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Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy

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Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy[†]

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The issue of high drug prices has recently exploded into public consciousness. And while many potential explanations have been offered, one has avoided scrutiny. Why has the growth in generic drugs not resulted in lower drug prices?

In this Article, we explore a phenomenon we call "playing both sides": companies that participate in pharmaceutical markets as both brand owners and generics. We hypothesize that companies that earn a significant amount of their revenue from patented drugs may have less incentive to aggressively pursue a generic agenda, since patented drugs generate far more revenue than generic drugs do.

To investigate this phenomenon, we built a comprehensive database of all major pharmaceutical companies, evaluating where their revenue comes from, how that has changed over time, and how it relates to their behavior in court. Despite broad industry trends toward specialization, about one third of the firms we study have opted for a mixed business model over time. Those firms behave differently than pure generic firms. Our data shows that when companies with significant generic sales play both sides, they behave differently than firms with a purer generic revenue stream. Dollar for dollar, the pure generic firms in our study challenged more patents as invalid or not infringed than the mixed firms. Further, "mixed generic" companies with growing brand sales (or a growing share of their revenue from brand sales) are more likely to settle the patent challenges they bring; companies with growing generic share are more likely to take those cases to judgment. And when they do go to judgment, patent challengers with a greater generic share are more likely to win those challenges.

In short, we find evidence to support the hypothesis that generic companies that make more of their revenue from patented drugs are less likely to pursue challenges to judgment and less likely to win when they do. Playing both sides may reduce the incentive of generic challengers to fight as hard as possible to win the case before them. That may be especially true of the sorts of challenges that affect not just the patent in the instant case but might change legal doctrines that may ultimately hurt the generic challenger's brand business.

Our Article's findings suggest a more nuanced antitrust analysis of mergers involving generic companies and patent settlements in which generics delay entering the market. In challenging more patents, settling fewer cases by agreeing to delay entry, and winning more of the cases they do bring, pure generic companies promise to unleash the generic competition that they were intended to. In the wide-ranging effort to lower drug prices, we must pay attention not only to whether a drug is patented but also to who is, or is not, challenging that patent and why.

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INTRODUCTION

In 2016, public outrage over high drug prices coalesced around the EpiPen, an epinephrine injector that is a critical, lifesaving technology for millions of people with serious allergies. The EpiPen had been around for decades, the basic technology was unpatented, and the epinephrine in the syringe cost no more than a dollar.[1] Nonetheless, Mylan Pharmaceuticals, which bought the rights to the EpiPen in 2007, patented a change in how the injector worked and jacked up the price for the EpiPen from $50 to over $600.[2] Insurance companies stopped reimbursing it, outraged patients and parents howled, the press wrote multiple stories about it, and Mylan's CEO was hauled before Congress and castigated for an act of outrageous profiteering.[3]

The EpiPen story may seem like nothing new. Other companies have radically increased drug prices in recent years, and some have been publicly shamed for it, including the infamous "Pharma Bro" Martin Shkreli.[4] But one thing was different about the EpiPen story: Mylan is a well-known *generic* pharmaceutical company, not a traditional branded (that is, patent-owning) firm.[5] In fact, Mylan's CEO was the head of the generic pharmaceutical trade association when she was called to account by Congress.[6]

Mylan is a generic pharmaceutical company offering low-price alternatives to patented drugs. But it is also a patent owner raising prices and excluding potential generic competitors. And it is not alone.

In this Article, we explore a phenomenon we call "playing both sides": companies that participate in pharmaceutical markets as owners of both brand and generic drugs.[7] We hypothesize that companies that earn a significant

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1. Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, BLOOMBERG BUSINESSWEEK (Sept. 23, 2015, 7:00 AM), https://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business.

2. *See* Anna Edney & Robert Langreth, *Mylan Blasted for Raising EpiPen Prices to Get "Filthy Rich,"* BLOOMBERG LAW (Sept. 21, 2016, 6:18 PM), http://www.bloomberg.com/news/articles/2016-09-21/mylan-criticized-on-profits-and-pay-at-house-oversight-hearing.

3. *See id.*

4. Andrew Pollack, *Drug Goes From $13.50 a Tablet to $750, Overnight*, N.Y. TIMES (Sept. 20, 2015), https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html (explaining how Shkreli increased the price of a drug that the FDA had approved in 1953 that treats a life threatening infection to "try[] to stay in business"). Shkreli is the drug executive famous for raising prices on his drug and going to jail for securities fraud. Grace Donnelly, *Here's Martin Shkreli's Jail Sentence*, FORTUNE (Mar. 9, 2018), https://fortune.com/2018/03/09/martin-shkreli-jail-sentence/. He is also famous (in some quarters) for buying the only copy of a Wu Tang Clan album for $2 million. Lake Schatz, *RZA Tried to Buy Back Once Upon a Time in Shaolin from Martin Shkreli*, CONSEQUENCE OF SOUND (Mar. 30, 2018, 1:03 PM), https://consequenceofsound.net/2018/03/rza-tried-to-buy-back-once-upon-a-time-in-shaolin-from-martin-shkreli/.

5. *Generic Products*, MYLAN, http://www.mylan.com/en/products/our-medicines/generic-products (last visited Jan. 24, 2020).

6. Paul J. Gough, *Mylan CEO Heather Bresch To Lead Pharma Trade Group*, BIZWOMEN (Feb. 23, 2016, 1:27 PM), https://www.bizjournals.com/bizwomen/news/latest-news/2016/02/mylan-ceo-heather-bresch-to-leadgeneric-pharma.html.

7. By "generics," we refer to "medication[s] created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics." *Generic*

amount of their revenue from patented brand drugs may have less incentive to aggressively pursue a generic agenda, since patented drugs generate far more revenue for firms than generic drugs do.

To investigate this phenomenon, we built a comprehensive database of all major pharmaceutical companies, evaluating where their revenue comes from, how that has changed over time, and how it relates to their behavior in court. We study in detail the behavior of firms with a significant generic percentage. We find that the phenomenon of playing both sides has been real and common, but is actually in decline in much of the industry. Large pharmaceutical companies are increasingly separating into one group that relies almost entirely on branded drugs, a second group that produces mostly generic drugs, and a third group that relies on a more diversified "mixed" model.

We find that the drug business is quite lucrative. Despite periodic claims that brand companies face a "patent cliff" and are on the verge of losing significant revenue, we find that in the past two decades brand revenues have risen enormously. Among the 36 major drug companies we study—which comprise about 80% of the U.S. industry—branded drug revenue between 1992 and 2016 rose from $35.2 billion to $292.2 billion, an increase of more than *730%*. At the same time, the increase in brand and branded generic sales has not come at the expense of generic firms. To the contrary, generic revenues are rising even more quickly. During the same period, generic sales increased from $2.27 billion to $47.1 billion, roughly *2000%*.

In such a rising market for all, it appears that most large firms have gravitated towards the business in which they believe they do best.[8] They specialize either in bringing lucrative new branded drugs to the market through research and development (R&D) or forgoing much of their own R&D and taking advantage of a generics market exploding at an even higher rate, albeit with lower total revenue.

Despite broad industry trends toward specialization, about one third of the 15 firms we study in depth have opted for a mixed business model over time.[9]

Drug Facts, FDA, https://www.fda.gov/drugs/generic-drugs/generic-drug-facts (last updated June 1, 2018). Our study covers generics as well as brand drugs, both in the "small molecule" pharmaceutical context. We do not specifically address biologic and follow-on biosimilar products, which face a different regulatory environment, one that is newer and far less established. Although we do not study these large-molecule products, we note that the high cost of development has resulted in biosimilars acting more like brands than generics and companies producing both biologics and biosimilars, each of which supports our "both sides" hypothesis. *See Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494, 504 (E.D. Pa. 2018) (discussing how Pfizer sued Johnson & Johnson (J&J) for exclusive contracts and rebates that had the effect of "creat[ing] anticompetitive consequences by foreclosing competition"); Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 9 (2018) (explaining that, on average, generic drugs cost $2 million to develop while biosimilars cost $200 million); *Worldwide Biologics Leader*, AMGEN BIOSIMILARS, https://www.amgenbiosimilars.com/heritage/worldwide-biologics-leader/ (last visited Jan. 24, 2020) (claiming that Amgen consists of "biologics experts—and now biosimilars experts").

8. This is consistent with a broader industry trend toward specialization. *See* Ajay Gautam & Xiaogang Pan, *The Changing Model of Big Pharma: Impact of Key Trends*, 21 DRUG DISCOVERY TODAY 379, 380 (2015).

9. They are Allergan, Inc., Endo Pharmaceutical Inc., Fresenius Kabi USA, Novartis-Sandoz, Pfizer, and Teva Pharmaceuticals USA.

And those firms behave differently than pure generic firms. Our data show that when companies with significant generic sales play both sides, they behave differently than firms with a purer generic revenue stream. In particular, accounting for firm revenue, the pure generic firms in our study challenge more patents as invalid or not infringed than the mixed firms. Further, "mixed generic" companies with growing brand sales (or a growing share of their revenue from brand sales) are more likely to settle the patent challenges they bring. By contrast, companies with growing generic share are less likely to settle and more likely to take those cases to judgment. And when they do go to judgment, patent challengers with a greater generic share are more likely to win those challenges while companies with higher brand sales are less likely to win.

In short, we find evidence to support the hypothesis that generic companies that make more of their sales from patented drugs are less likely to pursue challenges to judgment and less likely to win when they do. Playing both sides may reduce the incentive of generic challengers to fight as hard as possible to win the case before them. That may be especially true for the sorts of challenges that affect not just the patent in the instant case but might change legal doctrines that could ultimately hurt the generic challenger's brand business.

Our findings have implications for how the law should respond to market structure. One of the most critical antitrust issues in the past generation involves settlements by which brand firms pay generics to delay entering the market. How "pure" a generic company is could affect how the settlement is evaluated. And our findings could have an even more direct effect on how to assess mergers in the pharmaceutical industry, suggesting the application of heightened scrutiny and more robust remedies for transactions that could result in pure generics losing their incentive to challenge and litigate patents that might wrongfully be blocking competition. Our findings on true generic competition could play a role, until now unappreciated, in lowering drug prices. And they have broader implications for the adversary system. While playing both sides may help parties come to terms in a settlement or business deal, robust and opposing interests seem to produce different (and in our view better) results in court.

In Part I, we explain the role of generic competition in the pharmaceutical market. In Part II, we describe our data and methodology. In Part III, we present our results on the state of branded and generic sales and how a company's generic share affects its behavior. In Part IV, we consider some implications of our findings for antitrust policy.

I. NOT YOUR PARENTS' GENERICS

Brand and generic drugs each play a vital role in the pharmaceutical industry. A brand-name drug often results from lengthy research and development and is protected by patents and U.S. Food and Drug Administration

(FDA) exclusivity periods.[10] Those patents are quite valuable. Indeed, Jim Bessen and Mike Meurer find that most of the value of patents worldwide is concentrated in the pharmaceutical industry (and indeed within a few companies in that industry).[11] These periods of protection, however, are not intended to last forever. Generic competition is crucial in lowering prices and making drugs more affordable.

A. THE HATCH-WAXMAN ACT AND GENERIC DRUGS[12]

Widespread generic entry can be traced to the Hatch-Waxman Act, which Congress enacted in 1984 to foster innovation and competition. Generic drugs have the same active ingredients as brand drugs. At the time of the Act's passage, however, generic firms needed to undertake lengthy, expensive trials to demonstrate safety and effectiveness. Approval by the FDA took years, and because the required tests constituted infringement, generics could not even begin the process during the patent term. At the time Congress enacted the Act, there was no generic on the market for 150 brand-name drugs whose patents had already expired.[13]

The Act's drafters lamented "the practical extension of the [patentee's] monopoly position . . . beyond the expiration of the patent."[14] As a result, they sought to make available "low-cost, generic drugs for millions of Americans."[15] Generic competition would save the federal and state governments millions of dollars each year. And competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed."[16]

Congress employed several mechanisms in the Act to promote generic competition. First, it allowed generic firms to experiment on drugs during their patent terms in order to generate data needed for regulatory approval. Second, it created a new process for generics to obtain FDA approval, recognizing a new type of drug application, called an Abbreviated New Drug Application (ANDA). ANDAs allow generics to rely on brand firms' safety and efficacy studies, dispensing with the need for generics to conduct their own lengthy and expensive studies. Finally, to provide generics with an incentive to bring ANDA challenges, the Act granted 180 days of marketing exclusivity to the first generic to challenge the validity of a brand firm's patent or claim that the generic did

10. FDA exclusivities include the "30-month stay" a brand can obtain in litigation, 21 U.S.C. § 355(j)(5)(B)(iii) (2018); the 4- or 5-year period for companies offering drugs with new active ingredients, *id.* § 355(j)(5)(F)(ii); and the 3-year period for new clinical investigations, *id*. § 355(c)(3)(E)(iii).

11. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 109 (2008) (finding that 2/3 of the value of worldwide patents is provided in the chemical and pharmaceutical industries and that 1/2 is captured by a small number of large drug companies).

12. Discussion in the next two Subparts is adapted from Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 11–12 (2014) and Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and at-Last Denied*, 66 AM. U. L. REV. 305, 311–12 (2016).

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

14. H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688.

15. 130 CONG. REC. 24,427 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman).

16. *Id.*

not infringe the patent. This period is valuable to generic challengers, which make more than half of their money during that time.[17]

B. GENERIC COMPETITION UNDER HATCH-WAXMAN

The Hatch-Waxman Act was successful in increasing generic entry, with generic penetration rising from 19% of all prescriptions in 1984[18] to 89% in 2016.[19] For the most popular drugs with expired patents, the share facing generic competition burgeoned from 35% in 1983 to almost 100% today.[20]

Generic entry is a pivotal event in a drug's lifecycle. When generics enter the market, prices can fall dramatically. The first generic entrant typically prices its product 5% to 25% lower than the brand drug.[21] The presence of a second generic lowers the price to approximately half the brand price.[22] In markets in which six or more generics enter, the price falls to a quarter of the brand price.[23] One survey showed that patients could save 52% in the daily costs of their medications by purchasing generic drugs.[24] In fact, even though generics make up 89% of prescriptions, they amount to only 26% of drug costs.[25]

In addition, generic drugs quickly take sales from brand drugs. Once a generic enters the market, the brand product on average loses 90% of its market share within the first year.[26] Generic entry is most likely for drugs with large

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17. Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who's on First*, 25 BIOTECH. L. REP. 525, 525–26 (2006). Generic companies can forfeit that exclusivity in certain circumstances. *See* 21 U.S.C. § 355(j)(5)(D)(i) (2018); SHASHANK UPADHYE, GENERIC PHARMACEUTICAL PATENT AND FDA LAW § 29:1 (2018–2019 ed.).

18. *See Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration: Hearing Before the Subcomm. on Health of the Health Comm. on Energy and Commerce*, 107th Cong. 137 (2002) (statement of Gregory J. Glover, Pharmaceutical Research and Manufacturers of America).

19. ASS'N FOR ACCESSIBLE MEDS., GENERIC DRUG ACCESS & SAVINGS IN THE U.S. 16 (2017), https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.

20. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 37 (1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

21. *Id.* at xiii; *Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Aboutfda/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last updated Nov. 20, 2017).

22. *Generic Competition and Drug Prices*, *supra* note 21.

23. *Id.*

24. *Savings from Generic Drugs Purchased at Retail Pharmacies*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/resources-you-drugs/savings-generic-drugs-purchased-retail-pharmacies (last updated May 6, 2016).

25. ASS'N FOR ACCESSIBLE MEDS., *supra* note 19, at 16.

26. FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

markets, particularly those with blockbuster products, but occurs with respect to drugs in markets of many sizes.[27]

The generic industry of the 1980s and 1990s was far different than it is now. Today, the industry consists not only of companies that obtain most of their revenue from generic drugs, but also those that sell primarily *brand-name* drugs and some generics, as well as those pursuing a mixed model selling both brands and generics. Further, many brand-name companies have launched their own "authorized generic" versions of their own drugs.[28]

It is reasonable to question whether these hybrid companies serve the function that generics were designed to, challenging patents and introducing real competition into the market. We might worry that generic companies that make most of their money from their brand business will behave differently. They might, for instance, be less aggressive in challenging drug patents, particularly avoiding challenges that might benefit them in a particular case but risk bringing down a host of patents, including ones they own. For instance, companies that obtain follow-on "enantiomer" patents that cover standard modifications to drugs may be reluctant to challenge the whole idea of enantiomer patents.[29] An example of such behavior is provided by biotechnology companies that litigated gene patents for decades without challenging the general concept of gene patents. The reason was clear: even a company that could have benefitted as a defendant in a particular case was not interested in taking down the whole edifice of DNA patents. It was not until industry outsiders (doctors and patients) brought a challenge that the courts ever confronted the question of whether human DNA was patentable at all.[30]

II. DATA AND METHODOLOGY

We set out to test whether hybrid firms in fact behave differently. To do that, we first determine which firms are hybrid firms and how they are changing. Thus, we begin by investigating trends in pharmaceutical sales, broken down by generic and brand sales. We do so utilizing quarterly firm-level pharmaceutical sales data we obtained from IQVIA, formerly QuintilesIMS.[31] We obtained data

27. *E.g.*, Fiona M. Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the U.S. Pharmaceutical Industry*, 18 INT'L J. INDUS. ORG. 1085, 1102 (2000); Atanu Saha et al., *Generic Competition in the U.S. Pharmaceutical Industry*, 13 INT'L J. ECON. BUSINESS 15, 27 (2006).

28. *E.g.*, FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 11 (2011) [hereinafter FTC, AUTHORIZED GENERIC DRUGS].

29. For a discussion of the problems with enantiomer patents, see Mark A. Lemley, *Expecting the Unexpected*, 92 NOTRE DAME L. REV. 1369 (2017).

30. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

31. IQVIA, https://www.iqvia.com (last visited Jan. 24, 2020). IQVIA refers to the sales data it provided as National Sales Perspectives data. During March 2019 email and telephone conversations with us, IQVIA's representative explained: "National Sales Perspectives data are sourced from over 90 percent of wholesaler, distributor or manufacturer direct sales to the purchasing outlet (pharmacy, hospital, clinic, etc.) and projected to a national total. Dollar values are calculated based on the average invoice price on the ship-to transaction. Because of where and how the data is collected, the average invoice price will vary based on the

for 36 firms that include the top 25 in terms of total drug sales in the first quarter of 2017 and the top 18 in terms of generic sales in the same quarter.[32] For each of the firms in our analysis, IQVIA provided total quarterly sales from the first quarter of 1992 through the second quarter of 2017. IQVIA also provided quarterly brand sales, generic sales, and branded generics sales for the same period.

IQVIA defines "brand" drugs as those sold by the molecule originator and patent holder, traded under a brand name.[33] This designation remains within their sales database after loss of exclusivity. IQVIA defines "generic" pharmaceuticals as products traded under the molecule name and sold by a firm other than the molecule originator.[34] Finally, it defines "branded generic" products as those not sold by the molecule originator but sold, not under the generic signifier, but under a different brand name created by the generic manufacturer.[35]

IQVIA's sales database is forward-looking in that sales in earlier years by firms acquired by existing firms are assigned to the existing firm. As an example, because Endo Pharmaceutical acquired Par Pharmaceutical in 2015, Par's sales are added to Endo's sales. While aggregation of acquired firms' sales into existing firms' sales limits some uses of IQVIA's data, it is valuable for our purposes because it reveals a complete picture of sales by families of companies over time and allows us to investigate the impact of mergers on different types of drug sales.

From the quarterly data provided, we generate two measures of generic share each quarter for each firm. The first is pure generic share, which we define as the fraction of total sales attributable to pure generic sales and excluding branded generic sales. Second, we employ "total generic" to indicate the fraction of total sales attributable to pure generic or branded generic sales—essentially anything but brand sales. Given that branded generics do not include products sold by the molecule originator, we consider total generic a more complete measure of generic sales and utilize it for most of our analysis.

In the second half of our analysis, we take a closer look at the impact of generic share and changes in generic share over time on how aggressive firms are in seeking to enter a market with existing brand products. For our investigation of the impact of generic share on ANDA lawsuits where the firm

individual transaction and contractual relationship with the buyer. Post-shipment financial adjustments, such as rebates, are not reflected in the average invoice price."

32. IQVIA's definitions of "brand," "generic," and "branded generic" drugs were explained to us via March 2019 email and telephone conversations with the IQVIA representative who provided us with the sales data. Six of the firms we study are on both lists: Allergan, Inc., Endo Pharmaceutical Inc., Mylan Laboratories, Inc., Novartis-Sandoz, Pfizer, and Teva Pharmaceuticals USA. We did not obtain sufficient data from IQVIA on Sun Pharmaceuticals sales to include it in our analysis. Sun is not among the top 25 in terms of total sales but was 14th among the top 18 generics firms in 2017.

33. *Id.*

34. *Id.*

35. "Branded generic" products cover both molecules recently protected by patents and those that have long been under common use.

is an alleged infringer, we collected litigation data from Lex Machina, a database that collects all filings in every patent case filed since 2000.[36] Lex Machina also identifies and categorizes ANDA "Paragraph IV" litigation, which occurs when a brand company sues a generic that has certified that the brand's patent is either invalid or not infringed.[37] And it reports the outcome of each case, including whether it settled and, if it went to judgment, who won and on what grounds.

In collecting litigation data for the 36 firms in our study, we discovered that only 15 of the firms were alleged infringers in more than a few ANDA lawsuits. Accordingly, we limit the second half of the analysis to these firms that have regularly filed ANDAs. These firms include all but 2 of the firms in the top 18 in generic sales in 2017.[38]

Within IQVIA's sales database over time, acquired companies are dropped from the list of firms and those pre-acquisition sales are added to those of the acquiring firm. Accordingly, for each of the 15 litigious firms we study, we determined all of the drug companies acquired between 2000 and the present.[39] We then confirmed that IQVIA imputed these acquired entities' sales to one of the 15 firms by reference to a comprehensive list of firms currently present in their database. Finally, we created quarterly litigation time series for each of the 15 IQVIA firms that combine the lawsuits of acquired drug companies with those of the surviving acquirer. The names of the acquired firms added to each of the 15 IQVIA firms we study are listed in Appendix Table A.2.

III. ANALYSIS AND RESULTS

A. INCREASED BRAND AND GENERIC SALES

Both branded and generic firms often lament their fates in the market, with brand owners complaining about a "patent cliff."[40] With the exception of the last two years in our study, however, we find little supporting evidence. To the contrary, over the past 25 years, the pharmaceutical industry as a whole (both branded and generic) has been doing quite well. Between 1992 and 2016,[41] as Figure 1 shows, the 36 firms we studied witnessed a *nine-fold* increase in total drug sales. In 1992, they sold $10.3 billion per quarter; 25 years later, that figure

36. LEX MACHINA, https://lexmachina.com/patent-litigation/ (last visited Jan. 24, 2020).

37. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2018).

38. While we possess sales data for Mallinckrodt and Prasco Labs, these two firms were alleged infringers in only 3 and 0 ANDA lawsuits, respectively, during the last ten years. Prasco only makes authorized generics. We were unable to obtain sales data for one—and only one—of the top 18 firms in terms of generic sales, Sun Pharmaceuticals.

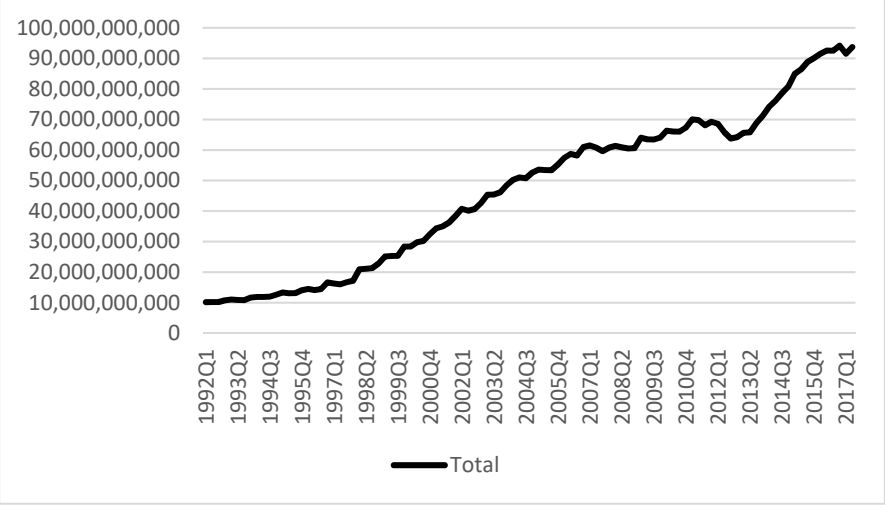
39. 2000 is the earliest year of patent litigation available in Lex Machina.

40. *See* ANNA SON, IBIS*WORLD*, M&A FOCUS: BIOTECHNOLOGY 1 (2013), https://perma.cc/8GNB-P6K7; *see also* PRICEWATERHOUSECOOPERS, FROM VISION TO DECISION: PHARMA 2020, at 6 (2012) (estimating that generics will eliminate $148 billion in pharmaceutical profits from 2012 to 2018); Mari Serebrov, *PharmaFocus: Facing Patent Cliff, Pharma Clings to Blockbusters*, BIOWORLD, http://www.bioworld.com/content/pharmafocus-facing-patent-cliff-pharma-clings-blockbusters (last visited Jan. 24, 2020).

41. 2016 is the last full year of data we possess, but we also utilize data for the first two quarters of 2017.

had skyrocketed to $92.7 billion per quarter. By contrast, from 1992 to 2016, U.S. Gross Domestic Product (GDP) only tripled (from $6.5 to $18.7 trillion) and inflation grew only 82%.[42] In other words, total drug sales grew three times as fast as the entire economy. Nor is this an artifact of our focus on only the top firms as of 2016. IQVIA reported to us its estimates of $50 billion in total U.S. pharmaceutical sales in 1992 and $445 billion in 2016.[43] As a result, our 36 firms, including all companies they acquired over the period of our study, accounted for a very large and surprisingly stable share of the American pharmaceuticals market—more than 82% in 1992, and 83% in 2016. Thus, during a period of significant industry consolidation, pharmaceutical sales have increased rapidly.

FIGURE 1. TOTAL QUARTERLY PHARMACEUTICAL SALES – ALL 36 FIRMS



*NOTE: "TOTAL" COMBINED QUARTERLY SALES FOR THE 36 FIRMS LISTED IN APPENDIX TABLE A.1. FROM IQVIA NATIONAL SALES PERSPECTIVES.

42. *National Income and Product Accounts: Table 1.1.5. Gross Domestic Product*, BUREAU OF ECON. ANALYSIS, https://apps.bea.gov/iTable/iTable.cfm?reqid=19&step=3&isuri=1&select_all_years=1&nipa_table_list=5&series=a&first_year=2016&scale=-6&last_year=2018&categories=survey&thetable=x (last updated Dec. 20, 2019). In recent years, overall health care costs have increased even faster than the cost of prescription drugs—4.4% versus 3.3% from 2017 to 2018. Erik Sherman, *U.S. Health Care Costs Skyrocketed to $3.65 Trillion in 2018*, FORTUNE (Feb. 21, 2019), http://fortune.com/2019/02/21/us-health-care-costs-2/?fbclid=IwAR3QHA6u-FO3ph1TTkh5T_6YdL5IQNgsPPT46jyVq87Hl5GMkgpa96GfXVY.

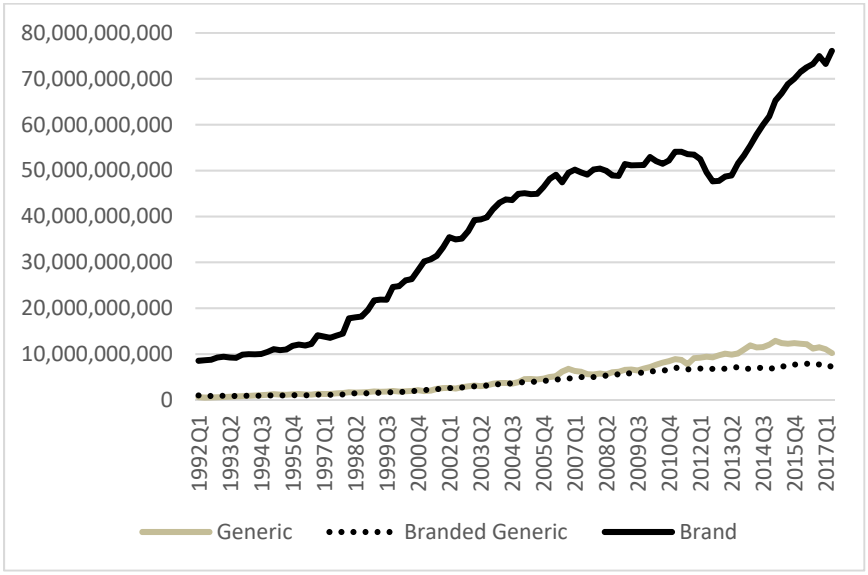
43. *See supra* notes 31–32. For a public explanation of the 2016 total, see *U.S. Drug 2016 Sales, at $450 Billion, Moderate to Single-Digit Growth*, PHARM. COMMERCE (last updated May 16, 2017), https://pharmaceuticalcommerce.com/latest-news/us-drug-2016-sales-450-billion-moderate-single-digit-growth/.

The data in Figure 1 do not distinguish between branded and generic revenue. It is possible that branded sales are driving the increase. It is also possible that all or most of the major firms—including many generic firms—are thriving but doing so by continuously relying on brand sales to subsidize their generic products. In fact, however, we see strong evidence against the story of a struggling pharmaceutical business in Figure 2, which charts quarterly trends in sales broken into the three components of generic, branded generic, and brand sales.

Figure 2 reveals that the huge increase in drug sales among the 36 firms over the 25-year period of our study is not solely attributable to either brand or generic sales.[44] In fact, from 1992 through 2016, generic sales increased by a greater percentage than either brand sales or branded generic sales. Both branded sales and branded generic sales increased approximately 830% from 1992 to 2016, with branded sales rising from $35.2 to $292.2 billion and branded generic sales increasing from $3.8 to $31.4 billion. The firms in our study made a total of $2.27 billion in pure generic sales in 1992 and a total of $47.1 billion in 2016—more than a *twenty-fold* increase! Combined with the fact that generic drugs are generally cheaper, implying a higher volume per dollar of sales, these trends seem to reveal a rapidly growing generic drug market alongside a thriving brand market.

44. The reduction of brand revenues in 2011 and 2012 could be explained by the "patent cliff" that saw the expiration of patents on (among others) Pfizer's cholesterol treatment Lipitor, Sanofi-Aventis's blood thinners Lovenox and Plavix, Eli Lilly's antipsychotic Zyprexa, and Takeda's diabetes-treating Actos. *E.g.*, Elisabeth Fischer, *The Patent Cliff: Rise of the Generics*, PHARMA. TECH. (Oct. 4, 2011), https://www.pharmaceutical-technology.com/features/featurethe-patent-cliff-rise-of-the-generics/; Charlotte Harrison, *The Patent Cliff Steepens*, 10 NATURE REVS. DRUG DISCOVERY 12, 12 (2011), https://www.nature.com/articles/nrd3356. But it is notable that it appears to be only a minor blip in the overall trend towards greater branded sales.

FIGURE 2. QUARTERLY GENERIC, BRANDED GENERIC AND BRAND SALES—ALL 36 FIRMS

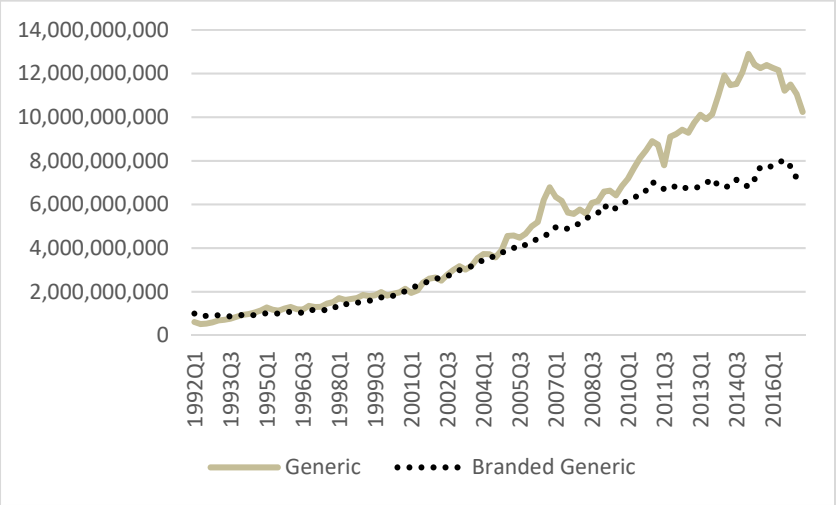


*NOTE: COMBINED QUARTERLY "GENERIC," "BRANDED GENERIC" AND "BRAND" SALES FOR THE 36 FIRMS LISTED IN APPENDIX TABLE A.1. FROM IQVIA NATIONAL SALES PERSPECTIVES.

Figure 3 further shows that pure generic sales have not been crowded out of the market by so called "branded generics"—generic products equivalent to a branded drug that are approved by the FDA and marketed as branded drugs by a third party.[45] From the early 1990s until roughly 2005, branded generics and generics sales increased at almost identical rates. Then, from 2005 through 2015, pure generic sales actually grew at a much higher rate than branded generics. Thus, for nearly 25 years, generic sales at least kept pace with branded generics.

45. FED.TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT 1 (2009). In a comprehensive report, the Federal Trade Commission (FTC) found that authorized generics were marketed during the 1990s but were "reportedly . . . not very profitable," which led to brands "abandon[ing] the practice by the end of the decade." FTC, AUTHORIZED GENERIC DRUGS, *supra* note 28, at 12. By 2003, however, because of the increased use of 180-day exclusivity periods (after courts eliminated the requirement that generics "successfully defend" litigation), they returned. *Id*. at 12 n.4.

FIGURE 3. GENERIC AND BRANDED GENERICS SALES—ALL 36 FIRMS



*NOTE: COMBINED QUARTERLY "GENERIC" AND "BRANDED GENERIC" SALES FOR THE 36 FIRMS LISTED IN APPENDIX TABLE A.1. FROM IQVIA NATIONAL SALES PERSPECTIVES.

Nevertheless, after peaking in 2015, pure generic revenue has declined sharply. Pure generic revenue averaged $12.5 billion per quarter in 2015, but by the first half of 2017 had declined to $10.7 billion per quarter. This represents a 15% decline in generic revenue over a year and a half. Comparing the same periods, branded generics held relatively steady and declined less than 1%, from about $7.36 to $7.30 billion per quarter. Brand revenue continued to rise as it has since 2013, increasing from an average of $67.7 billion per quarter in 2015 to $74.7 billion per quarter during the first half of 2017—a 10% increase over the same year and a half.[46]

Much of the remainder of our analysis supports the beneficial effects of a vibrant generics market on competition. For that reason, if generic sales remain stagnant or in decline, it will have important implications for drug competition. It remains to be seen whether the drop in generic revenue is short-term or long-term.[47]

46. Austin Frakt finds that much of the increase in overall spending on drugs in the United States is attributable to the higher prices on brand (as opposed to generic) drugs. Austin Frakt, *Why Are Drug Costs So High? Problem Traces to 1990s*, N.Y. TIMES, Nov. 13, 2018, at B4. Frakt adds that increased spending on brand drugs during the 1990s was driven by a record number of new drugs aimed at treating hypertension and cancer. *Id.* And Frakt points to other factors like increased advertising, faster FDA approvals, and expansion of public programs. *Id.* For a discussion of reimbursement rules and how they contribute to those price differentials, see Mark A. Lemley et al., *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. (forthcoming 2020).

47. One possible explanation, ironically enough, is the decline in the number of branded drugs going off patent. Generic firms make much of their money during the 180-day exclusivity period, so fewer patented drugs means fewer drugs going off patent and therefore fewer revenue-rich 180-day exclusivity periods. Fed. Trade Comm'n v. Actavis, 570 U.S. 136, 144 (2013) ("[T]he 'vast majority of potential profits for a generic drug

B. INCREASED SEGMENTATION: GENERAL

Across the 36 firms in our study, we find that generic sales have grown about twice as fast as brand sales. However, because brand sales in the early 1990s were 15 times higher than generic sales ($8.8 billion versus $0.57 billion per quarter in 1992), brand sales remain about 80% of all sales. How these facts relate to competition depends on how these sales are spread out over the firms in the industry and how the generic share of sales for these firms has changed over time.[48]

For example, because branded products sell at a much higher price than generics, is it the case that a subset of the industry selling exclusively branded drugs is driving these results? To analyze this, we determined the extent to which companies rely on brand versus generic drugs. We found that over the course of the 25 years of our study, the industry has separated into three discrete categories: (1) "pure" generic firms, (2) primarily brand firms, and (3) "mixed" firms.

Table A.1 in the Appendix lists the names, earliest available total generic share, and final Q2 2017 total generic share for each of the 36 firms in the study. We consider the 11 firms with final total generic shares ranging from 95 to 100%, as pure generic firms; the 16 firms with final total generic shares ranging from 0 to 9.5%, as primarily brand; and the 9 firms with final total generic shares ranging from 19 to 90%, as mixed.

We found that most of the largest firms in our study focus on brand sales or have moved in that direction throughout the study. In fact, every one of the 16 primarily brand firms is one of the "Top 25" in total sales. As a group, Figure 4 shows that brand sales rose for the 16 primarily brand firms from roughly $5 billion per quarter in 1992 to $60 billion per quarter in 2017.[49] These 16 companies earned $61.8 billion from brand drugs and $242 million from generic drugs, for a 0.4% "pure" generic share of sales.

Figure 4 also tracks the change in total generic share for the primarily brand firms, which again we define as the fraction of total sales derived from both pure and branded generic products. These 16 firms have never derived more than about 7% of their sales revenue from generic products, and since 2012 their generic share has been declining—to a mere 2.7% in 2017. Thus, the 16 primarily brand firms, which all were among the Top 25 in 2017 sales, have been and continue to be overwhelmingly dominated by brand sales.

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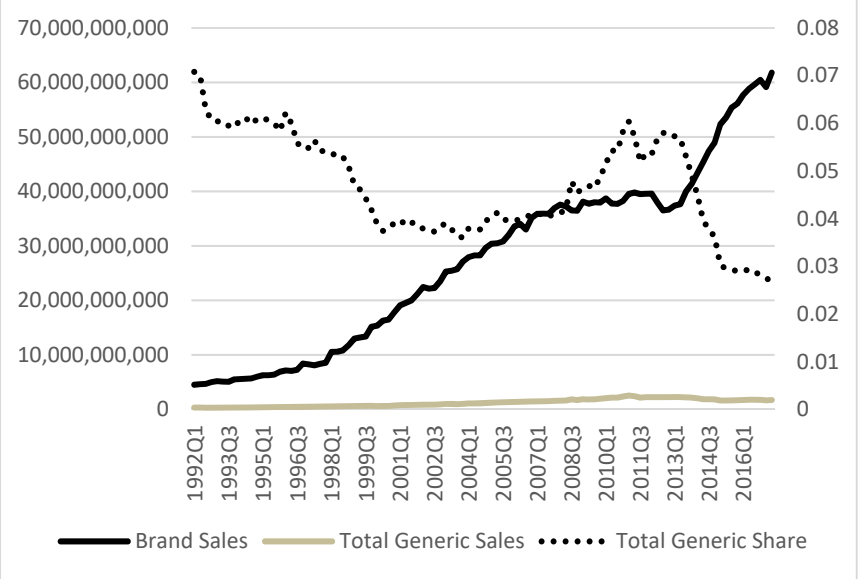
manufacturer materialize during the 180-day exclusivity period.'" (citing Brief for Petitioner at 6, *Actavis*, 570 U.S. 136 (No. 12-416)); *see also* Ari Altstedter, *Pharma Heir Seeks a New Holy Grail as Generic Drugs Run Dry*, BLOOMBERG, https://www.bloomberg.com/news/articles/2017-05-17/pharma-heir-seeks-a-new-holy-grail-as-generic-drugs-run-dry (last updated May 18, 2017).

48. The relationship between sales and competition in the drug industry also crucially depends on the various prices that the firms we study have charged for particular drugs over time and the quantities sold. Unfortunately, IQVIA cannot share the pricing data it possesses due to contractual restrictions with the drug companies that provide it with the data.

49. 2017 sales are measured based on the first two quarters of that year.

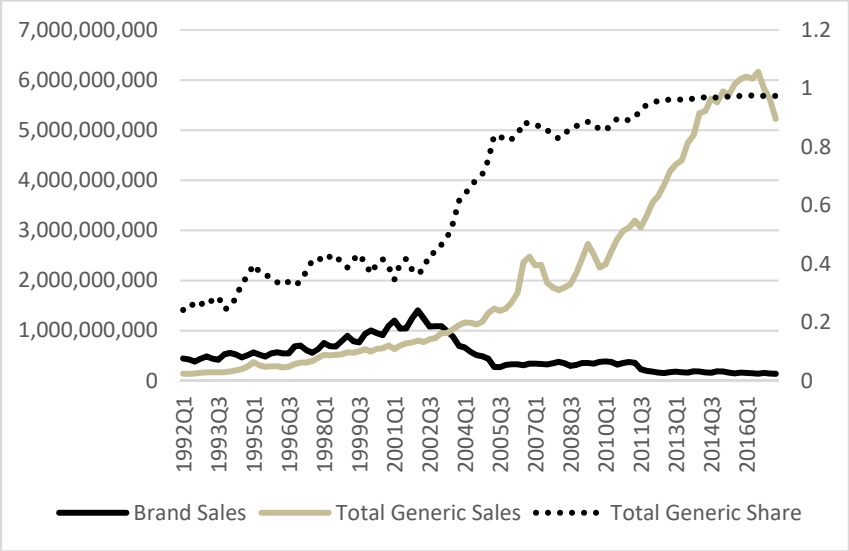
FIGURE 4. QUARTERLY BRAND, TOTAL GENERIC AND SHARE TOTAL GENERIC SALES—16 PRIMARILY BRAND FIRMS



*NOTE: QUARTERLY "BRAND" SALES FROM IQVIA NATIONAL SALES PERSPECTIVES. "TOTAL GENERIC SALES" (AND "TOTAL GENERIC SHARE") FROM IQVIA NATIONAL SALES PERSPECTIVES AND EQUAL TO SALES (AND SHARE) NOT ATTRIBUTABLE TO BRANDED SALES (AND SHARE) ACCORDING TO IQVIA'S DEFINITIONS. ALL CALCULATED BY COMBINING THE SALES OF THE 16 "BRAND" FIRMS LISTED IN APPENDIX TABLE A.1.

While many of the largest drug companies in terms of total sales remained highly invested in brand drugs, the 11 firms in our study that were primarily generic in 2017 became even more generic over time, as Figure 5 shows.

FIGURE 5. QUARTERLY BRAND, TOTAL GENERIC AND SHARE TOTAL GENERIC SALE—11 PURE GENERICS FIRMS



*NOTE: QUARTERLY "BRAND" SALES FROM IQVIA NATIONAL SALES PERSPECTIVES. "TOTAL GENERIC SALES" (AND "TOTAL GENERIC SHARE") FROM IQVIA NATIONAL SALES PERSPECTIVES AND EQUAL TO SALES (AND SHARE) NOT ATTRIBUTABLE TO BRANDED SALES (AND SHARE) ACCORDING TO IQVIA'S DEFINITIONS. ALL CALCULATED BY COMBINING THE SALES OF THE 11 "GENERIC" FIRMS LISTED IN APPENDIX TABLE A.1.

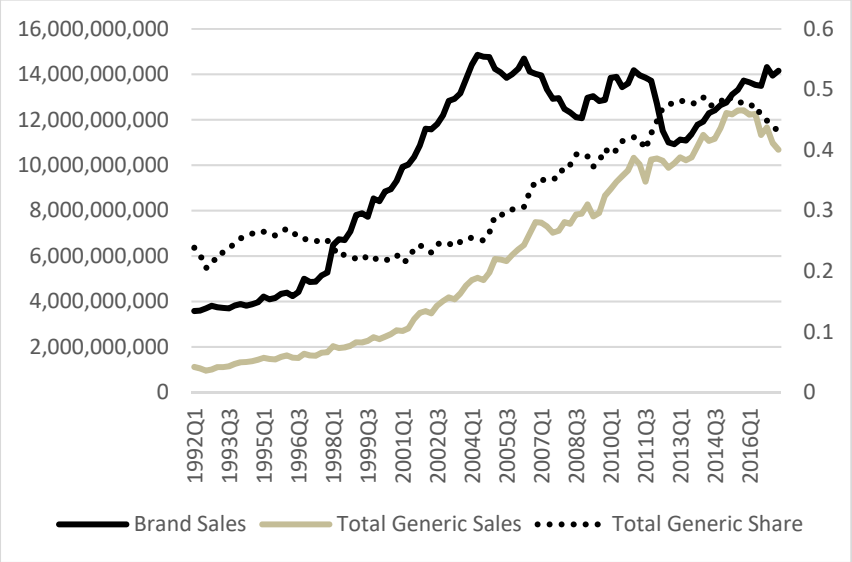
From 2002 to 2015, generic sales for these top generic companies skyrocketed from roughly $800 million to $6 billion in sales per quarter. During that period, the amount of these companies' brand sales fell from roughly $1.2 billion to $164 million per quarter. As a result, the contribution of generic drugs to these firms' sales increased from roughly 30% to nearly 100%.

Not all firms have shifted towards a pure generics or pure brand business model. Nine of the 36 firms have maintained a mixed model and 8 of these 9 are among the Top 25 in total sales.[50] Combined, in Figure 6 we see that these mixed firms fluctuated between 20 and 25% total generic share from the early 1990s through 2004. Then, from 2004 to 2015, their total generic share increased to nearly 50% due to stagnant or declining brand sales, while generic sales continued to climb. Like both the "pure" generic firms and "pure" brand firms described above, generic sales for these firms declined sharply from a peak in 2015 through the first half of 2017. Thus, as a group, these 9 mixed firms saw their generic share decline to 43%. Despite this setback, it is clear that unlike the other two broad categories of firms, these companies have maintained sizeable

50. All the mixed firms listed in Appendix Table A.1. except Fresenius Kabi are in the top 25 in total drug sales.

shares of both brand and generics sales over the past 25 years, rather than shifting their business (nearly) exclusively to one or the other.

FIGURE 6. QUARTERLY BRAND, TOTAL GENERIC AND SHARE TOTAL GENERIC SALES—9 MIXED FIRMS



*NOTE: QUARTERLY "BRAND" SALES FROM IQVIA NATIONAL SALES PERSPECTIVES. "TOTAL GENERIC SALES" (AND "TOTAL GENERIC SHARE") FROM IQVIA NATIONAL SALES PERSPECTIVES AND EQUAL TO SALES (AND SHARE) NOT ATTRIBUTABLE TO BRANDED SALES (AND SHARE) ACCORDING TO IQVIA'S DEFINITIONS. ALL CALCULATED BY COMBINING THE SALES OF THE 9 "MIXED" FIRMS LISTED IN APPENDIX TABLE A.1.

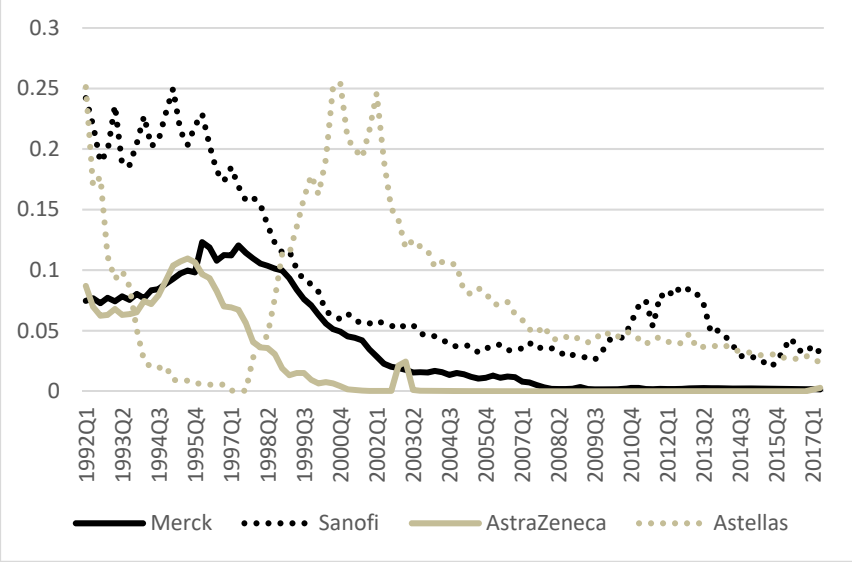
In short, the industry is separating into different categories, with one set specializing in brand products, a second focusing on generic drugs, and a third following more of a mixed business model.[51]

C. INCREASED SEGMENTATION: SPECIFIC FIRM CHANGES

We see the same separation when we focus on individual firms. As Figure 7 shows, some large firms that initially had a sizeable generics business but still more of a brand focus, such as Merck, Astellas, AstraZeneca, and Sanofi, became exclusively focused on brand-name drugs.

51. *Cf.* Andrew D. Goldsmith & Francisco E. Varela, *Fragmentation in the Biopharmaceutical Industry*, 22 DRUG DISCOVERY TODAY 433, 433 (2016) (finding an increased trend in fragmentation of the biopharmaceutical industry).

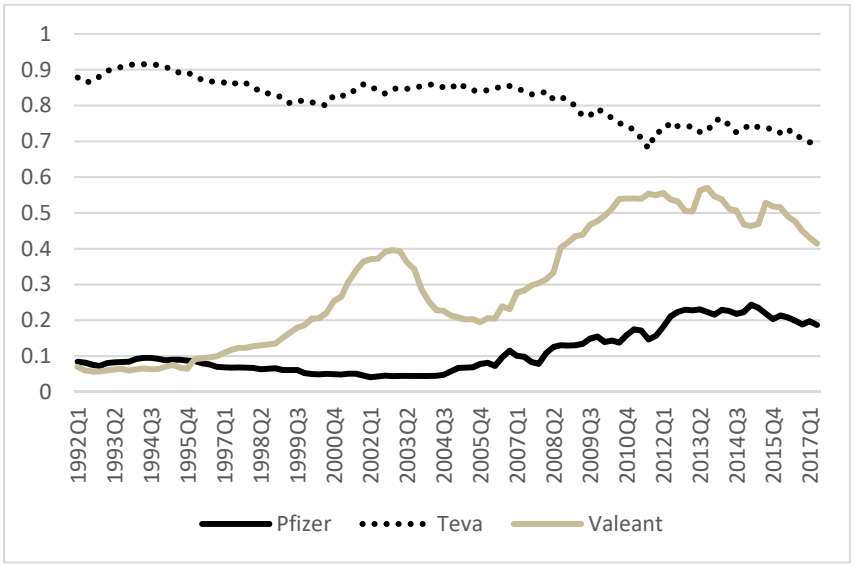
FIGURE 7. TOTAL GENERIC SHARE OVER TIME FOR SELECT PURE BRAND FIRMS



*NOTE: "TOTAL GENERIC SHARE" FROM IQVIA NATIONAL SALES PERSPECTIVES AND EQUAL TO SHARE OF ALL SALES NOT ATTRIBUTABLE TO BRANDED SALES ACCORDING TO IQVIA'S DEFINITIONS.

At the same time that some firms were becoming more exclusively "brand-like" in nature, other firms were becoming more mixed. As Figure 8 shows, Pfizer and Valeant, for example, became more generic, increasing their total generic share from about 10% in 1992 to about 20% and 50% (respectively) in 2015. Meanwhile, Teva became more brand-focused, with its total generic share decreasing from 90% in 1992 to about 75% in 2015.

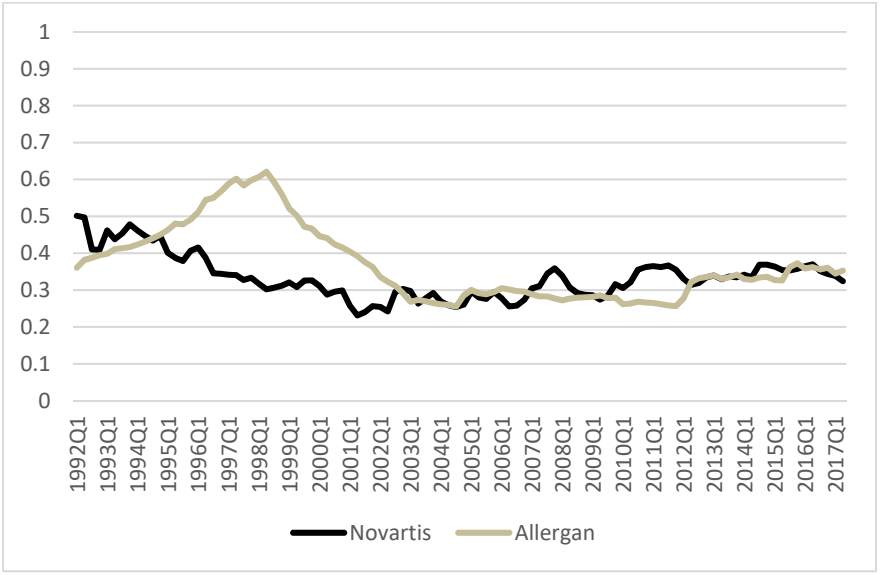
FIGURE 8. TOTAL GENERIC SHARE OVER TIME FOR SELECT MIXED FIRMS



*NOTE: "TOTAL GENERIC SHARE" FROM IQVIA NATIONAL SALES PERSPECTIVES AND EQUAL TO SHARE OF ALL SALES NOT ATTRIBUTABLE TO BRANDED SALES ACCORDING TO IQVIA'S DEFINITIONS.

Further, as shown in Figure 9, a few firms, including Novartis-Sandoz and Allergan, remained mixed throughout the 25 years of our study.

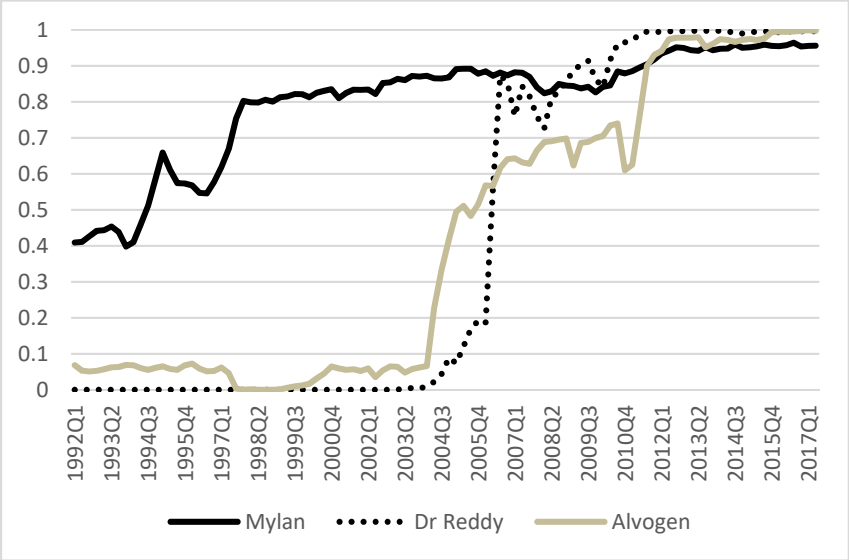
FIGURE 9. TOTAL GENERIC SHARE OVER TIME FOR SELECT MIXED FIRMS



*NOTE: "TOTAL GENERIC SHARE" FROM IQVIA NATIONAL SALES PERSPECTIVES AND EQUAL TO SHARE OF ALL SALES NOT ATTRIBUTABLE TO BRANDED SALES ACCORDING TO IQVIA'S DEFINITIONS.

Finally, many of the firms that are now pure generic started out with a large portion of their business from brand sales. Thus, Figure 10 shows that Mylan shifted from a mixed business to a nearly pure generic business. By contrast, Dr. Reddy and Alvogen began our time period as nearly pure brand firms and then shifted towards becoming pure generic over a short period of time.

FIGURE 10. TOTAL GENERIC SHARE OVER TIME FOR SELECT PURE GENERICS FIRMS



*NOTE: "TOTAL GENERIC SHARE" FROM IQVIA NATIONAL SALES PERSPECTIVES AND EQUAL TO SHARE OF ALL SALES NOT ATTRIBUTABLE TO BRANDED SALES ACCORDING TO IQVIA'S DEFINITIONS.

In short, in recent years, the generics industry has separated into companies that are "pure" generics, those that obtain most of their revenues from the sale of brand-name drugs, and those with a "mixed" business model.

D. ACTING LIKE BRANDS

The separation of companies that have had significant generics businesses into different categories reveals a group of mixed firms that now clearly plays both sides. Supporting this conclusion is the observation that firms in this category have *behaved* like brand companies when they have a branded product that faces generic competition. Seeking to forestall the price reductions that follow generic entry, mixed firms have engaged in an array of conduct to delay generic competition as long as possible. And even companies widely known as "generics" are pursuing this path, playing both sides of the brand/generic divide when it benefits them to do so. In addition to Mylan's behavior related to the EpiPen discussed in the introduction,[52] Teva and Allergan offer two other examples.

52. For additional detail on Mylan's conduct, including its use of settlements, questionable citizen petitions, and exclusive contracts with schools, see Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 53–55 (2017).

Though Teva is well-known as a generic company, its conduct in protecting its multiple-sclerosis-treating drug Copaxone more closely resembles that of a brand firm. To protect its $3-billion-per-year drug, Teva filed citizen petitions seeking to delay generic versions. Citizen petitions are supposed to ensure that the FDA is made aware of information related to a drug's safety,[53] but Teva used the procedure to stave off generic competition for Copaxone. It filed *eight* petitions against generics, [54] with two of these running more than 130 pages in length.[55] In each of the eight petitions, Teva argued that the FDA should refuse to approve a generic version of its drug because the drug was highly complex, and therefore no generic could produce the same active ingredient.[56] The FDA denied each of the eight petitions, with the final denial coming on the same day the agency approved rival Sandoz's generic application.[57] It is hard to

53. 21 C.F.R. §§ 10.25, 10.30 (2019). *But see* Carrier & Minniti, *supra* note 12, at 333 (finding that FDA denied 92% of petitions filed against pending generics between 2011 and 2015). For a discussion of anticompetitive abuse of citizen petitions, see 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.1 (3d ed. 2017).

54. *See, e.g.*, TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2015-P-1050-0001, CITIZEN PETITION REQUESTING THAT FDA CONSIDER NEW SCIENTIFIC INFORMATION AND REFRAIN FROM APPROVING ANY ABBREVIATED NEW DRUG APPLICATION REFERENCING COPAXONE® (GLATIRAMER ACETATE INJECTION) UNTIL CERTAIN CONDITIONS ARE MET (Mar. 31, 2015), https://www.regulations.gov/document?D=FDA-2015-P-1050-0001; TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2014-P-0933-0001, CITIZEN PETITION REQUESTING THAT FDA REFRAIN FROM APPROVING ANY ABBREVIATED NEW DRUG APPLICATION REFERENCING COPAXONE® (GLATIRAMER ACETATE INJECTION) UNTIL CERTAIN CONDITIONS ARE MET (July 2, 2014), https://www.regulations.gov/document?D=FDA-2014-P-0933-0001; TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2013-P-1641-0001, CITIZEN PETITION REQUESTING THAT FDA REFRAIN FROM APPROVING ANY ABBREVIATED NEW DRUG APPLICATION REFERENCING COPAXONE® (GLATIRAMER ACETATE INJECTION) UNTIL CERTAIN CONDITIONS ARE MET (Dec. 5, 2013), https://www.regulations.gov/document?D=FDA-2013-P-1641-0001; TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2013-P-1128-0001, CITIZEN PETITION REQUESTING THAT FDA REFRAIN FROM APPROVING ANY ABBREVIATED NEW DRUG APPLICATION REFERENCING COPAXONE® (GLATIRAMER ACETATE INJECTION) UNTIL CERTAIN CONDITIONS ARE MET (Sept. 12, 2013), https://www.regulations.gov/document?D=FDA-2013-P-1128-0001; TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2012-P-0555-0001, CITIZEN PETITION REQUESTING THAT FDA REFRAIN FROM APPROVING ANY ABBREVIATED NEW DRUG APPLICATION REFERENCING COPAXONE® (GLATIRAMER ACETATE INJECTION) UNTIL CERTAIN CONDITIONS ARE MET (June 4, 2012), https://www.regulations.gov/document?D=FDA-2012-P-0555-0001; TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2010-P-0642-0001, CITIZEN PETITION REQUESTING THAT FDA REFRAIN FROM APPROVING ANY ABBREVIATED NEW DRUG APPLICATION REFERENCING COPAXONE® (GLATIRAMER ACETATE INJECTION) UNTIL CERTAIN CONDITIONS ARE MET (Dec. 10, 2010), https://www.regulations.gov/document?D=FDA-2010-P-0642-0001; TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2009-P-0555-0001, CITIZEN PETITION REQUESTING THAT FDA REFRAIN FROM APPROVING ANY ABBREVIATED NEW DRUG APPLICATION REFERENCING COPAXONE® (GLATIRAMER ACETATE INJECTION) UNTIL CERTAIN CONDITIONS ARE MET (Nov. 13, 2009), https://www.regulations.gov/document?D=FDA-2009-P-0555-0001; TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2008-P-0529-0001 (SEPT. 26, 2008), https://www.regulations.gov/document?D=FDA-2008-P-0529-0001.

55. *See* TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2015-P-1050-0001, *supra* note 54 (133 pages); TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2014-P-0933-0001, *supra* note 54 (132 pages).

56. TEVA PHARMACEUTICAL INDUSTRIES, NO. FDA-2015-P-1050-0001, *supra* note 54, at 2–4 (asserting that the complexity of Copaxone includes unknown characteristics that are related to its safety and efficacy, so a generic could not contain the same active ingredient).

57. *Compare Drugs@FDA: GLATOPA*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090218 (showing Sandoz-sponsored ANDA 090218, the only approved generic referencing COPAXONE, approved on April 16, 2015) *with* TEVA

see this behavior as anything other than a delaying tactic—something generics complain about when it happens to them.

The second example involved another mixed firm, Allergan, which filed three repetitive citizen petitions seeking to delay generic entry on its dry-eye-disease-treating Restasis drug.[58] The FDA denied the second petition by stating that Allergan "should not be surprised" by its response,[59] and denied the third by explaining that the petition "repeats many of the assertions" central to the earlier petitions that it had already addressed.[60] Nor was that all. Allergan sought to avoid "inter partes review"[61] of its patents at the Patent Office by transferring patents to a Native American tribe to exploit tribal immunity.[62] Not only did this maneuver fail,[63] but it also garnered widespread criticism,[64] even in an area known for—as FDA Commissioner Scott Gottlieb has lamented—brand-firm "shenanigans."[65]

Mylan, Teva, and Allergan may have significant generic shares. But the behavior they have engaged in when exploiting their branded drugs looks more like what we have seen from brand companies. Perhaps this just reflects the simple fact that companies want to win their cases, no matter which side they are on. But it may also reflect a more general concern. As we explore in the next Subpart, companies in the industry may have different incentives in litigation, settlement, and acquisitions based on their mix of brand and generic drugs.

PHARMACEUTICAL INDUSTRIES, NO. FDA-2015-P-1050-0001, *supra* note 54, at 2–4 (arguing that no generic drug could mimic the brand-name drug's effectiveness).

58. ALLERGAN, INC., NO. FDA-2017-P-4745-0001 (Aug. 4, 2017), https://www.regulations.gov/document?D=FDA-2017-P-4745-0001; ALLERGAN, INC., NO. FDA-2015-P-0065-0001 (Dec. 23, 2014), https://www.regulations.gov/document?D=FDA-2015-P-0065-0001; ALLERGAN, INC., NO. FDA-2014-P-0304-0001 (Feb. 28, 2014), https://www.regulations.gov/document?D=FDA-2014-P-0304-0001.

59. FDA RESPONSE TO ALLERGAN, INC., NO. FDA-2015-P-0065 AND FDA-2015-P-1404-001, at 22 (Feb. 10, 2016), https://www.regulations.gov/document?D=FDA-2015-P-1404-0007.

60. FDA RESPONSE TO ALLERGAN, INC., NO. FDA-2017-P-4745-0001, at 4 (Jan. 2, 2018), https://www.regulations.gov/document?D=FDA-2017-P-4745-0026.

61. Inter partes review provides a means to challenge patent claims before the Patent Trial and Appeal Board on the grounds that the patent is not novel or nonobvious. *Inter Partes Review*, U.S. PATENT AND TRADEMARK OFFICE (last modified May 9, 2019, 10:15 AM), https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review.

62. After the transfer, a district court (in a decision later upheld) found that the alleged infringers "proved by clear and convincing evidence that the asserted claims of the Restasis patents are invalid for obviousness." Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4803941, at *65 (E.D. Tex. Oct. 16, 2017), *aff'd*, 742 F. App'x 511 (Fed. Cir. Nov. 13, 2018).

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

64. Meg Tirrell, *Allergan Responds to Mounting Criticism of Mohawk Patent Deal*, CNBC (Oct. 3, 2017, 9:45 AM), https://www.cnbc.com/2017/10/03/allergan-responds-to-mounting-criticism-of-mohawk-patent-deal.html.

65. Scott Gottlieb, Comm'r, U.S. Food & Drug Admin., Remarks at the FTC Workshop Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017) (transcript available at https://www.fda.gov/NewsEvents/Speeches/ucm584195.htm).

E. LITIGATION, SETTLEMENT, AND VICTORY

In the remainder of our analysis, we investigate whether hybrid firms compete as aggressively on the generic side of the market as pure generic firms. We limit our analysis to nine pure generic and six hybrid generic firms in our dataset that were drug patent challengers in more than a handful of lawsuits between 2009 and the second quarter of 2017.[66] The firms we include in this more detailed study are listed in Table 1, along with the number of ANDA lawsuits in which they were an alleged infringer, their generic share at the beginning and end of the series, their generic sales at the end of the series, and whether we group the firm as a "mixed" or "pure generic" firm. Except for IQVIA's proprietary sales information, we have published the data we utilize in this detailed study, including per firm quarterly generic share and litigation data.[67]

We consider a number of ways that playing both sides might affect a company's incentives to challenge pharmaceutical patents. We compare the mixed versus the pure group's litigation rate, settlement rate, and win rate. Further, for each of these categories of activity, we consider whether changes in generic share or sales over time, regardless of group, affect firm-level aggressiveness in the generics market. Finally, we investigate the impact of major acquisitions of generic firms on the combined firms' competition in the generics market.

66. The 21 firms excluded from this analysis fall into one of two categories: pure brand firms that rarely or never enter on the generic side of the market, and generic firms that specialize in authorized generics and do not enter without a deal with a patent-holding brand firm. We choose 2009 as the starting point of our litigation analysis because it is the earliest year that Lex Machina has comprehensively identified ANDA lawsuits.

67. Our data is available for download at http://npe.law.stanford.edu/pharma/playing_both_sides.

TABLE 1. FIRMS INVOLVED IN ANDA LAWSUITS AS ALLEGED INFRINGERS

Firm	ANDA Suits 2009-2017	Share All ANDA Suits 2009-2017	Total Generic Share Q1 2009	Total Generic Share Q1 2017	Total Generic Sales Q1 2017 ($B)	Group
Allergan	383	0.127	28%	34%	1.07	Mixed
Teva	239	0.079	80%	70%	3.11	Mixed
Novartis-Sandoz	215	0.071	29%	34%	1.63	Mixed
Endo	144	0.048	82%	90%	1.37	Mixed
Pfizer	62	0.021	13%	20%	1.17	Mixed
Fresenius	48	0.016	83%	80%	0.36	Mixed
Mylan	332	0.11	84%	96%	2.07	Pure
Apotex	201	0.067	100%	98.6%	0.35	Pure
Lupin	183	0.061	82%	95%	0.54	Pure
Amneal	120	0.04	100%	100%	0.37	Pure
Dr. Reddy	118	0.039	89%	99.5%	0.41	Pure
Aurobindo	98	0.032	100%	100%	0.23	Pure
Perrigo	64	0.021	56%	99.7%	0.28	Pure
Alvogen	28	0.009	62%	99.9%	0.42	Pure
West Ward	28	0.009	98.6%	99.8%	0.40	Pure
15-Firm Total	2263	0.75				
National Total	3016	1.00				

*NOTE: QUARTERLY DATA FOR ANDA LITIGATION FILED BETWEEN 1/1/2009 AND 6/30/2017. "ANDA SUITS 2009-2017" FROM LEX MACHINA AND FOR IQVIA FIRM TOTALS INCLUDES ALL CASES WHERE THE FIRM WAS AN ALLEGED INFRINGER. "TOTAL GENERIC SALES" (AND "TOTAL GENERIC SHARE") FROM IQVIA AND EQUAL TO SALES (AND SHARE) NOT ATTRIBUTABLE TO BRANDED SALES (AND SHARE) ACCORDING TO THEIR DEFINITIONS.

1. Importance of ANDA Litigation

First, we examined litigation—in particular, how often firms seeking to enter the market with a generic version of a drug covered by a patent are sued or

sue in ANDA litigation.[68] Generic entrants typically find themselves on the receiving end of a brand firm's lawsuit. The reason is simple: generics increase competition when they enter the market. The brand firm stands to lose a significant share of the market when generics enter because it can no longer exploit its monopoly position in the face of generics offering lower prices.[69]

The typical route of entry comes after the FDA approves a new drug application (NDA)[70] and lists the drug and any relevant patents in a publication known as the Orange Book.[71] The generic applicant, before entering the market, must then provide one of four certifications for each patent listed in the Orange Book relating to the relevant NDA.[72] Paragraph I, II, and III challenges apply where, respectively, there is no patent on the drug, the patent has expired, or the generic agrees to wait until the patent expires. Each of these promises to introduce generic competition, but not at the expense of patent rights.[73]

Of more interest is competition resulting from a "Paragraph IV" certification, by which the generic claims that the patents covering a brand drug are invalid or not infringed and seeks to enter before the patents expire.[74] Invalidating patents is a public good because it opens markets that should never have been off-limits.[75] The drafters of the Hatch-Waxman Act were so motivated to encourage competition and patent challenges that they provided 180 days of

68. We define "ANDA litigation" to signify a brand company suing a generic firm for infringement under the Hatch-Waxman Act after the generic firm files a "Paragraph IV" certification seeking to enter the market before the expiration of the patent on the ground that the patent is invalid or is not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2018).

69. *See Generic Competition and Drug Prices*, U.S. FOOD & DRUG. ADMIN., https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm (last modified Nov. 20, 2017) (noting that price falls to approximately 50% when 2 generics enter the market).

70. Companies also can enter the market through (1) "hybrid" 21 U.S.C. § 355(b)(2) applications, which contain reports of safety and effectiveness but also can include information from brand studies, and (2) "Section viii" carve-outs, which allow a generic to enter when it does not seek approval of the use covered by the patent, 21 U.S.C. § 355(j)(2)(A)(viii).

71. The technical name for the Orange Book is "Approved Drug Products with Therapeutic Equivalence Evaluations." OFF. OF GENERIC DRUG POL'Y, U.S. DEP'T OF HEALTH & HUMAN SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS iv (39th ed. 2019), https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.

72. § 355(j)(2)(A)(vii).

73. *Id.* §§ 355(j)(2)(A)(vii)(I)–(III).

74. *Id.* § 355(j)(2)(A)(vii)(IV).

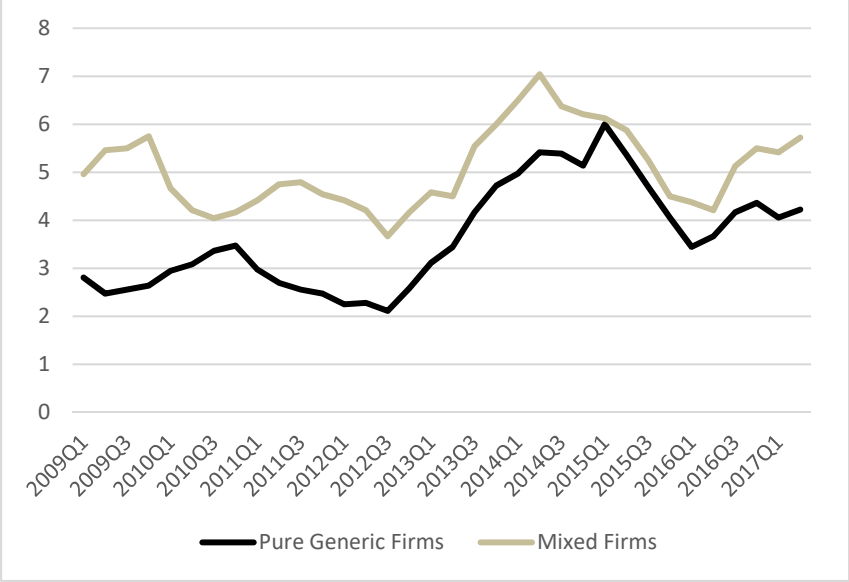
75. *E.g.*, Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 115 (2011) (Breyer, J., concurring) (offering measures designed to "increase the likelihood that discoveries or inventions will not receive legal protection where none is due"); MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 137 (2007) (finding that licensees have standing to challenge patent validity or infringement without repudiating their licenses); United States v. Glaxo Group, Ltd., 410 U.S. 52, 57 (1973) (emphasizing "public interest in free competition" in concluding that a licensee in an antitrust suit "may attack the validity of the patent under which he is licensed even though he has agreed not to do so in his license"); Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 349–50 (1971) (allowing alleged infringer to claim estoppel where patent was previously declared invalid); Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969) (stating that a patent "simply represents a legal conclusion reached by the Patent Office. . . . [I]n an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.").

exclusivity—potentially "worth several hundred million dollars"[76]—to the first generic to file a Paragraph IV certification and to enter before the patent expires.[77] ANDA lawsuits against generics for infringing the brand's patent are a consequence of the generic proposing to enter the market before the last patent expires, conduct that is central to the regulatory regime.

2. Share of Lawsuits

As a first measure of the intensity of generic competition, we compare the litigation rates of the nine pure generic firms in our analysis with the six mixed firms. Our hypothesis is that by playing both sides, mixed firms will tend to be less aggressive and thus, as compared to pure generic firms, less frequently end up as patent challengers in ANDA lawsuits. In Figure 11, however, we see that mixed firms were consistently responsible for more lawsuits per firm than the pure generic firms.

FIGURE 11. AVERAGE ANDA LAWSUITS AS INFRINGER PER FIRM—PURE GENERIC VERSUS MIXED

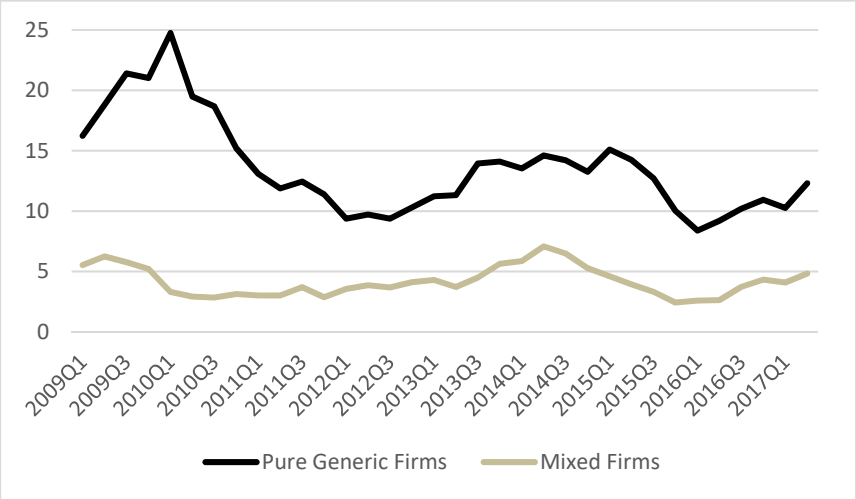


*NOTE: "QUARTERLY DATA FOR ANDA LITIGATION FILED BETWEEN 1/1/2009 AND 6/30/2017 FROM LEX MACHINA. "PURE GENERIC" CALCULATED BY COMBINING THE LITIGATION OF THE 9 "PURE" FIRMS LISTED IN TABLE 1. "MIXED" CALCULATED BY COMBINING THE LITIGATION OF THE 6 "MIXED" FIRMS LISTED IN TABLE 1.

76. F.T.C. v. Actavis, Inc., 570 U.S. 136, 155 (2013).
77. § 355(j)(5)(B)(iv).

Looks can be deceiving, however. From Table 1, we see that our mixed firms tend to be larger firms with higher generic sales than the pure generic firms we study. Thus, there is a considerable size effect that obscures the contributions of these firms to drug competition through ANDA litigation. In Figure 12, we eliminate this effect by tracking average ANDA suits not only as infringer per firm for each group, but also per billions of dollars of generic sales during the quarter. Taking into account the size of a firm's generics business, the picture flips, with the pure generic firms now appearing far more litigious over time. Thus, accounting for firm size, the pure generic companies have consistently brought more ANDA challenges per generic revenue dollar than the mixed firms.[78]

FIGURE 12. AVERAGE ANDA LAWSUITS AS INFRINGER PER FIRM PER $BILLION TOTAL GENERIC SALES—PURE GENERIC VERSUS MIXED



*NOTE: "QUARTERLY DATA FOR ANDA LITIGATION FILED BETWEEN 1/1/2009 AND 6/30/2017 FROM LEX MACHINA. "PURE GENERIC" CALCULATED BY COMBINING THE LITIGATION OF THE 9 "PURE" FIRMS LISTED IN TABLE 1. "MIXED" CALCULATED BY COMBINING THE LITIGATION OF THE 6 "MIXED" FIRMS LISTED IN TABLE 1.

3. Litigation and Generic Share

Turning from simple comparison of the two groups of firms, we next use firm-level data and regression analysis to investigate whether differences in generic share explain differences in litigation rates. Using our 15 firms and quarterly ANDA lawsuit counts from 2009 through the second quarter of 2017, we created as our dependent variable an average number of ANDA lawsuits filed

78. One possible explanation for this is that mixed firms gravitate towards larger generic markets. We do not have the sales data by drug to test this hypothesis.

where the firm was a patent challenger.[79] Our primary independent variable of interest is a backward-looking average total generic share.[80]

We control for average total generic sales. We also control for linear time trends in litigation rates for each firm ("Quarterly Count"). Finally, in one specification, we control for whether the firm is mixed, and in another we include 14 firm dummy variables indicating whether a firm was a patent challenger in the case.[81]

In Table 2, we see that except for specification 5, where we control for firm-level effects, average generic share is a statistically significant predictor of the average number of lawsuits filed with a firm as a patent challenger.[82] The same is true of average sales, but in the opposite direction. In other words, higher generic share is associated with fewer lawsuits, while higher generic sales are associated with more lawsuits.

The results in Table 2 are mixed and suggest that firms with higher generic shares in the present also tend to be less litigious in the present. However, we also find that pure generic firms and those with higher generic sales are more litigious. While the negative effect of generic share on litigation conflicts with our hypothesis that more generic firms will more aggressively compete, in specification 4 we also control for whether the firm is a mixed firm. Consistent with our hypothesis, we find that mixed firms are significantly less litigious. This is an indicator that movement towards a pure generic business model or maintenance of a mixed model matters.

79. The average lawsuit count each quarter is the average of the number of lawsuits filed in that quarter along with the following three quarters. We similarly measure all other average values except for generic shares throughout the remaining analysis.

80. In contrast with all other averages, average generic share is backward looking and an average of the generic share during the current quarter and the three preceding quarters. We use an earlier measure of generic share because we assume that insofar as generic share and changes in generic share impact a firm's competitive behavior, there will be a lag in the effect as business decisions are made in the firm.

81. We omit Lupin to avoid multicollinearity, which occurs when one variable in a regression model can be linearly predicted from the others. For an explanation of dummy variables and the problem of multicollinearity, see Daniel B. Suits, *Use of Dummy Variables in Regression Equations*, 52 J. AM. STAT. ASS'N 548, 548–51 (1957).

82. Thirteen of the fourteen firms have quarterly litigation rates that are significantly different than Lupin.

TABLE 2. OLS REGRESSION OF QUARTERLY ANDA LAWSUITS AS INFRINGER (2009–2017)

	1	2	3	4	5	6
Ave. Total Generic Share	-2.098*** (0.408)	-2.098*** (0.408)		-1.199*** (0.411)	-1.627*** (0.364)	0.105 (0.353)
Ave. Total Generic Sales ($MM)			0.0017*** (0.0002)	0.0017*** (0.0002)	0.0018*** (0.0002)	-0.0005 (0.0004)
Quarterly Count		0.070*** (0.006)	0.040*** (0.005)	0.046*** (0.006)	0.047*** (0.006)	0.081*** (0.007)
Mixed Firm?					-0.619** (0.239)	
Firm Dummies	No	No	No	No	No	Yes
Constant	4.840*** (0.300)	1.308*** (0.305)	0.178 (0.209)	0.798*** (0.256)	1.137*** (0.224)	-0.458 (0.343)
R-squared	0.04	0.14	0.31	0.32	0.32	0.62
Observations	818	818	818	818	818	818

*NOTE: QUARTERLY DATA FOR ANDA LITIGATION FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. DEPENDENT VARIABLE "AVEINFRINGE" EQUAL TO THE NUMBER OF ANDA LAWSUITS FILED WITH THE FIRM AS AN ALLEGED INFRINGER AVERAGED OVER THE CURRENT AND PRIOR THREE QUARTERS. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * P < .10; ** P < .05; AND *** P <.01.

Additionally, while we find a negative relationship between generic share and the number of lawsuits filed where a firm is a patent challenger, we do find a weak positive correlation between the growth rates of these two variables. Appendix Table A.3 reports a series of regressions replicating those in Table 2 but substituting growth variables for generic share and lawsuits. The results suggest that a 1% increase in the growth of generic share during a quarter is associated with about a 2% increase in the number of lawsuits involving a firm as a patent challenger in the following quarter. However, this relationship is only statistically significant in one specification and in the remainder significant to a 90% confidence level. While statistically weak, these results do provide some support for the idea that firms becoming more generic increase their rate of challenging patents.

4. Settlement

Most patent lawsuits settle.[83] One simple reason is that litigants may prefer the certainty of settlement to uncertain litigation outcomes.[84] In the context of ANDA litigation, however, settlements often indicate less aggressive

83. John R. Allison et al., *Patent Quality and Settlement Among Repeat Patent Litigants*, 99 GEO. L.J. 677, 680 (2011); Shawn P. Miller et al., *Who's Suing Us? Decoding Patent Plaintiffs Since 2000 with the Stanford NPE Litigation Dataset*, 21 STAN. TECH. L. REV. 235, 267 tbl.7 (2018) (finding that among patent lawsuits filed in 2014, 72% had settled by February 2016).

84. *E.g.*, *In re* Domestic Drywall Antitrust Litig., No. 243713-MD-2437, 2015 WL 5000954, at *2 (E.D. Pa. Aug. 20, 2015).

competition by firms seeking to enter the market as a generic seller. In fact, some ANDA settlements are anticompetitive because they include agreements to delay entry in exchange for payments.[85] Recognizing this possibility, in 2013, the Supreme Court in *F.T.C. v. Actavis* held that "reverse payment"[86] settlements are not immune from antitrust liability and suggested reasons to believe they are anticompetitive.[87]

In Table 3, we report the number of settlements and settlement rates for each of the 15 firms we analyze as well as for the two groups of firms—mixed and pure generic. Notably, the average settlement rate of the six mixed firms is within one percentage point of that of the nine pure generic firms. While we did see differences between the groups on litigation rates, the two groups have nearly identical settlement rates.

85. *E.g.*, F.T.C. v. Actavis, 570 U.S. 136, 140–41 (2013); King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 397 (3d Cir. 2015); 1 HOVENKAMP, *supra* note 53, at § 16.01.A; Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39–40 (2009); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1568–70 (2006); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 U. MINN. L. REV. 1719, 1721 (2003).

86. The settlements are called this because the consideration flows from patentee to alleged infringer, unlike typical settlements in which alleged infringers pay patentees.

87. *Actavis*, 570 U.S. at 141.

TABLE 3. SETTLEMENTS AND SETTLEMENT RATES (2009–2017)

Firm	Number of Settlements	Settlement Rate	Group
Allergan	211/269	78.4%	Mixed
Teva	124/154	80.5%	Mixed
Novartis-Sandoz	125 / 161	77.6%	Mixed
Endo	93 / 112	83.0%	Mixed
Pfizer	29 / 38	76.3%	Mixed
Fresenius	30/35	85.7%	Mixed
6 Mixed Firms	612/769	79.6%	
Mylan	193/238	81.1%	Pure
Apotex	108/138	78.2%	Pure
Lupin	114/133	85.7%	Pure
Amneal	64/84	76.2%	Pure
Dr Reddy	63/78	80.8%	Pure
Aurobindo	61/73	83.6%	Pure
Perrigo	48/54	88.9%	Pure
Alvogen	16/23	69.6%	Pure
West Ward	14/16	87.5%	Pure
9 Pure Firms	681/837	81.4%	

*NOTE: POPULATION OF 1606 ANDA LAWSUITS FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH AT LEAST 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. "SETTLEMENT" DEFINED AS LAWSUIT ENDING IN EITHER "LIKELY SETTLEMENT" OR "CONSENT JUDGMENT: CLAIMANT WIN" ACCORDING TO LEX MACHINA'S CASE-RESOLUTION DEFINITIONS.

To test whether the firms in our analysis differ in their propensity to settle depending on recent changes in their business mix, we ran a series of probit regressions investigating the drivers of settlement.[88] Our most interesting results are in Table 4, below. In specifications 1 through 4, our primary independent variable is a one-quarter lag in the growth of a firm's average total generic share,[89] and in specifications 5 through 8, we substitute growth in average brand

88. Probit regression is used to model dichotomous or binary outcome variables. In the probit model, the inverse standard normal distribution of the probability is modeled as a linear combination of the predictors. *Probit Regression: Stata Data Analysis Examples*, UCLA INST. FOR DIG. RESEARCH & EDUC., https://stats.idre.ucla.edu/stata/dae/probit-regression/ (last visited Jan. 24, 2020).

89. For a one-quarter lag, the value of the variable at t-1 is used for the observation in time, t. In other words, we determine the impact of the growth in average brand sales in the previous quarter on the probability that a case filed in this quarter eventually settles.

sales. For both, we define growth as the change in value as compared with the prior period so we can measure how much more or less likely the firm is to settle given recent increases or decreases in total generic share or brand sales.

We control for average brand sales and firm effects in all specifications. To determine whether *Actavis* had an impact on pharmaceutical settlement rates, we also controlled in all specifications for whether the lawsuit terminated after *Actavis* was decided. In the regressions, we alternatively include one additional control for total, average, or growth in average ANDA suits involving the entrant as a patent challenger.

In specifications 1 through 4, we consistently find that entrants that had growing total generic shares before the filing of ANDA lawsuits are significantly less likely to settle those suits. Further, we find in specifications 5 through 8 that firms litigating to enter as generics that had growing brand sales at the time of the lawsuit were more likely to settle those suits.[90] Both of these results support the hypothesis that companies that see their future as generic firms are more aggressive in seeking to enter markets and less willing to enter into settlements resulting in delayed generic entry.[91]

While most of our controls do not significantly affect settlement, we find that it matters whether the lawsuit was terminated after *Actavis* was decided. The *Actavis* effect is modestly negative: cases terminated after the decision were about 4% less likely to settle.[92]

To account for the statistical significance of the *Actavis* effect, Table A.4 reports eight regressions identical to those in Table 4, except that we substituted our Quarterly Count time control for the *Actavis* control. In those regressions, we see from the positive statistically significant impact of Quarterly Count on settlement that over time, cases were more likely to settle. Thus, *Actavis* has cut against the general trend towards more frequent settlement. Finally, we find that both the growth in average total generic share and growth in average brand sales are statistically significant in all specifications in Table A.4. This indicates a robust relationship between these two variables and settlement. Thus, we conclude that firms with a growing generic share are less likely to settle and those with growing brand sales are more likely to settle.

90. Growth in average brand sales just misses statistical significance in specification 7 ($p = 0.051$).

91. Another factor that may affect aggressiveness is the number of same-day ANDA filers. If a generic company must share 180-day exclusivity if it wins, it has less to gain from a successful challenge. Its win benefits its generic competitors as well. Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 951–60 (2004) (discussing this problem as a reason why patent challenges are undersupplied); Christopher R. Leslie, *Antitrust Law as Public Interest Law*, 2 U.C. IRVINE L. REV. 885, 897 n.84 (2012).

92. That effect is statistically significant in specifications 1 through 4 and significant at a 90% confidence level in specifications 5 through 8.

TABLE 4. PROBIT ESTIMATION OF THE LIKELIHOOD AN ANDA SUIT SETTLES

	1	2	3	4	5	6	7	8
Lagged Growth in Ave. Total Generic Share	-2.57** (1.03)	-2.44** (1.04)	-2.48** (1.04)	-2.58** (1.04)				
Growth in Ave. Brand Sales					4.4e-10** (2.1e-10)	4.1e-10** (2.1e-10)	4.1e-10* (2.1e-10)	4.4e-10** (2.1e-10)
Case Terminated After *Actavis*?	-0.0463** (0.0206)	-0.0466** (0.0205)	-0.0480** (0.0207)	-0.0463** (0.0206)	-0.0381* (0.0211)	-0.0390* (0.0210)	-0.0400* (0.0213)	-0.0378* (0.0211)
Average Brand Sales	-0.1e-11 (3.5e-11)	-0.4e-11 (3.5e-11)	-0.2e-11 (3.5e-11)	-0.1e-11 (3.5e-11)	0.4e-11 (3.6e-11)	0.1 e-11 (3.6e-11)	0.3e-11 (3.6e-11)	0.4e-11 (3.6e-11)
Total Suits as Infringer		0.0030 (0.0028)				0.00309 (0.00282)		
Ave Suits as Infringer			0.0026 (0.0045)				0.00242 (0.00455)	
Growth in Ave. Suits as Infringer				0.0004 (0.0082)				-0.0032 (0.0082)
Firm Dummies	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Log-likelihood	-483	-482	-483	-483	-483	-483	-484	-484
Observations	1217	1217	1217	1217	1217	1217	1217	1217

*NOTE: SAMPLE OF 1217 ANDA LAWSUITS FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH 1 AND ONLY 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. DEPENDENT VARIABLE "SETTLEMENT" EQUAL TO "1" IF THE CASE ENDED IN EITHER "LIKELY SETTLEMENT" OR "CONSENT JUDGMENT: CLAIMANT WIN" ACCORDING TO LEX MACHINA'S CASE RESOLUTION DEFINITIONS AND EQUAL TO "0" OTHERWISE. MARGINAL EFFECTS REPORTED WITH DISCRETE CHANGE OF DUMMY VARIABLES FROM 0 TO 1. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * P < .10; ** P < .05; AND *** P <.01.

5. Win Rate

So far, we have found evidence that pure generic firms are more likely to challenge patents in ANDA lawsuits and that firms moving towards a purer generics business model are less likely to settle. We also find that when pure generic firms litigate and do not settle, they are more likely to win. Table 5 reports the number of wins and win rates of each of the 15 firms in our litigation analysis and the average win rates for the six mixed firms and the nine pure firms. While there is significant variation within the two groups, the pure generics firms are nearly fifteen percentage points more likely to win cases that do not settle (55.8% versus 41.1%).

TABLE 5. PATENT CHALLENGER WINS AND WIN RATES (2009–2017)

Firm	Number of Wins '09–'17	Win Rate '09–'17	Group
Allergan	21/58	36.2	Mixed
Teva	17/30	56.7	Mixed
Novartis-Sandoz	9/36	25	Mixed
Endo	9/20	45	Mixed
Pfizer	7/9	77.8	Mixed
Fresenius	2/5	40	Mixed
6 Mixed Firms	65/158	41.1%	
Mylan	23/45	51.1	Pure
Apotex	17/30	56.7	Pure
Lupin	11/19	57.9	Pure
Amneal	8/20	40	Pure
Dr Reddy	11/15	73.3	Pure
Aurobindo	6/12	50	Pure
Perrigo	2/6	33.3	Pure
Alvogen	7/7	100	Pure
West Ward	2/2	100	Pure
9 Pure Firms	87/156	55.8%	

*NOTE: POPULATION OF 314 ANDA LAWSUITS FILED BETWEEN 1/1/2009 AND 6/30/2017 DECIDED ON THE MERITS (OR ENDING IN A CONSENT JUDGMENT IN FAVOR OF THE ALLEGED INFRINGER) WITH AT LEAST 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. "WIN" DEFINED AS THE LAWSUIT ENDING IN EITHER A MERIT WIN OR A CONSENT JUDGMENT IN FAVOR OF THE ALLEGED INFRINGER ACCORDING TO LEX MACHINA'S CASE RESOLUTION DEFINITIONS.

This relationship between generics focus and litigation success is also present in firm-level business changes over time. Notably, in bivariate analysis—which investigates the relationship between only two variables—a 10% increase in the average total generic share during the quarter a lawsuit was filed is associated with a 4.6% greater chance of the challenging firm winning the lawsuit ($p = 0.001$).

We also ran a series of regressions reported in Table 6 that investigate the impact of total generic share on the probability of winning.[93] In specification 1, we control for a linear time trend in infringer wins. In specification 2, we

93. We define winning narrowly, including only lawsuits ending in a final merits decision favorable to one side, according to Lex Machina data. On the complexities of defining patent wins, see John R. Allison et al., *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769 (2014).

alternately control for whether the lawsuit terminated after *Actavis*. In the remaining specifications, we include both time controls.

Interestingly, we find in specifications 1 and 2 that neither time control is by itself a significant predictor of the probability the patent challenger wins. Because both have significance at the 90% confidence level when combined, these results weakly suggest that patent challengers won less frequently in the wake of *Actavis* despite a general trend towards challengers winning more frequently.

In specifications 4 through 7, we also control for whether the lawsuit was a declaratory judgment action, as well as the total number of ANDA lawsuits in which the entrant was a patent challenger. In specifications 5 through 7, we add controls for average pure generic sales. Finally, we control for firm-level effects of the two most litigious firms, Novartis-Sandoz and Allergan, in specifications 7 and 8.

In specifications 1 through 6, we find that higher total generic share is associated with a significantly higher chance of winning a case decided on the merits. We report those results in Table 6. However, we see that these effects disappear when controlling for both an Allergan and a Novartis-Sandoz firm effect in specification 7. The reason is that Novartis-Sandoz and Allergan have much lower generic shares than every other firm in the analysis except Pfizer, and both win cases on the merits less frequently.[94] Neither firm control by itself eliminates the significance of generic share.[95] Given the small number of firms in our analysis and fact that Allergan and Novartis-Sandoz individually demonstrate the general finding, we believe the results in Table 6 show a strong connection between generic share and entrants winning patent challenges on the merits.

94. Novartis-Sandoz has a win rate of 25%, and Allergan has a win rate of 36%—both below the 41% average win rate of the mixed firms. *See supra* Table 5. Further, Novartis-Sandoz and Allergan respectively have 44% and 51% lower total generic shares than the other fourteen firms in the analysis.

95. In bivariate regressions of the probability of winning on average generic share and alternately either Novartis-Sandoz or Allergan, average generic share is a statistically significant predictor of the patent challenger winning ($p = 0.006$ and $p = 0.014$, respectively).

TABLE 6. PROBIT ESTIMATION OF THE LIKELIHOOD AN ANDA ALLEGED INFRINGER WINS

	1	2	3	4	5	6	7
Ave. Total Generic Share	0.449*** (0.137)	0.468*** (0.135)	0.430*** (0.138)	0.367** (0.147)	0.331** (0.152)	0.482** (0.230)	0.221 (0.318)
Quarterly Count	0.00145 (0.00433)		0.00902 (0.00598)	0.0112* (0.0063)	0.0109* (0.0063)	0.0097 (0.0065)	0.0104 (0.0065)
Case Terminated After *Actavis*?		-0.102 (0.089)	-0.222* (0.111)	-0.253** (0.111)	-0.237* (0.114)	-0.240* (0.114)	-0.241* (0.114)
DJ Case?				-0.059 (0.140)	-0.048 (0.141)	-0.038 (0.141)	-0.023 (0.141)
Total Suits as Infringer				-0.0122 (0.0084)	-0.0118 (0.0085)	-0.0153 (0.0094)	-0.0139 (0.0095)
Average Pure Generic Sales					3.18e-11 (5.26e-11)	6.35e-11 (6.41e-11)	5.57e-11 (6.48e-11)
Growth Ave. Tot. Gen Share Lag 3					2.35 (2.08)	2.39 (2.09)	2.47 (2.09)
Novartis-Sandoz							-0.264 (0.210)
Allergan						0.163 (0.175)	-0.003 (0.240)
Log-likelihood	-112	-111	-110	-109	-108	-108	-107
Observations	172	172	172	172	172	172	172

*NOTE: SAMPLE OF 172 ANDA LAWSUITS FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH 1 AND ONLY 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. DEPENDENT VARIABLE "DWIN" EQUAL TO "1" IF THE CASE ENDED IN EITHER A MERIT WIN OR A CONSENT JUDGMENT IN FAVOR OF ALLEGED INFRINGER AND EQUAL TO "0" IF THE CASE ENDED IN A MERIT WIN FOR THE PATENT HOLDER. MARGINAL EFFECTS REPORTED WITH DISCRETE CHANGE OF DUMMY VARIABLES FROM 0 TO 1. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * P < .10; ** P < .05; AND *** P <.01.

To determine if there are other indications that more generic-focused firms are more likely to win lawsuits, we ran three additional series of regressions. In the first set, reported in specifications 1 through 4 in Table A.5, we simply removed the *Actavis* time control. Our results are the same as in Table 6, except that now the linear time trend is insignificant in all specifications. Average total generic share remains statistically significant in all specifications except 4, where we control for both Novartis-Sandoz and Allergan.

In the second set, reported in specifications 5 through 8 in Table A.5, we removed the *Actavis* time control and also substituted average total generic share for average generic share, which excludes IQVIA's category of "branded generic" sales. The results here are identical to those using average total generic share, except that the coefficient on average generic share is smaller, indicating that an increase in generic share excluding "branded generics" has a smaller impact on the chance a firm wins a lawsuit decided on the merits.

Finally, we tested whether firms with higher average brand sales at the time a suit is filed are more or less likely to win lawsuits decided on the merits. In Table A.6, we see that, except when controlling for both Allergan and Novartis-Sandoz firm effects, firms with higher brand sales are significantly more likely to lose their patent challenges decided on the merits. The magnitude of the effect is quite small, with roughly $100 million more in brand sales associated with a

1% decrease in the chance of winning the lawsuit. Nevertheless, the significance of brand sales provides further support for the idea that mixed firms act more "brand-like" and are thus less likely to win and fulfill the competition-inducing role intended for generics.

The important result of more successful litigation applies when examined from multiple measures of how "generic" a company is. This robust conclusion highlights that the companies that are most "generic" are more likely to win patent litigation. This has significant practical consequences. Most notably, it can result in generics entering the market earlier than they would have if they had lost or settled, which directly lowers prices for consumers.

F. MERGERS AND ACQUISITIONS

In addition to studying the connection between generic share and competitive behavior in litigation, we analyzed the competitive effects of major generic firm acquisitions. Specifically, we examined 9 of the 10 largest acquisitions of generic companies between 1995 and 2016.[96] We created four dichotomous merger variables to measure the effect of the mergers as a group on generic competition at various points in time during and after the merger.[97] The first two merger variables capture sustained effects and the second two capture effects focused around the time of the merger.

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96. *See* Marc-Andre Gagnon & Karena D. Volesky, *Merger Mania: Mergers and Acquisitions in the Generic Drug Sector from 1995 to 2016*, 13 GLOBAL HEALTH, at tbl.2 (Aug. 22, 2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567637/. We did not include Takeda's acquisition of Nycomed A/S in 2011 because Takeda is not one of the fifteen firms for which we collected ANDA data. The nine acquisitions in our analysis are:

1) Teva acquisition of Barr Pharmaceuticals (Announced 7/18/2008 and completed 12/23/2008);

2) Teva acquisition of IVAX Corp (Announced 7/25/2005 and completed 1/26/2006);

3) Teva acquisition of Allergan's generic drug business (Announced 7/27/2015 and completed 8/2/2016);

4) Pfizer acquisition of Hospira (Announced 2/5/2015 and completed 9/3/2015);

5) Endo acquisition of Par Pharmaceuticals (Announced 5/18/2015 and completed 9/28/2015);

6) Allergan acquisition of Actavis (Announced 4/25/2012 and completed 10/31/2012);

7) Novartis acquisition of Hexal (Announced 2/21/2005 and completed 6/7/2005);

8) Mylan acquisition of Merck Generics (Announced 5/12/2007 and completed 10/2/2007); and

9) Mylan acquisition of Abbott Laboratories' developed markets branded generics pharmaceuticals (Announced 7/14/2014 and completed 2/27/2015).

97. These variables are:

1) After Merger Announced—equal to "1" for the quarter the merger was announced through the end of the time series and equal to "0" before the announcement;

2) After Merger Completed—equal to "1" for the quarter the merger was completed through the end of the time series and equal to "0" before completion;

3) Within Two Years After Announced—equal to "1" for the quarter the merger was announced and for the next seven quarters and equal to "0" for all other quarters; and

4) Within Two Years After Completed—equal to "1" for the quarter the merger was completed and for the next seven quarters and equal to "0" for all other quarters.

As Table 7 reveals, combined firms that acquired a generic competitor brought more ANDA challenges than the prior total of the two companies that merged. Their generic share also rose. Recall that the "firms" in our time series data are constructs that in prior years aggregate the sales of separate companies that would eventually merge before 2017. Thus, these results indicate that after a firm with an existing generics business acquires another larger generic firm, the resulting firm more aggressively litigates brand firm patents and also has a higher generic share of sales than the two firms had before the merger.

TABLE 7. IMPACT OF TOP GENERIC FIRM MERGERS ON LITIGATION AND GENERIC SHARE

	Dependent Variable = Ave. Suits as Infringer				Dependent Variable = Ave. Total Generic Share			
	1	2	3	4	5	6	7	8
After Merger Announced	1.43**				0.022**			
	(0.59)				(0.011)			
After Merger Completed		1.65***				0.028***		
		(0.59)				(0.011)		
E W/n 2 Yrs After Announced			0.839**				0.020***	
			(0.400)				(0.007)	
W/n 2 Yrs After Completed				0.883**				0.011
				(0.406)				(0.008)
Quarterly Count	0.050***	0.044**	0.077***	0.075***	0.0016***	0.0015***	0.0020***	0.0020***
	(0.017)	(0.018)	(0.012)	(0.012)	(0.0003)	(0.0003)	(0.0002)	(0.0002)
Teva?	-3.76***	-3.94***	-3.14***	-3.18***	0.608***	0.606***	0.618***	0.619***
	(0.74)	(0.75)	(0.68)	(0.68)	(0.014)	(0.014)	(0.013)	(0.013)
Pfizer?	-9.25***	-9.16***	-9.77***	-9.77***	0.118***	0.121***	0.110***	0.110***
	(0.76)	(0.76)	(0.73)	(0.73)	(0.014)	(0.014)	(0.014)	(0.014)
Endo?	-6.70***	-6.67***	-7.28***	-7.25***	0.553***	0.556***	0.545***	0.545***
	(0.76)	(0.75)	(0.72)	(0.72)	(0.014)	(0.014)	(0.014)	(0.014)
Mylan?	-4.47***	-4.64***	-4.06***	-4.09***	0.676***	0.675***	0.684***	0.684***
	(0.67)	(0.68)	(0.65)	(0.65)	(0.013)	(0.013)	(0.012)	(0.012)
Novartis-Sandoz?	-5.69***	-5.92***	-4.77***	-4.79***	0.231***	0.229***	0.246***	0.245***
	(0.77)	(0.79)	(0.69)	(0.65)	(0.014)	(0.014)	(0.013)	(0.013)
Constant	7.40***	7.78***	6.31***	6.42***	-0.110***	-0.108***	-0.132***	-0.131***
	(1.05)	(1.08)	(0.69)	(0.68)	(0.020)	(0.020)	(0.017)	(0.017)
R-squared	0.51	0.052	0.051	0.051	0.96	0.96	0.96	0.96
Observations	240	240	240	240	252	252	252	252

*NOTE—QUARTERLY DATA FOR 1/1/2009 THROUGH 6/30/2017 FOR THE 6 IQVIA FIRMS INVOLVED IN A TOP-10 ACQUISITION BETWEEN 1995 AND 2016. DEPENDENT VARIABLE "AVE SUITS AS INFRINGER" IN OLS REGRESSIONS EQUAL TO THE NUMBER OF ANDA LAWSUITS FILED WITH THE FIRM AS AN ALLEGED INFRINGER, AVERAGED OVER THE CURRENT AND PRIOR THREE QUARTERS. DEPENDENT VARIABLE "AVE TOTAL GENERIC SHARE" IN OLS REGRESSIONS EQUAL TO THE SHARE OF TOTAL SALES NOT ATTRIBUTABLE TO BRANDED SALES ACCORDING TO IQVIA'S DEFINITION, AVERAGED OVER THE CURRENT AND PRIOR THREE QUARTERS. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * P < .10; ** P < .05; AND *** P <.01.

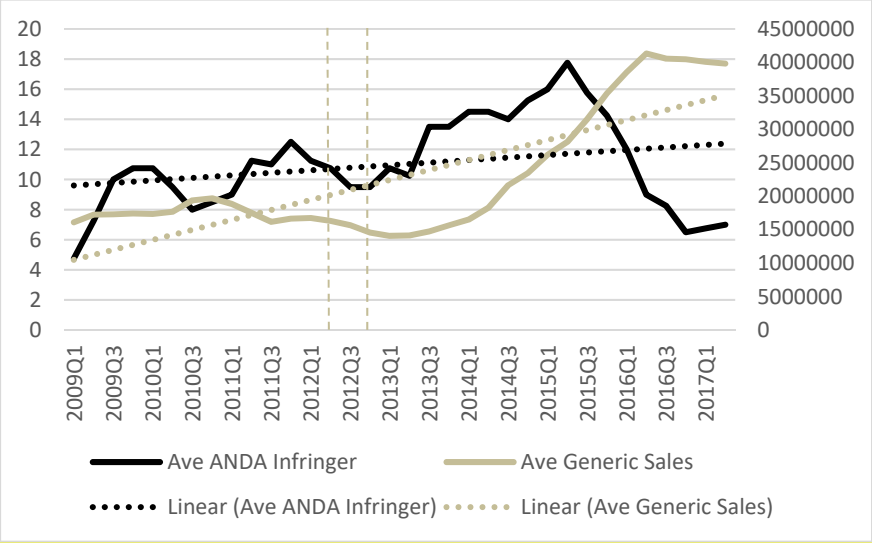
How much have these mergers benefitted generic competition? The six acquiring firms in our analysis were patent challengers in an average of 229 lawsuits per firm during the 34 quarters between 2009 and the second quarter of 2017, or 6.74 cases per firm, per quarter. Specification 4 in Table 7 reveals an average effect per quarter during the first two years after completion of the merger of approximately 0.9 additional cases per quarter or 7 cases over the two-year period. This amounts to about 13% more litigation over this two-year stretch than the average firm engaged in per quarter over the period we study.

In specification 6, we see that merger completion is associated with a 2.8% increase in total generic share. The average total generic share over the period

of our analysis for these six firms is 55.5%. These mergers are thus associated with about a 5% increase in generic share for the combined firm over the average for the two firms that merged. Both this and the estimate of the impact of merger on litigation seem to be economically important effects.

One example of the phenomenon of the combined company becoming more "generic" as a result of the merger is presented in Figure 13, which shows that Watson's acquisition of Actavis was followed by increased litigation and sales shortly after the April 2012 announcement and October 2012 competition of the acquisition.

FIGURE 13. ALLERGAN (INCLUDING WATSON AND ACTAVIS) ANDA LITIGATION AND PURE GENERIC SALES



*NOTE: QUARTERLY "AVE ANDA INFRINGER" EQUAL TO THE SUM OF ANDA LAWSUITS FILED WITH ANY ALLERGAN FIRM LISTED IN APPENDIX TABLE A.2 AS AN ALLEGED INFRINGER, AVERAGED OVER THE CURRENT AND PRIOR THREE QUARTERS. "AVE GENERIC SALES" EQUAL TO THE COMBINED ALLERGAN (INCLUDING ACTAVIS AND WATSON) SALES ATTRIBUTABLE TO "GENERIC" SALES ACCORDING TO IQVIA'S DEFINITION, AVERAGED OVER THE CURRENT AND PRIOR THREE QUARTERS. LINEAR TRENDS IN BOTH "AVE ANDA INFRINGER" AND "AVE GENERIC SALES" INCLUDED. VERTICAL LINES INDICATED THE DATE WATSON'S ACQUISITION OF ACTAVIS WAS ANNOUNCED (4/25/2012) AND COMPLETED (10/31/2012).

We emphasize that these are mergers among mixed and generic firms only. Mergers among branded firms, or between mixed and branded firms that increase their brand share, presumably would have the opposite effect.

IV. IMPLICATIONS

How pure a generic firm is affects how aggressively it pushes to enter markets. That fact has implications for how we set antitrust policy. Society benefits from more frequent, more aggressive, and more successful generic challenges to weak pharmaceutical patents. Pharmaceutical companies have significant regulatory incentives to assert weak patents and engage in other forms of regulatory gaming to artificially extend their market exclusivity.[98] Encouraging challenges to those patents is important. Once a generic has brought a challenge, we want that challenge to be resolved on the merits and lead to early generic entry if the patent is in fact invalid. Our findings suggest two areas of improved antitrust analysis: settlements and mergers. And they lead to insights on the U.S. adversary system.

A. SETTLEMENTS

For at least 20 years, brand firms paid generic companies to stay out of the market once those generics had brought ANDA challenges.[99] Many—including the drafters of the Hatch-Waxman Act—have lamented how the patent-challenge procedure is not working as intended.[100] Our findings are consistent in highlighting how effective challenges require not just bringing ANDA challenges, but seeing them through to completion.

We have shown that pure generic firms are more likely to take their challenges to judgment and win when they do. That is important. And that was a central purpose of the Hatch-Waxman Act. Although we can't prove causation, there is a plausible mechanism for *why* pure generic firms fulfill their intended role by litigating and winning. These companies benefit from changes in the law that make it easier to challenge patents. In contrast, mixed firms might benefit from those changes in the case before them, but such a benefit is more muted. Indeed, because branded drugs are more lucrative than generic drugs, even a firm that has more generic drugs than branded drugs may make most of its money from the branded drugs. As a result, even if these firms would like to make more money from generics, they will not do so if it makes their branded

98. *E.g.*, F.T.C. v. Actavis, Inc., 570 U.S. 136, 140–41 (2013); New York *ex rel.* Schneiderman v. Actavis, Inc., 787 F.3d 638, 642–43 (2d Cir. 2015); Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687 (2009).

99. *E.g.*, Press Release, Fed. Trade Comm'n, FTC Charges Drug Manufacturers with Stifling Competition in Two Prescription Drug Markets (Mar. 16, 2000), https://www.ftc.gov/news-events/press-releases/2000/03/ftc-charges-drug-manufacturers-stifling-competition-two.

100. *See* 148 CONG. REC. S7566 (daily ed. July 30, 2002) (statement of Sen. Hatch) (finding pay-for-delay settlements "appalling" and "conced[ing], as a drafter of the law, that we came up short in our draftsmanship"); Motion and Brief of Representative Henry A. Waxman as Amicus Curiae in Support of Petitioner, F.T.C. v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026, at *3 (noting that the agreements were an "unfortunate, unintended consequence" of the Act that "turned the . . . legislation on [its] head"); *see also* Transcript of Oral Argument at 11, 35, *Actavis*, 570 U.S. 136 (No. 12-416) (stating, as Justice Scalia put it, that "Hatch-Waxman made a mistake" and, as Justice Kagan lamented the Act's "glitch" that once the first generic filer "is bought off, nobody else has the incentive" to challenge patents).

business—the real cash cow—more difficult. As one industry executive put it to us, "If I am earning more on my patented products than on my generics, I will consider defending my patents to be a higher priority than attacking yours."[101] This effect may be particularly pronounced for mixed companies like Allergan, Pfizer, and Novartis-Sandoz that make most of their money from their brand business.

Mixed firms might worry us for other reasons. As Scott Hemphill has noted, pharmaceutical companies that engage in anticompetitive settlements of patent lawsuits by paying generic competitors to stay out of the market have a tendency to try to hide those payments, burying them in complex transactions or disguising what is really a payment for delayed entry as an (inflated) payment for something else.[102] That tendency will only grow greater after *Actavis* makes it harder to get away with explicit payments.[103] Those complex, multi-product deals are difficult to untangle because it is hard to know what each component of the deal is really worth. That may make it harder to challenge complicated anticompetitive deals on antitrust grounds.[104]

Mixed firms can sign more complex deals and therefore hide reverse payments more easily. For example, the settling parties in *Actavis* itself tried to pretend that a large payment for delay was really an effort to buy a generic's "help" in marketing a product that had been marketed for years without that help.[105] The FTC and the Court rightly rejected that claim as implausible. But such an agreement is much less implausible if the company agreeing to co-market the drug is also a branded pharmaceutical firm with its own marketing and distribution channels. Similarly, a mixed firm suing another mixed firm could disguise a reverse payment by agreeing to settle disputes that go both ways, leaving the agencies and plaintiffs unable to know for sure how much money was actually changing hands and what it was for. Supporting pure generics makes this sort of gamesmanship less likely and easier to detect. In fact, pharmaceutical firms may even be buying potential competitors to shut them down—so-called "killer acquisitions."[106]

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101. Email from anonymous source to Mark Lemley (May 1, 2019) (on file with author). During various personal conversations between anonymous sources and Mark Lemley, this idea was echoed by a former head of intellectual property at a mixed company—who was told by the business folks not to make arguments on the generic side that could hurt the brand business—and a former lawyer at an outside firm representing a mixed company—who was careful to coordinate arguments in the firm's generic cases so that they wouldn't interfere with the more lucrative, brand-side cases.

102. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 632 (2009); *see also* Michael A. Carrier, *Pharmaceutical Antitrust Complexity*, 2 CPI ANTITRUST CHRON., Nov. 2014, at 1, 12, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2530169.

103. *Actavis*, 570 U.S. at 158–59.

104. Hemphill, *supra* note 102, at 632; *see also* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249 (2019) (highlighting the complexity of settlements).

105. *Actavis*, 570 U.S. at 156.

106. Colleen Cunningham, Florian Ederer & Song Ma, Killer Acquisitions (Sept. 12, 2018) (unpublished Working Paper), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3241707. That coexists with acquisition or in-licensing from startups as a pipeline for new drugs, as established pharmaceutical companies are

B. MERGERS

Our findings also have implications for merger policy.[107] We should be more welcoming of market changes that create purer generics and more skeptical of market changes that dilute generics by mixing them with brand sales. That may point in favor of allowing some mergers and challenging others, not always in the obvious way.

How, for example, should the agencies analyze the merger of a pure brand firm and a pure generic firm? It would seem like that would create a mixed firm, which could have negative effects on patent challenges. But when a mixed firm merges with a pure generic firm, the expected effects on challenges may depend on the existing shares of the mixed firm and the relative size of the two firms. A sufficiently large generic business may "pull" a mixed firm towards the generic side and encourage more robust challenges by the merged firm. By contrast, a sufficiently large brand business may push the merged generic firm in the opposite direction. In settings in which the merging firms are at least potential competitors, the antitrust authorities should consider not only the nature, but also the relative size, of the merging firms in analyzing the effects on generic challenges. Our data could also be used in predictive econometric models employed in mergers, such as those used for unilateral effects analysis (in which competition between previously rival products is eliminated, which could lead to higher prices) and for analyzing the effects of partial ownership.[108]

There is precedent for such an examination in existing merger analysis. Antitrust agencies considering mergers can take into account the involvement of a "maverick" that "plays a disruptive role in the market to the benefit of customers."[109] As the antitrust agencies have explained, mergers involving mavericks "can involve the loss of actual or potential competition."[110] Along similar lines, a company that "has often resisted otherwise prevailing industry norms to cooperate on price setting or other terms of competition" can play a vital role in bringing about competition.[111]

Pure generic firms can play a role in the competitive landscape similar to mavericks. As our data show, they are more likely to challenge weak patents, less likely to abandon those challenges, and more likely to win them. They are therefore more likely to open up competition in markets that would otherwise be

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increasingly relying on outside firms as a source for new drugs. Barak Richman, Will Mitchell, Elena Vidal & Kevin Schulman, *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L.J. 787, 791–92 (2017).

107. Scott Hemphill would bar complex deals altogether. *See* Hemphill, *supra* note 102, at 669. We think that would be difficult to administer and could preclude some deals that enhance social welfare. But at a minimum the law should take the opportunities it has to reduce the ability to enter into such deals.

108. In fact, even the D.C. Circuit in *United States v. AT&T, Inc*., though it ruled against the government, accepted reliance on "Nash bargaining theory" (analyzing two-party bargaining situations) to predict merger-related price effects. 916 F.3d 1029, 1039–40 (D.C. Cir. 2019).

109. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 2.1.5 (2010).

110. *Id.*

111. *Id.*

locked up by invalid patents. Because of its importance, we believe the potential to dilute the incentives of generic firms to pursue vigorous challenges should be considered as a factor in evaluating mergers. For example, in applying this analysis, the antitrust agencies could consider how "pure" the generic company is and how vigorously it contested patents in the years before the merger.

Even if this factor does not end up being determinative in this setting, it still can matter in crafting merger remedies. The antitrust agencies regularly approve mergers subject to conditions, including divestiture of some or all of the assets of one or both of the firms.[112] The agencies could use that power to preserve some pure generic markets by requiring the sale of certain drugs or business units as a condition of merger approval. Such a remedy could be particularly effective if two mixed firms merge, as divestiture could unlock generic drugs from mixed firms that might not otherwise have strong incentives to push them. And in doing so, it could ensure that the generic drugs find a home in pure generic companies that have more robust incentives to vigorously serve the purpose for which generics were intended.

C. ADVERSARIES

Finally, our study offers an interesting window into the adversary system. Some, including one of the authors, have argued that companies with balanced interests might set more reasonable policies than companies that know their interests are all on one side.[113] And that is true when the goal is to reach a shared middle ground, as in a settlement or a neutral policy. But if the goal is to reach the right outcome in court, strong adversaries do better than those with conflicted interests.[114] We think that is the right goal here, because the "middle ground" between brand owners and generics is rarely a true middle. As the reverse-payment settlements demonstrate, all too often it is an agreement to split the profits made at the expense of consumers who aren't at the bargaining table. Our evidence suggests that parties with diverse interests are likely to fight harder to prevail. That is consistent with literature that suggests that common share ownership between brand owners and generics reduces the likelihood of generic entry,[115] and increases the likelihood of an anticompetitive reverse-payment

112. FEDERAL TRADE COMM'N, THE FTC'S MERGER REMEDIES 2006–2012 (2017), https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf (explaining a 1999 study on divestiture and summaries of orders issued subsequent to the study).

113. *See, e.g.*, Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CALIF. L. REV. 1889 (2002) (offering an overview on standard-setting organizations, and concluding that some adversity between parties is healthy to facilitate intellectual property policy); *cf.* Stephen McG. Bundy & Einer Richard Elhauge, *Do Lawyers Improve the Adversary System? A General Theory of Legal Advice and Its Regulation*, 79 CALIF. L. REV. 313 (1991) (questioning the value of adversarial argument in the search for truth).

114. On how conflicted interests can affect business decision-making more generally, see Einer Elhauge, *Horizontal Shareholding*, 129 HARV. L. REV. 1267 (2016).

115. Melissa Newham, Jo Seldeslachts & Albert Banal-Estanol, Common Ownership and Market Entry: Evidence from the Pharmaceutical Industry 33–34 (Sept. 5, 2018) (unpublished discussion paper), https://www.diw.de/documents/publikationen/73/diw_01.c.591375.de/dp1738.pdf.

settlement.[116] Where public policy encourages resolution of legal disputes, not settlement, we want the parties to be true adversaries.

Those adversaries might come from unlikely places. If generic companies cannot be relied upon to aggressively challenge patents because they have conflicts of interest, we might permit or even encourage challenges from other sources: consumer groups, public interest organizations, and even the much-reviled short-seller Kyle Bass.[117] Federal Circuit standing doctrine will prevent non-competitors from suing to invalidate patents, though it probably shouldn't. But they can bring inter partes review proceedings in the Patent Trial & Appeal Board.[118]

CONCLUSION

The "generics" industry is not as monolithic as it seems, consisting of three categories of companies that rely to varying degrees on branded drugs. Each of these categories is doing quite well, notwithstanding protestations of doom we've heard from all sides.

Which box a company is in affects its behavior. Mixed generic companies that play both sides have mixed incentives. As those companies become more brand-like, they are less likely to serve the competition-promoting function intended by the Hatch-Waxman Act because they settle more patent challenge cases, win fewer, and (controlling for firm size) challenge drug patents in fewer lawsuits. Playing both sides presents significant concerns for competition policy.

The antitrust agencies should take market structure into account in evaluating pharmaceutical mergers and patent settlements. In doing so, they should encourage pure generics with the incentive to bring robust challenges to drug patents. The payoff is clear, as these challenges would ensure that generic companies play the role they were intended to: lowering high drug prices.

116. Jin Xie & Joseph Gerakos, *Institutional Cross-Holdings and Generic Entry in the Pharmaceutical Industry* 31 (The Chinese Univ. of H.K. and Tuck Sch. of Bus. at Dartmouth Coll., Working Paper No. 26503416, 2018), http://abfer.org/media/abfer-events-2018/annual-conference/accounting/AC18P5001_Institutional_Cross-holdings_and_Generic_Entry.pdf.

117. Jeffrey Kuo & Afia Naaz, *Attack on Pharma Patents: Checking in on the Kyle Bass IPRs*, POLSINELLI (June 2, 2017), https://www.polsinellionpostgrant.com/blog/2017/6/2/attack-on-pharma-patents-checking-in-on-the-kyle-bass-iprs.

118. 35 U.S.C. § 311 (2018). Further, existing research shows that 8% of the patents challenged in inter partes review from its beginning through January 2017 are pharmaceutical patents. Brian J. Love, Shawn Miller & Shawn Ambwani, *Determinants of Patent Quality: Evidence from Inter Partes Review Proceedings*, 90 U. COLO. L. REV. 67, 132 tbl.7 (2019). Future research should investigate whether pure or mixed generic firms have been more aggressive and successful in bringing these challenges.

APPENDIX

TABLE A.1. IQVIA FIRMS, TOTAL GENERIC SHARES, AND GROUP

Firm	Total Generic Share Q1 1992 (or earliest available[+])	Total Generic Share Q2 2017	Group
Amgen	1.38%	0.00%	Brand
Boehringer Ingelheim	0.11%	0.00%	Brand
Gilead Sciences	0.00%[+]	0.12%	Brand
Merck	7.47%	0.16%	Brand
GlaxoSmithKline	1.71%	0.21%	Brand
Astrazeneca	8.69%	0.28%	Brand
Celgene	100.0%[+]	0.83%	Brand
Bristol-Myers Squibb	5.66%	1.23%	Brand
Astellas	25.1%	2.44%	Brand
Johnson & Johnson	8.50%	2.48%	Brand
Sanofi Aventis	24.2%	3.18%	Brand
Novo Nordisk	100.0%[+]	3.99%	Brand
Takeda	0.00%[+]	4.05%	Brand
Lilly	0.51%	4.77%	Brand
Hoffmann-La Roche	2.16%	5.40%	Brand
Abbvie	21.2%	9.52%	Brand
Pfizer	8.43%	18.7%	Mixed
Novartis-Sandoz	50.2%	32.4%	Mixed
Allergan	36.1%	35.3%	Mixed
Valeant	6.99%	41.4%	Mixed
Shire	40.1%	47.0%	Mixed
Teva	87.8%	68.2%	Mixed
Horizon	0.00%	71.7%	Mixed
Fresenius	42.7%	79.7%	Mixed
Endo	16.0%	89.1%	Mixed
Lupin	0.00%	95.2%	Generic
Mylan	40.9%	95.6%	Generic
Mallinckrodt	4.61%	97.2%	Generic
Apotex	0.00%[+]	98.4%	Generic
Prasco	0.00%	98.6%	Generic
Dr Reddy's	0.00%	99.7%	Generic
Perrigo	6.39%	99.7%	Generic
Alvogen	6.85%	99.8%	Generic
West Ward	68.2%	99.8%	Generic
Amneal	100.0%	100.0%	Generic
Aurobindo	100.0%[+]	100.0%	Generic

*NOTE: "TOTAL GENERIC SHARE" EQUAL TO THE SHARE OF TOTAL SALES NOT ATTRIBUTABLE TO BRANDED SALES ACCORDING TO IQVIA'S DEFINITION. QUARTERLY SALES AND SHARE DATA AVAILABLE FROM Q1 1992 THROUGH Q2 2017 FOR MOST FIRMS EXCEPT THE FIRST QUARTER OF SALES IN IQVIA'S DATABASE IS Q3 1996 FOR GILEAD SCIENCES, Q2 1997 FOR NOVO NORDISK, Q2 1995 FOR TAKEDA, Q4 1998 FOR CELGENE, Q1 1993 FOR APOTEX, AND Q1 2005 FOR AUROBINDO.

TABLE A.2. LIST OF ACQUIRED COMPANIES INCLUDED IN IQVIA FIRM LAWSUIT TIME SERIES

IQVIA Firm	Group	Acquired Firms
Allergan	Mixed	Actavis Warner Chilcott Watson Pharmaceuticals
Teva	Mixed	Auspex Pharmaceuticals Barr Pharmaceuticals Cephalon, Inc. IVAX Corporation Novopharm NuPathe Inc.
Novartis-Sandoz	Mixed	Eon Labs Inc. Fougera Pharmaceuticals Inc.
Endo	Mixed	Auxillium Pharmaceuticals, LLC Indevus Pharmaceuticals, Inc. Paladin Labs Inc. Par Pharmaceutical Companies Inc.
Pfizer	Mixed	Anacor Pharmaceuticals, Inc. Hospira Lederle Laboratories Wyeth Pharmaceuticals
Fresenius	Mixed	APP Pharmaceuticals Dabur Pharma
Mylan	Pure	Agila Specialties Famy Care Ltd. Matrix Laboratories
Apotex	Pure	None
Lupin	Pure	Gavis Pharmaceuticals Novel Laboratories, Inc.
Amneal	Pure	Interpharm Holdings
Dr. Reddy	Pure	None
Aurobindo	Pure	None
Perrigo	Pure	Agis Industries Omega Pharmaceutical Inc. Paddock Laboratories, Inc. PBM Pharmaceuticals, Inc. Rosemont Pharmaceuticals Ltd. Unico Pharmaceuticals
Alvogen	Pure	Lotus Pharmaceuticals, Inc.
West Ward	Pure	Bedford Laboratories

*NOTE: ACQUIRED FIRMS INCLUDE ALL COMPANIES THAT WERE BOTH ACQUIRED BY ONE OF THE FIFTEEN IQVIA FIRMS AND THAT WERE ALLEGED INFRINGERS IN AT LEAST ONE ANDA LAWSUIT BETWEEN 2000 AND 2017.

TABLE A.3. OLS REGRESSION OF GROWTH OF QUARTERLY ANDA LAWSUITS AS INFRINGER (2009–2017)

	1	2	3	4	5	6
Lagged Growth in Ave. Total Generic Share	1.896*	1.776*	1.862*	1.923*	2.254**	
	(1.011)	(1.011)	(1.014)	(1.012)	(1.108)	
Ave. Pure Generic Sales ($MM)			0.000018	0.000004	-0.000063	
			(0.000046)	(0.000056)	(0.000181)	
Quarterly Count		-0.0018	-0.0020	-0.0019	-0.0013	
		(0.0017)	(0.0017)	(0.0017)	(0.0024)	
Mixed Firm?				0.0474		
				(0.0837)		
Firm Dummies	No	No	No	No	Yes	
Constant	0.053*	0.150*	0.148*	0.139*	0.040	
	(0.031)	(0.084)	(0.084)	(0.082)	(0.185)	
R-squared	0.002	0.004	0.004	0.004	0.008	
Observations	805	805	805	805	805	

*NOTE: QUARTERLY DATA FOR ANDA LITIGATION FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. DEPENDENT VARIABLE "GINFRINGEAVE" EQUAL TO THE ONE QUARTER CHANGE IN THE AVERAGE NUMBER OF ANDA LAWSUITS FILED WITH THE FIRM AS AN ALLEGED INFRINGER. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * P < .10; ** P < .05; AND *** P <.01.

TABLE A.4. PROBIT ESTIMATION OF THE LIKELIHOOD AN ANDA SUIT SETTLES

	1	2	3	4	5	6	7	8
Lagged Growth in Ave. Total Generic Share	-2.03**	-1.96**	-2.05**	-2.02**				
	(0.98)	(0.98)	(0.99)	(0.98)				
Growth in Ave Brand Sales					5.4e-10***	5.4e-10***	5.7e-10***	5.3e-10***
					(2.0e-10)	(2.1e-10)	(2.1e-10)	(2.1e-10)
Quarterly Count	0.003***	0.003***	0.003***	0.003***	0.004***	0.004***	0.004***	0.004***
	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)
Average Brand Sales	-1.0e-13	-1.3e-12	-1.4e-14	-2.42e-13	1.6e-11	1.7e-11	2.2e-11	1.7e-11
	(3.4e-11)	(3.4e-11)	(3.4e-11)	(3.43e-11)	(3.6e-11)	(3.7e-11)	(3.8e-11)	(3.6e-11)
Total Suits as Infringer		0.0017				-0.0002		
		(0.0028)				(0.0022)		
Ave Suits as Infringer			-0.001				-0.0017	
			(0.004)				(0.0036)	
Growth in Ave Suits as Infringer				-0.001				0.0015
				(0.008)				(0.0064)
Firm Dummies	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Log-likelihood	-469	-469	-469	-469	-480	-480	-480	-480
Observations	1217	1217	1217	1217	1217	1217	1217	1217

*NOTE: SAMPLE OF 1217 ANDA LAWSUITS FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH 1 AND ONLY 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. DEPENDENT VARIABLE "SETTLEMENT" EQUAL TO "1" IF THE CASE ENDED IN EITHER "LIKELY SETTLEMENT" OR "CONSENT JUDGMENT: CLAIMANT WIN" ACCORDING TO LEX MACHINA'S CASE RESOLUTION DEFINITIONS AND EQUAL TO "0" OTHERWISE. MARGINAL EFFECTS REPORTED WITH DISCRETE CHANGE OF DUMMY VARIABLES FROM 0 TO 1. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * $p < .10$; ** $p < .05$; AND *** $p < .01$.

TABLE A.5. PROBIT ESTIMATION OF THE LIKELIHOOD AN ANDA ALLEGED INFRINGER WINS

	1	2	3	4	5	6	7	8
Ave Pure Generic Share					0.276** (0.120)	0.330*** (0.127)	0.444** (0.224)	0.057 (0.279)
Ave. Total Generic Share	0.427*** (0.150)	0.392** (0.155)	0.544** (0.238)	0.167 (0.325)				
Quarterly Count	0.003 (0.005)	0.003 (0.005)	0.002 (0.005)	0.003 (0.005)	0.004 (0.005)	0.0019 (0.0047)	0.0009 (0.0051)	0.002 (0.005)
DJ Case?	-0.436*** (0.106)	-0.429*** (0.109)	-0.423*** (0.112)	-0.418** (0.115)	-0.425*** (0.109)	-0.419** (0.114)	-0.411** (0.117)	-0.414** (0.119)
Total Suits as Infringer	-0.008 (0.008)	-0.007 (0.009)	-0.011 (0.009)	-0.009 (0.010)	-0.007 (0009)	-0.006 (0.009)	-0.007 (0.009)	-0.006 (0.010)
Average Pure Generic Sales		2.52e-11 (5.33e-11)	5.60e-11 (6.47e-11)	4.32e-11 (6.57e-11)		3.01e-11 (5.16e-11)	5.78e-11 (6.86e-11)	2.58e-11 (7.07e-11)
Growth Ave. Pure Gen. Share Lag 2						-7.01* (3.73)	-7.04* (3.73)	-7.33* (3.82)
Growth Ave. Tot. Gen. Share Lag 3		2.09 (2.02)	2.11 (2.03)	2.17 (2.03)				
Sandoz				-0.368* (0.172)				-0.435** (0.125)
Allergan			0.163 (0.183)	-0.086 (0.244)			0.139 (0.219)	-0.212 (0.262)
Log-likelihood	-106	-104	-104	-102	-106	-104	-104	-101
Observations	165	165	165	165	165	165	165	165

*NOTE: SAMPLE OF 172 ANDA LAWSUITS FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH 1 AND ONLY 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. DEPENDENT VARIABLE "DWIN" EQUAL TO "1" IF THE CASE ENDED IN EITHER A MERIT WIN OR A CONSENT JUDGMENT IN FAVOR OF ALLEGED INFRINGER AND EQUAL TO "0" IF THE CASE ENDED IN A MERIT WIN FOR THE PATENT HOLDER. MARGINAL EFFECTS REPORTED WITH DISCRETE CHANGE OF DUMMY VARIABLES FROM 0 TO 1. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * P < .10; ** P < .05; AND *** P <.01.

TABLE A.6. PROBIT ESTIMATION OF THE LIKELIHOOD AN ANDA ALLEGED INFRINGER WINS

	1	2	3	4	5	6
Ave Brand Sales	-0.000086***	-0.000083***	-0.000076**	-0.000079**	-0.000073**	-0.000023
(Millions)	(0.000032)	(0.000032)	(0.000033)	(0.000033)	(0.000037)	(0.000049)
Quarterly Count		0.00297	0.00371	0.00370	0.00386	0.00299
		(0.00439)	(0.00443)	(0.00443)	(0.00446)	(0.00450)
DJ Case?		0.014 (0.134)	-0.033	-0.029	-0.034	-0.013
			(0.139)	(0.139)	(0.140)	(0.140)
Total Suits as			-0.0138*	-0.0140*	-0.0124	-0.0106
Infringer			(0.0078)	(0.0079)	(0.0091)	(0.0092)
Average Pure				0.000047	0.000035	0.000025
Generic Sales				(0.000050)	(0.000062)	(0.000063)
(Millions)						
Allergan					-0.046	-0.149
					(0.143)	(0.156)
Sandoz						-0.321
						(0.179)
Log-likelihood	-114	-114	-112	-112	-112	-111
Observations	172	172	172	172	172	172

*NOTE: SAMPLE OF 172 ANDA LAWSUITS FILED BETWEEN 1/1/2009 AND 6/30/2017 WITH 1 AND ONLY 1 OF THE 15 IQVIA FIRMS LISTED IN TABLE 1 AS AN ALLEGED INFRINGER. DEPENDENT VARIABLE "DWIN" EQUAL TO "1" IF THE CASE ENDED IN EITHER A MERIT WIN OR A CONSENT JUDGMENT IN FAVOR OF ALLEGED INFRINGER AND EQUAL TO "0" IF THE CASE ENDED IN A MERIT WIN FOR THE PATENT HOLDER. MARGINAL EFFECTS REPORTED WITH DISCRETE CHANGE OF DUMMY VARIABLES FROM 0 TO 1. ROBUST STANDARD ERRORS INCLUDED IN PARENTHESIS. * P < .10; ** P < .05; AND *** P <.01.