# REMS: The Next Pharmaceutical Enforcement Priority?

BY DARREN S. TUCKER, GREGORY F. WELLS & MARGARET E. SHEER

CONGRESS PASSED THE FOOD AND Drug Administration Amendments Act of 2007 (FDAAA) to address potential serious side effects of beneficial drugs. Under the FDAAA, the Food and Drug Administration may require the use of risk evaluation and mitigation strategies (REMS) over and above professional labeling, to ensure that a drug's benefits outweigh its risks.

The Federal Trade Commission and the generic drug industry have raised concerns that branded drug companies are using these REMS to delay or prevent generic entry. They assert that branded firms are using REMS-mandated distribution restrictions to inappropriately limit access to product samples generic drug developers need for bioequivalence testing, a predicate for FDA approval of generic drugs.

Though the FTC has not yet brought an enforcement action, the agency has identified REMS misuse as an enforcement priority, has opened several investigations, and has filed an amicus brief in private litigation explaining its concerns.[1] For their part, generic drug companies have filed several antitrust claims against branded drug companies and raised their concerns with the FDA.

While two district courts have permitted antitrust claims to proceed, the extent to which the antitrust laws require branded drug companies to provide generic firms access to product samples for REMS-restricted drugs is unclear. This issue is of growing importance, given that nearly 40 percent of new drugs are subject to REMS restrictions, many of which include distribution restrictions.[2]

## An Overview of REMS

In 1984, Congress enacted the Hatch-Waxman Act, or the Drug Price Competition and Patent Term Restoration Act, to expedite and streamline generic drug approvals and related patent litigation.[3] The Act made it easier for generic drug manufacturers to demonstrate the safety and efficacy of their products, while also protecting branded manufacturers' patent rights. In doing so, Hatch-Waxman intended to foster competition between branded and generic drugs, to the ultimate benefit of consumers.[4] Under the Hatch-Waxman Act, generic firms seeking FDA approval must demonstrate, *inter alia*, that a generic formulation is bioequivalent to the brand drug (often referred to as the Reference Listed Drug (RLD)); this testing requires access to a limited amount of the brand product.

Under the FDAAA, the FDA may require the sponsor of a New Drug Application (NDA) to implement a REMS if "necessary to ensure that the benefits of the drug outweigh the risks of the drug."[5] The REMS may include a medication guide, a patient package insert, a communication plan, and, for drugs associated with serious risks, elements to assure safe use (ETASU). ETASU are special medical interventions or other actions intended to mitigate a drug's risks and may include, for example, requirements that the drug is dispensed with evidence of safe-use conditions, such as laboratory test results, or that the drug is dispensed only in certain health care settings (e.g., infusion settings or hospitals).[6] An abbreviated new drug application (ANDA) for a listed drug subject to a REMS must include a comparable REMS to that required of the brand drug equivalent.[7]

The FTC and generic drug companies have alleged that some branded firms have used REMS-restricted distribution systems to prevent generic firms from obtaining product samples through customary distribution channels. At the same time, these branded firms have refused to sell to the generic firms directly, thereby precluding them from satisfying FDA approval requirements. In the generic companies' view, these practices run afoul of the FDAAA, which prohibits branded drug companies from using ETASU "to block or delay approval" of an ANDA.[8] Although the mechanism is different, the FTC's concern is similar to its objection to "pay-for-delay" settlements: in the agency's view, they both involve branded firms impeding generic entry.

To date, three private antitrust lawsuits have been brought over branded drug companies' refusal to sell product samples to their would-be generic rivals:

- In 2008, Lannett Co. sued Celgene Corp. under the essential facilities doctrine seeking samples of Thalomid, a leprosy treatment.[9] The case settled after the district court denied Celgene's motion to dismiss.[10]
- In 2012, Actelion Pharmaceuticals filed an action against Apotex and other generic firms seeking a declaratory judgment that it had no obligation to supply samples of Tracleer, which is used to treat pulmonary arterial hypertension.[11] The generic firms counterclaimed, asserting Sherman Act and other violations.[12] The case settled in February 2014, a few months after the district court judge stated at oral argument that he intended to deny Actelion's

*Darren Tucker is a partner, Greg Wells is of counsel, and Margaret Sheer is an associate with Bingham McCutchen LLP in Washington, D.C. Darren Tucker was previously Attorney Advisor to FTC Commissioners J. Thomas Rosch and Joshua D. Wright.*

motion for judgment on the pleadings seeking dismissal of the counterclaims.[13]

- In April 2013, Accord Healthcare and other generic firms sued Acorda over that firm's alleged refusal to provide samples of Ampyra, a multiple sclerosis treatment.[14] The case settled a month later.

In addition, generic drug companies have sought the FDA's assistance. In August 2013, the FDA, in response to a 2009 citizen petition, stated that REMS requirements should not preclude branded firms from selling product samples to potential generic rivals.[15] The FDA noted that it had approved several generic firms' proposed bioequivalence "study protocols and related documents . . . to ensure that they contain safety protections" comparable to those required by the branded drug's REMS.[16] Where generic firms have "report[ed] difficulty obtaining samples of the RLD to complete necessary testing, [the] FDA has sent letters" to the branded firms that confirm the review of the bioequivalence protocols.[17] Nevertheless, the FDA appeared to disavow bringing any enforcement actions and asserted that "issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by the FTC, which is the Federal entity most expert in investigating and addressing anticompetitive business practices."[18]

## Are Refusals to Supply a REMS-Restricted Drug a Form of Exclusionary Conduct?

The FTC and generic drug companies have alleged that the refusal to supply product samples for certain REMS-restricted drugs can constitute a violation of Section 2 of the Sherman Act. To state a Section 2 claim under this theory, the plaintiff would have to show that the branded firm possessed monopoly power in the relevant market and acquired or maintained that monopoly power through exclusionary conduct.[19] We start our analysis with the assumption that the branded firm has monopoly power and focus on the question of whether the branded firm's refusal to deal could constitute exclusionary conduct.

The Supreme Court has held that firms do not have a duty to assist rivals except under narrow circumstances.[20] However, the "high value" placed on the right "to refuse to deal with other firms does not mean that the right is unqualified."[21] At the Supreme Court, the high water mark for refusal-to-deal claims occurred in *Otter Tail*[22] and *Aspen Skiing*.[23]

In its most recent refusal-to-deal case, *Trinko*, the Supreme Court appeared to retrench, describing *Aspen Skiing* as a "limited exception" that is "at or near the outer boundary of § 2 liability."[24] The Court identified two characteristics that supported finding that the *Aspen Skiing* refusal to deal was anticompetitive. First, in *Aspen Skiing*, "[t]he unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end."[25] In *Trinko*, there was no voluntary course of dealing, so the defendant's "prior conduct sheds no light upon the motivation of its refusal to deal."[26] Second, while in *Aspen Skiing*, "the defendant's unwillingness to renew the ticket even if compensated at retail price revealed a distinctly anticompetitive bent," in *Trinko*, the defendant could only obtain statutory, cost-based compensation, so its reluctance to sell at that price "tells us nothing about dreams of monopoly."[27]

Lastly, the *Trinko* Court identified three policy reasons why compelling a monopolist to deal with its rivals is disfavored. Forced sharing "may lessen the incentive for the monopolist, the rival, or both to invest" in developing economically beneficial facilities.[28] It also "requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill-suited."[29] Finally, compelling cooperation between competitors could, perversely, lead them to collude, which the Court described as "the supreme evil of antitrust."[30]

**Trinko*'s "Voluntary . . . Course of Dealing" Language.*** Both before and after the *Trinko* decision, there has been a robust debate regarding the circumstances under which a monopolist has a duty to deal with rivals. Every U.S. court of appeals to address the issue after *Trinko* has held or suggested in dicta that a Section 2 refusal to deal claim requires the monopolist to have terminated a voluntary prior course of dealing, as in *Aspen Skiing*;[31] although at least one lower court has held to the contrary.[32]

Under this interpretation, it would be difficult in most cases for a generic firm to state a Section 2 claim for a branded firm's refusal to supply RLD samples for bioequivalence testing. In theory, a prior course of dealing could arise if the branded firm had a pre-existing supply agreement with the generic firm for the drug at issue. Absent that unlikely scenario, the generic firm might be able to establish a prior course of dealing by showing that the branded company had sold samples of other drugs to the same generic or had sold the drug at issue to distributors, retailers, independent testing organizations, or other generic manufacturers.

A potential stumbling block for those arguments is language in *Trinko* referring to a "course of dealing *with its rivals*."[33] Likewise, lower courts that have adopted a prior course of dealing requirement have held that a prior course of dealing with retail customers, as opposed to the putative rivals, is insufficient under *Trinko*.[34]

**Otter Tail/*Profit Sacrifice Tests.*** Some have asserted that a prior course of dealing is not required under *Trinko* and *Aspen Skiing*. The FTC endorsed this view in its amicus curiae brief in *Actelion*. There, the Commission argued in a brief endorsed by all four sitting commissioners that "neither the Supreme Court nor the Third Circuit has ever held that a prior course of dealing is an essential element of a refusal to deal claim."[35]

Under one view, a refusal to deal claim is viable where the monopolist forsakes short-term profits to maintain a long-run monopoly, i.e., when the monopolist's refusal to deal fails the profit-sacrifice test. Under that approach (and its "no economic sense" cousin), conduct is deemed exclusionary where it would not be economically rational (i.e., profit maximizing) for the defendant absent a reduction in competition. Support for this test can be found in the *Trinko* Court's explanation that liability in *Aspen Skiing* was predicated on the defendant's "willingness to forsake short-term profits to achieve an anticompetitive end."[36]

Under another view, which finds its support in *Otter Tail*, a monopolist cannot refuse to sell a product to rivals that it voluntarily sells to other customers. In *Otter Tail*, the Supreme Court upheld an injunction requiring upstart competitors' access to the monopolist's power supply infrastructure, which they needed to compete in the market, even though there was no prior course of dealing.[37] Far from limiting or overruling *Otter Tail*, *Trinko* favorably cited *Otter Tail*, describing it as a situation where "the defendant was already in the business of providing a service to certain customers (power transmission over its network), and refused to provide the same service to certain other customers."[38] What distinguished *Trinko* from both *Otter Tail* and *Aspen Skiing* was not the termination of a prior course of dealing, but instead the fact that "the services allegedly withheld [were] not otherwise marketed or available to the public."[39]

Under either interpretation, a generic firm that has proposed purchasing RLD samples at full retail price would appear to have a basis for a Section 2 claim. As in *Aspen Skiing*, the generic firm's willingness to compensate the branded firm at full retail price supports an inference that the refused sales would have been profitable for the branded firm. And, like the defendant in *Otter Tail*, the branded firm is already voluntarily selling the product to non-competitors and only refusing to sell to customers that it believes will be rivals.

Because the branded firm already sells at retail, many of the problems with "forced sharing" that concerned the *Trinko* Court would appear to be minimized in this context. Requiring sales of RLD samples would be unlikely to reduce the monopolist's incentive to innovate because generic access to product samples and, ultimately, generic competition was contemplated under the Hatch-Waxman Act.

Requiring a one-time sale of RLD samples at the branded company's pre-existing retail price would also limit the extent to which a court would have to oversee the parties' commercial relationship. That relationship would be relatively minimal and of short duration, reducing the risk of collusion.

There is, however, a question of whether the branded drug's retail price is the appropriate benchmark for the profit-sacrifice test. Proper application of that test in this context may need to reflect the costs to the branded firm of any adverse events from the generic firm's testing or ultimate sale of the product. For example, in some states, a branded firm can be liable to users who only took the generic product.[40] In response to any adverse events from the generic, the FDA could institute a more demanding REMS for *both* the branded and generic firm, which could result in higher distribution costs or lower sales to the branded firm.[41]

Although these risks are to some degree inherent in a branded firm's retail sales, those costs are spread out over all of the branded units sold. The risks are magnified in the context of sales to a generic firm because the branded firm will receive revenue associated with sales of several hundred branded units but may be faced with risks associated with the sale of millions of generic units. Because the branded firm's retail price to consumers may not allow it to recoup all of the costs from sales to a generic competitor, branded firms could argue that a generic firm should be required to pay substantially above the retail price for the RLD to satisfy the profit-sacrifice test.

Generic firms could counter that Congress already accounted for these costs when it adopted the Hatch-Waxman Act and assumed that generic firms would have access to the RLD for bioequivalence testing purposes. In other words, the risks to the branded firm from generic testing or sales are deliberate byproducts of the Hatch-Waxman Act and are not unique to REMS-restricted drugs.

As an alternative to paying more than the retail price, a generic firm could attempt to mitigate potential costs by agreeing to indemnify the branded firm. Such an agreement would have the benefit of ensuring that the generic's proposed retail purchase of RLD samples covers all of the branded firm's reasonable costs associated with that sale, without requiring that the parties negotiate, or that a court determine on an *ex post* basis, what specific costs should be covered by the generic, how to measure those costs, and how to fairly reflect them in a price for a small batch of drug samples.

***The Essential Facilities Doctrine.*** A branded firm's refusal to supply REMS-restricted drug samples to a putative generic competitor could also be challenged under the essential facilities doctrine, which generally requires (1) a monopolist's control over an essential facility; (2) the competitor's inability to reproduce the facility; and (3) the monopolist's denial of access to the facility to a competitor when (4) it is feasible to do so.[42] To state a claim under this theory, the generic firm would argue that it is impossible to enter the market for a particular drug without samples from the branded firm, rendering the monopolist's control over samples an essential facility subject to compulsory sharing under the antitrust laws.

In *Trinko*, the Supreme Court described "essential facilities" as a "doctrine crafted by some lower courts" that the Court had "never recognized."[43] While *Trinko* expressly declined "to either recognize . . . or repudiate" it,[44] many lower courts have interpreted that decision as expressing skepticism about the continuing vitality of a Section 2 claim based on the essential facilities doctrine.[45] Nevertheless, *Lannett v. Celgene* was pled only as an essential facilities case, and the court denied the defendant's motion to dismiss in summary fashion.[46]

Even where courts accept the essential facilities doctrine, the standard can be challenging to satisfy in practice, particularly in showing that a facility is truly essential. Most successful cases invoking the doctrine involve physical infrastructure that would be prohibitively expensive (or impossible) to replicate, i.e., a natural monopoly.[47] Given that bioequivalence testing is an absolute barrier for a successful ANDA application, generic drug companies could argue that the branded firm's RLD product samples are analogous to those physical facilities.

Branded firms have argued that there are other means to enter the market, such as by filing a NDA for an equivalent compound. Generic firms counter that requiring resort to the more expensive NDA path involves substantially increased costs and delay compared to an ANDA, and undermines the Hatch-Waxman Act's goal of encouraging generic entry.[48]

Branded firms could also argue that the denial of access to the essential facility must be used to harm competition in a downstream market, a position that some courts have accepted.[49] A branded firm's refusal to supply RLD samples would appear to only affect competition in the market that includes that drug, as opposed to allowing the branded firm to extend its monopoly into another market.

With respect to the last element of the essential facilities test—whether providing access is feasible—branded companies argue that generic access to the RLD is not permissible under FDA-imposed REMS distribution requirements. We are not aware of any REMS to date that restrict sales from a branded to generic drug company for the purpose of conducting bioequivalence or other testing. In addition, the FDA has issued letters confirming that a branded firm's provision of RLD samples to a generic firm for bioequivalence testing does not violate a REMS distribution protocol.

***A New Duty to Deal?*** Even if branded firms' conduct does not violate existing Section 2 precedent, the courts could craft a new duty to deal for REMS-restricted drugs. The *Trinko* Court acknowledged that there might be new situations under which a monopolist has a duty to deal with rivals, especially as "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."[50]

The Hatch-Waxman Act was intended to improve consumer access to lower-cost generic drugs by allowing the generic firm to rely on the branded firm's safety and efficacy testing. To work, that statutory framework requires that the generic firm use the RLD for bioequivalence testing. In adopting the REMS regime, Congress further provided that branded firms shall not use the REMS to "block or delay" generic competition. It did not, however, provide a statutory mechanism to compel the branded firm to provide samples to the generic firm. To the extent that existing Section 2 precedent does not compel access to RLD samples, generic firms could argue that recognizing a new duty to deal may be the only way to effectuate Hatch-Waxman.

Although the *Trinko* Court did not explain when a new duty to deal would be appropriate, it did find that a "regulatory structure designed to deter and remedy anticompetitive harm" weighed against creating a new duty to deal.[51] Where, however, "there is nothing built into the regulatory structure which performs the antitrust function, the benefits of antitrust are worth its sometimes considerable disadvantages."[52]

Pharmaceutical companies operate in a heavily regulated environment, including REMS programs. The FDAAA prohibits a branded firm from using ETASU requirements within a REMS protocol "to block or delay approval" of a generic firm's ANDA.[53] The FDA has tools to enforce this and other REMS-related regulations, including deeming drugs "misbranded"[54] and seeking civil penalties of up to ten million dollars.[55] This extensive regulatory oversight suggests that the courts may hesitate to create a new duty to deal. Whether the FDA has actually exercised that regulatory authority is arguably irrelevant under *Trinko*.[56]

Nevertheless, it is not clear that this regulatory structure is "designed to deter and remedy anticompetitive harm" or that the FDA is "perform[ing] the antitrust function" of promoting competition. To date, the FDA has not undertaken any enforcement actions and has stated that it believes that it lacks authority to compel sales of RLD samples to a generic firm and that market competition issues "would be best addressed by the FTC."[57] Thus, the FDA's actions and statements generally suggest that its enforcement intentions are limited to the health-and-safety aspects of REMS protocols and do not promote the "antitrust function," unlike the regulators in *Trinko*.

## Justifications for a Refusal to Deal

Even if refusal to supply REMS-restricted product samples could form the basis for a Section 2 claim, a branded firm may have legitimate business justifications for its refusal to deal. A monopolist's conduct that is deemed exclusionary under Section 2, including refusals to deal, can be justified by a legitimate business reason.[58]

Branded firms have typically justified their refusals to sell samples by arguing that the generic firm will not ensure the safe use of the drug. REMS-restricted drugs—particularly those with ETASU—are likely to be more dangerous or more prone to abuse than other drugs. Any injuries caused by the generic could lead to product liability for the branded firm, and could cause the FDA to require additional REMS elements or, in extreme cases, withdrawal of the drug from the market.[59] Adverse events associated with the generic product could also hurt the branded firm's reputation, a concern that courts have recognized as a valid business justification.[60]

As the *Actelion* court found,[61] these safety concerns should not automatically preclude liability for the branded firm's refusal to deal. The Hatch-Waxman Act presumes that generic firms will obtain RLD samples for bioequivalence testing, and the FDAAA does not create a separate testing protocol for drugs subject to REMS. The FDA regulates that testing process and has increasingly been reviewing and approving generic firms' testing protocols. Courts are unlikely to second-guess the FDA's approval of those protocols. The generic firm might offer to indemnify or otherwise compensate the branded firm for any costs associated with the generic's bioequivalence testing, which should help alleviate any safety concerns. Generic firms may also be able to raise questions about a safety defense being pretexual where the branded firm provides product samples to other third parties. Thus, whether a health or safety defense applies is likely to turn on a fact-intensive analysis.

Allowing the branded firm to conduct due diligence into the generic's proposed testing protocols may also help alleviate any legitimate safety concerns. But this path also presents several downsides, including potential costs for the branded firm that it, quite reasonably, may not be interested in bearing. And encouraging this sort of cooperative relationship could lead to illegal collusion among potential competitors.[62]

Branded firms have asserted that they have an additional justification for their refusal to sell to competitors when a drug is patented. The Supreme Court has held that the unilateral refusal to sell a patented product is not actionable under the antitrust laws.[63] The FTC and the Department of Justice have similarly concluded "that liability for mere unconditional, unilateral refusals to license will not play a meaningful part in the interface between patent rights and antitrust protections."[64]

The issue is more complex in the pharmaceutical industry, however. The Bolar Amendment allows generic firms to perform the testing required to submit an ANDA for FDA approval without giving rise to an infringement claim.[65] Thus, the fact that a product may be patented does not appear, in this context, to lend anything to the refusal-to-deal analysis, because the generic firm's proposed use of the product would not infringe the branded firm's patent.

### Injury and Causation

For either private litigants or the government, plaintiffs bear the burden of showing an anticompetitive effect and causation between the refusal to deal and competitive injury.[66] It is unlikely that a generic firm could establish anticompetitive effects solely from being denied the opportunity to conduct bioequivalence testing. Instead, a plaintiff would likely have to show a causal chain that links the generic's inability to obtain samples for bioequivalence testing to injury to competition, which would to require the generic firm to show the following:

First, the generic would need to establish that it is both capable of and actually intends to conduct bioequivalence testing and submit an ANDA. For experienced generic drug companies, satisfying this requirement should not be particularly difficult.

Second, the generic would have to show that it was unable to procure the branded drug from other legitimate sources, such as U.S. distributors. Where the branded firm and its distributors have resolutely refused to sell to the generic, satisfying this requirement will be straightforward. However, where the branded firm has not refused to sell, but has instead demanded information or particular terms of sale, showing an inability to procure will be more challenging. Under those circumstances, the generic firm would likely have to demonstrate that further efforts to negotiate would be futile.

Third, the generic may need to show that there are no other impediments to the FDA approving its ANDA, such as marketing exclusivity for the branded firm. For example, the branded product may hold exclusivity under the Orphan Drug Act,[67] or the five-year exclusivity period for a New Chemical Entity.[68] If the potential generic entrant was legally precluded from entering even if it had product samples, courts may find it difficult to conclude that the refusal to provide testing samples had any anticompetitive effect.[69]

**Beyond potential antitrust exposure under Section 2, refusal to provide REMS-restricted product samples to a generic drug company could raise concerns under Section 5 of the FTC Act.**

### Liability Under Section 5 of the FTC Act

Beyond potential antitrust exposure under Section 2, refusal to provide REMS-restricted product samples to a generic drug company could raise concerns under Section 5 of the FTC Act.[70] Presumably, a proceeding under Section 5 would be predicated on harm to the competitive process established by Congress in the Hatch-Waxman Act and reinforced by the explicit language of FDAAA prohibiting the use of REMS to impede generic entry. To our knowledge, the FTC has not publicly discussed the potential application of Section 5 in this context, but the number of recent Section 5 cases involving novel conduct suggests at least the possibility for such action.[71]

For the FTC, the principal advantage to proceeding under Section 5 would be the ability to base a case on the "block or delay" language in the FDAAA rather than under the likely more demanding Section 2 refusal-to-deal standards. Nevertheless, even under a standalone Section 5 case, the FTC would still need to establish clear harm to competition and consumers,[72] and the branded firm would have the opportunity to justify its conduct.[73]

The FTC could plausibly argue that Congress's clear intent in the FDAAA offers a limiting principal for use of its Section 5 authority. Likewise, the business community has been on notice since the enactment of the FDAAA in 2007 that the use of REMS to prevent generic entry is prohibited. In addition, the FTC has made clear in Congressional testimony, its *Actelion* amicus brief, speeches, and interviews going back to at least 2008 that the agency views this practice as potentially problematic under the antitrust laws.

Finally, the agency could assert that use of Section 5 would be appropriate here given the agency's institutional advantages in evaluating Hatch-Waxman-related competition issues. The agency has studied competition in the pharmaceutical sector and has been investigating and challenging alleged anticompetitive conduct under the Hatch-Waxman Act for over a decade—its views largely being vindicated in the Supreme Court's *Actavis* decision.[74] Based on the agency's public statements, the FTC has been monitoring pharmaceutical distribution restrictions and related legal and regulatory developments for a number of years as well.

Application of Section 5 in this context appears to be consistent with several of the criteria set forth by Commissioners Joshua D. Wright and Maureen K. Ohlhausen in their recent Section 5 policy statements.[75] For example, both point to injury to competition as the *sine qua non* for a standalone Section 5 claim. The FTC has asserted that the improper use of restricted distribution programs "may impede generic competition," "preserve a brand firm's monopoly indefinitely," and lead to higher prices for consumers—each of which suggests possible injury to competition.[76] Use of Section 5 would not appear to raise any risks of institutional conflict, a concern cited in Commissioner Ohlhausen's policy statement, because the FDA has stated its intention to defer to the FTC in REMS-related competition enforcement matters.

Nevertheless, application of Section 5 in this context could raise a number of concerns, in particular that it could be viewed as an end run around the standards for refusals to deal set forth by the Supreme Court in *Trinko* and *Aspen Skiing*.[77] Former FTC Commissioner J. Thomas Rosch, a strong proponent of the use of the FTC's standalone Section 5 authority, acknowledged that Section 5 should not be used to prosecute conduct "clearly covered by the Sherman or Clayton Acts . . . just because there is a failure of proof of one of the elements of those statutory offenses."[78] And in its own investigations, the Commission has at times been cautious of overextending the reach of Section 5 in situations where a Section 2 claim under the Sherman Act could not be proven.[79]

Use of Section 5 would also raise concerns that liability could be based on the violation of nearly any federal statute, even one enforced by another federal agency. That type of redundancy seems to be precisely the type of interagency conflict the FTC should avoid, according to Commissioner Ohlhausen's policy statement, and may not have been intended by Congress in enacting the governing legislation. Commissioner Ohlhausen's policy statement also requires Section 5 cases to be predicated on the use of robust economic evidence to establish negative effects on consumer welfare and to be preceded by clear guidance to the business community. These factors appear to weigh against the use of Section 5, at least until the FTC develops empirical data on the alleged injury to competition from blocking generic access to product samples through a REMS program and advising the business community that this conduct may violate Section 5.

## Conclusion

The questions addressed by this article are unlikely to be the only antitrust issues arising from REMS-related distribution systems. In the *Actelion* case, for example, the generic firms alleged a Section 1 conspiracy between the branded firm and its distributor, as well as a broader "course of conduct" claim. In theory, antitrust issues could arise regarding the REMS itself or access to the branded firm's REMS program, which is ordinarily supposed to be shared by the branded firm with any generic rivals.[80]

In addition, even the question of a branded firm's duty to deal under Section 2 for REMS-restricted drugs may involve more complex circumstances than addressed in this article. For example, if a branded firm supplies a REMS-restricted drug to a single generic drug company but refuses to supply other firms, has there been a refusal to deal and, if so, does the prior sale create a prior course of dealing under *Trinko*? What if a branded firm refuses outright to supply REMS-restricted product samples but one or more generic rivals obtain samples anyway? Finally, what if the REMS has no limitations on distribution (or there is no REMS) but the branded firm prohibits its distributors from selling to rivals? As the number of drugs covered by REMS program continues to expand, the courts, the FTC, and the pharmaceutical industry will need to grapple with increasingly complex competition issues involving pharmaceutical distribution systems. ■

1 *See, e.g.*, Brief for Fed. Trade Comm'n as Amicus Curiae, Actelion Pharms. Ltd. v. Apotex Inc., No. 12-05743 (D.N.J. Mar. 11, 2013) [hereinafter FTC Amicus Brief]; *see also Oversight of the Enforcement of the Antitrust Laws: Hearing Before the S. Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, 113th Cong. 7 (2013) (statement of Edith Ramirez, Chairwoman, Fed. Trade Comm'n).

2 Brief for Generic Pharm. Ass'n as Amicus Curiae in Support of Defendants/Counterclaim Plaintiffs at 3, Actelion Pharms. Ltd. v. Apotex Inc., No. 12-05743 (D.N.J. Mar. 11, 2013).

3 Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

4 As described by the FDA's Chief Counsel, "The Hatch-Waxman Amendments were intended to balance two important public policy goals. First, Congress wanted to ensure that brand-name (also known as innovator) drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the statutory patent protection and marketing exclusivity for these new drugs has expired, consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs." *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments): Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (2003) (statement of Daniel E. Troy, Chief Counsel, U.S. Food & Drug Admin.).

[5] 21 U.S.C. § 355-1(a) (as amended by the FDAAA, Pub. L. No. 110-85, § 505-1, 121 Stat. 823, 926 (2007)). In the case of pre-existing drugs whose NDAs contained REMS elements, the FDAAA deemed those drugs to have REMS as well. § 505-1, 121 Stat. at 926–27.

[6] 21 U.S.C. § 355-1(f)(1); U.S. Food & Drug Admin, A Brief Overview Of Risk Evaluation & Mitigation Strategies (REMS) 13, *available at* http://www.fda.gov/downloads/aboutfda/transparency/basics/ucm328784.pdf.

[7] § 355-1(i)(1)(B).

[8] § 355-1(f)(8).

[9] Complaint, Lannett Co. v. Celgene Corp., No. 2:08-cv-03920 (E.D. Pa. Aug. 15, 2008).

[10] *See* Erin Coe, *Lannett Cuts Deal with Celgene in Thalomid Antitrust Case*, Law360 (Dec. 7, 2011).

[11] Complaint, Actelion Pharm. Ltd. v. Apotex, Inc., No. 1:12-cv-05743 (D.N.J. Sept. 14, 2012). In its Answer, defendant Roxane Laboratories, Inc. also alleged that Actelion failed to provide it with samples of its product Zavesca, which is used to treat Gaucher's Disease. *See* Answer of Roxane Labs., Inc. at 20, *Actelion*, No. 1:12-cv-05743 (D.N.J. Nov. 27, 2012).

[12] Answer of Apotex, Inc. & Apotex Corp. at 24–28, *Actelion*, No. 1:12-cv-05743 (D.N.J. Nov. 27, 2012); Answer of Roxane Labs., Inc. at 40–45, *Actelion*, No. 1:12-cv-05743 (D.N.J. Nov. 27, 2012); Answer of Actavis Elizabeth LLC at 22–26, *Actelion*, No. 1:12-cv-05743 (D.N.J. Dec. 26, 2012).

[13] Order of Dismissal, *Actelion*, No. 1:12-cv-05743 (D.N.J. Feb. 28, 2014); Transcript of Proceedings, *Actelion*, No. 1:12-cv-05743 (D.N.J. Oct. 17, 2013) [hereinafter *Actelion* Transcript]. The court did not issue a written opinion on the motion for judgment on the pleadings.

[14] Complaint, Accord Healthcare v. Acorda Therapeutics, No. 0:13-cv-60742 (S.D. Fla. Apr. 1, 2013).

[15] Partial Petition Approval & Denial at 6, No. FDA-2009-P-0266 (Aug. 7, 2013) ("FDA will not consider it a violation of the REMS for the RLD sponsor to provide . . . a sufficient quantity of the drug to allow [for bioequivalence testing]."). In its Citizen Petition, Dr. Reddy's complained about Celgene's refusal to provide another form of thalidomide, branded as Revlimid. *See* Citizen Petition of Dr. Reddy's Laboratories, Inc. at 7–10, No. FDA-2009-P-0266 (June 10, 2009). The FDA Citizen Petition process allows interested persons to request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30.

[16] Partial Petition Approval & Denial at 6, No. FDA-2009-P-0266 (Aug. 7, 2013). The FDA indicated it intends to offer guidance to streamline that procedure. *Id.*

[17] *Id.*

[18] *Id.* at 7.

[19] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, L.L.P., 540 U.S. 398, 407 (2004).

[20] *See Trinko*, 540 U.S. at 408 ("[A]s a general matter, the Sherman Act does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." (internal citation and quotation marks omitted)); Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 600 (1985) ("[E]ven a firm with monopoly power has no general duty to engage in a joint marketing program with a competitor."); Associated Press v. United States, 326 U.S. 1, 14–15 (1945) ("[T]he owner of the property can choose his associates and can, as to that which he has produced by his own enterprise and sagacity, efforts or ingenuity, decide for himself whether and to whom to sell or not to sell.").

[21] *Aspen Skiing*, 472 U.S. at 600.

[22] Otter Tail Power Co. v. United States, 410 U.S. 366, 378 (1973) (affirming district court's finding that incumbent power company's refusals to allow new municipal power companies to interconnect with its transmission system violated Section 2 because its "refusals to sell at wholesale or to wheel were solely to prevent municipal power systems from eroding [Otter Tail's] monopolistic position").

[23] *Aspen Skiing*, 472 U.S. at 611 (upholding jury verdict that dominant owner of ski facilities violated Section 2 when it canceled preexisting joint ticket program with smaller rival).

[24] *Trinko*, 540 U.S. at 409.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.* at 407–08.

[29] *Id.* at 408.

[30] *Id.*

[31] Novell, Inc. v. Microsoft Corp., 731 F.3d 1064, 1074–75 (10th Cir. 2013) ("To invoke *Aspen*'s limited exception . . . at least two features present in *Aspen* must be present in the case at hand. First, as in *Aspen*, there must be a preexisting voluntary and presumably profitable course of dealing between the monopolist and rival. . . . Second, as in *Aspen*, the monopolist's discontinuation of the preexisting course of dealing must suggest a willingness to forsake short-term profits to achieve an anticompetitive end." (internal citations and quotation marks omitted)); Eatoni Ergonomics, Inc. v. Research in Motion Corp., 486 Fed. App'x 186, 189–90 (2d Cir. 2012) ("Eatoni's attempt to analogize this case to *Aspen Skiing* . . . is unpersuasive because Eatoni did not have a preexisting product, developed and sold in collaboration with RIM, which consumers preferred."); Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 316 (3d Cir. 2007) (noting that liability under *Aspen* is limited to "the decision of a defendant who possessed monopoly power to terminate a voluntary agreement with a smaller rival"); Covad Commc'ns Co. v. Bell Atl. Corp., 398 F.3d 666, 673 (D.C. Cir. 2005) (dismissing case because "Covad alleges neither that Bell Atlantic had at one time voluntarily dealt with Covad nor that it would ever have been in Bell Atlantic's interest to have done so"); MetroNet Servs. Corp. v. Qwest Corp., 383 F.3d 1124, 1132 (9th Cir. 2004) (observing that liability in *Trinko* was premised on "the unilateral termination of a voluntary and profitable course of dealing"); Covad Commc'ns Co. v. BellSouth Corp., 374 F.3d 1044, 1049 (11th Cir. 2004) ("*Trinko* now effectively makes the unilateral termination of a voluntary course of dealing a requirement for a valid refusal-to-deal claim under *Aspen*.").

[32] *See, e.g.*, Helicopter Trans. Servs., Inc. v. Erickson Air-Crane Inc., No. 06-3077-PA, 2008 WL 151833, at *9 (D. Or. Jan 14, 2008) ("That Erickson and HTS had no prior course of dealing is immaterial. The Supreme Court has never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim.").

[33] *Trinko*, 540 U.S. at 409 (emphasis added); *see also Novell*, 731 F.3d at 1074 ("[T]here must be a preexisting voluntary and presumably profitable course of dealing between the monopolist and rival."); *Bell Atlantic*, 398 F.3d at 673 (affirming dismissal of refusal to deal claim where "[plaintiff] alleges neither that [defendant] had at one time voluntarily dealt with [plaintiff] nor that it would have ever been in [defendant's] interest to do so").

[34] *See* LiveUniverse, Inc. v. MySpace, Inc., 304 Fed. App'x 554, 556–57 (9th Cir. 2008) ("a prior course of dealing *between MySpace and its users*" is insufficient under *Trinko* and *Aspen*); Miniframe Ltd. v. Microsoft Corp., No. 11-cv-7419, 2013 WL 1385704, at *5 (S.D.N.Y. Mar. 28, 2013) ("[A] prior course of dealing between an alleged monopolist and its end users is not equivalent to the monopolist's prior cooperation with a rival.").

[35] FTC Amicus Brief, *supra* note 1, at 11; Press Release, Fed. Trade Comm'n, FTC Amicus Brief: Improper Use of Restricted Drug Distribution Programs May Impede Generic Competition (Mar. 12, 2013), http://www.ftc.gov/news-events/press-releases/2013/03/ftc-amicus-brief-improper-use-restricted-drug-distribution.

[36] *Trinko*, 540 U.S. at 409; *see also Actelion* Transcript, *supra* note 13, at 115 ("The defendants have alleged a profit motive which did not exist in *Trinko*.").

[37] Otter Tail Power Co. v. United States, 410 U.S. 366 (1973).

[38] *Trinko*, 540 U.S. at 410.

[39] *Id.* at 409–10.

[40] *See* Kellogg v. Wyeth, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010) ("There is no reason, under Vermont law, to limit [the branded manufacturer's] duty

of care to physicians by the pharmacist's choice of a generic bioequivalent drug to fill the physician's prescription."); Wyeth, Inc. v. Weeks, No. 1101397, 2013 WL 135753, at *19 (Ala. Jan. 11, 2013) ("[I]t is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce."); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 105 (Cal. Ct. App. 2008) ("[W]e have no difficulty concluding that [the name-brand defendant] should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide."). *But see* Schrock v. Wyeth, Inc., 727 F.3d 1273, 1284 (10th Cir. 2013) (noting that courts have "overwhelmingly rejected" the theory of holding branded manufacturer liable to users of generic equivalent product); Foster v. Am. Home Prods. Corp., 29 F.3d 165 (4th Cir. 1994).

Because generic firms are required by federal law to copy the brand label exactly, the Supreme Court has held that claims against the generic manufacturer based on product labeling are preempted. *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011). The FDA is considering a proposed rule that would allow generic firms to make safety-related changes to the product label, which would effectively abrogate the line of cases holding brand-name manufacturers liable to users of the generic product. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. §§ 314 & 601).

41 *See* U.S. Food & Drug Admin., *Questions and Answers on Revlimid (lenalidomide)* (Dec. 2005), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm109338.htm (discussing how if there are adverse results, "FDA will re-evaluate the program to see if it should be modified").

42 MCI Commc'ns Corp. v. AT&T Co., 708 F.2d 1081, 1132–33 (7th Cir. 1983).

43 *Trinko*, 540 U.S. at 410–11.

44 *Id.*

45 *See, e.g.*, Four Corners Nephrology Assocs., P.C. v. Mercy Med. Ctr. of Durango, 582 F.3d 1216, 1222–23 (10th Cir. 2009); Covad Commc'ns Co. v. BellSouth Corp., 374 F.3d 1044, 1049–50 (11th Cir. 2004); TKO Energy Servs., LLC v. M-I L.L.C., No. 12-cv-00108-GKF-PJC, 2013 WL 789458, at *5 & n.1 (N.D. Okla. Mar. 4, 2013) ("[R]ecent Supreme Court decisions have cast doubt on the entire essential facilities doctrine."), *aff'd*, No. 13-5028, 2013 WL 4767813 (10th Cir. Sept. 6, 2013); United Asset Coverage, Inc. v. Avaya, Inc., 409 F. Supp. 2d 1008, 1049 (N.D. Ill. 2006) (noting that the essential facilities doctrine "has been virtually disclaimed by [*Trinko*]").

46 *See* Order Denying Motion to Dismiss, Lannett Co. v. Celgene Corp., No. 2:08-cv-03920 (E.D. Pa. Mar. 31, 2011); Defendant Celgene Corporation's Memorandum of Law in Support of its Renewed Motion to Dismiss at 13, *Lannett*, No. 2:08-cv-03920 (E.D. Pa. May 28, 2010).

47 *See, e.g.*, Midwest Gas Servs., Inc. v. Ind. Gas Co., 317 F.3d 703, 714 (7th Cir. 2003) ("[T]he most economical route is not an essential facility when other routes are available.").

48 Generic firms could rely on case law holding that the mere existence of a theoretical alternative is not enough to make the preferred pathway non-essential. *See, e.g.*, Fishman v. Estate of Wirtz, 807 F.2d 520, 539–40 (7th Cir. 1986) (finding that a sports arena was an essential facility and rejecting the argument that the team who was denied access could theoretically have built another stadium as such expenditure "would have been unreasonable in light of the size of the transaction such duplication would have facilitated").

49 *See, e.g.*, MCI Commc'ns Corp. v. AT&T Co., 708 F.2d 1081, 1132 (7th Cir. 1983) (noting that a refusal to allow access to essential facility "may be unlawful because a monopolist's control of an essential facility (sometimes called a 'bottleneck') can extend monopoly power from one stage of production to another and from one market into another").

50 Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, L.L.P., 540 U.S. 398, 411 (2004).

51 *Id.* at 412.

52 *Id.* (internal citations and quotation marks omitted).

53 21 U.S.C. § 355-1(f)(8).

54 § 352(y).

55 § 333(f)(4)(A).

56 *See Trinko*, 540 U.S. at 412 (pointing to "*the existence* of a regulatory structure designed to deter and remedy anticompetitive harm" (emphasis added)).

57 Partial Petition Approval & Denial at 7, No. FDA-2009-P-0266 (Aug. 7, 2013). *Accord Actelion* Transcript, *supra* note 13, at 115–16 ("[I]t's clear to me that the FDA does not have the regulatory power to compel samples and that there is no other potential remedy to a defendant suffering anti-competitive conduct in that regulatory scheme.").

58 *See, e.g.*, Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 483 n.32 (1992) ("[A] firm can refuse to deal with its competitors . . . if there are legitimate competitive reasons for the refusal."); United States v. Dentsply Int'l, 399 F.3d 181, 196 (3d Cir. 2005) ("[E]ven if a company exerts monopoly power, it may defend its practices by establishing a business justification."); Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1183 (1st Cir. 1994) ("A monopolist may nevertheless rebut [a refusal to deal claim] by establishing a valid business justification for its conduct."), *abrogated on other grounds by* Reed Elsevier, Inc. v. Muchnick, 559 U.S. 154 (2010).

59 *Actelion* Transcript, *supra* note 13, at 116 ("I accept the notion that [safety concerns] . . . would be, if established, and not undermined by contrary evidence, a legitimate business reason not to deal.").

60 *See, e.g.*, *In re* Elevator Antitrust Litig., 502 F.3d 47, 53 (2d Cir. 2007) (noting elevator manufacturers' "obvious commercial interests" in a manufacturer's ability to control the maintenance of its own elevators "because maintenance is important in upholding the product's reputation for reliability and safety").

61 *Actelion* Transcript, *supra* note 13, at 116 ("[I]f the [generic firms] can prove that the [branded firms] are motivated not so much by safety concerns but instead by the desire to use the REMS . . . to maintain and extend a monopoly, then they may very well make out a Section 2 claim.").

62 *Trinko*, 540 U.S. at 408.

63 *See* Hartford-Empire Co. v. United States, 323 U.S. 386, 432 (1945) ("A patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention. He has no obligation either to use it or to grant its use to others."); United States v. United Shoe Mach. Co., 247 U.S. 32, 57 (1918) ("[A patent's] exertion within the field . . . is not an offense against the Anti-Trust Act."); Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 429 (1908) ("[E]xclusion may be said to have been the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not use it, without question of motive."). Even the Ninth Circuit, which arguably recognized a duty to deal for patented products under certain circumstances, held that "reluctance to sell . . . patented or copyrighted parts was a presumptively legitimate business justification." Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1219 (9th Cir. 1997); *see also In re* Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1327 (Fed. Cir. 2000) (declining to consider the "patentee's subjective motivation for refusing to sell or license its patented products").

64 U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition 30 (2007).

65 Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1)). The *Bolar* Amendment overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), in which the Federal Circuit held that a generic company's use of a patented invention during the patent term limited to conducting tests and developing information necessary to apply for regulatory approval constituted infringement.

66 *See* Rambus Inc. v. FTC, 522 F.3d 456, 466–67 (D.C. Cir. 2008) (finding no liability under Section 2 because the respondent might have acquired or maintained its monopoly power absent its allegedly exclusionary acts); United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001) ("That is, it must harm the competitive *process* and thereby harm consumers. In contrast, harm to one or more *competitors* will not suffice."); *see also* Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 225 (1993) ("Even an act of pure malice by one business competitor against

another does not, without more, state a claim under the federal antitrust laws . . . .”).

[67] Orphan Drug Act, Pub L. 97-414, § 527, 96 Stat. 2049, 2051 (1983) (codified as amended at 21 U.S.C. § 360cc(a)) (providing seven-year exclusivity for drugs approved to treat certain rare diseases).

[68] 21 U.S.C. § 355(j)(5)(F)(ii).

[69] *See, e.g.*, City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 267–68 (3d Cir. 1998) (rejecting claim of prospective injury to competition because anticompetitive effect was contingent on regulator permitting defendant to enter market: “The presence of the regulatory scheme and need for approval . . . cuts the causal chain.”). If, however, the only impediment to regulatory approval arises from the alleged anticompetitive conduct, a court is likely to find prospective injury even if the generic firm has not entered the market. *See, e.g.*, Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d. 540, 545–46 (D.N.J. 2000).

[70] 15 U.S.C. § 45(a)(1); FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 244 (1972) (“[U]nfair competitive practices were not limited to those likely to have anticompetitive consequences after the manner of the antitrust laws; nor were unfair practices in commerce confined to purely competitive behavior.”); FTC v. Brown Shoe Co., 384 U.S. 316, 320–22 (1966) (“[T]he Commission has broad powers to declare trade practices unfair.”).

[71] In recent years, the FTC has pursued a number of cases under its standalone Section 5 authority, including separate actions against Robert Bosch, GmbH and Motorola Mobility for alleged breaches of licensing commitments for standard-essential patents and against Bosley, Inc. for allegedly exchanging competitively sensitive, nonpublic information that could facilitate coordination. *See* Complaint, Motorola Mobility LLC, FTC No. C-4410 (July 23, 2013); Complaint, Bosley, Inc., FTC No. 121-084 (May 30, 2013); Complaint, Robert Bosch, GmbH, FTC No. C-4377 (Nov. 21, 2012).

[72] *How the Federal Trade Commission Works to Promote Competition and Benefit Consumers in a Dynamic Economy: Hearing Before the S. Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, 111th Cong. 11–12 (June 9, 2010) (prepared statement of the Fed. Trade Comm’n), *available at* http://www.ftc.gov/os/testimony/100609dynamiceconomy.pdf; *see also* Maureen K. Ohlhausen, Comm’r, Fed. Trade Comm’n, Section 5: Principles of Navigation (July 25, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/section-5-principles-navigation/130725section5speech.pdf; Joshua D. Wright, Comm’r, Fed. Trade Comm’n, Proposed Policy Statement Regarding Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act (June 19, 2013), *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/statement-commissioner-joshua-d.wright/130619umcpolicystatement.pdf.

[73] *See* E.I. du Pont de Nemours & Co. v. FTC, 729 F.2d 128, 139–40 (2d Cir. 1984) (conduct may violate Section 5 if there is an “absence of an independent legitimate business reason”); Statement of Chairman Leibowitz and Commissioner Rosch at 2, *In re Intel Corp.*, FTC Docket No. 9341 (Dec. 16, 2009) (noting that before finding liability under Section 5, the factfinder must take “into account any efficiency justifications for the conduct in question”).

[74] *See* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

[75] *See* Ohlhausen, *supra* note 72; Wright, *supra* note 72.

[76] FTC Amicus Brief, *supra* note 1, at 1, 7–8.

[77] *See* Boise Cascade Corp. v. FTC, 637 F.2d 573, 581–82 (9th Cir. 1980) (rejecting a Section 5 claim because there was “well forged” antitrust case law governing the conduct).

[78] J. Thomas Rosch, Comm’r, Fed. Trade Comm’n, The FTC’s Section 5 Hearings: New Standards for Unilateral Conduct? 1 (Mar. 25, 2009), *available at* http://www.ftc.gov/speeches/rosch/090325abaspring.pdf; *see also* Dissenting Statement of Chairman Majoras at 3, Negotiated Data Solutions LLC, FTC No. 051 0094 (Jan. 23, 2008), *available at* http://www.ftc.gov/os/caselist/0510094/080122majoras.pdf (noting a “scholarly consensus” that the Sherman and Clayton Acts, as currently interpreted, are broad enough to reach “nearly all matters that properly warrant competition policy enforcement”).

[79] *See* General Foods Corp., 3 Trade Reg. Rep. (CCH) ¶ 22,142 (FTC Apr. 6, 1984) (“While Section 5 may empower the Commission to pursue those activities which offend the ‘basic policies’ of the antitrust laws, we do not believe that power should be used to reshape those policies when they have been clearly expressed and circumscribed. . . . The record in this case does not offer a rationale for using the Federal Trade Commission Act to graft an extension onto Section 2 of the Sherman Act.”).

[80] *See* 21 U.S.C. § 355-1.