Antitrust Treatment of Acceleration Provisions in Hatch-Waxman Settlements

by Cristina M. Fernandez and Michael Keeley

Seven years after the Supreme Court's landmark decision in *FTC v. Actavis, Inc.*, the legality of Hatch-Waxman patent settlements remains one of the most intensely litigated issues at the intersection of patent and antitrust law. In *Actavis*, the Supreme Court held that reverse payment settlements in patent infringement litigation are not immune from antitrust scrutiny and that the anticompetitive effects of these agreements may be found unlawful under the Sherman Act.[1] Since then, lower courts have grappled with the broad contours of *Actavis*. Today, one of the most contentious subjects is what constitutes an unlawful payment from a brand manufacturer to a generic manufacturer. Early "pay-for-delay" cases—including *Actavis*—challenged monetary payments, but later-filed actions

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have tested whether reverse payment theories also bar non-monetary terms such as acceleration clauses.

Acceleration clauses allow a settling generic firm to launch its product before the agreed-upon entry date if any other generic brings its product to market before the specified entry date. These provisions are common in Hatch-Waxman patent settlements, particularly when multiple generic firms seek entry into the market. Acceleration clauses can be essential to achieve settlement because, without them, a settling generic firm risks being disadvantaged because of earlier entry by another generic.

These provisions are arguably pro-competitive because they facilitate settlements and also—if triggered—increase the number of competitors able to launch. Despite this, some have argued that acceleration clauses constitute unlawful reverse payments because they (1) confer value to the settling generic manufacturer by allowing them to compete if other generics enter earlier and (2) delay generic entry by inducing the settling generic manufacturer to accept a later launch date than it otherwise would have or by deterring other generic manufacturers from entering before the settling generic manufacturer.

This article describes the recent federal cases and a newly enacted state statute addressing whether acceleration clauses may constitute anticompetitive reverse payments and makes recommendations regarding how to structure acceleration provisions in future Hatch-Waxman settlements to avoid running afoul of state and federal antitrust laws.

Background

Hatch-Waxman Act

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (aka the Hatch-Waxman Act) to foster drug innovation and competition. The Act created mechanisms to increase competition by generic drugs. Chief among them were a shortened Food and Drug Administration (FDA) approval process for generic drugs and a method for generic firms to challenge the patents covering innovative drugs, along with incentives for bringing such challenges.

Since the enactment of the Hatch-Waxman Act, generic firms can file an abbreviated new drug application (ANDA) that demonstrates their drug is bioequivalent to the innovative drug and can rely on the clinical trials performed for the innovative drug to demonstrate safety and effectiveness. When filing an ANDA, generic firms may elect to make what is referred to as a Paragraph IV certification. This certifies that the patents covering the innovative drug are invalid and/or will not be infringed by the generic. The filing of an ANDA with a Paragraph IV certification as to an approved drug product listed in the Orange Book is an artificial act of patent infringement that provides federal courts with subject matter jurisdiction. But under the Hatch-Waxman Act, the generic firm does not face the risk of substantial damages as a result of infringing the patent because it is not based on any allegedly infringing use, sale, or offer for sale. Instead, the generic firm faces only litigation costs, even if the court finds that the patent is valid and infringed. The Hatch-Waxman Act thus incentivizes generic firms to challenge patents by using the Paragraph IV Certification.

The Hatch-Waxman Act further incentivizes generic firms to bring patent challenges by awarding 180 days of exclusivity to the first Paragraph IV filer upon the successful resolution of patent infringement litigation. During the exclusivity period, which begins after the first commercial marketing of the drug, FDA cannot approve an application from any other generic firm to market its drug. The 180 days of exclusivity are often very valuable. As the Supreme Court noted in *Actavis*, the exclusivity period can be "worth several hundred million dollars" to the generic company.[2]

Reverse Payment Settlements

Most settlements of Paragraph IV patent infringement litigation involve some restriction on generic entry,[3] typically a patent-term split agreement. Such agreements involve the parties dividing the remaining patent term by selecting a generic entry date that is earlier than the expiration date of the brand manufacturer's patent. Pure patent-term split agreements that do not involve a payment do not violate antitrust laws. Indeed, the Supreme Court recognized in *Actavis* that a settlement allowing entry before patent expiration could "bring about competition . . . to the consumer's benefit."[4] The FTC, too, acknowledged that the parties' entry date in a pure patent-term split agreement reflects nothing more than the parties' perceptions of the odds of their success in the patent infringement litigation—the more likely the patent is valid and infringed, the later the generic entry date.[5]

Potential antitrust liability lies in instances in which the parties' patent-term split agreements are accompanied by a payment from the brand manufacturer to the generic firm. Antitrust plaintiffs and regulators claim that, in these instances, the brand manufacturer makes a payment to the generic firm in exchange for the generic firm's agreement to a later entry date than it would have agreed to based on its perception of its probability of success in the patent infringement

litigation. These so-called "pay-for-delay" settlements were the subject of the Supreme Court's decision in *Actavis*.

FTC v. Actavis, Inc.

In *FTC v. Actavis*, the Supreme Court emphasized that harm to competition results when a brand manufacturer pays a generic firm to stay out of the market. Accordingly, the Court invited scrutiny of Hatch-Waxman settlements involving "large, unexplained" payments from the brand manufacturer to the generic company where the "rationale behind a payment . . . [cannot] be supported by traditional settlement considerations [and] . . . instead provide[s] strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."[6] The Court lamented that "payment in return for staying out of the market . . . simply keeps prices at patentee-set levels" to the benefit of the patentee and challenger and to the detriment of the consumer.[7]

The Court ruled that reverse payments must be evaluated under a fact-intensive rule of reason analysis "because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[8] However, the Court provided little in the way of a blueprint for lower courts to apply a rule of reason approach. Among the many questions *Actavis* left open is the thorny issue of what constitutes a "payment." Thus, in the years that followed, antitrust plaintiffs advanced numerous theories of anticompetitive reverse payments even in the absence of monetary remuneration, including allegations that acceleration provisions constitute unlawful pay-for-delay.

Acceleration Provisions

Acceleration provisions are a common feature of Hatch-Waxman patent settlements. FTC data reflect that these clauses appeared in at least 181 of 226 settlements in fiscal year 2016.[9] The clauses come in two basic formats: (1) a Most Favored Entry provision (MFE), which provides for the settling generic manufacturer to enter at the same time as any earlier entering generic manufacturer; and (2) a Most Favored Entry Plus (MFEP) provision, which provides that the settling generic's entry date advances to preserve a specified period of exclusivity upon any earlier market entry by another generic manufacturer.

The patentee brand manufacturer has strong incentives to pursue settlement of Hatch-Waxman patent infringement litigation. For example, a brand manufacturer might rationally accept a patent-term split agreement that allows the generic to enter 90% into the remaining patent life even if it believed it had a 90% chance of winning the patent litigation. Settlement also has the benefit of achieving predictability that allows the brand manufacturer to make strategic business decisions that may otherwise be stymied by uncertainty in sizeable future revenues.

The challenger generic manufacturer likewise has incentives to settle for a negotiated entry date earlier than the patent expiration to achieve greater certainty regarding its future revenues and to avoid litigation costs. However, absent an acceleration clause the generic firm faces the threat that another generic could launch earlier than its settlement-specified entry date by obtaining a ruling of non-infringement or invalidity in patent litigation, launching its product at risk of patent infringement, or negotiating a settlement with the brand manufacturer involving an earlier entry date. Accordingly, a generic firm has less incentive to enter a patent-term split agreement where it nonetheless faces the risk that the benefit of the settlement will later be diminished. Indeed, without acceleration provisions, generic firms would be incentivized to be the last to settle among generic firms seeking entry. Acceleration provisions, therefore, are often a critical component of settlement, and where multiple generic firms seek entry, settlements may be nearly impossible to achieve in their absence.

In re Actos End Payor Antitrust Litig.

Antitrust plaintiffs brought their first post-*Actavis* action challenging acceleration provisions *In re Actos End Payor Antitrust Litigation*.[10] In that case, Takeda Pharmaceutical Co. (Takeda) reached individual agreements with three generic drug manufacturers to settle independent patent disputes related to the diabetes drug, ACTOS. Each of the settlements allowed the respective generic manufacturer to enter the market with a generic product almost four years before the expiration of the disputed patents. Each agreement also contained an acceleration clause—specifically an MFE—that enabled the settling generic manufacturers to enter the market as soon as another generic manufacturer entered.

A putative class of indirect purchaser plaintiffs (IPPs) sued Takeda and the three generic drug manufacturers, alleging that the acceleration clauses constituted reverse payments because they induced the generic manufacturers to drop their challenges to Takeda's patents, while also deterring other generic drug companies from entering the market.[11] Defendants moved to dismiss

the complaint, arguing that the acceleration provisions, rather than reflecting a payment from brand manufacturer to generic manufacturer, provided for earlier and increased competition and thus could not be viewed as anticompetitive payments to keep the settling manufacturers off the market.[12]

The Court granted Defendants' motion to dismiss, finding that the terms at issue in the case were not anticompetitive because the generic manufacturers "received no compensation from Takeda, but rather were compensated only through the market when they began selling their generic product"—competition that would be "to the consumer's benefit."[13] The Court rejected the IPPs' argument the acceleration clauses were anticompetitive because other generic manufacturers were discouraged from entering the market knowing that three other manufacturers were waiting in the wings. The Court reasoned that if no other generic entered the market before the settlement entry date, the effect of the clauses would be neutral, and if another generic manufacturer did enter before the settlement entry date the effect would be "indisputably procompetitive" because the clauses would trigger more generics to enter the market.[14] In addition, the Court noted that even if it were to credit IPPs' speculation on how generics would have acted in the absence of the acceleration clauses, "[t]he mere possibility that the absence of an acceleration clause may result in more diverse generic competition is insufficient for [IPPs] to plausibly state a reverse payment claim."[15] "*Actavis* requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition."[16]

In re Loestrin 24 FE Antitrust Litig.

Another challenge to an acceleration provision was in *In re Loestrin 24 FE Antitrust Litigation*. That case involved Warner Chilcott's (Warner) settlement of Hatch-Waxman patent litigations relating to its oral contraceptive, Loestrin 24 FE. With respect to one generic manufacturer, Watson Laboratories, Inc. (Watson), Warner agreed to an acceleration provision, namely an MFEP that preserved Watson's 180-day exclusivity period in the event that another generic launched before Watson's settlement entry date.

A putative class of end payor plaintiffs (EPPs) challenged the acceleration clause, claiming it incentivized Watson to enter later than it otherwise would have and prevented generics from trying to enter the market before Watson's scheduled entry.[17] Defendants disputed EPPs' assertions in their motion to dismiss, arguing that the acceleration provision was inherently procompetitive because it facilitated early entry of Watson's generic.[18] Defendants also argued that the acceleration clause conferred value to Watson only from the opportunity to enter with its generic even earlier, which benefited competition.[19]

Denying Defendants' motion to dismiss, the Court found that the EPPs plausibly alleged that the acceleration clause was one component of an unlawful reverse payment.[20] The Court explained that it was "not prepared to hold that an acceleration clause like the one in the Watson Agreement may never be cognizable as a component of a complex settlement agreement amounting to a large and unjustified reverse payment."[21]

Later, Defendants moved for summary judgment, arguing that EPPs failed to adduce evidence showing that the acceleration clause delayed generic entry. Defendants claimed that the undisputed facts proved that the acceleration clause expedited Watson's entry date and led to additional competition because (1) other generics continued to pursue litigation with Warner and eventually entered the market; and (2) Watson, in fact, launched a Loestrin generic three weeks earlier than its entry date because its acceleration clause was triggered.[22] In addition, Defendants offered various procompetitive justifications for the acceleration provision, including expert testimony explaining how acceleration clauses facilitate patent settlements.[23]

EPPs argued in response that the acceleration clause delayed Watson's entry and deterred later filers from entering before Watson.[24] In addition, EPPs argued that generic entry was deterred because Warner was prohibited from agreeing to entry before Watson and no other generic manufacturer actually litigated to completion or entered at risk because doing so would succeed only in accelerating Watson's entry.[25] Finally, EPPs contended that the clause was valuable to Watson because it restored exclusivity that Watson had forfeited by failing to obtain FDA approval in the required time.[26]

The Court denied Defendants' motion, stating it was "satisfied that a reasonable jury could consider the acceleration clause anticompetitive" based on EPPs' expert testimony to the effect that, "absent the acceleration clause, generics would have entered earlier and that the clause deterred later filers, providing Watson with substantial value" in the form of its forfeited exclusivity.[27] The Court also rejected Defendants' proffered procompetitive justifications for the acceleration clause, concluding that a "reasonable jury could find that the agreement's anticompetitive effects outweighed the procompetitive effects."[28]

Staley v. Gilead Sciences, Inc.

Antitrust plaintiffs brought similar claims in *Staley v. Gilead Sciences, Inc.*, specifically a putative class action against Gilead Sciences, Inc. (Gilead) and other manufacturers of HIV medications alleging, among other things, that Gilead's dual MFE/MFEP acceleration clauses in a Hatch-Waxman settlements with Teva Pharmaceuticals (Teva) constituted anticompetitive reverse payments because they induced Teva to delay entry into the market and served as a disincentive for other generic manufacturers to try to enter the market before Teva.

In its motion to dismiss, Gilead argued that the acceleration clauses did not support a claim under *Actavis* because they were procompetitive. Gilead explained that if a generic manufacturer were to obtain an earlier entry date than Teva, then Teva would get its entry date advanced, thus ensuring more and not less competition.[29] In addition, Gilead contended that Plaintiffs failed to allege facts demonstrating that the acceleration clauses delayed competition, and instead theorized "that if a first-filing generic were to make the economically irrational decision to settle for an entry date without including an acceleration clause, subsequent patent challengers might then have a greater incentive to challenge the patent."[30] Citing *Actos*, Gilead argued that the settlement agreement need not encourage further theoretical competition.[31]

The Court denied Gilead's motion to dismiss, reasoning that Defendants' arguments were "problematic for at least three reasons: (1) [they] addresse[d] only the MFE, and not the MFEP (which gave Teva a preferential entry date compared to other generic manufacturers); (2) it ignore[d] Plaintiffs' theory that Teva agreed to a delayed entry date – *i.e.*, a later date than it otherwise would have – because it was given, in exchange, the benefits afforded by both the MFE and MFEP; and (3) it ignore[d] Plaintiffs' theory that the MFE/MFEP combination deterred second filers from trying to get an earlier entry date."[32]

The Court further rejected Gilead's contention that the acceleration provisions were procompetitive under *Actavis* and *Actos*. The Court explained that *Actavis* does not suggest that an early entry date relative to patent expiration is automatically procompetitive, and *Actos* merely stood for the proposition that, in that case, there was no deterrent effect with respect to generic entry.[33] Further distinguishing *Actos*, the Court stated that there were circumstances in the present case giving rise to anticompetitive concerns, namely (a) "even though Teva was allowed to enter the market prior to the patent expiration dates, the entry date was, relatively speaking, quite late – *i.e.*, close in time to the patent expiration dates (in one case, only six weeks before the patent expiration date and, in the other case, only a year before the patent expiration date)" and (b) Teva had already forfeited its 180-day ANDA exclusivity, which meant that the MFEP "resurrect[ed the] exclusivity, [which] could arguably be a significant deterrent to second filers."[34]

The Court concluded with the concession that the case would be "a closer call" if the Court were addressing only the MFE because the "second filer [would be] simply prevented from doing better than the first filer but nevertheless guaranteed *equality*," but the MFEP presented greater issues because the MFEP clause "guarantee[d] a second filer that it will be in a *worse* position compared to the first filer even where there [was] no ANDA exclusivity.[35]

California Assembly Bill 824

On January 1, 2020, California Assembly Bill 824 (AB 824) went into effect. AB 824 imposes a presumption of anticompetitive effect for certain Hatch-Waxman patent settlements. Under AB 824, patent settlements are presumptively unlawful if (1) the generic manufacturer obtains "anything of value" out of the agreement and (2) the generic manufacturer does not immediately attempt to sell its product.[36] The statute defines "anything of value" broadly to include exclusive licenses and so-called "no authorized generic" provisions,[37] but expressly excludes from the definition licenses to market a generic version of a drug before expiration of a listed patent and acceleration clauses based on the brand marketing a different dosage strength or form, among other things.[38]

AB 824 breaks from the rule of reason approach the Supreme Court established in *Actavis,* and the practical effect of the statute is to regulate almost any Hatch-Waxman patent settlement in the United States because these settlements typically apply nationally and cannot be effectively limited to exclude California, which is AB 824's jurisdictional reach. For these reasons, a consortium of generic drug manufacturers called Association for Accessible Medicines has challenged AB 824, arguing that it violates the Commerce Clause of the United States Constitution by regulating agreements not negotiated, completed, or entered in California; conflicts with the Patent Act, Hatch-Waxman Act, and the Biologics Price Competition and Innovation Act; imposes excessive fines in violation of the Eighth Amendment; and violates the Due Process clause by establishing an effectively irrebuttable presumption that covered settlements are anti-competitive and unlawful.[39]

A Path Forward

In spite of AB 824 and the courts' rulings in *Loestrin* and *Staley*, the parties' business incentives may continue to favor acceleration provisions as critical components of some Hatch-Waxman patent settlements. Thus, the question becomes how to best craft acceleration provisions to manage antitrust litigation risk. Combined, *Actos, Loestrin*, and *Staley* provide a roadmap.

In general, federal courts have found that MFEs are less likely to run afoul of *Actavis*. For example, in *Actos*, the court dismissed plaintiffs' claim that MFE provisions were unlawful reverse payments because the impact of the MFE provisions would be neutral if another generic failed to enter before the settlements' entry dates, and they would be procompetitive due to increased generic competition, if another generic triggered the settlements' MFEs.[40] By contrast, the courts in *Loestrin* and *Staley* distinguished the MFE at issue in *Actos* with MFEPs or MFEP/MFE combinations in those litigations. Both courts allowed plaintiffs' claims to proceed, and the *Staley* court expressly stated that would be "a closer call" if the court had been addressing only an MFE.[41]

But neither *Loestrin* nor *Staley* was decided on the merits, and the precedents may leave open avenues to agreeing to MFEPs. That is, the courts were concerned with preserving incentives for other generics to continue to pursue market entry,[42] and they were skeptical of provisions that significantly delayed entry towards the end of the brand manufacturer's patent term or conferred something of value to the generic firm other than early entry (i.e., exclusivity). These concerns may be managed in draft acceleration clauses moving forward.

Further, although AB 824 heightens the litigation risk and potentially augments litigation costs, the statute does not make *per se* illegal acceleration provisions other than those expressly carved out of the definition of "anything of value." Rather, pending the legal challenges to AB 824 itself, the statute allows defendant manufacturers to rebut the presumption of anticompetitiveness by demonstrating the settlement agreement generated procompetitive benefits. As discussed above, these procompetitive benefits may include facilitation of settlements with early entry dates and, if triggered, increases in the number of competitors able to launch a generic. Absent the concerning aspects of the *Loestrin* and *Staley* settlements, these procompetitive benefits may outweigh the presumption of anticompetitive effect.

Thus, acceleration clauses can be drafted with the following best practices in mind:

- Allow for an incentive for other generic manufactures to continue to pursue market entry. For example, the parties might draft the settlement agreement to merely prohibit the brand manufacturer from offering a licensed entry date more favorable than the first-settling generic firm (or restrict later licensed entry to 180 days after the first-settling generic's entry in the case of MFEPs). This would allow the generic firms to continue litigating to judgment in its patent infringement action or else enter at risk.
- Limit MFEPs to instances in which the settling generic firm has ANDA first-filer exclusivity. Notably, the courts in *Loestrin* and *Staley* addressed situations where the MFEPs revived exclusivity that had already lapsed, thereby creating value beyond the status quo, plus an early entry date.
- Ensure that market entry is reasonably in advance of the end of the patent term. This may impair settlements where the brand manufacturer believes its patent is particularly strong, but it will manage what the *Staley* court termed a "yellow flag" supporting plaintiffs' argument of anticompetitive effect.[43]

1. *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).
2. *Actavis, Inc.*, 570 U.S. at 144.
3. In fiscal year 2016, 192 of 226 Hatch-Waxman settlements restricted the generic manufacturer's ability to market its product. *See* Bureau of Competition, 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, *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf (Dec. 3, 2020) (hereinafter, "FTC Rep. re FY2017 Agreements").
4. *Actavis, Inc.*, 570 U.S. at 154.
5. *See In re Schering-Plough Corp.*, 136 F.T.C. 956, 987 (2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005) ("A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent. [Rather, i]n light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations.").
6. *Actavis, Inc.*, 570 U.S. at 154.
7. *Id.*
8. *Id.* at 159.
9. FTC Rep. re FY2017 Agreements.
10. *See In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015).
11. *Id.* at *6, *15.
12. *Id.* at *12.

13. *Id.* at *13-15.
14. *Id.* at *15.
15. *Id.* at *16.
16. *Id.*
17. *In re Loestrin 24 FE Antitrust Litig.*, 261 F. Supp.3d 307, 333-34 (D.R.I 2017) (quoting EPPs' complaint).
18. *Id.*
19. *Id.*
20. *Id.* at 334.
21. *Id.*
22. *In re Loestrin 24 FE Antitrust Litig.*, Mem. ISO Defs.' Mot. for Summary Judgment, 1:13-md-2472-S-PAS (D.R.I.), ECF No. 913 at 42-43; *In re Loestrin 24 FE Antitrust Litig.*, Mem. Reply ISO Defs.' Mot. for Summary Judgment, 1:13-md-2472-S-PAS (D.R.I), ECF No. 1172 at 32-33.
23. *In re Loestrin 24 FE Antitrust Litig.*, Mem. ISO Defs.' Mot. for Summary Judgment, 1:13-md-2472-S-PAS (D.R.I), ECF No. 913 at 42-43.
24. *In re Loestrin 24 FE Antitrust Litig.*, Mem. in Opp'n of Defs.' Mot. for Summary Judgment, 1:13-md-2472-S-PAS (D.R.I), ECF No. 1060 at 32-34.
25. *Id.*
26. *Id.*
27. *In re Loestrin 24 FE Antitrust Litig.*, 433 F. Supp.3d 274, 321 (D.R.I. 2020).
28. *Id.*
29. *Staley v. Gilead Sciences, Inc.*, Mem. ISO Defs.' Mot. to Dismiss, 3:19-cv-02573 (N.D. Cal.), ECF No. 913 at 26-27.
30. *Id.* at 28.
31. *Id.* at 28-29.
32. *Staley,* 446 F. Supp. 3d at 610.
33. *Id.* at 610-11.
34. *Id.* at 612.
35. *Id.* (emphasis in original).
36. AB 824 § 134002(a)(1).
37. *Id.* at § 134002(a)(1)(A).
38. *Id.* at § 134002(a)(2)(A)-(F).
39. *Ass'n for Accessible Medicines v. Bacerra*, 2:20-cv-01708, is pending in the Eastern District of California.
40. *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, *15.
41. *Staley,* 446 F. Supp. 3d at 612.
42. Economists have argued that this is not a valid concern, stating "firms regularly make the decision to enter with a generic even knowing that they will face competition from a generic already on the market. . . . [C]ompetition among generic companies supplying the same drug will occur as long as new suppliers can obtain sufficient sales to be profitable, including gaining sales by underpricing the existing suppliers." *See In re Loestrin 24 FE Antitrust Litig.*, Brief of Antitrust Economists as *Amici Curiae* ISO of Defendants-Appellees, 14-2071 (1st Cir.), Entry ID. 5933207 at 11-12. Courts have yet to squarely address this argument, even though later generic entry place in *Loestrin*, despite the existence of the MFE/MFEP.
43. *Staley,* 446 F. Supp. 3d at 612.