

# REVERSE PAYMENT: A COMPARATIVE STUDY

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## ABSTRACT

This Article compares reverse payment settlements, also known as pay-for-delay deals, in the United States and Europe. These deals occur where a branded drug manufacturer sues, settles with, and pays a generic manufacturer to delay the entry of its generic. Unlike the United States, which has a decentralized drug purchasing system, European healthcare systems such as those in France and the United Kingdom wield monopsony buying power over drugs. We investigate whether regulator and monopsony power can neutralize these anticompetitive agreements. We conclude that while the incentives to agree to a reverse settlement are more limited in Europe, they do not disappear. Regulators should do more to encourage the entry of generics by: (1) making patents protected by anticompetitive reserve settlement unenforceable and (2) linking generic entry to a clear statutory entry system instead of an opaque patent system.

## I. INTRODUCTION

Most pharmaceutical companies in both the United States (“US”) and the European Union (“EU”) face little competition for their drugs because of patent and statutory protections.

First, both US and EU regulators delegate to the pharmaceutical companies the task of assessing whether patents constitute entry barriers. In the US, the Federal Drug Administration (“FDA”) requires brand-name drug manufacturers to declare which patents cover a drug in its market authorization application. But the FDA does not scrutinize these patent declarations. Instead, the FDA relies on generic manufacturers to challenge the patents or assert that patents are invalid and/or not infringed if they want to produce the same drug.<sup>1</sup>

In the EU, the European Medicines Agency (“EMA”) ignores patent statuses

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1. 21 U.S.C. § 355(b)(2)(A). “(2) An application [ . . . ] shall also include [ . . . ] (A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—  
(i) that such patent information has not been filed,  
(ii) that such patent has expired,  
(iii) of the date on which such patent will expire, or  
(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and [ . . . ].”

for the issuance of market authorization.<sup>2</sup> Most European countries – including France and the United Kingdom (“UK”) – do not practice patent linkage.<sup>3</sup> Instead, generic manufacturers have to perform their own patent clearance studies to decide whether a generic drug infringes on brand-name patents.<sup>4</sup> Therefore, generic manufacturers must exercise more caution than in the US because they do not benefit from the market authorization disclosure.

Second, even without patent protection, pharmaceutical companies enjoy exclusivity periods in the US and EU. Filing a market authorization guarantees a market exclusivity of five years in the US and ten years in the EU for most drugs.<sup>5</sup> Many manufacturers use different strategies to expend these exclusivity periods.<sup>6</sup>

The lack of competition has a larger effect on consumer surplus in drug markets than other markets. The demand curves for most medications are highly inelastic<sup>7</sup> because they are necessities for most consumers. This inelasticity means that even a slight decrease in competition can lead to large price increase and deadweight loss.

To countervail these effects, many countries regulate the price of medications. Direct price regulation has proven difficult because costs are often difficult to assess.<sup>8</sup> Instead, many countries like France or the UK rely on the monopsony power of the healthcare system to negotiate prices against the costs

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2. Article 81 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and Article 126 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use.

3. *Global Guide to Patent Linkage*, BAKER MCKENZIE (Nov. 4, 2019), <https://www.bakermckenzie.com/en/insight/publications/guides/global-guide-to-patent-linkage> [<https://perma.cc/N237-U74T>] (“Patent linkage is generally understood to be the practice of linking the granting of marketing approval or any other regulatory approval for a generic or biosimilar medicinal product to the status of a patent for the originator reference product.”).

4. *Pharmaceutical Sector Inquiry Final Report*, EUR. COMM’N ¶¶ 1100-04 (2009) [hereinafter EC Report].

5. Valérie Junod, *Droit Pharmaceutique: Un Aperçu Global*, 4 EUR. L.J. 23, 26 (2006). Some medications, such as drugs for rare diseases (orphan drugs), have longer exclusivity periods in both the US and EU. See 21 U.S.C. § 360cc; Article 8(1) of Regulation (EC) No. 141/2000 of the European Parliament.

6. See, e.g., EC Report, *supra* note 4, at ¶ 1558 (identifying many strategies such as patent clusters around a medication, litigation against competitors, challenging market approvals, etc.).

7. See e.g., Justin Gatwood et al., *Price Elasticity and Medication Use: Cost Sharing Across Multiple Clinical Conditions*, 20 J. MANAGED CARE PHARMACY 1102 (2014).

8. See, e.g., Patricia M. Danzon, *Regulation of Price and Reimbursement for Pharmaceuticals*, OXFORD UNIV. PRESS 286 (2012) (discussing the different regulatory approaches including cost of production pricing).

of other existing treatments. Monopsony power plays a central role<sup>9</sup> in reducing prices of healthcare during negotiations between the purchasing governmental agency and the drug manufacturers. This negotiation approach has had some success.<sup>10</sup> Nonetheless, medication spending remains a substantial portion of total healthcare spending in France, the UK, and the US.<sup>11</sup>

Competition authorities in the US and the EU have cracked down on some practices that enable drug manufacturers to extend their monopoly power and add to healthcare costs. This Article focuses on one such practice: reverse payment settlements. It attempts to answer whether the centralized monopsony system common in the EU has decreased the incentives of drug manufacturers to carry out reverse payment settlements as compared to the US drug pricing system.

Section 2 focuses on drug pricing mechanisms in the US. These mechanisms remain opaque and do not provide many constraints on what drug manufacturers can charge. In this context, stopping competition becomes lucrative. Courts have failed to provide plaintiffs with the tools that drug consumers need to increase competition and lower prices.

Section 3 discusses pricing strategies in the UK and France. Drug manufacturers must negotiate with the agencies in charge of healthcare expenditure. These agencies wield a stronger bargaining position than private insurers in the US because of their monopsony power. However, reverse payments still occur, and the competition authorities still need to oversee drug settlements.

Section 4 provides some recommendations. First, the finding of an anticompetitive reverse payment should be coupled with a suspension of entry barrier—whether through compulsory licensing, rendering the patent unenforceable, or a price reduction of the branded drug. Second, the market exclusivity period and the pricing mechanism of branded drugs should be linked to market authorization instead of patent protection. This approach would nullify the need to regulate pay-for-delay settlements and streamline generic entry.

## II. REVERSE PAYMENTS IN THE US

This section highlights the complexity of the drug market in the US and the

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9. See e.g., Zack Cooper et al., *The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured*, 134 Q. J. ECON. 51 (2019) (finding concentration of US insurers lead to lower prices in local markets).

10. Pierre Dubois & Laura Lasio, *Identifying Industry Margins with Price Constraints: Structural Estimation on Pharmaceuticals*, 108 AM. ECON. REV. 3685 (2018) (discussing how the switch in regulatory setting leads to a 2% price decrease for anti-ulcer drugs).

11. According to the Organization for Economic Co-operation and Development, medication expenditure constituted 13.03%, 12.27%, and 11.55% of total healthcare expenditure in France, the UK, and the US in 2018 respectively. Medication expenditure includes over-the-counter and prescription drugs, but ignores drugs provided to patients “in hospitals and other health care settings.” *Pharmaceutical Spending*, ORG. ECON. COOP. & DEV. 1 (2021), <https://data.oecd.org/healthres/pharmaceutical-spending.htm> [<https://perma.cc/NMP8-5JXV>].

distorted incentives of market participants. Case law shows that many pharmaceutical companies have delayed generic entry. The Supreme Court decision on the topic has left much to interpretation. Public and private enforcers have faced problems proving payment amounts to pay-for-delay.

*A. Opaque Drug Pricing: Opportunities for Pay-For-Delay*

The US drug supply chain has been described as a “complex,”<sup>12</sup> “nonintuitive,”<sup>13</sup> and “Gordian”<sup>14</sup> system that is growing “curiouser and curiouser.”<sup>15</sup> A traditional supply chain has manufacturers, wholesalers, and retailers distributing products and negotiating prices. But the US pharmaceutical industry has two parallel chains that distribute and negotiate separately. Figure 1 is a simplified model of the distributing and pricing chains.

The distribution chain runs from drug manufacturers, which sell products to wholesalers, which distribute them to retailers (pharmacies), which sell to consumers.<sup>16</sup> Each participant in the distribution chain buys and sells drugs at close to list price. However, list price is misleading. A parallel pricing chain negotiates (usually in secret) rebates and other discounts.<sup>17</sup> Thus, no public data exists on how much manufacturers receive for their drugs in the US.<sup>18</sup>

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12. *The Prescription Drug Landscape, Explored*, PEW TRUSTS (Mar. 8, 2019), <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored> [<https://perma.cc/XC7Z-93YK>].

13. See Gary Novack, *What Determines How Much Your Patient Pays for their Medication in the United States?*, 167 AM. J. OPHTHALMOLOGY 48 (2016).

14. See NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE* (2018) [hereinafter “NATIONAL ACADEMIES”].

15. Wayne Winegarden, *The Economist Costs of Pharmacy Benefit Managers: A Review of the Literature*, PAC. RSCH. INST. 1, 3 (2017).

16. NATIONAL ACADEMIES, *supra* note 14, at 41-47.

17. *Id.*

18. *Id.*

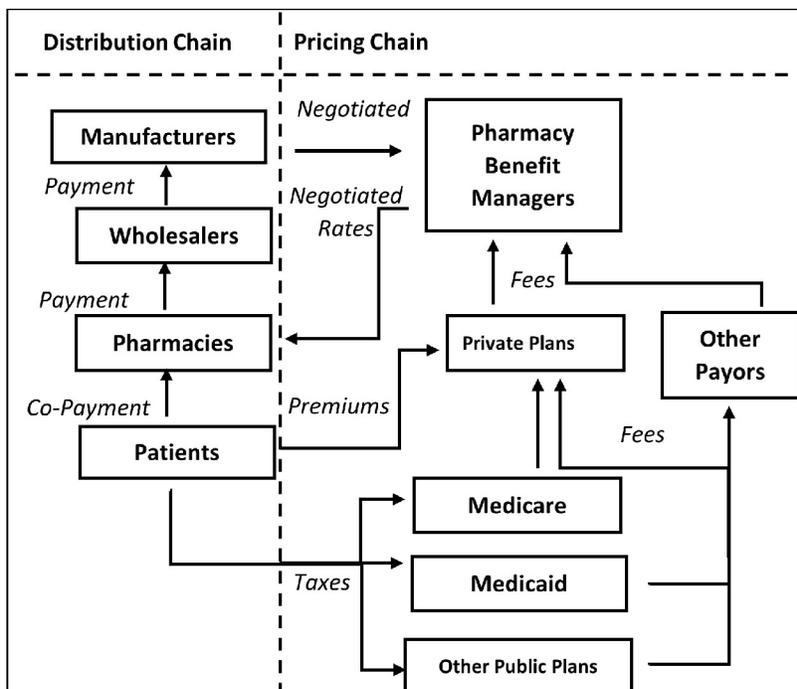


Figure 1: Simplified Model of U.S. Drug Pricing

Insurance companies sit at the bottom of the pricing chain. Insurance covered about 86% of drug spending in the United States in 2016.<sup>19</sup> The largest payors are private insurance (43%) followed by Medicare (29%) and Medicaid (10%).<sup>20</sup>

Medicare is a federal program that primarily supports the elderly and disabled. In theory, the federal government has significant buying power to negotiate rates and determine which drugs to cover. However, federal law prohibits the government from negotiating rates for most Medicare drugs.<sup>21</sup> The law also limits the ability of the government to use benchmarks, such as cost-effectiveness, to decide which drugs to cover.<sup>22</sup> So, Medicare's prescription drug program covers nearly all drugs that are approved by the FDA.<sup>23</sup>

19. Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2017-2026*, Table 11 Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds (Feb. 16, 2018) (on file with the author).

20. *Id.*

21. Section 1860D-11(i) of the Social Security Act, 42 U.S.C. § 1395w-111(i).

22. For a good discussion of the many relevant statutes, see NATIONAL ACADEMIES, *supra* note 14, at 49.

23. *Id.* ("Historically, CMS and its predecessor organizations have relied on approval by the FDA for those determinations, and have not used cost as a component of coverage

Medicaid is a federally financed program run by states that primarily covers the poor. Medicaid has rebates set by law that ensure states receive rates at lower costs than either Medicare or private insurers.<sup>24</sup> These rates are pegged to either a fraction of the average manufacturer price or the best price that a manufacturer charges wholesalers.<sup>25</sup> While regulating Medicaid prices ensures that states pay less, it also disincentivizes manufacturers to compete. Manufacturers that compete by lowering rates for other insurers risk reducing the prices used to calculate Medicaid rates.

Most Medicare and Medicaid plans, while publicly funded, are administered by private insurance companies. These private insurers can negotiate rates directly with drug manufacturers. However, they usually opt not to because of their weak bargaining power. The insurance market is decentralized. In 2016, the share of the largest five insurance companies was 39.4% based on market capitalization; the share of the next twenty was only 33%.<sup>26</sup> The rest of the market is covered by around 700 additional insurance companies.<sup>27</sup>

To make up for their limited buying power, insurers enlist pharmaceutical benefits managers (“PBMs”).<sup>28</sup> PBMs are third-party administrators of prescription drug plans and formularies. They use their market power to negotiate drug rates with pharmacies and rebates with manufacturers on behalf of insurers. To do so, they often manage tiered formularies for insurance plans. In a tiered formulary, drugs that are assigned to higher tiers have higher co-payments for patients. PBMs use tier placement as a bargaining chip to reduce rates and increase rates. These negotiations typically occur in secret.

PBMs could use their bargaining power to reduce drug costs for consumers; they have however mixed incentives. Unlike insurance, the PBM market is highly concentrated. The three largest PBMs negotiate rates and rebates for nearly 75% of the drug purchasing market.<sup>29</sup> PBMs not only have market power against manufacturers, but also against insurers. These insurers are not privy to the confidential rates and rebates that PBMs negotiate.<sup>30</sup> So, a PBM could encourage manufacturers to *increase* public list prices while decreasing private rebates and pocket the difference.<sup>31</sup> Then, manufacturers can use these higher list prices as the baseline for determining rebates for Medicaid plans and leverage

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determinations.”).

24. For a good discussion of the many relevant statutes, see *id.* at 107-08.

25. *Id.*

26. See Mitchell K. Ng et al., *U.S. Healthcare Insurance Market Concentration from 2001 to 2016: Increased Growth in Direct Written Premiums and Overall Decreased Market Consolidation*, 12 CUREUS 1 (2020).

27. *Id.*

28. See generally, NATIONAL ACADEMIES, *supra* note 14, at 47-53.

29. *Pharmacy Benefit Managers: As Drug Prices Soar, Policymakers Take Aim*, COLO. HEALTH INST. 1, 5 (2018).

30. *Id.*

31. *Id.* Because rebates are generally negotiated in secret, while list prices are often public, PBMs can theoretically pocket the rebate savings and charge insurers prices close to the list price.

these prices to negotiate rates for other insurers and out-of-pocket payors that lack buying power.

In conclusion, no major payor of pharmaceuticals in the US has both significant buying power and the incentive to lower effective prices. This distorted pricing model contributes to significantly higher prices for brand-name drugs compared to other countries. For example, a 2021 study by the Government Accountability Office determined that gross retail drug prices are 4.36 times higher in the US compared to France.<sup>32</sup> Another study estimates that retail drug prices are 2.56 times higher in the US compared to all OECD countries.<sup>33</sup>

### *B. Pay-for-Delay Tests*

The gap between brand-name and generic prices is also much higher in the US than in other countries. One study estimates that the average annual retail price of therapy for brand-name drugs is eighteen times higher than that of generics.<sup>34</sup> Another study concludes that brand-name drugs are more expensive, while generics are less expensive, in the US than in other OECD countries.<sup>35</sup>

Generic drugs save patients money while giving them a nearly identical drug to the brand-name medication. Nearly every state in the US permits pharmacies to substitute brand-name drugs with generic drugs.<sup>36</sup> Some states require patient consent before pharmacists make substitutions, while other states require pharmacists to substitute in nearly all cases.<sup>37</sup>

Brand manufacturers have a strong incentive to delay the entry of cheaper, substitutable generic drugs. Brand manufacturers can do so by suing generics alleging patent infringement—even when infringement was unlikely to have occurred. Then, the brand offers to settle with the generic for the lawsuit it initiated. In these *reverse payment* settlement schemes, brand companies often pay generics hundreds of millions of dollars to not enter the market. The cartel schemes draw antitrust scrutiny because the parties are sharing monopoly profits rather than competing. They are also known as pay-for-delay agreements.

The US regulatory framework incentivizes patent litigation that can lead to pay-for-delay settlements. Passed in 1984, the Hatch-Waxman Act offers generic companies an expedited approval process if they can show their generic is

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32. *Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average Than Prices in Australia, Canada, and France*, U.S. GOV'T ACCOUNTABILITY OFFICE 1, 15 (2021).

33. Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND CORP. 1, 12 (2021).

34. See Stephen W. Schondelmeyer & Leigh Purvis, *Price Decreases for Widely Used Generic Drugs Slow in 2017 After Two Years of Substantial Price Drops*, AARP PUB. POL'Y INST. 1 (2019).

35. Mulcahy, et al., *supra* note 33, at xii.

36. See Yan Song & Douglas Barthold, *The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs*, 27 HEALTH ECON. 1717 (2018).

37. *Id.*

chemically similar to the brand-name drug and does not violate any brand-name patents.<sup>38</sup> It encourages generic companies to more quickly introduce generics for drugs protected by weak patents. However, brand-name companies can delay the approval process for up to thirty months by timely filing a lawsuit against the generic alleging patent infringement.<sup>39</sup> Thus, brand-name manufacturers were incentivized to sue generic entrants irrespective of patent strength to delay the review process. As one court put it, “litigiousness was a product of Hatch-Waxman.”<sup>40</sup>

Reverse payment settlements that resolved patent infringement litigation thus became ubiquitous. In 2003, Congress responded by passing a law<sup>41</sup> that required pharmaceutical companies to report these settlements to the Federal Trade Commission (“FTC”).<sup>42</sup> The FTC would then investigate these settlements, challenge some in court, and publish annual reports that summarize the agreements formed each year.<sup>43</sup> The FTC argued that these agreements violated Section 1 of the Sherman Act by foreclosing competition between generic and brand-name drugs.<sup>44</sup>

Circuit courts agreed that manufacturers who engaged in reverse payment settlements were maintaining monopolies over their brand-name drugs.<sup>45</sup> But some circuits held that these monopolies are lawful because they are granted by patents. In *Schering-Plough v. FTC*, the Eleventh Circuit adopted a patent validity test.<sup>46</sup> This test holds that a “reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the

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38. Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §§ 301, 355, 360cc.

39. 21 U.S.C. § 355(c)(3)(C).

40. *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132, 158 (3d Cir. 2017) (internal quotation marks and citations omitted).

41. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, H.R. 1, 108th Cong. (2003).

42. 21 U.S.C. §§ 1112-13 (2011).

43. *Pharmaceutical Agreement Filings*, FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care/pharmaceutical-agreement-filings> [<https://perma.cc/9F2F-B26M>] (last visited April 5, 2021).

44. *Id.*

45. See generally *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799 (8th Cir. 2001); *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (In re Cardizem CD Antitrust Litig.)*, 332 F.3d 896 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2006); *Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.)*, 544 F.3d 1323 (Fed. Cir. 2008); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010); *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012); *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

46. *Schering-Plough Corp.*, 402 F.3d at 1064.

exclusionary potential of the patent.”<sup>47</sup> Because a valid patent grants a legal right to exclude, a brand manufacturer suing for patent infringement cannot be violating antitrust law. So, a pay-for-delay agreement could only be illegal if the patent was invalid.<sup>48</sup> This created a significant hurdle for the FTC and private plaintiffs, who were expected to show a patent was invalid when its infringement lawsuit had already been settled.

In *K-Dur Antitrust Litigation*,<sup>49</sup> the Third Circuit disagreed with the Eleventh Circuit in a case that concerned the same agreement as *Schering-Plough*. The court held that the manufacturer’s monopoly over its brand-name drug is only lawful if its patents are valid. Because the parties settled out of court with a large payment, the court reasoned that the contested patents were probably weak.<sup>50</sup> Thus, the payment could reveal that the generic was likely to win the case if it did not settle. So, the court ruled that the reverse payment settlement violated antitrust law even though the underlying patent validity was unknown because it eliminated the *possibility* of competition.<sup>51</sup>

The Supreme Court followed a similar line of reasoning in *FTC v. Actavis, Inc.*<sup>52</sup> The brand firm Solvay sued the generic firm Actavis for allegedly violating its patents in creating a generic alternative of the testosterone drug AndroGel.<sup>53</sup> Solvay then settled with Actavis, agreeing to pay \$19-30 million per year to delay generic entry.<sup>54</sup> Solvay sued and settled with other generic companies as well.<sup>55</sup> In 2009, the FTC sued all parties, alleging illegal monopoly profit sharing.<sup>56</sup> The appeals court ruled that the settlement scheme could not be illegal because Solvay’s agreements fell within the scope of its patent rights.<sup>57</sup> At the FTC’s request, the Court granted certiorari.

To evaluate whether a reverse payment scheme is anticompetitive, the Court adopted an unjustified payment size test.<sup>58</sup> In the Court’s reasoning, a larger payment by the plaintiff suggests that the plaintiff did not expect to win the infringement case. Payment size could serve as a proxy for patent validity. The question that courts must then resolve is whether the payment size is “large and

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47. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013) (citing *FTC v. Watson*, 677 F.3d 1298, 1312 (11th Cir. 2012)).

48. *Id.*

49. *In re K-Dur Antitrust Litig.*, 686 F.3d at 211 (“We do not find the Eleventh Circuit’s decision in *Schering-Plough* persuasive, and thus decline to follow it.”).

50. *Id.*

51. *Id.*

52. *Actavis, Inc.*, 570 U.S. at 136.

53. *Id.* at 144-46.

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.* at 159 (“The likelihood of a reverse payment bringing about anticompetitive effects depends upon its size.”)

unjustified.”<sup>59</sup> To do so, courts should look at “[the payment] size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing [procompetitive] justification.”<sup>60</sup>

Actavis was a victory for consumers. It established that reverse payment schemes can be subject to antitrust scrutiny under an unjustifiability standard. Since then, the number of illegal reverse payment schemes in the United States has reduced considerably (according to the FTC).<sup>61</sup> But this does not mean that reverse payment schemes have disappeared. Instead, pharmaceutical companies have established many creative arrangements that make prosecution harder.<sup>62</sup> Courts have also disarmed some public and private enforcers from disincentivizing pay-for-delay.

First, some courts have constricted the ability of private plaintiffs to claim antitrust injury. In *Wellbutrin*,<sup>63</sup> a pay-for-delay scheme settled several patent disputes for a brand-name drug but left one dispute unresolved because the patent belonged to a third party.<sup>64</sup> The court ruled that plaintiffs could not claim injury without showing that the outstanding patent dispute was likely to be resolved in favor of the generics.<sup>65</sup> To make this showing, the court expected plaintiffs to discuss the underlying patent’s validity; it held that the unjustified payment size alone was insufficient evidence.<sup>66</sup>

In *Nexium*, the First Circuit similarly ruled that defendants did not cause injury even though they were liable.<sup>67</sup> The companies AstraZeneca and Ranbaxy formed a billion-dollar reverse payment scheme. Ranbaxy, however, was soon thereafter suspended from marketing any drugs by the FDA after a quality control scandal.<sup>68</sup> So, the court reasoned that generic entry by Ranbaxy never would have

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59. *Id.*

60. *Id.*

61. Jamie Towey & Brad Albert, *Then, Now, and Down the Road: Trends in Pharmaceutical Patent Settlements After FTC v. Actavis*, FED. TRADE COMM’N (May 28, 2019, 12:23 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent> [<https://perma.cc/ZQ3X-6R7E>].

62. See Garry A. Gabison and Zaakir Tameez, *Multilateral Reverse Payment Settlements*, 16 RUTGERS BUS. L. REV. 340 (2021). In recent years, brand and generic companies have formed complex pay-for-delay schemes involving multiple parties, drugs, or jurisdictions.

63. *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132, 141 (3d Cir. 2017).

64. *Id.* at 167.

65. *Id.*

66. *Id.* at 168 n.58 (“We cannot resolve this aspect of the case without considering the merits of the underlying patent dispute.”).

67. See *Am. Sales Co., LLC v. AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig.)*, 842 F.3d 34 (1st Cir. 2016).

68. *Id.* at 43. See also Katherine Eban, *How Ranbaxy Hurtled Towards a Meltdown*, MINT, (July 11, 2019, 10:13 PM), <https://www.livemint.com/companies/news/how-ranbaxy-hurtled-towards-a-meltdown-1562861830620.html> [<https://perma.cc/TT4E-WW37>].

happened regardless of the illegal pay-for-delay scheme.<sup>69</sup> The court denied plaintiffs any relief.

Second, other courts have undermined the ability of the government to disincentivize pay-for-delay. In *FTC v. AbbVie, Inc.*,<sup>70</sup> the Third Circuit held that Section 13 of the Federal Trade Commission Act does not grant the agency the authority to order disgorgement of the profits made from a reverse payment scheme.<sup>71</sup> In the court's view, the FTC can only enjoin antitrust defendants from committing future harm.<sup>72</sup> This statutory interpretation was echoed by a unanimous Supreme Court in a recent ruling.<sup>73</sup>

Finally, courts have only accepted federal antitrust damage claims from direct purchasers of brand-name drugs.<sup>74</sup> While this approach is consistent with well-established Supreme Court doctrine,<sup>75</sup> it is poorly suited for a market where direct purchasers have mixed incentives on reducing prices. Direct purchasers are typically wholesalers but can also be PBMs, pharmacies, or insurers.<sup>76</sup> Wholesalers purchase drugs from manufacturers and re-sell them to pharmacies to make profit on the margins.<sup>77</sup> Pharmacies pass on most costs to consumers and make profit on privately negotiated reimbursements from PBMs. PBMs pass on most costs to insurers and make profit on privately negotiated rebates with manufacturers. And insurers pass on most costs to consumers indirectly through insurance premiums.<sup>78</sup>

Each of these participants in the pharmaceutical supply chain makes profit from private or nontransparent margins that are benchmarked to the public list prices set by manufacturers.<sup>79</sup> These public list prices, therefore, are subject to distorted incentives. But the downstream implications are serious for consumers, who suffer the brunt of brand-name drug overcharges but lack federal standing in antitrust claims as indirect purchasers. While this issue does not have a clear resolution under standard antitrust doctrine, it highlights an additional challenge that plaintiffs face to disincentivize pay-for-delay in the United States.

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69. *Id.*

70. *See* *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020).

71. *Id.* at 374-81.

72. *Id.*

73. *See* *AMG Cap. Mgmt., LLC v. FTC*, 141 S.Ct. 1341 (2021).

74. *See, e.g., In re Niaspan Antitrust Litigation*, 42 F. Supp. 3d 735 (2014); *In re Nexium Antitrust Litigation*, 777 F.3d 9 (1st Cir. 2015); *In re Aggrenox Antitrust Litigation*, 94 F. Supp. 3d 224 (2015); *In re Humira (Adalimumab) Antitrust Litigation*, 465 F. Supp. 3d 811 (N.D. Ill. 2020).

75. *See* *Illinois Brick v. State of Illinois*, 431 U.S. 720 (1977).

76. For example, all of these classes were litigants in *In re Lipitor Antitrust Litigation*, 868 F.3d 231 (3d Cir. 2017).

77. NATIONAL ACADEMIES, *supra* note 14, at 41-47.

78. *Id.*

79. Neeraj Sood et al., *Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System*, USC SCHAEFFER CTR. FOR HEALTH POL'Y & ECON., Figure 2 (2017).

### III. REVERSE PAYMENTS IN THE EU

This section investigates the importance of generics in Europe and the need to decrease reverse payment settlement in Europe – even though prices are controlled through a centralized health care system.

#### *A. Monopsony Decreases the Incentive but Does Not Eliminate Pay-For-Delay*

All European countries have socialized health care. The entities in charge of health care act as monopsonists. These monopsonists control prices and hence may decrease the incentive of pharmaceutical companies to attempt pay-for-delay. The first subsection below discusses the healthcare system in the UK and France. The second subsection discusses the need to enable generic competition.

##### *1. The Health Care System in the UK and France*

In both the UK and France, the regulated prices of medication used to be derived through a cost-plus-profit margin model. Both countries deviated from this model because of the difficulties in proving costs.<sup>80</sup>

In the UK, the National Health Service (“NHS”) is the main purchaser of medications. The National Institute for Health and Care Excellence (“NICE”) measures the cost efficiency of a medication based on the offer made by the manufacturer.<sup>81</sup> New drug manufacturers must show that the new drug “provides an economic advantage over the currently used next best treatment for the same condition.”<sup>82</sup> If the treatment passes a certain cost-effectiveness threshold, NICE recommends it for adoption.<sup>83</sup> If the threshold is not passed, the manufacturer may negotiate with the NHS.<sup>84</sup>

Generic entry undercuts brand-name drug profits in two ways. First, UK pharmacists can substitute a brand drug with a generic and pocket the difference.<sup>85</sup> Thus, they are incentivized to look for the cheapest generic<sup>86</sup> and often benefit from the cheaper products.<sup>87</sup> Second, after generic entry, NICE

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80. See Vivek Kotecha & Karl Claxton, *Who Decides the Price and Availability of NHS Medicines?*, CTR. FOR HEALTH & PUB. INT. 1 (2019).

81. See *The Pharmaceutical Price Regulation Scheme 2014*, U.K. DEP’T HEALTH 1 (2013).

82. *Id.* at ¶ 13.

83. *Changes to NICE Drug Appraisals: What You Need to Know*, NAT’L INST. FOR HEALTH & CARE EXCELLENCE (Apr. 4, 2017) <https://www.nice.org.uk/news/feature/changes-to-nice-drug-appraisals-what-you-need-to-know> [<https://perma.cc/J5VG-UDSE>].

84. See Leo Ewbank et al., *The Rising Cost of Medicines to the NHS: What’s the Story?*, KING’S FUND 1 (2018).

85. See *The Pharmaceutical Price Regulation Scheme 2009*, ASS’N BRIT. PHARM. INDUS. 1 (2008).

86. *Id.* at 23.

87. Panos Kanavos et al., *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis*, LONDON SCH. ECON. & POL. SCI. 1, 123 (2004).

measures the cost-effectiveness of the generic alternative rather than the original brand-name drug.

In France, the Social Security (*Sécurité Sociale*) reimburses the cost of medication. The system is financed through taxes on income and on alcohol and tobacco. According to the French pharmaceutical association, French pharmaceutical manufacturers earn over 80% of their income through sales to the social security system.<sup>88</sup>

The price of a medication depends on several factors.<sup>89</sup> First, the manufacturer must decide whether it wants the product reimbursed. If the medication is not reimbursed, the manufacturer can set its wholesale price based on economic forces (*i.e.*, competition, demand, etc.). Pharmacists can also set their margin freely. This may lead to double marginalization, which means higher prices but lower demand.

If a manufacturer decides to have its medication reimbursed, then the social security determines how the prices are fixed in accordance with the law.<sup>90</sup> Reimbursement will mean wider access and demand, but lower prices.

The *Comité économique des produits de santé* (“CEPS”) negotiates the price with the manufacturer. The price will depend on four factors: (1) improvement on existing medication(s); (2) price of existing therapeutic treatment(s); (3) expected demand of the medication; and (4) actual use of the medication.<sup>91</sup> Depending on its therapeutic offering, the medication will be reimbursed at 0%, 35%, 65%, or 100% of the medication price while the rest is paid by the consumer (or their complementary insurance).<sup>92</sup> The CEPS will negotiate the price up or down from the price of existing treatment based on the improvement offered.

Once a generic enters, the price of the generic is fixed at 60% of the original negotiated price and the price of the brand is decreased by 20%.<sup>93</sup> After 18 months, the branded medication is reimbursed based on the generic price or both

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88. *Bilan Économique*, LES ENTREPRISES DU MÉDICAMENT 1, 6 (2020). The industry makes €60bn in France. 50% of this revenue is from exports. €25.5bn come reimbursement from insurances, which include both the social security system and private top-up insurances, who complement the social security for deductibles.

89. Sophie Rémond, *The Price of Drugs*, INSTITUT NATIONAL DE LA CONSOMMATION (Sept. 12, 2020) <https://www.inc-conso.fr/content/le-prix-des-medicaments> [<https://perma.cc/M854-YV9L>].

90. L'article L. 162-16-4 du code de la sécurité sociale.

91. *Id.* (“La fixation de ce prix tient compte principalement de l'amélioration du service médical rendu par le médicament, le cas échéant des résultats de l'évaluation médico-économique, des prix des médicaments à même visée thérapeutique, des volumes de vente prévus ou constatés ainsi que des conditions prévisibles et réelles d'utilisation du médicament.”)

92. Rémond, *supra* note 89. The price will also depend on comparable European country. The reimbursement system was introduced because France was the highest consuming country in the world. See also Sylvain Duffaud & Sandra Liébart, *How Do General Practitioners Limit Their Prescriptions? Qualitative Study by Collective Interviews*, 26 SANTÉ PUBLIQUE 323 (2014).

93. Rémond, *supra* note 89.

prices are further dropped.<sup>94</sup> For reimbursed medication, the margins of pharmacists are also regulated: on average, 76% of the medication price is pocketed by the manufacturer, while the pharmacists and wholesalers make 22% combined and the remaining 2% is the tax.<sup>95</sup>

The monopsony power of the UK and French governments allows them to negotiate prices lower than US insurers.<sup>96</sup> However, monopsony power does not eliminate the need for generics. The next section investigates drug competition in countries with drug price regulations.

## 2. *Intra-brand vs. Inter-brand Competition: The EU Functioning and Drug Circulation in the EU*

Competition plays an important role in decreasing prices. In any country, competition comes from: (1) the same drug coming from abroad through parallel imports (intra-brand competition); (2) different drugs with similar therapeutical treatment (“me-too” drugs); and (3) generics competition (inter-brand competition). Of these three, only generic competition exerts significant downward pressure on drug prices.

First, intra-brand competition occurs when a branded drug competes with itself. In Europe, a branded drug may compete with itself through parallel imports. Parallel imports occur when a branded drug marketed for one country is sold in another country. Aside from the coronavirus pandemic (when the European Commission intervened),<sup>97</sup> each Member State individually negotiates with pharmaceutical companies.<sup>98</sup> These individual negotiations lead to different prices in different jurisdictions. Parallel importers can take advantage of those different prices to profit.<sup>99</sup>

Parallel imports rely on the patent exhaustion doctrine: once a patent holder sells a patented product, the product can circulate freely inside the stream of commerce. In the European Economic Area (“EEA”), the patent exhaustion doctrine applies to all patented products within the stream of commerce – even though patent protection remains Member State-specific.<sup>100</sup> In the post-Brexit United Kingdom, parallel imports are accepted from the EEA, but not vice-

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94. *Id.*

95. *Id.*

96. *Prescription Drugs*, *supra* note 32.

97. *See Commission Decision of June 18, 2020*, EUR. COMM’N 1 (2020) (approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures); *Annex to the Commission Decision*, EUR. COMM’N 1 (2020).

98. Nicole Scholz, *Medicinal Products in the European Union*, EUR. PARLIAMENTARY RSCH. SERV. 9 (2015).

99. Kanavos et al., *supra* note 87, Table 6.20 (showing parallel importers are the main beneficiary of this practice).

100. Garry A. Gabison, *Worldwide FRAND Licensing Standard*, 8 AM. U. BUS. L. REV. 139, 154-62 (2019).

versa.<sup>101</sup>

In *Centrafarm BV et Adriaan de Peijper v. Sterling Drug Inc.*,<sup>102</sup> Sterling Drug Inc. sought an injunction to stop the Dutch drug seller Centrafarm from importing Sterling-patented drugs from Germany and England to sell in the Netherlands.<sup>103</sup> The Dutch court referred the case to the European Court of Justice. The court concluded that the right of a patentee “to prohibit the sale . . . is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the common market.”<sup>104</sup>

The court also allowed parallel imports from a Member State where the patent holder freely marketed the drug but did not hold a patent<sup>105</sup> into a Member State where it did. More importantly, the court also barred laws that impede the movement of generics between European countries.<sup>106</sup> However, the court held that if the drug was manufactured in one country under a compulsory license, the patent holder may prevent import to another European country where it holds another patent.<sup>107</sup>

Parallel imports enabled some arbitrage. Prices decrease in countries where drugs are more expensive<sup>108</sup> and the national insurance system garner some benefits.<sup>109</sup> However, these benefits are limited. Regulated prices deter pharmaceutical manufacturers from introducing their own generics, which would create undesired intra-brand competition. Parallel imports increase this

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101. *Exhaustion of IP Rights and Parallel Trade*, UK I.P. OFF., <https://www.gov.uk/guidance/exhaustion-of-ip-rights-and-parallel-trade> (last updated June 21, 2021).

102. *Centrafarm BV and Adriaan de Peijper v. Sterling Drug Inc*, Case 15-74 (1974).

103. *Centrafarm B.V. and Adriaan de Peijper v Sterling Drug Inc.*, [1974] 2 C.M.L.R. 1.

104. Case 15-74 at ¶ 15.

105. *See e.g.*, *Merck & Co. Inc. v. Stephar BV*, Case 187/80 (1980) (allowing the free movement of a drug from a country where the patent holder marketed the drug but did not have a patent to a county where it holds a patent); *Merck & Co. Inc. v Primecrown Ltd.*, Case 267/95 (1997) (allowing the free movement of a drug from a country where the patent holder marketed the drug but did not have a patent because pharmaceutical were not patentable to a county where it holds a patent).

106. *Kohlpharma GmbH v. Bundesrepublik Deutschland*, Case C-112/02 (2004) (barring laws that affect the free movement of a drugs even when the parallel importer did not obtain marketing authorization when it has the same active ingredients as another authorized drug – even if the drug does not originate from the same entity); *Delfarma Sp. z o.o. v. Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*, Case C-387/18 (2019) (barring laws that affect the free movement of a generics even if the parallel importer did not obtain a marketing authorization when it has the same active ingredients as an authorized patented drug).

107. *Pharmon BV v. Hoechst AG*, Case 19/84 (1984) (allowing the patent holder to block the importation of patented drugs that were produced under a compulsory because he did not freely choose to market the drug).

108. *See e.g.*, Mattias Ganslandt & Keith E. Maskus, *Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union*, 23 J. HEALTH ECON. 1035 (2004) (finding parallel imports lead to a price decrease in Sweden).

109. Kanavos et al., *supra* note 87, Table 6.16.

deterrence because introducing a generic could affect all other countries in the European Common market.

Parallel imports have also incentivized drugs companies to negotiate higher prices in countries where prices were previously lower. These low-price countries have had to react and change their laws to account for parallel exports.<sup>110</sup> This reaction explains why the French CEPS looks at the prices set in the UK, Germany, Italy, and Spain when negotiating its prices with pharmaceutical companies.<sup>111</sup>

The limited success of parallel import at creating competition means that competition must either come from a drug with a similar therapeutic treatment or from a generic. Drugs with similar therapeutic treatment are known as “me-too” drugs. These me-too drugs have not created the desired competition.<sup>112</sup> This limited competition has been linked to the pricing mechanisms in countries with large monopsonist health insurance.<sup>113</sup>

For example, the French system creates no incentive for me-too drugs to compete on price: doctors prescribe the drug based on treatment, not on cost. The doctor has no incentive to look at treatment cost when prescribing drugs.<sup>114</sup> The decisionmaker in the market for drug consumption is the doctor, whereas the payors are the health agency and consumers (through deductibles). This relationship raises a principal-agent problem because the decisionmaker differs from the cost bearer.<sup>115</sup>

Thus, generics remain the only mechanism for competition in the

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110. *Id.* at Table 4.3.

111. *See* Rémond, *supra* note 89 (« Ce prix dépend : . . . des prix pratiqués à l'étranger : le CEPS est soumis au "comparateur de prix européen" qui est une disposition par laquelle il s'oblige à fixer un prix similaire à ceux pratiqués au Royaume-Uni, en Allemagne, en Italie et en Espagne. Le prix du médicament ne peut être inférieur aux prix pratiqués dans ces quatre pays. » which translates to “the price depends on the prices practiced abroad: the CEPS must “compares with other European prices” which obliges the CEPS to fix a similar price to those practices in the UK, Germany, Italy, and Spain. The price of medication cannot be inferior to the price practices in those four countries.”).

112. *See e.g.*, Gisela Hostenkamp, *Do Follow-On Therapeutic Substitutes Induce Price Competition Between Hospital Medicines? Evidence from the Danish Hospital Sector*, 111 HEALTH POL'Y 68 (2013) (finding limited evidence of price decreased linked to the introduction of competing therapeutic treatment).

113. *See* Mats Ekelund & Björn Persson, *Pharmaceutical Pricing in a Regulated Market*, 85 REV. ECON. & STAT. 298 (2003) (comparing the US to Sweden in their pricing, finding that, in Sweden, price less competition occurs when new therapeutic drugs were introduced when controlling to therapeutic improvements, and concluding that the price-cap system has led to less declining prices over time).

114. Duffaud & Liébart, *supra* note 92, at ¶ 41 & ¶ 47 (surveying French doctors and they observed that doctors did not consider the price or the reimbursement rate when making prescriptions).

115. *See e.g.*, Oliver D. Hart & Bengt Hölmstrom, *The Theory of Contracts*, ADVANCES ECON. THEORY: FIFTH WORLD CONG. 75-106 (T. Bewley ed. 1987).

pharmaceutical industry when health systems implement a regulated pricing mechanism. Therefore, health agencies in those countries should pay more attention to any barriers to generic entry because these barriers can cost taxpayers billions of pounds or euros.

Brand-name drug manufacturers in the UK and France have a strong incentive to cartelize with generic entrants because of the pricing mechanism. As discussed, UK generic manufacturers set their own prices, compete directly with brand-name drugs, and lower the cost-effectiveness benchmark for alternative branded drugs. This combination has the potential to destroy the monopoly profits of a brand-name drug. And in France, branded drugs lose 20% of the price of the medication immediately upon generic entry and 60% of the price after eighteen months.<sup>116</sup> This price decrease does not even account for the substitution effect linked to consumers buying from the generic company instead of the branded manufacturer.

The margins in the UK and France are still smaller than in the US, where pay-for-delay is more common.<sup>117</sup> But this does not negate the incentive for European drug manufacturers to introduce barriers to entry. The next section discusses European cases of pay-for-delay.

#### *B. The “No-Alternative-Explanation” Test*

The European Commission (“Commission”) has fined a few companies over the years for “pay-for-delay” agreements. However, cases are far and few by comparison with the number of cases in the US.

On June 19, 2013, the Commission fined a brand manufacturer, Lundbeck, and four generic manufacturers—Generics (UK) (a Merck subsidiary), Arrow, Alpharma, and Ranbaxy—for six agreements spanning across different countries within the European Economic Area.<sup>118</sup> The Commission found that the agreements did not resolve any patent disputes and delayed generic market entry beyond what the patent protection would have allowed: the brand manufacturer paid the generic companies lump sums and bought their drug stocks to destroy them.<sup>119</sup>

The participants appealed the Commission’s decisions.<sup>120</sup> In 2016, a General Court of the European Union found that the agreements had for object a restriction of competition and that the brand manufacturer failed to demonstrate

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116. Rémond, *supra* note 89.

117. *Comparaison Internationale Des Prix Des Medicaments*, MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ 1 (2015).

118. Case AT.39226 – Lundbeck (2013).

119. *Id.*

120. *See* Case T-460/13 Sun Pharmaceutical Indus. & Ranbaxy v. Comm’n; T- 467/13 Arrow Grp. & Arrow Generics v. Comm’n; T-469/13 Generics (UK) v Comm’n; T-470/13 Merck v. Comm’n; T-471/13 Xellia Pharmaceuticals & Alpharma v. Comm’n; T-472/13 Lundbeck v. Comm’n.

that the agreements were necessary to protect its intellectual property rights.<sup>121</sup> Because of the anticompetitive object of the agreement, the Commission did not have to investigate the effect of the agreement.<sup>122</sup> The General Court affirmed the €150 million fines.

The General Court spent a large part of the decision assessing whether generic manufacturers were competitors.<sup>123</sup> It looked at whether the companies believed that the generic had the ability to enter the market.<sup>124</sup> The court reasoned that the fact that brand manufacturer concluded these “agreements with the generic undertakings is a strong indication that it perceived those undertakings as a potential threat.”<sup>125</sup> The General Court also rejected the scope-of-the-patent test, citing *Actavis*.<sup>126</sup>

In 2013, the Commission fined the brand manufacturer, Janssen-Cilag (a Johnson & Johnson subsidiary), and the generic manufacturer, Sandoz (a Novartis subsidiary), for pay-for-delay in the Netherlands.<sup>127</sup> The “co-promotion” agreement set out profit transfer to Sandoz in exchange for promoting the branded product and refraining from introducing its own generic. This agreement delayed entry from July 2005 to December 2006. The parties did not appeal the €16 million fines.

In 2014, the Commission fined a brand manufacturer, Servier, and five generic manufacturers (Niche/Unichem, Matrix (a Mylan subsidiary), Teva, Krka and Lupin) €427.7 million for multiple deals delaying the entry of generics.<sup>128</sup> Servier deployed different strategies (including catch-and-kill<sup>129</sup> of compound manufacturers) to maintain its monopoly.

On appeal, the General Court affirmed the Commission’s decision with respect to four of the five generics based on the object of the agreements.<sup>130</sup> It confirmed the amount of Servier’s fine with respect to three agreements and reduced it with respect to the fourth agreement (with Matrix).

The General Court focused on the Commission’s findings to conclude that the agreement had an anticompetitive object. The court stated that the Commission

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121. Case T-472/13 at ¶¶ 478-501 (“In that respect, even if the agreements at issue also contained restrictions potentially falling within the scope of the applicants’ patents, those agreements went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market.”).

122. *Id.* at ¶¶ 418-40.

123. *Id.* at ¶¶ 88-330.

124. *Id.* at ¶ 131.

125. *Id.* at ¶ 181.

126. *Id.* at ¶¶ 353, 492-93 (citing *Actavis* to support its rejection of the patent scope test).

127. Case AT.39685 – Fentanyl.

128. Case AT.39612 – Perindopril (Servier)

129. Catch-and-kill or “killer acquisitions” refers to purchasing and shutting down a competitor before they can start marketing the product. *See e.g.*, Colleen Cunningham et al., *Killer Acquisitions*, 3 J. POL. ECON. 129, 649-702 (2021).

130. Case T-691/14.

rightly considered (1) “transfer of value from the originator company to the generic company”; (2) whether the parties were “potential competitors”; (3) “whether those settlements included non-challenge and non-marketing clauses”; and (4) whether the parties signed to these non-marketing and non-challenge clauses “in return for a transfer of value.”<sup>131</sup>

The General Court also focused on the existence of “side deals” that can be used to induce the parties to sign onto those agreements.<sup>132</sup> The court acknowledged that the Commission would struggle making connections between side deals unless they are “concluded on the same day, where they are legally linked, the binding nature of one of the agreements being conditional upon the conclusion of the other agreement, or . . . they are indissociable.”<sup>133</sup>

The General Court spent a lot of time on appeal establishing the market definition and discussing whether the non-identical generics compete with the branded products. The former question focused on treatment;<sup>134</sup> but the court found that me-too drugs “exercised little pressure on the prices of” the patented drug.<sup>135</sup> In the latter inquiry, the court found medications – generics included – with the same active ingredients may be considered competitors.<sup>136</sup>

These cases show that the Commission has taken an active role in enforcing pay-for-delay. Despite these cases, in many situations, pay-for-delays do not have a European dimension that would require the Commission’s involvement. For example, in the *Generics (UK) Ltd et al. v. Competition and Markets Authority*<sup>137</sup> case, the UK competition authority intervened in a case involving UK sales.<sup>138</sup>

In this case, the patent holder, GlaxoSmithKline plc (GSK), concluded multiple agreements with generic manufacturers who had submitted or obtained market authorization<sup>139</sup> applications in different European countries: IVAX in Ireland; GUK in Denmark; and Alpharma in the UK. The generic manufacturers agreed to stop ongoing challenges to GSK’s patent in exchange for exclusive dealing agreements.

The UK Competition and Markets Authority fined these companies for

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131. *Id.* at ¶ 406 and affirmed by the General Court in ¶ 418.

132. *Id.* at ¶ 797.

133. *Id.* at ¶ 798.

134. *Id.* at ¶¶ 123-40.

135. *Id.* at ¶ 125.

136. *Id.* at ¶ 131.

137. *Generics (UK) Ltd., GlaxoSmithKline plc, Xellia Pharmaceuticals ApS, Alpharma LLC, formerly Zoetis Products LLC, Actavis UK Ltd., Merck KGaA v. Competition & Markets Authority*, Case C-307/18 (2020).

138. Note that this case was expedited because of the UK’s exit from the EU.

139. Drug manufacturers must seek a market authorization from “the competent authorities of that Member State . . . in accordance with Regulation” to commercialize a drug in the EU. *Id.* ¶ 40. MAs ensure the protection of patients and public health. *Id.* ¶ 139. Patents are jurisdictional in the EU: with such authorization, the manufacturer can sell across EU borders as long as the drug does not infringe any patents.

forming a cartel (unlawful agreements and concerted practices) and GSK for abusing its dominant position. The parties appealed the decision to the Competition Appeal Tribunal who referred some questions to the General Court of the European Union. First, the Appeal Tribunal asked:

“For the purpose of Article 101(1) [TFEU], are the holder of a patent for a pharmaceutical drug and a generic company seeking to enter the market with a generic version of the drug to be regarded as potential competitors when the parties are in bona fide dispute as to whether the patent is valid and/or the generic product infringes the patent?”<sup>140</sup>

The UK Appeal Tribunal added further sub-questions to the General Court of the European Union. First, it asked whether ongoing litigations would impact the anticompetitive ruling. If it did, the Tribunal asked whether the probability of invalidation/success, or the duration of delay versus the duration of patent validity, would affect the anticompetitive finding. The European Court of Justice refers to this as the “effect” of the agreement.<sup>141</sup>

Second, it asked whether the benefit or payment size would affect this finding as compared to: (1) the litigation costs; and (2) the potential market earnings if the patent is invalidated. The European Court of Justice refers to this as the “object” of the agreement.<sup>142</sup>

These questions mirror the inquiry that took place in US courts. The General Court found that reverse payment can amount to a violation of the competition laws. However, the General Court went further.

First, the General Court stated that courts must still assess barriers to entry; but the lawsuits against the generic manufacturers can be used as evidence that the brand manufacturer sees the generic manufacturers as possible entrants.<sup>143</sup>

Second, the General Court stated that courts do not have to investigate the validity of the underlying patent.<sup>144</sup> The agreement to limit trade was sufficient in itself to find anticompetitive object.

Third, the General Court recognized that the agreements must be viewed in light of each other.<sup>145</sup> Because GSK concluded those three agreements, it could maintain its dominant position: together, they formed an overall multilateral reverse payment strategy.

In many respects, the General Court went further than the US Supreme Court and the Federal Circuit courts. The General Court presented a “no-alternative

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140. *Id.* at ¶ 21.

141. *Id.*

142. *Id.*

143. *Id.* at ¶ 52.

144. *Id.* at ¶ 122.

145. *Id.* at ¶ 155-57 (“[T]he set of settlement agreements concluded on the initiative of GSK were part of an overall strategy on the part of that manufacturer of originator medicines and had, if not as their object, at least the effect of delaying the market entry of generic medicines [. . .]. The anticompetitive effects of such a contract-oriented strategy are liable to exceed the anticompetitive effects inherent in the conclusion of each of the agreements that are part of it.”).

explanation” test: if the agreement has the object of restricting entry, then it is anticompetitive. Therefore, the court did not require looking at whether the agreement was effective at decreasing entry. However, if the competition authority tries to prove the agreement has anticompetitive effects, then the competition authority cannot presume that, without the agreement, the patent would have been invalidated or the parties could settle in a less restrictive manner. The patent holder could also present pro-competitive evidence.

The next section discusses what can be done to further disincentivize pay-for-delay and ease the entry of generics.

#### IV. RECOMMENDATIONS AND CONCLUSION

Pay for delays are hard to identify and even harder to prosecute. This section attempts to make some recommendation how pay-for-delay can be disincentivized or illuminated.

##### *A. Remedies Against Abuse*

Current remedies are maladapted for pay-for-delay suits. They do not optimally compensate the victims of cartels, nor do they optimally deter the cartel members.

In private suits, damages attempt to make the victims whole. In cartel suits, damages should compensate the purchasers of the good for the additional costs linked to the coordinated behavior. In the US, these damages are trebled to promote deterrence.<sup>146</sup> However, in practice most total damages do not even fully compensate consumers once.<sup>147</sup>

Even if they compensate for the price difference, compensatory damages do not cover the harm created by pharmaceutical companies carrying out pay-for-delay. Victims in this case would include both the drug purchasers and the individuals who had not been able to purchase the drug because of the cartel surcharge.<sup>148</sup> The latter victims cannot recover from the pain and suffering that would have been avoided had they had access to these medications. Since pharmaceutical companies do not internalize these costs, they are not optimally deterred.

In public suits, fines and declaratory judgements are also maladapted to deterring pay-for-delay cases for similar reasons. Fines attempt to make the cartel members internalize the cost of their past activities. Declaratory judgments invalidate agreements to stop the cartel from operating. However, these two remedies do not address the issues of future activities. In the case of pay-for-delay, the patents used to leverage a settlement remain in play. After the agreements are invalidated and the fines are paid, the branded companies would

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146. 15 U.S.C. § 15(a).

147. See John M. Connor & Robert H. Lande, Not Treble Damages: Cartel Recoveries are Mostly Less Than Single Damages, 100 IOWA L. REV. 1997 (2014).

148. See e.g., *Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982) (holding purchasers of alternative treatment had standing to recover damages).

still return to a monopoly position. The period until which generics may enter still leads to more monopoly deadweight loss.

To address the issue of future activities, courts and policymakers should impose three remedies. First, courts should create a compulsory licensing scheme. If a patent holder has been found to engage in an anticompetitive pay-for-delay, then any generic manufacturer should be able to enter the market.

Most countries – including France, the UK, and the US – have compulsory licenses.<sup>149</sup> Compulsory licenses are rare occurrences because some argue that it would deter future innovations; however, the evidence tends to contradict this argument.<sup>150</sup> Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”),<sup>151</sup> a government can create compulsory licenses for medications if the country faces a public health emergency.<sup>152</sup> The TRIPS agreements also permit these licenses to address “the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade.”<sup>153</sup> The TRIPS authors may not have contemplated pay-for-delay when drafting this article; but pay-for-delay is an unreasonable restraint of trade.

Compulsory licensing as a remedy for pay-for-delay would provide an additional deterrent. Courts may disfavor this remedy because it requires ongoing monitoring to ensure the compulsory licensing fee is properly set and paid. However, this remedy would address future sales from the patent holder.

Second, since most courts do not like constant supervision, courts may delegate that regulatory duty.<sup>154</sup> In most countries, governmental agencies (e.g., NICE in the UK and CEPS in France) regulate medication prices. These regulating entities could oversee compulsory licensing.

These regulating entities (e.g., France) benchmark the price of the generic against the branded drug and vice-versa benchmark: when a generic enters, the price of the generic is fixed at 60% of the branded drug price.<sup>155</sup> Such an entity could combine the compulsory licensing with an automatic price drop as soon as a court holds that a patent holder engaged in a pay-for-delay agreement: i.e., the branded drug would be set at 60% of its originally negotiated price. In doing so, the branded drug would not enjoy the remainder of the patent.

Finally, the courts and regulatory entity could avoid oversight issues

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149. See Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation*, 18 BERKELEY TECH. L.J. 853 (2003) (discussing compulsory licensing in the pharmaceutical industry in the United States).

150. See *id.*; Petra Moser & Alessandra Voena, *Compulsory Licensing: Evidence from the Trading with the Enemy Act*, 102 AM. ECON. REV. 396 (2012) (finding compulsory licenses boosted domestic inventions).

151. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization.

152. *Id.* at art. 8.

153. *Id.*

154. See Paul L. Joskow, *Transaction Cost Economics, Antitrust Rules, and Remedies*, 18 J. LAW, ECON. & ORG. 95 (2002) (discussing why courts favor certain remedies).

155. Rémond, *supra* note 89.

altogether by rendering the patent(s) used to protect the branded drug unenforceable. This unenforceability would extend to any compound that serves the same therapeutic treatment or any patents that cover the manufacturing process. Patents obtained through fraud can violate antitrust laws.<sup>156</sup> The U.S. Supreme Court has expressed that patents are like a “public franchise.”<sup>157</sup> An unlawful pay-for-delay amounts to an illegal extension of the public franchise that defrauds the public. Policymakers should investigate how to make unenforceable any patent maintained through anticompetitive behavior.

### *B. Beyond Regulated Prices*

Countries like France benchmark the pricing of generics against the branded drug manufacturer. While the benefits of those settlements are smaller than in other jurisdictions (e.g., the US), this approach still incentivizes pay-for-delay settlements.

Regulators can deter many practices by regulating the period of exclusivity and attaching generic market entry to the branded market authorization instead of the patent protection. Regulators already ignore patent validity when they guarantee years of exclusivity.<sup>158</sup> While pharmaceutical companies could use patents to protect their innovation during their research and development, the market exclusivity of a drug period should not be linked to patents.

First, such an approach could streamline market entry because generic manufacturers would no longer have to carry out a patent clearance studies. Instead, they could safely enter a market knowing that the statutory period has expired. Alleviating some patent uncertainties would promote generic entry.

Regulatory agencies should investigate what should be the optimal statutory period. Currently, patent protection duration varies from drug to drug because some manufacturers extend their protection through process patent protection or compound protection. Drug manufacturers complain that patent protection is necessary because research and development for drugs are expensive and that only a few drugs pan out.<sup>159</sup> However, much of this complaint seems

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156. See e.g., *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965) (holding enforcing a patent obtained through fraud on the patent office may be violative of the Sherman Act); *Therasense Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (“[I]nequitable conduct regarding any single claim renders the entire patent unenforceable,” “cannot be cured by reissue,” and “can spread from a single patent to render unenforceable other related patents and applications in the same technology family.”).

157. *Oil States Energy v. Greene's Energy Group*, 138 S. Ct. 1365 (2018). The US Supreme Court has referred to patent as “public franchise” instead of a right akin to property rights. *Id.* 1373-74. So, patents can be revoked without compensation or a review from Article III courts under the Seventh Amendment.

158. Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 *FOOD & DRUG L.J.* 479 (2004).

159. Melanie J. Brown, *Reverse Payment Settlements in the European Commission's Pharmaceutical Sector Inquiry Report: A Missed Opportunity to Benefit from U.S. Experience*, 33

exaggerated.

First, most of the manufacturers' cost are not linked to research. In a survey, the European Commission found that drug manufacturers spent more on marketing and promotion than on research (21% versus 18% of annual costs) in 2007.<sup>160</sup> The scale of marketing costs may also be underestimated: an industry observer noted that some marketing costs are classified as research costs.<sup>161</sup> This observation in Europe is surprising because most European countries do not allow most drugs to be advertised to consumers.<sup>162</sup>

Second, the cost survey did not ask about litigation costs. However, during a hearing, Congresswoman Katie Porter pointed out that AbbVie spent \$1.6 billion on litigation and settlements, \$2.45 billion on research and development, and \$4.71 billion on marketing between 2013 and 2018.<sup>163</sup> In total, AbbVie's litigation and settlements and marketing budgets were more than double its research budget. Incentivizing research and bringing drugs to the market through patent protection leads to more expenditure on rent-seeking than on research.

AbbVie is one of the companies most involved in US pay-for-delay cases.<sup>164</sup> The AbbVie expenditures show that the period of exclusivity approach would reduce the need for these litigations and settlements, many of which have been linked to pay-for-delay and the litigations discussed above. Ignoring marketing costs in the exclusivity calculation would disincentivize poor practices as well.

Second, regulatory agencies should investigate the optimal statutory protection period. These protection period may not need to be identical. Instead,

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COLUM. J.L. & ARTS 377, 378-79 (2009).

160. EC Report, *supra* note 4, Table 4.

161. *Id.* at fn. 51.

162. For example, in France, Article L. 5122-1 to L. 5122-16 Code de la santé publique (French Public Health Code) regulates advertisement to the general public and medical professionals. Article L. 5122-6 prohibits the direct advertisement to the general public of prescription-only medicinal products (i.e., « La publicité auprès du public pour un médicament n'est admise qu'à la condition que ce médicament ne soit pas soumis à prescription médicale » which translate to advertising the public for any medication is only possible if this medication is not subject to medical prescription (authors' translation)).

163. Tim Dickinson, *Katie Porter Delivers Another Knockout Punch*, ROLLING STONE (May 19, 2021, 3:51 PM), <https://www.rollingstone.com/politics/politics-news/katie-porter-abbvie-gonzalez-big-pharma-knockout-punch-1171735/> [<https://perma.cc/4ALS-XPJ6>].

164. AbbVie or AbbVie subsidiaries have been involved in at least ten federal pay-for-delay antitrust cases since 2003: *Andrx Pharms., Inc. v. Biovail Corp., Int'l*, 256 F.3d 799 (D.C. Cir. 2001); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010); *Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.)*, 544 F.3d 1323 (Fed. Cir. 2008); *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012); *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *In re Loestrin Antitrust Litigation*, Nos. 14-2071, 15-1250, 2016 WL 698077 (1st Cir. 2016); *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132, 141 (3d Cir. 2017); *In re Actos Direct Purchaser Antitrust Litig.*, 414 F. Supp. 3d 635, 640 (S.D.N.Y. 2019); *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020).

the regulatory agency could change the statutory protection based on the type of diseases and/or the existing therapeutical treatment. These governmental already do a cost-efficiency analysis to award prices: they could do the same to award protection.

The period should also depend on whether the drug gained its first market authorization, or the drug uses molecules that were already approved for a different therapeutic treatment. An additional therapeutic application does not involve the same cost of development as a novel application and hence should not be rewarded with the same exclusivity period. In other words, the period could depend on the marginal benefit of the drug.

More importantly, such an approach would avoid pay-for-delay. Patent validity would become irrelevant, and the generics could enter as soon as the statutory period is over. Furthermore, the agency could also terminate the statutory protection if the brand manufacturer were found to be acting anticompetitively.

While such widescale reform is unlikely because of vested interest, if nothing, the coronavirus pandemic has reinforced to many that the current healthcare system – including drug treatment – needs to be revisited. It is a unique market where the market participants have always found new ways to profit at the consumers' expense.