PRODUCT MARKET DEFINITION IN THE PHARMACEUTICAL INDUSTRY

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I. INTRODUCTION

The pharmaceutical industry has become a major target of antitrust investigations and litigation. Indeed, Federal Trade Commission officials have said that almost 25 percent of new competition investigations in recent years have involved pharmaceutical products, though prescription drugs account for only about 10 percent of health care spending and less than 2 percent of the U.S. gross domestic product.

Over the last several years, the FTC and state attorneys general have challenged both interim and permanent settlements of intellectual property litigation between pioneer and generic drug manufacturers alleged to delay generic entry. They have also attacked patent listings in the Food and Drug Administration “Orange Book” and have alleged monopolization through fraud on the Patent and Trademark Office and sham litigation. Yet other cases have condemned distribution agreements as unlawful exclusive dealing. These government actions have led to substantial private class action litigation against the pharmaceutical industry. The FTC has also challenged numerous mergers and acquisitions in the industry over the last decade.

One common feature in all of these cases is the need to define a relevant market. In nonmerger cases, the FTC and private plaintiffs


generally allege narrow markets, limited to a single drug and its generic equivalent in some cases and to generic drugs excluding the bio-equivalent “brand-name” drug in other cases. In its merger challenges, on the other hand, the FTC has alleged markets ranging from those based upon a particular chemical compound, to broader markets based upon various drugs’ manner of interaction or dosage form, to still broader markets of all drugs used to treat a disease or condition. In numerous pharmaceutical merger challenges, the government has included in the market not only currently marketed drugs but also other drugs under development, alleging “innovation markets.”

It is not obvious how all of these cases can meet the Supreme Court’s product market test of “reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.” Unfortunately, most of the government actions contain only barebones market allegations so they provide little guidance. In the one case the FTC staff has litigated, an administrative law judge found that complaint counsel failed to prove the alleged market definition and that the market must be broadened to include “therapeutically equivalent” drugs. That loss, even if reversed on appeal, suggests further attention to product market definition is needed.

The broad range of product market definitions alleged in the various cases warrants close examination to ensure that the government and private plaintiffs are not gerrymandering market definitions to fit desired outcomes in each case. This is particularly true because, at least in merger cases, where the drugs at issue often account for only a small part of the transaction, companies have strong incentives to address government concerns without litigation. Private actions also often settle, after motions to dismiss or motions for summary judgment. Because market definition issues are intensely factual and often not resolved until trial, there are only a handful of court decisions providing guidance about how to define markets in the pharmaceutical industry.

Court decisions in pharmaceutical cases that address market definition come out differently on a number of important questions that deserve

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4 The use of innovation markets to challenge such mergers, which has generated substantial controversy, is beyond the scope of this article. For a detailed analysis of innovation markets, see M. Howard Morse, The Limits of Innovation Markets, ABA, ANTITRUST AND INTELLECTUAL PROPERTY NEWSLETTER, Spring 2001, at 22–35, available at http://www.aba.net.org/antitrust/mo/premium-at/ip/5598172.pdf.


attention: Are pharmaceutical markets fundamentally different from other markets? Who is the customer? Does price matter? Should a single drug define the market? Should generic drugs be in the same market as pioneer drugs or a distinct product market? Few cases address perhaps the most important question of all, which is how one determines whether the “Cellophane trap” applies. This article will address all of these issues.

II. AN INDUSTRY OVERVIEW

Defining pharmaceutical product markets requires an understanding of the role of government regulation, technological innovation, and competition in the industry.

A. Government Regulation

Research and development, as well as marketing of pharmaceuticals, is heavily regulated by the FDA. Under the Federal Food, Drug and Cosmetic Act, any person seeking to market a new drug (a so-called “pioneer” applicant), must first obtain FDA approval by filing a New Drug Application (NDA) establishing the drug is safe and effective for its intended use. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, established a streamlined approval process for “generic” versions of approved drugs with the same active ingredients. The Act authorizes Abbreviated New Drug Applications (ANDAs) for generic drugs that are bio-equivalent to pioneer drugs as well as paper new drug applications (paper NDAs) that rely on published literature to demonstrate safety and efficacy.

Intellectual property law also significantly influences the pharmaceutical industry. Studies have shown that the industry is heavily dependent on intellectual property generally and the patent laws in particular to justify investment in research and development. Absent patent

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protection or a similar barrier, imitators could free ride on innovators’ R&D efforts.

B. TECHNOLOGICAL INNOVATION

The pharmaceutical industry is characterized by substantial expenditures on research and development, continual innovation, and introduction of new drugs. Development of new pharmaceuticals is an increasingly lengthy and costly business fraught with significant risk. Early-stage pharmaceutical R&D focuses on discovery of new molecular entities (NMEs) or new chemical entities (NCEs), which are new therapeutic compounds not previously used or tested in humans. Prospective drugs are discovered through designing new molecules or screening of existing compounds. Drug candidates must then undergo rigorous preclinical testing in laboratories and animals and clinical testing in humans to establish safety and effectiveness. Clinical testing proceeds through three successive phases, from testing on a small number of usually healthy volunteers principally to explore pharmacokinetics and establish safe dosages (Phase I), to testing relatively small numbers of subjects with the targeted disease or condition to obtain evidence on safety and preliminary data on efficacy (Phase II), to large-scale, multi-center trials to establish efficacy and uncover side-effects that may occur infrequently (Phase III). Even after a drug is approved and introduced, companies often undertake additional clinical R&D, as a condition of approval, to compare effectiveness with other products, or to test new therapeutic uses to expand the market. Pharmaceutical companies also conduct R&D on new drug delivery mechanisms—such as implantable drug infusion pumps or extended release tablets—to deliver therapeutic agents to the desired site in the body at the desired dose. Companies may also introduce follow-on products—new combinations, formulations, dosing forms, or dosing strengths—of existing compounds that must also be tested in humans before market introduction.

Drug development has been analogized to wildcatting in Texas, with many dry holes and a few gushers. That is, many drugs that companies developed if patent protection was not available; other industries are far less dependent on patents.


14 Philip J. Hilts, Seeking Limits to a Drug Monopoly, N.Y. Times, May 14, 1992, at D1.
develop and test prove unsuccessful and are never marketed. One recent study, in fact, estimates the success rate for compounds entering clinical testing at only 22 percent, and few compounds that companies research ever make it into clinical trials.15 The FDA has likened the process of discovering a new drug to searching for the proverbial needle in a haystack, noting “literally hundreds and sometimes thousands of chemical compounds must be made and tested to find one that can achieve the desirable result without too-serious side effects.”16

Recent studies have estimated that, on average, discovering and developing a new drug takes ten to fifteen years and costs over $800 million (taking into account expenses of failed development efforts and the cost of capital), more than twice what it cost a decade ago.17 Studies also show that the top 10 percent of newly marketed drugs account for half of the financial returns on all new drug development, and only one-third of newly introduced drugs generate returns that exceed average R&D costs.18

C. Competition

Competition in the pharmaceutical industry occurs on two levels: the development of new drugs, and the sale of drugs.

Companies compete to be the first to market with a drug to meet an unmet medical need or with a drug that is safer or more effective at treating a condition or disease than current treatments. The first to

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16 Food & Drug Admin., supra note 13, at 14.


18 Henry Grabowski, John Vernon & Joseph DiMasi, Returns on Research and Development for 1990s New Drug Introductions, 20 Pharmacoecon. suppl. 3, 11–29 (2002). The Congressional Budget Office reports that the present discounted value of the return from the average marketed drug—including both blockbusters and those that do not cover the cost of their own development—exceeded the capitalized costs of R&D by $22 to $36 million in the 1980s and total returns from marketing a new drug have on average decreased by about $27 million since 1984. Congressional Budget Office, supra note 17, at xv, 14–15, 38, 47.
market will often gain a substantial first-mover advantage, largely as a result of establishing standard physician prescribing practices.19

Pharmaceutical companies also compete in marketing drugs. Several different market participants are involved today in purchasing pharmaceuticals, which may complicate market definition analyses. The patient is the ultimate consumer, but patients cannot obtain prescription pharmaceuticals without a physician’s prescription. Traditionally, physicians selected drugs for their patients without considering price. Pharmaceutical companies still expend substantial sums on physician-directed marketing efforts, including so-called “detailing” visits by sales representatives, free samples, advertising in scientific and medical journals, and sponsorship of continuing medical education.20 These expenditures, like advertising in other industries, are viewed as procompetitive by some and as wasteful by others. Today, patients are also targeted by direct-to-consumer advertising aimed at influencing purchasing patterns, generating complaints about consumer pressure on physicians.21

Third party payers also play an important role in the market today. Increasingly, employer-sponsored health insurance policies cover pharmaceutical expenses, with third-party payments now accounting for two-thirds of national spending on prescription drugs.22 In recent years, there has also been a shift of large numbers of patients from conventional indemnity or fee-for-service health insurance plans to health maintenance organizations (HMOs), preferred provider organizations (PPOs), and other managed care organizations (MCOs). Many health care plans, including traditional fee-for-service plans, now rely on pharmacy benefit managers (PBMs) to administer pharmaceutical benefit plans and manage drug utilization. PBMs negotiate discounts and rebates with suppliers, establish formularies of approved or preferred drugs, and influence drug selection through multiple-tier reimbursement co-payment (fixed consumer payment per prescription) or co-insurance (fixed consumer percentage payment per prescription) and other policies. Drugs disfavored by the PBM can, for instance, be discouraged by higher co-

20 Congressional Budget Office, supra note 17, at 19–21.
22 Reinhardt, supra note 3, at 138.
payments or co-insurance rates and prior authorization requirements that impose additional costs on patients. PBMs also pay pharmacists higher dispensing fees for favored drugs, use maximum allowable cost (MAC) programs to limit reimbursement to prices of low-cost drugs, and pay pharmacists incentives for achieving levels of performance in distributing favored drugs. They also monitor drug use by patients with chronic conditions through disease management (DM) programs and track physician prescribing practices to identify physicians for educational interventions. Group purchasing organizations (GPOs) also now put pressure on pharmaceutical companies for reduced prices. As a result, manufacturers regularly offer discounts and rebates based in part on a firm’s ability to shift sales to the company’s drug.\(^{25}\)

Pharmaceuticals are approved for sale by the FDA for particular indications, though physicians may prescribe approved drugs for off-label use. While there are diseases or conditions for which there is only a single pharmaceutical available, other diseases or conditions may be treated by various drugs that compete to varying degrees. Alternative drugs may be chemically similar or very different, and may have the same or different mechanisms of action, yet be functionally similar. In such circumstances, drug prices are set considering length of use (whether the drug treats chronic or acute conditions), convenience of use, and relative safety and efficacy profiles. Studies have shown that the availability of alternatives limits drug manufacturers’ pricing ability and “new drug prices tend to reflect the degree of price sensitivity in the market and the perceived value of the product to patients.”\(^{24}\) In addition to drug alternatives, a patient with a particular disease or condition may at times be treated with an alternative form of medical therapy. While the suggestion that pain is an alternative to medical treatment and should be included in the relevant market as once proposed may be appropriately ridiculed,\(^{25}\)


\(^{25}\) See Can a High Pain Threshold Beat a Medical Cartel? FTC Watch No. 358, Jan. 13, 1992 (‘knowledgeable staff members reacted with shocked incredulity last month when an
surgery or other medical procedures may at times be a realistic alternative to medication.

Much has been made of increasing drug expenditures in recent years,\textsuperscript{26} and data do show total expenditures for prescription drugs in the United States rising almost 16 percent per year on average from 1996 to 2001.\textsuperscript{27} But studies attribute those increases much more to new drugs and increased utilization than to price increases on drugs in the market. The most recent study attributes 47 percent of recent price increases to increased utilization, 27 percent to changes in the types of drugs used, and only 26 percent to price increases.\textsuperscript{28} It is surprising that increased output and introduction of new products should be of concern to antitrust officials, yet they continue to emphasize total expenditures in public speeches.\textsuperscript{29}

It is worth noting that while there have been a number of major mergers and acquisitions among manufacturers in recent years, it is widely recognized that the pharmaceutical industry as a whole is not concentrated. The Department of Commerce identifies more than 700 companies in the United States engaged in pharmaceutical manufactur-

agency economist suggested that kidney stone victims could defeat any cartel controlling access to machines which pulverize [kidney] stones sonically by showing patience," quoting an internal FTC staff memo suggesting "an increase in the price of lithotripsy may lead some patients with smaller stones to be more patient and let the stones pass without lithotripsy" and noting "[t]he economic analysis which triggered internal revulsion . . . was part of a discussion of "the relevant product market").


\textsuperscript{27} Health Care Finance Administration, National Health Expenditure Table 2, Aggregate Amounts and Average Annual Percent Change by Type of Expenditure (Jan. 8, 2003), available at http://cms.hhs.gov/statistics/nhe/historical/t2.asp.


\textsuperscript{29} See, e.g., FTC Testimony, An Overview of Federal Trade Commission Antitrust Activities, Remarks Before the U.S. House Committee on the Judiciary Antitrust Task Force (July 24, 2003) ("The growing cost of prescription drugs is a significant concern. Drug expenditures doubled between 1995 and 2000. In response, the FTC has increased its pharmaceutical-related investigations."); FTC Testimony, Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements, Before the U.S. Senate Committee on the Judiciary (May 24, 2001) ("The surging cost of prescription drugs is a pressing national issue. Recent reports suggest expenditures for retail outpatient prescription drugs rose . . . 18.8% . . . from the previous year. This dramatic increase has helped focus attention on the need to ensure competition in pharmaceutical markets."); available at http://www.ftc.gov/os/2001/05/pharm.htm.
Product Market Definition

ing, accounting for $67 billion in sales, with the eight largest accounting for approximately 50 percent and the top 20 firms accounting for approximately 70 percent of total revenues. The largest firm, Pfizer has only about an 11 percent share of U.S. drug sales, followed by GlaxoSmithKline with about a 7 percent share, and AstraZeneca, Johnson & Johnson, and Merck, rounding out the top five with about a 5 percent share each. Smaller competitors include Abbott, Aventis, Bristol-Myers Squibb, Eli Lilly, Novartis, Roche, Schering-Plough, and Wyeth, with about a 2–4 percent share each. Concentration is of course higher in more narrowly defined segments of the industry.

Generic drugs—which are bioequivalent to their brand counterparts—are also an important part of the competitive landscape. When a firm introduces a generic drug, it typically does so at a substantial discount to the pioneer drug. The Supreme Court has explained, “[g]eneric drugs, also called ‘copycat’ or ‘me-too’ drugs, are usually marketed at relatively low prices because their manufacturers do not incur the research, development, and promotional costs normally associated with the creation and marketing of an original product.” Some studies have suggested that drug prices may fall even further with the introduction of additional generics. Data also demonstrate that, increasingly, sales shift very rapidly to generic entrants. PBM policies often strongly encourage use of generic drugs, particularly through use of lower co-payments required from consumers and higher dispensing fees paid to pharmacists. The trend also appears to be attributable at least in part to state generic substitution laws, which permit, and in some states require, pharmacists to dispense bioequivalent generic drugs (unless specifically


It is also now well documented that pioneer manufacturers often curtail detailing and raise the price of the pioneer drug in response to generic entry.\textsuperscript{37} The net effect may be a reduction in the average price of off-patent drugs, but with reduced marketing, a decline in total output rather than an increase in output, as one would normally expect with a price decrease.

III. FTC PHARMACEUTICAL MARKET DEFINITION ANALYSIS

The FTC’s approach to product market definition in its pharmaceutical cases is not transparent. While the Commission has challenged at least twenty mergers involving pharmaceuticals since 1990, including three in the last two years, each one was resolved through a consent order\textsuperscript{38} or abandonment of the transaction before the Commission filed suit.\textsuperscript{39} The Commission complaints accompanying consent orders in these matters are not very detailed; they generally allege relevant product markets in a conclusory manner with little support. Further discussion of market definition in these complaints would help the public to understand the Commission’s analysis.

\begin{footnotesize}
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\item[37] See Levy, supra note 23, at 18–19; Congressional Budget Office, supra note 17, at 29–31; Richard G. Frank & David S. Salkever, Generic Entry and the Pricing of Pharmaceuticals, 6 J. Econ. & Mgmt. Strategy 75 (1997); see also Inwood Labs., Inc. v. Ives Labs., Inc., 456 F.5. 844, 847 (1982) (“normal industry practice” for pioneer manufacturer to direct marketing efforts to convince physicians that product is superior, until generic entry).
\item[39] Cytoc Corporation’s proposed acquisition of Digene Corporation was abandoned in June 2002 after the FTC authorized its staff to file suit. See FTC Press Release, FTC Seeks to Block Cytoc Corp.’s Acquisition of Digene Corp. (Jun. 24, 2002), available at http://www.ftc.gov/opa/2002/06/ cytoc_digene.htm. In addition, a proposed acquisition by Abbott Laboratories of ALZA Corporation was abandoned in 2000 after the parties and the staff could not agree on the terms of a consent decree. See Richard Parker & David
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The FTC is required to allow public comment on proposed consent orders by publishing an explanation in the Federal Register, and some additional understanding of agency thinking may be discerned from review of those “analyses to aid public comment” and from agency press releases. Unlike European Commission merger decisions following second phase investigations, however, such statements do not address even significant overlaps between the merging firms that the agency decided not to challenge. Moreover, unlike EU decisions, such statements do not specifically address arguments presented to the agency by the merging firms or other interested parties. The analyses to aid public comment do not even constitute “official interpretations” and press releases are issued by the staff, under the direction of the FTC Chairman but generally without review by other Commissioners.

A review of recent FTC enforcement actions in the pharmaceutical industry provides a flavor of the range of market definitions alleged by the FTC. The various cases define markets based upon:

1. whether drugs treat the same disease, condition, or indication;
2. whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same “mechanism of action”);
3. whether drugs have the same specific chemical compounds;


40 16 C.F.R. § 2.34(c) provides: “Promptly after the acceptance of the consent agreement, the Commission will place the order contained in the consent agreement, the complaint, and the consent agreement on the public record for a period of 30 days, or such other period as the Commission may specify, for the receipt of comments or views from any interested person. At the same time, the Commission will place on the public record an explanation of the provisions of the order and the relief to be obtained thereby and any other information that it believes may help interested persons understand the order. The Commission also will publish the explanation in the Federal Register.”

41 The European Commission issues detailed decisions at the conclusion of each investigation whether it blocks the transaction, accepts “undertakings” from parties, or approves it without relief. See, e.g., Case No. Comp/M.2922, Pfizer/Pharmacia (Feb. 27, 2003) (focusing on “therapeutic indications” as the “operational market definition” and considering whether drugs are “substitutes for the treatment of a specific illness or disease,” taking into account mechanism of action, diagnosis profile, patient profiles, active ingredients, pathologies, and method of administration, considering marketed drugs and drugs at an “advanced stage of development”); see also Case No. Comp/M.1878, Pfizer/Warner-Lambert (May 22, 2000); Case No. Comp/M.1846, GlaxoWellcome/SmithKline Beecham (May 8, 2000); Case No. Comp/M.1403, Astra/Zeneca (Feb. 26, 1999); Case No. Comp/ M.1378, Hoechst/Rhone-Poulenc (Aug. 9, 1999).

(4) whether drugs have the same dosage form such as injectable, liquid, capsule, tablets, or topical;
(5) whether drugs have the same frequency of dosage, such as once-a-day or extended release;
(6) whether drugs have the same strength of dosage, distinguishing, for example, 30mg and 60mg tablets;
(7) whether drugs are branded or generic;
(8) whether drugs require a prescription or are sold over-the-counter; and
(9) whether drugs are currently marketed or are in development.

Product markets alleged in recent merger enforcement actions include (i) drugs for the treatment of a particular disease or condition, (ii) drugs that have the same mechanism of action, and (iii) specific compounds.

The broadest markets alleged cover all drugs for a disease or condition. For instance, in its most recent challenge to a blockbuster merger, Pfizer Inc.’s $60 billion acquisition of Pharmacia Corporation, in May 2003, the FTC alleged a market of “research and development, and the manufacture and sale of prescription drugs for the treatment of ED” or erectile dysfunction. Pfizer’s Viagra was alleged to have a 95 percent share in that market while Pharmacia had two drugs in early clinical development. 43 Addressing Pfizer’s earlier $90 billion merger with Warner-Lambert in 2000, the agency similarly alleged a market of “research, development, manufacture and sale of drugs for the treatment of Alzheimer’s disease.” There Pfizer was alleged to have a 98 percent market share while Warner-Lambert accounted for the rest of the market and a third firm had just launched a new product. 44

In challenging Glaxo Wellcome plc’s $182 billion merger with SmithKline Beecham plc, the FTC also defined certain markets by indication,
alleging markets of “drugs for the treatment of irritable bowel syndrome” and “prophylactic herpes vaccines.” In each of these cases, the merging parties were two of few firms marketing any drugs in the broad category, or one was marketing and the other was developing such a drug. That may explain in part why one would expect substitution between drugs that are based on different chemicals and different mechanisms of action with unique effectiveness and side effect profiles, in response to modest price increases, in these cases but not others. But the agency’s rationale is not clearly articulated.

Other alleged markets focus on mechanism of action or class of drug. In September 2002, for instance, addressing concerns raised by Amgen Inc.’s $16 billion acquisition of Immunex Corporation, the Commission alleged anticompetitive effects in three markets defined by mechanism of action. The agency alleged two separate markets (TNF inhibitors and IL-1 inhibitors) of drugs which block cytokines that trigger inflammation, for the treatment of rheumatoid arthritis and other autoimmune diseases. At the same time, the agency included distinct neutrophil regeneration or colony stimulating factors that stimulate different white blood cells used to treat cancer patients with a low white blood cell count, in the same market, without explanation.

In challenging the Glaxo-SmithKline merger, the FTC also defined certain markets by mechanism of action. There, the FTC alleged markets of (1) “prescription pharmaceuticals of the topoisomerase 1 inhibitor class . . . for the treatment of cancer,” (2) “drugs of the triptan chemical class . . . for the treatment of migraine headaches,” and (3) “any 5HT-3 receptor antagonist prescription pharmaceutical compound indicated for the prevention and treatment of nausea and vomiting associated with medical treatment.”

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47 Glaxo Wellcome plc & SmithKline Beecham plc, FTC Docket No. C-3990 (Jan. 26, 2001) (Complaint ¶¶ 16 (a), (g), (i)), available at http://www.ftc.gov/os/2000/12/glaxo
In another recent action, in February 2003, the FTC focused primarily on specific chemical compounds in addressing Baxter International Inc.’s acquisition of Wyeth Corporation’s generic injectable drug business. The Commission alleged that the acquisition would reduce competition in five distinct markets. One market was defined as the manufacture and sale of Propofol, a specific general anesthetic commonly used during surgery and as a sedative for patients on mechanical ventilators. The agency’s analysis to aid public comment emphasized the product’s unique characteristics and uses, compared to other anesthetics, noting its “many benefits” including “the ability to quickly adjust the amount of sedation and its superior safety profile,” and the fact that it is “the preferred anesthetic agent for out-patient surgery.” Three other markets, for two specific neuromuscular block agents used to freeze muscles during surgery and for patients mechanically ventilated, and a specific antiemetic used to prevent and treat nausea and vomiting in patients undergoing certain types of chemotherapy and for post-operative treatment, were similarly defined to include branded and generic equivalents of specific chemical compounds. In challenging the Glaxo/SmithKline merger, the FTC also defined one market narrowly as drugs that contain “ceftazidime . . . a semisynthetic, broad-spectrum antibacterial derived from cephaloridine.” In none of these cases is there any discussion of


See also Pfizer Inc. & Warner-Lambert Co., FTC Docket No. C-3957 (Jul. 27, 2000) (serotonin reuptake inhibitors (SRIs) and selective norepinephrine reuptake inhibitors (SNRIs) for the treatment of depression; Epidermal Growth Factor receptor tyrosine kinase (EGF-rtk) inhibitors for the treatment of solid cancerous tumors).


substitution to explain why the market is not defined more broadly by mechanism of action or indication.

The FTC has also used dosage form and dosage frequency to narrow the relevant market. For instance, in challenging Pfizer’s acquisition of Pharmacia, the FTC alleged one market limited to “extended release drugs for the treatment of overactive bladder.” The agency explained in its analysis that extended release products, dosed at once or twice-a-day, “offer a more convenient dosing schedule and fewer side effects” than generic products that must be taken three times a day, but did not tie such convenience to the possibility of substitution.50 The markets alleged in challenging the Glaxo/SmithKline merger similarly included “second generation oral and intravenous antiviral drugs for the treatment of herpes” and “prescription topical herpes antiviral medications indicated for the treatment of . . . oral herpes.” Such markets were justified based on the drugs’ “greater bioavailability, superior efficacy, and requirements for less frequent dosing” over the first-generation drug.51

In one recent nonmerger case, also settled before the complaint issued, the FTC even divided a market by dosage strength, alleging separate markets for 30mg and 60mg tablets of a drug. In August 2002, the Commission issued a complaint against Biovail Corporation and Elan Corporation challenging a distribution agreement, which the agency said provided incentives for the firms not to introduce competing generic drugs. The Commission alleged that the two firms had market power in U.S. markets for 30mg and 60mg dosages of a generic anti-hypertension drug, excluding the bio-equivalent brand-name drug, Adalat CC. There is no discussion at all of substitution between the 30mg and 60mg dosages (or generic and branded Adalat CC), though the agency did assert that


“[e]ntry of a second generic product at each dosage level would likely cause a significant reduction in the price of, and hence the profits from, that dosage.”52

Most of the actions discussed above either explicitly or implicitly focus on prescription pharmaceuticals. The FTC has also specifically alleged over-the-counter markets, including hydrocortisone creams and ointments, motion sickness medications, and cough drops in the Pfizer-Pharmacia merger challenge53 and histamine 2 blockers for acid relief in the Glaxo-SmithKline merger challenge.54

Another issue that has affected market definition is availability of generic forms of a drug. The Propofol market alleged in the Baxter-Wyeth matter explicitly included both the pioneer drug (manufactured by a company not involved in the transaction) and generics in the same market in challenging a merger between generic actual or potential competitors.55 That case and others have also challenged mergers combining branded and generic drugs.56


On the other hand, in at least one merger and two nonmerger cases, the agency has defined generic-only markets. In one early case, in a concurring statement, one Commissioner suggested that while it may seem obvious that two bio-equivalent drugs must be in the same relevant product market, “branded drugs and their generic counterparts typically vary dramatically in price, suggesting that consumers may not view the products as equivalent or interchangeable.” She suggested that “[t]his price differential may be greatest where there is intense price competition among different generic versions of a drug.” Most recently, in challenging Pfizer’s acquisition of Pharmacia, the agency included private-label products in certain markets and noted that generics accounted for “a significant share of the market,” but at the same time the FTC alleged the generics had “limited competitive significance and virtually no impact on the pricing,” or “do not constrain the pricing of the branded products.” These statements suggest confusion in the agency’s approach to market definition because if substitution to an alternative product does not constrain price, the alternative is generally excluded from the market.

A review of nonmerger matters is also instructive to understand FTC thinking. In October 2002, the Commission issued a final order in another matter involving Biovail (in this case as a pioneer manufacturer), involving an alleged wrongful listing of a patent in the FDA “Orange Book.” There the Commission alleged a market for Tiazac, a diltiazem-based prescription drug taken once a day to treat high blood pressure


59 In Dow Chem. Co & Marion Merrell Dow Inc., File No. 941-0019, 1994 FTC Lexis 86 at ¶7 (FTC May 24, 1994) (proposed consent) (Owen, Cmm’r, concurring) (“In general, where the price differential between the branded product and the generic product is great, the products are more likely to be in separate markets. Conversely, where the price gap between the branded product and the generic product is relatively small (for example, where there is only one generic version available to consumers), the products are more likely to be in the same market.”).

(hypertension) and chronic chest pain (angina), including generic bioequivalent versions of Tiazac. The Commission explained that other therapeutic agents could be used to treat hypertension and angina, including other branded and generic formulations of once-a-day diltiazem, but asserted those drugs “do not significantly constrain Tiazac’s pricing.” In contrast, the Commission alleged entry of a generic version of Tiazac “likely would result in a significant, immediate decrease in the sales of branded Tiazac and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents.” Thus Biovail was alleged to have a 100 percent market share and monopoly power in the relevant market.61

The FTC challenges to agreements among firms involved in patent litigation have garnered perhaps the most attention.62 In each of these cases, the product market definition alleged is similar, limited to the pioneer drug and its generic equivalents. In Abbott/Geneva, the FTC alleged a market of terazosin hydrochloride, used principally to treat benign prostatic hyperplasia or enlarged prostate, bioequivalent to Abbott’s Hytrin. The FTC complaint there alleged that “[o]ther drugs are not effective substitutes . . . because they are different in terms of chemical composition, safety, efficacy, and side effects” and “[i]n addition, there is little price sensitivity between terazosin HCL and non-terazosin HCL products.”63 In Hoechst/Andrx, the Commission alleged a market of once-a-day time-release diltiazem in capsule form, designed to be taken once every twenty-four hours. The Commission noted diltiazem belongs to a group of drugs known as calcium channel blockers, used principally to treat hypertension and to decrease the occurrence of angina. The agency complaint alleged that “[o]ther calcium channel blockers are not acceptable substitutes” for several reasons, including differences in efficacy and side effects and risks associated with switching


patients from one calcium channel blocker to another. Notably, however, there is no allegation that the loss of new patients to alternative channel blockers (even if current patients were locked in) would render a price increase unprofitable.

In the one Commission litigated case, against Schering-Plough and Upsher-Smith (the one case challenging a permanent settlement of litigation as opposed to an “interim” settlement), the Commission likewise alleged a market of a single drug and bioequivalent generics. The Commission alleged a market of 20 milliequivalent extended-release potassium chloride tablets and capsules, used to treat patients with depleted potassium levels. The complaint asserted that such patients have “no practical substitute for potassium chloride supplements” and “[f]or clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride.” The complaint asserted further that “[t]he existence of other potassium chloride products has not significantly constrained Schering’s pricing of K-Dur 20.” According to the complaint, Schering’s K-Dur 20 had 100 percent of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules.

The Schering case is currently on appeal to the full Commission after the ALJ found, inter alia, that “Complaint Counsel failed to prove or properly define the relevant product market.” The ALJ found that the there are many “therapeutically equivalent” products, and concluded that the relevant product market must be all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. The ALJ noted that advertisements urged doctors to substitute two 10 mEq pills for a 20 mEq pill and emphasized that the staff’s

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65 Id.


expert did not systematically study relative prices or rebates, in rejecting complaint counsel’s narrower proposed market. 68

IV. PRODUCT MARKET IN LITIGATION

With little explanation of product market in most of the government cases resolved through consent agreement, one must look to litigation for additional illumination. Case law teaches that (1) market definition is critical to the outcome of antitrust litigation, (2) the burden of proof on market definition is on the government or private antitrust plaintiff, and (3) market definition is seldom resolved early in litigation, though judicial standards do leave room for dismissing cases based on unsustainable market definition allegations.

A. Market Definition Is Critical to the Outcome of Antitrust Litigation

Market definition is often critical to the outcome of antitrust cases, whether brought under the Sherman Act, the Clayton Act, or the Federal Trade Commission Act. 69 Unilateral conduct, including filing of baseless patent infringement claims, does not raise antitrust concern unless the firm engaging in the conduct is a monopolist or its conduct creates a dangerous probability that it will become a monopolist. Similarly, most forms of joint conduct, including agreements to settle litigation and mergers, pose no harm to competition in the absence of market power. In most cases, therefore, it is necessary to define a relevant market.

It has long been recognized that, other than for conduct that is illegal per se without inquiry into actual effect, “rule of reason” analysis under Section 1 of the Sherman Act generally requires a detailed examination of a challenged agreement’s effect in a well-defined market. Without defining the market, there is no meaningful context in which to assess a restraint’s competitive effects. 70 If adverse effects are “obvious” and


69 See, e.g., Robert Pitofsky, New Definitions of Relevant Market and the Assault on Antitrust, 90 COLUM. L. REV. 1805, 1807 (1990) (“Knowledgeable antitrust practitioners have long known that the most important single issue in most enforcement actions—because so much depends on it—is market definition.”).

70 See, e.g., State Oil Co. v. Khan, 522 U.S. 3, 10 (1997) (“[M]ost antitrust claims are analyzed under a ‘rule of reason’...”); Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984) (rule of reason requires “an inquiry into market power and market structure designed to assess the combination’s actual effect”); Continental T.V.,
procompetitive effects are “implausible” or there is “proof of actual detrimental effects, such as a reduction of output,” restraints may be condemned under a “quick look” analysis without defining the relevant market because market power is but “a surrogate for detrimental effect.” The Supreme Court has made clear, however, that an abbreviated analysis is appropriate only where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question have an anticompetitive effect on customers and markets.”

Proof of the relevant market is similarly an essential element of any claim for monopolization or attempted monopolization under Section 2 of the Sherman Act. The Supreme Court has made clear that “[w]ithout

Inc. v. GTE Sylvania Inc., 433 U.S. 36, 45 (1977) (restraint must be examined “in light of the competitive situation in ‘the product market as a whole’”); Tanaka v. Univ. of S. Cal., 252 F.3d 1059, 1063 (9th Cir. 2001) (“A restraint violates the rule of reason if the restraint’s harm to competition outweighs its procompetitive effects. The plaintiff bears the initial burden of showing that the restraint produces ‘significant anticompetitive effects’ within a ‘relevant market.’”); California Dental Ass’n v. FTC, 224 F.3d 942, 952 (9th Cir. 2000) (“Proving injury to competition in a rule of reason case almost uniformly requires a claimant to prove the relevant market and to show the effects of competition within that market.”); Polygram Holding, Inc., FTC Docket No. 9298, slip op. at 29 (July 24, 2003) (“In most cases, conduct cannot be adjudged illegal without an analysis of its market context to determine whether those engaged in the conduct or restraint are likely to have sufficient power to harm consumers.”), available at http://www.ftc.gov/os/2003/07/polygramopinion.pdf.


72 California Dental Ass’n v. FTC, 526 U.S. 756, 770 (1999). See also Polygram Holding, Inc., slip op. at 29 (A “plaintiff may avoid . . . the pleading and proof of market power if it demonstrates that the conduct at issue is inherently suspect owing to its likely tendency to suppress competition” but such analysis is only appropriate for conduct where “past judicial experience and current economic learning have shown to warrant summary condemnation.”), available at http://www.ftc.gov/os/2003/07/polygramopinion.pdf. At the same time, California Dental teaches that there is “no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment,” suggesting that a long, lingering look, short of “the fullest market analysis,” might be sufficient in some cases and that not “every case attacking a less obviously anticompetitive restraint . . . is a candidate for plenary market examination.” California Dental, 526 U.S. at 779–81. The FTC has also suggested that, depending on the circumstances and the degree to which courts have experience with similar restraints, a quick look “may or may not require evidence about the particular market at issue.” Polygram Holding, Inc., supra, at 32.
a definition of [the] market there is no way to measure [a defendant’s] ability to lessen or destroy competition. 73

Proof of market definition is also essential to a plaintiff’s case under Section 7 of the Clayton Act, which prohibits mergers and acquisitions the effect of which may be substantially to lessen competition “in any line of commerce . . . in any section of the country.” The Supreme Court has explained that “[d]etermination of the relevant product and geographic markets is a ‘necessary predicate’” to a Section 7 claim. 74 Under the government’s Merger Guidelines, one must ask whether a transaction will significantly increase concentration in a relevant market and create market power, allowing the combined firm, unilaterally or through coordinated action, to raise price above competitive levels. 75

The Federal Trade Commission enforces the Sherman and Clayton Acts through the FTC Act’s prohibition on “unfair methods of competition.” Although the reach of Section 5 of the FTC Act is generally viewed as coextensive with that of the Sherman and Clayton Acts, the Supreme Court has held that the Commission may “define and proscribe an unfair competitive practice, even though the practice does not infringe either the letter or the spirit of the antitrust laws.” 76 Nonetheless, the Comm-

73 Walker Process Equip., Inc. v. Food Mach. and Chem. Corp., 382 U.S. 172, 177 (1965). See also Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 455–56, 459 (1993) (“[T]o establish monopolization or attempt to monopolize under §2 of the Sherman Act, it [is] necessary to appraise . . . the relevant market for the product involved.”); United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966) (“The offense of monopoly under §2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power . . . .”); United States v. Microsoft Corp., 253 F.3d 34, 50, 81 (D.C. Cir.) (en banc) (“A court’s evaluation of an attempted monopolization claim must include a definition of the relevant market. Such a definition establishes a context for evaluating the defendant’s actions as well as for measuring whether the challenged conduct presented a dangerous probability of monopolization”); Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1355 (Fed. Cir. 1999) (relevant market is “an indispensable element of any monopolization . . . case”).


75 U.S. Dep’t of Justice & Federal Trade Comm’n, Horizontal Merger Guidelines § 1.0 (1992) (“[T]he likely competitive impact of a merger [must be evaluated] within the context of economically meaningful markets; i.e., markets that could be subject to the exercise of market power”), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,104 [hereinafter Horizontal Merger Guidelines].

sion’s efforts to extend the FTC Act into areas beyond the limits of the Sherman and Clayton Acts have often been struck down,77 and the Commission has held that “[w]hile Section 5 may empower [it] to pursue those activities which offend the ‘basic policies’ of the antitrust laws, we do not believe that power should be used to reshape those policies when they have been clearly expressed and circumscribed.”78 Thus, the Commission generally relies upon Sherman Act and Clayton Act market definition principles in condemning particular practices.79

Importantly, standards for determining relevant market are the same under the various antitrust statutes, and courts routinely rely on cases decided under one statute when deciding cases under the other statutes. The Supreme Court has in fact explicitly held that there is “no reason to differentiate between ‘line of commerce’ in the context of the Clayton Act and ‘part of commerce for purposes of the Sherman Act.”80 And

77 See, e.g., Boise Cascade Corp. v. FTC, 637 F.2d 573 (9th Cir. 1980); Official Airline Guides, Inc. v. FTC, 630 F.2d 920 (2d Cir. 1980); E.I. du Pont de Nemours & Co. v. FTC, 729 F.2d 128 (2d Cir. 1984).
80 United States v. Grinnell Corp., 384 U.S. 563, 573 (1966). See also Apani Southwest, Inc. v. Coca-Cola Enters., 300 F.3d 620, 627 (5th Cir. 2002) (“The same test applied for determining the relevant product and geographic markets for Clayton Act claims is also used for alleged violations of the Sherman Act.”); Image Technical Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1204 n.3 (9th Cir. 1997) (noting that “[t]he Supreme Court has held that its precedent relating to the ‘line of commerce’ under § 7 of the Clayton Act applies to market definition under the ‘part of commerce’ language in the Sherman Act”); Hornsby Oil Co. v. Champion Spark Plug Co., 714 F.2d 1384, 1393 n.9 (5th Cir. 1983) (“Basic principles governing definition of the relevant product and geographic markets in section 2 cases may be applied in actions arising under section 1 of the Sherman Act, and section 7 of the Clayton Act.”); Borden, Inc. v. FTC, 674 F.2d 498, 509–10 (6th Cir. 1982); Photovest Corp. v. Fotomat Corp., 606 F.2d 704, 712 (7th Cir. 1979) (“The relevant factors for defining the market in a § 2 Sherman Act case are similar to those used to define the market in a § 7 Clayton Act case.”); United States v. Engelhard Corp., 970 F. Supp. 1463 (M.D. Ga. 1997) (“The standards applied in Sherman Act cases for defining the relevant product market are the same as in cases involving Section 7 of the Clayton Act.”), aff’d, 126 F.3d 1302 (11th Cir. 1997); United States v. Syufy Enters., 712
the FTC relied on the Merger Guidelines in defining the market in its most recent monopolization decision.  

B. THE GOVERNMENT AND PRIVATE ANTITRUST PLAINTIFFS  
B E A R  T H E  B U R D E N  O F  P R O O F  O N  M A R K E T  D E F I N I T I O N  

The burden of establishing the relevant market falls on the government or private plaintiff in federal court and on the FTC staff supporting an administrative complaint, known as “complaint counsel.” As explained in one recent case, “any gap in the evidence is a flaw in plaintiff’s case—not defendants.”

C. COURTS Seldom RESOLVE MARKET DEFINITION EARLY IN LITIGATION, THOUGH MAY DISMISS BASELESS CASES  

Despite the critical importance of product market to antitrust cases, it is the rare case in which market definition issues are resolved early in the litigation.

Because relevant market determinations are fact-intensive, and courts must accept the allegations in the complaint as true and construe them in the light most favorable to the plaintiff on motions to dismiss, courts are often reluctant to grant such motions directed to the way the market is defined, at least where the plaintiff has alleged a market.

F. Supp. 1386, 1396 (N.D. Cal. 1989) (“The relevant market is generally the same for cases brought under either Section 2 of the Sherman Act or Section 7 of the Clayton Act.”), aff’d 2903 F.2d 659 (9th Cir. 1990); U.S. Dep’t of Justice & Federal Trade Comm’n, Antitrust Guidelines for Collaborations Among Competitors § 3.32(a) (2000) (“[F]or goods markets affected by a competitor collaboration, the Agencies approach relevant market definition as described in Section 1 of the Horizontal Merger Guidelines.”), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,161.


See, e.g., United States v. Microsoft Corp., 253 F.3d 34, 50, 81 (D.C. Cir. 2001) (plaintiffs have the burden to “define the relevant market”); Double D Spotting Serv., Inc. v. Supervalu, Inc., 136 F.3d 554, 560 (8th Cir. 1998) (“It is the plaintiff’s burden to define the relevant market.”); Brokerage Concepts, Inc. v. U.S. Healthcare, Inc., 140 F.3d 494, 515 (3d Cir. 1998) (“The burden is on the plaintiff to define both components [product and geographic] of the relevant market.”); R.R. Donnelley & Sons Co., 120 F.T.C. 36, 38 (1995) (“Complaint Counsel bear the burden of proving a relevant market within which anticompetitive effects are likely as a result of the acquisition.”); Adventist Health Sys., 117 F.T.C. 224, 297 (1994) (dismissal of complaint by ALJ affirmed because “Complaint Counsel failed to carry the burden of proof” on market definition).


Todd v. Exxon Corp., 275 F.3d 191, 199–200 (2d Cir. 2001) (“Because market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure to plead a relevant product market.”); Double D Spotting Serv., Inc. v. Supervalu, Inc., 136 F.3d 554, 560 (8th Cir. 1998) (“Most often, ‘proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers.’ This general rule, however, does not amount to ‘a per se prohibition against dismissal of antitrust claims for failure to plead a relevant market under Fed. R. Civ. P. 12(b)(6).’”); In re
A number of courts have held, however, that bare legal conclusions are not enough to survive a motion to dismiss. The Third Circuit has suggested a minimal pleading standard that should allow courts to dismiss complaints based on market definition allegations that are internally inconsistent or nonsensical. In *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, the court explained:

> Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff’s favor, the relevant market is legally insufficient and a motion to dismiss may be granted.

Other courts have granted motions to dismiss where the plaintiff’s product market allegations failed to explain why apparent substitutes were not interchangeable or were conclusory, internally inconsistent, or implausible. Thus, unsupported narrow product market allegations may...
be dismissed. This approach is consistent with the Supreme Court’s caution that in an antitrust case “a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.”

Motions for summary judgment based on the plaintiff’s failure to establish a product market are more common. Of course, even at that stage, “[t]he evidence of the [plaintiff] is to be believed, and all justifiable inferences are to be drawn in [the plaintiff’s] favor.” Thus, summary adjudication is inappropriate where the pertinent economic facts are disputed.

The reluctance of some courts to grant summary judgment can be seen in Mutual Pharmaceutical Co. v. Hoechst Marion Roussel, Inc. The plaintiff there alleged monopolization based on manipulation of the FDA and pled a market of terfenadine, a non-sedating antihistamine sold under the brand name Seldane. The defendant moved for summary judgment on the ground that terfenadine competes with other antihistamines. The court found that such drugs treat the same symptoms, have similar mechanisms of action, are priced similarly, and are aggressively marketed and promoted against one another. Mutual even conceded that terfenadine “competes with other non-sedating antihistamines for some consumers” but asserted a relevant market of “consumers for whom only terfenadine provides therapeutic relief.” The court agreed that the plaintiff had produced evidence that terfenadine had “unique therapeutic benefit to some consumers.” Therefore, despite finding other drugs

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(CCH) ¶ 73,779 (E.D. Pa. 2002) (“[W]here a ‘complaint fails to allege facts regarding substitute products, to distinguish among apparently comparable products, or to allege other pertinent facts relating to cross-elasticity of demand,’ a motion to dismiss may be properly granted.”); Adidas Am., Inc. v. NCAA, 64 F. Supp. 2d 1097, 1103 (D. Kan. 1999) (plaintiff “failed to explain or even address why other similar [products] . . . are not reasonably interchangeable”); Synesoft, Inc. v. Sequential Software, Inc., 50 F. Supp. 2d 318, 325, 327–33 (D.N.J. 1999) (“[a]n antitrust plaintiff must plead facts sufficient to demonstrate a viable relevant market” and “explain its rationale for ignoring other existing or potential sources of supply”; plaintiff did not state in its pleading that defendant’s product was “unique” and “inexplicably ignored the broader . . . market”); B.V. Optische v. Hologic, Inc., 909 F. Supp. 162, 171–72 (S.D.N.Y. 1995) (rejecting market for chest equalization radiography based on the failure of the complaint to “refer to any reasonably interchangeable alternatives” or to “offer an explanation” as to why the product market was defined “in such narrow terms”).


90 Under the federal rules, summary judgment will be entered “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56.


92 1997-2 Trade Cas. (CCH) ¶ 72,001 (E.D. Pa. 1997).
“largely compete for the same customers,” and without suggesting a price discrimination theory, which might justify a narrower market in such circumstances, the court concluded that whether a relevant market for terfenadine exists “can only be decided on a full record at trial.”

Other courts have held, however, that market definition is an appropriate issue for summary judgment where relevant economic facts are not in dispute or where the antitrust plaintiff with the burden of proof provides only conclusory support for its alleged market. Courts hearing cases involving pharmaceutical products should follow these precedents.

V. ARE PHARMACEUTICAL MARKETS DIFFERENT?

The first question that one must ask in order to analyze market definition in cases involving pharmaceuticals is whether pharmaceutical markets are different—that is, do or should different rules apply to pharmaceutical markets. The case law offers two different answers. There are at least some cases that start from the premise that “the pharmaceutical market is fundamentally different from the market for other products.” On the other hand, the Supreme Court has long taught that while “[t]he ‘market’ which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration, . . . [t]he tests are constant.” Markets are composed of products that “have reasonable interchangeability for the purposes for which they are intended.”

93 Id. at 80,944–46; see also Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 547 (D.N.J. 2000) (“The relevant market element of an antitrust claim ‘can be determined only after a factual inquiry into the commercial realities’ of the market.

94 See, e.g., PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 107 (2d Cir. 2002) (summary judgment affirmed where there was “no discrete class of customers that has such a strong preference for [product] that it would not consider substitutes if other factors (especially price) changed” and there was a “high sensitivity to price change”); Golan v. Pingel Enter., Inc., 310 F.3d 1360, 1369 (Fed. Cir. 2002) (antitrust plaintiff “failed to provide sufficient evidence to establish a relevant market . . . only conclusory allegations”); Levine v. Cent. Florida Med. Affiliates, 72 F.3d 1538, 1551–53 (11th Cir. 1996) (holding that plaintiff’s “narrow definition of the relevant product market does not satisfy his burden of presenting prima facie evidence of the relevant market”); Rebel Oil Co. v. Atl. Richfield Co., 51 F.3d 1421, 1435 (9th Cir. 1995) (If plaintiff’s “evidence cannot sustain a jury verdict on the issue of market definition, summary judgment is appropriate.”); W. Parcel Express v. United Parcel Serv. of Am., Inc., 65 F. Supp. 2d 1052, 1057–60 (N.D. Cal. 1998) (plaintiff failed to produce evidence rebutting defendant’s proof that customers viewed services as a broad “continuum of . . . options and prices”), aff’d, 190 F.3d 974 (9th Cir. 1999).


produced—price, use and qualities considered.” Indeed, these principles were recognized by the Third Circuit in one of the few appellate decisions addressing pharmaceutical market definition, SmithKline Corp. v. Eli Lilly & Co.

Thus, in defining markets—including pharmaceutical markets—Supreme Court precedent requires the application of common market definition principles. Thus, one must examine evidence of “reasonable interchangeability of use” and “cross-elasticity of demand” as well as the Brown Shoe “practical indicia” or “evidentiary proxies” for direct proof of substitutability. Those indicia include “industry or public recognition...the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.” For more than twenty years, practitioners have also followed the government’s Merger Guidelines, which require one to examine whether a “small but significant and nontransitory” price increase would cause enough buyers to shift to other products so that the increase would be unprofitable for a hypothetical monopolist. This test, called the “SSNIP test,” is now used regularly by the courts, as well as by the enforcement agencies.

97 du Pont, 351 U.S. at 404.
99 Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962); Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 218 (D.C. Cir. 1986). While the Brown Shoe factors are certainly relevant to market definition, it is important to recognize that some of those factors are more important than others. Market analysis requires more than tabulating how many Brown Shoe factors support a proposed definition.
100 Horizontal Merger Guidelines, supra note 75, § I.11.
101 See United States v. Sungard Data Sys., Inc., 172 F. Supp. 2d 172, 182, 190 (D.D.C. 2001) (“in order to determine the relevant market, the critical question is whether a hypothetical monopolist could profitably raise price,” noting the Merger Guidelines’ “methodology has been adopted by the courts”); United States v. Visa USA, Inc., 163 F. Supp. 2d 322, 335 (S.D.N.Y. 2001) (“a market is properly defined when a hypothetical profit-maximizing firm could charge significantly more than a competitive price, i.e., without losing too many sales to other products to make its price unprofitable”); FTC v. Swedish Match, 131 F. Supp. 2d 151, 160 (D.D.C. 2000) (noting “one way to evaluate price sensitivity is to apply the...Horizontal Merger Guidelines’ ‘hypothetical monopolist’ test”); California v. Sutter Health Sys., 130 F. Supp. 2d 1109, 1120 (N.D. Cal. 2001) (examining whether firms could “profitably impose at least a ‘small but significant and nontransitory’ increase in price,” noting “[a]lthough the Merger Guidelines are not binding, courts have often adopted the standards set forth in the Merger Guidelines in analyzing antitrust issues”); FTC v. Staples, Inc., 970 F. Supp. 1066, 1076 n.8 (D.D.C. 1997) (adapting 5% test). But see United States v. Engelhard Corp., 970 F. Supp. 1463, 1467–68, 1484 (M.D. Ga.), (noting Merger Guidelines “are not binding on the courts,” and commenting that the government’s “steadfast application of the [5–10%] test as the foundation of its market definition analysis resulted in a pervasive failure to acknowledge relevant information through the evidence of record”), aff’d 120 F.3d 1302 (11th Cir. 1997).
VI. WHO IS THE CUSTOMER?

In order to address whether customers will switch to alternative products, one must first answer the question: “Who is the customer?” Even on this basic question, the case law provides conflicting answers.

The district court in *In re Cardizem CD Antitrust Litigation* suggests focusing on the alternatives available to the patient. According to the court, once a physician prescribes a particular drug, a “consumer patient” may only purchase that drug or its FDA-approved AB-rated bioequivalent. Emphasizing that the relevant market for antitrust purposes is determined by the choices available to “the consumer,” the court noted that “no . . . patient who entered a U.S. pharmacy with a physician’s prescription for [a particular drug] could obtain any drug other than [that prescribed].” Complaint counsel in *Schering-Plough* similarly focus on the patient, suggesting “the requirement that a physician must approve switching a prescription . . . prevents significant switching.”

Other courts have for many years focused on the options available to the “prescribing physician.” The administrative law judge in *Schering-Plough* similarly concluded that the “doctor is the most important in the chain of those involved in the decision of which [drug] to prescribe” since the doctor diagnoses and is knowledgeable about what drugs are available to meet the patient’s needs. He reasoned that “the only logical place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor.”

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104 Id. at 680–81. This discussion in *Cardizem* is arguably dictum, as the court held the agreement at issue between a pioneer manufacturer and prospective generic competitor not to compete to be per se unlawful, making market definition irrelevant. Id. at 676–79, 681 n.33. Moreover, even that court recognized “physician[,] prescribing practices” are relevant to defining the relevant market. Id. at 680.


106 See, e.g., SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063–64 (3d Cir. 1978); see also United States v. Glaxo Geigy Corp., 508 F. Supp. 1118, 1126 (D.N.J. 1976) (“The process of marketing specialty drugs is largely directed at the prescribing physician. While the doctor is not the consumer of the product, the patient-consumer is generally legally incompetent to choose between different medications.”).

The Third Circuit in *Barr Laboratories, Inc. v. Abbott Laboratories,* in fact, upheld jury instructions advising that “[i]n the case of prescription drugs . . . the person who selects the particular product in the first instance is the prescribing physician.” The trial court there instructed the jury that it should include in the relevant market drugs reasonably interchangeable in meeting the needs of patients. Barr argued that the instructions impermissibly removed from the jury the decision whether the physician or the pharmacist was the consumer from whose perspective the relevant market should be determined. The Third Circuit, however, upheld the instruction as accurately informing the jury that the evidence established that both physicians and pharmacists play a role in selecting a particular drug for patients. The court reasoned that the jury was left free to decide whether the pharmacist, the physician, or both should be considered the consumer for purposes of defining the relevant market.

Third-party payers, including insurance companies and managed care organizations, as well as PBMs acting on their behalf, are increasingly influencing the choice of pharmaceuticals, as discussed above. Therefore, in the future, actions of pharmacists, patients, and third-party payers, as well as physicians who influence selection of particular drugs, will have to be considered in defining markets.

VII. DOES PRICE MATTER?

A key question in defining markets is the extent to which customers shift their purchases in response to changes in price. This analysis is complicated in the case of pharmaceutical markets because—like other health care markets—they are sometimes said to be unresponsive to price because of the complex interactions among providers, patients and payers (who may be the patient, a third-party payer, or a combination of the two where the patient is required to make co-payments).

Twenty-five years ago, the trial court in *SmithKline* reasoned that price has little to do with physician prescribing practices. The court colorfully stated, “The blunt truth is that most physicians and hospital administrators, in their daily practice, are no closer to the cost-benefit analysis advocated by [the expert] than are little leaguers equal to the performance of the National League All-Star baseball team.” The court suggested that “[p]erhaps in the long run there will be some massive receptivity” to cost-conscious drug therapy that will dramatically alter...

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109 Id. at 115–16.
110 See supra notes 22–25 and accompanying text.
the prescribing habits of physicians. However, the court reasoned it must define the market on the basis of consumer-physician practices, “whether their practices are rational, irrational, or unnecessarily costly.” At about the same time, the FTC seemed to be wishing for price responsiveness. The Commission in one fully adjudicated case reasoned, “we cannot assume that all physicians are so fixed in their prescribing habits that a substantial increase in the existing price differential . . . would never cause some shift . . . [W]e can take notice that some physicians, even if a minority, are conscious of price differences . . . we see no reason to believe that price would never enter into some physicians’ decisions.”

Cross-elasticity of demand is often, of course, a critical factor in defining markets. That is, courts regularly consider “the extent to which consumers will change their consumption of one product in response to a price change in another.” The relevant inquiry is not whether products compete against each other in some broad sense, but whether products are “sufficiently substitutable that they could constrain” each other’s prices. The Supreme Court in du Pont explained that “[i]f a slight decrease in the price of cellophane causes a considerable number of customers of other flexible wrappings to switch to cellophane, it would be an indication that a high cross-elasticity of demand exists between them; that the products compete in the same market.” Thus, in Smith-Kline, the Third Circuit emphasized that “cephalosporins and non-cephalosporin anti-infectives do not demonstrate significant positive cross-elasticity of demand,” in concluding that these classes of antibiotics were in separate antitrust markets.

VIII. MUST PRODUCTS BE IDENTICAL?

It is well recognized that products need not be identical to be in the same market. This principle is well established. The Supreme Court’s du Pont decision teaches simply that it is not “a proper interpretation of

112 Id. at 1118.
113 Id.; see also United States v. Ciba Geigy Corp., 508 F. Supp. 1118, 1153 (D. N.J. 1976) (“When the physician prescribes, he is casting his drug decision in terms of therapeutic efficiency and not in terms of price if indeed he is aware of price variations among identical drugs. Perhaps a wide price variation resulting in patient complaints might influence the physician’s choice, but a small price differential will not. The blunt fact is that patients do not ‘shop’ for ethical pharmaceuticals.”).
116 Coca-Cola Bottling Co. of the Southwest, 118 F.T.C. 452, 541 (1994).
118 575 F.2d 1056, 1064 (3d Cir. 1978).
the Sherman Act to require that products be fungible to be considered in the relevant market."\textsuperscript{119} In any market with some degree of product differentiation, goods of a single brand will enjoy a certain degree of uniqueness, but that fact, without more, does not suffice to establish that the manufacturer enjoys monopoly power.\textsuperscript{120} As Judge Posner has noted, “[i]t would not be surprising . . . if every manufacturer of brand name prescription drugs had some market power.”\textsuperscript{121} That, however, is to say nothing more than every differentiated product has a downward-sloping demand curve.

The Supreme Court recognized in \textit{du Pont} that “[w]here there are market alternatives that buyers may readily use for their purposes, illegal monopoly does not exist merely because the product said to be monopolized differs from others.”\textsuperscript{122} Two products or services are reasonably interchangeable where there is sufficient cross-elasticity of demand.\textsuperscript{123} The Court there concluded that all flexible wrapping materials belonged in the same market, notwithstanding cellophane’s physical advantages.

It should also now be beyond question that preferences by some customers for a particular product is the beginning and not the end of the analysis. Absent an ability to discriminate against the customers with the preference, one must consider whether other customers more willing to switch will protect such infra-marginal customers.

The task in defining the relevant market is to identify products that compete to some substantial degree. As the Third Circuit put it in \textit{SmithKline}: “[D]efining a relevant product market is a process of describing those groups of producers which, because of the similarity of their products, have the ability—actual or potential—to take significant amounts of business away from each other.”\textsuperscript{124} The \textit{SmithKline} court concluded that while there was some overlap in therapeutic capability, there were “sufficiently unique features,” including “significant differences” in effectiveness and toxicity or undesirable side effects between cephalosporins and other antibiotics, to warrant the characterization of cephalosporins as a discrete market. In reaching that

\textsuperscript{119} \textit{du Pont}, 351 U.S. at 394.
\textsuperscript{120} \textit{SMS Sys. Maint. Serv., Inc., v. Digital Equip. Corp.}, 188 F.3d 11, 17 (1st Cir. 1999).
\textsuperscript{121} \textit{In re Brand Name Prescription Drugs Antitrust Litig.}, 186 F.3d 781, 787 (7th Cir. 1999).
\textsuperscript{123} \textit{Brown Shoe Co. v. United States}, 370 U.S. 294, 325 (1962).
\textsuperscript{124} \textit{SmithKline Corp. v. Eli Lilly & Co.}, 575 F.2d 1056, 1063 (3d Cir. 1978).
conclusion, the court emphasized that cephalosporins were generally used to treat specialized (penicillin-allergic) patients.125

IX. MAY A SINGLE DRUG CONSTITUTE AN ANTITRUST MARKET?

It is also now hornbook law that “relevant markets generally cannot be limited to a single manufacturer’s products.”126 Courts are appropriately skeptical of claims that a manufacturer has “monopolized” its own products. The Supreme Court in du Pont explained:

[O]ne can theorize that we have monopolistic competition in every nonstandardized commodity with each manufacturer having power over price and production of his own product. However, this power . . . is not the power that makes an illegal monopoly.127

The Supreme Court’s decision in Eastman Kodak Co. v. Image Technical Services, Inc.128 is sometimes relied upon to support single-firm markets.129 The case can be quoted to the effect that “in some instances one brand of a product can constitute a separate market.”130 That statement, however, must be read in the context of the unique claim at issue there. Kodak involved allegations that the company had tied the sale of service for Kodak machines to the sale of parts and had monopolized and attempted to monopolize aftermarket service for Kodak machines. In effect, the Court said the relevant market might be limited to parts and service for Kodak machines because once customers bought the equipment they were locked into buying only Kodak parts and service.

125 See id. at 1064; see also Mutual Pharm. Co. v. Hoechst Marion Roussel, Inc., 1997 WL 805261, at *3 (E.D. Pa. 1997) (noting evidence to establish that a drug was “a unique chemical compound with particular effectiveness and possibly a distinct set of consumer users”).
126 ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 566 (5th ed. 2002).
128 504 U.S. 451 (1992)
The Court held only that a proposed market in a unique and non-interchangeable derivative product or service cannot be defeated on summary judgment by the assertion that the primary market is competitive, where there were allegations that information and switching costs limited cross-elasticity in the aftermarket. *Kodak* is inapposite where there is no allegation of “lock-in” in an aftermarket.\(^{131}\)

It should not be surprising, therefore, that in *United States v. Ciba Geigy Corp.*,\(^{132}\) the court rejected a narrow hydrochlorothiazide market and instead found a market of all products indicated for the treatment of hypertension.\(^{133}\) The court noted that “different patients react in their own idiosyncratic ways to different drugs or to different combinations of drugs”\(^{134}\) and patients typically were given various dosages and combinations to obtain optimum control of the disease.\(^{135}\) The court concluded that the various medicines were, “from a medical point of view, reasonably interchangeable” and that interchangeability “translated into commercial competition.”\(^{136}\)

Despite the law’s aversion to single firm markets, the FTC appears to start with a presumption of narrow markets. FTC staff members summarized the Commission’s approach as follows:

> In determining a relevant market, the Commission usually will start with a presumption that the market is limited to a specific therapeutic compound and then broaden the market as evidence is available that physicians and hospitals use other compounds as substitutes. If sufficient substitution occurs, the market may be expanded to a whole class of drugs used to treat a particular condition or illness.\(^{137}\)

While this approach sounds much like the Merger Guidelines, the Guidelines in fact examine whether the threat of substitution in response to

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\(^{131}\) See *Hack v. President and Fellows of Yale College*, 237 F.3d 81, 86–87 (2d Cir. 2000) (noting “[c]ourts have consistently refused to consider one brand to be a relevant market of its own when the brand competes with other potential substitutes,” and *Kodak* “concerns are not present” where plaintiffs had “no ‘lock-in’ costs”); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 515 (3d Cir. 1998) (distinguishing *Kodak* where plaintiff did not identify high “switching costs”).


\(^{133}\) Id. at 1155.

\(^{134}\) Id. at 1154 n.28.

\(^{135}\) Id. at 1153–55.

\(^{136}\) Id. at 1154.

\(^{137}\) David A. Balto & James F. Mongoven, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, 54 Food & Drug L. J. 255, 259 (1999); see also Robert E. Bloch et al., *Product Market Definition in Pharmaceutical Mergers*, Antitrust Rep., Sept. 1997, at 17 (“[T]he FTC likely starts with the presumption that the relevant product market is limited to a specific compound or means of interaction and broadens the market only if it has specific evidence of substitutability, such as consumer switching.”).
a price increase would restrain a hypothetical monopolist. Evidence that
sellers base business decisions on the prospect of substitution as well as
evidence buyers have considered shifting purchases is relevant as well
as evidence buyers have shifted purchases in response to relative changes
in price.\textsuperscript{138}

\section*{X. DO GENERICs COMprise A DISTINCT
PRODUCT MARKET?}

Another important question that may have implications beyond the
pharmaceutical industry is whether generics should be treated as forming
a distinct market.

In a 1999 article, two FTC officials explained the Commission’s
approach to this question. They advised that “FTC investigations typically
have found that because of the significant price difference between
generic and brand name versions, an increase in the price of the brand
name version does not lead consumers to switch to the generic version,
and vice versa.”\textsuperscript{139} Thus, they conclude that brand-name and generic
drugs “typically are not in the same product market.”\textsuperscript{140} The FTC’s market
definition allegations, however, are not consistent, sometimes alleging
“generic only” markets, sometimes alleging “branded and generic” mar-
kets, and sometimes alleging “branded only” markets, as discussed
above.\textsuperscript{141}

The court cases that have addressed this issue directly, \textit{In re Cardizem
CD Antitrust Litigation}\textsuperscript{142} and \textit{Geneva Pharmaceuticals Technology Corp. v.
Barr Laboratories, Inc.},\textsuperscript{143} start from the premise that generic drugs are
essentially fungible and interchangeable with their branded bioequiva-
 lent. That is, there is a “government-assured complete interchangeability,”\textsuperscript{144} so that drugs and their AB-rated generics are “identical in all
material respects.”\textsuperscript{145} In order to obtain FDA approval, generic manufac-
turers must demonstrate that their drugs are bioequivalent to the pioneer
drug and have the same active ingredient, conditions of use, route of

\textsuperscript{138} Horizontal Merger Guidelines, \textit{supra} note 75, § 1.1.
\textsuperscript{139} Balto & Mongoven, \textit{supra} note 137, at 259.
\textsuperscript{140} Id.
\textsuperscript{141} See \textit{supra} notes 55–68 and accompanying text.
\textsuperscript{143} 201 F. Supp. 2d 236 (S.D.N.Y. 2002).
\textsuperscript{144} \textit{In re Cardizem CD Antitrust Litig.}, 200 F.R.D. 297, 311 (E.D. Mich. 2001); \textit{see also}
(quotting \textit{In re Cardizem CD Antitrust Litig.}).
\textsuperscript{145} \textit{In re Cardizem CD Antitrust Litig.}, 200 F.R.D. at 310; \textit{see also} Geneva Pharmas. Tech. Corp.,
201 F. Supp. 2d at 267 (quotting \textit{In re Cardizem CD Antitrust Litig.}).
administration, dosage form, strength, and labeling.\textsuperscript{146} By law, generic drugs are sold with the same package insert as the brand-name drug and are subject to the same prescribing indications and warnings.\textsuperscript{147} They may even be able to use the same tablet colors.\textsuperscript{148} As a result, courts have held that “AB-rated generics are freely substitutable and interchangeable with their brand name counterparts.”\textsuperscript{149} Indeed, in many states, pharmacies are allowed, and in some states are required, to substitute generic versions of brand-name drugs absent a contrary instruction from the physician or patient.\textsuperscript{150} Thus, by definition, a drug and its generic bioequivalents are “two interchangeable versions . . . of the same drug product.”\textsuperscript{151} Courts that have addressed the issue have reasoned that since “[a]ntitrust law requires only that the two products at issue be close substitutes for each other,” a drug and its generic bioequivalents necessarily “meet this requirement.”\textsuperscript{152}

Courts have further reasoned that “[m]arket behavior, which shows generics capturing a significant percentage of the branded drug market soon after they are introduced . . . supports the conclusion that the brand and generic drugs are essentially fungible and interchangeable.”\textsuperscript{153} They have also noted that brand-name and generic drugs are sold to the same customers—wholesalers, hospitals, retail pharmacy chains, mail order houses, clinics, and managed care organizations.\textsuperscript{154} The fact that generics are typically priced at a discount compared to pioneer drugs in order

\textsuperscript{147} Id.
\textsuperscript{148} See Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 169 (1995) (commenting that competitors “might be free to copy the color of a medical pill where that color serves to identify the kind of medicine . . . in addition to its source” (citing Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 853, 858 n.20 (1982))); Shire US Inc. v. Barr Labs., Inc., 329 F.3d 348, 355, 358 (3d Cir. 2003) (affirming denial of injunction to block generic drugs with same color scheme as pioneer since court found similarity in appearance enhances patient safety by facilitating compliance with dosing regimens and “promoting psychological acceptance” of generic drugs).
\textsuperscript{150} See Geneva Pharms. Tech. Corp., 201 F. Supp. 2d at 268 (discussing generic substitution); see also Inwood Labs., Inc. v. Ives Labs. Inc., 456 U.S. 844, 847 n.4 (1982) (“Since the early 1970’s, most States have enacted laws allowing pharmacists to substitute generic drugs for brand name drugs under certain conditions.”).
\textsuperscript{151} In re Cardizem CD Antitrust Litig., 200 F.R.D. at 311; see also Geneva Pharms. Tech. Corp., 201 F. Supp. 2d at 268 (quoting In re Cardizem CD Antitrust Litig.).
\textsuperscript{152} In re Cardizem CD Antitrust Litig., 200 F.R.D. at 311; see also Geneva Pharms. Tech. Corp., 201 F. Supp. 2d at 268 (quoting In re Cardizem CD Antitrust Litig.).
\textsuperscript{153} In re Cardizem CD Antitrust Litig., 200 F.R.D. at 311; see also Geneva Pharms. Tech. Corp., 201 F. Supp. 2d at 268 (quoting In re Cardizem CD Antitrust Litig.).
to convince customers to switch to the generic has also been used to support including both in the same market.\textsuperscript{155}

In cases involving other products, courts have sometimes considered price differences between products in finding products to be in different markets,\textsuperscript{156} but the Supreme Court has made clear that the mere fact of price differences is not “determinative.”\textsuperscript{157} Thus, the fact that generic drugs are typically priced lower than branded drugs should not be sufficient to define a separate market. Indeed, in \textit{Nifty Foods Corp. v. Great Atlantic \& Pacific Tea Co., Inc.},\textsuperscript{158} the Second Circuit determined that national and private label waffles were in the same market despite differences in price.\textsuperscript{159} Under the Merger Guidelines or a cross-elasticity test, the proper focus should be on responsiveness to price changes rather than absolute price differences.\textsuperscript{160}

In \textit{Warner-Lambert Co.},\textsuperscript{161} a pharmaceutical merger case litigated in the 1970s, the FTC even rejected the argument that branded and unbranded thyroid drugs should be in separate product markets where there was a lack of price elasticity at existing price levels, reasoning that an increase in the existing price differential may cause a shift in prescribing habits.\textsuperscript{162}

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{155} See \textit{id.} at 260.
\item \textsuperscript{156} See, e.g., \textit{United States v. Aluminum Co. of Am.}, 377 U.S. 271, 276–77 (1964) (emphasizing price differential between copper and aluminum); \textit{U.S. v. Archer-Daniel-Midland Co.}, 866 F.2d 242, 246 (8th Cir. 1988) (finding sugar prices artificially inflated by government price supports such that high fructose corn syrup prices could increase even though products were functionally interchangeable).
\item \textsuperscript{157} \textit{United States v. Continental Can Co.}, 378 U.S. 441, 455 (1964); \textit{see also United States v. E.I. du Pont de Nemours \& Co.}, 351 U.S. 371, 401 (1956) (finding cellophane was in the same market as aluminum foil, waxed paper, and other flexible packaging materials despite costing two to three times more).
\item \textsuperscript{158} 614 F.2d 832 (2d Cir. 1980).
\item \textsuperscript{159} \textit{id.} at 840–41. The Sixth Circuit has similarly held that generic heating, ventilating, and air conditioning parts are in the same market as branded parts, \textit{Tarrant Serv. Agency, Inc. v. Am. Standard, Inc.}, 12 F.3d 609, 614–15 (6th Cir. 1993), and the Ninth Circuit found that branded and private-label bread are in the same market, \textit{William Inglis \& Sons Baking Co. v. Cont’l Baking Co.}, 942 F.2d 1332, 1346 (9th Cir. 1991) (Noonan, J., concurring and dissenting), \textit{modified}, 970 F.2d 639 (1992), \textit{amended by} 981 F.2d 1023 (1992). On the other hand, in one case, the Eleventh Circuit concluded as a matter of law that the relevant market was lightweight generic anchors despite functional interchangeability of Danforth brand anchors finding a lack of significant cross-elasticity and given the “unusual circumstance of severe price discrimination against a distinct group of consumers based solely on brand preference.” \textit{U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.}, 7 F.3d 986, 996–97 (11th Cir. 1995).
\item \textsuperscript{160} In \textit{Nifty Foods}, the plaintiff argued that a private-label market was supported by a lack of sensitivity of demand for brand-name waffles to private-label price changes. 614 F.2d at 840 n.11. The court, however, found the evidence lacking. \textit{id.}
\item \textsuperscript{161} 87 F.T.C. 812 (1976).
\item \textsuperscript{162} \textit{id.} at 877.
\end{itemize}
\end{footnotesize}
On the other hand, in adjudicating a merger between competing soft drink bottlers in 1994, the FTC rejected an “all soft drink” market and excluded private-label soft drinks from the relevant market. After a detailed review of the evidence, the agency there concluded that private label soft drinks did not constrain branded pricing, emphasizing, for example, evidence that private-label soft drinks were not available in certain channels and that branded bottlers did not consider the price of private-label soft drinks in setting prices. The Commission explained that branded soft drinks may constrain nonbranded soft drinks, but nonbranded soft drinks did not constrain branded soft drinks.

The fact that pharmaceutical manufacturers may raise the price of the pioneer drug in response to introduction of low-priced generics has not led to different conclusions. At least one court has reasoned that price increases for branded drugs in response to generic entry demonstrate that “clearly there is some interrelationship” between the generic and branded drugs. Price movements over time are, of course, relevant to market determinations but can be difficult to interpret. With the burden of establishing market definition on the plaintiff, it is particularly important that the plaintiff present expert evidence to establish separate markets where branded and generic drugs are interchangeable.

XI. DOES THE “CELOPHANE FALLACY” REQUIRE A DIFFERENT APPROACH?

A. The Theory

There has been substantial academic criticism that the Supreme Court’s *United States v. E.I. duPont de Nemours & Co.* decision falls into what has become known as the “Cellophane fallacy” or “Cellophane trap.” Professor Herbert Hovenkamp, for example, advises that “the court’s definition of the relevant market was probably wrong.” That is because

163 Coca-Cola Bottling Co. of the Southwest, 118 F.T.C. 452, 574 (1994); see also Coca-Cola Co., 117 F.T.C. 795, 931–40 (1994) (finding branded soft drink concentrate, and not all soft drink concentrate, to be the relevant market for assessing Coca-Cola’s proposed acquisition of Dr Pepper).

164 Id. at 555–74.

165 Id. at 564.


167 See id. (emphasizing that the plaintiff “failed to conduct a formal test regarding the degree of purported differential impact” on price of a competitor’s entry).


169 Herbert Hovenkamp, Federal Antitrust Policy § 3.4b, at 104 (2d ed. 1999); see also Dennis W. Carlton & Jeffrey M. Perloff, Modern Industrial Organization 614 (3d ed. 1999) (“[I]t was an error to include other wrapping materials in the market.
every firm, whether or not a monopolist, will price at a level where further price increases will cause it to lose so many customers that the price increase is unprofitable. Thus, the existence of a high cross-elasticity may be indicative that a firm is currently exercising market power, rather than that it lacks market power. As explained by the Second Circuit:

The economic error allegedly committed by the Court in Cellophane was in failing to recognize that a high cross-elasticity of demand may, in some cases, be the product of monopoly power rather than a belief on the part of consumers that the products are good substitutes for one another. . . . "At a high enough price, even poor substitutes look good to the consumer." That is, in the Cellophane case, the high cross-elasticity between cellophane and wax paper simply may have been a function of the high price that du Pont demanded for cellophane.\textsuperscript{170}

The Supreme Court in du Pont failed to recognize that a monopolist that has reduced output and raised price may price its products so that even inferior substitutes begin to look good to consumers, and may therefore face highly elastic demand.

The difficulty is that determining whether or not the Cellophane fallacy applies is not easy. Some commentators have suggested looking at profitability data to determine whether a firm is earning monopoly profits.\textsuperscript{171} There is ample literature, however, which demonstrates that standard accounting data used to report corporate profits is an unreliable indicator of true economic profits.\textsuperscript{172} Among other problems, defining markets would require one to examine product-line, rather than firm, profitability. In addition, firms with monopoly power may become inefficient, with high costs rather than high profits.

\textsuperscript{170} United States v. Eastman Kodak Co., 63 F.3d 95, 105 (2d Cir. 1995) (citations omitted).


Hovenkamp advises that in deciding whether a group of products belong in the same market, one should consider looking for cost shocks that affect the alleged monopolist but not other firms arguably in the same market.\textsuperscript{173} A “true competitor, who faces a horizontal demand curve, would be unable to respond to a firm specific cost increase by raising price,” while “a firm with a downward sloping demand curve would calculate a new price that equated with its marginal cost and marginal revenues.”\textsuperscript{174} Hovenkamp also suggests looking at past price movements and changes in output of allegedly competitive products.\textsuperscript{175} Carlton and Perloff similarly advise that “a reasonable first step in defining economic markets is to examine the price correlations (a statistical measure of how closely prices move together) among different products.”\textsuperscript{176}

\section*{B. The Cellophane Fallacy in the Courts}

Despite its academic recognition, only a handful of antitrust cases have ever discussed or even mentioned the Cellophane fallacy. The Supreme Court in \textit{Eastman Kodak Co. v. Image Technical Services, Inc.}\textsuperscript{177} recognized the theory, noting that the existence of significant substitution at current prices does not disprove the existence of market power because sellers may already be charging a monopoly price.\textsuperscript{178} But the Court did not suggest any test to determine whether the fallacy applies.

Lower court cases that do discuss the Cellophane fallacy are skeptical of applying it to establish that a firm does have market power without corroborating evidence. The Second Circuit directly addressed the fallacy in a 1995 decision, \textit{United States v. Eastman Kodak Co.}\textsuperscript{179} The court there affirmed a trial court decision to terminate two old consent decrees, concluding that Kodak no longer possessed market power over the sale of film.\textsuperscript{180} The district court found that the relevant geographic market for film is worldwide while the government asserted Kodak still had power in a U.S. film market.\textsuperscript{181} According to the government, Kodak already was pricing its products at monopolistic levels and therefore

\textsuperscript{173} Hovenkamp, \textit{supra} note 169, § 3.4c, at 106.
\textsuperscript{174} Id.
\textsuperscript{175} Id. § 3.4c, at 106–07.
\textsuperscript{176} Carlton \& Perloff, \textit{supra} note 169, at 614.
\textsuperscript{177} 504 U.S. 451 (1992).
\textsuperscript{178} See id. at 471 (“[T]he 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.” (quoting Phillip Areeda \& Louis Kaplow, \textit{Antitrust Analysis} ¶ 340(b) (4th ed. 1988)))
\textsuperscript{179} 63 F.3d 95 (2d Cir. 1995).
\textsuperscript{180} Id. at 109.
\textsuperscript{181} Id. at 102–03.
consumers’ willingness to switch to other brands “actually demonstrates that Kodak possesses market power.”

The appellate court rejected the argument that the district court “fell victim to the Cellophane fallacy.”

The court explained that “the government’s contention assumes that Kodak film is priced well above competitive levels” and reasoned that that view was “simply . . . conjecture” and “not sufficient to call in question” the market definition. The Second Circuit noted in particular that the case before it did not involve highly differentiated products like cellophane and wax paper but rather products of comparable quality, suggesting that the Cellophane fallacy is inapposite where products are “excellent substitute[s].”

Similarly, in *PepsiCo, Inc. v. Coca-Cola Co.*, Pepsi “warn[ed] of the so-called Cellophane fallacy” and argued that Coca-Cola’s pricing to foodservice distributors was “already at a supracompetitive level.” Pepsi alleged Coca-Cola monopolized the market for fountain-dispensed soft drinks distributed through independent foodservice distributors. The court noted, however, that there was no pricing evidence and no evidence of Coca-Cola’s margins in the record, while there was evidence of discounting by Coca-Cola. Because Pepsi’s market definition could not be sustained, its monopolization and attempted monopolization claims failed.

Where a plaintiff merely presumes the existence of the Cellophane fallacy, rather than proving its applicability to the case at hand, courts should continue to reject the argument.

**C. Market Power and Intellectual Property**

A further complication arises in measuring market power where there is intellectual property.

It is well recognized by now, despite some contrary Supreme Court authority, that market power cannot be presumed from the existence

182 Id. at 105.
183 Id.
184 Id. at 105, 107, 108.
185 See id. at 104–05.
186 114 F. Supp. 2d 243 (S.D.N.Y. 2000), aff’d, 315 F.3d 101 (2d Cir. 2002).
187 Id. at 257.
188 Id. at 245.
189 Id. at 258.
190 Id. at 259; see also Aegerter v. City of Delafield, 174 F.3d 886, 892 (7th Cir. 1999) (noting the “'cellophane fallacy'”); Santa Cruz Med. Clinic v. Dominican Santa Cruz Hosp., 1995-2 Trade Cas. (CCH) ¶ 71,254 at 76,096–97 (N.D. Cal. Sept. 7, 1995) (finding that a genuine issue of material fact as to evidence of supracompetitive pricing precludes summary judgment as to the definition of the relevant market where Cellophane fallacy asserted).
of a patent. Like real property, intellectual property gives one only the right to exclude, not a monopoly. Whether or not a patent confers monopoly power depends on the availability of substitutes.191

For many goods protected by intellectual property, the most significant costs are fixed sunk costs incurred in developing the intellectual property that do not vary with the number of goods produced. Marginal costs are often small relative to the costs of initial development. Professors Hovenkamp, Lemley, and Janis offer an example of a copyright-protected movie, costing $150 million to produce, which can be duplicated onto videotape for $2 per copy but sells for $20 per copy.192 They explain that, at a price of $2, the movie “would lose money and a firm that had contemplated such a price would never have made [it] in the first place.”193 Therefore, they conclude that “price-cost relationships on a particular patent or copyright do not provide useful evidence about market power.”194 Accordingly, they argue, the “technically correct way” to measure whether intellectual property produces returns above cost is to compare development costs with profits generated during a product’s marketable life.195 In a high-risk enterprise, moreover, one must take into account failed products as well as those that are successful.196 Thus, focusing on relationships between price and short-run marginal cost cannot be said to provide useful evidence of market power.197


193 Id.

194 Id. § 4.1c, at 4–7.

195 Id. § 4.1c, at 4–6.

196 Id. § 4.1c, at 4–7.

197 Id.
D. Application to the Pharmaceutical Industry

These problems are particularly acute in the pharmaceutical industry which, as discussed above, faces huge research and development costs on drugs that are never introduced as well as on those that become successful, all of which must be recovered over the life of those drugs that are successful. Unlike many industries, for which patents are not an important incentive for innovation, many pharmaceuticals would not be developed but for patent protection. If firms price at short-run marginal cost, one would not expect new research and development leading to the introduction of new drugs.

Notably, the FTC staff has explicitly invoked the Cellophane fallacy in its challenge to the intellectual property litigation settlement agreements in Schering-Plough. Complaint counsel rely on the economic literature that generic drugs typically enter the market at a discount and pioneer drugs lose sales in response to such entry to support their theory that the branded drug had monopoly power. Under mandatory generic substitution laws, however, pharmacists often must dispense AB-rated generics, so it is not surprising that pioneer drugs lose sales and generics gain sales. That phenomenon takes place, however, even where pioneer drugs face good substitutes, and it seems particularly inappropriate to assume the Cellophane fallacy applies where drugs are good therapeutic substitutes. In fact, the same studies show that the price of the brand-name drug typically rises after generic entry. At the same time, the manufacturer of the brand-name drug typically reduces its promotional efforts dramatically. The end result at times may be that output falls rather than rises with generic entry, suggesting a higher average "quality-adjusted" price rather than a price decrease resulting from generic entry.

198 See supra notes 14–18 and accompanying text.


202 See Frank & Salkever, supra note 37, at 82.
Plaintiffs in pharmaceutical cases cannot simply assume the existence of market power from the existence of patents, from pricing above short-run marginal cost, from generic entry at prices below the price of a branded drug, or from reduced output of the branded drug upon generic entry. A plaintiff’s proposed narrow market definition that does not include therapeutic substitutes, like that in *Geneva Pharmaceuticals Technology Corp. v. Barr Laboratories, Inc.*, should be rejected unless the plaintiff presents a “formal test” showing the various drugs’ impact on the price and quantity of sales.\(^{203}\)

**XII. CONCLUSION**

Market definition in the pharmaceutical industry should not be different from that in other industries. The same rules apply. But they must be applied with sensitivity to the industry’s characteristics. It seems most appropriate for the government and courts to begin product market analyses in the industry by focusing on the therapeutic indications, both approved and off-label, for the drugs at issue in any matter. That is, one must consider whether drugs may be substitutes for the treatment of a particular disease or condition, taking into account the drugs’ mechanisms of action, therapeutic profiles, side effects, and methods of administration. The analysis must consider the impact of doctors, pharmacists, patients, and third-party payers on the use of drugs, to analyze the likelihood of switching in response to relative price increases, and the impact of such switching on profitability. While price differences may be considered, one must analyze price movements over time and the impact of such movements on the quantities of drugs sold. Evidence from knowledgeable witnesses and company documents, as well as data, will be relevant as in any other industry. Presumptions based on the existence of patents or experience with other drugs should not substitute for careful analysis of the facts.

\(^{203}\) See *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 201 F. Supp. 2d 236, 270 (S.D.N.Y. 2002); *see also* Bailey v. Allgas, Inc., 284 F.3d 1257, 1247 (11th Cir. 2002) (rejecting plaintiff’s proposed market definition where its expert failed to determine cross-elasticity of demand among possible substitutes); Alcatel USA, Inc. v. DGI Techs., Inc., 166 F.3d 772, 783 (5th Cir. 1999) (rejecting plaintiff’s proposed market definition where plaintiff “never compared [defendant’s] prices to its competitors’ prices”); Lantec, Inc. v. Novell, Inc., 146 F. Supp. 2d 1140, 1147–49 (D. Utah 2001) (rejecting plaintiff’s proposed market definition where there was “no evidence of price sensitivity”), aff’d, 306 F.3d 1003 (10th Cir. 2002).