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REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential General Competitors

Henry N. Butler

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REMS-RESTRICTED DRUG DISTRIBUTION PROGRAMS AND THE ANTITRUST ECONOMICS OF REFUSALS TO DEAL WITH POTENTIAL GENERIC COMPETITORS

*Henry N. Butler**

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INTRODUCTION

The Food and Drug Administration Amendments Act of 2007 (FDAAA) grants the Food and Drug Administration (FDA) authority to require a Risk Evaluation and Mitigation Strategy (REMS) from drug manufacturers to ensure that a certain drug's benefits outweigh its risks.¹ Through REMS, the FDA restricts the distribution of drugs with dangerous characteristics, such as high toxicities and severe side effects, to qualified medical professionals.² Such restrictions limit the ability of generic drug manufacturers to obtain samples of the REMS-restricted drugs for bioequivalence testing for an Abbreviated New Drug Application (ANDA).³ Without the ability to demonstrate bioequivalence in the ANDAs, potential generic entrants are unable to obtain FDA approval of drugs that would eventually compete with the REMS drugs.⁴ Recently, potential generic entrants have attempted to use the antitrust laws to force manufacturers of REMS-restricted drugs to provide them with samples.⁵ The Federal Trade Commission (FTC) has weighed in on behalf of generic entry.⁶

The FTC's recent actions are consistent with its long-standing policy concern regarding restrictions that limit generic drug competition. The FTC's actions demonstrate its belief that generic entry in the pharmaceutical market will create positive consumer welfare effects.⁷ The consumer welfare effects of such generic competition, however, are more complex than merely lowered prices. Indeed, the FTC has downplayed evidence that generic entry restricts drug utilization, chills industry investment, and may have unintended health and safety consequences.⁸ Yet, the FTC has continued unabatedly down the path to

1. SUSAN THAUL, CONG. RESEARCH SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 15–16 (2012).

2. *Id.*

3. David Rodi & Zach Hughes, *Are Branded Manufacturers Obligated to Sell Their Drugs to Generic Manufacturers So They Can Make Copies?*, BAKER BOTTS LLP (Feb. 28, 2012), http://www.bakerbotts.com/file_upload/Update_2012_02LifeSciencesNewsletterBrandedManufacturers.htm.

4. *See id.*

5. *See, e.g.*, Complaint at 4, Mylan Pharm. Inc. v. Celgene Corp., No. 2:14-CV-2094 (D.N.J. Apr. 3, 2014) [hereinafter *Mylan Complaint*]; Complaint for Declaratory Judgment at 7–8, Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743-NLH-AMD (D.N.J. Sept. 14, 2012) [hereinafter *Actelion Complaint*].

6. *See, e.g.*, Fed. Trade Comm'n Brief as Amicus Curiae at 2, *Mylan*, No. 2:14-CV-2094-ES-MAH, available at http://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf [hereinafter *FTC Mylan Brief*]; Fed. Trade Comm'n Brief as Amicus Curiae at 2, *Actelion*, No. 1:12-cv-05743-NLH-AMD [hereinafter *FTC Actelion Brief*].

7. *Mylan Complaint*, *supra* note 5, at 2–3; *Actelion Complaint*, *supra* note 5, at 1–2.

8. *See* Tracy Lewis et. al., *Does Generic Entry Always Increase Consumer Welfare?*,

generic drug nirvana, asserting that new entry by generics produces unambiguously positive effects for consumers.

The FTC's recent intervention on behalf of generic manufacturers that attempt to use federal antitrust laws to gain access to REMS-restricted drugs overlaps with the FDA's direct oversight of REMS-restricted drugs. So long as original-brand manufacturing companies (brand manufacturers) have unanswered questions related to their liability for the actions of generic companies, they are unwilling to provide potential competitors with product samples, as there is no valid business justification to give up those samples.⁹ Rather, REMS-restricted drug makers have many valid business justifications for their refusal to deal with a potential generic manufacturer. This ongoing dispute has spurred private litigation and an FTC investigation.¹⁰ In two private litigation cases, the FTC filed amicus briefs claiming that the antitrust claims under section 2 of the Sherman Act are cognizable and that the court should determine the merits of the claim.¹¹ To date, no court has addressed the merits of these antitrust claims and details of the FTC's investigation are unclear.¹²

This Article provides an antitrust and economic analysis of a refusal-to-deal claim in the REMS context. The analysis suggests that the antitrust claims involved do not provide a proper justification for a new exception to a competitor's right to refuse to deal. The FDA and Congress play important roles in the complex regulatory scheme of the U.S. pharmaceutical industry. With so much regulation and oversight, antitrust has little place in ensuring an efficiently functioning market for REMS-restricted pharmaceuticals.

Part I provides background about generic drug entry under the Hatch–Waxman Act, which lays out the framework for ANDAs, and discusses REMS-restricted drugs under the FDAAA. This Part also details current antitrust litigation stemming from refusal to deal in the REMS context, as well as the FTC's position on such conduct. Part II summarizes the antitrust refusal-to-deal doctrine under section 2 of the Sherman Act by

FOOD & DRUG L.J. 373, 381 (2012); Laura E. Panattoni, *The Effect of Paragraph IV Decisions and Generic Entry Before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. HEALTH ECON. 126, 144 (2011); Rodi & Hughes, *supra* note 3.

9. See, e.g., Rodi & Hughes, *supra* note 3 (noting a warning that giving samples “to generic manufacturers would impose undue . . . risks on [an] innovator company”).

10. *FTC Mylan Brief*, *supra* note 6, at 2; *FTC Actelion Brief*, *supra* note 6, at 3.

11. *FTC Mylan Brief*, *supra* note 6, at 8; *FTC Actelion Brief*, *supra* note 6, at 8.

12. See Kurt R. Karst, *Decision in Lannett THALOMID Bioequivalence Study Sample Antitrust Lawsuit Could Reignite Debate on Generic Drug Availability and REMS Restrictions*, FDA LAW BLOG (Apr. 3, 2011, 10:21 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/04/decision-in-lannett-thalomid-bioequivalence-study-sample-antitrust-lawsuit-could-reignite-debate-on-.html [hereinafter Karst, *Decision in Lannett*]; Rodi & Zach Hughes, *supra* note 3.

analyzing prior U.S. Supreme Court precedent. This Part then argues that refusal-to-deal claims in the REMS context fail under current refusal-to-deal jurisprudence. Part III argues that given the error costs associated with antitrust or agency intervention, such intervention would be contrary to public policy. Part IV suggests a narrow antitrust framework to analyze refusal to deal in the REMS context if the courts determine that antitrust analysis is appropriate. If the refusal to provide samples of REMS-restricted drugs to competitors does receive antitrust scrutiny, it should be evaluated under the profit-sacrifice test. Analysis under other theories of antitrust liability would be imprudent.

I. GENERIC DRUG APPLICATIONS, REMS-RESTRICTED DRUGS, AND ANTITRUST CLAIMS

The Hatch–Waxman Act provides an avenue and incentive for generic drug manufacturers to develop competitor drugs to brand-name drugs and enter the pharmaceutical market.¹³ This Part begins by detailing how the Hatch–Waxman Act incentivizes generic entry. The Part then outlines the complications that arise when generic drug manufacturers seek to develop generics for REMS-restricted drugs. Finally, it explains the antitrust claims by some generic drug manufacturers and the FTC regarding refusal-to-deal conduct in the REMS context.

A. *The Hatch–Waxman Act Enhances Generic Entry*

The Hatch–Waxman Act lays out the regulatory structure for pharmaceutical patent protection and the development of generic alternatives to brand-name drugs.¹⁴ Congress created the Hatch–Waxman Act as a mechanism to accelerate the entry of lower cost generic drugs into the pharmaceutical market,¹⁵ and it has certainly had that effect.¹⁶ The Hatch–Waxman Act allows FDA approval of generic versions of drugs through an ANDA, which is markedly cheaper and quicker than the approval of the original brand-name drugs through a New Drug Application (NDA).¹⁷ Approval of generic versions of drugs

13. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2012)).

14. *Id.*

15. *See id.*; *FTC Actelion Brief*, *supra* note 6, at 5.

16. Roxane, a generic drug manufacturer, points to an IMS Health Study from 2009 finding that generic prescription drugs saved the U.S. health care system more than \$800 billion from 2000 to 2009. Roxane Laboratories, Inc.’s Answer, Affirmative Defenses, and Counterclaim Complaint at 28, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD (D.N.J. Nov. 27, 2012) [hereinafter *Roxane Counterclaim*].

17. *See* 21 U.S.C. § 355(b)(2), (j).

requires only a showing of bioequivalence,¹⁸ which is considered an AB rating if the generic “contains the same active pharmaceutical ingredient as the brand-name drug, [has] the same dosage and form, and exhibits a similar . . . absorption.”¹⁹

This process of generic drug approval ensures that these pharmaceuticals “share the same safety and efficacy profile as their brand counterparts.”²⁰ In return for the heightened generic competition, brand manufacturers receive a longer patent term.²¹ The Hatch–Waxman Act also makes it easier for generic manufacturers to declare their intention to enter a market—even when a brand-name drug is covered by a patent—merely by filing a certification claiming that the patent is invalid or the generic version is non-infringing (this is known as a paragraph IV certification).²² The Hatch–Waxman Act thus places the onus of protecting the patent on the patent holder.

B. REMS-Restricted Drugs Under the FDA Amendments Act

Under the FDAAA, REMS restrictions protect patients by limiting the distribution of dangerous drugs and ensuring that certain safety standards regulate their use.²³ REMSs represent a very visible regulatory scheme designed to have a measured and incrementally increasing list of safety restrictions to ensure a uniform approach to concerns over drugs that have already been approved by the FDA and released for public use.²⁴ The FDAAA gives the FDA authority to require REMSs for new and previously approved drugs “to ensure the benefits . . . outweigh the risks of the drug.”²⁵

The system is designed to create a more uniform approach to potential side effects and health risks posed by already released drugs.²⁶ The FDA is now tasked with determining if each newly released drug should be accompanied by one of many different kinds of REMSs.²⁷ These restrictions are designed to ensure the safe administration of drugs to healthcare practitioners and patients, as well as provide more detailed

18. *See id.* § 355(j)(8).

19. *FTC Actelion Brief*, *supra* note 6, at 3–4.

20. *FTC Actelion Brief*, *supra* note 6, at 4.

21. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1598 (1984) (codified as amended at 35 U.S.C. § 156 (2012)).

22. *See* 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

23. R. William Soller & Eleanor M. Vogt, *The REMS Primer: Understanding the Strategies for Risk Management*, MEDSCAPE EDUCATION FAMILY MEDICINE (Dec. 28, 2010), <http://www.medscape.org/viewarticle/734712>.

24. *Id.*

25. *See Roxane Counterclaim*, *supra* note 16, at 27.

26. *See Soller & Vogt*, *supra* note 23.

27. *Id.*

and comprehensive data for post-marketing studies of rare but serious side effects or reactions.²⁸ The REMS restrictions are specific to individual drugs, and no two REMS programs are necessarily alike.²⁹ REMS restrictions may include any of the following categories: “a medication guide or patient package-insert requirement, a communication plan, . . . [a] timetable for sponsor submission to FDA of an assessment on the impact of a REMS program,” or detailed “elements to assure safe use (ETASU).”³⁰

REMS restrictions can significantly curtail a drug’s availability because REMS-restricted drugs are only available for purchase from the manufacturer rather than through normal distribution channels, such as wholesalers.³¹ REMS restrictions can result in similar availability issues for generic manufacturers that require testable samples in order to produce bioequivalent drugs.³² Even those REMS-restricted drugs that are sold by distributors are often subject to restrictive agreements that further limit a generic manufacturer’s ability to access samples.³³

The regulatory regime established by the FDAAA does not explicitly require brand manufacturers to provide product samples to generic manufacturers.³⁴ Congress did consider draft language creating this obligation, but did not include it in the final version of the amendment.³⁵

28. *FDA Basics Webinar: A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm> (last visited May 1, 2015).

29. *Id.*

30. Soller & Vogt, *supra* note 23. For instance, a REMS restriction for a drug that could cause birth defects might require a negative pregnancy test before the drug could be prescribed.

31. See *Roxane Counterclaim*, *supra* note 16, at 22.

32. *Id.*

33. See, e.g., *id.* A related issue involves the patenting of a REMS plan. Patented REMS plans can be listed with the FDA’s “Orange Book” and can substantially extend the life of an already-patented drug. Laura S. Shores, *Pharmaceutical Patent Life Extension Strategies: Are REMS Programs Next?*, PEPPER HAMILTON LLP (Mar. 28, 2012), http://www.pepperlaw.com/publications_article.aspx?ArticleKey=2335. Another hurdle created by REMS patents is that their administration can be labor intensive. Celgene Corporation patented a distribution program called S.T.E.P.S. for the drug Thalomid that requires 175 employees to implement. *Id.* The difficulty in administration could exclude the majority of smaller generic manufacturers. Although not a part of the current disputes over refusals to provide samples, this conduct is a likely candidate for future disputes and possible enforcement actions by the FTC. These patents can be challenged similarly to brand-name pharmaceuticals by filing “Paragraph IV certifications.” *Id.*

34. Rodi & Hughes, *supra* note 3.

35. Kurt R. Karst, *Actelion Preemptively Sues Generic Companies over REMS and Biostudy Product Availability Issues; Case Could Be a Bellwether for Future Efforts*, FDA LAW BLOG (Oct. 9, 2012), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/10/actelion-preemptively-sues-generic-companies-over-rems-and-biostudy-product-availability-issues-case.html [hereinafter Karst, *Actelion Preemptively Sues*].

Congress even had a second opportunity to include this language in 2012 when it passed the FDA Safety and Innovation Act (FDASIA), and again chose not to make sharing drug samples mandatory.³⁶ Current regulatory law does include an ambiguous statement that brand manufacturers should not use ETASU “to block or delay approval of an [ANDA].”³⁷ The interpretation of this requirement will be up to the courts, but it seems to fall far short of imposing an obligation on brand manufacturers to deal with their rivals.³⁸

The FDA has been slow to clarify its stance on whether brand manufacturers should have a duty to deal with potential generic competitors, but it has included language in REMS approval letters reiterating that brand manufacturers cannot use ETASU “to block or delay approval of an [ANDA].”³⁹ The FDA has referred generic manufacturers’ complaints about the anticompetitive effects of these refusals to the FTC.⁴⁰

The overall regulatory problem in these cases is the result of unresolved interest-group battles between generic and brand manufacturing companies.⁴¹ A promising compromise would have imposed a statutory obligation for brand manufacturers to provide samples of their drugs for bioequivalency testing, and in return, would have given them protection from liability for any mistakes, adverse events, or harmful payments that could arise from use of the samples or the resulting generic products.⁴² However, such a compromise collapsed,

36. The original draft of the FDASIA stated that “if a drug is a covered drug, no elements to ensure safe use shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for the purpose of conducting testing necessary to support an application under [FDC Act § (b)(2) or § 505(j) or PHS Act § 351(k)].” *Id.*; Food and Drug Administration Safety and Innovation Act, S. 3187, 112th Cong. § 1131 (2012); 158 Cong. Rec. S3371 (2012).

37. 21 U.S.C. § 355-1(f)(8) (2012).

38. Karst, *Actelion Preemptively Sues*, *supra* note 35.

39. *See, e.g.*, Letter from Judith A. Racoosin, Deputy Dir. for Safety, Ctr. for Drug Evaluation & Research, to Beth Connelly, Assoc. Dir. Regulatory Affairs, Purdue Pharma L.P. (Apr. 15, 2013) available at http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/019516Orig1s038ltr.pdf.

40. *See* Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to Kumar Sekar, Dr. Reddy’s Labs., Inc. (Aug. 7, 2013), available at http://www.fdalawyersblog.com/FDA_CDOR_to_Dr_Reddy's_Laboratories_Inc_Partial_Petition_Approval_and_Denial.pdf.

41. Merrill Goozner, *Rx Firms Use Safety Scare Tactics to Thwart Generics*, THE FISCAL TIMES (June 15, 2012), <http://www.thefiscaltimes.com/Articles/2012/06/15/RX-Firms-Use-Safety-Scare-Tactics-to-Thwart-Generics#sthash.xJG8jjG5.dpuf> (“Efforts to close the loophole,” which allows brand manufactures to avoid giving REMS-restricted drug samples to generic manufacturers, “have become the subject of a fierce behind-the-scenes lobbying campaign on rival bills that reauthorize industry user fees”).

42. *See* Goozner, *supra* note 41.

and the resulting regulatory scheme and brand manufacturers' liability issues remain unclear and muddled.

C. REMS Antitrust Claims

After the FDAAA became law in 2007, conflicts over the implementation of REMSs started almost immediately. Brand manufacturers began refusing to provide samples of brand-name drugs to generic manufacturers, who previously had access to these drugs for the bioequivalence testing required for the development of generic alternatives under the Hatch–Waxman Act.⁴³ Despite formal requests, protests, demands, and threats of litigation, brand manufacturers have asserted their right to refuse to sell their patented drugs to generic manufacturers while the generic manufacturers have complained of both regulatory and antitrust violations.⁴⁴ The FTC is conducting at least one investigation into the practice, and three high-profile cases deserve closer analysis.⁴⁵

1. *Lannett Co. v. Celgene Corp.*

In 2008, Lannett Co. (Lannett), a generic manufacturer, sued Celgene Corp. (Celgene), a brand manufacturer⁴⁶ in *Lannett Co. v. Celgene Corp.*⁴⁷ Lannett alleged that Celgene was restricting Lannett's access to the drug Thalomid (thalidomide), which is subject to some of the strictest REMS restrictions, to prevent bioequivalence testing for a proposed ANDA.⁴⁸

Celgene asserted that it would not consider providing the drug samples until it received proof from the study's sponsor or the FDA that

43. See *FTC Mylan Brief*, *supra* note 6, at 3–4; *FTC Actelion Brief*, *supra* note 6, at 3–4.

44. See, e.g., *FTC Mylan Brief*, *supra* note 6, at 14; *FTC Actelion Brief*, *supra* note 6, at 15.

45. Similar conduct has arisen in other cases. For example, Acorda Therapeutics has refused to sell samples of the brand-name drug Ampyra. *Contention in Making Generic Drugs*, N.Y. TIMES (Apr. 15, 2013), <http://www.nytimes.com/interactive/2013/04/15/business/Contention-in-Making-Generic-Drugs.html>. Ampyra is administered to improve walking in patients suffering from multiple sclerosis and had sales of over \$250 million in the United States in 2012. *Id.* Accord Healthcare, a generic manufacturer, has sued in federal court with claims similar to those in *Actelion* and *Lannett*. 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> [hereinafter Thomas, *Drug Makers Use Safety*]. Another brand manufacturer, Lundbeck, has refused to sell drug samples of Xenazine, a drug used to treat a movement disorder caused by Huntington's disease, to Apotex. *Id.* Lundbeck claims that it is waiting for the FDA's guidance. *Id.*

46. Rodi & Hughes, *supra* note 3.

47. *Lannett Co. v. Celgene Corp.*, No. 08-3920, 2011 WL 1193912 (E.D. Pa. Mar. 29, 2011).

48. *Id.* at *1; Karst, *Decision in Lannett*, *supra* note 12; Rodi & Hughes, *supra* note 3.

the study would comply with the REMS requirements and would not jeopardize the test subjects' safety.⁴⁹ The court initially dismissed the complaint on "ripeness grounds" because the study had not yet received approval from the FDA.⁵⁰ Lannett then received FDA approval and refiled the case; the court denied Celgene's subsequent motion to dismiss.⁵¹ Before the merits of the antitrust and regulatory claims were decided, the parties initially settled with a confidential agreement.⁵²

The FDA did not take a strong enough position to quell the ensuing litigation.⁵³ The FDA filed a letter stating that Lannett could access the necessary drugs once the company received approval for its bioequivalence study, but the FDA did not require Celgene to provide the requested samples.⁵⁴ The Lannett case represents the first time the FTC became actively involved in an investigation of this type of behavior, but the result of the investigation is unknown.⁵⁵

2. *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*

In *Actelion Pharmaceuticals Ltd. v. Apotex, Inc.*,⁵⁶ Actelion Pharmaceuticals Ltd. (Actelion), a brand manufacturer, refused to provide generic manufacturers with samples of the REMS-restricted drugs Tracleer (generic name bosentan) and Zavesca (generic name miglustat).⁵⁷ Actelion argued that its position was consistent with both the REMS regulatory requirements and its own assertion that the company lacked any statutory or legal obligation to deal with potential

49. *Lannett*, 2011 WL 1193912, at *1; Karst, *Decision in Lannett*, *supra* note 12.

50. Karst, *Decision in Lannett*, *supra* note 12.

51. *Id.*

52. Erin Coe, *Lannett Cuts Deal with Celgene in Thalomid Antitrust Case*, LAW360 (Dec. 7, 2011, 2:47 PM), <http://www.law360.com/articles/291483/lannett-cuts-deal-with-celgene-in-thalomid-antitrust-case>; *see also Lannett*, 2011 WL 1193912, at *3.

53. *See* Letter from Janet Woodcock, *supra* note 40 (noting that the FDA: (1) agreed that it should clarify the relationship between bioequivalence studies and REMS; (2) recognized that many bioequivalence tests do not violate REMS; (3) declined to add into the REMS a requirement to provide samples to generics; and (4) agreed that it will refer some cases to the FTC or open its own investigation if there are competitive concerns).

54. Rodi & Hughes, *supra* note 3.

55. *Id.* Note that Celgene's SEC filings from 2009 to 2012 state that it received two civil investigation demands from the FTC so the current status of this investigation is unclear. *Id.*

56. No. 1:12-cv-05743-NLH-AMD (D.N.J. Sept. 14, 2012).

57. *Actelion Complaint*, *supra* note 5, at 2; Kurt R. Karst, *Actelion's Preemptive Strike over REMS and Biostudy Product Availability Draws Antitrust Counterclaims, Another Drug, and Another Company into the Mix*, FDA LAW BLOG (Dec. 5, 2012, 5:57 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/12/actelions-preemptive-strike-over-rems-and-biostudy-product-availability-draws-antitrust-counterclaim.html [hereinafter Karst, *Actelion's Preemptive Strike*].

competitors.⁵⁸ Actelion claimed that the REMS restrictions only allowed Tracleer to “be dispensed through pharmacies, practitioners, and health care settings that [were] specially certified and bound by contract to follow a strict protocol to monitor and protect patient health.”⁵⁹ The restrictions further require

monthly follow-up[s] with patients to ensure that liver function testing and pregnancy testing have been completed; that only a limited supply of Tracleer can be distributed at a time; that Tracleer can only be dispensed to patients who are enrolled in the REMS program; and that certain defined patient counseling is completed regularly.⁶⁰

Actelion’s actions prevented generic manufacturers Roxane Laboratories Inc. (Roxane) and Apotex Inc. (Apotex) from moving forward with ANDAs for generic versions of Tracleer and Zavesca.⁶¹ As a result, Actelion was able to delay the development and entry of generic versions into the market, which may prevent price-lowering competition and access to cheaper versions of these two drugs for consumers.⁶² Actelion pointed to the REMS restrictions associated with the serious side effects of Tracleer as a justification for limiting distribution to its competitors.⁶³ Side effects for the use of Tracleer include serious liver damage, liver failure, and birth defects if taken during pregnancy.⁶⁴

Apotex sent letters to Actelion making clear its intention to begin an ANDA filing for a generic form of Tracleer.⁶⁵ Actelion responded with a formal denial, asserting its right to refuse to deal with a rival.⁶⁶ The same denial indicated that the REMS requirements prevented release of any samples without proof that Apotex’s bioequivalence study protocol, required under the Hatch–Waxman Act to develop a generic pharmaceutical, complied with the REMS requirements.⁶⁷

58. *Actelion Complaint*, *supra* note 5, at 2–3.

59. *Id.* at 6.

60. *Id.*

61. Karst, *Actelion’s Preemptive Strike*, *supra* note 57. One interesting twist in the case was that Apotex managed to procure a Canadian version of the drug for bioequivalence testing, but the FDA denied the use of this sample in a correspondence claiming that Apotex could only use “the approved US product as the reference product” and that the Canadian version was “not acceptable to use.” *Id.* (internal quotation marks omitted).

62. *See id.*

63. *Actelion Complaint*, *supra* note 5, at 6.

64. *Id.*

65. *Id.* at 7.

66. *Id.* at 10.

67. *Id.* at 9–10, 13–14.

Roxane similarly made multiple attempts to purchase the samples and was met with refusals.⁶⁸ It also received similar responses from Actelion's U.S. supplier, CuraScript.⁶⁹ On November 9, 2011, Actelion sent Roxane a definitive notification that it asserted a right to choose with whom it would deal and that it would not sell samples to Roxane.⁷⁰ Roxane then contended that the REMS restrictions were being used to "block or delay approval" of ANDAs in contravention of the FDA's anti-gaming provisions.⁷¹ Roxane continued that Actelion's responses were "nothing more than an anticompetitive scheme calculated to delay generic competition as long as possible."⁷² In response, Actelion asserted that declining to provide samples of its drugs fit squarely within its right to refuse to deal with actual or potential rivals.⁷³ Actelion's position was that it maintained proprietary control over its own patented drugs and owed no legal or regulatory obligation to provide samples to generic manufacturers.⁷⁴

Eventually, Actelion filed for declaratory judgment in the U.S. District Court for the District of New Jersey, seeking a court order affirming its right to refuse to deal with any potential rivals.⁷⁵ Both Apotex and Roxane brought counterclaims asserting that Actelion violated the New Jersey Antitrust Act and sections 1 and 2 of the Sherman Antitrust Act and also committed tortious interference; they sought treble damages and injunctive relief.⁷⁶ Another generic manufacturer, Actavis Elizabeth LLC (Actavis), tried to intervene as a similarly aggrieved generic manufacturer.⁷⁷ Actavis's Proposed Counterclaim made similar legal claims, including violations of the Sherman Act and the New Jersey Antitrust Act.⁷⁸ The FTC filed an amicus brief in this case arguing that current antitrust law supports reaching the merits of the arguments.⁷⁹

68. *Id.* at 9.

69. *Roxane Counterclaim*, *supra* note 16, at 35.

70. *Id.* at 35–36.

71. *See id.* at 23.

72. *Id.* at 39.

73. *Id.* at 58.

74. Stewart Bishop, *Actelion Says Antitrust Law Can't Make It Sell to Rivals*, LAW360 (Jan. 17, 2013, 2:41 PM), <http://www.law360.com/articles/408041/actelion-says-antitrust-law-can-t-make-it-sell-to-rivals>.

75. Karst, *Actelion Preemptively Sues*, *supra* note 35.

76. *See Roxane Counterclaim*, *supra* note 16, at 53.

77. Karst, *Actelion's Preemptive Strike*, *supra* note 57.

78. *Id.*

79. *FTC Actelion Brief*, *supra* note 6, at 17.

3. *Mylan Pharmaceuticals Inc. v. Celgene Corp.*

Most recently, the FTC submitted a second REMS-related amicus brief⁸⁰ to the District Court of New Jersey in *Mylan Pharmaceuticals Inc. v. Celgene Corp.*⁸¹ In that case, Mylan Pharmaceuticals (Mylan) sued Celgene alleging that Celgene's conduct relating to REMS-restricted drugs violated federal and state antitrust laws.⁸² Specifically, Mylan, a generic manufacturer, charged that Celgene, a brand manufacturer, was using the REMS restrictions on its drugs—Thalomid and Revlimid (lenalidomide)—as a pretext for refusing to provide Mylan with samples of these drugs.⁸³ Mylan further alleged that, due to distribution restrictions put in place by Celgene, it had also been unable to obtain samples of these drugs even from wholesalers.⁸⁴ Mylan sought samples of Thalomid and Revlimid to conduct the bioequivalence studies required for an ANDA and stated that the FDA had found Mylan's safety protocols for these studies acceptable.⁸⁵

Among other relief, Mylan asked the court for a preliminary and mandatory injunctive order compelling Celgene to sell Mylan a sufficient number of Thalomid and Revlimid samples at market price.⁸⁶ Additionally, Mylan sought compensatory damages for the loss of generic drug sales due to the delay of Mylan's ability to submit its ANDA.⁸⁷ Celgene argued in its motion to dismiss that it had no duty to deal with a potential competitor,⁸⁸ and that Mylan's claims were barred as a matter of law because, among other reasons, they failed to plead necessary elements, were outside the applicable statute of limitations, or were precluded by presumptively valid patents.⁸⁹ Oral arguments on Celgene's motion to dismiss took place on December 9, 2014.⁹⁰

4. Claims in the Private Antitrust Cases

The primary antitrust claim in these three cases was that REMS-restricted brand-name drug manufacturers violated the antitrust laws

80. *FTC Mylan Brief*, *supra* note 6.

81. No. 2:14-CV-2094 (D.N.J. Apr. 3, 2014).

82. *Id.* at 1.

83. *Mylan Complaint*, *supra* note 5, at 2, 4.

84. *Id.* at 4, 21–22.

85. *Id.* at 3, 4, 21.

86. *Id.* at 81.

87. *Id.*

88. Brief in Support of Defendant Celgene Corp.'s Motion to Dismiss at 14, *Mylan Pharm. Inc. v. Celgene Corp.*, No. 2:14-CV-2094 (D.N.J. May 25, 2014).

89. *Id.* at 25, 28–29, 36.

90. Oral Opinion at 2, *Mylan Pharm. Inc. v. Celgene Corp.*, No. 2:14-CV-2094 (D.N.J. Dec. 22, 2014).

when they refused to provide samples to generic manufacturers who sought to reverse engineer the bioequivalence of the patented brand-name drug.⁹¹ The REMS-restricted brand-name drug manufacturers claimed that they had a right to refuse to deal with their rivals and that there was no antitrust or other legal duty to provide drug samples to a rival.⁹² Although exceptions to the refusal-to-deal doctrine exist, the brand manufacturers asserted that these cases were not applicable.⁹³

The generic manufacturers responded that brand manufacturers have used the REMS program as a pretext to restrict access to brand-name drugs rather than as an actual effort to benefit consumers.⁹⁴ As evidence, they pointed to a letter from the FDA stating that the agency did not intend “to permit the restrictions of the [REMS] program to prevent manufacturers of generic drugs from obtaining [samples] for use in bioequivalence testing necessary to obtain [ANDA] approval.”⁹⁵ Generic manufacturers further argued that refusal to provide drug samples is merely an effort by brand manufacturers to maintain monopoly power and prevent otherwise lawful generic competition that would inevitably bring down prices and benefit consumers.⁹⁶ This argument alleged predatory intent and exclusionary conduct while denying any purported procompetitive justifications.⁹⁷

Generic manufacturers have also framed brand-name drugs as “essential facilities” necessary to enter into competitive antitrust markets.⁹⁸ Brand manufacturers responded that the essential-facilities doctrine is a dead letter that would not apply in a heavily regulated

91. See *Lannett Co. v. Celgene Corp.*, No. 08-3920, 2011 WL 1193912, at *1 (E.D. Pa. Mar. 29, 2011); *Actelion Complaint*, *supra* note 5, at 2; *Mylan Complaint*, *supra* note 5, at 2–4.

92. See, e.g., *Actelion Complaint*, *supra* note 5, at 9–10; *Mylan Complaint*, *supra* note 5, at 35.

93. See, e.g., *Actelion Complaint*, *supra* note 5, at 11–13.

94. See, e.g., *Roxane Counterclaim*, *supra* note 16, at 28; *Mylan Complaint*, *supra* note 5, at 2–4, 21.

95. *Roxane Counterclaim*, *supra* note 16, at 29. This statement did little to settle the ongoing litigation over the issue and fell substantially short of imposing a requirement on the brand manufacturer to give samples to generic manufacturers. See Karst, *Decision in Lannett*, *supra* note 12; Rodi & Hughes, *supra* note 3. The FDA has also given some assurances that bioequivalence studies are conducted with safe procedures, which should fulfill any concerns about the REMS requirements. See, e.g., DRAFT GUIDANCE ON THALIDOMIDE, U.S. FOOD & DRUG ADMIN. (Dec. 2012), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM320038.pdf>; How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protection Comparable to Applicable REMS for RLD, U.S. FOOD & DRUG ADMIN. (Dec. 2014), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf>.

96. See, e.g., *Roxane Counterclaim*, *supra* note 16, at 20–21.

97. *Id.* at 30, 41–42.

98. *Id.* at 45–46.

industry where the supposed monopolist is fully complying with its regulatory requirements.⁹⁹

5. The FTC's Analysis of the REMS Cases

The FTC and Connecticut's attorney general's office have both launched an investigation in the aftermath of *Lannett*.¹⁰⁰ Markus Meier, assistant director of the FTC's Healthcare Division, stated that the FTC "definitely see[s] REMS abuse] as a significant threat to competition."¹⁰¹ Then-FTC Chairman Jon Leibowitz echoed these sentiments at the 2012 ABA Spring Antitrust Meeting.¹⁰² Connecticut's Attorney General, George Jepsen, has expressed his concern that these refusals are part of "a disturbing, broader trend by certain branded drug manufacturers" to use the REMS program "as a weapon to blunt the development of generic drugs."¹⁰³

The FTC has publicly contributed to the debate on REMS-restricted drugs by filing amicus briefs in the *Actelion* and *Mylan* cases in support of the generics' viewpoint that restricting access to brand-name drugs may restrict competition and raise a triable antitrust issue.¹⁰⁴ In general, the FTC stated that "[u]nder certain circumstances, . . . a monopolist's refusal to sell to its rivals may violate Section 2 of the Sherman Act, and vertical agreements may violate Section 1."¹⁰⁵ The FTC, thus, believes that the generic manufacturers pled a plausible case for exclusionary conduct under section 2 by restricting access to a necessary product.¹⁰⁶

The FTC expressed concerns that this strategy by brand manufacturers could pose a serious impediment to competition in the

99. *Actelion Complaint*, *supra* note 5, at 13.

100. Dina ElBoghdady, *Generic-Drug Makers' Complaints over Brand-Name Access Prompt Investigations*, WASH. POST (May 22, 2012), http://www.washingtonpost.com/business/economy/generic-drug-makers-complaints-over-distribution-law-provoke-investigations/2012/0522/gIQAHEXKiU_story.html.

101. Thomas, *Drug Makers Use Safety*, *supra* note 45.

102. Jonathan M. Ritch, R. Brendan Fee & Sarah Sandok Rabinovici, *Healthcare Tops the Agenda of U.S. Antitrust Enforcers*, MORGAN LEWIS (Apr. 4, 2012), www.morganlewis.com/index.cfm/fuseaction/publication.detail/publicationID/decf0a6b-c206-4055-a3e0-d57f2976654d.

103. ElBoghdady, *supra* note 100 (internal quotation marks omitted).

104. Note that the FTC's filings do not go so far as to say that it believes there is a violation but merely state that it thinks there are cognizable antitrust claims. *See, e.g.*, Press Release, FTC Amicus Brief: Improper Use of Restricted Drug Distribution Programs May Impede Generic Competition, FED. TRADE COMM'N (June 19, 2014), <http://www.ftc.gov/news-events/press-releases/2014/06/ftc-amicus-brief-improper-use-restricted-drug-distribution>; *FTC Amicus Brief: Improper Use of Restricted Drug Distribution Programs May Impede Generic Competition*, FED. TRADE COMM'N (Mar. 12, 2013), <http://www.ftc.gov/opa/2013/03/actelion.shtm>.

105. *FTC Mylan Brief*, *supra* note 6, at 8.

106. *Id.* at 8–9.

pharmaceutical industry,¹⁰⁷ and might “prove costly for consumers of prescription drugs [because competition] from lower priced generic drugs saves American consumers billions of dollars a year.”¹⁰⁸ The FTC’s filings emphasized that the accelerated approval of generic drugs under the Hatch–Waxman Act was very important in facilitating competition and bringing down the cost of drugs for consumers.¹⁰⁹

The FTC claimed that refusing to provide drug samples subverted the goals of the Hatch–Waxman Act and possibly constituted violations of sections 1 and 2 of the Sherman Act.¹¹⁰ The agency noted that bioequivalence testing requires a limited amount of the brand-name drug in order for testing to proceed, and that allowing brand manufacturers to restrict access throws a wrench into the entire generic drug development process.¹¹¹ The FDA has clarified, and also noted in its briefs, that a brand manufacturer “may” sell samples of REMS-restricted drugs to a generic manufacturer for bioequivalence testing without violating the REMS.¹¹² The FTC believes that neither the REMS restrictions nor the drug’s patent protection is sufficient to justify restrictions on distribution to generic manufacturers.¹¹³ The FTC focuses on the need for generic substitution laws and the development of these generics under the Hatch–Waxman Act as essential elements of reducing healthcare costs by encouraging rapid development of lower priced drug options.¹¹⁴

II. REMS-RESTRICTED DRUGS AND THE BRAND MANUFACTURER’S RIGHT TO REFUSE TO DEAL WITH GENERIC COMPETITORS

The FTC, without expressing an opinion on the ultimate merits of the antitrust claims, provided an analysis of the Supreme Court’s section 2 jurisprudence in both of its amicus briefs and concluded in its *Actelion* brief that “[t]he allegations in this case therefore fall within the established contours of the Supreme Court’s refusal to deal precedent.”¹¹⁵ Although notably quiet as to the ultimate conclusions of

107. *Id.* at 7.

108. *Id.* at 1.

109. *Id.* at 3–4; *FTC Actelion Brief*, *supra* note 6, at 4. The FTC voted 4–0 to file an amicus brief in the *Actelion* case and voted 4–1 to file an amicus brief in the *Mylan* case, with only Commissioner Joshua Wright voting against the filing. *See* Press Release, *supra* note 104.

110. *FTC Mylan Brief*, *supra* note 6, at 7–8, 15–17.

111. *FTC Actelion Brief*, *supra* note 6, at 4.

112. *See* *FTC Mylan Brief*, *supra* note 6, at 19; *FTC Actelion Brief*, *supra* note 6, at 7.

113. *See* David Leichtman, *Inside the FTC’s Take on Generic Access to Branded Drugs*, LAW 360 (Apr. 5, 2013, 11:39 AM), <http://www.law360.com/articles/429209/inside-the-ftc-s-take-on-generic-access-to-branded-drugs>.

114. *See, e.g.,* *FTC Actelion Brief*, *supra* note 6, at 17.

115. *Id.* at 15. One practitioner has argued that the FTC’s distinction on section 2 cases in this area ignores “the public nature of the infrastructure” as the cause of monopoly power in the

these cases, the FTC has stated that “the evidence may not ultimately support any of the Sherman Act claims in this case, [but] the FTC respectfully submits that they are not barred as a matter of law.”¹¹⁶

This Part summarizes the antitrust refusal-to-deal doctrine under section 2 of the Sherman Act by analyzing prior Supreme Court precedent cited in the FTC’s amicus briefs. It then discusses the various tests in refusal-to-deal cases, such as the “no economic sense” or profit-sacrifice test, and determines how prior course of dealings factor into the tests. This Part then argues that refusal-to-deal claims in the REMS context should be evaluated under the profit-sacrifice test.

A. *Leading Refusal-to-Deal Cases*

In its amicus briefs, the FTC offered a tortured analysis of section 2 jurisprudence in an ill-fated attempt to ramrod the facts of *Actelion* into decades-old exceptions to the well-settled refusal-to-deal doctrine. Looking to *Otter Tail Power Co. v. United States*,¹¹⁷ *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*,¹¹⁸ and *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*,¹¹⁹ the FTC sought to distinguish these cases from the general rule that companies do not have a duty to assist their rivals.¹²⁰ Any comprehensive discussion of section 2 liability requires an examination of these cases to sufficiently consider the existing Supreme Court precedent. This Section analyzes the cases that the FTC relied on to support its refusal-to-deal antitrust claims as well as additional cases. This Section also distinguishes the present dispute from the leading refusal-to-deal cases.

1. *Otter Tail Power Co. v. United States*

In *Otter Tail*, the defendant, Otter Tail Power Co., was a power company that used its monopoly in the retail distribution of electric power to inhibit local towns from shifting their services to municipal power providers.¹²¹ Otter Tail used franchise agreements with local towns, but after the agreements expired, a number of the localities voted

case. See Leichtman, *supra* note 113. Thereby, the FTC’s argument—Actelion’s actions might foreclose competition—does not sufficiently consider that in *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973) and *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), the essential facilities were naturally limited resources or public goods, a limitation not present in the current controversy. *Id.*

116. *FTC Mylan Brief*, *supra* note 6, at 8; *FTC Actelion Brief*, *supra* note 6, at 8–9.

117. 410 U.S. 366 (1973).

118. 472 U.S. 585 (1985).

119. 540 U.S. 398 (2004).

120. *FTC Actelion Brief*, *supra* note 6, at 9.

121. 410 U.S. at 368.

to establish their own municipal electric systems.¹²² The new systems required Otter Tail's cooperation and transmission infrastructure to operate.¹²³ Otter Tail refused to cooperate and prevented development of the new systems, thereby maintaining Otter Tail's monopoly in retail distribution of electric power.¹²⁴ The Supreme Court affirmed a district court opinion finding that Otter Tail had "used its monopoly power in the towns in its service area to foreclose competition or gain a competitive advantage, or to destroy a competitor, all in violation of the antitrust laws."¹²⁵

Otter Tail is a case where the Court found section 2 antitrust liability despite a lack of a prior course of dealings between the parties and where the actions of a monopolist foreclosed competition with a mere "potential entrant[]." ¹²⁶ This characterization of the case is correct, and other commentators have reached the same conclusion.¹²⁷ Nevertheless, *Otter Tail* stands for a very limited proposition and rule. Rather than representing a strong duty to deal, the *Otter Tail* decision is restricted to its fairly limited facts. Otter Tail represented a natural monopoly where the high start-up costs and the low marginal costs of doing business only allowed a single operator in any one limited area.¹²⁸ The power industry is heavily regulated and controlled by outside regulatory agencies, making the Court's antitrust decision easier to implement because there was little need for the Court to oversee the resulting duty to deal.¹²⁹ Moreover, Otter Tail had already incurred the cost of the required infrastructure and, other than the ability to limit the development of future rivals, would have nothing to lose from complying with its regulatory obligation to "wheel" the power of municipal power providers.¹³⁰ Accordingly, Otter Tail's refusal made no economic sense

122. *Id.* at 371.

123. *Id.* at 370.

124. *Id.* at 371–73.

125. *Id.* at 377.

126. *FTC Actelion Brief, supra* note 6, at 9–10 (quoting *Otter Tail*, 410 U.S. at 377) (internal quotation marks omitted).

127. *See, e.g.,* Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50, 53 (2012) ("Fairly read, then, neither *Aspen [Skiing]* nor *Kodak* compels a prior course of dealing screen. And, importantly, *Otter Tail*—a decision that the Supreme Court has never questioned and often cites—is inconsistent with any such rule.").

128. *See Otter Tail*, 410 U.S. at 369.

129. *See Phillip Areeda, Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841, 848 (1990) ("[T]here was already in place a regulatory agency that supervised prices and terms of dealings with local distributors. Thus, the Court could airily require Otter Tail to deal but never burden itself with the administrative details, because the Federal Power Commission had the statutory authority and presumed expertness to regulate the prices and terms of dealing. *Otter Tail* is thus quite narrow.").

130. *See id.* at 847–48.

other than as an anticompetitive scheme.¹³¹

Refusing to provide brand-name drug samples is distinguishable from *Otter Tail* because the brand manufacturers are not under a clear regulatory obligation to provide samples and, as discussed below, these actions were taken with legitimate business justifications.¹³² The regulatory goals of Congress and federal agencies need to be held distinct from the broader and more generalized goals of antitrust, a position the Supreme Court eventually took in *Trinko*.¹³³

2. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*

In *Aspen Skiing*, the plaintiff (Aspen) owned three of four major ski resorts in Aspen, Colorado, while Aspen Highlands Skiing Corp. (Highlands) owned the fourth resort.¹³⁴ Aspen and Highlands provided a single pass that allowed entry into all four resorts.¹³⁵ But then Aspen terminated the pass, which severely limited Highlands' patronage.¹³⁶ Aspen refused to offer the four-resort pass despite Highlands' offer to accept a fairly low fixed percentage of the joint revenues.¹³⁷ Aspen also refused to sell tickets to Highlands' resort and refused to honor vouchers that Highlands issued as part of its competing pass.¹³⁸ Highlands sued, alleging that Aspen's refusal to deal constituted a violation of section 2 of the Sherman Act because Aspen had used its monopoly power to foreclose competition and act predatorily.¹³⁹ The Supreme Court affirmed the finding of the district court that Aspen did have a duty to deal because its conduct was not supported by any valid business or efficiency justifications.¹⁴⁰ The Court declared that a firm's refusal to deal is not unqualified and that the prior course of dealings between the two companies and Highlands' offer to essentially insure Aspen at full retail price amounted to a duty to offer the four-mountain pass.¹⁴¹ Moreover, the Court found that Aspen's behavior was exclusionary and was tantamount to predatory action that justified liability under section 2.¹⁴²

131. See Creighton & Jacobson, *supra* note 127, at 54.

132. See *infra* Section II.C.

133. See *infra* text accompanying note 157.

134. 472 U.S. 585, 587–88 & nn. 2–5 (1985).

135. *Id.* at 591.

136. *Id.* at 594.

137. *Id.* at 591–93.

138. *Id.* at 593–94.

139. *Id.* at 595.

140. *Id.* at 608–09, 611.

141. *Id.* at 601, 603.

142. *Id.* at 610.

In its *Actelion* brief, the FTC turned to *Aspen Skiing* for the proposition that exclusionary conduct is more suspect when it is undertaken for reasons other than efficiency.¹⁴³ The FTC noted that the Supreme Court in *Aspen Skiing* characterized the conduct as being taken for predatory reasons when it “does not further competition on the merits” and “impair[s] the opportunities of rivals.”¹⁴⁴ Nevertheless, the FTC provided no analogy or factual discussion that compared *Actelion* to the *Aspen Skiing* exception, and it merely presumed predatory intent.¹⁴⁵ As explained below, the rule from *Aspen Skiing* is notably limited by the Court’s subsequent decision in *Trinko*, which makes clear that *Aspen Skiing* is a rare exception that “is at or near the outer boundary of § 2 liability.”¹⁴⁶

The *Actelion*, *Lannett*, and *Mylan* cases are more distinguishable from *Aspen Skiing* than they are similar. First, as noted by the FTC, there is no prior course of dealing from which to infer that the refusal to deal would be profitable.¹⁴⁷ Second, as is true of all generic market entry, there are obvious reasons to believe that such generic entry would harm a brand manufacturer’s profits and reduce its incentive to invest in new drugs in the future.¹⁴⁸ Third, as discussed below, there are valid business reasons that justify the brand manufacturers’ refusals to deal.¹⁴⁹ Taken together, the FTC draws a shallow comparison to the exception in *Aspen Skiing* and assumes away all evidence to the contrary without a substantive discussion of the competitive merits of the alleged business conduct.

3. *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*

In *Trinko*, the Court found that Verizon, the incumbent local exchange carrier, “enjoyed an exclusive franchise within its local service area.”¹⁵⁰ Verizon competed with local exchange carriers but had a regulatory obligation to complete “orders for service through an

143. *FTC Actelion Brief*, *supra* note 6, at 10.

144. *Id.* (quoting *Aspen Skiing*, 472 U.S. at 605, n.32 (internal quotation marks omitted)).

145. *See id.*

146. *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004); *see also* *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (holding that the antitrust laws do “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”).

147. *FTC Actelion Brief*, *supra* note 6, at 12.

148. *See infra* Section III.A.

149. *See infra* Section II.C.

150. 540 U.S. at 402.

electronic interface with Verizon's ordering system."¹⁵¹ Complaints emerged that Verizon was discriminatorily fulfilling these orders and creating a substantial barrier to entry for potential rivals.¹⁵² Verizon was concurrently under investigation by the FCC and ultimately entered into a consent decree to ensure compliance with its regulatory obligations.¹⁵³ The Court concluded that Verizon did not have a duty to deal with its rivals and rejected the notion that separate congressional or regulatory obligations altered Verizon's antitrust obligations.¹⁵⁴ The Court reasoned that monopolists might legally charge monopoly prices and do not have expanded obligations to deal with rivals.¹⁵⁵ The Court also warned about error costs in complicated and heavily regulated industries.¹⁵⁶ It indicated that the general competition goals of the antitrust laws are often inconsistent with the more specific goals of congressional regulation: "Mistaken inferences and the resulting false condemnations 'are especially costly, because they chill the very conduct the antitrust laws are designed to protect.'"¹⁵⁷

In its *Actelion* brief, the FTC looked to *Trinko* for three exceptions to the general principle that there is no obligation to aid your rivals. First, the FTC did not believe that a prior course of dealing was a prerequisite to finding antitrust liability.¹⁵⁸ Instead, the FTC argued that the Court should look to the effects on competition and a company's decision to sacrifice short-term profits absent a procompetitive business justification.¹⁵⁹ This approach is correct and, regardless of the existence of a valid business reason, indicates that refusals to provide drug samples for generic development may warrant a searching inquiry into the details of the relevant market. As discussed above, the FTC does not delve into efficiency justifications and does not provide a closer comparison of the cases.¹⁶⁰

Second, the FTC looked to language in *Trinko* stating that the company was refusing to sell something it "was already in the business of providing."¹⁶¹ In other words, by the FTC's logic, providing these samples to generic manufacturers would not impose any increased

151. *Id.* at 403.

152. *Id.* at 404.

153. *Id.* at 403–04.

154. *Id.* at 409–11.

155. *Id.* at 407–08.

156. *Id.* at 414–15.

157. *Id.* at 414 (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)).

158. *FTC Actelion Brief*, *supra* note 6, at 11–12.

159. *Id.* at 12–13.

160. *See supra* text accompanying notes 143–49.

161. *FTC Actelion Brief*, *supra* note 6, at 14 (quoting *Trinko*, 540 U.S. at 410).

burden or harm on brand manufacturers because the companies were already supplying the drugs to someone other than the generic.¹⁶² This argument ignores the basic presumption that these companies have a right to choose with whom they do business. Brand manufacturers sell drugs to consumers, hospitals, and wholesalers, but none of these sales create a duty to sell to a competing generic manufacturer.¹⁶³ Again, it is true that the sales would have no immediate adverse effect,¹⁶⁴ but that fact is generally irrelevant to the overarching antitrust obligations. The FTC seemingly argued that brand manufacturers have an obligation to deal with their rivals merely because it is possible.¹⁶⁵ That argument is insufficient to clear the high hurdle imposed in *Trinko* and provides no illumination as to why such an obligation should exist.

Third, the FTC stated that many of the anticompetitive concerns expressed in *Trinko*, including (1) “undermin[ing] the incentive to invest” in the joint product, (2) “setting the terms and conditions on which the monopolist must deal,” and (3) “encouraging collusion between the monopolist and its would-be rivals,” are not present in these pharmaceutical cases.¹⁶⁶

Although the second and third points are likely true, the first is much less clear.¹⁶⁷ A substantial amount of research suggests that earlier generic entry and the uncertainty of patent terms created by the Hatch–Waxman Act may have significant effects on the incentive to invest in new drugs.¹⁶⁸ Patent length is less certain, and the return on investment is lower when there is the uncertainty of infringement lawsuits and

162. *Id.* at 15.

163. See *Actelion Complaint*, *supra* note 5, at 10.

164. *FTC Actelion Brief*, *supra* note 6, at 15.

165. See *id.* at 14–15.

166. *Id.* at 14–15 (citing *Trinko*, 540 U.S. at 407–08).

167. It is possible that the second point might also be a concern in the REMS context. It is unlikely that the FTC or federal courts will be effective central planners for terms and conditions or supply contracts between brand and generic firms for REMS-restricted drugs. It is equally unlikely that the FTC or courts will be the best day-to-day enforcer of any established supply contract provisions. See Jan M. Rybnicek, *When Does Sharing Make Sense?: Antitrust & Risk Evaluation and Mitigation Strategies*, CPI ANTITRUST CHRON., Apr. 2014, at 7, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2429330 (proposing that the FDA, not the FTC, should use its “existing tools” to regulate REMS-restricted drugs).

168. See Panattoni, *supra* note 8, at 144 (“Paragraph IV decisions, largely starting in the late 1990s, may have strong implications for R&D incentives and . . . brand firms may have a considerable incentive to avoid the uncertainty and large potential profitability [losses] associated with these decisions. . . . [A] practical reality for the pharmaceutical industry was that patent length was more certain before 1998 than it was in the period afterward. An uncertain patent length has the benefits of possible early generic entry but brand and generic reactions raise the potential for negative welfare consequences.”).

earlier generic entry.¹⁶⁹ Accordingly, a longer guaranteed period of brand exclusivity ensures a strong incentive for manufacturing companies to invest in new and innovative drugs.

Also, as one response has noted, *Trinko* departed from previous refusal-to-deal cases specifically because it emphasized that monopoly power is lawful, and often desirable, in markets, and that a strong right to refuse to deal has many economic justifications, such as increasing the “incentive to invest in markets characterized by scale economies” and avoiding the necessity for “courts to act as central planners.”¹⁷⁰ Both benefits would be realized in the REMS-restriction cases and weigh against antitrust intervention.

4. The Profit-Sacrifice Test, No-Economic-Sense Test, and Prior Course of Dealing

The starting point for any refusal-to-deal analysis is that there is no duty to deal and that only exceptional and exceedingly rare circumstances allow for such a finding under the antitrust laws. The Court has previously found antitrust liability for refusal to deal in cases where a firm refused to sell a product or service to some competitors but not others, or where a firm was engaged in a prior course of dealing with a competitor and then changed course by refusing to continue to deal.¹⁷¹ Literature identifies two main tests for a refusal-to-deal analysis: the profit-sacrifice test and the no-economic-sense test.¹⁷²

A prior course of dealing can serve as a proxy for evaluating the potential economic harms or benefits resulting from the conduct.¹⁷³ For example, a prior course of dealing suggests that the refusal results in the sacrifice of profits and likely indicates that there is no valid business justification for the change in course.¹⁷⁴ One commentator has explained the profit-sacrifice test as follows: “[T]he decision maker weighs the costs and benefits of the conduct *to the defendant*. In particular, under

169. *See id.*

170. Creighton & Jacobson, *supra* note 127, at 50–51.

171. *Guide to Antitrust Laws: Refusal to Deal*, FED. TRADE COMM’N, <http://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/single-firm-conduct/refusal-deal> (last visited May 1, 2015); *see also, e.g.*, *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605, 608–11 (1985); Areeda, *supra* note 129, at 852.

172. *See* A. Douglas Melamed, *Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles?*, 73 ANTITRUST L.J. 375, 389 (2006) (describing the profit-sacrifice test); Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The “No Economic Sense” Test*, 73 ANTITRUST L.J. 413, 422 (2006) (describing the no-economic-sense test).

173. *See* Creighton & Jacobson, *supra* note 127, at 52.

174. *See* *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004).

this test, conduct is anticompetitive if, but only if, it makes no business sense or is unprofitable for the defendant but for the exclusion of rivals and resulting supra-competitive recoupment.”¹⁷⁵ Note that the test sets a fairly high bar for finding antitrust liability.¹⁷⁶

This test is conceptually identical to the no-economic-sense test, which is named merely to avoid confusion with obviously procompetitive conduct that sacrifices short-run profits, such as research and development or the costs of training employees.¹⁷⁷ One reading of the relationship between the tests, rooted in *Aspen Skiing* and *Otter Tail*, is that a prior course of dealing can be evidence that the no economic sense test is satisfied.¹⁷⁸ To determine the justifiability of a firm’s behavior, Professor Douglas Melamed believes that “[f]irms will have to ask only whether their conduct makes good business sense regardless of increases in their market power.”¹⁷⁹ This is because a legitimate business purpose will generally succeed in defending even a suspicious refusal to deal against an alleged antitrust violation.¹⁸⁰

B. Regulation and Antitrust in Credit Suisse

There is ample literature on the relationship between regulation and antitrust, establishing that at times antitrust liability is not the most appropriate remedy, especially when other regulatory frameworks are already in place.¹⁸¹ If *Trinko* makes clear that refusal-to-deal cases are

175. Melamed, *supra* note 172, at 389. Professor Douglas Melamed argues that the two relevant inquiries for this test are whether the defendant has given up profitable sales in a cost-benefit analysis and whether the conduct allowed the defendant to increase or maintain its market power by forgoing otherwise unprofitable sales. *Id.* at 389–90; *see also* Werden, *supra* note 172, at 414 (“[T]hat test asks whether challenged conduct would have been expected to be profitable apart from any gains that conduct may produce through eliminating competition.”).

176. *See* Melamed, *supra* note 172, at 390 & n.42.

177. For an explanation of the no-economic-sense test, *see* Werden, *supra* note 172, at 422–25. For a discussion of the no-economic-sense test in the REMS context, *see* Rybnicek, *supra* note 167, at 6–7.

178. *See generally* *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 597 (1985).

179. Melamed, *supra* note 172, at 393.

180. Areeda, *supra* note 129, at 852.

181. *See, e.g.*, Bruce H. Kobayashi & Joshua D. Wright, *Federalism, Substantive Preemption, and Limits on Antitrust: An Application to Patent Holdup*, 5 J. COMPETITION L. & ECON. 469, 475 (2009) (“[T]he Supreme Court’s antitrust jurisprudence is consistent with the proposition that the extension of antitrust liability to conduct that is adequately regulated by alternative legal rules and institutions is appropriately limited when the marginal benefit of antitrust enforcement is low or negative.”); Howard A. Shelanski, *The Case for Rebalancing Antitrust and Regulation*, 109 MICH. L. REV. 683, 684–85 (2011) (discussing the changing role of and limitations on antitrust in regulated markets).

on the outer boundary of section 2 antitrust liability,¹⁸² *Credit Suisse Securities (USA) LLC v. Billing*¹⁸³ may put similar cases completely out of reach.¹⁸⁴ In *Credit Suisse*, a class of buyers of securities alleged that underwriting firms engaged in behavior that violated antitrust laws.¹⁸⁵ The buyers alleged that in order to purchase a popular new security, the underwriters set up an agreement that forced buyers to purchase additional shares of that security at increasingly higher prices (called “laddering”), pay the underwriters unusually high commissions on future purchases, or purchase less desirable securities (called “tying”).¹⁸⁶ The Court agreed with the underwriters that federal securities law and the active supervision of the Securities and Exchange Commission (SEC) impliedly exempted this behavior from antitrust scrutiny.¹⁸⁷

The Court believed that this case fell within their existing preemption test from *Gordon v. New York Stock Exchange, Inc.*,¹⁸⁸ where the Court would not apply antitrust law when: (1) the conduct fell “squarely within the heartland of securities regulations;” (2) the SEC had “clear and adequate” authority to regulate; (3) there was “active and ongoing agency regulation;” and (4) there was “a serious conflict between the antitrust and regulatory regimes.”¹⁸⁹ The fourth consideration was the most hotly contested, but the Court found that the complexities of securities law were best left to the SEC to regulate, and that a conflicting antitrust regime would “threaten[] serious securities-related harm.”¹⁹⁰ Moreover, the SEC already takes competition concerns into account in applying securities law, thereby making a separate cause of action in federal court unnecessary.¹⁹¹

Some commentators suggest that *Credit Suisse* takes a step beyond *Trinko* by disapproving antitrust scrutiny of behavior governed by regulatory bodies with active and ongoing supervision.¹⁹² The FTC’s

182. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408–09 (2004).

183. 551 U.S. 264 (2007).

184. See Kobayashi & Wright, *supra* note 181, at 474 (“Specifically, *Credit Suisse* recognizes the value of limiting antitrust enforcement under circumstances where an alternative and competent regulatory apparatus is available *and* antitrust enforcement is likely to result in little additional social value because of the potential for welfare-reducing errors.”).

185. 551 U.S. at 267.

186. *Id.*

187. *Id.* at 267–68.

188. 422 U.S. 659 (1975).

189. *Credit Suisse*, 551 U.S. at 285.

190. *Id.* at 279.

191. See, e.g., *id.* at 283.

192. See Kobayashi & Wright, *supra* note 181, at 477 (“The message from the Court in *Credit Suisse* is that caution and modesty are warranted in considering an expansion of antitrust

briefs in *Actelion* and *Mylan* notably omit *Credit Suisse*,¹⁹³ even though a colorable argument can be made that Actelion's or Celgene's actions should qualify for implied immunity from antitrust law under the *Credit Suisse* standard. Applying the *Gordon* test to these refusal-to-deal cases shows the first two prongs easily satisfied. That is, the FDA's authority in this case (1) likely fits squarely within the heartland of pharmaceutical regulation because (2) the FDA has authority to enforce its own rules.¹⁹⁴

Generic manufacturers will certainly argue that the FDA's failure to clarify the regulatory obligation in these cases means they have not met the third prong of the test involving active and ongoing regulation,¹⁹⁵ but a court would likely disagree with this characterization. The FDA is aware of and actively involved in these cases. The agency has responded to some of the citizen petitions and, as recently as July 2013, held a public meeting to receive outside comment for reform.¹⁹⁶ The generic manufacturers' dissatisfaction with the pace and level of FDA action is not an argument that the agency is failing to actively regulate. It should be noted, however, that the FDA has acknowledged that it is not best positioned to address the competition-related issues raised by REMSs.¹⁹⁷ In fact, the FDA stated in a recent citizen petition response 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."¹⁹⁸ Of course, the agencies do not decide their jurisdiction over REMS-related competition concerns; rather, Congress determines this issue.¹⁹⁹ This is why we should be careful not to construe the FDA's request for help as grounds for FTC intervention in this area.

The applicability of the fourth prong of the *Gordon* test to REMS restriction refusal-to-deal cases is unclear and likely a closer call than in *Credit Suisse*.²⁰⁰ It is difficult to determine if there is a conflict between

liability when there is a competent alternative regulatory structure in place and the risks of false positives is significant.").

193. See generally *FTC Mylan Brief*, *supra* note 6; *FTC Actelion Brief*, *supra* note 6.

194. See *Credit Suisse*, 551 U.S. at 285.

195. *Id.* at 285.

196. See *Public Meeting: Standardizing and Evaluating Risk Evaluation and Mitigation Strategies*, FOOD & DRUG ADMIN., <http://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm351029.htm> (last updated Sept. 17, 2013).

197. Letter from Janet Woodcock, *supra* note 40, at 7.

198. *Id.*

199. See *id.* at 7–8 (recognizing the limits of the FDA's existing authority to collaborate with the FTC over REMS-related issues); *Independent Agencies and Government Corporations*, USA.GOV, <http://www.usa.gov/Agencies/Federal/Independent.shtml> (last updated Feb. 2, 2015) (noting that Congress creates independent agencies and thus the extent of their jurisdictions).

200. See *Credit Suisse*, 551 U.S. at 285.

the goals of pharmaceutical regulation and antitrust law because resolution of this question requires the application of both claims prior to deciding whether the antitrust claims are even relevant. The antitrust laws focus on promoting competition, consumer welfare, and price-effects, while relevant pharmaceutical regulations, including the FDAAA, are more concerned with patient health and safety.²⁰¹ There is not an obvious conflict, but even critics of *Credit Suisse* have admitted that the result is broad and creates a wide area of antitrust immunity in regulated industries. Howard Shelanski, former-Deputy Director for Antitrust in the Bureau of Economics at the FTC, submitted a written statement to Congress that included the following:

Credit Suisse goes beyond prior implied immunity cases by blocking some antitrust claims that are based on legitimate antitrust principles, are consistent with securities laws, and are not potentially repugnant to the regulatory scheme, but where the underlying conduct is similar enough to regulated conduct that a judge might confuse the two and create a conflict with regulatory authority.²⁰²

The Court in *Credit Suisse* does not articulate a cogent statement of what it means for the statutes to conflict. The Court does, however, provide some factors to consider, including: (1) the regulatory agency's concern with antitrust policy; (2) the possibility of error costs in general district courts and private suits; (3) the likelihood of conflicting guidance or requirements; and (4) the likelihood that antitrust juries would make serious mistakes.²⁰³

Applied to REMS restriction refusal-to-deal cases, the first factor sways against the application of antitrust immunity because the FDA is not concerned with competition policy.²⁰⁴ But the remaining factors are certainly debatable. This Article argues that these REMS restriction-

201. Compare ANTITRUSTLAWS.ORG, <http://www.antitrustlaws.org/> (last visited May 1, 2015) (noting the goals of antitrust laws), with *Food and Drug Administration Amendments Act (FDAAA) of 2007*, FDA, <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/significantamendmentstotheact/foodanddrugadministrationamendmentsof2007/default.htm> (last updated Dec. 2, 2011) (explaining the benefits of the FDAAA).

202. *Is There Life After Trinko and Credit Suisse? The Role of Antitrust in Regulated Industries: Hearing Before the H.R. Comm. on the Judiciary, Subcomm. on Courts and Competition Policy*, 111th Cong. 6 (2010) (statement of the Federal Trade Commission), available at <http://www.ftc.gov/public-statements/2010/06/prepared-statement-federal-trade-commission-courts-and-competition-policy>.

203. See *Credit Suisse*, 551 U.S. at 275–76, 281–82. It can be inferred from this guidance that the analysis is more detailed than merely asking what the generalized goals of the two statutes at issue seek to promote. Accordingly, courts may need to evaluate the specific claims in a case—in a broader regulatory context—to reach a sensible conclusion.

204. See Letter from Janet Woodcock, *supra* note 40, at 7.

related cases raise a high likelihood of significant error costs²⁰⁵ and promote harmful market uncertainty.²⁰⁶ This Article also argues that if brand manufacturers are violating neither the FDAAA nor the antitrust laws, then *Credit Suisse* is inapplicable, meaning that antitrust law should be applied but it was not violated. Alternatively, if a brand manufacturer has violated antitrust law, then *Credit Suisse* might still provide a safe harbor from liability if a court determines that there is a conflict after comparing the complex goals of the two regimes.²⁰⁷ Another possibility is that the conduct violates antitrust law that is inconsistent with pharmaceutical regulations, meaning that there is a conflict and thus rendering the action immune from antitrust law.

Most likely, *Credit Suisse* will not apply because there is not an intuitive or obvious conflict between the relevant statutes, and there may not be a conflict in the interpretation of the specific actions and claims of the case; that is, a court may determine that the failure to give drug samples to generic drug manufacturers is not an antitrust violation and is not a regulatory violation. These two consistent findings mean that a court will not apply antitrust immunity under *Credit Suisse*, but—having already found no antitrust violation—a court would then dismiss the case.

C. *Legitimate Business Justifications for a Refusal to Provide REMS-Restricted Samples to Generic Competitors*

As stated in *Aspen Skiing* and reflected in all of the Supreme Court's refusal-to-deal cases, no refusal to deal by a monopolist is deemed anticompetitive for purposes of antitrust liability if it is justified by "valid business reasons In other words, if there were legitimate business reasons for the refusal, then the defendant, even if he is found to possess monopoly power in a relevant market, has not violated the

205. See *infra* Part III.

206. See *infra* Section III.B.

207. In one sense this is a chicken-and-the-egg argument because it is possible that a court would need to evaluate the merits of the antitrust claim to determine if it should apply antitrust law at all. It may be easiest to think about this prong as a matrix with four possibilities: (1) if regulatory law is violated and antitrust law is not, then the court could apply antitrust law although the outcome is moot; (2) if neither regulatory nor antitrust law were violated, then the court will have to consider the goals of both regimes to determine if they are in conflict, but again, the outcome is irrelevant; (3) if both regulatory and antitrust law were violated, then there is seemingly consistency but a court would still need to determine that those violations did not represent conflicting goals; or (4) if regulatory law was not violated but the antitrust laws were, then there is a clear conflict and antitrust law should be precluded, likely immunizing the behavior from scrutiny.

law.”²⁰⁸ Even when the conditions of a refusal to deal are substantially or obviously anticompetitive, a “legitimate business purpose always saves the defendant.”²⁰⁹ And, in cases with claims more comparable to the generic manufacturers than those by Highland in *Aspen Skiing*, many courts have directly recognized, for example, that the desire to exclude others from protected intellectual property is itself a presumptively lawful valid business justification insulating a refusal to deal from antitrust liability.²¹⁰

It is notable that the FTC did not take a stance on the issue of valid business justifications in the *Actelion* case. Instead, the FTC stated that “Actelion may ultimately demonstrate that its refusal to sell to the generic firms is supported by a legitimate business justification. For purposes of this motion, however, the generic firms[?] contrary allegations are accepted as true.”²¹¹ At least three valid business justifications, which are addressed in more detail below, support the decision to refuse to provide drug samples of REMS- and ETASU-restricted drugs.

1. Regulatory Compliance: Distribution of Drugs Outside of the Explicit ETASU Restrictions Could Result in Substantial Fines or Penalties

One example of a REMS-restricted drug that demonstrates some of the dangers posed by drugs subject to these restrictions is Thalidomide, also marketed under the name Thalomid.²¹² The drug has a horrific history. Prescribed in the 1960s to pregnant women for morning sickness, even a single dose of thalidomide could cause severe birth defects, or even death, in unborn babies.²¹³ Before the drug was banned from pharmacies in 1962, there were an estimated 12,000 “thalidomide babies” born with phocomelia—severely deformed arms and legs also

208. 472 U.S. 585, 597 (1985) (internal quotation marks omitted) (citing the case’s jury instructions).

209. Areeda, *supra* note 129, at 852.

210. See, e.g., *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1218 (9th Cir. 1997) (“Under the fact-based approaches of *Aspen Skiing* . . . a monopolist’s ‘desire to exclude others from its [protected] work is a presumptively valid business justification for any immediate harm to consumers.’” (second alteration in original) (quoting *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1187 (1st Cir. 1994))).

211. *FTC Actelion Brief*, *supra* note 6, at 11 n.32.

212. *Thalidomide*, U.S. NAT’L LIBRARY OF MED., NAT’L INST. OF HEALTH, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a699032.html> (last updated May 19, 2015).

213. *Id.*; Sheryl Gay Stolberg, *Thalidomide Approved to Treat Leprosy, with Other Uses Seen*, N.Y. TIMES (July 17, 1998), <http://www.nytimes.com/1998/07/17/us/thalidomide-approved-to-treat-leprosy-with-other-uses-seen.html> (reporting on the side effects of thalidomide).

called “seal-flipper limbs.”²¹⁴ Only about 5000 “thalidomide babies” were still alive in 1998, when the FDA approved the use of thalidomide in the United States for the first time after it proved effective at treating complications from leprosy.²¹⁵

Today, people use the drug to treat not only leprosy but also cancer and HIV-related symptoms.²¹⁶ The side effects, which can occur during and after treatment, are severe; aside from causing severe birth defects, thalidomide can seriously affect the human nervous system.²¹⁷ As a result, the drug is subject to a REMS program that one observer in 1998 described as “the most strictly regulated . . . in the nation’s history.”²¹⁸ The system includes guidelines that women must at all times use two methods of birth control, and must undergo regular pregnancy tests while using thalidomide.²¹⁹ Further, “[a]ll people who are prescribed thalidomide . . . must be registered with Thalidomide REMS[®], have a thalidomide prescription from a doctor who is registered . . . , and have the prescription filled at a [registered] pharmacy . . . to receive this medication.”²²⁰ Additionally, thalidomide patients cannot donate blood during and for four weeks after treatment, and doctors may only write “a prescription for up to a 28-day supply . . . with no refills,” which the patient must fill “within 7 days.”²²¹

REMS-restricted drugs have greater safety and health risks. The thalidomide example illustrates that REMS programs ensure that misuse or adverse effects of these drugs can result in the FDA or courts imposing substantial fines or regulatory penalties pursuant to federal law. In extreme cases, a single REMS violation, when recurring, can warrant up to a \$10 million fine.²²² Due to the significant confusion over the

214. Stolberg, *supra* note 213.

215. *Id.*

216. *Thalidomide*, *supra* note 212.

217. *Id.*

218. Stolberg, *supra* note 213.

219. *Id.*

220. *Thalidomide*, *supra* note 212.

221. *Id.*

222. The FDA has issued a draft guidance detailing potential fines for violations of the requirements. U.S. DEP’T OF HEALTH AND HUMAN SERVS., FDA, GUIDANCE FOR INDUSTRY: FORMAT AND CONTENT OF PROPOSED RISK EVALUATION AND MITIGATION STRATEGIES (REMS), REMS ASSESSMENTS, AND PROPOSED REMS MODIFICATIONS (Sept. 2009), *available at* <http://www.fda.gov/downloads/Drugs/Guidances/UCM184128.pdf>. One section states that

a responsible person who violates a REMS requirement is subject to civil monetary penalties of up to \$250,000 per violation These penalties increase if the violation continues more than 30 days after FDA notifies the responsible person of the violation. The penalties double for the second 30-day period, and continue to double for subsequent 30-day periods, up to \$1 million per period

requirements for compliance with REMS, brand manufacturers are understandably concerned about their potential exposure.

One commentator has raised concerns that brand manufacturers are selling drugs “to third parties who will conduct human trials over which the branded companies have no control. Third parties’ failure to follow the meticulous use provisions could result in liability litigation against the branded manufacturer.”²²³ Even limited studies need to ensure that the use of the drugs complies with REMS requirements and, absent a clear showing that they will be conducted safely and according to FDA standards, brand manufacturers raise valid questions regarding potential penalties.

Absent a more persuasive plan for use of the drugs and general clarification from the FDA over compliance with REMS requirements, brand manufacturers have little proof that providing drug samples would not carry a risk of substantial sanctions; and they have little recourse to protect themselves against third-party actions. This explains why Actelion demanded reasonable assurances from the counterclaimants and the FDA that its REMS-restricted drugs would be administered in compliance with ETASU requirements.²²⁴

2. Products Liability: Recent Changes to Pharmaceutical Products Liability Law Imposed a Heightened Duty on Brand Manufacturers to Control and Safeguard Dangerous Drugs

The state of brand-name and generic drug competition has recently taken a number of peculiar turns that appear perverse and shift heavy liabilities onto the brand manufacturer while at the same time insulating generic manufacturers from similar liability.²²⁵ The Supreme Court came to seemingly contradictory conclusions when it determined that people could sue brand manufacturers for failing to warn of potential risks on pharmaceutical labels in *Wyeth v. Levine*,²²⁶ but then found that victims

and \$10 million per proceeding.

Id. at 7.

223. Glenn G. Lammi, *Is FTC Becoming an All-Purpose Health Care Cost Regulator?*, FORBES (May 31, 2012, 1:00 PM), <http://www.forbes.com/sites/wlf/2012/05/31/is-ftc-becoming-an-all-purpose-health-care-cost-regulator>.

224. *See supra* Subsection I.C.2.

225. *See, e.g.*, Lawrence O. Gostin, *The FDA, Preemption, and Public Safety: Antiregulatory Effects and Maddening Inconsistency* (Georgetown Public Law and Legal Theory Research, Paper No. 11-129, 2011), available at <http://ssrn.com/abstract=1945985> (“Thus, in less than four years, the Court barred state health and safety litigation for FDA-approved medical devices, allowed failure-to-warn claims for branded pharmaceuticals, and then barred those same claims for generic pharmaceuticals.”).

226. 555 U.S. 555, 581 (2009).

of generic drugs could not sue the generic manufacturer because federal law preempted their tort claims in *PLIVA, Inc. v. Mensing*.²²⁷ The Court's justification in *Mensing* was that although there should be a remedy against the generic manufacturer under state labeling laws, federal law required that generic labels be identical to the brand-name drug label and thus precluded a separate cause of action.²²⁸ The result is that brand manufacturers face substantially more tort liability for the manufacture and production of their products than generic manufacturers selling, by legal mandate, an identical product.²²⁹

In some areas of the United States, legal liability has become even more confusing. In *Conte v. Wyeth, Inc.*,²³⁰ the California Court of Appeals held that a brand manufacturer has a duty of care that can lead to liability even when the patient has only taken the generic version of the drug.²³¹ This is because the patient and doctor foreseeably rely on the product warnings of brand-name drugs regardless of which product is ultimately used to fill a prescription.²³² In other words, the brand manufacturer can have substantial tort liability arising from errors, mistakes, or inconsistencies caused by its generic rivals.

Some state courts have followed suit. The Supreme Court of Alabama held that brand manufacturers could be liable for fraudulent or misrepresentative statements made “in connection with the manufacture of a brand-name prescription drug” to a plaintiff only harmed by a generic version.²³³ This cause of action has become known as *innovator*

227. 131 S. Ct. 2567, 2580–81 (2011), *reh'g denied*, 132 S. Ct. 55 (2011); *see also* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2470 (2013) (extending *Mensing* and holding that “state-law design-defect claims that turn on the adequacy of a drug’s warnings are pre-empted by federal law”).

228. *See Mensing*, 131 S. Ct. at 2572–74, 2581.

229. *See, e.g.*, Gostin, *supra* note 225.

230. 168 Cal. App. 4th 89 (2008).

231. *Id.* at 114 (holding that “Wyeth’s common-law duty to use due care in formulating its product warnings extends to patients whose doctors foreseeably rely on its product information when prescribing [its brand-name drug] . . . whether the prescription is written for and/or filled with [the brand-name drug] or its generic equivalent”). For a more extensive discussion of the consequences of this decision, *see* Bridget M. Ahmann & Erin M. Verneris, *Name Brand Exposure for Generic Drug Use: Prescription for Liability*, 32 HAMLIN L. REV. 767, 769 (2009). A similar unpublished decision issued from the Pennsylvania Court of Common Pleas. *Id.*; *see* Clark v. Pfizer, Inc., No. 1819, 2008 Phila. Ct. Com. Pl. LEXIS 74 (Mar. 14, 2008). Nevertheless, most states continue to follow the more sensible rule from *Foster v. American Home Products Corp.* that liability only arises when the injured plaintiff can show that she took the defendant’s manufactured drug. *See* 29 F.3d 165, 170 (4th Cir. 1994); *see also* Brian Wolfman & Anne King, Mutual Pharmaceutical Co. v. Bartlett and Its Implications, BLOOMBERG LAW (Oct. 21, 2013), <http://www.bna.com/mutual-pharmaceutical-co-v-bartlett-and-its-implications/> (stating that most courts do not follow *Conte* and that “[t]he lead case is . . . *Foster*”).

232. *Conte*, 168 Cal. App. 4th at 94–95.

233. *Wyeth, Inc. v. Weeks*, No. 1101397, 2014 WL 4055813, at *22 (Ala. Aug. 15, 2014).

liability.²³⁴ A court in Vermont issued a similar ruling, holding that brand manufacturers have a duty to warn users of the generic versions of their drugs about potential side effects and risks.²³⁵

Innovator liability does not only affect manufacturers of brand-name drugs while their patented products are in the market. Often, brand manufacturers abandon the production of certain pharmaceuticals after generic entry, because the drug's resulting lower cost no longer justifies the manufacturer's costs of production, distribution, and potential liability.²³⁶ Nevertheless, the brand manufacturer still may face liability for adverse events occurring from a generic drug that the brand manufacturer no longer produces or sells.²³⁷

Brand manufacturers face additional possible lawsuits for millions or even billions of dollars in damages in class-action or mass-tort cases where generic versions of brand-name drugs caused injury either post-release or during bioequivalence testing. Accordingly, brand manufacturers sometimes face a confusing landscape of liabilities for products they do not manufacture, for errors they did not cause, and for actions of companies they do not control. From a business standpoint, these liability issues are real, and giving drug samples to generic manufacturers provides absolutely no benefit to the brand manufacturer. So long as these liability issues remain murky, the possibility for severe financial consequences with no countervailing business-related benefits justifies a wide range of exclusionary behavior.

234. *The Threat of 'Innovator Liability,'* WALL ST. J. (Mar. 13, 2013, 7:12 PM), <http://www.wsj.com/articles/SB10001424127887323628804578346231780434760>; see also Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 *FORDHAM L. REV.* 1835, 1870–71 (2013) (“[Innovator] liability is certain to create new and significant financial pressures on brand-name drugs, the effects of which would harm health care consumers. . . . Ironically, some plaintiffs have argued that manufacturers of brand-name drugs can never escape competitor liability, even by withdrawing from the market, saying that the basis for liability can be the representations made when educating physicians about their drugs during the period of exclusivity. . . . [I]t will become riskier for brand-name manufacturers to dedicate resources to researching and developing potentially life-saving or life-improving medicines, particularly when those medicines have greater health risks or are for small communities of people that will not drive large revenues.”).

235. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 709 (D. Vt. 2010).

236. See Schwartz et al., *supra* note 234, at 1870–71 (“[T]he fear of such liability would likely drive many brand-name manufacturers from a drug’s market once it becomes available in generic form. . . . Should the brand-name manufacturer prematurely withdraw from the market over liability, consumers will have lost the company most familiar with a medicine and the one that likely has the greatest infrastructure and resources to facilitate postmarket research and analysis into any late developing safety issues with a drug.”).

237. See *id.* at 1870 (discussing some plaintiffs’ argument that “manufacturers of brand-name drugs can never escape competitor liability, even by withdrawing from the market”).

Brand manufacturers' liability is the most outstanding issue and also the one Congress could most easily remedy; legislators could address the issue with a statutory liability shield to protect brand manufacturers from possible liability for generic drugs. The FDA could also take a more active role in clarifying these issues. Absent those actions, limiting the development of generics for the most dangerous drugs is necessary to avoid these likely liabilities and protect brand manufacturers from lawsuits. The ETASU restrictions are a signal that brand manufacturers need to tread lightly and ensure that they closely restrict and supervise any drug distribution. Generic alternatives represent a substantial risk for brand manufacturers and, thus, the brand manufacturers' refusals to provide REMS-restricted drug samples represent another valid business justification.

3. Health and Safety: Generic Drugs Pose Potential Medical Risks to Patients and Reputational Harm to Brands

Evidence is mounting that generic drugs may not always be as "identical" to the brand-name drug as the statutes require—something even the FDA has admitted in isolated cases.²³⁸ Some have speculated that generic drugs do not consistently perform as well as their brand counterparts and that these differences may pose acute health risks in certain drug categories or in certain high-risk patients.²³⁹

Moreover, generic drug labels frequently differ from the brand-name labels. One study indicates that over two-thirds of generic labeling did not conform to the brand-name drug's labeling, as regulations require.²⁴⁰ Mislabelled drugs can pose severe health risks if the omission of contraindications, allergies, and side effects from the label causes

238. See, e.g., Katie Thomas, *An Increase in Scrutiny for Generics*, N.Y. TIMES (Oct. 31, 2012), <http://www.nytimes.com/2012/11/01/business/fda-increases-scrutiny-of-some-generic-drugs.html> ("[T]he F.D.A. took the rare step of conducting its own study of the 300-milligram strength [after adverse reports started piling up on long-release versions of some generic drugs]. In early October, it announced that the drug did not, in fact, perform as well as the brand.").

239. For an argument by one pharmacologist, Joe Graedon, see *id.* ("[T]here's still a cloud hanging over generic drugs . . . This may be far more common than the F.D.A. had realized.").

240. See Jon Duke, Jeff Friedlin & Xiaochun Li, *Consistency in the Safety Labeling of Bioequivalent Medications*, 22 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 294 (2013), <http://onlinelibrary.wiley.com/doi/10.1002/pds.3351/pdf> (noting that "68% of multi-manufacturer drugs had discrepancies in ADR labeling" and that "[d]espite FDA mandate, bioequivalent drugs often differ in their safety labeling"); see also Emma Hitt, *Safety Info for Generic Drugs Often Differs from Brand Label*, MEDSCAPE MED. NEWS (Dec. 18, 2012), <http://www.medscape.com/viewarticle/776347> ("Generic drugs often differ from brand name drugs in their safety labeling despite standards mandated by the [FDA] . . ."). The extent of the health risks from this revelation is unclear, but mislabeled drugs certainly carry a heightened risk of being prescribed incorrectly. See *id.*

doctors to mistakenly prescribe drugs to vulnerable patients. The list of evidence and clinical trials revealing adverse effects and harmful medical results from generic substitution is growing. One study focusing on Narrow Therapeutic Index drugs (NTI drugs)—those with “small differences between therapeutic and toxic doses”—found that:

there are patient safety concerns with [bioequivalence], especially for NTI drugs. NTI drugs have some challenges for clinical safety and efficacy when generic substitutions are introduced. From an economic perspective, the immediate cost savings of generic substitution for NTI drugs is not worth the cost of increased probability of hospitalization or adverse health effects.²⁴¹

Another study, which used a large Canadian dataset, found specific and acute health risks from a number of generic formulations including “increased seizure frequency, morbidity, and use of health care services, with a number of patients requiring a switch back to their previous formulation.”²⁴² Although few studies have examined the subject thus far, there are other examples of health and safety risks posed by generic versions of brand-name drugs.²⁴³ REMS-restricted drugs with ETASU are potentially dangerous drugs that pose valid safety concerns to patients.

241. See Michelle Hottinger & Bryan A. Liang, *Deficiencies of the FDA in Evaluating Generic Formulations: Addressing Narrow Therapeutic Index Drugs*, 38 AM. J.L. & MED. 667, 669, 685 (2012).

242. Bernhard J. Steinhoff et al., *Substitution of Anticonvulsant Drugs*, 5 THERAPEUTICS & CLINICAL RISK MGMT. 449, 455 (2009), available at www.dovepress.com/getfile.php?fileID=4977 (including an additional reference to an investigation into antiepileptic drugs (AED), which found a “large body of unpublished, anecdotal evidence that substitution of [generic] AED formulations was associated with efficacy or safety issues . . . [and] was highly suggestive of a link between generic substitution and adverse effects”).

243. The American Academy of Neurology, which represents 19,000 neurologists, issued a position statement that “opposes generic substitution of anticonvulsant drugs for the treatment of epilepsy without the attending physician’s approval.” *Position Statement on the Coverage of Anticonvulsant Drugs for the Treatment of Epilepsy*, AM. ACAD. OF NEUROLOGY (Nov. 2006), https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/6.Public_Policy/1.Stay_Informed/2.Position_statements/3.PDFs_of_all_Position_Statements/anticonv.pdf (noting that the FDA allows for significant variation between brand-name and generic drugs and that even small differences “can result in breakthrough seizures”). Some commentators have noted the differences between the FDA’s bioequivalence standard and therapeutic equivalence. See, e.g., Melissa Healy, *FDA Standards Are Questioned*, L.A. TIMES (Mar. 17, 2008), <http://articles.latimes.com/2008/mar/17/health/he-genericside17> (“[T]he FDA permits a generic drug to release 80% to 125% of an active ingredient into the bloodstream [M]edical and pharmacology specialists warn that the FDA’s range may be too broad for some drugs, especially in cases where a drug has a ‘narrow therapeutic index’—the fine line between an ineffective dose and a dangerous one.”).

Adverse effects caused by differences in brand-name versus generic drugs can harm the reputation of the brand manufacturer despite lack of any fault. Consumers often do not distinguish between the brand name of a drug and the generic version, and will unjustly hold the brand manufacturer responsible for mistakes of the generic manufacturer.²⁴⁴ Any difference between the brand and the generic may open the door to generic products liability, but adverse events arising from generic versions of brand-name drugs may have an equal or disproportionate impact on the reputation of the brand name, harming future sales and confidence in the brand manufacturer.²⁴⁵

Two important aspects of any pharmaceutical business model are managing potential health and safety risks, and taking a precautionary approach by limiting the distribution of drug samples to medically approved practitioners. Accordingly, these health risks are a valid business justification for brand manufacturers' refusal to deal with generic manufacturers.

III. ERROR COSTS AND ANTITRUST INTERVENTION

The Supreme Court has recognized that business entities have a broad and robust right to refuse to deal with their rivals. This right comes from a strong concern about Type I errors²⁴⁶ and over-enforcement of the antitrust laws, which could lead to harmful legal rules that deter

244. See generally Schwartz et al., *supra* note 234 (discussing court decisions related to brand manufacturer liability for mistakes of the generic manufacturer).

245. The relevant economic literature indicates that companies use brand names to differentiate their products and signal to consumers that they have invested in quality and excellence. See Benjamin Klein, *Brand Names*, in THE CONCISE ENCYCLOPEDIA OF ECONOMICS 42, 42–43 (3d ed. 2008). Consumers pay more for brands because the familiarity of the brand indicates consumer confidence in the product. See *id.* at 43 (“When it is difficult to determine the quality of a product before purchase and the consequences of poor quality are significant, it makes economic sense for consumers to rely on brand names and the company reputations associated with them. By paying more for a brand-name product in those circumstances, consumers are not acting irrationally. . . . A company’s high reputation indicates not only that the company has performed well in the past, but also that it will perform well in the future because it has an economic incentive to maintain and improve the quality of its products. A consumer who pays a high price for a brand-name product is paying for the assurance of increased quality.”). Consumers often have difficulty understanding the differences in pharmaceutical brand and generic versions and are confused about the way the entire industry works. See Carol Rados, *Drug Name Confusion: Preventing Medication Errors*, MEDICINET.COM, <http://www.medicinenet.com/script/main/art.asp?articlekey=53208> (last editorial review Nov. 10, 2005) (indicating that confusion between different forms of drug names is common and sometimes causes serious side effects).

246. See Geoffrey A. Manne & Joshua D. Wright, *Innovation and the Limits of Antitrust*, 6 J. COMPETITION L. & ECON. 153, 158–59 (2010) (describing Type I errors as false positives and Type II errors as false negatives).

procompetitive business behavior²⁴⁷—a major concern in REMS cases.²⁴⁸ Embedded in the principles of error costs is a concern that the realities of the competitive marketplace check the actions of monopolies and dominant firms, but poor legal rules that condemn or sanction procompetitive business behavior have no check.²⁴⁹ All things equal, the harms of the latter are greater than the harms of the former. Judge Frank Easterbrook expressed this theory in his article *The Limits of Antitrust* where he stated that:

If the court errs by condemning a beneficial practice, the benefits may be lost for good. Any other firm that uses the condemned practice faces sanctions in the name of stare decisis, no matter the benefits. If the court errs by permitting a deleterious practice, though, the welfare loss decreases over time. Monopoly is self-destructive. Monopoly prices eventually attract entry. True, this long run may be a long time coming, . . . [b]ut this should not obscure the point: judicial errors that tolerate baleful practices are self-correcting, while erroneous condemnations are not.²⁵⁰

Viewed through the lens of the error-cost framework, antitrust intervention in the REMS context would be more costly to competition and consumer welfare than allowing market forces and existing regulatory oversight to settle the dispute. The likely decision-theoretic outcome and the correct presumption to apply in the case of forced sharing of REMS-restricted drugs is that antitrust intervention will be destructive for several reasons. First, a new exception to the refusal-to-deal doctrine will adversely impact pharmaceutical market incentives and consumer welfare. Second, endorsing a new exception to the refusal-to-deal doctrine will diverge from the antitrust presumption to avoid uncertainty and confusion in the marketplace. Third, existing FDA regulatory oversight precludes a policy supporting contradictory antitrust obligations.

247. See *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004) (“Mistaken inferences and the resulting false condemnations ‘are especially costly, because they chill the very conduct the antitrust laws are designed to protect.’ The cost of false positives counsels against an undue expansion of § 2 liability.” (citation omitted) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986))).

248. Some academics have acknowledged that Type I errors are an even bigger problem in innovation-type industries than in other cases. See Manne & Wright, *supra* note 246, at 164–66. “From an error-cost perspective, the fundamental problem is that economists have had a longstanding tendency to ascribe anticompetitive explanations to new forms of conduct that are not well understood.” *Id.* at 164.

249. See *id.* at 159 (discussing the connection between the error-cost framework and monopolization).

250. Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 2–3 (1984).

A. *Generic Entry Jeopardizes Consumer Welfare and Patient Health Because of Reductions in Drug Capitalization, Communication, Marketing, and Reporting*

There is a general consensus in the literature that the overall price of a drug falls as generics enter the market. The benefits of generic competition to consumers are well-documented in terms of price,²⁵¹ but other results are less clear. Much research finds that the price of brand-name drugs may stay steady or increase after generic entry occurs.²⁵² This conclusion indicates that some consumers are infra-marginal and that, for many consumers, brand-name drugs are inelastic. Moreover, many studies find that the overall sales volume of combined generic and brand-name drugs typically falls steeply after the generics enter the market, likely because of reduced advertising and marketing.²⁵³ The implications of these facts are not to be understated. The FTC insists that generic entry is an unqualified benefit to consumers because of the cost savings of lower priced drugs, but consumer welfare is a calculus of price, output, and quality. Decreases in advertising and marketing indicate that the overall consumption of drugs and consumer access to pharmaceuticals may drop because of earlier generic entry.²⁵⁴ This drop

251. This literature is extensive. See, e.g., Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PHARMACOECONOMICS 110, 121 (1996), <http://fds.duke.edu/db/attachment/467> (determining that the Hatch–Waxman Act has successfully encouraged generic-drug entry by changing the mix of generic integration from around 10% in the mid-1980s to nearly 40% in the mid-1990s).

252. See, e.g., Ernst R. Berndt, Margaret K. Kyle & Davina C. Ling, *The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches*, NAT'L BUREAU ECON. RESEARCH 229, 249 (Jan. 2003), <http://www.nber.org/chapters/c9737.pdf>.

253. Empirical studies of the results of generic entry on market prices and overall quantity of drugs sold have found mixed results, but the general trend is that brands abandon advertising and marketing and that the amount of drugs sold decreases as generics enter the market. For an article highlighting case study evidence that this drop is likely related to decreases in brand manufacturer advertising and marketing of drug products, see Peter J. Huckfeldt & Christopher R. Knittel, *Pharmaceutical Use Following Generic Entry: Paying Less and Buying Less* 2–3 (Nat'l Bureau of Econ. Research, Working Paper No. 17046, 2011), available at <http://www.nber.org/papers/w17046> (finding also that overall drug utilization rates drop two years before generic entry and continue to drop after entry occurs). Another paper similarly finds that generic entry leads to drops in advertising, marketing, and overall reductions in brand-name and generic drug sales. See Berndt, Kyle & Ling, *supra* note 252, at 244–51. Additionally, another paper finds that overall drug utilization and advertising decline after generic entry. See Richard E. Caves, Michael D. Whinston & Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, BROOKINGS PAPERS: MICROECONOMICS 26–30, 37–42 (1991), http://www.brookings.edu/~media/Projects/BPEA/1991%20micro/1991_bpeamicro_caves.PDF (finding also that brand-name drug prices rise immediately before generic entry but then fall modestly after entry).

254. This issue is complicated because the use of more drugs is not always beneficial. Typically, classical economics regards output increases of any good as consumer welfare

in the quantity of sales, combined with the possible quality and efficacy issues discussed above, severely complicates the consumer welfare conclusions of the FTC. Lower prices are desirable, but drug utilization rates and access to the healthcare system may suffer. This implies that endorsing an antitrust rule that has, at best, ambiguous effects on consumer welfare is bad policy.

Another important consideration is that the REMS restrictions, especially the ETASU, are applied only to drugs that require more careful distribution and use. Many of the REMS restrictions are focused closely on increasing communication and the dissemination of information between pharmaceutical companies, doctors, and patients.²⁵⁵ ETASU requirements focus on monitoring, reporting, and evaluating the use of dangerous drugs.²⁵⁶ These requirements share common themes of high costs and intensive labor. Generic manufacturers are often undercapitalized and may lack the resources to adequately implement the REMS restrictions.²⁵⁷ Doctors frequently complain about the lack of communication and involvement from generic manufacturers, and generic manufacturers almost never contact physicians in any capacity.²⁵⁸ A related concern is that the same federal preemption laws discussed above, which shield generic manufacturers

enhancing, but obviously drugs need to be prescribed accordingly by doctors. There is substantial academic literature on the issue of overmedication. *See, e.g.*, Wim J. van der Steen, *Assessing Overmedication: Biology, Philosophy and Common Sense*, 51 ACTA BIOTHEORETICA 151 (2003), available at http://download.springer.com/static/pdf/372/art%253A10.1023%252FA%253A1025119821313.pdf?auth6=1421120696_feef85b00339b4b3dabd238ba3d124c6&ext=.pdf (discussing the connection between overmedication and the pharmaceutical industry). This Article raises the issue merely to highlight that the consumer welfare effects are ambiguous, complicated, and not nearly as cut-and-dry as some might indicate. Nevertheless, a full discussion of the economics of pharmaceutical consumer welfare is beyond the scope of this Article.

255. Soller & Vogt, *supra* note 23.

256. *Id.*

257. Katie Thomas, *Generic Drug Makers See a Drought Ahead*, N.Y. TIMES (Dec. 5, 2012), <http://www.nytimes.com/2012/12/04/business/generic-drug-makers-facing-squeeze-on-revenue.html> (indicating that the initial “patent cliff” has dried up and that robust competition in the generic markets has severely limited profit margins, forcing generic manufacturers to either branch out into branded markets, specialize, or aim for larger international markets); *see also* William Hubbard, *The Debilitating Effect of Exclusive Rights: Patents and Productive Inefficiency*, 66 FLA. L. REV. 2045, 2046–47 (2014) (discussing other downfalls of the pharmaceutical industry and the harm this causes to consumers).

258. *See* LINDA L. BARRETT, AARP, PHYSICIANS’ ATTITUDES AND PRACTICES REGARDING GENERIC DRUGS 12 (2005), available at http://assets.aarp.org/rgcenter/health/phys_generic.pdf (“[R]epresentatives of generic drugs manufacturers are less likely to visit or dispense samples. Three in four (74 %) physicians say they or their practice has *never* been visited by a representative of a generic drug manufacturer and they are equally likely (76%) to say they have not received samples of generic drugs.”).

from tort liability, may also prevent the updating of drug labels to incorporate newly discovered health risks.²⁵⁹ This problem is enhanced when generic manufacturers are the sole source of many drugs because the branded version drops out of the market after generic entry makes participation unprofitable.²⁶⁰

In the case of REMS with ETASU, the most dangerous drugs may go without adequate follow-up and evaluation if generic versions enter the market. Consequently, physicians might mishandle subsequent reports of adverse effects or prescribe drugs in instances that jeopardize patients' health. Both possibilities, albeit hypothetical, should bear weight in the consideration of whether the refusal to provide drug samples is reasonable. Potential harm to consumer welfare from reduced utilization, decreased communication, and inadequate post-prescription review all justify brand manufacturers' reluctance to aid in the development of generic alternatives. While the REMS restrictions are common among pharmaceuticals, the ETASU restrictions are limited to a small fraction of brand-name drugs and represent a rational regulatory response to dangerous side effects. Accelerating entry of generic versions jeopardizes the safe and effective administration of these restrictions.

*B. A New Judicially Crafted Antitrust Exception Would Amplify
Uncertainty over the REMS Program and Would Risk Depressing
Pharmaceutical Investment*

The REMS restrictions are new and lack regulatory clarity, creating an environment where brand manufacturers are legitimately uncertain about their obligations and potential liabilities.²⁶¹ Refusal to aid generic

259. *Inability of Generic Drug Manufacturers to Warn of Newly Discovered Hazards Puts Patients at Risk; Serious Safety Hazards Often Take Years to Emerge*, PUBLIC CITIZEN (June 24, 2013), <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3922> (quoting Dr. Michael Carome to emphasize that “[g]eneric drug manufacturers’ inability under current regulations to update the labeling of their products poses a threat to the safety of prescription drugs, creating unnecessary risks to patients”).

260. PUBLIC CITIZEN, *GENERIC DRUG LABELING: A REPORT ON SERIOUS WARNINGS ADDED TO APPROVED DRUGS AND ON GENERIC DRUGS MARKETED WITHOUT A BRAND-NAME EQUIVALENT 1* (2013), available at <http://www.citizen.org/documents/2138.pdf> (“For those drugs, patients and physicians cannot rely on the brand-name manufacturer to monitor reports of adverse effects and update the labeling.”).

261. See generally *REMS: The New Reality*, CAMPBELLALLIANCE, http://www.campbellalliance.com/articles/campbell_alliance_REMS_article.pdf (last visited May 1, 2015). This uncertainty is a common thread in all industry discussion of REMS. See, e.g., Jill Wechsler, *REMS Raise Concerns for Biotech Products*, BIOPHARMINTERNATIONAL (Apr. 1, 2010), <http://www.biopharminternational.com/node/221970> (noting that REMSs have created “uncertainty among manufacturers as to what information the agency wants, and when”) There have been substantial “delays in providing needed guidance for industry and in answering many questions about how to implement REMS procedures,” and “[a] main source of confusion for

entry for REMS-restricted drugs is a method of limiting this uncertainty.

Uncertainty over REMS compliance is a major concern in the pharmaceutical industry. One medical contract research organization conducted a study of the REMS program and concluded that REMSs are “still an area of uncertainty, confusion, and concern for many sponsors.”²⁶² Because of this uncertainty, the REMS programs are likely to be increasingly the target of pharmaceutical litigation, mass-tort cases, and potential class actions. The REMS and ETASU programs cover the most dangerous drugs on the market and thus will be connected to a disproportionate number of adverse events and lawsuits.

Many specifics of the regulatory obligations and implementation of the REMS program remain murky. While compliance for one company is confusing, the joint-REMS requirements for drugs with both brand-name and generic versions are also unclear. Expounding on these very issues, the brand manufacturer Prometheus Laboratories filed a citizen’s petition to the FDA asking for clarification.²⁶³ The citizen’s petition notes that: (1) the FDA’s single joint REMS program, which requires cooperation with any generic manufacturer, “will be scrutinized by the [FTC] for antitrust issues and likely the plaintiff’s bar in the context of product liability litigation” ; (2) many REMS program developments are costly and require substantial investment and there is no guidance on how those costs should be shared between the brand and generic manufacturers; and (3) there is no guidance on standards for how REMS programs should be “designed or modified after approval” because any agreement “will be subject to state court review in determining liability in a state tort failure to warn case.”²⁶⁴ The common theme of this complaint is that the FDA’s silence is creating a marketplace of uncertainty where liabilities, risks, and costs of the REMS program are high.²⁶⁵ This uncertainty in the pharmaceutical regulatory environment makes investment in the industry risky and less attractive to drug manufacturers. The likely result is depressed research and development budgets and reduced innovation—a socially harmful outcome.

More clearly, should brand manufacturers be saddled with the affirmative duty to provide samples of REMS-restricted drugs to a generic competitor, there is a danger that research and development, as

manufacturers is when to start discussing the need for a REMS with the FDA and what kind of information the agency wants to see.” *Id.*

262. *Risk Evaluation and Mitigation Strategies (REMS) and the Impact on Opioid Analgesics*, PREMIER RESEARCH, http://premier-research.com/images/uploads/REMS_White_Paper_April_2010.pdf (last visited Feb. 12, 2015).

263. PROMETHEUS THERAPEUTICS, CITIZEN PETITION, No. FDA-2013-P-0572 (May 10, 2013), available at <http://freepdfhosting.com/6d7631c7c7.pdf> [hereinafter PROMETHEUS CITIZEN PETITION].

264. *Id.* at 11–12.

265. *See id.* at 7–8.

well as marketing of the drug, becomes unappealing to the brand manufacturer. The risks associated with providing the samples, or the costs associated with ensuring that the generic will properly handle the drug, may be too high to undertake. This, in turn, would remove the product from the market, and harm consumers by limiting their choices. Refusing to provide drug samples to generic manufacturers is, therefore, a reasonable means of controlling a brand manufacturer's business calculus by avoiding the confusion of unclear joint REMS programs, and a reasonable step toward avoiding the uncertainty of managing REMS compliance where there are multiple actors.

*C. Concern over Type I Errors and Conflicting Regulatory Regimes
Necessitates a Presumption Against Antitrust Intervention*

Antitrust liability is not necessary in REMS cases because the Supreme Court in *Trinko* provided guidelines that limit the role of antitrust when there are alternative regulatory or statutory schemes involved.²⁶⁶ Congress often crafts policy goals that diverge substantially from those of the antitrust laws. When the statutory framework promoting these goals is clearly articulated and overseen by a regulatory agency, it should be generally assumed that the agency has the discretion and right to oversee its own statutory scheme—even if those outcomes diverge from the expectations of antitrust policy.²⁶⁷ This approach to antitrust law precludes the need for a new exception to the duty-to-deal jurisprudence.

Trinko clearly establishes that violations of a regulatory scheme—the Telecommunications Act in that case—could not be the basis of an antitrust claim.²⁶⁸ Similarly, in the REMS context it is unlikely that a court would infer an antitrust violation from violations of the Hatch–Waxman Act, the Leahy–Smith America Invents Act (the most recent Patent Act), or abuse of the FDAAA. It is also unclear whether brand manufacturers are in violation of any of those statutory schemes. Although the congressional language in the FDAAA mandates that brand manufacturers are not allowed to “block or delay approval” of ANDAs,²⁶⁹ the language does not impose a clear obligation to facilitate generic manufacture or provide samples. Congress and the FDA have had chances to change that language and, to date, have not done so.

Additionally, this system is closely regulated and overseen by Congress, the FDA, and the Patent and Trademark Office. Congress has

266. See *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 412 (2004).

267. *Id.* at 412.

268. *Id.* at 415–16.

269. 21 U.S.C. § 355-1(f)(8) (2012).

entered the realm of healthcare legislation multiple times before and after passage of the Hatch–Waxman Act,²⁷⁰ which indicates that the current legislation is not a mere oversight. With a lack of a clear statutory duty and at least these three decision-making bodies involved in future regulation, the courts should feel safe that this is an area where antitrust is assuredly unnecessary to clarify parties' obligations. Evidently, the FDA is the most appropriate agency with the most relevant knowledge to settle this dispute, and citizens' petitions have requested that the FDA do just that.²⁷¹ Accordingly, the court should make it clear that it has no role in this dispute and that the FTC has no authority to interpret congressional regulation of the pharmaceutical industry.

Similar to the local exchange carrier in *Trinko*, brand manufacturers have no duty to deal with rivals. No persuasive case has been made that providing drug samples should be an exception to this rule. There are multiple extensive regulatory frameworks and federal agencies involved in overseeing the pharmaceutical industry, and generic manufacturers have a clearly defined administrative remedy that does not require the crafting of new antitrust liabilities; the available remedy is petitioning the FDA to commence an enforcement action.²⁷² Given these facts, the standards from *Trinko* indicate that antitrust liability does not follow from a refusal to provide drug samples for bioequivalence testing.

A more substantive application of existing refusal-to-deal jurisprudence indicates that there are many reasons to reject new antitrust obligations. Among others, there is no prior course of dealings between the brand and generic manufacturers because they are potential competitors. A prior course of dealing may provide a way to evaluate the potential economic harms or benefits resulting from conduct.²⁷³ Basic common sense indicates that generic entry will not benefit a brand manufacturer in the long run.²⁷⁴ While this lack of benefit does not excuse a brand manufacturer for restricting all sales to generics in all circumstances (e.g., when a drug is not REMS-restricted), it does support a policy of not establishing a new exception to the well-recognized competitor's right to refuse to deal. To be sure, the FDA's direct oversight of REMS-restricted drugs makes it unlikely that a brand manufacturer could easily establish REMSs for a drug to avoid

270. See generally Natalie Pous, *Shifting the Balance Between Branded and Generic Pharmaceutical Companies: Amendments to Hatch-Waxman Past, Present, and Future*, 19 FED. CIR. B.J. 301 (2009) (discussing the Hatch–Waxman Act, its background, and the subsequent congressional attempts to amend it).

271. See, e.g., PROMETHEUS CITIZEN PETITION, *supra* note 263.

272. 21 U.S.C. § 355(b)(2).

273. See *supra* note 173 and accompanying text.

274. See *supra* notes 251–54 and accompanying text.

distribution of samples to potential generic rivals. Also, the alleged behavior involves exclusion within the scope of a validly obtained patent in an industry where the patent structure is generally considered well implemented. A patent holder's protection of her own intellectual property is generally considered a procompetitive justification for exclusionary conduct.²⁷⁵ Crafting antitrust exceptions to these well-established rules carries a distinct possibility for overbroad applications beyond a narrowly tailored exception.

Forcing a patent holder to participate in and expedite the entry of generic competition before the expiration of the patent date has the potential to decrease the length and value of pharmaceutical patents, which will deter investment and ultimately limit innovation industry-wide. Again, case law is clear that absent exceptional circumstances there is no obligation to deal with rivals.²⁷⁶ An antitrust rule supporting the opposite proposition—introducing a new obligation to deal in the REMS context—might be broadly interpreted to limit the value and use of intellectual property when even the agencies have suggested that antitrust and IP “share the common purpose of promoting innovation and enhancing consumer welfare.”²⁷⁷ Relatedly and more importantly, forcing the patent holder to provide REMS-restricted drug samples to generic manufacturers risks harm to consumers: it reduces incentives for the brand manufacturer to provide the REMS-restricted drug in the first place because doing so would raise the brand manufacturer's risk, and thus its operating costs, to a point of economic infeasibility.²⁷⁸

Context for the Supreme Court's approach to generic drugs, and how it might respond to brand manufacturers' refusals to deal in the context of REMS-restricted drugs, can be extrapolated from the *FTC v. Actavis, Inc.*²⁷⁹ case where the competitive concerns of the pharmaceutical industry were most recently addressed.²⁸⁰ The Supreme Court evaluated a potentially collusive agreement where a generic manufacturer agreed to settle a Hatch–Waxman paragraph IV patent challenge with a brand-name drug.²⁸¹ The Court determined that the competitive concerns were

275. See, e.g., Benjamin Klein & John Shepard Wiley Jr., *Competitive Price Discrimination as an Antitrust Justification for Intellectual Property Refusals to Deal*, 70 ANTITRUST L.J. 599, 600 (2003) (discussing “the Federal Circuit's premise . . . that it is not necessary to undertake a fact-based inquiry into a patent holder's business justifications for its refusal to deal”).

276. See *Trinko*, 540 U.S. at 408–09.

277. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 2 (1995).

278. See Henry Grabowski et al., *Does Generic Entry Always Increase Consumer Welfare?*, 67 FOOD & DRUG L.J. 373, 384–85 (2012).

279. 133 S. Ct. 2223 (2013).

280. See *id.* at 2227.

281. *Id.* at 2227–29.

both exclusionary and collusive, as the settlement was potentially anticompetitive in preventing generic entry and deterring other generic challenges to the drug.²⁸² Despite the FTC's desire to apply a presumptively unlawful rule to these agreements, a rule that puts a thumb on the scale in favor of illegality, the Court held that reverse payments should be evaluated under the rule of reason.²⁸³ The presumption and development of antitrust law generally holds that agreements between competitors are more suspect than single-firm conduct.²⁸⁴

Comparing these agreements to refusal-to-deal cases, a presumption arises from the nature of the basic conduct that a more stringent rule or condemnation from federal courts than the one applied in *Actavis* is unlikely. Although similar competitive concerns are at play, it is hard to find a refusal to sell a patented drug to a potential competitor who has no clear statutory right to access that intellectual property more suspect than an agreement between those competitors to avoid competition and share the resulting monopoly profits. The *Actavis* case is more like the latter situation than the former, although plenty of these settlements may be procompetitive or benign. A refusal to deal is certainly a more settled area of antitrust law, where the basic rule is that no obligation to deal exists.²⁸⁵ Refusals to cooperate are often telltale signs of fierce competition. The simple conclusion is that an agreement between competitors is far more likely to raise competitive concerns than a refusal to agree. If pay-for-delay cases receive the rule of reason, then a refusal to cooperate should likely be per se legal or analyzed under a searching inquiry similar to the rule of reason.

Finally, the FTC's amicus brief begs the question of why the FTC is involved in this case at all.²⁸⁶ The FTC brings less knowledge than the FDA to the areas of regulatory pharmaceutical policy, even if the Commission has prepared reports and studied competition including incentives in this area.²⁸⁷ The FTC seems to be grasping at proverbial section 2 straws with its antitrust arguments. The Commission even hit on the shortcomings of its own arguments when it pointed to language in *Trinko* stating that antitrust analysis should "reflect the distinctive economic and legal setting of the regulated industry to which it

282. *Id.* at 2229.

283. *Id.* at 2236.

284. *See, e.g.,* Terazosin Hydrochlorid Antitrust Litig., 352 F. Supp. 2d 1279, 1313 (S.D. Fla. 2005).

285. *See, e.g.,* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 597 (1985).

286. *See supra* note 104.

287. *FTC Actelion Brief, supra* note 6, at 2–3.

applies.”²⁸⁸ The FTC attempted to argue that this language supported the idea that the pharmaceutical industry was designed to strongly support generic drug development,²⁸⁹ but it ignored the simple distinction that the pharmaceutical industry is already heavily regulated, is frequently directed by congressional legislation, and already functions efficiently without arbitrary antitrust liabilities.

IV. A SUGGESTED ANTITRUST ANALYSIS

If the courts determine that antitrust analysis is appropriate, then refusals to deal in the REMS context should be evaluated under the profit-sacrifice test. This Part argues that although other theories of antitrust liability such as the essential-facilities doctrine or unfair methods of competition under section 5 of the FTC Act have been suggested as appropriate tools for addressing this conduct, courts should not adopt these frameworks.

A. The Profit-Sacrifice Test Is the Appropriate Antitrust Standard for Refusals to Provide Brand-Name Drug Samples to Generic Manufacturers

Antitrust is rarely the answer in heavily regulated industries where an independent regulatory body or congressional action can obviate the need for an antitrust obligation or liability.²⁹⁰ Congress has had multiple chances to refine the language of the FDAAA and the FDA has had ample time to weigh in on and settle the issue. In the absence of action from either authority, it is imprudent to arbitrarily impose an antitrust obligation, as the FTC stated, merely because Congress “considered legislative proposals that would have created a more explicit statutory requirement.”²⁹¹ Actions that Congress merely contemplated do not sway in favor of a statute’s interpretation. Even the FTC has admitted that Congress “has rejected proposals that would have provided for more explicit statutory obligations.”²⁹²

Moreover, the FTC’s briefs ignore crucial comparisons that weigh strongly against imposing a new duty to deal. Although *Trinko*

288. *Id.* at 17 (quoting *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) (internal quotation marks omitted)).

289. *Id.*

290. See Herbert Hovenkamp, *Antitrust and Innovation: Where We Are and Where We Should Be Going*, 77 ANTITRUST L.J. 749, 754 (2011). (“[A]ntitrust is not the exclusive protector of competition in innovation intensive markets. Many competition issues can be addressed more effectively through the IP statutes themselves, either alone or in addition to prudent application of the antitrust laws.”).

291. *FTC Actelion Brief*, *supra* note 6, at 15.

292. *Id.* at 16.

recognizes the language of *Aspen Skiing* that the right to refuse to deal is not “unqualified,”²⁹³ the remaining question is what the appropriate test is to determine the narrow exceptions to the right to refuse to deal.²⁹⁴ The intended manner of applying of section 2 remains unsettled, as nailing down the anticompetitive standard has proven difficult. This is because “the behavior at issue in cases alleging monopolization by exclusion of competitors necessarily will often be quite difficult to distinguish from the vigorous rivalry that antitrust law seeks to promote.”²⁹⁵ Nevertheless, should courts reach the merits of *Actelion* or other similar cases on a section 2 antitrust claim, the profit-sacrifice test is ultimately the appropriate standard for evaluating refusals to provide brand-name drug samples to generic manufacturers. As explained previously, under the profit-sacrifice test, conduct is anticompetitive only if the defendant has no legitimate business purpose for the conduct or it is unprofitable in the short run and makes business sense only if a rival is excluded, leaving the defendant with a supracompetitive recoupment in the long run.²⁹⁶ The profit-sacrifice test “asks whether the conduct is profitable to the defendant in light of its (incremental) costs and . . . benefits” and “whether the conduct enabled the defendant to gain additional market power or a dangerous probability thereof.”²⁹⁷ Again, the test sets a high bar for finding a defendant liable for an antitrust violation.

Although at least one prominent antitrust scholar has attacked the viability and usefulness of the profit-sacrifice test,²⁹⁸ this test is consistent with *Otter Tail*, *Aspen Skiing*, and *Trinko* and is the likely antitrust inquiry a court would make in these pharmaceutical cases.

293. *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004).

294. *Trinko* has also been affirmed and extended by *Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, where the Court “reaffirmed the rights of parties to refuse to deal, saying further that the ‘instances in which a dominant firm may incur antitrust liability for purely unilateral conduct’ are ‘rare.’” Creighton & Jacobson, *supra* note 127, at 51 (quoting *Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc.*, 555 U.S. 438, 448 (2009)).

295. Susan A. Creighton et al., *Cheap Exclusion*, 72 ANTITRUST L.J. 975, 978–79, 979 n.17 (2005) (finding that any sophisticated analysis requires a careful balancing of Type I and Type II errors, with particular concern for avoiding false positives).

296. Melamed, *supra* note 172, at 389.

297. *Id.* at 389–90.

298. See Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 326 (2006) (“[T]he analysis [is] circular and the standard an empty shell.”). Professor Steven Salop’s position hinges on the idea that this standard is complex and requires the court to perform predictive economics by constructing a hypothetical market and subjectively assessing “the defendant’s likely conduct in the hypothetical absence of an ability to raise prices.” *Id.* at 358. Professor Salop instead suggests a standard consumer-welfare test that inquires into legitimate business justifications of the alleged conduct and the effect such actions would have on consumers. *Id.*

Attorneys Susan Creighton and Jonathan Jacobson explain:

In *Otter Tail*, the refusal to sell to rivals at the same price as the defendant was selling to everyone else was a distinction based solely on the character of the customer and was profitable only because of the negative effects on the customer-rivals. In *Aspen [Skiing]*, the refusal to accept Highlands' tickets at par or its cash-like vouchers was equally based solely on the character of the payer and otherwise made no sense. . . . *Trinko* involved no such facts, and that allowed the defendant to prevail. . . . No economic sense, then, was an important or controlling basis for illegality in *Otter Tail* [and] *Aspen [Skiing]*. . . and a decision that would make economic sense in a competitive market excused the denial of access in *Trinko*.²⁹⁹

They conclude this discussion by noting that forcing a monopolist to provide access to its assets poses a threat to future investment in the industry and may harm consumer welfare in the long run.³⁰⁰

The brand manufacturers' refusals to provide REMS-restricted drug samples to generic manufacturers would survive the profit-sacrifice test. First, apart from a single and limited one-time sale of drug samples, brand manufacturers are not sacrificing any profits. There is no clear evidence of any economic harm, long-term or short-term, from the refusal to sell. The FTC brief latched onto the profit-sacrifice language from *Aspen Skiing* to argue three separate times that the refused drug sales would have been made at retail price and, thus, constitute a sacrifice of profits.³⁰¹ At best, this argument is misleading. Although the generic manufacturers have offered to purchase the drug samples at full price, these requests are only for samples to conduct a single clinical study for bioequivalence testing. Although it is unclear exactly what sales volume this would constitute, in the context of a drug like Tracleer that sells over \$1.5 billion annually,³⁰² it is disingenuous to imply that the refusal to sell is *sacrificing profits*. The FTC's argument relies on a *de minimis*

299. Creighton & Jacobson, *supra* note 127, at 54.

300. *Id.*

301. The FTC argued that a brand manufacturer's "refusal to sell to generic rivals may provide evidence of its willingness to sacrifice profitable sales." *FTC Actelion Brief, supra* note 6, at 12. It continued that the "generic firms' allegations that they would be willing to compensate Actelion at full retail price support an inference, like in *Aspen Skiing*, that the refused sales would have been profitable." *Id.* at 13–14. Finally, the FTC concludes that Actelion's "refus[al] to provide access to its potential competitors, even if compensated at full retail price—support a viable theory of exclusionary conduct." *Id.* at 14.

302. See, e.g., Jim Edwards, *Cialis Goes up Against Viagra in Hypertension Add-On War*, CBS MONEYWATCH (Aug. 18, 2009, 12:20 PM), <http://www.cbsnews.com/news/cialis-goes-up-against-viagra-in-hypertension-add-on-war/>.

standard that yields ridiculous results—a woman who throws a cup of water into the ocean and declares that there is now more water. The argument is technically true, but the exchange does not represent a significant sale or a major sacrifice of profits. The FTC even admits later in its brief that this is merely “a one-time sale of a limited quantity.”³⁰³

Second, the determination of whether a certain sale constitutes sacrificing profits includes more consideration than merely the single transaction. In this case, the potential legal liability costs and the future costs of almost certain patent litigation can all be considered part of the costs of the sale of the drug. Both costs are substantial. As discussed above, generic drug versions expose brand manufacturers to innovator liability claims and common law negligence tort claims arising from incorrectly prescribed or mislabeled generic drugs.³⁰⁴ This liability can be massive and indicates that the costs associated with the sale of drug samples are far steeper than the profits made off a single, one-time sale. Another cost that must be included in the calculus of whether a sale is profitable is the resulting Hatch–Waxman litigation over the filing of a paragraph IV ANDA. By one measure, the average litigation costs of patent infringement cases could exceed \$6 million.³⁰⁵ Some may argue that avoiding litigation costs of potential paragraph IV suits should not be analyzed as a measure to avoid profit losses but rather avoiding competition. Even ignoring potential paragraph IV suits, by any measure, the anticipated litigation costs faced by brand manufacturers forced to sell drug samples of REMS-restricted drugs are substantial. When factoring in the costs of research and development associated with creating a new drug and proceeding through the full NDA approval process, one concludes that the sales of these drug samples to generic manufacturers are not profitable and that no antitrust violation can be established on the basis of sacrificed profits.

303. *FTC Actelion Brief*, *supra* note 6, at 15.

304. *See supra* notes 233–34 and accompanying text.

305. A 2009 survey by the American Intellectual Property Law Association estimated the size of attorneys’ fees in U.S. patent litigation, finding that “where the amount in dispute [was] between \$1 million and \$25 million, total litigation costs average in excess of \$3 million.” *See* William R. Towns, *U.S. Contingency Fees—A Level Playing Field?*, *WORLD INTELL. PROP. ORG. MAG.* 3 (Feb. 2010), *available at* http://www.wipo.int/wipo_magazine/en/pdf/2010/wipo_pub_121_2010_01.pdf. When the amount in dispute was higher than \$25 million, the average litigation costs were around \$6 million. *See id.* When the amount in dispute was lower than \$1 million then often the costs of litigation exceeded the amount at stake. *Id.* at 4. Costs up to the end of discovery usually exceeded 60% of the amount in controversy. *Id.* This study was not specific to Hatch–Waxman pharmaceutical patent infringement cases, but, based on the size of known settlements in reverse payment cases, it can be inferred that they are typically even more costly than average patent litigation in the United States. It should not be controversial to conclude that the litigation costs are substantial.

Third, the patented products create the right to protect and exclude others from the brand-name drugs. Indeed, the FTC does note that the Hatch–Waxman Act exempts generic drug development from patent infringement, but infringement is not the issue in this case.³⁰⁶ Just because generic manufacturers can legally develop generics does not mean that brand manufacturers have to be complicit in the development of their own competition. Excluding others from the use of a patented product is exactly what a patent allows—so long as that exclusion is not solely for the purpose of harming competition.³⁰⁷ This right to exclude is certainly not unqualified, and the question for antitrust purposes is to ask *why* the exclusion is occurring. Theoretically, even under the profit-sacrifice test, one could imagine a scenario where conduct could violate the antitrust laws. As mentioned previously, however, there is already a framework for oversight in place and any complaints about the regulatory process should be directed to the Patent and Trademark Office, the FDA, or Congress. Accordingly, following principles the Court espoused in *Credit Suisse*,³⁰⁸ applying the profit-sacrifice test ultimately does not weigh in favor of allowing antitrust liability in the REMS context, and any predicate antitrust claims should be rejected.

B. *The Courts Should Reject Alternative Theories for Single-Firm Antitrust Liability*

Alternative theories for section 2 liability include application of the essential-facilities doctrine and encouraging the FTC to wield its section 5 authority to bring cases under unique theories of consumer harm. As

306. *FTC Actelion Brief*, *supra* note 6, at 5; *see also* 35 U.S.C. § 271(e)(1) (2012). This has become known as the Bolar Amendment, which states that it is not

an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Id. In *Eli Lilly & Co. v. Medtronic, Inc.*, the Supreme Court found that the Bolar Amendment is notably confusing and that “[n]o interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.” 496 U.S. 661, 679 (1990). Section 271(e)(2), however, “define[s] a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications,” which means that the filing of a paragraph IV certification can still be an infringement. *Id.* at 676.

307. *See* Darren S. Tucker et al, *REMS: The Next Pharmaceutical Enforcement Priority?*, 28 ANTITRUST 74, 78 (2014) (noting that liability for mere refusals to license will not interfere with patent rights or antitrust protections).

308. *Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 285 (2007) (describing the four prongs of the *Gordon* test).

shown through discussion below, both approaches would lead to an injurious and confusing antitrust policy while relying on antiquated theories of consumer harm.

1. The Essential-Facilities Doctrine

Although the FTC opted out of commenting on the doctrine,³⁰⁹ generic manufacturers have argued that brand-name drug patents represent an essential facility.³¹⁰ This doctrine arises from a series of district court cases, but the Supreme Court has neither adopted nor completely repudiated the doctrine.³¹¹ The premise is that a monopolist controls and can anticompetitively restrict the sole means of access to a competitive market.³¹² The essential-facilities doctrine finds liability for abuse of dominance where a monopolist holds a bottleneck control over a mandatory or required input or resource—a “facility”—necessary for market competition.³¹³ That facility is usually in an upstream market and the doctrine requires that the facility cannot be duplicated.³¹⁴ The doctrine states that in these circumstances the monopolist must share access.³¹⁵ The patented drug could be characterized as an essential facility to competition in the pharmaceutical market for patients that need the drug.

The essential-facilities doctrine has come under heavy scrutiny and criticism.³¹⁶ Professors Phillip E. Areeda and Herbert Hovenkamp originally suggested six limiting principles for the doctrine³¹⁷ and have since concluded that “the essential facilit[ies] doctrine is both harmful

309. See, e.g., *FTC Mylan Brief*, *supra* note 6, at 9 n.23.

310. See, e.g., Tucker et al., *supra* note 307, at 74.

311. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 410–11 (2004).

312. One court divided the doctrine into a four-part test. *Advanced Health-Care Serv., Inc. v. Radford Com. Hosp.*, 910 F.2d 139, 150 (4th Cir. 1990). The elements of the test included “(1) control of the essential facility by a monopolist; (2) a competitor’s inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; and (4) the feasibility of providing the facility to competitors.” *Id.*

313. See Tucker et al., *supra* note 307, at 74, 81 n.49 (citing *MCI Commc’ns Corp. v. AT&T Co.*, 708 F.2d 1081, 1132 (7th Cir. 1983), *superseded by statute*, 47 U.S.C. § 152 (2012)).

314. See PHILLIP E. AREEDA & HERBERT HOVENKAMP, *FUNDAMENTALS OF ANTITRUST LAW* § 7.07[A], at 7-136–7-137 (4th ed. 2014).

315. See *id.* at 7-136.

316. See, e.g., Areeda, *supra* note 129, at 841 (“You will not find any case that provides a consistent rationale for the doctrine or that explores the social costs and benefits or the administrative costs of requiring the creator of an asset to share it with a rival. It is less a doctrine than an epithet . . .”).

317. *Id.* at 852 (“Compulsory access, if it exists at all, is and should be very exceptional.”).

and unnecessary and should be abandoned.”³¹⁸ The argument follows that a preferable antitrust inquiry will take a sufficiently focused look at the harms and benefits of an industry and the alleged anticompetitive conduct, which would sufficiently incorporate any aspects of limited access to a market. A separate essential-facilities doctrine is, thus, not required to evaluate the antitrust claims in any case.

Even so, some application of the essential-facilities doctrine persists in the district courts,³¹⁹ which necessitates a discussion of its application. The REMS-restricted drug patents should not qualify as essential facilities and, even if they did, the decision to restrict access is not anticompetitive under the remaining—albeit limited—essential-facilities doctrine. There are three reasons for this conclusion. First, although the drug patents can confer some level of monopoly power, they are not essential facilities. This is because nothing is stopping generic manufacturers from developing their own brand-name drug for similar treatments to the drugs in question and undergoing the full NDA process. This process would not require samples of the patented drugs and, even if unlikely, would provide a path to future competition in the same market. Simply because generic pharmaceuticals are unlikely to take this path is irrelevant to the conclusion that a single patented drug is not an essential facility to a competitive market, and that other avenues exist to enter that market. Mere difficulty does not mean that a potential rival has been anticompetitively excluded from a market if other means of entry exist.³²⁰

Second, courts applying the essential-facilities doctrine have focused intently on the competitive relationship between the parties. In *Intergraph Corp. v. Intel Corp.*,³²¹ the U.S. Court of Appeals for the Federal Circuit held that “there must be a market in which plaintiff and defendant compete, such that a monopolist extends its monopoly to the downstream market. . . . Absent such a relevant market and competitive relationship, the essential facility theory does not support a Sherman Act violation.”³²² In these cases, the generic manufacturers are not yet competitors in the relevant market. Before becoming competitors, they

318. AREEDA & HOVENKAMP, *supra* note 314, § 7.07[C], at 7-140 (internal quotation marks omitted).

319. See Tucker et al., *supra* note 307, at 74.

320. See, e.g., *Mid-South Grizzlies v. Nat'l Football League*, 550 F. Supp. 558, 569–70 (E.D. Pa. 1982), *aff'd*, 720 F.2d 772 (3d Cir. 1983) (holding where a non-professional football team was excluded from membership in the only professional league, that the league was not an essential facility because “[a]lthough not an easy task, plaintiffs are free to again attempt to form a rival football league”). The court also noted that others had attempted this feat before, meaning it was not infeasible. *Id.*

321. 195 F.3d 1346 (Fed. Cir. 1999).

322. *Id.* at 1357.

would have to complete drug development, conduct bioequivalence testing, receive FDA approval for their ANDA, file a paragraph IV certification, and win a likely patent infringement suit. These are a large number of incomplete intervening events to being considered a competitor in the relevant market. At best, the generic manufacturers are merely potential future competitors and absent a stronger showing of exclusion, the essential-facilities doctrine cannot apply. Third, as discussed above, valid business justifications exist for the conduct of the brand manufacturers and insulate their decisions from scrutiny under the essential-facilities doctrine.³²³

2. Section 5 of the FTC Act: Unfair Methods of Competition

The FTC is authorized under section 5 of the FTC Act to prosecute conduct that utilizes “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices.”³²⁴ Although the history of section 5 has provided little explanation of the proper function of this right, current FTC commissioners have issued proposed policy statements seeking to elucidate the bounds of section 5.³²⁵ While these proposed statements certainly do not constitute formal guidance from the FTC, they provide some insight into how the agency conceptualizes its section 5 authority. The argument has been made that section 5 should be used to attack the brand manufacturers’ use of REMSs to exclude generic competition.³²⁶ However, based on the recent FTC guidance on section 5 and a sound approach to antitrust policy, these cases are not dealt with correctly under the FTC’s section 5 authority. Additionally, liability standards for “refusals to deal” in the REMS context have been the subject of considerable thought and discussion by courts of appeals and the Supreme Court; at least one court has declined to apply section 5 policy in this context.³²⁷

323. See *supra* Section III.B.

324. 15 U.S.C. § 45(a)(1) (2012).

325. See, e.g., STATEMENT OF COMMISSIONER JOSHUA D. WRIGHT, PROPOSED POLICY STATEMENT REGARDING UNFAIR METHODS OF COMPETITION UNDER SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT, FED. TRADE COMM’N (June 19, 2013), available at <http://www.ftc.gov/speeches/wright/130619umcpolicystatement.pdf>; see also Maureen K. Ohlhausen, *Section 5 of the FTC Act: Principles of Navigation*, J. ANTITRUST ENFORCEMENT 1 (2013), available at <http://www.ftc.gov/speeches/ohlhausen/131018section5.pdf>.

326. See, e.g., David A. Balto, *Can Antitrust Laws Prevent Abuse of FDA Risk Programs?*, LAW360 (Sept. 4, 2013, 12:36 PM), <http://www.law360.com/articles/468192> (“Section 5 can play a particularly important role in health care markets. Assuming the likely unfairness associated with brand-named manufacturers using REMS to prevent generic entry, the FTC should apply Section 5 to future cases.”).

327. One circuit court noted that section 5 should not be used in areas where there is “well-forged” case law under the traditional antitrust laws because it might improperly blur the lines

First, although section 5 does extend beyond the bounds of the Sherman and Clayton Acts—as FTC Commissioner Joshua Wright has written—“the act or practice in question must result in, or likely result in, significant harm to competition as that term is understood under the traditional federal antitrust laws”³²⁸ and the conduct “must not generate cognizable efficiencies.”³²⁹ While this Article already addresses the relevant antitrust claims under the Sherman Act, Commissioner Wright points to two areas outside of traditional antitrust approaches that draw section 5 scrutiny: (1) invitations to collude, and (2) “unfair methods of competition to acquire market power that does not yet rise to the level of monopoly power necessary for a violation of the Sherman Act.”³³⁰ Only the latter example qualifies as a potential violation in the current REMS cases. Accordingly, the following analysis is confined to a discussion of potential anticompetitive harm and cognizable efficiencies.

A violation of section 5 can most easily be established with “evidence that the challenged conduct has a harmful impact on price or output.”³³¹ The likely competitive effects of a refusal to sell drug samples to generic manufacturers have, at best, an ambiguous and unclear impact on output and price. The FTC would likely point to evidence of lower prices when generic competition occurs, but nearly all studies of post-generic entry pharmaceutical markets also indicate that drug utilization and industry output falls after generic entry.³³² Any individual case would necessarily be fact-based, but a situation where certain conduct leads to lower prices and lower output could still have ambiguous competitive effects. Commissioner Maureen Ohlhausen has emphasized the need to provide clear guidance to businesses and the importance of reducing uncertainty.³³³ Bringing a standalone section 5 case against conduct that has vague competitive harm and has been approved by Supreme Court precedent—the refusal-to-deal doctrine³³⁴—under a Sherman Act claim,

between what is legal and what is illegal. *See* Rybnicek, *supra* note 167, at 2 n.2 (citing *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 581–82 (9th Cir. 1980)); WRIGHT, *supra* note 325, at 6 (“At the same time, the Commission will not challenge conduct as an unfair method of competition where there is well-forged case law under the traditional federal antitrust laws because the Commission does not have an institutional advantage in discerning competitive effects under such circumstances and prosecuting conduct under disparate standards may blur the line between lawful and unlawful behavior.”).

328. WRIGHT, *supra* note 325, at 5.

329. *Id.* at 9.

330. *Id.* at 8.

331. *Id.* at 7.

332. *See supra* note 253 and accompanying text.

333. Ohlhausen, *supra* note 325, at 9 (“[T]he agency should provide clear guidance and minimize the potential for uncertainty in the [unfair methods of competition] area.”).

334. *See Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004) (noting that a refusal-to-deal case must fit within limited exceptions for the Court to

does not provide clear antitrust guidance and risks chilling procompetitive conduct.

Finally, the refusal to provide drug samples to generic manufacturers raises cognizable efficiencies that insulate the behavior from condemnation under section 5. Cognizable efficiencies occur when there are “benefits that enhance consumer welfare [or generate] . . . significant welfare gains for consumers.”³³⁵ As discussed previously, there are significant policy justifications for the refusal to deal.³³⁶ It would be unprecedented for a court to take a step that mandated cooperation with a competitor and also forced sharing of dangerous drugs that would end up being administered to humans while raising liability and potential health risks in consumers. The drugs covered by ETASU raise substantial health risks that cannot be adequately managed if generic versions are administered and the regulatory environment of REMS has fostered uncertainty in the marketplace that harms investment and research. Accordingly, these cases are poor candidates for a section 5 claim and would expand liability into an area previously untouched by antitrust, creating the very uncertainty and lack of clarity that the FTC professes to eschew.

CONCLUSION

Despite the FTC’s endorsement of antitrust claims for refusals to deal in the REMS context, antitrust law is not the solution to every dispute that arises between businesses. Antitrust law seeks to encourage a competitive market where firms are supposed to rigorously compete for advantages and profits. Competition often appears, at first glance, as predatory, exclusionary, or self-interested. That is exactly the situation that has arisen in the *Actelion*, *Lannett*, and *Mylan* cases, and in other examples of brand manufacturers refusing to provide samples of REMS-restricted drugs to generic manufacturers for bioequivalence testing.

Section 2 of the Sherman Act recognizes a strong right for dominant firms to refuse to deal with their rivals. Any exceptions to this rule must be well established in economic theory to benefit consumers, encourage competition, and avoid error costs. This scenario does not represent a good candidate for an exception to the right to refuse to deal. The effects of a duty to deal would be uncertain, and substantial harm to innovation and incentives for research and development would be at stake. The pharmaceutical industry is heavily regulated and has complex goals and statutory schemes. The proper remedy in this case comes from those bills and regulations overseen by Congress and the FDA. Imposing antitrust

hold a party liable).

335. WRIGHT, *supra* note 325, at 11.

336. *See supra* Part II.

liability would, instead, stifle competition and innovation. The FTC has done little to aid this process by contorting antitrust law to reach the exact opposite conclusion. Accordingly, district courts should be vigilant in recognizing that these cases are not the proper medium for an unprecedented expansion of section 2 antitrust liability.