

SYMPOSIUM
ANTITRUST ISSUES IN THE
PHARMACEUTICAL INDUSTRY

EDITOR'S NOTE

JONATHAN IAN GLEKLEN*

There is perhaps no industry that has been as constant a source of antitrust focus in recent years as the pharmaceutical industry. Indeed, the Federal Trade Commission has devoted such extensive resources to pharmaceutical matters that it maintains a regularly updated compendium of its enforcement actions since the early 1990s that runs twenty-eight pages and identifies fifty-nine matters.¹ The private antitrust bar and state attorneys general are frequent litigants in pharmaceutical cases as well, both in follow-on cases to FTC enforcement actions and in matters not initiated by the FTC.

The interest of antitrust enforcers and the antitrust bar in the pharmaceutical industry is not merely a function of the industry's sales figures. Americans spent \$142 billion on prescription drugs in 2001 (a figure the Department of Health and Human Services projects to will grow to \$414 billion by 2011).² This represents about one percent of the Gross National Product³ and about 15 percent of all health care expenditures.⁴ Larger industries—even larger components of health care spending—receive far less antitrust attention.

But given the sensationalized stories in the press about seniors and others forced to choose between medications and food, it should not

* Member of the District of Columbia Bar and Associate Editor, *Antitrust Law Journal*.

¹ FEDERAL TRADE COMMISSION BUREAU OF COMPETITION, FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS (2003), available at <http://www.ftc.gov/bc/0304rxupdate.pdf>.

² U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES 91 (2002), available at <http://www.census.gov/prod/2003pubs/02statab/health.pdf>.

³ *Id.* at 17, available at <http://www.census.gov/prod/2003pubs/02statab/income.pdf>.

⁴ PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), PHARMACEUTICAL INDUSTRY PROFILE 2003 at 75 (2003), available at <http://www.phrma.org/publications/publications/profile02/APPENDIX>.

come as a surprise that Federal Trade Commission Chairman Timothy Muris has characterized “[t]he growing cost of prescription drugs” as a “significant concern” that has led the FTC to increase its investigations in the pharmaceutical industry.⁵ When confronted with complaints about “high” prices, the industry’s representatives remind us that the lives of millions of people living with AIDS, cancer, and other life-threatening diseases literally depend upon the pace and quality of pharmaceutical innovation. But even if the cost of pharmaceutical R&D explains prescription drug prices, the pace of pharmaceutical innovation is an independent concern of antitrust enforcers as well.

The articles in this Symposium address a number of critical issues that frequently arise in antitrust cases involving the pharmaceutical industry. The authors featured in the Symposium were all members of the Antitrust Section’s Pharmaceutical Task Force. The Task Force was appointed by Roxane Busey in 2001 to analyze and report on developments affecting competition in the pharmaceutical industry—an assignment it performed over its two-year life under the leadership of co-chairs Stephen A. Stack, Jr. and David A. Balto.

Elizabeth Weiswasser and Scott Danzis provide a comprehensive review of the history, purpose, and operation of the Hatch-Waxman Act,⁶ which governs entry of generic pharmaceuticals either before or after the expiration of patents held by the manufacturer of the branded innovator drug.⁷ An understanding of the Hatch-Waxman Act is essential to make sense of the numerous cases brought by the FTC, state attorneys general, and the private bar challenging settlements of patent infringement litigation in the pharmaceutical industry.

Mark Kovner, Colin Kass, and Avery Gardiner address the applicability of immunity for petitioning conduct under the *Noerr-Pennington* doctrine⁸ to such patent settlements.⁹ Although some have argued that all patent settlements should be immune under *Noerr* (reasoning that if the decision

⁵ Timothy J. Muris, An Overview of Federal Trade Commission Antitrust Activities, Address Before the U.S. House Committee on the Judiciary Antitrust Task Force (July 24, 2003), available at <http://www.ftc.gov/os/2003/07/antitrustoversighttest.htm>.

⁶ Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355; 28 U.S.C. § 2201; 35 U.S.C. §§ 156; 271; 282). The Act’s common name refers to its primary sponsors, Senator Orrin Hatch and Representative Henry Waxman.

⁷ See Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585 (2003).

⁸ See *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

⁹ Mark L. Kovner, Colin R. Kass & Avery W. Gardiner, *Applying the Noerr Doctrine to Pharmaceutical Patent Litigation Settlements*, 71 ANTITRUST L.J. 609 (2003).

to file a lawsuit is immune, the decision to settle should be as well) and others have argued that patent settlements should never be entitled to *Noerr* immunity (because settling is not a form of petitioning for government action), the authors reject these “all-or-nothing” positions and argue for a more nuanced approach. After tracing the First Amendment and statutory interpretation bases for *Noerr* immunity, they analyze the petitioning-related issues that arise in different forms of patent settlements and identify the types of settlements that they believe should constitute protected petitioning.

Howard Morse's article addresses the difficult question of product market definition in pharmaceutical cases.¹⁰ Pharmaceutical product markets have been defined in a wide variety of ways, ranging from a particular dosage form of a given pharmaceutical compound (and excluding that dosage form of the branded product), at one extreme,¹¹ to all branded and generic drugs that treat a particular disease, at the other.¹² Morse's article identifies the myriad ways in which pharmaceutical product markets have been defined, discusses the particular challenges presented in defining pharmaceutical markets, and applies the teaching of cases from outside the pharmaceutical context to the market definition issue.

Ronald Davis's article is a detailed look at and comment on the application of the “innovation market” concept.¹³ Davis traces the development and application of the doctrine at the agencies and in the courts, and then identifies and discusses nine challenging issues in the application of innovation market analysis on which there is as yet no consensus.

The Symposium concludes with an Afterword by Stephen Stack that addresses a number of the issues raised by the articles in the Symposium and identifies a number of questions raised by the articles that merit consideration by Congress, the agencies, the antitrust bar, and scholars.

Although the articles in the Symposium address a variety of issues, two consistent themes can be seen in the articles and across pharmaceutical industry antitrust matters.

¹⁰ M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633 (2003).

¹¹ See, e.g., Biovail Corp. & Elan Corp., PLC, FTC Docket No. C-4057 (Aug. 15, 2002) (Complaint ¶ 6) (alleging separate markets for 30mg and 60mg dosage forms of generic Adalat), available at <http://www3.ftc.gov/os/2002/08/biovalcemp.pdf>.

¹² See, e.g., Pfizer Inc. & Warner-Lambert Co., FTC Docket No. C-3957 (Jul. 27, 2000) (Complaint ¶ 19) (alleging market for drugs used to treat Alzheimer's disease), available at <http://www.ftc.gov/os/2000/06/pfizercmp.htm>.

¹³ Ronald W. Davis, *Innovation Markets and Merger Enforcement: Current Practice in Perspective*, 71 ANTITRUST L.J. 677 (2003).

The Lack of Transparency in the FTC's Market Definition Process. Market definition is critical in antitrust analysis, and no less so in pharmaceutical antitrust cases. Proof of the required substantial lessening of competition in a case under Section 7 of the Clayton Act¹⁴ is impossible without a proper definition of the affected relevant markets.¹⁵ The plaintiff also bears the burden of proving a relevant market in monopolization and attempted monopolization cases¹⁶ and in cases under Section 1 of the Sherman Act¹⁷ that are not subject to condemnation under the per se rule.¹⁸ Indeed, the FTC staff lost the only litigated challenge to a pharmaceutical patent settlement because the administrative law judge rejected complaint counsel's market definition.¹⁹

Given the critical importance of market definition, the FTC's widely varying market definitions in pharmaceutical cases create a substantial challenge for antitrust counselors. The complaints filed in FTC merger challenges typically assert simply that "the relevant lines of commerce in which to analyze the effects of the merger" are X, Y, and Z, without any justification for why X, Y, and Z are proper antitrust markets. The required "analysis to aid public comment" that accompanies the FTC's consent decree rarely provides much more detail.

Unlike FTC consent decrees, European Commission merger decisions generally contain comprehensive justifications for the Commission's relevant market definition. For example, in Glaxo Wellcome's acquisition of SmithKline Beecham, both the FTC and the Commission required a divestiture of one of the parties' 5HT-3 antiemetic (anti-nausea) drugs. The FTC's Complaint contains a barebones assertion that "the research, development, manufacture and sale of 5HT-3 antiemetic drugs" is a "relevant line[] of commerce in which to analyze the effects of the [m]erger."²⁰ The FTC's Analysis of Proposed Consent Order to Aid

¹⁴ 15 U.S.C. § 18.

¹⁵ *See, e.g.*, United States v. Marine Bancorp., 418 U.S. 602, 618 (1974).

¹⁶ *See generally* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) ("Without a definition of that market there is no way to measure [a defendant's] ability to lessen or destroy competition.").

¹⁷ 15 U.S.C. § 1.

¹⁸ *See, e.g.*, SCFC ILC, Inc. v. VISA U.S.A., Inc., 36 F.3d 958, 965 (10th Cir. 1994) (in rule of reason cases, proof of market power "is a critical first step, or 'screen,' or 'filter,' which is often dispositive of the case").

¹⁹ Schering-Plough Corp., Upsher-Smith Labs. & Am. Home Prods. Corp., FTC Docket No. 9297 (June 27, 2002) (Initial Decision at 87-95), available at <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf> and <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf>. The ALJ's decision is currently on appeal to the full Commission.

²⁰ Glaxo Wellcome plc & SmithKline Beecham plc, FTC Docket No. C-3990 (Jan. 26, 2001) (Complaint ¶ 16), available at <http://www.ftc.gov/os/2000/12/glaxosmithklinecmp.pdf>.

Public Comment adds that "5HT-3 antiemetic products have revolutionized the treatment of patients with cancer because they are more effective than any of the older antiemetic products."²¹ While perhaps suggesting that other antiemetics are not reasonably interchangeable, there is no allegation that there is insufficient cross elasticity of demand with other products to discipline any price increase. The European Commission, in contrast, spends nine paragraphs over two pages addressing the contours of the relevant market in which 5HT-3 antiemetics compete.²²

Mindful of the Supreme Court's admonition that "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed,"²³ a number of courts have dismissed barebones allegations of the relevant market, insisting that relevant market allegations be pled "with reference to the rule of reasonable interchangeability and cross-elasticity of demand."²⁴ But because FTC merger challenges in the pharmaceutical industry have uniformly been resolved by consent decree (i.e., settlement) rather than by litigation, the Commission has not had to face a challenge to the sufficiency of a complaint in a merger case.²⁵

Even if the merging firms settle rather than putting the Commission to its proof, however, the bar would benefit from an explanation of the FTC's basis for its relevant market definition. For example, the complaint might allege that the parties' documents discount the importance of price or innovation competition from products outside the FTC's alleged market, or that pharmacy benefit managers or other pharmaceutical payers believe that only products within the market as alleged will constrain the price of the merging firms' products.

Given the comparative dearth of judicial decisions addressing pharmaceutical product market definition, and as the articles in this Symposium demonstrate, the antitrust bar has no choice but to rely on consent decrees to understand the Commission's approach to enforcement. A more detailed explanation of the Commission's reasoning on market

²¹ Glaxo Wellcome plc & SmithKline Beecham plc., FTC Docket No. C-3990 (Dec. 18, 2000) (Analysis of Proposed Consent Order to Aid Public Comment), *available at* <http://www.ftc.gov/os/2000/12/glaxoana.htm>.

²² See Case No. Comp/M.1846 GlaxoWellcome/SmithKline Beecham (May 8, 2000), at ¶¶ 32-41, *available at* http://europa.eu.int/comm/competition/mergers/cases/decisions/m1846_en.pdf.

²³ Associated Gen. Contractors of Cal., Inc. v. California State Council of Carpenters, 459 U.S. 519, 528 n.17 (1983).

²⁴ Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 436-37 (3d Cir. 1997).

²⁵ Morse, *supra* note 10, at 642 (noting that every merger challenge since 1990 has been resolved by consent decree or by the parties' abandonment of the transaction).

definition issues in the complaints or analyses to aid public comment in settled cases would increase transparency and improve predictability and thus might serve to speed the merger review process to the benefit of both private parties and the Commission.

The Need for Speculation. The inescapable role played by speculation is another theme that runs through the articles of this Symposium and pharmaceutical industry antitrust in general.

Because the owner of a drug patent has the right to exclude competition from infringing generic products for the term of the patent, a patent settlement that requires the generic firm to stay off the market cannot be the “but-for” cause of harm to competition if the innovator firm would have prevailed in the patent litigation. This inquiry into the likely result of infringement litigation is necessarily speculative, and the FTC staff conceded in the *Schering* case that “it is impossible to reliably determine . . . whether the alleged infringers would have prevailed in the infringement suits.”²⁶ Although the FTC staff has tried to avoid the inquiry by arguing that the likely outcome of patent infringement litigation between a branded firm and a generic entrant is irrelevant,²⁷ that position was rejected by the administrative law judge in the *Schering* litigation.²⁸ The Eleventh Circuit reached the same result in a private antitrust case.²⁹

If these decisions stand, it is unclear whether the FTC will try its hand at what it said in *Schering* was the “impossible” task of predicting the outcome of the patent litigation, or instead abandon its enforcement efforts where proof of harm to competition depends upon whether the innovator would have prevailed in the patent litigation. If the staff does decide to try its hand, there is not much comfort to be taken from the FTC’s record in predicting patent invalidity. In 1998 the Commission sued VISX, a maker of eye surgery equipment, alleging, inter alia, that several of its patents were invalid, and, indeed, that they had been procured by fraud on the Patent and Trademark Office.³⁰ An administra-

²⁶ Schering-Plough Corp., Upsher-Smith Labs. & Am. Home Prods. Corp., FTC Docket No. 9297 (June 27, 2002) (Initial Decision at 104) (citing Complaint Counsel’s Post Trial Brief at 67–76), available at <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf>.

²⁷ *Id.*

²⁸ See *id.* at 103–05.

²⁹ Valley Drug Co. v. Geneva Pharms., Inc., No. 02-12091, 2003 WL 22120130, at *9 (11th Cir. Sept. 15, 2003) (“If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit.”).

³⁰ Summit Tech. & VISX, Inc., FTC Docket No. 9286 (Mar. 24, 1988) (Complaint), available at <http://www.ftc.gov/os/1998/03/summit.cmp.htm>.

tive law judge dismissed the claims as lacking factual support,³¹ and the Commission dismissed the complaint after the Patent and Trademark Office conducted its own reexamination of the patent and found it valid.³²

Speculation is also required in every merger case, for merger enforcement is by its very nature prospective, asking whether the effect of the transaction if consummated “*may* be substantially to lessen competition, or to tend to create a monopoly.”³³ Antitrust enforcers do not seek to protect competition in innovation markets merely to ensure competition for competition’s sake, but rather based on the belief that innovation competition will eventually lead to products that are better, cheaper, or both.³⁴ This adds yet another layer of speculation.

When only one in five drugs that enter clinical trials ever reach the market,³⁵ predictions about when a loss of innovation competition will actually harm consumers are likely to be wrong at least occasionally. Perhaps the most glaring failed prediction is the Commission’s 1997 challenge to Ciba-Geigy’s proposed acquisition of Sandoz, a challenge based in part on the concern that the transaction would harm “innovation competition among researchers and developers of gene therapy products.”³⁶ The Commission’s press release announcing the consent decree claimed that “market for all gene therapy products is expected to reach upwards of \$45 billion by 2010, following introduction of the first gene therapy products, expected by the year 2000.”³⁷ In fact, today there are no gene therapy products on the market,³⁸ and gene therapy has made

³¹ VISX, Inc., FTC Docket No. 9286 (May 27, 1999) (Initial Decision), *available at* <http://www.ftc.gov/os/1999/06/visxid.pdf>.

³² See VISX, Inc., FTC Docket No. 9286 (Feb. 7, 2001) (Order Reopening the Record and Dismissing the Complaint), *available at* http://www.ftc.gov/os/2001/02/summitvisx_order.htm.

³³ Clayton Act § 7, 15 U.S.C. § 18 (emphasis added).

³⁴ See generally Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569, 587 (1995) (Consumer harm from loss of innovation competition comes from “cost increases from the merger, suppressed product improvements, or from reductions in future competition.”).

³⁵ Henry Grabowski & John Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT’L J. TECH. MGMT. 98 (2000).

³⁶ Ciba-Geigy Ltd., FTC Docket No. C-3725 (Apr. 8, 1997) (Complaint ¶ 31), *available at* <http://www.ftc.gov/os/1997/04/c3725cmp.htm>.

³⁷ FTC Press Release, FTC Accord in Ciba Geigy/Sandoz Merger to Prevent Slowdown in Gene Therapy Development and Preserve Competition in Corn Herbicides, Flea-Control Markets (Dec. 17, 1996), *available at* <http://www.ftc.gov/opa/1996/12/ciba.htm>.

³⁸ See *Science Notebook*, WASH. POST, May 19, 2003, at A7 (“[O]nly one disease—a childhood immune deficiency—has been cured by gene therapy, and those treatments are on hold in this country because of recent evidence that they can cause cancer.”).

the newspapers because of the deaths of patients in clinical trials rather than because of lives saved.³⁹

Ciba/Sandoz may be an outlier, but at the decade mark of innovation market enforcement (the *GM/ZF* case⁴⁰ was brought in 1993), there has been no systematic review of whether the FTC's predictions are right more often than they are wrong. The FTC has taken a critical look at the successes and failures of its divestiture program.⁴¹ In order to evaluate whether the innovation market approach is (to quote Ronald Davis's article in this Symposium) "worth the candle,"⁴² an evaluation of the FTC's forecasting record in merger cases alleging innovation markets would seem to be in order.

It may very well turn out after review that the FTC's record in predicting the future has been exemplary. And it may well be that, given the high costs to consumers of underenforcement against anticompetitive mergers or patent settlements and the low costs to consumers of overenforcement (what's the harm from an unnecessary divestiture?), that the FTC's pharmaceutical enforcement program meets the Hippocratic Oath standard of "to do no harm." But judgments in this area require data on the FTC's record of successfully prophesizing future events, data that has not yet been developed. The articles in this Symposium tackle a number of difficult antitrust issues in the pharmaceutical industry, but much work remains to be done.

³⁹ See Larry Thompson, *Human Gene Therapy: Harsh Lessons, High Hopes*, FDA CONSUMER, Sept.–Oct. 2000, available at http://www.fda.gov/fdac/features/2000/500_gene.html (noting six deaths in gene therapy trials).

⁴⁰ *United States v. General Motors Corp.*, No. 93-530 (D. Del. filed Nov. 16, 1993); see generally Davis, *supra* note 13, at 688.

⁴¹ See STAFF OF THE BUREAU OF COMPETITION, FEDERAL TRADE COMM'N, A STUDY OF THE COMMISSION'S DIVESTITURE PROCESS (1999), available at <http://www3.ftc.gov/os/1999/08/divestiture.pdf>.

⁴² Davis, *supra* note 13, at 697.