Most-Favored Entry Clauses in Drug-Patent Litigation Settlements: Reverse Payments and Anticompetitive Effects

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Settlements of drug-patent disputes that contain a payment from the brand to the generic signal a possible collusive profit split that threatens competition. Several forms of payment have been identified and studied in the literature in law and economics. A common feature of brand-generic settlements, so-called "most-favored entry" (MFE) clauses, has largely escaped scrutiny as a potential payment. This paper partly remedies this gap by considering the circumstances under which an MFE clause in a drug-patent settlement might constitute a pay to delay generic entry. The key to the analysis, as it is with other forms of brand-to-generic payment, is the inference about the anticompetitive effects that can be drawn from assuming that the inclusion of an MFE clause is a rational decision on the part of the brand. We find that MFE clauses can constitute a reverse payment. A notable feature of MFE clauses is that they may delay generic entry twice: by inducing the settling generic to agree to a later first entry date, and by reducing incentives to later generics to behave competitively. However, when a payment takes the form of an MFE clause, the brand-payment criterion is vulnerable to suggesting that a settlement is not anticompetitive, when in fact it is.

Background

Pharmaceutical spending in the United States is enormous. Purchasers in the U.S. spent $348.4 billion on pharmaceutical products in 2020, equal to nearly half of the total spending on physicians and other clinical services.[1] New patent-protected drugs are introduced at very high prices. Take, for example, Takeda's Exkivity, which treats lung cancer and debuted in 2021 at a cost of approximately $26,355 per month.[2]

In contrast to other high- and middle-income countries where governments regulate or negotiate prices paid to manufacturers, the U.S. depends largely on competition from generic drugs to control prices and spending. Because the production costs of most drugs are low relative to the initial price, when multiple generic firms enter and compete, the price of the drug commonly falls to 10% or less of the price that the brand charged before generic competition. The timing of this shift is thus critically important for healthcare costs and access to medicines, as well as for incentives to invest in research on new products.

Branded drug companies attempt to protect their products from generic competition by listing patents purportedly covering their drugs in the FDA's *Orange Book.* Competition from generics

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[1] *NHE Fact Sheet*, CMS (Dec. 15, 2021), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

[2] Press Release, Takeda, *Takeda's EXKIVITY™ (Mobocertinib) Approved by U.S. FDA as the First Oral Therapy Specifically Designed for Patients with EGFR Exon20 Insertion+ NSCLC* (Sept. 15, 2021), https://www.takeda.com/newsroom/newsreleases/2021/takeda-exkivity-mobocertinib-approved-by-us-fda/; *Exkivity Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/exkivity.

On the surface, MFE clauses would seem to increase competition by accelerating the settling generic's entry in certain circumstances. MFE clauses, however, can disadvantage the economic position of other potential competitors, discourage them from challenging a brand's patents, and therefore adversely affect competition.

sometimes waits until the expiry of patents and any other regulatory exclusivity periods, but not always. With so much money involved, the business model of many generics centers on challenging brand patents to obtain earlier entry.[3] Indeed, nearly 40-year-old federal regulations were specifically designed to enhance generic firms' incentives to do so. As a result, the date of the switch from monopoly to competitive prices often precedes a patent's expiration date and may be determined by a confidential brand-generic patent litigation settlement.

The idea that competitors signing a patent settlement agreement can structure the terms of competition raises obvious red flags—the brand and generic could strike a deal that maximizes their joint profits at the expense of consumers. If the parties agree not to compete for as long as possible, the brand can continue to sell at higher prices.

An agreement extending the brand's time to sell will only appeal to a generic, however, if the brand shares the higher joint profits with the generic. Clauses of brand-generic settlements that may involve a payment from the brand to the generic have undergone intensive scrutiny in law and economics literature.[4] Furthermore, parties to brand-generic settlements must report the agreements' details to the Federal Trade Commission (FTC). The agency challenges some agreements and publicly reports the frequency of potential brand-to-generic payments according to certain criteria.[5]

Brand-generic settlements might also contain so-called "acceleration" or "most-favored entry" (MFE) clauses.[6] Indeed, MFE clauses appear to have become standard in brand-generic settlements.[7] A typical MFE clause might specify that if *another* generic attains an entry date—through litigation or from the brand issuing a license—before the date granted to the settling generic, the settling generic can advance its date of entry to the earlier date, thereby retaining its MFE status.

On the surface, MFE clauses would seem to increase competition by accelerating the settling generic's entry in certain circumstances. MFE clauses, however, can disadvantage the economic position of other potential competitors, discourage them from challenging a brand's patents, and therefore adversely affect competition. In the context of brand-generic patent settlements, these clauses raise the additional concern that they may constitute a payment to the settling generic. If the payment induces the settling generic to agree to a later entry date, the MFE clause harms consumers.[8]

Unlike other forms of potential reverse-payment clauses in brand-generic settlements, MFE clauses have been the subject of little economic research. This paper seeks to remedy that gap. As explained more fully below, we find that MFE clauses in brand-generic settlements may threaten competition in the following ways:

. . . [T]hese clauses raise the additional concern that they may constitute a payment to the settling generic.

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3 In turn, the business model of many brand companies is to create "patent thickets" to inhibit generic competition.

4 *See, e.g.*, Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Texas L. Rev. 283 (2012); Aaron Edlin et al., *Activating* Actavis, Antitrust, Fall 2013; Edlin et al., *The* Actavis *Inference: Theory and Practice*, 67 Rutgers U. L. Rev. 585 (2015) [hereinafter Edlin et al., Actavis *Inference*].

5 Federal Trade Comm'n, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2017: A Report by the Bureau of Competition (Dec. 3, 2020), https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf.

6 Some forms of acceleration clauses are not MFE clauses. For example, one form of acceleration clause advances generic entry if brand sales drop to a certain level. *See* FTC, *supra* note 5, at 4.

7 The CEO of the generic manufacturer Apotex told Congress in 2009 that MFE clauses are "a standard component of every settlement today." Michael A. Carrier, *Payment After* Actavis, 100 Iowa L. Rev. 7, 37 (2014).

8 The CEO of Apotex also told Congress that MFE clauses "empower first filers to accept later entry dates." *Id.* at 38 n.184.

An MFE clause can be a brand-to-generic reverse payment. . . . Brand rationality implies that an MFE clause can delay expected dates of competition twice. In addition to buying delay from the settling generic, entry of third-party generics can also be delayed on expectation.

- An MFE clause can be a brand-to-generic reverse payment. With a chance that an MFE clause could be activated, the MFE clause costs the brand on expectation and creates value for the generic relative to a settlement without the MFE clause.
- Brand rationality implies that an MFE clause can delay expected dates of competition twice. In addition to buying delay from the settling generic, entry of third-party generics can also be delayed on expectation because the clause undermines other generics' incentives to behave competitively.
- An MFE can be anticompetitive but not associated with a payment by the brand above its avoided litigation costs because the payment to the settling generic comes at the expense of third-party generics and consumers. Paradoxically, as an MFE clause becomes more effective at deterring third-party generic entry, the probability that the brand will lose profits associated with activation decreases.

Reverse-Payment Settlements

As laid out in the Hatch-Waxman Act of 1984, to market a generic drug, the potential manufacturer must submit an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration (FDA). The drug may be protected from competition by patents that the brand has listed in the FDA's *Orange Book*, but a generic challenger can assert that the patents are invalid, unenforceable, or not infringed by submitting an ANDA with "Paragraph IV" certification.

By suing the generic for patent infringement within 45 days of receiving notice of its submission, the brand initiates a 30-month period during which it is protected from generic competition unless the brand loses a legal decision. The lawsuit also initiates confidential settlement negotiations between the parties. More than half of patents listed as applying to brand drugs, when challenged, do not hold up in court,[9] and it may be in the interest of both the brand and the generic to compromise on a date of licensed generic entry prior to patent expiry.

Regulators and researchers have called attention to numerous unintended consequences of Hatch-Waxman regulations.[10] The unintended consequence of Hatch Waxman that has attracted the most attention by far is the settlement of Paragraph IV patent litigation that includes (1) a brand-generic agreement on the date of the generic's entry and (2) a brand's payment to the generic. These are known as "reverse-payment" agreements, or more pejoratively, "pay-for-delay" arrangements.[11] A July 9, 2021 Presidential Executive Order on competition refers to these settlements and directs the FTC to attend to "unfair anticompetitive conduct or agreements in the

[9] *See, e.g.*, C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, SCIENCE, March 22, 2013, at 1386.

[10] *See, e.g.*, Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting*, 1 INNOVATION POLICY & ECON. 119 (2001); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012); Kerstin Vokinger et al., *Strategies That Delay Market Entry of Generic Drugs*, 177 JAMA INTERNAL MED., 1665 (2017); Matthew J. Higgins & Stuart J.H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, SCIENCE, October 16, 2009; Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491 (2007).

[11] *See* Elhauge & Krueger, *supra note* 4; Edlin et al., *Activating* Actavis, supra note 4; Edlin et al., Actavis *Inference*, *supra* note 4; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009); *see also* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).

prescription drug industries, such as agreements to delay the market entry of generic drugs or biosimilars."[12]

Reverse-payment agreements can have pronounced anticompetitive effects. The first generic to submit a substantially complete Paragraph IV ANDA—called the first filer or first-to-file—is eligible for a 180-day exclusivity period during which the FDA will not approve other ANDAs. By delaying the entry of the first ANDA filer with 180-day exclusivity, a reverse-payment agreement delays all *other* generic competitors as well. This is because the other generic competitors cannot obtain final FDA approval, and therefore begin selling, until the first filer's 180-day exclusivity has expired or been forfeited.

Scholars in law and economics propose a test to determine whether a reverse payment is anticompetitive. The condition of brand rationality implies that if the reverse payment exceeds the brand's anticipated costs of continued Paragraph IV litigation and the value of any other consideration received, the brand is buying a delay in generic entry. This inference has become the principal form of evidence for evaluating whether a brand-generic Paragraph IV settlement is anticompetitive.[13]

We formally state the implications of brand rationality in the simple one brand-one generic case as a prelude to the application of brand rationality to brand-generic settlements with MFE clauses.

A brand's expected profits depend on the expected date of generic entry. The later that a generic enters the market, the greater the brand's profits will be. Let t be the date of generic entry, $\pi_b(t)$ be brand profits as a function of t. Let t_{np} be the date of generic entry that the brand expects (through settlement or trial) in the absence of a payment, and let t_p be the agreed-upon date of entry if there is a brand-to-generic payment in connection with a settlement. Let p be the value of a payment from the brand's perspective and c be the brand's anticipated litigation costs in the absence of a settlement.[14] A rational brand elects the settlement with a payment if and only if:

$$\pi_b(t_p) - p > \pi_b(t_{np}) - c \qquad (1)$$

Alternatively,

$$\pi_b(t_p) > \pi_b(t_{np}) + (p - c) \qquad (1')$$

In plain language, a settlement with an otherwise unexplained reverse payment above the brand's anticipated litigation costs implies that the entry date is later than what the brand expected in an agreement without a payment.

Thus, if $p > c$, then $\pi_b(t_p) > \pi_b(t_{np})$. In plain language, a settlement with an otherwise unexplained reverse payment above the brand's anticipated litigation costs implies that the entry date is later than what the brand expected in an agreement without a payment. That is, $t_p > t_{np}$. This delay in competition harms consumers.

The criterion of an otherwise unexplained payment above litigation costs is a sufficient but not a necessary condition to imply that an agreement delays generic entry.[15] In other words, the converse of the rationality condition is *not true*: No payment from the standpoint of the brand *does not* imply that there has been no delay. A brand rationally accepts a settlement with a delay whether it has to pay for it or not.

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[12] Joseph R. Biden, Jr., *Executive Order on Promoting Competition in the American Economy*, White House (July 9, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.

[13] Edlin, Hemphill, Hovenkamp, and Shapiro refer to the logic as the "*Actavis* Inference" because it was adopted in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). Edlin et al., Actavis *Inference*, *supra* note 4, at 587.

[14] This c is at most the costs if litigation continues to conclusion. If an alternative no-payment settlement could be reached, c will be less, perhaps zero. *See* Elhauge & Krueger, *supra* note 4.

[15] Edlin et al., Actavis *Inference*, *supra* note 4, at 620. For discussion of the inference from brand rationality within an error cost framework, see generally Edlin et al., Actavis *and Error Costs: A Reply to Critics*, Antitrust Source, Oct. 2014.

Forms of reverse payments have evolved.[16] In the 1990s, brand manufacturers sometimes simply paid cash to settle Paragraph IV disputes with generic challengers. Cash payments fell out of favor as antitrust authorities and private plaintiffs began to scrutinize these agreements more closely and identify a payment as a red flag. New forms of potential value transfer emerged, such as side deals favorable to the generic and no-authorized generic or "no-AG" clauses, wherein the brand agrees not to sell its own generic product during the first filer's 180-day exclusivity period.

MFE Clauses as a Potential Reverse Payment

MFE clauses are another product of reverse-payment evolution. MFE clauses in brand-generic settlements that set a date for generic entry raise antitrust concerns for two reasons.

First, the clause may constitute a payment to the settling generic to induce the generic to accept a later entry date. When a generic agrees to accept the later entry date, consumers must pay high prices that the brand maintains until the generic's entry.[17]

[I]f the brand's payment exceeds its expected future litigation costs, brand rationality implies that at least one and possibly both of the entry dates of the settling and third-party generics must have been delayed by the payment.

Second, an MFE clause may deter competition from third-party generics. More specifically, the clause might delay the third-party generic's entry into the market, meaning that consumers lose the benefits of competition between generic suppliers.

A Reverse Payment from an MFE Clause Implies Delayed Entry of the Settling Generic and/or Third-Party Generics. This subsection draws the implications of brand rationality when, after settling Paragraph IV patent litigation with one generic, the brand faces later patent challenges from third-party generics.[18] As shown by the mathematical conditions below, if the brand's payment exceeds its expected future litigation costs, brand rationality implies that at least one and possibly both of the entry dates of the settling and third-party generics must have been delayed by the payment.

When the presence of third-party generics is considered, brand profits depend on two dates: (1) the expected date of entry for third-party generics, denoted s, and (2) the expected date of entry for the settling generic, denoted t. Profit for the brand is $\pi_b(t,s)$. The later generics enter (either the settling generic or third-party generics), the greater brand profits will be. As above, t_{np} is the date of generic entry the brand expects (through settlement or trial) in the absence of an MFE clause or other form of payment, and t_p is the agreed-upon date of entry in a settlement with the generic containing an MFE clause. Let s_{np} be the date of third-party generic entry that the brand expects (through settlement or trial) in the absence of a prior settlement with an MFE, and s_p be the expected date of entry for third-party generic entry with a prior agreement with the settling generic that included an MFE. Let p now be the value of the brand's payment embedded in an MFE clause as discussed above. Any change in expected litigation costs with third-party generics is ignored in this analysis.

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[16] *See generally* Hemphill, *An Aggregate Approach, supra* note 11. *See also* FTC, *supra* note 5.

[17] The logic described in this section applies regardless of whether the settling generic or third-party generics were first filers with rights to the 180-day exclusivity period. For example, the settling generic could share exclusivity with the third-party generics or the exclusivity could have been forfeited so none of the generics had a right to it.

[18] In Actavis *Inference,* the authors consider the implications of brand rationality with multiple generic competitors, observing that delaying competition from the first filer also delays additional competition until after 180 days. They make the point that a brand is even more highly motivated to pay for a delay in this context. Edlin et al., Actavis *Inference*, *supra* note 4, at 588-89. Although this paper considered brand rationality in the context of two dates, entry for the first filer and entry for later filers, they were tethered by the 180-day exclusivity, so only one date was subject to negotiation.

An MFE clause is a form of reverse payment when it both imposes a cost on the brand and provides a benefit to the settling generic.

The condition for the brand to prefer the settlement with an MFE for the settling generic is

$$\pi_b(t_p,s_p) - p > \pi_b(t_{np},s_{np}) - c \quad (2)$$

Alternatively,

$$\pi_b(t_p,s_p) > \pi_b(t_{np},s_{np}) + (p - c) \quad (2')$$

As before, the condition $p > c$ is sufficient (not necessary) to establish that $\pi_b(t_p,s_p) > \pi_b(t_{np},s_{np})$. For this to be true, it must be that $t_p > t_{np}$, $s_p > s_{np}$, or both.

How an MFE Clause Can Constitute a Reverse Payment. An MFE clause is a form of reverse payment when it both imposes a cost on the brand and provides a benefit to the settling generic. The MFE clause might be activated, and, in some circumstances, the brand bears a cost upon activation. The expected value of the payment from the brand from an MFE clause is the profit loss from the clause's activation multiplied by the chance of activation. While the MFE clause may never in fact be activated, at the time of the settlement, a rational brand would regard activation as a possibility. An MFE clause clearly benefits the settling generic, allowing it to sell in circumstances it otherwise would not.

It is useful to distinguish two common forms of MFE clauses in brand-generic drug settlements.[19] The first allows the settling generic to accelerate its entry date to the same entry date achieved by a third-party generic (through a settlement of its own or through at-risk entry, for example), and is a form of reverse payment. More competitors can reduce the brand's profits. If the brand plans to sell its own authorized generic in response to the third-party generic entry, presence of an MFE clause means the generic market is divided between more competitors (*e.g.*, three ways instead of two), which decreases the brand's authorized generic profits. Even if the brand were not planning to launch an authorized generic, one more generic competitor could also push down the price of the generic product and pull some sales from the brand's products.

The payment from the brand, calculated as the cost from the clauses' activation multiplied by the chance of activation, may easily exceed the brand's future anticipated litigation costs.

The magnitude of a brand's expected payment can be significant. Our prior empirical research indicates that, in certain circumstances, generic entry occurs before the settling generic's agreed-upon entry date, a circumstance that might trigger an MFE clause. Among 47 cases we identified in which the exclusivity period had been forfeited, generic entry occurred before the first filer's entry date seven times (14.9%). Additionally, among 17 cases in which the exclusivity period was shared, generic entry occurred before the earliest settling first filer's entry date six times (35.3%).[20] The payment from the brand, calculated as the cost from the clauses' activation multiplied by the chance of activation, may easily exceed the brand's future anticipated litigation costs.[21]

The second form of MFE clause allows the settling generic to accelerate its entry to the date of a final, unappealable court decision in a challenge brought by a third-party generic. This form of MFE clause may not represent a payment from the brand's perspective. Without the MFE clause, by regulation, the first filer would forfeit its exclusivity period if it could not launch within 75 days of

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[19] *See* Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, 16 J. COMPETITION L. & ECON. 188 (2020) (finding that these forms of MFE clauses appear in several publicly available settlement agreements).

[20] Drake & McGuire, *supra* note 19, at 194-95.

[21] In some circumstances, the deterrent effects of MFE clauses may protect an identifiable segment of the market for the generic product. For example, suppose a settling generic has forfeited rights to the 180-day exclusivity period. An "MFE+ clause" in the settlement might advance the settling generic's entry to three months before other ANDA-based competition. In this case, it would be feasible for the brand to charge royalties for the period of protected sales created by the MFE+ clause, and if the agreement were not connected to the generic's licensed entry date from the patent litigation settlement, a rational brand would do so. The profit sacrifice by the brand in the form of uncollected royalties is a component of the payment from the brand's perspective.

the final court decision. The MFE clause allows the first filer to launch quickly, retain its exclusivity period, and block the other generics from entering (including the generic that won the litigation) for the 180-day exclusivity period. In this case, the brand typically would *benefit* from the first filer's acceleration because the brand would earn more in profits during the first-filer's 180-day exclusivity period than it would in an open generic market.[22] In other words, activation of this form of MFE clause does not impose a cost on the brand.

Note that while any payment from the brand might be minimal, the payment to the settling generic remains and can be substantial.

As opposed to a payment born by the brand, the second form of MFE clause transfers value to the settling generic at the expense of third-party generics because it bars third-party generics from selling during the first filer's exclusivity period. During this period of prohibition, consumers would pay higher prices for drugs. This form of MFE clause is especially valuable to a first filer that has not forfeited its rights to the 180-day exclusivity period. If the extra expected profits from the MFE clause induce the generic to agree to a later initial entry date, consumers lose twice.

In our empirical research, when a sole first filer had retained its exclusivity period, we found not a single instance of generic entry before the first filer's agreed-upon entry date in settlement.[23] A very low probability of activation of the MFE clause indicates that any expected pay from the brand is minimal. Between typically not constituting a cost to the brand and having a very low likelihood of activation, it is extremely unlikely that the brand's reverse payment from this form of MFE clause would ever exceed the brand's future anticipated litigation costs.

Note that while any payment *from* the brand might be minimal, the payment *to* the settling generic remains and can be substantial. The MFE clause reduces the risk that the settling generic could get beat to market, potentially forfeiting its lucrative 180-day exclusivity period or simply losing out on being in the first wave of generic competition. The payment of an MFE to a first filer with retained exclusivity, even if not made by the brand, may induce the generic to accept delay in entry.

The Vulnerability Of The Brand-Pay-Above-Litigation-Costs Criterion For Identifying An Anticompetitive Settlement. A small (or nonexistent) expected payment from the brand's perspective can misleadingly suggest that a brand-generic agreement is not anticompetitive. When the MFE clause allows a first-filer generic to retain its exclusivity period, the burden of funding a payment to the first filer shifts from the brand to consumers and third-party generics. For this reason, the customary analysis of comparing the brand's profit sacrifice or payment from the clause to its expected future litigation costs would not flag the MFE clause's anticompetitive effects.

A small (or nonexistent) expected payment from the brand's perspective can misleadingly suggest that a brand-generic agreement is not anticompetitive.

Paradoxically, as an MFE clause in a settlement becomes more effective at deterring and delaying entry by third-party generics, the valuation of the brand's reverse payment in the settlement becomes lower while the harm to consumers increases.

MFE Clauses and Evidence of Anticompetitive Effects

The power of MFE clauses to deter competition in two ways makes them particularly important to evaluate as potentially anticompetitive. Our paper calls attention to the vulnerability of assessing whether an MFE clause is anticompetitive based on the magnitude of the brand's reverse payment

[22] Similarly, the authors in Actavis *Inference* recognized that the brand benefits from ensuring that the first filer retains its exclusivity period. Edlin et al., Actavis *Inference*, *supra* note 4, at 623.

[23] Drake & McGuire, *supra* note 19, at 194. This outcome may be rare in part because of the prolonged appeals process. *See, e.g.*, Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 Rutgers L.J. 81, 99 (2009) ("[G]iven the length of the appeals process (with decisions sometimes coming 6, 8, 11, and 13 years after settlement), such a ruling likely would occur so far into the future as to delay competition immeasurably.").

The price of the generic drug can be expected to fall with an additional competitor, a procompetitive benefit that can be assessed based on historical industry data.

associated with activation of the clause. In some circumstances, as we show, activation of the MFE clause may harm consumers *without representing a payment* from the brand. In other circumstances, the clause might be so effective at deterring third-party generic entry that the expected payment from the brand associated with activation *falls below avoided litigation cost* even for a grossly anticompetitive agreement.

One recourse in the face of these vulnerabilities is to consider alternative forms of evidence. For example, the magnitude of the payment received by the settling generic can provide evidence that it has been induced to delay its entry.[24] A generic ending up with expected profits from a settlement far above what it could have expected with a straight win in the patent litigation is evidence that the settlement has induced the generic to delay its entry. An MFE clause's effect on reducing third-party generic profits can also be examined, which may also provide evidence that competition has been harmed.

Notably, because the activation of an MFE clause brings the generic that previously settled to market earlier, the clause will sometimes have procompetitive benefits, at least on expectation.[25] These expected benefits will depend on the probability of activation (which might have been suppressed by the clause) and the value to consumers of advancing the settling generic to compete with one or more other generics that have achieved earlier entry. The price of the generic drug can be expected to fall with an additional competitor, a procompetitive benefit that can be assessed based on historical industry data. An important qualification is if the activation of an MFE clause allows a first filer to retain its exclusivity period, the activation typically reduces generic competition and provides no procompetitive benefits. ●

[24] FTC v. Actavis, Inc., 570 U.S. 136, 154 (2013).

[25] It is also sometimes argued that MFE clauses facilitate settlements and are therefore procompetitive. However, the same argument could be made about any form of reverse payment.