

The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs

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BRANDED PRESCRIPTION pharmaceutical manufacturers in recent years have gone to great lengths to delay the market entry of less expensive, but otherwise functionally identical, generic versions of their brand-name products. Delaying tactics have included, among others, paying generic companies not to sell their less expensive competing products as part of final or interim “settlements” of patent litigation. Tactics have also allegedly included gaming the drug approval process overseen by the U.S. Food & Drug Administration (“FDA”),¹

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1. These tactics have specifically included branded manufacturers, fraudulently or otherwise, improperly listing their brand-name products in the FDA’s “Orange Book,” as part of alleged schemes to delay generic competition. See CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (24th ed. 2004), available at <http://www.fda.gov/cder/ob/docs/preface/ecpreface.htm> (last accessed Aug. 27, 2004) [hereinafter ORANGE BOOK]. The FDA’s Orange Book was initially published to support the implementation of state generic-substitution laws and was subsequently mandated by the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered portions of 21 & 35 U.S.C.). The Orange Book lists “all prescription drug products that are approved by the FDA for safety and effectiveness, along with therapeutic equivalence determinations for multisource prescription products” and “provides patent information concerning the listed drugs which also may delay the approval of [Abbreviated New Drug Applications (“ANDAs”)] or Section 505(b)(2) applications.” ORANGE BOOK, *supra*.

fraudulently procuring and enforcing patents, and filing sham patent infringement suits against generic manufacturers—conduct designed to invoke “stays” of FDA marketing approval of generic drugs or to otherwise deter generic competition to brand-name products.² Because generic drugs are often substantially less expensive than their brand-name counterparts and because generics tend to rapidly replace sales of the corresponding brand, delaying generic entry enriches branded manufacturers at the expense of pharmaceutical purchasers and the public.

Introduction

The practice of retarding generic competition has recently taken on increased importance from a public policy perspective, particularly in light of the substantial and rapidly-growing impact of drug prices on aggregate healthcare costs in this country.³ Allegedly improper tactics used to delay generic entry have also become a significant focus of both United States government antitrust enforcement and private suits by direct purchasers, third-party payors, consumers, and state at-

2. Such tactics, which form the central allegations in several of the antitrust lawsuits discussed in this Article, have for years constituted actionable conduct under the federal antitrust laws. *See, e.g.*, *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (objectively groundless lawsuits instituted for anticompetitive purpose not afforded antitrust immunity as protected government petitioning); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) (enforcement of fraudulently obtained patent through baseless infringement litigation exposes patentee to liability under section 2 of Sherman Act); *In re Remeron Prods. Antitrust Litig.*, 335 F. Supp. 2d 522, 531–32 (D.N.J. 2004) (permitting claims of direct purchasers relating to the alleged gaming of the FDA approval process to delay the entry of generic competition to go forward as part of an overall scheme to monopolize in violation of section 2 of the Sherman Act).

3. According to a recent report from the Kaiser Family Foundation, drug expenditures are a substantial component of health expenditures (5.8% in 1992 and 10.5% in 2002) and are by far the fastest growing component of health care costs. KAISER FAMILY FOUND., *TRENDS AND INDICATORS IN THE CHANGING HEALTH CARE MARKETPLACE*, at Exhibits 1.5, 1.6, & 1.7 (2004), available at <http://www.kff.org/insurance/7031/index.cfm> (last accessed Oct. 25, 2004). A joint study by the Federal Trade Commission and the Department of Justice has similarly found:

In the last few years . . . dramatic cost increases have returned, attributable to both increased use of and increased prices for health care services. Inpatient hospital care and pharmaceuticals are the key drivers of recent increases in expenditures. These trends are likely to continue—and even accelerate—as new technologies are developed and the percentage of the population that is elderly increases.

FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION 3* (2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> (last accessed Oct. 25, 2004).

torneys general.⁴ These parties have sought, among other things, compensation for the artificially inflated prices resulting from such tactics.

This Article will examine two related underlying issues fundamental to much of the federal antitrust litigation spawned by the delaying tactics described above: whether conduct delaying generic entry (1) yields what the law traditionally considers “anticompetitive effects,” under Section 1 of the Sherman Act⁵, and (2) whether such conduct reflects the creation or maintenance of “monopoly power” under Section 2 of the Sherman Act.⁶ To establish a violation of Section 1, where the restraint of trade in question is not deemed per se illegal,⁷ private plaintiffs and governmental enforcement authorities are required to demonstrate that delaying generic entry results in “anticompetitive effects” (i.e., prices are raised above competitive levels) in demonstrating an unreasonable restraint of trade under the “rule of reason.”⁸ Similarly, proof of a violation of Section 2 requires, among other things, a showing that the underlying conduct involved the acquisition or maintenance of monopoly power.⁹ As will be shown below, the concepts of anticompetitive effects on the one hand, and the exercise of monopoly power, on the other, are really two sides of

4. Such practices have also been the subject of a good deal of scholarly debate and discussion, especially in cases involving payments from branded to generic manufacturers in exchange for the generic’s agreement to refrain from coming to market as part of interim or final “settlements” of patent litigation (so-called “reverse payments” agreements). See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 25–52 (July 2002); David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 *FOOD & DRUG L.J.* 321 (2000); Joseph F. Brodley & Maureen A. O’Rourke, *Patent Settlement Agreements*, 16 *ANTITRUST*, Summer 2002 at 53; Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 *MINN. L. REV.* 1719 (2003); Keith B. Leffler & Cristofer Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*, 2 *ABA ANTITRUST SEC. ECON. COMM. NEWSLETTER* (2002); Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, 17 *ANTITRUST*, Summer 2003, at 70; Kevin D. MacDonald, *Hatch-Waxman Settlements and Antitrust: On Probabilistic Patent Rights and False Positives*, 17 *ANTITRUST*, Spring 2003, at 68; FAMILIES USA, *COLLUSION AND OTHER ANTICOMPETITIVE PRACTICES: A SURVEY OF CLASS ACTION LAWSUITS AGAINST DRUG MANUFACTURERS* 7–8 (3d ed. Jan. 2004), at http://www.familiesusa.org/site/DocServer/3rd_edition_lawsuit_surveys_pmd.pdf (last accessed Aug. 28, 2004) (cataloging various private antitrust cases against drug manufacturers).

5. 15 U.S.C. § 1 (2000).

6. *Id.* § 2.

7. Courts appear to have split on whether agreements entered into by branded and generic manufacturers to delay generic entry should be viewed as straightforward market allocation agreements subject to the per se rule. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (applying the per se rule); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (applying certain conditions to the applicability of the per se rule).

8. See *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 457–59 (1986).

9. See *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966).

the same coin (the latter results in the former; the former flows from the latter). In delayed generic entry cases, where direct proof of the anticompetitive effects of the challenged conduct is available, the two concepts are appropriately analyzed in the same fashion.

This Article focuses on the two basic and distinct methods of proving these threshold elements of antitrust claims under Section 1 (anticompetitive effects) and Section 2 (monopoly power) of the Sherman Act. These distinct methods of analysis are commonly referred to as the "direct" and "indirect" methods of proving monopoly power and anticompetitive effects.

The direct methodology involves demonstrating with direct evidence that the alleged restraint of trade in question resulted in the inflation of prices above the level that would have prevailed in a competitive market.¹⁰ Thus, for instance, evidence showing that cessation of the alleged anticompetitive conduct (i.e., allowing generic competitors to enter the market) led directly to substantially lower prices or increased output (or both) would be *direct* proof that that conduct (1) had anticompetitive effects pursuant to Section 1 and (2) constituted the exercise of monopoly power under Section 2.¹¹

10. See *Ind. Fed'n of Dentists*, 476 U.S. at 456–57 (using direct evidence to conclude challenged conduct "impairs the ability of the market to advance social welfare by ensuring the provision of desired goods and services to consumers at a price approximating the marginal cost of providing them"); *Toys "R" Us v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (using defendant's ability to restrict output and thereby raise prices as proof of market power); *Rebel Oil Co., Inc. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir.1995) ("If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power."); *United States v. Microsoft Corp.*, 253 F.3d 34, 57 (D.C. Cir. 2001) (stating if "evidence indicates that a firm has in fact" profitably raised prices substantially above the competitive level, "the existence of monopoly power is clear"). As Justice Harlan once observed, the "clearest evil of monopoly is the excessive power the monopolist has over price." *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 597 (1967) (Harlan, J., concurring).

11. Cf. *Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256 (2d Cir. 2001) (in case under sections 1 and 2 of the Sherman Act, comparing competitive conditions where alleged anticompetitive conduct is present and where such conduct is absent); *In re Shopping Carts Antitrust Litig.*, 95 F.R.D. 299, 309 (S.D.N.Y. 1982) ("If an economically effective price conspiracy takes place over a long period of time and the industry suddenly becomes competitive, then ordinarily sales and profits of individual companies will change suddenly. A dramatic and sudden change might tend to indicate that a conspiracy did exist . . ."); *In re Folding Carton Antitrust Litig.*, 83 F.R.D. 251, 254 (N.D. Ill. 1978). *In re Folding Carton* states:

If an economically effective price conspiracy takes place over a long period of time and the industry suddenly becomes competitive, then profits and prices are expected to fall. A dramatic fall in prices in the last years of a conspiracy and the post-conspiracy period may indicate the presence of a price-fixing conspiracy . . .

Id.

The indirect method involves proving monopoly power and anticompetitive effects using circumstantial evidence.¹² For instance, in Section 2 cases generally, courts have traditionally permitted claimants to meet their burden of establishing maintenance or creation of monopoly power by first defining a “relevant product market” or “relevant market”¹³ and subsequently showing that the defendant firm possesses a dominant share of that market. Courts then permit factfinders to draw the inference that where a firm possesses a dominant share of a properly defined relevant market it has monopoly power, i.e., the power to inflate its price substantially above competitive levels.

Similarly, in the context of Section 1 cases, the same kind of circumstantial evidence can be employed to show that the alleged conspiracy in restraint of trade had (or would have) anticompetitive effects. This essentially amounts to showing that the conspiracy would enhance the firms’ combined share of a properly defined relevant market, permitting the inference that they would maintain a higher combined market share, thereby supplementing the firms’ joint market power. This, then, permits the additional inference that by exercising this combined market power, prices would be inflated above competitive levels—a result otherwise known as anticompetitive effects.

Where direct proof of market power and anticompetitive effects is available, it is considered the most straightforward—and should be the preferred—mode of proof. Yet, despite well-reasoned authorita-

12. See *Grinnell Corp.*, 384 U.S. at 571 (“The existence of such [monopoly] power ordinarily may be inferred from the predominant share of the market.”); *E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass’n*, 357 F.3d 1, 6 (1st Cir. 2004) (conventional way to determine whether the relevant actor or combination has sufficient percentage share of a “relevant market” is to give it power to raise prices or enter into arrangements to exclude competitors); *Coastal Fuels of Puerto Rico, Inc., v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196–97 (1st Cir. 1996) (using circumstantial evidence of market shares to prove monopoly power in Section 2 case); *Rebel Oil*, 51 F.3d at 1434.

13. The indirect method of proof can involve proof of a relevant “geographic market” as well. See, e.g., *E. Food Servs.*, 357 F.3d at 6–7. Indeed, “[t]he criteria to be used in determining the appropriate geographic market are essentially similar to those used to determine the relevant product market.” *Brown Shoe v. United States*, 370 U.S. 294, 336 (1962). A geographic market is “the area of effective competition.” *Re/Max Int’l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999). It is defined to be the “region such that a hypothetical monopolist that was the only present or future producer of the relevant product at locations in that region would profitably impose at least a ‘small but significant and nontransitory’ increase in price.” DEP’T OF JUSTICE & FED. TRADE COMM’N, HORIZONTAL MERGER GUIDELINES § 1.21 (1997) [hereinafter DEP’T OF JUSTICE & FED. TRADE COMM’N, MERGER GUIDELINES]. Among other reasons, because of the applicability of federal regulations pertaining to the sale and marketing of prescription drugs, there has been no dispute in delayed generic entry cases that the relevant geographic market is the United States.

tive support for reliance upon direct proof where it is available, some practitioners in the field, including pharmaceutical industry defenders, continue to insist that an indirect methodology is required. Industry defenders have exploited the unfortunate tendency of both courts and commentators, in setting forth the elements of Sherman Act Section 1 and Section 2 claims, to recite, often indiscriminately, the “necessity” of defining a “relevant market.”¹⁴ This supposed universal “requirement” arose, in part, because most reported cases involve one competitor suing another. In such cases, unambiguous direct proof of harm to *competition* as opposed to harm of the complainant *competitors themselves*, which is the appropriate focus of antitrust analysis,¹⁵ is rarely available.¹⁶ Indeed, the type of unambiguous direct evidence of market power in delayed generic entry cases is likely unprecedented in the universe of large scale, contested litigation. Despite the availability of this evidence in delayed generic entry cases, relevant market definition analysis has nevertheless been ripped from its moorings to be used in a wholly different context as a platform to try to defeat antitrust claims brought by *purchasers* armed with direct evidence of harm to competition in the form of supracompetitive pricing.

Although the direct and indirect methods are not contradictory, and indeed if properly applied should yield the same conclusions about the presence or absence of market power, industry defenders have nevertheless attempted to use the indirect method as a means to negate (or at minimum blur) the undeniable implications of the direct proof in delayed generic entry cases. It is observed that most brand-name drugs occupy therapeutic classes consisting of a number of other drugs that treat the same condition or disease and that a single brand rarely dominates a class. By arguing that the “relevant

14. See, e.g., *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1355 (Fed. Cir. 1999) (“Defining the relevant market is an indispensable element of any monopolization or attempt case, for it is the market in which competition is affected by the asserted predatory or anticompetitive acts.”); *Am. Bearing Co., Inc. v. Litton Indus., Inc.*, 729 F.2d 943, 949 (3d Cir. 1984) (“The market power analysis begins with a definition of the relevant product market for the particular product and is an element of a section 2 violation that plaintiff must establish to prevail. Without a definition of the relevant market, the defendant’s ability to exclude competitors cannot be determined.”).

15. See, e.g., *SmithKline Beecham, P.L.C. v. Apotex Corp.*, 2004 WL 2222388, at *8 (E.D. Pa. Sept. 29, 2004) (“The antitrust laws . . . were enacted for ‘the protection of competition not competitors’” (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962))).

16. See 2A PHILLIP E. AREEDA & HERBERT HOVENKAMP ET AL., *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* & 531a (2d ed. 1995); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (“direct proof [of monopoly power] is only rarely available”).

market” should include all of these “competing” drugs, industry defenders can improperly derive a conclusion completely at odds with the direct evidence, namely that delaying generic entry does not and cannot involve maintenance of substantial market (i.e., monopoly) power and, thus, does not and cannot yield anticompetitive effects.¹⁷

This Article seeks to clarify the conceptual confusion inherent in requiring a burdensome and potentially diversionary indirect test of market power and anticompetitive effects in the context of delayed generic entry cases where unambiguous direct proof is available. In a Section 1 case nearly twenty years ago, the Supreme Court in *Federal Trade Commission v. Indiana Federation of Dentists*¹⁸ made clear that “elaborate market analysis,” including defining a relevant market, is *not* required where direct evidence of anticompetitive effects is available.¹⁹ Based on similar reasoning, courts have drawn precisely the same conclusion in relatively recent cases relating to the appropriate use of direct proof of monopoly power under Section 2 as well.²⁰ These holdings strongly suggest that the tendency of courts and commentators to incorporate a “relevant market” requirement reflexively when reciting the elements of a Sherman Act claim is inapplicable in cases, like delayed generic entry cases, where direct proof is available and abundant.

Indeed, the direct evidence that the branded firm maintains prices above levels that prevail post-generic entry only by delaying generic entry is not even typically in material dispute in these cases.²¹ A typical statement in the economic literature is as follows: “[T]he aver-

17. In effect, pharmaceutical company lawyers have argued that antitrust enforcers, both public and private, should disregard the fact that delaying generic entry delays the clear competitive benefits that generics invariably bring in assessing whether such conduct violates the Sherman Act.

18. 476 U.S. 447 (1986).

19. *Id.* at 460–61.

20. *See, e.g., Microsoft Corp.*, 253 F.3d at 52 (if “evidence indicates that a firm has in fact” profitably raised prices substantially above the competitive level, “the existence of monopoly power is clear”); *Re/Max Int’l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1018 (6th Cir. 1999) (stating that monopoly power can be established “when there is direct evidence that the defendant has actually set prices or excluded competition”); *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) states:

Market power may be demonstrated through either of two types of proof. One type of proof is direct evidence of the injurious exercise of market power. If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.

21. In the context of cases in which the brand manufacturer pays generic manufacturers large exclusion payments in exchange for the generics’ agreement to refrain from marketing, Professors Hovenkamp, Janis, and Lemley have written: “The very fact that the

age price of a drug is likely to fall after generic entry because the generic price of a drug can be substantially lower than the brand-name price and the generic can capture a large share of sales of a drug shortly after generic entry.”²² Based on this consensus, the court in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*²³ rightly concluded as follows: “the anticompetitive effects of [delaying the entry of generic terazosin] cannot be seriously debated.”²⁴

Given this context, it is quite simply illogical to require an *indirect* analysis of monopoly power or anticompetitive effects in delayed generic entry cases. The Federal Trade Commission (“FTC”) itself recently, and unanimously, came to precisely the same conclusion in a delayed generic entry case, reversing the administrative law judge who followed the industry’s preferred indirect approach.²⁵ The FTC got it exactly right.

In cases where there is abundant and largely unambiguous direct evidence about the anticompetitive effects of generic competition, the antitrust analysis, in both Sherman Act Section 1 and Section 2 cases, should focus on that direct evidence. This is because the whole point of an indirect relevant market analysis is to create a framework for determining whether the challenged conduct *has the capacity* to cause anticompetitive effects, such as by maintaining artificially inflated prices. It elevates form over substance, then, to focus on an indirect means of analyzing potential or possible anticompetitive effects of an alleged restraint of trade—inviting confusion and increasing the likelihood of getting the wrong result—when direct evidence of actual anticompetitive effects not only exists, but where the effects are known and undisputed.

pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power.” Hovenkamp et al., *supra* note 4, at 1757.

22. This statement was authored by James Langenfeld, an economist serving as a testimonial expert for the pharmaceutical defendants in *In re Terazosin Hydrochloride Antitrust Litigation*, 335 F. Supp. 2d 1336 (S.D. Fla. 2004). It exemplifies the consensus that has emerged regarding the competitive effects of generic competition. James Langenfeld et al., *Intellectual Property and Agreements To Settle Patent Disputes: The Case of Settlement Agreements With Payments From Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777, 778 n.5 (2002).

23. 344 F.3d 1294 (11th Cir. 2003).

24. *Id.* at 1311 n.27 (emphasis added).

25. See *In re Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187, at *30–*31, *41–*47 (Dec. 8, 2003) (where anticompetitive effects of delaying generic entry are well known and understood, there is no need to define a relevant market), *appeal filed*, No. 04-10688 (11th Cir. Feb. 13, 2004).

Part I of this Article begins by examining how the concepts of monopoly power and anticompetitive effects are defined in the fields of law and economics. It then examines the two methods of assessing the presence of monopoly power and anticompetitive effects: the direct and indirect modes of analysis. The Article then argues that where direct evidence of the impact of delaying generic entry on drug prices not only exists, but is unambiguous and uncontroversial, an indirect market analysis involving defining a relevant market is wholly unnecessary.

Part I continues by explaining that indirect market power analysis, if undertaken, can obscure and confuse the underlying competitive issues in delayed generic entry cases. This is true both in cases brought under Section 2 of the Sherman Act (alleging unilateral conduct) and those brought under Section 1 of the Sherman Act (alleging conspiracy).

Part I then concludes by demonstrating that the same direct evidence of anticompetitive effects of delaying generic entry, namely, the forestalling of the substantially reduced price levels that generic competition for a given drug compound invariably yields, necessarily implies a relevant product market that is limited to the brand-name drug and its generic FDA-related therapeutic equivalents,²⁶ often referred to collectively in the pharmaceutical industry as the "molecule market." Thus, even if defining a "relevant market" were required, there would be no need to go through the motions of referring to or analyzing circumstantial indicia of whether various products are "reasonably interchangeable," and thus belong in the relevant market. Put simply, the Article shows that reference to circumstantial evidence is unlikely to provide pertinent additional information in delayed generic entry cases and more than likely serves to obscure competitive issues rather than elucidate them.

Next, in Part II, the Article goes on to explain that, if performed correctly, the indirect approach should confirm the validity of the result that the direct evidence reveals. In this section, the Article describes in some detail the key institutional features of the pharmaceutical business, focusing on the legal and regulatory backdrop that set the framework for competition in the industry. The Article provides an overview of the applicable web of laws, regulations,

26. The FDA classifies products as therapeutically equivalent if they are both pharmaceutically equivalent (in that they contain the same amount of the same active ingredient in the same dosage form) and bioequivalent (in that they are absorbed at the same rate, and to the same extent). See ORANGE BOOK, *supra* note 1, §§ 1.2, 1.7.

and institutional features, discussing (1) why it is that, absent generic competition, prices for a particular drug compound or active ingredient (i.e., "the molecule") tend to remain well above competitive levels, (2) why generic competition tends to have such significant ameliorative effects on prices, and thus (3) why the circumstantial evidence confirms that the market is the molecule.

Finally, in Part III, the Article discusses the industry defenders' argument that, when analyzing the pharmaceutical industry, one should essentially abandon traditional measures of market power due to the purportedly high "fixed," up-front, research and development costs, and the presence of marketing exclusivities flowing from patents or the Hatch-Waxman regulatory scheme.²⁷ Defenders observe that if traditional definitions of monopoly power were employed, for instance, all brands would be "monopolies" in purported violation of the Sherman Act. They argue, therefore, that strict antitrust enforcement could shut down the entire industry.

The Article points out, first, that this position is, at root, a fundamental acknowledgement that delaying generic entry permits branded companies to maintain market power and charge supracompetitive prices with obvious anticompetitive effects. Indeed, the apparent point of this argument is that monopoly power, supracompetitive prices, and anticompetitive effects should be tolerated, at least in the short-run, in order to further the supposed long-run and dynamic efficiency goals of the patent laws and the regulatory scheme.

The Article then concludes by addressing the substance of the industry argument directly pointing out (1) that a finding that a firm possesses monopoly power (or that joint conduct enhances market power and causes anticompetitive effects), standing alone, does not an antitrust violation make; also required is a determination that the challenged conduct was "willful" and/or unprotected by legitimate intellectual property or other exclusivity rights; and (2) if the allegations in delayed generic entry cases that patent or exclusivity rights were somehow improperly obtained and/or enforced are proven true, a defendant firm has no basis to rely upon those "rights" to defend its enhanced market power and the anticompetitive effects that such market power creates.

27. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered portions of 21 & 35 U.S.C.).

I. Assessment of Monopoly Power and Anticompetitive Effects in Delayed Generic Entry Cases

This section begins with a brief discussion of the tactics that branded companies have used to try to delay or block generic competition and the underlying antitrust foundation of the litigation these tactics have spawned. It then presents the conceptual framework for the discussion of “monopoly power” and “anticompetitive effects,” explaining that these terms are essentially two sides of the same coin, followed by a discussion of the prevailing methodologies for assessing monopoly power and anticompetitive effects in the context of delayed generic entry cases.

A. Types of Delayed Generic Entry Cases: Concerted Action and Unilateral Conduct

Most of the recent antitrust litigation relating to delayed generic entry falls into two basic categories: (1) cases challenging agreements in which branded manufacturers pay generic companies to refrain from competing, either in connection with a settlement of patent litigation or pending the outcome of ongoing patent litigation,²⁸ and (2) unilateral action by branded companies designed to exclude or delay generic competition, such as by fraudulently obtaining and enforcing invalid patents and improperly listing them in the FDA’s “Orange Book” as a means to gain the benefits of Hatch-Waxman’s thirty-month stay of generic competition.²⁹

28. See, e.g., *Valley Drug Co.*, 344 F.3d 1294; *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003); *In re Bupirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (discussing an agreement between branded manufacturer and generic manufacturer, in addition to unilateral conduct by branded manufacturer); *Action Alliance of Senior Citizens of Greater Phila. v. Elan Corp., P.L.C.*, No. CIV.A.02-CV-2095, 2003 WL 22358451 (E.D. Pa. Sept. 5, 2003) (discussing an agreement between brand manufacturer and generic manufacturer regarding Naprelan (naproxen sodium), in addition to unilateral conduct by brand manufacturer); *In re Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187 (Dec. 8, 2003). Cases alleging agreements in restraint of trade in violation of Section 1 of the Sherman Act do not arise exclusively from agreements between brand drug manufacturers and generic drug manufacturers; combinations of generic manufacturers have been the subject of such lawsuits as well. See *In re Nifedipine Antitrust Litig.*, 266 F. Supp. 2d 1382 (J.P.M.L. 2003); *In re Lorazepam & Chlorazepate Antitrust Litig.*, 202 F.R.D. 12 (D.D.C. 2001).

29. See *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899 (7th Cir. 2004) (Taxol (paclitaxel)); *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56 (D. Mass. 2003); *Organon, Inc. v. Mylan Pharms., Inc.* 293 F. Supp. 2d 453 (D.N.J. 2003) (Remeron (mirtazapine)); *Nichols v. SmithKline Beecham, P.L.C.*, No. CIV.A.00-6222, 2003 WL 302352 (E.D. Pa. Jan.

Antitrust claims in these two categories are brought under different provisions of the Sherman Act. The first type, involving alleged restraints in the form of conspiracies or agreements, is covered by Section 1.³⁰ The second type, involving unilateral conduct, is covered by Section 2, which prohibits monopolization and attempted monopolization.³¹

To prevail on a Section 1 claim, a plaintiff must show (1) concerted action that results in unreasonable restraint of trade, and (2) injury to business or property as a result of the concerted conduct.³² For a Section 2 case, the elements are typically stated as follows: (1) possession of monopoly power in a relevant market; (2) willful acqui-

29, 2003) (Paxil (paroxetine)); *In re Buspirone*, 185 F. Supp. 2d at 366; FED. TRADE COMM'N, *supra* note 4, at 39-56; FAMILIES USA, *supra* note 4, at 7-8 (cataloging various private antitrust cases against drug manufacturers). Because the 180-day exclusivity period offered as an incentive to the first generic to file an ANDA for a specific drug listed in the Orange Book will not begin to run until that generic manufacturer first sells its product, postponing the commencement of the 180-day exclusivity period through collusive conduct or sham litigation may also serve to lock out all generic manufacturers from the market. *See* FED. TRADE COMM'N, *supra* note 4, at vii, 26.

30. *See* 15 U.S.C. § 1 (2000). Section 1 of the Sherman Act provides in pertinent part:

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony

Id.

31. *Id.* § 2. Section 2 of the Sherman Act provides that "[e]very person who shall monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony." *Id.*

32. *See, e.g.,* *Denny's Marina, Inc. v. Renfro Prods., Inc.*, 8 F.3d 1217, 1220 (7th Cir. 1993) ("A successful claim under Section 1 of the Sherman Act requires proof of three elements: (1) a contract, combination, or conspiracy; (2) a resultant unreasonable restraint of trade in the relevant market; and (3) an accompanying injury."); *Austin v. McNamara*, 979 F.2d 728, 738 (9th Cir. 1992). *Austin* states:

To establish a Section 1 violation under the Sherman Act, a plaintiff must demonstrate three elements: (1) an agreement, conspiracy, or combination among two or more persons or distinct business entities; (2) which is intended to harm or unreasonably restrain competition; and (3) which actually causes injury to competition, beyond the impact on the claimant, within a field of commerce in which the claimant is engaged (*i.e.*, 'antitrust injury').

Id.; *see also* *Ancar v. Sara Plasma, Inc.*, 964 F.2d 465, 469 (5th Cir. 1992) ("The elements required to state a Section 1 claim are: (1) the existence of a conspiracy (2) affecting interstate commerce (3) that imposes an unreasonable restraint of trade."); *Fuentes v. S. Hills Cardiology*, 946 F.2d 196, 198 (3d Cir. 1991) ("Three elements must be alleged to sustain a cause of action under section 1 of the Sherman Act . . . a contract, combination or conspiracy; a restraint of trade; and an effect on interstate commerce.").

tion or maintenance of that power; and (3) injury to business or property as a result.³³

Section 1 cases involving conduct deemed to be per se illegal, such as certain horizontal price fixing and market allocation activities,³⁴ require no assessment of whether the challenged conduct resulted in maintenance or creation of substantial market power or whether the challenged conduct yielded anticompetitive effects.³⁵ Because courts are deemed to have had sufficient experience with restraints of trade such as horizontal price-fixing and market allocation, the law permits courts to presume that such conduct would yield anticompetitive effects without requiring specific proof.³⁶ Where the per se rule is not applicable, however, and the conduct is analyzed under the "rule of reason," one must assess the *ability* of the challenged con-

33. *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966) (reciting first two elements); *Rural Tel. Service Co. v. Feist Publ'ns, Inc.*, 957 F.2d 765, 768 (10th Cir. 1992) (noting presence of third element); *Advanced Health-Care Servs. v. Radford Cmty. Hosp.*, 910 F.2d 139, 147 (4th Cir. 1990) (same); *Cal. Computer Prods., Inc. v. Int'l Bus. Machs. Corp.*, 613 F.2d 727, 735 (9th Cir. 1979).

34. Whether delayed generic entry cases involving "reverse payment" agreements, under which brand companies pay generics not to come to market for certain periods of time or during the pendency of patent litigation, should be analyzed as a per se violation of Section 1 has been the source of controversy and debate. *Compare In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (holding reverse payments to be per se violations of the Sherman Act), *with Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (applying conditions to the possible applicability of the per se rule), *and In re Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187 (Dec. 8, 2003) (holding that reverse payments are adjudicable under quick-look analysis and reconciling *In re Cardizem* and *Valley Drug*), *and In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003). The debate has also split the academic community. *Compare Hovenkamp et al.*, *supra* note 4, *with MacDonald*, *supra* note 4.

35. *Nat'l Coll. Athletic Ass'n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 109–10 (1984). This case states:

As a matter of law, the absence of proof of market power does not justify a naked restriction on price or output. To the contrary, when there is an agreement not to compete in terms of price or output, "no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement." . . . We have never required proof of market power in such a case.

Id. (internal citation omitted); *see also* *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 430–31 (1990) ("If small parties were allowed to prove lack of market power, all parties would have that right, thus introducing the enormous complexities of market definition into every price-fixing case." (internal quotations omitted)). Judge Bork has also suggested that a firm's willingness to enter into an agreement to fix prices is itself proof of market power. ROBERT H. BORK, *THE ANTITRUST PARADOX* 269 (1993) ("Very few firms that lack power to affect market prices will be sufficiently foolish to enter into conspiracies to fix prices. Thus, the fact of agreement defines the market.").

36. *See, e.g., Superior Court Trial Lawyers Ass'n*, 493 U.S. at 430 (price fixing); *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 607–08 (1972); *N. Pac. R.R. v. United States*, 356 U.S. 1, 5 (1958).

duct to result in anticompetitive effects or whether the conduct actually has resulted in such effects.³⁷

B. Monopoly Power and Anticompetitive Effects: The Conceptual Framework

The Supreme Court has defined monopoly power as “the power to control prices or exclude competition.”³⁸ According to a standard economics text: “Whenever a firm can influence the price it receives for its product, the firm is said to have *monopoly power* (sometimes called *market power*).”³⁹ The existence of monopoly power presents an important public policy issue—and has been addressed as a national social, economic, and legal concern for over one hundred years—principally because of the social costs associated with the exercise of monopoly power.⁴⁰ Over the history of the antitrust laws, these social costs have been expressed primarily in economic terms.⁴¹ In general, the exercise of monopoly power permits an incumbent firm to raise or stabilize the price of its product significantly above competitive levels and causes a misallocation of productive resources.⁴²

Economists and courts often use the terms “market power” and “monopoly power” interchangeably.⁴³ Both terms mean “the ability profitably to maintain prices above competitive levels for a significant period of time.”⁴⁴ Some courts define “monopoly power” as “substantial market power.”⁴⁵ “Substantial market power” exists where a firm can maintain price substantially above the competitive level without a significant loss of sales due to consumer resistance (or competition).⁴⁶

37. *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 459 (1986).

38. *United States v. E.I. du Pont de Nemours*, 351 U.S. 377, 391 (1956).

39. DENNIS W. CARLTON & JEFFREY M. PERLOFF, *MODERN INDUSTRIAL ORGANIZATION* 137 (2d ed. 1994) [hereinafter CARLTON & PERLOFF, *SECOND EDITION*]; see also 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, & 525.

40. 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 502.

41. *Id.* ¶ 101.

42. *Id.* ¶ 502.

43. See CARLTON & PERLOFF, *SECOND EDITION*, *supra* note 39, at 137.

44. DEP’T OF JUSTICE & FED. TRADE COMM’N, *MERGER GUIDELINES*, *supra* note 13, § 0.1; see also 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 501; William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 HARV. L. REV. 937, 937, 939 (1981).

45. See, e.g., *Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, 899 F.2d 951, 966 (10th Cir. 1990); *Carpet Group Int’l v. Oriental Rug Imps. Ass’n, Inc.*, 256 F. Supp. 2d 249, 286–87 & n.32 (D.N.J. 2003).

46. See *The Package Shop, Inc. v. Anheuser-Busch, Inc.*, 675 F. Supp. 894, 939–40 (D.N.J. 1987) (citation omitted); see, e.g., *Nat’l Coll. Athletic Ass’n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 109 n.38 (1984) (“Market power is the ability to raise prices above those that would be charged in a competitive market.”); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (“[A] firm is a monopolist if it can profitably raise

To the extent that there is a distinction between market power and monopoly power, it reflects, in part, a recognition that market power exists on a continuum, ranging from its complete absence—perfect competition—to its fullest manifestation—a true sole-seller monopolist.⁴⁷ Given that nearly every firm has a small degree of market power, for market power to raise antitrust concerns, it must reflect a substantial level of power over pricing.⁴⁸ In its influential merger guidelines, which discuss the issue of market power at length, the Department of Justice generally defines this threshold as the ability to raise prices profitably, in a non-transitory fashion, approximately five percent above the level that would otherwise exist.⁴⁹

In the antitrust context, the term “anticompetitive effects,” refers to the economic conditions that flow from the exercise of substantial market power. The requirements of demonstrating anticompetitive effects under Section 1 (through the accumulation and exercise of market power due to concerted action) or the exercise of monopoly power under Section 2 effectively mirror one another because the concepts of monopoly power and anticompetitive effects are two sides of the same coin. Where prices in a marketplace can be shown to depart substantially from that which would exist under competitive conditions due to the restraint of trade in question, one can safely

prices substantially above the competitive level.”); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 994 (11th Cir. 1993) (“Monopoly power is ‘the power to raise prices to supra-competitive levels’” (internal citation omitted)); *Am. Academic Suppliers, Inc. v. Beckley-Cardy, Inc.*, 922 F.2d 1317, 1319 (7th Cir. 1991) (“[M]onopoly power [is] the power to charge a price higher than the competitive price”); Thomas G. Krattenmaker et al., *Monopoly Power and Market Power in Antitrust Law*, 76 GEO. L.J. 241, 247 (1987) (“Economists use both ‘market power’ and ‘monopoly power’ to refer to the power of a single firm or group of firms to price profitably above marginal cost. . . . We believe that antitrust law should dispense with the idea that market power and monopoly power are different concepts.”).

47. 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 501.

48. See *Coastal Fuels of Puerto Rico Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196 (1st Cir. 1996) (“Substantial market power that concerns antitrust law arises when the defendant (1) can profitably set prices well above its costs and (2) enjoys some protection against [a] rival’s entry or expansion that would erode such supracompetitive prices and profits.” (quoting 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 501)).

49. FED. TRADE COMM’N & U.S. DEP’T OF JUSTICE, *supra* note 3, § 1.11. This section states:

In attempting to determine objectively the effect of a “small but significant and nontransitory” increase in price, the Agency, in most contexts, will use a price increase of five percent lasting for the foreseeable future. However, what constitutes a “small but significant and nontransitory” increase in price will depend on the nature of the industry, and the Agency at times may use a price increase that is larger or smaller than five percent.

conclude that (1) monopoly power is being exercised and (2) the observed market flowing from the restraint effects are "anticompetitive."⁵⁰

By colluding with its competitors to raise or stabilize prices, for example, by agreeing to refrain from competitive actions designed to capture customers, or by excluding competition by unilaterally creating obstacles for actual or potential competitors, a firm can create or maintain market power and cause anticompetitive effects. Market power may also flow from conditions in the marketplace, such as product differentiation, the existence of intellectual property rights, or other factors that insulate a seller's product from competition.⁵¹ For instance, it is well recognized that one purpose of patents is to encourage investment in innovative activities by giving patent holders protection from competition over products and processes, which thereby can enable them to earn supracompetitive returns on those products and processes.⁵² As the Supreme Court has emphasized, "The patent laws 'promote the Progress of Science and useful Arts' by rewarding innovation with a temporary monopoly."⁵³

Monopoly power and anticompetitive effects can also flow from the unlawful or improper extension of a legal period of market exclusivity. Such an unlawful extension is what triggers potential Sherman Act liability in delayed generic entry cases. The court in one such case recently recognized that, in the pharmaceutical industry context, having a patent on a particular active ingredient can provide a seller with monopoly power, dissipated only by the expiration of the intellectual property protection of FDA granted exclusivity.⁵⁴ Therefore, "if a pat-

50. *Re/Max Int'l, Inc., v. Realty One, Inc.*, 173 F.3d 995, 1018–19 (6th Cir. 1999).

51. *Queen City Pizza v. Domino's Pizza*, 124 F.3d 430, 438 n.7 (3d Cir. 1997) ("[M]arket power exists in three circumstances: where the government has granted a seller a patent or similar monopoly, where the seller possesses a unique product, or where the seller possesses a high market share.") (citing *Mozart Co. v. Mercedes-Benz of N. Am.*, 833 F.2d 1342, 1345–46 (9th Cir. 1987)); *Hewlett-Packard Co. v. Boston Sci. Corp.*, 77 F. Supp. 2d 189, 196 (D. Mass. 1999) (holding monopoly power may be created where patents and regulatory hurdles pose barrier to entry of potential competitors).

52. *2A AREEDA & HOVENKAMP ET AL.*, *supra* note 16, ¶ 1780a.

53. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 730 (2002).

54. *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 531 (D.N.J. 2004) ("Although a patent holder lawfully acquires a monopoly power via the patent process, it subsequently may violate the second prong of the *Grinnell* test by unlawfully *maintaining* that monopoly power."); *see, e.g., Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 814 (D.C. Cir. 2001) (discussing ways in which delayed generic entry arrangement "can manipulate the statutory grant of a monopoly" and Hatch-Waxman Act provisions "bar competitive entries" and illegally extend market power); *United States v. Microsoft Corp.*, 253 F.3d 34, 51

ent holder's actions unlawfully maintain otherwise lawful monopoly power . . . such actions could lead to anticompetitive effects in the relevant market [violating Section 1 of the Sherman Act]."⁵⁵

C. Assessing Monopoly Power and Anticompetitive Effects: The Direct and Indirect Methods

Under antitrust analysis, "[m]arket power can be shown through two types of proof."⁵⁶ First, its exercise can be assessed directly from existing or past market conditions by examining whether the restraint of trade in question yielded prices that were significantly elevated over competitive levels.⁵⁷ This can be as straightforward as examining whether lifting the alleged anticompetitive restraint (i.e., allowing generics to enter the market) actually led to lower prices or increased output. It might also involve permitting a firm to charge prices substantially in excess of its marginal costs.⁵⁸ Given that direct evidence of

(D.C. Cir. 2001) (considering patents and regulatory barriers to entry in context of market power); *Hewlett-Packard Co.*, 77 F. Supp. 2d at 196 (finding allegations of barriers to entry, including patents and regulatory hurdles, sufficient to defeat a Rule 12(b)(6) motion).

55. *In re Remeron*, 335 F. Supp. 2d at 532.

56. *See, e.g., Re/Max Int'l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999) ("There are two ways to establish . . . that a defendant holds market power. The first is by presenting direct evidence showing the exercise of actual control over prices. . . . The second is by presenting circumstantial evidence . . . by showing a high market share within a defined market."); *see also* *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 97-98 (2d Cir. 1998) ("[Market power] may be proven directly by evidence of the control of prices . . . or it may be inferred from one firm's large percentage share of the relevant market."); *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996).

57. *See, e.g., Microsoft Corp.*, 253 F.3d at 51 ("Where evidence indicates that a firm has in fact profitably [raised prices substantially above the competitive level], the existence of monopoly power is clear."); *see also Re/Max*, 173 F.3d at 1016 (stating plaintiff can prove monopoly power by proving "actual control over prices or actual exclusion of competitors"); *Coastal Fuels Inc.*, 79 F.3d at 196 (direct evidence of market power can be shown through "actual supracompetitive prices and restricted output"); *Rebel Oil Co., Inc. v. Adl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir.1995) ("If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.").

58. In the absence of benchmarks reflecting the competitive price level that can be readily developed from actual market experience, such as the price that prevails upon generic entry, economists derive benchmarks from the economic theory that applies in competitive markets. *See, e.g.,* CARLTON & PERLOFF, SECOND EDITION, *supra* note 39, at 57. Economists use the term "perfect competition" to describe a market structure where market outcomes are unaffected by the exercise of market power. *Id.* In a perfectly competitive market outcome, prices will reflect marginal cost, i.e., the added cost associated with producing and selling the last (or incremental) unit of output. While a perfectly competitive market represents an idealistic economic model, economists use divergence of price levels from marginal costs as indicia of the existence (and exercise) of market power. *See* FTC v.

the present or past exercise of market power, i.e., establishing market prices substantially above competitive levels, is direct evidence of anticompetitive effects and vice versa, the proof requirements for monopoly power under Section 2 of the Sherman Act and anticompetitive effects under Section 1 should mirror one another when employing the direct method.⁵⁹

Because direct evidence of the exercise of monopoly power is often unavailable or ambiguous for the particular market or industry in question,⁶⁰ the more familiar approach to proof of market power is the *indirect* method, which focuses on *circumstantial evidence* of the possibility that a particular restraint of trade could create or enhance market power. The indirect method involves a two step process. First, an appropriate "relevant product market" (or simply "relevant market")⁶¹ must be defined. Under the modern view, as exemplified by the merger guidelines published by the FTC and the U.S. Department of Justice, a relevant market is the smallest group of products such that a firm that controlled the output for those products could profitably raise or maintain prices substantially above competitive levels for a non-transitory period of time.⁶² As will be discussed further in the

Ind. Fed'n of Dentists, 476 U.S. 447, 459 (1986) (invalidating an agreement because it permitted dentists to charge above a "price approximating the marginal cost of providing them"); Tasty Baking Co. v. Ralston Purina, Inc., 653 F. Supp. 1250, 1267 (E.D. Pa. 1987) (holding ability to maintain price above competitive levels is "powerful evidence of actual monopolization"); Nobelpharma AB v. Implant Innovations, Inc., 930 F. Supp. 1241, 1250 (N.D. Ill. 1996) (charging jury that "a relevant market is the smallest grouping of sales . . . that a firm with 100% of that grouping could profitably reduce output and increase price substantially above marginal cost" (internal citation omitted)), *aff'd in part and rev'd in part*, 129 F.3d 1463 (Fed. Cir. 1997), *vacated and substituted*, 141 F.3d 1059 (Fed. Cir. 1998). While marginal cost as a theoretical concept is not always readily measurable, other measures of cost such as average variable cost and operating cost often serve as reasonable proxies. See, e.g., Alan S. Blinder, *Why Are Prices Sticky? Preliminary Results From an Interview Study*, 81 AM. ECON. REV. 89, 95-96 (1991); MICHAEL OLIVE, IS AVERAGE VARIABLE COST A GOOD PROXY FOR SHORT-RUN MARGINAL COST AND WHY IS IT IMPORTANT? 1-2 & 17 (Aug. 2002), available at <http://www.econ.mq.edu.au/research/2002/82002Olive.pdf> (last accessed Sept. 20, 2004).

59. See, e.g., *Re/Max*, 173 F.3d at 1019 (applying direct evidence analysis from Section 1 cases, and stating that "we see no reason to believe that monopoly power in the Sec. 1 context is any different from the Sec. 2 monopoly power").

60. See generally 2A AREEDA & HOVENKAMP, *supra* note 16, ¶ 531a ("Because they seldom have such data, antitrust courts traditionally define a market and examine the firms' market shares.").

61. *Id.*

62. A market is defined as:

[A] product or group of products and a geographic area in which it is produced or sold such that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future producer or seller of those products in that area likely would impose at least a "small but significant and non-transi-

next section of this Article, relevant market analysis with circumstantial proof involves an evaluation of whether products are “reasonably interchangeable.” Only those products that are both functionally similar *and* economically substitutable belong in the same relevant market.⁶³

Second, a showing must be made that the incumbent firm has a dominant share of the sales in that market.⁶⁴ If such dominance can be demonstrated, an inference may be drawn that the dominant firm possesses monopoly power, the exercise of which results in anticompetitive effects.⁶⁵ The basis for this sort of inference is the large body of economic literature linking market structure—most importantly, market share—and market power.⁶⁶

The foundation of the indirect method of assessing monopoly power, and anticompetitive effects, is the notion that the existence of one or more close economic substitutes for a product will constrain the ability of the firm selling that product to raise or maintain prices above the competitive level.⁶⁷ Under the indirect approach, the principal issue is always the constraining capabilities of existing competitors to prevent an incumbent firm from charging prices above competitive levels.⁶⁸ Where an incumbent product faces close economic substitutes, those substitutes will force the prices to or near competitive levels. Those substitutes, then, belong in an appropriately defined relevant market. Where existing products do not force the incumbent’s prices to or near competitive levels (e.g., levels that prevail only upon the lifting of the restraint of trade in question), those products do not belong in the relevant market.

tory” increase in price, assuming the terms of sale of all other products are held constant.

FED. TRADE COMM’N & U.S. DEP’T OF JUSTICE, *supra* note 3, § 1.0. Again, under the FTC/DOJ guidelines, that threshold is taken to be five percent for one year. *Id.* § 1.11.

63. See *infra* notes 170–71 and accompanying text.

64. *Graphic Prods. Distribs., Inc. v. Itek Corp.*, 717 F.2d 1560, 1569 (11th Cir. 1983).

65. F.M. SCHERER & DAVID ROSS, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 422 (3d ed. 1990); W. KIP VISCUSI ET AL., *ECONOMICS OF REGULATION AND ANTI-TRUST* 143–50 (3d ed. 2000).

66. See Richard Schmalensee, *Inter-Industry Studies of Structure and Performance*, *HANDBOOK OF INDUSTRIAL ORGANIZATION* 966–67, 973–77 (1989).

67. *Microsoft Corp.*, 253 F.3d at 57 (“Structural market power analyses are meant to determine whether potential substitutes constrain a firm’s ability to raise prices above the competitive level . . .”).

68. *2A AREEDA & HOVENKAMP ET AL.*, *supra* note 16, ¶¶ 533, 536.

D. Direct Evidence of the Exercise of Monopoly Power Is Superior to Indirect Evidence

In most antitrust cases, detailed pricing and cost data reflecting the marketplace with and without the alleged competitive restraint is unavailable, unusable, or ambiguous. This circumstance often exists because the alleged anticompetitive conduct is continuing and there is no "after" market to use for comparison purposes. In others, the pertinent issue may be the *potential* for certain conduct to have anticompetitive effects or to create or maintain monopoly power. In such circumstances, economists must revert to inferential (indirect) means for assessing the likely market power effects.⁶⁹

Where direct proof is available, however, litigants are increasingly permitted in both Section 1 and Section 2 cases to employ the direct methodology, not merely in addition to, but *in lieu of* pursuing the indirect approach.⁷⁰ The Supreme Court has held in a Section 1 case, and other courts have followed in both Section 1 and Section 2 con-

69. See, e.g., *Microsoft Corp.*, 253 F.3d at 51-56; *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995).

70. Andrew I. Gavil, *Copperweld 2000: The Vanishing Gap Between Sections 1 And 2 of the Sherman Act*, 68 ANTITRUST L.J., 87, 101 (2000); see also *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (direct proof of actual anticompetitive effects sufficient in a Section 1 case); *Conwood Co., L.P. v. United States Tobacco Co.*, 290 F.3d 768, 783 n.2 (6th Cir. 2002) ("Whether a company has monopoly or market power 'may be proven directly by evidence of the control of prices or the exclusion of competition . . .'" (citation omitted)); *Microsoft Corp.*, 253 F.3d at 51 (stating that in a Section 2 case, if "evidence indicates that a firm has in fact [profitably raised prices substantially above the competitive level], the existence of monopoly power is clear"); *Toys "R" Us, Inc., v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (finding that market power in a Section 1 case may be shown directly with proof of anticompetitive effects); *Re/Max Int'l, Inc. v. Realty One, Inc.* 173 F.3d 995, 1018 (6th Cir. 1999) (market power in Section 2 case can be established "when there is direct evidence that the defendant has actually set prices or excluded competition"); *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 97-98 (2d Cir. 1998) (monopoly power in a Section 2 case "may be proven directly by evidence of the control of prices or the exclusion of competition, or it may be inferred from one firm's large percentage share of the relevant market"); *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996) (Section 2 case); *Rebel Oil Co.*, 51 F.3d at 1434. In a Section 2 case,

Market power may be demonstrated through either of two types of proof. One type of proof is direct evidence of the injurious exercise of market power. If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.

Id. The Court of Appeals for the Eighth Circuit states:

Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, "proof of actual detrimental effects, such as a reduction of output," can obviate the need for an inquiry into market power, which is but a "surrogate for detrimental effects."

texts, that formally defining a relevant market and assessing whether the incumbent firm has a dominant share of that market are unnecessary in cases where direct proof of monopoly power and anticompetitive effects is available.⁷¹

This is because indirect monopoly power analysis is merely a surrogate for proving monopoly power and anticompetitive effects when direct evidence is not available or is ambiguous.⁷² If monopoly power may be shown directly, there is no need to define a relevant market as part of an indirect method of assessing the existence of something that can be demonstrated directly.⁷³ This is true regardless of whether the action has been brought under Section 1 or Section 2 of the Sherman Act.⁷⁴ Indeed, if direct proof exists then a direct assessment of monopoly power is not only the preferred methodology, but in such a

Flegel v. Christian Hospital Northeast-Northwest, 4 F.3d 682, 688 (8th Cir. 1993) (citations omitted); see also *Palmer v. BRG of Georgia, Inc.*, 874 F.2d 1417, 1437 (11th Cir. 1989) (in Section 1 case, "plaintiffs can show actual detrimental effects, such as a reduction of output or increased price, instead of an inquiry into market power"), *rev'd on other grounds*, 498 U.S. 46 (1990).

71. See *infra* note 73 and cases cited therein.

72. See 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 515.

73. See *FRC v. Ind. Fed'n of Dentists*, 406 U.S. at 460–61; *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) ("If a plaintiff can show that a defendant's conduct exerted an actual adverse effect on competition, this is a strong indicator of market power. In fact, this arguably is more direct evidence of market power than calculations of elusive market share figures." (citation omitted)); *Toys "R" Us*, 221 F.3d at 937 ("[T]he share a firm has in a properly defined relevant market is only a way of estimating market power, which is the ultimate consideration."); *Re/Max*, 173 F.3d at 1018 ("[A]n antitrust plaintiff is not required to rely on indirect evidence of a defendant's monopoly power . . . when there is direct evidence that the defendant has actually set prices or excluded competition."); *Microsoft Corp.*, 253 F.3d at 51 ("Where evidence indicates that a firm has in fact profitably [raised prices above the competitive level], the existence of monopoly power is clear."); *Am. Floral Servs., Inc. v. Florists' Transworld Delivery Ass'n*, 633 F. Supp. 201, 221–22 (N.D. Ill. 1986) ("After all, market share is at best a proxy for market power, and a rough one at that. What really counts is the ability of a producer to control output and obtain supracompetitive prices." (citing *Nat'l Coll. Athletic Ass'n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85 (1984))); 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 531a ("Finding the relevant market and its structure is not a goal in itself but a surrogate for market power."); *id.* ¶ 515 (resorting to "market-definition approach" is warranted when "no other observable facts establish the existence and degree of market power more directly").

74. For decisions under Section 1 of the Sherman Act approving of the use of direct proof of monopoly power in place of circumstantial evidence of dominant share of a relevant market, see, for example, *Indiana Federation of Dentists*, 476 U.S. at 460–61; *Todd*, 275 F.3d at 206; *Toys "R" Us*, 221 F.3d at 937; and *In re Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187 (Dec. 8, 2003). For decisions under Section 2 of the Sherman Act approving of the use of direct proof of monopoly power in place of circumstantial evidence of dominant share of a relevant market, see, for example, *Microsoft Corp.*, 253 F.3d at 51; *Re/Max*, 173 F.3d at 1016; *Tops Markets*, 142 F.3d at 97–98; *Coastal Fuels*, 79 F.3d at 196; and *Rebel Oil Co.*, 51 F.3d at 1434.

case the indirect method may amount to little more than an inappropriate and wasteful diversion.

The pertinent inquiry is whether a defendant's conduct has permitted (or would permit) it to profitably raise or maintain prices above competitive levels. If one can prove that directly—for instance, by showing with direct evidence that after the restraint of trade in question has lifted the price dropped substantially, what possible legitimate purpose would be served by *requiring* indirect proof of that same point? Indeed, direct evidence of market prices materially exceeding competitive levels for a substantial period of time is evidence that the restraint in question misallocates resources in an economic sense, has reduced consumer welfare, and thus yielded anticompetitive effects.⁷⁵ From a public policy perspective, the promotion of consumer welfare is a well-accepted goal of the federal antitrust laws—including both Sections 1 and 2.⁷⁶ As one commentator has written:

75. *Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001) (finding acts that harm allocative efficiency and raise the price of goods above the competitive level harm consumer welfare); *Rebel Oil Co.*, 51 F.3d at 1433 (stating conduct harms consumer welfare “when it harms both allocative efficiency *and* raises the prices of goods above competitive levels or diminishes their quality”); *Consol. Metal Prods., Inc. v. Am. Petroleum Inst.*, 846 F.2d 284, 293 (5th Cir. 1988) (“driv[ing] up prices . . . reduce[s] consumer welfare”); *Storer Cable Communications, Inc. v. City of Montgomery*, 826 F. Supp. 1338, 1352 (M.D. Ala. 1993) (“eliminat[ing] or significantly diminish[ing] an important source of competitive pressure on price” has “a substantial adverse effect on consumer welfare”); *Liggett Group, Inc. v. Brown & Williamson Tobacco Corp.*, 748 F. Supp. 344, 352 (M.D.N.C. 1990) (“Injury to competition occurs only if a competitor is able to raise and maintain prices in the relevant market above competitive levels because this is the only situation where consumer welfare is threatened.”). The Eleventh Circuit court states that [t]he purpose of the Sherman Act is . . . to protect the public from the failure of the market. The law directs itself . . . against conduct which unfairly tends to destroy competition itself. It does so not out of solicitude for private concerns but out of concern for the public interest.

Spanish Broad. Sys. of Fla., Inc. v. Clear Channel Communications, 376 F.3d 1065, 1069 (11th Cir. 2004) (citation omitted). *See also* *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 129, (2d Cir. 1995) (equating “competitive pressure on price” with “consumer welfare”).

76. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 221 (1993) (acknowledging “antitrust laws’ traditional concern for consumer welfare and price competition”); *Nat’l Coll. Athletic Ass’n*, 468 U.S. at 107 (“Congress designed the Sherman Act as a “consumer welfare prescription.” A restraint that has the effect of reducing the importance of consumer preference in setting price and output is not consistent with this fundamental goal of antitrust law.” (citation omitted)); *Major League Baseball v. Crist*, 331 F.3d 1177, 1186 (11th Cir. 2003) (“[T]he antitrust laws form the bedrock of our capitalist system premised upon competition, and . . . anticompetitive conduct harms consumer welfare.”); *Schachar v. Am. Acad. of Ophthalmology, Inc.*, 870 F.2d 397, 399 (7th Cir. 1989) (“Antitrust law is about consumers’ welfare and the efficient organization of production.”); *Westman Comm’n Co. v. Hobart Int’l, Inc.*, 796 F.2d 1216, 1220 (10th Cir. 1986) (“[T]he purpose of the antitrust laws is the promotion of consumer welfare.”);

Today, a consensus is emerging that . . . antitrust should be viewed as “a consumer welfare prescription.” Under this interpretation a practice constrains trade, monopolizes, is unfair, or tends to lessen competition if it harms consumers by reducing the value or welfare they would have obtained from the market-place absent the practice.⁷⁷

Thus, whether the claim is brought under Section 1 or Section 2 of the Sherman Act, determining whether a company has obtained or is maintaining monopoly power is not an end in itself. Rather, it is a *means* of determining whether the firm’s conduct—unilateral or concerted—is likely to, or has in fact, resulted in artificially inflated excessive prices (or reduced output). In other words, if the purpose of federal antitrust laws is to punish and deter conduct that is likely to, or does in fact, harm consumer welfare through supracompetitive pricing, then logically, direct proof that conduct is likely to, or does, harm consumer welfare through supracompetitive pricing is not only sufficient, but *superior* to indirect proof. At best, indirect proof could merely show inferentially what is already known directly.

Again, relevant market analysis provides merely an *indirect*, circumstantial way of demonstrating monopoly power and the ability of challenged conduct to have anticompetitive effects. Accordingly, courts increasingly, and correctly, recognize that where direct evidence of “actual supracompetitive prices and restricted output”—that is, actual anticompetitive effects—is available, there is no need to define a “relevant market.”⁷⁸

Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 218 (D.C. Cir. 1986) (“[T]he purpose of the antitrust laws [is] the promotion of consumer welfare.” (citation omitted)).

77. Krattenmaker et al., *supra* note 46, at 244.

78. *Coastal Fuels*, 79 F.3d at 196–97; *see also* PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 107–08 (2d Cir. 2002) (relevant market must be shown only “[i]n the absence of direct measurements of a defendant’s ability to control prices or exclude competition”). A Sixth Circuit case states:

[W]e find that although the plaintiffs failed to define the relevant market with precision and therefore failed to establish the defendants’ monopoly power through circumstantial evidence, there does exist a genuine issue of material fact as to whether the plaintiffs’ evidence shows direct evidence of a monopoly, that is, actual control over prices or actual exclusion of competitors.

Re/Max, 173 F.3d at 1016 (6th Cir. 1999). *Cf.* Conceptual Eng’g Ass’n, Inc. v. Elec. Bonding, Inc., 714 F. Supp. 1262, 1268 (D.R.I. 1989) (“The purpose of market definitions is not to frustrate antitrust plaintiffs by requiring the proof of bright lines which do not exist, but is to help identify monopoly power, that is, ‘the power to control prices or exclude competition.’” (citing *Home Placement Serv., Inc. v. Providence Journal Co.*, 682 F.2d 274, 280 (1st Cir. 1982))), *cert. denied*, 460 U.S. 1028 (1983).

In sum, where direct evidence of the exercise of monopoly power and anticompetitive effects is available, it is the *preferred* mode of analysis because, in such circumstances, using relevant market analysis can obscure rather than elucidate competitive concerns.⁷⁹ As one commentator recently observed:

[I]f a firm or firms successfully engage in either collusionary or exclusionary conduct, the law presumes that it has or they have market power. Their success would be otherwise inexplicable. In that case, evidence of low market share is viewed as irrelevant at best, and at worst as a demonstrably unreliable index of that power. The burden then shifts to the defendant to defeat the evidence of market power—and to do so it must challenge the direct evidence; it cannot simply rely on contrary, circumstantial evidence in the form of low market shares.⁸⁰

E. In Delayed Generic Entry Cases, Monopoly Power and Anticompetitive Effects Can Be Established Solely with the Direct Method

In delayed generic entry cases there is an abundance of direct evidence showing that the challenged conduct has clear and substantial anticompetitive effects. As a result, there is no need to require an analysis of monopoly power or anticompetitive effects by the indirect method. Indeed, defining a relevant market with circumstantial proof in this context is not only unnecessary, it is likely wasteful, diversionary, and confusing.

While, at best, the indirect method can confirm what is already known from examination of the direct evidence, at worst, it can confuse and obscure the competitive issues involved.⁸¹ It is useful here to

79. See, e.g., *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001); *Allen-Myland v. Int'l Bus. Machs. Corp.*, 33 F.3d 194, 209 (3d Cir. 1994) (“Market share [in a relevant market] is just a way of estimating market power, which is the ultimate consideration. When there are better ways to estimate market power the court should use them.” (citation omitted)); *Fineman v. Armstrong World Indus.*, 980 F.2d 171, 202 (3d Cir. 1992) (“‘proof of actual detrimental effects’ is proof, standing alone, of monopoly power (citation omitted)”; *Graphic Prods. Distribs., Inc. v. Itek Corp.*, 717 F.2d 1560, 1570–71 (11th Cir. 1983) (describing market share as but a “surrogate for market power”); 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 531a (“Finding the relevant market and its structure is not a goal in itself but a surrogate for market power.”).

80. Gavil, *supra* note 70, at 99. Gavil states, “It is hard to see why circumstantial evidence in the form of market share should ever be sufficient to rebut a showing of market power based on direct evidence or reduced output and higher prices.” *Id.* at 109.

81. Interestingly, while one industry defender argues that relevant market is “an essential element of *any* claim for monopolization or attempted monopolization under section 2 of the Sherman Act,” M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 653 (2003) (emphasis added), the authority he cites for the proposition does not support his sweeping generalization. For instance, he quotes from

analogize to a murder case, in which two types of proof are potentially available: (1) direct evidence, including a signed confession and a videotape of the crime; and (2) indirect evidence such as facts indicating that the defendant had the opportunity and motive to kill the victim. In the typical delayed generic entry case, the plaintiff has the equivalent of the signed confession and videotape of the crime—namely the undisputed direct evidence that generic entry brings down prices and delaying that entry results in the maintenance of prices above the post-entry levels. That is to say, there is no material dispute in any of these cases about whether, by gaming the system to delay generic entry, purchasers are forced to pay more for drugs. Only through possession of monopoly power would it be possible for the branded company to charge prices, typically *two to ten times* more than those that were available following the entry of generic competition. Thus, direct evidence of anticompetitive effects *is* evidence of maintenance of monopoly power, and vice versa.

Why, then, would it be necessary to go through the circumstantial method of proving that a firm had market power sufficient to cause certain anticompetitive effects when those very effects are not in dispute? Returning to the murder case analogy, requiring indirect analysis of market power in delayed generic entry cases is akin to mandating circumstantial evidence of a time-line showing that the defendant had the opportunity to kill the victim in a case where the signed confession and videotape evidence are not in material dispute. Where the uncontested direct evidence shows that the defendant stabbed the victim to death, no material fact turns on the resolution of a hypothetical debate about whether the defendant had a plausible motive or alibi.

It is for this reason that the proper response to an indirect market power analysis purporting to show that a firm (or firms) did not maintain monopoly power by delaying generic entry, and thus could not have maintained higher prices through the challenged conduct,

Walker Process Equipment, Inc. v. Food Machine & Chemical Corp., 382 U.S. 172, 177 (1965), in which the Supreme Court stated that “[w]ithout a definition of [the] market there is no way to measure [a defendant’s] ability to lessen or destroy competition.” Note that the language quoted implicitly assumes that the parties do not already know whether the defendant had indeed “lessen[ed] or destroy[ed] competition.” Of course, the context in delayed generic entry cases is that *we already know through direct evidence* that by delaying generic entry, competition was diminished (destroyed), and prices were inflated. Accordingly, since the point of the exercise is to determine whether the defendant “had the ability to lessen or destroy competition,” and it is known that through direct evidence that such was the case, the relevant market exercise is superfluous in these cases.

would be to question the methods by which the circumstantial analysis was done (or the data that was used). It would *not* be an occasion to ignore what all parties *know* before the indirect analysis begins, namely, that generic entry brings down prices and, as a result, increases consumer welfare. Moreover, dismissing a delayed generic entry case for failure to define a relevant market using circumstantial evidence would be just as illogical as requiring the dismissal of the hypothetical stabbing case, despite the videotape and uncontested signed confession, because circumstantial evidence showing that the defendant had a motive to kill the victim was not produced or was unclear.

The simple fact is that the competitive effects of generic entry, and therefore, of delaying generic entry, is not typically in material dispute in these cases. Generic entry almost always yields substantially lower prices for the vast majority of purchasers of the drug molecule at issue.⁸² The matter of fact conclusion of the court in *Valley Drug Co. v. Geneva Pharmacies, Inc.*⁸³—a delayed generic entry case—bears repeating here: “the anticompetitive effects [of delaying generic entry] cannot be seriously debated.”⁸⁴ Given that the anticompetitive effects flow, by definition, from the exercise of market power, this means that the maintenance of market power also, in the words of the Eleventh Circuit, “cannot be seriously debated.”⁸⁵

There are numerous academic and government studies of the effects of generic entry and thus of the competitive effects that flow from its delay.⁸⁶ This literature reveals a consistent pattern. Initial ge-

82. See *infra* notes 167–69 and accompanying text.

83. 344 F.3d 1294 (11th Cir. 2003).

84. *Id.* at 1311 n.27. The District Court of Massachusetts states:

A generic drug typically enters the market at a price substantially below that of a branded drug. For this reason, the generic drug quickly captures a large market share. As other generic versions enter the market, prices of the generic drugs drop further, leading to a corresponding increase in their market share. To compensate, the manufacturer of the branded drug frequently increases its level of discounts and other price adjustments.

In re Relafen Antitrust Litig., 218 F.R.D. 337, 344 (D. Mass. 2003).

85. *Valley Drug Co.*, 344 F.3d at 1311 n.27.

86. See, e.g., Duane M. Kirking, et al., *Economics and Structure of the Generic Pharmaceutical Industry*, 41 J. AM. PHARMACY ASS'N 578–84 (2001); CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 23 (1998), available at <ftp://ftp.cbo.gov/6xx/doc655/pharm.pdf> (last accessed Oct. 25, 2004); OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS (1993), available at <http://www.wws.princeton.edu/cgi-bin/byteserv.prl/~ota.disk/1993/9336/9336.pdf> (last accessed Aug. 28, 2004); U.S. FOOD & DRUG ADMIN., THE PEDIATRIC EXCLUSIVITY PROVISION: JANUARY 2001 STATUS REPORT TO CONGRESS (2001), available at <http://www.fda.gov/cder/pediatric/re>

neric entry occurs at prices substantially below the pre-entry price of the brand.⁸⁷ Brand customers quickly respond by shifting purchases to the generic product; indeed, seventy percent of the market typically shifts from the brand to the generic within the first several weeks.⁸⁸

Subsequently, once the generic exclusivity often granted to the first generic entrant lapses,⁸⁹ additional generic firms enter the market and the process accelerates.⁹⁰ The generic sellers compete with each other on price, rapidly driving prices down toward short-run production and selling costs.⁹¹ Nearly all of the sales formerly enjoyed by the brand shift to generic sellers.⁹² Once this process is completed, prices paid for the drug molecule—brand plus generic sales combined—are substantially less, often more than eighty-percent less,

portcong01.pdf (last accessed Sept. 20, 2004); Jay P. Bae, *Drug Patent Expirations and the Speed of Generic Entry*, 32 HEALTH SERVICES RES. 87–101 (1997); Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 MICROECONOMICS (Brookings Papers on Economic Activity) 1–66 (1991); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing for Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75–90 (1997) [hereinafter Frank & Salkever, *Generic Entry*]; Richard G. Frank & David S. Salkever, *Pricing, Patent Loss and the Market for Pharmaceuticals*, 59 S. ECON. J. 165–79 (1992) [hereinafter Frank & Salkever, *Pricing*]; Henry Grabowski & John Vernon, *Longer Patent for Increased Generic Competition in the U.S. The Waxman-Hatch Act After One Decade*, 10 PHARMACOECONOMICS, 110, 110–23 (Supp. No. 2, 1996) [hereinafter Grabowski & Vernon, *Longer Patent*]; Henry Grabowski & John Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331–50 (1992) [hereinafter Grabowski & Vernon, *Brand Loyalty*]; Richard P. Rozek & Ruth Berkowitz, *The Costs to the U.S. Health Care System of Extending Marketing Exclusivity to Taxol*, 9 J. RES. PHARMACY. ECON. 21–41 (1999); Dong-Churl Suh et al., *Effect of Multiple-Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry*, 35 HEALTH SERV. RES., 529, 529–47 (2000); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. (forthcoming 2005) (manuscript at 35), available at <http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf> (last accessed Sept. 20, 2004); DONG-CHURL SUH, EFFECT OF MULTIPLE SOURCE ENTRY ON PRICE COMPETITION AFTER PATENT EXPIRATION IN THE PHARMACEUTICAL INDUSTRY (1993) (doctoral dissertation, University of Minnesota) (on file with authors).

87. See Grabowski & Vernon, *Brand Loyalty*, *supra* note 86, at 335 (noting the “general pattern is that generic products enter at a significant discount to the pioneering product”); Caves et al., *supra* note 86 at 35–36; Frank & Salkever, *Generic Entry*, *supra* note 86, at 83–84; Reiffen & Ward, *supra* note 86, at 1, 22–24.

88. DOUG LONG, 2003 YEAR IN REVIEW: TRENDS, ISSUES, FORECASTS 34 (IMS 2004) (on file with authors).

89. The Hatch-Waxman Act grants 180 days of marketing exclusivity to the first applicant to file a substantially-complete ANDA that successfully challenges an invalid, improperly listed, or noninfringed patent. See *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003).

90. See Caves et al., *supra* note 86, at 35–36.

91. See Reiffen & Ward, *supra* note 86, at 1, 35–36.

92. Generic penetration now typically exceeds seventy-five percent (reaching as much as ninety percent) after just two months. LONG, *supra* note 88, at 34.

than the price the brand had enjoyed prior to generic entry.⁹³ In short, generic entry allows purchasers to buy the same product at a substantially reduced cost, greatly enhancing consumer welfare with reference to widely-used pharmaceuticals.⁹⁴

Generic entry, then, is a textbook case of procompetitive price competition.⁹⁵ Recently, in the first full consideration on the merits of these questions in a delayed generic entry case, *In the Matter of Schering-Plough Corp.*,⁹⁶ the FTC Commission came to the same conclusion based on the evidence that had been presented during trial. Analyzed under Section 1 of the Sherman Act, *Schering* concerned agreements between Schering-Plough, the manufacturer of the brand-name drug K-Dur 20, and two generic manufacturers, Upsher-Smith and American Home Products, in which Schering settled Hatch-Waxman patent litigation with the generic manufacturers by agreeing to pay them not to enter the market with generic versions of Schering's brand-name drug.⁹⁷ Noting that the generic entered the market at *half* the price of the brand,⁹⁸ the FTC explicitly recognized the "uniquely significant" impact of generic entry:

[T]here is credible evidence in the record . . . which indicates that generic entry was a uniquely significant market event, and recognized as such by both parties. Their predictions about the likely effects of generic entry, which were consistent with historic experience of other branded drugs, are just as compelling as predictions

93. See Caves et al., *supra* note 86, at 36; CONG. BUDGET OFFICE, *supra* note 86, at 32. It appears that some brand-name manufacturers respond to generic entry by offering increased discounts to certain significant customers that are perceived by manufacturers as having the ability to influence prescribing behavior, but for the most part, decline to compete on price with generics. See, e.g., CONG. BUDGET OFFICE, *supra* note 86, at 29–31; *In re Relafen Antitrust Litig.*, 218 F.R.D. 337, 344 (D. Mass. 2003). Given that most customers substitute less-expensive generics for the brand in either case, it really does not matter whether brand manufacturers respond by lowering their prices to generic levels or cede the vast majority of the market. Either way, the same drug is being sold at much lower prices to most purchasers after generic entry.

94. See Reiffen & Ward, *supra* note 86, at 23, 35–36 (stating that the premium of price over cost margins eventually "shrinks and disappears" as multiple generic competitors enter the market).

95. See, e.g., CONG. BUDGET OFFICE, *supra* note 86, at ix (generic drugs "have played an important role in holding down national spending on prescription drugs from what it would otherwise have been" and estimating savings between eight and ten billion dollars in 1994 alone); FED. TRADE COMM'N, *supra* note 4, at 9 ("competition from generic drugs can deliver large savings to consumers").

96. Docket No. 9297, 2003 FTC LEXIS 187 (Dec. 8, 2003) (final order), *appeal filed*, No. 04-10688 (11th Cir. Feb. 13, 2004).

97. *Id.* at *15–*19.

98. *Id.* at *53.

based upon market shares. Moreover, these predictions turned out to be true.⁹⁹

In a lengthy and cogent opinion (now on appeal to the Eleventh Circuit), based upon the same essential facts regarding generic competition present in all of the delayed generic entry cases, the Commission reversed the decision of an administrative law judge who had required proof of a relevant market and defined the market in terms of therapeutic category.¹⁰⁰ The Commission concluded that "it is not necessary to rely on indirect proof that Schering has a monopoly share in a relevant market when the competitive effects of the 'restraint' can be shown directly."¹⁰¹ As the FTC continued:

We conclude that the Initial Decision's approach—which defines a relevant market, calculates shares, and then draws inferences from these shares and from other industry characteristics—is not the most appropriate way to proceed in cases like this one where more direct evidence of competitive effects is available.¹⁰²

In reversing what the FTC described as the Administrative Law Judge's "error" in requiring indirect proof of market power and anticompetitive effects, the FTC reminded antitrust practitioners that

some in the antitrust community have become so accustomed to the traditional way of proceeding that they forget that this complex market analysis provides only an *indirect* indication that trade has been or may be restrained. It is not necessary to weigh all of these [relevant market related] factors if a case presents more *direct* evidence of actual or likely competitive effects.¹⁰³

The FTC's *Schering* decision builds upon the FTC's victory nearly two decades earlier in the Supreme Court in another case, *Federal Trade Commission v. Indiana Federation of Dentists*.¹⁰⁴ In *Indiana Federation of Dentists*, the Supreme Court held that "the finding of actual, sustained adverse effects on competition . . . is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis."¹⁰⁵

In *Schering*, the FTC adopted a direct assessment of anticompetitive effects over the indirect relevant market approach under Section 1 of the Sherman Act. In our view, where direct evidence that the restraint of trade in question substantially inflated prices is available,

99. *Id.* at *46 (holding that agreements between pharmaceutical manufacturers not to compete can constitute violations of the Sherman Act).

100. *Id.*

101. *Id.* at *39 (citing *FTC v. Ind. Fed'n of Dentists* 476 US 447, 460 (1986)).

102. *Id.* at *23.

103. *Id.* at *41 n.32 (emphasis added).

104. 476 U.S. 447 (1986).

105. *Id.* at 461.

there should be no analytical distinction between using actual anticompetitive effects for assessing an unreasonable restraint of trade under Section 1 of the Sherman Act and assessing monopoly power under Section 2. To the extent that courts and commentators have, however, distinguished between assessing market power under these two Sherman Act sections, it has been to note that a Section 2 analysis might require showing a higher degree of market power.¹⁰⁶ In delayed generic entry cases, however, it is both unambiguous and clear that delaying generic entry permits maintenance of prices *at least* double the competitive level. That amount of artificial price inflation is substantial by any measure.¹⁰⁷

Moreover, given that, as explained above, both sections of the Sherman Act discussed here are, at root, concerned with enhancing consumer welfare—i.e., preventing anticompetitive effects in the form of supracompetitive prices or reduced output—the presence of direct evidence that delaying generic entry harms consumer welfare through the exercise of monopoly power obviates the need to pursue the indirect approach. Requiring a relevant market analysis using circumstantial evidence would simply increase the likelihood of misinterpreting the results and of getting the wrong answer.

F. In Delayed Generic Entry Cases, the Direct Evidence Necessarily Implies a Relevant Market Limited to the Molecule

As discussed above, given the availability of direct evidence of the anticompetitive effects of delaying generic entry, there is no need to define a relevant market in any of these cases. It is nevertheless note-

106. Many courts use the terms “market power” and “monopoly power” interchangeably. *See, e.g., Advo, Inc. v. Phila. Newspapers, Inc.*, 854 F. Supp. 367, 374 n.22 (E.D. Pa. 1994) (“‘Market power’ is a synonym for ‘monopoly power.’” (citation omitted)), *aff’d*, 51 F.3d 1191 (3d Cir. 1995). Economists also use the two terms interchangeably. *See e.g., DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION* 92 (3d ed. 2000) [hereinafter CARLTON & PERLOFF, THIRD EDITION] (“The terms monopoly power and market power typically are used interchangeably to mean the ability to profitably set price above competitive levels.”). Other courts use “monopoly power” to mean “substantial market power.” *See, e.g., Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, 899 F.2d 951, 966 (10th Cir. 1990); *Carpet Group Int’l v. Oriental Rug Imps. Ass’n, Inc.*, 256 F. Supp. 2d 249, 286–87 & n.32 (D.N.J. 2003). “Substantial market power” exists where a firm can maintain price substantially above the competitive level without a significant loss of sales due to consumer resistance. *See The Package Shop, Inc. v. Anheuser-Busch, Inc.*, 675 F. Supp. 894, 939–40 (D.N.J. 1987).

107. Such pricing far in excess of competitive levels, for instance, greatly exceeds the five percent materiality benchmark set by the FTC. FED. TRADE COMM’N & U.S. DEP’T OF JUSTICE, *supra* note 3, § 1.11.

worthy that the same direct proof of market power—evidence that by delaying generic entry a firm can profitably command prices substantially above competitive levels—also constitutes proof that the relevant market must be limited exclusively to the molecule, namely, the brand and its generic equivalents.

To return to the murder case analogy, in a case where one has an uncontested signed confession and videotape of the crime, logic dictates that the outcome of any raging debates about the probity of the circumstantial proof taken as a whole, such as, whether the fingerprint evidence from the crime scene matches those of the defendant, must ultimately confirm what the uncontested direct proof shows. That is to say, if analyzed correctly, the circumstantial evidence regarding whether the defendant killed the victim should logically confirm what the undisputed videotape evidence shows. Moreover, any argument by the defendant that the circumstantial proof is exculpatory, despite the videotape and confession, could hardly be taken seriously. Yet, the industry defenders' position in delayed generic entry cases is not materially different from that of the hapless murder defendant in this analogy.

For cases involving delayed generic entry, an appropriately defined relevant market must be the narrowest universe of products, starting with the molecule itself, which a hypothetical monopolist would need to control in order to profitably raise the price above competitive levels.¹⁰⁸ Courts have consistently adopted this "above competitive level" approach.¹⁰⁹ Viewed this way, the direct and indi-

108. *Cf. id.* § 1.0.

A market is defined as a product or group of products and a geographic area in which it is produced or sold such that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future producer or seller of those products in that area likely would impose at least a "small but significant and nontransitory" increase in price.

Id. The relevant market is "no bigger than necessary to satisfy this test" and may encompass only a single product. *Id.* § 1.11.

109. *See, e.g., Rebel Oil v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir.1995) ("A 'market' is any grouping of sales whose sellers, if unified by a monopolist or hypothetical cartel, would have market power" (citation omitted)); *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 197 (1st Cir. 1996) ("The definition of relevant market depends upon economic restraints which prevent sellers from raising prices above competitive levels." (citation omitted)); *see also SMS Sys. Maint. Servs., Inc. v. Digital Equip. Corp.*, 188 F.3d 11, 16 (1st Cir. 1999) ("The purpose of defining a relevant market is to assist in determining whether a firm has market power. . . . [T]he monopolist's market power consists of having sufficient economic muscle to permit it to raise prices well in excess of competitive levels without inducing customers to turn elsewhere."); *Picker Int'l Inc. v. Leavitt*, 865 F. Supp. 951, 959 (D. Mass. 1994) ("[T]he ultimate question concerning

rect methods of establishing market power should effectively be indistinguishable when direct evidence is available. *By definition*, the very same facts that establish directly that a firm has market power must mean that the relevant market *is* the molecule. Put another way, the smallest set of products that the brand firm must control in order to set prices at a supracompetitive level is the drug molecule in both its branded and generic forms. Controlling a smaller market, e.g., the brand alone, is not enough. Controlling a larger market, namely, other therapeutic substitutes, is not necessary.

Inasmuch as control over the molecule gives rise to substantial market power and thereby permits profitable above-competitive level pricing, it is the market that is relevant to analyzing competitive effects in delayed generic entry cases. Given that the molecule is the *narrowest* set of products, control over which confers substantial market power (i.e., a branded company would not need to control any drug products other than the molecule in order to price the brand at supracompetitive levels), it must be *the* relevant market pertinent to these cases.¹¹⁰

It is useful to note in this context that a relevant product market is always defined in relation to the claims that give rise to the inquiry in the first place. As the court noted in *U.S. Healthcare, Inc. v. Healthsource, Inc.*,¹¹¹ in defining markets and deciding between direct and

market definition is whether a hypothetical cartel could raise prices significantly above the competitive level.”).

110. Critiquing the FTC for disagreeing with him, one apparent industry defender argues that the law has an “aversion to single firm [relevant] markets.” Morse, *supra* note 81, at 666. The reason Mr. Morse gives for his view appears to be little more than that courts have, at times, rejected markets defined to include a single brand. Yet, first, the relevant market implied by the facts in delayed generic entry cases is *the molecule*, i.e., the brand plus generic equivalents, *not* one brand by itself. To the extent that there is only one firm making and selling the molecule during the period in which generic entry is alleged to have been improperly delayed, that is because the branded firm has taken steps, which are the focus of the antitrust challenge, to exclude generic competition. But, the relevant market is composed of all the actual and potential generic competitors for that drug molecule. Second, as Mr. Morse himself acknowledges, the Supreme Court has taken a different view. See *Eastman Kodak v. Image Technical Servs., Inc.*, 504 U.S. 451, 482 (1992) (“[I]n some instances one brand of a product can constitute a separate product market.”); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000) (“[A] single brand product can constitute a relevant market for antitrust purposes.”). Mr. Morse tries to distinguish *Eastman Kodak* on the ground that “switching costs limited cross-elasticity” between products in a broader market. Morse, *supra* note 81, at 666. Mr. Morse’s argument, thus, reduces to little more than this: when a single brand meets the pertinent criteria, it can be a relevant market, and when it does not, it cannot. To the extent that *that* is his argument, there can be no disagreement.

111. 986 F.2d 589 (1st Cir. 1993).

indirect proof, practitioners must keep in mind “*why* we are [asking the question in the first place]: that is, what is the antitrust question in this case that market definition aims to answer?”¹¹² In other words, without the existence of a competitive issue, there is no sensible way to define a relevant market. Hence, the starting point for an appropriate relevant market analysis must be the claims in question.

It is this principle that explains the fallacy in the charge that “[t]he broad range of product market definitions alleged in the various cases warrants a closer examination to ensure that the government and private plaintiffs are not gerrymandering market definitions to fit desired outcomes.”¹¹³ Market definition is no more than a tool that is sometimes useful in assessing whether challenged conduct had or could possibly have (in cases seeking prospective relief, for instance) anticompetitive effects. It makes perfect sense that such an analytical tool would vary depending upon the conduct being assessed. For instance, if the allegations in a particular case relate to, say, a merger of two branded manufacturers, the market relevant to analyzing that claim might legitimately be different than the market relevant to assessing competitive issues in a delayed generic entry case. There is nothing conceptually wrong with that result. There is no *a priori* “relevant market” that relates to all possible claims and circumstances in a particular industry.

Control over all drugs in a therapeutic class might allow branded companies to charge even *higher* prices than those that prevail pre-generic entry. This could mean that a case involving a proposed merger between branded manufacturers of two or more brand-name drugs in a therapeutic class could imply a relevant market consisting of various branded manufacturers. But, the mere fact that eliminating competition between brands might pose competitive issues does *not* negate the substantial market power that manufacturers possess over the molecule prior to generic entry. It also does not and cannot negate the anticompetitive effects of delaying generic entry, nor the fact that this direct evidence implies a relevant market that includes only the brand and its generic equivalents.

In the final analysis, it is simply diversionary to attempt to define broad relevant markets in cases where it is known that merely by excluding generics a firm can maintain prices well above levels the firm could charge if market exclusivity, for whatever reason, came to an

112. *Id.* at 598.

113. Morse, *supra* note 81, at 634.

end. In these cases, there is powerful, indeed overwhelming, *direct* evidence that generic entry is a competitively significant event—because *it is known* that when generics enter, prices drop substantially. Therefore, arguing about whether “competing” brands discipline prices somewhat in a therapeutic class pre-generic entry is simply a distraction from the real competitive issues in delayed generic entry cases. No discussion of the disciplining effect of “competing” brands can possibly explain away the undeniable fact that generic entry leads to a price level far below that which previously prevailed. Industry defenders *must* instead explain in a straightforward way why it is that generic entry, and the competitive benefits it brings, should not be considered pro-competitive—and thus how it is that the effects of delaying entry are not clearly anticompetitive under the antitrust law—given the well-recognized substantial price benefits generics afford pharmaceutical purchasers.

Delaying these benefits, and thereby forcing purchasers to overpay, constitutes nothing less than the very kind of injury the antitrust laws were intended to prevent. As the appellate court in one delayed generic entry case explained with respect to this very question: “Preventing that kind of injury [i.e., forcing purchasers to buy a higher priced brand in place of a cheaper generic] was undoubtedly a *raison d’être* of the Sherman Act when it was enacted in 1890.”¹¹⁴ That is to say, merely by delaying generic competition a branded firm causes antitrust injury. If true, as it clearly is, this must mean that the challenged conduct yields anticompetitive effects in a relevant market limited to the molecule.

II. Circumstantial Economic Evidence in Delayed Generic Entry Cases Confirms that the Relevant Market is the Molecule

Those who advocate broadly defined relevant markets in delayed generic entry cases, i.e., markets that would include more than merely the brand and its generic equivalents, typically suggest that all of the pharmaceuticals that are indicated for treatment of the same medical condition—all drugs in the therapeutic class—must be included in the relevant market.¹¹⁵ Industry defenders point to the small share of

114. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 910 (6th Cir. 2003).

115. Morse, *supra* note 81, at 639–40, 662–63. Cf. Gregory J. Glover, Competition in the Pharmaceutical Marketplace, Address Before the Federal Trade Commission and the Department of Justice—Antitrust Division, in FED. TRADE COMM’N & U.S. DEP’T OF JUSTICE—ANTITRUST DIV., HEARINGS ON COMPETITION AND INTELLECTUAL PROPERTY LAW AND POLICY

that broadly defined “market” claimed by the defendant firm’s brand-name product, and presto, “no monopoly power and no anticompetitive effects.”

This Section puts aside the fundamental illogic of reaching such a conclusion in cases where the competitive importance of generic entry is not seriously disputed. Here, the Article shows that even working within the confines of typically available circumstantial evidence relating to market definition, the “therapeutic class as relevant market” position in delayed generic entry cases is unsustainable. The Article explains that proper application of the indirect evidence in delayed generic entry cases is fully consistent with, and indeed confirms, the direct evidence. This is so largely because of certain idiosyncratic and unique institutional features of the pharmaceutical industry, which taken as a whole, begin to explain what at first glance may seem counterintuitive: that the presence of multiple prescription pharmaceuticals in a therapeutic class does not typically diminish the substantial market power branded manufacturers have to price their products well above competitive levels before generic entry.

Accordingly, Section (A) describes certain institutional features of the pharmaceutical industry, (B) demonstrates how these aspects of the business create the competitive conditions in which generics end up playing such a significant economic role, and (C) shows how under the traditional indirect method of market definition, these institutional features, and the competitive conditions they create, confirm what is already known, namely, that different drugs within a therapeutic category are unlikely to be “reasonably interchangeable” as the law defines that term, and thus the relevant market in delayed generic entry cases is limited to the molecule.

A. Institutional Features of the Pharmaceutical Industry Diminish Price Competition Between Drugs in the Same Therapeutic Class and Enhance the Significance of Generic Competition

The complexity and uniqueness of the United States prescription pharmaceutical business—and the role of generic competition within it—flows in large part from the manner in which the industry is regulated. The Drug Enforcement Administration (“DEA”), the FDA, the Patent and Trademark Office (“PTO”), and state generic-substitution

laws¹¹⁶ all play a role in shaping salient institutional features of the industry. The interplay of these regulatory bodies, and the legal framework within which they operate, helps explain *why* generic competition has such important price reducing effects despite the proliferation of multiple drugs treating the same condition or disease.

1. The Role of Physicians

One of the key features of the prescription drug industry pertinent to this discussion is familiar to anyone who has visited a physician or taken a prescription drug in this country—consumers do not make independent decisions about the prescription drugs they consume. Instead, consumers must obtain prescriptions from licensed practitioners.¹¹⁷ As one study explains, “Prescription drug purchases are economically unique because they are a ‘directed’ demand. Physicians direct the purchase through drug selection and determination of appropriateness, with minimal input from the consumer.”¹¹⁸ Insurers and managed care organizations also play important roles in the purchase of prescription drugs.¹¹⁹ While these so-called third-party payors may have had some effect in recent years in increasing price

116. Examples of generic substitution laws: COLO. REV. STAT. ANN. §12-22-124 (West 2001) (pharmacist permitted to substitute generic for brand); CONN. GEN. STAT. ANN. § 20-619(b) (West 2000 & Supp. 2003) (same); FLA. STAT. ANN. § 465.025 (West 2001) (pharmacist required to substitute generic for brand); GA. CODE ANN. § 26-4-81 (2004) (pharmacist permitted to substitute generic for brand); GUAM CODE ANN. § 5271 (2004) (same); HAW. REV. STAT. ANN. § 328-92 (Michie Supp. 1997) (pharmacist required to substitute generic for brand).

117. See 21 U.S.C. § 829 (2004); 21 C.F.R. § 1306.03 (2004); see, e.g., ARK. CODE ANN. § 5-64-308 (Michie 2004).

118. Michael E. Ernst et al., *Prescription Medication Costs: A Study of Physician Familiarity*, 9 ARCH. FAM. MED. 1002, 1004 (2000); see also OFFICE OF ATTORNEY GEN. MIKE HATCH, HEALTH CARE: MAKING THE MOST OF A BAD BARGAIN 15 (working draft) (explaining “economic tension” inherent because physician selects treatment without regard to cost), <http://www.ag.state.mn.us/consumer/PDF/PR/HealthCareMakingReportText.pdf> (last accessed Dec. 3, 2004); Füsün F. Gönül et al., *Promotion of Prescription Drugs and Its Impact on Physicians’ Choice Behavior*, 65 J. MARKETING 79, 89 (2001). Drugs are typically dispensed by licensed pharmacists, rather than directly by physicians. See 21 C.F.R. § 1306.06 (2002). For ethical and logistical reasons, few physicians currently dispense drugs. Statutes in each state regulate and limit the dispensing of drugs by physicians. See, e.g., ARIZ. REV. STAT. ANN. § 32-1871 (West 2002) (physician dispensing of drugs permitted under limited conditions); CAL. BUS. & PROF. CODE § 4056 (West 2003) (physician dispensing of drugs permitted under limited conditions); CAL. HEALTH & SAFETY CODE § 11158 (West 1991) (same); MONT. CODE ANN. § 37-2-104 (2003) (physician dispensing of drugs severely limited).

119. See Rika Onishi Mortimer, *Demand for Prescription Drugs: The Effects of Managed Care Pharmacy Benefits 2-3* (Nov. 1997) (unpublished manuscript, on file with Washington University of St. Louis Department of Economics), available at <http://econ.wpa.wustl.edu/eps/hew/papers/9802/9802002.pdf> (last accessed Dec. 3, 2004).

competition between brand-name drugs,¹²⁰ there nevertheless is a fundamental disconnect between the purchasers, on the one hand, and the physicians who are making the buying decisions, on the other. This disconnect diminishes (though by no means eliminates) the role that price plays in the competition between different brand-name drugs.¹²¹

Brand-name pharmaceuticals are grouped into therapeutic categories known as therapeutic classes, based on the medical indications for which drugs are approved.¹²² Yet, there is typically significant differentiation in chemical composition, mechanism of action, side-effects, effectiveness, and other attributes between the different drug molecules in the same therapeutic class.¹²³ Individual drugs within therapeutic categories and sub-categories are also often differentiated based on their suitability for treating particular patient populations and sub-populations.¹²⁴ Additionally, physicians and their patients may be uncertain about treatment side-effects and the efficacy of particular drug molecules within a class or subclass. Moreover, there is often substantial variability and considerable uncertainty in how individual patients will respond to particular drugs.¹²⁵

Insofar as physicians choose among a group of brand-name products, each approved for the same or similar indications, pharmaceutical company promotional efforts assume a competitive character of a sort. Each branded company works to persuade physicians to prescribe its product instead of other products within a particular therapeutic category, often by portraying its product as different and better than other drugs, if not for all patients then at least for niche groups

120. *Id.* at 1–2.

121. See ROY LEVY, FED. TRADE COMM'N, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE 187* (1999) (Bureau of Econ. Staff Report), <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf> (last accessed Aug. 28, 2004); Fiona M. Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the U.S. Pharmaceutical Industry*, 18 INT'L J. INDUS. ORG. 1085, 1088 (2000).

122. See CONG. BUDGET OFFICE, *supra* note 86.

123. David A. Kessler et al., *Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace*, 331 NEW ENG. J. MED. 1350, 1350–53 (1994).

124. ALBERT WERTHEIMER, RICHARD LEVY & THOMAS O'CONNOR, *TOO MANY DRUGS? THE CLINICAL AND ECONOMIC VALUE OF INCREMENTAL INNOVATIONS*, in 14 RESEARCH IN HUMAN CAPITAL AND DEVELOPMENT: INVESTING IN HEALTH; THE SOCIAL AND ECONOMIC BENEFITS OF HEALTH CARE INNOVATION 78, 86–98 (2001).

125. *Id.* at 78; see also Deborah Gesensway, *Drug Switching: Lowering Costs vs. Adverse Interactions, Potential Errors*, ACP-ASIM OBSERVER, Jul.–Aug. 2000, <http://www.acponline.org/journals/news/jul-aug00/drugswitching.htm>. (last accessed Dec. 3, 2004).

of patients.¹²⁶ Choices among products within a given therapeutic class result from a complicated interaction involving physicians, patients, and in some circumstances, health care management companies.¹²⁷ Branded product sellers rely upon large sales and marketing forces to influence physicians, health care managers, and patients in an effort to differentiate their products and promote preference for their use.¹²⁸ Product differentiation created through these and other tactics effectively reduces the degree of therapeutic substitutability that physicians associate with products in the same therapeutic class. In essence, branded companies are seeking to increase their share of total prescriptions in a particular therapeutic class.

Product heterogeneity and variation in individual patient response to medication are factors that create conditions in which product differentiation and promotion—in the form of sales calls to physicians (“detailing”), journal advertising, direct to consumer advertising, and drug sampling—often become the primary driver of demand for brand-name products. These marketing activities tend to increase perceptions of product difference among prescribers and consumers, often resulting in reduced sensitivity to prices and price changes among purchasers. Consequently, demand tends to be relatively price inelastic—more so than that which typically prevails in other industries with differentiated products.¹²⁹ The typical low price sensitivity and inelastic demand reflect what can be minimal price competition between different drug molecules within a therapeutic class, and begin to explain the crucial competitive role that generics play in this industry.

2. The Role of Hatch-Waxman and FDA Regulations

All prescription pharmaceuticals must be approved by the FDA as safe and effective treatments for specified therapeutic indications.¹³⁰

126. John A. Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs*, 42 J.L. & ECON. 95, 104–05, 107 (1999).

127. See, e.g., Caves et al., *supra* note 86, at 4–6; Mortimer, *supra* note 119.

128. Morton, *supra* note 121, at 1085–88; CONG. BUDGET OFFICE, *supra* note 86, at 21; Joel Lexchin & Barbara Mintzes, *Direct-to-Consumer Advertising of Prescription Drugs: The Evidence Says No*, 21 J. PUB. POL'Y & MARKETING 194, 195 (2002); Rizzo, *supra* note 126, at 89–90, 107, 112–13.

129. See, e.g., Rizzo, *supra* note 126, at 89–90, 107, 112–13; see also NAT. INST. FOR HEALTH CARE MGMT., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 3 (2002) (“This pattern suggests that when there are several new NMEs [(New Molecular Entities)] in a therapeutic class, price competition among them is limited . . .”), available at <http://www.nihcm.org/innovations.pdf> (last accessed Dec. 3, 2004).

130. 21 U.S.C. § 355 (2000).

There are two routes to FDA approval for a new drug product: (1) a New Drug Application ("NDA") and (2) an Abbreviated New Drug Application ("ANDA").¹³¹ In general, the former refers to the process followed for approval of brand-name drugs, while the latter describes the process used by generics.¹³² NDA applicants must demonstrate the safety and effectiveness of their products through extensive clinical trials.¹³³ However, ANDA applicants (generics) need demonstrate only that their products are therapeutically equivalent to the Reference Listed Drugs ("RLD") already approved under NDAs (brands).¹³⁴ ANDA applicants can rely on the clinical trials that have already demonstrated the safety and effectiveness of that RLD.¹³⁵

The FDA classifies products as therapeutically equivalent if they are pharmaceutically equivalent, in that they contain the same amount of the identical active ingredient in precisely the same dosage form, and bioequivalent, in that they are absorbed at the same rate and to the same extent.¹³⁶ Again, products approved under NDAs are marketed as brands, while those approved under ANDAs are generally marketed as generic equivalents. Only a generic that the FDA deems therapeutically equivalent may be substituted for its corresponding brand-name version by a pharmacist.¹³⁷

The FDA's therapeutic equivalence rating that comes with generic approval assures physicians, pharmacists, and patients that the product will have the same therapeutic efficacy and safety profile as the brand.¹³⁸ A generic drug, therefore, is a compound that meets

131. Compare *id.* § 355(b) (NDA), with *id.* § 355(j) (ANDA).

132. See generally *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1325–26 (Fed. Cir. 2003) (describing difference in regulatory approval routes between branded and generic drugs); *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (11th Cir. 2002) (same); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 192–93 (E.D.N.Y. 2003) (same).

133. See 21 C.F.R. §§ 314.50(c)(2)(viii), (d)(5)–(d)(6), 314.125(b)(2)–(b)(5), 314.126.

134. *Id.* § 314.94(a)(7).

135. *Id.*

136. See ORANGE BOOK, *supra* note 1, § 1.2; 21 C.F.R. §§ 314.94(a)(7), 314.127(a), 320.24.

137. See *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 310–11 (E.D. Mich. 2001).

138. The FDA emphasized in 1997 and 1998 that brands and their generic versions are therapeutically equivalent, even for so-called narrow therapeutic index drugs. See Letter from Stuart L. Nightingale, M.D., Associate Commissioner for Health Affairs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (Jan. 28, 1998), <http://www.fda.gov/cder/news/nightgenlett.htm> (last accessed Dec. 3, 2004); Letter from Roger L. Williams, M.D., Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, to Carmen A. Catizone, Executive Director/Secretary, National Association of Boards of Pharmacy (Apr. 16, 1997), <http://www.fda.gov/cder/news/ntiletter.htm> (last accessed Dec. 3, 2004).

FDA standards for bioequivalence with an existing FDA-approved brand-name product for that product's FDA-approved uses. Generics provide the same efficacy and safety as brand-name drugs, but typically at substantially lower prices.¹³⁹

Once FDA-approved generic equivalents become available, statutes in all states permit (and in some cases require) pharmacists to fill prescriptions for the brand with a generic, unless the physician has indicated that the prescription be filled as written.¹⁴⁰ States enacted these statutes to reduce aggregate drug expenditures by accelerating generic substitution.¹⁴¹ The rules governing and encouraging generic substitution contrast sharply with those applicable to brand-name drugs, even for those brands indicated to treat the same disease or condition. There are no comparable state laws encouraging, requiring, or even permitting pharmacists to substitute less-expensive brand-name alternatives for other brand-name prescription drugs. Once a physician chooses a brand-name drug, the pharmacist is required to fill the prescription with that same drug—unless an FDA approved, therapeutically equivalent generic is available.

Due to these laws and regulations generics are the only FDA-approved complete therapeutic substitutes for their corresponding brands. As a result of these factors (and others described in this Section), the introduction of a generic is often a key factor in spurring substantial price competition in the prescription pharmaceutical marketplace.

3. The Role of Intellectual Property

Intellectual property, and the means by which it is attained, enforced, and regulated, plays a substantial role in shaping the economics of the pharmaceutical industry. Branded manufacturers devote considerable resources to developing, patenting, testing, gaining regulatory approval for, and then ultimately bringing new pharmaceutical products to market.¹⁴² While branded companies (and their principal trade group, PhRMA) appear to have historically exaggerated both

139. See Kirking et al., *supra* note 86.

140. See statutes cited *supra* note 116; LEVY, *supra* note 121, at 18.

141. ALISON MASSON & ROBERT L. STEINER, FED. TRADE COMM'N, *GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 4-7* (1985).

142. See Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107, 107-09 (1991); OFFICE OF TECH. ASSESSMENT, *supra* note 86; Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 152-53 (2003).

the amount spent on this R&D, and its effectiveness in creating truly innovative drugs,¹⁴³ it is beyond the scope of this Article to engage in this controversial debate about the levels, efficiency, and social benefits of research and development expenditures by the U.S. pharmaceutical industry. For this Article's purposes, it is sufficient to note the uncontroversial point that spending money on developing, securing, and commercializing intellectual property is a significant focus of branded manufacturers. These expenditures are motivated by the substantial profits that typically await commercially successful new pharmaceutical products.¹⁴⁴

Developers of new medicines may acquire patents covering the compound itself, the manufacturing process, or the compound's use.¹⁴⁵ Moreover, under the Hatch-Waxman Act, the FDA can grant patent extensions beyond the life of applicable patents to compensate for the often substantial time needed to obtain necessary approvals to bring the product to market, time that effectively limits the patent term.¹⁴⁶

As referenced above, under Hatch-Waxman, generic companies are allowed to bypass filing a full NDA with new safety and efficacy studies and instead may rely on the pioneer manufacturer's work by submitting an ANDA with "data demonstrating the generic product's bioequivalence to the previously approved drug."¹⁴⁷ When seeking approval to bring a product to market, the generic applicant must then specifically indicate its position with respect to whether the generic

143. See, e.g., Donald W. Light & Joel Lexchin, *Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet*, 4 AM. J. BIOETHICS W1, at W3 (2004); Arnold S. Relman & Marcia Angell, *America's Other Drug Problem: How the Drug Industry Distorts Medicine and Politics*, NEW REPUBLIC, Dec. 16, 2002, at 28-30; OFFICE OF ATTORNEY GEN. MIKE HATCH, *supra* note 118, at 49-50.

144. CONG. BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY* 3 (1988).

145. FED. TRADE COMM'N, *supra* note 4, at 41.

146. *Id.* at 4; CONG. BUDGET OFFICE, *supra* note 86, at 3-4. For instance, by statute, a company seeking to market a generic product cannot file its ANDA until five years after FDA approval of the originator's "new chemical entity" drug, the de facto period of exclusivity, thus effectively running until the generic applicant obtains final FDA approval and comes to market, a process which is by no means immediate. However, where an originator drug with "new chemical entity" status obtains a patent and lists that patent in the Orange Book as covering the drug, the time within which an ANDA filing can be accepted shrinks to four years. See 21 U.S.C. § 355(j)(5)(D)(ii) (2000); FED. TRADE COMM'N, *supra* note 4, at A-35 n.33; CONG. BUDGET OFFICE, *supra* note 86, at xiv, 41.

147. Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1325-26 (Fed. Cir. 2001); CONG. BUDGET OFFICE, *supra* note 86, at 3; 21 U.S.C. § 355(j)(2)(A).

product infringes any existing patents listed by the branded manufacturer in the FDA's Orange Book.¹⁴⁸

If the generic applicant accepts those patents as valid and applicable to its product, it must wait until they expire before receiving final FDA approval to bring its product to market.¹⁴⁹ If, on the other hand, the generic company challenges the validity or applicability of those patents, it must indicate as such in connection with its ANDA.¹⁵⁰ The branded manufacturer then has the opportunity to file suit to protect its patent position. Significantly, if the branded manufacturer sues the generic within forty-five days of receipt of the ANDA notice, the FDA, without evaluating the validity of the lawsuit or the validity or applicability of the claimed patent rights, will delay final approval of the generic for thirty months or until the resolution of any court proceeding declaring the patent not infringed or invalid or until the patent expires, whichever come first.¹⁵¹

In sum, Congress attempted to promote generic competition through passage of the Hatch-Waxman Act.¹⁵² At the same time, elements of Hatch-Waxman, together with other laws and regulations, have offered significant protections to branded manufacturers and their intellectual property.¹⁵³ These laws set the framework within which generics play such a substantial competitive role.

148. 21 C.F.R. § 314.94 (2004); *Mylan Pharms.*, 268 F.3d at 1326; FED. TRADE COMM'N, *supra* note 4, at 5. After FDA approval, brand-name companies list patents covering their products with the FDA in the Orange Book. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1351 n.6 (Fed. Cir. 2003); 21 C.F.R. § 314.53.

149. 21 U.S.C. § 355(j)(2)(A)(vii)(II)-(III).

150. *Id.* § 355(j)(2)(A)(vii)(IV).

151. FED. TRADE COMM'N, *supra* note 4, at 7. The first generic firm to file such an ANDA challenging a patent is rewarded with a priority position after approval—i.e., no other generic can enter the market until 180 days after either (1) the first commercial marketing of the first generic version of the drug, or (2) the resolution of any court proceeding declaring the patent not infringed or invalid, whichever is earlier. *Id.* at 7, 57; 21 U.S.C. § 355(j)(5)(B)(iv).

152. See *In re Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187, at *11-*12 (Dec. 8, 2003) (Hatch-Waxman Act "was intended to facilitate earlier entry by the manufacturers of generic drugs . . . and thereby reduce average prices paid by consumers. At the same time, Congress wanted to preserve incentives for continued innovation by research-based pharmaceutical companies . . ."); *Mylan Pharms.*, 81 F. Supp. 2d at 32 ("The stated purpose of this legislation [Hatch-Waxman] was to 'make available more low cost generic drugs'").

153. *Id.*

4. Generic Drugs Introduce Price Competition and Reduce Consumer Costs in the Prescription Drug Industry

Patents and other forms of exclusivity conferred through, and regulated by, Hatch-Waxman, provide branded drug makers a significant, but *limited*, period of market exclusivity.¹⁵⁴ This ability to legally, albeit temporarily, foreclose the entry of generic competitors gives branded manufacturers the power to set prices on brand-name products generally far above marginal costs, typically generating substantial profits even taking into account expenditures associated with developing and commercializing new drug products.¹⁵⁵ In fact, a great deal of branded company behavior can best be understood as creating and maximizing the returns from these temporary periods of market exclusivity. From this perspective, the regulatory scheme functions, in significant part, as a means for Congress to balance the long-term incentives for companies to continue to invest in the development and marketing of new drugs (and the other objectives of the pharmaceutical industry) against the interests of promoting competition, economic efficiency, and low prices.

The value of the market exclusivity conferred on brand-name drugs depends, of course, upon how often doctors prescribe the drug. Hence, branded pharmaceutical companies devote considerable effort to persuade doctors to prescribe their products, and consumers to seek out those prescriptions.¹⁵⁶ Significantly, this form of competition tends *not* to be primarily about price. Indeed, prescription choices typ-

154. See *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003) (recognizing provisions of Hatch-Waxman provide a five-year period of exclusivity following FDA approval of an NDA and an additional six months of exclusivity if child-safety studies are submitted); Grabowski & Vernon, *Longer Patent*, *supra* note 86, at 118–19. Indeed, since marginal production costs are typically low in relation to fixed costs of developing and commercializing brand-name drugs, the inability to defer generic competition for at least some period of time after brand-name products are launched would present a fundamental economic problem for the prescription drug industry. Generic competition would tend to drive prices down toward marginal production costs—as potential generic competitors could readily enter the market cheaply by copying brand-name drugs. See Reiffen & Ward, *supra* note 86, at 23. In a hypothetical world with no intellectual property protection at all, branded companies might potentially have difficulty achieving attractive rates of return on capital invested in R&D, as well as for other costs associated with the development and commercialization of new drugs.

155. *Id.*

156. CONG. BUDGET OFFICE, *supra* note 86, at 21; Mark A. Hurwitz & Richard E. Caves, *Persuasion or Information? Promotion and the Share of Brand-Name and Generic Pharmaceuticals*, 31 J.L. & ECON. 299, 302 (1988).

ically are relatively insensitive to price.¹⁵⁷ This is not to say that physicians never take price into account in choosing among brands within a particular therapeutic class or that price is never a factor in prescription choice pre-generic entry. This is also not to say that branded companies have unlimited discretion in setting price. Prior to generic entry, the presence of other brand-name products (as well as non-therapeutically equivalent generic drugs, i.e., generics corresponding to other brands) in the same therapeutic class certainly exert some real restraint on brand pricing, though, not close to the degree a generic drug exerts on its corresponding brand.¹⁵⁸ Moreover, the intense public concern with, and scrutiny of, medical costs,¹⁵⁹ particularly prescription pharmaceutical costs, creates a variety of pressures to exercise discretion in setting prices.¹⁶⁰

Nevertheless, vigorous advertising and promotion, known to economists as forms of “non-price” competition, tends to be the dominant mode of competition between different brand-name drugs in the same therapeutic class. Such competition is manifestly insufficient to force the prices down to the lower, competitive post-generic entry levels before the advent of generic competition, as strikingly demonstrated by the dramatic price declines that typically accompany generic entry.¹⁶¹ Once the right to market exclusivity (i.e., the right to block generic entry) expires, the economics of low production and entry costs associated with generic drugs take over. Generic entrants enter the market and rapidly drive average prices for the drug down, erasing the exclusivity premium formerly embedded in the brand-name price.¹⁶²

As generics enter, the usual response by the branded seller is to cease its marketing efforts for that product and switch promotional

157. See *supra* notes 117–29 and accompanying text. Increasing insurance coverage of drug costs has reduced price sensitivity among physicians and patients. Managed care has responded with cost-containment efforts. One of the key effects of these efforts has been to further encourage brand to generic substitution. See Rika Onishi Mortimer, Demand for Prescription Drugs: The Effects of Managed Care Pharmacy Benefits (Nov. 1997) (unpublished manuscript, on file with Department of Economics, University of California at Berkeley). Promotional efforts by branded manufacturers tend to further decrease price sensitivity. Rizzo, *supra* note 126, at 107, 112–13.

158. Z. John Lu & William S. Comanor, *Strategic Pricing of New Pharmaceuticals*, 80 REV. ECON. & STAT. 108, 110, 115–17 (1998); CONG. BUDGET OFFICE, *supra* note 86, at 23–24.

159. SARA FISHER ELLISON & CATHERINE WOLFRAM, PHARMACEUTICAL PRICES AND POLITICAL ACTIVITY 1–5, available at <http://econ-www.mit.edu/faculty/sellison/files/drugpol6.pdf> (last accessed Dec. 3, 2004).

160. See Frank & Salkever, *Generic Entry*, *supra* note 86, at 89.

161. See, e.g., Grabowski & Vernon, *Longer Patent*, *supra* note 86, at 111–18.

162. *Id.*

efforts to a new brand-name product.¹⁶³ The branded seller may also decide to compete on price with the generics with certain buyers that the manufacturer believes can substantially influence prescribing behavior.¹⁶⁴ For the most part, though, the branded seller typically cedes the vast majority of the molecule market to the generic competitors.¹⁶⁵ Generic manufacturers view their market as essentially composed only of the total universe of sales of its corresponding brand-name drug during the brand's period of market exclusivity. Generics typically spend very little on promotional efforts, instead letting their low prices and generic substitution laws serve as the principal inducements for sales growth.¹⁶⁶

With the branded seller having effectively surrendered to its corresponding generic equivalents, its former customers shift most of their business to generic suppliers within a short time, paying a fraction of the prices they formerly did for the same drug.¹⁶⁷ At the same time, because the branded firm's efforts to build and maintain prescription volume ceases, and because generics typically do little advertising or promotion, the emergence of generic entry correlates with a plateauing of growth, or sometimes even a slight unit sales volume decline in the specific drug molecule, despite the substantially lower average price.¹⁶⁸

In sum, institutional features of the industry—including, among others, intellectual property protections and other forms of market exclusivities, prescriber directed demand, product heterogeneity, and individual variation in therapeutic effectiveness—significantly limit price sensitivity in pharmaceutical markets. The result is often relative price and demand inelasticity for brand-name products prior to generic entry, even where multiple brands are available in the same therapeutic class and are approved for the same uses. These factors

163. J.P. MORGAN, 2003 DISTRIBUTION OUTLOOK, NORTH AMERICAN EQUITY RESEARCH 16 (Apr. 21, 2003).

164. CONG. BUDGET OFFICE, *supra* note 86, at xi.

165. See Frank & Salkever, *Pricing*, *supra* note 86, at 174–75; Grabowski & Vernon, *Brand Loyalty*, *supra* note 86, at 335–36, 339; CONG. BUDGET OFFICE, *supra* note 86, at 29. Branded manufacturers now typically cede over 90% of the molecule market to generics within one year.

166. CONG. BUDGET OFFICE, *supra* note 86, at xi.

167. CONG. BUDGET OFFICE, *supra* note 86, at 27–29.

168. Because branded companies need to replace lost revenues, they typically release a “next generation” version of the brand-name drug undergoing generic competition, which can, and often does, have the effect of increasing total prescriptions in a therapeutic category, even where the prescriptions of the molecule facing direct generic competition fall. See *infra* notes 195–97 and accompanying text.

describe a marketplace in which price competition between brand-name products tends to be limited, and so-called "non-price" competition is dominant. Prices typically only fall substantially after the low priced generics enter the market rapidly displacing the premium priced brands. These factors help explain why, under Hatch-Waxman, generic entry has been a singularly powerful competitive force.¹⁶⁹

B. Drugs in the Same Therapeutic Category Are Not Typically "Reasonably Interchangeable" and Thus Do Not Belong In the Same Relevant Market in Delayed Generic Entry Cases

By law, only products that are deemed "reasonably interchangeable" belong in the same relevant product market.¹⁷⁰ To meet this test, products must be both (1) functionally interchangeable and (2) economically substitutable.¹⁷¹ In most industries, the simple fact that products are, to some degree, "functionally interchangeable" for their intended purpose is a good indication that those products will substantially constrain each other's ability to raise price above competitive levels, in other words, that they are fully economically substitutable as well. But, as the foregoing institutional features discussion makes clear, the pharmaceutical industry is decidedly *not* most industries.

First, given the role of physicians and the uniqueness of individual patients, arguments that different brands are effectively "therapeutically interchangeable" tend to be weak. Often, within a therapeutic

169. The powerful effects of generic competition are described in the following sources, among others: OFFICE OF TECH. ASSESSMENT, *supra* note 86, at 83, 87, 89 n.17, 243; CONG. BUDGET OFFICE, *supra* note 86, at ix, xii-xiii, 8-9, 13, 27-35; Kirking et al., *supra* note 86, at 578-84.

170. See *Queen City Pizza v. Domino's Pizza*, 124 F.3d 430, 436 (3d Cir. 1997); *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001).

171. *Lucas Auto. Eng'g, Inc. v. Bridgestone/Firestone, Inc.*, 275 F.3d 762, 767 (9th Cir. 2001). *Lucas Auto* states:

The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it. Where an increase in the price of one product leads to an increase in demand for another, both products should be included in the relevant product market. The determination of what constitutes the relevant product market hinges, therefore, on a determination of those products to which consumers will turn, given reasonable variations in price.

Id. (citations omitted); see also *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 995-99 (11th Cir. 1993); *Hayden Publ'g Co. v. Cox Broad. Corp.*, 730 F.2d 64, 70-71 (2d Cir. 1984); *SmithKline, Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064-65 (3d Cir. 1978); *Pinder v. Hudgins Fish Co.*, 570 F.2d 1209, 1219 n.17 (5th Cir. 1978).

class, there are sub-classes of drugs, defined by their differing modes of action, and each with a different set of side-effects.¹⁷² And, even within therapeutic subclasses, small differences in molecular structure, combined with the uniqueness of individual patients, their medical histories and conditions, can deter substitution between and among different drug molecules.¹⁷³

This latter point is especially true when a patient is being treated with a particular drug therapy that happens to be working. In such a case, physicians and patients may be loath to switch to a different treatment within a therapeutic class.¹⁷⁴ It is not an insignificant feature of the economics of the pharmaceutical industry that these products treat disease in human beings, each of whom has a different history, reacts differently to medications, and presents with numerous unique individual characteristics. Switching from, say, one floor polish to another does not carry the same implications. Accordingly, while product heterogeneity certainly exists in most non-commodity markets, this characteristic takes on added significance in the pharmaceutical industry.

Further, this aspect of the competitive landscape is not lost on the branded pharmaceutical industry. The set of institutional features outlined above—such as the fact that physicians tend to focus mainly on factors other than price as a key determinant of the drug therapy—helps explain why the phenomenon of therapeutic switching from one branded drug therapy to another does not constrain prices to the rock-bottom levels that prevail only upon generic entry.

Industry defenders nevertheless point to market data that sometimes reveals “switching” from one drug therapy to another. This “switching” evidence is put forth as “Exhibit A” for the proposition that these drugs are therapeutically “interchangeable” and thus belong in the same relevant market. Yet, evidence of switching between molecules by itself is insufficient to show reasonable interchangeability. First, the mere fact that data reveals patients appearing to “switch” from one therapy to another does not mean that the physician or patient believes that the two products are interchangeable. Indeed, switches are often made because one product fails to work, or because it has side effects that another may not.¹⁷⁵ Thus, to a certain degree switching may actually reveal a lack of therapeutic interchangeability.

172. See *supra* notes 122–25 and accompanying text.

173. See *supra* notes 122–25 and accompanying text.

174. See, e.g., Kessler et al., *supra* note 123, at 1352; Gesensway, *supra* note 125.

175. WERTHEIMER, LEVY & O'CONNOR, *supra* note 124, at 86–98.

But, even if brands were therapeutically identical, switching would be relevant only where price is a material reason for switching.¹⁷⁶ Indeed, if switching between molecules relates principally to issues of therapy, and not price, then the presence of numerous similar treatments may not restrain the price of other brands to competitive levels. Put another way, that price is not the principal reason why switching tends to occur (outside of substitution that occurs from a brand to its FDA-rated generic equivalents upon generic entry), helps explain why the existence of many brands in a therapeutic class generally does not bring prices down close to the post-generic entry competitive levels.

The law recognizes the dichotomy between mere substitutability based upon similarity in use and substitutability based on relative differences in price. For instance, the economic concept of cross-price elasticity of demand measures the degree to which products are "economic substitutes," i.e., whether the relative change in the price of one causes commensurate shifts in sales to, or from, the other. As one court puts it:

When one gets down to brass tacks, or any other specific product, almost all products have substitutes: even buses, skywriters and road signs compete with newspapers for advertising. Antitrust law, however, is only concerned with products reasonably interchangeable with one another, in other words, products for which there is some cross elasticity of demand.¹⁷⁷

Evidence that two products are sometimes, or even often, substituted for one another because of functional similarities is, without a finding of significant positive cross-price elasticity of demand, not useful for purposes of defining relevant markets.¹⁷⁸ Yet, due to the insti-

176. Cf. *SmithKline Corp.*, 575 F.2d at 1063-64 (holding that two drug molecules that could be used for the same purpose were not part of the same market because cross-price elasticity between the two was absent).

177. *Auburn News Co., Inc. v. Providence Journal Co.*, 504 F. Supp. 292, 302 (D.R.I. 1980) (citing *Brown Shoe, Inc. v. United States*, 370 U.S. 294 (1962)), *rev'd on other grounds*, 659 F.2d 273 (1st Cir. 1981). In addition, the degree of cross-elasticity of demand must be significant. See, e.g., *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1483 (9th Cir. 1997) ("A high cross elasticity of demand indicates that products are close substitutes, and should probably be treated as part of the same market. A low or zero cross elasticity of demand is evidence that products do not compete in the same relevant market."); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 201 F. Supp. 2d 236, 267 (S.D.N.Y. 2002) (requiring "sufficient cross-elasticity of demand"); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1078 (D.D.C. 1997) (stating that low cross-elasticity results in exclusion of products in antitrust market).

178. See, e.g., *Telecor Communications, Inc. v. Southwestern Bell Tel. Co.*, 305 F.3d 1124, 1132 (10th Cir. 2002) ("Reasonable interchangeability does not depend on product similarity . . ."); *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001) ("The test of reasonable interchangeability, however, required the District Court to consider only substitutes that constrain pricing in the reasonably foreseeable future . . .");

tutional features of the pharmaceutical industry¹⁷⁹ it is often the case that cross-price elasticity of demand between different drug molecules is relatively low. Indeed, as discussed above, when a brand experiences FDA-rated generic competition, the price of the generic, which enters the market at a significant discount to the pre-generic entry brand price, then often drops twenty to forty percent of the pre-generic entry branded price over a matter of months.¹⁸⁰ Purchasers of the brand rapidly substitute the generic until the vast majority of the “molecule market,” sometimes well-above ninety percent, becomes generic.¹⁸¹ Pertinent here, despite the fact that the average price drops to as low as twenty percent of the pre-generic entry level, total prescriptions of the molecule stay flat and even drop over time as the branded manufacturer stops promoting the product.¹⁸² Thus, the relative price of one molecule drops substantially with respect to most of the other drugs in the therapeutic class, without a substantial shift in volume from the now relatively higher priced alternative brand-name drugs, to the newly low priced alternative. This typical pattern indicates that cross-price elasticity of demand between drugs in a therapeutic class is low. The drop in the price of one drug molecule that occurs with generic entry tends not to result in the kind of volume shifts from other drugs in the therapeutic class that would be expected if cross-price elasticity of demand were relatively high.

Thus, different drug molecules within the same therapeutic class, despite possible therapeutic similarities, tend not to be close economic substitutes for purposes of defining relevant markets in delayed generic entry cases. This, once again, explains why the entry of a generic has such a substantial competitive effect even though there may

U.S. Anchor Mfg., 7 F.3d at 995–99 (finding despite functional interchangeability, absence of price-related demand and supply elasticities prevents products from residing in same market); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 & n.1 (8th Cir. 1989) (finding that sugar and high fructose corn syrup, though functionally interchangeable, do not reside in the same antitrust product market because “a small change in the price of HFCS would have little or no effect on the demand for sugar” such that cross-elasticity of demand is low, despite evidence of actual substitution of corn syrup for sugar by consumers); *Staples*, 970 F. Supp. at 1074, 1080 (finding, on basis of absence of cross-elasticity of demand, that products reside in separate product markets despite functional interchangeability of products); *id.* at 1075 (“[T]he mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes.”).

179. *See supra* Part IIA.

180. *Id.*

181. *Id.*

182. *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 603 (7th Cir. 1977).

be several drugs in a particular therapeutic class of drugs. This also, of course, means that branded companies typically possess market power with respect to their brands before generics enter. As Judge Posner has recognized, "[I]n an industry such as pharmaceuticals many of the products . . . are patented. The sellers may be selling goods that although close substitutes are not perfect substitutes, with the result that each seller has some monopoly power."¹⁸³

Industry defenders nevertheless suggest that the only way to define a relevant market in this context is to conduct a detailed quantitative analysis of cross-price elasticity of demand among different brand-name products prior to generic entry. Such a study would presumably constitute an effort to determine quantitatively whether delaying generic competition preserved monopoly power by examining the price restraining effects on the brand by existing branded competitors. In cases where no direct evidence of monopoly power is available, such a study might assist in determining whether the entry of an additional source of competition would have a substantial effect on prices. In delayed generic entry cases, however, where direct evidence is available in abundance, such a formal price elasticity study would be wholly unnecessary and would likely be a time-consuming and costly distraction.

This is so for at least two reasons. First, as shown above, the direct proof of supracompetitive pricing in these cases not only obviates the need for indirect proof entirely, but also simultaneously serves as proof that the relevant market *must* be limited to the molecule. Second, such a quantitative analysis, at best, would merely reflect the competitive conditions existing before the lifting of the restraint on generic competition. In other words, at best the study would provide a snapshot in time of the price restraining effects of existing competition. Yet, analyzing actual market conditions pre-generic entry as a baseline to define and assess whether substantial market power is being exercised is improper because it falls prey to what is commonly known as the "cellophane fallacy."¹⁸⁴ The study of a firm's pricing in

183. Morse, *supra* note 81, at 676, 670 n.167.

184. CARLTON & PERLOFF, SECOND EDITION, *supra* note 39, at 804-06. The cellophane fallacy refers to the Supreme Court's expansive definition of a relevant market in *United States v. E.I. du Pont de Nemours and Co.*, 351 U.S. 377 (1956), to include all packing materials rather than just cellophane because evidence revealed that consumers switched to other materials when the price of cellophane went up. Economists generally consider this holding to be wrong, because, among other reasons, the Court overlooked record evidence that cellophane prices vastly exceeded marginal cost. CARLTON & PERLOFF, SECOND EDITION, *supra* note 39. More recently, the Supreme Court has noted that even those already exercis-

the face of existing competition as a means to rule out the present exercise of market power is considered fallacious. This is because a snapshot look at a firm's pricing at any point in time should always reveal significant sources of discipline limiting further price increases. All firms, even those presently exercising monopoly power, face pricing discipline at some level.¹⁸⁵

Indeed, economics teaches that even a true sole-seller monopolist will not increase its prices without limit.¹⁸⁶ Instead, such a monopolist will raise prices to the point where other products become viable substitutes to consumers (or to the point at which consumers will forego the product altogether) solely *because* the monopolist's price is so high.¹⁸⁷ In short, the monopolist will price to the level the market will bear. As Judge Learned Hand explained in *United States v. Aluminum Co. of America*,¹⁸⁸ "substitutes are available for almost all commodities, and to raise the price enough is to evoke them."¹⁸⁹ Any hypothetical quantitative study of cross-elasticity revealing that an incumbent firm faces substantial discipline in its ability to raise prices does not represent evidence that the firm is not exercising monopoly power during the period under study. Put another way, the fact that the seller cannot raise prices even higher than the prevailing price does not mean that the seller lacks market power; it may simply mean it has *already exercised it*.¹⁹⁰

Therefore, quantitative analysis of the price constraining effects of existing competition pre-generic entry is most appropriately used to provide insight about whether particular conduct *going forward* could result in the maintenance, enhancement, or creation of market

ing market power may be constrained in their ability to raise price, and that evidence of significant price constraints does not foreclose a finding of the present exercise of market power. See *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 471 (1992).

185. See, e.g., *Eastman Kodak*, 63 F.3d at 105 (explaining the cellophane fallacy); VISCUSI ET AL., *supra* note 65, at 261 ("A rational monopolist would, in fact, raise price until its product became a substitute for alternatives. Hence, substitutes in consumption should be evaluated at prices that are reasonably close to marginal costs."); RICHARD A. POSNER, *ANTI-TRUST LAW* 150 (2d ed. 2001) ("[A] monopolist always tries to sell in the elastic portion of his demand curve" and therefore "at a high enough price, even poor substitutes look good to the consumer.").

186. *Eastman Kodak*, 504 U.S. at 470-71.

187. *Id.*

188. 148 F.2d 416 (2d Cir. 1945).

189. *Id.* at 426.

190. See, e.g., Landes & Posner, *supra* note 44, at 977-79; *Eastman Kodak*, 504 U.S. at 471 ("The existence of significant substitution in the event of *further* price increases or even at the *current* price does not tell us whether the defendant *already* exercises significant market power." (internal quotation omitted)).

power relative to existing circumstances. But, in cases where there is clear and largely undisputed evidence of supracompetitive pricing, quantitative analysis of cross-price elasticity of demand will likely not clarify the competitive issues, but rather would tend to yield misleading results.

In sum, determining quantitatively whether cross-price elasticity of demand between molecules pre-generic entry is low (and thus brand-name drugs are not close economic substitutes) or high (potentially reflecting the cellophane fallacy) would not be particularly useful in the context of delayed generic entry cases. Rather, the focus here should be on the following salient fact: that by restraining generic competition, the branded company delays the advent of substantially lower prices. The fact that existing competitors may restrain price, but not sufficiently to make the challenged conduct competitively insignificant, *means* that the pre-existing competitors do not belong in the market relevant to analyzing the antitrust claims in question in delayed generic entry cases. As one commentary explains, even where "the degree of substitutability is very high," products are not in the same relevant market "unless the availability of one effectively limited the price of the other to the competitive level or something slightly above."¹⁹¹ The fact that generics have such a significant effect on prices *means* that the relevant market in delayed generic entry cases is limited to the molecule.

C. Extensive "Non-Price" Competition Within a Therapeutic Class Does Not Mean that the Relevant Market is Broader than the Molecule in Delayed Generic Entry Cases

Industry defenders point to "non-price" competition that occurs between brands as proof that the relevant market in delayed generic entry cases will likely include an entire therapeutic class.¹⁹² This argument is, however, flawed for at least two reasons. First, as discussed above, promotion in the pharmaceutical industry tends to *increase* perceptions of differentiation among products, lowering price sensitivi-

191. 2A AREEDA & HOVENKAMP ET AL., *supra* note 16, ¶ 507a; *see also* Coastal Fuels, Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 197 ("The definition of relevant market depends upon economic restraints which prevent sellers from raising prices above competitive levels." (internal quotations omitted)); VISCUSI ET AL., *supra* note 65, at 261; POSNER, *supra* note 185, at 150-51.

192. Morse, *supra* note 81, at 675.

ties and demand elasticities.¹⁹³ This result has the effect of *increasing* levels of market power for firms that engage in it. Accordingly, the proliferation of non-price competition in the form of massive promotional spending is one of the features of the industry indicating that the relevant market in delayed generic entry cases is limited to the molecule, and not the other way around.

Second, industry defenders rarely suggest that, on net, consumers are usually better off when generic entry is delayed. While it is true that the branded manufacturer cuts promotional spending on the brand-name product facing therapeutically equivalent generic competition, branded firms typically plow that money back into promoting *a different* brand-name product, namely, one that has remaining patent life.¹⁹⁴ Thus, to the extent the argument is that pharmaceutical advertising is always good for consumers—despite its inflationary effect on prices—there is no evidence that drug companies spend less overall on promotion due to the growth in importance of generic drugs over time.

Furthermore, the fact that the total number of prescriptions of a particular drug molecule (brand plus generic) tends to plateau or even fall post generic entry does not prove that total prescription drug output falls as a result of generic entry. Indeed, generic entry tends to induce branded manufacturers to replace lost revenues with new versions of the old products (with new dosage forms, delivery mechanisms, etc.) known as “line extensions” or “next generation” products.¹⁹⁵ As a recent FTC report explains: “The generic competition spurred by Hatch-Waxman has forced brand-name firms to come up with new products to replenish their revenue streams. Brand-name companies have often introduced Incrementally Modified Drugs (“IMDs”) for which they can seek patent protection to lessen the impact of this generic competition.”¹⁹⁶ This competitive process can have the effect of *increasing* total prescription sales in a therapeutic class. These “line extensions” then become the focus of a new promotional campaign, inducing *additional* overall sales. To that extent, it is simply a fallacy to suggest that generic entry causes “output” to fall in any sense that would be harmful to consumers.¹⁹⁷

193. See *supra* notes 215–17 and accompanying text; Rizzo, *supra* note 126, at 99–100; Morton, *supra* note 121, at 1097.

194. J.P. MORGAN, *supra* note 163, at 16.

195. J.P. MORGAN, *supra* note 163, at 16.

196. FED. TRADE COMM’N, *supra* note 4, ch. 3, at 11.

197. See Morse, *supra* note 81, at 675.

Ultimately, however, the point here is that non-price competition does not indicate "reasonable interchangeability" of different brands, but rather indicates the opposite. This confirms what all of the circumstantial and direct evidence reveals—that the relevant market is limited to the molecule in delayed generic entry cases.

In sum, the various institutional features of the pharmaceutical industry described in this section, extensive efforts at product differentiation between drug molecules, the presence of non-price competition, the relatively low price sensitivity and cross-elasticity of demand between brands constitute substantial—if not overwhelming—circumstantial evidence that different brand drugs in a therapeutic class are not generally close economic substitutes for purposes of analyzing delayed generic entry cases, and thus are not "reasonably interchangeable" as the term is used in the context of relevant market definition. Therefore, even if the direct evidence of market power in delayed generic entry cases is ignored or disregarded, the indirect evidence tends to confirm that the relevant market is limited to the molecule in these cases, clearly showing that a branded company maintains substantial market power by forestalling generic entry.

III. Traditional Conceptions of Market Power and Anticompetitive Effects Apply to the Pharmaceutical Industry

As discussed above, the principal response of industry defenders to the use and implications of the direct evidence of monopoly power and anticompetitive effects in delayed generic entry cases involves (1) downplaying the significance of the direct evidence, (2) asserting the necessity of the indirect proof, and (3) ignoring or distorting the implications of the institutional features of the industry on the relevant market analysis. Perhaps the most diversionary (and fallacious) of the industry's arguments, however, is the suggestion that standard measures of market power and anticompetitive effects should be abandoned in industries, like the pharmaceutical industry, in which the up-front fixed costs, such as R&D, tend to be large.¹⁹⁸ In essence, defenders fall back on arguments used to justify the granting and enforcing of intellectual property rights or regulatory exclusivities to justify extended periods of supracompetitive pricing. Industry defenders claim that imposing standard definitions of monopoly power and anticompetitive effects under these circumstances would effectively

198. See Morse, *supra* note 81, at 674.

make every brand “a monopoly,” subject to liability under the Sherman Act, and thereby purportedly discourage investments in R&D. This entire argument is a non-sequitur.

It must be noted at the outset of this discussion that the mere assertion of this defense implicitly concedes the central point of this Article, i.e., that by delaying generic entry, firms maintain substantial market power and cause anticompetitive effects as these terms have traditionally been defined in the fields of both law and economics. If a firm by virtue of certain conduct (such as the assertion of patent or regulatory rights) enables itself to profitably charge prices substantially above its marginal costs or the competitive level—sufficient to recover such non-marginal costs as R&D expenditures—that firm has by definition maintained or created monopoly power, and that conduct has thereby yielded anticompetitive effects as traditionally recognized by the antitrust laws.

Indeed, one of the main reasons patents and regulatory exclusivities were established in the first place was to permit firms to exclude competitors and charge supracompetitive prices in order to be able to recover fixed and up-front costs, thereby encouraging investments in innovation. That is to say, the point of granting rights to marketing exclusivity is that the anticompetitive harms flowing from the exercise of that power are, it is argued, offset by corresponding benefits to *long-run* competition that the enhanced market power allows. Professors Baumol and Ordover explain in a more straightforward fashion the point industry defenders are implicitly making:

The Schumpeterian analysis tells us that the innovator obtains its reward via the temporary (and generally desirable) monopoly power that priority can confer on it by permitting it to outperform its rivals until they are able to respond through imitation or by some other means. Obviously, patents are a means to increase this incentive by providing legal support for such monopoly power and, perhaps, by extending the period during which it endures.¹⁹⁹

In the pharmaceutical industry, where fixed costs are often high, Congress intended for Hatch-Waxman, in conjunction with intellectual property rights, to balance the incentives for investments in innovation with the needs of consumers and the public for affordable

199. WILLIAM J. BAUMOL & JANUSZ A. ORDOVER, ANTITRUST: SOURCE OF DYNAMIC AND STATIC INEFFICIENCIES?, ANTITRUST, INNOVATION, AND COMPETITIVENESS 84 (Thomas Jorde et al. eds., 1992).

medications.²⁰⁰ Hatch-Waxman contains a trade-off: short-run anticompetitive effects for hoped-for long-run dynamic benefits. Significantly, these dynamic benefits, to the extent that they exist, flow from the substantial market power conferred upon branded manufacturers through the exclusivity grant. That is to say, there could be no positive long-run benefits without the endurance of the short-run competitive welfare harms. While it is beyond the scope of this Article to engage in a debate about whether the patent system and Hatch-Waxman strike the appropriate balance between short and long term competitive effects or whether the industry is sufficiently innovative to merit the exclusivity rights that are conferred through this scheme,²⁰¹ it is clear that this industry defense constitutes an implicit concession that delaying generic entry confers substantial market power and causes short-run anticompetitive effects as those terms have traditionally been defined.²⁰²

200. See, e.g., *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 628 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003); *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000).

201. There is a vast literature on the intersection between intellectual property and antitrust law. See, e.g., FED TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 1-39 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (last accessed Dec. 3, 2004). This subject is largely beyond the scope of this Article. It is sufficient to note that while intellectual property law and antitrust law share common goals of promoting competition and consumer welfare, they do so in different ways. See, e.g., Maureen A. O'Rourke, *Striking a Delicate Balance: Intellectual Property, Antitrust, Contract, and Standardization in the Computer Industry*, 12 HARV. J.L. & TECH. 1, 31 (1998). O'Rourke states:

Antitrust law seeks to encourage innovation by safeguarding the competitive process [while] intellectual property grants exclusive rights that protect against the same competition antitrust was meant to foster. . . . [T]o assume that there [is] no conflict between [the two] . . . is to ignore that antitrust and intellectual property use quite different means in attempting to achieve their respective ends.

Id.

202. Mr. Morse is correct that "market power cannot be presumed from the existence of a patent." Morse, *supra* note 81, at 673-74. But, of course, claimants in delayed generic entry cases do not claim that market power flows from the mere existence of the patent or exclusivity grant. Rather, as this Article notes, under the peculiar conditions under which prescription drugs are sold, including the applicable laws and regulations, branded manufacturers are typically empowered to inflate prices above competitive levels. When that power is extended beyond the limitations of the patent or other exclusivity grant, what was once the legal exercise of market power becomes the possible unauthorized exercise of market power. This Article simply advocates the application of traditional antitrust principles to these cases. See *In re Remeron Antitrust Litig.*, 355 F. Supp. 2d 522, 531 (D.N.J. 2004) ("Although a patent holder lawfully acquires a monopoly power via the patent process, it subsequently may violate the second prong of the *Grinnell* test by unlawfully *maintaining* that monopoly power." (citation omitted)); *id.* at 532 ("[I]f a patent-holder's actions unlawfully maintain otherwise lawful monopoly power . . . such actions could lead to anticompetitive effects in the relevant market.").

Further, the argument that traditional definitions of monopoly power and anticompetitive effects should not apply in delayed generic entry cases because it would amount to deeming all branded companies “monopolists” conflates wholly distinct elements of a Section 2 claim. The first element (possession of monopoly power) is necessary, but not sufficient to establish a Section 2 violation. Mere possession of monopoly power is *not illegal by itself*. It is only through the satisfaction of the *second* element—the illegal willful acquisition or maintenance of that power—that an entity possessing substantial market power faces liability.²⁰³ This Article, and relevant market/market power analysis more generally, are concerned only with the distinct requirements of satisfying the *first* element. In a Section 2 case, where a plaintiff establishes monopoly power, liability only conceivably attaches where a plaintiff succeeds in proving the second element. Thus, the supposed “public policy” problem with the application of traditional notions of market power and anticompetitive effects in the pharmaceutical context is illusory. Branded firms can only be held liable under Section 2 if improper means were used to block generics, such as through an anticompetitive scheme designed to monopolize.²⁰⁴

Accordingly, the mere innocent assertion of legitimate patent rights resulting in delayed generic entry is not, standing alone, an antitrust violation even though that conduct permits the maintenance of substantial market power and has anticompetitive effects. Again, the question of whether the conduct confers substantial market power is not the same as the question of whether the challenged conduct amounts to a Section 2 violation. This analysis implies at least two possible outcomes: (1) the court determines that the challenged conduct constitutes proper enforcement or defense of intellectual property right or Hatch-Waxman exclusivity, or (2) the court determines that the conduct exceeded the scope of those rights and was improper. In the former case, the exercise of monopoly power is potentially immune; in the latter it can be subject to liability.

The options are so limited because “[a] patent affords no immunity for monopoly not fairly or plainly within the grant.”²⁰⁵ To the

203. See, e.g., *Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.*, 810 F.2d 243, 252 (D.C. Cir. 1987) (“[A claimant] must show more than monopoly power in order to establish a Section 2 violation; [it] must also show that the defendant exercised its power in an anticompetitive fashion.”).

204. See e.g., *In re Remeron*, 355 F. Supp. 2d at 531–32.

205. *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942); see also *United States v. Line Material Co.*, 333 U.S. 287, 300 (1948) (“[T]he precise terms of the [patent] grant

extent that the branded firm has exceeded the legitimate scope of its patent or other exclusivity grant, the firm has, by definition, conferred upon itself more protection against competition than the competitive balance established by those laws will allow.²⁰⁶ As pointed out by professors Hovenkamp, Janis, and Lemley in this context,

[short term] competitive harms are tolerable if—but only if—they are part of the supracompetitive return the government has granted to an [intellectual property] owner under a social policy designed to encourage innovation. [Intellectual property] law requires that we tolerate departures from a competitive marketplace, but only where legitimate [intellectual property] rights in fact exist and are infringed.²⁰⁷

Returning one last time to the murder case analogy, this industry defense is akin to asserting that the accused did not actually stab the victim—the same victim that the accused admitted stabbing—*because* the stabbing was justifiable on grounds of self-defense. This contention represents not only an obvious non-sequitur, but it reflects an implicit admission that the defendant actually did the very thing he was accused of doing. Similarly, here the question of whether branded manufacturers should be permitted to engage in conduct designed to

define the limits of a patentee's monopoly and the area in which the patentee is freed from competition"); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) ("We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted to the patentee.").

206. See, for example, the following statement by Robert Harmon:

It should not be supposed, however, that there are no public costs associated with the right to exclude. These include inflated prices (invariably absorbed by the consumer), which frequently accompany exclusive rights, and overinvestment. The patent system seeks to maintain an efficient balance between incentives to create and commercialize and the public costs engendered by these incentives.

ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.2, at 12 (2003) (citations omitted).

207. Hovenkamp et al., *supra* note 4, at 1747. These authors elaborate on this concept specifically in the context of Section 1 claims relating to so-called "reverse payment" agreements in which branded manufacturers pay generic companies to stay off the market:

The purpose of the rule of reason is to determine whether, on balance, a practice is reasonably likely to be anticompetitive or competitively harmless—that is, whether it yields lower or higher market-wide output. By contrast, patent policy encompasses a set of judgments about the proper tradeoff between competition and the incentive to innovate over the long run. Antitrust's rule of reason was not designed for such judgments and is not adept at making them. A properly defined *per se* rule represents a judicial judgment that a particular restraint is so highly likely to be anticompetitive—that is, output reducing and price increasing in the short run—that a full inquiry into market power and applicable defenses is not worth the court's trouble.

Id. at 1729 (citations and footnotes omitted).

enhance and extend their market exclusivities is wholly distinct from analyzing whether that conduct has, or does not have, certain economic effects on prices and output.

In the final analysis, shorn of the patent (or other legitimate rights to market exclusivity), industry defenders have very little to stand on. They are left arguing that antitrust laws should not be concerned about branded firms preserving monopoly power by fraudulently enforcing invalid patents or buying off competitors. Yet, they reach this conclusion in large part by looking to the very intellectual property rights that are being challenged in the underlying cases.

Where branded companies pay generic manufacturers not to compete, or unilaterally game the Hatch-Waxman and/or patent system to keep generics off the market, these companies have, by doing so, extended the period during which they can profitably maintain substantial sales at supracompetitive prices. Assuming the underlying conduct is separately found to be improper, the conduct has effectively converted what had been a legal right to exclude competitors and exercise market power—a power existing by virtue of a patent or FDA-granted period of exclusivity—into an improper and unauthorized use of that power. More narrowly, the extension of exclusivity invariably involves the continued exercise of monopoly power, yielding substantial anticompetitive effects as these terms have traditionally been defined. There is no legitimate reason to alter those traditional definitions in delayed generic entry cases.

Conclusion

As the analysis of the unique institutional features of the pharmaceutical industry set out above reveals, generics are a critical source of price competition in an industry where substantial price competition is lacking despite a proliferation of drug products. In the end, after the underbrush of the industry arguments are cleared away, the market power issues in delayed generic entry cases are rather straightforward.

Where the anticompetitive effects of the challenged conduct are not the subject of serious debate, requiring the plaintiffs to prove indirectly what is already known directly is entirely unnecessary. Worse than that, relevant market analysis in delayed generic entry cases, if performed incorrectly by failing to take into account the complex institutional features of the pharmaceutical industry as well as the implications of the direct evidence itself, distracts from the actual competitive issues in these cases. The root of the problem is that the

indirect method creates unnecessary hurdles that can obscure what all parties effectively recognize in these cases: that delaying generic entry preserves monopoly power and generates anticompetitive effects.