Most-Favored Entry Clauses in Drug-Patent Litigation Settlements: A Reply to Drake and McGuire (2022)

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Most settlements between brand and generic drug manufacturers in patent cases have two key features. First, they give the generic a license to enter the market before patent expiration. Second, they allow the generic's licensed entry to be accelerated under certain conditions.

Drake and McGuire (2022) argue that this second type of term, which they call most-favored entry clauses (MFEs), is anticompetitive.[1] According to Drake and McGuire, MFEs can delay the entry of the first generic to file a patent challenge, as well as delay the entry of later filers.[2]

This paper explains why Drake and McGuire's antitrust analysis does not fully reflect the regulatory structure and economics of the pharmaceutical industry. Accounting for these factors demonstrates that MFEs have no impact on the first filer's entry when they (i) involve no profit sacrifice from the brand and (ii) convey no economic value to the settling first filer. In addition, such MFEs do not affect the economic incentives of later filers. At most, MFEs can prevent drug-patent settlements from increasing the incentives of later filers to litigate the patents. Indeed, MFEs can be procompetitive by making drug-patent settlements possible and thereby lowering both private and public litigation costs.

I. Background

Economic Incentives of the Hatch-Waxman Act. The 1984 Drug Price Competition and Patent Term Restoration Act (known as the Hatch-Waxman Act, or the HWA) balances the competing goals of (i) maintaining incentives for new drug innovation and (ii) encouraging price competition through generic entry.[3] The HWA maintains incentives for innovation by creating mechanisms through which drug innovators can obtain more exclusivity protection.[4] The HWA encourages generic price competition by decreasing the cost of obtaining Food and Drug Administration (FDA) approval for generic drugs, and by reducing the risks and increasing the rewards associated with challenging patents that cover branded drugs.[5]

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1 *See generally* Keith M. Drake & Thomas G. McGuire, *Most-Favored Entry Clauses in Drug-Patent Litigation Settlements: Reverse Payments and Anticompetitive Effects*, Antitrust Magazine Online, August 2022, at 2–3.

2 *Id.* at 3.

3 *See, e.g.*, Henry Grabowski et al., *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. Med. Econ. 908, 909 (2021) (noting that "[u]nder the Hatch–Waxman Act framework, therefore, the [market exclusivity period] for new brand-name drugs reflects the interaction of a number of factors, including provisions aimed at facilitating earlier generic entry [and] other provisions aimed at maintaining incentives for innovation").

4 *See id.* (describing the HWA's "patent term restoration" and "data exclusivity" provisions).

5 *Id.* at 908–09.

An MFE, often referred to as an acceleration clause, moves up the generic's licensed entry date when a defined trigger event occurs.

The HWA reduced generic-drug-development costs by allowing a generic to submit an Abbreviated New Drug Application (ANDA) to the FDA that relies on the brand's demonstrations of safety and efficacy. This change eliminated the need for generics to conduct expensive and time-consuming clinical trials.[6] The HWA reduced the risks associated with challenging patents by creating a mechanism, called a Paragraph IV ANDA certification, through which a generic can challenge the brand's patents before receiving FDA approval or launching a product. Under a Paragraph IV ANDA, the generic certifies that the patent(s) covering the brand product are invalid, unenforceable, and/or will not be infringed by the generic product.[7]

The HWA incentivized patent challenges by providing the first generic to file a substantially complete Paragraph IV ANDA (a "first filer") a period of regulatory exclusivity that lasts up to 180 days from the firm's entry ("180-day exclusivity").[8] During this period, the FDA cannot issue final approval to any other ANDAs that claim the same reference brand drug.[9] As a result, the only competition the first filer could face during this 180-day period is from the brand product and authorized generic (AG) products that are marketed under the brand product's New Drug Application.[10]

First filers can forfeit this exclusivity if certain conditions occur.[11] If the first filer forfeits, the FDA can grant final ANDA approval to any other generic that has filed a Paragraph IV ANDA, but later filers do not receive the first filer's exclusivity.[12] This means that if the first filer forfeits exclusivity, a patent invalidity win by a later filer allows other generics to enter without risk of patent damages.

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[6] *Id.* at 908. *See also* John R. Thomas, Cong. Rsch. Serv., The Hatch-Waxman Act: A Primer 6 (2016), https://crsreports.congress.gov/product/pdf/R/R44643/3.

[7] Filing an ANDA with a Paragraph IV certification is considered a technical act of infringement under the HWA and allows the brand to bring patent infringement litigation immediately once the ANDA is filed—i.e., without the generic needing to enter the market and put itself at risk of paying patent infringement damages. *See generally* 21 U.S.C. §355(j); U.S. Food & Drug Admin., Guidance for Industry 180-Day Exclusivity: Questions and Answers, Draft Guidance 3–4 (2017), https://www.fda.gov/media/102650/download [hereinafter Guidance for Industry 180-Day Exclusivity].

[8] *See* Grabowski et al., *supra* note 3, at 909 ("The Hatch-Waxman Act also created economic incentives for generic manufacturers to file challenges to brand-name drugs' patents prior to expiration."); Guidance for Industry 180-Day Exclusivity, *supra* note 7, at 4 ("The statute provides an incentive and a reward to generic drug applicants that expose themselves to the risk of patent litigation. It does so by granting a 180-day period of exclusivity vis-à-vis certain other ANDA applicants to the applicant that is first to file a substantially complete ANDA containing a paragraph IV certification to a listed patent."). The 180-day exclusivity can last for fewer than 180 days if the first filer enters the market fewer than 180 days prior to the patents on the brand drug expiring. *See id.* at 10–11.

[9] Note that the 180-day exclusivity will prevent other generics from launching at risk or after a settlement with the brand until the exclusivity has expired. It is possible, however, for multiple generics to receive first filer status and share the 180-day exclusivity if they all file on the same day. *See id.* at 9, 12.

[10] *See* Thomas, *supra* note 6, at 13; Guidance for Industry 180-Day Exclusivity, *supra* note 7, at 13.

[11] *See* 21 U.S.C. §355(j)(5)(D)(i); Thomas, *supra* note 6, at 11; Guidance for Industry 180-Day Exclusivity, *supra* note 7, at 15. A first filer will forfeit its exclusivity if it fails to enter the market within 75 days of a later filer winning a final court judgment that the brand's patents are invalid or not infringed. Final court judgment is defined by the statute as a decision "from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed." *See* 21 U.S.C. §355(j)(5)(D)(i)(I). A first filer can also forfeit exclusivity if it fails to obtain tentative approval within 30 months of submitting its ANDA. *See* 21 U.S.C. §355(j)(5)(D)(i)(IV).

[12] Guidance for Industry 180-Day Exclusivity, *supra* note 7, at 26.

A first filer usually earns a large share of its total profits from the sales of the drug during the 180-day exclusivity period when it faces limited competition.[13] These dynamics create a strong incentive for a generic to be the first to file a Paragraph IV ANDA.[14]

Drake and McGuire Argue the HWA Creates Incentives for Inclusion of Anticompetitive MFEs in Patent Settlements. Paragraph IV patent disputes often settle with the generic receiving a license to enter the market before brand patents expire.[15] These settlements are viewed as anticompetitive when they include a so-called "reverse" payment from the brand (the patent holder) to the generic (the alleged infringer) in exchange for the generic accepting a later (or "delayed") licensed entry date.[16] Agreements with reverse payments that have been the subject of antitrust challenges have usually had at least one of the following three features: (i) large cash payments from the brand to the generic,[17] (ii) some sort of contemporaneous side deal,[18] or (iii) a commitment from the brand not to launch an AG during the first filer's 180-day exclusivity period.[19]

Drake and McGuire argue that MFEs in patent settlements are likely to be anticompetitive and could constitute such a reverse payment.[20] An MFE, often referred to as an acceleration clause, moves up the generic's licensed entry date when a defined trigger event occurs.[21] Examples of

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[13] *See* Grabowski et al., *supra* note 3, at 909 ("During these 180 days, its generic drug is the only ANDA-approved generic version of the branded drug that is allowed on the market, allowing it to charge higher prices and realize higher sales and profits than it would when additional competing generic drugs launch."). Generic drug profits erode quickly when there are multiple generic entrants. *See* Ryan Conrad & Randall Lutter, U.S. Food & Drug Admin., Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices 2, 9 (2019), https://www.fda.gov/media/133509/download (finding that "[g]reater competition among generic drug makers is associated with lower generic drug prices").

[14] *See, e.g.*, Henry Grabowski et al., *Pharmaceutical Patent Challenges: Company Strategies and Litigation Outcomes*, 3 Am. J. Health Econ. 33, 43 (2017) (reflecting this incentive through charts illustrating how quickly large-selling new molecular entities may now expect to face patent challenge litigation).

[15] *See, e.g.*, Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 Santa Clara Comput. & High Tech. L.J. 489, 495 (2006) ("[M]ost agreements that terminate a patent dispute involve a negotiated market entry date for the generic product that substantially precedes the date of patent expiration."); Fed. 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, at 3–4 (n.d.), https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf [hereinafter Overview of Agreements Filed in FY 2017].

[16] Such settlements are referred to as reverse payment settlements because typically it is the alleged infringer that needs to make a payment to the patent holder when settling patent infringement litigation. In most patent litigation, the alleged infringer is at risk of paying damages if it loses the patent litigation. However, because generics do not have to enter the market to challenge the patents covering brand drugs, that is typically not the situation with Paragraph IV patent litigation. As a result, the brand has no reasonable royalties or lost profits claim against the generic and one would not expect to see a payment flow from the generic to the brand when settling Paragraph IV patent litigation.

[17] Justice Breyer's majority opinion in the 2013 Supreme Court decision *Actavis* stated that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects." FTC v. Actavis, Inc., 570 U.S. 136, 158 (2013).

[18] Side deals have been alleged as reverse payments in numerous court cases. *See, e.g.*, In re Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 713–14, 717 (N.D. Ill. 2016) (discussing an alleged reverse payment that involved, among other things, a development and co-promotion agreement entered into simultaneously with the patent litigation settlement agreement); In re Loestrin 24 Fe Antitrust Litig., 261 F. Supp. 3d 307, 334–36 (D.R.I. 2017) (examining an alleged reverse payment that involved, among other things, promotional deals entered into simultaneously with the patent litigation settlement agreement).

[19] For examples of cases involving allegations that a brand's commitment to not launch an AG constituted a reverse payment, see King Drug Co. v. SmithKline Beecham Corp., 791 F.3d 388, 393 (3d Cir. 2015) (adjudicating a dispute regarding the brand-name drug Lamictal); *In re Opana ER*, 162 F. Supp. 3d at 713, 717; and *In re Loestrin 24 Fe*, 261 F.Supp.3d at 333.

[20] See Drake & McGuire, *supra* note 1, at 2–3.

[21] Overview of Agreements Filed in FY 2017, *supra* note 15, at 4 (describing acceleration clauses as "provisions that accelerate the effective date of the licenses or covenants not to sue based on other events").

triggers include a court finding of patent invalidity or non-infringement, a launch by another generic willing to take the risk of a patent infringement claim (an "at-risk launch"), or an AG launch.[22] The specifics of the triggers vary across patent settlements, but almost all pharmaceutical patent settlements have acceleration clauses of some type.[23]

[F]rom an economic perspective, identifying whether a settlement includes a reverse payment requires analyzing whether the settlement includes both (i) a profit sacrifice from the brand and (ii) an economic benefit to the generic

Drake and McGuire argue that MFEs have two anticompetitive effects. First, they argue that first filers value MFEs and consequently will agree to a delayed licensed entry date in exchange for the MFE.[24] Second, they argue that an MFE in the first filer's settlement agreement reduces the incentive for later filers to litigate their patent cases against the brand, which leads to later filers settling for delayed licensed entry dates as well.[25]

In this paper, we explain why Drake and McGuire's antitrust analysis does not fully reflect the regulatory structure described above.

II. The Competitive Effects of MFEs on First Filers

Drake and McGuire first focus on whether a settlement includes an anticompetitive reverse payment from the brand to the generic. As Drake and McGuire acknowledge, from an economic perspective, identifying whether a settlement includes a reverse payment requires analyzing whether the settlement includes both (i) a profit sacrifice from the brand and (ii) an economic benefit to the generic.[26]

There is no economic basis for concluding that a settlement has an anticompetitive reverse payment if the settlement includes terms that convey benefits to the generic, but do not require a profit sacrifice by the brand. This is because—as Drake and McGuire acknowledge—it is economically rational for a brand to include any settlement term as long as the term does not constitute a profit sacrifice to the brand.[27]

A Brand Can Enter into an MFE without Sacrificing Profits. Drake and McGuire claim that a brand may sacrifice profits with an MFE in two ways. First, they argue that a brand that does not plan to launch an AG may sacrifice profits because an MFE, if triggered, can increase the number of generic entrants at the time of initial generic entry. Drake and McGuire claim that this

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[22] *See also id.* (noting that "[s]ome of the most common events that accelerate a licensed entry date are: (i) another company selling a generic version of the branded product, (ii) another company obtaining a final court decision of patent invalidity or unenforceability or of non-infringement, (iii) the brand manufacturer licensing a third party with an earlier entry date, (iv) sales of the branded product falling below specified thresholds, or (v) the brand manufacturer obtaining FDA approval for another product with the same active ingredient").

[23] *Id.* (finding acceleration clauses in "181 of the[] 192 agreements" examined in the report). *See also* Fed. 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 2016, at 3 (n.d.), https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf [hereinafter Overview of Agreements Filed in FY 2016] (noting that "177 of the[] 187 agreements" described in the report "contain provisions that accelerate the effective dates of the licenses or covenants not to sue based on other events").

[24] *See* Drake & McGuire, *supra* note 1, at 3.

[25] *See id.* As part of Paragraph IV patent litigation with the brand, later filers may obtain access to a first filer's settlement agreement, which would inform the later filers to the existence of any MFE. However, even if a later filer did not have access to a first filer's settlement agreement, it is reasonable to expect that any later filer would anticipate that an MFE would be included in the first filer's settlement agreement because (i) first filers commonly make public announcements regarding patent settlements where they indicate that any agreed-upon license entry date can be accelerated "under certain circumstances" and (ii) public reports from the Federal Trade Commission indicate that almost all patent settlements have MFEs. *See* Overview of Agreements Filed in FY 2016, *supra* note 23.

[26] *See id.* at 6.

[27] *See id.* at 4. As Drake and McGuire explain, for a settlement term to make economic sense, it would have to cost the brand less than continuing the patent litigation and less than any other consideration that the brand may receive via the settlement. *See id.*

increase in generic competition could increase the erosion of brand sales by lowering the generic price.[28] However, Drake and McGuire do not cite evidence that increasing the number of generic entrants (beyond one) causes additional significant decline in brand sales. Nor do they acknowledge research that appears inconsistent with such a decline.[29]

Second, Drake and McGuire argue that if a brand plans to launch an AG, an MFE constitutes a profit sacrifice because the MFE increases the number of generics, thereby lowering the brand's AG profits.[30] However, they also acknowledge that this is not always the case. Specifically, Drake and McGuire note that, if the first filer has maintained 180-day exclusivity, an MFE that enables a first filer to launch upon patent invalidation would increase the brand's AG profits. The MFE would increase the brand's AG profit because, if the first filer launches upon patent invalidity, then the later filing generics must wait 180 days to receive approval. As a result, if the MFE is triggered, then the AG would face competition from only the first filer in the 180 days after patent invalidation.[31]

Drake and McGuire argue that an MFE that enables a first filer to launch upon an earlier licensed or at-risk entry of a later filer is a profit sacrifice because the MFE would prompt more generic competition with the brand's AG product.[32] This assertion fails to acknowledge that, for such an MFE to have any effect on the number of competitors, the first filer must have forfeited its 180-day exclusivity. If the first filer did not forfeit its exclusivity, the HWA would prevent any later filer from entering the market before the first filer with or without such an MFE.[33] And if the first filer did forfeit its 180-day exclusivity, an MFE that leads to accelerated generic entry is procompetitive even if the MFE adversely affects the brand's AG profits. For these reasons, this type of profit sacrifice cannot be an anticompetitive payment to delay generic entry. Indeed, it has the opposite effect.

An MFE Can Lead to No Delay Even If It Conveys Economic Value to the Generic. Drake and McGuire recognize that MFEs may not involve a profit sacrifice by the brand, in which case they cannot be identified as anticompetitive reverse payments from an economic perspective.[34] Yet they argue that if an MFE conveys economic value to the settling generic, it *could* be anticompetitive if the generic agreed to delay entry in exchange for that economic value. In doing so, however, Drake and McGuire do not appear to offer any economic basis to support the assertion that the generic *would* agree to delay its entry in those circumstances. That assertion, moreover, has multiple potential infirmities.

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[28] *Id.* at 6 ("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.").

[29] *See, e.g.*, Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affs. 790, 795–96 (2007) (finding no difference in the share of prescriptions captured by brands in the six months after initial generic entry depending on whether there was a successful Paragraph IV filing); Grabowski et al., *supra* note 3, at 916 (showing no break in the trend observed for the share of prescriptions captured by brands in the seventh month after initial generic entry when the average number of generic competitors should increase).

[30] *See* Drake & McGuire, *supra* note 1, at 6 ("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.").

[31] *Id.* at 6–7. Drake and McGuire acknowledge that, without the MFE, patent invalidation by one generic is typically accompanied by mass generic entry.

[32] *Id.* at 6.

[33] 21 U.S.C. §355(j)(5)(B)(iv)(I).

[34] Drake & McGuire, *supra* note 1, at 6 ("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 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.").

Given the complexity involved in assessing the effect of any one term [of a settlement agreement] on the licensed entry date, conducting . . . a term-by-term evaluation and assessing the aggregate effect of all such terms would be an unworkable method for determining whether the licensed entry date was delayed.

First, later entry can be costly to a generic. The time value of money alone suggests that a generic wants to enter as early as possible.[35] Later entry also carries the economic risk of more competition, as a later entry date gives competitors more time to obtain FDA approval and enter the market.[36]

Second, if the MFE involves no profit sacrifice to the brand, there is no economic basis to presume that the brand would demand a delay in exchange for the clause. To the contrary, if one party can offer something of value to the other party at no cost to itself, it could be economically rational to do so to reach an agreement.

Third, it would also be economically rational for the generic to demand a clause that the generic finds valuable and that costs the brand nothing. Crucially, the generic should not have to give up something of value to obtain a clause that costs nothing for the brand to give. In this way, the presence of such clauses is evidence of economic rationality, and not necessarily evidence of anticompetitive payments.

Fourth, Drake and McGuire's theory of harm implies that any settlement term that one party values and costs the other party nothing to give would impact the agreed-upon licensed entry date.[37] If correct, this theory would require an evaluation of every term in the settlement to determine if there was a delay in the licensed entry date. Such an evaluation would require an analysis of both the terms that the brand values that are costless for the generic to give and the terms that the generic values that are costless for the brand to give.

For example, it is our understanding that settling generics typically acknowledge that the brand patents are valid and infringed in exchange for the patent licenses they obtain.[38] In view of the other terms in the settlement (including MFEs), it is essentially costless for a settling generic to agree to this term, but it is valuable to the brand because it protects the brand from the settling generic launching prior to its licensed entry date. According to Drake and McGuire's theory, any such term—which in isolation provides value to the brand—could result in an *earlier* licensed entry date.[39] Therefore, according to this theory, one must evaluate the effect of each such term and analyze the aggregate effect of all such terms to determine if the settlement agreement led to a

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[35] *See, e.g.*, Stephen A. Ross et al., Fundamentals of Corporate Finance 129 (6th ed. 2002) ("[T]he phrase *time value of money* refers to the fact that a dollar in hand today is worth more than a dollar promised at some time in the future. On a practical level, one reason for this is that you could earn interest while you waited; so a dollar today would grow to more than a dollar later.") (emphasis in original).

[36] *See generally* Atanu Saha et al., *Generic Competition in the US Pharmaceutical Industry*, 13 Int'l J. Econ. Bus. 15, 26 (2006) (finding that the average number of generic competitors increased from just over two in the first month after initial generic entry to almost eight after 12 months, and over 12 after 36 months).

[37] Drake & McGuire argue that MFEs "may induce the generic to accept delay in entry" because the generic receives value from the MFE. *See* Drake & McGuire, *supra* note 1, at 7. By logical implication, any other clause that is valuable to the generic could also induce delay. Similarly, any clause that is valuable to the brand may induce the brand to accept early entry.

[38] *See, e.g.*, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 102 (2d Cir. 2010) (abrogated by New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015)) (noting that in litigation involving ciprofloxacin hydrochloride, "Barr conceded the patent's validity"); In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 381–82 (D. Mass. 2013) ("In consideration for Ranbaxy's agreeing to (1) admit that the '504, '192, '789, '872, '810, and '085 patents were enforceable and valid; (2) admit that Ranbaxy's generic Nexium would infringe the '504, '192, '789, and '872 patents; and (3) delay the launch of its generic Nexium until May 27, 2014, AstraZeneca agreed to pay Ranbaxy over $1,000,000,000.").

[39] According to Drake & McGuire, the brand accepts a settlement whenever its value exceeds the expected profits after litigation minus the cost of litigation. *See* Drake & McGuire, *supra* note 1, at 5. In their model the earlier the first filer's entry date the lower the brand's profits, all else equal. This means that anything that increases expected profits post-settlement, while leaving post-litigation profits unaffected, reduces the minimum exclusivity period necessary for the brand to prefer settlement over litigation. Thus, the generic acknowledging the validity and infringement of patents in a settlement can push the brand to accept an earlier licensed entry date than would be otherwise acceptable to it.

delay in the licensed entry date. Given the complexity involved in assessing the effect of any one term on the licensed entry date, conducting this type of a term-by-term evaluation and assessing the aggregate effect of all such terms would be an unworkable method for determining whether the licensed entry date was delayed.

An MFE Does Not Necessarily Convey Value to the Generic. An MFE does not always create value for the settling generic. For example, as noted above, if the first filer has maintained its 180-day exclusivity, then an MFE that is triggered by an earlier at-risk launch or an earlier licensed ANDA entry has no economic value to the settling generic.[40] Such entry by another generic is simply not possible because of the HWA.[41] And without economic value from such an MFE, obtaining it would not give the settling generic any reason to delay its entry in exchange.

Situations like these raise the question of why settling brands and generics include MFEs in their settlement agreements. The answers could be non-economic. Negotiators can include terms in settlements that may provide protection against unlikely or impossible events.[42] Testimony from attorneys involved in pharmaceutical-patent settlements is consistent with this thesis. As stated by Timothy Hester, Merck's outside counsel in *In re Zetia (Ezetimibe) Antitrust Litigation*, "[t]here can be circumstances where — where one side asks, the other side doesn't care, and there is no real purpose. There are provisions in these settlement agreements that aren't important and you see that."[43]

Additionally, concluding that an MFE conveys value to the settling generic (and can therefore be anticompetitive) assumes that an MFE's key value to a generic is that the license granted under an MFE permits the generic to enter the market immediately if the patents are invalidated by another generic.[44] However, a generic—even one that reached an earlier patent settlement—might not need a license to enter the market if the patents are invalidated. If a patent license is not necessary for entry to occur upon patent invalidation, then an MFE granting a patent license would provide little to no economic value.[45]

An MFE triggered by a later court finding of patent non-infringement rather than invalidity may also not provide much value. Without an MFE, the settling generic could enter the market (without a patent license) if a rival obtained a ruling of non-infringement, and then defend itself against patent-infringement claims.[46] If the successful non-infringement defenses of the rival generic are

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[40] *See supra* notes 32–33 and accompanying text.

[41] *See* 21 U.S.C. §355(j)(5)(B)(iv)(I); *supra* note 33 and accompanying text.

[42] *See, e.g.,* Robert E. Scott et al., Contract Law and Theory at 749 (4th ed. 2007).

[43] *See* In re Zetia (Ezetimibe) Antitrust Litigation, 2022 WL 4354620, at *15 (E.D. Va. 2022) (order granting in part and denying in part a motion for an order precluding specified argument and evidence at summary judgment and trial based on privilege assertions).

[44] Drake & McGuire, *supra* note 1, at 6–7.

[45] Such an MFE could remove the small risk that a settling generic that enters the market without a patent license could then face a Supreme Court decision that overturns the appeals court's decision.

[46] If the settlement agreement stays the same and just the MFE were removed, the settling generic may not be able to enter upon a finding of non-infringement for another generic if it has agreed to a settlement provision acknowledging that the brand patents are valid and infringed. *See supra* note 38 and accompanying text. Given such a provision, it is our understanding that a settling generic that enters prior to its licensed entry date would have no defense against a claim of patent infringement. However, a generic would have limited incentive to agree to a provision stating the patents are valid and infringed in the absence of an MFE. In an agreement that has an MFE, this provision is costless to the settling generic. *See supra* notes 37–39 and accompanying text. In an agreement without an MFE, it would no longer be costless. Thus, it is likely that settlements that did not include MFEs would also not include provisions acknowledging the brand patents are valid and infringed.

equally applicable to the settling generic, the latter would face limited risk of incurring patent-infringement damages due to such unlicensed entry.

III. The Competitive Effects of MFEs on Later Filers

Drake and McGuire further argue that an MFE, when included in a settlement with a first filer, can deter later filers from behaving competitively.[47] Specifically, Drake and McGuire suggest that an MFE diminishes the incentives of a later filer to obtain an entry date prior to the licensed entry date of an earlier filer—either through litigation or settlement.[48] In our view, however, there are many situations where an MFE does not affect that calculus.

Consider again the scenario in which the settlement with a first filer with 180-day exclusivity includes an MFE that is triggered by another generic receiving a license entry date before the first filer. In this scenario, even if a later filer were to settle for an entry date that preceded the first filer's date, the later filer would have no ability to launch because the HWA precludes the FDA from issuing approval to ANDAs of non-first filers until after the 180-day exclusivity period is expired or forfeited.[49] As such, this MFE would have no impact on the incentive of later filing generics over and above the incentives that generics already face due to the HWA.

[R]ather than reducing the incentives of later filers to litigate, an MFE merely prevents the settlement from increasing the incentives of later filers to litigate.

Further, as also discussed above, if previously settled generics can enter the market upon another generic invalidating the patents, then an MFE that is triggered by patent invalidation would have no impact on the incentives of later-filing generics. In this case, the MFE does not change the economic incentives of later-filing generics.

Even if one were to assume that an MFE is necessary for a previously settled generic to launch following patent invalidation, Drake and McGuire's conclusions about the competitive impact of such an MFE on later filers' incentives are subject to debate. Again, Drake and McGuire's claim is that the MFE would reduce a later filer's incentives to litigate the patents because, if that generic were to win, it would face competition from all previously settled generics with agreements that included MFEs.[50] The reality, however, is that rather than reducing the incentives of later filers to litigate, an MFE merely prevents the settlement from *increasing* the incentives of later filers to litigate.

Adopting Drake and McGuire's logic, a rational generic would choose to litigate the branded drug's patents if:

$$p * \pi(t, N) > C$$

where p is the probability the generic wins the litigation, $\pi(t, N)$ is the generic's profits, and C is the anticipated litigation costs. The generic's profits are assumed to depend on two factors: the time of launch (t) and the number of competitors (N), where fewer competitors results in increased profits.

If MFEs were banned, then the profitability of litigating the brand's patents would increase for each remaining (non-settling) generic. The incentive to litigate would increase as more generics settled without MFEs, as, if a non-settling generic were to litigate and win, it would face fewer competitors (i.e., N would be lower). In other words, an MFE prevents the settlement from *increasing* the incentives of later filers to litigate.

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[47] *See* Drake & McGuire, *supra* note 1, at 5.

[48] *See id.*

[49] *See* 21 U.S.C. §355(j)(5)(B)(iv)(I); *supra* notes 33 and 41, as well as their accompanying text.

[50] *See* Drake & McGuire, *supra* note 1, at 5.

Drake and McGuire's conclusion that MFEs reduce the incentives of later filers to litigate thus appears to rest on the wrong comparison. From an economic perspective, rather than comparing (i) the situation where the first filer settles with an MFE to (ii) the situation where the first filer settles without it, the competitive effects on later filers should be evaluated by comparing (iii) the situation where a first filer settles with an MFE to (iv) the situation that existed before the first filer's settlement. If later filers' incentives to litigate are unchanged between situations (iii) and (iv), there is no economic basis to conclude that the first filer's settlement with an MFE had any anticompetitive effect.

Consider an example that involves only two generics: a first filer and a second filer, and a potential MFE that is triggered by a finding of patent invalidity. If the first filer has not settled with the brand (and does not have 180-day exclusivity), the second filer's payoff from litigation will recognize that a patent-litigation win would allow the first filer to launch at the same time that the second filer launches. If the first filer has settled with the brand, but has an MFE triggered by patent invalidation, the second filer faces the same litigation payoff: if it wins litigation, it will still face competition from the first filer. If alternatively, the first filer's settlement does not include an MFE (and if the firm could not enter without the MFE), then the second filer's incentive to litigate is enhanced by the first filer's settlement. The reason for this is that in the absence of the MFE, after invalidity of the patents the second filer would not face competition from the first filer until the first filer's licensed entry date.

IV. MFEs and the Ability to Settle Pharmaceutical Patent Litigation

Based on statistics published by the Federal Trade Commission, upwards of 94 percent of all pharmaceutical-patent settlement agreements include an MFE.[51] The claim that MFEs can be anticompetitive clashes with these provisions' ubiquity. That ubiquity has a procompetitive explanation.[52]

As discussed above, if settlements did not allow settling generics to enter upon the entry of another generic, then the settlements would increase the incentives of any generic that has not yet settled to obtain an earlier entry date in order to leapfrog earlier settling generics.[53] When the first filer has maintained its 180-day exclusivity, the only way to accomplish this is for a later generic to litigate to a final court decision.[54] As more generics settle, the incentives to litigate to a final court decision for generics that have not yet settled would get larger and larger, so much so that the brand would be unable to settle with all generics in most situations. But if a brand knows it will eventually have to litigate the patents, it will prefer to settle with no one. This is because settling with any generic would limit the upside of a later patent litigation win (because settling generics would still be able to enter prior to patent expiration), but it would not limit the downside of a later patent litigation loss. MFEs thus facilitate the settlement of patent litigation.

The same would be true if the first filer has forfeited its 180-day exclusivity. Here, a later generic could leapfrog the entry of the settling generic either through litigating to a final court decision or by settling with an earlier licensed entry date. Because of the increased incentives to litigate to a final court decision, a later generic would settle only if it is able to obtain an earlier licensed date

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[51] *See* Overview of Agreements Filed in FY 2016, *supra* note 23, at 3; Overview of Agreements Filed in FY 2017, *supra* note 15, at 4.

[52] The consideration of whether an MFE may be necessary for settlement to occur is based on the assumption that an MFE is necessary for a settling generic to be able to launch if a later filer successfully litigates the brand's patents.

[53] *See* discussion above at Section III.

[54] As noted above, a first filer will forfeit its 180-day exclusivity if it fails to enter the market within 75 days of a later filer winning a final court judgment that the brand's patents are invalid or not infringed. *See* Guidance for Industry 180-Day Exclusivity, *supra* note 7, at 15.

than prior settling generics. The brand would either have to concede to an earlier licensed entry or face litigation. In this situation, too, the brand would rather not settle with any generic and instead litigate to a final court decision.

If MFEs are necessary for settlement to occur, they do not constitute a profit sacrifice by the brand and therefore cannot be a reverse payment. An MFE would instead convey value to the brand—the opposite of profit sacrifice—because it makes settlement possible and avoids increasing litigation incentives of later filers.

Without the ability to include MFEs in patent settlements . . . it may not be possible for the parties to reach settlement.

By making settlements possible, then, MFEs also provide procompetitive benefits in the form of lower private- and public-litigation costs, such as the cost(s) of (i) business disruption for the companies[55] and (ii) the time of lawyers, judges, and other court personnel. These cost savings could in turn be devoted to more socially beneficial activities.

V. Conclusion

In many instances, MFEs are unlikely to provide much, if any, value to generics, and they are unlikely to involve a profit sacrifice to the brand. They also do not reduce the incentives of later filers to challenge and litigate the brand patents. Instead, they prevent increases in the incentives of generics to litigate to final court decisions as their potential generic competitors choose to settle. This, in turn, enables brand and generic firms to reach settlement. Without the ability to include MFEs in patent settlements, then, it may not be possible for the parties to reach settlement. As a result, MFEs are procompetitive in both encouraging settlement and, potentially, accelerating generic competition. ●

[55] Note that this is business disruption during the litigation proceedings and the uncertainty of how and when the litigation would conclude. It does not refer to cost from having to face generic competition if the generic wins the patent litigation.