month stay.) As stated above, antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework.[342]

5. Other Cases Concerning Antitrust Claims

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[341] *Id.* at 251 (internal citations omitted).

[342] *In re* Schering-Plough Corp., 28-29, FTC Docket No. 9297 (Dec. 18, 2003), *at* " http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion (internal citations omitted).

Arising from Hatch-Waxman Patent Litigation Settlements

In *In re Tamoxifen Citrate Antitrust Litigation*,[343] the court dismissed under Fed. R. Civ. P. 12(b)(6) an antitrust claim arising from the generic's agreement not to market until patent expiration due to insufficient allegations that the patent litigation settlement was not entered into in good faith and absent any allegations of a subsequent course of anticompetitive conduct.[344]

In *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals., Inc.*,[345] Judge Richard Posner of the Seventh Circuit stated in dicta[346] that a patent litigation settlement should not be illegal under the antitrust laws provided there was an objectively reasonable basis for the underlying patent infringement suit. In the underlying patent litigation, Judge Posner had upheld the patent's validity (although he found that the defendant did not infringe the patent).[347] He noted, however, that there was "nothing to suggest that the claim of infringement was frivolous."[348] Also, although the case was on appeal before the Federal Circuit, Judge Posner reasoned

[343] 277 F. Supp. 2d 121, 133 (E.D.N.Y. 2003), *appeal pending*, No. 03-7641 (2d Cir.).

[344] The court found no evidence of bad faith in the plaintiffs' allegations, for three reasons. First, the settlement agreement "[t]erminated the entire litigation." *Id.* Second, the generic's subsequent effort to preclude generic competition by claiming it remained entitled to a 180-day exclusivity period was not evidence of the parties' intent at the time they entered their settlement agreement. *Id.* at 133-34. Third, the complaint did not allege a "pattern of settlements or continuing behavior" to exclude competition subsequent to the settlement agreement. *Id.* at 135-36.

[345] 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003). Judge Posner was sitting in the district court by designation because of his familiarity with the patents in suit.

[346] Judge Posner first held that Asahi Glass did not have standing to sue under the antitrust laws because it was merely a supplier of a competitor in the relevant market—Asahi did not compete in that market itself. *Id.* at 990-91.

[347] *Id.* at 988-89.

[348] *Id.* at 992.

that "the patent *may well* be valid, so that Glaxo cannot be faulted for trying to enforce it."[349]

Judge Posner noted that the case did not involve reverse payments, and further questioned whether even reverse payments are anticompetitive: "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options . . ., and so might well be thought anticompetitive."[350] The FTC responded to this reasoning in *Schering*: "*Any* antitrust restrictions on settlement agreements have the effect of reducing settlement options, but Judge Posner expressly states in the same opinion that some provisions should be condemned,"[351] such as resale price maintenance in patent licenses.[352]

6. Conclusions

There is an emerging consensus in the courts that agreements settling Hatch-Waxman patent litigation are unlawful if their exclusionary effect exceeds the lawful exclusionary scope of the patent. There is a divergence, however, in the courts' and the FTC's treatment of settlements involving reverse payments. *Terazosin* and *Cipro* hold that reverse payments are not per se unlawful, in part because of the asymmetrical litigation risks created by the regulatory scheme. Judge Posner, an experienced antitrust jurist and scholar, has also criticized application of the per se rule to reverse payments because it disincentivizes patent challenges.

On the other hand, the Sixth Circuit in *Cardizem* has held that a cash payment in exchange for a horizontal competitor's agreement not to market is per se unlawful regardless of the regulatory context in which the payment is

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[349] *Id.* (emphasis in original).

[350] *Id.* at 994.

[351] *In re* Schering-Plough Corp., 27 n.54, FTC Docket No. 9297 (Dec. 18, 2003), *at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.

[352] *Asahi Glass*, 289 F. Supp. 2d at 992 (discussing United States v. General Elec. Co., 272 U.S. 476 (1926)).

made. The FTC is not far behind *Cardizem* in substance, if not in terminology, because the rule of reason approach in *Schering* appears to presume illegality absent proof that there was other consideration for the reverse payments besides the generic's agreement not to market. In addition, the FTC assumes that an agreement not to market a generic equivalent of a patented brand name drug will have an anticompetitive effect because generic drugs are typically cheaper than the brand-name equivalent.[353]

III. TELECOMMUNICATIONS

A. Impact of Deregulation

Some of Professor Hovenkamp's remarks relate to the so-called "filed-rate" doctrine, which has been a focus in important recent cases and promises to be a focus of other cases in the near future. Under the most recent formulation of this doctrine by the Supreme Court, it preempts "those suits that seek to alter the terms and conditions provided for in the [filed] tariff."[354]

Ongoing controversy exists over whether the filed-rate doctrine should have continuing viability when the essential premise of the doctrine—that it is regulatory ratemaking procedures rather than competition that protects purchasers from unfair prices in the relevant market—is no longer applicable in a largely deregulated environment. Professor

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[353] The issue of whether a brand name drug and its generic equivalents constitute a properly defined relevant market under antitrust law may be more controversial than the FTC recognizes. *See* Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 38 n.7 (1984) (O'Connor, J., concurring) ("A common misconception has been that a patent or copyright, a high market share, or a unique product that competitors are not able to offer suffice to demonstrate market power."); M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 675-76 (2003). The FTC did not address the issue in *Schering*. *See In re* Schering-Plough Corp., 15, 83-84, FTC Docket No. 9297 (Dec. 18, 2003), *at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf.

[354] AT&T v. Central Office Telephone, Inc., 524 U.S. 214, 229 (1998).

Hovenkamp's comments reiterate his previously published view—which could be said to echo views expressed by Judge Friendly in *Square D Co. v. Niagara Frontier Tariff Bureau, Inc.*[355]—that once deregulation progresses to an extent that competition rather than rate regulation is the guardian against unfair pricing in a particular industry, the filed-rate doctrine should no longer apply to that industry. In principle, recent case law has expressed sympathy for views such as those articulated by Professor Hovenkamp.[356] Congress likewise has recognized that deregulation can make application of the filed-rate doctrine inappropriate, by enacting a limited repeal of the filed-rate doctrine as part of its deregulation of the interstate motor carrier industry.[357]

Importantly, however, Professor Hovenkamp's argument that the filed-rate doctrine should no longer apply in a deregulated environment[358] was rejected in the context of ICC-approved tariffs, in the Supreme Court's decision in *Square D*. Under an expansive reading of *Square D*, the case can be viewed as holding that, regardless of whether the filed-rate doctrine still makes sense, it must continue to be woodenly applied in all industries under principles of stare decisis, absent action to the contrary "from Congress, rather

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[355] 760 F.2d 1347 (2d Cir. 1985), *aff'd on other grounds*, 476 U.S. 409 (1986).

[356] *See, e.g.*, Fax Telecommunicaciones v. AT&T, 138 F.3d 479, 491 (2d Cir. 1998) (the filed-rate doctrine "is plainly a creature of a different time," and "strict application of the filed rate doctrine" can frustrate the governing policy objectives "in today's era of deregulation and multiple competing carriers.").

[357] *See* 49 U.S.C. § 13710(a)(4) (2000); Tempel Steel Corp. v. Landstar Inway, Inc., 211 F.3d 1029, 1030 (7th Cir. 2000).

[358] *See* PHILLIP E AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶¶ 247b&c, at 107-10 (2000) (explaining that modern legal developments have undermined rationales for the filed rate doctrine); HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE § 19.6, at 660 (2d ed. West 2000) ("[N]one of these arguments [in classic filed rate doctrine] had much to be said for them at the time they were originally made, and they are even less sensible today.").

than this Court."[359] Under a narrower interpretation, however, *Square D* could be said instead to direct its reasoning only at interstate commerce regulation by the ICC. For example, the opinion rests on assertions that Congress had not seen fit to change prior judicial authority in the ICC context "when Congress carefully reexamined this area of the law in 1980,"[360] and that the filed-rate doctrine "has been an established guidepost at the intersection of the antitrust *and interstate commerce* statutory regimes for some 6-1/2 decades."[361] Recent efforts to avoid the filed-rate doctrine in the deregulated electric and gas industries have received short shrift in the courts.[362]

By contrast, regulation continues to play a major role in competition in the telecommunications industry, as the Supreme Court just recognized in its opinion in *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*.[363] Although that case did not involve the filed-rate doctrine, the Court did expound upon the role of telecommunications regulation in antitrust analysis.

Trinko involved a claim that the incumbent local telephone exchange carrier ("ILEC") committed anticompetitive acts against competitive local exchange

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[359] *Square D*, 476 U.S. at 424; *see* Klein v. MCI Communications Corp., 98 F. Supp. 2d 69, 73 (D. Mass. 2000) ("Plaintiffs fail to . . . offer any legitimate reasons why, after nearly a century of its application, the 'filed-rate' doctrine should give way to a borrowed principle of 'no meaningful review.").

[360] 476 U.S. at 420.

[361] *Id.* at 423 (emphasis added).

[362] *E.g.*, *In re* California Wholesale Electricity Antitrust Litig., 244 F. Supp. 2d 1072, 1079 (S.D. Cal. 2003) ("This argument that the introduction of a market-based rate system skirts the reach of the filed-rate doctrine has been uniformly rejected by the courts"), *appeal pending*, No. 03-55191 (9th Cir); Pacific Gas and Elec. Co. v. Lynch, 216 F. Supp.2d 1016, 1041 (N.D. Cal. 2002) ("Such arguments—that the introduction of competition into a regulated industry brings into question the continuing application of the filed rate doctrine—have been, to the court's knowledge, uniformly rejected by courts in the regulatory contexts in which they have been raised.").

[363] 124 S. Ct. 872 (2004).

carriers ("CLECs") by failing to complete the CLECs' telephone service orders.[364] Under the Telecommunications Act of 1996 ("1996 Act"), the ILEC, Verizon, must provide its competitors with access to certain elements of its local network if Verizon wants the Federal Communication Commission's ("FCC") authorization to enter the market for long distance telephone services.[365] In late 1999, several CLECs had complained to the FCC that Verizon was not fulfilling their service orders. Investigations by the FCC and the New York State Public Service Commission ("PSC") concluded with a consent decree between Verizon and the FCC, and with a series of orders by the PSC. The consent decree and orders required Verizon to pay damages to the CLECs, and also subjected Verizon to new performance and reporting requirements under the 1996 Act.[366]

The day after Verizon entered into the consent decree, the Law Offices of Curtis V. Trinko, a customer of one of the CLECs, filed suit alleging monopolization and attempted monopolization as a result of Verizon's failure to fulfill the CLECs' service orders in violation of the 1996 Act.[367] The district court dismissed plaintiff's complaint pursuant to Fed. R. Civ. P. 12(b)(6) because "allegations of deficient assistance to rivals" in violation of the 1996 Act failed to plead a section 2 claim.[368] After the Court of Appeals for the Second Circuit reversed, the Supreme Court affirmed dismissal because the complaint did not plead facts sufficient to come within the exception to the general rule that a monopolist does not have a duty to deal with rivals.[369]

The Supreme Court went on to discuss how the fact of continued regulation in the telecommunications industry justified the foreclosure of causes of action premised on violations of the 1996 Act. According to the Court, the 1996

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[364] *Id.* at 877.
[365] *Id.* at 875-76.
[366] *Id.* at 876-77.
[367] *Id.* at 877.
[368] *Id.*
[369] *Id.* at 880-84.

Act "'significantly diminishes the likelihood of major anticompetitive harm'"[370] by having regulators evaluate and oversee whether the ILEC has sufficiently opened local telephone service markets to competition during their process of determining whether the ILEC should be granted the right to compete in long distance markets.[371]

> When several competitive LECs complained about deficiencies in Verizon's servicing of orders, the FCC and PSC responded. The FCC soon concluded that Verizon was in breach of its sharing duties under § 251(c), imposed a substantial fine, and set up sophisticated measurements to gauge remediation, with weekly reporting requirements and specific penalties for failure.[372]

The Court reasoned that such oversight "would surely be a daunting task for a generalist antitrust court . . . destined to distort investment and lead to a new layer of interminable litigation, atop the variety of litigation routes already available to and actively pursued by competitive LECs" under the 1996 Act.[373]

Therefore, "the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny."[374] "Where, by contrast, 'there is nothing built into the regulatory scheme which performs the antitrust function,' the benefits of antitrust are worth its sometimes considerable disadvantages."[375] The extent to which this reasoning can be used to argue for or against protection from the antitrust laws in other regulated industries promises to be a major issue.

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[370] *Id.* at 881 (quoting Concord v. Boston Edison Co., 915 F.2d 17, 25 (1st Cir. 1990).

[371] *Id.* at 881-82.

[372] *Id.* at 882.

[373] *Id.* at 883.

[374] *Id.* at 881.

[375] *Id.* at 882 (quoting Silver v. New York Stock Exch., 373 U.S. 341, 358 (1963)).

B. Non-Price Restraints

Another major emphasis of the filed-rate litigation in antitrust relates to whether the antitrust challenge in question actually "seeks to alter the terms and conditions provided for in the tariff," under the legal standard articulated by the Supreme Court in *Central Office*. Generally, case law in which the filed-rate doctrine has been applied has involved claims that directly sought to alter terms and conditions of a filed tariff.[376] Where a case instead challenges non-price restraints that are not provided for in a filed tariff—such as actions taken to exclude competitors from a geographic market—it is not clear that the filed-rate doctrine applies.

In the telecommunications industry, for example, plaintiffs would argue that Incumbent Local Exchange Carriers' exclusion of Competitive Local Exchange Carriers from the incumbents' territories involves territorial exclusionary conduct that is not provided for or covered by tariff filings. Cases supporting an argument that the filed-rate doctrine is therefore inapplicable include *In re Lower Lake Erie Iron Ore Antitrust Litigation*,[377] in which the Third Circuit reasoned that the purpose of the filed-rate doctrine is merely to preclude claims "that [regulator]-approved rates were the product of an antitrust violation," and that that rationale was inapplicable to the territorial exclusion as

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[376] *See* Marcus v. AT&T Corp., 138 F.3d 46, 61 (2d Cir. 1998) (plaintiffs could not be excused from billing in "whole-minute increments" for which it was uncontested that a filed tariff explicitly provided); Sun City Taxpayers' Ass'n v. Citizens Utils. Co., 45 F.3d 58 (2d Cir. 1995) (claim that false information had been submitted to regulators to secure approval of excessive utility rates); Wegoland Ltd. v. NYNEX Corp., 27 F.3d 17 (2d Cir. 1994) (ratepayers cannot challenge agency's rate determination notwithstanding utility's misrepresentations to agency); H.J., Inc. v. Northwestern Bell Tel. Co., 954 F.2d 485 (8th Cir. 1992) (RICO claims alleging that regulatory rate approval was obtained by bribes to regulatory officials); Taffet v. Southern Co., 967 F.2d 1483, 1489 (11th Cir. 1992) (RICO claims alleging that regulatory rate approval was obtained by fraud).

[377] 998 F.2d 1144 (3d Cir. 1993).

distinguished from price-fixing because "the plaintiffs showed that the railroads conspired to protect their stronghold in the ore transport market by blocking entry by low-cost competitors, not that the railroads charged an unlawful rate."[378] In other words, it was defendants' "hindering the development of the market which defines this antitrust litigation,"[379] and not that the tariffed rate was itself established through a conspiracy, as in *Square D*.

IV. SECURITIES

On November 3, 2003, U.S. District Court Judge William Pauley (S.D.N.Y.) dismissed a major consolidated class action alleging antitrust violations arising from the initial public offering allocation practices of certain underwriters during the Internet bubble of the late 1990s.[380] Following the lead of two recent Second Circuit decisions, Judge Pauley dismissed the action based on the doctrine of implied immunity, holding that the conduct at issue was subject to the broad regulatory oversight of the Securities and Exchange Commission (the "SEC" or the "Commission") and was therefore immune from antitrust scrutiny. This decision adds to the growing body of jurisprudence in the Second Circuit concerning implied immunity.

A. The Doctrine of Implied Immunity

Implied immunity (often referred to as "implied repeal") applies where there is a "plain repugnancy" between antitrust liability and another regulatory scheme.[381] This principle is grounded in the notion that a well-defined body of regulation may impliedly repeal antitrust proscription with respect to certain conduct due to an inherent conflict

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[378] *Id.* at 1159.

[379] *Id.* at 1160.

[380] *In re* Initial Public Offering Antitrust Litig., 287 F. Supp. 2d 497 (S.D.N.Y. 2003) (the "*IPO Antitrust Litigation*"), *appeal pending*, No. 03-9288 (2d Cir.).

[381] Gordon v. New York Stock Exch., Inc., 422 U.S. 659, 682 (1975).

between the two regulatory regimes. Recognizing that "repeals by implication are not favored,"[382] the Second Circuit has identified "two narrowly defined situations" where implied immunity operates: "first, when an agency, acting pursuant to a specific Congressional directive, actively regulates the particular conduct challenged, . . . and second, when the regulatory scheme is so pervasive that Congress must be assumed to have forsworn the paradigm of competition."[383]

In the securities context, the Second Circuit recently examined the nature of the conflict required between the antitrust and securities regimes to trigger the "plain repugnancy" threshold. In *Friedman v. Salomon/Smith Barney, Inc.*,[384] the court held that *affirmative* SEC regulation was not required to invoke the implied immunity doctrine. There, plaintiffs alleged that numerous underwriters engaged in a price-fixing conspiracy with respect to the sale of securities by disincentivizing the practice of "flipping" (i.e., re-selling shares shortly after acquiring them in an offering) as a means of price stabilization. Plaintiffs alleged that these underwriters employed a variety of anticompetitive methods to discourage flipping in the aftermarket, including denying equity allocations in future offerings to those who sold stock within a certain period of time after the offering. According to plaintiffs, these methods artificially inflated the price of the relevant shares by limiting supply of those securities in violation of section 1 of the Sherman Act. The trial court refused to reach the merits of plaintiffs' contentions, dismissing their claims instead on the ground of implied immunity.

The Second Circuit affirmed, noting that Congress charged the SEC with the exclusive responsibility to regulate price fixing and stabilization practices in the securities

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[382] United States v. Borden Co., 308 U.S. 188, 198 (1939).

[383] Northeastern Tel. Co. v. Amer. Tel. & Tel. Co., 651 F.2d 76, 82 (2d Cir. 1981).

[384] 313 F.3d 796 (2d Cir. 2002).

aftermarket principally under Section 9(a)(6) of the Securities Exchange Act of 1934 (the "Exchange Act").[385] Although the SEC at that time chose not to actively regulate price stabilization activities, this did not preclude the application of implied immunity. Rather, the *Friedman* court determined that the SEC had previously studied such stabilization practices and made a reasoned assessment that their benefits outweighed their anticompetitive effects. Unlike the antitrust laws, which would impose a blanket prohibition on price stabilization practices, section 9(a)(6) required "the SEC to consider other factors [in addition to market competition] such as the public interest and protection of investors."[386] Consequently, implied repeal was necessary as interference by the antitrust laws would effectively undermine the SEC's exclusive authority in this area.

Only months after the *Friedman* decision, the Second Circuit Court of Appeals in *In re Stock Exchanges Options Trading Antitrust Litigation*,[387] held that section 1 of the Sherman Act was impliedly repealed as it applied to the listing and trading of options on securities exchanges. The court based its ruling on the precept that implied repeal was appropriate where the antitrust laws had the *potential* to conflict with the regulatory authority of the SEC. There, plaintiffs brought suit against various securities exchanges claiming that they conspired to limit the trading of certain options to a single exchange in violation of antitrust laws. The Second Circuit rejected plaintiffs' argument that there was no conflict between securities and antitrust regimes because the SEC prohibited exclusive listings at that particular time. Instead, the court found that implied repeal was necessary in order to "preserve the *authority* of the SEC

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[385] 15 U.S.C. § 78i(a)(6) (2000).

[386] Friedman v. Solomon/Smith Barney, Inc., 313 F.3d 796, 802 (2d Cir. 2002).

[387] 317 F.3d 134 (2d Cir. 2003).

to regulate" the listing and trading of equity options.[388] In particular, the court was concerned with the fact that

> [t]he Exchange Act itself does not prohibit agreements for exclusivity in options listing, and, as described, the Commission has taken varied positions with respect to the appropriateness of multiplicity, in part because under the Exchange Act it is concerned with more than just the protection of competition, which is the sole aim of antitrust legislation. The SEC must consider, in addition, the economic health of the investors, the exchanges, and the securities industry.[389]

In this way, it was important to preserve "the potential for a change in the Commission's view," and repeal of the antitrust laws "was necessary to avoid render[ing] nugatory the legislative provision for regulatory agency supervision."[390] The imposition of a blanket prohibition on single listings under an antitrust paradigm created the very potential for conflict with the SEC's authority that the implied immunity doctrine was intended to avoid.

B. The IPO Antitrust Litigation[391]

In the *IPO Antitrust Litigation*, the crux of the complaint was that major underwriters of initial public offerings during the technology boom of the late 1990s conspired to inflate the aftermarket prices of the issuers' securities by using the underwriting system to impose anticompetitive charges, as well as aftermarket "laddering" and "tie-in" arrangements, in violation of federal and state antitrust laws. Specifically, the

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[388] *Id.* at 148 (emphasis added).

[389] *Id.* (internal quotations omitted) (citations omitted).

[390] *Id.* at 149 (internal quotations omitted).

[391] Co-author Andrew Frackman represented Robertson Stephens, Inc., one of the underwriter defendants, in *In re Initial Public Offering Antitrust Litigation*, 287 F. Supp. 2d 497 (S.D.N.Y. 2003). Moreover, the law firm of O'Melveny & Myers, LLP, of which Mr. Frackman is a partner and co-author Jonathan Kim is an associate, represents Robertson Stephens in various other federal and state court actions.

complaint alleged that underwriters required their customers to purchase additional shares of the issuers in the aftermarket to boost the issuers' stock price (a practice known as "laddering") and share profits made on the sales of their IPO shares as a condition of receiving allocations of the highly desired IPO shares. The purpose of the alleged conspiracy was to increase the consideration that aftermarket purchasers paid for the IPO securities and create artificial demand for the securities, which would result in additional compensation to the underwriters in the form of underwriting charges, commissions, and investment banking fees. There was a parallel action alleging violations of the commercial bribery provisions of the Robinson-Patman Act arising from the same conduct. The complaints put at issue the entire syndicate underwriting system.

The District Court dismissed plaintiffs' federal antitrust claims, noting that there was a "plain repugnancy" (or conflict) between antitrust liability and the federal securities laws in this case. Recognizing the premise that implied immunity will apply where a governmental agency actively regulates the conduct at issue, the court echoed the Second Circuit's analytical framework set forth in *Friedman* and *Stock Exchanges Options*, and applied the implied immunity doctrine to plaintiffs' claims.

First, much of the alleged conduct, according to the District Court, was expressly permitted by the SEC. In particular, the court noted that the gravamen of plaintiffs' allegations—that the underwriters combined into underwriting syndicates, that the lead underwriter was permitted to distribute the shares of the IPO among the syndicate, and that all syndicate members shared in the commission irrespective of whether they sold all of their allotted shares—was simply an indictment of the syndicate system, which has been categorically recognized and approved by the SEC. Moreover, plaintiffs' concerns regarding generally accepted practices such as "road shows" merely described conduct expressly permitted under the federal securities laws. Proscribing such conduct as violative of the antitrust laws would, according to the District Court,

"render nugatory the legislative provision for regulatory agency supervision."[392]

Second, and more significantly, the court found that although much of the remaining conduct at issue could be deemed prohibited under both securities and antitrust regimes, such conduct was nevertheless subject to the broad regulatory arm of the SEC. In a detailed overview of the SEC's jurisdictional reach, Judge Pauley found that

> [t]he broad general authority to regulate IPO allocation and underwriter commission practices is granted to the SEC by: (1) the Securities Act [of 1933, 15 U.S.C. § 77a, et seq. (the "Securities Act")], under which the Commission regulates the offering process; (2) the Exchange Act, under which the Commission defines and regulates manipulative acts in connection with the purchase or sale of securities; and (3) its reservoir of rulemaking authority over SROs [(Self-Regulatory Organizations)].[393]

The court cited a familiar refrain, noting that in contrast to antitrust laws, "the securities laws take into consideration more than just free competition, and in fact permit price manipulation in certain instances despite its effect on competition."[394]

Against this backdrop, the District Court found that the manipulative conduct alleged in connection with the purchase and sale of securities in the complaint—such as "tie-ins," "laddering," and agreements to purchase securities of other issuers or secondary offerings of the same issuer—fell within the core of the SEC's supervisory authority pursuant to these federal securities laws and rules. The court demonstrated "the Commission's well-documented history of considering the very conduct alleged in this action, and its current activity aimed at formulating responses to

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[392] *IPO Antitrust Litig.*, 287 F.Supp. 2d at 506-07 (quoting Gordon v. New York Stock Exch., 422 U.S. 659, 661 (2003).

[393] *IPO Antitrust Litig.*, 287 F.Supp.2d at 511.

[394] *Id.* (citing S. Rep. No. 94-75, at 13 (1975), *reprinted in* 1975 U.S.C.C.A.N. 179, 191).

the alleged 'hot issue' abuses of the late 1990s."[395] In particular, the court detailed the SEC's prior consideration of the conduct at issue, including SEC's Proposed Rule 10b-20 (considering—and eventually rejecting—bright-line rules concerning "tie-ins" and other relevant aftermarket practices), the "Report of the Securities and Exchange Commission Concerning the Hot Issues Market" in August 1984 (addressing "artificial restrictions on supply or attempts to stimulate demand"), and SEC Release No. 33-7283, 61 Fed. Reg. 17108, 17124 (April 11, 1996) (announcing that the SEC "intended to gather information about aftermarket activities so that it could evaluate whether any additional regulation was necessary.")[396]

Moreover, the court highlighted the Commission's pending consideration of the conduct at issue, such as its investigation for "potential violations of existing statutes, regulations and rules concerning the price setting process and allocation practices of 'hot issue' underwriters," and the various injunctive actions brought by the SEC's Division of Enforcement against certain underwriters alleging violations of securities laws based upon conduct similar to those described in the complaint.[397] The court also referred to current proposals advanced by the National Association of Securities Dealers ("NASD")—which the Commission oversees—designed to address much of the harms raised by the conduct alleged in the complaint.

Given that the alleged misconduct by the underwriters fell within the scope of the SEC's regulatory power, the District Court held that a finding of implied immunity was required to prevent conflicting mandates between the antitrust and securities paradigms.[398]

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[395] *IPO Antitrust Litig.*, 287 F. Supp.2d at 519.

[396] *Id.* at 519-21.

[397] *Id.* at 521-23.

[398] *Id.* at 523 ("it is clear that the SEC, both directly and through its pervasive oversight of the NASD and other SROs, either expressly permits the conduct alleged in the [complaint] or has the power to regulate the conduct such that a failure to find implied immunity would 'conflict with an overall regulatory scheme that empowers the [SEC] to allow conduct

The *IPO Antitrust Litigation* decision, like its predecessors in the Second Circuit, may be appealed to the Court of Appeals in 2004, adding another appellate authority on implied immunity from suit under federal antitrust law. In addition, the case is likely to address implied immunity under state antitrust law, which has not been a focus of recent Second Circuit decisions such as *Friedman* and *Stock Exchange Options*[399]. In his opinion Judge Pauley observed that neither the Supreme Court nor the Second Circuit had ever "addressed the doctrine of implied immunity as it relates to state antitrust laws," and concluded that "the same conduct that is immune from Sherman Act antitrust scrutiny must also be immune from state antitrust scrutiny."[400] Plaintiffs have filed a motion for *reconsideration* in the case, arguing that under *California v. ARC America Corp.*,[401] antitrust is an area of law "traditionally regulated by the states," and that in such areas of law, there can be no preemption absent plain statement" of a "clear and manifest" intent of Congress to preempt state regulation under various Supreme Court precedents such as *Gregory v. Ashcroft*.[402] Even if Judge Pauley denies the motion for reconsideration, this issue will almost certainly be raised on appeal, and may give rise to the first major precedent after *ARC America* to address the applicability of theories of implied preemption to claims asserted under state antitrust law.

V. CONCLUSION

In sum, the extent to which regulation was able to displace antitrust as the primary tool of competition policy has varied. In the pharmaceutical industry, bedrock

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that the antitrust laws would prohibit.'") (quoting *Stock Exchs. Options*, 317 F.3d at 149).

[399] *In re* Stock Exchs. Options Trading Antitrust Litig., 317 F.3d 134 (2d Cir. 2003).

[400] 287 F. Supp. 2d at 524.

[401] 490 U.S. 93 (1989).

[402] 501 U.S. 452 (1991).

principles of antitrust and patent law were marshaled to confront the exclusion of generic competition through the regulatory mechanism of the Hatch-Waxman Act. On the other hand, courts applied the filed-rate doctrine to bar antitrust suits in the telecommunications and energy industries despite noteworthy criticism of the doctrine's continued relevance in a deregulated environment, and the Supreme Court in *Trinko*[403] erected a formidable barrier to antitrust complaints based on the Telecommunications Act of 1996. Antitrust was displaced in the securities industry where it has been viewed to interfere with the SEC's authority to ensure proper functioning of financial markets.

Professor Hovenkamp offers a perspective on antitrust that helps reconcile this variation: "[A]ntitrust's role is 'residual.'"[404] The Supreme Court echoed this view in *Trinko*. In deciding to leave local telephone providers with sole recourse to the 1996 Act, the Court looked to whether there was anything "built into the regulatory scheme which performs the antitrust function," and concluded that there was.[405] In contrast, there is no such construct in the Hatch-Waxman Act, thus warranting intervention by the antitrust laws.

As for the important to properly functioning financial markets of a uniform set of rules enforced by a single authority, particularly when such regulation traces its roots to the political choices that arose is apparent out of the stock market crash of 1929. The exclusive application of the securities laws is thus explained by Professor Hovenkamp's recognition that regulation often has political objectives beyond antitrust.

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[403] Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP, 124 S. Ct. 872 (2004).

[404] Herbert Hovenkamp, *Antitrust and the Regulatory Enterprise*, 2004 COLUM. BUS. L. REV. 335, 342.

[405] 124 S. Ct. at 882.