

# THE UNTOLD EPIPEN STORY: HOW MYLAN HIKED PRICES BY BLOCKING RIVALS

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## INTRODUCTION

In the summer of 2016, Mylan found itself under fire for high EpiPen prices. Between 2009 and 2016, Mylan raised the price of this life-saving device, which delivers epinephrine to treat anaphylaxis shock, 15 times, resulting in an increase of more than 400%.<sup>1</sup> The medicine in an EpiPen costs only pennies per dose.<sup>2</sup> But a pack of two, which needs to be replaced each year and which families buy multiples of for various locations, costs more than \$600.<sup>3</sup> The consequences of these prices are felt in all corners, as life-threatening allergies from peanuts, shellfish, and other substances affect fifteen million Americans and 1 in 13 children.<sup>4</sup>

The uproar has thundered across the spectrum.

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<sup>1</sup> Sy Mukherjee, *How Mylan Got Away With Its Enormous Price Hike for the EpiPen*, FORTUNE, Aug. 22, 2016, <http://fortune.com/2016/08/22/mylan-epipen-price-hike-monopoly/> [<http://perma.cc/CKN9-W8EP>]; Matt Egan, *How EpiPen Came to Symbolize Corporate Greed*, CNN MONEY, Aug. 29, 2016, <http://money.cnn.com/2016/08/29/investing/epipen-price-rise-history/> [<http://perma.cc/JF48-5KQ6>]; Anna Edney & Cynthia Koons, *Mylan Plans Generic EpiPen to Quell Outcry Over \$600 Cost*, BLOOMBERG, Aug. 29, 2016, <http://www.bloomberg.com/news/articles/2016-08-29/mylan-to-sell-generic-epipen-to-quell-outcry-over-600-cost> [<https://perma.cc/JB86-TSLY>].

<sup>2</sup> Letter from Jason Chaffetz (R-UT) & Elijah E. Cummings (D-MD) to Heather Bresch, Aug. 29, 2016, <http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2016-08-29%20JC%20and%20EEC%20to%20Bresch-Mylan%20EpiPen%20Pricing.pdf> [<https://perma.cc/42HM-UCWV>] (questioning price increase and commencing congressional investigation).

<sup>3</sup> *Id.*

<sup>4</sup> Mukherjee, *supra* note 1.

Politicians from both parties have expressed concern,<sup>5</sup> including through vigorous criticism at a September 2016 hearing.<sup>6</sup> And the company has been accused of “corporate greed,”<sup>7</sup> with particular ire directed towards CEO Heather Bresch.<sup>8</sup>

Many reasons have been offered for the price hike. Some have blamed the FDA for a slow-moving generic approval process.<sup>9</sup> Others have lamented a broken healthcare system.<sup>10</sup> And Bresch has indicted a convoluted distribution chain, with multiple parties each taking a portion of the profits.<sup>11</sup>

Missing in this debate has been *Mylan’s* role in clearing the field of present and future competitors. Piecing together this stealth campaign in outlining a potential antitrust case is the goal of this Essay. After providing a history of the product, it investigates Mylan’s blocking of *future* competitors, most notably Teva, through an entry-delaying settlement and a questionable citizen petition. It then examines Mylan’s

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<sup>5</sup> Chaffetz & Cummings Letter, *supra* note 2; Letter from Charles E. Grassley (R-IA) to Heather Bresch, Aug. 22, 2016, [http://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20\(EpiPen\).pdf](http://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20(EpiPen).pdf) [<https://perma.cc/9DSC-GEXZ>].

<sup>6</sup> Full House Comm. on Oversight & Gov’t Reform, *Hearing on Reviewing the Rising Price of EpiPens* (Sept. 21, 2016), available at <https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2/> [<https://perma.cc/A6FU-QKGF>]; Anna Edney & Robert Langreth, *Mylan Blasted for Raising EpiPen Prices to Get “Filthy Rich.”* BLOOMBERG (Sept. 21, 2016), <http://www.bloomberg.com/news/articles/2016-09-21/mylan-criticized-on-profits-and-pay-at-house-oversight-hearing> [<https://perma.cc/3YZ5-D2CQ>].

<sup>7</sup> Egan, *supra* note 1.

<sup>8</sup> Andrew B. Polumbo, *To the EpiPen CEO: My Daughters Will Be Nothing Like You*, HUFFINGTON POST, Aug. 31, 2016, [http://www.huffingtonpost.com/entry/father-to-epipen-ceo-my-daughters-will-be-nothing\\_us\\_57c48b04e4b024fca58c9367](http://www.huffingtonpost.com/entry/father-to-epipen-ceo-my-daughters-will-be-nothing_us_57c48b04e4b024fca58c9367) [<https://perma.cc/YMV5-95BA>].

<sup>9</sup> Rand Paul, *Sen. Rand Paul: EpiPen Scandal Is a Perfect Example of Crony Capitalism*, TIME (Sept. 7, 2016), <http://time.com/4482179/sen-rand-paul-epipen-scandal/> [<https://perma.cc/B7VA-F3B7>]; *A Drug Cartel at the FDA*, WALL ST. J. (Sept. 26, 2016) (criticizing FDA’s generic label regulations and commenting that “next time you hear a political sermon on the scandalous expense of treatments, remember this government collusion to keep drug prices high”), <http://www.wsj.com/articles/a-drug-cartel-at-the-fda-1474931423> [<https://perma.cc/4ZSM-BEX7>].

<sup>10</sup> *E.g.*, Charley Grant, *The EpiPen Controversy Isn’t About Mylan*, WALL ST. J., Aug. 25, 2016, <http://www.wsj.com/articles/the-epipen-controversy-isnt-about-mylan-1472145456> [<https://perma.cc/N4C9-YWT7>]; Aaron E. Carroll, *The EpiPen, a Case Study in Health System Dysfunction*, N.Y. TIMES, Aug. 23, 2016, [http://www.nytimes.com/2016/08/24/upshot/the-epipen-a-case-study-in-health-care-system-dysfunction.html?\\_r=0](http://www.nytimes.com/2016/08/24/upshot/the-epipen-a-case-study-in-health-care-system-dysfunction.html?_r=0) [<https://perma.cc/JF2D-YMRX>].

<sup>11</sup> Dan Mangan & Anita Balakrishnan, *Mylan CEO Bresch: ‘No One’s More Frustrated than Me’ About EpiPen Price Furor*, CNBC, Aug. 25, 2016, <http://www.cnbc.com/2016/08/25/mylan-expands-epipen-cost-cutting-programs-after-charges-of-price-gouging.html> [<https://perma.cc/934Q-PH59>].

blocking of *present* competitors, including Adrenaclick and Auvi-Q, by requiring schools to agree not to stock their products.

## I

## EPIPEN HISTORY

A brief history puts Mylan's conduct into perspective. Adrenaline was first marketed by Parke-Davis, a Pfizer subsidiary, at the turn of the twentieth century as a vasoconstrictor.<sup>12</sup> Since then, epinephrine (also known as adrenaline) has become the essential treatment for anaphylaxis, a condition in which the sudden release of inflammatory mediators leads to immediate respiratory or cardiac arrest and potentially death.<sup>13</sup>

Until 1980, epinephrine was delivered primarily through vial and syringe.<sup>14</sup> But a series of events involving NASA and chemical warfare research in the military led to the development of autoinjectors, a new means for delivering epinephrine.<sup>15</sup> Because time is a "grim factor" in anaphylactic episodes and autoinjectors (as compared to vial and syringe) allow a drug to be rapidly administered,<sup>16</sup> the advance was critical.

On the manufacturing side, Survival Technology—which ultimately became Meridian Medical Technologies—introduced the EpiPen to the market in 1980 and received FDA approval in 1987.<sup>17</sup> King Pharmaceuticals acquired Meridian in 2002, and Pfizer purchased King in 2010.

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<sup>12</sup> See Steve Brachmann, *EpiPen Gives Dose of Life-Saving Epinephrine for Nearly 50 Years*, IPWATCHDOG, June 28, 2016, <http://www.ipwatchdog.com/2016/06/28/evo-of-tech-sheldon-kaplans-epipen-gives-doses-of-life-saving-epinephrine-for-nearly-50-years/id=70024/> [https://perma.cc/8FXJ-BQ9T]; Walter Sneader, *The Discovery and Synthesis of Epinephrine*, 2001 DRUG NEWS & PERSPECTIVE 14(8), 491 (Oct. 2001).

<sup>13</sup> Taiil Song, et al., *Anaphylaxis Treatment: Current Barriers to Adrenaline Auto-Injector Use*, 69(8) ALLERGY 983 (2014).

<sup>14</sup> See Stephen Lockey, *A New Method of Administering Aqueous Epinephrine: The EpiPen, an Automatic Syringe*, 17(4) J. ASTHMA RESEARCH 153 (1980).

<sup>15</sup> *Id.*; Lydia Ramsey, *The Strange History of the EpiPen, the Device Developed by the Military that Turned into a Billion-Dollar Business*, BUSINESS INSIDER (Aug. 27, 2016), <http://www.businessinsider.com/the-history-of-the-epipen-and-epinephrine-2016-8/#when-mylan-acquired-the-epipen-the-drug-was-making-about-200-million-a-year-now-it-makes-more-than-11-billion-a-year-mylan-has-about-90-of-the-market-share-for-epinephrine-devices-9> [https://perma.cc/SNL7-4G8Y].

<sup>16</sup> Lockey, *supra* note 14.

<sup>17</sup> NDA 019430, DRUGS@FDA: FDA APPROVED DRUG PRODUCTS, <http://www.accessdata.fda.gov/scripts/cder/daf/> (enter 019430 into the Search by Drug Name, Active Ingredient, or Application Number field).

On the distribution side, in 1997 Meridian granted exclusive marketing and distribution rights to Dey Pharma, a Merck subsidiary.<sup>18</sup> In 2007, Mylan acquired Merck's generic pharmaceutical business, in the process obtaining the EpiPen and expanding its corporate structure to include a "Specialty Segment."<sup>19</sup> As of this writing, Meridian, a Pfizer subsidiary, continues to manufacture the EpiPen, while Mylan has the exclusive right to market and distribute the EpiPen.<sup>20</sup>

After acquiring the rights to the EpiPen, Mylan did not have high hopes. Management "first thought to divest the aging device, which logged only \$200 million in revenue."<sup>21</sup> But it then decided to "us[e] old-fashioned marketing . . . to boost sales among concerned parents of children with allergies."<sup>22</sup>

Mylan's marketing strategy proved successful. In the years since it acquired the EpiPen, revenues increased from \$200 million to more than \$1 billion.<sup>23</sup> Today, the device provides roughly 40% of Mylan's operating profits, with margins that increased from 9% in 2008 to 55% in 2014.<sup>24</sup> Financial reports reveal the consistency of Mylan's grip on the epinephrine auto-injector market. After acquiring the rights to the EpiPen, Mylan regularly informed investors that the product possessed a staggering 95% market share.<sup>25</sup>

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<sup>18</sup> *King Pharmaceuticals to Acquire Meridian Medical Technologies*, PR NEWSWIRE, Oct. 21, 2002, <http://www.prnewswire.com/news-releases/king-pharmaceuticals-to-acquire-meridian-medical-technologies-76364227.html> [<https://perma.cc/FL2S-HKZQ>].

<sup>19</sup> Mylan, Annual Report (Form 10-KT/A), at 3 (Mar. 7, 2008).

<sup>20</sup> For a breakdown of EpiPen's manufacture and distribution, see Mylan NV, Annual Report (Form 10-K), at 9 (Feb. 16, 2016). The EpiPen is a drug-device combination product. 21 C.F.R. § 3.2; see generally FDA, *Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices & Additional Product Classification Issues*, June 2011 (providing guidance on issues related to whether a product should be classified as a drug or a device); Bo Wang & Aaron S. Kesselheim, *Promoting Therapeutic Innovation: What Do We Do About Drug-Device Combinations?*, JAMA, Mar. 1, 2016 (outlining controversies over whether a product should be classified as a drug or a device).

<sup>21</sup> Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen into a Billion-Dollar Business*, BLOOMBERGBUSINESSWEEK, Sept. 23, 2015, <http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business> [<https://perma.cc/2NMA-T2SV>].

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* Mylan has not offered an explanation for this increase, resorting to general justifications like "work[ing] tirelessly over the past years advocating for increased anaphylaxis awareness, preparedness, and access to treatment." *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *E.g.*, Mylan, Annual Report (Form 10-K), at 8 (Feb. 21, 2012) ("The EpiPen Auto-Injector is the number one prescribed epinephrine auto-injector with more than 95% market share in the U.S. and more than 90% market share worldwide in the defined auto-injector market during 2011."). Mylan reported these figures

Marketing efforts alone, however, do not explain the EpiPen's success. At least four government actions contributed. First, in December 2010, the National Institute of Allergy and Infectious Diseases (NAID), a division of the National Institutes of Health, released guidelines anointing epinephrine autoinjectors as the preferred first-line treatment for severe allergic reactions.<sup>26</sup> Second, the NAID guidelines required that epinephrine be sold in packages of two doses,<sup>27</sup> with Mylan thereafter refraining from selling single pens.<sup>28</sup>

Third, as discussed more fully below,<sup>29</sup> in November 2013, Congress enacted the School Access to Emergency Epinephrine Act, which increased schools' incentives to stock epinephrine auto-injectors. And fourth, in 2010, the FDA "changed label rules to allow devices to be marketed to anyone at risk, rather than only those who had already suffered an anaphylaxis reaction."<sup>30</sup>

The spreading of the EpiPen was matched by the failure of alternatives. Rivals that have offered competing, but not equivalent, products either dropped out of the market or failed to gain traction as a monopoly-constraining alternative to the EpiPen. In 2003, the first challenger appeared: Twinject, which was eventually renamed Adrenaclick.<sup>31</sup> For the past 13 years, various companies have produced Adrenaclick, with Impax acquiring the rights in March 2015.<sup>32</sup> The current list price is as low as \$142,<sup>33</sup> far below that of the EpiPen, but the

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from 2008 through 2011, but stopped including this data in its 2012 annual report.

<sup>26</sup> Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel, 126 J. ALLERGY & CLINICAL IMMUNOLOGY S1 - S58 (Dec. 2010), <http://www.jacionline.org/article/S0091-6749%2810%2901566-6/fulltext#sec7.3.1.1>; see § 6.3.1.1 ("Epinephrine is the drug of choice for anaphylaxis and should be administered as first-line therapy").

<sup>27</sup> *Id.* § 6.4.2.2.

<sup>28</sup> Koons & Langreth, *supra* note 21.

<sup>29</sup> See *infra* Part IV.

<sup>30</sup> Koons & Langreth, *supra* note 21.

<sup>31</sup> *Twinject Auto-Injector*, DRUGS.COM, <https://www.drugs.com/pro/twinject-auto-injector.html> [<https://perma.cc/5BLU-25H5>]; *Adrenaclick and Its Generic Twin Back*, ANAPHYLAXIS EDUCATORS, July 10, 2013, <http://anaphylaxiseducators.com/blog/adrenaclick-and-its-generic-twin-back-june-12-2013> [<https://perma.cc/5KDM-57C6>].

<sup>32</sup> Gillian Mohny & Kavita Vakharia, *EpiPen Users Have Few Options for Generic or Alternative Drugs*, ABC NEWS, Aug. 26, 2016, <http://abcnews.go.com/Health/epipen-users-options-generic-alternate-drugs/story?id=41667390> [<https://perma.cc/A7MG-PVQ9>].

<sup>33</sup> *E.g.*, Thomas Hemphill, *Mylan's EpiPen Pricing Decision Was Predictable*, REALCLEARMARKETS, Sept. 9, 2016, [http://www.realclearmarkets.com/articles/2016/09/09/mylans\\_epipen\\_pricing\\_decision\\_was\\_predictable\\_102344](http://www.realclearmarkets.com/articles/2016/09/09/mylans_epipen_pricing_decision_was_predictable_102344)

product's market share has ranged between only 2% and 8%.<sup>34</sup> One reason for this low share is Impax's lack of an automated process and inability to meet customer demand.<sup>35</sup>

Between January 2013 and October 2015, Sanofi and Intelliject's Auvi-Q (initially introduced as "e-cue") also competed with the EpiPen.<sup>36</sup> This device differed in using a recorded voice to instruct users to operate the autoinjection device.<sup>37</sup> Despite its promise, the product was removed from the market because it failed to deliver the correct dose, solidifying EpiPen's influence and demand.<sup>38</sup>

As for future rivals offering direct generic competition, Teva and Sandoz, in 2009 and 2011 respectively, each sought approval through the Abbreviated New Drug Application (ANDA) process by which they (by showing that their products work similarly to the EpiPen) could rely on EpiPen safety and

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.html [<https://perma.cc/D384-DXCH>]; see also Sam Wood, *A Cheaper Way to Get Epinephrine Pen, if You Know How*, PHILLY.COM, Aug. 31, 2016, <http://www.philly.com/philly/health/Theres-a-cheaper-way-to-get-an-epinephrine-pen—but-you-have-to-know-how.html> [<https://perma.cc/88GZ-X5R8>] (reporting that a generic form of Adrenaclick could be purchased for \$146).

<sup>34</sup> Wood, *supra* note 33.

<sup>35</sup> Mohny & Vakharia, *supra* note 32.

<sup>36</sup> *Sanofi-Aventis U.S. and Intelliject, Inc. Sign Licensing Agreement for Novel Epinephrine Auto Injector in North America*, SANOFI, Nov. 30, 2009, <http://www.news.sanofi.us/press-releases?item=118506> [<https://perma.cc/5BC4-HSXQ>]; *Sanofi Announces Auvi-Q™, the First and Only Voice-Guided Epinephrine Auto-Injectors, Is Now Available in the U.S.*, PRNEWswire, Jan. 28, 2013, <http://www.prnewswire.com/news-releases/sanofi-announces-auvi-q-the-first-and-only-voice-guided-epinephrine-auto-injector-is-now-available-in-the-us-188651061.html> [<https://perma.cc/CW6S-Z2YS>].

<sup>37</sup> *Sanofi's Auvi-Q*, FIERCEPHARMA, <http://www.fiercepharma.com/special-report/sanofi-s-auvi-q> [<https://perma.cc/9RH8-EHAD>] (last visited Sept. 9, 2016).

<sup>38</sup> Eric Palmer, *Sanofi Recalls All of Its Auvi-Q Devices, Undercutting Its Push to Steal EpiPen Market Share*, FIERCEPHARMA, Oct. 29, 2015, <http://www.fiercepharma.com/m-a/sanofi-recalls-all-of-its-auvi-q-devices-undercutting-its-push-to-steal-epipen-market-share> [<https://perma.cc/Z4KC-RKMM>]. As of the date of this Essay, the manufacturer was planning to reintroduce the Auvi-Q in the first half of 2017. Dan Mangan, *Mylan's EpiPen Will Get Competition from Return of Kaleo's Auvi-Q in 2017*, CNBC, Oct. 26, 2016, <http://www.cnbc.com/2016/10/26/mylans-epipen-will-get-competition-from-return-of-kaleos-auvi-q-in-2017.html> [<https://perma.cc/JBM6-LFNW>].

Further hampering Auvi-Q was the role played by pharmacy benefit managers (PBMs), most notably Express Scripts. Auvi-Q received FDA approval in August 2012 and entered the market in January 2013, but suffered as Express Scripts removed the product from its list of preferred drugs in 2014. The apparent reason for the removal was that, unlike the EpiPen, there were not discounts or rebates on the Auvi-Q. See Matthew Harper, *The Insurance Rip-Off at the Heart of the EpiPen Scandal*, FORBES, Aug. 30, 2016, <http://www.forbes.com/sites/matthewherper/2016/08/30/the-consumer-rip-off-at-the-heart-of-the-epipen-scandal/2/#5cc54ac57187> [<https://perma.cc/UR7B-5TXT>].

effectiveness findings and avoid the need to undertake independent clinical studies.<sup>39</sup> As discussed more fully below,<sup>40</sup> Mylan has employed multiple anticompetitive acts to block Teva's ANDA. And as of November 2016, the FDA had yet to approve Sandoz's ANDA application, with litigation over the EpiPen patents ongoing.<sup>41</sup>

The inability of generics to compete in the market and effectively restrain EpiPen pricing has received attention. But that is not just a random occurrence resulting from the challenges of offering a successful epinephrine treatment. Rather, it also has resulted from the confluence of three separate anticompetitive actions by Mylan, two targeting future rivals and one against present competitors. The next three Parts show how Mylan has engaged in an expansive and aggressive array of actions that exploited (1) the litigation process through settlement, (2) the administrative process through FDA citizen petitions, and (3) the laws requiring auto-injectors in schools through exclusive contracts.

## II

### ACT 1: SETTLEMENTS

In the pharmaceutical industry, patent litigation concerning generic entry is prevalent. The typical first step involves a brand firm's listing of patents in the "Orange Book," an annual compilation of drugs and their associated patents.<sup>42</sup> In this case, Mylan currently lists four patents in the 2016 Orange Book: U.S. Patent Nos. 7,440,012; 7,794,432; 8,048,035; and 8,870,827.<sup>43</sup> All four claim the same priority date and will expire in November 2025, and each claims a variation of an autoinjector for dispensing a predetermined dose of medicine.

After a brand firm lists its patents in the Orange Book, a generic that wishes to enter the market files one of four certifications, with the "Paragraph IV" version having the most direct competitive effect since the generic—on the grounds that the patent is invalid or the generic version will not infringe it—

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<sup>39</sup> See, e.g., Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 46 (2009).

<sup>40</sup> See *infra* Parts II & III.

<sup>41</sup> Pfizer, Quarterly Report (Form 10-Q), at 33 (Aug. 11, 2016).

<sup>42</sup> See FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (36th ed. 2016), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/ucm071436.pdf> [<https://perma.cc/2VUA-78J7>].

<sup>43</sup> See *id.* at ADA 68 of 225.

seeks to enter before the end of the patent term.<sup>44</sup>

Mylan has enforced its rights under the '012 and '432 patents<sup>45</sup> on three occasions. Two of the cases have settled, while one is ongoing.

First, on August 28, 2009, Meridian Medical Technologies and King Pharmaceuticals sued Teva for infringement of its patents soon after it filed its ANDA in December 2008 and Paragraph-IV notice letter on July 20, 2009.<sup>46</sup> After a four-day bench trial in early 2012,<sup>47</sup> the parties settled on April 26, 2012,<sup>48</sup> only weeks before post-trial briefings were due in late May 2012.<sup>49</sup> While the terms of the settlement are confidential, a Mylan press release confirms that Teva agreed to delay entering the market for more than three years, until June 22, 2015.<sup>50</sup> During the period in which Teva could not enter the market, EpiPen prices more than doubled, from (roughly) \$220 to \$460.<sup>51</sup>

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<sup>44</sup> 21 U.S.C. §355(j)(2)(A)(vii)(IV).

<sup>45</sup> Patents are typically referred to by the last three digits of their patent number. Ian Burns, *How To Read Patents*, ATIPLAW, Jan. 10, 2014, <http://atintellectualproperty.com/how-to-read-patents/> [https://perma.cc/5ET3-QQM2].

<sup>46</sup> Complaint, *King Pharm., Inc. v. Teva Parenteral Med. Inc.*, Case No. 09-652-GMS (D. Del. Aug. 28, 2009). At the time of this suit, the 2009 Orange Book listed Meridian as EpiPen's sponsor. Mylan Specialty took over as EpiPen's sponsor in the 2014 Orange Book. Even though Meridian and King formally filed the lawsuit, this Essay connects the conduct to Mylan given (1) its wholly-aligned interests as exclusive marketer and distributor, (2) the division of responsibility by which Meridian/King filed lawsuits and Mylan listed patents in the Orange Book, and (3) Mylan's announcement of the settlement, which quotes executives not from Meridian or Pfizer but only from Mylan. See *infra* note 48 and accompanying text (quoting CEO Heather Bresch: "We are pleased with this settlement, and are confident that the EpiPen® Auto-Injector will continue to be a market leader.").

<sup>47</sup> Case No. 09-652, D.I. 150-54 (D. Del. July 25, 2012) (transcript of trial held on Feb. 16, 2012 and Mar. 7-9, 2012).

<sup>48</sup> See *Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement with Teva*, MYLAN (Apr. 26, 2012), <http://newsroom.mylan.com/pressreleases?item=123144> [https://perma.cc/3KAL-L8TG].

<sup>49</sup> Case No. 09-652-GMS, D.I. 146 (D. Del. Apr. 12, 2012).

<sup>50</sup> *Id.* The West Virginia Attorney General has opened an antitrust investigation of the settlement. Chris Morran, *West Virginia Investigating EpiPen Maker Mylan for Alleged Medicaid Fraud, Antitrust Violations*, CONSUMERIST, Sept. 20, 2016, <https://consumerist.com/2016/09/20/west-virginia-investigating-epipen-maker-mylan-for-medicaid-fraud-antitrust-violations/> [https://perma.cc/A2YR-BE6R].

It also bears mention that Teva proposed acquiring Mylan during the period in which it was kept off the market. *Teva Proposes to Acquire Mylan for \$82.00 Per Share in Cash and Stock*, TEVA, Apr. 21, 2015, [http://www.tevapharm.com/news/teva\\_proposes\\_to\\_acquire\\_mylan\\_for\\_82\\_00\\_per\\_share\\_in\\_cash\\_and\\_stock\\_04\\_15.aspx](http://www.tevapharm.com/news/teva_proposes_to_acquire_mylan_for_82_00_per_share_in_cash_and_stock_04_15.aspx) [https://perma.cc/EL5Y-ZJFJ].

<sup>51</sup> See Dan Mangan, *This Chart Shows Why Everyone's Angry About Soaring*



One cannot know with certainty how the court would have decided the case. But ominous tea leaves on the patents' validity are revealed by the court's *Markman*<sup>52</sup> claim construction hearing. On October 17, 2011, the court construed three terms of the '012 patent and six terms of the '432 patent.<sup>53</sup> Teva fared well on the '012 patent, as the court rejected two of King's proposed constructions and adopted one of Teva's constructions.<sup>54</sup>

As to the '432 patent, the court adopted two "plain and ordinary meaning"<sup>55</sup> constructions, rejected two generic constructions, and rejected two King constructions, resulting in a more mixed conclusion.<sup>56</sup> Again, while it is a challenge to determine what the outcome would have been, the court's *Markman* construction signaled greater success for Teva than for the patent owners. The settlement was concerning not just

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*Price of Lifesaving EpiPen*, CNBC, Aug. 23, 2016, <http://www.cnbc.com/2016/08/23/this-chart-shows-you-why-a-lot-of-people-are-angry-about-the-price-of-epipen.html> [https://perma.cc/532J-HKKU] (providing figures from July 2012 and May 2015).

<sup>52</sup> See generally *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that claim construction is a matter of law and that judges are to construe the meaning of patent claims).

<sup>53</sup> Case No. 09-652-GMS, D.I. 118 (D. Del. Oct. 17, 2011).

<sup>54</sup> For the terms "first locked retracted position" and "second locked position," the court rejected King's broad construction of "locked" as a "relative state" and instead ruled that the term more narrowly meant a position "held in place in a retracted state distinct from an extended state." The court also agreed with Teva that the term "locking mechanism for" is a means-plus-function term, and therefore narrower than King's interpretation that sought a plain and ordinary meaning construction. The parties' claim chart can be found at Case No. 09-652-GMS, D.I. 100 (D. Del. July 29, 2011).

<sup>55</sup> See generally *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) ("[T]he words of a claim are generally given their ordinary and customary meaning [which is] . . . the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.").

<sup>56</sup> The two plain and ordinary meaning constructions included: (1) "to prevent transfer of the residual force to the needle cover" (using the ordinary meaning of "prevent" rather than a transfer of some force); and (2) "the cartridge container having a closed front end except for an opening therein sized to receive the needle there through during a medicament dispensing operation, the closed front end operative to engage the cartridge and oppose continued movement of the cartridge after the needle passes through the front end opening" (which did not receive significant attention in the briefing or court opinion).

The court rejected two of Teva's constructions: (1) "residual force," for wrongly importing a limitation from the '432 patent's preferred embodiment; and (2) "to prevent kickback of the auto-injector during the dispensing operation," as lacking support in the specification and importing a limitation from the '432 patent's preferred embodiment. Conversely, the court rejected two of King's constructions: (1) "a needle cover," for lacking support in the specification; and (2) "attenuating kickback," for not sufficiently limiting the claim and contradicting a prosecution history in which King had limited the claim. Case No. 09-652-GMS, D.I. 118 (D. Del. Oct. 17, 2011).

because it delayed a successful generic from the market but also because of its effects on other, later-filing generics. The Hatch-Waxman Act awards 180 days of exclusivity to the first generic to challenge a brand firm's patent claiming that it is invalid or not infringed.<sup>57</sup> This period does not begin until the first-filing generic enters the market, in this case three years in the future. Teva was the first filer on the patents-in-suit.<sup>58</sup> In other words, as a result of delaying Teva's entry into the market, Mylan and its partners delayed *all generics* that sought to file applications based on the EpiPen.<sup>59</sup>

Settlements of patent litigation threaten potential landmines of anticompetitive effects. The Supreme Court made clear in *FTC v. Actavis*<sup>60</sup> that a settlement by which a brand pays a generic to delay entering the market could have "significant adverse effects on competition" and violate the antitrust laws.<sup>61</sup>

Although the *Actavis* decision post-dated the settlement, the parties could not have been unaware at the time they settled in April 2012 that potentially rigorous scrutiny was on the horizon. Any appeal of the Delaware court's decision would be heard by the Third Circuit. And the settlement was signed shortly after that court's December 2011 oral argument in *In re K-Dur Antitrust Litigation*, in which the judges expressed skepticism of arguments for minimal antitrust scrutiny.<sup>62</sup> In July 2012, the court adopted a test of presumptive illegality.<sup>63</sup>

Because the terms of the settlement are confidential, it is not possible to know whether there was a transfer of

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<sup>57</sup> 21 U.S.C. §355(j)(5)(B)(iv) (2012).

<sup>58</sup> *Update: Teva and Antares's Generic Challenge to Epi-Pen*, SEEKINGALPHA, Feb. 23, 2012, <http://seekingalpha.com/article/388681-update-teva-and-antares-generic-challenge-to-epipen> [<https://perma.cc/RAR7-4A6Y>].

<sup>59</sup> See Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 15 (2014) (noting that the 2003 Medicare Amendments, which were designed to encourage expedited entry by specifying events that led to a forfeiture of the exclusivity period, were ineffective).

<sup>60</sup> 133 S. Ct. 2233 (2013).

<sup>61</sup> *Id.* at 2231.

<sup>62</sup> Oral Argument, *In re K-Dur Antitrust Litig.*, Nos. 10-2077, 10-2078, 10-2079, & 10-4571, at 25, 36, 37 (3d Cir. Dec. 12, 2011) (noting that "Senator Hatch himself has said that he thinks these reverse payments are anti-competitive" and questioning arrangement by which brand purchased generic product on grounds that it "le[d] to the presumption that [it] could have been buying off the generic from entering the market earlier" and that "what [the parties] ended up [with] was an allocation of the market – which violates the antitrust laws").

<sup>63</sup> *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012), *cert. granted and judgment vacated by* *Upsher-Smith Lab., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013).

consideration to Teva.<sup>64</sup> But the generic-friendly claim construction bolstering Teva's leverage, together with the vast scale of the market,<sup>65</sup> increased the likelihood that Meridian delayed Teva's entry through payment.<sup>66</sup>

Nor was this the only settlement. On January 19, 2011, King commenced litigation against Intelliject (now Kaleo) for infringement of the '012 and '432 patents after the company sought approval for Auvi-Q.<sup>67</sup> Rather than pursuing approval as an ANDA, Intelliject filed a new drug application under Section 505(b)(2)—in other words, a “paper NDA.”<sup>68</sup>

On February 16, 2012, the parties settled.<sup>69</sup> Pursuant to the agreement, Auvi-Q could enter the market 273 days later, on November 15, 2012.<sup>70</sup> Because the FDA approved the product on August 10, 2012,<sup>71</sup> the settlement delayed entry by

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<sup>64</sup> See Notice of Removal of Action from State Court Pursuant to 28 U.S.C. §§ 1331, 1332, 1338, 1367, 1441, 1446 & 1454 at Exhibit A at ¶¶ 34–35, *Teamsters v. King Pharms.*, No. 1:15-cv-04666-LAK (N.Y. filed June 16, 2015) (requesting access to settlement agreement and stating that “[u]pon information and belief, Teva received unjustifiable consideration, incentives, and benefits in exchange for their collusion” since “[n]o rational economic actor with a viable product would refrain from entering a lucrative ‘blockbuster’ market unless they received some form of valuable consideration”).

<sup>65</sup> One analyst anticipated that a Teva victory could have resulted in it “captur[ing] 40% of the Epi-Pen unit market and roughly 20% of current sales, or about \$54 million, in the first year of introduction.” Larry Smith, *The Promise of the Antares Pipeline is the Basis of My Buy Recommendation*, SMITH ON STOCKS, Jan. 25, 2012, <https://smithonstocks.com/the-promise-of-the-antares-pipeline-is-the-basis-of-my-buy-recommendation-ais-2-40/> [<https://perma.cc/ZEG3-L7ST>].

<sup>66</sup> In the midst of the EpiPen price-hike saga, Teva has declined to comment on whether payment was made in exchange for the settlement. Chris Glorioso & Evan Stulberger, *I-Team: Company Behind EpiPen Fought to Keep Cheaper Generic off Market*, NBC NEW YORK, Aug. 30, 2016, <http://www.nbcnewyork.com/news/local/EpiPen-Cheap-Generic-Teva-Product-Mylan-Investigation-Drug-Cost-391758871.html> [<https://perma.cc/4WYV-L3CX>]. As of this writing, Teva has not received FDA approval. But that is the result of a history in which it delayed entering for several years, and which conceivably lessened its incentives to enter the market.

<sup>67</sup> Complaint, *King Pharm., Inc. v. Intelliject Inc.*, Case No. 1:11-cv-00065-UNA (D. Del. Jan. 19, 2011).

<sup>68</sup> A “paper NDA” is similar to an ANDA in relying on others’ information for approval but differs from an ANDA since it “must include some safety and efficacy information that is different from the regular NDA.” SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 8:1–9 (2016).

<sup>69</sup> Phil Milford, *Pfizer, Mylan Settle with Sanofi over Epinephrine Injector*, BLOOMBERG, Feb. 16, 2012, <http://www.bloomberg.com/news/articles/2012-02-16/pfizer-mylan-settle-with-sanofi-over-device-for-severe-allergic-reactions>.

<sup>70</sup> *Mylan and Pfizer Announce Epinephrine Auto-Injector Settlement Agreement*, FIERCEPHARMA, Feb. 16, 2012, <http://www.fiercepharma.com/pharma/mylan-and-pfizer-announce-epinephrine-auto-injector-settlement-agreement> [<https://perma.cc/NGZ3-PV6Y>].

<sup>71</sup> NDA 201739, DRUGS@FDA: FDA APPROVED DRUG PRODUCTS,

97 days. On October 28, 2015, Auvi-Q was pulled off the market for safety reasons.<sup>72</sup>

### III

#### ACT 2: CITIZEN PETITION

In addition to delayed-entry settlements, Mylan sought to forestall Teva's entry by reaching into its toolkit of anticompetitive behavior to pull out a "citizen petition," which is meant to raise safety concerns with the FDA but which has been used by brand firms to delay generic entry. As we have recently shown in separate work, "citizen" petitions are filed mostly by brand firms, and are almost always (92%) denied.<sup>73</sup>

Mylan filed its citizen petition against Teva's ANDA on January 16, 2015.<sup>74</sup> A response from the FDA was anticipated no later than June 15, 2015<sup>75</sup>—only weeks before Teva was permitted to enter the market pursuant to its settlement. As our study revealed, Mylan's petition appears to have been filed as a delay tactic to avoid generic approval and the loss of its overwhelming share of the market.<sup>76</sup>

Just as concerning, in May 2015, four months after filing the petition, Mylan filed a supplemental study asserting that patients would not be able to operate Teva's proposed device without retraining.<sup>77</sup> Experts have explained, however, that

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<http://www.accessdata.fda.gov/scripts/cder/daf/> (enter 201739 into the Search by Drug Name, Active Ingredient, or Application Number field).

<sup>72</sup> Eric Palmer, *Sanofi Recalls All of Its Auvi-Q Devices, Undercutting Its Push to Steal EpiPen Market Share*, FIERCEPHARMA, Oct. 29, 2015, <http://www.fiercepharma.com/m-a/sanofi-recalls-all-of-its-auvi-q-devices-undercutting-its-push-to-steal-epipen-market-share> [<https://perma.cc/P7UF-D6SD>].

On July 14, 2010, King filed a Hatch-Waxman lawsuit against Sandoz on the '012 and '432 patents. Complaint, King Pharm., Inc. v. Sandoz, Inc., Case No. 10-3568-MLC (D.N.J. July 14, 2010). Sandoz requested a stay of proceedings in May 2011 and the litigation is ongoing. Case No. 10-3568-MLC, D.I. 66. Little information on Sandoz's generic development is publicly available.

<sup>73</sup> Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed and At-Last Denied*, 66 AM. U. L. REV. 305, 333 (2016) (examining all 505(q) petitions (which ask the FDA to take action against a pending generic application) filed between 2011 and 2015); see also Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 274 (2012) (finding that the FDA denies 81% of petitions).

<sup>74</sup> Citizen Petition from Mylan Specialty, L.P., Docket No. FDA-2015-P-0181-0001 at \*1 (posted on Jan. 16, 2015).

<sup>75</sup> See 21 U.S.C. § 355(q)(F) (2012) ("The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted.").

<sup>76</sup> See Carrier & Minniti, *supra* note 73, at 350–51.

<sup>77</sup> Supplement from Mylan Specialty, L.P., Docket No. FDA-2015-P-0181-0007 at \*10 (posted on May 5, 2015).

Mylan's supplemental study "had a lot of problems" as it "lacked a control group; did not study the actual generic but a prototype instead; used a small number of participants; failed to provide them with proper instructions for use; and told participants to watch a video rather than actually use the Teva device."<sup>78</sup>

Shedding even more light on the questionable petition and supplemental study is its timing. In a development of which the industry would be keenly aware, Teva filed its ANDA against the Epi-Pen in 2008.<sup>79</sup> And court documents show that Teva produced its ANDA filing in the course of litigation on September 17, 2010.<sup>80</sup> This material included "detailed product descriptions, drawings, and instructions for use" for Teva's proposed generic.<sup>81</sup>

At the time (and to this day), Mylan was working hand-in-hand with Meridian/King, with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.<sup>82</sup> It thus seems exceedingly likely that Mylan would have been aware of Teva's ANDA in 2008 and aware of documents explaining Teva's product in 2010. In fact, it was *Mylan* that announced the settlement of the litigation, confirming its close connection to the case.<sup>83</sup> This connection raises significant concerns that Mylan waited more than four years to file its citizen petition in 2015.

Even though Teva's ANDA was ultimately denied in February 2016,<sup>84</sup> Mylan would not have known this when it filed its petition in January 2015. And our comprehensive study of citizen petitions found that in 2015, the FDA approved three ANDAs on the *same day* it denied a petition, suggesting

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<sup>78</sup> Ed Silverman, *How Mylan Tried to Keep Teva from Selling a Generic EpiPen*, STAT, Aug. 31, 2016, <https://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/> [<https://perma.cc/ESK3-339W>]. The petition also included a statement from Dr. Eli Meltzer—who received roughly \$95,000 from Mylan between 2014 and 2015—that users trained on the EpiPen would not "be able to reliably use a different operational platform in an emergency situation as safely and effectively." *Id.*

<sup>79</sup> Smith, *supra* note 65.

<sup>80</sup> Defendants' Brief in Support of their Motion to Dismiss at 6, King Pharm., Inc. v. Teva Parenteral Med. Inc., Case No. 09-652-GMS at \*6 (D. Del., filed Dec. 13, 2010).

<sup>81</sup> *Id.*

<sup>82</sup> See *supra* note 46.

<sup>83</sup> See *supra* note 48.

<sup>84</sup> Carly Helfand, *FDA Swats Down Teva's EpiPen Copy, Putting Mylan in Cruise Control*, FIERCEPHARMA (Mar. 1, 2016), <http://www.fiercepharma.com/sales-and-marketing/fda-swats-down-teva-s-epipen-copy-putting-mylan-cruise-control> [<https://perma.cc/8RF5-YEGN>].

that generic approval was at least partially delayed until the petition was resolved.<sup>85</sup>

We think it reasonable to conclude that Mylan's (1) filing of a petition years after invariably knowing about Teva's generic, (2) filing of a petition calculated to delay entry after settlement, and (3) late-filing of a supplemental study together comprised a strategy to delay Teva's ANDA approval *beyond* the *already-delayed* agreed entry date of July 22, 2015. Although the FDA is required to respond to petitions within 150 days, on numerous occasions the agency offers only an interim response explaining that it requires more time due to "complex issues raised" in the petition.<sup>86</sup> As a result, a strategy similar to the one Mylan used easily could have pushed a petition's disposition (and thus generic approval) past 150 days. For a billion-dollar drug product like the EpiPen, each day of delay meant an extra \$3 million.

Parties filing petitions with government agencies often can rely on the immunity from the antitrust laws provided by the *Noerr-Pennington* doctrine, as "[t]hose who petition [the] government for redress are generally immune from antitrust liability."<sup>87</sup> But this defense is not absolute. In particular, there is a well-established "sham" exception, which could be satisfied in this case by Mylan's likely longstanding knowledge of Teva's generic, the timing of the petition in relation to the settlement, and the questionable nature of the supplemental study.<sup>88</sup> On a broader level, the petition could be viewed as an integral part of an overall scheme of monopolization, together with settlement and (as discussed immediately below) exclusive dealing.<sup>89</sup>

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<sup>85</sup> Carrier & Minniti, *supra* note 73, at 341–44.

<sup>86</sup> *E.g.*, Interim Response Letter from FDA CDER to Cubist Pharm., Inc., Docket No. FDA-2015-P-1595-0004 (posted on Oct. 26, 2015) (interim response from FDA, 173 days after petition filing, stating that "FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials").

<sup>87</sup> *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 56 (1993).

<sup>88</sup> *E.g.*, *Tyco Healthcare Group v. Mutual Pharm.*, 762 F.3d 1338, 1348 (Fed. Cir. 2014); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 317 (E.D. Pa. 2011); *In re Prograf Antitrust Litig.*, 2012 WL 293850, at \*5 (D. Mass. Feb. 1, 2012). *See also* *Tyco Healthcare Group v. Mutual Pharm.*, 2015 WL 3460790, at \*9 (D.N.J. May 29, 2015) (denying summary judgment because generic offered evidence that petition delayed entry).

<sup>89</sup> *See, e.g., In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at \*15 (D.N.J. Aug. 28, 2009) ("Courts have routinely upheld the validity of 'overall monopolization scheme' claims in the patent context, even in the absence of allegations that any one of the scheme's predicate actions was independently

## IV

## ACT 3: EXCLUSIVE DEALING

In addition to delaying *future* generic entry from Teva (and others waiting in line behind it) through settlement and petition, Mylan blocked *present* competitors through its program for distributing the EpiPen to schools.<sup>90</sup>

In November 2013, in response to a seven-year-old girl at a Virginia school dying after an allergic reaction to peanuts,<sup>91</sup> Congress passed the School Access to Emergency Epinephrine Act.<sup>92</sup> Under this law, the Secretary of Health and Human Services is authorized to give preferential funding to states with schools that maintain an emergency supply of epinephrine for students.<sup>93</sup> The law has had a significant effect: 11 states require<sup>94</sup> and 38 encourage<sup>95</sup> schools to stock epinephrine.<sup>96</sup> This federal legislation has been supplemented by state laws that mandate that public schools obtain autoinjectors.<sup>97</sup>

Mylan played a role in the enactment of the 2013 Act. Bresch “successfully pushed legislation to encourage use of the EpiPen in schools nationwide, making it a must-have drug for patients with allergic reactions.”<sup>98</sup> In particular, lobbying

violative of antitrust laws.” (quoting *Abbott Labs v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D.Del. 2006)).

<sup>90</sup> The New York Attorney General launched an antitrust investigation of this conduct. Press Release, *N.Y. Attorney General, A.G. Schneiderman Launches Antitrust Investigation into Mylan Pharmaceuticals Inc., Maker of EpiPen*, Sept. 6, 2016, <http://www.ag.ny.gov/press-release/ag-schneiderman-launches-antitrust-investigation-mylan-pharmaceuticals-inc-maker> [https://perma.cc/QPM9-SS42].

<sup>91</sup> Koons & Langreth, *supra* note 21.

<sup>92</sup> Pub. L. No. 113–48, 127 Stat. 575 (2013) (codified at 42 U.S.C. § 280g(d)(1)(F)–(G)).

<sup>93</sup> *Id.*

<sup>94</sup> *School Access to Epinephrine Map*, FOOD ALLERGY RES. & EDUC. <https://www.foodallergy.org/advocacy/epinephrine/map> [https://perma.cc/78A6-Y7R3] (last updated July 6, 2016).

<sup>95</sup> *Id.* Hawaii is the only state that does not require or allow schools to stock epinephrine, though it has pending legislation on this issue.

<sup>96</sup> Koons & Langreth, *supra* note 21. The White House explained that “[a]n estimated 9.5% of American children suffer from asthma, and between 4 and 6% of children are affected by food allergies, either of which can strike in an instant, and have life threatening consequences.” Valerie Jarrett, *President Obama Signs New EpiPen Law to Protect Children with Asthma and Severe Allergies, and Help Their Families to Breathe Easier*, WHITE HOUSE BLOG (Nov. 13, 2013, 5:17 PM), <https://www.whitehouse.gov/blog/2013/11/13/president-obama-signs-new-epipen-law-protect-children-asthma-and-severe-allergies-an> [https://perma.cc/EK7G-8WMU].

<sup>97</sup> See Aimee Nienstadt, *Comment, The Insufficiency of the Law Surrounding Food Allergies*, 36 PACE L. REV. 595, 611 (2016) (providing analysis on state epinephrine autoinjector laws).

<sup>98</sup> Edney & Koons, *supra* note 1. See also Jayne O’Donnell, *Family Matters:*

disclosure forms made clear that “Mylan spent about \$4 million in 2012 and 2013 on lobbying for access to EpiPens generally and for legislation, including the 2013 [Act].”<sup>99</sup>

Nor are schools the only setting in which Mylan has sought to promote the EpiPen. Bresch explained that Mylan was “continuing to open up new markets, new access with public entity legislation that would allow restaurants and hotels and really anywhere you are congregating” to have “access to an EpiPen.”<sup>100</sup> And it “signed a deal with Walt Disney to stock EpiPens in Disney’s theme parks and on cruise ships.”<sup>101</sup>

On one hand, such an arrangement could increase access to a life-saving device. But on the other, it could exclude competitors. As a condition of receiving discounted EpiPens,<sup>102</sup> schools were required to agree that they would “not in the next twelve (12) months purchase any products that are competitive to EpiPen® Auto-Injectors.”<sup>103</sup> Although Mylan admitted such a practice,<sup>104</sup> it claims that this requirement is no longer in force.<sup>105</sup> If so, this would be a recent change, as the language appeared in order forms in August 2014, June 2015, and April 2016.<sup>106</sup>

In antitrust terms, this conduct offers a discount price

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*EpiPens Had High-Level Help Getting into Schools*, USA TODAY, Sept. 21, 2016, <http://www.usatoday.com/story/news/politics/2016/09/20/family-matters-epipens-had-help-getting-schools-manchin-bresch/90435218/> [<https://perma.cc/RX3W-LY8U>] (noting that, after becoming president of the National Association of State Boards of Education in 2012, Gayle Manchin, Heather Bresch’s mother, “spearheaded an unprecedented effort that encouraged states to require schools to purchase medical devices that fight life-threatening allergic reactions”); Anna Edney & Billy House, *The Senator’s Daughter Who Raised Prices on the EpiPen*, BLOOMBERG (Aug. 24, 2016), <http://www.bloomberg.com/politics/articles/2016-08-24/the-senator-s-daughter-who-raised-prices-on-anti-allergy-epipen> [<https://perma.cc/XK9W-LNUG>].

<sup>99</sup> Edney & Koons, *supra* note 1.

<sup>100</sup> Koons & Langreth, *supra* note 21.

<sup>101</sup> *Id.*

<sup>102</sup> Ike Swetlitz & Ed Silverman, *Mylan May Have Violated Antitrust Law in its EpiPen Sales to Schools, Legal Experts Say*, STAT, Aug. 25, 2016, <https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/> [<https://perma.cc/ES2J-SSZJ>] (noting that the “discounted price was \$112.10,” roughly “a quarter of the cost charged to pharmacies at the time”).

<sup>103</sup> *Id.*

<sup>104</sup> Full House Comm., *supra* note 6 (pt. 1, at 1:44:00) (in testimony to House Committee, Bresch responded to Representative Duckworth’s question about whether “schools purchasing discounted EpiPens had to make any representations or warranties to Mylan that they would adhere to certain conditions in order to access the discount price by conceding: ‘For people that wanted to buy it at the discounted rate, yes’”).

<sup>105</sup> Swetlitz & Silverman, *supra* note 103.

<sup>106</sup> *Id.*



based on exclusivity. As the leading treatise explains, such an arrangement “should generally be treated as no different from an orthodox exclusive-dealing arrangement.”<sup>107</sup> Exclusive dealing case law stems from Section 3 of the Clayton Act, which prohibits a “discount . . . or rebate . . . on the condition, agreement, or understanding that the . . . purchaser . . . shall not use or deal in the goods . . . of a competitor” where there is an adverse effect on competition.<sup>108</sup> Exclusive dealing also can constitute monopolization under Section 2 of the Sherman Act if the defendant has monopoly power.<sup>109</sup> The general concern with exclusive dealing arrangements is that they block competitors from the market and result in higher prices and lower output.

In evaluating the antitrust aspects of such arrangements, courts have historically focused on the share of the market foreclosed by the arrangement, requiring plaintiffs to show roughly 30 to 40% foreclosure.<sup>110</sup> Assuming this threshold is cleared, courts then analyze other factors, such as the duration of the contracts, prevalence in the industry, existence of entry barriers, distribution alternatives, and other competitive effects.<sup>111</sup>

Recent cases have shifted the emphasis away from foreclosure. One commentator has concluded that courts “have looked beyond foreclosure to focus instead on the effect of exclusive dealing in creating, enhancing, or preserving the defendant’s market power.”<sup>112</sup> Recent cases “have . . . found exclusive dealing and similar arrangements unlawful despite minimal, or even zero, levels of percentage foreclosure from access to the ultimate consumer.”<sup>113</sup> In fact, the “precise percentage of the market asserted to be foreclosed . . . appears to be a wasteful exercise” as “[f]ew serious cases today are based on assertions that foreclosure alone is the source of the asserted competitive harm.”<sup>114</sup>

Applying antitrust law to Mylan’s EpiPen contracts, the first question is whether distribution through schools

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<sup>107</sup> XI HERBERT HOVENKAMP, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* ¶ 1807b, at 133 (3d ed. 2006).

<sup>108</sup> 15 U.S.C. § 14 (2012); *see id.*

<sup>109</sup> 15 U.S.C. § 2.

<sup>110</sup> HERBERT HOVENKAMP, *FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE* 596 (5th ed. 2016).

<sup>111</sup> *Id.* at 597.

<sup>112</sup> *See* Jonathan M. Jacobson, *Exclusive Dealing, “Foreclosure,” and Consumer Harm*, 70 *ANTITRUST L.J.* 311, 311 (2002).

<sup>113</sup> *Id.* at 363.

<sup>114</sup> *Id.*

constitutes its own market. An expansive view would combine distribution in varied settings including schools, hospitals, amusement parks, and families. According to such an interpretation, the share distributed to schools would likely be a modest subset of the total number of devices.

But a more justified interpretation is that schools constitute their own separate market. While each state law differs on the particular age through which students are required to attend school, it is generally accepted that children up to the age of eighteen must do so.<sup>115</sup> After the passage of the 2013 legislation, schools are either required, or receive significant incentives, to stock epinephrine auto-injectors. Schools' decisions on which devices to purchase are not tied to those of parents and hospitals. And given the number of children that do not carry EpiPens with them, school nurses play an irreplaceable role during school hours on the front lines of treating anaphylactic shock, buttressing the conclusion of a market for distribution through schools.<sup>116</sup>

In the market of school distribution for epinephrine autoinjectors, the precise extent of foreclosure is unclear.<sup>117</sup> There are roughly 129,000 elementary, middle, and high schools in the U.S. today: 98,000 public<sup>118</sup> and 31,000 private.<sup>119</sup> While more than half of these schools, over 65,000, receive free EpiPens, the number of schools that have bought EpiPens at a discount is less clear, which prevents definitive conclusions on foreclosure.<sup>120</sup>

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<sup>115</sup> See 78A C.J.S. School and School Districts § 988 (2016).

<sup>116</sup> See David Stukus, *New Epinephrine Study Shows Alarming Results*, KIDS WITH FOOD ALLERGIES: KFA MEDICAL ADVISORY TEAM (July 14, 2014), <http://community.kidswithfoodallergies.org/blog/new-epinephrine-study-shows-alarming-results> [<https://perma.cc/3A67-QFN5>] (study showed that only 40% of families carried self-injectable epinephrine with them).

<sup>117</sup> *E.g.*, *EpiPen4Schools Program*, MICH. ASS'N OF INTERMEDIATE SCH. ADMINS., <http://www.gomaisa.org/epipens-4-schools-program> [<https://perma.cc/KW9E-PJ72>] (covering "qualifying public and private kindergarten, elementary, middle and high schools in the U.S.").

<sup>118</sup> Jill Barshay, *Number of U.S. Charter Schools Up 7 Percent, Report Shows*, THE HECHINGER REPORT (Nov. 3, 2014), <http://www.usnews.com/news/articles/2014/11/03/number-of-us-charter-schools-up-7-percent-report-shows> [<https://perma.cc/4SYY-J5XY>].

<sup>119</sup> *Facts and Studies*, COUNCIL FOR AM. PRIV. EDUC., <http://www.capenet.org/facts.html> [<https://perma.cc/2CAF-T39T>].

<sup>120</sup> Swtlitz & Silverman, *supra* note 102; Mylan Letter to Sen. Elizabeth Warren et al., Sept. 12, 2016, at 7–8 (noting that 1,348 schools purchased EpiPens at a discount between September 2015 and September 2016 but not explaining whether restrictive contracts were in place for entire period or whether such figures were representative of earlier periods); Ed Silverman, *Lawmakers Call for FTC Probe into Potential Antitrust Violations in EpiPen School Program*, STAT, Nov. 8, 2016, <https://www.statnews.com/pharmalot/2016/11/08/ftc->

Regardless of the percentage of the market foreclosed, other factors favor antitrust liability.<sup>121</sup> For competitors not yet on the market, there are high entry barriers in the form of FDA approval. It is particularly difficult for companies to obtain approval of epinephrine autoinjectors as the FDA is cautious given the potentially fatal consequences from misapplication.<sup>122</sup> Barriers also applied to alternatives on the market like Adrenaclick and Auvi-Q, as the Mylan contracts made it more difficult to gain a foothold. Nurses would be trained on the EpiPen, and caregivers whose children's lives were saved by a nurse using an EpiPen—or even who merely knew that the devices were present at the school—would tend to purchase (and tell relatives and others to buy) EpiPens.

In addition, the competitive effects are as clear as they ever are in these cases: a 400% surge from 15 price increases between 2009 and 2016.<sup>123</sup> For each of those increases, Mylan hiked the EpiPen's price at least 9%, and as much as 15%.<sup>124</sup> In short, Mylan's exclusive dealing agreements appeared to block competitors from the market and to increase price.

Given that Mylan has 94% of the market,<sup>125</sup> which easily clears the threshold of monopoly power, this analysis forms the basis for not only a Clayton Act Section 3 claim but also a monopolization claim.<sup>126</sup>

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mylan-epipen-antitrust/ [https://perma.cc/C5YY-FN6D] (noting that “700,000 free pens have been distributed to schools” and that “another 45,000 pens” were distributed at a discount).

<sup>121</sup> The 12-month duration of the contract would present the sole factor that would counsel against liability, but would likely be significantly outweighed by the other factors.

<sup>122</sup> See Helfand, *supra* note 84 (“regulators flagged ‘certain major deficiencies’”); see generally Pauline Bartolone, *EpiPen's Dominance Driven by Competitors' Stumbles and Tragic Deaths*, NPR: SHOTS HEALTH NEWS FROM NPR (Sept. 7, 2016), <http://www.npr.org/sections/health-shots/2016/09/07/492964464/epipen-s-dominance-driven-by-competitors-stumbles-and-tragic-deaths> [https://perma.cc/29YJ-8BXU].

<sup>123</sup> See *supra* note 1.

<sup>124</sup> Jayne O'Donnell et al., *EpiPen's Steady Price Increases Masked Until Deductibles Rose*, USA TODAY, Aug. 25, 2016, <http://www.usatoday.com/story/news/politics/2016/08/23/epipens-steady-price-increases-masked-until-deductibles-rose/89123786> [https://perma.cc/G756-388U].

<sup>125</sup> E.g., Matt Egan, *EpiPen Outrage May Fuel Cheap Generic in 2017*, CNNMONEY: THE BUZZ (Aug. 26, 2016), <http://money.cnn.com/2016/08/26/investing/epipen-price-hike-generic-alternative/> [https://perma.cc/8WBY-DDED].

<sup>126</sup> In fact, courts have accepted lower foreclosure figures in the context of monopolization. See *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001) (“[A] monopolist's use of exclusive contracts, in certain circumstances, may give rise to a § 2 violation even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a § 1 violation.”).

## CONCLUSION

There are many reasons why the price of the EpiPen has surged more than 400% in recent years. This Essay has shown that Mylan bears significant responsibility for this increase. Through entry-delaying settlements and a citizen petition, Mylan forestalled future generics that could have offered a similar version of the EpiPen. Most directly, it blocked Teva, one of the most successful generics of all time, from entering the market. And because of Teva's privileged perch as a first filer, the delay also prevented all other generics from entering. In addition, given Mylan's likely longstanding knowledge of Teva's generic, the timing of its citizen petition in relation to settlement, and the questionable nature of the supplemental study, Mylan further delayed Teva's entry through its petition.

At the same time, through its exclusive contracts with schools, Mylan made it much more difficult for current rivals like Adrenaclick and Auvi-Q to establish a foothold to challenge its monopoly.

From the information publicly available, Mylan's conduct, individually and in combination, raises red flags that strongly implicate an antitrust case based on monopolization. And that evidence raises even more questions about information that is not publicly available. Did the settlement with Teva include payment? How about the settlement with Intelliject? Why did Mylan file a petition more than 4 years after it likely knew of Teva's generic product? What percentage of schools was foreclosed by exclusive contracts? Does the Disney contract (and perhaps others) have similar exclusivity clauses as the one with schools?

Mylan's full range of behavior—both known and unknown—raises significant antitrust concerns and deserves a thorough investigation. Given the consequences of a \$600 treatment for a life-saving device and an array of conduct that exploited the litigation process through settlement, the administrative process through FDA citizen petitions, and the auto-injector school laws through exclusive dealing, the public deserves no less.