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Keith M. Drake
Thomas McGuire

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Most-Favored Entry Clauses in Drug Patent Litigation Settlements as a Potential Reverse Payment

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ABSTRACT

Settlements of drug patent disputes that involve a potential payment from the brand to the generic signal a possible collusive profit split with a threat to competition, and have undergone intensive scrutiny in the literature on law and economics. A common feature of these brand-generic settlements, so-called "most-favored entry" (MFE) clauses, have not been investigated to the same extent. The expectation that brand drug companies make settlement decisions rationally implies that an otherwise unexplained brand payment above savings from expected future litigation costs derives from a delay in competition achieved by the settlement. This paper applies the condition of brand rationality to settlements with MFE clauses, with the added consideration that an MFE clause may affect two dates: the date of entry for the settling generic and the date of entry of third-party generic challengers. A brand payment from an MFE clause above future expected litigation costs implies delays in at least one and possibly two of these expected dates for competition. We find that MFE clauses can constitute a reverse payment. When a payment takes the form of an MFE clause, the pay-above-saved-litigation-cost criterion is, however, vulnerable to suggesting that a settlement is not anticompetitive, when in fact it is.

Keith M. Drake
Greylock McKinnon Associates
35 S. Main Street
Suite 306
Hanover, NH 03755
kdrake@gma-us.com

Thomas McGuire
Department of Health Care Policy
Harvard Medical School
180 Longwood Avenue
Boston, MA 02115
and NBER
mcguire@hcp.med.harvard.edu

I. Introduction

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. For example, Takeda's Exkivity, treating certain forms of lung cancer, debuted in 2021 at a cost of approximately $6,500 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 in relation to the initial price, when multiple generic firms enter and compete, price commonly falls to 10% or less of the price the brand charged prior to generic competition. The timing of this shift from a single to multiple suppliers is thus critically important for health care costs, access to medicines, as well as for incentives to invest in research on new products.

Brand drug companies list patents in the FDA's *Orange Book* as covering their drugs, which may be eligible for other regulatory exclusivity periods. Competition from generics sometimes waits until the expiry of patents and regulatory exclusivity, but not always. With so much money involved, the business model of many generic manufacturers centers around seeking earlier entry by challenging brand patents.[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 oftentimes precedes expiration dates of asserted patents and may be determined by the outcome of a confidential settlement of patent litigation agreed upon by the brand and the challenging generic.

Reliance on potential competitors to structure the terms of competition raises obvious red flags, the danger being that the brand and generic strike a deal that maximizes their joint profits at the expense of consumers. It is easy to see how joint profits are maximized in this context. If the parties agree not to compete for as long as possible, the brand can continue to sell at higher prices. For an agreement with delayed entry to work for the generic, however, the brand needs to share the higher joint profits with the generic. Clauses of brand-generic patent settlements that

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* Director, Greylock McKinnon Associates. E-mail: kdrake@gma-us.com. We are grateful to Amie Price and Martha Starr for comments on an earlier draft.

† Professor of Health Economics, Department of Health Care Policy, Harvard Medical School, National Bureau of Economic Research, and Greylock McKinnon Associates. Email: mcguire@hcp.med.harvard.edu. McGuire has been an expert witness for class-action plaintiffs in antitrust trials challenging brand-generic patent settlements as being anticompetitive. Drake works at Greylock McKinnon Associates, which has supported McGuire in development of his reports and testimony.

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

[2] *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), *available at* https://www.takeda.com/newsroom/newsreleases/2021/takeda-exkivity-mobocertinib-approved-by-us-fda/. *Exkivity Prices, Coupons and Patient Assistance Programs*, *available at* https://www.drugs.com/price-guide/exkivity.

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

may involve a payment from the brand to the generic, signaling an anticompetitive profit split, have undergone intensive scrutiny in the literature on law and economics.[4] Furthermore, details of brand-generic settlements of patent disputes must be reported to the Federal Trade Commission (FTC). The agency challenges some agreements and reports the frequency of potential brand-to-generic payments according to certain criteria.[5]

In addition to a negotiated date for generic entry, brand-generic settlement agreements may 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 (via a court case or a license from the brand) prior to 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. MFE clauses would seem on the surface to increase competition by accelerating the settling generic's entry in certain circumstances, but like their cousins, "most-favored nation" pricing clauses, MFE clauses may disadvantage the economic position of other potential competitors and adversely affect competition. In the context of brand-generic patent settlements, these clauses raise the additional concern that they may also constitute a payment to the 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, there is little economic research on MFEs. This paper seeks to remedy that gap. We find that MFE clauses in brand-generic patent settlements threaten competition:

- An MFE can be a brand-to-generic reverse payment. With a chance that an MFE clause could be activated, it 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 can delay expected dates of competition twice. In addition to buying delay from the settling generic, by undermining incentives for other generics to behave competitively, entry of third-party generics can also be delayed on expectation; and
- 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

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[4] For example, see Einer Elhauge and Alex Kreuger, *Solving the Patent Settlement Puzzle*, 91 TEXAS L. REV. 283 (2012); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16 (2013); and Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585 (2015).

[5] Federal Trade Commission (FTC), *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*, December 3, 2020.

[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 the FTC Report in *supra* note 5.

[7] The CEO of the generic manufacturer Apotex told Congress in 2009 that MFE clauses are "a standard component of every settlement today." See Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 38 (2014).

[8] The CEO of Apotex also told Congress that MFE clauses "empower first filers to accept later entry dates." See Carrier *supra* note 7.

effective at deterring third-party generic entry, the probability the brand will lose profits associated with activation decreases.

II. 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 uninfringed 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 exclusivity period during which it is protected from generic competition unless it 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] By far, however, the unintended consequence of Hatch Waxman that attracted the most attention is a joint brand and generic act, settling Paragraph IV patent litigation with an agreement about a date of entry for the generic challenger accompanied by a payment from the plaintiff (the brand) to the defendant (the generic), a so-called, "reverse-payment" agreement, or more pejoratively, a "pay-for-delay."[11] President Biden's July 9, 2021 Executive Order on competition made reference to these settlements, directing the FTC to attend to "unfair anticompetitive conduct or agreements in the prescription drug industries, such as agreements to delay the market entry of generic drugs or biosimilars."[12]

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[9] For example, see Scott Hemphill and Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386 (2013) and Ruben Jacobo-Rubio, John Turner, and Jonathan Williams, The Distribution of Surplus in the US Pharmaceutical Industry: Evidence from Paragraph IV Patent-Litigation Decisions, J. LAW ECON. 203 (2020).

[10] For example, see Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting*, 1 INNOV. POLICY ECON. 119 (2000); Scott Hemphill and Bhaven Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012); and Kerstin Vokinger, Aaron Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *Strategies That Delay Market Entry of Generic Drugs*, 177 JAMA INTERN. MED., 1665 (2017); Matthew Higgins and Stuart Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE 370 (2009) and Henry Grabowski and Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAG. DEC. ECON. 491 (2007).

[11] See *supra* note 4 and Herbert Hovenkamp, Mark Janis, and Mark Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. LAW REV. 1719 (2003); Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N. Y. UNIV. LAW REV., 1553 (2006); and Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Columbia L.J. 629 (2009)

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

Reverse-payment agreements within the Hatch-Waxman regulatory framework can have particularly pronounced anticompetitive effects. The first generic to submit a substantially complete Paragraph IV ANDA – called the first filer or first-to-file – is eligible to receive 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, the agreements delay all other generic competitors as well, because they cannot obtain final FDA approval and enter until the first filer's 180-day exclusivity has expired or been forfeited.

The condition of brand rationality implies that if the reverse payment exceeds the brand's anticipated litigation costs, and the value of any other consideration received, the brand is buying a delay in generic entry; otherwise, it would not make a payment. This inference has become the principal form of evidence for evaluating whether a brand-generic Paragraph IV patent 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 in the next section. Brand expected profits depend on the expected date of generic entry, with later entry increasing profits. Let t be the date of generic entry, $\pi_b(t)$ be brand profits as a function of t, and $d\pi_b(t)/dt > 0$. Let t_{np} be the date of generic entry the brand expects (through settlement or trial) in the absence of a payment, and t_p be the agreed-upon date of entry in settlement with the generic containing a brand-to-generic payment. Let p be the value of a payment from the brand's perspective and c be the expected continued litigation costs the brand faces if a settlement is not reached.[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,

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

Thus, if $p > c$, then $\pi_b(t_p) > \pi_b(t_{np})$. A settlement with an otherwise unexplained reverse payment above the brand's anticipated litigation costs therefore implies that the entry date is later than what the brand expected in an agreement without a payment. In other words, $t_p > t_{np}$. 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

[13] Edlin, *et al.* (2015), *supra* note 4, refer to the logic as the "*Actavis* Inference" because it was adopted in the *FTC v. Actavis*, 133 S. Ct. 2223 (2013), at 2235-2237.

[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 and Kreuger, *supra* note 4.

[15] Edlin, *et al.* (2015) at 620, *supra* note 4. For discussion of the inference from brand rationality within an error cost framework, see Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Actavis and Error Costs: A Reply to Critics*, ANTITRUST SOURCE, Oct. 2014.

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.

The 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. 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.

III. MFE Clauses as a Potential Reverse Payment

MFE clauses in brand-generic settlements setting 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, maintaining high prices to consumers.[17] Second, an MFE clause may deter competition from third-party generics, which delays their expected entry and maintains high prices to consumers in another way. Both of these concerns emerge in consideration of when a brand would rationally include an MFE clause in a settlement with a generic that would otherwise reduce its expected profits.

A. A REVERSE PAYMENT FROM AN MFE CLAUSE IMPLIES DELAYED ENTRY OF THE SETTLING GENERIC AND/OR THIRD-PARTY GENRICS

This subsection draws the implications of brand rationality when the brand faces subsequent patent challenges from third-party generics (which is common) and the agreement with the settling generic may or may not contain an MFE clause.[18] Now, brand profits depend on the expected date of entry for third-party generics, denoted s, as well as the expected date of entry for the settling generic, t. Profit for the brand is $\pi_b(t,s)$, with first derivatives $d\pi_b(t,s)/dt$, $d\pi_b(t,s)/ds > 0$. 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

[16] See Hemphill (2009) in *supra* note 9.

[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] Edlin *et al.* (2015), *supra* note 4, 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. 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.

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.

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

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

Alternatively,

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

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. In other words, if the brand's payment exceeds its expected future litigation costs, at least one of the entry dates of the settling and third-party generics must have been delayed by the payment.

B. HOW AN MFE CLAUSE CAN CONSTITUTE A REVERSE PAYMENT

An MFE clause is a form of reverse payment when it imposes a cost on the brand and benefits 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 an AG 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 AG profits. Even if the brand were not planning to launch an AG, one more generic competitor could also push down the price of the generic product and pull some sales from the brand's products.

The magnitude of a brand's expected payment can be significant. Our prior empirical research indicates that, in certain circumstances, it is not uncommon for generic entry to occur before the settling generic's agreed-upon entry date, a circumstance that might trigger an MFE clause. For example, among 47 cases 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

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

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, but 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 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.

In any case, it remains true that the second form of MFE clause transfers value to the settling generic at the expense of third-party generics, which could not sell during the first filer's exclusivity period, and consumers, who 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 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 may induce the generic to accept delay in entry.

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[20] Drake and McGuire, *supra* note 19.

[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.

[22] Similarly, Edlin *et al.* (2015) at 623, *supra* note 4, recognized that the brand benefits from ensuring that the first filer retains its exclusivity period.

[23] Drake and McGuire, *supra* note 19.

C. 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 an agreement is not anticompetitive. When the MFE clause allows a first-filer generic to retain its exclusivity period, the burden of paying the first filer shifts from the brand to consumers and third-party generics. The customary analysis comparing the brand's profit sacrifice or payment from the clause to its expected future litigation costs would fail to identify the MFE clause as anticompetitive even though it is.

The "probability of activation" of an MFE clause plays two roles in the analysis of reverse-payment agreements. On the one hand, the probability of activation is directly and positively related to the expected brand payment, as the product of the probability times the loss (if any) if the clause is activated. On the other hand, the probability of activation is negatively related to the magnitude of harm to consumers. (As the MFE reduces the probability of activation, consumer harms increase.) 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.

IV. Discussion

MFE clauses appear to be a common feature of confidential brand-generic settlements specifying the start of generic competition. Although MFE clauses have not received the same level of economic or legal scrutiny as other potential forms of reverse payment, that may be changing. Recent antitrust actions brought by private plaintiffs have challenged MFEs as being anticompetitive.[24] We hope, in this paper, to contribute to the economic understanding of MFE clauses in this important legal context.

The condition of brand rationality is central to the economics of potential reverse payments in Paragraph IV patent settlements, including those with an MFE clause. The special feature of an MFE clause as a potential reverse payment is that the MFE may affect two dates that generic competition begins, initial generic entry because of the value transferred to the settling generic, and entry by third-party generics because of the deterrent effect. Brand rationality implies at least one and possibly both dates could be pushed back by an MFE clause.

Our paper calls attention to the vulnerability of assessing whether an MFE clause is anticompetitive based solely on the magnitude of the brand's reverse payment associated with activation of the clause. In some circumstances, 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

[24] Allegations by private plaintiffs that MFEs were anticompetitive were initially dismissed in cases involving the drugs Actos and Loestrin, but the Loestrin ruling was vacated and remanded by an appeals court. Defendant motions to dismiss claims that MFEs are anticompetitive have been denied in at least five cases. See order granting in part and denying in part Defendants' Motion to Dismiss, in re Xyrem (Sodium Oxybate) Antitrust Litigation, Case No. 20-MD-02966, (N.D. Cal. Aug. 13, 2021).

brand associated with activation falls below avoided litigation cost even for a grossly anticompetitive agreement. One recourse 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.[25] An MFE clause's effect on reducing third-party generic profits can also be examined empirically, which may also provide evidence that competition has been harmed.

Because, with activation, an MFE clause brings a generic to market earlier, the clause will sometimes have procompetitive benefits, at least on expectation. 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 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 empirically based on industry experience. An important qualification is if the activation of an MFE clause allows a first filer to retain its exclusivity period, it typically reduces generic competition so provides no procompetitive benefits.

Any factor affecting expected profits in the pharmaceutical industry may affect a brand's incentives to invest in R&D or a generic's incentives to challenge patents. There are abundant tradeoffs involved in setting regulatory policy governing drug company profits and it is beyond the scope of this paper to investigate whether the profit incentives for brand or generic firms are too great or too small. We focus here on profits created by potentially anticompetitive agreements restraining competition which cannot, in our view, be excused by appeal to incentives to invest.

[25] 133 S. Ct. 2223 (2013).