

FROM PAY-FOR-DELAY TO PRODUCT HOPPING: THE  
LIMITED UTILITY OF ANTITRUST LAW IN THE  
PHARMACEUTICAL INDUSTRY

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INTRODUCTION

Before the passage of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman)<sup>1</sup> in 1984, generic drugs occupied only

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eight percent of the prescription drug market.<sup>2</sup> This weak market presence was not the result of excessive patent protection of brand-name drugs<sup>3</sup>—many branded drugs faced no competition despite the fact that their patents had expired years ago.<sup>4</sup> Nor was it the result of disinterested consumers—entry of generic drug manufacturers to the pharmaceutical market would have resulted in massive savings for both consumers and the government.<sup>5</sup> The problem was regulatory. Under the then-controlling 1962 Drug Amendments to the Food, Drug and Cosmetic Act (FDCA),<sup>6</sup> producing generic drugs made little economic sense. Would-be generic manufacturers were required to undergo the same extensive approval process as completely novel pioneer drugs—tests, clinical trials, multi-year back-and-forths with the Food and Drug Administration (FDA)<sup>7</sup>—all of which made bringing a generic drug to

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<sup>1</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35 U.S.C.).

<sup>2</sup> Ralph A. Lewis, Comment, *The Emerging Effects of the Drug Price Competition and Patent Term Restoration Act of 1984*, 8 J. CONTEMP. HEALTH L. & POL'Y 361, 365 (1992). Note that the eight-percent-market-share figure represents the most generous estimate; other sources put the generic market share closer to six percent. *Id.* at 366 n.41 (citing Christopher S. Eklund, *Generics Grab More of the Drug Action*, BUS. WK., May 13, 1985, at 64); Sari Horwitz, *New Law Stimulating Generic-Drug Market; Certification Process Simplified*, WASH. POST, June 28, 1985, at B2.

<sup>3</sup> Indeed, the 1962 Amendments to the Food, Drug and Cosmetics Act, which controlled prior to the passage of Hatch-Waxman, had attempted to *decrease* the strength of pharmaceutical patents. Kimiya Sarayloo, *A Poor Man's Tale of Patented Medicine: The 1962 Amendments, Hatch-Waxman, and the Lost Admonition to Promote Progress*, 18 QUINNIPIAC HEALTH L.J. 1, 14 (2015) (noting that the 1962 amendments represent a “congressional attempt to use the FDA drug approval process to weaken the patents”).

<sup>4</sup> See Holly Soehnge, Article, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 52–53 (2003) (“Before the Hatch-Waxman legislation, there were about 150 new drugs with expired patents, but no generic equivalents existed . . .”).

<sup>5</sup> See H.R. REP. NO. 98-857(I) (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2650 (“[T]he availability of generic versions of pioneer drugs approved after 1962 would save American consumers \$920 million over the next 12 years. Older Americans, in particular, would benefit because they use almost 25 percent of all prescription drugs. Moreover, the lack of generics for post-1962 pioneer drugs will cost federal and state governments millions of dollars. For the drug metronidazole, purchased by the department of defense, the taxpayers saved approximately \$1.2 million in one year as a result of the availability of a lower priced generic version. Federal and state governments will be denied comparable savings on drugs approved after 1962 because of the lack of an approval procedure.”); Soehnge *supra* note 4, at 53 (“[A]vailability of such generics would save American consumers, as well as federal and state governments, hundreds of millions of dollars.”).

<sup>6</sup> Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. § 355).

<sup>7</sup> Sarayloo, *supra* note 3, at 16 (“After the 1962 Amendments were enacted, the average pharmaceutical company spent between seven and thirteen years undergoing testing and obtaining FDA approval for a new drug. Between four and six of those years were spent undergoing clinical research to determine safety and efficacy side effects in humans, and two to three of those years were spent pending FDA drug approval.” (footnote omitted)).

market extremely expensive.<sup>8</sup> Manufacturers of pioneer drugs could justify this upfront expense with the expectation of profits earned by selling drugs at high prices; but generic drug manufacturers, whose competitiveness depended on their prices staying low, were often unable to justify the expense.<sup>9</sup> So they stayed out of the market,<sup>10</sup> leaving brand drug manufacturers free to charge monopolistic prices for their products long after their patents had expired.<sup>11</sup>

In short, the FDCA created an inefficient market.<sup>12</sup> By instituting a regulatory environment with high barriers to entry, the FDCA restricted output and consumption—many generic firms that would have entered the market but for regulatory hurdles remained on the sidelines, and many consumers who would have bought drugs at generic prices chose not to do so at branded prices. Addressing this problem by simply making generic entry easier, however, risked trading inefficiencies. If generic entry became too easy, then pioneer drug companies would lose a valuable incentive to invest in the research and development necessary

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<sup>8</sup> From 1962 to 1980, the average cost of developing a new drug rose from \$6.5 million to \$70 million. Barry S. Roberts & David Z. Bodenheimer, *The Drug Amendments of 1962: The Anatomy of a Regulatory Failure*, 1982 ARIZ. ST. L.J. 581, 606.

<sup>9</sup> Another hindrance to generic entry was the fact that engagement in any of the necessary steps for drug approval—including testing and filing with the FDA—was considered to be patent infringement under 35 U.S.C. § 271 (2012). See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (“Bolar’s intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the ‘053 patent. Bolar may intend to perform ‘experiments,’ but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter’s [sic] business is a violation of the rights of the patentee to exclude others from using his patented invention.” (emphasis added)). Thus, generic companies were required to wait until pioneer drug patents had expired to even begin the lengthy testing process. Hatch-Waxman overruled the *Bolar* decision with 35 U.S.C. § 271(e)(1) (“It shall not be an act of infringement to make, use, offer to sell, or sell [a patented invention] . . . solely for uses reasonably related to the development and submission of information under a Federal law . . .”).

<sup>10</sup> See discussion *supra* note 2 and accompanying text.

<sup>11</sup> See Mary Atkinson, Comment, *Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada*, 11 PAC. RIM L. & POL’Y J. 181, 184 (2002) (“[T]he entry of generic drugs into the market was often delayed for several years after the brand-name drug’s patent expired. These regulations gave pioneer drugs a *de facto* patent term extension.” (footnote omitted)).

<sup>12</sup> Efficiency tends to be an oft-used—and seldom explicated—term in antitrust analysis. See, e.g., Joseph F. Brodley, *The Economic Goals of Antitrust: Efficiency, Consumer Welfare, and Technological Progress*, 62 N.Y.U. L. REV. 1020, 1025 (1987) (“Although rarely defined, the term ‘economic efficiency’ increasingly dominates antitrust discourse.”); Maurice E. Stucke, *Reconsidering Antitrust’s Goals*, 53 B.C. L. REV. 551, 577–78 (2012). As used by economists, economic efficiency encompasses three types of efficiencies: (1) production efficiency, achieved by using the most cost-effective means to produce goods; (2) innovation or dynamic efficiency, achieved by developing and diffusing new products that increase social wealth; and (3) allocation efficiency, achieved by allocating the existing productive output to the buyers who value them most. Brodley, *supra*, at 1025. Under these definitions, the FDCA framework created allocative inefficiencies because it restricted productive output.

to discover, approve, and market new drugs.<sup>13</sup> Fostering generic competition in this way would fix the inefficiency created by monopolistic pricing, but it would also create a new inefficiency by hindering the development of new drugs,<sup>14</sup> which would lead to a less productive market in the long term.<sup>15</sup> Too little generic competition leads to an allocatively inefficient market,<sup>16</sup> but too much generic competition leads to an innovatively inefficient market.<sup>17</sup>

Hatch-Waxman, which, to a large extent, shapes the current regulatory landscape,<sup>18</sup> was Congress' attempt to balance these competing concerns.<sup>19</sup> Whether or not it succeeded in this attempt is beyond the scope of this Note. But the policy consideration behind the Act—balancing patent-incentives for pioneer drug manufacturers with opportunities for generic drug manufacturers to compete—remains apposite to pharmaceutical regulation as it presently operates.<sup>20</sup> Considering that antitrust laws are designed to protect competition from monopolistic market power, while patent law holds out monopolistic power as an incentive to innovate,<sup>21</sup> Hatch-Waxman's balancing of incentives to innovate with opportunities to compete

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<sup>13</sup> Most brand drug profits are dependent on keeping generics off the market because generics often take the majority market-share away from the brand drugs within months of entry. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 191 (1999) (“Three months after Naprosene® went off-patent, its manufacturer, Syntax, lost seventy-five percent of its market to the generic product.”).

<sup>14</sup> See H.R. REP. NO. 98-857(I), at 18 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2651 (“[R]esearch intensive firms . . . stated that the legislation would create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs.”).

<sup>15</sup> See Herbert Hovenkamp, *Restraints on Innovation*, 29 CARDOZO L. REV. 247, 254 (2007) (“[A] policy of encouraging the optimal amount of innovation would very likely produce greater economic gains than a . . . policy of driving prices to marginal cost.”).

<sup>16</sup> See *supra* note 12 and accompanying text.

<sup>17</sup> See *supra* note 12 and accompanying text.

<sup>18</sup> For a discussion of the entire regulatory scheme, see *infra* Part I.

<sup>19</sup> See Lewis, *supra* note 2, at 361 (“[The Act] was enacted to serve two competing objectives: 1) to make more low cost generic drugs available to the public; and 2) to create new incentives for research and development of certain products subject to premarket approval by the government.”).

<sup>20</sup> For instance, there is a current debate over the extremely high prices charged for patented Hepatitis C treatments (\$95,000 for a twelve-week course of Harvoni). Jake Harper, *States Deny Pricey Hepatitis C Drugs to Most Medicaid Patients*, NPR: HEALTH SHOTS (Dec. 27, 2015, 5:32 AM), <http://www.npr.org/sections/health-shots/2015/12/27/460086615/states-deny-pricey-hepatitis-c-drugs-to-most-medicare-patients>.

<sup>21</sup> Robin Feldman, *Patent and Antitrust Differing Shades of Meaning*, 13 VA. J.L. & TECH 5, 1 (2008) (“In reductionist form, [antitrust law and patent law] pose a natural contradiction: One encourages monopoly, while the other restricts it. The inherent tension can be framed in the following manner: Can a body of case law that grants monopoly opportunities be reconciled with a body of case law that curtails monopolization?”).

provides an analytically fertile backdrop against which to evaluate recent antitrust scrutiny of patent use in the pharmaceutical industry.

This Note examines two recent antitrust suits brought against pharmaceutical companies for engaging in two different patent uses: pay-for-delay settlements,<sup>22</sup> and product-hopping.<sup>23</sup> In pay-for-delay arrangements, manufacturers of patented drugs pay would-be generic entrants to resolve patent infringement suits.<sup>24</sup> By settling with their generic challengers, these manufacturers can maintain market exclusivity with patents that are potentially invalid. In *Federal Trade Commission v. Actavis, Inc.*, the Supreme Court found that such settlements were subject to antitrust scrutiny.<sup>25</sup>

Product hopping, on the other hand, occurs when brand-name drug manufacturers attempt to shift consumers from drugs with nearly-expired patents to almost identical (but therapeutically inequivalent) drugs with new patents.<sup>26</sup> Most state substitution laws<sup>27</sup> require pharmacists to substitute generic drugs for branded drugs only when

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<sup>22</sup> See generally *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>23</sup> *New York ex rel. Schneiderman v. Actavis P.L.C.*, 787 F.3d 638 (2d Cir. 2015).

<sup>24</sup> Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 511 (2016) (“[Pay-for-delay] is an ingenious approach in which the brand-name drug company shares a portion of its monopoly profits with the generic company in exchange for the generic company agreeing to stay out of the market.”); Kendyl Hanks et al., “Pay-for-Delay” Settlements: Antitrust Violation or Proper Exercise of Pharmaceutical Patent Rights?, BUS. L. TODAY, Jan. 2011 (“Known as . . . ‘pay-for-delay’ settlements, these arrangements are characterized by payments from pharmaceutical patent holders to generic manufacturers in return for settling challenges to the patent’s validity, and for delaying the introduction of generics into the market.”).

<sup>25</sup> *Actavis*, 133 S. Ct. at 2237 (“In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent . . .”).

<sup>26</sup> Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472 (2008) (“Product hopping brand name manufacturers (‘product hoppers’) make a slight alteration to their prescription drug and engage in marketing efforts to shift consumers from the old version to the new. Generic manufacturers must follow the hop to the new version in order to realize and maintain a high volume of sales. The delay to generic manufacturers from developing a new generic equivalent and obtaining FDA approval to market it allows the product hopper to insulate itself from generic competition for several years.” (footnotes omitted)).

<sup>27</sup> In order to address the information gap created between doctors who are insensitive to price and consumers who are not aware of generic alternatives, state substitution laws allow pharmacists to substitute generic drugs for brand-name drugs when available. Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?*, 97 J. PAT. & TRADEMARK OFF. SOC’Y 663, 669 (2015) (“Around the same time that Hatch-Waxman was passed, all fifty states passed drug substitution laws designed to reduce prices for consumers. These laws allow—and in many cases require—pharmacists, in the absence of a doctor’s contrary instructions, to substitute generic versions of brand-name prescriptions.”).

the generics are therapeutically equivalent.<sup>28</sup> This means that if branded manufacturers can get doctors to prescribe the newly patented drug before the old patent expires, then pharmacists must fill prescriptions with the new drug even once an inexpensive generic of the old drug—which is often very similar to the new drug<sup>29</sup>—becomes available.<sup>30</sup> In *New York ex rel. Schneiderman v. Actavis P.L.C.*, the Second Circuit upheld a preliminary injunction against a product-hopping arrangement, holding that—on the merits—this practice would likely be subject to antitrust scrutiny.<sup>31</sup>

This Note argues that *Actavis* got it right and *Schneiderman* got it wrong. While antitrust enforcement may be an appropriate solution to the pay-for-delay problem, it is a poor solution to the product-hopping one. Pay-for-delay settlements *circumvent* the regulatory system to achieve their anticompetitive result, but product hopping *utilizes* the regulatory system to achieve its intended result. When companies product-hop, they essentially cash-in on a loophole in the Hatch-Waxman framework.<sup>32</sup> Rather than condemn use of the loophole as anticompetitive, the more effective solution to the product-hopping problem would be to close the loophole.

This Note proceeds in four parts. Part I examines the current framework of pharmaceutical regulation as it has developed over the last sixty years. Part II looks more closely at the pay-for-delay and product-hopping problems as they existed in the *Actavis* and *Schneiderman* cases. Part III analyzes the differences between *Actavis* and *Schneiderman* in order to show why antitrust law may have been an effective tool in *Actavis*, but was not in *Schneiderman*. The Note concludes by considering possible solutions to the product-hopping problem.

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<sup>28</sup> See *Schneiderman*, 787 F.3d at 649 (“Defendants introduced Namenda XR [extended release] and, before generic IR [instant release] was available, withdrew Namenda IR in order to force patients to switch from IR to XR (for which generic IR will not be substitutable under most states’ laws).” (emphasis added)).

<sup>29</sup> See Feldman & Frondorf, *supra* note 24, at 527 (describing product hopping as involving companies “making slight modifications to the delivery mechanism, dosage, or other characteristics [of the old drug] to make the [new] drug eligible for additional exclusivity or patents” (emphasis added)).

<sup>30</sup> *Id.* at 527–28.

<sup>31</sup> *Schneiderman*, 787 F.3d at 651 (“The district court did not abuse its discretion in granting a preliminary injunction because New York has demonstrated a substantial likelihood of success on the merits of its monopolization and attempted monopolization claims under § 2 of the Sherman Act.”).

<sup>32</sup> IP & ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.03 (“[P]roduct hopping presents a paradigmatic case of a regulatory game . . .”).

## I. THE REGULATORY FRAMEWORK

A. *Regulatory Provisions Under the FDCA*

Before the passage of Hatch-Waxman, the FDCA provided the statutory framework through which new drugs were approved for market.<sup>33</sup> By requiring the FDA to approve all new drugs sold in the United States,<sup>34</sup> these amendments shifted the role of the FDA from passive watchdog to active participant in the drug approval process. Under the FDCA scheme, manufacturers seeking to bring new drugs to market were required to submit to the FDA a new drug application (NDA) containing preclinical and clinical data that demonstrated the safety and efficacy of the drug, and which the FDA would either approve or deny.<sup>35</sup> The FDA later created an abbreviated NDA (ANDA) to expedite the approval process for bioequivalent generic drugs.<sup>36</sup> There were two standards for would-be generics; however, which standard was used depended on when the pioneer drug had been introduced. For would-be generics of drugs pioneered before 1962, the FDA would not require the generic manufacturer to submit duplicates of previously approved tests; for would-be generics of drugs pioneered after 1962, the FDA did require manufacturers to duplicate these tests.<sup>37</sup> This essentially nullified the abbreviated approval process for generic

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<sup>33</sup> Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

<sup>34</sup> See Colleen Kelly, Article, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 420 (2011) (“In 1962, Congress passed the Drug Amendments of 1962, which immensely strengthened FDA’s regulatory authority.” (footnote omitted)). Previously, new drugs were presumptively permitted to go to market and were only pulled if the FDA intervened with safety concerns; but the amendments required that all new drugs receive FDA approval before being sold. Peter Barton Hutt & Robert Temple, *Commemorating the 50th Anniversary of the Drug Amendments of 1962*, 68 FOOD & DRUG L.J. 449, 452 (2013) (“Whereas under the 1938 Act a new drug could be marketed unless FDA affirmatively disapproved it, under the 1962 Amendments a new drug could not be marketed until FDA affirmatively approved it.”).

<sup>35</sup> Kelly, *supra* note 34, at 420 (“Under the amendments, a pioneer drug manufacturer must submit to FDA its own preclinical and clinical data demonstrating the drug’s safety and efficacy and then must receive FDA’s affirmative approval of the NDA before marketing its drug.”).

<sup>36</sup> 21 C.F.R. § 314.92 (2017) (explaining that ANDAs are appropriate for “[d]rug products that are the same as a listed drug,” and defining the term ‘same as’ to mean “identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use.”). For the FDA’s current definition of bioequivalence, see discussion *infra* note 49 and accompanying text.

<sup>37</sup> H.R. REP. NO. 98-857(II), at 4 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686, 2688 (“With respect to drugs approved before 1962 . . . FDA has permitted generic substitution without a requirement that the generic substitute duplicate previously approved tests. However, with respect to drugs approved after 1962, the FDA has adopted the view that generics must virtually duplicate the same health and safety tests conducted by the original applicant for marketing approval.”).

versions of drugs approved after 1962.<sup>38</sup> As discussed in the Introduction, this meant that generic companies often stayed out of the market even after pioneer drug patents had expired.<sup>39</sup> Despite the introduction of paper NDAs in 1980—whereby generic drug manufacturers could file an NDA without conducting their own clinical trials and instead rely on published scientific literature to evidence safety and efficacy<sup>40</sup>—the dispute over the lack of ANDAs for post-1962 drugs continued until the Hatch-Waxman Act was passed in 1984.<sup>41</sup>

### B. *Regulatory Provisions Under Hatch-Waxman*

The Hatch-Waxman Act sought to balance the competing interests of pioneer and generic drug manufacturers.<sup>42</sup> The Act amended the FDCA by creating an ANDA approval process for post-1962 pioneer drugs.<sup>43</sup> It also amended the Patent Act by offering a patent life extension to compensate pioneer drug companies for the portion of the patent term lost to the drug approval process.<sup>44</sup> These two amendments were aimed at accomplishing the Act's dual purposes of "encouraging generic drug competition in order to lower drug prices and incentivizing brand drug manufacturers to innovate through patent extensions."<sup>45</sup>

As a prerequisite of the ANDA scheme, the Act requires the FDA to publish a list of all the drugs that it has approved (whether by NDA, paper NDA, or ANDA) and to include in that list any relevant patents associated with the drugs.<sup>46</sup> The FDA has complied with this portion of

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<sup>38</sup> See Kelly, *supra* note 34, at 420.

<sup>39</sup> See discussion *supra* notes 2–4.

<sup>40</sup> Publication of "Paper NDA" Memorandum, 46 Fed. Reg. 27,396-02, 27,396 ("[I]n the case of duplicate NDAs for already approved post-62 drugs, the Agency will accept published reports as the main supporting documentation for safety and effectiveness.")

<sup>41</sup> As late as 1983, generic drug manufacturers were filing lawsuits to compel the FDA to offer an ANDA process for post-1962 drugs. See Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 276 (1985) ("The generic drug industry increased the pressure for such a policy change by filing a lawsuit to compel [the] FDA to begin to approve ANDAs for generic versions of post-1962 pioneer drugs on the same basis as pre-1962 drugs.")

<sup>42</sup> H.R. REP. No. 98-857(II), at 4 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686, 2689–90.

<sup>43</sup> 21 U.S.C. § 355(j)(1) (2012).

<sup>44</sup> 35 U.S.C. § 156(c); see also Kelly, *supra* note 34, at 425 ("Hatch-Waxman created the opportunity for patent term restoration for a drug patent, in order to remedy the decline in the patent's life due to the lengthy testing and FDA premarket approval process.")

<sup>45</sup> New York *ex rel.* Schneiderman v. Actavis P.L.C., 787 F.3d 638, 644 (2d Cir. 2015).

<sup>46</sup> 21 U.S.C. § 355(j)(7)(A). The information that paragraph (7) requires the FDA to list is provided either by pioneer drug companies as part of the initial NDA, *id.* § 355(b), or by generic drug companies as part of paper NDAs or ANDAs. *Id.* § 355(j)(2)(A)(vii)–(viii). This



the statute by publishing the *Approved Drug Products with Therapeutic Equivalence Evaluations*, or the Orange Book,<sup>47</sup> which contains not only the list of approved drugs and their relevant patents, but also an evaluation of the therapeutic equivalence of generic drug products as determined by the FDA.<sup>48</sup> When filing an ANDA, generic drug manufacturers must submit scientific studies that demonstrate “bioequivalence” with a drug listed in the Orange Book in order to obtain FDA approval.<sup>49</sup> In citing to a listed drug for bioequivalence, however, the generic ANDA filers must make one of four certifications about the relationship between their drug and each patent listed in the Orange Book under the bioequivalent drug.<sup>50</sup> An ANDA can certify: (1) that the brand-name manufacturer has not listed any relevant patents, (2) that any relevant patents have expired, (3) that it is requesting

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information about the so-called “listed” drug forms the basis for the ANDA application. *Id.* § 355(j)(2)(A)(i) (requiring that ANDAs contain “information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7)”).

<sup>47</sup> Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676-01, 36,676 (June 18, 2003) (“Under section 505(b)(1) of [Hatch-Waxman], we publish patent information after approval of an NDA application in our approved drug products list entitled ‘Approved Drug Products With Therapeutic Equivalence Evaluations.’ This list is known popularly as the ‘Orange Book’ because of its orange-colored cover.”). The Orange Book is publicly available online at the FDA’s website. See *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last updated Jan. 25, 2017).

<sup>48</sup> See Kelly, *supra* note 34 at 422. A drug receives a therapeutic equivalence rating of A, meaning that the drug is considered therapeutically equivalent, or B, which means that the drug is not clearly bioequivalent. PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 757 (3d ed. 2007). These equivalency ratings, while not integral to the approval process of a drug, play an important role in determining whether pharmacies can substitute generics for brand drugs under state substitution laws. See *Schneiderman*, 787 F.3d at 644–45 (“Today, all 50 states and the District of Columbia have drug substitution laws. Although the specific terms of these laws vary by state, drug substitution laws either permit or require pharmacists to dispense a *therapeutically equivalent*, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician . . . .” (emphasis added) (footnote omitted)).

<sup>49</sup> 21 U.S.C. § 355 (j)(2)(A)(iv) (requiring an ANDA to include “information to show that the new drug is bioequivalent to the listed drug referred to”). The Act also requires a generic manufacturer to show that the active ingredients are the same, the drugs have the same route of administration, dosage and strength, and that the labeling of the two drugs is the same. *Id.* § 355(j)(2)(A). Drugs are defined as bioequivalent if “the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose.” *Id.* § 355 (j)(8)(B)(i). See generally *Schneiderman*, 787 F.3d at 644 (“In other words, two drugs are bioequivalent if they deliver the same amount of the same active ingredient content into a patient’s blood stream over the same amount of time.”).

<sup>50</sup> Kelly, *supra* note 34 at 423 (“[A]s part of the ANDA application, generic manufacturers are required to file one of . . . four certifications for *each* Orange Book patent listing covering the listed drug.”).

approval to market for when the patents expire, or (4) that any listed patent is invalid or will not be infringed.<sup>51</sup> The last certification, commonly referred to as a Paragraph IV claim, constitutes a technical act of patent infringement,<sup>52</sup> and requires that the ANDA filer notify the patent owner and NDA holder of the claim against their patents.<sup>53</sup> The patent holder then has forty-five days to bring a patent infringement action against the ANDA applicant,<sup>54</sup> which stalls the approval of the ANDA for thirty months or until the resolution of the patent infringement proceedings.<sup>55</sup>

Believing that Paragraph IV certification would encourage generic manufacturers to ferret out dubious patents on pioneer drugs, Congress gave ANDA filers an extremely valuable incentive for pursuing Paragraph IV certification<sup>56</sup>: granting 180 days of generic marketing

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<sup>51</sup> 21 U.S.C. § 355(j)(2)(A)(vii); *see also* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013) (“[An ANDA] can certify that the brand-name manufacturer has not listed any relevant patents. It can certify that any relevant patents have expired. It can request approval to market beginning when any still-in-force patents expire. Or, it can certify that any listed, relevant patent ‘is invalid or will not be infringed . . . .’”).

<sup>52</sup> *See, e.g., Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1672 (2012) (“[A Paragraph IV] filing is treated as an act of infringement, giving the brand an immediate right to sue . . . .”). Congress instituted this scheme by amending the Patent Act. 35 U.S.C. § 271(e)(2) (“It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . .”). Under this amendment, a Paragraph IV filing, which seeks ANDA approval for the purpose of manufacturing and selling the drug, necessarily constitutes infringement. *See* Wansheng Jerry Liu, Article, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 448–49 (2008) (“[T]he filing of an ANDA under the paragraph IV certification automatically constitutes an act of patent infringement because the generic company seeks approval from the FDA to begin selling the drug before the expiration of the NDA holder’s patent.”).

<sup>53</sup> 21 U.S.C. § 355(j)(2)(B).

<sup>54</sup> *Id.* § (j)(5)(B)(iii).

<sup>55</sup> *Id.* § (c)(3)(C). If the patent holder fails to bring an infringement action against a Paragraph IV ANDA filer during the forty-five-day window, then the FDA is required to approve the ANDA immediately after the forty-five days. *Id.* In practice, NDA holders bring infringement actions against Paragraph IV filers seventy-two percent of the time. FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY*, at ii, 3–5, 14 (2002), [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf).

<sup>56</sup> *See, e.g., In re Cipro Cases I & II*, 61 Cal. 4th 116, 134 (2015) (“Congress wrote into the act a substantial incentive for generics to enter markets earlier by offering a 180-day exclusivity period to the first generic filer, and only that filer, to challenge a patent. The theory was that a generic would be more likely to challenge dubious patents if offered the carrot of an enormously valuable six-month period in which only it and the brand could produce a drug.” (citation omitted)); *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 5 (2003) (statement of Timothy J. Muris, Chairman, Fed. Trade Comm’n) (“[The 180-day

exclusivity to the first Paragraph IV ANDA filer to receive FDA approval.<sup>57</sup> It is important to emphasize that this 180-day exclusivity period can be a huge money-maker for generic drug companies, and serves as a strong incentive to file ANDAs under Paragraph IV certification.<sup>58</sup>

While providing this ANDA process for generics mainly benefitted generic manufacturers, Hatch-Waxman also included provisions that benefitted pioneer pharmaceutical companies. Firstly, making Paragraph IV certifications automatic patent infringements and providing the patent holders with up to a thirty-month stay on such ANDA proceedings offered pioneer pharmaceutical companies at least some protection under the new procedures.<sup>59</sup> More importantly, though, the Act provided pioneer drug companies with market exclusivity for approved new drugs<sup>60</sup> and patent term restoration to account for the portion of the patent term lost to the application process.<sup>61</sup> The exclusivity consists of a five-year period following the approval of a new chemical entity (NCE) NDA<sup>62</sup> (or three years for a non-NCE NDA) during which the FDA will not approve ANDAs from would-be generics.<sup>63</sup> The patent restoration extends the life of a patent “by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued,”<sup>64</sup>

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exclusivity] provision provides an incentive for companies to challenge patent validity and to design around patents.”).

<sup>57</sup> 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period begins at the earlier of either (1) when the generic drug actually goes to market, or (2) when a court rules that the patent challenged by the ANDA is invalid or not infringed. Kelly, *supra* note 34 at 424–25. Note that this 180-day exclusivity period only prevents other generics from gaining FDA approval, and that the brand drug remains on the market, effectively creating a duopoly between the brand and generic drug. See Liu, *supra* note 52, at 450 (“During the 180-day market exclusivity period, the first ANDA applicant enjoys a market duopoly along with the NDA holder.”).

<sup>58</sup> See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1560 (2006) (“An important feature of the regime is a large incentive to litigate the validity and scope of an innovator’s patents, a ‘bounty’ worth hundreds of millions of dollars for a major drug.”); Liu, *supra* note 52 at 450 (“[T]herefore, the market exclusivity is a ‘highly lucrative’ reward for the generic drug company.”).

<sup>59</sup> See Kelly, *supra* note 34, at 424 (“The Hatch-Waxman Act added this artificial infringement provision to protect NDA patent holders . . .”).

<sup>60</sup> See *id.* at 418 n.13 (citing Peter Barton Hutt, *Landmark Pharmaceutical Law Enacted*, 1 HEALTH SCAN, No. 3 (1984)).

<sup>61</sup> 35 U.S.C. § 156(c).

<sup>62</sup> “New chemical entity” is another term for a pioneer drug. See Robert Alan Hess, Article, *Excavating Treasure from the Amber of the Prior Art: Why the Public Benefit Doctrine Is Ill-Suited to the Pharmaceutical Sciences*, 66 FOOD & DRUG L.J. 105, 106 (2011).

<sup>63</sup> Kelly, *supra* note 34, at 425. However, if the ANDA filer is claiming patent invalidity or non-infringement, then the exclusivity period for NCE NDAs is limited to four years. *Id.*

<sup>64</sup> 35 U.S.C. § 156(c).

provided that the patent meets the requirements outlined in the statute.<sup>65</sup>

### C. *The 2003 Amendments to Hatch-Waxman*

While the 2003 amendments to Hatch-Waxman do not bear directly on the challenges raised in *Actavis* and *Schneiderman*, they are a useful example of Congress' ability to legislatively resolve regulatory ambiguity and close loopholes. In the years following the passage of Hatch-Waxman, two major questions arose regarding how the statutory framework was to function. First, did the statute allow NDA holders to obtain multiple thirty-month stays by introducing new patents *after* a generic manufacturer had filed an ANDA?<sup>66</sup> In one particularly acute case, SmithKline Beecham Corporation filed nine late-listed patents for its brand drug Paxil (used to treat obsessive-compulsive disorder), which resulted in five additional thirty-month stays.<sup>67</sup> Second, did the 180-day exclusivity period granted to the first Paragraph IV ANDA filers begin only after a successful defense of the patent infringement claim, or on a first-to-file basis; and was a decision of an appeals court required to trigger the exclusivity period, or would a district court decision suffice?<sup>68</sup>

In 2003, Congress attempted to answer these open questions by amending the Hatch-Waxman Act with the passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).<sup>69</sup> The MMA limits a pioneer drug company to one thirty-month stay per ANDA by preventing companies from receiving thirty-month stays for patents listed in the Orange Book *after* the filing of an ANDA.<sup>70</sup> To further clarify the terms under which stays are to be granted, the MMA offers a bright-line rule for what types of patents can be listed in the Orange Book—drug products, substances, and methods of use are allowed, but intermediates, metabolites, processing, and packaging are

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<sup>65</sup> *Id.* § 156(a). The requirements are that: (1) the patent has not expired; (2) the patent has not already been extended; (3) the patent holder has submitted the appropriate extension application; (4) the product was subject to regulatory review prior to commercial marketing; and (5) the commercial marketing happened as soon as statutorily allowed. *Id.*

<sup>66</sup> Kelly, *supra* note 34, at 428. These so called "late-listed" patents required ANDA filers to make *additional* certifications (Paragraph IV) about the newly listed patent claims, which could potentially result in a new thirty-month period beginning at the time of the subsequent ANDA certification. *Id.*

<sup>67</sup> *Id.* at 428–29.

<sup>68</sup> *Id.* at 430.

<sup>69</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

<sup>70</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

not.<sup>71</sup> The MMA also clarifies that the 180-day exclusivity is granted “on a ‘first-to-file’ basis per drug product and not per patent.”<sup>72</sup> Just as the NDA holder cannot claim new thirty-month exclusivity periods based on late-listed patents (on patents listed *after* the approval of the NDA), so too subsequent ANDA filers cannot file *new* ANDAs based on late-listed patents and receive another 180-day exclusivity period.<sup>73</sup>

Finally, the MMA clarifies that there is no roll-over exclusivity period, meaning that if the first ANDA filer loses the exclusivity period, then no other ANDA applicant is eligible to receive exclusivity.<sup>74</sup> An ANDA filer can lose its exclusivity period according to forfeiture provisions added by the MMA to the regulatory scheme. The first ANDA filer can lose its right to the 180-day exclusivity period if one of six forfeiture events occurs, including: (1) the filer fails to market;<sup>75</sup> (2) the filer withdraws its application; (3) the filer withdraws or amends all of its Paragraph IV certifications that would have qualified it for 180-day exclusivity; (4) the filer fails to obtain ANDA approval within thirty months of filing; (5) the filer enters into an agreement with the patent holder that the FTC or a court finds violates the antitrust laws; or (6) all relevant patents expire.<sup>76</sup>

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<sup>71</sup> 21 C.F.R. § 314.53(b)(1) (2017). Before the introduction of the MMA, generic and brand manufacturers disputed what kinds of patents could be listed in the Orange Book. Kelly, *supra* note 34, at 430. The generics claimed that when NDA holders listed patents that were only peripherally relevant to the active ingredient of a method of use of a drug, ANDA filers were forced to make Paragraph IV certifications (that their products did not infringe) for patents that were only peripherally relevant to the drug. *Id.* at 429. This, they claimed, resulted in a thirty-month exclusivity windfall for the NDA holders. *Id.* at 428–29.

<sup>72</sup> Kelly, *supra* note 34, at 445; *see also* 21 U.S.C. § 355(j)(5)(B)(iv).

<sup>73</sup> 21 U.S.C. § 355(b)(4)(A).

<sup>74</sup> *See* Kelly, *supra* note 34, at 445.

<sup>75</sup> *Id.* at 441 (“The ‘failure to market’ forfeiture provision is a complex provision that requires two dates to occur before forfeiture is triggered. The provision states that the first Paragraph IV ANDA applicant will forfeit 180-day exclusivity if it fails to market the drug by the *later of*: (1) 75 days after the ANDA is approved, or 30 months after the ANDA is filed, whichever is earlier; or (2) 75 days after one of the following has occurred: (i) a court enters a decision, from which no appeal has been or can be taken, that finds the pioneer’s patent is either invalid or not infringed; (ii) a settlement agreement is approved that includes a finding that the pioneer’s patent is either invalid or not infringed; or (iii) the patent holder withdraws the patent information from the Orange Book.”).

<sup>76</sup> *Id.* at 441 (citing 21 U.S.C. § 355(j)(5)(D)(i)).

## II. ANTITRUST CHALLENGES: PAY-FOR-DELAY AND PRODUCT HOPPING

### A. *Pay-for-Delay*: FTC v. Actavis

In 1999, Solvay Pharmaceuticals filed an NDA for AndroGel, a hormone supplement that raises the level of testosterone in patients who do not naturally produce enough.<sup>77</sup> The NDA was approved in 2000, and in 2003, Solvay obtained a relevant patent and disclosed the patent to the FDA.<sup>78</sup> Later that year, Actavis, followed by Paddock Laboratories and Par Pharmaceutical (co-defendants in the ensuing patent infringement suit), filed a Paragraph IV ANDA for a drug modeled after AndroGel, claiming that Solvay's patent was invalid and that their products did not infringe.<sup>79</sup> Solvay responded by initiating patent infringement litigation against Actavis.<sup>80</sup> Even though Actavis would have first-to-file ANDA approval after the thirty-month stay, it chose instead to settle with Solvay in 2006, and its co-defendants followed suit.<sup>81</sup> Under the terms of the settlement, Actavis and its co-defendants agreed not to bring a generic version of AndroGel to market until August 31, 2015.<sup>82</sup> In addition, Actavis agreed to promote AndroGel to urologists in exchange for cash payments.<sup>83</sup>

The Federal Trade Commission (FTC) brought an action against all settling parties, claiming that the point of the payments was not, as the companies claimed, for services that the generics promised to perform, but rather to compensate the generics for agreeing not to compete against AndroGel until 2015.<sup>84</sup> In particular, the claim was not only that the parties agreed not to compete, but that the settling parties were essentially splitting the monopoly profits of the patent.<sup>85</sup> The

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<sup>77</sup> FTC v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013); see also *What Is AndroGel 1.62%?*, ANDROGEL, <https://www.androgel.com/about-androgel-1-62-percent> (last visited Apr. 23, 2017).

<sup>78</sup> *Actavis*, 133 S. Ct. at 2229.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

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

<sup>82</sup> *Id.* Five years before Solvay's patent expired; however, if another generic were marketed before that date, the agreement would be terminated. *Id.*

<sup>83</sup> *Id.* Paddock was to be paid \$12 million in total; Par was to be paid \$60 million in total; and Actavis was to be paid an estimated \$19–\$30 million annually for nine years. *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* "The arrangement is thus similar to a situation in which two firms cartelize their market but one of them shuts down its plant altogether while the other compensates it out of its monopoly profits." Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 MINN. J.L. SCI. & TECH. 3, 8 (2014). *But see* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1046

district court disagreed, however, finding that because the settlement was within the scope of Solvay's patent, it was immunized from antitrust scrutiny.<sup>86</sup> The Eleventh Circuit agreed; because a patent holder has a "lawful right to exclude others from the market," a patent "conveys the right to cripple competition."<sup>87</sup> Therefore, patent holders were immune to antitrust scrutiny for any action that occurred within the scope of the patent.<sup>88</sup>

The antitrust concept of patent scope originally developed as a device to *restrict* patentee behavior.<sup>89</sup> Used restrictively, patent scope limits patentee activity to whatever rights were clearly conferred by the patent—any behavior that reached beyond these rights was outside the scope of the patent and therefore vulnerable to antitrust scrutiny.<sup>90</sup> For example, patent scope informed the antitrust doctrine against patent tying arrangements, in which the sale of a patented good was conditioned on the concordant sale of an unpatented good.<sup>91</sup> For a tying arrangement, patent or otherwise, to violate section 1 of the Sherman Act,<sup>92</sup> antitrust courts require (1) that a substantial volume of commerce in the tied product market was restrained because of the tying arrangement, and (2) that the anticompetitive effects of the tying were a result of monopoly power in the tying product market.<sup>93</sup> Historically,

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(2004) (arguing that this position has been challenged as not faithful to how markets really function).

<sup>86</sup> *In re Androgel Antitrust Litig.* (No. II), 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010).

<sup>87</sup> *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1307, 1310 (11th Cir. 2012), *rev'd and remanded sub nom.* *FTC v Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>88</sup> *Id.* at 1312.

<sup>89</sup> Herbert Hovenkamp, *The Rule of Reason and the Scope of the Patent*, 52 SAN DIEGO L. REV. 515, 525 (2015). The concept surfaced in both antitrust law, in the context of tying and price resale maintenance, and also in patent law, in the context of the exhaustion doctrine. *Id.* at 525–26.

<sup>90</sup> *Id.*

<sup>91</sup> The classic example is *International Salt Co. v. United States*, 332 U.S. 392 (1947), *abrogated by* *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006), in which the International Salt Company conditioned the lease of its two patented machines—one that dissolved rock salt into a brine, and another that injected salt into canned products—on customers also purchasing any salt used in the machines from International Salt Company. *Id.* at 394. The Court found that while the patents conferred a "right to restrain others from making, vending or using the patented machines," they conferred "no right to restrain use of, or trade in, unpatented salt." *Id.* at 395–96.

<sup>92</sup> 15 U.S.C. § 1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.").

<sup>93</sup> *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 608–09 (1953) ("When the seller enjoys a monopolistic position in the market for the 'tying' product, or if a substantial volume of commerce in the 'tied' product is restrained, a tying arrangement violates the narrower standards expressed in § 3 of the Clayton Act because from either factor the requisite potential lessening of competition is inferred. And because for even a lawful monopolist it is 'unreasonable, per se, to foreclose competitors from any substantial market', a tying

patents served as an easily administrable proxy for this second requirement;<sup>94</sup> inasmuch as they permitted a patentee to exclude others from selling the patented goods,<sup>95</sup> patents were seen to confer the monopoly power necessary to find a § 1 tying violation.<sup>96</sup> While courts now see patents as evidence, not proof, of monopoly power,<sup>97</sup> they still recognize monopoly power in the tying market as being within the exclusionary scope of the patent.<sup>98</sup> Only leveraging this power to influence markets in unpatented goods violates the Sherman Act.<sup>99</sup>

In addition to its restrictive function, the scope of the patent analysis has also been used defensively to immunize facially anticompetitive agreements from antitrust scrutiny, provided that the agreements are within the rights conferred by the patent.<sup>100</sup> For example, in its *Actavis* decision,<sup>101</sup> the Eleventh Circuit held that even though reverse payment settlements were facially anticompetitive, they

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*arrangement is banned by § 1 of the Sherman Act whenever both conditions are met.*" (emphasis added)).

<sup>94</sup> As a technical matter, a patent is no longer *per se* proof of monopoly power. In *Illinois Tool Works v. Independent Ink, Inc.*, the Supreme Court noted that "Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee," and therefore held that "in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product." 547 U.S. at 45–46.

<sup>95</sup> The right to exclude others from producing or selling a patented good is guaranteed by the Patent Act, 35 U.S.C. § 271 ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."), and is one of "the entire bundle of rights residing in a patent." *CMS Indus., Inc. v. L.P.S. Int'l, Ltd.*, 643 F.2d 289, 294 (5th Cir. 1981).

<sup>96</sup> *See, e.g.*, *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 379 (1952) ("Price control through cross-licensing was barred as beyond the *patent monopoly*." (emphasis added)); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) ("It is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the *patent monopoly*." (emphasis added)); *Int'l Salt*, 332 U.S. at 395 ("The appellant's patents confer a limited monopoly of the invention they reward."); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) ("Beyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law.").

<sup>97</sup> *See* discussion *supra* note 94 and accompanying text.

<sup>98</sup> *See, e.g.*, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013) (recognizing the "exclusionary potential of the patent").

<sup>99</sup> *Carbice Corp. of Am. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 33 (1931) (recognizing that a patent grants a limited monopoly, but holding that "[c]ontrol over the supply of such unpatented material is *beyond the scope of the patentee's monopoly*" (emphasis added)).

<sup>100</sup> Hovenkamp, *supra* note 89 at 526. Professor Hovenkamp likens the scope of the patent test in its defensive manifestation to "a walled garden whose contents are free from antitrust scrutiny" provided they stay within the wall. *Id.* at 527.

<sup>101</sup> *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev'd and remanded sub nom. Actavis, Inc.*, 133 S. Ct. 2223. Although the action in *Actavis* was brought under section 5 of the Federal Trade Commission Act (FTCA), 15 U.S.C. §§ 41–58, the patent scope analysis remains the same.



fell within the scope of the monopoly conferred by the patent and were therefore immune from antitrust scrutiny.<sup>102</sup> For the Eleventh Circuit, any cartelization that resulted from the reverse payments was less anticompetitive than the general anticompetitive potential of the patent,<sup>103</sup> and so antitrust laws took a backseat to patent laws.

However, as the Supreme Court pointed out, the primary flaw in using patent scope to analyze pay-for-delay settlements is that when such settlements are made, the validity of the patent is in question. Reverse payment settlements arise in the context of infringement suits in which the validity of brand drug patents are being *challenged*.<sup>104</sup> Thus, if the parties do not settle and a court finds the patent invalid, then no action could be within the scope of the patent because the patent would have no scope; and if the court finds no infringement, then the ability to stall generic entry would be beyond the scope of the brand drug patent anyway.<sup>105</sup> In reversing the Eleventh Circuit, the Court found that while “Solvay’s patent, if valid and infringed, might have permitted it to charge [higher-than-competitive] drug prices . . . [t]he patent here may or may not be valid, and may or may not be infringed.”<sup>106</sup> Note that the Court left alive the theory that within the scope of a patent there exists a level of antitrust immunity,<sup>107</sup> but found that because reverse payments

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<sup>102</sup> *Watson*, 677 F.3d at 1309 (“In keeping with those principles, we said in *Valley Drug* that parties to a reverse payment settlement are immune from antitrust liability if the anticompetitive effects of their settlement fall ‘within the scope of the exclusionary potential of the patent.’” (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003))).

<sup>103</sup> *Id.* at 1312 (“[A] reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”). Courts often frame the patent scope inquiry by asking: “Is more being monopolized than what the patent grants, or is the practice merely maximizing the reward attributable to the . . . patent?” WARD S. BOWMAN, JR., *PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL* 9 (1973).

<sup>104</sup> Because the parties settled, the validity of Actavis’ patent was never determined. *Watson*, 677 F.3d 1298.

<sup>105</sup> Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. & TECH. L. REV. 197, 234 (2015) (“The majority opinion appears to acknowledge the rights conferred by a patent as conferring immunity under the antitrust laws, but . . . that an invalid patent confers no right to exclude competitors and that ‘even a valid patent confers no right to exclude products or processes that do not actually infringe’ . . .”).

<sup>106</sup> *Actavis*, 133 S. Ct. at 2230–31.

<sup>107</sup> *Id.* at 2231 (“[A] *valid* patent excludes all except its owner from the use of the protected process or product, [a]nd that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product.” (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948))); Eisenberg & Crane, *supra* note 105, at 234 (“The majority opinion appears to acknowledge the rights conferred by a patent as conferring immunity under the antitrust laws . . .”).

operate independent of a patent's validity,<sup>108</sup> they are not located within the scope of the patent for purposes of antitrust immunity.<sup>109</sup>

How far the scope of the patent extends and what antitrust immunity is afforded to patentees remains unclear. The Court emphasized that *both* patent and antitrust policies should inform the determination of what that scope is,<sup>110</sup> but despite claiming that patent law remains part of the inquiry, the Court seemed as eager as the Eleventh Circuit to avoid dissecting the merits of the underlying patent claim.<sup>111</sup> However, whereas the Eleventh Circuit avoided the question of patent validity by holding a reverse payment settlement was within the scope of the patent and therefore *immune from antitrust scrutiny*,<sup>112</sup> the Supreme Court avoided the question by holding that reverse payment settlements were outside the scope of the patent and *presumptively subject to antitrust scrutiny*.<sup>113</sup> This application of antitrust law to reverse payment settlements implies that the underlying validity of a patent need not be resolved in order to find that a reverse settlement is anticompetitive. As a substitute for analysis of the underlying patent, the *Actavis* decision suggests courts can use the size of a reverse settlement as evidence of both the anticompetitive character of the settlement *and* the patent's validity.<sup>114</sup>

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<sup>108</sup> A reverse payment settlement is really just a method for pharmaceutical companies to regulate the risk of a patent being found invalid; if a company is at all uncertain about the validity of its patent, then it has an incentive to settle *whether the actual patent would have turned out to be valid or invalid*. Hovenkamp, *supra* note 85, at 12 (“[T]he *likelihood* of a pay-for-delay settlement is not driven by the likelihood that the patent will be found invalid, although the *size* of the settlement will be.”).

<sup>109</sup> *Actavis*, 133 S. Ct. at 2231.

<sup>110</sup> *Id.* at 2231 (“[I]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.”). However, while the Court insists on retaining patent policy as part of an antitrust analysis, its holding would allow a pharmaceutical patent holder to be held liable under the antitrust laws just for choosing settlement over the uncertainty of litigation, even if its patent was valid and infringed. Eisenberg & Crane, *supra* note 105, at 234 (“[The Court] called for a balance of the policies of the patent laws with the policies of the antitrust laws in deciding whether the settlement agreement is within the scope of the patent, leaving open the possibility that a pay-for-delay settlement might still violate the antitrust laws even if the patent were valid and infringed.”(footnote omitted)).

<sup>111</sup> *Actavis*, 133 S. Ct. at 2237 (“To say this is not to require . . . that the Commission need litigate the patent’s validity . . .”).

<sup>112</sup> *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012) (“Our *Valley Drug*, *Schering-Plough*, and *Andrx* decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”), *rev’d and remanded sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>113</sup> *Actavis*, 133 S. Ct. at 2236–37 (“In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”).

<sup>114</sup> *Id.* at 2237 (“[A] court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity

While the *applicability* of antitrust laws is presumed, the anticompetitive nature of the settlements is not. The Court rejected the FTC's contention<sup>115</sup> that reverse settlements should be viewed under a quick-look analysis,<sup>116</sup> which would hold such settlements presumptively anticompetitive, and instead insisted on applying a rule of reason analysis to the settlements.<sup>117</sup> Whether a reverse settlement brings about anticompetitive effects depends on "its 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 justification."<sup>118</sup> Thus not all reverse settlements will trigger antitrust liability. In lieu of a bright-line rule, the Court offered five considerations that guide the liability inquiry, including: (1) whether the specific restraint at issue has the potential for genuine adverse effects; (2) whether these anticompetitive consequences are justified (i.e., by other considerations such as avoided litigation costs or fair value for services); (3) whether the size of the reverse payment suggests that the brand drug manufacturer has the market power to bring about anticompetitive harm; (4) whether the size of the reverse payment provides an adequate surrogate for a patent's weakness, such that a court need not conduct a detailed exploration of the validity of the patent itself; and (5) whether the parties have another means of settling a lawsuit that would not trigger antitrust liability.<sup>119</sup>

These considerations are meant to limit the danger of finding antitrust liability where a branded manufacturer has a valid patent. After all, if the underlying infringement lawsuit would have been resolved in favor of the patentee and generics would have been enjoined from entering the market, then the settlement does not really disadvantage

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*of the patent . . .*" (emphasis added)). As Professor Hovenkamp notes, the size of a reverse settlement signals the degree of doubt a patentee likely has about her patent. Hovenkamp, *supra* note 85, at 10. However, he also emphasizes that the majority of questionable pay-for-delay settlements involve extension patents (those obtained by product hopping, discussed *infra* at Section II.B), which have a much higher failure rate than patents on primary active ingredient patents. Hovenkamp, *supra* note 85, at 11 ("The Solvay Pharmaceutical patent for Androgel, at issue in this case, is a likely illustration. The active ingredient, synthetic testosterone, had been around since 1935, and the gel delivery system that it incorporated had been commonly known for decades.").

<sup>115</sup> Reply Brief for Petitioner, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 1099171, at \*1.

<sup>116</sup> Quick-look analysis presumes an antitrust violation and shifts the burden onto a defendant to show empirical evidence of procompetitive justifications for her actions. 7 PHILIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1508, at 435–40 (3d ed. 2010).

<sup>117</sup> *Actavis*, 133 S. Ct. at 2237.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at 2234–37.

consumers<sup>120</sup>—even if it included a reverse payment.<sup>121</sup> Such a settlement would result in the same amount of competition that the patent permits within the market for the patented drug: none. But relying on the scope of the patent doctrine to protect the right of a valid patent holder to settle is problematic because at the time of the settlement the patent may be invalid.<sup>122</sup> So instead of using patent scope, and instead of resolving the validity of the patent, the Court uses these external considerations as a surrogate for the underlying patent validity.<sup>123</sup>

### B. *Product Hopping*: *Schneiderman v. Actavis*

In 2003, Forest Laboratories, a wholly-owned subsidiary of Actavis, obtained FDA approval for its drug Namenda instant release (IR) based on a patent that expired in July 2015.<sup>124</sup> Namenda IR is a twice-daily memantine hydrochloride-based drug designed to treat moderate-to-severe Alzheimer's disease.<sup>125</sup> When released to market in January 2004, it was the first and only medication approved for individuals suffering from the disease.<sup>126</sup> In June 2010, the FDA approved Namenda extended release (XR), a once-daily version of IR, and Forest began marketing XR in 2013.<sup>127</sup> Once on the market, Forest began an aggressive campaign to convince the memantine drug-user market to switch from IR to XR. Forest's strategy included soft-switch tactics, in which it used marketing

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<sup>120</sup> Both the majority and dissent in *Actavis* agree that consumer welfare is the target of antitrust enforcement. Hovenkamp, *supra* note 85, at 7 ("Another significant thing about the Court's decision is that, notwithstanding sharp differences on the issue before it, the Court unanimously agreed that 'consumer welfare' rather than total welfare is the goal of antitrust enforcement. In general, consumer welfare looks at the welfare only of consumers, refusing to offset producer benefits against consumer harms." (footnote omitted)).

<sup>121</sup> Eisenberg & Crane, *supra* note 105, at 239. The theory here is that if the patent is valid, then the patentee is entitled to monopolistic profits on her patented drug; all a reverse settlement does in such a case is distribute those monopoly profits between the settling parties. The consumer pays the same above-market price whether the parties settle or resolve the infringement suit in favor of the patentee. *Id.* at 240–41.

<sup>122</sup> See text accompanying notes 104–109.

<sup>123</sup> Hovenkamp, *supra* note 85, at 21 ("In one sense, the size of the payment operates as a surrogate for direct patent-law-based questions about patent quality. Indeed, payment size may actually be a more reliable indicator to the extent it reflects the settling parties' market-based judgment about the patent's probable prospects in a fully litigated infringement suit. Data on claim construction error rates, the high percentage of litigated patents found to be invalid, and high reversal rates, all suggest that the size of the payment may in fact be at least as good a tool for assessing patent quality as a direct look at the patent itself." (footnotes omitted)).

<sup>124</sup> *New York ex rel. Schneiderman v. Actavis P.L.C.*, 787 F.3d 638, 642 (2d Cir. 2015).

<sup>125</sup> *Namenda Prescribing Information*, ACTAVIS, [https://www.allergan.com/assets/pdf/namenda\\_pi](https://www.allergan.com/assets/pdf/namenda_pi) (last updated Oct. 2013).

<sup>126</sup> *Schneiderman*, 787 F.3d at 646–47.

<sup>127</sup> *Id.* at 647.

to convince consumers to switch to XR, and hard-switch tactics, in which it forced consumers to switch to XR by restricting access IR.<sup>128</sup>

If successful, this strategy would allow Forest to extend the life of its monopoly in the memantine-drug market by shifting its patent protection from IR, which would expire in 2015, to XR, which would not expire until 2029.<sup>129</sup> Because IR and XR are not therapeutically equivalent,<sup>130</sup> under state substitution laws, pharmacists would not be able to substitute a generic version of IR if the prescribing physician wrote a prescription for XR.<sup>131</sup> Forest assumed that the majority of patients, once they had switched from IR to XR, would not switch back even if generics became available for IR.<sup>132</sup> New York's theory of antitrust liability asserted that Forest had utilized the hard-switch tactic in order to restrain generics from competing in the memantine market and to maintain its monopoly in that market.<sup>133</sup> This, the State argued, constituted monopolization or, in the alternative, attempted monopolization in violation of section 2 of the Sherman Act.<sup>134</sup>

In order to establish monopolization under section 2, a plaintiff must show not only that the defendant possessed monopoly power in the relevant market, but also that the defendant acted willfully to acquire

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<sup>128</sup> The terms "soft-switch" and "hard-switch" were introduced in the respondent's brief. Final Brief for Appellee at 31–35, *Schneiderman*, 787 F.3d 638 (No. 14-4624), 2015 WL 1010525 (defining soft-switch as "using marketing, advertising, and other persuasive techniques to convince Namenda IR users to switch to XR" and hard-switch as "taking action to severely limit patient access to Namenda IR"). The terms were later adopted by the court. *Schneiderman*, 787 F.3d at 648 ("The parties have referred to Defendants' efforts to transition patients to XR while IR was still on the market as the 'soft switch,' and we will adopt that term. . . . The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR. . . .").

<sup>129</sup> *Schneiderman*, 787 F.3d at 642.

<sup>130</sup> See discussion *supra* note 48 and accompanying text.

<sup>131</sup> *Schneiderman*, 787 F.3d at 647 ("Because Namenda XR has a different strength and daily dosage regimen . . . the generic IR versions that are poised to enter the market will be therapeutically equivalent under FDA regulations to Namenda IR, but not to Namenda XR. Therefore, pharmacists are prohibited from substituting generic IR for Namenda XR under most, if not all, state drug substitution laws.").

<sup>132</sup> See *New York v. Actavis, P.L.C.*, No. 14 Civ. 7473, 2014 WL 7015198, at \*30 (S.D.N.Y. Dec. 11, 2014) ("In April 2014, Forest's head of sales told investors that perhaps 5–30% of patients taking Namenda XR might switch from Namenda XR to generic Namenda at some point after generic entry."), *aff'd sub nom. Schneiderman*, 787 F.3d 638.

<sup>133</sup> *Schneiderman*, 787 F.3d at 649 ("New York's theory of antitrust liability, in substance, is as follows. As Namenda IR neared the end of its exclusivity period, Defendants introduced Namenda XR and, before generic IR was available, withdrew Namenda IR in order to force patients to switch from IR to XR (for which generic IR will not be substitutable under most states' laws). In doing so, Defendants intended to thwart generic entry into and competition in the memantine-drug market in order to maintain their monopoly in that market.").

<sup>134</sup> 15 U.S.C. § 2 (2012) ("Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . .").

or maintain such power.<sup>135</sup> If the plaintiff successfully establishes these criteria, then the defendant has the opportunity to present procompetitive justifications for the allegedly anticompetitive conduct.<sup>136</sup> In *Schneiderman*, the parties did not dispute that Actavis possessed monopoly power within the market, defined at trial as the U.S. memantine drug market.<sup>137</sup> And so the case turned instead on whether Forest had intentionally taken steps to maintain that monopoly.<sup>138</sup> The Second Circuit agreed with New York that the hard-switch tactics used to shift patients from IR to XR constituted the anticompetitive conduct necessary to prove a section 2 violation.<sup>139</sup> Forest raised several procompetitive justifications for its conduct, but the court dismissed these as pretextual.<sup>140</sup>

Having found Forest liable for monopolization under section 2, the court then considered whether Forest's patent rights shielded it from liability.<sup>141</sup> Relying, in part, on the Supreme Court's *Actavis* decision,<sup>142</sup> the Second Circuit rejected this argument, reasoning instead that by

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<sup>135</sup> See, e.g., *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966) (“The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”).

<sup>136</sup> This burden shifting was most clearly articulated in *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001). In the words of the *Microsoft* court:

[I]f a plaintiff successfully establishes a *prima facie* case under § 2 by demonstrating anticompetitive effect, then the monopolist may proffer a ‘procompetitive justification’ for its conduct. If the monopolist asserts a procompetitive justification—a nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal—then the burden shifts back to the plaintiff to rebut that claim.

*Id.* at 59 (citations omitted).

<sup>137</sup> Market determination was not disputed on appeal, and as defined, Forest was effectively the only firm in the market. *Schneiderman*, 787 F.3d at 647 (“The two drugs [Namenda IR and Namenda XR] are the only memantine therapies in their class . . . currently on the market.”).

<sup>138</sup> *Id.* at 652.

<sup>139</sup> The hard-switch not only reduced competition in the memantine drug market by effectively preventing generics from utilizing state substitution laws to enter the market, but also coerced consumers to switch to XR by removing IR from the market before the entry of generic alternatives. *Id.* at 654.

<sup>140</sup> The characterization of these justifications as pretextual relied heavily on evidence presented at trial, including the CEO of Forest describing the soft- and hard-switches as an attempt to “put up barriers or obstacles” to generic entry. *Id.* at 658.

<sup>141</sup> *Id.* at 659–60.

<sup>142</sup> In particular, the Second Circuit relied on *Actavis* for the assertion “that a patent does not confer upon the patent holder an ‘absolute and unfettered right to use its intellectual property as it wishes.’” *Id.* at 660 (citation omitted). However, like the *Actavis* Court, the Second Circuit still recognized an exclusionary scope within patents that is immune from antitrust scrutiny. *Id.* at 659 (“[P]atent and antitrust policies are both relevant in determining the scope of the patent monopoly . . .” (emphasis added) (quoting *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013))).

combining the withdrawal of IR with the introduction of XR, Forest placed its conduct “beyond the scope of their patent rights for IR or XR *individually*.”<sup>143</sup> While each individual patent may have given Forest the right to a temporary monopoly on each drug *individually*, neither patent conferred a right to combine them as part of a scheme that would interfere with competition.<sup>144</sup>

As a final note, because plaintiffs were seeking to enjoin Forest from taking IR off the market until its patent expired and generics had an opportunity to compete via state substitution laws, *Schneiderman* was not decided on the merits.<sup>145</sup> However, the trial court issued a 137-page opinion, of which ninety-seven pages were spent discussing the merits of plaintiff’s antitrust case.<sup>146</sup> On appeal, the Second Circuit also engaged primarily with the merits of the antitrust case as well.<sup>147</sup> Given the thorough treatment of the case’s merits, this Note addresses the Second Circuit’s decision on the product-hopping issue as though it were made on the merits.

### III. ANTITRUST LIABILITY AND PRODUCT HOPPING: A POOR FIT

#### A. Actavis v. Schneiderman: *The Scope of the Patent*

While the Second Circuit followed the Supreme Court in dismissing the scope of the patent defenses, the facts of the *Schneiderman* and *Actavis* cases differ significantly and such a dismissal may have been inappropriate. Unlike Solvay’s patent in *Actavis*, the validity of Forest’s patent on Namenda XR was not in question in *Schneiderman*.<sup>148</sup> In pay-for-delay scenarios, the validity of the patent is

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<sup>143</sup> *Id.* at 660 (emphasis added).

<sup>144</sup> *Id.*

<sup>145</sup> Complaint, *New York v. Actavis, P.L.C.*, No. 14 Civ. 7473 (S.D.N.Y. Dec. 11, 2014) (No. 14 Civ. 7473), 2014 WL 4627802 (“In this action, the Attorney General seeks, among other things, an injunction that would restrain Defendants from continuing their unlawful scheme, require them to take appropriate steps to keep Namenda IR available in the market without disruption, and let patients—and their doctors—decide which drug is right for them.”). The injunction affirmed by the Second Circuit grants this. It requires Forest to continue producing and selling Namenda IR until after its patent has expired, at which point generic companies will have the opportunity to compete via state substitution laws before customers are forced to switch from IR to XR. *New York v. Actavis, P.L.C.*, No. 14 Civ. 7473, 2014 WL 7015198, at \*43 (S.D.N.Y. Dec. 11, 2014) (“The present Forest sales program is consistent with an accepted industry practice of a soft switch when a new product is introduced, a practice that maintains consumer choice before and after generic entry into the market. To maintain the status quo is appropriate relief under the circumstances here presented.” (citation omitted)).

<sup>146</sup> *Actavis*, 2014 WL 7015198.

<sup>147</sup> *Schneiderman*, 787 F.3d 638.

<sup>148</sup> *See generally id.*

always in question; it is only in the context of patent infringement suits that the anticompetitive settlements agreed upon by the parties arise in the first place.<sup>149</sup> But in product-hopping scenarios, the patents are presumably valid. This means that inasmuch as there remains a scope of the patent that is immune to antitrust challenge—and inasmuch as scope survives *Actavis*<sup>150</sup>—such a scope bears on the product-hopping analysis.

The Second Circuit did recognize a scope of the patent argument, but it reasoned that the *combination* of the IR and XR patent rights placed Forest's conduct outside the scope of each *individual* patent's rights.<sup>151</sup> This suggests that lawful action under one patent plus lawful action under another results in unlawful action, which might make sense if neither action is made expressly legal by the Patent Act and the combined action is made expressly illegal by the Sherman Act.<sup>152</sup> In short, if the Patent Act does not expressly permit certain behavior, but the Sherman Act would prohibit that behavior, then there is really no conflict between the laws—the Sherman Act controls.<sup>153</sup> If, however, the Patent Act expressly allows for certain behavior that the Sherman Act would prohibit, then there is a conflict between the laws, and the antitrust law should not upset rights granted by the patent.<sup>154</sup>

The *Actavis* Court adhered to this formulation. It only applied antitrust laws to reverse payment settlements after asking whether the Patent Act permitted such settlements.<sup>155</sup> There the question had a clear answer; the Patent Act does not explicitly authorize reverse payment settlements. In *Schneiderman*, however, the answer was less clear. Forest's product-hopping scheme involved two different patent uses: (1)

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<sup>149</sup> See generally discussion *supra* Section II.A.

<sup>150</sup> The *Actavis* decision left the antitrust concept of patent scope intact. See discussion *supra* Section II.A. Furthermore, the *Schneiderman* court also recognized the scope of the patent monopoly. See discussion *supra* notes 142 and accompanying text.

<sup>151</sup> See *Schneiderman*, 787 F.3d at 660 (“[I]t is the *combination* of Defendants’ withdrawal of IR and introduction of XR . . . that places their conduct beyond the scope of their patent rights for IR or XR individually.”); see also *supra* text accompanying note 143.

<sup>152</sup> See Hovenkamp, *supra* note 89, at 534 (“A more helpful understanding of the beyond the scope formulation considers whether the practice in question was or was not authorized by the Patent Act.”).

<sup>153</sup> In *United States v. Line Material Co.*, 333 U.S. 287 (1948), the Court made “an adjustment between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act” by limiting the patent monopoly to those rights that “the patent statute specifically gives.” *Id.* at 310–11.

<sup>154</sup> Hovenkamp, *supra* note 89, at 518 (“[I]f the practice falls completely within an express authorization of the Patent Act . . . then antitrust rarely has a place. The rather general language of the antitrust laws yields to specific provisions of the Patent Act.”).

<sup>155</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013) (“To strike that balance [between lawful restraints of trade inherent in patent rights and illegal restraints prohibited by the Sherman Act], the Court asked questions such as whether ‘the patent statute specifically gives a right’ to restrain competition in the manner challenged.” (quoting *Line Material*, 333 U.S. at 311)).



the exclusionary use of the XR patent; and (2) the nonuse of the IR patent.<sup>156</sup> The Patent Act expressly permits the exclusionary use of a patent, like the XR patent in *Schneiderman*.<sup>157</sup> On the other hand, the Patent Act does not expressly provide for the nonuse of a patent, yet it has been read into the Act by the Court such that a patent-holder generally has no obligation to use a patent or to license its use to others.<sup>158</sup> In *Hartford-Empire Co. v. United States*, the Supreme Court held that a patent owner “has no obligation either to use [the invention] or to grant its use to others.”<sup>159</sup> Nonetheless, the Second Circuit found that Forest’s decision to stop producing IR and exclusively produce and sell XR was not permitted by the Patent Act.<sup>160</sup>

While the patent scope doctrine may not apply in pay-for-delay scenarios, where patents are only questionably valid, it certainly applies where the holder of a valid patent acts according to express authorizations of the Patent Act.<sup>161</sup> To put the argument differently, paying-for-delay calls into question patent scope arguments by signaling the potential *invalidity* of the underlying patent; but product hopping involves the exercise of rights afforded by *valid* patents, and so the exercise should be immune from antitrust scrutiny. Because Forest’s

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<sup>156</sup> The scheme depends on Forest excluding generics from producing XR and discontinuing production of IR. See *supra* text accompanying notes 129–134.

<sup>157</sup> 35 U.S.C. § 271; see discussion *supra* note 95 and accompanying text.

<sup>158</sup> Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389, 402 (2002) (“As a general rule, a patentee is not obligated, under either patent or antitrust laws, to use or allow others to use a patent. Instead, patented technologies may be shelved in the same way that the owner of a piece of real property or an item of private property may choose not to use it or to exclude all others from using it.”).

<sup>159</sup> *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432 (1945).

<sup>160</sup> *New York ex rel. Schneiderman v. Actavis P.L.C.*, 787 F.3d 638, 660 (2d Cir. 2015) (“[P]atent law gives defendants a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition ‘beyond the limits of the patent monopoly.’” (quoting *Line Material*, 333 U.S. at 308)). Note, however, that while Forest’s actions may interfere with generics’ ability to compete with XR, the XR patent *grants that right*. What perhaps seems troubling about this is not that Forest’s XR patent might grant it a monopoly over XR, but that XR and IR are essentially the same drug—notwithstanding the difference in dosage frequency. See *id.* at 647 (“Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect. The relevant medical difference between the two is that IR, which is released immediately into the bloodstream, is taken twice a day while XR, which is released gradually, is taken once a day.”). Inasmuch as Forest interferes with generics’ ability to compete with IR, the Patent Act allows it to do so. See Saunders, *supra* note 158.

<sup>161</sup> Hovenkamp, *supra* note 89, at 542 (“If a practice poses a significant competitive threat and is not authorized by the Patent Act, then its antitrust legality can typically be assessed without a determination of patent validity or scope. By contrast, if a practice is expressly authorized by the Patent Act, then the antitrust legality of the practice may depend on the validity or scope of the patent.”).

patent is assumed to be valid, the patent scope doctrine should, unlike *Actavis*, carry the day in *Schneiderman*.

### B. *Actavis v. Schneiderman: Regulatory Failure*

Another difference between the *Actavis* and *Schneiderman* decisions is that the pay-for-delay problem represents failure of the Hatch-Waxman regulatory scheme, while the product-hopping problem does not. The Hatch-Waxman framework contemplated that Paragraph IV ANDA filers would resolve questions of patent validity either by prompting pioneer drug manufacturers to acquiesce to generic competition by not bringing an infringement suit, or by litigating infringement suits.<sup>162</sup> What the framework failed to anticipate, however, is that the parties in Paragraph IV proceedings have an incentive to agree to delay generic entry—sharing the monopoly profits of the patent.<sup>163</sup> By applying antitrust law to pay-for-delay settlements, the *Actavis* decision takes away this incentive and forces brand firms to either litigate the patent infringement suit or risk liability under the antitrust laws.<sup>164</sup> In short, the Hatch-Waxman regulatory scheme was malfunctioning,<sup>165</sup> and the Court leveraged antitrust liability to ferret out weak patent claims and make the system function more efficiently.<sup>166</sup>

Product hopping, on the other hand, represents the Hatch-Waxman framework functioning properly. It may seem counterintuitive to say that a regulatory framework that allows a company to extend its market dominance fourteen years beyond the expiration of its initial patent is functioning properly, but the *framework* is not the problem. The problem is that add-on drugs like XR, which have little innovative

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<sup>162</sup> See *id.* at 522 (“The Hatch-Waxman statutory mechanism contemplated that the generic would begin production after pioneer acquiescence, or upon winning the infringement lawsuit, or settling with a production license.”); see also *supra* Section I.B.

<sup>163</sup> Hovenkamp, *supra* note 89, at 522.

<sup>164</sup> The trade-off offered to branded pharmaceuticals post-*Actavis* is that they can either (1) not challenge the Paragraph IV ANDA application and face generic competition in the market; (2) litigate, whether successfully or not, the infringement suit prompted by a Paragraph IV ANDA application; or (3) settle with the Paragraph IV ANDA filers and risk being held liable for damages under the antitrust laws. The hope is that drug companies will choose one of the first two options. See generally *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>165</sup> In highly regulated industries, the Court typically imposes antitrust liability only if the regulatory scheme is not “an effective steward of the antitrust function.” *Verizon Commc’ns v. Law Offices of Curtis V. Trinko, L.L.P.*, 540 U.S. 398, 413 (2004).

<sup>166</sup> Hovenkamp, *supra* note 85, at 21 (“Data on claim construction error rates, the high percentage of litigated patents found to be invalid, and high reversal rates, all suggest that the size of the payment may in fact be at least as good a tool for assessing patent quality as a direct look at the patent itself.” (footnotes omitted)).

value, receive full patent protection. If, for example, Forest had developed a new Alzheimer's treatment that was entirely distinct from and more effective than IR, then it would not likely be subject to antitrust scrutiny for ceasing production of IR to exclusively produce this new drug—even if doing so would force many patients to switch to the new drug. Were it subjected to antitrust scrutiny, Forest would likely raise a successful defense based on the pro-competitive justifications of its new drug.<sup>167</sup> It is the fact that Namenda IR and Namenda XR are essentially the same drug (biologically speaking),<sup>168</sup> that on a gut level, makes the shift from IR to XR and subsequent extension of patent protections so loathsome.

### C. Actavis v. Schneiderman: Remedies

The nature of the remedy granted by the court in *Schneiderman* suggests that antitrust laws may be an inappropriate tool with which to address the product-hopping problem. According to the Supreme Court, antitrust remedies are designed “both to avoid a recurrence of the violation and to eliminate its consequences.”<sup>169</sup> Typically, monetary damages are imposed on an offending firm in order to both eliminate the consequences of its anticompetitive conduct and to deter future firms from attempting similar conduct.<sup>170</sup> Both the Sherman Act<sup>171</sup> and the Clayton Act<sup>172</sup> contain provisions that explicitly allow for monetary damages in antitrust actions.<sup>173</sup> Although the *Actavis* case is still being litigated in the district court,<sup>174</sup> it seems probable that monetary

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<sup>167</sup> See *supra* text accompanying note 136.

<sup>168</sup> *New York ex rel. Schneiderman v. Actavis P.L.C.*, 787 F.3d 638, 647 (2d Cir. 2015) (“Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect. The relevant medical difference between the two is that IR, which is released immediately into the bloodstream, is taken twice a day while XR, which is released gradually, is taken once a day.”).

<sup>169</sup> *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 697 (1978).

<sup>170</sup> William H. Page, *Optimal Antitrust Remedies: A Synthesis*, in 1 THE OXFORD HANDBOOK OF INTERNATIONAL ANTITRUST ECONOMICS 254, 265 (Roger D. Blair & D. Daniel Sokol eds., 2015) (“Penalties are the preferable remedy in the abstract, because, if deterrence is effective, the legal system need not devote further resources to correcting and monitoring competitive behavior.”).

<sup>171</sup> 15 U.S.C. § 1 (2012) (providing that, if convicted of violation of the Sherman Act, an infringer “shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000”). While § 1 speaks primarily to monopolization, § 2 repeats the monetary damages. *Id.* § 2.

<sup>172</sup> *Id.* § 15 (providing that injured persons “shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney’s fee”).

<sup>173</sup> The Sherman Act also provides for “imprisonment not exceeding 10 years.” *Id.* § 1.

<sup>174</sup> The most recent battle in the court was over whether evidence from the settlement negotiation between Solvay and its co-defendants could be withheld as privileged. See, e.g.,

damages will occupy the large part of any consent agreement between the offending pharmaceuticals and the FTC. The goal of the FTC in such an agreement will be to eliminate any incentive to engage in pay-for-delay settlements by making the risk of antitrust liability larger than the reward of pay-for-delay profits.<sup>175</sup>

In *Schneiderman*, however, the court granted an injunction against Forest that required it to continue to produce and sell IR at the same quantity and prices as it had before initiating the hard-switch.<sup>176</sup> While courts often utilize conduct injunctions to restore competitive conditions,<sup>177</sup> conduct injunctions<sup>178</sup> that require specific action on the part of the defendant are rare because they require judicial oversight.<sup>179</sup> Instead, conduct injunctions are usually granted in refusal-to-deal cases, whereby they force a monopolist to deal with would-be competitors.<sup>180</sup> As commentators have noted, conduct injunctions that require judicial oversight are “costly to implement, both in the direct costs of administration and the indirect costs of deterring efficient conduct.”<sup>181</sup>

The oversight in this particular case is not particularly onerous. The court only needed to ensure that Forest continued to sell IR until its patent expired, allowing generics to enter the market via state substitution laws. In this case, the time span from the trial court’s initial injunction<sup>182</sup> to the expiration of the IR patent<sup>183</sup> was only six months. However, the small time-window present in the facts of this case may not be true for all instances of product hopping. If, for example, Forest

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Plaintiffs’ Reply in Support of Motion to Compel Production of Settlement Negotiations Withheld as Privileged, *FTC v. Actavis, Inc.*, Nos. 1:09-CV-955-TWT, 1:09-MD-2084-TWT (N.D. Ga. Oct. 9, 2015), 2015 WL 7075715.

<sup>175</sup> Page, *supra* note 170, at 256 (discussing optimal fines for antitrust violations as removing the incentive to engage in practices that impose a new social cost).

<sup>176</sup> See *supra* text accompanying note 145.

<sup>177</sup> Page, *supra* note 170, at 265 (discussing three types of injunctions: “a prohibitory injunction against specific conduct; a mandatory injunction regulating conduct; or a structural injunction requiring a firm to divest (or not acquire) assets”). The affirmative injunction against *Actavis* would likely fit into the second mandatory injunction category.

<sup>178</sup> Conduct injunctions require a firm to *do* something specific, as opposed to structural injunctions, in which the court creates an injunction that restructures a market. *Id.* at 265–67. Structural injunctions tend to require much more administrative cost than conduct injunctions. *Id.* at 271 (“In a simple case like *Lorain Journal*, the defendant was only required to sell advertising on equal terms that it was free to prescribe, so the task of supervision was minimal. In *AT&T*, however, the process of supervising the conduct provisions of the decree required the district judge to act very much as a regulator for years.”).

<sup>179</sup> *Id.* at 271 (“[C]ourts hesitate to supervise the process of contracting, because doing so may place the court in the role of a regulator.”).

<sup>180</sup> *Id.* at 266.

<sup>181</sup> See, e.g., *id.* at 266.

<sup>182</sup> December 11, 2014. *New York v. Actavis, P.L.C.*, No. 14 Civ. 7473, 2014 WL 7015198, at \*45 (S.D.N.Y. Dec. 11, 2014).

<sup>183</sup> July 2015. *New York ex rel. Schneiderman v. Actavis P.L.C.*, 787 F.3d 638, 642 (2d Cir. 2015).

had initiated a hard-switch two or three years prior, then a conduct injunction of the kind the Second Circuit granted would require the court to continually monitor IR production and sales for multiple years. These administrative burdens make the kind of conduct injunction that the *Schneiderman* court granted both uncommon and unattractive. As several amicus briefs filed on behalf of Forest have emphasized, because antitrust law rarely grants injunctions ordering firms to *continue* a certain behavior,<sup>184</sup> and because one of the central rights granted by a patent is the right *not* to produce a good,<sup>185</sup> antitrust law is an inappropriate tool for dealing with the product-hopping problem.

#### CONCLUSION

Product hopping is, to be sure, problematic. As the *Schneiderman* court noted, if Forest were allowed to shift the Namenda IR market to Namenda XR before generics became available, consumers would end up paying almost \$300 million more for memantine therapy, third-party payors would pay almost \$1.4 billion more, and Medicare would, over ten years, foot a bill of at least \$6 billion.<sup>186</sup> These costs would all result from the inability of generics to use state substitution laws to compete in the memantine drug market. However, increased costs resulting from a lack of competition does not, in itself, signal an antitrust violation. After all, Forest was granted a patent for Namenda XR, and that patent entitles it to a level of freedom from competition.<sup>187</sup> Absent abuse of the XR patent—and simply selling XR and excluding generic manufacturers from making or selling XR does not constitute abuse<sup>188</sup>—Forest should

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<sup>184</sup> See HERBERT HOVENKAMP, *THE ANTITRUST ENTERPRISE: PRINCIPLE AND EXECUTION* 268 (2008) (“Under the antitrust laws a firm, even a monopolist, has no general duty to sell to someone else.”); see also discussion *supra* note 158 and accompanying text.

<sup>185</sup> See, e.g., Final Form Brief of Defendants-Appellants (Redacted), *Schneiderman*, 787 F.3d 638 (No. 14-4624) 2015 WL 862486, at \*35 (“Forest’s right to control or stop IR distribution falls in the heartland of its patent rights.”); Brief of Professors Dolin, Holte, Lande, Mossoff and Osenga as Amici Curiae in Support of Defendants-Appellants and Urging Reversal, *Schneiderman*, 787 F.3d 638 (No. 14-4624), 2015 WL 401495, at \*8 (“The district court’s order entering an injunction that forces Forest to manufacture its patented product . . . violates black letter law that grants a patent owner the right to suppress or withhold its patented product from the market . . .”).

<sup>186</sup> *Schneiderman*, 787 F.3d at 661.

<sup>187</sup> *Id.* at 642 (“The patents on XR ensure exclusivity, and thus prohibit generic versions of XR from entering the market, until 2029.”).

<sup>188</sup> See, e.g., *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1307, 1310 (11th Cir. 2012) (holding that because a patent holder has a “lawful right to exclude others from the market,” a patent “conveys the right to cripple competition” (citations omitted)), *rev’d and remanded sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

be able to use its patent to maintain whatever market exclusivity it can until the patent expires.

If product hopping feels slimy, it is not because a pharmaceutical company can limit competition in the market for a new drug. That is what pharmaceutical patents were designed to do: grant exclusivity in order to incentivize companies to spend the massive amounts of money that go into researching and developing new drugs.<sup>189</sup> Instead, product hopping feels slimy because it grants exclusivity for drugs that are not really new, or at least not innovative. What feels wrong about Forest being able to shut out competition in the memantine market is that Namenda XR and Namenda IR essentially do the same thing.<sup>190</sup> They are both memantine drugs, and they both treat Alzheimer's.<sup>191</sup> The only difference between Namenda IR and Namenda XR, medically speaking, is that you have to take Namenda IR twice a day.<sup>192</sup> The problem is not that Forest tried to use its patent to exclude generic competition, but that it obtained a patent on a drug that is essentially the same as its predecessor drug. The patent itself is the problem, not how it is used.

Patent laws express a social bargain in which market exclusivity is exchanged for innovation.<sup>193</sup> Product hopping violates this bargain by giving drug manufacturers market exclusivity without requiring that they provide any real innovation. Giving Namenda XR, which treats Alzheimer's patients in essentially the same way as the preexisting Namenda IR, the same exclusivity as a pioneer drug, which would treat Alzheimer's patients in a new and perhaps more effective way, seems wrong. Forest is getting more than it gives.

If the heart of what makes product hopping a problem is not its anticompetitive effect, but the insufficiently innovative patents that companies use to product-hop, then patent law—not antitrust law—is the appropriate tool for solving the problem. What this solution looks like is uncertain. The Patent and Trademark Office (PTO) could create stricter standards that would make it harder to obtain patents for compounds that add little to the state of medical knowledge.<sup>194</sup> At the same time, courts could formulate new tests in patent litigation suits

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<sup>189</sup> See *supra* text accompanying notes 12–17.

<sup>190</sup> *Schneiderman*, 787 F.3d at 647 (“Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect.”).

<sup>191</sup> *Id.*

<sup>192</sup> *Id.* (“The relevant medical difference between the two is that IR, which is released immediately into the bloodstream, is taken twice a day while XR, which is released gradually, is taken once a day.”).

<sup>193</sup> See *supra* text accompanying notes 12–17.

<sup>194</sup> Allison A. Schmitt, Article, *Competition Ahead? The Legal Landscape for Reverse Payment Settlements After Federal Trade Commission v. Actavis, Inc.*, 29 BERKELEY TECH. L.J. 493, 532 (2014) (noting that secondary patents are typically for “the method of use for a compound or other procedural aspects beyond the active compound itself”).

that make it easier to challenge add-on drugs like Namenda XR.<sup>195</sup> Heightening standards for granting pharmaceutical patents, however, would represent a significant change in how the pharmaceutical industry operates and would likely require congressional action. The 2003 amendments to the Hatch-Waxman framework suggest that regulatory reform of the pharmaceutical approval process is a realistic possibility,<sup>196</sup> but what those standards would look like is hard to either project or propose.

Another solution might involve the FDA, which stands in the best position to detect product-hopping schemes.<sup>197</sup> Through the provisions of Hatch-Waxman, the agency not only compiles a list of all relevant patents associated with approved drugs,<sup>198</sup> but also serves as a gatekeeper for any new drugs that enter the market.<sup>199</sup> Therefore, Congress could empower the FDA to flag drug applications for add-on drugs and reexamine those patents that may lead to a product-hopping scenario.

However, courts should not take the nebulous nature of product-hopping solutions as license to shoehorn antitrust law into a place it does not rightly belong. If a pharmaceutical company is granted a patent, it should be able to use that patent according to the express terms of the Patent Act without fear of antitrust scrutiny.<sup>200</sup> Regulatory gaming like product hopping may be anticompetitive, but it is anticompetitive *by the book*. And rather than prosecute this kind of loop-holing for being anticompetitive, the appropriate solution is to close the loopholes.

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<sup>195</sup> Feldman & Frondorf, *supra* note 24, at 558 (“[T]he first step in a systems approach would involve focusing on the extent to which different systems interact in the process. These include not only the patent approval system, but *also the patent litigation system . . .*” (emphasis added)).

<sup>196</sup> See discussion *supra* Section I.C.

<sup>197</sup> Eisenberg & Crane, *supra* note 105, at 244–45 (“FDA oversight has significant advantages over litigation in minimizing abuses of the Hatch-Waxman scheme. First, FDA is in a position to detect abuses at a much earlier stage than the courts, and thus to minimize improper delays in generic entry. . . . Second, FDA is better able than the courts to make certain statutory determinations that play a central role in the Hatch-Waxman scheme.”).

<sup>198</sup> The list is compiled into the Orange Book. See *supra* note 47 and accompanying text.

<sup>199</sup> See generally discussion *supra* Part I.

<sup>200</sup> Hovenkamp *supra* note 89, at 518 (“[I]f the practice falls completely within an express authorization of the Patent Act . . . then antitrust rarely has a place. The rather general language of the antitrust laws yields to specific provisions of the Patent Act.”).