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Having Our Cake and Eating it Too: Five Things Congress Can Do To Address Anticompetitive Pharmaceutical Conduct and Consolidation

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Hearing on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"
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I. Introduction

A. Drug prices too high; consumers unable to afford needed medicines. Why?
  1. Brand drug companies abuse system by delaying generic entry
    a) Examples: product hopping, pay-for-delay settlements, citizen petitions, biosimilar disparagement
    b) None of this conduct can be justified by patents or innovation
      (1) Like the proverbial boy who cried wolf, the pharmaceutical industry for at least the past 60 years has claimed that every legislative proposal to restrict patents or apply antitrust would decimate innovation.[1]
  2. At the same time, the industry has undergone significant consolidation, which has increased price
    a) In response, the FTC has not blocked mergers but has only required divestitures of overlapping products

B. Congress can address these anticompetitive abuses and consolidation through legislation

II. My Background

A. I have studied pharmaceutical antitrust law as co-author of leading IP/antitrust treatise; author of more than 130 articles (65 on pharmaceutical antitrust law); drafter of 20 "amicus" briefs on behalf of hundreds of professors; and one frequently cited in media (2000+ times) and courts (including Supreme Court)

III. Product Hopping: Harm

A. Brand firms have switched drugs so generics can't be substituted and migrated patients before generic entry
  1. Examples: capsule to tablet, different dosage, single- and dual-scored tablet
  2. Product hopping combines reformulation of product with encouragement of doctors to write prescriptions for new version
    a) No innovation reason: brand does not *expand* prescription base but just *migrates* base to block generics

B. Every time brand changes drug slightly, generic cannot be substituted
  1. Substitution requires "AB rating": generic "therapeutically equivalent" to brand (same active ingredient, form, dosage, strength, safety/efficacy profile) and "bioequivalent" (absorbed into body at same rate).[2]
  2. Product hopping exploits this regulation as minor changes prevent generic from obtaining AB rating
  3. Generic then must start over: reformulate drug, get FDA approval, and fight new set of patents (litigation, automatic 30-month stay)

C. Harms from both "hard switches" (original drug pulled from market) and "soft switches" (original remains)
  1. Greater harms when brand switches before generic enters market (promotion/marketing more effective in convincing doctors to prescribe reformulated version)

D. Product hopping harms consumers
  1. Most recent (2009) empirical analysis found $28 billion worth of drugs subject to product hopping, including Advair, Allegra, Augmentin, Caduet, Clarinex, Kapidex, Lexapro, Nexium, Prozac, Risperdal.[3]
    a) For $1 billion blockbuster drug, consumers pay extra $765 million each year from delayed competition.[4]
  2. Consumers have overpaid $1.7 billion for Namenda, $200 million for Effexor, $700 million/year for TriCor, and (according to legal complaints) $11.5 billion for Nexium and $650 million annually for Suboxone.[5]

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[1] Michael A. Carrier & Genevieve Tung, *The Industry that Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019).

[2] FDA, *Orange Book Preface* (last visited Apr. 25, 2021).

[3] Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1 (2009).

[4] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010) (multiple generics take 90% of sales at average 85% discount).

[5] *New York ex rel. Schneiderman v. Actavis*, 787 F.3d 638, 661 (2d Cir. 2015) (Namenda); *Explainer: Evergreening and How Big Pharma Keeps Drug Prices High*, THE CONVERSATION (Nov. 5, 2014) (Effexor); Kevin Drum, *How To Keep Healthcare Costs High*

3. *E.g.*: Opioid-dependence-treating Suboxone was switched from tablet to sublingual (under-the-tongue) film
   a) Reckitt publicly announced removal of tablets for safety reasons (even though safer than film), waited 6 months to remove, disparaged (and raised price of) tablets, and promoted film to doctors.[6]
   b) *Made no sense*: Raising price of tablets (even though film more expensive) costly, as was warning of false safety concerns, all to receive "substantially reduced profit margins" on $700 million in annual sales![7]

E. Product hopping can harm innovation
   1. No empirical evidence has shown that innovation would be deterred by applying antitrust law
   2. Brand firms often *withhold* incremental innovations from market to use later as part of product hop:
      a) TriCor: Abbott delayed seeking new indication for original product, reserving it for reformulation, even though "data necessary to get the new indication was available much earlier."[8]
      b) Neurontin: Warner-Lambert conceded that "principal reason[] for not seeking FDA approval" for off-label uses was that it "wanted to reserve them for a later promotional campaign for its reformulated product."[9]
      c) Namenda: Forest waited until generic competition for twice-daily Namenda was imminent before introducing once-daily version (even though obtained FDA approval three years earlier!).[10]
      d) If value of "innovation" to consumers was greater than value to brand firm of delaying generic, would immediately introduce innovation to reap increased gains

IV. Product Hopping: Solution

A. Affordable Prescriptions for Patients Act of 2021 offers strong and effective approach to product hopping
   1. Gives FTC power under Section 5 to challenge anticompetitive hard and soft switches
      a) Hard switch = (1) withdraw drug or destroy inventory and impede competition + (2) sell follow-on drug
      b) Soft switch = (1) unfairly disadvantage original and impede competition + (2) sell follow-on drug
      c) Several provisions provide strong support to drug manufacturers:
         (1) Competition window limits liability to reformulations made when generic entry expected
         (2) Exclusions protect promotional marketing and cessation of marketing
         (3) Justifications allowed based on (a) taking action regardless of effect on competition and (b) safety/supply-disruption/procompetitive reasons for switch
   2. Legislation ensures courts recognize harms of soft switches when only reason for change is to harm generic
      a) *Walgreen's* court ignored price disconnect in asserting that AstraZeneca did not "eliminate[] any consumer choices" but instead "added choices," with superiority determinations "left to the marketplace."[11]
         (1) Pharmaceutical markets characterized by "price disconnect": doctor who prescribes product does not pay and consumer/insurer who pays for it does not choose
         (2) This characteristic could reduce choice when patients are switched from original drug (expiring patent, impending generics) to reformulated version (patented, no generics)
      b) *Doryx* court upheld product hop, focusing on competitor rather than consumer even though company "made . . . 'hops' primarily to 'delay generic market entry.'"[12]
      c) Congress is uniquely situated to recognize the harms of soft switches not acknowledged by courts

V. Pay-for-Delay Settlements: Harm

A. Brand firms have colluded with generic companies, paying them to delay entering the market
   1. Alone among anticompetitive pharmaceutical conduct, settling generics align with brands against consumers

B. Patients harmed from collusion, not innovation, as generics delay entry from payment, not patent
   1. FTC has calculated that pay-for-delay settlements cost consumers $3.5 billion a year.[13]
   2. Generics agree to delay entry in return for dropping patent challenge

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in One Easy Lesson, MOTHER JONES (Apr. 18, 2012) (TriCor); Complaint, *Louisiana Wholesale Drug Co. v. AstraZeneca Pharms LP*, (D.D.C. filed Feb. 28, 2007) (Nexium); Complaint, *In re: Suboxone Antitrust Litig.* (E.D. Pa. filed Apr. 13, 2015) (Suboxone).

[6] *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

[7] *Suboxone Complaint* ¶ 38.

[8] Steve Shadowen, Keith B. Leffler, & Joseph T. Lukens, *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 42 IIC 698, 710 (2011) (data "used to get approval for the new indication had been developed in studies for the original product").

[9] *Id.* (noting that Warner-Lambert "was concerned" that generics "would undermine sales" of the new drug).

[10] *Namenda*, 787 F.3d at 647.

[11] *Walgreen v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

[12] *Mylan Pharmaceuticals v. Warner Chilcott*, 838 F.3d 421, 431 (3d Cir. 2016).

[13] FTC, PAY-FOR-DELAY.

a) But most (89%) of the patents at issue in settlements are secondary patents on which the brand firm is less likely to win (32%), as compared to active-ingredient (92%) patents.[14]
b) Examples of settlements on secondary patents: Actos, AndroGel, Cephalon, Effexor, K-Dur, Lidoderm, Loestrin, Niaspan, Opana, Solodyn, Wellbutrin

3. Consumers unable to afford high prices cut pills in half, choose between paying for drugs and food/rent, and do not take needed medicines

VI. Pay-for-Delay Settlements: Solution

A. H.R. 2375, the Preserve Access to Affordable Generics and Biosimilars Act, would play a critical role in stopping anticompetitive settlements
1. Legislation provides that generic receiving "anything of value" for delayed entry is presumptively illegal
a) Common-sense approach reflects Supreme Court's *Actavis* ruling, which broadly considered payment.[15]
b) Important to recognize that "anything of value" includes "an exclusive license"
(1) Settling parties have claimed that subjecting exclusive licenses to potential antitrust liability would be "extraordinary" and "call[] into question the continued viability of any patent litigation settlement."[16]
(2) To the contrary, as the Third Circuit has explained, defendants seek not "a patentee's right to grant licenses" but "a right to use valuable licensing in such a way as to induce a patent challenger's delay."[17]
c) Legislation helpfully rejects mistaken presumptions that courts have adopted that entry will not occur until patent expires and that pre-expiration entry is procompetitive
2. Legislation offers beneficial provisions for defendants:
a) Exception when payment for goods/services or procompetitive effects outweigh anticompetitive effects
b) Exclusion from liability for right to market and secure regulatory approval, payment of reasonable litigation expenses, and covenant not to sue

B. Benefit 1: Standard makes clear that pay-for-delay settlements anticompetitive and helps FTC prove cases in court
1. Payments are taking the form not of cash but of compensation hidden in increasingly obscure corners
2. Treating pay-for-delay settlements as presumptively anticompetitive will deter blatantly illegal conduct that courts do not always recognize and that bogs down the FTC for years in resource-intensive litigation
a) *E.g.*: The FTC's *Actavis* litigation, which did not even involve a trial, took *10 years* to settle.[18]

C. Benefit 2: Legislation addresses judicial errors relating to payment, "scope of patent," and risk aversion. *E.g.*:
1. *AbbVie*: Brand provided generic with drug at price "well below what is customary" but court (despite recognizing deal's "large value") concluded that it "was not a reverse payment."[19]
2. *AbbVie* and Administrative Law Judge in *Impax*: Assumed entry before patent expiration procompetitive (despite Supreme Court's overturning of scope-of-patent test).[20]
3. *Wellbutrin*: Relied on risk aversion defense (rejected by Supreme Court) to dismiss argument that payment size reflects patent weakness.[21]

D. Potential strengthening amendment 1: Make clearer that risk aversion is not legitimate procompetitive justification
1. A new subsection 27(b)(3) could provide that the fact finder shall not presume that "arguments based on the reduction of risk or promotion of certainty mean that the agreement is procompetitive"

E. Potential strengthening amendment 2: Expand H.R. 2375 to private plaintiffs (who litigate most settlement cases), which could address overly strict causation standards so that plaintiffs need not definitively prove patent invalidity (as *Wellbutrin* and *Nexium*[22] courts required)

F. Potential strengthening amendment 3: Expand H.R. 2375 to open 180-day bottleneck, which would have even stronger effect on settlements
1. *E.g.*: H.R. 1506, Fair and Immediate Release (FAIR) of Generic Drugs Act, enlarges category of "first applicants" to include generics obtaining judicial invalidity/noninfringement decision

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[14] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013).

[15] *FTC v. Actavis*, 570 U.S. 136 (2013).

[16] Petition for a Writ of Certiorari, *SmithKline Beecham Corp. v. King Drug Co.*, at 1, 14 (U.S. filed Feb. 19, 2016).

[17] *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405–06 (3d Cir. 2015).

[18] FTC, *Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments,"* Feb. 28, 2019.

[19] *FTC v. AbbVie*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), *aff'd*, 976 F.3d 327 (3d Cir. 2020).

[20] *In the Matter of Impax Labs.*, Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

[21] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017). For a discussion of additional errors in settlement cases, see Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 SANTA CLARA L. REV. 613 (2020).

[22] *In re Nexium Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016). *See generally* Kevin B. Soter, *Causation in Reverse Payment Antitrust Claims*, 70 STAN. L. REV. 1295 (2018).

2. This addresses perversion of Hatch-Waxman Act by which 180-day period has morphed from incentive to invalidate patents to bottleneck blocking entry

VII. Citizen Petitions: Harm

A. Meant to raise legitimate concerns, but really used to delay generic entry, with my empirical study showing that FDA denies 92% of "505(q)" petitions (against pending generic), 98% of late-filed petitions.[23]
B. Concerning examples: Shire ViroPharma's 46 filings, Teva's multiple Copaxone petitions, Bayer's Mirena petition 1 day before patent expiration, Mylan's delayed filing of petition on EpiPen alternative.[24]
C. From 2011 to 2015, 118 petitioners filed 505(q) petitions: *108* brand firms, 4 generic firms, 4 law firms or consultants, but only *2* public interest groups and *0* individuals
D. FDA has shown "concern[] that section 505(q) may not be discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[25]
    1. FDA "remains concerned" that the resources it is forced to incur come "at the expense of completing the other work of the Agency."[26]

VIII. Citizen Petitions: Solution

A. The Stop Stalling Access to Affordable Medications Act is helpful in giving the FTC authority to bring Section 5 claim (and obtain strong penalties) against sham petitions. Benefits:
    1. Finding that delaying conduct is sham could help courts cut through firewall of *Noerr-Pennington* immunity.[27]
    2. Helpful to include as "sham" not only individual petitions but also "series" of such petitions
    3. Beneficial to give FTC Section 5 authority and put stamp of disapproval on abusive citizen petitions
    4. Useful deterrent to impose penalty of drug revenue (while petition under review) or (if larger) $50,000 a day
B. Potential strengthening amendment 1: Add supporting detail to general "sham" conduct
    1. Because of importance of petitioning, courts set high bar before finding sham exception to *Noerr* immunity
    2. Legislation could make clear that sham conduct bears specific markers of abusive behavior
    3. Relevant factors appear in FDA draft guidance[28] on "primary purpose of delay": (a) unreasonable length of time to submit petition; (b) multiple petitions challenging conduct that reasonably could have been known at time of earlier petition; (c) petition submitted close in time to date on which application could be approved; (d) petition submitted without supporting data/information; (e) petition raising same or substantially similar issues as prior petitions that have received response; (f) petition addressing standards for which FDA provided opportunity for public input but petitioner did not comment; (g) petition requesting that other applicants meet standards more rigorous than petitioner; (h) petitioner's history
    4. These factors common in abusive petitions
        a) In my empirical studies, I did not come across sham petitions not covered by these categories
        b) The factors also appear in S. 1895, the Lower Health Care Costs Act (approved 20-3 by Senate HELP Committee in June 2019) and H.R. 2455, the Ensuring Timely Access to Generics Act of 2019
C. Potential strengthening amendment 2: Recognize difficulty of proving subjective prong
    1. The legislation reflects the caselaw's "subjective" prong in a petitioner's use of the governmental process, as opposed to the outcome, to interfere with a rival
        a) But it is difficult to know why a petition is filed, and this information is often shielded by privilege issues
        b) For that reason, the court in *FTC v. AbbVie* made clear that:
            (1) Because of the difficulty of proving state of mind, intent "is usually a matter of inference."[29]
            (2) Subjective intent could be shown by the actions of experienced attorneys filing objectively baseless suits, which makes it "reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did."[30]

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[23] Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305 (2016).

[24] *See id.* at 344–47; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 64–66 (2017).

[25] FDA, REPORT TO CONGRESS: EIGHTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2015, at 8 (2016).

[26] *Id.*

[27] *Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49 (1993); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *E.R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961).

[28] FDA, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*, 2018.

[29] *FTC v. AbbVie*, 329 F. Supp. 3d 98, 125 (E.D. Pa. 2018), *aff'd on this ground*, 976 F.3d 327 (3d Cir. 2020).

[30] *Id.* at 126.

2. Like *AbbVie*, legislation could make clear that:
   a) Evidence of intent can be shown not only through direct evidence but also through indirect evidence
   b) Experienced actors engaging in objectively baseless conduct could satisfy subjective prong

D. Potential strengthening amendment 3: Administrative changes
1. In addition to addressing antitrust liability for sham behavior, legislation could make helpful administrative changes, such as those offered in S. 660, the Efficiency and Transparency in Petitions Act.[31]
2. Because of delayed and serial petitions, require petition to be filed within finite period (60 days) of learning of safety/efficacy issue and mandate explanation for why repetitive petitions filed
3. Because of lack of transparency, require FDA to include comprehensive list of 505(q) petitions in annual reports to Congress, including:
   a) Timing of petition in relation to patents listed in Orange Book
   b) Time FDA expended on petition
   c) Delay (if any) in generic approval caused by petition and determination of how delay calculated
4. Such provisions would be helpful because FDA does not maintain an easily searchable list of 505(q) petitions, nor does it explain what constitutes a "delayed" petition
   a) FDA claims that only one petition each year is delayed, but considers delay only if it responds after 150-day deadline for addressing 505(q) petitions.[32]
   b) FDA does not consider that there could be delay from not approving generic until it resolves petition.

IX. Biosimilar Disparagement: Harm

A. Biosimilars have been subject to disparagement claims in a way that generics have not
1. Because of their complexity, biosimilars differ more from biologics than generics differ from brand drugs
2. Biosimilars also rely on advertising campaigns rather than (as generics do) state substitution laws

B. Biosimilars are legally required to be "highly similar" to and have "no clinically meaningful differences" from biologics.[33]
1. FDA has made clear that "[m]inor differences . . . in clinically inactive components are acceptable,"[34] and even biologics themselves are "not identical batch-to-batch."[35]

C. Despite this, biologic firms have raised safety concerns with biosimilars, using four types of disparagement:
1. Fearmongering: *E.g.*, warning that a switch to a biosimilar could result in "another thalidomide" (which famously caused birth defects) or that a patient "could end up in an emergency room, or be[] hospitalized."[36]
2. Biosimilars act differently: *E.g.*, asserting that biosimilar "can behave differently in the body."[37]
3. Biosimilars not identical: *E.g.*, "no two biologic medicines are identical."[38]
4. Biosimilars not interchangeable: *E.g.*, "Even though infliximab biosimilars are very similar to REMICADE®, that doesn't mean they are interchangeable with REMICADE®."[39]

D. FDA has shown frustration with this conduct
1. Former Commissioner Scott Gottlieb "worried" about "efforts by branded companies to create confusion" about biosimilars' safety and effectiveness.[40]
   a) These messages "can potentially undermine consumer confidence in biosimilars in ways that are untrue" and "negatively impact a patient's judgment about an otherwise safe and effective product."[41]
2. FDA and FTC jointly explained that they "support competitive markets for biologics" and "have serious concerns about false or misleading statements and their negative impacts on public health and competition."[42]

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[31] For an explanation of these changes, see Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUM. L. REV. ONLINE 81 (2018).

[32] FDA, REPORT TO CONGRESS: SEVENTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2014, at 9 (2015).

[33] 42 U.S.C. § 262(i)(2).

[34] FDA, *Biosimilar and Interchangeable Products*, https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products (last visited Apr. 24, 2021).

[35] Boehringer Ingelheim letter to FDA, Docket #FDA-2018-P-3281, at 3, Jan. 25, 2019.

[36] Christopher Rowland, *Marketers Are Having a Field Day*, WASH. POST, Jan. 9, 2019.

[37] *Pfizer Citizen Petition to FDA*, Aug. 22, 2018, https://www.bigmoleculewatch.com/wp-content/uploads/sites/2/2018/08/Citizen_Petition_from_Pfizer.pdf (referring to Amgen YouTube video).

[38] *Id.*

[39] Janssen Biotech, Inc., *Finely Tuned Patient Brochure*, Dec. 2017 (cited in *Pfizer Citizen Petition*, at 8).

[40] Rowland, *Marketers Are Having a Field Day*.

[41] *Id.*

E. Most courts apply approaches not likely to recognize harm to biosimilars and patients from disparagement
   1. Judicial approach 1: No liability for disparagement-based antitrust claims.[43]
   2. Judicial approach 2: Presumption that exclusionary effects of disparagement de minimis, rebutted only by making difficult showing that alleged anticompetitive conduct is (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization or other offsets by rivals.[44]
   3. Judicial approach 3: Case-by-case approach to determine antitrust liability.[45]
   4. Most courts apply first or second approach, making it nearly impossible to find antitrust liability even for monopolists that disparage rivals and harm consumers

X. Biosimilar Disparagement: Solution

A. Legislation could provide presumption that false advertising by monopolists constitutes monopolization.[46]
   1. As mentioned above, most courts excessively defer to advertising-related conduct
   2. The most fundamental critique against applying antitrust to false advertising conduct—that it does not require marketwide effects—is addressed by the defendant's control over the market
   3. Before presumption applies, plaintiff must show defendant has monopoly power
      a) Biologics likely to have such power, as judged by charging of high prices without suffering losses

B. Presumption applies if plaintiff shows that defendant engaged in false advertising
   1. Liability for false advertising requires that defendant's conduct is literally false or misleading, is material, actually deceived (or was likely to deceive) consumers, and caused (or was likely to cause) harm to plaintiff.[47]
   2. False advertising's requirements assist antitrust by focusing on bad conduct, showing its relevance, and demonstrating harm
   3. A monopolist's materially false advertising makes it more difficult to compete on merits, can be repurposed to harm any rival, and is hard to credibly rebut without souring consumers on factual claims more generally
   4. Presumption also is appropriate given the near certainty of anticompetitive effects: in small field, at least one competitor is harmed, with safety-based claims against biosimilars likely to harm all competitors

C. Defendant can rebut presumption by showing ineffectiveness of false or deceptive statement
   1. Monopolist could show that, despite likelihood of deception from literally false or misleading claim, harm from deception did not materialize
      a) Rebuttal not likely for biologic firms, as consumers are not able to do own testing and rely on results

D. Framework for attempted monopolists
   1. Because attempted monopolists do not control the market, I do not propose a rebuttable presumption of an antitrust violation
   2. But in determining whether the defendant engaged in exclusionary conduct, legislation could focus on four key factors: (a) targeting a new entrant; (b) actual harm from the false or misleading advertising; (3) the degree of materiality; and (d) interactions with other anticompetitive conduct.

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[42] Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace, at 3, Feb. 3, 2020.

[43] Retractable Tech. v. Becton Dickinson & Co., 842 F.3d 883, 895 (5th Cir. 2016); Sanderson v. Culligan Int'l Co., 415 F.3d 620, 624 (7th Cir. 2005).

[44] Nat'l Ass'n of Pharm. Mfrs. v. Ayerst Labs., 850 F.2d 904, 916 (2d Cir. 1988); Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, 323 F.3d 366, 370 (6th Cir. 2003); Am. Prof'l Testing Serv., v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, 108 F.3d 1147, 1152 (9th Cir. 1997); Lenox MacLaren Surgical Corp. v. Medtronic, 762 F.3d 1114, 1127–28 (10th Cir. 2014); Duty Free Am.'s v. Estee Lauder, 797 F.3d 1248, 1268–69 (11th Cir. 2015).

[45] W. Penn. Allegheny Health Sys. v. UPMC, 627 F.3d 85, 108–09 (3d Cir. 2010); Caribbean Broad. Sys. v. Cable & Wireless PLC, 148 F.3d 1080, 1087 (D.C. Cir. 1998); Int'l Travel Arrangers v. W. Airlines, 623 F.2d 1255, 1268 (8th Cir. 1980).

[46] For a more complete elaboration of this framework, see Michael A. Carrier & Rebecca Tushnet, *An Antitrust Framework for False Advertising*, 106 IOWA LAW REVIEW __ (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3593914.

[47] *Id.* [draft at 131].

XI. Pharmaceutical Consolidation: Harm

A. In recent years, the pharmaceutical industry has become more consolidated, which has contributed to higher prices.[48]

B. The consolidation is not driven by innovation
   1. If innovation and individual drugs' competitive advantage determined success, we would see turnover among leading firms, reflecting success in R&D
   2. In contrast, the industry is marked by the dominance of the same large firms over time, with the top 20 firms (by global pharmaceutical sales) nearly identical (other than acquisitions) between 2009 and 2019.[49]
   3. Large firms' share of New Active Substances submitted to FDA declined from 30% in 2009 to 20% in 2018, with small firms' share increasing to 70%.[50]
   4. The industry's consolidation shows expansion "through M&A" rather than "organic growth and innovation."[51]
      a) At the same time, "the pace of merger activity" has "become disconnected from FTC enforcement."[52]

C. The FTC has continued its longstanding approach of addressing potentially anticompetitive mergers by requiring the divestiture of overlapping products in specific markets
   1. Between 1994 and 2020, the FTC "challenged 67 drug mergers worth over $900 billion, moved to block only one, and settled virtually all of the remainder subject to divestitures."[53]
      a) Result of narrow focus on specific markets? "[T]he swapping of assets within a relatively small group of large and increasingly powerful firms."[54]
   2. Commissioner Chopra has lamented that "[t]he FTC's strategy of focusing on whether pharmaceutical companies have any overlaps in their drug product lineup is narrow, flawed, and ineffective."[55]
   3. Then-Commissioner (current Acting Chair) Slaughter has demonstrated "concern[]" that the "analytical approach [based on drug overlaps] is too narrow" and called for an approach looking "more broadly" at whether a merger "is likely to exacerbate anticompetitive conduct . . . or to hinder innovation."[56]

XII. Pharmaceutical Consolidation: Solution

A. Theories of merger enforcement
   1. Traditional theory of competitive harm is based on coordinated effects: in reducing number of firms in market, merger would make it easier for remaining firms to collude.[57]
   2. But the agencies also have recognized a role for unilateral effects, as "[t]he elimination of competition between two firms" resulting from the merger "may alone constitute a substantial lessening of competition."[58]

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[48] *E.g.*, Alice A. Bonaime & Ye (Emma) Wang, *Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry* (June 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3445753; Chintan V. Dave, Aaron S. Kesselheim, Erin R. Fox, Peihua Qiu, & Abraham Hartzema, *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 ANN. INTERN. MED. 145 (2017).

[49] See Patricia M. Danzon & Michael A. Carrier, *The Neglected Concern of Firm Size in Pharmaceutical Mergers*, 84 ANTITRUST LAW JOURNAL [draft at 5, Table 1] (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3787161 (8 of top 10 in 2019 were in top 10 in 2009, with remaining 2 in top 15).

[50] IQVIA INSTITUTE, THE GLOBAL USE OF MEDICINE IN 2019 AND OUTLOOK TO 2023, at 36 (Jan. 2019).

[51] AMERICAN ANTITRUST INSTITUTE, FROM COMPETITION TO CONSPIRACY: ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR 12, Sept. 3, 2020.

[52] *Id.*

[53] *Id.* at 10.

[54] *Id.* at 3.

[55] Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of AbbVie, Inc. / Allergan plc*, Comm. File No. 1910169, at 3, May 5, 2020.

[56] Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb and Celgene*, Comm. File No. 191-0061, at 1, Nov. 15, 2019.

[57] DOJ & FTC, HORIZONTAL MERGER GUIDELINES ¶ 7.1 (2010).

[58] *Id.* ¶ 6.

a) In particular, by "eliminating competition," a merger "gives the merged firm incentives different from those of the merging firms."[59]
b) The FTC has used the concept of bargaining leverage in settings as varied as hospitals, pharmacy chains and insurers, and broadband.[60]

3. Congress can address pharmaceutical consolidation by applying this leverage analysis to four settings:

B. Solution 1: Adopt Presumption Against Mergers Between Large Firms[61]

1. Large firms (roughly top 10[62]) possess advantages in insurance and reimbursement, marketing, and financing
   a) Insurance and reimbursement advantages as company with large portfolio has more leverage in negotiating with PBMs through bundled rebates
   b) Detailing, marketing, and sales benefits from, for example, combining multiple drugs on same visit to doctor's office
      (1) Firms also gain from economies of scope in marketing drugs across multiple therapeutic areas to large, multi-specialty doctor groups
   c) Financing advantages as firms with large portfolios use retained earnings from sales to fund marketing and acquisitions, providing a lower cost of capital than is available to smaller firms relying on external sources
2. Combination of large firms' enduring and unique advantages, typically without any countervailing efficiencies, supports presumption that merger of two large firms harms competition
   a) Empirical data provides no evidence that mergers between large firms improve R&D productivity through economies of scale or scope.[63]
   b) In fact, some studies show *negative* impact on R&D, patents, and the number of new molecular entities after large firms merge.[64]
   c) Any efficiency savings are not likely to be passed on to consumers through lower prices because of insurance and patients' lack of information about alternatives
   d) In rare case, firms could rebut presumption by showing synergies from cross-national complementarity of assets or better utilization of excess manufacturing capacity without risk of increased market power

C. Solution 2: Consider Multiple Factors for Mid-size Firms

1. For mid-size firms (roughly 11-20[65]), the agencies should apply heightened scrutiny
   a) These firms compete with the largest firms in marketing and as potential acquirors of smaller firms
   b) Ownership of a "must-have" blockbuster product favors aggressive enforcement
2. Example: AbbVie/Allergan, combining large (AbbVie) and mid-size (Allergan) firms
   a) Merger threatened harm because of presence of must-have blockbuster products
      (1) AbbVie's Humira and Allergan's Botox are blockbuster drugs that PBMs must include on formularies
   b) Relatedly, merger raises concern of rebate walls, which occur when manufacturers provide rebates or discounts on condition that payors purchase bundled collection of drugs
      (1) In theory, "rebates" sound good but in reality, they can be used to stifle competition, preventing patients from accessing quality, lower-cost medicines
      (2) *E.g.*: Pfizer sued J&J for threatening not to pay rebates unless insurers limited coverage of Pfizer's Inflectra; as a result, 90% of accounts did not purchase Inflectra, resulting in 4% market share

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[59] FTC & DOJ, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 25 (2006).

[60] *ProMedica Health System, Inc. v. FTC*, 749 F.3d 559 (6th Cir. 2014) (hospitals); FTC, *Price Increases May Result from Combination of the Two Full-service Hospitals in Slidell, Louisiana*, Sept. 13, 2006, http://www.ftc.gov/opa/2003/04/lahospmerger.htm (same); *FTC v. OSF Healthcare System*, 852 F. Supp. 2d 1069 (N.D. Ill. 2012) (same); FTC, MERGER GUIDELINE COMMENTARY, at 35–36 (retail drug store chains); U.S. Dept. of Justice, *Revised Competitive Impact Statement in U.S. v. Aetna Inc. and The Prudential Ins. Co.* (N.D. Tex., filed Aug. 3, 1999), https://www.justice.gov/atr/case-document/file/483491/download (health insurance); Cecilia Kang & Emily Steel, *Regulators Approve Charter Communications Deal for Time Warner Cable*, N.Y. TIMES, at B1, Apr. 25, 2016, https://www.nytimes.com/2016/04/26/technology/charter-time-warner-cable-bright-house-cable-deal.html (broadband).

[61] For additional detail, see Danzon & Carrier, *Neglected Concern of Firm Size*.

[62] Based on 2019 global sales, the top 10 firms are Pfizer, Roche, Novartis, Johnson & Johnson, Merck, Sanofi, AbbVie, GlaxoSmithKline, Takeda, and Bristol Myers Squibb. *See id.* at 5 (Table 1).

[63] *See, e.g.*, Patricia M. Danzon, Sean Nicholson, & Andrew J. Epstein, *Mergers and Acquisitions in the Pharmaceutical and Biotech Industry*, 28 MANAGERIAL & DECISION ECON. 307 (2007).

[64] Justs Haucap, Alexander Rasch, & Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence*, 63 INT'L J. INDUS. ORG. 283 (2019); Carmine Ornaghi, *Mergers and Innovation in Big Pharma*, 27 INT'L J. INDUS. ORG. 70 (2009); Bernard Munos, *Lessons from 60 Years of Pharmaceutical Innovation*, 8 NATURE REVIEWS DRUG DISCOVERY 959 (2009).

[65] Based on 2019 global sales, firms 11 through 20 are AstraZeneca, Amgen, Gilead, Eli Lilly, Bayer, Novo Nordisk, Allergan, Boehringer-Ingelheim, Celgene, and Biogen. *See* Danzon & Carrier, *Neglected Concern of Firm Size*, at 5 (Table 1).

(3) Consumer groups worried that "combining AbbVie's blockbuster drugs with Allergan's is likely to exacerbate . . . anticompetitive conduct" because of merged firm's "increased ability to bundle rebates across its enlarged drug portfolio in order to keep competing branded drugs, generics, and biosimilars off of PBMs' and insurers' preferred position on their drug formularies."[66]

3. Also raising concern was the firms' history of potentially anticompetitive behavior
   a) AbbVie: ongoing cases on pay-for-delay settlements, sham conduct, and patent thickets
      (1) The Third Circuit reversed the dismissal of the FTC's complaint alleging that AbbVie paid Teva to delay entering the market with a generic version of a testosterone gel by providing Teva with an authorized generic version of a cholesterol drug with expected sales of more than $175 million over four years.[67]
      (2) The court upheld the refusal to dismiss the FTC's claim that AbbVie engaged in objectively baseless litigation because "no reasonable litigant" in its position "would believe it had a chance of winning."[68]
      (3) A court dismissed a lawsuit[69] challenging AbbVie's "thicket" of more than 100 patents covering rheumatoid-arthritis-treating Humira, but the case is on appeal and the opinion has been criticized.[70]
   b) Allergan: citizen petitions and sovereign immunity
      (1) Filed repetitive citizen petitions to delay generic competition on dry-eye-disease-treating Restasis; FDA denied second by stating that Allergan "should not be surprised" by its response and denied third by lamenting that petition "repeats many of the assertions" central to petitions already addressed.[71]
      (2) In a maneuver that failed[72] and garnered widespread criticism,[73] sought to avoid "inter partes review" at Patent Office by transferring patents to a Native American tribe to exploit tribal immunity

D. Solution 3: Address Incentives in "Killer Acquisitions" and Innovation Markets Settings

1. "Killer acquisitions" worrisome, with empirical study showing a 23% reduced likelihood that a drug would be developed after being acquired by an incumbent with an overlapping drug.[74]
   a) *E.g.*: Questcor had monopoly on infant-seizure-treating ACTH, acquired rights to competing Synachten, then repeatedly raised price, which increased 85,000% from 2001 ($40/vial) to 2017 ($34,000/vial).[75]
2. Drug mergers are structured to avoid Hart-Scott-Rodino Act's (HSR's) pre-merger notification requirements
   a) Empirical analysis found "clear bunching of deals right below the review threshold," but only for "deals in which the target has projects that overlap with the acquirer.[76]
      (1) Below-threshold acquisitions resulted in lower product launch rate (1.8% vs. 9.1%) and higher discontinuation rate (94.6% vs. 83.3%).[77]
3. Congress could consider HSR adjustments in pharmaceutical industry
   a) Could lower thresholds by a certain percentage for size-of-person and size-of-transaction tests
   b) Size of reduction would depend on tradeoff between greater chance of finding anticompetitive deals and increased burden of heightened reporting requirements
   c) Congress could solicit guidance from agencies on threshold adjustments to balance these objectives
4. Related concept is "innovation markets" (markets for research and development)
   a) The concern is that a merger between the two firms most advanced in R&D results in a heightened incentive to suppress one of the research paths
   b) Antitrust agencies have challenged mergers in innovation markets, like (1) Glaxo and Wellcome, (2) Upjohn and Pharmacia, (3) GlaxoWellcome and SmithKline Beecham, and (4) Baxter and Immuno.[78]

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[66] Letter from Families USA et al. to The Honorable Joseph J. Simons, at 5, Sept. 12, 2019.

[67] *FTC v. AbbVie*, 976 F.3d 327, 357 (3d Cir. 2020).

[68] *Id.* at 366.

[69] *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020).

[70] HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE, & MICHAEL A. CARRIER, IP AND ANTITRUST § 15.03[A][2][c], at 15–42.4 to 15-42.4–4 (Supp. 2020).

[71] Citizen Petition Denial Response Letter from FDA CDER to Allergan and Physical Pharmaceutica, Feb. 10, 2016; Citizen Petition Denial Response Letter from FDA CDER to Allergan, Jan. 2, 2018.

[72] Saint Regis Mohawk Tribe v. Mylan Pharm. Inc., 896 F.3d 1322, 1325 (Fed. Cir. 2018).

[73] Meg Tirrell, *Allergan Responds to Mounting Criticism of Mohawk Patent Deal*, CNBC, Oct. 3, 2017.

[74] Colleen Cunningham, Florian Ederer, & Song Ma, *Killer Acquisitions*, 129 J. POLIT. ECON. 649, 652 (2021).

[75] FTC, *Mallinckrodt Will Pay $100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants*, Jan. 18, 2017.

[76] Cunningham, Ederer, & Ma, *Killer Acquisitions*, at 685.

[77] *Id.* at 686.

c) A framework for innovation markets could examine (1) concentration among firms reasonably likely to reach the market, (2) anticompetitive theories of innovation suppression, and rebuttals based on (3) rivals' entry, (4) efficiencies, and (5) a "Schumpeterian" need for size.[79]

E. Solution 4: Encourage More Nuanced Analysis of Generic Mergers

1. In recent years, the generics industry has been changing, with certain companies earning a significant amount of revenue from patented brand drugs
2. My co-authored empirical analysis of the industry found that, as compared to "pure" generics, "mixed" generics do not as robustly promote competition: they are less likely to challenge patents, more likely to abandon those challenges, and less likely to win them.[80]
   a) The mixed generic firms (in decreasing order of generic share) are Endo, Fresenius, Horizon, Teva, Shire, Valeant, Allergan, Novartis-Sandoz, and Pfizer
   b) The pure generic firms (in decreasing order of generic share) are Aurobindo, Amneal, West Ward, Alvogen, Perrigo, Dr. Reddy's, Prasco, Apotex, Mallinckrodt, Mylan, and Lupin.[81]
3. The agencies should consider the nature of "generic" companies that merge, welcoming mergers that create purer generics and exercising more scrutiny of those diluting generics by mixing them with brand sales
   a) When a mixed firm merges with a pure generic, the expected effects on "acting like a generic" may depend on the shares of the mixed firm and the relative size of the two firms
   b) Pure generics can act like "mavericks" that "play[] a disruptive role in the market to the benefit of customers."[82]
4. Congress can require the agencies, when evaluating mergers, to consider a generic firm's nature as a mixed or pure firm and its incentives to pursue the initially intended function of promoting competition

XIII. Conclusion

A. Anticompetitive behavior costs consumers billions in unnecessary payments and untold suffering when patients go without food or rent, split pills in half, or don't take needed medicines

B. Legislation on product hopping, pay-for-delay settlements, citizen petitions, biosimilar disparagement, and pharmaceutical consolidation would make patients' lives better without harming innovation

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[78] Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393 (2008).

[79] *Id.* at 415–29.

[80] Michael A. Carrier, Mark A. Lemley, & Shawn Miller, *Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy*, 71 HASTINGS LAW JOURNAL 307 (2020).

[81] *Id.* at 353 (Table A.1).

[82] DOJ & FTC, HORIZONTAL MERGER GUIDELINES § 2.1.5 (2010).

The Neglected Concern of Firm Size in Pharmaceutical Mergers

84 ANTITRUST LAW JOURNAL __ (forthcoming 2021)

Patricia M. Danzon[*] and Michael A. Carrier[**]

I. Introduction

Pharmaceutical markets are complex. Multiple agents, including doctors, insurers, and pharmacies, play critical roles that affect competition between manufacturers and patient choice between drugs. This complexity, however, is neglected in standard antitrust analysis. In evaluating proposed mergers, the antitrust agencies have focused almost exclusively on whether the merging firms have potentially competing products in specific drug markets in the firms' portfolios. If they do, the remedy sought in nearly every case is divesture of the overlapping products.[1]

In many cases, such an approach adequately addresses the competitive concerns by ensuring that the combined entity does not have increased market power in specific drug markets and that the buyer of the divested product can compete with the merged entity.[2] Such settlements can be viewed as a natural outgrowth of pre-merger notification systems such as the Hart-Scott-Rodino Antitrust Improvements Act, which, in providing the federal antitrust agencies ("agencies") with the ability to review transactions before completion, "create[s] a natural opportunity for negotiation as the government identifies possible problems and brings them to the attention of the merging parties."[3] A market-by-market analysis also can be viewed as the result of prospective merger reviews, together with the burden on the agencies to show a "likely effect" of "substantially [] lessen[ing] competition"[4] in a setting in which courts do not always appreciate theories of harm that push the boundaries.[5]

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[**] Distinguished Professor, Rutgers Law School. We are grateful to anonymous referees from the Antitrust Law Journal for very helpful comments.

[1] *See, e.g.*, FTC, NEGOTIATING MERGER REMEDIES 4 (Jan. 2012) ("Anticompetitive horizontal mergers are most often remedied by a divestiture."), https://www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf.

[2] *See* FTC, *Frequently Asked Questions About Merger Consent Order Provisions*, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/merger-faq (last visited Mar. 23, 2021) (explaining divestiture packages, buyers, and goal "to preserve fully the existing competition in the relevant market").

[3] ANDREW I. GAVIL, WILLIAM E. KOVACIC, JONATHAN B. BAKER, & JOSHUA D. WRIGHT, ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY 867 (3d ed. 2017).

[4] *Statement of Chairman Joseph J. Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson Concerning the Proposed Acquisition of Allergan plc by AbbVie Inc.*, at 1, May 5, 2020. *See FTC v. Procter & Gamble Co.*, 386 U.S. 568, 577 (1967) ("The core question is whether a merger may substantially lessen competition, and necessarily requires a prediction of the merger's impact on competition, present and future.").

[5] *See* Jonathan B. Baker & Carl Shapiro, *Detecting and Reversing the Decline in Horizontal Merger Enforcement*, 22 ANTITRUST 29, 32 (2008) (criticizing *United States v. Oracle*, 331 F. Supp. 2d 1098 (N.D. Cal. 2004), for "clear error in economic reasoning" in applying unilateral-effects theory by requiring plaintiff to "prove a relevant market in which the merging parties would have essentially a monopoly or dominant position").

But there is unease with an analysis focusing solely on overlapping products. For example, Commissioner Rohit Chopra dissented from the majority's analysis in AbbVie's acquisition of Allergan, lamenting that "[t]he FTC's strategy of focusing on whether pharmaceutical companies have any overlaps in their drug product lineup is narrow, flawed, and ineffective" as it "fails to account for how executives make decisions about their drug product portfolios, how larger portfolios can suppress new entry, and how companies use portfolios to increase bargaining leverage across the supply chain."[6] Similarly, then-Commissioner (and current Acting Chair) Rebecca Kelly Slaughter dissented from the majority's disposition of Bristol-Myers Squibb's (BMS) acquisition of Celgene, "support[ing] the Commission's effort to remedy [the] drug-level overlap" but "remain[ing] concerned that this analytical approach is too narrow" and that "the Commission should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct by the merged firm or to hinder innovation."[7]

A recent comprehensive report by the American Antitrust Institute (AAI) found that between 1994 and 2020, the Federal Trade Commission (FTC) "challenged 67 drug mergers worth over $900 billion, moved to block only one, and settled virtually all of the remainder subject to divestitures."[8] As AAI explained, the result of this narrow focus on drug-specific markets has been "the swapping of assets within a relatively small group of large and increasingly powerful firms."[9]

This Essay examines potential inadequacies of the traditional merger analysis by evaluating the firm-wide effects of mergers, particularly those involving large firms. By focusing on individual product markets in isolation, the agencies neglect the advantages of overall firm size and the potential for spillover or cross-market effects across product markets. Size, measured by a firm's number of products and overall sales value, conveys significant advantages in negotiations, marketing, and financing that a large firm can exploit to impede entry and thwart competition in multiple drug markets. Mergers and acquisitions (hereinafter "mergers") involving large firms exacerbate these size advantages.[10] These cross-market effects, however, are not considered in the standard antitrust analysis that focuses narrowly on increased concentration in individual drug markets to determine whether – as the Clayton Act provides –

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[6] Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of AbbVie, Inc. / Allergan plc, Comm. File No. 1910169*, at 3, May 5, 2020.
[7] Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb and Celgene, Comm. File No. 191-0061*, at 1, Nov. 15, 2019. *But see* Statement of Commissioner Noah Joshua Phillips, *In the Matter of Bristol-Myers Squibb and Celgene, Comm. File No. 191-0061*, at 2, Nov. 15, 2019. ("we need to articulate a viable theory of harm to competition posed by the merger and produce evidence to support that theory" and "must convince a judge that [a merger] violates the law").
[8] AMERICAN ANTITRUST INSTITUTE, FROM COMPETITION TO CONSPIRACY: ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR [AAI REPORT] 10, Sept. 3, 2020.
[9] *Id.* at 3.
[10] Our observations on size apply equally to mergers and acquisitions.

the merger threatens to "substantially lessen competition."[11] After examining all 67 pharmaceutical mergers the FTC challenged between 1994 and 2020, AAI concluded that the largest companies "have grown through hundreds of mergers and acquisitions."[12]

In this Essay, we first document the stability of leading firms in the pharmaceutical industry and contend that mergers, not innovation, have enabled these firms to maintain their dominance. We then identify three characteristics of prescription drug markets in the United States that lead to advantages related to overall firm size. First, insurance and reimbursement create size advantages in negotiations for formulary placement and pricing. Second, size conveys benefits in detailing, marketing, and sales to physicians. Third, size-related advantages in retained earnings provide a relatively low-cost source of financing for acquisitions. In all three contexts, any real efficiency savings are unlikely to be passed on to consumers through lower prices because insurance undermines competition on the final price.[13]

After explaining the advantages possessed by large firms, we outline a framework for applying these considerations to the antitrust analysis of pharmaceutical mergers. When two large firms (roughly the top 10 firms ranked by global pharmaceutical sales) merge, the already significant advantages each firm has are compounded in a manner likely to harm competition across many drug markets in the firm's portfolio (not just markets with overlapping products). This tends to entrench the enlarged firm's dominance and effectively block smaller rivals from competing.

As a result of these size-related advantages, we suggest a presumption that a merger between two large firms substantially lessens competition. Mergers involving mid-size firms (roughly the second decile) are less likely to harm competition, with the extent of harm depending on the size of the merged entity and whether dominant products are involved. We therefore recommend heightened scrutiny of mergers involving mid-size firms, especially where one of the merging firms has a dominant product. We recommend the continuation of the current approach for mergers involving small firms.

Our analysis applies primarily to the originator brand-drug industry. But similar concerns about cross-market effects may apply to mergers in other industries in which large firms span multiple markets. Vistnes and Sarafidis[14] and Dafny et al.[15] have shown that even if there is no

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[11] 15 U.S.C. § 14.

[12] AAI REPORT, *supra* note 8, at 11. For example, during the period, Johnson & Johnson and Roche each made more than 40 acquisitions while Pfizer made more than 30. *Id.*

[13] Further research is needed to quantify these effects but is impeded by data confidentiality.

[14] Gregory S. Vistnes & Yianis Sarafidis, *Cross-Market Hospital Mergers: A Holistic Approach*, 79 ANTITRUST L. J. 253 (2013).

[15] *See* Leemore Dafny, Kate Ho, & Robin S. Lee, *The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry*, 50 RAND J. ECON. 286, 286-87 (2019) and references cited therein. S*ee also* Case No COMP/M.2220 – General Electric/Honeywell, Regulation (EEC) No 4064/89 Merger Procedure ¶ 353 (July 3, 2001), https://ec.europa.eu/competition/mergers/cases/decisions/m2220_en.pdf (noting ability of GE and Honeywell to "cross-subsidise discounts across . . . products composing the packaged deal").

increase in concentration in separate product markets, mergers of hospitals in different geographic or diagnostic markets can increase the leverage of the merged hospitals in bargaining with insurers and lead to higher prices. Such cross-market effects are expected when the two merging firms contract with an intermediary (such as an insurance company) that serves customers with demand for both hospitals, for example, employers with employees in both areas. In such contexts, failure to reach a bargaining agreement with the merged hospital system increases the loss incurred by the insurer, relative to bargaining with each hospital separately, which enables the merged hospital system to extract higher prices in a simple Nash bargaining context.[16] Dafny et al.'s empirical analysis confirms that mergers of hospitals in unrelated markets raised prices more than similar hospitals not involved in mergers. Lewis and Pflum[17] find similar price-increasing effects of cross-market mergers on prices charged by target hospitals, which they also attribute to increased bargaining weight. Similarly, mergers of two hospitals in distinct therapeutic niches, for example, pediatrics and geriatrics, may increase the hospitals' market power in bargaining with insurers because loss of the combined system would reduce the insurers' appeal to employers and/or families who anticipate needing either service.

Our analysis breaks new ground in considering similar cross-market concerns in the context of branded pharmaceuticals, where large firms' product portfolios span multiple therapeutic markets that increase their bargaining leverage in negotiations with pharmacy benefit managers (PBMs). As in the hospital context, consumer price-sensitivity is blunted by extensive insurance coverage. But pharmaceutical markets raise unique issues due to the role of PBMs as agents for insurers/payers, physicians as dual agents for patients and payers, and patients who are poorly informed about the range of products potentially available.[18] These factors make exclusionary contracts hard to detect and undermine customer price-sensitivity and competitive pressures to pass through any efficiency savings from mergers.

Granted, some of the potential harms we discuss can in theory be addressed directly through enforcement actions outside the merger setting. As discussed below, plaintiffs have filed lawsuits challenging exclusionary contracts as monopolization.[19] The confidentiality of pharmaceutical contracts and rebates, however, is a significant barrier to potential plaintiffs bringing such suits, as the factual data needed to support a case can only be obtained through discovery. The agencies should therefore also consider the potential for anticompetitive, cross-market effects as part of their analysis of mergers, in particular, those involving large firms. Such an analysis would limit the harm of cross-market mergers and reduce the need for costly

[16] Nash bargaining describes a simple bargaining situation in which two rational, self-interested actors decide how to share a surplus that they can generate.
[17] Matthew S. Lewis & Kevin E. Pflum, *Diagnosing Hospital System Bargaining Power in Managed Care Networks*, 7 AMERICAN ECONOMIC JOURNAL: ECONOMIC POLICY 243 (2015); Matthew S. Lewis & Kevin E. Pflum, *Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions*, 48 RAND J. ECON, 579 (2017).
[18] We use the term "payer" to refer to both insurers and self-insured employers who contract directly with PBMs.
[19] *See infra* notes 60-61 and accompanying text.

litigation that takes years to resolve and that comes after a company's increased size has exacerbated the problem.

II. Persistence of Large Firms: Acquisitions vs. R&D

If the competitive advantage of individual drugs in their specific markets were the sole determinant of firm success, we would expect to see continual turnover of leading firms in the industry. Market leadership would change, reflecting each firm's relative success in research and development (R&D) of new products that are essential to survival and growth, as older drugs face patent loss and product obsolescence. In contrast to this expectation of only individual drugs mattering, the pharmaceutical industry is characterized by the persistent dominance of the same large firms over time. The Top 20 pharmaceutical firms in 2019, by global pharmaceutical sales, are remarkably similar to the Top 20 in 2009, with modest shifts in ranking driven more by acquisition of other firms with innovative product portfolios and/or blockbuster products than by discoveries of their own R&D departments. Of the 20 top firms in 2009, three firms in the top decile (Pfizer, Merck, and Roche) each acquired one firm in the second decile (Wyeth, Schering, and Genentech, respectively) and another second-decile firm (Astellas) exited the group. This made space for four new entrants to the 2019 Top 20 firms, and two of these (Allergan and Celgene) have already been acquired by larger firms (AbbVie and Bristol Myers Squibb (BMS)).

Table 1
Top 20 Biopharmaceutical Companies, by Global Pharmaceutical Sales, 2009 and 2019

Company	2009 Rank[i]	Company	2019 Rank[ii]
Pfizer	1	Pfizer	1
Sanofi-Aventis	2	Roche	2
GlaxoSmithKline	3	Novartis	3
Novartis	4	Johnson & Johnson	4
AstraZeneca	5	Merck & Co.	5
Merck	6	Sanofi	6
Johnson & Johnson	7	Abbott Labs/AbbVie	7
Roche	8	GlaxoSmithKline	8
Eli Lilly	9	Takeda	9
Bristol Myers Squibb	10	Bristol Myers Squibb	10
Wyeth [a]	11	AstraZeneca	11
Schering-Plough[b]	12	Amgen	12
Abbott Labs	13	Gilead	13
Amgen	14	Eli Lilly	14
Takeda	15	Bayer	15
Bayer	16	Novo Nordisk	16
Boehringer-Ingelheim	17	Allergan[d]	17
Genentech[c]	18	Boehringer-Ingelheim	18
Astellas	19	Celgene[e]	19
Novo Nordisk	20	Biogen	20

[i] Source: 2009 *Top 20 Pharmaceutical Companies Report*, Contract Pharma at https://www.contractpharma.com/issues/2009-07/view_features/2009-top-20-pharmaceutical-companies-report/. And *2009 Top 10 Biopharmaceutical Companies Report*, Contract Pharma at https://www.contractpharma.com/issues/2009-07/view_features/2009-top-10-biopharmaceutical-companies-report/?widget=listSection. Accessed Jan. 14, 2021. Based on 2008 pharma revenues.

[ii] Source: *The 2020 Top 25 Pharma and Biopharma Companies*, Contract Pharma at https://www.contractpharma.com/issues/2020-07-01/view_top-companies-report/top-25-pharma-and-biopharma-companies-751659/ Accessed Jan. 14, 2021. Data from EvaluatePharma, June 2020.
We omit Teva (ranked 17 in both years) because generics account for a large share of its sales.
[a] Wyeth was acquired by Pfizer
[b] Schering-Plough was acquired by Merck
[c] Genentech was acquired by Roche
[d] Allergan was acquired by AbbVie in 2020
[e] Celgene was acquired by BMS in 2020

These top firms in 2009 already owed their persistent industry dominance to M&A, as has been noted by previous authors.[20] For example, Pfizer acquired Warner-Lambert to obtain its blockbuster statin, atorvastatin (Lipitor), and then, when the Lipitor patent approached expiration, acquired Wyeth to obtain its pneumococcal conjugate vaccine (Prevnar) and other biologics in 2009. Other recent mergers include Merck with Schering-Plough (Schering's five lead products disappointed but pembrolizumab (Keytruda) became an unexpected blockbuster); BMS with Celgene (both built on prior acquisitions, especially in cancer); and AbbVie with Allergan, both built on prior acquisitions, and with AbbVie's lead product, adalimumab (Humira, obtained through the acquisition of Knoll Pharmaceuticals), now approaching patent expiry and Allergan's Botox (obtained from an ophthalmologist) also facing competition.

In contrast to this success in M&A, the in-house innovation of these large firms has played a modest and declining role in their continued success. Large firms' share of the New Active Substances (NAS) submitted each year to the U.S. Food and Drug Administration (FDA) declined from 30 percent in 2009 to roughly 20 percent in 2018; by contrast, the share of NAS originated by very small "emerging" firms has increased to roughly 70 percent.[21] Many of these very small firms are formed around promising research compounds, often spun out from academic laboratories funded by the National Institutes of Health (NIH). Similarly, in its comprehensive report, AAI found that the industry's "pattern of consolidation" in the past 30

[20] The twelve leading pharmaceutical firms, ranked by worldwide sales in 2010, were influenced by 19 significant mergers and acquisitions from 1989 to 2011, not including smaller consolidations. William S. Comanor and F.M. Scherer, *Mergers and Innovation in the Pharmaceutical Industry*, 32 J. HEALTH ECON. 106 (2013).

[21] New Active Substances (NAS) are a measure of innovative, novel compounds, in contrast to new formulations and new indications that simply extend use for older compounds. Data from IQVIA Institute, *The Global Use of Medicine in 2019 and Outlook to 2023* (Jan. 2019). Companies are assigned to segments based on 2018 revenues or 2017 R&D spending (because the smallest firms have no sales revenues). Segments are defined as: Large > $10 billion; Mid $5-10 billion; Small $500 million-$5 billion; Emerging < $500 million or R&D Spending < $200 million. If multiple companies are involved in a project, it is assigned to the larger segment.

years "reveals the extent to which many pharmaceutical companies have expanded through M&A, as opposed to through organic growth and innovation."[22]

This disconnect between small firm dominance in innovating new compounds and a stable pack of large firms dominating product sales is reconciled by the extensive, industry-wide pattern of acquisition, as mid-size firms acquire smaller firms and large firms acquire small, mid-size, and large firms. This chain of acquisition serves large firms' need for products and small firms' need for financing and expertise. Although small firms discover and do early development on most new drugs, they may lack the financing and expertise needed to develop their drugs through large clinical trials and regulatory approval, and then market and sell the drugs nationally and globally. The R&D cost of bringing a new drug through regulatory approval at the FDA has been estimated to range between $790 million[23] and $2.7 billion.[24] Small firms typically obtain initial funding from venture capital (VC) and other sources of private and public equity. But for funding costly late-stage clinical trials and undertaking sales and marketing, many small firms either out-license their drugs or accept acquisition by larger companies that need new drugs as patents expire on their older drugs and their in-house R&D fails to replenish their product pipelines. Early-stage investors in small firms also welcome such acquisition as a financial exit that enables them to recoup a return on their investment.

This pattern of acquisition of innovation-focused small firms by larger firms with expertise in marketing and sales can create real resource savings. And it generally poses no significant antitrust concerns, as we discuss below. By contrast, when mergers occur between larger firms that each already has significant sales revenues and marketing expertise, the efficiency gains are less and the risks of harm to competition are greater due to the potential increase in size-related bargaining leverage we elaborate below.

Although large pharmaceutical firms often rationalize their mergers by claiming synergies in R&D and marketing, the evidence on the declining R&D productivity of large firms relative to smaller firms, despite the large firms' sequence of mergers, casts doubt on both the claimed scale economies and the effectiveness of large mergers in enhancing R&D efficiency.[25] Empirical studies confirm that larger pharmaceutical mergers are often a response to patent

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[22] AAI REPORT, *supra* note 8, at 12.

[23] Vinay Prasad and Sham Mallankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues after Approval*, 177(11) JAMA INTER MED. 1569 (2017). This median estimate appropriately includes the cost of failures and cost of capital prior to launch; however, it is unrepresentative because it is based solely on very small firms.

[24] Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016). This mean estimate appropriately includes the cost of failures and cost of capital prior to launch; however, it is unrepresentative because it is based solely on the largest firms, and it uses proprietary data that cannot be verified.

[25] Comanor & Scherer, *supra* note 20, argue that the pharmaceutical merger waves between 1989 and 2011 may have contributed to the decline in R&D productivity over the same time period, reflected in the declining number of new drug approvals despite rising aggregate R&D spending, as the consolidation of large firms reduced the number of independent pathways seeking to solve major medical problems.

expirations on a large firm's major products and gaps in its own pipeline of follow-on products. Such patent expirations generate excess capacity in the firm's administration, sales, and marketing functions and threaten to erode its future revenues and profitability. Large acquisitions are a strategy to acquire new compounds and to cut costs through restructuring that is at least partially imposed on the target company.

The empirical data, however, provide no evidence that such mergers improve the firms' underlying R&D productivity through economies of scale or scope,[26] and much of the cost-cutting in marketing and sales is not merger-specific, in other words, is possible without the merger. One possible exception occurs if one firm brings global expertise and marketing reach that the other firm lacked, as the synergies in such a case would be merger-specific. On the other hand, size also brings the potential for increased bargaining leverage that may benefit the merged firm and enhance its market dominance, but to the possible detriment of consumers. Unfortunately, no studies have attempted to tease out how much each of these effects—real efficiencies vs. increased leverage—contributes to the continued dominance of incumbent large firms. Our objective here is simply to explain how mergers increase the bargaining leverage of large pharmaceutical firms and to point out that these potential harms of size-increasing mergers should be considered alongside any claimed synergies in evaluating such mergers.

The next sections describe how the institutional contexts of pharmaceutical markets in the United States create competitive advantages for large firms and reveal potential anticompetitive effects not captured absent the consideration of overall firm size in merger analysis.

III. Negotiating with Insurers for Reimbursement[27]

Size is an advantage for drug companies in their dealings with insurance payers in healthcare markets. Insurance is a "necessary evil" that creates a third-party payer norm in these

[26] Patricia M. Danzon, Sean Nicholson, Andrew J. Epstein. *Mergers and Acquisitions in the Pharmaceutical and Biotech Industry*, 28 MANAGERIAL & DECISION ECON. 307 (2007) confirms that mergers tend to be undertaken by firms that anticipate distress (low expected earnings growth as measured by Tobin's Q). This implies that measurement of the effects of mergers must adjust for the non-random selection of merging firms. In a study of 202 biotech and pharmaceutical mergers between 1988 and 2001 and controlling for merger propensity, Danzon et al. found that firms that merged experienced, in the subsequent three years, a similar change in enterprise value, sales, employees, and R&D, and had slower growth in operating profit, compared to similar firms that did not merge. A more limited sample of 160 R&D-related acquisitions by 60 public firms between 1994 and 2001 also found that firms with a high "desperation index" (expected years of patent life including marketed drugs and pipeline products) were more likely to acquire another firm. This study found that pre-merger alliances between the parties were positively correlated with both announcement period abnormal returns and one-year post-merger pipeline improvement. They conclude that pre-merger alliances are a means to reduce information asymmetries. M.J. Higgins and D. Rodriguez, *The Outsourcing of R&D through Acquisitions in the Pharmaceutical Industry.* 80 J. FINANCIAL ECON. 351 (2006).

[27] For detail on the effects of insurance, reimbursement rules, and PBMs, see Patricia M. Danzon, *Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues*, 36 PHARMACOECONOMICS 1395 (2018); Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?*, 22(2) INTERNATIONAL J. ECON. BUS. 245 (2015); Patricia M. Danzon, *Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA*, in 3 ENCYCLOPEDIA OF HEALTH ECON. 127 (Anthony J. Culyer ed., 2014).

markets. Patients desire insurance as protection from the high and unpredictable costs of healthcare. But insurance means that "someone else is paying." This makes patients insensitive to price, which creates incentives for health care producers to raise prices unless insurers adopt constraints through their reimbursement rules.[28] In all high-income countries other than the United States, payers limit the prices they pay for pharmaceuticals, for example, using cost-effectiveness or other measures of a drug's value. By contrast, in the United States, pharmaceutical firms set their list prices freely. Private and public payers (insurers, employers, Medicare, and Medicaid) then use PBMs[29] to negotiate rebates off list prices, in return for favorable reimbursement.

In these reimbursement negotiations with insurers, size is an advantage for pharmaceutical firms. The mechanisms through which size advantage operates depend on the specifics of the payers' reimbursement rules, which differ across dispensing channels in the United States. We focus here on the two main channels, which together account for more than 80% of pharmaceutical sales: (1) pharmacy-dispensed drugs (pills, capsules, and liquids) and (2) physician-dispensed drugs (injections and infusions, such as cancer drugs).

A. Pharmacy-dispensed drugs

Most private payers and Medicare Part D plans (which cover outpatient drugs for seniors) use PBMs to manage price negotiations and make payments to drug firms and drug-dispensing pharmacies. PBMs establish tiered formularies (lists of covered drugs), with drugs on preferred tiers having lower co-payments as an inducement to patients. This ability to steer patients to preferred drugs through formularies enables PBMs to negotiate rebates off drug companies' list prices in return for preferred and/or more exclusive formulary position and, consequently, larger market share.[30] This PBM strategy is effective at reducing costs without significant harm to patients in crowded drug classes (such as anti-ulcerants) in which several drugs are close therapeutic substitutes, such that patients and physicians are willing to switch to the preferred drugs in response to lower cost-sharing. By contrast, for specialty drugs that are more expensive and more differentiated, patients and physicians are unwilling to change treatment plans for modest co-payment differences, and formulary exclusions or barriers to access for some drugs can cause harm to consumers. PBMs generally place these specialty drugs on separate tiers with

[28] Although most insured patients are responsible for co-payments, such cost-sharing is usually modest and capped by an annual "catastrophic" limit on a patient's out-of-pocket expenses.

[29] Medicare Part D uses intermediaries called Prescription Drug Plans (PDPs) that are similar to PBMs but bear some insurance risk. We include this category in PBMs. As discussed below, *see infra* note **Error! Bookmark not defined.**, Medicaid obtains mandatory discounts off list prices.

[30] For example, a formulary with only two drugs per class on the preferred tier will get larger rebates from drug firms than a formulary with five preferred drugs per class, because each of the two preferred drugs on the more restrictive formulary will gain larger market share than each of the five drugs on the less restrictive formulary.

high co-insurance (20% to 30% of the list price) and may impose other barriers to coverage, such as prior authorization or step edits,[31] which may be linked to rebates.

PBM contracts with insurers or self-insured employers, for whom PBMs act as agents, typically require that most rebates related to formulary structure are passed through to the payers. The confidentiality of these drug-specific rebates has been deemed necessary to preserve the incentives of drug firms to offer competitive rebates.[32] But the full pass-through of rebates is unlikely and indeed would undermine the incentives of PBMs to negotiate rebates.

These arcane details of pharmaceutical markets have important implications for the analysis of mergers. First, because consumers are heavily insured and price-insensitive, PBMs act as agents for payers – and ultimately for consumers – to negotiate drug rebates on behalf of payers and consumers. Price competition in these markets operates through drug firms offering confidential rebates off their freely-set list prices, in return for preferred placement on a payer's formulary. One unfortunate by-product of this competitive mechanism is that drug firms and PBMs both have incentives to prefer a strategy of high list prices and large rebates, rather than lower list prices and smaller rebates. This incentive structure contributes to the high and rising list prices for brand-name drugs and the increasingly acrimonious debate over rebates.

A second unfortunate by-product of competition through rebates rather than list prices is that it creates advantages for large firms. Specifically, a drug company with a large portfolio of products, including blockbuster drugs (with high sales and potentially large rebate volume), has more leverage and flexibility in negotiating with PBMs than a company with fewer or smaller products.[33] This size advantage can be used in ways that are harmful to competition and to consumers. For example, a large, multi-product firm with blockbuster products that generate significant rebate revenue for a PBM can leverage the blockbuster through a bundled rebate strategy to gain more exclusive positioning with less rebate for its own products or, in the extreme, require exclusivity on the preferred tier for one or more of its drugs, which effectively

[31] Prior authorization means that, as a condition of reimbursement, the physician must obtain the insurer's approval prior to treatment. Step edits require that a patient fail on a preferred drug before gaining coverage of a less-preferred drug.

[32] George J. Stigler, *A Theory of Oligopoly*, 72 J. POLITICAL ECON. 44 (1964); Congressional Budget Office Cost Estimate: "H.R. 1 Medicare Prescription Drug and Modernization Act of 2003 as passed by the House of Representatives on June 27, 2003 and S. 1 Prescription Drug and Medicare Improvement Act of 2003 as passed by the Senate on June 27, 2003, with a modification requested by Senate conferees" (July 22, 2003). https://www.cbo.gov/sites/ default/fles/108th-congress-2003-2004/costestimate/hr1s100.pdf; Danzon, *Differential Pricing of Pharmaceuticals*, *supra* note 27. For a discussion of the interchangeability of rebates with other "financial benefits" provided to PBMs, see Michael Carrier, *A Six-Step Solution To The PBM Problem*, HEALTH AFFAIRS BLOG (Aug. 30, 2018).

[33] In a Nash bargaining model, a firm with a large portfolio, including a "must-have" blockbuster product with high sales and rebate volume, can impose a large loss of rebate revenue if it fails to reach agreement with the PBM, compared to a small firm with a single product with small sales.

blocks entry of a new drug to preferred status in these classes for the customers of this PBM, even if the new drug has therapeutic advantages and/or offers a lower list and net price.[34]

How a large firm would allocate its bargaining leverage between increased exclusivity and higher prices in theory depends on the characteristics of the drug class, including price elasticities. Despite this, several generalizations are possible. First, any increase in price would take the form of lower rebates with specific PBMs, rather than an increase in list price because a higher list price applies to all customers and may trigger an excess inflation rebate that a firm must pay to Medicaid for list price increases that exceed inflation. Second, any use of bargaining leverage to reduce the rebates offered would be very difficult to measure, as the reduction is relative to the unobservable counterfactual of what would have been required to achieve a given level of exclusivity in the absence of the bargaining leverage.

Third, for an incumbent firm with a leading product in a class, an exclusive contract that obstructs the entry of a potential competitor, especially a superior competitor, would likely be more profitable to both the firm and the PBM than raising its price to the PBM by reducing its rebates because a competitor would reduce the incumbent's revenues by stealing share and likely reduce class-wide revenues, assuming the competitor enters at a lower list price and that class-level demand is price-inelastic, due to both extensive insurance and disease-related limits on most classes. Essentially, competitive entry is zero or even negative sum for the incumbent firm and for the PBM, if class-level demand is price-inelastic and entry reduces average prices.

Fourth, the negative effect of entry on the potential surplus to be split between incumbent and PBM is true *a fortiori* if the new entrant is a biosimilar competitor for the incumbent producer of a biologic blockbuster that is nearing patent expiry. An incumbent has strong incentives to use exclusive contracting, including bundled rebates, to bar entry of biosimilar competitors for that blockbuster, whereas it is generally futile for a firm to attempt to block generic entry following patent expiry on a blockbuster chemical drug. Under the Hatch-Waxman Act, generic versions of chemical drugs can be approved by showing bioequivalence to the originator drug.[35] Bioequivalent generics are substitutable by pharmacies, unless the physician expressly requires the originator brand. PBMs generally place generics on their lowest co-

[34] The pharmaceutical firm may make a large rebate on a high volume, "must have" blockbuster product conditional on each of its products being one of at most two preferred drugs in their respective classes on the formulary. If the PBM were to add a new drug to any of these classes as a third option, it would forgo large rebate revenue on the blockbuster drug that it could not make up from a low-volume new entrant, especially if the entrant has a lower price and lower rebate. In *Shire v. Allergan*, for example, Shire has alleged that Allergan made its rebates on its dry eye drug, Restasis, and rebates on its glaucoma eye products conditional on Restasis being the sole preferred drug on formularies of most large Medicare Part D drug plans, which allegedly blocked the adoption by Medicare Part D plans of Shire's superior drug for dry eye, Xiidra. 375 F. Supp. 3d 538 (D.N.J. 2019). Shire has argued that it would be required to offer its drug below average cost in order to compensate the PBM for its loss of rebate revenue from Allergan which was conditional on preferred tier exclusivity for Restasis. This differs from standard predation because the incumbent is not offering its product below cost; rather, it relies on its large volume and product bundling to offer a combined rebate that Shire could not match and cover its average cost. Unlike standard predation, this is a sustainable strategy for the incumbent.

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

payment tier, to encourage patient acceptance of these cheaper products. Moreover, PBMs profit directly from generic substitution through their own mail-order pharmacies. Given pharmacy substitution of generics, it would be futile for the producer of the originator brand to attempt to bar generic entry through an exclusive contract with a PBM, because pharmacies can substitute, even if the brand is prescribed.

Biosimilars, on the other hand, are not bioequivalent and are not substitutable for the originator biologic by pharmacies. Thus, biosimilars' ability to compete by offering lower prices depends critically on PBMs' willingness to place them on preferred formulary tiers. But given their lower list prices and their low expected initial volumes, biosimilars cannot offer rebate revenue to PBMs comparable to that offered by the incumbent originator. As a result, both the originator and the PBM can gain by agreeing to a contract that excludes the biosimilar, as, for example, the plaintiffs alleged in *Pfizer Inc. v. Johnson & Johnson*, discussed below.[36]

In short, although large firms may use their bargaining leverage to either reduce rebates or exclude competitor products, exclusion is likely to be the more profitable strategy if the large firm has products in classes with few competitors and inelastic class-level demand, especially if the large firm has biologics approaching patent expiry. Of course, some large firms may have bargaining leverage based on prior mergers or even unrelated to mergers; nevertheless, permitting large mergers that expand the portfolios and sales of already large firms exacerbates these risks.

A group of unions and consumer and public interest organizations raised such concerns in objecting to the recent proposed merger between AbbVie and Allergan.[37] The groups warned that the merger "would enable AbbVie to use exclusionary practices . . . to limit the ability of rivals to expand and enter."[38] In particular, they pointed to "rebate wall[s]," which occur when "a manufacturer leverages its market-dominant position to secure preferred formulary access for its products by offering lucrative incentives to PBMs and health insurers in the form of volume-based rebates."[39] The rebates "are often offered across multiple products, indications, and therapeutic specialties, the breadth of which cannot be matched by new and innovative therapies."[40] The groups worried that "combining AbbVie's blockbuster drugs with Allergan's is likely to exacerbate . . . anticompetitive conduct, because the merged firm will have an increased ability to bundle rebates across its enlarged drug portfolio in order to keep competing branded drugs, generics, and biosimilars off of PBMs' and insurers' preferred position on their drug formularies."[41]

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[36] 333 F. Supp. 3d 494 (E.D. Pa. 2018).
[37] Letter from Families USA et al. to The Honorable Joseph J. Simons, Sept. 12, 2019, https://www.fdanews.com/ext/resources/files/2019/09-16-19-LetteronMerger.pdf?1568653634.
[38] *Id.* at 4.
[39] *Id.*
[40] *Id.*
[41] *Id.* at 5.

One final advantage large firms can exploit comes from Medicaid. The "best price" rule requires that a drug company give Medicaid the "best price" it offers to private buyers.[42] This benefits large firms, which can allocate their rebates across products to achieve a given overall price concession to the PBM with minimum revenue losses. A smaller firm with only a single drug lacks the flexibility to allocate its rebates strategically across a portfolio of products and thus has less leverage and faces higher overall contracting costs. This places small firms at a competitive disadvantage relative to larger firms in bargaining for formulary placement. Although in theory the enforcement of Medicaid best price rebates is the responsibility of Medicaid, it is simply not practical for Medicaid to monitor evasions that occur through the bundling of rebates across drugs in complex, multiproduct contracts that are confidential. As a result, even though an antitrust issue is not presented by the use of bundled rebating to avoid paying Medicaid best price, it is relevant to determining the competitive effects of mergers.

In summary, mergers between large firms can expand their ability to use bundled rebate strategies as an effective barrier to coverage or preferred tier status for competitor drugs in multiple therapeutic categories, thereby blocking new drugs from smaller companies from the preferred tier status that is needed to gain widespread adoption by patients, even if the new drugs are superior, lower-priced, or both. The potential for such portfolio contracting to generate cross-market effects from mergers of large firms is neglected by traditional, market-specific merger analysis.

B. Physician-administered drugs

A drug firm's overall size can convey similar advantages in negotiating to sell physician-administered drugs that are covered under a private insurer's medical benefit or Medicare Part B (for seniors or the disabled). Traditionally, these drugs – infusions and injections that require special handling – were distributed by specialty pharmacies that delivered them to the dispensing physicians, who "buy and bill" the insurers directly. "Buy and bill" means that dispensing physicians can profit (or incur loss) from the margin between the drug's acquisition cost and reimbursement. Most payers follow Medicare, which reimburses physicians at the "Average Sales Price (ASP)" + 6%, where a drug's average sales price in quarter t is calculated as the manufacturer's average price to all customers net of all discounts, lagged 2 quarters. This reimbursement rule creates incentives for firms to set high initial list prices, because the 6% margin has greater absolute value to dispensing customers on a high-priced product. The rule

[42] Brand drugs are required to give Medicaid a discount equal to the greater of 23.1% or the "best price" given to private buyers. A large firm that wants to give, say, a 30% rebate on drug A to PBM X may avoid having to give the same 30% discount to Medicaid on drug A if the equivalent rebate value is achieved through a bundled rebate contract with PBM X that simultaneously specifies, say, a 20% rebate on several drugs including but not limited to A. This bundled contract could achieve the same overall rebate revenue for the PBM while allowing the drug company to avoid paying a "best price" rebate to Medicaid beyond the required 23.1%. Firms are required to report their rebates to Medicaid, but in this case the 20% rebate on all drugs would appear within allowable limits and not trigger any best price penalty.

also discourages discounting, because any discounts in quarter t would reduce the ASP that is reimbursed to all customers two quarters later.

Again, however, large firms may have advantages not available to smaller firms. A small, single-product firm that wishes to provide a rebate on a drug, in order to get the business of a large customer, may be deterred because this rebate would reduce its ASP and hence the future reimbursement for *all* customers.

By contrast, a larger, multi-product firm may be able to bundle the desired rebate for the large customer over a portfolio of products. The large firm might even be able to shift some of the rebate to the firm's pharmacy-dispensed drugs, for which there is no ASP effect—on the contrary, rebates on these drugs would *increase* their appeal to the PBM. Such contracting across physician- and pharmacy-dispensed drugs entails higher administrative costs and is almost certainly much less common than portfolio rebating across only pharmacy-dispensed drugs described earlier, as physician-dispensed drugs were traditionally distributed and managed by specialty pharmacies that contracted directly with physicians, with no role for PBMs. But as PBMs have acquired specialty pharmacies, contracting across pharmacy- and physician-dispensed drugs has become more feasible. Thus, M&A in the PBM-pharmacy-distribution space has increased contracting advantages of size for large drug firms with portfolios of drugs that span both pharmacy- and physician-dispensed platforms. These advantages of overall firm size are neglected in traditional merger analysis.

IV. Marketing and Selling

A second context in which portfolio size brings advantages to large drug firms is in marketing and selling to physicians. Physicians have traditionally been considered the primary customers for drugs because physicians advise patients on drug choice and write the prescriptions that are required to obtain all prescription drugs.[43] And in the United States, as discussed above, certain physicians also buy, dispense, and bill for some drugs requiring infusion or injection. Drug companies therefore invest significant resources in marketing to physicians. This section discusses three related contexts in which a firm's size, specifically the number and sales value of its overall product portfolio, can convey marketing advantages over smaller firms: detailing to physicians, contracting with physician groups, and portfolio rebating. The potential competitive harms from increasing these size effects are neglected by traditional merger analysis.

A. Scale Economies in Detailing to Physicians

The primary marketing tool used by drug companies to persuade physicians to prescribe their drugs is detailing, that is, the practice of sending representatives to physicians' offices to provide information about the drugs and leave free samples for patients. Detailing is expensive. It requires knowledgeable representatives who spend time traveling between offices and awaiting

[43] PBMs are now also important customers because, as discussed above, insurance coverage is necessary for patients to afford expensive drugs.

openings on doctors' busy schedules. Relationships between representatives and physicians are crucial and are built through frequency and scope of contact.

In this context, a large, multi-product company that has two or more drugs that can be promoted on the same visit saves time and adds more value for the company and the physician, compared to a smaller company with only one product relevant for a particular physician's specialty. Although the small company can seek some benefits of scale by hiring a contract marketing organization that markets drugs produced by multiple, smaller firms, such a strategy offers each small firm less control over the timing and messaging of detail visits. As a result, contract marketing is considered less effective than an in-house sales force trained and dedicated to a company's products. Gaining access to a large company's sales force and expertise in marketing is a major reason why small companies out-license their products to larger companies.

B. Scope Economies in One-Stop Shopping for Groups

In recent years, most physicians have organized into large, multi-specialty groups, for example, multiple oncology specialties in one center. Marketing to large, multi-specialty groups increases the potential for a large firm to realize economies of scope in marketing their drugs across multiple therapeutic areas. A large firm with a broad portfolio of drugs can offer one-stop-shopping convenience to these multi-specialty customers, for example, drugs to treat multiple cancers. This size advantage can create a barrier to entry for a smaller company with only one or two products for one disease, say breast cancer, even if the small company offers lower prices on its few drugs. A merger analysis that focuses solely on whether the merging companies have overlapping products in breast cancer ignores the merged company's enhanced marketing advantage from the number and importance of its products across multiple cancers. Focusing only on breast cancer will underestimate the merger's adverse effects on potential entry for other firms in breast cancer and other disease classes where the merged entities do not have overlapping products but where the merged firm has an increased size advantage due to its overall portfolio breadth and the one-stop-shopping convenience it offers.

C. Portfolio Rebating to Multi-Specialty Groups

Large drug companies also can exploit advantages in multi-product negotiations with large, multi-specialty physician groups for physician-dispensed drugs that they buy and bill. In such negotiations, a large company can strategically allocate rebates across a product portfolio. The rebating opportunities increase with portfolio size, benefitting large firms relative to smaller firms. These size-related advantages spill over across product lines, including those for which the merging firms may have no overlapping products. These effects for physician-dispensed drugs are analogous to the portfolio rebating advantages large firms enjoy in dealing with PBMs for pharmacy-dispensed drugs. Again, the increased leverage of a large firm in these price/access negotiations could be used by the firm to gain higher prices for a given exclusivity level, or could be used to increase exclusivity for the firm's products, which reduces patients' access to new products from smaller companies. Confidentiality of these contracts makes it very difficult for

harmed patients or competitors to document and challenge such harms after the event. Expanding the traditional product-by-product merger analysis to consider these potential cross-market harms before they occur therefore seems warranted.

In evaluating the antitrust implications of these size-related economies of scale and scope in marketing, it could be argued that at least the detailing advantages may entail real resource savings for drug companies and their physician customers that could be considered cognizable efficiency savings from a merger. While acknowledging this potential, we suggest two offsetting factors that warrant consideration. First, any such efficiencies are unlikely to be passed on to consumers; rather, they are likely to be captured by large drug firms as increased market share and ultimately profits for their products. In normal price-competitive markets, marketing efficiencies might be passed on as firms lower their prices to compete for price-sensitive customers. But as discussed above, patient price-sensitivity in drug markets is very low because insurance covers most of the price, with the patient paying only a modest co-payment that is often independent of the drug price and is capped by "catastrophic" annual limits on a patient's out-of-pocket cost. Moreover, patients lack information about the relative merits of alternative drugs; rather, their drug choices are heavily influenced by physicians and by PBMs that may benefit from higher list prices with larger rebates, not lower list prices.

This lack of price-sensitivity of patients, PBMs, and physician customers to a drug's list price means that any cost savings related to marketing are likely to be realized as profit to pharmaceutical companies and physician groups, not passed on to consumers as lower drug prices. Moreover, to the extent that increased size also enhances a firm's bargaining leverage, there is offsetting potential to either raise prices or increase the exclusivity of the firm's products. Separating these effects empirically would be extremely difficult and, unfortunately, we know of no empirical evidence that has attempted to measure economies of scale and scope in pharmaceutical marketing or the likely associated increases in leverage.

Second, the U.S. pharmaceutical industry's expenditure on marketing and sales is already very large, driven by the huge margins between prices and marginal cost.[44] While some marketing is informative, providing physicians and consumers with information about new products, heavy marketing of well-established products is more likely intended to persuade and promote brand loyalty, which is of questionable social value, particularly for healthcare products that are heavily tax-subsidized. For these reasons, all developed countries except the United States place significant restraints on the volume and forms of pharmaceutical marketing. A full evaluation of pharmaceutical marketing is beyond the scope of this paper. But to the extent that the antitrust evaluation of pharmaceutical mergers involves weighing efficiency savings against the risks of anticompetitive harm, claimed efficiency savings from spending on marketing

[44] Estimates of total marketing spend as a percent of sales is very sensitive to whether the cost of free samples is measured at input cost or full potential sales price.

functions of questionable social value call into question their treatment as standard cognizable efficiencies under merger analysis.

V. Financing

The third advantage of size is that large firms with portfolios of marketed drugs generate huge revenue flows from current sales. Large firms use these retained earnings to fund their marketing and in-house R&D and acquisitions of small- and mid-size firms, turning to external capital markets only if additional funding is needed for the largest acquisitions. By contrast, smaller firms with few or no marketed products must raise funds from external capital markets to undertake costly pre-clinical and clinical trials required for drug approval and to develop in-house marketing and sales functions. Most start-ups rely on venture capital and private equity to fund drugs through early R&D but then turn to public capital markets and licensing or acquisition deals with larger companies to fund the more costly late-stage clinical trials and drug commercialization.

This flow of retained earnings from marketed products gives large firms a lower cost of capital than is available to smaller firms that must raise capital from external private or public equity.[45] Indeed, high drug prices are often defended as necessary to fund the next generation of innovation.[46] This claim ignores the fact that small firms lacking marketed products can and do raise their R&D funding from external capital markets. But the claim recognizes that retained earnings provide a cheaper source of funding for R&D than raising external funds through capital markets.

This advantage of retained earnings also facilitates large firms' acquisitions of other firms, both large and small. The lower cost of retained-earnings financing might be considered a real efficiency saving that large firms bring to their mergers. But such saving benefits consumers *only* if it is passed through as lower drug prices. As argued earlier, the lack of price-conscious customers in the industry makes savings pass-through unlikely in U.S. pharmaceutical mergers.

Nevertheless, in considering the appropriate antitrust posture towards mergers in the pharmaceutical industry, it is important to recognize the reality that small- and even mid-size firms may lack retained earnings and expertise needed to fund R&D and build marketing/sales capabilities, and this is a motive for selling their companies to larger firms that already have retained earnings and sales capabilities. In this context, larger firms' acquisition of smaller firms can offer efficiencies by eliminating the building of additional regulatory, marketing, and sales

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[45] Stewart Myers & Nicholas Majluf, *Corporate financing and investment decisions when firms have information that investors do not have*, 13 J. FIN. ECON.187 (1984).

[46] *E.g.*, Information Technology and Innovation Foundation, *Price Controls Would Harm Drug Discovery and Innovation* (Nov. 5, 2018), https://itif.org/publications/2018/11/05/price-controls-would-harm-drug-discovery-and-innovation-new-report-shows#:~:text=Price%20Controls%20Would%20Harm%20Drug%20Discovery%20and%20Innovation%2C%20New%20Report%20Shows,-November%205%2C%202018&text=%E2%80%9CPrice%20controls%20and%20other%20steps,critical%20to%20new%20drug%20discovery.%E2%80%9D.

functions by smaller firms. Instead, the merged entity can realize economies of scale and scope by using the large firm's established capabilities—indeed, large firms often seek out acquisitions to replenish their pipelines of new products when they anticipate excess capacity in their overhead and sales capabilities relative to their in-house products. In such contexts, acquisitions of smaller firms may bring new drugs to market more quickly, even if the savings are not reflected in lower prices. And as noted, larger firms' acquisition of smaller firms also provides a financial exit for VC and private equity investors in the smaller firms when they sell their shares to the acquiring firm. Such exit potential is important to induce early-stage investors to continue investing in risky small firms. Where a small company's lead product(s) have already been licensed to a large firm, that same large firm is the only likely acquiror of the small firm and the efficiency case for merger is even greater.[47]

These efficiency arguments, based on efficiencies in R&D financing through retained earnings and avoiding duplication of marketing and sales capabilities, argue in favor of allowing large firms to acquire small firms. Such rationales, however, do not apply to mergers between large firms that each already have marketed products that generate retained earnings for funding future R&D and established marketing and sales capabilities.

VI. Antitrust Implications

In this Essay, we have described the significant advantages of overall firm size in the pharmaceutical industry that have contributed to the continued dominance of the largest firms and that threaten to undermine competition. Size conveys advantages to large firms in negotiating with insurance payers for both pharmacy-dispensed and, in some cases, physician-administered drugs. Size conveys marketing advantages in detailing to physicians, and contracting and portfolio rebating with physician groups that dispense drugs. And size assures a stable flow of retained earnings, providing a relatively low-cost source for financing R&D and acquisitions. While these advantages may offer some real resource efficiencies, any efficiency savings are unlikely to be passed on to consumers as lower prices, and they may in fact be used to exclude competitors and harm competition.

An important implication of this thesis, that overall firm size conveys advantages, is the inadequacy in certain cases of traditional merger analysis, which focuses narrowly on increased concentration in specific drug markets, with divesture of specific overlapping products as the only remedy and condition for merger approval. Market-by-market analysis is an important first step, and the divestiture of overlapping products may be necessary to preserve market-specific competition. But this should not be the *only* consideration. Cross-market effects across individual product markets of the merged entity should also be considered. These effects may enable

[47] For example, Medarex's lead product had been licensed to BMS before BMS acquired Medarex, and this licensing deal made BMS the only likely acquiror of Medarex. Disclosure: Patricia Danzon was on the Medarex board when it was acquired by BMS.

mergers to "substantially lessen competition," contrary to the Clayton Act, in the various settings to which we now turn.[48] At the core of our proposals is the size of the merging entities.

What constitutes "large" or "midsize" for these purposes may depend on not only total sales but also such portfolio characteristics as, for example, the number and relatedness of therapeutic areas, possession of blockbuster or "must have" products, and involvement of biologic products rather than chemical drugs susceptible to generic entry.[49] As a first approximation, we suggest that "large" includes the top 10 firms and "mid-size" includes at least the next decile, ranked by global pharmaceutical sales as in Table 1 above.

Our proposed approach fits comfortably in the agencies' recent recognition of potential harms based on unilateral effects. The traditional theory of competitive harm has been based on coordinated effects: that in reducing the number of firms in a market, a merger would make it easier for the remaining firms to collude.[50] But the agencies have explained that "[t]he elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition."[51]

Central to unilateral effects is the concept of incentives. By "eliminating competition," a merger "gives the merged firm incentives different from those of the merging firms."[52] The Merger Guidelines note that "[a] merger between two competing sellers prevents buyers from playing those sellers off against each other in negotiations," which "can significantly enhance the ability and incentive of the merged entity to obtain a result more favorable to it."[53]

[48] 15 U.S.C. § 18.
[49] This is an important subject for future research.
[50] U.S. DEPT. OF JUSTICE & FED. TRADE COMM., HORIZONTAL MERGER GUIDELINES ¶ 7.1 (2010) (analyzing "whether a merger is likely to change the manner in which market participants interact, inducing substantially more coordinated interaction").
[51] *Id.* ¶ 6.
[52] FED. TRADE COMM. & U.S. DEPT. OF JUSTICE, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 25 (2006); *see also id.* ¶ 1 (mergers "enhance[] market power" if they "harm customers as a result of diminished competitive constraints or incentives").
[53] *Id.* ¶ 6.2.

The FTC has used the concept of bargaining leverage in settings as varied as hospitals,[54] pharmacy chains and insurers,[55] and broadband.[56] Leverage refers to the ability of one party in the bargaining context to harm the other party by refusing to deal. As we discuss above,[57] mergers between pharmaceutical firms that are large, in terms of total sales and/or number of products, enhance their leverage in negotiations with PBMs and in marketing to physician customers.

A. Mergers Between Large Firms

The most significant concern is presented by mergers between two large pharmaceutical companies. We suggest that these mergers be presumed to harm competition. The reason stems from large firms' unique advantages, as detailed above. In particular, a large firm benefits from spillover advantages across product classes through bundled contracting with PBMs and detailing and contracting advantages with physician customers. Since these advantages increase with the number of products in the individual firm's portfolio, they are magnified when two large firms merge. The harms to competition can include bundled contracts/rebates by which the larger firm takes advantage of flexibilities not available to smaller competitors or, more egregiously, imposes contract/rebate provisions that set limits on the number or formulary positioning of

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[54] *ProMedica Health System, Inc. v. FTC*, 749 F.3d 559, 563 (6th Cir. 2014) (noting larger hospitals' greater bargaining leverage over insurers known as managed care organizations (MCOs) and explaining that "[i]t is harder for an MCO to exclude the county's most dominant hospital system than it is for the MCO to exclude a single hospital that services just one corner of the county"); FTC, *Price Increases May Result from Combination of the Two Full-service Hospitals in Slidell, Louisiana*, Sept. 13, 2006, *available at* http://www.ftc.gov/opa/2003/04/lahospmerger.htm (full-service acute care hospital's proposed acquisition of the only other such hospital in the area would have confronted insurers with "the choice of either meeting [the acquirer's] price terms or excluding [the two hospitals] from their provider network"); *FTC v. OSF Healthcare System*, 852 F. Supp. 2d 1069, 1083, 1084 (N.D. Ill. 2012) (explaining that "the merger of two closely substitutable hospitals will increase the combined system's bargaining leverage," that this leverage "would in turn allow the combined entity to extract higher prices," and that a defense based on "large, sophisticated insurance companies . . . defeat[ing] any threatened post-merger price increases" by refusing to contract with the merged entity "ignores the current realities of the health insurance market").

[55] FTC, MERGER GUIDELINE COMMENTARY, *supra* note 52, at 35-36 (noting that a merger between the two largest U.S. retail drug store chains, Rite Aid and Revco, would have left "less attractive options for assembling networks that did not include the merged firm," which would have led the merged firm to "unilaterally . . . demand[] higher dispensing fees as a condition of participating in a network"); U.S. Dept. of Justice, *Revised Competitive Impact Statement in U.S. v. Aetna Inc. and The Prudential Ins. Co.* (N.D. Tex., filed Aug. 3, 1999), at 13, https://www.justice.gov/atr/case-document/file/483491/download (explaining that Aetna's proposed acquisition of health insurance assets from Prudential would give it "the ability to unduly depress physician reimbursement rates, . . . likely leading to a reduction in quantity or degradation in the quality of physicians' services").

[56] Cecilia Kang & Emily Steel, *Regulators Approve Charter Communications Deal for Time Warner Cable*, N.Y. TIMES, at B1, Apr. 25, 2016, https://www.nytimes.com/2016/04/26/technology/charter-time-warner-cable-bright-house-cable-deal.html (noting that merged company resulting from Charter Communications' acquisition of Time Warner Cable and Bright House Networks "would have greater incentive and ability to impose or broaden contractual restrictions on programmers that limit their ability to distribute their content through [online video distributors]").

[57] *See supra* Parts III through V.

competitor products with which the PBM may contract, in one or more classes, as a condition of access to the merged firm's products.

These risks are most pronounced when a large firm has one or more "must have" blockbuster products that they can leverage to gain an advantage in other classes with few competitors. The notion of must-have blockbuster pharmaceutical products that cannot be excluded from a PBM's formulary is analogous to the notion of a dominant hospital system that cannot be excluded from a health insurer's contract.[58] By contrast, classes that already include multiple similar products are less vulnerable to anticompetitive contracting strategies, particularly if generics are or will soon become available for one or more products in a class.

Recent lawsuits outside the merger setting illustrate how incumbents can use rebate contracting to impede new competitors' entry.[59] One example involves Pfizer's claims that Johnson & Johnson (J&J) and its subsidiary Janssen Biotech, to protect the market share of its tumor necrosis factor (TNF) blocker infliximab (Remicade), employed exclusionary contracts, bundled discounts, and coercive rebates with insurers aimed at thwarting Pfizer's biosimilar Inflectra and future entrants from gaining market share.[60] In a second example, Shire alleged that Allergan impeded the marketing of Shire's dry eye disease product, lifitegrast (Xiidra), through bundled discounts that were so aggressive that Medicare Part D plans would not purchase Shire's product even if it were offered for free.[61]

In these cases, the alleged exclusionary behavior is tied to rebate volume on a blockbuster product and bundled discounts on other products in the incumbent firm's portfolio. The more products there are in a firm's portfolio, the greater are the opportunities to use bundling for anticompetitive effects. Combining two large firms increases the potential for such anticompetitive behavior, particularly when the merged entity has widely-used blockbuster products that a PBM cannot exclude from its formulary. Even if the merger has offsetting efficiencies in marketing or overhead, any savings are unlikely to result in lower prices for consumers because, as discussed above, insurance blunts consumer price-sensitivity, and PBMs benefit from higher, not lower, list prices.

As a result, we suggest a presumption that a merger between large firms is anticompetitive, with the burden on the merging parties to demonstrate cognizable, merger-specific efficiencies that outweigh the significant risks of anticompetitive effects. The standard efficiencies that acquirors have claimed in order to rationalize megamergers have been the

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[58] *See supra* note 54.
[59] We provide these allegations in lawsuits as the best available evidence on anticompetitive rebate contracts. The confidentiality of all rebate contracts precludes public access to hard data on these agreements.
[60] *Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494 (E.D. Pa. 2018).
[61] *Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538 (D.N.J. 2019). For additional discussion of these cases, see HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.03[D] (2019 Supp.)

elimination of duplicative R&D, administration, and sales functions.[62] As discussed earlier in section II, larger firms have usually undertaken large acquisitions when they face patent expiry on their blockbuster product(s) and gaps in their own pipeline of new products to replace the expiring products, which implies excess capacity in administration, sales, and other functions. [63] Significant cost-cutting in support functions is thus arguably inevitable and largely not specific to the opportunities created by the merger, as required by the notion of cognizable efficiencies. Moreover, post-merger integration is also disruptive, consumes resources, and may lead to the exit of the most productive individuals who have the best external opportunities.

The evidence presented in section II shows that sequential large acquisitions have enabled the dominant firms to replenish their product pipelines and survive until the next acquisition becomes necessary and that shareholders of acquired firms have captured abnormal returns in the form of acquisition premia. However, even if the announcement of abnormal returns for the combined merged entities are weakly positive, that could reflect increases in market power that are of concern here rather than efficiency savings. Unfortunately, we cannot observe the counterfactual of what might have happened had these large mergers been blocked, permitting the upcoming firms to remain independent and perhaps become market leaders, rather than be absorbed into existing larger entities that have, at best, survived. As a result, we propose that mergers between two large firms be treated as anticompetitive, with the burden of proof shifted to the firms to rebut such a presumption by, for example, showing synergies from cross-national complementarity of assets or better utilization of excess capacity in manufacturing without risk of increased market power in negotiations or sales.

B. Mergers Involving Mid-Size Firms

When a large pharmaceutical firm merges with a mid-size firm, there also should be heightened scrutiny, albeit not rising to the level of a presumption of harm to competition. Firms that are mid-size by revenues and number of marketed products (roughly, those ranked 11 through 20 in industry rankings by sales) play an important competitive role in the pharmaceutical industry, serving as viable competitors for the largest firms in marketing and as potential acquirors of smaller firms.

These mid-size firms typically have proven competence of their own with in-house drug discovery and development, marketing and sales, and partnerships with or acquisitions of smaller

[62] For example, AbbVie anticipated that its acquisition of Allergan "will provide annual pre-tax synergies and other cost reductions of at least $2 billion in year three while leaving investments in key growth franchises untouched." AbbVie continued: "The synergies and other cost reductions will be a result of optimizing the research and early stage portfolio, and reducing overlapping R&D resources (~50%), driving efficiencies in SG&A, including sales and marketing and central support function costs (~40%), and eliminating redundancies in manufacturing and supply chain, and leveraging procurement spend (~10%)," with this estimate "exclude[ing] any potential revenue synergies." AbbVie, *AbbVie to Acquire Allergan in Transformative Move for Both Companies*, June 25, 2019, https://news.abbvie.com/news/press-releases/abbvie-to-acquire-allergan-in-transformative-move-for-both-companies.htm.

[63] *See, e.g.*, Patricia M. Danzon, Sean Nicholson, & Andrew J. Epstein, *Mergers and Acquisitions in the Pharmaceutical and Biotech Industry*, 28 MANAGERIAL & DECISION ECON. 307 (2007).

companies. The mid-size firms are attractive acquisition targets for larger firms, as the mid-size firm's marketed products can provide rapid replenishment for gaps in the large firm's pipeline when its patents on lead products approach expiration or internal R&D fails. Mergers involving mid-size firms also remove a potential acquiror for smaller firms and competitor for the largest firms. Large firms' acquisition of mid-size firms assures the continued market dominance of the same large firms over time. At the same time, these large/mid-size acquisitions offer no obvious efficiency savings.

The likelihood of the agencies challenging a merger between a large and a mid-size firm should increase based on the combined entity's product portfolio. Concerns would be heightened when the merged entity has a must-have blockbuster product with large sales and few good substitutes that PBMs cannot exclude from their formularies, to which the firm can tie preferential treatment of its other products. Concern is heightened if there is a blockbuster product that is a biologic approaching patent expiry, with the potential for biosimilar entry that the incumbent may seek to block. AbbVie's acquisition of Allergan is a case in point, as AbbVie's Humira is a must-have blockbuster that PBMs cannot exclude and that will soon face potential biosimilar entry. Similarly, Allergan's Botox is a must-have blockbuster facing increased would-be competitors. We suggest that such a merger warrants careful scrutiny for the potential for anticompetitive contracting to obstruct potential competitors for both of these products.

BMS's acquisition of mid-sized Celgene provides a recent example involving a large and mid-size firm. On the positive side, the two firms' complementary portfolios of cancer products could create marketing synergies for the merged firm. But these marketing synergies may be employed to disadvantage competitors, especially new entrants and smaller firms with fewer products that are not able to offer competitive portfolio-wide deals. And as argued earlier, it is highly unlikely that any real efficiency savings in marketing that the merged firm realizes will be passed through to consumers as lower prices.[64]

Mergers between two mid-size firms warrant modestly less scrutiny than those involving a large firm, albeit still more attention than the usual concerns with overlapping products. Such mergers can create yet another relatively large firm, with increased portfolio power compared to the two stand-alone firms. One example is provided by Takeda's acquisition of Shire, with the new firm now ranking ninth industrywide. In particular, if the acquired firm has one or more must-have products with large sales and rebate volume, these may be leveraged over unrelated classes in the acquiror's portfolio. In addition, if the parties' drugs are predominantly in classes with few competitors, especially biologics that are protected from competition by restrictive rules for biosimilars, such classes are more vulnerable to anticompetitive behavior by powerful players.

[64] As described earlier, these physician-dispensed drugs are generally reimbursed at the firm's average selling price + X% (ASP + 6% for Medicare), which creates incentives for firms to compete by setting higher, not lower, prices.

On the other side, the parties might offer the defense that all the relevant products are in relatively crowded classes, preferably with (or at least subject to) generic entry, which mitigates the risk of anticompetitive contracting. Or they could contend that the mid-size firm has a promising, early-stage product that has the potential to address an unmet need, which the financing and expertise of the other mid-size or larger firm could help develop and bring to market more quickly. The weighing of potential benefits and risks is context-specific, with risks increasing based on must-have products and decreasing the smaller the merged entity.

C. Mergers Involving Small Firms

In general, mergers involving small firms do not require heightened scrutiny beyond the traditional concerns with overlapping products in specific markets.[65] Market-by-market analysis is still important in these settings to determine whether a small company's product could potentially compete with one owned by the large firm or create excessive concentration due to related products.[66] For example, in Roche's acquisition of Spark Therapeutics, Spark's pipeline gene therapy program for hemophilia A could reinforce Roche's existing share of that market based on its Hemlibra treatment. Antitrust agencies in the United States and United Kingdom carefully reviewed this acquisition before authorizing it. Such review reflects appropriate concern that the acquisition might give Roche undue power in that product market or even cause Roche to discontinue the gene therapy. The existence of other companies with competing gene therapy programs mitigated this risk.

Large firms' acquisitions of small firms can provide important efficiencies. As discussed above, large firms generally can provide a lower-cost source of financing for the small firm's R&D, compared to private or public equity, and an exit for early investors. Further, acquisition by a larger firm with established marketing experience eliminates the need for the small firm to develop its own marketing and sales functions. In particular, in contexts in which the large firm already has a licensing agreement with the small firm for either sole or shared development and marketing of the small firm's lead product, the large firm's acquisition of the smaller firm can eliminate costly coordination and duplication of functions.[67] Consistent with this, empirical evidence for merger efficiencies is strongest in cases where a prior licensing relationship already exists between the acquirer and the target, plausibly because this both provides information and the potential for elimination of duplicative, shared functions.

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[65] The discussion in the text focuses on mergers in product markets. But even mergers in "innovation markets" can present concern as a merger between the two companies closest to the market with a particular treatment could result in suppression of one of the research paths. *See* Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393 (2008).

[66] We assume that, where required as a condition of approval, divested products are sold to companies that are plausible strong and committed competitors. This depends on such factors as having related products that can yield synergies in marketing and rebating across categories.

[67] For example, BMS's acquisition of Medarex eliminated potentially duplicative co-marketing of ipilumimab provided for in BMS's licensing agreement for ipilumimab. *See supra* note 47.

More generally, even without a prior licensing arrangement, acquisition by a larger firm with experience and retained earnings can accelerate the development of the small firm's promising product(s). For example, Gilead, a mid-size firm with extensive experience in developing and marketing drugs to treat HIV/AIDS, was an effective acquiror for Pharmacyclics, a small firm with early stage products to treat Hepatitis C. Gilead was able to rapidly develop and launch these acquired compounds to become the first effective treatments for Hepatitis C. Gilead has remained an important competitive player in the Hepatitis C market that would otherwise be dominated by a few large firms.[68]

In short, absent overlapping products, acquisitions of small firms by large and mid-size firms tend to offer cognizable efficiencies without posing significant anticompetitive threats.

D. Application to Other Industries

We have argued that the pharmaceutical industry warrants special consideration for merger analysis on account of the characteristics related to firm size discussed above. Although these characteristics combine and interact with patents to make pharmaceuticals an extreme case, some similar features exist in other industries and are worth noting although their full consideration is beyond the scope of this paper. We have already analogized the similarities to the cross-market effects of hospital mergers, especially those involving dominant hospitals. The potential for the use of bundled contracts to exploit cross-market leverage exists in other industries in which common customers use products from separate but linked markets.

As one example, Amazon Prime gives customers that use Amazon for mail-order book purchases an incentive to also use Amazon for other mail-order products, movies, and grocery deliveries.[69] This is somewhat akin to a large pharmaceutical company using its must-have blockbuster drug for disease X to gain a competitive advantage and/or restrict competition in diseases Y, Z, etc. Also, the broad scope of Amazon's product offerings enables it to offer one-stop-shopping convenience to customers that could act as a barrier to entry to smaller competitors with more limited product range.

There are important differences in the non-pharmaceutical space, however. For example, Walmart and other firms can offer their own free delivery programs on a broad range of products to compete with Amazon Prime and Amazon's broad product range. By contrast, in pharmaceutical markets, PBMs control access for consumers and the top 3 PBMs have roughly 75% market share.[70] Similarly, the potential for entry of other large rival drug firms offering similar products and size advantages is limited by the natural size limits on disease classes, stickiness in product switching, high R&D costs, and the role of patents and barriers to post-

[68] AstraZeneca recently proposed acquiring Gilead but abandoned the attempt.
[69] Amazon, *Amazon Prime*, https://www.amazon.com/gp/help/customer/display.html?nodeId=G6LDPN7YJHYKH2J6 (last visited Apr. 9, 2021).
[70] *E.g.*, Advisory Board, *Pharmacy benefit managers explained*, Nov. 13, 2019, https://www.advisory.com/en/daily-briefing/2019/11/13/pbms.

patent biosimilar entry that limit the market potential for competitor products in any therapeutic class. Further, consumers are largely unaware of new products until they are covered by insurance and prescribed by their physicians. Finally, in most industries there is a reasonable presumption that competition for price-sensitive consumers forces the pass-through of efficiency savings from mergers. By contrast, in the pharmaceutical context, insurance undermines consumer price sensitivity and informational asymmetries make it impossible for consumers to aggressively monitor the insurers, PBMs, and physicians that are supposed to act as consumer agents but in reality have opportunities and incentive to also serve their own interests.

VII. Conclusion

In this Essay, we have described the complex environment and structure of competition in the pharmaceutical industry. The industry is characterized by the persistent dominance of the same large firms, which have maintained their preeminence through acquisitions and the advantages of size, rather than innovation.

This perspective challenges the standard antitrust analysis of mergers, which focuses exclusively on increased concentration in specific markets and the divestiture of overlapping products. Although the agencies have long applied an analysis based on overlapping products in particular markets, we argue that overall firm size conveys advantages across product markets. These advantages appear in negotiations with payers, PBMs, and physicians. They also appear in marketing and selling to physicians. And they take the form of retained earnings advantages in financing all costly functions, especially R&D and acquiring other, promising firms.[71] Each of these elements increases with a firm's size, as measured by number of products and overall sales. This size can be used to the competitive detriment of smaller firms or those seeking to enter markets dominated by large firms.[72]

When two large firms merge, the presumption should be that the merger harms competition. When mergers involve mid-size firms, the agencies should carefully scrutinize effects outside the overlapping markets. And when a small firm is involved, the agencies should apply the typical market-by-market approach. Such a framework is more consistent with industry realities than the approach applied today and ensures that antitrust merger enforcement can play a vital role in the pharmaceutical industry.

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[71] Further research is needed to quantify these effects but is impeded by data confidentiality.

[72] As discussed above, see note 13 and accompanying text, although some of the conduct we consider in the merger context—such as rebate traps—can be challenged outside the setting of mergers, we believe it is important for the agencies to consider the conduct before approving combinations of firms that could exacerbate these competitive concerns.

An Antitrust Framework for False Advertising

Michael A. Carrier & Rebecca Tushnet***

ABSTRACT: Federal law presumes that false advertising harms competition. Federal law also presumes that false advertising is harmless or even helpful to competition. Contradiction is not unknown to the law, of course. This contradiction, though, is acute. For not only are both regimes at issue designed to protect competition, but they are both enforced by the same agency: the Federal Trade Commission, which targets "unfair competition" through antitrust and consumer protection enforcement.

Courts' treatment of false advertising in antitrust cases makes no sense. While courts have reasonably evidenced concern that not all false advertising violates antitrust law, the remedy is not to abandon the false advertising/antitrust interface. Instead, the solution is to focus on the actors most likely to harm the market: monopolists and attempted monopolists.

This Essay proposes an antitrust framework for false advertising claims. It introduces a presumption that monopolists engaging in false advertising violate antitrust law and a rebuttal if the false advertising is ineffective. The framework also applies to attempted monopolization by incorporating factors such as falsity, materiality, and harm inherent in false advertising law, along with competition-centered issues like targeting new market entrants.

Antitrust has dismissed false advertising that entrenches monopoly power for too long. This Essay seeks to resolve the contradiction in the law by showing how false advertising threatens the proper functioning of markets. Such an approach promises benefits for false advertising law, antitrust law, and consumers.

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I. INTRODUCTION

Federal law presumes that false advertising harms competition. Federal law also presumes that false advertising is harmless or even helpful to competition. Contradiction is not unknown to the law, of course. This contradiction, though, is acute. For not only are both the regimes at issue designed to protect competition, but they are both enforced by the same agency: the Federal Trade Commission ("FTC"), which targets "unfair competition" through antitrust and consumer protection enforcement.

Anticompetitive conduct, the focus of antitrust law, increases price and reduces quality. False advertising, the focus of much consumer protection law, deceives consumers and distorts markets. Both types of conduct harm consumers. Despite this overlap, nearly all courts have dismissed private antitrust claims based on false advertising. They have concluded that the conduct cannot violate antitrust law. Or they have presumed that the harm is *de minimis*. This makes no sense. As the Supreme Court has long established, "false or misleading advertising has an anticompetitive effect."[1]

1. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 n.9 (1999) (citing FTC v. Algoma Lumber Co., 291 U.S. 67, 79–80 (1934)).

Courts' concerns stem from the reasonable notion that not every instance of false advertising violates antitrust law. And (usually implicitly) they have worried about applying antitrust's robust remedies of treble damages and attorneys' fees. These courts fear that antitrust liability will disincentivize companies from engaging in advertising that is merely questionable and that might provide useful information to some consumers. But false advertising law preserves a robust space for puffery and debatable opinions; overdeterrence concerns don't justify analysis that is inconsistent with both the economics and psychology of advertising and that, at a minimum, essentially makes it impossible to bring a successful antitrust case based on false advertising. Nor do the Lanham Act's remedies for false advertising fully address harms to competition. Reasoning that conduct that is already illegal on other grounds need not concern antitrust law ignores the multiple other contexts in which breaches of non-antitrust laws are considered to be potential antitrust violations.

One example illustrates how false advertising can entrench powerful positions that harm consumers and the market as a whole.[2] In 2010, AT&T was worried that it was about to lose its exclusivity as sole provider of the iPhone. So it adopted a bait-and-switch plan: it offered "unlimited" data to consumers who signed long-term contracts. But this was a ruse. The company wasn't planning to make good on its promise. It was already clear that smartphone-owning customers used much more data than previous customers had.

AT&T then began to throttle data to its consumers so that webpages took longer to load, streaming video failed to stream, and GPS and email failed.[3] To make the switch stick, AT&T imposed expensive termination fees on consumers who did not want to be bound by the deceptive "unlimited" contracts or encouraged them to buy far more expensive plans.[4] In short, AT&T used deceptive behavior to extend its competitive advantage over other carriers.

False advertising law allows consumers to receive some redress for the money they paid for "unlimited" data that wasn't,[5] but there's no obvious

2. For additional examples in an industry in which the problem is getting worse, see *infra* Section IV.D (discussing the biologics industry).

3. Complaint for Permanent Injunction and Other Equitable Relief at 4–7, FTC v. AT&T Mobility LLC, 87 F. Supp. 3d 1087 (N.D. Cal. 2015) (No. C-14-4785 EMC), *rev'd and remanded*, 835 F.3d 993 (9th Cir. 2016), *reh'g en banc granted*, 864 F.3d 995 (9th Cir. 2017).

4. Fed. Trade Comm'n, Statement of Commissioner Rohit Chopra re: AT&T Mobility, LLC, Commission File No. X150009 (Nov. 5, 2019).

5. With AT&T's false "unlimited promise," the FTC acted. But without government intervention, consumers likely would not have had options for redress because of mandatory arbitration that removes the ability to bring a consumer-protection class action. *See* AT&T Mobility LLC v. Concepcion, 563 U.S. 333, 350–52 (2011). The use of adhesion contracts to prevent consumers from obtaining restitution for false advertising is one significant distortion in the current competitive environment. The ironic result is that competitors may have an easier

remedy for the damage AT&T caused to the market as a whole. Antitrust law has been kneecapped by the courts and thus is powerless to act. In short, the law's neglect of the injuries caused by false advertising threatens structural harm to competitive markets.

In this Essay, we address these problems. We do so by focusing on the actors most likely to harm the market: monopolists and attempted monopolists. These actors are a numerically small percentage of businesses (and of false advertising defendants), but they can do great harm. Our emphasis on monopolists and attempted monopolists addresses courts' concerns of overbroad enforcement, preventing false advertising from morphing automatically into an antitrust violation. And it carves out a critical role for antitrust while embracing—rather than neglecting—antitrust's partner in fighting unfair competition, false advertising law.

We begin by introducing the laws of antitrust and false advertising, explaining the regimes' objectives and methods. We then survey the antitrust caselaw, critiquing three approaches courts considering false advertising claims have taken. Finally, we introduce our antitrust framework for false advertising claims. At the heart of the framework is a presumption that monopolists engaging in false advertising violate antitrust law, with that presumption rebuttable if the defendant can show that the false advertising was ineffective. The framework also applies to cases of attempted monopolization by incorporating factors (falsity, materiality, and harm) inherent in false advertising law, along with competition-centered issues on targeting new market entrants and entrenching barriers to entry. To illustrate how our framework should work, we apply it to an important area: advertising for biosimilars, which are pharmaceutical products with a substantial and growing role in treating numerous diseases.

False advertising that exacerbates monopoly power has been dismissed by antitrust law for too long. This Essay seeks to resolve the contradiction in the law by showing how false advertising threatens the proper functioning of markets.

II. ANTITRUST AND FALSE ADVERTISING

Antitrust and false advertising bear some overlap in goals and methods but operate in different ways. This Part separately considers antitrust and false advertising law before comparing the two.

time suing each other for false advertising than consumers do. But private antitrust enforcement has also been limited by arbitration. *See* Am. Express Co. v. Italian Colors Rest., 570 U.S. 228 (2013); Mark A. Lemley & Christopher R. Leslie, *Antitrust Arbitration and* Illinois Brick, 100 IOWA L. REV. 2115, 2116 (2015).

A. ANTITRUST

Antitrust's widely acknowledged goal is to promote competition.[6] A competitive market maximizes "consumer welfare."[7] Operationalizing this, antitrust law targets conduct that reduces competition and harms consumer welfare by increasing price, reducing output, or offering consumers inferior options.

One central element of a competitive market is advertising, which, as the Supreme Court has recognized, plays "an indispensable role . . . in a free enterprise system."[8] Restrictions on truthful advertising harm competition by "mak[ing] it more difficult for consumers to discover information about the price and quality of goods or services, thereby reducing competitors' incentives to compete with each other with respect to such features."[9] For that reason, the FTC sued 1-800 Contacts, the largest online U.S. retailer of contact lenses, for its "web of anticompetitive agreements with rival online contact lens sellers that suppress[ed] competition in certain online search advertising auctions and that restrict[ed] truthful and non-misleading internet advertising to consumers."[10]

The advertising cases courts have considered have addressed agreements between competitors. But antitrust law also scrutinizes single-firm conduct, which occurs when a firm unilaterally engages in false advertising.[11] The relevant law in this setting is Section 2 of the Sherman Act, which targets

6. *E.g.*, 1 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 100a (4th ed. 2013).

7. *E.g.*, *id.*; Maureen K. Ohlhausen, Acting Chair, Fed. Trade Comm'n, Roundtable Conference with Enforcement Officials at the ABA Section of Antitrust Law Spring Meeting (Mar. 31, 2017), *in* ANTITRUST SOURCE, June 2017, at 1, 20. The consumer-welfare standard is under attack by the "neo-Brandeisian" movement, though it is unclear what standard would replace it. Herbert Hovenkamp, *Is Antitrust's Consumer Welfare Principle Imperiled?*, 45 J. CORP. L. 65, 67 (2019).

8. Bates v. State Bar of Ariz., 433 U.S. 350, 364 (1977).

9. Polygram Holding, Inc., 136 F.T.C. 310, 355 (2003); *see also* Brief of the Federal Trade Commission at 1, 1-800 Contacts, Inc. v. FTC, No. 18-3848 (2d Cir. Oct. 7, 2019) ("Without timely information about competing products and sellers, . . . consumers cannot make informed choices and markets cannot function properly.").

10. *1-800 Contacts, Inc., In the Matter of*, FED. TRADE COMM'N (Oct. 8, 2019), https://www.ftc.gov/enforcement/cases-proceedings/141-0200/1-800-contacts-inc-matter [https://perma.cc/CQ4C-LY5Q]; *see also Polygram Holding*, 136 F.T.C. at 354 (finding agreement among rivals not to advertise products was "presumptively anticompetitive").

11. Other examples of single-firm conduct include predatory pricing (in which a monopolist lowers its price below cost to drive a rival out of the market and then raises it), tying (in which a monopolist sells a product only on the condition that the buyer purchases a second product from it), and refusals to deal (in which a monopolist refuses to deal with a competitor). *See* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE ch. 6 (5th ed. 2016).

monopolization.[12] This offense has two elements: (1) monopoly power and (2) exclusionary conduct.

First, a plaintiff needs to show that a defendant has monopoly power, which has been defined as "the power to control prices or exclude competition."[13] Monopoly power can be shown in one of two ways. First, it can be proved indirectly by examining a defendant's market share along with barriers to entry that could entrench that market position.[14] Courts regularly hold that a 90 percent market share supports market power, with some courts finding a 75 percent share to be sufficient.[15] Second, monopoly power can be proved directly,[16] such as when a brand firm is able "to maintain the price of [a] drug . . . at supracompetitive levels without losing substantial sales."[17] Direct proof of monopoly power also can consist of observable effects on the market such as a price increase or output reduction.[18]

High market share alone, however, is not sufficient for the offense. The defendant also must engage in exclusionary conduct. Courts typically address this question by relying on the distinction in *United States v. Grinnell Corp.* between "the willful acquisition or maintenance of [monopoly] power" and "growth or development as a consequence of a superior product, business acumen, or historic accident."[19]

The monopolization caselaw has developed conservatively, with courts finding violations, for example, when the defendant's conduct does not bear any legitimate justification and where there are harms to the market as a whole. For example, in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, the owner of three downhill skiing facilities in Aspen, Colorado failed to offer a justification for withdrawing from a joint ticketing arrangement with the owner of the only other facility.[20] The Supreme Court found that the monopolist was willing to forgo ticket sales and consumer goodwill in order to harm its smaller competitor.[21] Although monopolization claims often are

12. Section 2 punishes "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2 (2018).

13. United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).

14. *See* HOVENKAMP, *supra* note 11, § 6.2b, at 359–60.

15. *Id.* § 6.2a, at 357.

16. I ABA SECTION OF ANTITRUST L., ANTITRUST LAW DEVELOPMENTS 70 (Jonathan I. Gleklen et al. eds., 7th ed. 2012) (noting that "direct proof has provided the basis for findings of substantial anticompetitive effects in some prominent cases").

17. *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 389 n.19 (D. Mass. 2013)*; see also, e.g.*, *In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 246 (D. Conn. 2015) ("[W]hen direct evidence is available that a party profitably charges supracompetitive prices, the existence of market power can be established from that fact alone.").

18. Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL L. REV. 1, 22 (2017); *see* Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007).

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

20. Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 608–11 (1985).

21. *Id.* at 608.

brought by competitors, consumers also can sue for harm caused by exclusionary conduct.

B. FALSE ADVERTISING

The goal of false advertising law is to protect consumers and competitors from decisions distorted by deception. When consumers make purchasing choices based on sellers' false or misleading claims, they lose and so do honest competitors.[22] There are multiple possible enforcers of false advertising law. Federal and state regulators can sue businesses for deceptive advertising under the Federal Trade Commission Act and similar state "little FTC" acts. Businesses can sue other businesses under the federal Lanham Act, which covers trademark infringement and false advertising. And consumers can bring state-law claims under consumer protection laws barring deceptive trade practices.[23]

Public enforcers have highly limited resources and responsibility for entire markets. They tend to focus on outright scams and on situations in which no single competitor suffers so greatly that it has an incentive to sue. As a result, the most relevant body of law for the false advertising/antitrust interface is the Lanham Act, which allows private parties to challenge the use in commerce of

> any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities.[24]

Courts have added doctrinal flourishes to this broad language. Lanham Act plaintiffs must suffer injury to their interests as commercial entities, which means that consumers don't have standing, but victims of disparagement may even if they aren't direct competitors.[25] Courts have also interpreted the statute to make clear that the false or misleading advertising must be material—likely to influence a purchasing decision—and must deceive or be likely to deceive a substantial segment of the relevant audience.[26] When advertising is explicitly (also known as literally) false, courts presume that it is

22. Of course, the details can be contentious, raising questions like: What counts as deceptive? When is failure to disclose deceptive? How many consumers need be diverted for a remedy to be appropriate? But the core commitment to honesty in material claims is clear.

23. *See generally* REBECCA TUSHNET & ERIC GOLDMAN, ADVERTISING & MARKETING LAW: CASES AND MATERIALS ch. 3 (5th ed. 2020) (providing an overview of varying sources of regulatory authority).

24. Lanham Act § 43(a)(1)(B), 15 U.S.C. § 1125(a)(1)(B) (2018).

25. Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 131–32, 138 (2014).

26. *See, e.g.*, Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310–11 (1st Cir. 2002).

deceptive. And when advertising is ambiguous but potentially misleading, courts generally require the plaintiff to show that a substantial number of consumers receive a false message, usually by a consumer survey.[27] Lanham Act liability is strict; even an advertiser's good-faith belief in the truth of its claims is no defense.[28]

C. COMPARATIVE ASSESSMENT

The primary goal of antitrust law is to enhance consumer welfare by targeting anticompetitive conduct. The primary goal of false advertising law is to provide consumers with truthful information so that rivals can compete on the merits. Both can be seen as variants of a general idea of "unfair competition." But the mechanisms of the unfairness targeted differ.

On the most general level, there is a higher bar to the application of antitrust law, as harm is required to the market as a whole. False advertising, in contrast, can occur even if just an individual competitor is injured (along with the deceived consumers who are both the mechanisms by which harm is inflicted on a competitor and victims in their own right). Reciprocally, there are significant barriers to proving a monopolization claim. Demonstrating monopoly power involves the challenges of defining a market and showing power within that market. And showing exclusionary conduct also presents hurdles, such as rebutting procompetitive justifications the defendant offers. When these stringent requirements are satisfied, antitrust comes down hard on the defendant, who is potentially liable for treble damages, attorneys' fees, and costs.[29]

False advertising is more granular than antitrust law in protecting against not only structural harms to the market, but also economic injuries to individual competitors. It does so even if other competitors remain and the particular competitor (though not unscathed) survives. For consumers, protection against false advertising serves a number of goals that could be described in general terms as "consumer welfare." Harms from false advertising can be economic, when deceived consumers are deprived of the benefits of their bargains. The harms also can be physical, when safety or

27. *See, e.g.*, Design Res., Inc. v. Leather Indus. of Am., 789 F.3d 495, 501 (4th Cir. 2015); C.B. Fleet Co., Inc. v. SmithKline Beecham Consumer Healthcare, L.P., 131 F.3d 430, 434 (4th Cir. 1997).

28. *See, e.g.*, AMCO Ins. v. Inspired Techs., Inc., 648 F.3d 875, 882 (8th Cir. 2011) (noting that neither knowledge nor intent is an element of false advertising under the Lanham Act); Vector Prods., Inc. v. Hartford Fire Ins., 397 F.3d 1316, 1319 (11th Cir. 2005) (per curiam) ("It is well-settled that no proof of intent or willfulness is required to establish a violation of Lanham Act § 43(a) for false advertising. Rather, Section 43(a) provides a strict liability tort cause of action." (footnote omitted) (citations omitted)); Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 944 (3d Cir. 1993) (holding that even false statements made with a reasonable, but wrong, basis are actionable).

29. 15 U.S.C. § 15.

health characteristics are involved. And they can be moral, when an advertiser deliberately deceives and thus disrespects the autonomy of consumers.[30]

False advertising can also harm markets and competitors in a more general way. Consumers expecting false advertising are likely to distrust even truthful claims. The false advertiser thus erects barriers to the success of truthfully advertising competitors, creating a "market for lemons."[31] Bad advertising, that is, is likely to drive out good. This principle is generally accepted (indeed, it won George Akerlof, who coined the phrase "market for lemons," a Nobel prize in economics). False advertising law implements the idea that promoting the flow of truthful information can prevent a destructive cycle of consumer cynicism and lower investment in truthful claims.[32] As one court recently explained, "the harm the Lanham Act addresses is one shared by all competitors in the market—the encroachment on the ability to compete in a fair market."[33] This makes it even more puzzling that courts in antitrust cases have explicitly endorsed the contrary proposition.

III. ANTITRUST'S FALSE ADVERTISING FAILURE

For several reasons, antitrust courts have not sufficiently recognized the harms presented by false advertising. One reason seems to be the perceived comparative ease of alleging false advertising claims, which makes courts hesitant to allow such allegations to form the basis for antitrust claims. A related rationale is antitrust's powerful remedies that include treble damages, or three times the damages suffered. Courts' hesitation to award such damages often affects their substantive analysis of whether an antitrust violation has occurred.

This skepticism of antitrust claims based on false advertising, however, is fundamentally dishonest when it maintains, as too many cases do, that false advertising is never or rarely a competitive concern. This rationale for excluding false advertising from antitrust coverage flies in the face of the Supreme Court's longstanding acknowledgement "[t]hat false or misleading advertising has an anticompetitive effect, as that term is customarily used."[34]

The idea that antitrust's powerful remedies should be reserved for the worst cases is not inherently dubious. But greater honesty about that rationale

30. *See, e.g.*, TUSHNET & GOLDMAN, *supra* note 23, ch. 4; Lee Goldman, *The World's Best Article on Competitor Suits for False Advertising*, 45 FLA. L. REV. 487, 494 (1993).

31. *See generally* George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488 (1970) (analyzing "the interaction of quality differences and uncertainty" in the labor market and "the economic costs of dishonesty").

32. *See, e.g.*, Howard Beales, Richard Craswell & Steven C. Salop, *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 513 (1981).

33. Boltex Mfg. Co. v. Ulma Piping USA Corp., No. 4:17-CV-01400, 2020 WL 598284, at *6 (S.D. Tex. Feb. 7, 2020).

34. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 n.9 (1999) (citing F*TC v. Algoma Lumber Co.*, 291 U.S. 67, 79–80 (1934), which held a false advertisement to be unfair competition).

would allow courts to confront directly the question of when false advertising is poisonous to competition. Even accepting that most instances of false advertising do not violate antitrust law, it doesn't make sense to immunize conduct when monopolists controlling the market entrench their power by engaging in false advertising. And as a baseline principle, the presence of one set of remedies is not preclusive of another set when the facts implicate both bodies of law.[35]

Cases addressing the false advertising/antitrust intersection fall into three groups. The first category completely absolves false advertisers of antitrust liability. The second assumes that false advertising causes *de minimis* harm. The third offers a "case by case" approach. This Part introduces and critiques the tests.

A. ABANDONED ANALYSIS

The U.S. Courts of Appeals for the Fifth and Seventh Circuits offer examples of the first approach: an abandonment of antitrust analysis. These courts have reasoned that false statements enhance competition in advertising markets and that antitrust claims based on disparaging rivals are not actionable. For example, the Seventh Circuit in *Sanderson v. Culligan International Co.* stated bluntly that "[c]ommercial speech is not actionable under the antitrust laws."[36] In particular, the court asserted that "[a]ntitrust law condemns practices that drive up prices by curtailing output" but that "[f]alse statements about a rival's goods do not curtail output in either the short or the long run," but instead "just set the stage for competition in a different venue: the advertising market."[37]

Similarly, the Fifth Circuit in *Retractable Technologies v. Becton Dickinson* drew a distinction between "business torts, which harm competitors, and truly anticompetitive activities, which harm the market," and stated that "absent a demonstration that a competitor's false advertisements had the potential to eliminate, or did in fact eliminate, competition, an antitrust lawsuit will not lie."[38] The court found that the plaintiff "may have lost some sales or market share because of [the defendant's] false advertising, but it remains a vigorous competitor" and did not face "barriers to entry" from the conduct.[39]

The court endeavored to support its conclusion that "false advertising alone hardly ever operates in practice to threaten competition" based not only

35. *See, e.g.*, POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 112–13 (2014) (holding that the Lanham Act and Food, Drug, and Cosmetic Act both apply to regulate advertising claims about food and finding that a Lanham Act claim is not precluded even if the FDA has also issued regulations about the relevant advertising); *see infra* Section IV.A.2 (discussing antitrust cases based on non-antitrust causes of action).

36. Sanderson v. Culligan Int'l Co., 415 F.3d 620, 624 (7th Cir. 2005).

37. *Id.* at 623.

38. Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883, 895 (5th Cir. 2016).

39. *Id.*

a "dearth of Fifth Circuit precedent but [also] by two other considerations."[40] First, it relied on *Culligan* to assert that "false or misleading advertising generally sets competition into motion."[41] And second, it found it "difficult to determine whether such false statements induced reliance by consumers and produced anticompetitive effects, or whether the buyer attached little weight to the statements and instead regarded them as biased and self-serving," which might occur where "the relevant consumers are sophisticated."[42]

The Fifth and Seventh Circuits correctly conclude that some (in fact, many) instances of false advertising will not violate antitrust law and that the receivers of the information will have different abilities to assess it. But the answer to these scenarios is not to abandon antitrust analysis. The fact that most acts of false advertising—or arson or bribery—don't violate the antitrust laws says nothing about how to identify the subset that could.

By engaging in deception that resembles exclusionary conduct, a company—in particular, a monopolist—could entrench its position in the market. There is not, in fact, a "rigid distinction" "between business torts, which harm competitors, and truly anticompetitive activities, which harm the market," since competitors make a market.[43] For one thing, many false statements are made about the defendant's *own* products; a false superiority claim, like AT&T's false "unlimited" data promise, can discourage consumers from trying *any* competitor. For another, many false claims can readily be repurposed when a new competitor appears. Further undermining the Seventh Circuit's rationale, deceptive disparaging statements could readily depress demand for the criticized product, thereby reducing output and increasing price: classic antitrust concerns.[44]

The deeper problem is the premise that misleading advertising "generally sets competition into motion."[45] This reasoning makes "competition" an empty term and specifically erases the governing concept of *unfair* competition. Burning a building down generally sets firefighters into motion and can trigger insurance payouts and new construction, but we don't think that makes arson productive for the overall economy. At best, misleading advertising forces competitors to fight back on unfair ground, expending resources defending truth against falsehood instead of investing

40. *Id.*

41. *Id.*

42. *Id.*

43. Shubha Ghosh, *The Antitrust Logic of Biologics*, 2018 U. ILL. L. REV. ONLINE 46, 53 (quoting *Retractable Techs.*, 842 F.3d at 895).

44. *See* Kevin S. Marshall, *Product Disparagement Under the Sherman Act, Its Nurturing and Injurious Effects to Competition, and the Tension Between Jurisprudential Economics and Microeconomics*, 46 SANTA CLARA L. REV. 231, 253 (2006) (finding it "short-sighted to conclude that the intentional dissemination of false information about a rival's product does not constitute a restraint of trade" since it "restrains the autonomous forces of supply and demand, and is therefore injurious to competition").

45. *Retractable Techs.*, 842 F.3d at 895.

them elsewhere, harming their overall ability to compete. The Supreme Court has reasoned similarly: false and misleading advertising harms competition because it can confuse consumers and make it harder for them to believe any claim they encounter.[46] Furthermore, as one of us has written elsewhere, "corrective advertising, especially by an inherently-less-credible-because-self-interested competitor, is unlikely to fix all the damage of false advertising."[47] That is why false advertising law recognizes that self-help is not a sufficient remedy and intervenes on the side of the victim.

The Fifth and Seventh Circuits also expressed concerns that defendants shouldn't be punished just for promoting their own products.[48] We agree, and so does false advertising law, which requires showings of falsity and materiality, and which has developed a number of doctrines identifying the type of proof required in particular situations.

The Fifth Circuit in *Retractable Technologies* additionally reasoned that advertising that was "wrong, misleading, or debatable" was "indicative of competition on the merits," as opposed to, for example, bribery.[49] But by definition, false advertising is *not* competition "on the merits" because it is deceptive about the merits. And on the Fifth Circuit's theory, if competitors also have the ability to engage in bribery, antitrust should not worry about that either—it is all fair game, and the parties compete on their ability to most effectively seduce or bribe officials (or burn down each other's factories).

A better conclusion would be that both bribery and false advertising are unlawful and that both lead to decisions based on something other than the actual merits of the parties' products. Stated differently, both bribery and false advertising undermine trust and corrode the actual mechanisms of marketplace competition.

The strongest distinction between bribery and false advertising involves an epistemological intuition: factfinders might be wrong about whether false advertising occurred, and if they were wrong, then they might block truthful

46. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 n.9 (1999); *see id.* at 773–74 (providing that "reducing the occurrence of unverifiable and misleading . . . advertising" would promote competition).

47. Rebecca Tushnet, *Fifth Circuit Reverses Multimillion-Dollar Antitrust Verdict Based on False Advertising, Remands*, TUSHNET.COM (Dec. 6, 2016), https://tushnet.com/2016/12/06/fifth-circuit-reverses-multimillion-dollar-antitrust-verdict-based-on-false-advertising-remands-2 [https://perma.cc/7KVC-GNEY]; *see* Akerlof, *supra* note 31, at 495 (explaining that "dishonest dealings tend to drive honest dealings out of the market"); Stephan Lewandowsky, Ullrich K.H. Ecker, Colleen M. Seifert, Norbert Schwarz & John Cook, *Misinformation and Its Correction: Continued Influence and Successful Debiasing*, 13 PSYCH. SCI. PUB. INT. 106, 124 (2012) (discussing the many difficulties of correcting misinformation); *cf.* Richard Craswell, *Static Versus Dynamic Disclosures, and How Not to Judge Their Success or Failure*, 88 WASH. L. REV. 333, 345 n.21 (2013) (noting that studies of corrective advertising ordered as a remedy for false advertising "typically show small but non-zero effects on consumer beliefs" (citations omitted)).

48. *E.g.*, Sanderson v. Culligan Int'l Co., 415 F.3d 620, 623 (7th Cir. 2005); Stearns Airport Equip. Co. v. FMC Corp., 170 F.3d 518, 526 (5th Cir. 1999).

49. *Retractable Techs.*, 842 F.3d at 894 (quoting *Stearns*, 170 F.3d at 523–25).

advertising, which is good for competition. Of course, factfinders might also be wrong about whether bribery occurred, but if they were wrong, it is less likely they would have deterred procompetitive conduct. Given recent Supreme Court precedents, one could characterize many bribery situations as businesses merely giving their opinions to regulators on matters of policy and engaging in First Amendment-protected political speech through money, but that is not (yet) accepted by the courts.[50] Still, the intuition remains that the competitive consequences of factfinders being wrong about false advertising are more dangerous than those accompanying errors about bribery.

We think this concern is vastly overstated. Because false advertising already is illegal, there are well-recognized mechanisms for identifying falsifiable and false statements in advertising. Moreover, this concern should be confronted directly, rather than being buried in statements about the good that false advertising can do.[51] In other areas of antitrust law, the idea that there are procompetitive reasons for conduct does not immunize that conduct from antitrust scrutiny. False advertising is anticompetitive conduct that is theoretically confusable with procompetitive truthful advertising. The solution is to work on minimizing that confusion, not to abandon the field.

B. DE MINIMIS APPROACH

The second approach, represented by the Second, Sixth, Ninth, Tenth, and Eleventh Circuits, applies a presumption that the exclusionary effects of false advertising are *de minimis*.[52]

50. For example, the Court narrowed the "official acts" that can justify a bribery charge so that arranging a meeting only if a constituent agrees to pay is not itself an "official act." McDonnell v. United States, 136 S. Ct. 2355, 2372 (2016); *cf.* McCutcheon v. FEC, 572 U.S. 185, 227 (2014) (holding that "corruption" requires a quid pro quo exchange); Fred Wertheimer, *Symposium:* McDonnell *Decision Substantially Weakens the Government's Ability to Prevent Corruption and Protect Citizens*, SCOTUSBLOG (June 28, 2016, 12:38 PM), https://www.scotusblog.com/2016/06/symposium-mcdonnell-decision-substantially-weakens-the-governments-bbility-to-prevent-corruption-and-protect-citizens [https://perma.cc/2K8K-5TYZ].

51. The term "falsifiable" signifies that it is capable of being proved false, as opposed to a statement that is so vague or ambiguous that it cannot reasonably be deemed either true or false. An unfalsifiable statement is often labeled "puffery," which is nonactionable. *See, e.g.*, Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1145 (9th Cir. 1997).

52. *See* Nat'l Ass'n of Pharm. Mfrs., Inc. v. Ayerst Lab'ys, 850 F.2d 904, 916 (2d Cir. 1988); Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 370 (6th Cir. 2003); Am. Pro. Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Pro. Publ'ns, Inc., 108 F.3d 1147, 1152 (9th Cir. 1997); Lenox MacLaren Surgical Corp. v. Medtronic, Inc., 762 F.3d 1114, 1126–28 (10th Cir. 2014); Duty Free Ams., Inc. v. Estée Lauder Cos., 797 F.3d 1248, 1268–69 (11th Cir. 2015).

1. Introduction: The Treatise and Its Framework

The *de minimis* framework originated in the leading antitrust treatise, *An Analysis of Antitrust Principles and Their Application*.[53] First introduced in 1978 by Philip Areeda and Donald Turner and continued by Areeda and Herbert Hovenkamp, the treaty's influence is unmatched.[54] Justice Breyer has remarked that "most practitioners would prefer to have two paragraphs of Areeda's treatise on their side than three Courts of Appeals or four Supreme Court Justices."[55] "Courts commonly quote portions of the treatise at length . . . . And courts will often explicitly adopt propositions offered by the treatise as law."[56]

The skepticism of antitrust's application to false advertising claims traces back to the 1978 version of the treatise, written at a time before courts had developed robust doctrines establishing the boundaries of Lanham Act false advertising.[57] In considering the relationship between false advertising and antitrust, the treatise highlights the "key problem" presented by "the difficulty of assessing the connection between any improper representations and the speaker's monopoly power."[58] It posits that the "more typical deception defendant is the smaller firm or recent entrant that makes its false claims, collects the payments from deceived consumers, and then disappears or becomes judgment-proof."[59] In contrast, the "false claim leading to or perpetuating durable market power by a firm capable of being sued is much less likely."[60] Relying on these claims, the treatise then concludes that "[b]ecause the likelihood of significant creation of durable market power is so small in most observed instances—and because the prevalence of arguably improper misrepresentation is so great—the courts would be wise to regard misrepresentations as presumptively de minimis."[61]

Before analyzing the treatise's suggested test, it is worth noting that its description of the "typical deception defendant" is not reflected in the case law. Although public enforcers often go after such fly-by-night entities, they

53. *See* 3 PHILLIP E. AREEDA & DONALD F. TURNER, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶¶ 738c, 739 (1978).

54. *See* Rebecca Haw Allensworth, *The Influence of the Areeda–Hovenkamp Treatise in the Lower Courts and What It Means for Institutional Reform in Antitrust*, 100 IOWA L. REV. 1919, 1921 (2015).

55. Justice Stephen Breyer, *In Memoriam: Phillip E. Areeda*, 109 HARV. L. REV. 889, 890 (1996).

56. Allensworth, *supra* note 54, at 1922 (footnote omitted).

57. AREEDA & TURNER, *supra* note 53, ¶ 738c, at 281 (finding a "serious de minimis test" to be "[e]ssential" and "go[ing] further" to "suggest that [disparagement] claims should presumptively be ignored").

58. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 782b, at 351.

59. *Id.*

60. *Id.*

61. *Id.*

also successfully challenge household names like Kellogg and AT&T.[62] Lanham Act false advertising cases are rarely brought against judgment-proof defendants and, in the cases we are concerned with, are brought against monopolists or plausible attempted monopolists—entities distinct from those that concern the treatise—whose market power and durability themselves make their claims more credible and thus more harmful than the claims of unknown market entrants.[63] The treatise accurately describes a set of fraudsters, and we agree that those actors are not good targets for antitrust law. But it does not capture the full scope of consumer deception—nor, in all likelihood, the vast majority of damages done by false advertising. AT&T can take a lot more money from consumers than a small dietary supplement seller that operates only until discovered.[64]

The treatise (again, beginning in 1978) suggests that a plaintiff can rebut the *de minimis* presumption by showing that the alleged anticompetitive conduct is (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of subject matter, (5) continued for prolonged periods, and (6) not readily susceptible of neutralization or other offsets by rivals.[65] Although it is appropriate to ensure that the vast majority of false advertising, perpetuated by firms lacking market power, does not automatically violate antitrust law, the *de minimis* approach overshoots the mark by making it nearly impossible to find antitrust liability even for monopolists bringing about substantial competitive harm. Below, we directly address the concern that animates the test—that most false advertising is not carried out by firms with market power—by focusing on false advertising by firms with monopoly power or a real threat of becoming monopolists.

Although courts have not explicitly invoked it to defend their test, the *de minimis* approach's best theoretical defense comes from an advertising model in which what matters to consumers is merely the fact of advertising rather than its content, meaning that consumers don't actually believe specific

62. *See, e.g.*, Complaint for Permanent Injunction and Other Equitable Relief, *supra* note 3, at 1–2; *Kellogg Settles FTC Charges that Ads for Frosted Mini-Wheats Were False*, FED. TRADE COMM'N (Apr. 20, 2009), https://www.ftc.gov/news-events/press-releases/2009/04/kellogg-settles-ftc-charges-ads-frosted-mini-wheats-were-false [https://perma.cc/R7UJ-WVHP].

63. *See generally* Anne L. Roggeveen & Gita Venkataramani Johar, *Perceived Source Variability Versus Familiarity: Testing Competing Explanations for the Truth Effect*, 12 J. CONSUMER PSYCH. 81 (2002) (discussing strong evidence that repetition of an advertising message increases belief).

64. *See* Rory Van Loo, *Broadening Consumer Law: Competition, Protection, and Distribution*, 95 NOTRE DAME L. REV. 211, 214–15 (2019) (noting that deceptive conduct by major entities such as Amazon, Facebook, and credit card companies substantially harms consumers, with these harms likely underestimated).

65. Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 371 (6th Cir. 2003) (citing AREEDA & TURNER, *supra* note 53, ¶ 738a, at 278–79). Courts are not consistent on whether a plaintiff must show each of the six factors. *See, e.g.*, *id.* ("[W]e decline to consider each element or hold that all elements must be satisfied to rebut the *de minimis* presumption.").

factual claims in advertising.[66] In the content-is-meaningless account, the fact that the advertiser is spending money touting its products is credible evidence that the advertiser believes it has something worth consumers' money, and that general assertion is the only thing consumers are likely to rely on.[67] In this theory, extensive advertising is like the biologically costly peacock's tail that demonstrates reproductive fitness to potential mates: costly advertising evidences marketplace fitness, with the specific claims just window dressing for consumers. If this were true, then we could indeed expect that the effects of false advertising would be *de minimis*.

The content-indifferent approach, however, contradicts what courts, advertisers, and marketing researchers think about the power of advertising generally. Advertisers don't just buy ad space and tell consumers how much they spent on it. Instead, they routinely focus on product features that consumers care about, from price to health and safety, revealing their own expectations that factual claims in advertising influence consumers.[68] Advertisers carefully test marketing claims, and a persuasive claim can drive changes in market share.[69] In fact, false advertising/antitrust claims often arise in highly concentrated markets with consumers who, despite a generally high level of sophistication, lack the ability to verify technical claims. For example, product manufacturers who pay intermediaries to put promotional material in grocery stores care very much about how well the stores implement the promotions, but cannot necessarily perform nationwide audits themselves, making them vulnerable to misrepresentations about competitors' performance.[70]

2. Specific Problems with the Multifactor Test

Not only does the *de minimis* approach conflict with false advertising law, but the individual factors themselves also are not justified, as they are

66. *See* Lillian R. BeVier, *Competitor Suits for False Advertising Under Section 43(a) of the Lanham Act: A Puzzle in the Law of Deception*, 78 VA. L. REV. 1, 8 (1992); Phillip Nelson, *Advertising as Information*, 82 J. POL. ECON. 729, 730–31 (1974); Phillip Nelson, *The Economic Consequences of Advertising*, 48 J. BUS. 213, 214 (1975).

67. BeVier, *supra* note 66, at 10–11.

68. *See* Beales et al., *supra* note 32, at 492–95; Goldman, *supra* note 30, at 491–94; Roger E. Schechter, *Additional Pieces of the Deception Puzzle: Some Reactions to Professor BeVier*, 78 VA. L. REV. 57, 68–79 (1992); *see also* Schick Mfg., Inc. v. Gillette Co., 372 F. Supp. 2d 273, 278 (D. Conn.) ("Because of the expense of television advertising, companies have a very short period of time in which to create a 'reason to believe' and are generally forced to pitch only the key qualities and characteristics of the product advertised."), *modified*, No. 3-05-cv-174 (JCH), 2005 WL 8168764 (D. Conn. June 20, 2005); *id.* at 286–87 ("Gillette's employees testified that television advertising time is too valuable to include things that are 'unimportant.'").

69. *See, e.g.*, Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharms. Co., 290 F.3d 578, 584, 595–96 (3d Cir. 2002) (detailing how the new antacid product claiming nighttime superiority has quickly gained market share).

70. *See* Insignia Sys., Inc. v. News Am. Mktg. In-Store, Inc., 661 F. Supp. 2d 1039, 1049–53 (D. Minn. 2009).

disconnected from the ways in which false advertising does harm. As we discuss the elements of the *de minimis* approach, we will explain why false advertising law's simpler framework accommodates the relevant concerns without discounting the damage false advertising can do.

The first factor requires the advertising to be "clearly false." Although antitrust courts have never had to explain exactly what they mean by that factor, it seems to be something like "not capable of some innocent interpretation."[71] But false advertising law has long recognized that statements that are misleading—literally true[72] or ambiguous, but which induce consumers to reach false conclusions—are actionable.[73] It makes sense for false advertising law to cover both literally false and literally true but misleading claims. Claims that mislead a substantial number of consumers can cause the same kinds of harm as literally false statements. In fact, the literature shows that implications can be *more* persuasive than literal statements, even when they convey the same message to consumers: by making the relevant inferences, consumers essentially persuade themselves.[74] Indeed, the

71. In theory, it could also mean something like "false or misleading by clear and convincing evidence," but that's an awkward way to specify a quantum of evidence, and courts have not provided a reason for requiring a higher standard of proof for antitrust claims based on false advertising.

72. For example, the truthful statement "BMW vehicles passed their emissions tests" implies that their emissions were within legal limits, but this implication is false when BMW designed its vehicles to pass the tests while otherwise emitting unlawful amounts of pollutants. *Cf. Volkswagen to Spend up to $14.7 Billion to Settle Allegations of Cheating Emissions Tests and Deceiving Customers on 2.0 Liter Diesel Vehicles*, FED. TRADE COMM'N (June 28, 2016), https://www.ftc.gov/news-events/press-releases/2016/06/volkswagen-spend-147-billion-settle-allegations-cheating [https://perma.cc/DK2Z-KTDH].

73. All three types of advertising regulation (FTC/state regulators, competitor Lanham Act claims, and state consumer protection law allowing consumer suits) prohibit both false and misleading claims. *See, e.g.*, Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260–61 (11th Cir. 2004) (applying the Lanham Act); FTC v. Roca Labs, Inc., 345 F. Supp. 3d 1375, 1384–85 (M.D. Fla. 2018) (following usual FTC practice of alleging "false or misleading" claims); Hoang v. Reunion.com, Inc., No. C-08-3518 MMC, 2010 WL 1340535, at *5 (N.D. Cal. Mar. 31, 2010) ("Historically, many states have enacted consumer protection laws prohibiting the dissemination of false or misleading statements made in connection with the advertising of products or services, and have not required the plaintiff to prove actual reliance on the false or misleading statement, but, rather, to prove that the false or misleading statement is, objectively, the type of statement likely to deceive a reasonable consumer."); *cf.* 15 U.S.C. §§ 52, 55 (2018) (defining "false advertisement" for "food, drugs, devices, services, or cosmetics" as any advertisement that is "misleading in a material respect").

74. "Consumers are less likely to argue against associations they came up with themselves, and more likely to remember and act on them." Edward F. McQuarrie & Barbara J. Phillips, *Indirect Persuasion in Advertising: How Consumers Process Metaphors Presented in Pictures and Words*, ASS'N FOR CONSUMER RSCH., https://www.acrwebsite.org/web/acr-content/749/indirect-persuasion-in-advertising-how-consumers-process-metaphors-presented-in-pictures-and-words.aspx [https://perma.cc/LW8V-8J3D] (summarizing Edward F. McQuarrie & Barbara J. Phillips, *Indirect Persuasion in Advertising: How Consumers Process Metaphors Presented in Pictures and Words*, J. ADVERT., Summer 2005, at 7); Alan G. Sawyer, *Can There Be Effective Advertising Without Explicit Conclusions? Decide for Yourself*, *in* NONVERBAL COMMUNICATION IN ADVERTISING 159, 170

Supreme Court has specifically recognized that confusing and misleading advertising can harm competition, both by distorting consumer decisions and by clouding the market generally, eroding consumers' willingness to rely on advertising.[75]

The factor of clear falsity seems to be motivated by the concern that courts should not impose antitrust liability unless they are absolutely certain it is justified. The treatise worries that "distinguishing false statements on which buyers do, or ought reasonably to, rely from customary puffing is not easy."[76] But 70 years of Lanham Act precedents (and an even longer record of FTC enforcement) establish that false advertising law maintains a robust doctrine of puffery that excuses claims that are too vague or multivalent to be falsifiable, while identifying claims that are capable of being proven false. When an advertiser makes a factual, falsifiable claim, that claim should be true, and if it is not, the advertiser proceeds at its peril.

Especially in combination with the other factors, the first factor works to preclude liability if there is any way the defendant can spin its advertising, regardless of how the relevant consumers actually understood the message. It is a mistake, however, to ignore how the market in fact reacted to the advertising. If we are hesitant to impose antitrust liability, we should choose a limiting principle focused more on the actual market effects than on the difference between that which is "clearly" false and that which is misleading. The law of false advertising itself strikes an appropriate balance in requiring a showing of falsity or misleadingness—both of which can be shown by a preponderance of the evidence—to a substantial number of reasonable consumers.

The second factor requires the false advertising to be "clearly material." Again, it's not entirely clear what this means; it could be something like "material to every consumer." This is another example of antitrust stepping in with its own formulation of a test that false advertising law has already developed. The ordinary standard for materiality in false advertising law provides that the fact at issue must be one (like a medication's effectiveness or price) that reasonable consumers would consider relevant to purchase decisions.[77] Materiality focuses on whether a claim is likely to influence a

(Sidney Hecker & David W. Stewart eds., 1988) ("Research . . . offers strong evidence that audience members will spontaneously strive to make inferences and conclusions under certain conditions. . . . [A]dvertising audiences are also very likely to 'complete' ambiguous advertising statements or claims. Under conditions [where consumers aren't paying extremely careful attention], . . . subjects tended to make false conclusions . . . which, if the advertiser could or should be considered as the cause of the incorrect conclusion, would be judged deceptive." (footnote omitted) (citations omitted)).

75. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 778 (1999) (noting the "procompetitive effect" of "preventing misleading or false claims that distort the market").

76. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 782d, at 356.

77. *See, e.g.*, U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922 (3d Cir. 1990) (requiring that misrepresentations in advertisements be "likely to influence the purchasing

reasonable consumer's decision, not whether *every* consumer's behavior is changed as a result.[78] False advertising law offers a definition of "reasonable" consumers as ordinary consumers entitled to their preferences, whether those preferences are rational or not.[79] And false advertising law makes clear that not every consumer needs to be affected for there to be serious competitive injury.[80] Indeed, it's easy to imagine scenarios in which competition could be suppressed particularly effectively by targeting specific subgroups, such as price-sensitive consumers (as AT&T did with its false claims), early adopters, or risk-averse consumers.

Another reason why clear materiality is not needed is that false advertising already has a harm causation requirement. A plaintiff is required to show that they suffered (or is likely to suffer) a real injury from the false advertising, though that injury need not be precisely quantifiable.[81] If there was more than a trivial injury from the false advertising, it naturally follows that consumers were in fact deceived by the falsity: They acted on it.[82] In short, an additional requirement that the false advertising be "clearly material" is not necessary.

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decision[s]" of the public to satisfy the materiality requirement (quoting Toro Co. v. Textron, Inc., 499 F. Supp. 241, 251 (D. Del. 1980))); AT&T Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1428 n.9 (3d Cir. 1994) (holding that materiality should be assessed from the consumer's perspective).

78. *See* Rebecca Tushnet, *Running the Gamut from A to B: Federal Trademark and False Advertising Law*, 159 U. PA. L. REV. 1305, 1345 (2011) ("Materiality is an intuitive part of harm, because harm only comes when there is a causal link between the falsehood and consumers' behavior. Materiality is now generally enumerated as a separate requirement in the more elaborate modern multifactor test for false advertising." (footnote omitted)).

79. FTC v. Colgate-Palmolive Co., 380 U.S. 374, 389 (1965); *cf.* Benton Announcements, Inc. v. FTC, 130 F.2d 254, 255 (2d Cir. 1942) (per curiam) ("[P]eople like to get what they think they are getting, and courts have steadfastly refused in this class of cases to demand justification for their preferences. Shoddy and petty motives may control those preferences; but if the buyers wish to be snobs, the law will protect them in their snobbery.").

80. Most strikingly, courts routinely find false advertising when 15 percent or more of consumers are deceived (net of a control group not exposed to the accused advertising); there is no required percentage of deception, but it is clear that deceiving a majority of the relevant consumers is not required for liability. J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32:193 (5th ed. 2021).

81. *See, e.g.*, Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 204 (3d Cir. 2014) (accepting lost control of reputation and lost goodwill caused by false comparative advertising as irreparable harm); PBM Prods., LLC v. Mead Johnson & Co., No. 3:09-CV-269, 2010 WL 957756, at *1 (E.D. Va. Mar. 12, 2010) (evidence of harm to goodwill and lost market share resulted in $13.5 million in damages).

82. Again, one could argue that there is residual uncertainty: Maybe the consumers did not really rely on the false advertising and the harm shown by the plaintiff resulted from something else. But if courts seek to impose a clear and convincing standard on false advertising/antitrust cases, they should do so outright, and explain why the ordinary preponderance of the evidence standard is unjustified or why factfinders shouldn't be allowed to make causation judgments based on the evidence before them.

The third factor provides that the false advertising must be "clearly likely to induce reasonable reliance." On its face, such a requirement may sound justifiable. But it duplicates the materiality factor while overemphasizing the fraud-like idea of "reasonable" reliance. Consumers are not required to treat advertising like the testimony of a hostile witness, parsing each statement for small ambiguities and investigating each one.[83] They need not do this because hundreds of years of history have shown that they don't and won't treat ads with that level of suspicion.[84] As a result, false advertising law has long recognized that protecting consumers from deception requires a standard other than that appropriate for a lawyer in an adversarial process. And while there are reasons that consumers might disbelieve advertising, even about factual and material claims, there is no reason to presume such disbelief. Once again, a requirement to show actual harm from the false advertising more directly addresses the question of whether the false advertising worked.

Fourth, the false advertising must be directed to buyers without knowledge of the subject matter. This, however, is just a reason that consumers might believe claims made to them. There's no need for a separate requirement. If a statement is false or misleading, material, and actually deceived consumers, their knowledge of the subject matter demonstrably was not enough to protect them from deception.[85] For example, in a recent false advertising case, the sellers falsely advertised to large, experienced oil and gas companies about the characteristics of their carbon steel flanges, which are used to attach parts together in, among other things, oil and gas pipelines. As the court pointed out, the technical claims made by the defendant about its production process were difficult to verify; buyers had no practical alternative to relying on the sellers' representations, which included falsified test

83. *See, e.g.*, Am. Home Prods. Corp. v. FTC, 695 F.2d 681, 689 (3d Cir. 1982) (declining to require ordinary consumers to read ads with "sedulous" attention).

84. *See generally* DEE PRIDGEN, RICHARD M. ALDERMAN & JOLINA C. CUARESMA, CONSUMER PROTECTION AND THE LAW § 2:10 (2020) (discussing policymakers' reasons for removing traditional stringent fraud requirements in modern consumer protection law); Jessica M. Choplin, Debra Pogrund Stark & Jasmine N. Ahmad, *A Psychological Investigation of Consumer Vulnerability to Fraud: Legal and Policy Implications*, 35 L. & PSYCH. REV. 61 (2011) (discussing how consumers fall for fraud because they do not carefully evaluate details).

85. One consequence of this factor's disconnection from reality is that courts will interpret it in varying ways. In *Chase Mfg., Inc. v. Johns Manville Corp.*, No. 19-cv-00872-MEH, 2020 WL 1433504, at *13 (D. Colo. Mar. 23, 2020), for example, the court held that buyers in a highly concentrated, sophisticated market lacked firsthand knowledge of the "subject matter" primarily because most of them had never bought the plaintiff's product, and it was not clear that the plaintiff's advertising of its own test results was widely disseminated or that it covered the alleged misrepresentations about asbestos content. The real issue was not that these parties lacked information about the product, but that the plaintiff was a new market entrant and that the defendant's alleged misrepresentations related to product safety and litigation risk, where buyers might be particularly cautious. *Id.*

results.[86] Again, the underlying intuition might be that correcting the record should be easy with knowledgeable consumers, and thus that antitrust remedies are heavy-handed and unnecessary. But there is no reason to make such an assumption. (Indeed, the flange manufacturer instead doubled down and sent letters to customers accusing the plaintiff of lying; only years later did it admit the truth.[87]) And, as we noted in the previous Section, there are many reasons why misinformation can be hard to correct, especially for new entrants that do not yet have an established base of customers.[88]

Fifth, the false advertising must be continued for prolonged periods. This factor also seems to be a rough proxy for likelihood and amount of harm. But it does not justify duration as an independent requirement and does not offer a metric by which duration could be measured.[89]

Finally, the false advertising must not be readily susceptible of neutralization by rivals. Like other factors, this one duplicates deceptiveness and harm. If the false advertising worked, then it damaged the fair functioning of the marketplace, regardless of what theoretically could have happened. Relatedly, this factor, like the fourth factor, is inconsistent with what we know about the difficulty of correcting a misperception once established.[90] Presuming that neutralization is possible does not reflect marketplace reality.[91]

As a final point, putting the burden on competitors to correct material falsehoods is inconsistent with the basic antitrust concept that incumbents shouldn't be able to erect barriers to market entry just to deter rivals. To the contrary, the multifactor test, as well as the no-liability rule, bakes in the idea that it is legitimate for entrants to face additional costs to overcome exclusionary false advertising. False advertising law is designed to take false advertising off the table as a method of competition. It substitutes for countermeasures because, among other things, of the waste and lack of trust such free-for-all systems generate. Antitrust should not undercut false advertising law by presuming that already-illegal conduct is easy to correct.

In short, false advertising doctrine makes clear that none of the factors in the current test justifies a presumption that harm to competition is *de minimis*. The factors and the general assumption that false advertising has only a minimal effect on competition have been influential but not supported by evidence.

86. Boltex Mfg. Co. v. Ulma Piping USA Corp., No. 4:17-CV-01400, 2020 WL 598284, at *5 (S.D. Tex. Feb. 7, 2020).

87. *Id.* at *3.

88. *See supra* notes 46–47 and accompanying text.

89. *See Chase*, 2020 WL 1433504, at *14 (finding that misstatements that occurred over a period of months, during the plaintiff's attempt to launch its business, were of sufficient duration).

90. *See supra* notes 46–47 and accompanying text.

91. *See* Maurice E. Stucke, *When a Monopolist Deceives*, 76 ANTITRUST L.J. 823, 829 (2010) ("If product disparagement is ineffectual, why would any firm, much less a monopolist, engage in it?").

C. CASE-BY-CASE APPROACH

A third group of courts, led by the Third, Eighth, and D.C. Circuits, takes a case-by-case approach in assessing whether the conduct violates antitrust law. For example, the Third Circuit in *West Penn Allegheny Health System, Inc. v. UPMC* explained "that anticompetitive conduct can include . . . making false statements about a rival to potential investors and customers" and that "defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts."[92] Similarly, the D.C. Circuit in *Caribbean Broadcasting System, Ltd. v. Cable & Wireless PLC* noted that "fraudulent misrepresentations" are "well within" the recognition that there are multiple forms of anticompetitive conduct.[93] And the Eighth Circuit in *International Travel Arrangers, Inc. v. Western Airlines, Inc.* explained that a concerted campaign by an alleged monopolist involving newspaper advertisements, radio commercials, and a letter to customers was "a form of competition[,] and because competition is the object sought to be preserved by the antitrust laws, [courts] must be careful in drawing a line between fair competition, unfair competition and competition that is so unfair as to rise to the level of an unreasonable restraint of trade."[94]

Courts applying the case-by-case approach have appreciated that anticompetitive conduct takes "too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties."[95] Under this approach, one relevant factor has been the role the conduct plays in a competitor's ability to finance itself. In one case, for example, the Third Circuit determined that false statements to investors about a competitor's financial health caused the rival to pay inflated financing costs on its debt and demonstrated anticompetitive conduct sufficient to survive a motion to dismiss.[96]

A second factor that courts have analyzed under the case-by-case approach is the extent to which false statements lock in decision-making. In *United States v. Microsoft Corp.*, for example, the D.C. Circuit found that deceptive statements to Java-based software developers about the interoperability of Windows-based systems with other platforms resulted in developers' inadvertently producing software compatible only with Windows and demonstrated anticompetitive conduct violating Section 2 of the Sherman Act.[97]

By analyzing conduct as a whole without requiring a showing exceeding *de minimis* harm, the case-by-case approach offers flexibility. This is the most justifiable of the three approaches. But the approach could be strengthened

92. W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 109 & n.14 (3d Cir. 2010).
93. Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC, 148 F.3d 1080, 1087 (D.C. Cir. 1998).
94. Int'l Travel Arrangers, Inc. v. W. Airlines, Inc., 623 F.2d 1255, 1267 (8th Cir. 1980).
95. *Caribbean Broad.*, 148 F.3d at 1087.
96. *W. Penn Allegheny*, 627 F.3d at 109–10.
97. United States v. Microsoft Corp., 253 F.3d 34, 76–77 (D.C. Cir. 2001).

by highlighting relevant factors and drawing on learning from false advertising law.

IV. AN ANTITRUST FRAMEWORK

As the previous Part showed, antitrust could benefit from a new framework for false advertising. The approaches abandoning antitrust liability and applying a *de minimis* analysis are not justified: the law and practice of false advertising is far more consistent with antitrust's own general vision of the marketplace. And the case-by-case evaluation could use development.

The reasons courts have not applied approaches faithful to false advertising are not hard to see. The leading antitrust treatise has worried that "plaintiffs are often less disciplined in making tort-like claims in antitrust suits than in tort suits."[98] Courts also reasonably want to impose requirements that prevent every false advertising case from morphing into an antitrust case. Antitrust analysis could use assistance since the "exclusionary conduct" needed for monopolization doesn't have much content. This Part explains the need for antitrust and offers frameworks that courts can apply to monopolists and those seeking to become monopolists.

A. ANTITRUST'S NECESSITY

False advertising liability alone cannot address the marketwide harms caused by deceptive behavior. This Section first addresses antitrust's comparative advantage for marketwide harms. It then offers examples of antitrust properly targeting conduct that violates other, non-antitrust laws, demonstrating that antitrust's treatment of false advertising is an outlier. It concludes by showing that false advertising's remedies cannot fully protect competition on their own.

1. Antitrust's Comparative Advantage

An antitrust-based framework for false advertising claims is necessary because of the unique role that the discipline can play. When companies engaging in false advertising have monopoly power, they possess the ability to harm not only an individual competitor but also the market as a whole. The consequences can be significant, especially for nascent competitors not able to enter the market, as the deception of consumers deprives them of the opportunity to obtain lower prices, more options, or enhanced quality.

One way to understand the harms of false advertising to the market as a whole is revealed by George Akerlof's classic explanation of the market for lemons.[99] As Akerlof explains, in the absence of some way to guarantee the

98. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶782a, at 345.

99. Akerlof, *supra* note 31, at 488–90. Akerlof focuses on information asymmetry, but if consumers trusted that producers were constrained to make only truthful claims, the asymmetry would disappear because producers with above-average products would be credible when they

truth of claims about products, such as a used car's quality, consumers reasonably respond by discounting all such claims. This distrust means that producers with actually superior products cannot charge the amount consumers would pay if they believed the superiority claim, which pushes superior (but more expensive to produce) products out of the market.

If truthful advertisers are not able to guarantee their claims, producers unable to compete on their product characteristics suffer. And consumers are harmed by an unattractive (and perhaps even harmful, in the case of false health or safety claims) mix of products. Meanwhile, many false advertising techniques can be readily repurposed for new uses, meaning that a false advertiser can go from success to success in the absence of false advertising liability.[100] Regulation that suppresses false claims—especially where such claims are most likely to have an effect—thus does more than protect individual consumers from fraud. It allows truthful producers to compete on a level playing field. In other words, addressing false advertising protects competition, not just competitors.

The Supreme Court relied on Akerlof's insights when it endorsed the pro-competitive effects of restrictions on false advertising. In *California Dental Ass'n v. FTC*, the Court addressed a dental association's attempts to restrict "false or misleading" advertising that imposed significant limits on advertising "low prices" or other general price claims.[101] The Court rejected the idea that such limits were inherently anticompetitive. Especially where information is hard to evaluate, even broad restrictions with the aim of preventing false advertising can be procompetitive.[102]

When false advertising threatens harms to the market as a whole, antitrust liability offers advantages over false advertising law. For starters, antitrust offers a more powerful toolkit deterring this conduct. Although false advertising law allows recovery of damages (albeit not as a penalty) and disgorgement of the profits from false advertising, courts impose high barriers to disgorgement, including requiring a showing of willfulness. In addition, courts have required plaintiffs to show a robust connection to the harm suffered to receive damages or disgorgement of profits. As a result, courts have denied awards in precisely the cases of concern: where there are a small number of potential competitors and where some of the monopolist's gains from false advertising likely came at the expense of the overall market rather

said so, and the failure to disclose quality information would itself be a worthwhile signal. As a result, falsity (either explicit or through implication) is a key driver of the degeneration in the market. *See* Beales et al., *supra* note 32, at 505–06, 510–11.

100. *Cf.* Telebrands Corp. v. FTC, 457 F.3d 354, 361 (4th Cir. 2006) (noting that certain falsities may be readily replicable).

101. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 783 (1999).

102. *Id.* at 771–73 (noting that customers' access to information in the dental market was limited and the implemented restriction increased the reliability of the information consumers had).

than a single plaintiff, making it difficult to allocate false advertising-based damage awards.[103]

There are two key ways in which antitrust offers more powerful protection against monopolists' false advertising than federal false advertising law: remedies and eligible plaintiffs. First, antitrust offers the more powerful remedies of treble damages and automatic (as opposed to the Lanham Act's exceptional[104]) attorneys' fees that promise to provide robust deterrence against companies considering this behavior. Antitrust also offers injunctive relief preventing the continuation of the conduct. While a Lanham Act false advertising injunction generally is limited to the specific false claims that have been proven, an antitrust injunction could more generally target false advertising and marketwide harm to competition.[105] Antitrust offers a more expansive territorial jurisdiction.[106]

Second, unlike the federal Lanham Act, which denies consumers standing to sue despite the direct harm they suffer from false advertising, antitrust law, importantly, allows customers to challenge the harms they experience from false advertising. State consumer protection laws are limited in important ways, including state-law variation that makes multistate consumer class actions all but impossible[107] and restrictions in many states that preclude businesses from bringing claims in their roles as consumers[108] even though businesses are often important customers for the subset of false advertising cases involving monopolists and would-be monopolists. Thus, antitrust provides remedies that would otherwise be unavailable to plaintiffs who were themselves deceived by a monopolist or threatened monopolist's false advertising.

A separate and independently compelling reason to use antitrust where appropriate is that, in antitrust law, it would be possible to consider false advertising as part of an overarching scheme used to harm a competitor, something false advertising law by definition can't do. In fact, the inclusion of this behavior could push the range of conduct over the threshold of antitrust liability. For example, in *In re Suboxone Antitrust Litigation*, the court found that the plaintiff could not demonstrate that its claim that the defendant had

103. *See, e.g.*, Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883, 893–97 (5th Cir. 2016).

104. *See* 15 U.S.C. § 1117 (2018).

105. When the FTC sues, courts often recognize that a particular false advertising technique (e.g., false claims of efficacy) can readily be adapted to new products or situations. *See, e.g.*, *Telebrands Corp.*, 457 F.3d at 361–62. With its competition focus, an antitrust injunction could similarly protect against repurposing false advertising to exclude other competitors.

106. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶782a, at 344 & n.1.

107. *See, e.g.*, Castano v. Am. Tobacco Co., 84 F.3d 734, 741 (5th Cir. 1996) ("In a multi-state class action, variations in state law may swamp any common issues and defeat predominance.").

108. *See, e.g.*, MacDonald v. Thomas M. Cooley L. Sch., 724 F.3d 654, 660–61 (6th Cir. 2013) (noting that the Michigan Consumer Protection Act does not protect against false advertising claims involving commercial purchases).

refused to participate in a safety program required by the U.S. Food and Drug Administration ("FDA") individually made out a violation of antitrust law.[109] But it found that "a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable."[110] Such global assessment can allow consideration of a monopolist software provider's practices of promising "vaporware" that it couldn't deliver to prevent customers from turning to competing software alternatives and of creating fear, uncertainty, and doubt about the competition as part of a larger constellation of anticompetitive activities.[111] As the Third Circuit noted in *LePage's Inc. v. 3M*, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."[112]

2. Need for Two Regimes

We suspect that much of the courts' hostility to considering false advertising as part of an antitrust claim comes from the conviction that antitrust remedies are harsh, and that false advertising remedies are thus more appropriate, even for false advertising with anticompetitive effects. This Section shows how this approach is inconsistent with antitrust's treatment of other illegal conduct. Indeed, to the extent that courts want to constrain antitrust's scope to avoid overdeterring legitimate behavior, it is illogical to be *less* willing to deter conduct that is already illegal than to deter conduct that is otherwise legal. Although there are some areas (specifically, parts of the telecommunications industry) in which competition is so closely regulated that antitrust has a limited role, that is not true across the wide range of industries where false advertising can be successful in harming competition.

109. *In re* Suboxone Antitrust Litig., No. 13-MD-2445, 2017 WL 36371, at *7–9 (E.D. Pa. Jan. 4, 2017).

110. *Id.* at *8; *see also, e.g.*, Abbott Lab'ys v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not."); *In re* Gabapentin Pat. Litig., 649 F. Supp. 2d 340, 359 (D.N.J. 2009) ("If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability."); *In re* Neurontin Antitrust Litig., MDL No. 1479, 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009) ("The distinction is between analyzing individual acts or categories of anticompetitive conduct as contrasted with individual theories of liability derived from those acts.").

111. Caldera, Inc. v. Microsoft Corp., 72 F. Supp. 2d 1295, 1300–01, 1309–20 (D. Utah 1999) (discussing alleged use of vaporware and "fear, uncertainty, and doubt" to harm competitors); *cf.* Robert Prentice, *Vaporware: Imaginary High-Tech Products and Real Antitrust Liability in a Post-Chicago World*, 57 OHIO ST. L.J. 1163, 1172–73 (1996).

112. LePage's Inc. v. 3M, 324 F.3d 141, 162 (3d Cir. 2003); *see also, e.g.*, Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 698–99 (1962) (concluding that it is improper to treat antitrust claims as "separate and unrelated lawsuits" and that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each").

Thus, antitrust remedies are desirable even if false advertising remedies are also available.

Antitrust's hostility to false advertising as a basis for liability becomes even more puzzling when we look at the overall legal environment. There is a strong basis in twentieth century Supreme Court precedent for considering deception to be anticompetitive in the antitrust sense. For example, the Supreme Court in *FTC v. Winsted Hosiery Co.* found that false labeling that "deceive[d] a substantial portion of the purchasing public" constituted an "unfair method of competition" because "when misbranded goods attract customers by means of the fraud which they perpetrate, trade is diverted from the producer of truthfully marked goods."[113] The Court also held, in *FTC v. R.F. Keppel & Bro.*, that "[i]t would seem a gross perversion of the normal meaning of the word . . . to hold that the [conduct at issue] is not 'unfair'" when "it [was] clear that the practice is of the sort which the common law and criminal statutes have long deemed contrary to public policy."[114]

More broadly, as *Keppel* suggests, there are many examples of courts finding antitrust liability in cases in which the conduct also violates a separate legal regime. In one of the most oft-cited cases, the court in *Conwood Co. v. U.S. Tobacco Co.* upheld a jury verdict of monopolization based on tortious conduct in the moist snuff (smokeless tobacco) market.[115] In this market, point of sale advertising (through racks in stores containing the product) is crucial because of advertising restrictions.[116] One manufacturer, Conwood, challenged multiple types of tortious conduct by another, U.S. Tobacco Company ("USTC"), claiming:

> that USTC (1) removed racks from stores without . . . permission . . . and discarded and/or destroyed these racks, while placing Conwood products in USTC racks . . . to bury Conwood's products and reduce their facings; (2) trained their "operatives to take advantage of inattentive store clerks with various 'ruses' such as obtaining nominal permission to reorganize or neaten the moist snuff section," in an effort to destroy Conwood racks; (3) misused its position as category manager by providing misleading information to retailers in an effort to dupe retailers into believing, among other things, that USTC products were better selling so that retailers would carry USTC products and discontinue carrying Conwood products; and (4) entered into exclusive agreements with retailers in an effort to exclude rivals' products.[117]

113. FTC v. Winsted Hosiery Co., 258 U.S. 483, 493 (1922).

114. FTC v. R.F. Keppel & Bro., 291 U.S. 304, 313 (1934).

115. Conwood Co. v. U.S. Tobacco Co., 290 F.3d 768, 795 (6th Cir. 2002).

116. *Id.* at 774.

117. *Id.* at 783.

After a trial, the jury found that this behavior constituted "exclusionary conduct without a sufficient justification, and that USTC maintained its monopoly power by engaging in such conduct."[118] The Sixth Circuit affirmed the jury's verdict.[119] Similarly, the Fifth Circuit, in *Associated Radio Service Co. v. Page Airways, Inc.*, found exclusionary conduct from "evidence of foreign bribes" and "a contract [that] was the result of improper influence."[120]

The pharmaceutical industry has provided the setting for other examples of antitrust scrutiny of conduct that violates non-antitrust rules, particularly those relating to fraud. The *Walker Process*[121] line of cases holds that the fraudulent procurement of a patent or enforcement of a patent obtained by fraud can violate antitrust law.[122] Other cases involve the allegedly fraudulent listing of patents in the "Orange Book,"[123] an annual compilation of drugs and their associated patents.[124] And courts have recognized antitrust liability when a brand company makes "repeated and allegedly false patent descriptions" to the FDA.[125]

Despite these cases, one could conceivably argue that antitrust should not apply to actions that are also governed by a separate regulatory regime. In *Verizon Communications v. Law Offices of Curtis V. Trinko*, the Supreme Court indicated that where another regulatory regime is guaranteeing competition, there may not be a need for antitrust enforcement.[126] That case can only be fully understood, however, in relation to the industry in which it arose. The Court in the case was evaluating the Telecommunications Act, which provides the Federal Communications Commission ("FCC") with general—and *effective*—regulatory authority over the industry, including its competitive

118. *Id.* at 788.

119. *Id.* at 795; *cf.* Byars v. Bluff City News Co., 609 F.2d 843, 854 n.30 (6th Cir. 1979) (discussing allegations similar to *Conwood*'s that "if credited, could result in a finding of predatory conduct"). Nonetheless, shortly afterwards, the Sixth Circuit explicitly adopted the *de minimis* approach to false advertising. Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 370 (6th Cir. 2003).

120. Associated Radio Serv. Co. v. Page Airways, Inc., 624 F.2d 1342, 1354 (5th Cir. 1980).

121. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965).

122. *See, e.g.*, *In re* Lipitor Antitrust Litig., 868 F.3d 231, 271 (3d Cir. 2017) (refusing to dismiss the "plausibl[e] alleg[ation] that the PTO did not find a lack of fraud in initial patent proceedings through its reissuance of the . . . [p]atent"); *In re* Loestrin 24 Fe Antitrust Litig., 261 F. Supp. 3d 307, 346 (D.R.I. 2017) (denying motion to dismiss because "[p]laintiffs plead sufficient underlying facts to support a reasonable inference of intent to deceive the PTO and materiality").

123. U.S. DEP'T OF HEALTH & HUM. SERVS., FDA APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (41st ed. 2021), https://www.fda.gov/media/71474/download [https://perma.cc/DZ8W-9D7H].

124. *E.g.*, *In re* Buspirone Pat. Litig., 185 F. Supp. 2d 363, 366–67 (S.D.N.Y. 2002).

125. *E.g.*, *In re* Actos End-Payor Antitrust Litig., 848 F.3d 89, 100 (2d Cir. 2017).

126. Verizon Commc'ns Inc. v. Law Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 411–12 (2004).

structure (e.g., restrictions on concentrated ownership and must-carry requirements).[127]

Other settings require more robust antitrust enforcement. For example, the FDA has very specific authority over drugs and medical devices, but it does not pervasively regulate industry structure in the way that the FCC does. Instead, the FDA has concluded "that issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by the FTC, which is the Federal entity most expert in investigating and addressing anticompetitive business practices."[128] Much more similar to the FDA than FCC, false advertising regulation lacks the pervasive control and monitoring, including reporting requirements, of telecommunications law.[129]

False advertising litigation cannot effectively stand in for the antitrust function. False advertising, unlike the FCC's jurisdiction, is broad rather than deep: it covers a wide variety of competitive situations, from mouthwash to specialized airline components, but only by barring falsity and deception rather than by pervasively dictating market structure. Of critical significance, moreover, false advertising law is itself underenforced. The FTC has substantial resource constraints. And consumers themselves are rarely able to sue for the harms they suffer. Consumer contracts typically contain mandatory arbitration provisions, making schemes like AT&T's market-shaping deception harder to fight. As a result, there is no "false advertising regime" that effectively fosters competition and negates the need for antitrust enforcement.[130]

127. For an argument supporting antitrust enforcement in settings covered by heavy regulation, see Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009).

128. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Opinion Letter for Docket No. FDA-2009-P-0266 (Aug. 7, 2013), at 7; *see also* Scott Gottlieb, Comm'r of Food & Drugs, Food & Drug Admin., Remarks at the FTC Workshop Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017) (indicating frustration with conduct that "game[s] the system" in "mak[ing] it hard, or altogether impossible, for generic firms to get access to" samples needed to show equivalence); Transcript of Motions Hearing at 115–16, Actelion Pharms. Ltd. v. Apotex, Inc., 12-cv-05743-NLH (D.N.J. Oct. 17, 2013), ECF No. 96 (denying motion to dismiss on grounds that "[t]he FDA is not the FCC," "that there is no other potential remedy to a defendant suffering anticompetitive conduct," that "*Trinko* can't repeal Section 2," and that Section 2 "prevent[s] the improper maintenance and extension of a monopoly through improperly motivated conduct").

129. *See Verizon*, 540 U.S. at 412.

130. Nor would antitrust courts be forced to conduct a completely foreign analysis in determining issues related to false advertising. To pick a contrary example, courts considering "reverse payment settlements," in which brand drug firms pay generics to settle patent litigation and delay entering the market, would be forced to engage in a different—and more complex—analysis if they were forced to determine the merits of the patent litigation to assess the antitrust claim. *See* FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012) (recognizing difficulty of courts "deciding a patent case within an antitrust case about the settlement of the patent case," which it analogized to the southern dish of turkey, duck, and chicken known as "turducken"), *rev'd and remanded sub nom.*, FTC v. Actavis, Inc., 570 U.S. 136 (2013).

B. FRAMEWORK FOR MONOPOLISTS

One concern courts have raised with making false advertising the basis for an antitrust violation is that much of this behavior does not affect the market as a whole. Courts are right that even if one company engages in this conduct, and even if an individual rival is harmed as a result, that does not mean that competition in the market as a whole is affected. But there is a simple solution to this concern: focus on the defendant's market power. Of all the actors employing false advertising, monopolists are the most likely to affect the market, with those attempting to monopolize making up the second-most-likely category. Targeting these two categories of actors recognizes that Section 2 of the Sherman Act provides the appropriate—and in fact only—framework for antitrust liability for unilateral conduct such as false advertising.

Focusing attention on only monopolists and attempted monopolists dramatically narrows the universe of false advertising/antitrust claims. Such an emphasis also is consistent with the approach taken in the Areeda/Hovenkamp treatise, which recognizes that antitrust may be appropriate when "the practice makes a durable contribution to the defendant's market power."[131] The treatise crafts a *de minimis* presumption because of the relative unlikelihood that any given false claim would "lead[] to or perpetuat[e] durable market power."[132] But the treatise also recognizes that "misrepresentations and organized deception by a dominant firm may have Section 2 implications when used against a nascent firm just as it is entering the market."[133] Once we understand that the treatise's concerns about overapplication of false advertising law are addressed by requiring monopoly (or, as discussed below, attempted monopoly) status, the treatise would lend support to liability when the defendant's monopoly power makes false advertising especially likely to affect the market as a whole and harm competition.

Our focus on monopolists and attempted monopolists also is consistent with antitrust injury doctrine. As the Supreme Court famously explained in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, plaintiffs must prove "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful."[134] In other words, plaintiffs must challenge a harm that affects the market as a whole. Limiting our scrutiny to monopolists and attempted monopolists helps effectuate *Brunswick*'s objectives.

We suggest a presumption that false advertising by monopolists constitutes monopolization. Crucially, the most fundamental critique against

131. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 780, at 341.

132. *Id.* ¶ 782b, at 351.

133. *Id.* ¶ 782b, at 353.

134. Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977).

applying antitrust to false advertising—that "false advertising" does not require marketwide effects—are addressed by the defendant's control over the market.

To satisfy the first of the two elements of a monopolization case, a plaintiff must show that the defendant has monopoly power. As discussed above,[135] a plaintiff can do so indirectly by showing a market share of at least 75 percent (and more likely 90 percent) along with barriers to entry that could entrench that market position. A plaintiff also can prove market power directly, such as by showing the defendant's power to impose price increases or output reductions.

Second, the plaintiff must show that the defendant engaged in false advertising. As a matter of underlying substantive law, liability for false advertising already requires findings that the defendant's conduct was literally false or misleading, was material, actually deceived or was likely to deceive consumers, and caused or was likely to cause harm to the plaintiff.[136] These elements are logically and practically linked to each other; they constitute the *wrong* of false advertising, just as an agreement to set prices constitutes the wrong of price fixing.

In particular, deception is generally presumed from literal falsity, or is demonstrated by showing misleadingness—if consumers receive a false message from a facially ambiguous or even literally true claim, they have been deceived. Likewise, once both deception and materiality have been shown, courts generally find a likelihood of harm, as consumers have been misled about facts that are likely to affect their decisions.

The false advertising foundation provides a unique advantage for antitrust law, one not available in other settings. The reason is simple. False advertising's underlying requirements focus on the bad conduct, show its relevance, and demonstrate the harm. These elements offer on a silver platter what antitrust needs to prove monopolization. In addition, materially false advertising by a monopolist threatens multiple concerns: it makes it more difficult to compete on the merits, can easily be repurposed to harm any competitor, and is hard to credibly rebut without souring consumers on factual claims more generally. Because of these harms and the satisfaction of false advertising's elements, a monopolist's materially false advertising should be presumed to affect the market as a whole.

A presumption that a monopolist using false advertising has engaged in illegal monopolization also is appropriate given the near certainty of anticompetitive effects. Unlike other lawbreaking by a monopolist such as tax

135. *See supra* text accompanying notes 13–18.

136. The Lanham Act additionally requires that the statements be made "in commercial advertising or promotion" and occur in interstate commerce. 15 U.S.C. § 1125(a)(1)(B) (2018); Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310 (1st Cir. 2002). Neither requirement is particularly demanding in this context, nor relevant to the harm of false advertising.

fraud, false advertising by definition harms at least one competitor, in what is a relatively small field. That is, by definition a monopolist controls most of the market, so there will be fewer competitors to harm. False advertising may even directly harm *all* the other competitors if the false claim is one of general superiority, or, as in the AT&T example, is directed at keeping existing customers from switching products. And by poisoning the informational environment, false advertising inherently threatens the key mechanism by which rivals can compete: by explaining to consumers what they can offer in a way that might persuade them. False advertising is also a technique that can easily be extended to the next competitor, further justifying a presumption that its use by a monopolist caused harm to competition.

Another way to frame the presumption of harm to competition centers on how we know that harm to actual entities has crossed into the legal category of "harm to competition." When an entity that meets the standards for monopoly power engages in materially false advertising that causes damage, we know that it is a monopolist and that it harmed identified victims (such as consumers or competitors) in a way likely to push the market as a whole toward an untrusting and untrustworthy market for lemons. When a monopolist introduces a valuable innovation to the market, in contrast, that can harm competitors, but it also produces social benefit, meaning that the harm should be tolerated. So too when a monopolist truthfully and non-misleadingly advertises a superior product. But when the ready-made template of false advertising law makes clear that a monopolist harms consumers' ability to trust information in the market and causes consumers to pay prices or buy products they otherwise wouldn't have chosen, at the very least the burden should be on the monopolist to show that it did no structural damage to the market.

The presumption we propose fits comfortably in antitrust analysis. Antitrust courts historically have applied two modes of analysis. The first, appropriate for conduct among competitors such as price fixing, agreements to limit output, and agreements to allocate markets, is viewed as *per se*, or automatically, illegal.[137] The second, the Rule of Reason, which is considerably more deferential and upholds nearly all agreements today,[138] considers an agreement's anticompetitive and procompetitive effects.[139] A

137. *E.g.*, United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940) (price fixing); Hartford-Empire Co. v. United States, 323 U.S. 386 (1945) (output restrictions); Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990) (market allocation agreements).

138. *See* Michael A. Carrier, *The Rule of Reason: An Empirical Update for the 21st Century*, 16 GEO. MASON L. REV. 827, 828 (2009) ("Courts dispose of 97% of cases . . . on the grounds that there is no anticompetitive effect.").

139. Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 BYU L. REV. 1265, 1268–69 (explaining that courts apply a burden-shifting analysis in which (1) "the plaintiff must show a significant anticompetitive effect," (2) "the defendant [must] demonstrate a legitimate procompetitive justification," (3) the plaintiff can "show either that the restraint is not reasonably necessary . . . or that the objectives could be achieved by" a less restrictive alternative,

third, intermediate, approach has more recently developed, called a "quick look" Rule of Reason or (as the FTC has applied it) "inherently suspect" analysis.

In these cases, the court presumes harm to competition even if a plaintiff does not show adverse effects or market power. For example, in *National Society of Professional Engineers v. United States*, the Supreme Court found that "an agreement among competitor[] [engineers] to refuse to discuss prices with potential customers until after" an engineer was selected may "not [be] price fixing as such," but "no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement," which "operates as an absolute ban on competitive bidding . . . . and substantially deprives the customer of 'the ability to utilize and compare prices in selecting engineering services.'"[140] Similarly, in *NCAA v. Board of Regents of the University of Oklahoma*, the Court found that the NCAA's plan to limit the number of games that could be televised was a "naked restraint on price and output," which "requires some competitive justification even in the absence of a detailed market analysis."[141]

Similarly, as discussed above,[142] restrictions on truthful advertising harm competition by "mak[ing] it more difficult for consumers to discover information about the price and quality of goods or services, thereby reducing competitors' incentives to compete with each other with respect to such features."[143] In many cases, the FTC has relied on empirical studies finding that restrictions on truthful advertising "result in consumers' paying higher prices."[144] The agency thus treats restrictions on truthful advertising as inherently suspect, similar to a "quick look" analysis in presuming anticompetitive effects.[145] The Supreme Court's decision in *California Dental Ass'n v. FTC* also supports an abbreviated analysis. In that case, the Court

and (4) "the court balances the restraint's anticompetitive and procompetitive effects" (footnote omitted)).

140. Nat'l Soc'y of Pro. Eng'rs v. United States, 435 U.S. 679, 692–93 (1978) (quoting United States v. Nat'l Soc'y of Pro. Eng'rs, 404 F. Supp. 457, 460 (D.D.C. 1975)).

141. NCAA v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 110 (1984); *see also* FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 448, 461 (1986) (finding "that a conspiracy among dentists to refuse to submit x rays to dental insurers for use in benefits determinations" resulted in "actual, sustained adverse effects on competition in those areas where [the] dentists predominated" and was "legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis").

142. *See supra* text accompanying notes 8–10.

143. Polygram Holding, Inc., 136 F.T.C. 310, 355 (2003); *see also* Brief of the Federal Trade Commission at 1, 1-800 Contacts, Inc. v. FTC, No. 18-3848 (2d Cir. Oct. 7, 2019) ("Without timely information about competing products and sellers, . . . consumers cannot make informed choices and markets cannot function properly.").

144. *Polygram*, 136 F.T.C. at 355.

145. Brief of the Federal Trade Commission at 51, *1-800 Contacts*, No. 18-3848; *see also Polygram*, 136 F.T.C. at 354 (finding agreement among rivals not to advertise products was "presumptively anticompetitive").

found that an association's broad restrictions on discount and non-discount advertising were "designed to avoid false or deceptive advertising."[146] As a result, the restrictions had a procompetitive justification as well as a potentially anticompetitive effect, and the Court applied a more expansive analysis than the "quick look" scrutiny but one less than the "fullest market analysis" of the Rule of Reason.[147]

As these cases show, it is possible to calibrate antitrust scrutiny based on the likelihood that a particular type of conduct is anticompetitive. For "per se" offenses, courts require no additional proof beyond showing that the defendant's behavior falls into a class of activities that is inherently dangerous to competition. For conduct satisfying "quick look" scrutiny, the plaintiff is relieved of certain showings and the burden is more quickly shifted to the defendant to justify the conduct. In both sets of cases, the expense and risks of "false negative" errors that would be entailed by additional proof requirements are unjustified.

When a monopolist's false advertising has already been shown to be likely to have harmed at least one competitor, a presumption of anticompetitive conduct adapts this type of intermediate approach to the unilateral conduct situation. The setting is not precisely the same as a coordinated agreement to limit truthful advertising. But truthful advertising, which lies at the core of a competitive market, is threatened not only by coordinated restrictions but also by the unilateral dissemination of false advertising.[148]

It's conceivable, however, that a false statement could be material and still not affect the market as a whole. For that reason, we would allow the defendant to rebut the presumption by showing that the false or deceptive statement was ineffective. In other words, the monopolist could show that, despite a *likelihood* of deception from a literally false or misleading claim, harm from deception did not materialize—where, for example, sophisticated consumers did their own testing and relied on their results rather than on the defendant's claims. Our approach, however, would not support immunity for false advertising by entities with market power simply because it's difficult to tell exactly how much harm was done to each member of a small group of competitors.

One example of how our approach could change outcomes is the Fifth Circuit's ruling in *Retractable Technologies, Inc. v. Becton Dickinson & Co.*[149] In that case, the court erroneously rejected an antitrust verdict against an

146. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 (1999).

147. *Id.* at 779.

148. *See* Stucke, *supra* note 91, at 841–44 (suggesting quick-look standard for deception); Susan A. Creighton, D. Bruce Hoffman, Thomas G. Krattenmaker & Ernest A. Nagata, *Cheap Exclusion*, 72 ANTITRUST L.J. 975, 990 (2005) ("[T]ortious conduct . . . can be a cheap form of exclusion.").

149. *See generally* Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883 (5th Cir. 2016) (holding that false advertising cannot violate antitrust laws).

attempted monopolist because, even though it acknowledged that the plaintiff "may have lost some sales or market share" in the market for specialized medical syringes, the court adopted the blanket rule that false advertising can't violate the antitrust laws: The plaintiff lost its antitrust claim because the court said that false advertising harms only competitors, not competition.[150]

The court remanded on whether false advertising alone would permit a remedy. On remand, the district court ordered disgorgement of the defendant's profits under the Lanham Act, noting that at least some of the defendant's sales were attributable to its false advertising. The court of appeals reversed again, reasoning that, although it was true that the defendant had been proved to have *gained* from its false advertising, there were other potential competitors, and so the plaintiff was not able to sufficiently prove that all of the defendant's sales came at the plaintiff's expense. In other words, the plaintiff then lost its Lanham Act claim because the false advertising harmed *competition* generally.[151]

Applying our approach, the key question would have been whether the defendant/false advertiser was in fact a monopolist; if so, a presumption of monopolization would have been appropriate. The false advertising factors (false/misleading, materiality, deception, and harm) appeared to be satisfied. Nor would the rebuttal be met as there was no showing that the false advertising was ineffective. The plaintiff could not quantify how much it lost versus how much other competitors lost because of the false advertising—but that was because the false advertising was apparently successful across the board. In fact, as this example shows, it will often be the case that false advertising—even to sophisticated consumers—is effective in sustaining a monopolist's market share: The monopolist by definition is big, is credible because of its experience, and has sustained reach in the relevant industry.

Our proposal might not change the number of entities exercising monopoly power. Truthful and non-misleading or neither-true-nor-false advertising can also support market power, though it seems unlikely that it can do so quite as effectively as materially false claims. If, as a result of our proposal, monopolists spend less on advertising that might later give rise to falsity-based antitrust claims, they will not necessarily decrease resources devoted to advertising in general. But because American antitrust policy accepts that some monopolies can persist legitimately, it is not a problem that nondeceptive advertising can be effective at maintaining monopoly power. Our proposal could allow more confidence that monopolists' advertising

150. *Id.* at 895. The court reasoned that, because the plaintiff had survived the false advertising without being driven out of the market, no competitive harm had occurred. *Id.* But this is illogical. In the absence of the false advertising the monopolist might have less of a monopoly—surviving as a competitor doesn't mean surviving with a fair competitive position.

151. Retractable Techs., Inc. v. Becton Dickinson & Co., 919 F.3d 869, 877 (5th Cir. 2019).

produces social benefits, and new entrants would have the same ability to use truthful and non-misleading or neither-true-nor-false claims.

C. FRAMEWORK FOR ATTEMPTED MONOPOLISTS

While antitrust liability is most appropriate for monopolists engaging in false advertising, it also could apply to actors seeking to control the market. Section 2 of the Sherman Act applies not only to monopolists but also attempted monopolists, which have been defined as those that (1) have a specific intent to achieve monopoly power, (2) have engaged in exclusionary conduct furthering its specific intent, and (3) have a dangerous probability of success.[152]

The three elements don't provide much guidance. Regarding the first factor, because "the essence of competition is the intent to triumph over one's rivals[,] [o]ne of the most perplexing problems in antitrust policy is discerning between illegitimate and legitimate intent."[153] For the second element, the nature of exclusionary conduct is similar in attempted monopolization as monopolization cases. And third, a dangerous probability of success is designed to determine whether the conduct is conducive to monopoly.[154] Some courts have articulated market share requirements of at least 30 percent (and more likely 50 percent) in most cases, though a leading hornbook explains that "it is impossible to generalize[] [since] some attempts to monopolize require the defendant to have significant market power while others do not."[155]

Because attempted monopolists, unlike monopolists, do not control the market, a rebuttable presumption of an antitrust violation is not appropriate. But neither is the skepticism that courts have applied to false advertising claims. For that reason, in determining the second element, whether the defendant engaged in exclusionary conduct, we suggest several factors that direct the most robust scrutiny to the situations most likely to present marketwide harms: (1) targeting a new entrant; (2) actual harm from the false or misleading advertising; (3) degree of materiality; and (4) interactions with other anticompetitive conduct.[156]

The first factor analyzes whether the conduct is aimed at a new, rather than established, market entrant. New entrants are particularly susceptible to the effects of false advertising. A nascent firm just entering the market "has

152. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993).

153. HOVENKAMP, *supra* note 11, § 6.5a, at 371.

154. *Id.* § 6.5b, at 374–75.

155. *Id.* § 6.5b2, at 376–77.

156. False advertising liability always requires falsity or misleadingness and, relatedly, likely or actual deception. Our framework is designed to draw courts' attention to the types of false advertising that are particularly likely to harm overall competition, leaving some false advertising that will be actionable as such, but not as an antitrust violation, where it harms competitors or consumers.

no established customer base and typically lacks the resources to answer the dominant firm's deception effectively."[157] A new entrant in a small field, such as the maker of a specialized blood collection device that only a few companies manufacture, likely would qualify as an appropriate plaintiff under our framework.[158] In contrast, Anheuser Busch's false advertising in the highly concentrated light-beer market that targets the other major competitor in that market would not.

The second factor examines whether the statements impose harm on the rival. The clearest case of harm will occur when the rival is prevented from entering the market. But it could also be satisfied when the rival is not able to expand its market share. In false advertising cases, courts often decline to award monetary damages (even when they enjoin future false advertising) unless the plaintiff shows not just that the false advertising is likely to deceive, but also that the deception has materialized in the form of diverted sales, which also proves materiality and harm.[159] Because attempted monopolists lack the control over the market that monopolists have, a similar requirement would be appropriate here.

The third factor focuses on whether the statements center on facts likely to be material to most of the relevant consumers. The usual standard of materiality asks "whether reasonable consumers would have a tendency to rely on th[e] misleading statement of fact in making their purchasing decisions."[160] Courts in false advertising cases have not generally distinguished between the materiality of the general topic to which the claim relates and the materiality of the difference between the claim and the truth. For example, where a company falsely claimed that its razor extended hair, creating a

157. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 782b, at 353.

158. *See* Kurin, Inc. v. Magnolia Med. Techs., Inc., No. 3:18-cv-1060-L-LL, 2019 WL 5422931, at *1 (S.D. Cal. Oct. 23, 2019) (exemplifying a Lanham Act false advertising case brought by new entrant against earlier entrant).

159. *See, e.g.*, Pizza Hut, Inc. v. Papa John's Int'l, Inc., 227 F.3d 489, 497 (5th Cir. 2000); Balance Dynamics Corp. v. Schmitt Indus., Inc., 204 F.3d 683, 690 (6th Cir. 2000); U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922 (3d Cir. 1990). Intentional deception can also justify a presumption of harm for purposes of receiving monetary damages. *See, e.g.*, Porous Media Corp. v. Pall Corp., 110 F.3d 1329, 1333 (8th Cir. 1997) (intentional deception), *superseded by statute on other grounds*, Trademark Amendments Act of 1999, Pub. L. No. 106–43, 113 Stat. 219; Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1146 (9th Cir. 1997) (holding that deliberate false advertising "gives rise to a presumption of actual deception and reliance" and "allow[s] monetary damages even without a showing of actual consumer confusion" (quoting U-Haul Int'l, Inc. v. Jartran, Inc., 793 F.2d 1034, 1040–41 (9th Cir. 1986))); George Basch Co., v. Blue Coral, Inc., 968 F.2d 1532, 1537 (2d Cir. 1992), *superseded by statute on other grounds*, Trademark Amendments Act of 1999, Pub. L. No. 106–43, 113 Stat. 219, *as recognized in* Cartier v. Aaron Faber, Inc., 512 F. Supp. 2d 165 (S.D.N.Y. 2007); *Balance Dynamics*, 204 F.3d at 694). And courts have generally held that in two-player markets, false comparative advertising also leads to a presumption of harm. *See, e.g.*, Dependable Sales & Serv., Inc. v. TrueCar, Inc., 377 F. Supp. 3d 337, 342 (S.D.N.Y.), *on reconsideration*, 394 F. Supp. 3d 368 (S.D.N.Y. 2019).

160. *Pizza Hut*, 227 F.3d at 502.

smoother shave, the court reasoned that, because the extension claim was material, misrepresentations as to the "magnitude and frequency of that effect" were necessarily also material.[161] This distinction, however, is usually not even raised in false advertising cases, as the materiality of the claim's general subject matter (e.g., safety, price, durability) typically suffices.

The specificity with which materiality must be proved can, however, be calibrated to ensure that only the most market-threatening false advertising can support an attempted monopolization claim. For example, for monopolists, who by definition control the market, a five percent misrepresentation about price deserves no more legal protection from antitrust liability than a 50 percent misrepresentation. False advertising inherently threatens competition, price is generally material to consumers, and if consumers are likely to act on the misrepresentation, then harm should be presumed.

In contrast, for attempted monopolists, who by definition have not yet achieved monopoly power, courts could reasonably demand more specificity about materiality. If price is misrepresented by five percent, an antitrust plaintiff should be required to show that a substantial number of consumers would be affected (which certainly might be the case, as some groups of consumers are extremely price sensitive). Common sense also has a role to play in the amount of additional specificity courts should demand. Because price is a central product characteristic and the magnitude of the difference between the advertising and the truth is so much greater, a 50 percent misrepresentation needs less, if any, extrinsic evidence of materiality. But not all material claims will rise to that magnitude qualitatively or quantitatively. A searching materiality inquiry—which has resonance with the "clearly material" requirement from the multifactor test discussed above[162]—thus appropriately constrains antitrust law.

This inquiry should recognize that statements about risk are particularly important and likely to have a broad impact. For example, a safety claim may almost always be material—consumers predictably and reasonably value even a one percent lower chance of death quite highly.[163] Alternatively, companies could falsely claim that there are capacity issues preventing a rival from

161. Schick Mfg., Inc. v. Gillette Co., 372 F. Supp. 2d 273, 287 (D. Conn.) (denying preliminary injunction in part and granting in part), *modified*, No. 3-05-cv-174 (JCH), 2005 WL 8168764 (D. Conn. June 20, 2005); *see also* Kraft, Inc. v. FTC, 970 F.2d 311, 327 (7th Cir. 1992) (applying similar reasoning to misleading calcium content claims for processed cheese slices). *But see* Danone, US, LLC v. Chobani, LLC, 362 F. Supp. 3d 109, 118–19 (S.D.N.Y. 2019) (denying preliminary injunction and distinguishing between materiality of a general claim and materiality of the difference between the truth and the advertising, where the advertiser had overclaimed an actual superiority in sugar content of yogurt).

162. *See supra* notes 77–82 and accompanying text.

163. *See In re* Figgie Int'l, Inc., 107 F.T.C. 313, 389 (1986) ("Even a very small amount of additional protection from death or serious injury caused by fire would no doubt be considered significant by some consumers.").

meeting customers' supply needs—a different risk, but one that is highly salient.

Materiality interacts with the other factors. Where the plaintiff is a new market entrant, claims about risk may be particularly persuasive in deterring customers from switching to the competition.[164] And where the plaintiff can show that it suffered substantial harm as a result of the misrepresentation, that is itself strong evidence of a high degree of materiality.

Finally, courts should consider whether false advertising in a near-monopoly situation is accompanied by other types of exclusionary conduct, which can amplify or reinforce the effects of false advertising.[165]

In any given case, courts should balance these factors to see if there is a reason to treat the false advertising at issue as exclusionary. Consider, for example, *Insignia Systems* v. *News America Marketing In-Store, Inc.*[166] This long-running case involved the in-store promotions and advertising business. The parties contracted with product manufacturers to sell them promotional materials like end-cap displays, inserts in grocery carts, and floor stickers, and they also contracted with retailers like grocery stores for the right to place those materials in their stores. Defendant NAMI told manufacturers that the plaintiff successfully placed materials in less than 20 percent of the retail stores with which it had contracts, while claiming for itself "compliance rates of 90-95%."[167] The court reasoned that, if NAMI deliberately deceived customers with the intent to enforce a monopoly, it could be liable for attempted monopolization.[168]

We agree with the court's outcome, but our framework more readily explains what made this particular false advertising actionable in antitrust. In our framework for attempted monopolization, the court could have pointed to the evidence that NAMI's allegedly false advertising caused actual harm to two competitors—apparently the only two competitors in that space—as well as to the overriding materiality of NAMI's compliance claim to manufacturers. As NAMI itself asked, "how effective can an in-store program be if it's not actually seen in-store?"[169] In addition, although the plaintiff apparently wasn't a new entrant, NAMI combined its allegedly false advertising with other

164. In this setting, it may be harder to prove that the defendant made a falsifiable statement given that predictions about the future are often held to be nonactionable opinion.

165. *See, e.g.*, Associated Radio Serv. Co. v. Page Airways, Inc., 624 F.2d 1342, 1356 (5th Cir. 1980) ("Probably no one of the instances of improper conduct [including bribery and contracts resulting from improper influence], standing alone, would lead to section 2 liability. Taken together, however, they show a pattern of exclusionary behavior sufficient to support the jury's verdict." (footnote omitted)); *infra* text accompanying note 188.

166. Insignia Sys., Inc. v. News Am. Mktg. In-Store, Inc., 661 F. Supp. 2d 1039 (D. Minn. 2009).

167. *Id.* at 1050.

168. *Id.* at 1062. The court also denied the defendant's motion to dismiss the monopolization claim on similar grounds. *Id.* at 1061.

169. *Id.* at 1050. The plaintiff, meanwhile, alleged "that its [actual] compliance rate was 75% or higher." *Id.* at 1049.

exclusionary conduct such as exclusive contracts with retailers.[170] This constellation of facts supports allowing an antitrust claim to proceed.

In short, our suggested factors apply a competition lens to false advertising. If the activity targets nascent rivals or imposes barriers to entry, it reveals competitive harm. And if it targets claims that are nearly universally material, it can readily harm the market as a whole.

* * *

Our restriction of antitrust claims for false advertising to defendants that are monopolists or attempted monopolists is consistent with Section 2 of the Sherman Act. Our approach cabins the reach of antitrust liability for false advertising in a manner that addresses overreach concerns, recognizing that most false advertising will not violate the antitrust laws. At the same time, a rebuttable presumption against monopolists engaging in false advertising captures the general anticompetitive market harm from the behavior while still giving the monopolist a chance to show that the statement was ineffective. And focusing on the most relevant factors presented by false advertising and marketwide harm addresses the ways in which attempted monopolists can harm competition through false advertising.

D. AN EXAMPLE: BIOSIMILARS

An example illustrates our framework. The pharmaceutical industry is marked by high barriers to entry. It is expensive to enter the market, and there are significant hurdles such as receiving approval from the FDA. These barriers are even higher in the biologics setting. Compared to the "small molecule" drugs that have made up the pharmaceutical market for the past several decades, biologic products are more complex and less predictable. As a result, unlike the near-identical relationship between brand and generic drugs, the connection between biologics and "follow-on biosimilars" is not as direct.[171]

The relevant statute, the Biologics Price Competition and Innovation Act ("BPCIA"),[172] requires a biosimilar to be "highly similar to" the biologic and have "no clinically meaningful differences" in relation to "safety, purity, and potency."[173] But the uncertainty surrounding the products has resulted in biologic manufacturers stating or implying that biosimilars are unsafe, sometimes by omitting relevant information about their functional

170. *Id.* at 1051.

171. Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 8.

172. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (2010).

173. 42 U.S.C. § 262(i)(2) (2018).

equivalence with the reference biologics.[174] In a setting in which even the most minute differences between products could be enough to dissuade patients from trying new medications, the assertions at least implied dissimilarities that could have significant safety effects.

For example, Genentech noted on its "Examine Biosimilars" website that "FDA requires a biosimilar to be highly similar, but not identical to the [reference product]."[175] More explicitly, Amgen tweeted: "Biologics or biosimilars? It's not just apples to apples. While #biosimilars may be highly similar to their #biologic reference products, there's still a chance that patients may react differently."[176]

Given the context of life-saving medications, it's easy to imply dire consequences. For example, Amgen created a YouTube video asserting that a switch "carries risks, given that no two biologic medicines are identical," which suggests that they "can behave differently in the body."[177] Amgen also cautioned that "[s]witching drugs is not a good idea if your medicine is working for you" and that "an inadvertent substitution . . . is not appropriate care."[178] Finally, some biologic manufacturers have warned that patients could face "additional risks" by taking biosimilars or even "could end up in the emergency room."[179]

These claims raise several concerns. Most significant, the statements at issue imply that biosimilars create serious risks, failing to disclose that the FDA approves a biosimilar only when "there are no clinically meaningful differences [from] the biologic product."[180] To the contrary, biologic and biosimilar products are required to have the same safety and effectiveness

174. As a manufacturer of biosimilars, Pfizer filed a citizen petition with the FDA that referenced many of these statements. Citizen Petition from Pfizer Inc. to the Food & Drug Admin. (Aug. 22, 2018), https://www.bigmoleculewatch.com/wp-content/uploads/sites/2/2018/08/Citizen_Petition_from_Pfizer.pdf [https://perma.cc/9849-SRT6].

175. *Id.* at 7 (alteration in original) (quoting Genentech, *Examine Biosimilars – Biosimilars vs. Generics*).

176. Ned Pagliarulo, *Pfizer Calls Out Pharma Peers for 'Scare Tactics' on Biosimilars*, BIOPHARMA DIVE (Aug. 29, 2018, 11:48 AM), https://www.biopharmadive.com/news/pfizer-calls-out-pharma-peers-biosimilar-scare-tactics-fda-guidance/531214 [https://perma.cc/5E4J-BMQ6] (quoting @AmgenBiosim, TWITTER (Apr. 13, 2018)).

177. Citizen Petition from Pfizer, *supra* note 174, at 8 (quoting Amgen, *The Arrival of Biosimilars – What's in a Name*, YOUTUBE).

178. *Id.*

179. Hillel P. Cohen & Dorothy McCabe, *Combatting Misinformation on Biosimilars and Preparing the Market for Them Can Save the U.S. Billions*, STAT (June 19, 2019), https://www.statnews.com/2019/06/19/misinformation-biosimilars-market-preparation [https://perma.cc/AJE2-7Z7S] (quoting Christopher Rowland, *'Marketers Are Having a Field Day': Patients Stuck in Corporate Fight Against Generic Drugs*, WASH. POST (Jan. 9, 2019, 8:00 PM), https://www.washingtonpost.com/business/economy/drugmakers-alleged-scare-tactics-may-hold-back-competition/2019/01/09/612ac994-046d-11e9-9122-82e98f91ee6f_story.html [https://perma.cc/D2DL-H7ER]).

180. 42 U.S.C. § 262(i)(2)(B) (2018).

profile.[181] Evidence from Europe, which has witnessed robust biosimilar entry, has confirmed that "over 700 million patient days of treatment" demonstrated "that clinical outcomes with biosimilars match the outcomes of the reference biologics."[182] This evidence also has revealed that "patient switching from the reference biologic to the biosimilar . . . is not of concern" since the more than 14,000 switches from biologic to biosimilar resulted in "[n]o change in clinical outcomes."[183]

Given significant development costs, regulatory barriers, thickets of dozens of (or even more than 100) patents,[184] and exclusive contractual arrangements,[185] biologic manufacturers are likely to have monopoly power.[186] Taking the absence of clinically meaningful differences in FDA-approved biosimilars as a given, plaintiffs challenging false statements are likely to satisfy our presumption if they can show that, under false advertising law, the statements (or omissions) are false and material, and therefore are likely to deceive consumers and cause harm. False advertising principles establish that biologic manufacturers will not be liable unless their statements are false or mislead substantial numbers of relevant consumers. But, if falsity or misleadingness are established, they are not likely to be able to rebut the presumption of anticompetitive conduct given the significance of health risk claims to consumers.

Even for attempted monopolists, as long as a plaintiff establishes falsity or misleadingness, the factors would seem to favor liability. Given the lack of biosimilar entry to date, in many cases biosimilars will be seeking to enter the market. The statements, which focus directly on risk, pose significant barriers to entry, as doctors and consumers are not likely to take a chance on drugs that have even the possibility of safety concerns. It is hard to think of examples that would more concretely affect consumers than warnings that drug products are potentially unsafe. In fact, the FTC recently issued warning letters to a number of plaintiff-side law firms for advertising that linked FDA-approved drugs with serious side effects, potentially frightening patients away

181. *Patient Materials*, FOOD & DRUG ADMIN., https://www.fda.gov/drugs/biosimilars/patient-materials [https://perma.cc/VDE3-XS95] (last updated Oct. 7, 2020).

182. BIOSIMILARS F., STRUCTURAL MARKET CHANGES NEEDED IN U.S. TO ACHIEVE COST-SAVINGS FROM BIOSIMILARS 8 (2019), https://biosimilarsforum.org/PDF/BIosimilars_WhitePaper-final.pdf [https://perma.cc/U5SE-2X2A].

183. *Id.*

184. *Humira Patent Fortress at Center Stage During Pharma Execs' D.C. Showdown*, CRAIN'S CHI. BUS. (Feb. 26, 2019, 2:28 PM), https://www.chicagobusiness.com/health-care/humira-patent-fortress-center-stage-during-pharma-execs-dc-showdown [https://perma.cc/GL3Y-3EX9] (noting that AbbVie has 136 patents on arthritis- and Crohn's-treating Humira).

185. *See infra* text accompanying note 188.

186. *E.g.*, Carrier & Minniti, *supra* note 171, at 3.

from useful medications.[187] In addition, a biologic manufacturer's disparagement of a biosimilar rival may be part of a broader range of anticompetitive conduct. For example, disparagement could entrench barriers to entry that convince insurance companies to favor biologics through potentially anticompetitive exclusive dealing, bundling, and rebates.[188]

In short, false advertising law provides useful tools for determining if substantial numbers of relevant consumers are being misled to their detriment. And our framework would likely find that a biologic manufacturer's proven false advertising that raises safety concerns against a biosimilar constitutes monopolization.

V. CONCLUSION

In their fear of being overrun by false advertising claims, antitrust courts have veered in the opposite direction, essentially making it impossible to bring these actions. But they have overshot the mark. To say that most false advertising claims don't constitute antitrust violations is not to say that antitrust law should reject false advertising claims brought against monopolists or attempted monopolists. Most bribery doesn't violate the antitrust laws either, but antitrust courts still understand that bribery is relevant when it's used to sustain or approach monopoly.

Underlying courts' hesitancy to use antitrust law is likely a sense that false advertising may not be all that bad. Courts may also think that it is difficult enough to identify truly false advertising that they risk accidentally suppressing truthful advertising. In other words, the risk of overenforcement reaching truthful advertising justifies allowing a certain amount of false advertising to go unscathed. But false advertising is already defined by a robust body of case law. And when a monopolist or attempted monopolist is engaging in the behavior, we believe underdeterrence is much more dangerous to consumers and markets, especially given the significant burdens on plaintiffs bringing antitrust claims to show monopoly power or a realistic threat of monopoly power. In this Essay, we have argued for a revival of antitrust's deterrent role in policing anticompetitive false advertising that harms marketwide competition.

The frameworks we construct for monopolists and attempted monopolists promise to employ the learning of false advertising law in a conservative manner in the antitrust realm. Such an approach would benefit false advertising law by removing contradictory assumptions about the effects

187. *FTC Flags Potentially Unlawful TV Ads for Prescription Drug Lawsuits*, FED. TRADE COMM'N (Sept. 24, 2019), https://www.ftc.gov/news-events/press-releases/2019/09/ftc-flags-potentially-unlawful-tv-ads-prescription-drug-lawsuits [https://perma.cc/PTV5-QJ4H].

188. *See, e.g.*, Michael S. Sinha, Gregory D. Curfman & Michael A. Carrier, *Antitrust, Market Exclusivity, and Transparency in the Pharmaceutical Industry*, 319 JAMA 2271, 2271–72 (2018).

of false advertising now prevalent in antitrust cases. It would benefit antitrust law by removing its blind spots about how false advertising harms markets. Most important, it would benefit consumers, who would be subject to less false advertising and who would gain more competitive markets.

PRODUCT HOPPING: A NEW FRAMEWORK

Michael A. Carrier & Steve D. Shadowen

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PRODUCT HOPPING: A NEW FRAMEWORK

Michael A. Carrier & Steve D. Shadowen***

ABSTRACT

One of the most misunderstood and anticompetitive business behaviors in today's economy is "product hopping," which occurs when a brand-name pharmaceutical company switches from one version of a drug to another. These switches, benign in appearance but not necessarily in effect, can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the "improved" branded product.

The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it occurs in uniquely complicated markets characterized by doctors who choose the product but don't pay for it, and consumers who buy the product but don't choose it.

It is thus unsurprising that courts have offered inconsistent approaches to product hopping. They have paid varying levels of attention to the regulatory structure, offered a simplistic analysis of consumer choice, adopted an underinclusive antitrust standard based on coercion, and focused on whether the brand firm removed the original drug from the market.

Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. This rigorous and balanced framework is the first to incorporate the economic characteristics of the pharmaceutical industry. For starters, it defines a "product hop" to include only those instances in which the brand manufacturer (1) reformulates the product in a way that makes the generic non-substitutable and (2) encourages doctors to write prescriptions for the reformulated product rather than the original. The test also offers two safe harbors, which are more deferential than current caselaw, to ensure that the vast majority of reformulations will not be subject to antitrust scrutiny.

The analysis then examines whether a brand's product hop passes the "no-economic-sense" test. In other words, would the reformulation make economic sense for the brand if it did not have the effect of impairing generic competition? Merely introducing new products would pass the test. Encouraging doctors to write prescriptions for the reformulated rather than the original product—"cannibalizing" the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense other than through its impairment of generic competi-

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tion offers a conservative approach and minimizes "false positives" in which courts erroneously find liability. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, practicalities of prescription drug markets, manufacturers' desire for clear-cut rules, and consumers' needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve and standardize the antitrust analysis of product hopping.

INTRODUCTION

One of the most misunderstood and anticompetitive business behaviors in today's economy is "product hopping." A brand-name pharmaceutical company switches from one version of a drug (say, capsule) to another (say, tablet). The concern with this conduct is that some of these switches can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the "improved" branded product.

The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it involves uniquely complicated markets characterized by buyers (insurance companies, patients) who are different from the decisionmakers (physicians).

It thus should not be a surprise that courts have offered inconsistent approaches to product hopping. Some have emphasized the regulatory structure while others have ignored it. Some have offered a simplistic analysis of consumer choice, while others have adopted an underinclusive test based on coercion. Nearly all have focused on whether the brand firm removed the original drug from the market (a "hard switch") or left it on the market (a "soft switch").

Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. The framework, which is balanced and rigorous, is the first to incorporate the characteristics of the pharmaceutical industry. For starters, it defines a "product hop" to include only those instances in which the brand manufacturer:

(1) reformulates the product in a way that makes the generic non-substitutable; and

(2) encourages doctors to write prescriptions for the reformulated product rather than the original.

This definition excludes many product reformulations, such as those in which the brand manufacturer does not "cannibalize"[1] sales of the original

1 "Cannibalize" is an industry term loosely defined as the brand manufacturer's marketing against its own original product to encourage doctors to switch their prescriptions to the reformulated product. *See* Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 44–45 (2009).

product. It also avoids targeting brand reformulations designed to improve the product by competing with other brands or growing the market, reserving its focus for the switching of the market in order to stifle generic competition.

Where the brand's conduct does not satisfy both elements of a product hop, it is not subject to antitrust scrutiny. And when the conduct does meet both elements, our framework offers two stages of analysis. First, we propose two safe harbors that are more deferential than current caselaw and that ensure that the vast majority of reformulations will not face antitrust review.

And second, for reformulations that are product hops and are outside the safe harbors, the framework examines whether the hop passes the "no-economic-sense" test. In other words, would the product hop make economic sense for the brand if the hop did not have the effect of impairing generic competition? Merely introducing new products would pass the test (indeed, would not even constitute a product hop). Encouraging doctors to write prescriptions for the reformulated rather than the original product—cannibalizing the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense—other than through its impairment of generic competition—offers a conservative approach and minimizes "false positives" in which courts erroneously find liability. In fact, our framework offers manufacturers three opportunities to sidestep antitrust liability: (1) avoid our definition of "product hop"; (2) be covered by one of the safe harbors; or (3) undertake conduct that makes economic sense. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, realities of prescription drug markets, manufacturers' desire for clear-cut rules, and consumers' needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve the antitrust analysis of product hopping.

Part I offers a background on product hopping. Section A categorizes various types of reformulations. Sections B and C address the relevant regulations: the Hatch-Waxman Act and state substitution laws. Section D then focuses on the crucial element of timing, explaining how generic entry before a brand reformulates a drug dramatically reduces price.

Part II highlights the market failure that is unique to the pharmaceutical industry. Section A describes the "price disconnect" that distinguishes prescription drugs from other products and that separates the consumer's price/quality determination that is unified in other markets. Section B analyzes drug patents, emphasizing the limited role of the patent system and, in particular, the lack of a requirement of a medical improvement over earlier versions. Part C then provides several indicia of market failure based on medical evidence, the price of patented drugs in Mexico, U.S. prices before prescriptions were required, and lower prices in countries that have solved

the price disconnect. Given the absence of these measures in the United States, Part D highlights the importance of antitrust law.

Part III examines the five judicial analyses of product hopping. Section A begins with *TriCor*, in which the court offered a nuanced analysis, albeit one that some later courts limited to "hard switches," i.e., those in which the brand withdraws the original product from the market. Section B covers the *Walgreens* case, which offered a simplistic analysis of consumer choice in the context of a "soft switch" in which the brand did not withdraw the original product from the market. The first two product-hopping decisions, *TriCor* and *Walgreens*, framed the analysis for later decisions, with some courts assuming that hard switches could violate the antitrust laws but soft switches could not.

The *Suboxone* case addressed in Section C revealed aspects of both hard and soft switches, with the court offering a nuanced understanding of the regulatory regime. The *Doryx* case covered in Section D, in contrast, is an outlier that neglected the regime altogether. Section E then focuses on *Namenda*, which considered the regulatory regime in the context of hard switches, offering an underinclusive framework based on coercion. While the courts generally have considered the regulatory regime, Section F discusses the recent work of scholars that have paid less attention to this important issue.

Part IV then presents a new framework for courts to analyze the antitrust implications of product hopping. Section A begins with two safe harbors that brand firms can use if they implement the product hop (1) outside a "Generic Window" in which generic entry is expected or (2) after a generic version of the original drug has entered the market. If the product hop occurs during one of these windows, it will be immune from antitrust liability.

For product hops subject to antitrust scrutiny, Section B introduces a test based on whether the hop would make business sense for the brand manufacturer if it did not have the effect of impairing generic competition. Courts and commentators have advocated a no-economic-sense test in other areas, but the test remarkably has not been employed in a setting tailor-made for it. If a brand acquires or maintains monopoly power by engaging in product hopping that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.

Through the application of the no-economic-sense test, we show the errors of courts that have treated as outcome-determinative the distinction between hard and soft switches. In particular, a brand might be anticompetitively undertaking actions that make no economic sense not only when it makes a hard switch and withdraws the original product from the market, but also when it makes a soft switch, leaving the original drug on the market but reformulating the product and "cannibalizing" it (switching sales to the new version), for example by denigrating, misrepresenting features of, increasing the price of, or pulling the marketing and promotion from, its original product.

Part V then applies the new framework to the five product-hopping cases presented in Part III. It supports the conclusions of potential liability in *TriCor*, *Suboxone*, and *Namenda*, albeit on the different ground of the no-economic-sense test. And it suggests a different outcome from that in the *Walgreens* and *Doryx* cases on the ground, again, that the product hop lacked economic sense except for its impairment of generic competition. The fact that judicial analysis would be so different under the defendant-friendly no-economic-sense test shows just how far the courts have veered from justified economic analysis.

I. PRODUCT HOPPING

Product hopping, which is also known as "evergreening" or "line extension," refers to "a drug company's reformulation of its product"[2] and encouragement of doctors to prescribe the reformulated, rather than original, product. Under our definition, a brand manufacturer engages in a "product hop" by combining two actions:

(1) reformulating the product in a way that makes a generic version of the original product not substitutable; and

(2) encouraging doctors to write prescriptions for the reformulated rather than the original product, i.e., switching the prescription base from the original to the reformulated product.

This definition of product hopping does not include any instance in which the manufacturer promotes the original and reformulated products equally and without encouraging doctors to switch to the reformulated product. For example, brands often, without reducing their promotion of the original version, introduce modestly adjusted versions of their products to fill out a product line or satisfy demand for a particular formulation or delivery mechanism. In contrast, our definition of a product hop is limited to the brand's switch of the prescription base to a reformulated product for which the generic is not substitutable. Limiting potential antitrust liability to instances in which the brand switches the prescription base is crucial: our test does not target rational brand efforts to *expand* the prescription base by competing with other branded products or growing the market. The test instead identifies and targets a brand's efforts to *migrate* the base in order to impair generic competition.[3]

2 Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016 (2010).

3 The generic-impairing product switches are particularly concerning given the "price disconnect" between buyers and decisionmakers discussed below. *See infra* Section II.A and text preceding Section IV.A. From a policy and regulatory perspective, the act of switching the prescription base raises anticompetitive concerns in threatening the generic-promoting goals of the Hatch-Waxman Act and state drug product substitution laws, *see infra* Sections I.B, I.C, through a switch to a reformulation for which a generic cannot be substituted. And that conduct lacks any innovation-based justifications because the brand does not build up the prescription base by competing with other brands or expanding the market, but merely leverages already-gained power solely by blocking generic entry.

There are several types of reformulations, which Section A catalogs. Sections B and C introduce the foundations of the regulatory regime: the Hatch-Waxman Act and state substitution laws. Section D then focuses on a crucial element of pharmaceutical competition: the timing of the brand's reformulation in relation to generic entry.

A. Forms of Product Hopping

Product hopping occurs through one (or more than one) of several types of reformulations. One category involves new forms, which consist of switches from a capsule, tablet, injectable, solution, suspension, or syrup to another form, such as any of the above, as well as extended-release capsules or tablets, orally dissolving tablets, and chewable tablets.[4] For example, the makers of antidepressant Prozac and cholesterol treatment TriCor switched from capsule to tablet form, while anxiety-treating Buspar was switched from tablet to capsule.[5]

A second type of reformulation involves changing molecule parts (known as "moieties") by adding or removing compounds. More technically, a manufacturer can switch from a mix of two enantiomers (one of a pair of chemical compounds that has a mirror image[6]) to a single enantiomer. For example, and foreshadowing the change discussed below from heartburn-treating Prilosec to Nexium, a manufacturer can "switch from a chemical compound that is an equal mixture of each enantiomer, only one of which contains the active ingredient, to a compound that includes only the enantiomer that contains the active ingredient."[7] Chemical changes also explain the switches from allergy medication Claritin to Clarinex, antidepressant Celexa to Lexapro, and heartburn medication Prevacid to Kapidex.[8]

A third category of reformulation involves a combination of two or more drug compositions that had previously been marketed separately.[9] Combinations have involved migraine-treatment Treximet (combining Imitrex and Naproxen Sodium) and high-blood-pressure medications Azor (Norvasc and Benicar), Caduet (Norvasc and Lipitor), and Exforge (Norvasc and Diovan).[10]

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4 Shadowen et al., *supra* note 1, at 24.

5 *Id.* at 37.

6 *Enantiomer*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/enantiomer (last visited Oct. 22, 2016).

7 Shadowen et al., *supra* note 1, at 24; *see also id.* at 25 (also including changes to molecules already on the market resulting in "new esters, new salts, or other non-covalent derivatives"); *infra* Section III.B.

8 Shadowen et al., *supra* note 1, at 38.

9 *Id.* at 25.

10 *Id.* at 38–41.

B. Hatch-Waxman Act

A crucial element of the regulatory framework forming the backdrop of product hopping is the Hatch-Waxman Act, enacted by Congress in 1984 to increase generic competition and foster innovation in the pharmaceutical industry.[11]

The Act promoted generic competition by creating a new process for obtaining U.S. Food and Drug Administration (FDA) approval, encouraging generics to challenge invalid or noninfringed patents by introducing a 180-day period of marketing exclusivity for the first generic to do so, and resuscitating a defense that allowed generics to experiment on a brand drug during the patent term.[12] The drafters of the Act sought to ensure the provision of "low-cost, generic drugs for millions of Americans"[13] and recognized that generic competition would save consumers, as well as the federal government, millions of dollars each year.[14]

One central goal of the Act was to expedite generic competition.[15] Generic drugs are very similar to patented brand drugs, having the same active ingredients, dosage, administration, performance, and safety.[16] Despite this equivalence, however, generic manufacturers were required, before the Act, to demonstrate safety and effectiveness by engaging in lengthy and expensive trials. They could not begin the process during the patent term since the FDA approval process took several years[17] and the required tests constituted infringement.[18] Generics thus waited until the end of the term to begin these activities. As a result, they were not able to enter the market until two or three years after the patent's expiration. At the time of the Hatch-Waxman Act, there were roughly 150 drugs for which the patent term had lapsed but there was no generic on the market.[19]

In the Act, Congress encouraged competition through several mechanisms. First, it allowed generics to experiment on the drug during the patent

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11 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, 35 U.S.C.).

12 Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 42–43 (2009).

13 130 CONG. REC. 24,410, 24,427 (1984) (statement of Rep. Waxman).

14 *Id.* at 24,456 (statement of Rep. Minish).

15 For an overview of the mechanisms employed to carry out the other primary goal, fostering innovation, see Carrier, *supra* note 12, at 43–45 (discussing patent term extensions, non-patent market exclusivity, and an automatic 30-month stay of FDA approval of generics).

16 *Generic Drugs: Questions and Answers*, FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last updated Jan. 7, 2015).

17 CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998).

18 *Id.* at 3.

19 *See* H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

term.[20] Along these lines, the legislature exempted from infringement the manufacturing, use, or sale of a patented invention for uses "reasonably related to the development and submission of information" under a federal law regulating drugs' manufacture, use, or sale.[21]

Second, the Act provided 180 days of marketing exclusivity to the first generic to challenge a brand's patent or claim that it did not infringe the patent.[22] This exclusivity "was reserved for the first generic firm—known as a 'Paragraph IV filer'—that sought to enter during the patent term."[23] During the 180-day period, which begins after the drug's first commercial marketing, the FDA is not able to approve other generic applications for the same product.[24]

Third, and most relevant for our purposes, Congress created a new process for generics to obtain FDA approval. Before the Act, generic firms that offered identical products to approved drugs were required to prove safety and efficacy.[25] In fact, one reason that generics decided not to bring drugs to the market after the expiration of a patent was the time and expense involved in replicating clinical studies.[26] The Act created a new type of drug application, called an Abbreviated New Drug Application (ANDA), through which generics could rely on brands' safety and effectiveness studies, thereby avoiding the need to engage in lengthy and expensive preclinical or clinical studies.[27]

In short, faced with the problem of insufficient generic entry and high drug prices, Congress enacted legislation that introduced several industry-shaping mechanisms to encourage generic entry.

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20 35 U.S.C. § 271(e)(1) (2012).

21 *Id.* For an elaboration on this discussion, see Carrier, *supra* note 2, at 1013, from which this passage draws.

22 21 U.S.C. § 355(j)(5)(B)(iv) (2012). Three other patent certifications apply if the drug is not patented, the patent has expired, or the generic agrees it will not seek approval until the patent expires. 21 U.S.C. § 355(j)(2)(A)(vii).

23 21 U.S.C. § 355(j)(5)(B)(iv).

24 Carrier, *supra* note 2, at 1014; *see also* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 7 (2002) [hereinafter FTC, GENERIC DRUG STUDY], https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf. Until amended in 2003, the Hatch-Waxman Act included as a second trigger for the 180-day period a court decision finding invalidity or lack of infringement. Colleen Kelly, Note, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 439–40 (2011).

25 Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 588 (2003).

26 *See id.*

27 FTC, GENERIC DRUG STUDY, *supra* note 24, at 5. For an elaboration on this discussion, see Carrier, *supra* note 2, at 1013, from which this passage draws.

C. State Drug Product Selection Laws

States have also made it easier for generics to reach the market through their enactment of drug product selection (DPS) laws. Such laws, in effect in all fifty states today, are designed to lower consumer prices.[28] The laws allow (and in some cases require) pharmacists—absent a doctor's contrary instructions—to fill prescriptions for brand-name drugs with generic versions.[29]

States enacted DPS laws to address the price disconnect in the industry, described in detail below,[30] between doctors, who prescribe a drug but are not directly responsive to drug pricing, and insurers and consumers, who pay but do not directly select a prescribed drug.[31] In particular, the laws ensure an important role for pharmacists, who are more price-sensitive than doctors.[32] Doctors are subject to "a vast array of drug promotion, which includes detailing (sales calls to doctor's offices), direct mailings, free drug samples, medical journal advertising, sponsored continuing medical education programs, and media advertising."[33] Pharmacists, in contrast, make greater margins on generics and recommend them to consumers,[34] competing with other pharmacies on price.[35]

The DPS laws "typically allow pharmacists to substitute generic versions of brand drugs only if they are 'AB-rated' by the FDA."[36] This is solely a safety regulation, unconcerned with and unresponsive to the requirement's effect on competition. For a generic drug to receive an AB rating, it must be "therapeutically equivalent" to the brand drug, which means that it "has the same active ingredient, form, dosage, strength, and safety and efficacy profile."[37] The drug also must be "bioequivalent," which means "the rate and extent of absorption in the body is roughly equivalent to the brand drug."[38]

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28 *See, e.g.*, Norman V. Carroll et al., *The Effects of Differences in State Drug Product Selection Laws on Pharmacists' Substitution Behavior*, 25 MED. CARE 1069 (1987).

29 Carrier, *supra* note 2, at 1017.

30 *See infra* Section II.A.

31 BUREAU OF CONSUMER PROT., DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMMISSION 2–3 (1979); *see also In re* Schering-Plough Corp., 136 F.T.C. 956, 985 (2003) ("The underlying premise of these [DPS] laws . . . is that generic competition has the potential to lower prices," and "these regulations need to be accepted as real market factors in an antitrust analysis.").

32 ALISON MASSON & ROBERT L. STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 7 (1985).

33 STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 87–93 (2d ed. 2007). For an elaboration on this discussion, see Carrier, *supra* note 2, at 1017, from which this passage draws.

34 Shadowen et al., *supra* note 1, at 16.

35 MASSON & STEINER, *supra* note 32, at 7; *see generally* Carrier, *supra* note 2, at 1017–18.

36 Carrier, *supra* note 2, at 1018.

37 *Orange Book Preface: Approved Drug Products with Therapeutic Equivalence Evaluations*, CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm (36th ed. last updated June 10, 2016).

38 *See id.* For an elaboration on this discussion, see Carrier, *supra* note 2, at 1018, from which this passage draws.

Product-hopping schemes exploit this regulation. By making minor changes to the original product—for example, switching from a capsule to a tablet, or from a 10-mg to a 12-mg dose—the brand can prevent the generic from obtaining the AB rating the generic needs to be substituted for the brand. After the brand's reformulation, the generic cannot be substituted for the new version. To become substitutable it must start the FDA approval process all over again. And while the generic may eventually obtain an AB rating to the reformulated product, such a showing likely will not occur for years as the generic reformulates its product, seeks FDA approval, and typically files a Paragraph-IV certification, which tends to be "followed by the brand firm's automatic 'thirty month stay' of FDA approval and additional delays from patent litigation."[39] All of these delays prevent the effective operation of the DPS laws, removing the role of pharmacists and depriving consumers of the practical opportunity to consider a lower-priced generic version of the drug.

D. Timing of Generic Entry

A seminal event in the lifecycle of a prescription drug is generic entry. When multiple generics enter the market, the price falls to a fraction of the brand price.[40] Brand firms thus have every incentive to delay the entry of generic competition as long as possible. The dramatic effects of generic entry explain the crucial role played by the Hatch-Waxman Act and state DPS laws. And they shed light on the essential characteristic, in the product-hopping context, of the timing of generic entry.

Put simply, the brand firm will be much more successful in forestalling generic competition if it can switch the market to the reformulated drug *before* a generic of the original product enters the market.[41] Without a generic on the market, the brand's heavy promotion and marketing artillery can convince doctors to prescribe the reformulated drug. If the brand successfully switches the market to the reformulated product before the generic enters, the generic entry is of no practical significance: there are few or no prescriptions for the original product for which the generic can be substituted.[42]

Several examples demonstrate the crucial role of timing, in particular the brand's recognition of its dramatically higher success if it can switch the

39 Carrier, *supra* note 2, at 1018.

40 *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last updated May 13, 2015); *see generally* Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, *in* 2 HANDBOOK OF HEALTH ECONOMICS 763, 792–93 (Mark V. Pauly et al. eds., 2012) (summarizing recent studies on generic penetration rates and prices).

41 *See* Shadowen et al., *supra* note 1, at 51 (explaining how introduction of reformulated product before generic entry ensures that not only will there be almost no competition on price but also that there will be almost no competition on quality).

42 For a discussion of why managed care organizations are not able to solve the problem, see *infra* note 113.

market to the reformulated drug before a generic version of the original drug enters the market. In the *TriCor* case, discussed below,[43] the brand firm predicted that it would sell more than *ten times* as many tablets if it was able to switch doctors to the reformulated product before the generic version of the original product entered the market.[44] Another example involved a confidential analysis of a product for which projected sales would be *three times* higher if the reformulation (replacing a twice-daily version with a once-a-day version) occurred two years before the generic of the original product entered the market.[45] Another brand firm acknowledged that "its reformulation was 'a gimmick' and that switching the market before generic entry was the 'cardinal' determinant of success."[46]

Similar testimony in a different case referred to a "[t]otal [d]isaster" if the reformulated product was introduced after the generic of the original product entered the market.[47] The brand's internal documents in the hearing in the *Namenda* case, discussed below,[48] revealed that "if we do the hard switch and . . . convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back."[49] And a recent empirical review of product hops concluded that "after a patient is on the new drug and the old drug has gone generic, the new brand did not lose share," which was true "regardless of clinical differentiation."[50]

The European Commission (EC) also recognized the importance of timing in its Pharmaceutical Sector Inquiry Report, which addressed obstacles blocking generic entry.[51] The EC concluded that brands would suffer reduced prices and sales if generics entered the market earlier than, or at the same time as, the reformulated product.[52] Brands thus viewed it as "of [the] utmost importance . . . to bring the follow-on product on the market before the first product effectively loses exclusivity."[53] And the brand firm is able to facilitate such a switch by "channeling . . . demand from the first product to the follow-on product" and by "delay[ing] or prevent[ing] generic entry for the sensitive period of the product switch."[54] For 13 of the 22 second-generation products mentioned in the report, the reformulated product was

43 *See infra* Section III.A.

44 Shadowen et al., *supra* note 1, at 52.

45 *Id.* at 53.

46 *Id.* (footnote omitted).

47 Meijer, Inc. v. Barr Pharm., Inc., 572 F. Supp. 2d 38, 43 (D.D.C. 2008).

48 *See infra* Section III.E.

49 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 656 (2d Cir. 2015).

50 Aaron Gal, Why Does Lifecycle Management Still Work? 3 (2013).

51 European Comm'n, Pharmaceutical Sector Inquiry Final Report ¶ 3 (2009), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

52 *Id.* ¶ 1010.

53 *Id.*

54 *Id.* ¶ 1011.

launched before the first lost its exclusivity,[55] with an average lead time of 17 months.[56]

Suggesting a reason for this timing, the report included multiple telling comments from drug companies. One explained that "the switch rate is dramatically reduced" if generics enter at the time of, or before, the introduction of the second-generation product.[57] Along similar lines, another brand firm conceded that "each patient that is not switched quickly enough" to the second-generation product is "forever lost to the generics."[58] On the other side, as a third brand firm admitted: "Once the patient is switched to [the new product] the physician does not have to, cannot and will not switch him to a generic, and . . . more important: the pharmacist cannot substitute!!"[59]

In short, the timing of a product hop is a crucial factor in a brand's ability to switch the market to a reformulated drug. It is therefore critical to incorporate timing into an appropriate antitrust analysis of product hopping.[60]

Moreover, the outsized importance of timing provides evidence that the high prices in many prescription drug markets result not from valuable innovations, but from market failure. If these markets were competitive, it would make little difference that the generic of the original product beat the reformulated brand product to the market, or vice-versa. A competitive market would make the same adjustment in either circumstance, probably with a modest first-mover or incumbent advantage. The fact that beating the generic to the market results in a three- or ten-fold increase in sales strongly suggests that these markets have quite significant imperfections. An appropriate antitrust analysis must also take this unique industry characteristic into account.

We now explore additional evidence of that market failure.

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55 *Id.* ¶ 1030 fig.138.

56 *Id.* ¶ 1031.

57 *Id.* ¶ 1025.

58 *Id.* ¶ 1028.

59 *Id.*; *see also* Abuse of a Dominant Position by Reckitt Benckiser Healthcare (UK) Ltd. & Reckitt Benckiser Grp., PLC, Case CE/8931/08, ¶ 2.194 (Office of Fair Trading Apr. 12, 2011) (Eng.), https://assets.publishing.service.gov.uk/media/555de4bbe5274a7084000156/rb-decision.pdf (quoting numerous documents in which brand insisted that "we must implement [the product hop] . . . before a generic name is granted"); Case T–321/05, AstraZeneca v. European Comm'n, 2010 E.C.R. II-2830, 3108 ("Astra intended to launch Losec MUPS before generic omeprazole products entered the market in large volumes and drove prices down to lower levels."). For an elaboration on this discussion, see Carrier, *supra* note 2, at 1021.

60 One commentator has suggested that whether patients will switch back after a generic becomes available is an empirical question "that has not yet been tested." Daniel A. Crane, *Provigil: A Commentary*, 3 HASTINGS SCI. & TECH. L.J. 453, 454 (2011). But the European Commission's final report and a comprehensive product-hopping article, Shadowen et al., *supra* note 1, were published two years earlier and extensively quoted industry sources on the issue. The *Namenda* litigation has also now revealed additional data establishing that substantial percentages of patients will not switch back to the original drug. *See infra* Section III.E.

II. Market Failure

Understanding market failure in the pharmaceutical industry is important in determining the appropriate role for antitrust law. As we discuss in Section A, a "price disconnect" distinguishes prescription drugs from other products, separating the price/quality determination that is unified in other markets. Section B focuses on pharmaceutical patents, highlighting the limited and incomplete role played by the patent system. Section C then provides several indicia of market failure based on medical evidence, the price of patented drugs in Mexico (where a prescription is not required), U.S. prices before prescriptions were required, post-patent prices in the United States, and lower prices in countries that have addressed the disconnect. Given that the United States has not utilized the means employed in other countries to respond to the disconnect, Section D highlights the importance of antitrust law.

A. The Price Disconnect

Many prescription drug markets in the United States fail to deliver innovative drugs at reasonable prices because the markets suffer from a market failure. Fundamentally, these markets are characterized by a *price disconnect*: the doctor who prescribes the product does not pay for it, and the consumer (or her insurer) who pays for it does not choose it. In these markets, consumers do not make the fundamental trade-off between price and quality, and it is this balancing or trading-off that makes markets function well.

In well-functioning markets, large numbers of consumers are personally knowledgeable about the comparative quality and attributes of competing products, and those same consumers are themselves responsible for paying for the products. Being both knowledgeable and responsible for paying, consumers decide whether the quality and attributes of a particular product make it worth paying a higher price than for other products in the market. Competition for the dollars of knowledgeable, paying consumers keeps prices at competitive levels.[61]

In a competitive market with knowledgeable and price-sensitive consumers, a firm can reap a price premium above the competitive level *only if, and only to the extent that*, it provides a product with characteristics that those consumers value. For example, if Product A is sold at a monopoly price of $50, and a competitor introduces Product B, which is the same quality and has essentially the same attributes as Product A, but with some relatively modest "new and improved" aspects, the price should fall to, say, $25 for Product A

61 *See, e.g.*, Paul A. Samuelson & William D. Nordhaus, Economics 80 (16th ed. 1998) (asserting that choice and utility theory are founded on "the fundamental premise that people tend to choose those goods and services they value most highly" (emphasis omitted)); *see also* Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 1 at 3 (2003) http://www.ftc.gov/os/2003/10/innovationrpt.pdf (arguing that increased consumer welfare results from "the optimum mix of products and services in terms of price, quality, and consumer choice").

and $30 for Product B. Competitive entry drives down the price of the products to the extent of their overlapping quality and attributes, while Product B can command a price premium only for its "new and improved" aspects. Competition allows consumers to reap the full benefit of both price competition and innovation.

Prescription drug markets are different. Consumers are not knowledgeable buyers of prescription drugs. State drug-safety laws prevent consumers from buying the drugs without a permission slip—a prescription—from their doctors. But the doctor who chooses which product the consumer will buy does not herself have to pay for it. So the person who chooses does not pay, and the person who pays does not choose. *No one* makes the price/quality decision or trade-off that ensures that manufacturers sell products at competitive prices.[62]

The price disconnect makes product hopping a viable competition-impairment strategy in prescription drug markets. This is shown with a simple, stylized example. Assume that a brand manufacturer competes in an ordinary, not-price-disconnected market. Assume further that the brand currently makes $200 million in annual sales of the product; that the research and development (R&D) costs of redesigning the product are $20 million; and that redesigning the product in fact would not improve it and therefore would not result in any sales above $200 million. The manufacturer would not redesign the product because the redesign would: (1) not increase sales; (2) not impair competition; and (3) cost $20 million, resulting in a net loss.

Now assume the same facts, except that the redesign *would* significantly impair competition from generics, preventing them from taking $160 million of the $200 million in existing sales. In this situation, the manufacturer has a strong incentive to redesign the product even though it is in fact not an improvement that would entice consumers to buy more or pay more. If the manufacturer redesigns the product, the R&D costs are an investment not in improving consumer welfare, but in impairing competition.

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62 The "price disconnect" market failure in prescription drug markets has been recognized in the economics literature since at least the early 1960s. *See, e.g.*, STAFF OF S. COMM. ON THE JUDICIARY SUBCOMM. ON ANTITRUST & MONOPOLY, 87TH CONG., REP. ON ADMINISTERED PRICES: DRUGS 3 (Comm. Print 1961) [hereinafter ADMINISTERED PRICES]; RONALD S. BOND & DAVID F. LEAN, FED. TRADE COMM'N, STAFF REPORT ON SALES, PROMOTION, AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS 75 (1977); BUREAU OF CONSUMER PROT., supra note 31, at 2–3; MASSON & STEINER, *supra* note 32, at 5; Shadowen et al., *supra* note 1, at 9 n.31 (summarizing economics literature). And it was introduced in the legal literature in the late 2000s. *See, e.g.*, Carrier, supra note 2, at 1011; Bengt Domeij, *Anticompetitive Marketing in the Context of Pharmaceutical Switching in Europe*, *in* JOSEF DREXL & NARI LEE, PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW 273, 282 (2013); Richard Gilbert, *Holding Innovation to an Antitrust Standard*, 3 COMPETITION POL'Y INT'L 47, 66 (2007); Shadowen et al., *supra* note 1, at 9. Although some courts have ignored the price disconnect, the Second Circuit recognized it in the *Namenda* decision discussed below. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 645–46 (2d Cir. 2015); *see infra* Section III.E.

B. Drug Patents' Role

There is a general misperception that the high prices of prescription drugs in the United States are the natural (and earned) result of patents. The government grants a patent on an innovative product, so the argument goes, and high prices and profits are the inventor's just reward for developing that product.

Antitrust scrutiny of prescription drug product hops is needed, however, because high prices and profits might be the result not of valued innovations, but of the exploitation of market failures. The granting of a patent by the U.S. Patent and Trademark Office (PTO) certainly does not guarantee, or even suggest, that the reformulated product is superior in any way to existing products. The PTO requires only that the product be "novel[]"[63] and "non-obvious,"[64] not that it be an improvement. The Federal Circuit has explained that "[f]inding that an invention is an 'improvement' is not a prerequisite to patentability," as "[i]t is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability."[65] Under this standard, the PTO routinely grants patents on minor differences in existing chemical entities, such as different crystalline forms of a chemical, or different formulations that do not necessarily improve the product in any meaningful way.[66] Likewise, before approving a new product for marketing, the FDA requires that the product be superior only to a placebo, not to existing products.[67]

In competitive markets, patents do not always, or even usually, create the ability to charge supracompetitive prices.[68] Patent law simply prevents others from using or making the exact same (or very similar) invention. Competitors can offer consumers similar products that perform the same function in an analogous way, and this competition is typically sufficient to keep market prices at or near the competitive level.

This competition point is crucial. Society grants patents to inventors as an inducement for them to innovate and bring valuable new products to the market. But in an otherwise competitive market, a patent will allow the man-

63 35 U.S.C. § 102(a) (2012).

64 *Id.* § 103.

65 Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986); *see also* Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 393 (1960) (discussing "the unsound notion that to be patentable an invention must be better than the prior art").

66 *See, e.g.*, Forest Labs., Inc. v. Ivax Pharm., Inc., 501 F.3d 1263 (Fed. Cir. 2007) (upholding patent on enantiomers); Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007) (upholding a patent on a particular salt); AstraZeneca AB v. Mut. Pharm. Co., 384 F.3d 1333 (Fed. Cir. 2004) (upholding a formulation patent).

67 *See generally* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709 (2009) (noting that the FDA "has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products"); Jeanne Whalen, *Glaxo Strategy Threatened by FDA Delays*, WALL ST. J., June 17, 2008, at B3.

68 *See, e.g.*, Ill. Tool Works, Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006).

ufacturer to price the product above the competitive level *only if and to the extent that the patented technology reflects a real, valuable innovation* for which knowledgeable, price-sensitive consumers are willing to pay a premium.[69]

The vast majority of products protected by patents or other IP rights command little or no premium price in the market, precisely because most markets are otherwise competitive.[70] While some consumers strongly prefer one brand over the other—indeed, wouldn't want the other brand if it were given away for free—most consumers would not pay a price premium for one over the other.[71] The result is that consumers are able to obtain many patented products at competitive prices despite the manufacturers' extensive IP rights.

These same principles would apply in prescription drug markets if they were otherwise competitive. The additional profits arising from a pharmaceutical patent would reflect the additional consumer value created by the invention covered by the patent. As in the example above, the entry of a new competing pill that provided the same medical benefits as an existing pill would drive the market price down toward the competitive level, and the new pill could command a premium over that competitive price only if and to the extent that it had some patented attribute for which a substantial number of knowledgeable and price-sensitive consumers were willing to pay a premium. For example, if the new product were in capsule form while the existing competitor were a tablet, the new entry would drive the market price down, and the new entrant would enjoy a price premium, only if and to the extent that consumers who paid out of their own pockets were willing to pay a price premium for the patented capsule (e.g., if it was substantially easier to swallow).

Of course, the key here is the important qualification "in an otherwise competitive market." Given the price disconnect, there is no *a priori* reason to think that the high prices of many prescription drugs reflect an efficient reward that society intentionally granted to inventors in exchange for valuable innovations. Those prices instead might well reflect a market failure that society unintentionally created as a by-product of drug-safety regulations—the prescription requirement.

C. Evidence of Market Failure

Determining whether the high prices in prescription drug markets are the result of valuable innovations or market failure is vitally important. If the

69 *See* Arjun Jayadev & Joseph E. Stiglitz, *Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices*, 28 HEALTH AFF. 165 (2008); Panos Kanavos & Uwe Reinhardt, *Reference Pricing for Drugs: Is It Compatible with U.S. Health Care?*, 22 HEALTH AFF. 16, 21 (2003); Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1707 (2008).

70 *See, e.g.*, *Ill. Tool Works*, 547 U.S. at 28; Christopher R. Leslie, *Patent Tying, Price Discrimination, and Innovation*, 77 ANTITRUST L.J. 811, 823 (2011).

71 *See, e.g.*, Mark A. Lemley & Mark P. McKenna, *Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP*, 100 GEO. L.J. 2055 (2012).

high prices are the consequence of innovation in an otherwise competitive market, society should accept those prices as the presumably efficient cost of rewarding inventors for valuable new products. But if the high prices result from market failure, society should not blindly accept them but should try to prevent manufacturers from exploiting the market failure.

The available evidence indicates that the high prices in many drug categories result from market failure rather than valuable innovations. This includes medical evidence—that many drugs perform essentially the same function in the same way—as well as an array of economic evidence, including data from circumstances where prescription drugs are patented but the price disconnect does not exist. Without the price disconnect, drug patents often do not result in high returns for the inventor.[72]

1. Medical Evidence

In a recent five-year period, 67% of the "new" drugs approved by the FDA were "me-too" drugs—drugs that are slight chemical variants of their predecessor and that produce essentially the same medical results in patients.[73] With four or five me-too branded drugs available, in a competitive market the price on all of these drugs should be competed down to the equilibrium level. But that is not what happens. Instead, the entry of the second and third competitors, and even the fourth and fifth, rarely results in competitive prices. The industry's profit pie does not get substantially smaller; it just gets split among more manufacturers. Doctors might prescribe one of the me-too drugs rather than another, but consumers pay supracompetitive prices regardless of which prescription they get. It is only competition from generic drugs that typically causes the average price of the molecule to drop toward competitive levels, and the generic competition has

72 The market failure caused by the price disconnect in the United States is exacerbated by the shielding of consumers from direct responsibility to pay for prescription drugs. As a result of private, employer-sponsored, and government insurance, by 2010 consumers directly paid only 8% of the total costs of prescription drugs. Morton & Kyle, *supra* note 40, at 788. This compares to 70% in 1980. *Id.* The consumer-patient today is removed in large part from the economics of the prescription decision. The physician mainly decides what drug is used, and the third-party insurer, whether private or public, pays most of the bill.

73 Our analysis of FDA data shows that from 2011 through 2015, the FDA approved 548 NDAs, only 182 (33%) of which were for New Molecular Entities. Of those 182 NMEs, the FDA gave priority review (which is reserved for drugs that treat a serious condition and provide a significant improvement in safety or effectiveness) to only 90. Thus, just 16% of NDA approvals were for truly innovative drugs. Previous analyses came to similar conclusions. *See, e.g.*, MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 53–56 (2005) (analyzing data for the period from 1998 to 2002). Our figures might overstate the rate of innovation for standard prescription drugs, because we include data for biologics.

that effect only for its AB-rated branded counterpart, not for other branded drugs in the therapeutic class.[74]

Perhaps the most infamous example is presented by the GERD/heartburn therapeutic class. This consists of "proton pump inhibitors" (PPIs), including Prilosec, Prevacid, Protonix, Aciphex, and Nexium, which ease the symptoms of chronic indigestion. In the early 2000s, this class "feature[d] competition among five branded products, all of which treat[ed] essentially the same conditions and did so equally effectively—they were all "me too" versions of Prilosec."[75] The entry of multiple, nearly identical branded competitors did not cause the price of PPIs to fall substantially. Instead, the net prices (after including rebates and discounts) remained high, with each of the competitors making sales in the hundreds of millions of dollars annually.[76] As demonstrated by the prices charged by generic versions of the drugs, the brands were sold at net prices more than 25 times their marginal costs of production.[77]

A market consisting of "five close functional substitutes could not yield margins anywhere near that magnitude if consumers made the relevant price/quality choices."[78] The astronomically high price of me-too drugs in crowded therapeutic classes is strong evidence that the prices result from market failure, not from valued innovations.

2. Prices of Patented Drugs in Mexico

The prices of drugs that are patented but not subject to a price disconnect provide further data to determine whether high drug prices result from valuable innovations or market failure. In these circumstances, high prices could potentially reflect innovations valued by consumers in a competitive market. On the other hand, lower prices would provide further evidence that patented "innovations" do not command a price premium in the

74 Transcript of Record at 123–26, *In re* Nexium (Esomeprazole) Antitrust Litig., 309 F.R.D. 107 (D. Mass. 2015) (No. 12-md-02409) (testimony of Richard Fante) (on file with authors); *id.* at 79–84 (testimony of Dr. Meredith Rosenthal) (on file with authors); *id.* at 88–92 (testimony of Linda Palczuk) (on file with authors).

75 Shadowen et al., *supra* note 1, at 69; *see, e.g.*, STANLEY IP ET AL., AGENCY FOR HEALTHCARE RES. & QUALITY, PUB. NO. 06-EHC003-EF, COMPARATIVE EFFECTIVENESS OF MANAGEMENT STRATEGIES FOR GASTROESOPHAGEAL REFLUX DISEASE 35 (2005), http://effectivehealthcare.ahrq.gov/reports/final.cfm (finding no differences in effectiveness of equal doses of omeprazole, esomeprazole, lansoprazole, pentoprazole, and rabeoprazole); AGENCY FOR HEALTHCARE RES. & QUALITY, Pub. No. 06-EHC003-A, *Comparing Health Care Choices: Gastroesophageal Reflux Disease (GERD)* (2005), http://effectivehealthcare.ahrq.gov/repfiles/consumer.gastro.pdf ("Studies show that, overall, each PPI works about as well as another for relieving symptoms."); *See also generally* ANGELL, *supra* note 72, at 74–93 (explaining "me-too" drugs and using PPIs as an example).

76 Transcript of Record at 70–74, *In re Nexium*, 309 F.R.D. 107 (No. 12-md-02409) (testimony of Dr. Meredith Rosenthal).

77 *Id.* at 83–84. Accounting data have shown that brands' profit margins, even including R&D and marketing in the costs, are 70%. *Id.* at 86.

78 Shadowen et al., *supra* note 1, at 70.

absence of the price disconnect. It is the market failure, not valued innovation, that is generating the monopoly power.

Prescription drug markets in Mexico provide just such an experiment. For the most part, major prescription drugs patented in the United States also are patented in Mexico.[79] Until 2010, however, many patented drugs that require a prescription in the United States did not require a prescription in Mexico (or pharmacies routinely dispensed the drugs without requiring prescriptions).[80] For these drugs, in the United States there were patents and prescriptions (and thus a price disconnect), but in Mexico there were patents and no prescriptions (and no price disconnect). In Mexico, consumers simply walked into a pharmacy, chose for themselves which patented drug to buy, and paid for it out of their own pockets.[81]

Studies of comparative prices of brand, on-patent pharmaceuticals in the two countries consistently found during the relevant time period that prices in Mexico were substantially lower.[82] For example, a study comparing prices in El Paso, Texas, and its sister city, Ciudad Juarez, Mexico, found, after controlling for exchange rates, that retail prices were on average 29% lower in Juarez.[83] The study noted that consumers could buy these patented drugs

79 Elías Mizrahi Alvo, CEPAL de Mex., Serie Estudios y Perspectivas No. 121, Regulación y Competencia en el Mercado de Medicamentos: Experiencias Relevantes para América Latina 8, 38 (2010).

80 Thomas M. Fullerton Jr. & Osvaldo Miranda, Univ. Tex. El Paso, Tech. Rep. TX10-1, Are Brand Name Medicine Prices Really Lower in Ciudad Juarez? 9 (2010); José A. Pagán et al., *Self-Medication and Health Insurance Coverage in Mexico*, 75 Health Pol'y 170, 170–71 (2006); Peter Temin, *Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry*, 10 Bell J. Econ. 429, 434 (1979); Pierre Moïse & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Mexico* 43–44 (Org. for Econ. Cooperation & Dev. Health Working Paper No. 25, 2007). Beginning in 2010, Mexico required prescriptions for large numbers of medicines. *See* Comisión Federal Para la Protección Contra Riesgos Sanitarios, Guía para el Cumplimiento del "Acuerdo por el que se Determinan los Lineamientos a los que estará Sujeta la Venta y Dispensación de Antibióticos" (2010) (guide issued by Mexican government to pharmacies outlining the requirements of Article 226 of Mexico's Public Health Code, which took effect on August 25, 2010). Many pharmacies, however, countered that measure by having on-site doctors who would write prescriptions for a nominal fee. *See* Nuria Homedes & Antonio Ugalde, *Mexican Pharmacies: Benefits and Risks for Border Residents in the United States of America and Mexico*, 33 Rev. Panam Salud Publica 196, 201–02 (2013).

81 *See, e.g.*, Ernesto Enriquez Rubio et al., Hacia una Política Farmacéutica Integral para México 79 (2005) (noting that, even for drugs requiring a prescription, 43% of purchases were made without one). Before 2010, various government plans paid for approximately 40% of prescription drugs in Mexico. *See* David J. Cantor, *Prescription Drug Price Comparisons: The United States, Canada, and Mexico*, *in* The Pharmaceutical Industry: Access and Outlook 45, 47 (Ethan N. Parvis ed., 2002). We do not include the prices of those drugs in our analysis.

82 *See, e.g.*, Patricia M. Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, Health Aff. Online, Oct. 29, 2003, at W3-521, W3-527 Ex. 4.

83 Fullerton & Miranda, *supra* note 80, at 8–9, 14 tbl.3; Temin, *supra* note 80, at 434.

without a prescription in Mexico but required a prescription in the United States.[84]

The Mexican experience provides additional evidence that, holding patents constant, prices are consistently and substantially higher when prescriptions are required. This again strongly suggests that market failure, not valuable innovation, causes supracompetitive drug prices.[85]

3. Non-Prescription Prices in the United States

Another example of market failure is provided by drug prices in the United States before the law required prescriptions.

In 1938, the Federal Food, Drug, and Cosmetic Act (FDCA) created for the first time a distinction between prescription and over-the-counter drugs.[86] A leading historian of the industry discerned the beginnings of the price disconnect:

> As the number of prescription drugs increased . . . the marketing of drugs was directed more and more at the medical profession. These new "customers" had a peculiar characteristic; they did not pay for the drugs they ordered. In fact, they often did not even know how much these drugs cost. As a result, the demand for prescription drugs was more inelastic than it would have been without the FDA's regulation on prescription sales.[87]

In 1951, the FDA began routinely designating drugs as "for prescription use only."[88] The manufacturers quickly took advantage of this safety-based interposition of a doctor between the consumer and the product choice. In 1954, the brands formed a trade association, the National Pharmaceutical

84 FULLERTON & MIRANDA, *supra* note 80, at 9.

85 To be clear, we do not suggest that prescriptions are undesirable from a safety perspective, but instead that they create a price disconnect between doctor and payor.

86 Temin, *supra* note 80, at 434.

87 *Id.*; *see also* DONALD C. KING, MARKETING PRESCRIPTION DRUGS 10 (1968) ("[I]n the purchase of prescription drugs, the consumer is unable to protect himself against the element of monopoly inherent in trademarking by choosing from among a number of competing brands."); Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91 (1979).

88 From 1906 to 1938, the FDA had closely regulated some narcotics and had required certain information in product labels, though consumers were free to choose whatever pharmaceutical concoctions they desired. Temin, *supra* note 87, at 91. But in 1937, more than 100 people died from taking Massengill's Elixir of Sulfanilamide, which had been manufactured with an untested, and poisonous, solvent. *See id.* at 94–95. In response to public outcry, Congress passed the FDCA, which revised the original 1906 Act. *See id.* at 91–94. In addition to requiring new drugs to prove their safety prior to marketing, the Act required drugs to have expanded labels with adequate directions for safe use. From 1938 to 1951, the FDA used this provision of the FDCA to extend its regulatory reach by ruling that some drugs could not be labeled for safe use because consumers lacked sufficient expertise to comprehend the label and that those drugs could be sold only through a doctor's prescription. *See generally* Temin, *supra* note 87. The 1951 Durham-Humphrey Amendment to the FDCA extended the FDA's right to designate pharmaceuticals "for prescription use only." *See id.* Today, there are thousands of pharmaceuticals that can be purchased only after obtaining a doctor's prescription.

Council (NPC), whose first concerted effort was to lobby state boards of pharmacy to tighten their substitution laws.[89]

Those laws had previously allowed pharmacists in some circumstances to substitute among brands of the same type of prescription drug, prohibiting only substitution of one *type* of drug for another.[90] For example, a pharmacist receiving a prescription for Eli Lilly's erythromycin could substitute Pfizer's oleandomycin, which had a different chemical structure but performed essentially the same antibiotic function. The pre-1954 substitution laws merely prevented the pharmacist who received a prescription for an antibiotic such as erythromycin from substituting an aspirin.[91]

Under intense NPC lobbying, 44 state boards of pharmacy had by 1959 changed their substitution laws to prohibit substitution of one manufacturer's brand for another's.[92] The manufacturers simultaneously began intensifying their marketing to doctors, encouraging them to write prescriptions for a particular branded drug rather than for a drug class.[93] These changes "combined to prestructure a more favorable context for high profitability."[94] Congressional hearings from 1957 to 1963 examined high drug prices and led to the conclusion that the new state restrictions on substitution heightened the price disconnect and monopoly power. The Senate Report discussed the disconnect and its economic effects:

> Regardless of how well intentioned the physician may be, another party can never be expected to be as interested in price as the individual who has to spend his own money. Once the physician has written his prescription (usually in terms of a brand name), the consumer is limited to the product prescribed under that brand name; he cannot "shop around" for the same product under a different (or no) brand name at a lower price. Hence in [prescription] drugs the ability of the ordinary consumer to protect himself against the monopoly element inherent in trademarks by being able to choose from a number of competing brands is nonexistent. The consumer is "captive" to a degree not present in any other industry.[95]

The constriction in state substitution laws, together with the manufacturers' "remarkable success in persuading physicians to prescribe by trade names rather than generic names," resulted in "the opportunity for price competition disappear[ing]."[96] This was true "regardless of whether the drugs are patented or non-patented."[97]

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89 *See* HOWARD ALDRICH, ORGANIZATIONS AND ENVIRONMENTS 146 (2008).

90 Paul M. Hirsch, *Organizational Effectiveness and the Institutional Environment*, 20 ADMIN. SCI. Q. 327, 332–33 (1975).

91 ADMINISTERED PRICES, *supra* note 62, at 235.

92 *Id.* at 236.

93 Hirsch, *supra* note 90, at 336; *see generally* ADMINISTERED PRICES, *supra* note 62, at 235–38.

94 Hirsch, *supra* note 90, at 336.

95 ADMINISTERED PRICES, *supra* note 62, at 3.

96 *Id.* at 223.

97 *Id.*

Not surprisingly, economic historians have traced the rise of "Big Pharma" and the industry's outsized profits to exactly this time period in which regulations were introduced requiring a prescription and limiting substitutability.[98] By "restrict[ing] the sale of some drugs (including almost all of the new drugs) to prescription sales," the FDA "reduc[ed] sharply the elasticity of demand."[99]

4. Post-Patent Prices in the United States

Just as history shows that the price disconnect, not patents, sharply reduced cross-price elasticity, so too does history show that prices remain inelastic when patents expire but the price disconnect remains.

In 1984, Congress enacted the Hatch-Waxman Act to streamline the entry of generic drugs.[100] The legislature's fundamental premise in enacting the statute was that, even after patents had expired, competition among branded pharmaceuticals was insufficient to drive prices to competitive levels. Congress understood that only competition from generic drugs could bring about competitive prices.[101]

Due to then-applicable FDA requirements that generic manufacturers duplicate the brand's clinical studies, as of 1983 only 35% of branded drugs that were *off-patent* faced generic competition.[102] The fundamental economic premise upon which Congress enacted the Hatch-Waxman Act was that, even after patents expired, *brands were continuing to sell at supracompetitive levels and only generic competition could generate competitive prices.*[103] In Senator Hatch's words, the Act was designed to "significantly lower the price of off-

98 *See, e.g.*, ALFRED D. CHANDLER, JR., SHAPING THE INDUSTRIAL CENTURY: THE REMARKABLE STORY OF THE EVOLUTION OF THE MODERN CHEMICAL AND PHARMACEUTICAL INDUSTRIES 179–80 (2005); KING, *supra* note 87, at 21 tbl.5 (industry sales, in dollars, nearly quadrupled from 1946 to 1960); TOM MAHONEY, THE MERCHANTS OF LIFE: AN ACCOUNT OF THE AMERICAN PHARMACEUTICAL INDUSTRY 4 (1959) ("As late as 1939 no ethical drug manufacturer in America had a sales volume as large as a department store like Macy's in New York or Hudson's in Detroit."); Temin, *supra* note 80, at 443–44.

99 Temin, *supra* note 80, at 443–44.

100 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, 35 U.S.C.).

101 Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY: MICROECONOMICS 1, 10.

102 *Id.*; Carrier, *supra* note 12, at 49; *see generally* H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

103 *See, e.g.*, H.R. REP. NO. 98-857, pt. 1, at 17 ("Currently, there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent . . . . The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years."); *id.* pt. 2, at 4, *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688 ("The FDA rules on generic drug approval for drugs approved after 1962 have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests."). Generic competition usually erodes the market power of only the

patent drugs, by many times in some cases, through increased generic competition."[104]

In short, the entire premise of Hatch-Waxman's generic-encouraging provisions is that the market fails to generate adequate price competition among branded alternatives, even when the brand drugs are off patent. Once again, the price disconnect, not patents, permits supracompetitive prices. Generic competition is necessary precisely because the price disconnect creates a significant market failure.

5. Prices When the Disconnect Is Solved

Finally, many jurisdictions outside the United States require prescriptions but have taken effective action to reconnect the price/quality decision. The success of these price-reconnection techniques in delivering competitive prices again points to the price disconnect, not valuable innovations, as the culprit in generating supracompetitive prices in the United States.[105]

Some nations reunite the drug choice and payment obligation by having the payor—often a state agency—participate in drug selection by imposing a formulary or determining reimbursement levels under state-run insurance plans. Other nations reunite choice and payment by giving the doctor a financial stake in the product selection, for example by requiring a prescription "budget" and giving the doctor a financial incentive to stay within it.[106] Recognizing that the price disconnect is itself the result of government regulation—the requirement that the consumer get a prescription—other nations directly regulate the price of prescription drugs.[107]

All of these techniques have been successful in bringing more competitive prices to consumers. Although methodological issues complicate international price comparisons, one conclusion is beyond dispute: the prices of branded prescription drugs in the United States significantly exceed those in other developed nations.[108] By contrast, when there is no price disconnect—for example, for generic prescription drugs and over-the-counter drugs—the

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generic's AB-rated counterpart, not other drugs in the therapeutic class. *See supra* note 74 and *infra* notes 106–07 and accompanying text.

104 130 CONG. REC. 15791, 15847 (1984) (statement of Sen. Hatch).

105 *See* Jayadev & Stiglitz, *supra* note 69; Steve D. Shadowen et al., *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 41 INT'L REV. OF INTELL. PROP. & COMPETITION L. 698 (2011) (including a detailed survey of international price-disconnect remedies).

106 Shadowen et al., *supra* note 105, at 718–20.

107 *Id.* at 716–17.

108 *See, e.g.*, MCKINSEY GLOBAL INST., ACCOUNTING FOR THE COST OF HEALTH CARE IN THE UNITED STATES (2008); DAVID A. SQUIRES, THE U.S. HEALTH SYSTEM IN PERSPECTIVE: A COMPARISON OF TWELVE INDUSTRIALIZED NATIONS 6–7 (2011); Patricia M. Danzon & Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals in 2005*, 27 HEALTH AFF. 221, 227–29 (2008); Richard G. Frank, *Prescription-Drug Prices*, 351 NEW ENG. J. MED. 1375 (2004); Marcio Machado et al., *International Drug Price Comparisons: Quality Assessment*, 29 REV. PANAM SALUD PUBLICA 46, 49 (2011).

United States has among the most competitive prices among developed nations.[109]

D. Market Failure's Relevance to Antitrust Analysis

To date, the United States has resisted the regulatory remedies that other developed nations have applied to the price-disconnect market failure. Instead, the United States has relied exclusively on two more market-oriented remedies: generic drugs and antitrust law.

As noted above, the Hatch-Waxman Act provides a pathway for the FDA to approve the marketing of generic drugs. The Act has effectively promoted price competition in limited circumstances. Generic drugs offer substantial price competition, but *only to the specific branded drug for which the prescription was written*, and *only after the patent for that specific drug is no longer in effect.* In a crowded class of me-too drugs, the entry of a generic version of Brand A will quickly cause most of the consumers of Brand A to switch to the generic. But the price disconnect almost always prevents that generic entry from generating competitive prices for Brands B, C, D, or E.[110]

In other words, generic competition may prevent the specific brand counterpart from extending its monopoly power beyond the expiration of its patents. But the price disconnect prevents generic competition from generating competitive prices within the therapeutic category. Price competition exists within only one slice of the therapeutic-category pie, with consumers unlucky enough to have doctors prescribing other branded drugs in the class continuing to pay supracompetitive prices. This is unsurprising given that this was the limited, stated purpose of the Hatch-Waxman Act.[111]

Through product reformulations, brand firms can disable even this limited, generic-drug-based, partial remedy to the price disconnect. U.S. courts have recently begun subjecting these reformulations to antitrust scrutiny. Although such scrutiny cannot solve the price-disconnect problem within a therapeutic class, it can help prevent manufacturers from extending their market power even after their patents are no longer effective.[112]

The importance of antitrust's role in this setting should be apparent. These markets suffer from a market failure resulting from the price disconnect. This market failure has prompted other developed nations to imple-

109 CHRIS L. PETERSON & RACHEL BURTON, CONG. RESEARCH SERV., RL34175, U.S. HEALTH CARE SPENDING: COMPARISON WITH OTHER OECD COUNTRIES 22–24 (2007); Danzon & Furukawa, *supra* note 108, at 229–30.

110 *See generally* E.M. KOLASSA, THE STRATEGIC PRICING OF PHARMACEUTICALS 232 (2009) ("Generics, in general, devastate the sales *only* of the originator brand . . . . There is a misconception that the entrance of a generic into a market will affect the shares and use of other products in the category as well. We have not found this to be true in most cases."); *see also supra* note 74 (citing testimony from *Nexium* antitrust litigation).

111 *See supra* Section I.B.

112 Preventing this extension of market power (often after the brand has received nonpatent exclusivities and a 30-month stay) would promote a central purpose of the Hatch-Waxman Act: facilitating price competition.

ment comprehensive regulatory remedies including direct price regulation, state-run formularies, and financial incentives for prescribing doctors. The United States has responded with a market-based solution—the promotion of generic drugs—that solves only one small part of the problem. When manufacturers try to disable even that modest remedy, the United States again forgoes any comprehensive regulatory solution, but instead relies solely on the ad hoc application of antitrust law.[113]

Fortunately, antitrust law is able to consider the regulatory regime, in this case, the Hatch-Waxman Act, state DPS laws, and the price disconnect. In *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, the Supreme Court made clear that courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry"[114] and must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."[115] In an important case discussed below,[116] the *Namenda* court relied on this principle in rejecting the argument that "antitrust law is not a vehicle for enforcing the 'spirit' of drug laws."[117] And the *Namenda* court specifically recognized that "what Defendants call 'free riding' . . . is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition and by preventing the 'practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]."[118]

113 Economic and structural hurdles prevent managed care organizations (MCOs) from defeating product-hopping schemes. *See generally* GAL, *supra* note 50, at 1 (discussing how a survey of benefit managers revealed that "the top two reasons [that MCOs cannot defeat product hops] are (i) pharma companies' resources and ingenuity in addressing formulary restrictions and (ii) the symbiotic relationship between pharma and managed care (blocking drug A would lead to lower rebate on drug B)"). Importantly, a collective action problem prevents individual MCOs from countering product-hopping schemes. *See, e.g.*, *id.* at 6 ("The US payor system is fragmented—a well motivated, organized pharma company with a portfolio of drugs can effectively overcome payor tools or at least make them so costly to implement that the payors are forced to the negotiation table."); Shadowen et al., *supra* note 1, at 21 ("An individual MCO's success in discouraging doctors from writing scripts for the new product is . . . dependent on the action of its competitors. Paradoxically, those competitors' incentive is to do nothing and instead free-ride on others' efforts.").

114 540 U.S. 398, 411–12 (2004) (quoting United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 91 (1975)).

115 *Id.* (quoting Concord v. Bos. Edison Co., 915 F.2d 17, 22 (1st Cir. 1990)).

116 *See infra* Section III.E.

117 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 658 (2d Cir. 2015).

118 *Id.* at 657–58 (second, third, fourth, and fifth alterations in original) (citation omitted) (citing FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688); *see also Actavis*, 133 S. Ct. at 2228 (recognizing Hatch-Waxman Act's bestowal on generics of ability to "piggyback" on brand's approval efforts, which speed "'the introduction of low-cost generic drugs to market' . . . thereby furthering drug competition" (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012))).

If any industry requires a specialized, nuanced analysis, it is the pharmaceutical industry. There is market failure, generic drugs can remedy one small part of the problem, product reformulations can disable even that partial remedy, and antitrust law is the only available means in the United States of policing reformulations. We now turn to courts' analyses of these issues, which have garnered mixed results in considering the regulatory regime and understanding the competitive consequences of product hopping.

III. Judicial and Academic Analysis

Given the complexity of the relevant economics and market structure, it is not a surprise that judicial analysis of product hopping has varied widely. Just as important, the timing of the cases has shaped the development of the law. In particular, the factual settings of the first two cases set the stage for the analysis in later cases.

Section A begins with *TriCor*, in which the court offered a nuanced analysis, albeit one that some later courts restricted to "hard switches" (in which the brand firm removes the old product from the market). Section B discusses the *Walgreens* case, which addressed a "soft switch" (in which the brand leaves the original product on the market) and offered a simplistic analysis of consumer choice.

The *Suboxone* case, addressed in Section C, revealed aspects of both hard and soft switches, with the court offering a nuanced understanding of the regulatory regime. The *Mylan* case addressed in Section D, in contrast, is an outlier that completely neglected the regime. The *Namenda* opinion, addressed in Section E, understood the regulatory regime in the context of hard switches, but overemphasized the distinction between hard and soft switches and introduced a new, underinclusive framework based on coercion. While the courts generally have considered the regulatory regime, Section F discusses the recent work of scholars who have paid less attention to this context.

A. TriCor*: Hard Switch, Nuanced Analysis*

In *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* (*TriCor*), the Delaware district court provided the first analysis of product hopping.[119] It considered Abbott's series of changes to its billion-dollar cholesterol and triglycerides drug, TriCor. Abbott marginally lowered the drug's strength, switched from a capsule to a tablet, stopped selling capsules, bought back existing supplies of capsules from pharmacies, and changed the code for capsules in the national drug database to "obsolete."[120] After the generics developed equivalents for the reformulated tablets, Abbott again transitioned to a new (marginally lower-strength) tablet, stopped selling the original tablets, and again changed the database code to "obsolete."[121] In removing the old

119 432 F. Supp. 2d 408 (D. Del. 2006).
120 *Id.* at 415–16.
121 *Id.* at 418.

drugs from the market, Abbott engaged in what has since been deemed a "hard switch."

Because of the "nature of the pharmaceutical drug market," the court applied the Rule of Reason.[122] The defendants' proposed standard of per se legality "presuppose[d] an open market where the merits of any new product [could] be tested by unfettered consumer choice."[123] But in this case the complaint alleged a price disconnect, and in addition the defendants "allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations."[124] Both circumstances justified "an inquiry into the effect of Defendants' formulation changes."[125]

The court did not require the plaintiffs "to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate [generic competition]."[126] Rather, "if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants."[127]

The court also found it irrelevant that the reformulation did not completely bar the generics from entering the market, but only prevented automatic substitution at the pharmacy counter.[128] The analysis asks not whether exclusionary conduct bars competitors "from all means of distribution," but only whether it precludes access to the "cost-efficient ones."[129] While generics "may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market."[130] Such an opportunity "has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes," and "[s]uch a restriction on competition, if proven, is sufficient to support an antitrust claim."[131]

In short, in the first judicial treatment of product hopping, the court offered a thoughtful approach that considered the realities of pharmaceutical markets—in particular, the existence of the price disconnect and the importance of generic substitution—and relied on the Rule of Reason in balancing the anticompetitive and procompetitive effects of product hopping. Some later courts, however, limited the reach of the ruling by cabining its reasoning to the "hard switch" scenario.

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122 *Id.* at 422.

123 *Id.*

124 *Id.*

125 *Id.* (citing HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW §§ 12.5, 15.3c1 (2015)).

126 *Id.*

127 *Id.* (citing United States v. Microsoft Corp., 253 F.3d 34, 59, 66–67 (D.C. Cir. 2001)).

128 *See id.* at 423 (citing United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir. 2005)).

129 *Id.* (quoting *Microsoft Corp.*, 253 F.3d at 64).

130 *Id.*

131 *Id.*

B. Walgreens*: Soft Switch, Simplistic Choice*

In particular, such a course was shaped by the second case, *Walgreen Co. v. AstraZeneca Pharmaceuticals* (*Walgreens*), which involved AstraZeneca's conversion from heartburn drug Prilosec to Nexium.[132] The plaintiffs alleged that there was "almost no difference" between the drugs and there was "no pharmacodynamic reason" the two forms would have different effects in the body.[133] The plaintiffs also alleged that AstraZeneca "aggressively promoted and 'detailed' Nexium to doctors" while stopping its promotion and detailing of Prilosec.[134] And they claimed that AstraZeneca was able to switch the market (to a drug receiving patent protection for an additional thirteen years) only through "distortion and misdirection in marketing, promoting and detailing Nexium."[135]

Unlike the court in *TriCor*, the District of Columbia court ignored the plaintiffs' detailed allegations of the price disconnect in pharmaceutical markets. The court granted AstraZeneca's motion to dismiss, concluding that "there is no allegation that AstraZeneca eliminated any consumer choices."[136] But that conclusion rested on three factual assertions, all of which required the court to ignore the price disconnect. The court asserted as facts that:

> [1] AstraZeneca added choices . . . [by] introduc[ing] a new drug to compete with already-established drugs . . .[;]
>
> [2] [D]etermin[ations of] which product among several is superior . . . are left to the marketplace[; and]
>
> [3] New products are not capable of affecting competitors' market share unless consumers prefer the new product.[137]

Each of those factual assertions contradicted plaintiffs' allegations regarding the price disconnect and its effects. In a price-disconnected market, switching doctors' prescriptions from an original branded product (facing impending generic competition) to a reformulated product (not facing generic competition)—what the court called "add[ing] choices"—significantly impairs consumers' ability to choose a generic product. The "added choice" of the reformulated product is actually the means by which consumers' real choice is eliminated. Moreover, the question is not which product among several is superior, but rather which product offers the consumer the *best trade-off between price and quality*, a determination that "the marketplace" cannot make in a price-disconnected market. In fact, the switching of the market from the original to the reformulated version certainly *is* capable of affecting competitors' market shares despite consumers' preferences. The court's contrary assertion ignored not only the plaintiffs' detailed allegations,

132 534 F. Supp. 2d 146 (D.D.C. 2008).
133 *Id.* at 149.
134 *Id.* (footnote omitted).
135 *Id.* at 148–49.
136 *Id.* at 151.
137 *Id.*

but also the economic rationale of fifty state DPS statutes and the Hatch-Waxman Act.[138] None of those statutes would be necessary if consumers in fact revealed their preferences through price/quality choices.

In addressing a soft switch, the court confronted a different scenario than that in *TriCor*. But the divide between hard and soft switches did not need to be as stark as the court made it. The die was cast, however, when the court articulated an analysis of consumer choice that, even if it would make sense in non-pharmaceutical markets where consumers make the price/quality tradeoff, does not capture the realities of drug markets.

C. Suboxone*: Hard/Soft Switch, Nuanced Analysis*

A third court considered elements of both hard and soft switches in a nuanced analysis of the regulatory regime. In *In re Suboxone Antitrust Litigation*,[139] the Eastern District of Pennsylvania court considered allegations that Reckitt switched the market from opioid dependence-treating Suboxone tablets to sublingual film. Reckitt allegedly promoted Suboxone film to physicians, disparaged Suboxone tablets, warned of false safety concerns, publicly announced the removal of tablets for these fabricated safety reasons but did not remove the tablets until six months later, and raised the price of tablets in relation to film even though film was more expensive to manufacture and package.[140]

The court began its analysis by noting that "[b]ecause ordinarily innovation will also inflict harm upon competitors, 'courts should not condemn a product change . . . unless they are relatively confident that the conduct in question is anticompetitive.'"[141] But "when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate,"[142] with the test (similar to *TriCor*) for whether conduct is exclusionary based "not [on] total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."[143]

The court found that the conduct at issue "seems to fall somewhere between that alleged in" *Walgreens* and *TriCor*.[144] The behavior was more concerning than that in *Walgreens* because Reckitt removed tablets from the market, but less concerning than that in *TriCor* because Reckitt did not buy back tablets or label an old product "obsolete."[145] The court made clear that "simply introducing a new product on the market, whether it is a superior

138 *See id.* The district court acknowledged the price disconnect only inadvertently, alternately identifying patients and doctors as the "consumers" who supposedly did not suffer the "elimination of consumer choice." *Id.* at 151–52.

139 64 F. Supp. 3d 665 (E.D. Pa. 2014).

140 *Id.* at 674.

141 *Id.* at 679–80 (second alteration in original) (quoting Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 421 (D. Del. 2006)).

142 *Id.* at 680 (quoting *TriCor*, 432 F. Supp. 2d at 421).

143 *Id.* (quoting United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir. 2005)).

144 *Id.* at 681.

145 *Id.*

product or not, does not, by itself, constitute exclusionary conduct."[146] Rather, "[t]he key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit."[147] Crucially, "[t]his analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind."[148]

Applying this analysis, the court found that "the facts presented sufficiently allege that the disparagement of Suboxone tablets took place alongside 'coercive' measures," as "[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film."[149] The court recognized that "Plaintiffs have plausibly alleged that various market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals."[150] In particular, the court noted that the "disconnect" that "exists between the person paying for the prescription and the person selecting the appropriate treatment" led to "the ordinary market forces that would allow consumers to consider price when selecting a product [being] derailed."[151] A patient would not be able to "simply request to receive a generic from his or her pharmacist because the film and the generic tablets are not [bioequivalent] and thus may not be substituted."[152] The court noted but did not rely on the dichotomy between hard and soft switches, instead conducting an analysis rooted in the regulatory framework and ultimately concluding that the plaintiffs "plausibly pleaded exclusionary conduct."[153]

D. Doryx*: Ignored Regulatory Regime*

While the *Suboxone* court grounded its decision in the regulatory framework, the Third Circuit in *Mylan Pharmaceuticals v. Warner Chilcott* (*Doryx*)[154] did not. In that case, Warner Chilcott engaged in an array of behaviors that resembled those of Abbott in *TriCor*: it stopped selling capsule versions of acne-treating Doryx to wholesalers; removed Doryx capsules from its website; worked with retailers to "auto-reference" the Doryx tablet whenever a doctor filed a Doryx prescription; informed wholesalers, retailers, and dealers that "Doryx Capsules have been replaced by Doryx Tablets;" and bought back and

146 *Id.* at 682.
147 *Id.*
148 *Id.*
149 *Id.*
150 *Id.* at 683–84.
151 *Id.* at 684.
152 *Id.*
153 *Id.*
154 No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

destroyed capsule inventory.[155] Despite allegations of hard switches and lack of economic sense, the court rejected Mylan's claims of anticompetitive conduct, finding that "Mylan was not foreclosed from the market."[156] Even though it found, "viewing the facts in the light most favorable to Mylan, that Defendants had indeed made the Doryx 'hops' primarily to 'delay generic market entry,'" it affirmed summary judgment for the Defendants.[157]

After concluding that the plaintiff—the competitor generic manufacturer—failed to adduce evidence of monopoly power,[158] the court indicated that it would have affirmed summary judgment on the alternative ground that the plaintiff failed to satisfy its initial burden of introducing evidence of anticompetitive conduct under the Rule of Reason.[159] But the court never explained what it considered to be an anticompetitive effect; nor did it consider whether a substantial reduction in the prescription base available for automatic generic substitution would count. Instead, in direct opposition to the Supreme Court's instruction that the relevant effect is on consumers, not competitors,[160] the court focused exclusively on the effect of Warner Chilcott's conduct on Mylan, the generic *competitor*, never even mentioning the effect on *consumers*.[161]

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155 *Id.* at *3.

156 *Id.* at *10.

157 *Id.* at *5 (quoting Mylan Pharm., Inc. v. Warner Chilcott, PLC (*Doryx*), No. 12-3824, 2015 WL 1736957, at *5 (E.D. Pa. Apr. 16, 2015)).

158 This Article does not address the monopoly-power element of the case. But just to mention some of the most glaring of the *Doryx* court's fundamental errors on this issue: (1) the court's conclusion that Warner Chilcott lacked monopoly power is inconsistent with the district court's finding that Warner Chilcott's "primary" purpose was to "delay generic market entry," *id.* (internal quotation marks omitted), as a manufacturer without monopoly power typically will not spend money to exclude a rival; (2) the court engaged in a muddled analysis of direct evidence of market power in the form of price-cost margins and output reductions; (3) the court acknowledged the existence of the price disconnect, *id.* at *2, but ignored its role in generating market power; (4) the court's crediting of anecdotal evidence that "some" and a "number" of managed care organizations "sought to" generate price competition among therapeutic alternatives, *id.* at *9 (quoting *Doryx*, 2015 WL 1736957, at *9 (internal quotation marks omitted)), did not address the relevant issue—the *actual effect* of these efforts on *marketwide* prices; (5) the court applied the wrong legal (and economic) standard for defining relevant antitrust markets, incorrectly holding that products are in the same market if there is "the existence of cross-elasticity" between them, *id.* at *10, when the proper standard is whether *sufficient* cross-elasticity exists between them *to constrain the price to the competitive level*; and (6) relatedly, the court failed to consider that its analysis succumbed to the *Cellophane* fallacy in its assumption that lost sales from price increases revealed a lack of monopoly power instead of a monopolist's inability to charge an infinite price.

159 *Id.*

160 *E.g.*, Harrison Aire, Inc. v. Aerostar Int'l, Inc., 423 F.3d 374, 385 (3d Cir. 2005) (noting that the Supreme Court in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477 (1977), held that "antitrust laws protect consumers, not competitors").

161 *Doryx*, 2016 WL 5403626, at *11. We focus our analysis on only some of the most glaring of the court's fundamental mistakes, not addressing, for example, its mischaracterization of the facts and fundamental holding in *Namenda*. *See id.*

Regarding the product hops' effects on Mylan (and assuming this were an appropriate inquiry, which it is not), the court offered only a series of non-sequiturs, asserting that Warner Chilcott's conduct was not anticompetitive because:

(1) Mylan received a 180-day exclusivity period under the Hatch-Waxman Act[162] (although Mylan's sales at relatively high generic prices are irrelevant to whether Warner Chilcott substantially reduced the number of sales and profits that Mylan would have made absent the product hops);

(2) Mylan set its generic price higher than the brand price for a period of time[163] (although the court failed to explain the relevance of this fact and did not consider whether the product hop caused Mylan's pricing strategy—a generic unable to distribute its product through automatic substitution might well increase price for the sales it can make);

(3) Mylan made profits of $146.9 million on the sales of generic Doryx[164] (although that number is meaningless unless compared to the profits that Mylan would have made absent the product hops).[165]

Finally, the Court offered a hodge-podge potpourri for courts to decide other product-hopping cases, stating that courts should balance exceedingly broad policy goals, such as "encouraging innovation," "protect[ing] consumers," and "ensur[ing] fair competition."[166] Among the "non-exhaustive" factors that courts may consider is the need to be "wary" of "turning courts into tribunals over innovation sufficiency."[167] Presumably another factor to consider is the decisions of fifty states and Congress to promote generic competition. The court provided no guidance at all on how courts are to balance these objectives.

E. Namenda*: Robust Regulatory Analysis, Improper Coercion Focus*

The Second Circuit has offered another recent treatment. In *New York ex rel. Schneiderman v. Actavis PLC* (*Namenda*), the court upheld a preliminary injunction preventing brand firm Forest from withdrawing its original drug from the market.[168] As Forest's Alzheimer's drug Namenda IR (taken twice a day) neared the end of its patent term, it introduced Namenda XR (taken

162 *Id.*

163 *Id.*

164 *Id.*

165 The court also asserted that Warner Chilcott had "offered strong evidence" of procompetitive justifications but did not discuss evidence sufficient to defeat summary judgment such as whether Mylan could rebut those justifications, show that Warner Chilcott could have achieved those objectives in a less restrictive manner, or show that the conduct was anticompetitive on balance.

166 *Id.* at *12.

167 *Id.* While the court noted that Congress could have chosen to expressly make product hopping unlawful, *id.* at *12 n.88, it also could have enacted special antitrust rules for product hops or made them immune from antitrust scrutiny altogether. The court also implied, without citation to any facts, that the price disconnect generates market power only in the presence of "extreme [doctor] coercion" or other similar factors. *Id.* at *12.

168 787 F.3d 638 (2d Cir. 2015).

once a day), with a patent expiring fourteen years later.[169] Although it initially planned to keep IR on the market (the soft switch), it later implemented a plan to effectively withdraw IR from the market (the hard switch).[170]

The court found that "neither product withdrawal nor product improvement alone is anticompetitive," but "when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition, its actions are anticompetitive under the Sherman Act."[171] The court also rejected a defense based on "free riding" since "generic substitution by pharmacists following the end of Namenda IR's exclusivity period [ ] is authorized by law; is the explicit goal of state substitution laws;" and also "furthers the goals of the Hatch-Waxman Act by promoting drug competition and by preventing the 'practical extension of [the brand firm's] monopoly . . . beyond the expiration of the[ ] patent[ ].'"[172]

The court held that the defendants' justifications were pretextual, and that even if they were not, any benefits were "outweighed by the anticompetitive harms."[173] It found monopolization from the combination of "withdrawing a successful drug from the market" and "introducing a reformulated version of that drug," which forced patients to "switch to the new version" and "imped[ed] generic competition, without a legitimate business justification."[174] The court then upheld an injunction because of the irreparable harm from the "planned hard switch strategy."[175] The court required the defendants to continue making Namenda IR tablets available.[176]

While the court understood the regulatory framework, it applied a test based on coercion that was underinclusive in targeting antitrust harm. The court stated that

> [a]s long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.[177]

The court focused on Forest's "forc[ing] patients to switch" from Namenda IR to Namenda XR, and cited the defendants' figures that a soft

169 *Id.* at 642.

170 *Id.* at 658.

171 *Id.* at 653–54 (citations omitted).

172 *Id.* at 657–58 (second alteration in original) (citation omitted) (citing FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688).

173 *Id.* at 658.

174 *Id.* at 659.

175 *Id.* at 660–61 (quoting New York v. Actavis, PLC, No. 14-Civ.-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014)).

176 *Id.* at 649.

177 *Id.* at 654.

switch would convert only 30% of patients while a hard switch would convert 80 to 100%.[178] The court stated that "[h]ad Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR)," but "[b]y removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice."[179]

While the court appreciated the regulatory regime, its coercion-based framework does not make room for potential soft-switch harms that arise from the unique nature of drug markets and that might not make economic sense.

F. Commentators: Abandonment of Antitrust Analysis

Though many of the courts could have benefited from further attention to the price-disconnect market failure, at least (with the exception of *Walgreens* and *Doryx*) they anticipated a nontrivial role for antitrust law. That is more than can be said for commentators Joshua D. Wright, a former Federal Trade Commissioner, and Judge Douglas H. Ginsburg, a Senior Judge on the U.S. Court of Appeals for the D.C. Circuit, in their joint comment to the Canadian Competition Bureau on its draft updated Intellectual Property Enforcement Guidelines.[180] In that comment, the authors offer a constricted approach to product hopping that would limit antitrust more than any of the judicial approaches described above.

Wright and Ginsburg "recommend against imposing a competition law sanction on product switching absent clear and convincing objective evidence that [the reformulated product] represents a sham innovation with zero or negative consumer welfare benefits."[181] The authors worry that "applying a standard competition law analysis is likely to deter innovation that would have benefitted consumers."[182] The given reason is that "innova-

178 *Id.*

179 *Id.* at 655.

180 Joshua D. Wright & Douglas H. Ginsburg, Comment on the Canadian Competition Bureau's Draft Updated Intellectual Property Enforcement Guidelines (Aug. 10, 2015), https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf. The Guidelines concluded that product switching could constitute an abuse of a dominant position based on factors such as the likely effect of a brand's conduct on a generic's ability to compete and whether the brand's purpose was "to delay or foreclose" generic supply. COMPETITION BUREAU CAN., ENFORCEMENT GUIDELINES: INTELLECTUAL PROPERTY, Ex. 9A, at 37–39 (2016). To the extent it is relevant, Carrier served as a consultant to the Bureau on the Guidelines.

181 Wright & Ginsburg, *supra* note 180, at 1.

182 *Id.* at 2. For a similar argument, see Dennis W. Carlton et al., A Critical Evaluation of the FTC's Theory of Product Hopping as a Way to Promote Competition 13–15 (July 8, 2016) (unpublished manuscript), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2808822.

tions, including even small changes in product design, can generate significant consumer benefits."[183]

The authors claim that "[c]ompetition law is not a suitable instrument for micromanaging product design and innovation" as it "requires competition agencies and courts to weigh the benefits to consumers from the innovation against any costs to consumers arising from the diminution of competition."[184] The agencies and courts are "ill-equipped" to make these determinations, and it is "unclear" whether such a balancing "can be done at all."[185]

The authors also contend that "product switching does not amount to exclusionary conduct because the generic company is still free to compete and is 'able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development.'"[186]

The authors trust not the antitrust agencies but the "judgment [of] the value of product design changes levied by consumers in the market."[187] The apparent problem of applying antitrust law is that agencies and courts would be "substituting their judgment for the judgment made by consumers."[188] The authors claim that subjecting drug reformulations to antitrust scrutiny "most remarkably assumes that pharmaceutical markets are somehow so different from other product markets that producers are free to ignore consumer judgments about the value of product innovations."[189]

At least four problems undermine the authors' argument. First, no empirical or other evidence suggests that a well-structured antitrust analysis would deter innovation in this setting. Quite the contrary. A proper antitrust framework could subject to scrutiny only those reformulations that are temporally linked to the imminent introduction of the generic. Clear, bright lines could signal to brand companies that their reformulations would not be subject to *any* antitrust scrutiny unless they engage in certain suspect behavior. In essence, brand firms would "volunteer" for antitrust scrutiny by engaging in the identified conduct. The sole empirical analysis on this subject indicates that just 20% of reformulated drugs are temporally linked to the imminent introduction of the generic.[190] And the five cases litigated to date represent no more than 1% of all reformulations in the past twenty years.[191]

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183 Wright & Ginsburg, *supra* note 180, at 2.

184 *Id.*

185 *Id.*

186 *Id.* at 3 (quoting Mylan Pharm., Inc. v. Warner Chilcott, PLC (*Doryx*), No. 12-3824, 2015 WL 1736957, at *14 (E.D. Pa. Apr. 16, 2015)); *see also* Carlton et al., *supra* note 182, at 8–9.

187 Wright & Ginsburg, *supra* note 180, at 3.

188 *Id.* at 4.

189 *Id.*

190 Shadowen et al., *supra* note 1, at 26–27 (finding that 344 of 425 reformulations occurred outside the Generic Window).

191 *Id.*

The evidence makes clear that, for the subset of potentially anticompetitive reformulations, antitrust scrutiny is likely not to deter innovation, but to spur it. Brand firms often *withhold incremental innovations from the market* to use them later as part of a product hop.[192] For example, manufacturers in the *TriCor* case delayed seeking a new indication for the original product, reserving it exclusively for the reformulated product, even though "[t]he data necessary to get the new indication was available much earlier."[193] Similarly, in Warner-Lambert's admission of criminal liability for promoting off-label uses of seizure-treating Neurontin, it conceded that a "principal reason[ ] for not seeking FDA approval for those uses was that it wanted to reserve them for a later promotional campaign for its reformulated product."[194] And in *Namenda*, Forest waited until generic competition for twice-daily Namenda was imminent before introducing the once-daily version, even though "[a]ll other Alzheimer's disease treatments are administered once a day."[195] It is telling that Forest had obtained FDA approval to market the once-daily version three years earlier but had withheld it from the market until entry of the twice-daily generics was looming.[196]

More broadly, in *Namenda* the court found that the defendants "presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation."[197] The Second Circuit noted that "immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations."[198] Any serious argument that antitrust scrutiny might deter innovation must contend with the substantial indications that the *absence* of scrutiny tempts brands to withhold innovations from the market and invest in trivial modifications. In short, industry realities undercut contrary, evidence-free pronouncements about adverse effects on innovation.[199]

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192 MARIBEL RIOS, THE OUTSOURCING ADVANTAGES IN FORMULATION DEVELOPMENT 40 (2005) (brands often "intentionally hold[ ] back a twice- or once-a-day formulation to use against generic competition later on").

193 Shadowen et al., *supra* note 105, at 710.

194 *Id.*

195 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 647 (2d Cir. 2015).

196 *Id.*

197 *Id.* at 659.

198 *Id.*; *see also* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 615 (2011) ("Brand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.").

199 Nor is it true, as Wright and Ginsburg assert, that an antitrust analysis would require agencies and courts to weigh the benefits and detriments to consumers. Wright & Ginsburg, *supra* note 180, at 2. As we develop in detail below, agencies and courts can and

Second, after assuming that antitrust scrutiny would harm innovation, Wright and Ginsburg double down by positing, without support, that these asserted effects outweigh product hopping's well-established negative price effects. On a blockbuster drug, a product hop can deprive consumers of $1 billion or more in cost savings, with little, no, or negative gain in product quality.[200] Wright and Ginsburg offer no empirical or even theoretical basis for believing that *in this industry*, where the gains from price competition are so enormous, any supposed positive innovation effects would outweigh the documented negative price effects.[201] Indeed, the fact that brands withhold innovations from the market to impair generic competition speaks volumes. Such delayed reformulations provide strong evidence that losses to consumers from impaired generic competition are greater than any gains from increased quality.[202]

Third, Wright and Ginsburg's assertion that, notwithstanding the product hop, generic firms are still able to reach "consumers"[203] is curious. As the *TriCor* and *Suboxone* courts explained, the law (and economics) is clear that conduct can harm consumers—that it can be condemned as exclusionary—if it substantially impairs competition while not preventing it altogether.[204] Wright and Ginsburg suggest that generics, like brands, can market their products through detailing and product innovation.[205] But again, this ignores the industry's regulatory structure and competitive dynamics. Typically, once the brand's patents are no longer effective, *no one*—neither the brand nor any generics—can profitably market the product on a basis other than price.[206]

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should apply a no-economic-sense test that judges product reformulations based on objective economic evidence of their value *to the manufacturer*.

200 On a brand drug with $1 billion in annual sales, the lost savings from impairing generic competition can easily be $765 million annually: generics take 90% of the unit sales, at an average price discount (with multiple generics in the market) of at least 85%. *See, e.g.*, John LaMattina, *Patent Expirations of Crestor and Zetia and the Impact on Other Cholesterol Drugs*, Forbes (Jan. 18, 2016), http://www.forbes.com/sites/johnlamattina/2016/01/18/patent-expirations-of-crestor-and-zetia-and-the-impact-on-other-cholesterol-drugs/#2b708f805c59.

201 Wright & Ginsburg, *supra* note 180.

202 If the value of the "innovation" to consumers were greater than the value to the manufacturer of impairing generic competition, the manufacturer would immediately introduce the innovation in order to reap the increased gains. *See, e.g.*, Natalie Mizik & Robert Jacobson, *Trading Off Between Value Creation and Value Appropriation: The Financial Implications of Shifts in Strategic Emphasis*, 67 J. Marketing 63, 65 (2003).

203 Wright & Ginsburg, *supra* note 180, at 3.

204 *See In re* Suboxone, 64 F. Supp. 3d 665 (E.D. Pa. 2014); Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 416–18 (D. Del. 2006); *see also* Teva Pharm. USA, Inc. v. Abbott Labs. (*TriCor II*), 580 F. Supp. 2d 345 (D. Del. 2008).

205 *See also* Carlton et al., *supra* note 182, at 8–9.

206 This is why, when facing imminent generic competition, brands almost always stop promoting the product. Shadowen et al., *supra* note 1, at 15. To the extent Wright and Ginsburg suggest that generics are free to market their products based on price, they fail to

In this setting, costs incurred to encourage a doctor to write a prescription for one's product would be squandered because the pharmacist could fill the prescription with a competitor's AB-rated product.[207] As *Namenda* concluded, "additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors."[208]

The inability of generics to profitably market to doctors is desirable. If a generic could do so, this would reintroduce the price-disconnect failure. The generic-substitution regime is *designed* to render unprofitable active marketing of the product to doctors. Yet Wright and Ginsburg suggest that generics try to defeat product hops by engaging in the doctor-focused marketing that is the problem and that DPS laws intentionally render unprofitable.

Fourth, Wright and Ginsburg find it "remarkabl[e]" that scholars and courts conclude that the price disconnect substantially impairs these markets.[209] This is the crux of their analysis. Yet they provide neither empirical nor theoretical support for second-guessing the judgment of Congress in 1963 and 1984, the repeated conclusions of the FTC, and the unanimous judgment of all fifty states. The price disconnect is the economic premise around which all states and the federal government have for the past forty years built a robust generic-substitution regulatory regime.[210] And it is the bedrock principle around which respected industry scholars have based their work.[211] Yet Wright and Ginsburg try to wave it away based on their say-so and nothing else.

Having denied the existence of the price disconnect, Wright and Ginsburg do not address the question whether, given its existence and importance in these markets, the disconnect (as opposed to valued innovations) is a likely source of market power and sound basis for antitrust scrutiny. It is

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address the viability and strength of that competition in the face of substitutability at the pharmacy counter. Wright & Ginsburg, *supra* note 180, at 2.

207 Shadowen et al., *supra* note 1, at 15.

208 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 656 (2d Cir. 2015).

209 Wright & Ginsburg, *supra* note 180, at 4.

210 *See also Namenda*, 787 F.3d at 657–58 (recognizing that "what Defendants call 'free riding' . . . is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition and by preventing the 'practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]" (second, third, fourth, and fifth alterations in original) (citations omitted) (citing FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688)); *see also Actavis*, 133 S. Ct. at 2228 (recognizing the Hatch-Waxman Act's bestowal on generics of the ability to "piggy-back" on brands' approval efforts, which speed "'the introduction of low-cost generic drugs to market' . . . thereby furthering drug competition" (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012))).

211 *See* Shadowen et al., *supra* note 1, at 10 n.32 (collecting sources).

well-established that lesser market failures, such as strong network effects, are a basis for scrutiny.[212] Generic products are substitutable only if they are AB-rated to the brand, and, just as in network industries, this requirement of "compatibility" with the brand increases the opportunity and incentive for competition-impairing reformulations.[213] This premium on compatibility (as well as attention to the regulatory regime) fully justifies antitrust scrutiny in drug markets.[214]

In short, limiting antitrust scrutiny of product hopping to "sham innovations" is a recipe for anticompetitive behavior in complex markets that would have dramatic effects on consumers.[215]

IV. A New Product-Hopping Framework

As should be crystal clear, the pharmaceutical industry is unique in its complexity. Any antitrust analysis of product-hopping conduct must therefore, as the Supreme Court has explained, "be attuned to the particular structure and circumstances of the industry at issue."[216] With courts veering from simplistic "choice," to underinclusive coercion, to varied attention to the regulatory regime, it is time for a new antitrust framework for product hopping. This Part embarks on such a project.

Section A begins by offering two safe harbors for brand firms based on the timing of the reformulation. The first applies when the brand introduces a reformulation outside the temporal window in which generic entry is expected. The second applies when the brand introduces the reformulation after the generic version of the original product has entered the market. Section B then introduces a no-economic-sense test that has been applied elsewhere in antitrust law, which offers greater certainty for brand firms, and which results in a finding of monopolization when the brand engages in conduct that makes sense only by stifling generic competition.

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212 *See* IIIB Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 776c, at 297 (3d ed. 2008) (explaining that network effects justify antitrust scrutiny of Microsoft's product redesigns); *see also* John M. Newman, *Anticompetitive Product Design in the New Economy*, 39 Fla. St. U. L. Rev. 681 (2012) (arguing for antitrust scrutiny of computer code redesigns).

213 Shadowen et al., *supra* note 1, at 79–81.

214 *See, e.g.*, Hovenkamp et al., *supra* note 125, § 15.3 (pharmaceutical reformulations should be subjected to the same antitrust analysis as product redesigns in network industries); Jonathan Jacobson et al., *Predatory Innovation: An Analysis of* Allied Orthopedic v. Tyco *in the Context of Section 2 Jurisprudence*, 23 Loy. Consumer L. Rev. 1, 8 (2010) ("There are two scenarios where an exclusionary redesign may be especially harmful: (a) in the context of networked markets . . .; and (b) in pharmaceutical markets . . . .").

215 Like Wright and Ginsburg, Richard Gilbert worries about the effect on innovation of subjecting product-hopping to antitrust scrutiny. Gilbert, *supra* note 62, at 71. His analysis also implies that withholding a true innovation from the market reduces consumer welfare. *Id.* at 52. But he never puts the two concepts together by realizing that the *failure* to subject product hopping to antitrust scrutiny will impair innovation.

216 Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004).

This Part focuses on the safe harbors and no-economic-sense test. But many reformulations will not even reach these stages. Our definition of product hopping requires:

(1) reformulating the product in a way that makes a generic version of the original product not substitutable; and

(2) encouraging doctors to write prescriptions for the reformulated product rather than the original product, i.e., switching the prescription base from the original to the reformulated product.

The second factor in particular distinguishes between the brand's expansion of the prescription base by taking away sales from other branded products or enticing new patients into the market, and switching the base solely to impair generic competition. The former, which will be satisfied by the mere introduction of a product (even one predicted to lose money) or the equal promotion of the old and reformulated products, will not raise antitrust concern. The other could, however, depending on the application of the safe harbors and no-economic-sense test.

The switching of the prescription base is particularly concerning in the pharmaceutical industry because of the price disconnect, as the doctor who prescribes the product does not pay, and the consumer (or her insurer) who pays does not choose. With no one making the fundamental judgment as to whether the "innovation" is worth the price, the brand manufacturer has an incentive and opportunity to make product redesigns with welfare-reducing intent and effect. The market cannot prevent the brand from switching the prescription base to a product that is not in fact worth the consumer savings that are lost from the impaired generic competition.

A. Safe Harbors

Brand firms often introduce new versions of existing drugs. The vast majority of these reformulations do not threaten competitive harm. For example, brands often, without reducing their promotion of the original version, introduce modestly-adjusted versions of their products to fill out a product line or satisfy demand for a particular formulation or delivery mechanism. We offer two safe harbors to ensure that antitrust liability is off the table for changes like these.

The first safe harbor immunizes reformulations made long enough before generic approval that they typically are not intended to impair generic competition. The second safe harbor exempts reformulations that are not likely to thwart generic competition because they are introduced after the generic version of the original drug has entered the market. The safe harbors ensure that brands have the certainty to engage in most of their anticipated reformulations without facing potential antitrust liability. And they offer a more deferential analysis than currently exists in the caselaw.

1. Outside Generic Window

The first safe harbor applies when a brand introduces a reformulated drug outside a "Generic Window" in which generic entry is expected. We propose immunity for the introduction of reformulations outside a four-year window, as these reformulations are less likely to have the purpose and effect of impairing generic competition.

Such a window would begin 18 months before the first generic application (Abbreviated New Drug Application or ANDA) is filed seeking approval to market a generic version of the original brand product. The rationale for granting a safe harbor for reformulations made prior to the 18-month period immediately before the ANDA filing is straightforward. Eighteen months is sufficient time for the generic firm to reformulate the generic product to match the new brand product and file an ANDA on the reformulated version. Thus, a reformulation implemented earlier than 18 months before the first ANDA is filed is unlikely to alter the competitive landscape. In such a case, no ANDA is about to be filed, and the reformulation is not temporally linked to generic entry.[217]

The rationale for denying a safe harbor once the ANDA is filed is also straightforward: the brand can get an automatic 30-month stay on approval of the generic.[218] The brand should not enjoy antitrust immunity for reformulations made while the generic is statutorily prohibited from entering the market. Reformulations made while the generic is prohibited from entering are likely to be aimed at delaying generic competition. The combination of the 18- and 30-month periods results in a four-year window. Outside this window, a brand's reformulation should be immune from antitrust scrutiny.

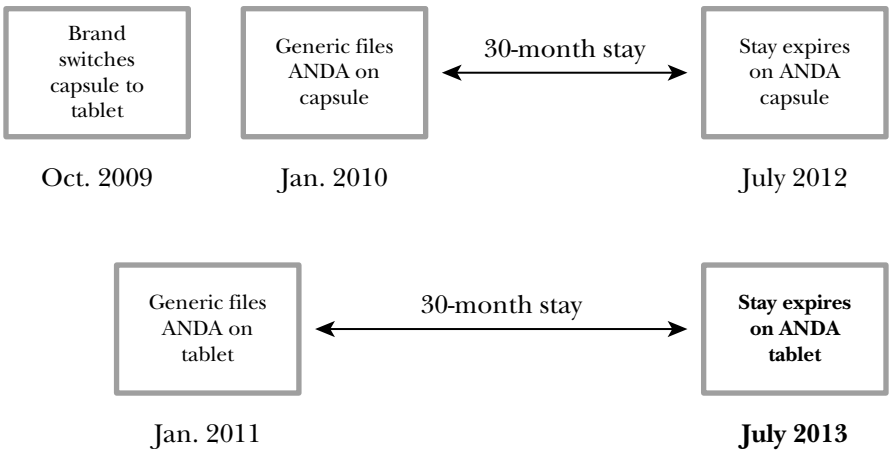
Two examples clarify. Assume that the brand reformulates from a capsule to a tablet and begins switching the market in October 2009—three months before the first ANDA is filed in January 2010 (see Figure 1). Assume further that the ANDA contains a Paragraph IV certification that the brand's *capsule* patent is invalid—a certification that elicits a patent lawsuit by the brand and an automatic 30-month stay, prohibiting generic entry until July 2012. A strong possibility in this case is that (1) the brand had anticipated the filing of the ANDA and timed the reformulation to impair the anticipated competition; (2) the generic's planning was so far advanced that it made sense to file the ANDA despite the reformulation; and (3) the reformulation could delay generic competition by prompting the generic firm to reformulate its product to match the new brand tablet, a process that could take, say, 15 months. In January 2011, the generic files a new ANDA, with a new Paragraph IV certification for the *tablet* product. The brand sues again, which results in an automatic stay that expires in July 2013—a one-year delay

217 The event that triggers the safe harbor is the brand's introduction on the market of the reformulated version. The event is not FDA approval of the reformulation because the brand could still, after approval, delay entering the market, even for years, to forestall generic entry.

218 Carrier, *supra* note 2, at 1018.

from July 2012, when the 30-month stay on the *capsule* product expired. This reformulation would not enjoy a safe harbor under our framework because the reformulation occurred within 18 months of the filing of the first ANDA.

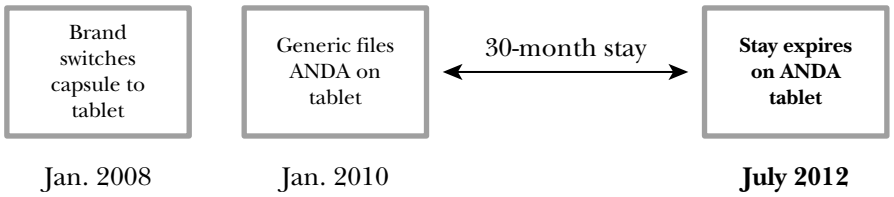
FIGURE 1



Now consider the same reformulation from a capsule to a tablet, but assume that the brand begins switching the market in January 2008—24 months before the first ANDA is filed in January 2010 (see Figure 2). This switch is not likely to alter the competitive terrain because the generic manufacturer has ample time to reformulate from a capsule to a tablet and get the ANDA and Paragraph IV certification for the *tablet* on file by January 2010. Because the generic has the time to file an ANDA directly on the brand's reformulated tablet, no delay beyond the original 30-month stay results from the reformulation. Under our framework, this reformulation enjoys a safe harbor because the reformulation occurred more than 18 months before the filing of the first ANDA.[219]

219 We offer a slightly different rule when the brand product enjoys five-year NCE exclusivity. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (2012). In that setting, we would provide a safe harbor only for a reformulation that begins 30 months or less after the start of the NCE exclusivity period. The FDA is precluded from accepting for filing any ANDA for such a product until four years after the start of the NCE exclusivity period. To ensure that the generic manufacturer has 18 months to react to any reformulation and still be in as good a competitive posture as it would have been absent the reformulation, we would subject to antitrust scrutiny any reformulation that begins 30 months (18 months plus 12 months (representing the one-year period within the five-year exclusivity in which the generic can file an ANDA)) or less before the end of the five-year period.

FIGURE 2



In short, a reformulation that occurs within 18 months of the filing of the first ANDA often appears to have the purpose and effect of impairing generic competition. In contrast, a reformulation made more than 18 months before the first ANDA is filed likely had neither that purpose nor that effect. Historically, the vast majority of product reformulations have fallen outside this Generic Window and thus would enjoy the antitrust safe harbor under our proposal.[220] Procedurally, antitrust agencies could simply announce and apply this safe harbor. Private litigation is unlikely to ensue if the brand introduced the reformulated product outside the Generic Window because the reformulation typically will not have caused any damage. If any private litigation does ensue, the brand could point to the reformulation's timing and ask the court to give dispositive (or near-dispositive) weight to it in the no-economic-sense analysis we advocate below.

2. Reformulation After Generic Entry

One characteristic of the safe harbor for reformulations outside the Generic Window is that obtaining immunity is not within the brand's direct control. The safe harbor is tied to the filing of the ANDA, an event that the generic, not the brand, controls.

In contrast, the second safe harbor is entirely within the brand firm's control. We propose immunity for a reformulation introduced after a generic version of the original product has entered the market.[221] As noted in detail above, reformulations introduced after generic entry are far less effective in impairing generic competition. Generics make three to ten times more sales if the reformulation is introduced after (compared to before) generic entry.[222]

To be sure, quality competition between the reformulated brand and generic original products may not be ideal. The brand firm may have withdrawn all of its promotion and marketing from the original product. Or it may have switched all of its promotion and marketing to the reformulated product. But at least doctors, third-party payors, and consumers are gener-

220 Shadowen et al., *supra* note 1, at 2, 26.

221 Even the introduction of the generic *contemporaneously* with the brand results in significant sales to the generic. *See, e.g.*, Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFF. 790, 797 (2007).

222 *See generally* Haiden A. Huskamp et al., *Generic Entry, Reformulations, and Promotion of SSRIs*, 26 PHARMACOECONOMICS 603, 604 (2008).

ally aware that a generic is on the market and the industry's generic-promoting mechanisms have a chance to work.[223] And because reformulations after generic entry have such a significantly reduced effect on generic competition, we offer a safe harbor, freeing the brand firm even from the task of showing that its conduct makes economic sense.[224]

On balance, we believe the antitrust agencies and courts should recognize this safe harbor to ensure that the brand has the ability, within its sole control, to completely avoid antitrust scrutiny. This guarantees that consumers will get the benefit of any innovations whose true purpose is to offer an improved product, not to impair generic competition.

B. No-Economic-Sense Test

The safe harbors introduced in the previous section provide far more protection for brands than is offered under the caselaw. In contrast, the no-economic-sense test we introduce in this section reaches more aggressively than some of the caselaw—specifically, *Walgreens* and *Doryx*—to deter anticompetitive conduct. The fact that a test so universally viewed as defendant-friendly leads to such different results shows how far those two cases

223 Devlin and Jacobs come to a similar result, but on erroneous grounds. *See* Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 BERKELEY TECH. L.J. 1 (2012). As we understand it, they would subject to antitrust scrutiny only those product hops in which the reformulated version enters before the generic of the original product has received FDA approval. *Id.* at 49. They would do so, however, based on the incorrect assertion that the FDA is prohibited from approving an ANDA if the brand firm has removed its product from the market. *Id.*

More fundamentally, Devlin and Jacobs wrongly assert that a product hop that does not prohibit a generic from gaining FDA approval "cannot exclude an equally or more efficient rival, [and therefore] fails to arouse the concern at the heart of Section Two jurisprudence." *Id.* at 50. Like Wright and Ginsburg, they fail to address, let alone satisfactorily include in their analysis, the price disconnect, which *does* substantially impair competition from equally efficient rivals. Also erroneous is their assertion that courts should not apply antitrust principles to drug markets because "antitrust rules are designed to operate in unregulated markets . . . ." *Id.* at 51. To the contrary, courts are *required* to apply antitrust principles to regulated markets and to take into account unique characteristics such as the price disconnect. *See also* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234, 2235 (2013) (noting the "general procompetitive thrust" of the Hatch-Waxman Act and holding that courts must apply antitrust law to prevent brands from manipulating the "unique regulatory framework" that "unintentionally . . . created special incentives" for anticompetitive conduct).

224 Carlton gives an example of a product hop in which the brand stops promoting the original product two years *after* introducing the reformulated product. Carlton et al., *supra* note 182, at 7. That example would almost certainly fall within one of our safe harbors and/or would pass the no-economic-sense test. Brand manufacturers engaged in a product hop designed to impair generic entry make the switch *before* the generics enter, and they achieve the switch by stopping promotion of the original product in favor of the reformulated product. So if a brand manufacturer has continued promoting the original product for two years after introducing the reformulated product, as in the Carlton example, it is doing something other than trying to impair generic competition.

veered from justified economic analysis. And while the no-economic-sense test leads to the same result in *TriCor*, *Suboxone*, and *Namenda*, the test keeps the antitrust analysis focused on economic realities rather than any artificial distinctions between "hard" and "soft" switches.

The no-economic-sense analysis asks whether conduct allegedly maintaining a monopoly by excluding nascent competition "likely would have been profitable if the nascent competition flourished and the monopoly was not maintained."[225] Applying the test requires a comparison of the conduct's gains (not including those from eliminating competition) and costs to the monopolist.[226] Conduct yielding a net negative payoff to the monopolist fails the test.[227] The test focuses on the conduct's "reasonably anticipated impact" (according to "objective economic considerations for a reasonable person") when undertaken rather than its actual impact.[228]

The no-economic-sense inquiry offers an economic test to determine whether the monopolist's sole motive was to impair competition. If a firm undertakes conduct that makes no economic sense, then its "anticompetitive intent" can be "unambiguously . . . inferred."[229] As one commentator has explained, the test's application "could not be simpler if . . . the conduct cannot possibly confer an economic benefit on the defendant other than by eliminating competition."[230] Even the "technological superiority" of a new product should not prevent a finding of exclusionary conduct since the "value to consumers of the new system relative to the preexisting system" may not be "greater than the required development costs."[231] In short, if a brand

225 Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 ANTITRUST L.J. 413, 415 (2006). For conduct allegedly creating a monopoly, the test asks "whether the conduct likely would have been profitable if the existing competitors were not excluded and monopoly was not created." *Id.*

226 *Id.* at 416.

227 *Id.*

228 *Id.*

229 A. Douglas Melamed, *Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles?*, 73 ANTITRUST L.J. 375, 393 (2006); *see also id.* at 391–92 (employing the "sacrifice test" because it is "widely used," but recognizing that both this test and the no-economic-sense test depend "not on the timeline, but rather on the nature of the conduct—on whether it would make no business or economic sense but for its likelihood of harming competition"); Shadowen et al., *supra* note 1, at 76 (explaining that conduct that is economically irrational absent reduced competition leads to the natural inference that the actor "was aware of and motivated solely to achieve that reduction").

230 Werden, *supra* note 225, at 415.

231 Janusz A. Ordover & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation*, 91 YALE L.J. 8, 49 (1981); *see also* Spirit Airlines v. Nw. Airlines, 431 F.3d 917, 953 (6th Cir. 2005) (Moore, J., concurring) (involving predation claims based on the theory that "an incumbent seeks to retain monopolist control in the future by ceasing to engage in economically rational behavior in the present in an effort to drive potential rivals from the market"); ROBERT H. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF 144 (1978) (laying out a test used to identify business practices that "would not be considered profit maximizing except for the expectation either that (1) rivals will be driven from the market, leaving the predator with a market share sufficient to command

acquires or maintains monopoly power by engaging in product hopping that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.

Our use of the no-economic-sense test avoids some of the recognized shortcomings of the profit-sacrifice test.[232] In particular, the profit-sacrifice test could punish short-term sacrifices such as investments in R&D or capital equipment even though they would lead to a higher profit in the long term.[233] The no-economic-sense test does not punish such investments "because they make economic sense apart from any tendency to eliminate competition and because they have no such tendency."[234] The test also avoids disputes about whether the manufacturer anticipated that it would recoup its sacrificed profits sometime in the future.[235] Some anticompetitive product hops could be profitable to the brand immediately, with no lost profits to be recouped later.

1. Virtues of the No-Economic-Sense Test

From the brand firm's perspective, the no-economic-sense test has three advantages as compared to existing caselaw. First, the test judges conduct *ex ante* rather than *ex post*. That is, the relevant inquiry under the no-economic-sense test is whether *at the time of the reformulation* the firm *projected* that the additional profits would justify the additional costs. The no-economic-sense test does not impose liability when the brand projects that the profits would exceed the costs but miscalculates because the costs were greater or the sales lower than reasonably projected. This is a significant advantage as the brand

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monopoly profits, or (2) rivals will be chastened sufficiently to abandon competitive behavior the predator finds inconvenient or threatening").

232 The profit-sacrifice analysis determines if conduct would be "unprofitable for the defendant but for the exclusion of rivals and resulting supra-competitive recoupment." Melamed, *supra* note 229, at 389; *see also* Ordover & Willig, supra note 231, at 9–10 ("[P]redatory behavior is a response to a rival that sacrifices part of the profit that could be earned under competitive circumstances, were the rival to remain viable, in order to induce exit and gain consequent additional monopoly profit." (footnotes omitted)).

233 Werden, *supra* note 225, at 424; *see also* Herbert Hovenkamp, *The Harvard and Chicago Schools and the Dominant Firm* 14 (Univ. Iowa Legal Studies Research Paper No. 07-19, 2010), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1014153 (noting that the profit-sacrifice test "does not adequately distinguish anticompetitive 'sacrifice' from procompetitive 'investment'").

234 Werden, *supra* note 225, at 424.

235 *See* Christopher R. Leslie, *Predatory Pricing and Recoupment*, 113 COLUM. L. REV. 1695, 1699 (2013) (describing "unnecessary and counterproductive" recoupment analysis); Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 319–20 (2006) (noting that the no-economic-sense test "is primarily different from the conventional profit-sacrifice standard because it does not require a showing that there is a period of time in which the defendant's profits are lower than they were before the exclusionary conduct was undertaken" and "[t]he reduction in profits can be conceptual rather than temporal").

can be fairly certain whether a given reformulation will avoid antitrust liability.

Second, and relatedly, the no-economic-sense test is based on objective economic evidence rather than ambiguous qualitative evidence of "intent." Emails, narratives in memoranda, and the like may provide some surrounding "flavor" as to whether a reformulation makes economic sense. But the foundation of the no-economic-sense test consists of the manufacturer's sales and costs projections: Did the brand project that its reformulation of the product and cannibalization of the prescription base would expand sales sufficiently to justify the additional costs? Such an inquiry promotes certainty in business planning.

Third, the no-economic-sense test offers an easier antitrust hurdle for the brand to clear, substantively, than the rule-of-reason standard, which considers anticompetitive effects and procompetitive justifications. As noted above, the no-economic-sense test is essentially an economic test to determine whether the brand's *sole* motive was to impair competition. The brand will clear the no-economic-sense hurdle with a mixed motive of impairing competition and offering an improved product, even if the former motive swamps the latter.

This can be seen with an example that applies both the no-economic-sense test and the Rule of Reason. Assume that a product hop (1) will cost $20 million in additional R&D; (2) will be valued by a small group of new purchasers (enticed away from other therapeutic alternatives), resulting in additional sales of $40 million; and (3) will impair generic competition at a cost to existing purchasers of $160 million. Under the Rule of Reason, this reformulation would likely be unlawful because the costs *to purchasers* far outweigh the benefits *to purchasers*. But under the no-economic-sense test, the reformulation would likely be lawful because the costs *to the manufacturer* are less than the benefits *to the manufacturer*.

Courts and agencies apply a no-economic-sense test when the type of conduct in which the manufacturer is engaged—here, designing products and bringing them to market—is *generally* the type of conduct that benefits consumers. So even if the conduct might not be welfare-enhancing when analyzed on a product-by-product basis, it may well be welfare-enhancing when viewed through a wider lens. Legal rules attempt to avoid deterring the type of conduct that generally results in welfare gains unless the evidence makes clear that the particular instance of the conduct is anticompetitive and should not be countenanced. In short, the no-economic-sense test imposes liability only when, *ex ante*, objective evidence shows that the brand's sole motive was to impair competition.[236]

236 Gilbert contends that a rule targeting "predatory innovation" could falsely condemn "[r]eally good" innovations that are costly to develop but that in the long run may "make old technologies obsolete." Gilbert, *supra* note 62, at 52. Under the test we propose, a manufacturer that projected that its design change would revolutionize the therapeutic class and thus take sales from other branded drugs in the class would easily clear our no-economic-sense threshold. In contrast, the design changes that would not pass are those

2. Support for the No-Economic-Sense Test

Many courts, most notably the Supreme Court, have endorsed and applied the no-economic-sense test.[237] In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, the Court found that the defendant "was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival."[238] And in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, the Court confirmed that the evidence in *Aspen Skiing* reflected "a willingness to forsake short-term profits to achieve an anticompetitive end."[239] Lower courts have offered similar approaches.[240]

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that the manufacturer projects will not take sales from other *branded* products in the class and thus whose only motivation is to impair competition from imminent *generic* competition. Gilbert worries about falsely condemning a breakthrough innovation that involves "a sacrifice of profit in the short run followed by elimination of rivals and higher prices (or lower consumer surplus) . . . ." *Id.* at 53. Our test accurately condemns only those design changes that make no economic sense and result in eliminating *only the generic competitor.*

Gilbert also goes awry in his treatment of the role of regulation in the antitrust analysis. He asserts that if the regulatory structure of the pharmaceutical industry generates competition concerns unique to the industry, the remedy is to change the regulations. *Id.* at 74; *see also* Carlton et al., *supra* note 182, at 11–13. We believe, and the courts have consistently held, that antitrust enforcers and courts must *take the existing regulatory structure as a given.* That means that courts must apply antitrust law unless the regulatory structure displaces it (and it is clear that in the pharmaceutical industry it does not). Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004). Courts cannot get into the business of deciding whether competition from generic drugs—especially competition that is encouraged by comprehensive federal and state law—is bad for consumers. Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978); *see also generally* Dogan & Lemley, *supra* note 67, at 709, 717 (noting that "[t]he pharmaceutical industry presents a perfect storm for regulatory gaming" and that "[i]f a pharmaceutical company designs its products for the sole purpose of dragging out a regulatory process for years and thereby forestalling competition, it has engaged in exclusionary behavior that harms consumers").

237 Many of the courts' versions apply the related profit-sacrifice test, which offers an even more aggressive test that may not credit short-term profit sacrifice even for long-term economic gain. *See supra* notes 232–33 and accompanying text.

238 472 U.S. 585, 610–11 (1985).

239 540 U.S. 398, 409 (2004).

240 *See, e.g.*, Novell, Inc. v. Microsoft Corp., 731 F.3d 1064, 1075 (10th Cir. 2013) (stating that the test is satisfied when a "monopolist's conduct [is] irrational but for its anticompetitive effect" (citing *Trinko*, 540 U.S. at 407; *Aspen*, 472 U.S. at 597; IIIB AREEDA & HOVENKAMP, *supra* note 212, at 223; Werden, *supra* note 225, at 422–25)); Covad Commc'ns Co. v. Bell Atl. Corp., 398 F.3d 666, 676 (D.C. Cir. 2005) (considering a predatory practice to be "one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor" (citing Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 222–23 (1993))); Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp., 910 F.2d 139, 148 (4th Cir. 1990) (explaining that conduct is exclusionary if a monopolist made "a short-term sacrifice in order to further its exclusive, anticompetitive objectives" (citing SmithKLINE Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1065 (3d Cir. 1978))); Ne. Tel. Co. v. AT&T, 651 F.2d 76, 94–95 (2d Cir. 1981) (finding a properly instructed jury could reasonably find that a monopolist designed the product to impede competition); Response of Carolina, Inc. v. Leasco Response, Inc., 537 F.2d 1307,

Commentators have advocated the test.[241] So have the leading antitrust treatises.[242] And the Department of Justice (DOJ) has advanced it in several important cases. For example, in *Trinko*, the agency asserted that "conduct is not exclusionary or predatory unless it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition."[243] In *United States v. Microsoft Corp.*,[244] the DOJ contended that Microsoft's protection of its operating system monopoly was exclusionary because it "would not make economic sense unless it eliminated or softened competition."[245] In *American Airlines*,[246] the agency asserted that the defendant excluded rivals by

1330 (5th Cir. 1976) (finding technological tying cases "limited to those instances where the technological factor tying the hardware to the software has been designed for the purpose of tying the products, rather than to achieve some technologically beneficial result"); ILC Peripherals Leasing Corp. v. IBM, 458 F. Supp. 423, 439 (N.D. Cal. 1978) (no liability where "there was no evidence that IBM was sacrificing present profits with the expectation of recouping its losses with subsequent price increases"); Abuse of a Dominant Position by Reckitt Benckiser Healthcare (UK) Ltd. & Reckitt Benckiser Grp., PLC, Case CE/8931/08, ¶¶ 6.34, 6.42 (Office of Fair Trading Apr. 12, 2011) (Eng.), https://assets.publishing.service.gov.uk/media/555de4bbe5274a7084000156/rb-decision.pdf (concluding that the product hop at issue would "result in a decrease in RB's profitability that would render the strategy commercially irrational in the absence of benefits derived from hindering the development of full generic competition").

241 *See, e.g.*, Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50, 54 (2012) (noting that, as applied to rival's access demands, rule "runs the least risk of reducing investment incentives while maintaining society's critical interest in preserving consumer welfare through competition"); Melamed, *supra* note 229, at 389 (offering test providing that "conduct is anticompetitive if, but only if, it makes no business sense or is unprofitable for the defendant but for the exclusion of rivals and resulting supracompetitive recoupment"); Werden, *supra* note 225, at 422–25 (articulating the "no economic sense" framework); *cf.* Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential Generic Competitors*, 67 FLA. L. REV. 977, 1023 (2015) ("[U]nder the profit-sacrifice test, conduct is anticompetitive only if the defendant has no legitimate business purpose for the conduct or it is unprofitable in the short run and makes business sense only if a rival is excluded, leaving the defendant with a supracompetitive recoupment in the long run."). For additional sources, see generally Shadowen et al., *supra* note 1, at 75–77.

242 *See generally* IIIA PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 773e, at 209–13 (2d ed. 2002) (explaining that refusal to deal is unlawful if irrational in the sense that the defendant sacrificed an opportunity to make a profitable sale only because of the adverse impact the refusal would have on rival); *see also generally* HOVENKAMP ET AL., *supra* note 125, § 12.3, at 13 ("If a design change makes no economic sense unless the exclusion of rivals is taken into account, it is reasonable to infer both that the purpose behind the design change was anticompetitive and, more importantly, that the anticompetitive effects of the design change predominated over any technological benefits.").

243 Brief for the United States and the FTC as Amici Curiae Supporting Petitioner at 15, Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004) (No. 02-682) (emphasis omitted).

244 253 F.3d 34 (D.C. Cir. 2001).

245 Brief for Appellees United States and the State Plaintiffs at 48, United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001) (Nos. 00-5212, 00-5213).

246 United States v. AMR Corp. (*American Airlines*), 335 F.3d 1109 (10th Cir. 2003).

adding "money-losing capacity" and that "distinguishing legitimate competition from unlawful predation requires a common-sense business inquiry" based on "whether the conduct would be profitable, apart from any exclusionary effects."[247] And in *United States v. Dentsply International, Inc.*,[248] the DOJ argued that "Dentsply's exclusionary policies made no economic sense but for their tendency to harm rivals, and so were predatory."[249]

* * *

Courts and commentators have offered the no-economic-sense test as a basis for antitrust liability in settings like predatory pricing and refusals to license, where the vast majority of conduct is likely to not present antitrust concern. In such a setting, satisfying the test has been treated as a necessary element of liability. Given the benefits of low prices and difficulties inherent in punishing refusals to license, courts have been hesitant before finding monopolization.

Similar considerations support applying the no-economic-sense test to product hops in prescription drug markets. Most innovation in most markets is beneficial to consumers. A lenient (to the monopolist) standard[250] is thus appropriate so as not to deter genuinely beneficial product redesigns. The no-economic-sense test also provides guidance to product developers, who can know with a high degree of precision whether the redesign will clear antitrust hurdles.

Given the unique aspects of the pharmaceutical industry, most notably the price disconnect, it is conceivable that application of the no-economic-sense test would not capture every switch that ultimately is anticompetitive. For example, and as discussed above,[251] a brand could avoid liability by engineering a switch that would allow it to enjoy modest profits but result in significant losses to consumers. Our conservative approach would allow the reformulation.

Stated differently, our no-economic-sense test (together with a rigorous two-factor threshold for product hops and two safe harbors) would lead to far more false negatives than false positives. In fact, the construction of the test ensures that there should be few if *any* false positives since the only firms subject to antitrust liability would be those that engage in behavior that literally does not make sense absent its impairment of generic competition. The test would allow false negatives to the extent firms engage in conduct that does not involve a lack of economic sense, but offers few innovations for consumers while preventing significant price reductions. We believe such a

247 Brief for Appellant at 2, 30, *American Airlines*, 335 F.3d 1109 (No. 01-3202) (public redacted version).

248 399 F.3d 181 (3d Cir. 2005).

249 Brief for the United States at 28, *Dentsply*, 339 F.3d 181 (No. 03-4097) (public redacted version).

250 *See infra* note 252 and accompanying text.

251 *See supra* subection IV.B.1.

tradeoff is justified based on the importance of innovation and business certainty.

C. No-Economic-Sense Versus Hard Switch/Soft Switch

Courts' and commentators' product-hopping analyses have veered far from justifiable economic analysis. The no-economic-sense test would lead to dramatically different analyses and results. Courts and commentators have drawn rigid distinctions between hard switches, viewed as anticompetitive because the brand removes the original drug from the market, and soft switches, viewed as not concerning because the original remains on the market. The lesson of this Section is that the no-economic-sense test is far superior to the hard switch/soft switch dichotomy for at least two reasons: (1) the fundamental conduct that impairs generic competition is the reformulation of the brand product and "cannibalization" of its sales *by any means* before the generic enters the market, and (2) the "choice" theory that underlies the dichotomy between hard and soft switches is not satisfactory.

First, it is not always, or even often, necessary for the brand to remove the original product from the market to substantially impair generic competition. What matters is whether the brand has successfully moved the prescription base from the original to the reformulated product before the generic enters the market. The essential exclusionary conduct is the reformulation of the product and cannibalization of the prescription sales base. The *particular* means used to cannibalize the sales is not critical to the anticompetitive effect. Some means may be more effective than others in moving the sales base, but it is the moving of the sales base, not the particular means, that causes the anticompetitive effect.

This can clearly be seen with an example. The brand in *TriCor* reformulated the product, cannibalized it, interfered with the generics' insurance coverage, drained the supply chain of the original product, and entirely removed it from the market.[252] The result was that the generics made only 2% of unit sales.[253] In *Walgreens*, the brand reformulated the product, cannibalized it, and interfered with the generics' insurance coverage, but did not remove the product from the market.[254] The result was that the generics made roughly 25% of unit sales.[255]

According to the well-established economics of the industry, absent the reformulations, the generics in both cases would have captured at least 85%

252 Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 416–18 (D. Del. 2006).

253 Transcript of Record at 534–35, Teva Pharm. USA, Inc. v. Abbott Labs. (*TriCor II*), 580 F. Supp. 2d 345 (D. Del. 2008) (No. 02-1512) (on file with authors).

254 First Amended Complaint & Demand for Jury Trial at 32–33, 36, Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146 (D.D.C. 2008) (No. 1:06 CV 02084) [hereinafter Walgreens Complaint].

255 *Id.* ¶¶ 104–06. Several years after entry, the generics had captured just 7.4 million of Prilosec's 29.6 million pre-reformulation unit sales. *Id.* ¶ 106.

of unit sales.[256] With a product withdrawal in *Tricor*, they gained only 2%. But even without a product withdrawal in *Walgreens*, they gained only 25%. In this example, the product withdrawal was more effective in impairing generic competition, but the cannibalization without product withdrawal also inflicted massive losses on consumers—60% of additional unit sales should have been generic rather than branded, which would have saved consumers roughly $1.9 billion annually.[257] No difference in *anticompetitive effect*—in the nature or essential magnitude of losses—can differentiate "hard" from "soft" switches.

Second, despite broad statements to the contrary,[258] no differences in the *nature of the conduct*—in preserving or denying consumer "choice"—distinguish hard from soft switches. The court in *Namenda*, for example, suggested in dicta that consumers would have had the relevant "choice" if the brand had left the original product on the market.[259] The court asserted that withdrawal of the brand product "forced" doctors to write prescriptions for the reformulated rather than the original product.[260] But at the time doctors were forced to switch to the reformulated product, no generic was available, so the forced switch obviously did not prevent consumers from choosing a generic at that time. Their prescriptions were simply moved from one brand for which there was no generic to another brand for which there was no generic. Nor were consumers deprived of "choice" (in the sense in which the *Namenda* court apparently meant it) when the generics entered. Doctors at that time were perfectly free to write prescriptions for the original product and have them filled with the generic.[261]

The *Namenda* court's intuition was right. It correctly perceived that removing the brand product "forced" doctors to write prescriptions for the reformulated brand and that doctors would not move prescriptions back to the original product after the generics entered. But the court's dictum erred in failing to realize that doctors will not move prescriptions back to the original product *regardless of* the means the brand used to switch them to the

256 FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010) (generics take 90% of unit sales at an average 85% discount from the brand price).

257 Walgreens Complaint, *supra* note 254, ¶ 64. An average 80% discount on 60% of the $4 billion in pre-reformulation annual sales of branded Prilosec, *see id.* ¶ 42, equals annual lost savings to consumers of $1.9 billion. The evidence in *Namenda* showed that the brand projected that if it did not withdraw the original product, it could have switched only 30% of patients to the reformulated product, but by withdrawing the original product, it could switch between 80% and 100%. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 654 (2d Cir. 2015). This evidence may have led the *Namenda* court to give near-dispositive significance to whether the brand withdrew the product. *See id.* at 655. As we demonstrate in detail below, the court reached the correct conclusion but used an incorrect analysis. *See infra* Section V.A.

258 *See, e.g.*, *Namenda*, 787 F.3d at 654–55; HOVENKAMP ET AL., *supra* note 125, § 15.3.

259 *Namenda*, 787 F.3d at 655.

260 *Id.* at 654.

261 *Id.* at 654–55.

reformulated product. It is the timing of the reformulation in relation to generic entry—does the reformulated product beat the generic onto the market or not?—that determines whether consumers are able to make the relevant price/quality choice.

The *Namenda* court's dichotomy based on whether the brand removed the original product has a rhetorical appeal but reflects an insupportably narrow view of consumer "choice." What deprives consumers of the ability to make a price/quality trade-off is the combination of a price-disconnected market and the brand's reformulation and cannibalization of the original product's sales *by any means*. It is the absence of prescriptions for which the generics can automatically be substituted that deprives consumers of the relevant choice. Of crucial significance, the brand eliminated those prescriptions through its reformulation and cannibalization. The withdrawal of the original product is relevant only indirectly—solely to the extent it causes a reduced prescription base that limits substitution when the generics enter. It is the reduced prescription base that directly impairs generic substitution, and that reduced base can be caused by conduct other than withdrawal of the product.

Manufacturers engage in a variety of tactics to cannibalize the product before generic entry. In *TriCor*, Abbott bought back existing supplies of its capsules from pharmacies and changed the code for the capsules in the national drug database to "obsolete," each of which encouraged doctors to switch prescriptions to the reformulated product.[262] In *Doryx*, Warner Chilcott stopped selling capsules to wholesalers; removed capsules from its website; informed wholesalers, retailers, and doctors that "Doryx capsules have been replaced by Doryx tablets"; and destroyed and bought back some of the remaining capsules.[263] In *Suboxone*, Reckitt raised the price of its original tablets in relation to the reformulated film version, disparaged tablets, and warned of purported safety concerns.[264] The point is not that these tactics involved a lack of economic sense singly and in isolation. Some of them, such as buying back stock and creating artificial price differentials, might well lack economic sense even when viewed in isolation.

But these are mere tactics. The exclusionary conduct on which the competition analysis focuses is the reformulation and cannibalization of the product; in other words, switching the prescription base. The no-economic-sense test applies to *that* conduct. Withdrawing (or not) the product, creating an artificial price gap between the branded products, buying back stock, changing drug codes, etc., are merely tactics, i.e., particular means by which the brand engages in the suspect conduct of switching the prescription base.

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262 Abbott Labs. v. Teva Pharm. USA (*TriCor*), 432 F. Supp. 2d 408, 416 (D. Del. 2006).

263 Mylan Pharm., Inc. v. Warner Chilcott PLC (*Doryx*), No. 12–3824, 2015 WL 1736957, at *3 (E.D. Pa. Apr. 16, 2015).

264 End Payor Plaintiffs' Consolidated Amended Class Action Complaint ¶¶ 42–44, *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014) (No. 2:13-md-02445).

D. Applications

Part V below applies our framework to the five product-hopping cases litigated to date. But to provide more guidance to courts, the antitrust agencies, and companies themselves, it is worth highlighting three general points.

First, a brand's introduction of a new product, standing alone, will not violate our test. Indeed, it would not even constitute a product hop. To state the obvious, brands are allowed to introduce new products. In the presence of the price disconnect, antitrust concerns arise when the brand:

(1) reformulates the product in a way that prevents generic substitution and

(2) cannibalizes its own sales by switching the prescription base from the original to the reformulated product.[265]

These are the elements that, combined, require scrutiny under the no-economic-sense test.[266] As mentioned above,[267] our focus on the switching of the prescription base distinguishes between the expansion of the base by taking away sales from other branded products or enticing new patients into the market, and the switching of the base solely to impair generic competition. The concern with the latter conduct is particularly apparent in the pharmaceutical industry, which is plagued by the price disconnect, and where the conduct may even make the original drug *less desirable*.

Second, whether the reformulated product is patented is irrelevant to the no-economic-sense test. An example makes this clear. Assume that the brand manufacturer projects that (1) without a product hop, the original product will have annual sales (before the onset of generic competition) of $500 million; (2) R&D and other costs of switching to the reformulated product will be $80 million; (3) without a product hop, generics will quickly take 90% of the unit sales, leaving the brand with annual sales of only $50 million; and (4) with a product hop, annual sales of the reformulated product are likely to be $400 million (and sales of the original product will be $0).

Given this set of facts, application of the no-economic-sense test is straightforward. The brand manufacturer could be tempted to make the product hop. Without the hop, the brand would make $50 million in annual sales. With the hop, it would make $400 million in sales, at a cost of only $80

265 As mentioned earlier, *see supra* note 3, the switching of the prescription base raises anticompetitive concern in threatening the generic-promoting goals of the Hatch-Waxman Act and state drug product substitution laws, through a switch to a reformulation for which a generic cannot be substituted. And that conduct lacks any innovation-based justifications because the brand does not build up the prescription base by competing with other brands or expanding the market, but merely leverages already-gained power solely by blocking generic entry.

266 Companies outside the pharmaceutical industry introduce new-generation products even when there is economic life remaining in the old, and the mere introduction of new products in the drug industry does not cause concern. But competition concerns arise when, in the presence of the price disconnect, the brand combines product reformulation with switching the prescription base.

267 *See supra* text preceding Section IV.A.

million. But the hop fails the no-economic-sense test because, absent the effect of impairing generic competition, it would not make economic sense. The brand would be spending $80 million to move from a product with *$500 million* in annual sales to a product with *$400 million* in annual sales. The only reason the brand gains anything is that it impairs generic competition.

This analysis holds true regardless of whether the reformulated product is patented. For example, the reformulated product might not be patented. Product hops can fail the no-economic-sense test when the reformulated product is unpatented. A product hop to an unpatented product can buy the brand two years or more of life without generics, as the generics reformulate their products and are required to start the lengthy FDA-approval process all over again. In granting approval of the brand's reformulated product, the FDA does not determine whether the reformulated product is an improvement, let alone one that is worth the cost of lost generic savings.[268] We therefore apply an objective, economic test to pinpoint product hops where it is crystal clear that the "improvement" not only is not worth the cost to consumers, but also is not even worth the cost to the manufacturer.

On the other hand, the reformulated product in the example could be protected by a patent. Our framework would apply the no-economic-sense test in a similar manner. For starters, the mere act of obtaining a patent is not even subject to the test since it does not involve encouraging doctors to write prescriptions for the reformulated, instead of original, drug. And regarding the broader course of conduct involving a patented reformulation, as demonstrated in detail in Section II.B, patent law does not require that the product be an improvement and in fact allows patents on "less effective" products.[269] That is why the PTO routinely grants patents on minor differences in existing chemical entities such as different crystalline forms of a chemical or different formulations that do not necessarily improve the product in any meaningful way.[270] Our framework thus appropriately does not depend on whether the PTO issued any applicable patents. Again, we apply an objective, economic test. Patent law provides no reason to do otherwise.[271]

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268 The FDA requires only that the product is superior to a placebo, not to existing products. *See generally* Dogan & Lemley, *supra* note 67 (explaining that the FDA "has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products"); Jeanne Whalen, *Glaxo Strategy Threatened by FDA Delays*, WALL ST. J., June 17, 2008, at B3.

269 Custom Accessories v. Jeffrey-Allan Indus., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986); *see also* Rich, *supra* note 65, at 393 (discussing "the unsound notion that to be patentable an invention must be better than the prior art").

270 *See, e.g.*, Forest Labs. v. Ivax Pharm., 501 F.3d 1263 (Fed. Cir. 2007) (upholding patent on enantiomer); Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007) (patent on particular salt); AstraZeneca AB v. Mutual Pharm., 384 F.3d 1333 (Fed. Cir. 2004) (upholding a formulation patent).

271 In addition to patent and FDA law not requiring that the new product is an improvement, the price disconnect prevents the market from determining whether the product is an improvement worth the cost of lost savings from generic competition. Anti-

Third, we emphasize again that our framework applies the no-economic-sense test to the product hop itself—to reformulating and cannibalizing the original product—not to any particular cannibalization tactics. For instance, assume that, in our example above, the brand's documents show that, given the decision to switch to a reformulated product, withdrawing the original product from the market would increase the combined sales of the original and reformulated products from $350 million to $400 million by eliminating confusion in the marketplace. Under our framework, this is not relevant because we apply the test to the product hop, not to the cannibalization tactic of withdrawing the original product. This example illustrates why: withdrawing the original product increases sales only compared to not withdrawing it. Withdrawal increases sales from $350 million to $400 million *given the decision to cannibalize*. But the no-economic-sense test applies to the product hop itself—reformulation and cannibalization—which *decreased* sales from $500 million to $400 million.

On the other hand, a product hop with a hard switch might well pass the no-economic-sense test. Change the fourth assumption in our example above: the brand manufacturer projects that sales of the reformulated product will be $600 million annually, rather than $400 million as the example originally posited. The product hop, even with a hard switch, passes the no-economic-sense test because the projected increase of $100 million in annual sales is greater than the $80 million in R&D costs.

The no-economic-sense test does not apply to individual cannibalization tactics (even to the one that some courts have thought dispositive—withdrawal of the original product from the market). Instead, it applies to the product hop itself—reformulating and cannibalizing the original product.

V. The Cases: A Second Look

Applying the new product-hopping framework to the five cases would lead to markedly different results. Two of the cases would come out the other way, and all would employ a new analysis. For starters, neither safe harbor would protect the brand in any of the five cases. Each brand implemented the reformulation within 18 months of the filing of the first ANDA, and none waited to launch the reformulated product until after generic entry. Consequently, each of the five cases would be resolved by applying the no-economic-sense test.

The big picture is that the plaintiffs alleged in each case that the brand projected that, compared to the sales it was enjoying with the original product, it would not make any additional sales by switching to the new formulation. That is, the "new and improved" version would not entice patients away from other therapeutic choices and would not allow the brand to increase the product's price. In fact, in each case, plaintiffs alleged that the switch to the new product was costly to the brand, usually in the form of *lost* unit sales

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trust law must play a role because no other element of the regulatory regime is available to analyze the conduct.

(as doctors reacted to the reformulation by switching to a different therapeutic alternative), and additional R&D, marketing, and licensing costs. The brand made these investments not to improve products and make new sales, but *solely* to impair generic competition.

It is not surprising that each reformulation fails the no-economic-sense test, at least based on plaintiffs' allegations, because plaintiffs presumably bring the most egregious cases first. A detailed review of each case illustrates how the no-economic-sense test can be applied to product reformulations in the pharmaceutical industry.

A. TriCor*: No Economic Sense*

In *TriCor*, Abbott's conduct made no economic sense, except as a generic-impairment strategy. TriCor was a successful drug, with its original capsule form garnering sales of $200 million in 2001.[272] But after the FDA approved the tablet formulation in September 2001, Abbott encouraged doctors to write prescriptions only for the reformulated product by, in part, "prevent[ing] pharmacies from filling TriCor prescriptions with a generic capsule formulation."[273] Plaintiffs alleged that Abbott did not project that it would make any additional sales or profits.[274] Yet Abbott incurred substantial costs to accomplish the switch,[275] including costs for additional R&D and marketing, new royalty payments, buying back existing supplies of capsules from pharmacies, and forgoing a new indication for the original product. Absent the impairment of generic competition, the reformulation and cannibalization made no sense since Abbott incurred all of these costs despite in-house projections showing no new sales or profits.

Abbott's tactics in the cannibalization included withdrawing the original products, changing the drug product codes to "obsolete" in national databases, and buying back supplies of the original product.[276] Considered separately, the first two of those tactics might or might not make economic sense, while the third almost certainly does not. As noted above, however, it is the reformulation and cannibalization (by whatever means) that is subject to the no-economic-sense test, not the particular cannibalization tactics. And such conduct doesn't make sense here because Abbott did not project any increased sales, but incurred substantial costs to make the hop. Abbott's reformulation and cannibalization did not make sense absent the effect on generic competition.

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272 Amended Complaint ¶ 40, Teva Pharm. USA, Inc. v. Abbott Labs. (*TriCor II*), 580 F. Supp. 2d 345 (D. Del. 2008) (No. 1:05-cv-00340).

273 Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 416 (D. Del. 2006).

274 Amended Complaint ¶ 63, *supra* note 272; Class Action Complaint ¶¶ 93–94, *TriCor II*, 580 F. Supp. 2d 345 (No. 1:05-cv-00340).

275 Amended Complaint ¶¶ 61–65, *supra* note 272.

276 *TriCor*, 432 F. Supp. 2d at 416.

B. Walgreens*: No Economic Sense*

The *Walgreens* court dismissed the plaintiffs' complaint, but the allegations reveal conduct that does not make economic sense. Prilosec produced an astounding $4 billion in revenues in 1999.[277] Despite this success, and the fact that it was AstraZeneca's most profitable drug,[278] AstraZeneca stopped its promotion and detailing of the drug after it introduced Nexium.[279]

Plaintiffs alleged that AstraZeneca marketers, lawyers, and scientists charged with "finding a solution to the impending patent expiration of the company's best-selling drug"[280] conceded that "of the dozens of potential actions that they considered to replace the anticipated lost Prilosec sales, launching and switching prescriptions to Nexium was the worst for consumers."[281] The company's then-chief executive officer purportedly admitted that "[i]f we had left it to R&D, Nexium would not have been developed," but "[t]he project was driven by the marketing people."[282]

These broad allegations were bolstered by detailed, direct averments of lack of economic sense. Plaintiffs alleged that AstraZeneca expected (accurately, as it turned out) that switching the market from Prilosec to Nexium would cause a loss of sales.[283] During the shift from Prilosec to Nexium between 2000 and 2002, AstraZeneca's unit sales increased only 11%, far less than the increase of more than 30% enjoyed by prescriptions for other drugs in the therapeutic class.[284]

This is not surprising, because, according to plaintiffs, there was "no pharmacodynamic reason why a dose of (S)-omeprazole would interact with" the body any differently than an equal dose of omeprazole.[285] Confirming this lack of innovation, the plaintiffs alleged that "[t]he FDA Medical Officer who reviewed the entire set of clinical studies . . . concluded that '*superiority* of NEXIUM over omeprazole *was not demonstrated*,'"[286] with the review finding that "[t]here are no studies which demonstrate that [Nexium] is superior to [Prilosec], clinically or even statistically."[287] Similarly, the administrator of the Federal Centers for Medicare & Medicaid Services told attendees at a physicians convention: "You should be embarrassed if you prescribe Nexium," as "Nexium is Prilosec. . . . It is the same drug. It is a mirror com-

277 Walgreen Co. v. AstraZeneca Pharm., 534 F. Supp. 2d 146, 148 (D.D.C. 2008).

278 *Consumers Sue AstraZeneca over Nexium Ad Campaign*, CONSUMER AFF. (Oct. 19, 2004), http://www.consumeraffairs.com/news04/nexium_suit.html.

279 *Walgreens*, 534 F. Supp. 2d at 149; Walgreens Complaint, *supra* note 254, ¶ 62.

280 Walgreens Complaint, *supra* note 254, ¶ 45.

281 *Id.* ¶ 47.

282 *Id.* ¶ 67.

283 *Id.* ¶ 65–66.

284 *Id.* ¶ 65.

285 *Id.* ¶ 54.

286 *Id.* ¶ 85.

287 *Id.* (second and third alterations in original).

pound," and "Nexium is a game that is being played on the people who pay for drugs."[288]

To obtain *reduced* unit sales, AstraZeneca allegedly incurred "enormous out-of-pocket expenses" of "billions of dollars" to cover

> the costs of research and development to produce and obtain FDA approval for Nexium, incremental detailing and marketing expenses, stocking allowances paid to retailers to induce them to carry Nexium, and returned goods allowances paid to wholesalers and other direct purchasers in connection with the return of unused shipments of Prilosec.[289]

This conduct made economic sense for AstraZeneca only because it impaired generic competition.

Regarding the specific tactics used to cannibalize the product, AstraZeneca allegedly "stopped making positive product claims about Prilosec and, instead, began making negative (and false) claims," in the process "attempt[ing] to weaken the competitive position" of Prilosec in favor of its reformulated Nexium.[290] In general, AstraZeneca allegedly "used distortion and misdirection in marketing, promoting, and detailing Nexium."[291]

Assuming the facts to be true (which the court should have done on a motion to dismiss), the case thus could easily have survived based on the conduct's lack of economic sense. In this industry, the price disconnect prevents consumers from making the relevant price/cost trade-off. Monopolists therefore have an increased incentive and ability to make welfare-reducing switches from original to reformulated products. The complaint in this case alleged not only that the product hop reduced consumer welfare, but also that its sole purpose was to impair generic competition.

C. Suboxone*: No Economic Sense*

The third case also could have been decided on grounds of an absence of economic sense. Plaintiffs alleged that Reckitt projected that the reformu-

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288 *Id.* ¶ 94 (alteration in original).

289 *Id.* ¶ 66.

290 *Id.* ¶ 62.

291 Walgreen Co. v. AstraZeneca Pharm., 534 F. Supp. 2d 146, 149 (D.D.C. 2008). For example, plaintiffs alleged that AstraZeneca falsely told doctors

> that "Nexium is the first [proton pump inhibitor][or PPI] to demonstrate a significant clinical advantage over other PPIs;" that Nexium has "significantly greater healing and symptom resolution rates for . . . patients;" that Nexium has a "clinical advantage" over Prilosec; that the alleged clinical advantage "is demonstrated in longer term maintenance therapy, as well as in the initial healing stage;" that "more Nexium patients are symptom free;" that Prilosec has a "higher number of treatment failures;" that "Nexium has been shown to have a clinical advantage over omeprazole;" that "Nexium has a greater clinical advantage for more severe patients;" that Nexium is "a better PPI;" and that Nexium is "expected to positively affect other associated outcomes such as patient satisfaction, [quality of life] and productivity."

Walgreens Complaint, *supra* note 254, ¶ 91 (first and fourth alterations in original).

lated sublingual film would not generate any additional sales or profits as compared to the original tablets.[292] In fact, Reckitt predicted that it would make "as much as 30% fewer" unit sales of the reformulated drug.[293] The *sole* benefit that Reckitt expected to gain from the switch from tablets to film came *exclusively* from destroying generic substitutability.[294]

Absent the effect of impairing generic competition, the switch made no economic sense because it was very costly to Reckitt. The company raised the price of its original tablets in relation to the reformulated film version[295] even though the film was more expensive to manufacture and package.[296] Plaintiffs alleged that Reckitt increased the price of tablets by 15% while leaving the price of film unchanged, which resulted in the price of tablets rising 27% above the price of film.[297]

Further revealing an absence of economic sense, plaintiffs alleged that Reckitt "incurred substantial . . . costs to develop and manufacture Suboxone film and switch prescriptions from the tablets to the film" that took the forms of

> developing the film product and gaining FDA approval to market it . . .[;] pay[ing] a substantial royalty to a third-party manufacturer that supplies the film technology to Reckitt . . .[; and] pa[ying] tens or hundreds of millions of dollars more for its sales force to get doctors to prescribe the film rather than the tablets.[298]

As a result, Reckitt's North American business "experience[d] substantially reduced profit margins and net revenue in 2011 and 2012."[299]

In fact, based on plaintiffs' allegations, Reckitt conceded an absence of economic sense in its 2010 "Annual Business Review," which stated that Reckitt's "rapid[ ] conver[sion of] Suboxone tablets to . . . sublingual film" would lead to "a short-term dilutive impact on net revenue and operating profit" but "much better protects the medium and long-term earnings stream from the Suboxone franchise in the US."[300]

Reckitt's cannibalization tactics allegedly included disparaging the tablets to physicians and "warn[ing] of false safety concerns."[301] In particular, Reckitt claimed that the absence of unit dose packaging raised the risk of pediatric exposure.[302] Plaintiffs also alleged that Reckitt "directed its sales force to tell doctors that the film was more difficult than the tablets for

292 End Payor Plaintiffs' Consolidated Amended Class Action Complaint ¶ 40, *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014) (No. 2:13-md-02445) [hereinafter Suboxone Complaint].

293 *Id.* ¶ 37.

294 *Id.* ¶ 39.

295 *Id.* ¶ 42.

296 *Id.* ¶ 38.

297 *Id.* ¶ 42.

298 *Id.* ¶ 38.

299 *Id.*

300 *Id.* ¶ 40.

301 *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

302 *Id.* at 683.

patients or others to abuse by crushing and then ingesting in order to 'get high,'" even though "Suboxone film is far easier than the tablets for patients or others to dissolve and inappropriately inject or otherwise ingest."[303] These purported safety concerns did not seem so concerning given that Reckitt waited six months after publicly announcing its removal of tablets, until the FDA approved generic entry, before actually removing them.[304]

Absent the effect on generic competition, Reckitt's reformulation and cannibalization does not make sense.

D. Doryx*: No Economic Sense*

The *Doryx* case provides another example of lack of economic sense. Based on data from the first quarter of the year, Doryx capsules were profitable, garnering $50 to $60 million in revenues in 2003 and 2004.[305] According to plaintiffs, Warner Chilcott projected that the product switches would not garner any additional sales or profits.[306]

Plaintiffs additionally alleged that Warner Chilcott incurred additional costs

> to change Doryx's dosage form from capsules to tablets, to add a score to 75 and 100 mg Doryx tablets, to change Doryx's labeling to include applesauce dosing, to introduce a 150 mg Doryx tablet, and to launch promotional campaigns to shift demand from Doryx capsules to tablets (and discontinue capsules), and then from Doryx 75 and 100 mg tablets to the 150 mg tablet (and discontinue unscored 75 and 100 mg tablets).[307]

Moreover, the reformulated version was "more costly and difficult for the defendants to manufacture than the existing capsule formulation, and even required a reformulation of the delayed-release enteric coating on the pellets of doxycycline hyclate that comprise Doryx capsules so that they could withstand the compression force required to manufacture a tablet."[308] Given that Warner Chilcott did not expect any of these added costs to result in any increased sales or profits, these costs made sense only as investments in impairing competition.

Regarding the tactics of cannibalization, Warner Chilcott stopped selling capsules to wholesalers and removed capsules from the website.[309] It

303 Suboxone Complaint, *supra* note 292, ¶ 44.

304 *See id.* ¶ 45.

305 *See Galen Holdings PLC Results for the First Quarter Ended 31 December 2003*, PR NEWSWIRE (Feb. 10, 2004), http://www.prnewswire.com/news-releases/galen-holdings-plc-results-for-the-first-quarter-ended-31-december-2003-58942652.html (identifying $13.8 million revenues in first quarter of 2003 and $15.7 million in the first quarter of 2004).

306 *See* Direct Purchaser Class Plaintiffs' Consolidated Amended Class Action Complaint ¶ 80, Mylan Pharm. Inc. v. Warner Chilcott PLC, 2013 WL 5692880 (E.D. Pa. June 12, 2013) (No. 2:12-cv-03824).

307 *Id.*

308 *Id.* ¶ 57.

309 Mylan Pharm. Inc. v. Warner Chilcott PLC (*Doryx*), 2016 WL 5403626, at *3 (3d Cir. Sept. 28, 2016).

ensured that retailers would "auto-reference" the tablet whenever doctors filled prescriptions.[310] And it further reduced demand for the product by informing wholesalers, retailers, and doctors that "Doryx Capsules have been replaced by Doryx Tablets,"[311] and destroying and buying back some of the remaining capsules.[312] Whether or not these specific tactics made economic sense when viewed individually and in isolation, the reformulation and cannibalization, through whatever tactics they were achieved, reveal a lack of economic sense.

E. Namenda*: No Economic Sense*

The *Namenda* case provides the final example of a manufacturer's conduct that made no economic sense (absent the effect of impairing competition). Namenda was one of Forest's best-selling drugs, generating roughly $1.5 billion in annual sales in 2012 and 2013.[313] Plaintiffs pointed in the complaint to Forest's documents, which revealed that its product-hopping strategy would produce a significant reduction in profits resulting from "patients who, in response to the lack of availability of Namenda IR, decide not to switch to Namenda XR."[314] The documents treated this loss as a "disruption," and projections estimated "as much as '20% franchise disruption' if [Forest] withdraws Namenda IR from the market prior to generic entry."[315] Providing a hornbook application of the no-economic-sense test, one Forest presentation included sales projections that showed that under any potential scenario, it would "lose tens if not hundreds of millions of dollars in the short term if it withdraws Namenda IR from the market."[316]

The *Namenda* court noted that "in deciding to take [the original product] off the market, Defendants were willing to give up profits they would have made selling IR—Forest's best-selling drug,"[317] revealing a "willingness to forsake short-term profits to achieve an anticompetitive end" and demonstrating anticompetitive behavior.[318] But the court appears to have applied such a test only to the discrete conduct of withdrawing the old product from the market, rather than, as we urge, to the manufacturer's overall conduct of reformulating the product and cannibalizing its sales (by whatever means).

Forest's cannibalization tactics included a cessation of active marketing of IR when it brought the reformulated version to the market.[319] In addition, Forest announced that it would discontinue Namenda and published

310 *Id.*
311 *Id.*
312 *Id.*
313 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 647 (2d Cir. 2015).
314 Complaint ¶ 101, *Namenda*, 787 F.3d 638 (No. 14-cv-7473).
315 *Id.*
316 *Id.*
317 *Namenda*, 787 F.3d at 659.
318 *Id.* (quoting *In re* Adderall XR Antitrust Litig., 754 F.3d 128, 135 (2d Cir. 2014)).
319 *Id.* at 648.

letters on its website urging healthcare providers and caregivers to "discuss switching to Namenda XR" with their patients.[320] Finally, Forest sought to convert the largest customer base of Medicare patients to the reformulated version "by sending a letter to the Centers for Medicare & Medicaid Services requesting that the agency remove IR from the formulary list, so that Medicare health plans would not cover it."[321] Absent the effect on generic competition, Forrest's product hop did not make economic sense.

* * *

In short, application of the no-economic-sense test would lead to a different outcome in two of the cases and a different analysis in all of them. Such a framework conservatively recommends liability only when behavior literally makes no sense other than through its stifling of generic competition. At the same time, it focuses on the low-hanging fruit of straightforward economic analysis rather than getting bogged down in the tempting, but far-from-compelling, tangent of hard versus soft switches. The no-economic-sense test is widely recognized as favorable to defendants, but applying it leads to more rigorous outcomes in two of five cases and different reasoning in all five. This dissonance shows just how far the caselaw has veered from justifiable economic analysis.

Conclusion

Judicial and scholarly treatment of product hopping has varied. It has paid various levels of attention to the regulatory framework. And it has overemphasized the distinction between hard and soft switches, and offered a simplistic and unsustainable analysis of "coercion" and "choice."

This Article introduces a more justifiable framework for the antitrust analysis of product hopping that is based on the economics of the pharmaceutical industry. Most generally, it offers three ways for a brand manufacturer to avoid antitrust liability. First, it defines product hopping so that scrutiny is limited to reformulations involving the switching of the prescription base. This articulation limits antitrust scrutiny to hops designed to impair generic competition rather than reformulations designed to compete with other brands or grow the market.

Second, it introduces two safe harbors that ensure that the vast majority of reformulations are not subject to antitrust scrutiny, providing brand firms with more certainty and predictability than they receive under existing caselaw. Third, it provides a no-economic-sense test—a simple framework that avoids a complex, open-ended analysis and that minimizes false positives. Imposing antitrust liability on behavior that does not make economic sense other than through its impairment of generic competition provides a justifiable framework.

320 *Id.*
321 *Id.*

Under the no-economic-sense framework, merely introducing new products would pass the test—indeed, it would not even constitute a product hop. But when the brand combines a reformulation that destroys generic substitutability with cannibalizing the original product's sales, the framework would not treat as dispositive the distinction between hard and soft switches. Removing the original product from the market is just one of many cannibalization tactics. Our framework applies the no-economic-sense test not to specific cannibalization tactics, but to the product hop itself—reformulating the product and cannibalizing its sales (by whatever means). A soft switch might fail the no-economic-sense test, and a hard switch might pass it. As in every application of the no-economic-sense test in other industries and circumstances, each case will depend on the brand's *ex ante* projections of sales and costs.

Product hopping presents some of the most nuanced issues in antitrust and IP law. The consequences for consumers and the industry are significant, and courts' analyses of these issues have varied. This Article offers a conservative framework rooted in the economics of the pharmaceutical industry that courts, government enforcers, plaintiffs, and manufacturers can use to distinguish between investments in innovation and investments in impairing generic competition.