Nonmerger enforcement at the FTC: an aggressive proconsumer agenda

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I. Introduction

In a recent paper, FTC general counsel William Kovacic issued a rigorous critique of the "pendulum narrative" of U.S. antitrust enforcement experience, which posits that antitrust enforcement swings through distinct phases of "too much," "too little," and "properly moderate," depending largely on which administration is in office.[1] Some antitrust commentators, who perhaps subscribe to the

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[1] William E. Kovacic, *The Modern Evolution of U.S. Competition Policy Enforcement Norms*, 71 ANTITRUST L.J. 377 (2003). Borrowing from *Goldilocks*, the famous children's story, Kovacic described the pendulum narrative as positing that federal antitrust enforcement swings from being too hot to too cold, to just right. He rejects the hypothesis as simplistic and inaccurate.

pendulum narrative, predicted that FTC antitrust enforcement under the current administration would swing back toward the "too little" end of the spectrum. At the outset of his current tenure at the FTC, Chairman Timothy Muris stated that those critics would be proved wrong—antitrust enforcement under his leadership would continue the essential continuity of antitrust enforcement over recent decades, including the Pitofsky Commission, with differences at the margin.[2] This article focuses on the nonmerger agenda, and demonstrates a very aggressive proconsumer enforcement program that has, in a very short period of time, borne much fruit in terms of enforcement actions, amicus briefs, studies, and hearings.[3]

By the numbers alone, the FTC under Chairman Muris has pursued the most vigorous nonmerger agenda in almost a quarter century. In fiscal year 2001, the FTC opened 56 new nonmerger investigations, and it opened another 59 nonmerger investigations in 2002. This case generation effort bore fruit in fiscal year 2003 as the Commission instituted 21 enforcement actions, which represents the highest level since 1980.[4] Over the two full fiscal years that Chairman Muris has been in office, the Commission instituted 32 nonmerger enforcement actions for an average of 16 per year, compared to an average of approximately nine per year during the Clinton administration and seven during the first Bush presidency.[5]

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[2] Timothy J. Muris, Chairman, Federal Trade Commission, Antitrust Enforcement at the Federal Trade Commission: In a Word—Continuity, Prepared Remarks Before American Bar Association Antitrust Section Annual Meeting, Chicago, Illinois (Aug. 7, 2001), *available at* http://www.ftc.gov/speeches/muris/murisaba.htm.

[3] The FTC's merger enforcement program (which we do not address in this article) has also been quite vigorous and in line with previous policy. *See* Joseph J. Simons, Director, Bureau of Competition, FTC, Merger Enforcement at the FTC, Keynote Address to the Tenth Annual Golden State Antitrust and Unfair Competition Law Institute, Antitrust and Unfair Competition Law Section, State Bar of California (Oct. 24, 2003), *available at* http://www.ftc.gov/speeches/other/021024mergeenforcement.htm.

[4] FTC, *Fulfilling the Original Vision: The FTC at 90*, at 9 (Apr. 2004), *available at* http://www.ftc.gov/os/2004/04/040402abafinal.pdf.

[5] Data for the Clinton and Bush presidencies compiled from Kovacic, *supra* note 1, at tables 3, 4 & 5.

An enforcement program obviously should be judged by more than mere numbers. The record shows that the FTC's nonmerger program is substantively strong as well as numerically active. The program builds on principles of competition policy outlined by Chairman Muris in his "Handler" speech.[6] First, the overarching goal is to promote competition as the basic norm in the functioning of markets. This means that the agency's work covers a broad spectrum of competition issues. Second, consumer welfare and economic efficiency are the fundamental guideposts in targeting FTC enforcement. Third, the enforcement program should make full use of the capabilities of the agency's distinctive institutional attributes, including a broad charter to conduct studies and perform research about the economy, authority to use administrative adjudication to resolve competition issues, and, in the Chairman's words, the resources of "one of the world's preeminent teams of industrial organization economists in our Bureau of Economics."[7]

The FTC's distinctive institutional capabilities enable the agency to tackle some of the most difficult and challenging competition issues, as we will illustrate. Studies and research complement and inform our investigations. The FTC's administrative litigation process allows a detailed record to be built and analyzed by an expert agency, and FTC cases can result in the establishment of key competition principles through subsequent judicial rulings that benefit consumers broadly over time.

In applying the principles of competition policy outlined by Chairman Muris, a number of criteria are used to direct investigational resources to specific matters:

> whether the conduct allegedly involved is of a type (such as agreements among competitors about price or other elements of competition) that poses the greatest threat to consumer welfare;

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[6] Timothy J. Muris, Chairman, Federal Trade Commission, Looking Forward: The Federal Trade Commission and the Future Development of U.S. Competition Policy, Remarks Before the Milton Handler Annual Antitrust Review, New York, New York (Dec. 10, 2002), *available at* http://www.ftc.gov/speeches/muris/handler.htm, *published at* 2003 COLUM. BUS. L.R. 359.

[7] *Id.*

whether the matter involves a sector of the economy that significantly affects consumers' budgets (e.g., health care, including prescription drugs; energy; and e-commerce);

whether the agency has enforcement experience in an area that will enable us to make an impact quickly and efficiently; and

whether the matter presents a legal issue that might benefit from further study and illumination.

We discuss below the agency's application of these principles and enforcement criteria.

II. Anticompetitive abuses of intellectual property rights

Cases challenging the abuse of intellectual property (IP) rights have been a major focus of the FTC's nonmerger program. There are several reasons for this. First, intellectual property is a pervasive force in our economy. IP is an important driver for innovation, and it is a key, potentially controlling asset in many major markets. The agency is very careful not to intrude on legitimate IP interests, but IP rights also can be abused for anticompetitive purposes. Thus it is important to be vigilant to detect and where appropriate, to challenge conduct that utilizes IP rights that results in anticompetitive exclusion, instead of appropriate exclusion within the scope of the granted IP property rights. Second, IP involves complex statutes and regulatory schemes that sometimes may be manipulated in anticompetitive fashion to create artificial blockages to competition, and to innovation itself. Third, the agency has been at the forefront in studying the cutting edge of intellectual property and antitrust issues. The public hearings on intellectual property and antitrust (convened jointly with the Antitrust Division)[8] are a prime example, as is the FTC's seminal 2002 study of patented drug manufacturers' response to generic drug competition.[9] This is an area where the FTC's distinctive institutional

[8] Federal Trade Commission, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Oct. 2003), *available at* http://www.ftc.gov/opp/intellect/index.htm.

[9] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

attributes, discussed above, should be, and have been, usefully brought to the fore.

The focus on IP issues in antitrust cases can be expected to grow, since IP is an increasingly important part of business value-added, and, thus, of business transactions and disputes in general. Issues involving IP rights in two particular areas—standard setting, and pharmaceuticals—have been the subject of substantial recent enforcement activity, as discussed below.

A. *Standard setting*

Standard setting is an important area for antitrust review because the activity can have broad implications for entire industries and many markets. Further, private standards often are inputs to regulatory action that can create impediments to the operation of market forces.[10] While most standard setting is procompetitive, there are sometimes opportunities for anticompetitive manipulation that may "tax" innovation and prevent efficient decisions that take into account price and alternative technologies.

Standard setting often involves intellectual property rights, thereby adding another layer of complexity. Promulgation of a standard that "reads on" intellectual property can have important consequences for the cost of products that comply with the standard, particularly if the existence of those IP rights is not disclosed before the standard is promulgated. Recent FTC actions—*Rambus*[11] and *Unocal*[12]—have challenged conduct by patentees that are alleged to have abused the standard-setting process in an effort to convert a patent grant into a market monopoly and otherwise restrict

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[10] *E.g.*, Union Oil Co. of California, Docket No. 9305 (Mar. 4, 2003) (complaint) (see discussion *infra*), *available at* http://www.ftc.gov/os/2003/03/unocalcmp.htm; *cf.* Indian Head, Inc. v. Allied Tube & Conduit Corp., 486 U.S. 492 (1988); American Society of Sanitary Engineering, 106 F.T.C. 324 (1985) (consent order).

[11] Rambus Inc., Docket No. 9302 (June 18, 2002) (complaint), *available at* http://www.ftc.gov/os/adjpro/d9302/020618admincmp.pdf.

[12] Union Oil Co. of California, Docket No. 9305 (Mar. 4, 2003) (complaint), *available at* http://www.ftc.gov/os/2003/03/unocalcmp.htm.

competition in the relevant markets.[13] Such conduct can result in higher costs for consumers when there are substantial costs in switching to an alternative technology. The competitive danger is greater in these IP cases than in some other standard-setting situations because of the risk of monopolization by a single firm. In addition, patent obstacles may make the monopoly more durable than it would otherwise be.[14] These cases should provide important clarification of the scope of antitrust law and FTC section 5 in governing conduct involving standards.

1. *RAMBUS* In a complaint issued in June 2002, the Commission charged that Rambus Inc., a participant in an electronics industry standards-setting organization known as JEDEC, failed to disclose—in violation of the organization's rules and policies—that it had a patent and several pending patent applications on technologies that eventually were adopted as part of the industry standard. The standard at issue involved a common form of computer memory used in personal computers and other electronic products. According to the complaint, the inclusion of Rambus's patented technology in the standard placed it in a position to gain millions of dollars in royalties each year, and potentially more than a billion dollars over the life of the patents, all at the expense of consumers in the form of higher prices.

According to the complaint, JEDEC had a policy that favored open standards. To that end, it had a commitment "to avoid, where possible, the incorporation of patented technologies into its published standards, or at a minimum to ensure that such technologies, if incorporated, will be available to be licensed on a royalty-free or otherwise reasonable and discriminatory terms."[15] JEDEC policy

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[13] *See also* Dell Computer Corp., 121 F.T.C. 616 (1996) (consent order). That case similarly involved the alleged failure of a participant in a standard-setting process to disclose its patent position, contrary to the rules of the organization. After its technology was adopted in the standard, the company sought to enforce the patent.

[14] *See* Timothy J. Muris, *supra* note 6, at n.89.

[15] Rambus Inc., Docket No. 9302 (June 18, 2002), Complaint ¶ 20, *available at* http://www.ftc.gov/os/adjpro/d9302/020618admincmp.pdf.

therefore required the disclosure of patents and patent applications relating to a technology under consideration by JEDEC.[16] According to the complaint, Rambus's failure to disclose its patent interests in the technology being considered by JEDEC, and its other bad-faith, deceptive conduct, subverted the very policies that govern JEDEC's standard-setting activities.

JEDEC's alleged deception and other bad-faith conduct violates the principle articulated by the Second Circuit and endorsed by the Supreme Court in *Allied Tube*: when a firm or group of firms, with the purpose "of achieving an anticompetitive result," has "subverted," "undermined," and "violated the integrity" of a standard-setting association's processes, its anticompetitive conduct is subject to the antitrust laws. *Indian Head, Inc. v. Allied Tube & Conduit Corp.*, 817 F.2d 938 (2d Cir. 1987), *aff'd*, 486 U.S. 492 (1988); *see also Dell Computer Corp.*, 121 F.T.C. 616 (1996) (consent order).

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[16] Paragraph 24 of the complaint alleges:

> Fairly interpreted, the policies, procedures, and practices existing within JEDEC throughout all times relevant herein imposed upon JEDEC members certain basic duties with regard to the disclosure of relevant patent-related information and the licensing of relevant patent rights:
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> a. First, to the extent any JEDEC member knew or believed that it possessed patents or pending patent applications that might involve the standard-setting work that JEDEC was undertaking, the member was required to disclose the existence of the relevant patents or patent applications and to identify the aspect of JEDEC's work to which they related.
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> b. Second, in the event that technologies covered by a member's known patents or patent applications were proposed for inclusion in a JEDEC standard, the member was required to state whether the technology would be made available either "without compensation" or under "reasonable terms and conditions that are demonstrably free of any unfair discrimination." Absent the member's agreement to one of these two conditions, the JEDEC rules would not allow the technology to be incorporated into a proposed standard.

On February 23, 2004, the administrative law judge (ALJ) issued an initial decision dismissing the *Rambus* complaint.[17] The judge concluded as a factual matter that Rambus did not violate JEDEC rules, did not behave deceptively or in bad faith, and did not have relevant but undisclosed patents or applications during the time it was a JEDEC member.[18] The judge also concluded that Rambus had a business justification for its conduct and thus did not engage in exclusionary conduct.[19] In terms of issues of market power and effects, the judge determined that complaint counsel did not demonstrate the absence of technological alternatives to the Rambus technology, that the Rambus technology would have been used in any event, and thus, that the challenged conduct did not result in higher prices or otherwise reduce consumer welfare.[20]

Complaint counsel has appealed the initial decision, arguing that it is so riddled with error that it cannot assist the Commission in its review of the record and suggesting that the Commission set it aside entirely.[21] Oral argument before the Commission is scheduled for September 21, 2004.[22]

2. *UNOCAL* The *Unocal* complaint, issued in March 2003, charges that Unocal subverted the process under which the California Air Resources Board (CARB) adopted regulations on phase 2 reformulated gasoline. The complaint alleges that Unocal made materially false and misleading statements to CARB and others, which led CARB unknowingly to adopt regulations requiring the use

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[17] Rambus Inc., Docket No. 9302 (Feb. 23, 2004) (initial decision), *available at* http://www.ftc.gov/os/adjpro/d9302/040223initialdecision.pdf.

[18] *Id.* at 7.

[19] *Id.*

[20] *Id.*

[21] Rambus Inc., Docket No. 9302, Appeal Brief of Counsel Supporting the Complaint 7 (Apr. 16, 2004), *available at* http://www.ftc.gov/os/adjpro /d9302/040422appealbrief.pdf.

[22] Rambus Inc., Docket No. 9302, Order Granting Motions to File Briefs Amici Curiae and Scheduling Oral Argument (Apr. 30, 2004), *available at* http://www.ftc.gov/os/adjpro/d9302/040430orderreamicus.pdf.

of technology covered by Unocal patents. According to the complaint, Unocal misrepresented that certain information was nonproprietary and in the public domain, and failed to disclose that it had pending patent claims for which it intended to assert its proprietary interests in the future. Unocal's deceptive conduct precluded the timely consideration of other technologies. By the time Unocal disclosed its patent interests and its intention to seek royalties, the refining industry had made billions of dollars in capital expenditures to reconfigure refineries to produce gasoline that would comply with CARB phase 2 regulations. In effect, the refiners were locked-in to producing gasoline covered by Unocal's patents. Unocal's enforcement of its patents could result in hundreds of millions of dollars per year in additional consumer costs for gasoline.

One of the more interesting aspects of the case, in addition to the exclusionary conduct issue, is Unocal's assertion that its presentations to CARB constitute petitioning activity that is shielded from antitrust prosecution by the *Noerr* immunity doctrine.[23] Anticipating that argument, the complaint rejects the claim of immunity on several grounds: (1) Unocal's misrepresentations were made in the course of quasi-adjudicative rulemaking proceedings; (2) Unocal's conduct did not constitute petitioning behavior; and (3) Unocal's misrepresentations and materially false and misleading statements to two non-governmental industry groups involved in the process were not covered by any petitioning privilege.[24] In addition to those reasons, there is a more fundamental reason to reject the claim: there is nothing in the policy underlying *Noerr*'s protection of the right to petition that warrants a license for fraudulent conduct before a government agency to obtain monopoly power.[25]

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[23] The *Noerr* doctrine and the FTC's initiatives in that regard are further discussed *infra* at section V.

[24] Union Oil Co. of California, Docket No. 9305 (Mar. 4, 2003), Complaint ¶ 96, *available at* http://www.ftc.gov/os/2003/03/unocalcmp.htm.

[25] Indeed, fraud before the Patent Office in the procurement of a patent was the basis for a claim of monopolization under the Sherman Act in Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965).

On November 25, 2003, the administrative law judge dismissed the *Unocal* complaint on a motion to dismiss.[26] In spite of the fact that the Commission specifically addressed the applicability of *Noerr* issues in the complaint, the judge concluded that the facts set forth therein could not overcome respondent's argument that its actions vis-a-vis the CARB were protected petitioning activities.[27] With respect to the remaining conduct, the judge concluded that it was so intertwined with patent issues as to divest the Commission of jurisdiction. In the ALJ's view, only the federal courts have jurisdiction over substantial patent issues.[28]

On July 7, 2004, the Commission issued an order reversing the ALJ's decision in all respects (Union Oil of California, Docket No. 9305 (July 7, 2004) (commission opinion) *available at* http://www.ftc.gov/os/adjpro/d9305/040706commissionopinion.pdf). The Commission's opinion provides an extensive discussion of the misrepresentation exception to the *Noerr* doctrine. In particular, the Commission held that misrepresentation can warrant denial of *Noerr* immunity either as a separate doctrinal exception or as a variant of the sham exception. The Commission explained, however, that false petitioning only loses *Noerr* immunity when it occurs outside the political arena, is deliberate, factually verifiable, and central to the outcome of the case or proceeding.

3. SECTION 5 THEORIES Another noteworthy aspect of both *Rambus* and *Unocal* is that the unilateral conduct theory in both cases was not limited to traditional monopolization and intent-to-monopolize theories based on section 2 of the Sherman Act. Both cases included a section 5 theory that does not require a showing of monopoly power or intent to monopolize. The complaint in *Rambus*, for example, alleges:

> Third Violation Alleged
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> 124. . . . Rambus has willfully engaged in a pattern of anticompetitive and exclusionary acts and practices, . . . , whereby it has unreasonably

[26] Union Oil Co. of California, Docket No. 9305 (Nov. 26, 2003) (initial decision), *available at* http://www.ftc.gov/os/adjpro/d9305/031125 aljsinitialdecision.pdf.

[27] *Id.* at 1.

[28] *Id.* at 2.

> restrained trade in the synchronous DRAM technology market and narrower markets encompassed therein, which act and practices constitute unfair methods of competition in violation of Section 5 of the FTC Act.[29]

The significance of this "pure" section 5 count is that a unilateral conduct violation may be found even if the firm's market power does not reach traditional "monopoly" proportions, so long as there is proof of exclusionary conduct *and* harm to consumers. The economics here is straightforward, i.e., it is uncontroversial as a matter of economics that a firm that does not have monopoly power as defined in the law may in some circumstances nonetheless have market power sufficient to cause significant anticompetitive harm.[30]

B. IP abuses in pharmaceuticals

Anticompetitive IP abuses in the pharmaceutical industry have been another major focus of FTC nonmerger enforcement. The growing cost of prescription drugs is a significant concern for consumers, government, and private entities that reimburse health costs. Various forms of anticompetitive conduct seeking to forestall generic entry have been a major focus of enforcement.[31] There have been three generations or phases of cases, involving (1) agreements between a brand-name drug manufacturer and a generic firm to delay generic entry, (2) unilateral conduct by a branded manufacturer to

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[29] Rambus Inc., Docket No. 9302 (June 18, 2002), Complaint ¶ 124, *available at* http://www.ftc.gov/os/adjpro/d9302/020618admincmp.pdf; *see also* Union Oil Co. of California, Docket No. 9305 (Mar. 4, 2003), Complaint ¶¶ 102, 103, *available at* http://www.ftc.gov/os/2003/03/unocalcmp.htm. Neither the ALJ's decision in *Rambus* nor *Unocal* addressed this issue. The judge in *Rambus* found no anticompetitive effects, while the *Unocal* opinion focused only on *Noerr* and patent issues.

[30] *See, for example*, David Scheffman, *The Application of "Raising Rivals' Costs" Theory to Antitrust*, 37 ANTITRUST BULL. 187 (1992).

[31] This is an area where there has been seamless continuity from the Pitofsky era. Chairman Pitofsky launched a number of pharmaceutical IP investigations, as well as a study of the generic drug industry, and the FTC under Chairman Muris has continued and extended those initiatives.

delay generic entry, and (3) agreements among generic drug manufacturers.

The first and second generation cases involved the statutory and regulatory framework of the Hatch-Waxman amendments[32] to the Food, Drug and Cosmetic Act (FDC Act).[33] Some detail about the FDC Act and the Hatch-Waxman amendments is needed to understand the context of the cases.

I. THE STATUTORY & REGULATORY FRAMEWORK Pursuant to the FDC Act, a branded drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application (NDA). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[34] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled *Approved Drug Products with Therapeutic Equivalence*, commonly known as the Orange Book.[35]

One stated purpose of the Hatch-Waxman amendments is to "make available more low cost generic drugs."[36] The concern that prompted the amendments was that the FDA's lengthy drug approval process was unduly delaying market entry by low-cost generic versions of brand-name prescription drugs. Because a generic drug manufacturer was required to obtain FDA approval before selling its product, and could not begin the approval process until any conflicting patents on the relevant branded product expired, the FDA approval process essentially functioned to extend the term of the branded manufacturer's patent monopoly. To correct this problem, Congress enacted a compromise: an expedited FDA approval process

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[32] Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[33] 21 U.S.C. §§ 301 *et seq.*

[34] *Id.* § 355(b)(1).

[35] *Id.* § 355(j)(7)(A).

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

to speed generic entry balanced by additional intellectual property protections to ensure continuing innovation. Under the amendments, certain conduct related to obtaining FDA approval, which would otherwise constitute patent infringement, would be exempted from the patent laws.

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the amendments permit the company to file an Abbreviated New Drug Application (ANDA), which incorporates data that the "pioneer" manufacturer has already submitted to the FDA regarding the branded drug's safety and efficacy. The object of the ANDA process is to demonstrate that the generic drug is "bioequivalent" to the relevant branded product.[37] The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.[38] One way to satisfy this requirement is to provide a "paragraph IV certification," asserting that the patent in question is invalid or not infringed.[39]

Filing a paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to the operation of two significant provisions of the statute. The first of these is an automatic 30-month stay protection afforded patents. An ANDA filer that makes a paragraph IV certification must provide notice, including a detailed statement of the factual and legal basis for the ANDA filer's assertion that the patent is invalid or not infringed, to both the patent holder and the NDA filer.[40] Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory stay provision must bring an infringement suit within 45 days.[41] If the patent holder

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[37] 21 U.S.C. § 355(j)(2)(A)(iv).

[38] *Id.* § 355(j)(2)(A)(vii).

[39] *Id.* § 355(j)(2)(A)(vii)(IV).

[40] *Id.* § 355(j)(2)(B). Although the patent holder and the NDA filer are often the same person, this is not always the case. The Hatch-Waxman amendments require that all patents that claim the drug described in an NDA must be listed in the Orange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

[41] *Id.* § 355(j)(5)(B)(iii).

does not bring suit within 45 days, as soon as other regulatory conditions are fulfilled, the FDA must approve the ANDA immediately.[42] If the patent holder does bring suit, however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the ANDA.[43] During this period, unless the patent litigation is resolved in the generic's favor, the generic cannot enter the market.

The second significant component of the Hatch-Waxman amendments is the "180-day period of exclusivity." The amendments provide that the first generic manufacturer to file an ANDA containing a paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA.[44] Through this 180-day provision, the amendments provide an incentive for companies to challenge patents and develop alternative forms of patented drugs.[45] The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.[46] The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file an ANDA and get to market.[47] After the 180 days, subject to regulatory approvals and determination of the outcomes of any patent suits, other generics can enter the market.

The 30-month stay and the 180-day period of exclusivity were both a part of the Hatch-Waxman balance. The imposition of a stay in some cases could forestall generic competition for a substantial period of time. The 180-day period of exclusivity can, in some circumstances, limit the number of generic competitors during this period. These provisions also provided branded and generic drug

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[42] *Id.* For example, the statute requires the ANDA applicant to establish bioequivalence. *See supra* note 37.

[43] *Id.*

[44] *Id.* § 355(j)(5)(B)(iv).

[45] *See* Granutec, Inc. v. Shalala, 1998 U.S. App. Lexis 6685 (4th Cir. 1998) (139 F.3d 889).

[46] 21 U.S.C. § 355(j)(5)(B)(iv).

[47] *Id.*

manufacturers opportunities to game the system, attempting to restrict competition beyond what the Hatch-Waxman amendments intended.

2. THE FIRST GENERATION CASES: SETTLEMENTS BETWEEN PIONEER MANUFACTURERS AND GENERIC ENTRANTS The Commission's first generation cases, initiated under Chairman Pitofsky, focused on patent settlement agreements between pioneer manufacturers and generic entrants that were alleged to have delayed the entry of one or more generics. Resolving patent infringement litigation through settlement can be efficient and procompetitive. Certain patent settlements between brands and generics, however, drew the Commission's attention when it appeared that their terms may have maintained monopolies through abuses of the Hatch-Waxman regime.

Because of the difference in prices between branded and generic products, the profit earned by a successful generic is substantially less than the loss of profits by the branded product. As a result, both parties can have economic incentives to collude to delay generic entry. By blocking entry, the branded manufacturer can preserve its monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry—and with it, the triggering of the 180 days of exclusivity—the branded and first-filing generic firms can sometimes forestall the entry of other generics.

Agreements settling patent infringement litigation between the branded manufacturer and the first-filing generic could be one method to effect such a collusive scheme. Provisions that provide for "reverse" payments—i.e., payments from the patent holder to the alleged infringer—raise questions, since they may represent an anticompetitive division of monopoly profits.[48] In effect, the branded

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[48] *See* Thomas B. Leary, Commissioner, Federal Trade Commission, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II, available at* http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm. This article is an essay based on a speech before the American Bar Association Healthcare Program, in Washington, DC (May 17, 2001), and is published in 34 J. HEALTH L. (Dec. 2001), at 657.

manufacturer may be paying the generic to delay entry. While the identification of a reverse payment may not be a simple matter, a payment that appears to be disproportionate to the generic's expected profit upon entry is particularly suspect.

The Commission's first case in this area, *Abbott/Geneva*, involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. relating to Abbott's branded drug Hytrin.[49] The Commission's complaint alleged that Abbott paid Geneva approximately $4.5 million per month to delay the entry of its generic Hytrin product, potentially costing consumers hundreds of millions of dollars a year. The complaint further alleged that Geneva agreed not to enter the market with *any* generic Hytrin product including a non-infringing product until (1) final resolution of the patent infringement litigation involving Geneva's generic Hytrin tablets, or (2) market entry by another generic Hytrin manufacturer. Geneva also allegedly agreed not to transfer its 180-day marketing exclusivity rights.

The second case involved an agreement between Hoechst Marion Roussel and Andrx Corp. relating to Hoechst's branded drug Cardizem CD.[50] The Commission's complaint alleged that Hoechst paid Andrx over $80 million, during the pendency of patent litigation, to refrain from entering the market with its generic Cardizem CD product.[51] As in the *Abbott/Geneva* case, the Commission also asserted that the agreement called for Andrx, as the first ANDA filer, to use its 180-day exclusivity rights to impede entry by other generic competitors.[52]

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[49] Abbott Laboratories, No. C-3945 (May 22, 2000) (consent order) *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm; complaint *available at* http://www.ftc.gov/os/2000/05/c3945complaint.htm.

[50] Geneva Pharmaceuticals, Inc., No. C-3946 (May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/03/genevad&o.htm; complaint *available at* http://www.ftc.gov/os/2000/05/c3946complaint.htm.

[51] *See* Hoechst Marion Roussel, Inc., No. 9293 (May 8, 2001) (consent order), *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm; complaint *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm.

[52] *Abbott/Geneva* and *Hoechst/Andrx* were settled by consent order. The orders prohibited the respondent companies from entering into brand/generic

The Commission subsequently settled another case involving a drug settlement in which the brand-name company, Bristol-Myers, allegedly had paid a generic drug manufacturer $72.5 million to abandon its challenge to a Bristol-Myers patent and to stay off the market until the patent expired.[53] Similar issues are raised by another case, *Schering-Plough*, which involves allegations that Schering illegally paid Upsher-Smith Laboratories $60 million to delay marketing a generic version of K-Dur 20.[54] The complaint was issued by the Pitofsky Commission but was largely litigated after Chairman Pitofsky's departure. Although the administrative law judge issued an initial decision dismissing the case,[55] the Commission reversed the ALJ and upheld the complaint.

The *Schering* case provided the Muris Commission with its second opinion in which to develop antitrust jurisprudence involving the rule of reason. The Commission's first opportunity occurred in *PolyGram*

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agreements pursuant to which a generic company that is the first ANDA filer with respect to a particular drug agrees not to (1) enter the market with a noninfringing product, or (2) transfer its 180-day marketing exclusivity rights. In addition, the companies were required to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action, that provided for payments to the generic to stay off the market, with advance notice to the Commission to allow it time to present its views to the court. Advance notice to the Commission was also required before the respondents could enter into such agreements in nonlitigation contexts.

[53] Bristol-Myers Squibb Co., Docket No. C-4076 (Apr. 18, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf.

[54] *See* Schering-Plough Corp., Docket No. 9297 (Mar. 30, 2001) (complaint), *available at* http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf. In April 2002, the Commission resolved all claims against one of the three respondents, American Home Products (AHP), by issuing a final consent order. Pursuant to that order, AHP is prohibited from entering into two categories of agreements: (1) those in which the brand makes a payment to the generic in return for delayed entry, and (2) those in which the generic agrees not to enter the market with a noninfringing product. *See* Schering-Plough Corp., Docket No. 9297 (consent order as to AHP issued Apr. 2, 2002), *available at* http://www.ftc.gov/os/2002/04/scheringplough_do.htm.

[55] Schering-Plough Corp., Docket No. 9297 (July 2, 2002) (initial decision), *available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf; http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf.

Holding (also known as the *Three Tenors*), which concerned the extent to which an agreement not to discount or advertise was ancillary to a legitimate joint venture.[56] There, the FTC's decision lays out a fundamental framework for rule of reason analysis, synthesizing prior case law, and explicating generally the continuum of analysis required by the rule of reason. The Commission explained that where the conduct at issue is of a type that is almost always anticompetitive ("inherently suspect" in the Commission's terminology), and the plaintiff advances no cognizable and plausible efficiency justification, that is sufficient for the plaintiff and the case ends. Where such justification is advanced, however, the plaintiff must then show that the restraints in question are likely to harm competition in the circumstances presented.

In its *Schering* opinion, the Commission took the rule of reason analysis a step further, explaining:

> In this case, we will apply and build on fundamental principles that were discussed at length in *PolyGram Holding*—a Commission opinion that was itself based on a synthesis of recent Supreme Court decisions. Our *PolyGram Holding* opinion explains that bright-line distinctions are not normally helpful; the appropriate methods extend over a continuum. This case differs from *PolyGram Holding*, however, not because the principles are different, but because it occupies a different place along the continuum. While scrutiny of the restraint itself was sufficient in *PolyGram Holding*, the facts of this case require us to look beyond the nature of the challenged restraint and consider the nature of the market.[57]

But the Commission did not look to every aspect of the market. Its *Schering* opinion specifically stated that market definition analysis was not required in light of the substantial evidence of anticompetitive effects, evidence largely ignored in the initial decision.[58] Given the

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[56] PolyGram Holding, Inc., Docket No. 9298 (July 28, 2003) (Commission opinion), *available at* http://www.ftc.gov/os/2003/07/polygramopinion.pdf.

[57] Schering-Plough Corp., Docket No. 9297, at 15 (Dec. 18, 2003) (Commission opinion), *available at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf.

[58] *Id.* at 58. Our own view is that it may be better not to dispense with market definition in such cases. In this case, specifically, the market definition issues were somewhat complex, and the Commission could have provided more guidance on that important subject.

evidence of effects, the burden then shifted to the respondents to prove legitimate justifications, not merely suggest hypothetical efficiencies. Having found a failure to meet this burden, the Commission upheld the complaint.

3. SECOND GENERATION CASES: IMPROPER ORANGE BOOK LISTINGS The Commission's second generation cases have focused on improper Orange Book listings. Unlike the settlement cases discussed above, which typically involve allegations of collusion between private parties, an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process to restrain trade.[59] Since the FDA does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria.[60] Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any validly listed patent, thereby delaying generic entry and potentially costing consumers millions, or even billions, of dollars without valid cause. Brand-name drug manufacturers may sometimes act strategically to obtain more than one 30-month stay of FDA approval of a particular generic drug.

The Commission's enforcement action against Biovail Corp. alleged precisely that kind of conduct.[61] The complaint alleged that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its branded drug Tiazac. Prior to the events giving rise to the Commission's complaint, Biovail had already triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against

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[59] Such conduct has also raised *Noerr-Pennington* immunity issues, which we discuss in section V, *infra.*

[60] The FDA takes at face value the declaration of the NDA filer that listing is appropriate.

[61] Biovail Corp., Docket No. C-4060 (Oct. 2, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/10/biovaildo.pdf; complaint *available at* http://www.ftc.gov/os/2002/10/biovailcmp.pdf.

Andrx. Andrx prevailed in the courts, however, so that by February 2001, the stay would have been lifted. According to the Commission's complaint, Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired a newly issued patent from a third party and listed it in the Orange Book as claiming Tiazac—thereby requiring Andrx to recertify to the FDA under paragraph IV, and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

According to the Commission's complaint, Biovail knew that the new patent did not claim the form of Tiazac that it had been marketing, and Biovail did not need this new patent to continue marketing Tiazac without infringement risk. In fact, the FDA later learned that Biovail's position was that the newly listed patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the patent. The newly listed patent did not cover the version of Tiazac that the FDA had approved and that Biovail had been marketing. FDA told Biovail that the new Tiazac formulation therefore lacked FDA approval and that it would de-list the patent from the Orange Book unless Biovail certified that the patent claimed the approved version of Tiazac. The Commission alleges that Biovail misleadingly represented to the FDA that the new patent claimed existing-and-approved, rather than revised-and-unapproved, Tiazac, to avoid de-listing from the Orange Book and termination of the stay against Andrx.[62] The Commission alleges that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of section 5

[62] After learning that Biovail had taken the position that its newly acquired patent covered a formulation of Tiazac developed after acquisition of the patent, the FDA contacted Biovail to determine whether this formulation was the same as the formulation approved under the Tiazac NDA. In response, Biovail submitted a declaration stating simply that its newly acquired patent claimed Tiazac and, therefore, was eligible for listing in the Orange Book. The Commission asserts that this declaration was misleading, because it did not clarify whether the term "Tiazac" as used by Biovail meant FDA-approved Tiazac (as the FDA required) or Biovail's revised form of the product.

of the FTC Act[63] and that the acquisition also violated section 7 of the Clayton Act.[64]

In another action, the Commission charged that Bristol-Myers Squibb Company (Bristol) engaged in a series of anticompetitive acts over the past decade to obstruct the entry of low-price generic competition for three of its widely-used pharmaceutical products: two anticancer drugs, Taxol and Platinol, and the antianxiety agent BuSpar.[65] According to the complaint, Bristol's illegal conduct protected nearly $2 billion in annual sales at a high cost to cancer patients and other consumers, who—being denied access to lower-cost alternatives—were forced to overpay by hundreds of millions of dollars for important and often life-saving medications.

The complaint alleges that Bristol submitted patents for listing in the Orange Book after an Abbreviated New Drug Application already had been filed with the FDA—and in the case of BuSpar, literally hours before generic rivals were set to enter the market. The complaint charges that each of these patent listings was improper and unlawful because the patent did not meet the statutory listing criteria, and Bristol could not reasonably believe that it did.

In addition to alleging improper listings, the complaint also states that Bristol entered into two unlawful agreements—one concerning BuSpar and another concerning Taxol—to obstruct generic competition and share monopoly profits. With respect to the BuSpar agreement, Bristol is alleged to have paid its potential buspirone rival over $70 million to withhold competition until patent expiration, eliminating the only potential generic threat to BuSpar for the entire patent period. With respect to the Taxol agreement, the complaint alleges that Bristol conspired to list improperly an invalid patent in the Orange Book.

The consent order restricts Bristol's ability to act in concert with other firms to delay generic competition. The consent order, among

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[63] 15 U.S.C. § 45.

[64] *Id.* § 18.

[65] Bristol-Myers Squibb Company, Docket No. C-4076 (Apr. 18, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf.

other restrictions, eliminates Bristol's ability to obtain a 30-month stay on later-listed patents. By denying Bristol the benefit of the 30-month stay on later-listed patents, the order will reduce Bristol's incentive to engage in improper behavior before the Patent and Trademark Office (PTO) and the FDA to obtain and list a patent for the purpose of obtaining an unwarranted automatic 30-month stay. The order also bars a 30-month stay, regardless of when the patent was listed, in cases where Bristol has engaged in certain types of misconduct in connection with obtaining and listing the patent, including: inequitable conduct before the PTO in obtaining the patent; making false or misleading statements to the FDA in connection with listing the patent; or providing information about the patent to the FDA that is inconsistent with information provided to the PTO.

4. THIRD GENERATION CASES: SETTLEMENTS BETWEEN GENERICS The third generation focuses on market division agreements. As in the case of agreements between brands and generics, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70%–80% of the price of the corresponding brand and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share. Collusion between the generics can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market. In a complaint against Biovail and Elan Corp.,[66] the Commission charged that the two companies entered into an agreement that effectively divided the market for the 30 mg and 60 mg dosage forms of generic Adalat CC.

C. Other IP-related cases

The FTC IP cases brought to date only scratch the surface of potentially anticompetitive stratagems involving patent rights. The agency is also looking at other potential anticompetitive misuse of

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[66] Biovail Corp. and Elan Corp., Docket No. C-4057 (Aug. 15, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/06/biovailelanagreement.pdf.

IP, such as anticompetitive settlements that end interference proceedings before the PTO;[67] anticompetitive settlements of patent disputes in proceedings under section 337 of the Tariff Act of 1930, before the International Trade Commission;[68] and anticompetitive settlements of patent litigation in federal court.[69] The agency is also

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[67] The United States patent laws grant a patent to the first to invent, not the first to file a patent application. 35 U.S.C. § 102(g). A patent interference proceeding is an administrative proceeding before the Board of Patent Appeals and Interferences, conducted to determine priority to an invention, i.e., to determine which of two (or more) applicants was the first to invent the matter. 35 U.S.C. § 135. An interference proceeding may also determine issues of patentability. *Id.* § 135(a). It is possible that the parties to an interference proceeding could enter into a colllusive settlement through which the potential unpatentability of a claimed invention, for example, could be "covered up"—and the parties could split monopoly proceeds. Recognizing the potential for anticompetitive settlements, Congress required that settlements of interference disputes be filed in writing with the PTO. 35 U.S.C. § 135 (c); *see* CTS Corp. v. Piher Int'l Corp., 727 F.2d 1550, 1555–57 (Fed. Cir. 1984); United States v. FMC Corp., 717 F.2d 775, 777–80 (3d Cir. 1983); H.R.REP. NO. 1983, 87th Cong., 2d Sess. 1 (1962), *reprinted in* 1962 U.S.C.C.A.N. 3286.

[68] Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, bans unfair methods of competition and unfair acts in the importation of articles into the United States. It has been observed that section 337 has been invoked primarily in intellectual property cases, particularly those concerning patent infringement. *See* Harvey M. Applebaum, *The Interface of the Trade Laws and the Antitrust Laws,* 6 GEO. MASON L. REV. 479, 483 (1998). Section 337 authorizes a United States patent holder to obtain an order excluding imports that infringe its U.S. patent. The alleged infringer may put forth a full array of defenses, including the invalidity or unenforceability of the patent, 19 U.S.C. § 1337(c). Thus, for example, it is conceivable that the complainant and the alleged infringer could enter into the colllusive settlement of a section 337 action, through which the potential invalidity or unenforceability of a patent could be "covered up"—and the parties could split monopoly proceeds resulting from continued exclusion of imports.

[69] A federal court patent settlement may create market power beyond the legitimate scope of the intellectual property rights conveyed by the patent or patents in question. For example, a settlement may "cover up" issues of patent invalidity or unenforceability (thus allowing the patent holder or holders to engage in illegitimate exclusion that harms consumers), or may be used as a vehicle to facilitate clearly anticompetitive arrangements between the settling parties, such as market division.

examining potential abuses involving extensive patent portfolios apparently acquired and sought to be enforced without regard to the validity of any particular patent. Such conduct may be an inefficient, anticompetitive stratagem to extract royalties that harms consumers.

D. A common theme: abuses of the regulatory process and/or legal regime

Several of the cases discussed above can be described as involving an abuse of a regulatory process and/or legal regime. The interplay between competition and a regulatory process is of interest from an enforcement perspective because many regulatory regimes are susceptible to anticompetitive abuses, in ways that run counter to the policies underlying the regulatory regime. Those abuses warrant close attention because the consumer welfare consequences can be far-lasting. The agency in the past has made significant contributions to the law in this area,[70] and it remains of great interest.

Broadly understood, regulatory processes subject to manipulation include laws that may have a socially desirable purpose, but are subject to potential manipulation in an anticompetitive fashion. The term "regulatory process" thus encompasses a wide range of regulatory regimes and governmental processes that govern market behavior in some way. The concept includes regulatory regimes involving intellectual property, such as the Hatch-Waxman statutory framework for facilitating entry of generic drugs;[71] it involves proceedings before the Patent and Trademark Office and other governmental agencies regarding patent claims;[72] it includes

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[70] *E.g.*, FTC v. Ticor Title Ins. Co., 504 U.S. 621 (1992); Dell Computer Corp., 121 F.T.C. 616 (1996) (consent order); AMERCO, 109 F.T.C. 135 (1987) (consent order); American Society of Sanitary Engineering, 106 F.T.C. 324 (1985) (consent order).

[71] See discussion *infra* at section VII.

[72] *E.g.*, Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965); *In re* American Cyanamid Co., 72 F.T.C. 623, 684–85 (1967), *aff'd*, Charles Pfizer & Co. v. FTC, 401 F.2d 574 (6th Cir. 1968).

standard setting by private and governmental entities;[73] and it includes state and local business regulation,[74] as well as other governmental and judicial processes.[75] Anticompetitive activity involving abuse of a regulatory process has the greatest potential for long-term harm to consumers, because it generally cannot be eliminated by normal market processes. Entry—a natural constraint on anticompetitive behavior in many markets—is typically restricted in these situations by the law or regulatory process that is involved, and competition may be restrained by the regulatory scheme in other ways.

III. Single-firm conduct

As discussed above, the Muris FTC has been active in bringing cases under monopolization theory. Both of the aforementioned standards cases, *Rambus* and *Unocal*, are based, in part, on a monopolization theory, as are several patent abuse cases—*Schering-Plough*, *Biovail (Tiazac)*, and *Bristol-Myers Squibb*.[76] This should not be a surprise. Chairman Muris has stated that, despite strong misgivings about some of the FTC monopolization cases brought prior to the 1980s, there are some economically sound monopolization cases.[77] The Chairman cited standards cases and

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[73] *E.g.*, Allied Tube & Conduit Corp., 486 U.S. 492 (1988); American Society of Sanitary Engineering, 106 F.T.C. 324 (1985) (consent order). Private standard setting may be thought of as a self-regulatory process, and private standards often become the basis for governmental standards.

[74] *E.g.*, FTC v. Ticor Title Ins. Co., 504 U.S. 621 (1992); Indiana Household Movers and Warehousemen, Inc., Docket No. C-4077 (Mar. 18, 2003) (proposed consent order accepted for public comment), *available at* http://www.ftc.gov/os/2003/03/indianahouseholdmoversagree.pdf.

[75] *E.g.*, AMERCO, 109 F.T.C. 135 (1987) (postcomplaint consent order).

[76] It is interesting to note that the agency filed only four monopolization cases during the 8 years of FTC enforcement during the Clinton Presidency. *See* Kovacic, *supra* note 1, at table 4.

[77] Muris, *supra* note 6.

abuse of patent rights as examples. There is nothing ambiguous about the conduct at issue in the recent FTC standards and patent abuse cases; the exclusionary nature of the conduct is clear, the lack of legitimate business justification is clear, and the anticonsumer effect also is quite clear.

IV. Vertical restraints

Economically sound, proconsumer vertical restraints cases are more difficult to find and to prove are meritorious. Since the 1980s, including during the Pitofsky Commission, notable vertical restraints cases have been relatively infrequent.[78] The *Microsoft* case has demonstrated the potential viability of monopoly maintenance cases, and this has largely been the focus of the Muris Commission. In general, several conditions must be present to show that a vertical restraint results in anticompetitive exclusion. First, the firm must have market power in a well-defined relevant market. Second, the restraint must be a credible means of foreclosing a threat to that market power, or removing an important constraint on that power. Third, the targets of the restraint must lack viable defensive measures that would thwart potential anticompetitive impact on consumers. Fourth, the evidence on countervailing efficiencies must be weak. The Commission has thus far had two (publicly announced) investigations in which vertical issues were prominent—the proposed Cytyc/Digene and Avant!/Synopsys vertical mergers.

Cytyc/Digene involved a proposed merger of two leading producers of cervical cancer screening tests. Cytyc had market power in liquid PAP tests, but there was a threat to that market power from new entry that had received FDA approval for liquid PAP testing. Such competition could be thwarted by interfering with the ability of rivals to have their product interface with Digene's product. There was credible evidence that access to Digene's HPV test was necessary for successful entry into liquid PAP testing. By not cooperating with upstream entrants to gain FDA approval for using their tests in combination with Digene's test, the ability of those entrants to

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[78] Kovacic, *supra* note 1, at table 5.

compete would be limited.[79] In addition, there was evidence indicating that Digene, on its own, might develop a combination test that would gain FDA approval, which would present a competitive threat to Cytyc. Representative "customers" (health care providers who administered or interpreted the tests) indicated significant concerns with the proposed merger on both grounds. There was no convincing evidence that significant efficiencies would accrue from the merger. The potential for consumer harm was very real, and so the Commission voted to sue to block the deal (which the parties then abandoned).[80]

Avant!/Synopsys involved software that is used in the design of computer chips. Synopsys had a nearly 90% share of "logical synthesis" or "front-end" tools for chip design, and Avant! had a share of about 40% of so-called place and route or back-end tools. There was a possible threat to Synopsys's market power from competition at the other level if in the future, integrated solutions might threaten Synopsys's market power. This threat, however, was considerably more speculative and distant than in the Cytyc/Digene matter.[81] Agency staff examined numerous theories of competitive harm, including whether the merger would give Synopsys the ability and incentive to enhance the back-end competitive position of the formerly independent Avant!, by making it harder for competing back-end products to communicate with Synopsys's dominant front-end product. They found little evidence, however, that Synopsys would have either the incentive or the ability (primarily because of customer power) to foreclose competitive products sufficiently to

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[79] In addition, because many liquid PAP tests never actually are used in conjunction with HPV tests (although having that option is important), Digene would not be able to capture the monopoly rents of both markets through its pricing of HPV. Cytyc/Digene might be able to bundle the two products in a way that increased combined prices and limited upstream competitors from competing.

[80] FTC Press Release, Federal Trade Commission Seeks to Block Cytyc Corporation's acquisition of Digene Corporation, File No. 021-0098 (June 24, 2002), *available at* http://www.ftc.gov/opa/2002/06/cytyc_digene.htm.

[81] For example there were imminent entrants that would need the cooperation of Digene in order to get through the regulatory process.

harm consumers.[82] It was not clear that access to Avant!'s place and route product was necessary for backward integration by other firms, and it was also not clear that Synopsys would have the incentive to deny access to other firms or to significantly disrupt their ability to interface with the Synopsys product. Finally, there was widespread belief (including by customers) that the merger might speed integration of the products and provide substantial benefits to customers. The agency did not challenge the merger, with a unanimous decision by the five Commissioners.

Both of these investigations focused on monopoly maintenance theories, and we believe that they shed significant light on the characteristics of viable monopoly maintenance cases—both vertical mergers and vertical restraints.[83]

V. Addressing *Noerr* and state-action immunities

The *Noerr* and state-action doctrines have carved out a substantial amount of commercial activity from the beneficial forces of competition. As Robert Bork observed nearly a quarter century ago, we have seen "an enormous proliferation of regulatory and licensing

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[82] *See* FTC Press Release, Federal Trade Commission Votes to Close Investigation of Acquisition of Avant! Corporation by Synopsys, Inc., File No. 021-0049 (July 26, 2002), *available at* http://www.ftc.gov/opa /2002 /07/avant.htm. As three Commissioners noted in their separate statements, the Commission intends to watch this market closely in the future, and we have not ruled out the possibility of seeking relief in the future if market effects prove to be more harmful than was apparent in advance of the merger. *Statement of Commissioner Thomas B. Leary, Synopsys Inc./Avant! Corp.*, File No. 021-0049 (July 26, 2002), *available at* http://www.ftc.gov /os/2002/07/avantlearystmnt .htm; *Statement of Commissioner Mozelle W. Thompson, Synopsys Inc./Avant! Corp.*, File No. 021-0049 (July 26, 2002), *available at* http://www.ftc.gov/os/2002 /07/avantthompsonstmnt.htm; *Statement of Commissioner Sheila F. Anthony, Synopsys Inc./Avant! Corp.*, File No. 021-0049 (July 26, 2002), *available at* http://www.ftc.gov/os /2002/07/avantanthonystmnt.htm.

[83] For further discussion, *see* David Scheffman & Richard Higgins, *20 Years of Raising Rivals' Costs*, forthcoming, *George Mason Law Review* (*draft posted at* http://www.ftc.gov/be/RRCGMU.pdf).

authorities at every level of government."[84] The result of this growth in the role of government, he warned, has been "almost limitless possibilities for abuse."[85] At the same time, the *Noerr* and state-action doctrines restrict the role of antitrust in protecting consumers from rent seeking behavior.

While the core principles underlying these doctrines have validity, some lower court decisions have expanded the reach of both doctrines well beyond the precepts originally articulated by the Supreme Court. By bringing carefully-selected enforcement actions, the agency has sought to ensure that these doctrines are not applied more expansively to create broader immunity than indicated by the Supreme Court's decisions.

A. State action

The state-action doctrine, first articulated by the Supreme Court in *Parker v. Brown*,[86] maintains that Congress did not limit the sovereign regulatory power of the states when it passed the antitrust laws. The doctrine is thus grounded on notions of federalism. The state-action doctrine shields from antitrust liability not only actions of the state itself, but also political subdivisions of a state, such as municipalities, acting under a clearly articulated state policy to displace competition with regulation,[87] as well as private entities acting pursuant to a clearly articulated state policy to displace competition with regulation *and* actively supervised by the state.[88]

In applying the state-action doctrine, some courts have not fully considered whether the anticompetitive conduct in question was intended by the state legislature to accomplish the state's objective. In other instances, courts have granted broad immunity to quasi-

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[84] ROBERT H. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF 347 (1978).

[85] *Id.*

[86] 317 U.S. 341 (1943).

[87] Town of Hallie v. City of Eau Claire, 471 U.S. 34 (1985).

[88] California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 U.S. 97 (1980).

governmental entities, including entities composed of market participants, with only a tangential connection to the state. Courts also have not articulated clear working tests for what constitutes active supervision. Unsupervised anticompetitive private conduct, or lack of clear state articulation, should not be deemed to be "*Parker* protected"—such acts go well beyond the Supreme Court's articulation of the doctrine, and beyond any legitimate bow to the needs of federalism.

The Commission recently addressed standards for active supervision in connection with the *Indiana Movers* consent agreement.[89] Indiana Household Movers and Warehousemen, Inc. (IHM&W) is an association of household movers doing business in Indiana. One of the association's primary functions is to prepare and file tariffs and supplements on behalf of its members with the Indiana Department of Revenue. These tariffs and supplements contain collective rates and charges for the intrastate and local transportation of household goods and related services. While Indiana law specifically contemplates common carriers' entering into "joint rates" under certain circumstances, to employ the state-action defense successfully, IHM&W had to show that this or some other provision of state law constitutes a clear expression of state policy to displace competition and allow for collective ratemaking among competitors, and that state officials actively supervised the conduct. IHM&W did not show active supervision.

The consent order therefore would enjoin IHM&W from collectively setting rates, and require IHM&W to cancel all tariffs it has filed with the state that contain intrastate collective rates. The proposed order provides IHM&W with an opportunity to attempt to modify its terms in the future, if it can demonstrate that the state-action defense would immunize its conduct, allowing it to engage in collective ratemaking. In the *Analysis to Aid Public Comment* that was issued in conjunction with the consent agreement, the Commission described four factors relevant to showing sufficient

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[89] Indiana Household Movers and Warehousemen, Inc., Docket No. C-4077 (April 29, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/04/ihmwdo.htm.

supervision: (1) notice and comment; (2) a written decision; (3) reference to the statutory standards; and (4) if consumer welfare is one standard, a quantitative estimate of effects on consumers. We expect this consent will be a model for future settlements, and, more generally, an incentive for getting states to step up supervision and reshape rate (and other regulatory) proceedings in a more procompetitive fashion.[90] Other matters that involve state action issues are under review, and there well may be additional enforcement actions that address those issues.

B. Noerr

The *Noerr* doctrine states that firms may collectively petition for anticompetitive decisions, or may individually petition for a grant of monopoly rights, without violating the Sherman Act.[91] In such cases, any anticompetitive effects will come from the government action (which is subject to correction through the political process) rather than through the firms' own market power.

There are a number of troubling issues regarding application of the *Noerr* doctrine. Material misrepresentations to the government, intended to manipulate competitive processes, should not be viewed as legitimate "petitioning" under *Noerr*.[92] Nor should conduct that merely triggers a ministerial governmental action, one not requiring discretionary governmental action. Also troublesome is a pattern of questionable conduct. Actions that, individually, are on the fringe of

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[90] There may be reason to question the policy rationale for rate-setting laws in most areas. However, if those laws are on the books, at the very least they should be closely supervised by states to preclude the "rubber stamping" of private cartel-like rate agreements.

[91] Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961).

[92] Misrepresentations may disguise the nature of what the "petitioner" is really requesting, causing the government in some instances to take actions that differ from those it would have taken had it been apprised of the true nature of the "petition" (i.e., had it not been misled). Accordingly, misrepresentations are not the sort of statements that enhance the petitioning process, and thus they should not be shielded by *Noerr*.

possible *Noerr* protection become more troublesome when taken in combination. While the *Noerr* doctrine is an important limitation on the antitrust laws that protects the right of individuals to communicate with government entities, the *Noerr* doctrine was never intended to protect what Robert Bork has characterized as "[p]redation through the misuse of government processes."[93]

Noerr issues are involved in several recent FTC enforcement actions. In *Unocal*, that company's presentations to CARB, a state agency, arguably constitute a form of petitioning. In reversing the ALJ's dismissal of the complaint, the Commission held that *Noerr*'s protection of the right to petition does not include the right to commit fraud before a government agency to obtain monopoly power.[94] In *Biovail (Tiazac)* and *Bristol-Myers Squibb*, the agency took the position that the listing of a patent in FDA's Orange Book is not petitioning conduct, and therefore is not protected by *Noerr*.[95]

VI. Horizontal restraints

Another category of major enforcement activity—the focus on horizontal restraints—flows directly from the guideposts of economic efficiency and consumer welfare. Horizontal restraints without sound business justification do not promote economic efficiency and they are the most likely to harm consumers. Here, again, past FTC cases have made significant contributions to the law,[96] and the agency has continued actively to pursue the more

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[93] BORK, *supra* note 84, at 348.

[94] *See* text accompanying footnotes 23 through 28 *supra*.

[95] The Commission had earlier taken that position in an amicus brief filed in private litigation. *See* Memorandum of Law of Amicus Curiae Federal Trade Commission in Opposition to Defendant's Motion to Dismiss, *In re* Buspirone Patent Litigation/*In re* Buspirone Antitrust Litigation, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (MDL No. 1410 (JAK)) (brief filed Jan. 8, 2002), *available at* http://www.ftc.gov/os/2002/01/busparbrief.pdf. The district court held that Orange Book filings are not "petitioning" under *Noerr*.

[96] *E.g.*, Superior Court Trial Lawyers Ass'n v. FTC, 493 U.S. 411 (1990); FTC v. Indiana Fed'n of Dentists, 476 U.S. 447 (1986); American

difficult horizontal restraints cases as well as the "bread and butter" examples of clearly anticompetitive horizontal conduct.

A. Price fixing in unique settings

Price fixing sometimes occurs in novel settings. In a case known as the *Three Tenors*,[97] the price fixing occurred in the context of an unusual promotional arrangement, but at its heart it is a price-fixing scheme that does not truly involve efficiencies. According to the complaint, in 1997, Warner Communications and PolyGram (predecessor to Vivendi Universal), two of the largest music distribution companies in the world, formed a joint venture to distribute compact discs, cassettes, videocassettes, and videodiscs to be derived from the next public performance of the Three Tenors. Warner would distribute the 1998 releases in the United States, and PolyGram would distribute the 1998 releases outside of the United States. As the concert date approached, both companies became concerned that the new products would be neither as original nor as commercially appealing as the 1990 and 1994 Three Tenors products already available to consumers. In an effort to shield the new 1998 products from competition, Warner and PolyGram implemented a "moratorium" on competitive activity. The parties agreed that PolyGram would not discount or advertise the 1990 Three Tenors album and video from August 1, 1998 to October 15, 1998. In return, Warner would not discount or advertise the 1994 Three Tenors album and video during this period.[98]

Med. Assn., 94 F.T.C. 701 (1979), *aff'd as modified*, 638 F.2d 443 (2d Cir. 1980), *aff'd* by an equally divided Court, 455 U.S. 676 (1982) (order modified 99 F.T.C. 440 (1982), 100 F.T.C. 572 (1982)).

[97] PolyGram Holding, Inc., Docket No. 9298 (July 24, 2001) (Commission opinion), *available at* http://www.ftc.gov/os/2003/07/polygramopinion.pdf.

[98] Distribution rights to the 1990 recordings were held by PolyGram, and distribution rights to the 1990 recordings were held by Warner.

Warner settled the charges before trial,[99] and the Commission upheld the charges against the remaining respondents.[100] The Commission found that parties' scheme was naked price fixing; the restrictions on price and advertising for the older products were not reasonably necessary for the joint venture to distribute the new recordings. The Commission also determined that to the extent there were any efficiencies limiting free riding between the joint venture product and the two earlier albums, those efficiencies were not cognizable as a matter of law because those earlier albums were not a part of the venture.

B. Health care

The health care sector remains enormously significant to both consumers and the national economy. It also has been an important area for enforcement action. The FTC under Chairman Muris has brought enforcement actions against nine groups of physicians for allegedly colluding on prices; all were resolved with a settlement.[101]

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[99] Warner Communications, Inc., Docket No. C-4025 (Sept. 17, 2001) (consent order), *available at* http://www.ftc.gov/os/2001/09/warnerdo.htm.

[100] PolyGram Holding, Inc., Docket No. 9298 (July 24, 2003) (Commission opinion), *available at* http://www.ftc.gov/os/2003/07/polygramopinion.pdf.

[101] SPA Organization, Docket No. C-4088 (June 9, 2003) (consent agreement accepted for public comment), *available at* http://www.ftc.gov/os/2003/06/swphagreement.pdf; Grossmont Anesthesia Services Med. Group, Inc., Docket No. C-4086 (May 30, 2003) (consent agreement accepted for public comment), *available at* http://www.ftc.gov/os/2003/05/gasca.pdf; Anesthesia Service Med. Group, Inc., Docket No. C-4085 (May 30, 2003) (consent agreement accepted for public comment), consent order *available at* http://www.ftc.gov/os/2003/07/asmgdo.htm; Carlsbad Physician Ass'n, Inc., Docket No. C-4081 (May 2, 2003) (consent agreement accepted for public comment), *available at* http://www.ftc.gov/os/2003/05/carlsbadagree.pdf; System Health Providers, Docket No. C-4064 (Oct. 24, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/11/shpdo.pdf; R.T. Welter & Assoc., Inc. (Professionals in Women's Care), Docket No. C-4063 (Oct. 8, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/08/profwomenagree.pdf; Physician Integrated Servs. of Denver, Inc., Docket No. C-4054 (July 16, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/05/pisdagreement.pdf; Aurora

Some of these cases involved transparent attempts to fix prices, without any pretense of financial or clinical integration between the parties. For example, the complaint in *Grossmont Anesthesia Services Medical Group, Inc.* charges that two competing groups of anesthesiologists in San Diego County, California, jointly agreed on certain fees and other competitively significant terms that they would demand from Grossmont Hospital for providing on-call services.[102] There was no clinical or financial integration between the two groups, so the agreement was pure, naked price fixing.[103]

The physician groups in other cases were only slightly more subtle. For example, the complaint against the Carlsbad Physician Association (CPA) and certain individual physicians charged that CPA was formed to negotiate contracts for physician services between CPA physician members and payors.[104] CPA's primary goal, according to its own "position statement," was "to negotiate contracts between physicians and employers, insurers and administrators independent of influence from any Health [sic] care organization or facility," and a board member stated that among CPA's main goals was to "[n]egotiate favorable reimbursement for physicians."[105] CPA represented more than 75% of all doctors practicing in and around

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Associated Primary Care Physicians, L.L.C., Docket No. C-4055 (July 16, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/05/auroraagreement.pdf; Obstetrics and Gynecology Med. Corp. of Napa Valley, Docket No. C-4048 (May 14, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/05/obgyndo.pdf.

[102] Grossmont Anesthesia Services Med. Group, Inc., Docket No. C-4086 (May 30, 2003) (consent agreement accepted for public comment), *available at* http://www.ftc.gov/os/2003/05/gasca.pdf; Anesthesia Service Med. Group, Inc., Docket No. C-4085 (May 30, 2003) (consent agreement accepted for public comment), consent order *available at* http://www.ftc.gov/os/2003/07/asmgdo.htm.

[103] *See also* Obstetrics and Gynecology Med. Corp. of Napa Valley, Docket No. C-4048 (May 14, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/05/obgyndo.pdf.

[104] Carlsbad Physician Ass'n, Inc., Docket No. C-4081, Complaint ¶ 12, *available at* http://www.ftc.gov/os/2003/05/carlsbadcmp.pdf.

[105] *Id.*

Carlsbad, New Mexico, and more than 80% of the primary care physicians in the area,[106] and was successful in extracting higher payments from payors.

Many of the cases involved improper use of the "messenger model" of facilitating negotiations between physicians and a payor.[107] Under this model, an agent acts as a messenger to convey information and contract offers between the payor and individual physicians, who then independently and unilaterally decide whether to accept or reject an offer.[108] Employed properly, the messenger model facilitates bilateral agreements between a payor and individual physicians and avoids the risk of unlawful collusion. In a number of cases, however, the professed use of a messenger model was essentially a sham. For example, in the *Carlsbad Physician* case noted above, CPA, which claimed to be operating as a legitimate messenger, did not transmit any payor's contract offer to the members unless CPA's Contract Committee approved the terms of the contract. CPA's executive director actively bargained over price and other contract terms with payors, and dictated to payors the minimum compensations terms its

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[106] *Id.* ¶ 6.

[107] *See, e.g.*, SPA Organization, Docket No. C-4088 (June 9, 2003) (consent agreement accepted for public comment), *available at* http://www.ftc.gov/os/2003/06/swphagreement.pdf; Carlsbad Physician Ass'n, Inc., Docket No. C-4081 (May 2, 2003) (consent agreement accepted for public comment), *available at* http://www.ftc.gov/os/2003/05/carlsbadagree.pdf; System Health Providers, Docket No. C-4064 (Oct. 24, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/11/shpdo.pdf; R.T. Welter & Assoc., Inc. (Professionals in Women's Care), Docket No. C-4063 (Oct. 8, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/08/profwomenagree.pdf; Physician Integrated Servs. of Denver, Inc., Docket No. C-4054 (July 16, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/05/pisdagreement.pdf; Aurora Associated Primary Care Physicians, L.L.C., Docket No. C-4055 (July 16, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/05/auroraagreement .pdf.

[108] The messenger model is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the FTC and U.S. Department of Justice, *available at* http://www.ftc.gov/reports/hlth3s.htm.

members would accept. At CPA's general membership meetings physicians frequently decided collectively the prices to demand from payors, and CPA's Contract Committee and board made recommendations to members about which offers the physicians should accept collectively. CPA's members also jointly decided whether to allow payor contracts to renew automatically, and whether to allow contract negotiations with payors to move forward.[109]

C. Other professions and associations

Agreements among professionals to restrict competition, often under the guise of professional association bylaws, codes of conduct, or other rules, can harm consumers in the same manner and degree as a "smoke-filled room" conspiracy. The agency recently completed three consent agreements in this area, and is actively pursuing many other potentially harmful restrictions imposed by professional associations, trade associations, or boards. The Institute of Store Planners (ISP), for example, through its code of ethics, prohibited its members from providing their services for free and competing with other members for work on the basis of price.[110] ISP's code of ethics, states, among other things, that "a member shall not render professional services without compensation" and that "a member shall not knowingly compete with other members on the basis of professional charges, or use donations as a device for obtaining a professional advantage." The code also states "a member shall not offer his services in competition except as provided by such competition codes as the Institute may establish."[111] These are pure and simple price restraints.

Similarly, the 3100-member American Institute for the Conservation of Historic and Artistic Works, agreed to settle charges

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[109] Carlsbad Physician Ass'n, Inc., Docket No. C-4081, Complaint ¶¶ 14–17, *available at* http://www.ftc.gov/os/2003/05/carlsbadcmp.pdf.

[110] Institute of Store Planner, Docket No. C-4080 (May 27, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/05/ispdo.pdf.

[111] Institute of Store Planner, Docket No. C-4080 (May 27, 2003), Complaint ¶ 7, *available at* http://www.ftc.gov/os/2003/05/ispcomplaint.pdf.

that its Commentaries to the Guidelines for Practice condemn as "unprofessional behavior" the "consistent undercutting of local or regional market rates."[112] Another consent agreement resolved charges that the National Academy of Arbitrators' Code of Professional Responsibility restricted truthful, nondeceptive advertising and solicitation.[113]

The *National Academy of Arbitrators* case is a reminder that the agency has unfinished business regarding advertising restraints. In light of the Supreme Court's decision in *California Dental Association*,[114] the agency should revisit this area to develop a workable approach that is consistent with the Court's opinion. As Chairman Muris has suggested, the key to successfully prosecuting an advertising restraints case under a truncated analysis is to build a record that explains why the advertising restraints should be analyzed under a truncated approach and contains support for claims of probable anticompetitive effect.[115] The agency is on the lookout for a case to apply that kind of analysis.

VII. Making use of the FTC's resources and capabilities

The FTC's research agenda is a key input into case selection and enforcement practices at the agency. Public hearings, workshops, and studies, provide a broad perspective on competition issues and highlight areas of potential anticompetitive concern. In addition, the agency's research expertise strengthens its hand in recommending that

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[112] American Institute for Conservation of Historic and Artistic Works, Docket No. C-4065 (Nov. 1, 2002) (consent order), *available at* http://www.ftc.gov/os/2003/01/naado.pdf, complaint *available at* http://www.ftc.gov/os/2002/11/aiccmp.pdf.

[113] National Academy of Arbitrators, Docket No. C-4070 (Jan. 17, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/01/naado.pdf.

[114] California Dental Ass'n v. FTC, 526 U.S. 756, 759 (1999).

[115] *See* Timothy J. Muris, *California Dental Association v. Federal Trade Commission: The Revenge of Footnote 17*, 8 SUP. CT. ECON. REV. 265 (2000); *see also* Timothy J. Muris, *GTE Sylvania and the Empirical Foundations of Antitrust*, 68 ANTITRUST L.J. 899 (2001).

governmental entities avoid adopting laws or rules that facilitate anticompetitive outcomes.

Congress provided the FTC with a unique collection of capabilities to address competition-related policy issues. These capabilities include expansive power to conduct studies or perform research about the economy and a broad charter to act as an advocate for competition before other government bodies, in addition to the authority to initiate administrative and federal court litigation. The agency makes full use of these capabilities in pursuing a multi-dimensional approach to its mission. As with our merger and nonmerger enforcement work, the agency applies its nonenforcement tools to those sectors of the economy that have the greatest impact on consumers.

A. Health care

The agency has sponsored two recent public forums on competition law and policy in health care. In September 2002, the agency held a workshop featuring presentations by academics, providers, insurers, employers, patient groups, and representatives of the Commission, the Department of Justice, and state attorneys general.[116] The discussion panels focused on clinical integration, payor/provider issues, group purchasing organizations, generics and branded pharmaceuticals, and direct-to-consumer advertising of pharmaceuticals. Each panel presented a broad range of views on each of these subjects from knowledgeable panelists. Several hundred people attended the workshop. The workshop also made clear that there is a considerable diversity of views on the appropriate role and priorities for the Commission and other enforcement agencies.

Because the workshop only began to explore the complex and interdependent issues, the Commission authorized an extended set of hearings on health care and competition policy, commencing in

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[116] *See* FTC Press Release, FTC to Host Workshop on Health Care and Competition Law and Policy September 9–10, 2002—Washington, D.C. (Jul. 10, 2002), *available at* http://www.ftc.gov/opa/2002/07/hlthcarecompwrkshop.htm. Agenda, transcript, public comments and other materials are *available at* http://www.ftc.gov/ogc/healthcare/index.htm.

February 2003 and continuing through the year.[117] Cosponsored with the Department of Justice, the hearings examined the state of the health care marketplace and the role of antitrust and consumer protection in satisfying the preferences of Americans for high-quality, cost-effective health care. A final report was issued in July 2004.[118]

The agency has also addressed a number of state legislative proposals to authorize physicians to engage in collective bargaining,[119] and provided several advisory opinions relating to health care services markets.[120]

B. Prescription drugs

In July 2002, the Commission released a report, *Generic Drug Entry Prior to Patent Expiration*, focusing on certain aspects of generic drug competition under the Hatch-Waxman amendments.[121] The study examined whether drug firm conduct at issue in FTC enforcement actions, which relies upon certain Hatch-Waxman provisions, represents a typical pattern of behavior of pharmaceutical companies or a few isolated examples. The study also examined more broadly how the process that Hatch-Waxman established to permit generic entry prior to expiration of a brand-name drug product's patents has worked between 1992 and 2000.

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[117] FTC Press Release, FTC Chairman Announces Public Hearings on Health Care and Competition Law and Policy to Begin in February 2003 (Nov. 7, 2002), *available at* http://www.ftc.gov/opa/2002/11/murishealthcare.htm.

[118] Agenda, transcripts, public comments, and other materials are *available at* http://www.ftc.gov/ogc/healthcarehearings/index.htm. The final report FTC, IMPROVING HEALTHCARE: A DOSE OF COMPETITION (July 2004), is *available at* www.ftc.gov/reports/healthcare/040723healthcarept.pdf.

[119] Letter to the Insurance Committee of the Ohio House of Representatives on Ohio House Bill 325 (Oct. 16, 2002), *available at* http://www.ftc.gov/os/2002/10/ohb325.htm; Letter to the Alaska House of Representatives on Senate Bill 37 (Jan. 18, 2002), *available at* http://www.ftc.gov/be/v020003.htm; Letter to the Washington House of Representatives on House Bill 2360 (Feb. 8, 2002), *available at* http://www.ftc.gov/be/v020009.pdf.

[120] Advisory opinions are *available at* http://www.ftc.gov/bc/advisory.htm.

The report suggested certain changes in balance between competition and intellectual property law, such as permitting only one automatic 30-month stay per drug product, per generic entry application pending patent infringement litigation, which the FDA has proposed. As one example of the value of FTC analysis and information dissemination efforts, President Bush prominently cited the report when he announced the FDA's proposed regulatory measures to foster competition in the pharmaceutical industry in October 2002.[122] FDA published final rules in June 2003, amending its regulations governing patent listing in the Orange Book and eligibility for the 30-month stay of ANDA approval.[123] The final rule limits brand-name companies to one 30-month stay per drug product. It is an important reform that would eliminate most of the potential for unwarranted delay of FDA approval of generic drugs the FTC study identified. If upheld against legal challenge, it would eliminate seven of the eight instances the Commission identified in the study in which brand-name companies filed patents in the Orange Book after a generic applicant had filed an ANDA application and, thus, delayed FDA approval of the ANDA for an additional 30 months.

The final rule also tightens up the Orange Book patent listing requirements. The FTC study had identified several types of patents that raise questions about whether they are properly listed in the

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[121] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[122] White House Press Release, President Takes Action to Lower Prescription Drug Prices by Improving Access to Generic Drugs (Oct. 21, 2002), *available at* http://www.whitehouse.gov/news/releases/2002/10/20021021-2.html; *see* Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed; Proposed Rule, 67 Fed. Reg. 65,448 (Oct. 24, 2002).

[123] Department of Health and Human Services, Food and Drug Administration, Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, Final Rule (June 12, 2003).

Orange Book, and which can form the basis for a 30-month stay. The final FDA rule prohibits the listing of two of these types of patents, and requires additional information from the brand-name company if it seeks to list in the Orange Book the third type of patent identified by the study.

C. Professions

In many regulated professions, regulatory bodies and groups of practitioners regularly attempt to restrict advertising and prevent competition from those outside the profession. These restrictions result in higher prices, less information, and fewer choices for consumers. When it is not feasible to use the agency's enforcement authority to challenge competitive restraints in the professions, it seeks to persuade policy makers of the benefits of competition. For example, the Commission and the Department of Justice's Antitrust Division submitted a joint letter to the ABA urging it to substantially narrow or reject a proposed model definition of the practice of law, which would likely reduce or eliminate competition from nonlawyers in providing certain services.[124] Previously, the Commission submitted a joint letter with the Antitrust Division urging the North Carolina State Bar to approve a proposed opinion that would explicitly permit nonlawyers to compete in real estate and mortgage closing services.[125]

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[124] Letter from Federal Trade Commission and U.S. Department of Justice to American Bar Association Task Force on the Model Definition of the Practice of Law (Dec. 20, 2002), *available at* http://www.ftc.gov/opa/2002/12/lettertoaba.htm.

[125] Letter from Federal Trade Commission and U.S. Department of Justice to North Carolina State Bar (Jul. 11, 2002), *available at* http://www.ftc.gov/os/2002/07/non-attorneyinvolvment.pdf; *see also* Letter to the Ethics Committee of the North Carolina State Bar re: State Bar Opinions Restricting Involvement of Non-Attorneys in Real Estate Closings and Refinancing Transactions (Dec. 14, 2001), *available at* http://www.ftc.gov/be/V020006.htm; Letter to the Rhode Island House of Representatives re: Bill Restricting Competition from Non-Attorneys in Real Estate Closing Activities (Mar. 29, 2002), *available at* http://www.ftc.gov/be/v020013.pdf.

In other advocacy work, agency staff provided comments to the Alabama Supreme Court on attorney advertising rules, urging that any restrictions should be narrowly tailored to prevent unfair or deceptive acts or practices, and that the rules permit communication of truthful and nondeceptive information.[126] The Commission also filed an amicus brief in a case seeking to overturn an Oklahoma law that permits only funeral directors to sell caskets.[127]

D. Energy

The Commission is pursuing a number of projects involving the petroleum industry, given its overall importance to consumers. In light of increased public concern about the level and volatility of gasoline prices in recent years, the Commission is studying the central factors that may affect the level and volatility of refined petroleum products prices in the United States. The Commission held a second public conference on this topic in May 2002.[128] The Commission expects to summarize and discuss its work in a public report to be issued this year. A major revision of the 1982 and 1989 FTC staff reports on oil mergers is also underway,[129] as is an empirical study of the effects of various oil mergers of the past decade. The agency also is monitoring wholesale and retail prices of gasoline. Members of the staff inspect wholesale gasoline prices for 20 cities and retail gasoline prices for

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[126] Letter from Federal Trade Commission Staff to Alabama Supreme Court (Sept. 30, 2002), *available at* http://www.ftc.gov/be/v020023.pdf.

[127] Memorandum of Law of Amicus Curiae the Federal Trade Commission, Powers v. Harris, Case No. CIV-01-445-F (W.D.OK. Aug. 29, 2002), *available at* http://www.ftc.gov/os/2002/09/okamicus.pdf.

[128] FTC Press Release, *Factors* That Affect Gasoline Prices To Be Discussed at FTC Conference (May 1, 2002), *available at* http://www.ftc.gov/opa/2002/05/gasolineprices.htm; agenda, transcripts, public comments, and other materials *available at* http://www.ftc.gov/bc/gasconf/index.htm.

[129] FEDERAL TRADE COMMISSION, MERGERS IN THE PETROLEUM INDUSTRY (Sept. 1982); FEDERAL TRADE COMMISSION, BUREAU OF ECONOMICS, MERGERS IN THE U.S. PETROLEUM INDUSTRY, 1971–1984: AN UPDATED COMPARATIVE ANALYSIS (1989).

360 cities throughout the United States and seek explanations of any pricing anomalies.[130]

The Commission authorized staff comments to the Environmental Protection Agency in connection with its study of the impact of different environmental regulations on product distribution and, ultimately, on supply and price of products in various markets.[131] FTC staff also submitted comments to several states on the effect of state laws requiring a mandatory minimum mark-up on the price of gasoline or prohibiting below-cost sales,[132] and addressed competition issues raised by the deregulation of electricity, in a number of separate comments filed with the Federal Energy Regulatory Commission.[133]

E. e-Commerce

The Internet boom, heralded by many as the next industrial revolution, has immense potential as an engine for commerce and offers

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[130] *See* FTC Press Release, FTC Chairman Opens Public Conference Citing New Model to Identify and Track Gasoline Price Spikes, Upcoming Reports (May 8, 2002), *available at* http://www.ftc.gov/opa/2002/05/gcr.htm.

[131] Federal Trade Commission Staff, *Comments on Study of Unique Gasoline Fuel Blends ("Boutique Fuels"), Effects on Fuel Supply and Distribution and Potential Improvements*, EPA 420-P-01-004 Public Docket No. A-2001-20 (Jan. 20, 2002), *available at* http://www.ftc.go/be/v020004.pdf.

[132] Federal Trade Commission Staff Testimony, *Competition and the Effects of Price Controls in Hawaii's Gasoline Market* (Jan. 28, 2003), *available at* http://www.ftc.gov/be/v030005.htm; Letter from Federal Trade Commission Staff to New York Governor George E. Pataki (Aug. 8, 2002), *available at* http://www.ftc.gov/be/v020019.pdf; Letter to the Virginia House of Delegates on Senate Bill No. 458 (Feb. 15, 2002), *available at* http://www.ftc.gov/be/V020011.htm.

[133] *E.g.*, FERC, Docket No. RM01-12 (Remedying Undue Discrimination Through Open Access Transmission Service and Standard Electricity Market Design) (Nov. 15, 2002); FERC, Docket No. RM01-12 (Working Paper on Standardized Transmission Service and Wholesale Electric Market Design) (Jul. 23, 2002); FERC, Docket No. RM01-12 (Electricity Market Design and Structure: RTO Cost/Benefit Analysis Report) (Apr. 23, 2002); FERC, Docket No. RM01-12 (Electricity Market Design and Structure: Strawman Discussion Paper for Market Power Monitoring and Mitigation) (Apr. 3, 2002).

consumers enormous freedom. Contrary to the perception of the Internet as a virtually unfettered free market, however, extension of preexisting state regulations to the Internet or potentially anticompetitive business practices may be limiting the cost savings or convenience that the Internet affords, without offsetting benefits. The FTC's Internet Task Force has been analyzing state regulations that may have proconsumer or procompetition rationales, but that nevertheless may restrict the entry of new Internet competitors. It also is examining barriers that arise when private parties employ potentially anticompetitive tactics, such as when suppliers or dealers apply collective pressure to limit online sales. This work has resulted in investigations into possible anticompetitive restrictions on e-commerce, and the task force has taken the lead in drafting several competition advocacy pieces, including comments to the Connecticut Board of Opticians concerning restrictions on Internet and out-of-state contact lens sellers.[134]

In October 2002, the Commission hosted a 3-day public workshop examining potential barriers to e-commerce in ten different industries.[135] The Commission also testified before Congress concerning these issues.[136]

F. IP hearings

In November 2002, the Commission and Department of Justice concluded 24 days of hearings over 9 months on Competition and

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[134] *See* FTC Staff Comment Before the Connecticut Board of Examiners for Opticians (Mar. 27, 2002), *available at* http://www.ftc.gov/be/v020007.htm. FTC staff subsequently provided testimony before the Board. *See* FTC Press Release, June 12, 2002 (FTC Staff Testifies Before Connecticut Board of Examiners for Opticians).

[135] FTC Press Release, FTC Releases Agenda for Public Workshop on Possible Anticompetitive Efforts to Restrict Competition on the Internet (Sept. 30, 2002), *available at* http://www.ftc.gov/opa/2002/09/ecomagenda.htm; agenda, transcripts, and public comments *available at* http://www.ftc.gov/opp/ecommerce/anticompetitive/index.htm.

[136] Federal Trade Commission, Testimony Before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, United States House of Representatives (Sept. 26, 2002), *available at* http://www.ftc.gov/os/2002/09/020926testimony.htm.

Intellectual Property Law and Policy in the Knowledge-Based Economy.[137] The hearings responded to the growth of the knowledge-based economy, the increasing role in antitrust policy of dynamic, innovation-based considerations, and the importance of managing the intersection of intellectual property and competition law to realize their common goal of promoting innovation. A public report that incorporates the insights of business persons, consumer advocates, inventors, practitioners, and academics who participated in the hearings, as well as other research, is being prepared.

G. Amicus briefs

Participation as amicus curiae in non-FTC litigation that raises important competition policy issues is another way the agency can contribute to the protection of consumer welfare.[138] The agency's amicus brief in the *Buspirone* litigation is a good example.[139] The district court's ruling in that instance resulted in an important limitation on *Noerr* immunity for administrative filings that do not involve true petitioning. In another pharmaceutical matter involving Orange Book listings, the Commission filed an amicus brief describing the consumer harm that occurs when an invalid patent forms the basis of a 30-month stay of a generic drug application.[140]

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[137] FTC Press Release, Muris Announces Plans for Intellectual Property Hearings (Nov. 15, 2001), *available at* http://www.ftc.gov/opa/2001/11/iprelease.htm; agendas, transcripts, public comments, and other materials *available at* http://www.ftc.gov/opp/intellect/index.htm.

[138] *See generally* R. Ted Cruz, Director, Office of Policy Planning, FTC, Friend of the Court: The Federal Trade Commission's Amicus Program, Remarks Before Antitrust Section, American Bar Association, Washington, DC. (Dec. 12, 2002), *available at* http://www.ftc.gov/speeches/other/tcamicus.pdf.

[139] *See* discussion *supra* at note 95.

[140] *See* Memorandum of Law of Federal Trade Commission as Amicus Curiae Concerning Torpharm's Cross Motion for Entry, SmithKline Beecham Corporation et al. v. Apotex Corporation, Apotex, Inc. and Torpharm, Inc., and Other Related Cases (E.D. PA, Jan. 28, 2003), *available at* http://www.ftc.gov/ogc/briefs/smithklineamicus.pdf.

The Commission also has a continuing interest in ensuring fair and adequate compensation for consumers involved in class action litigation. Recent advocacy efforts in this area include amicus briefs challenging an award of attorney's fees to private class counsel in a case prosecuted principally by government attorneys[141] and opposing a nonpecuniary "coupon" settlement that offered class members inadequate relief.[142] The Commission also filed written comments on the Judicial Conference's proposed amendments to Federal Rule of Civil Procedure 23, governing class actions.[143]

Finally, the Commission filed comments with the U.S. Department of Transportation (DOT) concerning proposed rules governing computer reservations systems.[144] The Commission addressed and clarified two aspects of antitrust doctrine discussed by the DOT.[145]

First, the Commission addressed DOT's suggestion that, under Commission law, a monopolist can be held liable for engaging in unfair methods of competition by virtue of the impact of its business practices on an adjacent market in which the monopolist does not operate. That is a position the FTC unsuccessfully argued in the

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[141] Federal Trade Commission's Memorandum of Points and Authorities in Opposition to Class Plaintiffs' Petition for Award of Counsel Fees and Reimbursement of Expenses (Jan. 2, 2002), *available at* http://www.ftc.gov/os/2002/01/hearstbrief.pdf.

[142] Memorandum of Law of Amicus Curiae the Federal Trade Commission in Opposition to Class Action Settlement (June 21, 2002), *available at* http://www.ftc.gov/os/2002/06/eriksonmemo.pdf.

[143] Letter to the Judicial Conference on Proposed Amendments to Rule 23 of the Federal Rules of Civil Procedure (Feb. 15, 2002), *available at* http://www.ftc.gov/os/2002/02/ rule23letter.pdf.

[144] Letter from Federal Trade Commission to United States Department of Transportation (June 6, 2003), re Dockets OST-97-2881, OST-97-3014, and OST-98-4775, *available at* http://www.ftc.gov/os/2003/06/dotcomment.htm.

[145] The Commission also addressed the "unfairness" doctrine under section 5 of the FTC Act. We do not discuss that aspect here, as the Commission's discussion related primarily to the Commission's consumer protection jurisdiction.

Official Airline Guides (*OAG*) case.[146] The DOT noted that shortly after *OAG*, the Commission indicated in dicta that the Second Circuit's decision was erroneous.[147] In its letter, the Commission informed the DOT that the agency would not take that position today, and that since *OAG* the Commission's single-firm conduct cases have focused on the alleged monopolist's conduct in markets in which it operated.

Second, the Commission addressed the DOT's discussion of the "monopoly leveraging" and "essential facilities" doctrines. The Commission's letter reiterated the position that the Commission and the United States had recently argued in a joint amicus curiae brief filed in the United States Supreme Court: neither of these doctrines provides an independent basis for liability under section 2 of the Sherman Act.[148] Rather, unilateral conduct should be condemned under the Sherman Act only if it "reasonably appear[s] capable of making a significant contribution to creating or maintaining monopoly power"[149] and is "exclusionary," in that it "not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way."[150]

VIII. Conclusion

Based on over 3-years-experience, it is clear that Chairman Muris came in with an activist proconsumer agenda, and the Commission has very quickly acted upon it. The Commission has followed this

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146 Airline Guides, Inc. v. FTC, 630 F.2d 920 (2d Cir. 1980).

147 *See* General Motors Corp., 99 F.T.C. 464, 580 (1982).

148 Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP (Sup. Ct. May 2003) (No. 02-682), *available at* http://www.usdoj.gov/atr/cases/f201000/201048.pdf.

149 P. AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶ 651f, at 83–84 (2d ed. 2002); *see Spectrum Sports, supra*, 506 U.S. at 458-59.

150 Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 602, 605 n.32 (1985).

clearly and specifically articulated agenda, particularly in nonmerger antitrust enforcement. It has used its various enforcement and policy tools to challenge abuses, especially in the important health care and high-tech industries. These actions have attacked anticompetitive practices of both large and small entities, and in particular when these entities have attempted to use government rules to defeat legitimate competition. Although one might debate whether the Commission's proconsumer agenda could be improved upon, it is remarkable what has been accomplished in terms of "end products" of enforcement actions, studies, amicus filings, hearings, and investigations, which clearly have benefited consumers.