Antitrust Plays Whack-a-Mole as Exclusion of Competition by Drug Monopolists Pops Up Again: Gaming the "REMS"

Antitrust Committee

I. Introduction

The pharmaceutical industry is a big business. Top selling drugs, many protected by patents, often sell at prices reflecting the monopoly power that brand-name drug manufacturers may enjoy. Enter the fray, generic competition, offering patients therapeutic equivalents to brand-name drugs at a fraction of the cost—saving consumers hundreds of ***billions*** of dollars each year.[1] The first generic drug to come to market is typically offered at a price discount of 20% to 30% off the brand-name, with entry by additional generic competitors driving the discount to as much as 90%.[2]

Often, brand-name drug manufacturers have hundreds of millions of dollars in yearly sales at risk from generic drug competition. Given the stakes, some brand-name drug manufacturers have used various tactics—some lawful and some arguably unlawful—in an effort to delay generic competition and maintain monopoly profits. As a result, brand-name manufacturers have come under heavy scrutiny from private plaintiffs, the Federal Trade Commission (FTC), and the New York Attorney General's Office for using so-called "reverse payments"[3] and "product hopping"[4] to delay generic entry.

Most recently, several brand-name drug manufacturers have also sought to forestall generic competition by using federally mandated distribution restrictions—known as Risk Evaluation Mitigation Strategies, or REMS—which apply to particular drugs with potentially dangerous side effects. Specifically, some brand-name drug manufacturers selling REMS-restricted drugs have declined to provide to potential generic competitors the brand product samples that the generics need for Food and Drug Administration (FDA) approval in order to bring the generic version to market. Generic companies, supported by the FTC, have challenged this conduct, arguing that where the generic company cannot otherwise obtain samples for bioequivalence testing, the brand-name drug manufacturer has a duty to deal under the antitrust laws. Brand-name manufacturers have defended their approach on the grounds that REMS prevent them from providing samples to generic manufacturers, that selling samples outside of the REMS process would raise safety concerns, that brands would face an enhanced risk of products liability if they were to sell these potentially dangerous drugs to generic manufacturers, and finally, that brands—as patentees—have no duty to deal.

Litigation over REMS-restricted drugs is now emerging, and is unlikely to go away. According to one commentator, nearly 40 percent of new FDA approvals are subject to REMS.[5] Thus far, courts have largely upheld antitrust claims asserting that a brand-name drug manufacturer has a duty to deal with its generic competitor. However, the rulings have come on motions to dismiss, thus leaving the challenging "details" for another day. These include (1) what business or procompetitive justifications (*e.g.*, safety concerns) can justify a branded-drug manufacturer's refusal to deal, (2) what showing of "pretext" must be made to support a monopoly maintenance claim, and (3) can would-be generic competitors demonstrate "antitrust injury," bearing in mind product development, testing and regulatory steps that are prerequisites for market entry?

In this article, we discuss this emerging area of contention between brand-name drug manufacturers and generic competitors. We first consider the framework of brand-generic competition under the Hatch-Waxman Act and REMS legislation. We then discuss and consider the leading Supreme Court refusal-to-deal precedent and review recent REMS antitrust litigation against this doctrinal backdrop. Finally, we consider the potential procompetitive justifications for, and the potential anticompetitive effects of, brand-name manufacturers refusing to provide REMS-restricted samples to generic manufacturers.

II. The Hatch-Waxman Framework

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act (the "Act"). A primary purpose of the Act is to encourage the development of generic drugs by offering an abbreviated pathway for approval by the FDA, as an alternative to proving that a generic drug is safe and effective through clinical trials. Under the Act, a generic drug company can file an Abbreviated New Drug Application (ANDA) that relies on the safety and efficacy research performed by the brand-name drug manufacturer in connection with the branded product's approval.[6] As a result, generic drugs can receive expedited FDA review and approval so long as the FDA is satisfied that the generic product is bioequivalent to the brand product.[7] A generic drug is considered bioequivalent or "AB-rated" if it contains the same active ingredient, is the same dosage and form (*e.g.*, tablet, capsule, etc.), and is absorbed into the bloodstream at the same rate and to the same extent as the brand-name drug.[8]

III. REMS and the Food and Drug Administration Amendments Act of 2007

The Food and Drug Administration Amendments Act of 2007 (FDAAA) authorizes the FDA to require brand-name drug manufacturers to implement safety measures beyond routine professional labeling where the agency "determines that [such measures are] necessary to ensure that the benefits of the drug outweigh the risks of the drug."[9] These REMS include requiring a medication guide, including a patient packet insert to inform patients of potential risks and side effects,[10] or implementing communication plans to healthcare providers concerning the drug's risks.[11] If a drug's potential risks or side effects are particularly dangerous, the REMS also may include distribution restrictions, known as Elements to Assure Safe Use (ETASU), which restrict the ability of doctors to prescribe the drug, and of wholesalers and pharmacies to distribute it. In addition, an ETASU may require (1) that the drug only be dispensed in certain healthcare settings such as hospitals or infusion centers, and (2) that patients using the drug be monitored or enrolled in a registry.[12]

brand-name drug manufacturer to provide the requisite branded samples needed to perform bioequivalence testing in support of the generic's ANDA.[15] Once the generic receives such a letter, it can request the FDA to advise the brand-name drug manufacturer of the agency's conclusions.[16] Despite its tough talk and draft guidance, however, the FDA has disclaimed any ability to enforce REMS abuse, publicly stating that "issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by the FTC."[17]

Indeed, the FTC and other antitrust enforcers have expressed concerns that brand-name drug manufacturers may use REMS as a pretext to exclude generic competition.[18] Recently, FTC Chair Edith Ramirez testified before Congress that "we continue to be very concerned about potential abuses by branded pharmaceutical companies of safety protocols known as REMS...to impede generic competition" by using "REMS-mandated distribution restrictions to inappropriately limit access to product samples."[19] Similarly, Connecticut's Attorney General described "a disturbing, broader trend by certain branded

"The FDAAA explicitly prohibits a brand-name drug manufacturer from using REMS to 'block or delay approval' of a would-be generic competitor's ANDA."

IV. The Hatch-Waxman/REMS Intersection

To file an ANDA under the Hatch-Waxman Act, a generic manufacturer needs to demonstrate the bioequivalency of its product, and that requires the generic to secure a limited amount of the branded product for testing. Thus, branded product samples for testing are essential to the generic manufacturer obtaining FDA approval of its ANDA, a prerequisite to marketing the generic drug. Ordinarily, a would-be generic competitor can purchase necessary quantities of the brand drug from wholesale distributors or specialty pharmacies. But where a drug is subject to REMS, distribution restrictions may make the brand-name drug manufacturer the only available source for product samples. Hence, the opportunity for brand-name drug manufacturers to delay entry of the generic.

The FDAAA explicitly prohibits a brand-name drug manufacturer from using REMS to "block or delay approval" of a would-be generic competitor's ANDA.[13] Moreover, the FDA has assured generic manufacturers that REMS cannot be used as a shield against generic competition.[14] Indeed, the FDA has issued draft guidance procedures by which a generic drug company can obtain an FDA letter stating that (1) the generic's bioequivalence protocol complies with the applicable REMS and (2) the FDA will not consider it a violation of the REMS for the

drug manufacturers" to use the REMS program "as a weapon to blunt the development of generic drugs."[20]

The FTC has twice filed amicus briefs supporting generic manufacturer suits, discussed below, which alleged that brand-name drug manufacturers took advantage of REMS requirements to block generic competition.[21] The agency also has issued at least one civil investigative demand to a brand-name drug manufacturer.[22] However, to date, no government enforcer has initiated litigation against a brand-name drug manufacturer alleging antitrust or any other claim stemming from branded companies' distribution restrictions.

A 2014 analysis concluded that brand-name drug manufacturer abuse of restricted access programs to prevent generic competition costs the health care system $5.4 billion annually, including $1.8 billion to the federal government.[23] To date, legislation to remedy this abuse has stalled in Congress.[24] Therefore, as things now stand, we can expect litigation to increase—and to become increasingly important in addressing claims of REMS abuse.[25]

V. Private Antitrust Litigation: The REMS Overview

Although government enforcers have not sued brand-name drug manufacturers alleging REMS abuse,

generic manufacturers and other private plaintiffs have. The common thread of these cases is that the brand-name drug manufacturer violated the antitrust laws by refusing to sell its generic competitor the REMS-restricted drug samples necessary for bioequivalence testing. And while none of the cases has produced a merits ruling based on a factual record, courts have come out both ways on pretrial motions.

Plaintiffs have made several arguments why such conduct is anticompetitive. The most successful one thus far is that REMS restrictions prevent generic companies from purchasing branded product in normal distribution channels of distribution—specifically, wholesale distributors or specialty pharmacies. Therefore, a generic firm's only option is to buy product directly from the brand-name drug manufacturer, which can shut out the generic by simply refusing to sell the required samples. Plaintiffs have thus argued that the brand-name drug manufacturer, as a monopolist, has a duty to sell branded product samples to its generic competitor on commercially reasonable terms.[26]

This approach bumps up against the principle that a business should generally be free to choose to deal with whomever it pleases.[27] As the Supreme Court wrote in its seminal ruling on the point, "[i]n the absence of any purpose to create or maintain a monopoly, the [Sherman] [A]ct does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal."[28] Nevertheless, that right is not absolute: "[u]nder certain circumstances a refusal to cooperate with rivals can constitute anticompetitive conduct and violate § 2 [of the Sherman Act]."[29] Determining when and under what circumstances a monopolist has a duty to deal with its rivals is "one of the most unsettled and vexatious [questions] in the antitrust field."[30] Thus, this is a primary battleground in REMS cases: in what circumstances must a brand-name drug manufacturer sell to its would-be generic rival to enable the rival to seek FDA approval of the rival's ANDA?

VI. The Antitrust Duty to Deal Framework

As a general matter, an antitrust plaintiff asserting a Sherman Act § 2 refusal-to-deal claim must demonstrate that the defendant (1) has monopoly power in the relevant market and (2) acquired or maintained that monopoly power through exclusionary or predatory conduct—conduct that, broadly speaking, tends to impair the opportunities of rivals or customers, and does so either on a basis other than product price or merit, or in an unnecessarily restrictive way.[31] In addition, in the REMS cases discussed below, the brand-name drug manufacturer defendants have argued that an additional element is essential to state a refusal-to-deal claim under Section 2: the defendant's termination of a prior course of dealing with its rival.

Here, we focus on the second element—whether a brand-name drug manufacturer's company's refusal to provide samples to its generic competitor in the REMS context constitutes exclusionary conduct—and whether the termination of a prior course of dealing is also a necessary feature of such a claim.[32]

Four Supreme Court decisions provide the framework for analyzing refusal-to-deal claims:

Otter Tail: An electric power company, Otter Tail, denied access to its power transmission lines to several towns that sought to offer their own electrical power to consumers in competition with Otter Tail.[33] Without access to Otter Tails lines, the towns could not compete with Otter Tail in the retail power market. Otter Tail did, however, provide its power transmission lines to non-competing customers, and no capacity or technical restrictions prohibited it from selling the same services to the towns.[34] The Supreme Court found that Otter Tail's refusal to deal was motivated "***solely*** to prevent municipal power systems from eroding its monopolistic position," and Otter Tail thus violated Section 2.[35]

Aspen Skiing: In *Aspen Skiing*, defendant Ski Co. owned three of the four ski resorts in Aspen, Colorado, and also sold ski passes to Highlands, which owned the fourth ski resort, so that both resorts could offer a multi-day pass covering all four mountains.[36] Ski Co. stopped doing business with Highland, which responded by trying to offer a four-mountain pass by itself. Ski Co., however, refused to sell Highland's passes to its three mountains, even at retail prices; nor would it honor vouchers from Highland's customers.[37] By eliminating the four-mountain pass, Ski Co. adversely affected consumer choice and had a negative impact on Highland's ability to compete.[38]

The Supreme Court held that Ski Co. violated the Sherman Act because its refusal to deal was motivated by anticompetitive goals. As the Court wrote, "[i]f a firm has been 'attempting to exclude rivals on some basis other than efficiency,' it is fair to characterize its behavior as predatory."[39] Moreover, Ski Co.'s refusal to sell ski tickets to Highland at full retail price "supporte[d] an inference that Ski Co. was not motivated by efficiency concerns and that it was willing to sacrifice short-run benefits...in exchange for a perceived long-run impact on its smaller rival."[40] Although Ski Co. offered business justifications for its conduct, the Supreme Court found them pretextual.[41] It should be noted also that Highland's claim arose after Ski Co. had ended the two companies' prior business relationship—a circumstance that, as we will see, factors into the Supreme Court's subsequent *Trinko* ruling, as well as the more recent REMS-based cases.

Trinko: This more recent case arose from Verizon's failure to share its telephone network with its rivals as required by the Telecommunications Act.[42] Distinguishing *Aspen Skiing*, the Supreme Court held that Verizon's

refusal to deal did not constitute monopolization under § 2 of the Sherman Act for several reasons.

First, both the Federal Communications Commission ("FCC") and state public utilities had extensive statutory enforcement authority to ensure that Verizon made its network available to potential competitors.[43] Thus, unlike Ski Co., Verizon's duty to deal was mandated and enforced by legislation separate from the Sherman Act. Indeed, the FCC fined Verizon $3 million for failing to share its network with potential competitors.[44]

Second, Ski Co. unilaterally terminated "a voluntary (*and thus presumably profitable*) course of dealing" with Highland, and refused "to renew the [ski] ticket *even if compensated at retail price*."[45] Ski Co.'s conduct "suggested a willingness to forsake short-term profits to achieve an anticompetitive end," as well as "a distinctly anticompetitive bent."[46] On the other hand, there was no reason to presume that Verizon's dealings with its rivals would have been profitable, because its duty to deal was compelled by statute, not voluntary.

Third, Ski Co., refused to sell to Highland a product (its three-mountain pass) that it sold to others at retail. By contrast, rivals sought services that Verizon had not previously offered to the public.[47]

Linkline: *Trinko* involved a claim that Verizon had refused to make its network available to the plaintiff, a competing telephone company. In a more recent decision, the Supreme Court applied *Trinko*'s duty-to-deal analysis where the competitor challenged the supplier's price terms to do business.[48] In *Linkline*, a competing phone company alleged that the wholesale price terms on which the defendant, AT&T, was prepared to deal were so onerous that they "squeezed" the plaintiff out of the retail market. The Supreme Court rejected the claim:

> *Trinko* . . . makes clear that if a firm has no antitrust duty to deal with its competitors at wholesale, it certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous. . . . If AT&T had simply stopped providing DSL transport service to the plaintiffs, it would not have run afoul of the Sherman Act. Under these circumstances, AT&T was not required to offer this service at the wholesale prices the plaintiffs would have preferred.[49]

VII. The REMS Refusal-to-Deal Cases

As previewed above, brand-name drug manufacturers in REMS cases have cited *Trinko* for the proposition that to plead a Section 2 refusal to deal claim, the plaintiff must plausibly allege that the brand terminated a prior course of dealing without a legitimate business reason for doing so. This argument, if credited, would create a significant hurdle for plaintiffs, however, because in many instances, the brand-name drug manufacturer does not have a pre-existing business relationship with its generic competitor for any drug, let alone for the REMS-restricted drug for which samples are needed to do bioequivalent testing.[50]

In response, plaintiffs have maintained they need allege only that the brand-name drug manufacturer's conduct was economically irrational absent an exclusionary motive. In other words, the brand-name drug manufacturer's refusal to provide samples was predicated on its "willingness to forsake short-term profits to achieve an anticompetitive end."[51] To support this allegation, plaintiffs have pleaded that (1) the brand-name drug manufacturer sold the REMS-restricted drug to wholesaler distributors, specialty pharmacies and independent testing organizations on commercially reasonable terms and (2) the FDA has advised brand-name drug manufacturers in writing that the FDA has approved the generic company's safety protocols and that the sale of the samples to the generic would not violate the applicable REMS.

District courts have directly addressed this question in five cases. In three of those cases, district courts in the Third Circuit held that a prior course of dealing between brand and generic was not required.

The Thalomid & Revlimid Cases. There have been two decisions in the District of New Jersey to address the refusal by a brand-name drug manufacturer (Celgene) to sell REMS-restricted samples to a generic rival. Both decisions—one in a case brought by Mylan, a generic drug company, and the other in a case by a putative class of third-party payors and end-users—involve Thalomid and Revlimid, two drugs that can be used to treat certain forms of blood cancer, among other conditions.[52] The plaintiffs in both cases alleged that Celgene engaged in anticompetitive conduct to perpetuate its Thalomid and Revlimid monopolies, including refusing to sell potential generic competitors samples of the drugs under the pretext of its REMS program.

In the *Mylan* case, the court issued a thorough oral opinion, replete with citation to applicable case law, after full briefing and oral argument of Celgene's motion to dismiss.[53] The court concluded that Mylan was not required to plead a prior course of conduct to state a duty to deal claim. Discussing both *Aspen Skiing*—where there was a prior course of dealing—and *Trinko*—where there was not—the court said: "the *Trinko* Court considered [that] fact[] not for [its] independent significance, but rather for what [it] *suggest[s]*: A willingness to engage in irrational, anticompetitive conduct."[54]

The *Mylan* court also interpreted several prior Third Circuit decisions to "suggest that a 'prior course of dealing' is relevant—but not dispositive—in determining whether such a duty applies."[55] It further observed that "the Supreme Court has 'never held that termination of a

preexisting course of dealing is a necessary element of an antitrust claim,' and there remains valid Supreme Court law imposing an affirmative duty to deal when no prior course of dealing was alleged."[56] The court found particular support for its conclusion in *Otter Tail*, noting that the *Trinko* court discussed *Otter Tail* without overruling it. Indeed, although Celgene had not previously dealt with Mylan, Celgene—like Otter Tail—had sold product at retail to non-competitors (here, research organizations).[57]

The court also denied the motion to dismiss the class action brought by customers in *In re Thalomid and Revlimid Litigation*.[58] According to the court, both *Aspen Skiing* and *Trinko* demonstrate that, in a Section 2 refusal-to-deal case, the defendant's "motivation is central."[59] A prior course of dealing, the court noted, was only one means of "circumstantial evidence" demonstrating "anti-competitive motivation, along with [a] lack of legitimate business justifications" for refusing to deal.[60] The court further concluded that the plaintiffs' complaint "raise[d] a plausible inference that Celgene's reliance on its distribution programs [was] pretextual"[61] because (1) Celgene sold drug samples to researchers who were not seeking to enter the market, while denying samples to would-be competitors and (2) potential generic competitors seeking to buy product had provided Celgene with FDA letters stating that Celgene could supply samples without violating REMS.

Tracleer. Unlike the *Thalomid* and *Revlimid* cases, the litigation involving Tracleer's REMS program was initiated by the brand-name drug manufacturer, Actelion Pharmaceuticals. Actelion sought a declaratory judgment in the District of New Jersey that, under its REMS distribution program, it had no duty to sell to its rivals samples of Tracleer, a treatment for pulmonary (lung) artery hypertension that is also linked to severe liver problems.[62] After oral argument on Actelion's motion for judgment on the pleadings and to dismiss antitrust counterclaims by Actelion's generic competitors, the court denied relief in an oral opinion.[63]

The *Actelion* court held that *Trinko* did not require plaintiffs to plead a prior course of dealing to state a refusal-to-deal claim in all circumstances. Like the *Revlimid/Thalomid* opinions, the *Actelion* court considered Actelion's motivation in refusing to sell samples to the generics central to whether the rivals had stated an actionable antitrust claim. Because the generics had pleaded facts demonstrating that the brand-name drug manufacturer was "motivated by the desire to use the REMS . . . to maintain and extend a monopoly,"[64] the court denied Actelion's motion to dismiss the plaintiffs' counterclaims. Issuing the ruling, the court stated that a written opinion would follow, but the case settled first.[65]

Suboxone. The only decision from a court in the Third Circuit dismissing a REMS-based refusal-to-deal claim comes from the Eastern District of Pennsylvania in *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*.[66] Unlike all other cases to date, the plaintiffs in *Suboxone*—direct and indirect purchasers of the drug—did not allege that the brand-name drug manufacturer failed to sell its generic competitors samples necessary for bioequivalence testing. Instead, they alleged a refusal to deal arising from the defendant's failure to cooperate with its generic competitors to develop and implement a ***shared*** REMS program, as instructed by the FDA.[67] The *Suboxone* court appeared to interpret *Trinko* as requiring a prior course of dealing,[68] although the court recognized that other district courts in the Third Circuit had previously upheld antitrust claims alleging abuse of REMS distribution restrictions even without a prior course of dealing.[69] The *Suboxone* court concluded that these prior decisions were distinguishable, however, because, unlike the generics in those cases, the plaintiffs in *Suboxone* were able to create a REMS program without Reckitt's cooperation—and ultimately did just that.[70]

"In the REMS cases to date, brand-name drug manufacturers have offered several justifications for refusing to sell drug samples to their generic competitors, such as safety concerns, enhanced risk of product liability exposure, and patent exclusivity."

Letairis. In addition to the decisions from district courts in the Third Circuit, one other district court decision, *Natco Pharma Ltd. v. Gilead Sciences, Inc.*,[71] is worthy of mention. Granting the defendants' motion to dismiss, the court held that Natco, the generic company, failed to state a refusal-to-deal claim because Natco could obtain samples of the drug by following the distribution procedures set forth in the brand-name drug manufacturer's FDA-approved REMS program, which included obtaining a prescription from a REMS-certified doctor.[72] The court also held that "complying with FDA requirements . . . constitutes a valid business reason to refuse to dispense Letairis."[73] Although not explicitly referred to in the district court's opinion, Natco, unlike the generics in the other refusal to deal cases, never obtained an FDA letter approving its bioequivalence safety protocol.[74]

VIII. Refusal to Deal: Business Justification or Pretext?

Although some of the plaintiffs in the REMS-related cases have survived motions to dismiss, they have only

scratched the litigation surface. A defendant can rebut a refusal to deal case or, indeed, any case alleging facially anticompetitive unilateral conduct, by demonstrating a legitimate procompetitive justification for the restraint.[75] In the REMS cases to date, brand-name drug manufacturers have offered several justifications for refusing to sell drug samples to their generic competitors, such as safety concerns, enhanced risk of product liability exposure, and patent exclusivity. Plaintiffs, in turn, have countered that the justifications are pretextual.[76] We examine these justifications, which—once a motion to dismiss is denied—can be resolved only after discovery on summary judgment or at trial.

A. Safety Concerns

Brand-name drug manufacturers have argued that selling samples to their generic competitors would violate the terms of the REMS program, which, in the interest of safety, can limit drug distribution to REMS-certified pharmacies or distributors. This argument may ultimately gain little traction, however, because FDAAA statutory provisions explicitly provide that no brand-name drug manufacturer of a REMS-restricted drug shall use the program to "block or delay approval" of a generic drug manufacturer's ANDA.[77] Moreover, as discussed above, the FDA has approved generic company safety protocols and so informed brand-name drug manufacturers in writing that their sale of samples would not violate the applicable REMS.[78] While at least one court has recognized that safety concerns may constitute a legitimate reason for a brand-name drug manufacturer to refuse to provide samples to its generic competitors,[79] demonstrating that the justification is not pretextual may prove difficult where (1) there is appropriate FDA approval and (2) the brand-name drug manufacturer has previously sold the drug to third parties, such as research organizations operating under safety protocols comparable to those offered by the generic.

B. Enhanced Risk of Products Liability Exposure

Brand-name drug manufacturers also have argued that it would enhance their exposure to product liability lawsuits to sell potentially dangerous drugs to generic competitors. This is so, they maintain, because some courts have held brand-name drug manufacturers liable for the injuries caused by generic versions of their drugs. At least one court has rejected this justification as a matter of law, however:

> Those states holding brand name manufacturers liable do so on a failure-to-warn theory. These decisions rely on the laws regulating a generic drug's labeling, which require it to use the identical labeling that was approved for the brand name drug. These courts held that a brand name manufacturer owes a duty to a consumer injured by a generic manufacturer's drug when a risk of that drug is not adequately disclosed on its labeling because the generic drug must use the same labeling as the brand name drug. A brand name manufacturer would not be liable for defects in the generic's formulation or manufacture. In fact, a failure-to-warn claim relies on the fact that the brand name and generic drugs are bioequivalents, having the same formulation. The possibility that Celgene could be liable for a generic drug's harm is ***therefore not a legitimate justification*** that would support its refusal to supply generic manufacturers with samples of Thalomid and Revlimid.[80]

Defendants might argue that the cost-benefit analysis of providing product samples to generic manufacturers favors withholding the sample. While the brand-name manufacturer would not profit from generic sales, it could be exposed to damages to patients injured from use of the generic product were they to prevail on a failure-to-warn theory. However, potential generic competitors could eliminate this risk by offering to provide indemnity to the brand-name drug manufacturer for damages arising from any potential liability associated with the generic manufacturer's eventual drug distribution.[81]

c. The Brand Manufacturer's Patent Exclusivity

Finally, brand-name drug manufacturers also have asserted that drug patents justify their refusal to sell product samples. The exclusivity conferred by the patent is said to legitimize refusing to help the would-be generic competitor to gain ANDA approval for the drug, a step that itself often leads to protracted patent validity litigation. Indeed, the brand-name manufacturers assert a central principle of the patent and antitrust laws: that, "[i]n the absence of any indication of illegal tying, fraud on the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws.'"[82]

But this argument seems contrary to the clear policy underlying the Hatch-Waxman Act, which was adopted to encourage development of generic versions of brand-name drugs and their submission to the FDA for approval, even during the period of patent protection and exclusivity. The ANDA process itself requires the generic manufacturer to perform the bioequivalency tests that will allow the FDA to approve market entry by the generic.[83]

Moreover, the "Bolar Amendment" to the Hatch-Waxman Act provides that it "shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information" for FDA ap-

proval.[84] The Amendment addresses Congress's concern that if generic companies could not begin the testing necessary to submit an ANDA until after the brand-name drug manufacturer's patents had expired, "the patentee's *de facto* monopoly would continue for an often substantial period until regulatory approval was obtained," amounting to an "effective extension of the patent term."[85]

Accordingly, the brand-name drug manufacturer's interest in avoiding challenges to its drug patents seems unlikely to be a legally cognizable justification for refusing to sell samples of REMS-restricted drugs to potential generic competitors.

IX. Causation and Antitrust Injury

Business justification issues aside, brand-name drug manufacturers also have argued on motions to dismiss that would-be generic competitors and direct and indirect customers cannot satisfy the threshold showing of "but for" causation—that, but for the brand-name drug manufacturer's refusal to sell, the generic company would have brought the generic drug to market by a date certain. This argument posits that, besides obtaining samples necessary for bioequivalence testing, the generic must overcome other hurdles before it can begin marketplace sales. For example, the generic must (1) develop its own version of the drug, (2) perform and successfully complete studies demonstrating that its drug is bioequivalent to the brand-name manufacturer's drug, (3) file an ANDA and obtain FDA approval to market and sell the drug, and (4) establish that the generic drug does not infringe the brand-name drug manufacturer's patent, or that the patent is invalid—often the greatest challenge the generic faces.[86]

The D.C. Circuit addressed a similar argument in upholding Microsoft's Section 2 liability for preventing Netscape from competing against Microsoft's Internet Explorer browser:

> We may infer causation when exclusionary conduct is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes. Admittedly, in the former case there is added uncertainty, inasmuch as nascent threats are merely *potential* substitutes. But the underlying proof problem is the same—neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct. To some degree, "the defendant is made to suffer the uncertain consequences of its own undesirable conduct."[87]

Here too, a brand-name drug manufacturer might not be heard to complain about causation when its own refusal to sell samples denies nascent competition the opportunity even to germinate. Both the Hatch-Waxman Act—designed to promote generic competition—and the REMS provision—prohibiting REMS abuse—favor the *Microsoft* court's approach.[88]

In a related vein, brand-name drug manufacturers also have argued that "antitrust injury" cannot be alleged in a REMS case. Antirust injury—that is, "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful"[89]—is, of course, a prerequisite in a private antitrust claim. Thus, Celgene—the brand manufacturer—argued that because Mylan failed to plead that its intended generic drug would not infringe Celgene patents—and thus would be a bona fide competitor of Celgene—the absence of a cognizable antitrust injury doomed the complaint. The district court rejected Celgene's argument, reasoning that, with discovery, Mylan could develop facts to demonstrate that Celgene's patents were invalid, or that Mylan could enter the market with a competing, non-infringing product.[90] Moreover, even if Mylan were unsuccessful in proving patent invalidity or non-infringement, it still could satisfy antitrust injury by showing that Celgene's refusal to deal "prevent[ed] it from entering the market immediately upon the expiration of [Celgene's] patents."[91]

In sum, courts that have addressed this issue thus far have held that antitrust injury is not susceptible of resolution on a motion to dismiss, but must, instead, await discovery permitting a factual record to be developed. As more REMS-related cases are litigated, there may be opportunities to explore possible "workable surrogate[s],"[92] such as presumptions and burden shifting, to facilitate resolving patent validity and infringement issues underpinning arguments regarding a potential absence of a cognizable antitrust injury.

X. Conclusion

If brand-name drug manufacturers increasingly attempt to use REMS restrictions to block or delay generic competition, challenges to their conduct are likely to play out in the courtroom. As with the health care industry in general, there are big bucks—and important questions of antitrust doctrine—at stake.

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Endnotes

1. Generic Pharmaceutical Ass'n, Generic Drug Savings in the U.S.1 (6th ed. 2014), <http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf>.
2. *See generally* FTC, Authorized Generic Drugs Short Term Effects and Long Term Impact (2011); FTC, Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions: A Federal Trade Commission Staff Study (2010), <https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>.
3. A "reverse payment" refers to a brand-name drug manufacturer with a patent paying a potential generic competitor to abandon the generic's patent challenge and to refrain from selling its generic drug for a number of years. *See, e.g., F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).
4. Product hopping describes a branded drug manufacturer's making minor changes to its drug (e.g., from a tablet to a capsule), while also taking affirmative steps to shift users of the original drug formulation to the newer version, in order to prevent generic substitution at pharmacies, thereby preserving the brand monopoly. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643, 652-59 (2d Cir.), *cert denied*, 136 S. Ct. 581 (2015).
5. Alex Brill, Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry 1 (2014).
6. 21 U.S.C. § 355(j).
7. *Id.* at § 355(j)(2)(A)(iv).
8. *Id.* at §§ 355(j)(2)(A)(ii), (iii), (iv).
9. 21 U.S.C. § 355-1(a)(1).
10. *Id.* at § 355-1(e)(2).
11. *Id.* at § 355-1(e)(3).
12. FDA, Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS) 9-10 (2014).
13. 21 U.S.C. § 355-1(f)(8).
14. Jane Axelrad, Associate Director of Policy at the FDA Center for Drug Evaluation and Research (CDER), stated that the FDA "take[s] [the prospective effects on generic competition] into account when we write the REMS, and I don't think that any of the REMS with restricted distribution programs per se would block generic competition." Transcript of Public Meeting, FDA, Center for Drug Evaluation and Research, Risk Evaluation & Mitigation Strategy (REMS), at 270-71 (July 28, 2010); Partial Petition Approval & Denial, Citizen Petition of Dr. Reddy's Laboratories at 6-7, No. FDA-2009-P-0266 (Aug. 7, 2013).
15. FDA, How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD—Guidance for Industry 1 (Dec. 2014) ["*REMS Letter Guidance*"],, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf>.
16. *Id.* at 3-4.
17. Partial Petition Approval & Denial, Citizen Petition of Dr. Reddy's Laboratories at 7, No. FDA-2009-P-0266 (Aug. 7, 2013).
18. Henry Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential General Competitors*, 67 Fla. L. Rev. 977, 991 (2015).
19. *Oversight of the Enforcement of the Antitrust Laws: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the H. Comm. on the Judiciary*, 114th Cong 41 (2015) (statement of Edith Ramirez, Chairwoman, FTC), <https://www.gpo.gov/fdsys/pkg/CHRG-114hhrg94604/pdf/CHRG-114hhrg94604.pdf>.

    Other FTC officials have expressed these concerns. Markus Meier, assistant director of the FTC's Healthcare Division, stated that the FTC "definitely see[s] [REMS misuse] as a significant threat to competition." Katie Thomas, *Drug Makers Use Safety Rule to Block Generics*, N.Y. Times (Apr. 15, 2013), <http://www.nytimes.com/2013/04/16/business/drug-makers-use-safety-rule-to-block-generics.html>. Similarly, at the 2012 spring ABA Antitrust Meeting, then-FTC Chairman Jon Leibowitz stated that "the FTC plans to ramp up its efforts in the coming year to stop pioneer drug manufacturers from using REMS as a 'pretext' for denying generic drug manufacturers access to drug samples that would enable them to do bioequivalence testing as a prerequisite to the filing of an Abbreviated New Drug Application." R. Brendan Fee & Jonathan M. Rich, MORGAN, LEWIS & BOCKIUS LLP *Healthcare Tops the Agenda of U.S. Antitrust Enforcers* (Apr. 4, 2012), <https://shar.es/16AZN8>.
20. Butler, 67 Fla. L. Rev. note 18, at 991 (internal citations omitted).
21. *See* Brief for FTC as Amicus Curiae, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094 (ES) (MAH) (D.N.J. June 17, 2014), ECF No. 26-3;Brief for FTC as Amicus Curiae, *Actelion Pharms. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743 (NLH) (AMD) (D.N.J. Mar. 11, 2013), ECF No. 61-2.
22. Celgene Corporation reported publicly that the FTC issued a civil investigative demand requesting information relating to requests by manufacturers of generic drugs to purchase Celgene's patented REVLIMID® and THALOMID® brand drugs. *See* Celgene Corp., Annual Report (Form 10-K) at 113 (Feb. 11, 2016).
23. Alex Brill, Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry note 5, at 1 (2014).
24. Fair Access for Safe and Timely Generics Act, H.R. 2841, 114th Cong. (2015).
25. Outside the REMS content, brand-name drug manufacturers have similarly sought to restrict product distribution as a way to impede competition by generic manufacturers. Actavis used distribution restrictions as part of a strategy to switch users of Namenda—a drug for treatment of Alzheimer's disease—from the company's existing twice-a-day dosage to its forthcoming once-a-day dosage. The switch was designed to thwart competition from generics who offered only twice-a-day dosage. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (affirming a preliminary injunction). More recently, the New York Attorney General began an investigation of Turing Pharmaceuticals, which increased the price of Daraprim—a drug used to treat infectious diseases that attack cancer and AIDS patients—by 5,000 percent, while implementing distribution restrictions that prevented potential generic competitors from obtaining samples necessary for bioequivalence testing. *See* Andrew Pollack, *New York Attorney General Examining Whether Turing Restricted Drug Access*, N.Y. Times (Oct. 12, 2015), <http://www.nytimes.com/2015/10/13/business/new-york-attorney-general-examining-if-turing-restricted-drug-access.html>; DARAPRIM, About, <http://www.daraprimdirect.com/patients> (last visited Feb. 23, 2016).
26. With varying degrees of success, private plaintiffs have also asserted that such conduct violates the antitrust laws under the essential facilities doctrine, as well as § 1 of the Sherman Act, which prohibits unreasonable agreements in restraint of trade. *See, e.g.*, Order Den. Mot. to Dismiss, *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920 (TJS) (E.D. Pa. May 13, 2010), ECF No. 27 (denying the brand-name drug manufacturer's motion to dismiss a complaint alleging a § 2 essential facilities claim); Tr. of Mot. Hr'g, *Actelion Ltd. v. Apotex Inc.*, No. 12-cv-05743 (NLH) (AMD) (D.N.J. Oct. 17, 2013), ECF No. 93 ("*Actelion Mot. Hr'g and Oral Decision*") (denying the brand-name drug manufacturer's motion for judgment on the pleadings and to dismiss the generic's counterclaims, pleading both refusal to deal and essential facilities claims); Transcript of Oral Opinion, *Mylan Pharms.*, No. 2:14-cv-02094 (ES) (MAH) (D.N.J. Dec. 22, 2014), ECF No. 56 ("*Mylan Oral Opinion*") (granting the brand-name drug manufacturer's motion to dismiss the generic's § 1 claim because the generic failed to plead non-conclusory allegations of an unlawful agreement between the brand and its distributors, while denying the motion to dismiss the generic's § 2 claim, without addressing the essential

facilities doctrine). In response, defendants have argued, among other things, that plaintiffs are not seeking access to an essential facility, such as a network or pipeline, but are, instead, proposing a one-time transaction. Defendant Celgene Corp.'s Mem. of Law in Supp. of its Mot. to Dismiss or, in the Alternative, for a Stay at 15, *Lannett*, No. 2:08-cv-03920 (TJS) (E.D. Pa. Nov. 4, 2008), ECF No. 12.

27. *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 448 (2009).
28. *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919).
29. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004). *See also Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985) ("The high value . . . placed on the right to refuse to deal with other firms does not mean the right is unqualified."); *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973).
30. *Byars v. Bluff City News Co.*, 609 F.2d 843, 846 (6th Cir. 1979).
31. *See generally Aspen Skiing*, 472 U.S. at 605 & n.32.
32. In litigation, the monopoly power element can also be hotly contested, as defendants have argued that the absence of generic competition does not, standing alone, prove monopoly power in the "market" relevant for antitrust purposes. *Compare Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, No. 12-cv-3824, 2015 WL 1736957 (E.D. Pa. Apr. 16, 2015) (granting summary judgment in favor of the brand manufacturer where court concluded that the generic failed to demonstrate that the relevant market was limited to a single drug), *with* George Farah & Laura Alexander, *Prominent Market Definition Issues in Pharmaceutical Antitrust Cases*, 30 ANTITRUST 46 (2015) (citing authorities for the proposition that "in the pharmaceutical context, formal market definition is not necessary to establish market or monopoly power").
33. *Otter Tail*, 410 U.S. 366.
34. *Id.* at 377-79.
35. *Id.* at 378.
36. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610 (1985).
37. *Id.* at 592-94.
38. *Id.* at 606-608.
39. *Id.* at 605 (citation omitted).
40. *Id.* at 610-11.
41. *Id.* at 608-11.
42. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-15 (2004).
43. *Id.* at 403-04.
44. *Id.* at 404.
45. *Id.* at 409.
46. *Id.*
47. *Id.* at 409-10.
48. *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438 (2009).
49. *Id.* at 450-51.
50. *See generally* Darren S. Tucker et al., *REMS: The Next Pharmaceutical Enforcement Priority?*, 28 ANTITRUST 74, 75 (2014).
51. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004) (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610-11 (1985)).
52. *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094 (ES) (MAH) (D.N.J. June 17, 2014), ECF No. 26-3. Lannett, a second generic manufacturer, twice sued Celgene under § 2 for refusing to sell samples of Thalomid. *See Lannett Co. v. Celgene Corp.*, No. 2:08-cv-00233 (E.D. Pa., filed Jan. 14, 2008); *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920 (TJS) (E.D. Pa., filed Aug. 15, 2008). The cases settled after the court denied Celgene's motion to dismiss. Order Den. Mot. to Dismiss, *Lannett*, No. 2:08-cv-03920 (TJS) (E.D. Pa., Dec. 7, 2011), ECF No. 51.
53. Oral Opinion, *Mylan*, No. 2:14-cv-02094 n. 26, at 12. The Third Circuit subsequently denied Celgene's petition for interlocutory appeal. *See* Order Den. Interlocutory Appeal, *Mylan Pharms., Inc. v. Celgene Corp.*, No. 15-8017 (3d Cir. Mar. 5, 2015).
54. Oral Opinion, *Mylan*, No. 2:14-cv-02094 n. 26, at 12 (emphasis added).
55. *Id.* at 12-13 (citing *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007)). Court of Appeals decisions outside the Third Circuit can, however, be read to require a prior course of dealing factor. *See, e.g., Transhorn, Ltd. v. United Tech. Corp.*, 502 F.3d 47, 53 (2d Cir. 2007).
56. Oral Opinion, *Mylan*, No. 2:14-cv-02094 n. 26, at 16-17 (quoting *Helicopter Transp. Servs., Inc. v. Erickson Air-Crane, Inc.*, No. 06-cv-3077-PA, 2008 WL 151833, at *9 (D. Or. Jan. 14, 2008)).
57. Oral Opinion, *Mylan*, No. 2:14-cv-02094 n. 26, at 17-18. Significantly, the Supreme Court in *Otter Tail* did not suggest that there were any prior dealings between the power company and the towns. To the contrary, the Court noted that Section 2 precluded conduct aimed at hindering even "potential entrants." *Otter Tail Power Co. v. United States*, 410 U.S. 366, 337 (1973).
58. *In re Thalomid & Revlimid Antitrust Litig.*, No. 2:14-cv-06997 (KSH) (CLW), 2015 WL 9589217 (D.N.J. Oct. 29, 2015).
59. *Id.* at *15.
60. *Id.*
61. *Id.*
62. Complaint for Declaratory Judgment, *Actelion Pharms. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743 (NLH) (AMD) (D.N.J. Sept. 14, 2012), ECF No. 1.
63. Mot. Hr'g and Oral Decision, *Actelion* , No. 1:12-cv-05743 note 26.
64. *Id. supra* note 26, at 117.
65. *See* Order Den. Mot. for J. on the Pleadings, *Actelion Pharms.*, No. 1:12-cv-05743 (NLH) (AMD) (D.N.J. Oct. 21, 2013), ECF No. 90; Order of Dismissal, *Actelion Pharms.*, No. 1:12-cv-05743 (NLH) (AMD) (D.N.J. Feb. 28, 2014), ECF No. 113.
66. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 688 (E.D. Pa. 2014).
67. *Id.* at 685-88.
68. *Id.* at 688.
69. *Id.*
70. *Id.*
71. No. 14-cv-3247 (DWF/JSM), 2015 WL 5718398 (D. Minn. Sept. 29, 2015).
72. *Id.* at *5.
73. *Id.*
74. *See id.* at *2.
75. *See, e.g., Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 483 n.32 (1992) ("It is true that as a general matter a firm can refuse to deal with its competitors. But such a right is not absolute; it exists only if there are legitimate competitive reasons for the refusal."); *Morris Commc'ns Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1295-98 (11th Cir. 2004) (affirming summary judgment for the defendant where the refusal to deal was justified by its desire to prevent free-riding); *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."); *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1569-73 (11th Cir. 1991) (affirming summary judgment where the defendant's refusal to deal with plaintiff was motivated by a desire to prevent free-riding and where the plaintiff was not harmed because there were sources of supply besides the defendant).

76. *See Mot. Hr'g and Oral Decision, Actelion Pharms. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743 (NLH) (AMD) (D.N.J. Sept. 14, 2012), ECF No. 1 n. 26, at 117 ("[I]f the [generic manufacturer] can prove that the [brand-name manufacturers are] motivated not so much by safety concerns but instead motivated by the desire to use the REMS or REMS equivalent...to maintain and extend a monopoly, then [the generic manufacturer] may very well make out a [§] 2 claim."); Oral Opinion, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094 (ES) (MAH) n. 26, at 17 (D.N.J. June 17, 2014) (denying the motion to dismiss where "Mylan has pled that there is no legitimate business reason for Celgene's actions, which it argues are solely motivated by its goal to obtain long-term competitive gain."); *In re Thalomid & Revlimid Antitrust Litig.*, No. 2:14-cv-06997 (KSH) (CLW), 2015 WL 9589217 at *16 (D.N.J. Oct. 29, 2015) (denying the motion to dismiss where "[p]laintiffs' allegations plausibly show that Celgene lacked a legitimate business justification for withholding samples of its drugs").

77. 21 U.S.C. § 355-1(f)(8). *But see Natco Pharma Ltd.v. Gilead Sciences, Inc.*, No. 14-cv-3247 (DWF/JSM), 2015 WL 5718398 (D. Minn. Sept. 29, 2015) (holding that the generic manufacturer failed to state a refusal to deal claim where it did not attempt to comply with the REMS by obtaining a REMS-certified physician to write the prescription).

78. In late 2014, the FDA issued draft guidance procedure allowing a generic manufacturer to request the FDA to inform its branded competitor that supplying it with the requisite samples would not be a violation of the applicable REMS program. *See REMS Letter Guidance, supra* note 15.

79. Mot. Hr'g and Oral Decision, *Actelion*, No. 1:12-cv-05743 note 26, at 116 (accepting the notion that safety concerns may be a "legitimate business reason" for the brand name company's refusal to deal, but emphasizing that the generic manufacturer "paint[s] a very different scenario . . . that the existence of safety concerns is really just a beard, if you will, to mask the true motivation [of the brand manufacturer] . . . to extract monopolistic profits . . . beyond the patent term").

80. *In re Thalomid & Revlimid Antitrust Litig.*, 2015 WL 9589217, at *16 (emphasis added).

81. *See* Oral Opinion, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094 (ES) (MAH) n. 26, at 6-8 (D.N.J. June 17, 2014).

82. *CSU, L.L.C., v. Xerox Corp.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000); Defendant Celgene Corp.'s Mem. of Law in Supp. of Mot. to Dismiss Class Action Compl. at 13-16, *In re Thalomid & Revlimid Antitrust Litig.*, No. 2:14-cv-06997 (D.N.J. Feb. 3, 2015), ECF No. 20-1.

83. *See* 21 U.S.C. § 355(j).

84. 35 U.S.C. § 271(e)(1).

85. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990).

86. In addition to patent exclusivities, a brand-name drug may be entitled to regulatory exclusivities for a New Chemical Entity or under the Orphan Drug Act. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (providing for five-year exclusivity for a New Chemical Entity); 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)).

87. *United States v. Microsoft Corp.*, 253 F. 3d 34, 79 (D.C. Cir. 2001) (quoting 3 Areeda & Hovenkamp, ANTITRUST LAW ¶ 651c, at 78) (emphasis in original) (en banc), *cert denied*, 534 U.S. 952 (2001).

88. As one commentator has written, where the brand-name drug is protected by a patent, "determining whether the generic product candidate at issue in a REMS abuse action (one that has yet to establish it is in fact bioequivalent to the brand's product) will yield a generic product that infringes on the brand's patents is an exercise in predictive speculation." Anna Fabish, *REMS Abuse and Antitrust Injury: Round Peg, Square Hole*, COMPLAW360 (Nov. 4, 2015), <https://www.law360.com/competition/articles/723053/rems-abuse-and-antitrust-injury-round-peg-square-hole>.

89. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).

90. Oral Opinion, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094 (ES) (MAH) n. 26, at 30 (D.N.J. June 17, 2014). *See also In re Thalomid & Revlimid Antitrust Litig.*, No. 2:14-cv-06997 at *27 (D.N.J. Feb. 3, 2015), ECF No. 20-1. (finding that the plaintiffs adequately pleaded causation despite the branded manufacturer's argument that the drug was covered by "almost three dozen patents" because "[t]he law does not demand that plaintiffs allege all alternative theories of causation to survive a motion to dismiss . . . . Plaintiffs are simply required to allege facts showing that they suffered the type of injury or harm the antitrust laws were intended to prevent, and their injury flows from [the brand manufacturer's] anticompetitive conduct") (quotations and citations omitted).

91. Oral Opinion, *Mylan*, No. 2:14-cv-02094 note 26, at 30.

92. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236-37 (2013) (holding that, in the context of reverse payments, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself").