

## Payment After *Actavis*

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*One of the most pressing issues in patent and antitrust law involves agreements by which brand-name drug companies pay generic firms to delay entering the market. In FTC v. Actavis, the Supreme Court held that these settlements could violate the antitrust laws. In the wake of the decision, courts, the parties, and commentators have been fiercely debating the question of what constitutes a payment, with courts reaching divergent outcomes. This Article offers a framework that answers this question. It first articulates two justifications based on litigation costs and brand payments for generic services. It then introduces a test based on whether the brand conveys to the generic a type of consideration not available as a direct consequence of winning the lawsuit. Such a showing—accompanied by a finding of an exclusion payment that violates the antitrust laws—demonstrates that the generic’s exclusion from the market is based on the payment rather than the patent. Applying the framework, the Article finds that the test is satisfied when generics delay entering the market after receiving cash, “poison pill” clauses allowing the acceleration of generic entry, and brand agreements not to introduce their own generics. In contrast, the test is not satisfied when the brand forgives damages accrued by a generic that has entered the market. The test, in other words, solves the puzzle articulated by Judge Posner that every settlement provides something of value to the generic. And it offers a framework that resolves a contentious issue with significant consequences for health care and the economy while being consistent with common sense, economics, and the policies underlying the relevant legal regimes.*

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One of the most pressing issues in patent and antitrust law today involves agreements by which brand-name drug companies pay generic firms to delay entering the market. In the landmark case of *FTC v. Actavis*,<sup>1</sup> the Supreme Court concluded that these settlements “tend to have significant adverse effects on competition”<sup>2</sup> and could violate the antitrust laws.

In ensuring a robust role for antitrust analysis, the Court handed down one of the most important business cases in the past generation. But it left unresolved several critical issues. It is no surprise, then, that courts, the parties, and commentators are already fiercely debating the scope of the decision. One of the most contentious issues, with which numerous courts are currently wrestling,<sup>3</sup> involves the question of what constitutes a payment from a brand to a generic.

There is no dispute that settlements by which brands pay cash to generics for delayed entry constitute payment. But beyond this scenario, opinions diverge. How should more recent, complex settlements be analyzed? Should courts find a payment when a brand pays for unrelated services provided by the generic? When a brand promises not to introduce its own generic drug during the first-filing-generic’s exclusivity period? When a brand forgives damages for which a generic could be liable after entering the market? This Article answers this question, articulating a framework for determining what constitutes an “exclusion payment” that violates the antitrust laws.

The analysis begins by articulating two justifications that do not constitute exclusion payments. The first, which will be simple to show but will typically not apply, involves payments that do not exceed the brand firm’s litigation costs that would be incurred after settlement. The rationale

<sup>1</sup> 133 S. Ct. 2223 (2013).

<sup>2</sup> *Id.* at 2231.

<sup>3</sup> *E.g.*, *In re Lamictal Direct Purchaser Antitrust Litig.*, 2014 WL 282755 (D.N.J. Jan. 24, 2014), notice of appeal filed; *In re Nexium Antitrust Litig.*, 2013 WL 4832176 (D. Mass. Sept. 11, 2013); *In re Lipitor Antitrust Litig.*, 2013 WL 4780496 (D.N.J. Sept. 5, 2013). *See generally* Julia K. York, *Reverse-Payment Litigation in the Wake of FTC v. Actavis*, ABA SECTION OF ANTITRUST LAW: INTELLECTUAL PROPERTY COMMITTEE NEWSLETTER 4, 5 (Winter 2014) (noting that “the question of non-monetary consideration is present in at least ten of the fifteen pending reverse-payment antitrust litigations”).

is that the brand would be required to pay these costs in any event and that this relatively small amount does not present significant anticompetitive harm.

The second justification involves brand payments for generic services rather than for delay. Given that brands are increasingly paying generics for these “side deals,” this justification could apply in many cases. But it must be taken with a significant grain of salt. These arrangements typically do not occur outside the settlement context, and many—such as an arrangement by which a brand relies on a generic for its marketing expertise—belie common sense.

The Article then offers the test for determining exclusion payments. The test asks if the brand conveys to the generic a type of consideration not available as a direct consequence of winning the lawsuit. If the generic is able to obtain such consideration, its exclusion from the market cannot be traced to the strength of the brand’s patent. In such a case, the brand is providing compensation beyond what even a valid and infringed patent would justify. And the generic delays entering the market because of this payment.

In addition to articulating a clear framework, such a test also helps resolve one of the most difficult issues introduced by drug patent settlements: the presence of a patent. Antitrust law typically has no tolerance for one company paying a second not to enter the market.<sup>4</sup> But the presence of a patent complicates the analysis. The settling parties have justified payments based on the patent. And under the “scope of the patent” test that the Federal, Second, and Eleventh Circuits had adopted before being overturned by the Supreme Court in *Actavis*, brand payments to generics were automatically upheld as a form of exclusion available to patent holders, with courts assuming the patent was valid and infringed.<sup>5</sup>

The simplicity of the test offered in this Article makes clear that when a brand conveys a type of consideration not otherwise available to the generic, it does not matter if the patent is valid and infringed. The reason is that the brand is offering more than it would be able to as a result of a court decision upholding the patent and finding infringement.

The test thus provides the first framework by which courts can effectuate the *Actavis* Court’s instruction—which is already being tested by the settling parties—not to litigate the merits of every patent dispute. It

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<sup>4</sup> *E.g.*, *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (per curiam).

<sup>5</sup> *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005). The courts only recognized exceptions where the patent suit was a sham or the patent was obtained by fraud.

solves the puzzle articulated by Judge Posner of every settlement providing something of value to the generic. It pinpoints for condemnation settlements in which exclusion is based on the payment rather than the patent. And it offers a simple and predictable analysis that resolves nearly all the disputed cases that arise today.

Part I of this Article provides an overview of the relevant regulatory framework, the Hatch-Waxman Act, focusing on the pathway by which generics reach the market. Part II explains why exclusion payments present antitrust concern, paying particular attention to the Court's opinion in *Actavis*. Part III then sets forth the justifications of payments not exceeding litigation costs and payments for unrelated generic services.

Part IV introduces the test for determining exclusion payments that analyzes whether the brand conveys to the generic a type of consideration not available as a direct consequence of winning the lawsuit. This Part explains that the category of exclusion payments does not encompass every transfer of consideration between the settling parties. And it offers support for the test based on the economic substance of the transaction, the predictable treatment of an important subset of payment cases, and the implementation of the *Actavis* Court's general unwillingness to consider the merits of the patent case.

Part V then applies the test to four of the most frequent settings in which these issues have arisen. It unsurprisingly finds that the test is satisfied in the case of cash payments. But it also finds an exclusion payment when a brand offers a "poison pill" clause that ensures that a settling generic can accelerate its entry when a later-filing generic enters the market. And it concludes that the test is satisfied when a brand agrees not to introduce its own generic drug during the first-filing-generic's exclusivity period.

To the contrary, the test concludes that an exclusion payment is not present when the brand forgives damages potentially accrued by a generic that has entered the market before a district court finding of patent invalidity or noninfringement. In such a case, the forgiveness of damages falls within the range of potential litigation outcomes. And under the more complex analysis required in such a setting, a court would need to consider other factors to make an antitrust assessment of the compensation.

## I. REGULATORY FRAMEWORK

The regulatory regime is essential to understanding drug patent settlements in the United States today. In 1984, Congress enacted the

Hatch-Waxman Act to foster drug innovation and competition.<sup>6</sup> The pharmaceutical marketplace in the early 1980s suffered from sparse generic entry and stifled brand-drug innovation.

Generic drugs have the same active ingredients as brand drugs. At the time of the Hatch-Waxman Act, however, generic firms needed to undertake lengthy, expensive trials to demonstrate safety and effectiveness. Approval by the U.S. Food and Drug Administration (FDA) took years, and because the required tests constituted infringement, generics could not even begin the process during the patent term. At the time Congress enacted the Act, there was no generic on the market for 150 brand-name drugs whose patents had already expired.<sup>7</sup>

The Act's drafters lamented the "practical extension" of the patentee's "monopoly position" beyond expiration of the patent.<sup>8</sup> They thus sought to "make available more low cost generic drugs."<sup>9</sup> Generic competition would save the federal and state governments millions of dollars each year. And given that older Americans used nearly 25 percent of prescription drugs,<sup>10</sup> competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed."<sup>11</sup>

A central mechanism that Congress used to foster generic competition was a 180-day period of marketing exclusivity, reserved for the first generic to file an Abbreviated New Drug Application ("ANDA"), certifying that the brand's patent was invalid or not infringed.<sup>12</sup> When the FDA approves a new drug application ("NDA"), it lists the drug and any relevant patents in a publication known as the Orange Book.<sup>13</sup>

Before entering the market, a generic applicant must provide one of four certifications for each patent listed in the Orange Book relating to the relevant NDA.<sup>14</sup> The first three certifications—no patent on the drug, an expired patent, and a promise to wait until the patent expires—do not result

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<sup>6</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2013)).

<sup>7</sup> H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

<sup>8</sup> H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688.

<sup>9</sup> H.R. REP. NO. 98-857, pt. 1, at 14.

<sup>10</sup> *Id.* at 17.

<sup>11</sup> 130 CONG. REC. 24427 (Sept. 6, 1984) (statement of Rep. Waxman).

<sup>12</sup> For a discussion of other provisions in the legislation, including those benefiting generics through a process for expediting generic entry and an expansion of an experimental-use defense, as well as measures benefiting brands through patent term extensions, non-patent market exclusivity, and an automatic 30-month stay of FDA approval, see Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 41-47 (2009).

<sup>13</sup> The technical name for the Orange Book is "Approved Drug Products with Therapeutic Equivalence Evaluations." ELECTRONIC ORANGE BOOK (2013), <http://www.fda.gov/cder/ob/>.

<sup>14</sup> 21 U.S.C. § 355(j)(2)(A)(vii).

in periods of exclusivity.<sup>15</sup> Only the “Paragraph IV” certification, by which the generic claims that the patent “is invalid or will not be infringed by the generic drug,” leads to exclusivity.<sup>16</sup> During the period, which begins after the first commercial marketing of the drug, the FDA cannot approve other ANDAs for the same product.<sup>17</sup>

The purpose of encouraging patent challenges is confirmed by Congress’s provision of exclusivity only for generics challenging patents and seeking to enter before the end of the patent term. The exclusivity does not apply when generics delay approval until the end of the patent term or enter after the patent has expired.<sup>18</sup> And this exclusivity period is valuable to the generic. As the Supreme Court recognized in *Actavis*, it can be “worth several hundred million dollars” to the generic.<sup>19</sup>

## II. PAYMENT

By granting exclusivity to the first generic to challenge a brand’s patent, the Hatch-Waxman Act made it easier for the brand to pay a single generic (or, in recent years, group of generics) for delayed market entry. This Part explains the antitrust concern presented by drug patent settlements that involve payment. It describes the anticompetitive effects of payments, highlighting the settling parties’ aligned incentives and ability to engage in conduct akin to market division. It then explains why “time entry” splits of the remaining patent term do not present similar antitrust concern.

Before elaborating upon these concepts, a quick word on nomenclature is in order. This Article refers to payments from brands to generics that exceed what the generic could have obtained through patent litigation as “exclusion payments.” The more general category of brand payments to generics is often referred to as “reverse payments” because of the direction in which the payment flows. Unlike typical patent settlements in other industries, in which an alleged infringer pays the patentee to enter the market, these settlements involve payments from the patentee to the alleged infringer.

Much ink has been spilled on how the direction of the payment does not portend economic significance.<sup>20</sup> But the primary concern is not based on

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<sup>15</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(I, II, III).

<sup>16</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

<sup>17</sup> 21 U.S.C. § 355(j)(5)(B)(iv)(I); FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 7 (2002), *available at* [www.ftc.gov/os/2002/07/genericdrugstudy.pdf](http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf) [hereinafter FTC, GENERIC DRUG STUDY].

<sup>18</sup> 21 U.S.C. § 355(j)(2)(A)(vii).

<sup>19</sup> 133 S. Ct. at 2229, 2235. *See infra* notes 195-200 and accompanying text.

<sup>20</sup> *E.g., id.* at 2243 (Roberts, C.J. dissenting) (“The term “reverse payment agreement”—coined to create the impression that such settlements are unique—simply highlights the fact

the direction in which the payment flows. Instead, it derives from the exclusion—exacerbated by the Hatch-Waxman regime—that brands can obtain by paying generics to delay entering the market. A focus on “exclusion payments” thus places the focus squarely on the aspect of the payment that is most concerning.

#### A. Anticompetitive Effects

Settlements with exclusion payments threaten severe anticompetitive harms. The Supreme Court has explained that “[o]ne of the classic examples of a per se violation . . . is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition.”<sup>21</sup> Courts have consistently found that territorial allocations between competitors are per se illegal.<sup>22</sup> For example, in *Palmer v. BRG of Georgia*,<sup>23</sup> the Supreme Court applied per se illegality to an agreement by which competitors divided markets, agreeing not to compete in the other's territory.<sup>24</sup>

Settlement agreements by which brands pay generics not to enter the market threaten dangers similar to territorial market allocation. But instead of allocating geographic space, in which the parties reserve for themselves particular territories, they allocate time.<sup>25</sup> The brand and generic, in other words, agree that the brand will not be subject to competition for a period of time, thereby dividing the market and preventing competition. Market division is particularly concerning because it restricts all competition between the parties on all grounds.<sup>26</sup>

Nor is it a defense that the generic might not have been successful in its attempt to show that the patent is invalid or not infringed. The D.C. Circuit

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that the party suing ends up paying . . . [b]ut this is no anomaly, nor is it evidence of a nefarious plot”); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 388-89 (2010) (arguing that “reverse payment” label is “based on flawed logic” since Hatch-Waxman Act “creates an unusual circumstance in the pharmaceutical industry whereby the patent holder can sue the alleged infringer before the infringing products make it to market”); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 776 (2002) (contending that “‘directional flow’ of the settlement payment does not, standing alone, provide a basis for evaluating the potential anticompetitive effects of a settlement agreement”).

<sup>21</sup> *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972). This and the next two paragraphs are adapted from Carrier, *supra* note 12, at 71-72.

<sup>22</sup> ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 103 (6th ed. 2007).

<sup>23</sup> 498 U.S. 46 (1990) (per curiam).

<sup>24</sup> *Id.* at 49-50.

<sup>25</sup> *In re Schering-Plough Corp.*, 136 F.T.C. 956, 968-74 (2003), *vacated by Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

<sup>26</sup> *Palmer*, 498 U.S. at 49-50.

in *United States v. Microsoft* made clear that “the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant’s continued monopoly power.”<sup>27</sup> In fact, “it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will.”<sup>28</sup> Similarly, the leading antitrust treatise makes clear that “the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition.”<sup>29</sup>

The unique framework provided by the Hatch-Waxman Act exacerbates the exclusion obtained by the brand firm. In other industries, potential infringers stand ready to challenge the patent. In contrast, the Hatch-Waxman Act created a 180-day exclusivity period reserved for the first generic to challenge the brand’s patent. As a result of the Medicare Modernization Amendments Act of 2003,<sup>30</sup> this period is not triggered until the generic begins the commercial marketing of its drug, even if that period occurs years in the future.<sup>31</sup>

In addition, there are several significant obstacles reducing challenges by later-filing generics. First, even a win in litigation would not result in an exclusivity period that they could enjoy. The only entity able to obtain exclusivity is the first generic to file a Paragraph IV certification.<sup>32</sup>

Second, the 2003 Medicare Amendments, which were designed to encourage expedited entry by specifying events that led to a forfeiture of the exclusivity period, were largely toothless. The reason is that they provide for the forfeiture of the first-filer’s exclusivity period upon the later of: (1) 75 days after FDA approval and (2) 75 days after an appellate court decision finding invalidity or non-infringement.<sup>33</sup> But appellate court decisions typically will not occur until years in the future. For example, such rulings have come 6,<sup>34</sup> 8,<sup>35</sup> 11,<sup>36</sup> and 13<sup>37</sup> years after settlement. As a

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<sup>27</sup> 253 F.3d 34, 79 (D.C. Cir. 2001).

<sup>28</sup> *Id.*

<sup>29</sup> 12 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2030b, at 220 (3d ed. 2012).

<sup>30</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 21, 26, and 42 U.S.C.).

<sup>31</sup> Before this amendment, a second trigger for the 180-day period was a court decision finding invalidity or lack of infringement. *See* Erika Lietzan & David E. Korn, *Issues in the Interpretation of 180-Day Exclusivity*, 62 FOOD & DRUG L.J. 49, 63 (2007).

<sup>32</sup> 21 U.S.C. § 355(j)(5)(B)(iv). These hurdles are exacerbated by “poison pill” clauses that allow first filers to accelerate their entry into the market upon later filers’ success in litigation. *See infra* notes 186-193 and accompanying text.

<sup>33</sup> 21 U.S.C. § 355(j)(5)(D)(i).

<sup>34</sup> *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (1997 settlement, 2003 decision).

<sup>35</sup> *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (1997 settlement, 2005 decision).



result, the forfeiture provisions do not typically apply.

Third, it is unclear whether subsequent filers even would have standing to challenge the patent. In many cases, to avoid the chance that the later filer's win would trigger the first-filer's exclusivity,<sup>38</sup> the brand will not sue a subsequent filer, and the case law does not make clear whether the generic could obtain a declaratory judgment.<sup>39</sup>

In short, the 180-day period plays a vital role in exclusion-payment settlements. By paying the generic to delay entering the market, the brand can prevent entry by not only that generic but also all other generics.

As a result of this regime, the brand and first-filing generic share incentives. Because the brand makes more by keeping the generic out of the market than the brand and generic would receive in total by competing in the market, they have an incentive to cede the market to the brand and split the monopoly profits.<sup>40</sup> The brand then can use a portion of this additional profit from delayed competition to pay the generic. In an extreme case, as elaborated more fully below,<sup>41</sup> the brand could even pay more than the generic would have received by competing on the market after winning its patent challenge. Consumers, on the other hand, suffer by paying higher prices and forgoing access to needed medicines from the quashing of challenges to patents that often are invalid or not infringed.<sup>42</sup>

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<sup>36</sup> *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (1997 settlement, 2008 decision).

<sup>37</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) (1993 settlement, 2006 decision). *See generally* Hearing on H.R. 1706 before Subcomm. on Commerce, Trade, & Consumer Protection of H. Energy & Commerce Comm., 111th Cong., at 6 n.6 (2009) (testimony of Dr. Bernard C. Sherman) [hereinafter Sherman testimony].

<sup>38</sup> *See infra* notes 201-204 and accompanying text.

<sup>39</sup> The Supreme Court in *MedImmune v. Genentech*, 549 U.S. 118 (2007), loosened the standards for declaratory judgment, finding that a licensee did not need to suffer a "reasonable apprehension" of suit in order to bring a case. *Id.* at 122. Subsequently, the Federal Circuit made it easier for generics to file declaratory judgment actions against brand companies where (1) the brand listed patents in the Orange Book, (2) the generic filed a Paragraph IV certification, and (3) the brand sued the generic on one or more of the patents. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007). But the court has split on the existence of standing when the brand has not sued the generic. *Compare Caraco Pharm. v. Forest Labs.*, 527 F.3d 1278, 1297 (Fed. Cir. 2008) (granting declaratory judgment) with *Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1363-64 (Fed. Cir. 2008) (denying declaratory judgment).

<sup>40</sup> Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003).

<sup>41</sup> *See infra* Part III.

<sup>42</sup> *See* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013) (finding that brand won 32% of cases involving secondary patents covering "ancillary aspects of drug innovation"); RBC CAPITAL MARKETS, PHARMACEUTICALS: ANALYZING SUCCESS RATES 1, Jan. 15, 2010, available at <http://amlawdaily.typepad.com/pharmareport.pdf> (finding that generics won 48% of court decisions from 2000 to 2009); Paul M. Janicke & LiLan Ren, *Who Wins Patent Infringement*

In sum, the combination of market division and shared incentives for delayed entry, in the context of a regulatory regime that imbues one particular generic with outsized power, threatens severe anticompetitive effects.

### B. Patent-Term Split Agreements

Not every settlement between a brand and a generic creates antitrust concern. Some do not delay entry at all. For example, in the Federal Trade Commission's (FTC's) 2012 report on settlements, 19 of 140 settlements did not restrict generic entry.<sup>43</sup> And others do not involve payment: in the FTC report, 81 settlements contained a restriction but did not provide compensation.<sup>44</sup> Focusing on this latter category reveals the problem with settlements that do involve payment.

It is not contested that pure "patent-term split agreements" by which brands and generics divide the remaining patent term by selecting a time for generic entry do not violate the antitrust laws.<sup>45</sup> For example, in 2003, the FTC carved out an exception to its prohibition on reverse-payment settlements for an "agreed-on entry date, without cash payments."<sup>46</sup> The Commission explained that "a settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent."<sup>47</sup> Rather, "[i]n light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation

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*Cases?*, 34 AIPLA Q.J. 1, 20 (2006) (concluding that pharmaceutical patentees were successful on the merits in 30% of Federal Circuit decisions between 2002 and 2004); FTC, GENERIC DRUG STUDY, *supra* note 17, at 16 (finding that generic prevailed in 73% of Paragraph IV challenges between 1992 and 2000).

<sup>43</sup> FTC BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2012 1 (2013), [hereinafter FTC, FY 2012 AGREEMENTS], available at <http://www.ftc.gov/os/2013/01/130117mmareport.pdf>.

<sup>44</sup> *Id.* Forty settlements contained compensation to the generic and a restriction on the generic's ability to market its product. *Id.*

<sup>45</sup> It is more contested if the settling generic retains 180 days of exclusivity as a result of settlement. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1590 (2006) (explaining that settlements with retained exclusivity "confer[] value upon the generic firm," which "disrupts the equivalence between litigation and a term-dividing settlement").

<sup>46</sup> *In re Schering-Plough Corp.*, 136 F.T.C. 956, 987 (2003), *vacated by* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005). See also Bristol-Myers Squibb, FTC Dkt. No. C-4076, 135 F.T.C. 444 (Consent, 14 April 2003) (refusing to prohibit settlements in which the value received by the generic was "no more than . . . the right to market" the generic "prior to the expiration of the patent").

<sup>47</sup> *Schering-Plough*, 136 F.T.C. at 987.

expectations.”<sup>48</sup>

Similarly, the Supreme Court in *Actavis* stated that settlement allowing entry before patent expiration could “bring about competition . . . to the consumer’s benefit.”<sup>49</sup> In contrast, “payment in return for staying out of the market simply keeps prices at patentee-set levels,” which leads to “consumer los[s]es.”<sup>50</sup>

The parties’ compromise on the entry date reflects the odds of the parties’ success in patent litigation.<sup>51</sup> The greater the likelihood that the patent is valid and infringed, the later in the period generic entry would be expected to occur. The lower the likelihood, the earlier entry would be anticipated.

By way of example, if there were ten years remaining in the patent term and the parties agreed there was a 60 percent chance that a court would uphold the patent’s validity (and find that it was infringed), the mean probable date of entry in litigation would occur in six years.<sup>52</sup> Such an agreement provides the generic with nothing more than it could have received if it had won the patent case.

A brand is likely to gain additional exclusivity by supplementing the parties’ entry-date agreement with a payment to the generic. Continuing the example above, the brand might pay the generic to delay entering the market from Year 6 until Year 9. The monopoly profits the brand earned in these three years would vastly exceed the reduced profits it would earn from sharing the market with the generic. Even with a payment to the generic, the brand would still come out ahead. And the generic would also benefit from the guaranteed stream of revenues, which is not subject to being lost in litigation and which could exceed the profits it could have gained by entering the market. The quid pro quo for the payment would appear to be the generic’s agreement to stay out of the market beyond Year 6—in other words, beyond the date that otherwise reflects the parties’ assessment of the patent’s strength and the likely outcome of the patent litigation.

In short, time-split entry settlements are based on the strength of the

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<sup>48</sup> *Id.*

<sup>49</sup> *FTC v. Actavis*, 133 S. Ct. 2223, 2234 (2013).

<sup>50</sup> *Id.* at 2234-35.

<sup>51</sup> HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 15.3, at 15-45 (2d ed. Supp. 2010); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660 (2004).

<sup>52</sup> See Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1043 (2004). This and the following paragraph are adapted from Carrier, *supra* note 12, at 75-76.

patent,<sup>53</sup> not supplemented by payment from brand to generic. If the brand were to win its patent case, the generic would not be able to enter until the patent expired. But if the generic were successful in showing that the patent was invalid or not infringed, it could enter immediately. The selection of a date for generic entry lying between immediate entry and patent expiration thus falls naturally within the potential range of litigation outcomes.

### C. *Payment under Actavis*

In *FTC v. Actavis*, the Supreme Court highlighted the antitrust harms from brand payments to generics. It explained that the payment “in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.”<sup>54</sup> It stated that “a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee’s market.”<sup>55</sup> And it lamented that “payment in return for staying out of the market . . . simply keeps prices at patentee-set levels,” which leads to gains for the patentee and challenger and losses for the consumer.<sup>56</sup>

Continuing the focus on payment, the Court provided a roadmap to compensation that presents anticompetitive concern by instructing courts to analyze future payments’ “size, . . . scale in relation to the payor’s anticipated future litigation costs, . . . independence from other services for which it might represent payment, and . . . lack of any other convincing justification.”<sup>57</sup> In addition, the “size of the payment” serves as “a strong indicator of power,” thereby allowing the plaintiff to dispense with required showings of market power.<sup>58</sup>

The Court also revealed its strong preference for determining patent strength by examining the payment rather than the patent. An “unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.”<sup>59</sup> In addition, “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>60</sup> Even strong patents are not

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<sup>53</sup> The strength of the patent includes the likelihood of infringement as certain patents may be valid but not infringed.

<sup>54</sup> *Actavis*, 133 S. Ct. at 2234.

<sup>55</sup> *Id.* at 2233.

<sup>56</sup> *Id.* at 2235.

<sup>57</sup> *Id.* at 2237.

<sup>58</sup> *Id.* at 2236.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 2236-37.

immune from the concern with payments, as an unexplained payment on a “particularly valuable patent . . . likely seeks to prevent the risk of competition.”<sup>61</sup> And “that consequence constitutes the relevant anticompetitive harm.”<sup>62</sup>

In short, the Court focused the antitrust analysis like a laser on the payment from the brand to the generic, making clear that this payment constituted the anticompetitive harm and that even strong patents were not immune from scrutiny. The Court, however, did not fully elaborate what constituted a payment. This Article next picks up this project.

### III. JUSTIFICATIONS

Not every payment from a brand to a generic violates the antitrust laws. In particular, the Court in *Actavis* recognized two categories for which the settling parties could offer justifications. This Part more fully sketches the contours of these two justifications. Before concluding that a brand makes an exclusion payment that violates the antitrust laws, courts should allow the settling parties to show that the payment (1) is no larger than litigation costs or (2) is for unrelated generic services rather than delayed entry.<sup>63</sup>

#### A. *Justification 1: Litigation Costs*

If any justification for settlements has been accepted in the past decade, it is that payments less than the amount of the costs of future litigation are justified. For example, in its consent decree in *Bristol-Myers Squibb*,<sup>64</sup> the Federal Trade Commission did not prohibit settlements in which the value received by the generic was “the lesser of the [brand firm’s] expected future litigation costs . . . or \$2 million.”<sup>65</sup> And in *In re Schering Plough*, the FTC created an exception to its prohibition on settlements for “payments to the generic that are linked to litigation costs, up to \$2 million.”<sup>66</sup>

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<sup>61</sup> *Id.* at 2236.

<sup>62</sup> *Id.*

<sup>63</sup> It is appropriate to impose the burden of showing the justifications on the settling parties given their access to the information and the complexity of the arrangements. *See id.* (“An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term.”); *see also* Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 18 (2013) (explaining that “the defendants are in possession of the relevant evidence about their side deals,” that “the complexity is the result of the defendants’ own actions,” and that “[t]he parties to a payment for delay have ample reason to pack complexities into the deal . . . to conceal its genuine nature”).

<sup>64</sup> FTC Dkt. No. C-4076, 135 F.T.C. 444 (Consent, 14 April 2003).

<sup>65</sup> *Id.* at 496.

<sup>66</sup> *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1062 (2003), *vacated by* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

More recently, the Court in *Actavis* found that defendants could show “offsetting or redeeming virtues” justifying payment when the payment “amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement.”<sup>67</sup> In such a case, “there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”<sup>68</sup>

Most generally, the concept of litigation costs encompasses expenditures incurred in conducting litigation.<sup>69</sup> The most frequently cited survey of costs in intellectual property litigation is assembled every two years by the American Intellectual Property Law Association (AIPLA). The AIPLA definition of the term includes “outside legal and paralegal services, local counsel, associates, paralegals, travel and living expenses, fees and costs for court reporters, photocopies, courier services, exhibit preparation, analytical testing, expert witnesses, translators, surveys, jury advisors, and similar expenses.”<sup>70</sup>

The figures from the most recent AIPLA survey show that patent litigation in which there is more than \$1 million at risk costs \$2.6 to \$5.5 million on average.<sup>71</sup> In Hatch-Waxman litigation in particular, the figures range from \$2.65 million to \$6 million.<sup>72</sup> One study found that generics spent an average of \$10 million for each challenge to a brand’s patent.<sup>73</sup> In other words (and offering a conservative synthesis), a transfer of \$5 million or \$10 million seems to be a rough approximation for litigation costs.

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<sup>67</sup> 133 S. Ct. at 2236.

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

<sup>69</sup> David M. Trubek et al., *The Costs of Ordinary Litigation*, 31 UCLA L. REV. 72, 91 (1983).

<sup>70</sup> AIPLA REPORT OF THE ECONOMIC SURVEY 2013, at 34. *See also* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1760 n.177 (2003) (explaining that litigation costs “should be limited to a good faith estimate of the out-of-pocket costs and attorney’s fees the patentee could expect to pay between the time of the settlement and the time the case was concluded”). It is possible to enlarge the concept to include opportunity costs and the value of uncertainty, but this would be overly expansive, introduce undue complication, and “impermissibly bring[] in the value of certain exclusion based on a doubtful patent under the rubric of litigation expenses.” HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 15.3a, at 15-53 (2012 Supp.).

<sup>71</sup> AIPLA REPORT OF THE ECONOMIC SURVEY 2013, at 34 (providing figures of \$2.6 million where \$1 million to \$25 million is at risk and \$5.5 million where more than \$25 million is at risk).

<sup>72</sup> *Id.* (providing figures of \$2.65 million where \$1 million to \$25 million is at risk and \$6 million where more than \$25 million is at risk).

<sup>73</sup> Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011) (quoting MARC GOODMAN, GARY NACHMAN & LOUISE CHEN, MORGAN STANLEY EQUITY RESEARCH, *QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS* 9 (2004)).

Transfers of less than this amount should be covered under the exception.

If a brand's payment to a generic is no higher than its future litigation costs, it is more likely to represent an objective assessment of patent validity. Once the brand sues the generic, each side must pay its litigation costs.<sup>74</sup> An exclusion payment that does not exceed the brand's future costs does not present significant concern since the brand would have been required to spend this money in any event.<sup>75</sup>

This is not a controversial justification. All the cases brought by the FTC and private plaintiffs have involved settlements that have greatly exceeded this amount.<sup>76</sup> And given the FTC's limited resources, it makes sense that the challenged agreements would be those involving payments that exceed future litigation costs.<sup>77</sup>

#### B. *Justification 2: Unrelated Generic Services*

The second justification involves brand payments for unrelated generic services. For example, the brand could pay for a generic (1) to market or co-promote its product, (2) to provide inventory or backup manufacturing services, (3) to supply the brand with raw material or with finished drug products, or (4) for development agreements in the form of up-front payments, milestones, sales percentages, or development fees for unrelated products.<sup>78</sup>

In these settings, the defendants could attempt to show that the payment is not for the generic to delay its entry into the market. If the brand really is paying for generic services in a transaction that does not involve the dividing of monopoly profits to pay for delayed entry, it could offer a

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<sup>74</sup> This standard is conservative since the generic also would save its litigation costs as a result of settlement. Any agreement thus would be expected to be less than the entirety of the brand's saved costs. See Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255, 304-05 (2009).

<sup>75</sup> Carrier, *supra* note 12, at 76-77.

<sup>76</sup> See *infra* notes 174-181 and accompanying text (discussing cases involving brand payments of \$65 million, \$90 million, and \$398 million).

<sup>77</sup> See Edlin et al., *supra* note 63, at 22 (demonstrating that settlement is anticompetitive if the payment "exceeds the patent holder's avoided litigation costs"); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283, 303 (2012) (payment "exceed[ing] the patent holder's anticipated litigation costs is never necessary to secure a desirable settlement") (emphasis in original).

<sup>78</sup> FTC BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006 4-5 (2007), available at [www.ftc.gov/reports/mmact/MMAreport2006.pdf](http://www.ftc.gov/reports/mmact/MMAreport2006.pdf); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 664 (2009).

legitimate justification. As the Court explained in *Actavis*, a defendant's demonstration "that legitimate justifications are present . . . explain[s] the presence of the challenged term and show[s] the lawfulness of that term under the rule of reason."<sup>79</sup> In particular, the settlement might reflect "fair value for services."<sup>80</sup>

For this reason, the second justification is provided by a brand's purchase of unrelated generic services. But while this constitutes a justification in theory, a heavy dose of salt must be applied before the defendants can seek refuge in it. The reason is that the payment for unrelated services often is a disguised payment for delay.

### 1. General findings

In most cases, brands are not interested in generic services outside the settlement context. Based on a review of settlements between 1993 and 2000, as well as settlements filed under the Medicare Modernization Act of 2003, former FTC Chairman Jon Leibowitz testified that "side deals" between brands and generics were "observed in settlements that restrained generic entry, but virtually never in settlements that did not."<sup>81</sup> Leibowitz observed that there had been only two exceptions to this pattern, and one was then under investigation.<sup>82</sup> And he concluded that the side deals "may be serving as a vehicle to compensate a generic challenger for its agreement to a later entry date than the generic firm would otherwise accept."<sup>83</sup>

Similarly, based on a review of the securities filings of brands and generics that have entered into settlements, Scott Hemphill has concluded that "[o]utside of settlement, brand-name firms seldom contract with generic firms for help with the activities that form the basis of side deals."<sup>84</sup> In particular, Hemphill found that the 25 total combinations among five major brand firms and five major generic firms yielded only two minor business arrangements.<sup>85</sup>

While the facts of individual settlements call for review, the simple application of common sense calls for rigorous scrutiny. Do brands really need promotion by generics? As seen by armies of pharmaceutical sales representatives and commercials with wind-swept actors walking along the

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<sup>79</sup> *FTC v. Actavis*, 133 S. Ct. 2223, 2236 (2013).

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

<sup>81</sup> Paying Off Generics to Prevent Competition with Brand Name Drugs: Hearing Before the Senate Comm. on the Judiciary, 110th Cong. 17 (2007) (statement of Jon Leibowitz, Comm'r of the Federal Trade Comm'n), available at [www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements\\_senate.pdf](http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> Hemphill, *supra* note 78, at 666.

<sup>85</sup> *Id.* at 666-67.



beach, brands tend not to be at a loss in marketing their drugs. And while brands sometimes rely on other brands for promotion, they do not use generics for this task outside the settlement context.<sup>86</sup>

## 2. Specific examples

A few examples are illustrative. One is provided by the case of *In re Schering-Plough Corporation*.<sup>87</sup> Although the Eleventh Circuit rejected its analysis, the FTC, after an exhaustive review, concluded that the licenses that the brand paid to the generics greatly exceeded the value of the products it received.<sup>88</sup> Even though there were significant safety and market concerns with one product,<sup>89</sup> the brand (1) did not include its knowledgeable employees in the negotiations,<sup>90</sup> (2) failed to request sales projections or research relating to the drug,<sup>91</sup> (3) never followed up on unfulfilled requests for information,<sup>92</sup> and (4) did not object when the generic suspended its work.<sup>93</sup> This lack of interest supported the FTC's conclusion that the brand paid the generics to delay entering the market.<sup>94</sup>

Another example was presented by the facts alleged in *Actavis*. In its complaint (which was dismissed before being reinstated by the Supreme Court), the FTC asserted that the brand's co-promotion deals with generics were not independent business transactions. The FTC explained that before entering into settlement discussions with the generics: (1) "Solvay [the brand firm] had not been looking for a co-promotion partner"; (2) the company's business plan had "assumed no co-promotion"; (3) "two prior AndroGel co-promotion efforts had been canceled because they had 'no significant impact' on sales trends"; and (4) an "analysis from a consulting firm had concluded that future AndroGel co-promotion offered 'little revenue upside.'"<sup>95</sup>

In addition to the lack of interest in co-promotion, Solvay's payments "far exceed[ed] the value of the services provided."<sup>96</sup> Solvay "projected that it would pay" the generics more than "\$300 per sales call," far more than a previous co-promotion deal that had "involv[ed] projected payments of around \$30-\$45 per sales call" and even more than the \$150 per call that a

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<sup>86</sup> *Id.* at 668.

<sup>87</sup> 136 F.T.C. 956, 1060-61 (2003).

<sup>88</sup> *Id.* at 967.

<sup>89</sup> *Id.* at 1038.

<sup>90</sup> *Id.* at 1019.

<sup>91</sup> *Id.* at 1037.

<sup>92</sup> *Id.* at 1043.

<sup>93</sup> *Id.* at 1051.

<sup>94</sup> *Id.* at 1014.

<sup>95</sup> Second Amended Complaint for Injunctive and Other Equitable Relief, *FTC v. Watson Pharms., Inc.*, No. 1:09-CV-00955-TWT ¶ 82 (N.D. Ga. May 28, 2009).

<sup>96</sup> *Id.*

senior Watson (now Actavis) executive had called “ridiculous.”<sup>97</sup>

Nor was Solvay’s back-up manufacturing deal with generic Paddock an “independent business transaction.” The FTC alleged that: (1) the deal guarantees the generic “\$2 million per year for six years” even if it did not “ever manufacture[] AndroGel or ever become[] FDA-qualified to manufacture AndroGel”; (2) before Solvay entered into settlement discussions with the generic, it “had considered and rejected several options for AndroGel back-up manufacturing” and “had concluded that the \$10-12 million in capital expenditures required to qualify a back-up manufacturer could not be justified” in light of its already-existing “reliable source of supply”; and (3) before entering the deal, Solvay “conducted no diligence” on the generic’s manufacturing facilities (which led to “substantial and lengthy efforts to conform [the] facilities and processes to FDA-approved standards”).<sup>98</sup>

A final example is provided by the case of *King Drug Company v. Cephalon*.<sup>99</sup> The plaintiffs in that case alleged that the “side-term inducements” that brand Cephalon provided to the first-filing generics “[we]re not independent business transactions, but [we]re instead inextricably linked with the agreed-upon generic entry date” for multiple reasons: (1) The inducements “were entered simultaneously with the associated patent litigation settlements, and were often contained in the same document”<sup>100</sup>; (2) “Prior to patent settlement negotiations, Cephalon had no significant discussions with the generic companies regarding the matters covered by the side-term inducements”<sup>101</sup>; (3) “Cephalon was willing to agree to the side-term inducements only if the generic companies agreed to refrain from competing with their generic versions of Provigil”<sup>102</sup>; (4) “Cephalon did not need licenses to the generic companies’ modafinil-related intellectual property to manufacture or sell Provigil or planned successor products”<sup>103</sup>; and (5) “By entering into a series of supply agreements, Cephalon created, in the words of a senior supply manager, a ‘supply chain nightmare’ that makes little sense, absent offsetting consideration in the form of the elimination of potential competition.”<sup>104</sup>

Given the complexity of these arrangements and their greater access to

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<sup>97</sup> *Id.*

<sup>98</sup> *Id.* ¶ 84.

<sup>99</sup> 702 F. Supp. 2d 514 (E.D. Pa. 2010).

<sup>100</sup> Plaintiff Federal Trade Commission’s First Amended Complaint for Injunctive Relief, *Federal Trade Commission v. Cephalon, Inc.*, No. 2:08-cv-2141-MSG, ¶ 59 (E.D. Pa. Aug. 12, 2009) [Cephalon complaint].

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

<sup>102</sup> *Id.*

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

<sup>104</sup> *Id.*

the information, the defendants should have the burden of showing that the payment is justified.<sup>105</sup> The Supreme Court in *Actavis* confirmed this in explaining that “[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term.”<sup>106</sup>

Such a burden recalls the requirement in merger review that the parties demonstrate that proffered efficiencies are “merger-specific.”<sup>107</sup> Such efficiencies are “likely to be accomplished with the proposed merger” and “unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects.”<sup>108</sup> The rationale is that the parties can avoid merger and its anticompetitive harms<sup>109</sup> if they could attain the efficiencies through “practical alternatives that mitigate competitive concerns, such as divestiture or licensing.”<sup>110</sup>

Similarly here, the parties are engaging in complex transactions that they typically do not engage in outside settlement and that are difficult to trace. In the context of potential collusion, which is “the supreme evil of antitrust,”<sup>111</sup> such arrangements need to be rigorously demonstrated.

If the settling parties can show that their payment is in fact for unrelated services, they can proffer a justification. But because of the infrequency of business arrangements between brands and generics outside settlement and because of the ease with which payments for delay can be disguised in a web of complex business arrangements, courts should apply a heavy dose of salt to this justification.

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<sup>105</sup> See, e.g., Edlin et al., *supra* note 63, at 18 (explaining defendants’ role in creating complexity and incentives to do so “to conceal [the arrangement’s] genuine nature”); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758 (2003) (explaining, in the context of determining patent infringement, that “the burdens of production and proof properly rest with the antitrust defendants (or proponents of the settlement) because they typically control the information upon which resolution of the infringement issue will be made”); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 534-35 (2002) (arguing that the courts should place the burden of proof on the antitrust defendants due to their access to relevant information).

<sup>106</sup> *FTC v. Actavis*, 133 S. Ct. 2223, 2236 (2013).

<sup>107</sup> U.S. DEPARTMENT OF JUSTICE & FEDERAL TRADE COMMISSION, HORIZONTAL MERGER GUIDELINES, ¶ 10, Aug. 19, 2010, <http://www.justice.gov/atr/public/guidelines/hmg-2010.html#foot13>.

<sup>108</sup> *Id.*

<sup>109</sup> The concern with mergers is that they “should not be permitted to create, enhance, or entrench market power or to facilitate its exercise.” *Id.* ¶ 1. A merger “enhances market power if it is likely to encourage one or more firms to raise price, reduce output, diminish innovation, or otherwise harm customers as a result of diminished competitive constraints or incentives.” *Id.*

<sup>110</sup> *Id.* ¶ 10.

<sup>111</sup> *FTC v. Actavis*, 133 S. Ct. 2233 (2003) (quoting *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004)).

#### IV. FRAMEWORK FOR EXCLUSION PAYMENTS

One of the crucial open issues after *Actavis* is the type of brand compensation to generics that constitutes an exclusion payment violating the antitrust laws. This Part offers a framework for answering this question. After introducing the test, it explains the consequences of finding an exclusion payment, and then concludes by offering support for the test.

##### A. Test

This Section introduces the framework for exclusion payments in several steps. First, it makes clear that the concept does not include every exchange of value between the parties. Second, it examines the type of consideration a generic can obtain through a district court victory where the generic has entered the market at the time of the decision. Third, it sketches the narrower universe of consideration that could potentially be expected by a generic that has not entered the market at the time of the district court decision.

##### 1. Requirement greater than transfer of value

The most expansive definition of an exclusion payment would encompass every settlement that involves the transfer of any consideration between the parties. Under this framework, an exclusion payment would be present when a brand conveys anything of value to a generic.

This test would be too broad. It is hornbook contract law that parties would not settle a case if they do not receive *some* consideration. The most frequently cited source for this proposition is Judge Richard Posner, sitting by designation in the Northern District of Illinois in *Asahi Glass Company v. Pentech Pharmaceuticals*.<sup>112</sup> In granting defendants' motion to dismiss, Judge Posner explained that "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement."<sup>113</sup>

Judge Posner appropriately observed that settlements tend to give each of the settling parties something of benefit. For that reason, the test for exclusion payments that violate the antitrust laws should not be triggered by the broadest conception of value transferred to the generic. Of particular concern, such a test would encompass settlements in which the brand and generic reach agreement solely on the date for generic entry. For these settlements allow the generic to obtain something of value: the right to enter before the end of the patent term.

Instead, more guidance is to be found by considering whether the brand

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<sup>112</sup> 289 F. Supp. 2d 986 (N.D. Ill. 2003).

<sup>113</sup> *Id.* at 994.

conveys to the generic a type of consideration not available as a direct consequence of winning the lawsuit. This showing will not occur in every case in which the generic receives anything of value. But it will be present in the subset of cases in which the generic receives something it could not have achieved through a district court decision finding the patent invalid or not infringed.

The type of allowable consideration will vary considerably based on whether the generic has entered the market before the district court decision. In each of the two possible scenarios, a generic files a Paragraph IV certification claiming the patent is invalid or not infringed.

## 2. Scenario 1: At-risk entry

In the first (less typical) scenario, the generic has entered the market before a district court ruling finding the patent invalid or not infringed. Such conduct is known as an “at risk” launch.<sup>114</sup> This entry is risky because if the generic loses the litigation, it would be responsible for the brand’s damages. This is taking a significant chance since the generic might need to pay a reasonable royalty or, even more concerning, the brand’s (monopoly) profits, which tend to greatly exceed the generic’s profits.

From 2003 through 2009, there were 28 at-risk launches out of 238 lawsuits involving first-filing Paragraph IV generics.<sup>115</sup> More than half of these launches were undertaken by two generic companies: Teva (12) and Sandoz (6).<sup>116</sup>

Even though Paragraph IV certifications contemplate entry before the end of the patent term, most generics that file the certifications do not enter at risk because, in addition to being dangerous, they do not need to. The patent laws make clear that the mere filing of a Paragraph IV certification is considered an artificial act of infringement that allows the patentee to sue the generic.<sup>117</sup>

But where a generic has entered the market, it will be subject to damages if a court finds that it infringes a valid patent. In such a case, a brand’s payment to the generic could potentially be justified by the patent. In particular, the payment could take the form of forgiveness of a portion of the generic’s damages. In general, the more likely that the patent is invalid or not infringed, the greater the damages the brand will forgive. To be sure,

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<sup>114</sup> RBC CAPITAL MARKETS, *supra* note 42, at 7 (referring to “at risk” entry as “any launch without a lower court ruling”); Joseph M. O’Malley, Jr. et al., *Failure to Launch*, 2011 INTELLECTUAL PROPERTY MAGAZINE 30 (describing “at risk” launches as entry “prior to any trial decision addressing validity or infringement”).

<sup>115</sup> *Id.* at 3, 7.

<sup>116</sup> *Id.* at 7.

<sup>117</sup> 35 U.S.C. § 271(e)(2)(A).

the forgiveness might be excessive considering the strength of the patent and size of the payment. But as discussed below,<sup>118</sup> this will not automatically fall into the category of exclusion payments.

### 3. Scenario 2: No entry

In the second scenario, which is far more common, the generic has not entered at risk before a district court decision. The best result this generic can hope for is a ruling that the patent is invalid or not infringed. If the generic achieves this success, the brand is not able to enforce the patent, with the result that the generic could enter the market.<sup>119</sup>

The unexceptional consequence of generic entry after a district court victory explains why the FTC and commentators have long agreed that settlements involving an entry date unaccompanied by payment do not present antitrust concern.<sup>120</sup> As the Court explained in *Actavis*, such settlements could “bring about competition,” which redounds to “the consumer’s benefit.”<sup>121</sup>

Where the generic has not entered at risk, the brand’s best-case scenario from litigation is to exclude the generic from the market for the duration of the patent term. And the best-case scenario for the generic is immediate entry. Under legitimate settlements based on the strength of the patent, then, generic entry would be anticipated at some point between immediate entry and the expiration of the patent term. As discussed above,<sup>122</sup> the particular entry date within the allowable range would depend on the parties’ assessments of patent strength, with stronger patents resulting in later generic entry and weaker patents leading to earlier entry.

In contrast, where a generic that has not entered at risk receives a type of consideration *other than entry*, it cannot trace its bounty to its victory in patent litigation. For in this case, it receives a type of consideration that *cannot be explained* by patent litigation. In other words, the generic obtains something that would not be available even upon a resounding decision that the patent is invalid or not infringed.<sup>123</sup>

The setting also differs from the first scenario since the generic has not entered at risk. Generics that do not enter the market do not take the chance that they will be compelled to pay damages, in particular the brand’s profits

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<sup>118</sup> See *infra* Section V.D.

<sup>119</sup> This conclusion assumes the absence of restrictions such as non-patent exclusivity provided by the FDA.

<sup>120</sup> See *supra* notes 43-52 and accompanying text.

<sup>121</sup> *Actavis*, 133 S. Ct. at 2234.

<sup>122</sup> See *supra* notes 46-52 and accompanying text.

<sup>123</sup> In cases in which a generic has filed a counterclaim against a brand, the test is satisfied if the brand pays the generic an amount greater than the sum of litigation costs and the generic counterclaim.

or a reasonable royalty.<sup>124</sup> As a result, brand forgiveness of damages the generic could have accrued is not a type of consideration available to the generic from winning its lawsuit.

Of course, after a victory in district court, the generic ultimately could compete in the market, naturally seeking to maximize its profits. But as a direct result of a victory in district court, the generic that has not entered at risk can only obtain the reward of market entry.<sup>125</sup> In no conceivable scenario would the occasion of the district court ruling finding the patent invalid or not infringed result in the brand paying the generic money.

Settlements in which the brand excludes the non-at-risk generic from the market by providing a type of compensation not available through a victory in district court reveal the danger of aligned incentives. As discussed above,<sup>126</sup> because the brand makes more by keeping this generic out of the market than the parties would receive by competing in the market, they have an incentive to delay generic entry, cede the market to the brand, and split the monopoly profits. Money obtained by the non-at-risk generic thus flows from the brand's (now guaranteed) monopoly profits, not from any potential district court ruling on patent validity and infringement.

In short, any conveyance above litigation costs<sup>127</sup> from a brand to a generic for delayed entry when the generic has not yet entered the market (and thereby set itself up for potential damages liability) will constitute an exclusion payment. In this setting, the settlement cannot be justified by the strength of the patent.

As the next Part will show,<sup>128</sup> exclusion payments take the form of more than just cash payments. More complex arrangements that have the same economic effect and that the generic could not obtain as a direct result of winning the lawsuit also will suffice. One type of compensation is a clause by which the brand promises not to introduce an "authorized generic" during the first-filing generic's 180-day exclusivity period. Another type is a "poison pill" clause that ensures that a settling generic can

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<sup>124</sup> SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 16.1 (2009) (noting that generic that loses infringement litigation before entering market is not responsible for paying damages to brand).

<sup>125</sup> The dividing line between (acceptable) entry and (prohibited) other forms of consideration provided to non-at-risk generics also is supported by (1) the *Actavis* Court's acceptance of entry-date settlements and concern with "unusual" agreements allowing non-at-risk generics to receive money, *see supra* note 49 and *infra* notes 131-133 and accompanying text; and (2) the Hatch-Waxman Act's goal of encouraging generic entry, which was designed to introduce "low-cost, generic drugs for millions of Americans" and would be facilitated by 180-day marketing exclusivity. 130 CONG. REC. 24427 (1984).

<sup>126</sup> *See supra* notes 40-42 and accompanying text.

<sup>127</sup> *See supra* notes 64-76 and accompanying text.

<sup>128</sup> *See infra* Part V.

accelerate its entry when a later-filing generic enters the market.

### B. Consequences of Exclusion Payments

A court that finds an exclusion payment in exchange for delayed generic entry<sup>129</sup> should conclude that the payment violates the antitrust laws. As discussed above,<sup>130</sup> the Court in *Actavis* focused like a laser on the harm from payments. The reason is that payments “in effect amount[] to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.”<sup>131</sup>

The Court stated that “a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee’s market.”<sup>132</sup> And it lamented that “payment in return for staying out of the market . . . simply keeps prices at patentee-set levels,” which leads to gains for the patentee and challenger and losses for the consumer.<sup>133</sup> In fact, the Court found it “unusual” for a plaintiff to pay defendants “many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages.”<sup>134</sup>

Although the *Actavis* Court stated that “the FTC must prove its case as in other rule-of-reason cases,” its version offered a more targeted approach than the typical exhaustive consideration of a restraint’s anticompetitive and procompetitive effects.<sup>135</sup> As the Supreme Court explained in *California Dental Association v. FTC*<sup>136</sup> and affirmed in *Actavis*: “[t]here is always something of a sliding scale in appraising reasonableness,” with “the quality of proof . . . vary[ing] with the circumstances.”<sup>137</sup>

<sup>129</sup> Settlements that do not delay generic entry do not present anticompetitive concern. See FTC, FY 2012 AGREEMENTS, *supra* note 43, at 1 (finding that 19 of 140 final settlements “have no restriction on generic entry”). This Article focuses on settlements in which entry is delayed.

<sup>130</sup> See *supra* notes 54-61 and accompanying text.

<sup>131</sup> 133 S. Ct. 2223, 2234 (2013).

<sup>132</sup> *Id.* at 2233.

<sup>133</sup> *Id.* at 2235.

<sup>134</sup> *Id.* at 2231.

<sup>135</sup> See, e.g., Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 B.Y.U. L. REV. 1265. See also Thomas F. Cotter, *FTC v. Actavis, Inc.: When is the Rule of Reason Not the Rule of Reason?*, at 2 [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2281291](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2281291) (“In reality, the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject.”); Christopher Sagers, *The U.S. Supreme Court Reverses the Judgment of the 11th Circuit and Leaves the Structuring of the Rule of Reason Antitrust Litigation to the Lower Courts*, E-COMPETITIONS, June 2013 (Court “lay[s] out the elements of what looks like a special § 1 cause of action, which doesn’t look at all like a full rule of reason inquiry”).

<sup>136</sup> 526 U.S. 756, 780 (1999).

<sup>137</sup> 133 S. Ct. at 2238.



The *Actavis* Court directed lower courts to focus on “the presence of significant unjustified anticompetitive consequences.”<sup>138</sup> And its suggested analysis emphasized four elements related to the payment, instructing future courts to analyze payments’ “size, . . . scale in relation to the payor’s anticipated future litigation costs, . . . independence from other services for which it might represent payment, and . . . lack of any other convincing justification.”<sup>139</sup> Further confirming the propriety of a more abbreviated analysis, elaborate showings of market power could be avoided because the “size of the payment” serves as “a strong indicator of power.”<sup>140</sup>

The test for exclusion payments offered in this Article provides a simple way to effectuate the four elements in the *Actavis* Court’s framework. It initially removes from automatic condemnation payments that do not exceed litigation costs or are for unrelated services. A third factor will not play a significant role, as the Court failed to provide any detail on its half-hearted category of “other convincing justifications” for the payment.<sup>141</sup> The framework thus devolves to the size of the payment.

The Court’s emphasis on a payment’s size overlaps with its concern about “large and unjustified”<sup>142</sup> payments. Some commentators, however, have lamented the difficulties of determining whether payments of a certain size violate the antitrust laws and applying a framework based on “large and unjustified” payments.<sup>143</sup>

The operation of the proposed test, however, addresses these concerns. Payments exceeding litigation costs are, by definition, likely to be large since they would exceed a threshold of \$5 million to \$10 million.<sup>144</sup> As a

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

<sup>139</sup> *Id.* at 2237.

<sup>140</sup> *Id.* at 2236.

<sup>141</sup> See Edlin et al., *supra* note 63, at 18 (“The Court leaves the door open to other ‘justifications’ for a reverse payment, but is skeptical, and does not explicitly identify any.”).

<sup>142</sup> 133 S. Ct. at 2237.

<sup>143</sup> E.g., John P. Bigelow, “Reverse Payments” After *Actavis*, CPI ANTITRUST CHRONICLE, Sept. 2013, at 9 (contending that “[t]he difficulty with implementing” the Court’s decision “will surely be determining what constitutes an ‘unexplained large reverse payment’”); Alan Morrison, *Commentary: Subjecting Reverse Payments in Patent Cases to Antitrust Scrutiny: Sounds Like a Good Idea, But Can it Work?*, SCOTUSBLOG, July 25, 2013, <http://www.scotusblog.com/2013/07/commentary-subjecting-reverse-payments-in-patent-cases-to-antitrust-scrutiny-sounds-like-a-good-idea-but-can-it-work/> (asserting that “the Court may have created a theoretically beautiful lawsuit model that cannot work in practice”); Richard Parker et al., *U.S. Supreme Court Weighs Reverse-Payment Patent Settlements: Antitrust “Rule of Reason” Applies*, O’MELVENY & MYERS LLP, June 18, 2013, <http://www.omm.com/us-supreme-court-weighs-reverse-payment-patent-settlements-antitrust-rule-of-reason-applies-06-18-2013/> (explaining that the Court “does not clearly define when a payment becomes so large as to trigger antitrust scrutiny”).

<sup>144</sup> See *supra* notes 70-73 and accompanying text.

result, the focus then shifts to whether the payment is justified.<sup>145</sup> And for several reasons, a generic's receipt of a type of consideration not available as a consequence of winning the lawsuit falls comfortably within the category of "unjustified" payments.

For starters, the payment cannot be justified on the grounds that it is no larger than future litigation costs or is for unrelated services. The justifications remove those cases from consideration.

And by asking whether the brand is providing the generic with a type of consideration that is not otherwise available, the test determines whether the rewards flow from patent litigation. If they do not, then exclusion cannot be traced to the patent. And in that case, it is not necessary for the court even to analyze the patent. Because the patent is not driving the exclusion, whether the patent is valid and infringed is not relevant in determining the appropriate antitrust analysis. The reason is simple: *Even the brand's control of a valid and infringed patent cannot justify its conveyance of a type of consideration that it could not bestow as a result of a court ruling upholding the patent.*

In short, an exclusion payment cannot find a justification in the defenses of litigation costs or unrelated generic services. Nor is it justified by the patent itself. As a result, it constitutes a payment from one company to another to delay entering the market. That is an example of market division. And just like market division outside the patent setting is illegal,<sup>146</sup> so should courts find that exclusion payments violate the antitrust laws.

### C. Support for Test

In addition to the reasons elaborated in the previous section, the framework based on whether the generic obtains a type of consideration not available as a direct consequence of winning the lawsuit is supported on several additional grounds.

First, the test accords with the more fact-intensive but more egregious setting of generics receiving more through settlement than they would have *by entering the market*. Underlying the Court's analysis of drug patent settlements is the commonsense reaction that such agreements are suspicious. In the *Actavis* oral argument, Justice Ginsburg pointed to the concern of "the generic . . . getting an offer that they would never get on the street."<sup>147</sup> Justice Kennedy explained that this "was [his] concern too," and asked the attorney for the settling parties: "[W]hy don't you just put a cap

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<sup>145</sup> See Michael A. Carrier, *Actavis and "Large and Unjustified" Payments*, SCOTUSBLOG, July 25, 2013, <http://www.scotusblog.com/2013/07/actavis-and-large-and-unjustified-payments/>.

<sup>146</sup> *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) (per curiam).

<sup>147</sup> Transcript of Oral Argument at 41, *FTC v. Actavis*, No. 12-416 (Mar. 25, 2013).

on what the generic can make and then we won't have a real concern with the restraint of trade, or we'll have a lesser concern."<sup>148</sup> And as the Court explained in its opinion: "[T]here are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market" and that this was true of the challenged settlement.<sup>149</sup>

Even the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*, which applied extremely deferential analysis to the settlements, admitted the concern. On the issue of whether reverse payments were "excessive," the court conceded that it seemed "suspicious" for a patentee to settle litigation against a potential generic manufacturer by paying "more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder."<sup>150</sup> The court, however, magically found the suspicion to "abate[] upon reflection."<sup>151</sup> Applying the simpler test introduced in this Article of what the generic could have gained by obtaining a type of consideration not available as a direct consequence of winning the lawsuit draws on similar concerns while not requiring courts to determine what the generic would have received by entering the market.<sup>152</sup>

Second, carving out a category of unjustified exclusion payments makes sense of the *Actavis* Court's repeated admonitions not to wade into the patent merits. The Court made clear that "it is normally not necessary to litigate patent validity to answer the antitrust question."<sup>153</sup> Rather, "by examining the size of the payment," a court "may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent."<sup>154</sup> In fact, "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>155</sup> And even strong patents are not immune from the concern with payments since an unexplained payment on a "particularly valuable patent . . . likely seeks to prevent the risk of competition."<sup>156</sup>

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<sup>148</sup> *Id.* at 42; *see also id.* at 29 (Justice Kennedy suggests test based on "what the generic would have made" if it had entered the market).

<sup>149</sup> 133 S. Ct. at 2235.

<sup>150</sup> 466 F.3d 187, 208 (2d Cir. 2006).

<sup>151</sup> *Id.*

<sup>152</sup> Most settlements have not involved payments larger than the amount the generic would have earned by entering the market after winning a patent victory in district court. But the obvious concern presented by this category supports the test offered in this Article, which is based on the easier analysis of the type of consideration bestowed by the brand.

<sup>153</sup> 133 S. Ct. at 2236.

<sup>154</sup> *Id.* at 2237.

<sup>155</sup> *Id.* at 2236-37.

<sup>156</sup> *Id.* at 2236.

By ensuring that courts need not examine the merits of the patent in cases in which the brand conveys a type of consideration not available as a consequence of winning the lawsuit, the test ensures that the Court's concerns with the challenges of litigating patent invalidity and infringement are effectuated. Going forward, one of the most profound concerns is that—regardless of what the Court said in *Actavis*—district courts will be inundated in every case with defendants seeking to introduce evidence of the patent merits, claiming that “at least in this one case,” the court must examine the merits because “this really is a valid and infringed patent.”<sup>157</sup>

A court deciding a single case might find it difficult to repel such entreaties. But by recognizing, as discussed below,<sup>158</sup> that the generic would not be able to receive consideration such as a poison-pill clause or no-authorized-generic pledge even by proving in district court that the patent is invalid or not infringed, the test makes clear that the consideration cannot be justified by even a valid and infringed patent. And that means that the court does not need to determine if the patent is valid and infringed.

Third, the approach depicts a scenario reflecting the concern (though from the opposite direction) revealed in the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*.<sup>159</sup> In that case, the court found a settlement to be per se illegal in part because the brand blocked competition not only on the patented product at issue but also on other generic versions not implicated in the litigation.<sup>160</sup>

The test presented here offers the mirror image of *Cardizem*. In that case, the brand sought to obtain something other than what it was entitled to based on the patent itself. Here, the generic is receiving a type of consideration that would not have been available through a patent victory in district court. Just like it is not controversial that the brand's conduct in *Cardizem* violated the antitrust laws, so should it not be contentious to find an antitrust violation when the generic obtains a type of consideration that would not have been available as a result of a patent victory.

Fourth, the test focuses on the economic substance of the transaction,

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<sup>157</sup> See Sumanth Addanki & Henry N. Butler, *Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements*, at 10, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2326604](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2326604) (“One essential element of the rule of reason inquiry is to evaluate, at least to a first approximation, the likelihood of success in the patent infringement suit.”); Bigelow, *supra* note 143, at 9 (stating that it would be “unfortunate” if lower courts were “not to consider the patent's validity” because “a comparison between the negotiated entry date and the expected entry date arising from litigation is the economic determinant of whether the settlement is pro- or anti-competitive”).

<sup>158</sup> See *infra* notes 184-209 (poison-pill clause), 210-234 (no-authorized-generic agreement) and accompanying text.

<sup>159</sup> 332 F.3d 896 (6th Cir. 2003).

<sup>160</sup> *Id.* at 908 n.13.

not its form. Along those lines, some parties have contended that the *Actavis* decision was limited to cash payments. For example, in one recent case, GlaxoSmithKline asserted that the *Actavis* Court “repeatedly tied its concerns about anticompetitive effects to substantial cash payments”<sup>161</sup>; that “[e]xtending [the Court’s] holding beyond settlements involving cash payments to other forms of ‘consideration’ would undermine” the Court’s ruling<sup>162</sup>; and that “[t]he Court’s focus on cash payments has no application” to a settlement involving a brand’s no-authorized-generic pledge, which “entail[s] no payment whatsoever.”<sup>163</sup>

Even more concerning, in *In re Lamictal Direct Purchaser Antitrust Litigation*,<sup>164</sup> a district court adopted such a formalistic analysis, restricting *Actavis* to cash payments. The court believed that “nothing in *Actavis* says that a settlement agreement contains a reverse payment when it confers substantial financial benefits.”<sup>165</sup> The court also pointed to passages in *Actavis* that focused on the “exchange of money”<sup>166</sup>; found that support for a reading of payment beyond cash was “thin”<sup>167</sup>; and stated that “[b]oth the majority and the dissenting opinions reek with discussion of payment of money.”<sup>168</sup> Mirroring Judge Posner’s point raised above,<sup>169</sup> the *Lamictal* court stated that the generic’s receipt of consideration through settlement was not exceptional since, otherwise, “there would be no incentive to settle.”<sup>170</sup> In fact, “there is ‘payment’ in every settlement.”<sup>171</sup>

But in contrast to this cramped interpretation, the Supreme Court has consistently required antitrust analysis to “be based upon demonstrable economic effect rather than . . . upon formalistic line drawing.”<sup>172</sup> Similarly, the Court has explained that “formalistic distinctions” are “generally disfavored in antitrust law.”<sup>173</sup> A focus on the substance of a generic obtaining more—in whatever form—through settlement than litigation is consistent with this instruction.

Fifth, the test provides a simple framework to efficiently dispense with

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<sup>161</sup> GSK’s Memorandum of Law Regarding the Applicability of *FTC v. Actavis, In re Wellbutrin XL Antitrust Litigation*, Case No. 2:08-cv-2431-MAM, at 6 (E.D. Pa. Aug. 5, 2013).

<sup>162</sup> *Id.* at 13.

<sup>163</sup> *Id.* at 8.

<sup>164</sup> 2014 WL 282755 (D.N.J. Jan. 24, 2014).

<sup>165</sup> *Id.* at \*7.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at \*8.

<sup>168</sup> *Id.* at \*7.

<sup>169</sup> See *supra* notes 112-113 and accompanying text.

<sup>170</sup> 2014 WL 282755, at \*8.

<sup>171</sup> *Id.*

<sup>172</sup> *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 58-59 (1977).

<sup>173</sup> *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992).

the (now) easy cases, which make up a significant number of the total number of settlements today. Some of the cases, in particular those in which the brand forgives damages where generics have entered the market, will call for a more nuanced analysis. But the test provides an easy way to carve out a significant subset of settlements and apply a predictable, straightforward analysis. The next Part applies the test to four typical situations.

## V. APPLICATIONS

The variety of arrangements by which brands have conveyed value to generics in recent years has burgeoned. This Part examines four of the most common scenarios involving brand consideration to the generic. The first involves a cash payment from brand to generic. Second is a “poison pill” clause that ensures that a settling generic can accelerate its entry date when a later-filing generic enters the market. Third, a brand could promise not to introduce its own generic version during the first-filing generic’s exclusivity period. Fourth, the brand could forgive damages that a generic potentially would accrue upon entering the market before a court found that the patent was invalid or not infringed.

### A. Case 1: Cash

The first setting involves a cash payment from a brand to a generic. This activity, which occurred in the early generation of settlements in the late 1990s, involved the brand paying cash to the generic to delay entering the market. A few examples are instructive.

In *In re Cardizem CD Antitrust Litigation*,<sup>174</sup> the parties entered into an interim settlement by which the brand promised to pay the generic \$40 million per year not to enter the market until it obtained a favorable, unappealable determination that the patent was not infringed.<sup>175</sup> When the FDA approved the drug, the brand and generic terminated their interim agreement and settled the case, with the brand paying a final sum of \$50 million, for total payments of \$90 million.<sup>176</sup>

Similarly, in *In re Tamoxifen Citrate Antitrust Litigation*,<sup>177</sup> the brand paid the generic \$21 million for the generic to switch from a Paragraph IV

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<sup>174</sup> 332 F.3d 896 (6th Cir. 2003).

<sup>175</sup> The amount would increase to \$100 million per year if a court made a final determination that the patent was not infringed, the brand dismissed the infringement case, or the brand failed to refile the case after a court issued a final decision that did not determine issues of validity, enforcement, or infringement. *Id.* at 902-03. Figures in the text are sometimes rounded for ease of exposition.

<sup>176</sup> *Id.* at 903.

<sup>177</sup> 466 F.3d 187 (2d Cir. 2006).

to a Paragraph III certification (ensuring that it would not enter the market until the patent expired).<sup>178</sup> In addition, the brand agreed to pay the generic's supplier more than \$45 million.<sup>179</sup>

Finally, in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,<sup>180</sup> the brand paid \$398 million for the generic to convert from a Paragraph IV to a Paragraph III certification and to affirm the patent's validity and enforceability and admit infringement.<sup>181</sup>

These three cases present clear examples of exclusion payments for delayed generic entry. In each case, the generic received a type of consideration that would not have been available as a result of a district court victory. Under no conceivable scenario would a generic that has not entered the market and that is challenging a brand's patent or claiming that its product does not infringe obtain a victory that takes the form of a court finding that the patent is invalid or not infringed accompanied by *the brand's conveyance of money*. Under the best-case scenario, the generic would obtain a court ruling that the patent was invalid or not infringed and then (assuming the absence of FDA-regulatory bars<sup>182</sup>) enter the market.<sup>183</sup> In no case would the brand supplement the generic's entry into the market by paying it money.

#### B. Case 2: Poison Pills

The second case involves what is known as "poison pill" or acceleration clauses. These promises ensure that a generic that has settled with the brand can expedite its entry when another generic enters the market at an earlier time. The provisions are "typical" in settlements,<sup>184</sup> with one observer testifying that they are "a standard component of every settlement today."<sup>185</sup>

A representative poison-pill clause provides that the settling generic "agrees not to market a generic version of the patented drug until a specific date," but "may immediately market such a version, and still reap the benefit of its 180-day period of generic market exclusivity, if another

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<sup>178</sup> *Id.* at 193-94.

<sup>179</sup> *Id.* at 194.

<sup>180</sup> 544 F.3d 1323 (Fed. Cir. 2008).

<sup>181</sup> *Id.* at 1328-29 & n.5.

<sup>182</sup> One FDA exclusivity bar is the "30-month stay" that a brand can obtain by suing a generic within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii). Another is the four-year period (five years outside the setting of Paragraph IV certifications) for companies offering drugs with new active ingredients. 21 U.S.C. § 355(j)(5)(F)(ii). A third is the three-year period for new clinical investigations essential to approval. 21 U.S.C. § 355(c)(3)(E)(iii).

<sup>183</sup> See *supra* notes 119-124 and accompanying text.

<sup>184</sup> Brief for the Petitioner at 52, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416).

<sup>185</sup> Sherman testimony, *supra* note 37, at 11.

generic company is successful in challenging the drug's patent.”<sup>186</sup>

For example, in challenging the settlement involving Takeda's diabetes-treating Actos, the plaintiffs alleged that “the acceleration clauses . . . provided that, in the event that any [] manufacturer managed to enter the market with a generic . . . before [the agreed-upon entry date,] . . . the licensed date for [the three settling generics] would be accelerated to that earlier date.”<sup>187</sup> The acceleration clauses “thus ensured that no other generic manufacturer, no matter how much time and resources it spent in its litigation . . . , and no matter how successful the generic manufacturer was in that litigation, could enter the market before [the three settling generics.]”<sup>188</sup>

The complaint in the *Actos* case alleged that “[t]he purpose and effect of the acceleration clauses was to dramatically reduce—essentially eliminate—[the later filer's] incentive to try to enter the market before [the three settling generics.]”<sup>189</sup> In fact, “[a]bsent the acceleration clauses, [the later filer] had a significant possibility of entering the market with generic ACTOS . . . enjoying a substantial period with the only generic ACTOS product on the market.”<sup>190</sup>

Under the Medicare Amendments of 2003, a later-filing generic can enter upon the later of (1) 75 days after FDA approval and (2) 75 days after an appellate court decision finding that the patent is invalid or not infringed.<sup>191</sup> In many cases, even if this late filer waits out the 180-day period (which the settling generic cannot take advantage of because of its entry-delaying settlement), it still will enter the market before the settling first-filer can enter. The reason is that if the brand and first-filing generic agree that the generic will enter years in the future, that date binds the first filer, who cannot market its product at the earlier time the successful later-filing generic enters.

And that is why poison-pill clauses are so powerful. For they allow a settling first filer to accelerate its entry upon a later filer's victory, giving itself 180 days of exclusivity. This offers the settling generic significant

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<sup>186</sup> Brief of Apotex, Inc. as Amicus Curiae Supporting Petitioner at 6, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416).

<sup>187</sup> Complaint, *United Food & Commercial Workers Local 1776 v. Takeda*, No. 1:13-cv-09244-RA, ¶ 138 (S.D.N.Y. Dec. 31, 2013) [*Actos* complaint].

<sup>188</sup> *Id.*

<sup>189</sup> *Id.* ¶ 139.

<sup>190</sup> *Id.* See also Cephalon complaint, *supra* note 34, ¶ 99 (alleging “most favored nation” clause that “allowed for accelerated entry by the [settling generics] in the event that another generic company entered the market,” and explaining that the “effect of that clause was to make it less attractive for each successive generic company to continue to litigate or enter at risk because that clause would automatically permit each generic company that had settled to compete without any risk with any non-settling generic company”).

<sup>191</sup> 21 U.S.C. §355(j)(5)(D)(i).



benefits within and after<sup>192</sup> the period and reduces incentives for later filers to pursue litigation challenging the brand's patent.<sup>193</sup>

Poison-pill clauses are important to settling generics because of the unique significance of the exclusivity period. Under the Hatch-Waxman Act, the first generic to file a Paragraph IV certification asserting that the patent is invalid or not infringed enjoys a 180-day exclusivity period that begins when the generic commercially markets the drug.<sup>194</sup>

As the Court in *Actavis* explained, this period “can prove valuable” and could be “worth several hundred million dollars.”<sup>195</sup> Indeed, the Generic Pharmaceutical Association has stated that “[t]he vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.”<sup>196</sup> And other commentators have explained that “most generic drug companies estimate that 60% to 80% of their potential profit . . . is made during th[e] exclusivity period.”<sup>197</sup>

The reason this period is important is that drug prices decrease as the number of generics on the market increases. An FDA analysis showed that the first generic entrant prices its product, on average, only 6% lower than the brand drug.<sup>198</sup> The presence of a second generic lowers the price to approximately half the brand price.<sup>199</sup> In markets in which six or more generics enter, the price falls to a quarter of the brand price.<sup>200</sup>

A generic that settles with a brand by agreeing to delay entry (and its 180 days of exclusivity) takes the chance that it will not be able to take advantage of this valuable exclusivity period.

<sup>192</sup> See *infra* notes 225 and 228 and accompanying text.

<sup>193</sup> Sherman testimony, *supra* note 37, at 11 (explaining that poison pill clauses “empower first filers to accept later entry dates” and to “retain exclusivity no matter how long the period of delay it agrees to is”).

<sup>194</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

<sup>195</sup> 133 S. Ct. at 2229 (citation omitted); see *id.* at 2235 (citation omitted) (“[T]he special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product . . . can be worth several hundred million dollars.”).

<sup>196</sup> Generic Pharmaceutical Association letter to Federal Trade Commission, June 27, 2006, at 2, <http://www.ftc.gov/os/comments/genericdrugstudy3/062806gpha.pdf>.

<sup>197</sup> Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who's on First*, 25 BIOTECHNOLOGY L. REP. 525, 525-26 (2006). See generally C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 953 (2011) (noting that “[f]or many drugs, the exclusivity period offers the majority of the profits available to the generic firm,” and that once other generics enter, “the falloff in sales can be extreme”).

<sup>198</sup> FDA, *Generic Competition and Drug Prices*, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> 1 (2010).

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*

Several scenarios demonstrate how poison-pill clauses allow settling generics to receive consideration they could not have obtained through a district court victory finding the patent invalid or not infringed. First, the settling first-filing generic is able to use a later filer as a surrogate allowing it the benefit of earlier entry if the later filer wins litigation without taking the risk that it will lose its own patent litigation.

If the settling generic were to lose litigation challenging the brand's patent, FDA regulations would require that it withdraw its Paragraph IV certification and substitute a Paragraph III certification, promising not to enter the market until the patent expires.<sup>201</sup> The lack of a Paragraph IV certification would ensure that the generic loses exclusivity before the end of the patent term.<sup>202</sup> Nor, pursuant to a Paragraph III certification, would the generic be able to obtain exclusivity when the patent expires.<sup>203</sup>

The settling first-filing generic avoids this scenario through a poison-pill clause, which allows it to have the best of both worlds, drafting the later-filing, litigating generic as its risk-free surrogate ensuring its exclusivity. If the surrogate *loses*, the settling generic still can exploit its 180-day period, which is delayed under the settlement. And if the surrogate *wins*, the settling generic can show up on the scene after the hard work has been done, claiming the 180-day period that the Hatch-Waxman Act reserves for first filers and that is triggered by the success of the litigating generic.<sup>204</sup> The poison pill thus gives the settling first filer more than it could have gained by litigating, giving it the exclusivity it could attain by winning the patent case while protecting it from one of the principal risks of losing: the risk that a second filer would enter before it.

Second, and relatedly, the settling generic reduces later-filing generics' incentives to continue litigation challenging the brand's patent, thereby increasing the likelihood of enjoying the 180-day exclusivity period. Later filers cannot take advantage of the valuable 180-day period possessed by

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<sup>201</sup> 21 C.F.R. § 314.94(a)(12)(viii)(A) (2012) (finding that Paragraph IV certification is not maintained "if a final judgment in the action against the applicant is entered finding the patent to be infringed"); 64 Fed. Reg. 42,873, 42,877 (Aug. 6, 1999) (explaining that if first filer is sued and loses patent litigation, applicant must "change its certification from a paragraph IV to a paragraph III" and thus would "lose any claim to exclusivity eligibility").

<sup>202</sup> DONALD O. BEERS & KURT R. KARST, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS* § 4.02[H], at 4-59 n.252 (8th ed. 2012).

<sup>203</sup> 21 U.S.C. § 355(j)(5)(D)(i)(VI) (describing forfeiture event where "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired"); 64 Fed. Reg. at 42,877; *see generally* BEERS & KARST, *supra* note 202, § 4.02[H], at 4-66 & n.281. The regulations explain that "[n]othing in the statute or the regulations supports an award of exclusivity to an ANDA applicant that loses its lawsuit." 64 Fed. Reg. at 42,877. In fact, "such an award would run counter to the statutory goal of promoting earlier entry of generic drug products into the market." *Id.*

<sup>204</sup> 21 U.S.C. § 355(j)(5)(B)(iv)(I).

the settling generic. Absent the poison-pill clause, later filers could start the running of the first-filer's exclusivity by winning litigation. And even after waiting for the 180-day period to run, the litigating generic still could enter the market long before the settling generic, which typically has entered into a binding settlement not to enter the market for years.

The third example involves a later filer that is able to enter the market before a settling first filer that forfeits exclusivity. One means of forfeiture involves a later filer's successful litigation, as the settling generic forfeits exclusivity if it does not enter the market within 75 days of an appellate court's ruling that the patent is invalid or not infringed.<sup>205</sup> And there are several other ways in which forfeiture could occur, including the failure to obtain tentative approval from the FDA within 30 months, an amendment of the Paragraph IV certification, and a withdrawal of the application.<sup>206</sup> In each of these cases, the settling generic could not obtain protection against forfeiture through a district court finding that the patent is invalid or not infringed.

The fourth setting involves the generic's ability to accelerate its entry against later filers not subject to the 180-day exclusivity period. Some later filers do not file Paragraph IV certifications, but file what are known as "section viii" statements, seeking approval for a use not covered by the brand's patent.<sup>207</sup> In such a case, the generic "carves out" uses from its labeling that are covered by the brand's patents and seeks a label covering only the unpatented uses.<sup>208</sup> Absent a poison-pill clause, a later generic filing a section viii statement could enter before the settling generic enters years in the future. A poison-pill clause gives the settling generic an ability to delay entry by section viii filers by obtaining rights not available through a patent victory.

Finally, poison-pill clauses are often accompanied by "no-license" clauses by which the brand agrees not to grant a license to any other generic to enter within 180 days of the first-filer's entry. For example, in the Actos settlement, the plaintiffs alleged that the brand agreed that "it would not grant any other manufacturer a license to enter the market with generic ACTOS until 180 days after [the three first-filing generics] entered."<sup>209</sup> Yet again, the first filer cannot obtain such a guarantee by winning patent litigation.

In short, poison-pill clauses provide a type of consideration that the generic could never obtain as a result of winning a district court ruling that

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<sup>205</sup> 21 U.S.C. § 355(j)(5)(D)(i)(I).

<sup>206</sup> 21 U.S.C. § 355(j)(5)(D)(i)(II, III, IV).

<sup>207</sup> 21 U.S.C. § 355(j)(2)(A)(viii).

<sup>208</sup> 21 C.F.R. § 314.94(a)(8)(iv); 21 C.F.R. § 314.127(a)(7).

<sup>209</sup> Actos Complaint, *supra* note 187, ¶ 103.

the patent is invalid or not infringed. Such provisions allow settling generics to enjoy exclusivity even after agreeing to late entry dates that occur long after a subsequent generic wins in litigation. In no case could the generic that won a district court patent victory obtain a guarantee that it could accelerate its entry from a late agreed-upon entry date. In short, poison-pill clauses constitute exclusion payments.

### C. Case 3: No-Authorized-Generic Provision

As discussed above, the 180-day exclusivity period is uniquely valuable to the first-filing generic, potentially worth hundreds of millions of dollars.<sup>210</sup> But even though this period is designed to encourage generic entry, the brand is free to introduce its own generic version during the period.<sup>211</sup> This version, known as an “authorized generic,” is approved by the FDA as a brand drug but marketed as a generic.<sup>212</sup> Although the authorized generic is chemically identical to the brand drug, the brand firm lowers the price to sell it in the generics sector of the market.

Courts that have analyzed the question have uniformly found that the 180-day period does not prevent the brand from entering with its own authorized generic. For example, in *Mylan Pharmaceuticals v. Food and Drug Administration*,<sup>213</sup> the Northern District for Western Virginia court held that “the plain and unambiguous language” of the Hatch-Waxman Act “does not prohibit the holder of an approved [New Drug Application] from marketing an ‘authorized generic’ during the 180-day exclusivity period given to a paragraph IV ANDA holder.”<sup>214</sup> And in *Teva Pharmaceutical Industries v. Crawford*,<sup>215</sup> the D.C. Circuit concluded that the Act “clearly does not prohibit the holder of an approved [New Drug Application] from marketing, during the 180-day exclusivity period, its own ‘brand-generic’ version of its drug.”<sup>216</sup>

One increasingly popular form of settlements today involves a promise by the brand that it will not launch an authorized generic that would compete with the first-filing generic during the exclusivity period. The FTC found that of 39 agreements involving a no-authorized-generic promise and delayed entry between 2004 and 2010, 15 took place in 2010.<sup>217</sup>

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<sup>210</sup> See *supra* notes 195-200 and accompanying text.

<sup>211</sup> See *Mylan Pharmaceuticals, Inc. v. U.S. Food and Drug Admin.*, 454 F.3d 270, 275-76 (4th Cir. 2006); *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

<sup>212</sup> FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT i (2011) [hereinafter FTC, AUTHORIZED GENERIC REPORT].

<sup>213</sup> 2005 WL 2411674 (N.D. W. Va. Sept. 29, 2005).

<sup>214</sup> *Id.* at \*7.

<sup>215</sup> 410 F.3d 51 (D.C. Cir. 2005).

<sup>216</sup> *Id.* at 55.

<sup>217</sup> *Id.* at 145.

In its most recent survey, the FTC concluded that 19 of 40 potential reverse-payment settlements reported in 2012 involved no-authorized-generic provisions.<sup>218</sup> This was a “record number” that was “significantly greater” than that in previous years.<sup>219</sup> Not only are settlements with no-authorized-generic clauses increasingly common, but they also have occurred for some of the most popular drugs, including attention-deficit-hyperactivity-disorder (ADHD) drug Adderall, antidepressant Effexor, reflux drug Nexium, and clot-preventing Plavix.<sup>220</sup>

Competition from an authorized generic has a significant adverse impact on the first-filing generic’s sales and profits.<sup>221</sup> A comprehensive FTC study on authorized generics concluded that the first-filing generic loses 25% of its market share when it competes with an authorized generic during the exclusivity period.<sup>222</sup> In addition, the first-filer’s revenues are approximately twice as high when it enjoys the period without the authorized generic.<sup>223</sup> These effects result from “increased pricing pressure” from authorized generics as well as reduced quantities.<sup>224</sup> Even after the exclusivity period, the effects continue, with revenues of the first-filing generic 53 to 62% lower in the 30 months following exclusivity.<sup>225</sup> For these reasons, a brand’s promise not to introduce an authorized generic during the 180-day exclusivity period is valuable to the first-filing generic.

At the same time, brands that launch an authorized generic during the 180-day exclusivity period increase their own profits by 6 to 21%.<sup>226</sup> Brands recognize that authorized generics “can generate incremental revenue when a branded product loses exclusivity.”<sup>227</sup> And even after the end of the 180-day period, the brand continues to benefit.<sup>228</sup> As one commentator put it: “[B]ecause the brand company has usually recovered its costs many times over, additional sales are simply added to the profit.”<sup>229</sup>

Courts have recently split on the issue of whether a no-authorized-generic promise could be considered a payment that potentially violates the

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<sup>218</sup> FTC, FY 2012 AGREEMENTS, *supra* note 43, at 1.

<sup>219</sup> *Id.* at 2.

<sup>220</sup> Hemphill, *An Aggregate Approach to Antitrust*, *supra* note 78, at 684 n.230 (describing agreements).

<sup>221</sup> This and the next two paragraphs are adapted from Brief Amici Curiae of the American Antitrust Institute and Consumers Union, In re Wellbutrin WL Antitrust Litigation, Case No. 2:08-cv-2431, 2:08-cv-2433 (E.D. Pa. Sept. 26, 2013).

<sup>222</sup> FTC, AUTHORIZED GENERIC REPORT, *supra* note 212, at 57.

<sup>223</sup> *Id.* at 58-59.

<sup>224</sup> *Id.* at 59.

<sup>225</sup> *Id.* at iii.

<sup>226</sup> *Id.* at 62.

<sup>227</sup> *Id.* at 68.

<sup>228</sup> *Id.* at 93.

<sup>229</sup> UPADHYE, *supra* note 124, § 13.12, at 549.

antitrust laws. In *In re Nexium Antitrust Litigation*,<sup>230</sup> the Massachusetts district court denied the defendants' motion to dismiss challenging a settlement containing a no-authorized-generic clause, explaining that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment."<sup>231</sup> Instead, the court correctly recognized that "[a]dopting a broader interpretation of the word 'payment' . . . serves the purpose of aligning the law with modern-day realities."<sup>232</sup>

In contrast, in *In re Lamictal Direct Purchaser Antitrust Litigation*,<sup>233</sup> the New Jersey district court found that "nothing in *Actavis*" revealed that "a no-[authorized-generic] agreement is a 'payment.'"<sup>234</sup> The court stated "[t]hat [the settling generic] was allowed early entry, that there was no payment of money and that the duration of the No-[authorized-generic] Agreement was relatively brief," leading it to conclude that "the settlement was reasonable and not of the sort that requires *Actavis* scrutiny."<sup>235</sup>

A brand's promise not to introduce an authorized generic provides a type of consideration that would not be available as a consequence of winning a district court ruling that the patent was invalid or not infringed. The courts have been clear that a brand is able to introduce its authorized generic during the first filer's 180-day period. Generics—even those that win patent litigation—cannot prevent this. A no-authorized-generic promise thus provides a clear bestowal of consideration on the generic that never would have been available as a result of a district court patent victory. In short, a no-authorized-generic promise for delayed generic entry constitutes an exclusion payment.

#### D. Case 4: Brand Forgiveness of Damages

The first three scenarios in this Part involved generics that did not enter the market. The Hatch-Waxman Act treats the filing of a Paragraph IV certification as an act of infringement, which allows a brand to file suit before the generic enters the market and begins selling the product.<sup>236</sup> And in fact, in most cases, the generic has not entered the market during the litigation. But despite the potential liability from entering before a judicial finding of invalidity or noninfringement, some generics have entered the

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<sup>230</sup> 2013 WL 4832176 (D. Mass. Sept. 11, 2013).

<sup>231</sup> *Id.* at \*15.

<sup>232</sup> *Id.*; see also *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at \*26 (D.N.J. Sept. 5, 2013) (concluding that amendment to plaintiff's complaint would not be futile since "nothing in *Actavis* strictly requires that the payment be in the form of money").

<sup>233</sup> 2014 WL 282755 (D.N.J. Jan. 24, 2014).

<sup>234</sup> *Id.* at \*7.

<sup>235</sup> *Id.* at \*9.

<sup>236</sup> 35 U.S.C. §271(e)(2)(A).

market “at risk.” For example, and as discussed above, from 2003 through 2009, there were 28 at-risk launches.<sup>237</sup> In this period, Teva launched at risk 12 times, and Sandoz launched 6 times.<sup>238</sup>

If a court finds that the patent is valid and infringed, generics that enter at risk could be responsible for the brand’s damages.<sup>239</sup> Even though generics sell their products more cheaply than brands, generics liable for infringement could be liable for the higher level of damages evidenced by the brand’s lost profits.<sup>240</sup> To obtain lost profits, the brand would be required to show “a reasonable probability that ‘but for’ the infringing activity, the patentee would have made the infringer’s sales.”<sup>241</sup> This should not be difficult to show since generic sales typically come directly at the expense of brand sales.<sup>242</sup>

In addition to these damages, generics also could be responsible for the reduction in brand drug prices resulting from the introduction of the generic drug.<sup>243</sup> And generics might need to pay a reasonable royalty, which would require a court to consider a hypothetical negotiation between the parties, relying on evidence such as negotiated rates in other licenses.<sup>244</sup> Two examples of liability for launches at risk were presented by Teva and Sun’s \$550 million payment to Pfizer and Takeda for heartburn reliever Protonix, and Apotex’s \$442 million payment to Bristol-Myers Squibb and Sanofi for

<sup>237</sup> See *supra* note 115 and accompanying text.

<sup>238</sup> See *supra* note 116 and accompanying text.

<sup>239</sup> 35 U.S.C. § 271(e)(4)(C) (2010) (“damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product”); 35 U.S.C. § 284 (2012) (“Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.”).

<sup>240</sup> JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 451 (2005).

<sup>241</sup> E.g., *Crystal Semiconductor Corp. v. TriTech Microelectronics Int’l, Inc.*, 246 F.3d 1336, 1353 (Fed. Cir. 2001); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995).

<sup>242</sup> Once a generic enters the market, the brand loses between 45 and 90 percent of its market share within the first twelve months. See CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xiii (July 1998), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf> (44 percent); Doug Long (IMS), *2003 Year in Review: Trends, Issues, Forecasts*, at 35 (2004) (on file with author) (50-90 percent within 13 weeks); Atanu Saha et al., *Generic Competition in the U.S. Pharmaceutical Industry*, 13 INT. J. ECON. BUS. 15, 31 (2006) (55 percent within first year).

<sup>243</sup> *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1378 (Fed. Cir. 2003) (upholding damages award for lost profits attributable to price erosion); see generally THOMAS, *supra* note 240, at 452.

<sup>244</sup> E.g., *Mitutoyo Copr. v. Central Purchasing, LLC*, 499 F.3d 1284, 1292 (Fed. Cir. 2007); see generally UPADHYE, *supra* note 124, § 16.12, at 609-10. See also UPADHYE, *id.* § 16.14, at 613-14 (listing factors that court could consider).

anticoagulant drug Plavix.<sup>245</sup>

In short, generics that enter the market at risk could be liable for significant amounts of damages. And in this scenario, the brand could settle by agreeing to forgive some of these damages. For example, if the generic faced a total liability of \$100 million, the brand could forgive \$40 million, resulting in a payment from the generic to the brand of \$60 million. This settlement falls within the range of potential expected litigation outcomes. If the brand wins, it would be entitled to \$100 million in damages. If it loses, it would be entitled to zero. A \$40 million “payment” from the brand to the generic falls comfortably within this range.

This presents a difficult case. Because the payment falls within the range of potential litigated outcomes, it is possible that exclusion comes from the patent. In this case, the court typically<sup>246</sup> cannot determine the appropriate antitrust analysis based on the existence of the payment alone.

The court thus may need to look at more than just the payment. It might be compelled to evaluate the strength of the patent. In certain cases, such as where the issue is patent validity, this could be difficult. Along these lines, the Eleventh Circuit in the *Actavis* case was not willing to “decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment.”<sup>247</sup> For “if we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task.”<sup>248</sup>

In this scenario, courts may need to wade into these issues. Some infringement issues might not be excessively complicated. Where the patent is secondary in nature, it generally will be easier for a generic to invent around it. For example, a court found that Cephalon failed to demonstrate infringement when the generic, in creating a pharmaceutical composition to treat wakefulness disorders, used particles of a certain size.<sup>249</sup> Similarly, the plaintiffs in *Actavis* alleged that the generics could not have infringed the brand’s patent, which covered a testosterone gel that (mistakenly) contained 1 percent sodium hydroxide that would burn the patient’s skin since their

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<sup>245</sup> Peter Loftus, *Pfizer, Takeda to Get \$2.15 Billion Settlement*, WALL ST. J., June 12, 2013, <http://online.wsj.com/news/articles/SB10001424127887324188604578541080995659790>.

<sup>246</sup> Other cases involving damages forgiveness could be easier. One scenario could take the form of a brand forgiving damages potentially accrued by multiple generics with shared exclusivity (where more than one generic files a Paragraph IV challenge on the same day), allowing the generics to enter one at a time for a defined period and then exit.

<sup>247</sup> *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012).

<sup>248</sup> *Id.* “Turducken” is a combination of turkey, duck, and chicken. *Turducken*, WIKIPEDIA, <http://en.wikipedia.org/wiki/Turducken>.

<sup>249</sup> *Apotex, Inc. v. Cephalon, Inc.*, 2012 WL 1080148, at \*\*1, 16 (E.D. Pa., Mar. 28, 2012).



product was 50 to 250 times less powerful.<sup>250</sup>

Also, some determinations will call for other non-validity inquiries such as application of the “on sale” bar (by which the product is offered for sale more than one year before the application date<sup>251</sup>) or inequitable conduct (which covers a material misrepresentation or omission the applicant makes to the Patent Office with an intent to deceive).<sup>252</sup>

Finally, the type of patent at issue could be instructive as well. Empirical research has found that 89 percent of patents in settled litigation are secondary patents covering ancillary aspects of drug innovation (such as formulation or composition) rather than the active ingredient.<sup>253</sup> The brand firm is far less likely to win on these secondary patents (32%) than it is on active ingredient patents (92%).<sup>254</sup>

To be clear, the *Actavis* Court appropriately explained that ordinarily the court need not “conduct a detailed exploration of the validity of the patent itself.”<sup>255</sup> And the vast majority of the cases do not involve generic entry at risk. But where a brand forgives damages for an at-risk generic, it is a lot less clear that the payment is “unexplained.”<sup>256</sup> The conduct could instead represent a reasonable forgiveness of damages.<sup>257</sup> A more complex analysis is called for since a brand’s forgiveness of damages could fall within the range of potential litigation outcomes.

The relevant analysis could compare the amount forgiven as a percentage of potential damages to the likelihood that the patent was invalid or not infringed. In general, the stronger the patent is, the smaller is the

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<sup>250</sup> *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1380 (N.D. Ga., 2010).

<sup>251</sup> 35 U.S.C. § 102(b); *see, e.g.*, *Apotex Inc. v. Cephalon*, 2011 WL 6090696, at \*\*14-17 (E.D. Pa., Nov. 7, 2011) (finding commercial offer for sale and that invention was ready for patenting more than one year before patent application).

<sup>252</sup> *American Calcar, Inc. v. American Honda Motor Co.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011); *Apotex*, 2011 WL 6090696 at \*\*25-28 (finding that, with intent to deceive, Cephalon failed to disclose prior art, which resulted in Patent Office issuing patent).

<sup>253</sup> C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386 (2013) (examining completed patent litigation on drugs first eligible for challenges between 2000 and 2008).

<sup>254</sup> *Id.* at 1387.

<sup>255</sup> *FTC v. Actavis*, 133 S. Ct. 2223, 2236-37 (2013). The test still effectuates the *Actavis* Court’s instruction to not normally examine the patent merits since the number of cases in which the generic has entered at risk (and thus has damages that can be forgiven) is a small subset of the total number of settlements involving payment for delayed entry. *See supra* notes 115 and 116 and accompanying text.

<sup>256</sup> *Id.*

<sup>257</sup> The *Actavis* Court was not concerned with a damages-forgiveness settlement outside the antitrust setting (where infringers typically have entered the market), but (in focusing on “reverse payment settlements [in which] a party with no claim for damages . . . walks away with money”) did not consider the case of forgiveness of damages incurred by at-risk generics. *Id.* at 2233.

amount of damages the brand would be able to forgive (since it would be more likely to win the litigation and the generic would be more likely to be responsible for the full amount of damages). Such an analysis typically would require at least a cursory examination of the patent merits as well as potential damages. Although these inquiries are complicated, they are necessary given that it is not immediately apparent if the amount of damages forgiven can be explained by the patent. And given the legitimacy of excluding rivals under the patent, courts should condemn forgiveness only if it is clear that it stems from the payment. But again, limiting these complex inquiries to the setting of damages forgiveness effectuates the *Actavis* Court's instruction to avoid the patent merits whenever possible.<sup>258</sup>

### CONCLUSION

In its landmark *Actavis* decision, the Supreme Court ensured that antitrust courts would carefully scrutinize drug patent settlements for years to come. One of the most pressing issues centers on the type of payment that triggers antitrust scrutiny.

This Article introduces a framework that can guide courts in addressing this question. If the settling parties are able to show that the payment is no larger than future litigation costs, the settlement can be justified.

And if the parties can show that the payment is actually for unrelated generic services rather than delay, such compensation can be justified. A heavy dose of common sense must be applied in this setting, however. Brands and generics almost never enter into side deals outside the settlement context. And brands tend not to need generic assistance in promoting their products or providing manufacturing services. But if the parties nonetheless are able to show that the payment really is for the generic services, then courts should find a justification.

The test then focuses on whether the generic delays entering the market after the brand conveys a type of consideration that would not have been available as a direct consequence of showing that the patent was invalid or not infringed. Most settlements today do not take the "quaint" and simple form of the brand paying cash to the generic. But to the extent they do, such a payment (above litigation costs) to a generic that has not entered the market offers a type of consideration that would not be available through a

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<sup>258</sup> The conclusion on damages forgiveness only applies to damages forgiven in the lawsuit at issue. Given (1) the labyrinthine nature of arrangements that seem to have no purpose other than disguising payment for delayed entry (*see supra* notes 81-111 and accompanying text), (2) the additional layer of complexity introduced by adding a second set of patents and potential damages, and (3) the *Actavis* Court's profound concern with payments, this deferential treatment does not apply where the brand forgives damages potentially accrued by a generic in a separate lawsuit.

district court victory. The same conclusion holds for poison-pill clauses and no-authorized-generic provisions, neither of which is a possible result from a district court finding that a patent is invalid or not infringed.

The exclusion of the generic in these cases thus comes from the transfer of consideration rather than the patent, which results in a finding of an exclusion payment that violates the antitrust laws. In contrast, a brand's forgiveness of accrued damages against a generic that has already entered the market calls for more nuanced analysis since it falls within the range of potential expected litigation outcomes.

With each passing day, brands and generics are settling patent litigation by entering into an array of increasingly complex business arrangements. Any test to ascertain the antitrust liability of such agreements must recognize that all settlements provide something of value to the settling parties. It also must effectuate the *Actavis* Court's instruction to avoid an examination of the patent merits—which the settling parties will forcefully demand—in the vast majority of cases.

The Supreme Court in *Actavis* was clear in its concern that large and unjustified payments had the potential for “significant adverse effects on competition”<sup>259</sup> and were likely to violate the antitrust laws. The test introduced in this Article makes sense of this standard. If a generic delays entry after the brand conveys a type of consideration not available as a consequence of winning the lawsuit, the exclusion cannot be justified by the patent but must result from the payment. Courts need not analyze whether the patent is valid and infringed because the brand would not be able to provide such consideration even if a court were to find that the patent was valid and infringed. In short, the test offers a simple and effective framework that courts can use to determine when a conveyance from a brand to a generic violates the antitrust laws.

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<sup>259</sup> 133 S. Ct. at 2231.