

Reviving Essential Facilities to Prevent REMS Abuses

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The Hatch-Waxman Act permits generic drug manufacturers to bypass the clinical drug trial requirement for drug approval if the generic product is the bioequivalent of a previously approved brand product. Generic drug companies typically purchase the brand drug through wholesalers to perform the bioequivalence testing. The Food and Drug Administration Amendment Act of 2007 granted the Secretary of Health and Human Services the power to restrict how high-risk products are distributed. A restricted distribution plan may prohibit wholesalers and pharmacies from dispensing the drug to anyone who is not registered with the FDA. Generics are therefore unable to obtain the brand product from wholesalers and must instead purchase directly from the brand manufacturer. However, some brand manufacturers have been reluctant to share their patented products with competitors who might challenge the validity of their patents. This Note argues that courts should hold brand drug companies that refuse to sell their products to generic manufacturers for bioequivalence testing in violation of section two of the Sherman Act based on the “essential facilities” doctrine.

I. INTRODUCTION

Patent law and competition law act as opposing forces which, when balanced, maximize the incentive to innovate.¹ The pharmaceutical industry has been a central focus in the debate over

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1. See FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), available at <http://www.ftc.gov/os/2003/10/innovationrptsummary.pdf>. See also JOHN G. MILLS ET AL., 5 PAT. L. FUNDAMENTALS § 19:25 (2d ed. 2013).

the appropriate balance between patent law and antitrust for the last decade. The Supreme Court recently held that courts should review pay-for-delay settlements (also known as “reverse settlements”) between brand and generic drug manufacturers, in which a brand company pays a generic competitor to delay its entry to the market, under the “rule of reason” to determine if the agreement is anticompetitive.² Recent legislation to promote drug safety has the potential to ensure that the pharmaceutical industry remains a key area in the intersection between antitrust and patent law for the foreseeable future.

The Federal Drug Administration Amendments Act of 2007 (“FDAAA”) altered that balance in favor of brand pharmaceutical companies at the expense of generic drug companies, and, ultimately, consumers. Under the Hatch-Waxman Act of 1984, generic companies could rely on extensive clinical trials completed by brand drug companies (who enjoy monopoly profits during the life of the drug patent) to satisfy the requirements for FDA approval merely by establishing that the generic product is the bioequivalent to the already-approved brand product.³ The FDAAA gave the FDA (through the Secretary of Health and Human Services) the power to require drug manufacturers to comply with Risk Evaluation and Mitigation Strategies (“REMS”) for potentially hazardous drugs.⁴ In some cases, a REMS requires the manufacturer to ensure that the product is sold only to certified wholesalers, who will pass the product on to certified pharmacies and hospitals, which will only dispense the product to registered patients.⁵ A few brand drug companies have seized upon these distribution restrictions as an opportunity to refuse to provide their product to generic competitors for bioequivalence testing.⁶

2. See *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

3. 21 U.S.C.A. § 355-1 (West 2013).

4. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at scattered sections of 21 U.S.C.).

5. See 21 U.S.C.A. § 355-1(f)(3).

6. See Defendants’ Rule 12(b)(6) Motion to Dismiss and Memorandum of Points and Authorities in Support, *Burlington Drug Co. v. Reckitt Benckiser Group*, No. 2:12-cv-282-JGM (D.V.T. Mar. 8, 2013); Complaint for Declaratory Judgment, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD, 2012 WL 4363827 (D.N.J. Sept. 14, 2012); Defendant Celgene Corporation’s Memorandum of Law in Support of Its Renewed Motion to Dismiss, *Lannett Co., Inc. v. Celgene Corp.*, No. 08-3920, 2011 WL 1193912 (E.D. Pa. Mar. 29, 2011) (No. 08-3290). See also End Payor Plaintiffs’ Consolidated Amended Class Action Complaint, *In re Suboxone Antitrust Litig.*, No. 2:13-md-02445-MSG, 2013 WL 5467390 (E.D. Pa. Aug. 15, 2013); Citizen petition letter from Kumar Sekar, Ph.D., Senior

Generic manufacturers can expect significant litigation expenses if the brand company sues for an injunction to prevent entry.⁷ However, generic manufacturers who succeed in gaining early entry can benefit from additional years of revenue, and if they are the first generic to enter, they also gain a limited period of exclusivity relative to other generic companies.⁸ Generic companies therefore only challenge a patent when they have a sufficiently high likelihood of successfully challenging the patent and can expect to make sufficient profits to overcome the initial litigation costs. Hemphill and Sampat analyzed 479 drugs between 2000 and 2009 and empirically demonstrated that generic companies challenge patents as predicted: “[Brand] sales have a strong and positive effect on the likelihood of challenge. But conditional on sales, challenges are also responsive to the presence of weak patents, particularly those generating the largest increments to nominal patent term.”⁹ Generics serve as a check against brand companies by challenging weak, inefficient patents, particularly where the drug generates significant revenue for a monopolist brand manufacturer.

Brand drug companies depend on blockbuster drugs as a key source of revenue.¹⁰ While patents last twenty years, the FDA approval process typically occupies a large portion of that period.¹¹ Brand companies must try to recoup their research and de-

Dir., Regulatory Affairs and Compliance, Dr. Reddy’s Laboratories, Inc., to FDA (Jun. 10, 2009) [hereinafter “Citizen Petition”], available at <http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0266-0001>.

7. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1574 (2006) (citing AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY 2005 22 (2005)) (reporting that litigation can cost each side millions of dollars; the median expense for a patent dispute worth more than \$25 million was \$4.5 million in 2005).

8. The FDA grants the first generic to enter a 180-day period of exclusivity from other generic competition. 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

9. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. OF EMPIRICAL LEGAL STUD. 613, 635–36 (2011).

10. See, e.g., JOHNSON & JOHNSON, ANNUAL REPORT (Form 10-K) 3 (Feb. 23, 2012) available at <http://sec.gov/Archives/edgar/data/200406/000119312512075565/d281803d10k.htm> (reporting that REMICADE, the company’s most successful product, alone accounted for 8.4% of Johnson & Johnson’s total revenues for 2011); PFIZER INC., ANNUAL REPORT (FORM 10-K) 4 (Feb. 21, 2012) available at http://sec.gov/Archives/edgar/data/78003/000119312512085703/d278590d10k.htm#toc278590_6 (reporting that each of twelve Pfizer biopharmaceutical products earned over \$1 billion in 2011, which accounted for 56% of total revenues for the biopharmaceutical division).

11. The FDA approval process only begins after the patent issues, which can cause a delay of four or more years. Drug manufacturers must then complete the necessary FDA

velopment costs and turn a profit in a much shorter period of exclusivity, usually in the last five to six years of the original patent's life.¹² Generic competition significantly decreases prices and draws away sales from brand drug companies,¹³ and where the potential windfall from a blockbuster product is available, generic competition is particularly intense and can quickly erode a brand company's revenues.¹⁴ Thus, brand companies have a significant incentive to shield their blockbuster products in particular from generic competition through the acquisition and protection of patents.

While the Federal Trade Commission (FTC) and the Connecticut State Attorney General have launched investigations into potential REMS abuses, it remains unclear whether a brand drug company has a duty to aid generic competitors.¹⁵ Congress twice tested and rejected language which would require brand drug companies to supply generics with sufficient product for bioequivalence testing¹⁶ and instead has selected language which merely prohibits "block[ing] or delay[ing]" approval of a generic competitor's drug application.¹⁷ The FDA has received a citizen petition asking for clarification of what a brand drug company is obligated to do to meet the standard, but several years later the agency has not offered a definitive answer.¹⁸

clinical trials over a ten-year period before they can sell the drug to consumers. See Dennis S. Fernandez et al., *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay can Affect Market Entry*, in IP HANDBOOK OF BEST PRACTICES 965, 967 (A. Krattiger et al. eds., 2007), available at <http://www.iphandbook.org/handbook/chPDFs/ch10/ipHandbook-Ch%2010%2009%20Fernandez-Huie-Hsu%20Patent%20and%20FDA%20Interface%20rev.pdf>.

12. *Id.*

13. See Atanu Saha et al., *Generic Competition in the US Pharmaceutical Industry*, 13 INT. J. OF THE ECONOMICS OF BUSINESS 15, 29 (2006) (demonstrating that increased generic competition led to decreased prices and decreased market share for a sample panel of drugs).

14. See *id.* at 35. See, e.g., JOHNSON & JOHNSON, *supra* note 10 (reporting that sales of LEVAQUIN, a brand product which faced generic competition for the second half of 2011, decreased 54.1% from the prior year.)

15. Dina ElBoghdady, *Generic-Drug Makers' Complaints Over Brand-Name Access Prompt Investigations*, WASH. POST, May 22, 2012, available at http://www.washingtonpost.com/business/economy/generic-drug-makers-complaints-over-distribution-law-provoke-investigations/2012/05/22/gIQAhExKiU_story.html.

16. H.R. 2900, 110th Cong. § 901(f)(6) (1st Sess. 2007); S. 3187, 112th Cong. § 1131(k) (2d Sess. 2012).

17. 21 U.S.C.A. § 355-1(f)(8) (West 2013).

18. See Citizen Petition, *supra* note 6.

This Note explains the conflict between brand and generic drug companies created by REMS distribution restrictions and investigates potential solutions to the dispute. Part II explains the process by which generic drug companies challenge brand patents and seek FDA approval, identifying the problematic legislative history underlying the FDAAA related to refusals to deal.¹⁹ Part III evaluates several methods to address REMS abuses, including patent law and antitrust remedies. Part IV argues that, absent legislation which specifically requires brand drug companies to provide generic competitors samples for bioequivalence testing, courts should rely on the essential facilities doctrine to hold REMS abusers in violation of section two of the Sherman Act. A recently approved drug, Kynamro, appears throughout this Note as an example of a brand product subject to distribution restrictions.²⁰ There is no evidence that Genzyme, the company which developed Kynamro, has refused to provide a generic company with sufficient product for bioequivalence testing. However, the REMS restrictions and market conditions surrounding Kynamro demonstrate many of the unresolved issues regarding brand refusals to deal REMS-restricted products.

II. CHALLENGING A PHARMACEUTICAL PATENT

A. TRADITIONAL PATENT CHALLENGES

Generic drug companies can challenge brand drug patents through two review processes: *ex parte* review and *inter partes* review. In *ex parte* review,²¹ the generic company submits a challenge to the PTO which argues there is a “substantial new question of patentability.”²² The patent holder may respond to the challenge initially, but it may also wait until the reexamination

19. “Refusals to deal” occur when a firm refuses to contract with a competitor.

20. Kynamro was selected because it the most recently approved product subject to a distribution restriction. Since Kynamro is not the subject of any current controversy, this Note can address some of the potential issues surrounding REMS abuses without the influence of pending complaints and motions. See *FDA Approved Drug Products*, FDA, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/> (last visited Nov. 26, 2013) (follow: “K” hyperlink; then follow “Kynamro” hyperlink).

21. “Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301.” 35 U.S.C. § 302 (2006).

22. ROBERT A. MATTHEWS, JR., 4 ANNOTATED PATENT DIGEST § 25:97 (2013).

hearing to dispute the invalidity of its patent.²³ The generic petitioner may respond to any interim statements made by the patent holder, but the petitioner may not participate in the final reexamination hearing.²⁴

Generic drug companies can also challenge brand patents through *inter partes* review.²⁵ *Inter partes* review is a trial before a panel of the Patent Trial and Appeal Board,²⁶ instituted to “provide faster, less costly alternatives to civil litigation to challenge patents.”²⁷ *Inter partes* review cannot be made anonymously, like *ex parte* review, but may be instituted by anyone “who is not the owner of the patent.”²⁸ The Patent Trial and Appeal Board has one year to issue a final ruling after receiving the *inter partes* challenge,²⁹ and losing parties may appeal to the Federal Circuit.³⁰ The final results of *inter partes* review estop the petitioner and the patent holder from relitigating the claims in civil litigation, in front of the PTO, and in front of the International Trade Commission.³¹ The *inter partes* process, and, in particular, the ability of third parties to comment on the litigation, has been cited as an important factor in eliminating pro-patent bias observed in some *ex parte* proceedings.³² Generic companies can only use *inter partes* review to challenge patents filed after November 30, 1999.³³

While there are several vehicles for generic competitors to challenge brand patents and gain access to the market occupied

23. *See id.*

24. *See id.*

25. “(a) In general.--Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an *inter partes* review of the patent . . . (b) Scope.--A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.”

35 U.S.C. § 311 (2006).

26. *See* MATTHEW A. SMITH, *INTER PARTES* REVOCATION PROCEEDINGS § 15:1 (2012).

27. 157 Cong. Rec. S936-02 (Feb. 28, 2011).

28. *See* 35 U.S.C. § 311.

29. *See* SMITH, *supra* note 26, at § 15:34.

30. *See id.*

31. *See id.* § 15:56.

32. *See id.* § 2:4.

33. *See* MATTHEWS, *supra* note 22 (“ . . . this subtitle and the amendments made by this subtitle shall take effect on the date of the enactment of this Act and shall apply to any patent that issues from an original application filed in the United States on or after that date.” (citing Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, sec. 4608(a))).

by REMS-restricted products, those remedies are incomplete. Patent litigants incur significant costs to demonstrate the invalidity of a patent.³⁴ Once the patent is invalidated by the PTO, however, any generic company can take advantage of the absence of patent exclusivity. There is a potential freeriding problem if the generic litigant who prevails in invalidating a patent is unable to reap the rewards because other generic companies swoop in to divide up the few rents remaining in the now-liberated market. Even though FDA approval presents a regulatory hurdle before generics enter the market, there is no guarantee that the generic litigant will be the first to receive approval after successfully invalidating the patent. Congress addressed this freeriding problem within a broader regulatory reform of pharmaceutical regulation which redesigned the incentives of brand and generic drug companies to foster both innovation and competition: the Hatch-Waxman Act.

B. ABBREVIATED NEW DRUG APPLICATIONS: A LEGISLATED TOOL FOR THE PHARMACEUTICAL INDUSTRY

1. *The Hatch-Waxman Act*

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, created a statutory framework which makes generic drug companies dependent upon access to brand drugs. The Act introduced Abbreviated New Drug Applications (ANDAs) which permit generic companies to circumvent the FDA's stringent clinical testing requirements for new drugs if the generic product is the bioequivalent of an already-approved product.³⁵ The FDA has released several non-binding recommendations for bioequivalence testing.³⁶ There are

34. See Hemphill, *supra* note 7.

35. See 21 U.S.C.A. § 355(j)(2)(A)(iv) (West 2013). Bioequivalent drugs have active ingredients of the same pharmaceutical or therapeutic class and have the same therapeutic effects when used to treat patients with the related condition. *Id.*

36. See, e.g., U.S. DEP'T OF HEALTH AND HUMAN SERVICES ET AL., GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES FOR ORALLY ADMINISTERED DRUG PRODUCTS — GENERAL CONSIDERATIONS (Mar. 2003); U.S. DEP'T OF HEALTH AND HUMAN SERVICES ET AL., GUIDANCE FOR INDUSTRY: FOOD-EFFECT BIOAVAILABILITY AND FED BIOEQUIVALENCE STUDIES (Dec. 2002); U.S. DEP'T OF HEALTH AND HUMAN SERVICES ET AL., GUIDANCE FOR INDUSTRY: SUBMISSION OF SUMMARY BIOEQUIVALENCE DATA FOR ANDAS (May 2011).

a variety of methods to establish bioequivalence,³⁷ but generally speaking generic companies conduct single-dose studies with twenty-four to thirty-six healthy adult subjects.³⁸ New drug approval is a costly and time-consuming process, and ANDAs permit generic companies to enter the market without an inefficient replication of clinical trials.³⁹ The statute stratifies brand and generic drug manufacturers. Brand companies have a relative advantage in research and the new drug approval process, and generic companies (in reliance on ANDAs) have a relative advantage in producing drugs at low cost. Brand companies that complete the costly full approval process are rewarded with a period of monopoly profits as the exclusive producer of the drug.⁴⁰ Generic companies, in contrast, must immediately compete with the original brand company and potentially with other generic companies.⁴¹ Generic companies rely upon the ANDA process to minimize entry costs as they enter a competitive marketplace. Yet without access to the brand drug to prove bioequivalence, generic companies cannot take advantage of the ANDA process.

ANDAs are also the main mechanism generic companies use to challenge brand drug patents and attempt to enter the market

37. See GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES, *supra* note 36, at 6 (“In descending order of preference, these include pharmacokinetic, pharmacodynamic, clinical, and in vitro studies.”).

38. See Sam H. Haidar et al., *Bioequivalence Approaches for Highly Variable Drugs and Drug Products*, 25 PHARM. RES. 237, 238 (2007).

39. In 2006, the Congressional Budget Office estimated that the average research and development costs of a new molecular entity were \$800 million. DAVID H. AUSTIN, CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 19 (2006). An alternative study conducted by the Manhattan Institute on behalf of the FDA estimated that the average cost to develop one new drug through clinical trials was \$1.3 billion in 2005, up from \$100 million in 1975. AVIK S. A. ROY, THE MANHATTAN INSTITUTE, STIFLING NEW CURES: THE TRUE COST OF LENGTHY CLINICAL DRUG TRIALS 1 (Mar. 2012). By contrast, an ANDA application costs about \$1 million to prepare. Hemphill & Sampat, *supra* note 9, at 618. The research and development costs for biopharmaceutical companies also far outstrip many other research-intensive industries; from 2000–2007, research and development cost \$105,428 per employee for biopharmaceuticals compared to \$34,978 per employee for the chemical industry and \$22,162 per employee in the aerospace industry. See ROY, *supra*, at 10.

40. In addition to the twenty-year period before patent expiration, 35 U.S.C. § 154(a)(2) (2006), the FDA grants additional exclusivity periods during which generics are not permitted to challenge brand patents. *Id.* § 154(a)(2). Drugs which contain a new chemical entity receive a five-year exclusivity period, 21 C.F.R. § 314.108(b)(2) (2013), and drugs which contain a previously-approved active ingredient but are still subject to a New Drug Approval process receive a three-year exclusivity period. *Id.* § 314.108(b)(5)(ii).

41. See 21 U.S.C.A. § 355 (West 2013).

before the patent period expires.⁴² When generic companies submit an ANDA before the brand patents have expired, they must include Paragraph IV challenges which allege either that the generic product does not infringe on the brand patents or that the brand patents are invalid.⁴³ The ANDA notifies the brand company that a generic intends to enter during the patent period, and the brand company can seek an injunction to defend its patents and prevent entry.

Hemphill and Sampat demonstrate that Paragraph IV challenges have risen dramatically in recent years.⁴⁴ At the same time, however, brand companies significantly increased the size of their patent portfolios.⁴⁵ Hemphill and Sampat argue that the increase in patent portfolio size has led to a significant increase in the rise of weak patents.⁴⁶ Over the past few years, brand drug companies began a practice of evergreening, applying weaker patents to their drugs to extend the monopoly patent period, and generic companies challenged brand patents more frequently to combat the extension of brand exclusivity.⁴⁷ As a result, the effective market life of brand drugs has remained roughly the same.⁴⁸ If generic drug companies are unable to complete ANDAs because they lack a necessary resource for bioequivalence testing, brand companies stand to benefit greatly from weak patents which maintain inefficiently high prices. Brand companies would also harm consumers by undoing the intended effect of the Hatch-Waxman Act to increase generic access to the market.⁴⁹ It would also stifle innovation in the pharmaceutical industry by protecting weak patents which restrict the ability of other companies to develop new products.

42. See Hemphill & Sampat, *supra* note 9, at 614.

43. 21 U.S.C.A. § 355(j)(2)(A)(vii)(III), (IV) (West 2013). “Paragraph IV” refers to section IV, in which the Hatch-Waxman act requires generic drug companies submitting an ANDA for a generic version of a patented drug to explain how “such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” See *id.*

44. See Hemphill & Sampat, *supra* note 9, at 615.

45. See *id.* at 619.

46. See *id.* at 643.

47. See *id.* at 642.

48. See *id.* at 643.

49. As Upadhye notes, “[t]he very nature of the Hatch Waxman Act sets up a regime conducive to patent infringement.” SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 2:1 (2013).

2. *The FDAAA and REMS*

The Federal Drug Administration Amendment Act of 2007 (FDAAA) gave the FDA (through the Secretary of Health and Human Services) the power to require drug manufacturers to comply with Risk Evaluation and Mitigation Strategies (“REMS”) for high-risk drugs.⁵⁰ REMS are additional safety measures for drug labeling and distribution that the Secretary may enact before or after a drug is approved by the FDA to “ensure that the benefits of the drug outweigh the risks of the drug.”⁵¹ Typical REMS requirements include enhanced labeling (Medication Guides to inform doctors and/or patient package inserts to inform patients), communication plans to health care providers to ensure safe use of the product, or “elements to ensure safe use.”⁵² In practice, “elements to ensure safe use” are various forms of restricted distribution.⁵³ The FDAAA also gave the FDA the power to inspect drug companies for REMS compliance and fine companies who fail to meet the terms of the REMS.⁵⁴

50. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at scattered sections of 21 U.S.C.).

51. 21 U.S.C.A. § 355-1(a) (West 2013). The law prescribes that the Secretary should consider the following factors to determine whether a REMS is appropriate:

- (A) The estimated size of the population likely to use the drug involved.
- (B) The seriousness of the disease or condition that is to be treated with the drug.
- (C) The expected benefit of the drug with respect to such disease or condition.
- (D) The expected or actual duration of treatment with the drug.
- (E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.
- (F) Whether the drug is a new molecular entity.

Id. § 355-1(a)(1).

52. FDA, GUIDANCE FOR INDUSTRY FORMAT AND CONTENT OF PROPOSED RISK EVALUATION AND MITIGATION STRATEGIES (REMS), REMS ASSESSMENTS, AND PROPOSED REMS MODIFICATIONS 5 (2009), available at <http://www.fda.gov/downloads/Drugs/Guidances/UCM184128.pdf>.

53. The FDAAA lists six kinds of elements to ensure safe use: requirements that

- (A) health care providers who prescribe the drug have particular training or experience, or are specially certified . . . ;
- (B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified . . . ;
- (C) the drug be dispensed to patients only in certain health care settings, such as hospitals;
- (D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;
- (E) each patient using the drug be subject to certain monitoring; or
- (F) each patient using the drug be enrolled in a registry.

21 U.S.C.A. § 355-1(f)(3).

54. See FDA GUIDANCE., *supra* note 52, at 7 (“A responsible person who violates a REMS requirement is subject to civil monetary penalties of up to \$250,000 per violation, not to exceed \$1 million in a single proceeding. These penalties increase if the violation

The FDA can require a drug manufacturer to draft a REMS for a drug prior to FDA approval, but the agency may also require manufacturers to institute a REMS after the drug has been approved if safety concerns arise post-approval.⁵⁵ If the FDA requires the manufacturer to draft a REMS post-approval, there is no indication that the drug company must halt sales during the 120-day time period they have to draft the REMS.⁵⁶ In the first six months after the FDAAA passed, the FDA required drug manufacturer to comply with REMS for about a third of all new drug molecules, and by 2010 the FDA had increased that implementation rate.⁵⁷ There are currently sixty-six individual drugs and six drug classes which are subject to REMS.⁵⁸ Of those, twenty-eight individual drugs and all six drug classes are subject to an implementation system which may include distribution restrictions.⁵⁹ The FDA has also released 136 drugs from a REMS, indicating that the list of drugs subject to a REMS may exhibit significant turnover in the future.⁶⁰

i. Kynamro: An Example REMS With Distribution Restrictions

Kynamro is a drug developed by Genzyme and Isis Pharmaceuticals Inc. which was recently approved by the FDA as a treatment for Homozygous Familial Hypercholesterolemia (HoFH).⁶¹ HoFH is a genetic condition that affects approximately one in one million people worldwide and occurs when the body is

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 and \$10 million per proceeding.”)

55. 21 U.S.C.A. § 355-1(a). See also FDA GUIDANCE., *supra* note 52, at 2.

56. See FDA GUIDANCE., *supra* note 52.

57. See Jennifer L. Bragg & Maya P. Florence, *Life with a REMS: Challenges and Opportunities*, 13 J. HEALTH CARE L. & POL'Y 269, 273 (2010).

58. See *Approved Risk Evaluation and Mitigation Strategies (REMS)*, FDA, <http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm> (last updated Oct. 10, 2013).

59. *Id.*

60. *Id.*

61. The FDA approved the new molecular entity Kynamro on January 29, 2013, subject to a REMS. See *FDA Approved Drug Products*, FDA, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/> (last visited Nov. 26, 2013) (follow: “K” hyperlink; then follow “Kynamro” hyperlink).

unable to remove “bad” cholesterol.⁶² People who suffer from HoFH often suffer heart attacks and death before age thirty.⁶³ Kynamro is an injection, taken weekly, that helps inhibit the formation of lipid particles which otherwise would form “bad” cholesterol.⁶⁴ However, Kynamro also has the potential for significant side effects. In addition to common side effects like flu-like symptoms and injection-site reactions, Kynamro also caused dangerous hepatotoxicity in 12% of patients who received Kynamro in the clinical trials.⁶⁵ Kynamro may also cause significant harm to unborn babies — patients who become pregnant while using Kynamro are required to cease treatment and contact their doctor.⁶⁶

The FDA approved Kynamro subject to a REMS which includes elements to ensure safe use (including restricted distribution), a specified implementation system, and a requirement for Genzyme to submit additional assessments of Kynamro six months after approval, twelve months after approval, and annually thereafter.⁶⁷ The REMS limits the distribution of Kynamro to specially certified pharmacies and patients diagnosed with HoFH who have undergone sufficient liver-related laboratory tests whose doctors are specially certified through the Kynamro REMS program.⁶⁸ This REMS program is a direct reflection of Congress’s intent to give the FDA the necessary tools to approve high-risk drugs while limiting the use of those drugs to patients who pass the cost-benefit analysis weighing the necessity of treatment against the significant, and perhaps life-threatening, side effects. For those HoFH patients who risk heart attack and possible death by the age of thirty, a high-risk treatment is ap-

62. See Press Release, FDA, FDA Approves New Orphan Drug Kynamro to Treat Inherited Cholesterol Disorder (Jan. 19, 2013), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm337195.htm>.

63. *Id.*

64. *Id.*

65. See Press Release, Genzyme, Genzyme and Isis Announce FDA Approval of KYNAMRO™ (mipomersen sodium) Injection for the Treatment of Homozygous Familial Hypercholesterolemia (Jan. 29, 2013), available at <http://news.genzyme.com/press-release/genzyme-and-isis-announce-fda-approval-kynamro-mipomersen-sodium-injection-treatment-h>.

66. See FDA, MEDICATION GUIDE KYNAMRO (2013).

67. See FDA, KYNAMRO RISK EVALUATION AND MITIGATION STRATEGY (REMS) (2013).

68. *Id.*

appropriate. For other patients, the high risk of liver damage far outweighs the potential benefits of Kynamro.

3. *Congress's Unclear Guidance Regarding Refusals to Deal*

Both the House and the Senate, at different times, have passed language which would require brand drug companies to sell products subject to REMS to generic manufacturers at a market rate for the purposes of bioequivalence testing.⁶⁹ However, neither of those attempts produced clear final legislation. Instead, the FDAAA included a general requirement that “[n]o holder of an [NDA] shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of . . . a drug that is the subject of an abbreviated new drug application.”⁷⁰ At least one drug company has cited Congress’s failure to pass more definitive language as evidence of legislative intent to permit brand companies to refuse to sell products subject to REMS distribution restrictions to generic manufacturers.⁷¹

On June 28, 2007, thirty-four Senators introduced H.R. 2900, the first draft of what would become the FDAAA.⁷² This draft included language requiring brand pharmaceutical companies to sell their product at market price to generic companies for the purposes of bioequivalence testing.⁷³ H.R. 2900 passed the House on July 11, 2007, but the Senate failed to address the bill any fur-

69. H.R. 2900, 110th Cong. § 901(f)(6) (1st Sess. 2007); S. 3187, 112th Cong. § 1131(k) (2d Sess. 2012).

70. See 21 U.S.C.A. § 355-1(f)(8) (West 2013).

71. See Complaint for Declaratory Judgment at 11, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD (D.N.J. Aug. 14, 2012).

72. See Food and Drug Administration Amendments Act of 2007, H.R. 2900, 110th Cong. (1st Sess. 2007).

73. Regarding bioequivalence testing, the bill stated:

Notwithstanding any other provisions in this subsection, the holder of an approved application that is subject to distribution restrictions required under this subsection that limit the ability of a sponsor seeking approval of an application under subsection 505(b)(2) or (j) to purchase on the open market a sufficient quantity of drug to conduct bioequivalence testing shall provide to such a sponsor a sufficient amount of drug to conduct bioequivalence testing if the sponsor seeking approval under section 505(b)(2) or (j)—(A) agrees to such restrictions on distribution as the Secretary finds necessary to assure safe use of the drug during bioequivalence testing; and (B) pays the holder of the approved application the fair market value of the drug purchased for bioequivalence testing.

H.R. 2900 § 901(f)(6).

ther.⁷⁴ Instead, the House passed H.R. 3580 on September 19, 2007.⁷⁵ H.R. 3580 is very similar to H.R. 2900, yet it omitted the requirement that drug companies selling products subject to REMS must sell the product to generic companies for bioequivalence testing. The Senate approved H.R. 3580 without amendment, and President Bush signed the FDAAA into law on September 27, 2007.⁷⁶

Future drafts of legislation also considered and rejected language which would have required drug manufacturers to sell sufficient quantities of their REMS-restricted products to generic manufacturers for bioequivalence testing. The Senate version of the Food and Drug Administration Safety and Innovation Act (“FDASIA”), passed on May 24, 2012, would have required brand pharmaceutical companies to sell their product at market price to generic companies for the purposes of bioequivalence testing, but this language was also dropped from the final draft enacted on June 9, 2012, just a few weeks later.⁷⁷ The Federal Trade Commission lobbied for Congress to separate the discussion of REMS provisions from the larger FDASIA bill in order to fully address the Commission’s recommendation that it receive jurisdiction to prosecute brand companies who refuse to provide samples to generic manufacturers.⁷⁸ Congress has yet to act on the FTC’s recommendation.

The REMS provisions did not pass unnoticed within the massive text of the FDAAA. While the FDAAA was a vast amendment that altered a significant portion of the FDA’s powers, in

74. See *H.R. 2900 (110th): Food and Drug Administration Amendments Act of 2007*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/110/hr2900> (last visited Dec. 9, 2013).

75. See *Food and Drug Administration Amendments Act of 2007*, H.R. 3580, 110th Cong. (1st Sess. 2007) (enacted).

76. See *Food and Drug Administration Amendments Act of 2007*, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended at scattered sections of 21 U.S.C.).

77. Notwithstanding any other provision of law, 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 subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act, if the Secretary has issued a written notice described in paragraph (2), and the eligible drug developer has agreed to comply with the terms of the notice.

S. 3187, 112th Cong. § 1131(k) (as passed by Senate, May 24, 2012).

78. Letter from J. Thomas Rosch, Comm’r, Fed. Trade Comm’n to Senator Harry Reid and Senator Mitch McConnell, (May 4, 2012), available at <http://www.ftc.gov/speeches/rosch/120504payfordelayletter.pdf>.

debate preceding the vote to approve the House bill a few Senators discussed the REMS provisions to caution against the overuse of REMS⁷⁹ and criticize the regulation.⁸⁰

The existing provision does not explicitly create either a duty for brand manufacturers to sell their products to generic competitors or, alternatively, permit brand manufacturers to refuse to deal with generic competitors. Particularly where both Houses of Congress independently authored provisions which required brand manufacturers to provide REMS-restricted products to generic competitors at the market rate, the final language could be read as a calculated omission of such a duty. However, the existing text does state that a brand manufacturer cannot specifically act to block an ANDA, which is a stripped version of the clearer duty. The statute permits brand manufacturers to refuse to sell their REMS-restricted products to generic companies for reasons unrelated to the generic's ANDA. This loophole could make the brand manufacturer's duty unenforceable in practice. Instead of creating a clear rule requiring affirmative action from brand drug manufacturers, the statute's prohibition against certain inactions leaves the REMS statute on shaky ground. It is unclear which party would bear the burden of demonstrating that the brand

79. This legislation is a very delicate balancing act. No drug is completely safe—otherwise a doctor's prescription wouldn't be needed—but we do have to ensure that lifesaving medicines are able to get to patients. New authorities in the area of Risk Evaluation and Mitigation Strategies, REMS, labeling, and postmarket commitments should not be taken lightly. These new authorities we are giving the FDA need to be used based on a measured assessment of risk vs. benefit in the intended patient population. For instance, labeling changes should only be undertaken when reliable data clearly shows safety problems that are not already reflected in the drug's label. If that data happens to come from a third party unknown to the application holder they should have the opportunity to review it along with the Agency so that appropriate labeling changes can be made based on sound science.

153 Cong. Rec. S11, 831-01 (daily ed. Sept. 20, 2007) (statement of Sen. Tom Coburn).

80. For example, Senator Burr commented that:

The REMS does not add any significant new authority. The FDA currently uses Risk Maps which do the same things as REMS. Now Risk Map regulations, which have never been studied for their effectiveness, are becoming law. It means more paperwork, deadlines, and checkpoints for drug companies, with no guarantee that it will improve patient safety. I do not support regulation for the sake of regulation.”

153 Cong. Rec. S11, 831-01 (daily ed. Sept. 20, 2007) (statement of Sen. Richard Burr). Note that Senator Burr's commentary is not completely correct. While REMS and Risk Maps imposed many of the same restrictions, Risk Maps were generally voluntary agreements, whereas the FDAAA gave the Secretary of Health and Human Services the power to impose REMS on a pharmaceutical company. See Bragg & Florence, *supra* note 57, at 269–70.

drug company's offered explanation for refusing to deal with a generic competitor is or is not merely pretext to prevent the approval of an ANDA. Unfortunately, neither the text nor the legislative history of the FDAAA offer clear guidance on what a brand manufacturer may and must do with respect to its generic competitors.

C. THE IMPACT OF REMS ON THE EFFICACY OF ABBREVIATED NEW DRUG APPLICATIONS

REMS distribution restrictions threaten to upset the balance between brand companies' patents and generic company Paragraph IV challenges to those patents. REMS distribution restrictions can prohibit pharmacies and drug wholesalers from selling high-risk products outside of a limited set of consumers such as certified doctors or registered patients.⁸¹ Though generic companies typically purchase brand products for bioequivalence testing through wholesalers.⁸² REMS restrictions may require to try to purchase the product directly from the manufacturer. In several instances, the brand manufacturers have refused to sell their product to generic competitors, citing the freedom to choose with whom they do business.⁸³ These manufacturers foreclose generics' ability to submit Paragraph IV challenges to brand patents through ANDAs by blocking generic access to brand drugs needed for testing.

III. POTENTIAL SOLUTIONS

The only section of the FDAAA which potentially addresses brand drug company refusals to deal with generic competitors does not include an affirmative duty on the part of the brand company to trade with a generic competitor.⁸⁴ Phrased in the negative to prohibit "block[ing] or delay[ing] approval" of an ANDA, the section leaves unclear what a brand drug company

81. See 21 U.S.C.A. § 355-1(f)(3)(C)–(E) (West 2013).

82. See ElBoghdady, *supra* note 15.

83. See, e.g., Complaint for Declaratory Judgment at 10, Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743-NLH-AMD (D.N.J. Aug. 14, 2012); Defendant Celgene Corporation's Memorandum of Law in Support of Its Renewed Motion to Dismiss at 2, Lannett Co. v. Celgene Corp., (No. 08-cv-3920) 2010 WL 3159752 (E.D. Pa. May 28, 2010).

84. See 21 U.S.C.A. § 355-1(f)(8).

must do to comply with the law, and opens a window to possible abuses. This section discusses potential solutions for REMS abuses. First, products subject to REMS could face enhanced patent scrutiny to ex ante mitigate the ability of REMS restrictions to protect bad patents from challenges. Second, plaintiffs could rely on antitrust doctrine, including vertical restraints, refusals to deal, and the essential facilities doctrine, to bolster their claims against brand companies who actually withhold REMS-restricted products. While no solution is perfect, the essential facilities doctrine is the best tool available for courts to maintain the regulatory competitive balance envisioned in the Hatch-Waxman Act absent Congressional action to require brand drug manufacturers to provide generic companies with sufficient samples for bioequivalence testing.

A. HEIGHTENED SCRUTINY OF PATENTS ON REMS-RESTRICTED PRODUCTS

If Congress is unwilling to pass clear legislation requiring brand drug manufacturers to provide their products to generic companies for bioequivalence testing, it could instead alter patent law to enforce better quality control before patents are approved. The law would require the patent office to review a patent application with increased scrutiny when a company applies for a patent on a drug which will be subject to restricted distribution under a REMS. This approach would permit brand companies to refuse to sell their patented REMS-restricted products to generic competitors once the brand companies have overcome the enhanced patent application process.

The current patent system has the potential to provide protection for bad patents, and refusals to sell REMS-restricted products to generic competitors could further insulate brand companies' bad patents from litigation. Currently, courts must presume all patents approved by the Patent and Trademark Office (PTO) are valid, and any litigant seeking to overcome a patent bears the burden of demonstrating the patent's invalidity.⁸⁵ In *Microsoft v. i4i*, the Supreme Court interpreted this burden to mean that a party challenging a patent must establish "clear and convincing

85. 35 U.S.C. § 282 (2006).

evidence” of the patent’s invalidity.⁸⁶ This high threshold for overcoming the presumption of patent validity necessarily strikes a balance between incentives to innovate (and compete against patents) and proper deference for an expert agency.⁸⁷ However, the *Microsoft* Court failed to address the adequacy of the balance, instead relying on precedent to uphold the “clear and convincing evidence” standard.⁸⁸ Critics point to the high patent invalidation rate⁸⁹ to argue that the high burden of proof protects bad patents once the PTO has approved the patent.⁹⁰ The PTO has significant incentives to issue patents which can lead to the approval of an artificially high number of bad patents.⁹¹ Congress has attempted to address the patent approval process by increasing the ability of third parties to challenge patents in the first nine months after the PTO approves a patent.⁹² Yet this *inter partes* review process is unlikely to help generic companies because the primary way generic drug companies challenge brand patents is through Paragraph IV challenges⁹³ which, by statutory requirement, take place years after patent approval.⁹⁴ The FTC has also recommended that Congress change the standard of pa-

86. *Microsoft Corp. v. i4i Ltd. P’hip*, 131 S. Ct. 2238, 2242 (2011).

87. *Id.* at 2251–52 (“Microsoft and its *amici* contend that the heightened standard of proof dampens innovation by unduly insulating ‘bad’ patents from invalidity challenges For their part, i4i and its *amici*, including the United States, contend that the heightened standard of proof properly limits the circumstances in which a lay jury overturns the considered judgment of an expert agency.”).

88. *Id.* at 2252.

89. A 2005 study found that 50% of litigated patents are declared invalid. See Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 76 (2005). A more recent white paper found that from 2007 to 2011, 86% of patents challenged in federal district court were declared invalid. See MICHAEL J. HOULIHAN, UNITED STATES PATENT INVALIDITY STUDY 2012: WHITE PAPER REPORT 2 (Sept. 2012). There is also an increased trend of patent invalidation at the Federal Circuit. See *id.* at 6.

90. See, e.g., Alan Devlin, *Revisiting the Presumption of Patent Validity*, 37 SW. U. L. REV. 323, 326 (2008). See also *Microsoft*, 131 S. Ct. at 2252.

91. Patent examiners spend an average of eighteen hours on each patent application, and patent applications can only close if the patent is approved. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1496 n.3 (2001). Examiners are required to write an explanation for patent rejections, but not for patent approvals. See *id.* And in 1999, at least, bonuses for patent examiners may have been based on the number of patents approved. See Robert P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 609 (1999) (“The current bonus system is believed to skew incentives in favor of granting patents.”).

92. 35 U.S.C. § 311(a) (2006). See also *Microsoft*, 131 S. Ct. at 2252.

93. See Hemphill & Sampat, *supra* note 9, at 615.

94. See 21 C.F.R. § 314.108(b)(2) (2013).

tent validity review to a “preponderance of the evidence,”⁹⁵ but Congress has not acted on this suggestion.

The kind of stratified patent review process which could prevent REMS-restrictions from increasing the protection for bad patents has been advanced as a broader solution to the inefficiencies of the current patent system.⁹⁶ Alan Devlin argues for a two-tiered patent system which permits patent applicants to choose either the current standard of review or an alternative, more rigorous evaluation of the patent application.⁹⁷ Defendants could overcome patents approved under the current standard of review by establishing the patent was invalid “on the balance of probabilities,” meaning the standard review process would offer less protection than the current system.⁹⁸ Patents which passed the more rigorous review would receive an enhanced presumption of validity which should better shield the patents from litigation and invalidation.⁹⁹ Devlin argues that a stratified patent review is superior to post-approval litigation both because it lowers the cost of review and also because patent review remains in the hands of a sophisticated agency with relevant expertise.¹⁰⁰

While Devlin’s two-tiered approach would permit applicants to choose which level of scrutiny their application will receive, a mandatory stratification for only patents on REMS-restricted products could yield many of the same benefits. Enhanced scrutiny would decrease the number of bad patents approved, and the enhanced process would benefit from the PTO’s expertise through the extended review of scientifically complex questions.

However, focusing on the patent approval process is an imperfect solution. First, the heightened scrutiny could stifle innovation in potentially dangerous products. The review process shifts the risk of patent rejection or invalidation to earlier in the process, meaning a manufacturer who develops a “new” product which is nonetheless unable to pass the more rigorous patent review has had no opportunity to recoup the research and development costs of that product. *Ex ante*, one would expect a marginal decrease in research in potentially hazardous products to result

95. See FED. TRADE COMM’N, *supra* note 1.

96. See Devlin, *supra* note 90, at 327.

97. See *id.*

98. See *id.*

99. See *id.* at 323.

100. See *id.* at 360.

from the heightened review. Second, an enhanced patent review solves only one of the several problems underlying REMS abuses. While the increased standard for patent approval deals with the concern that brand drug companies would use REMS to protect weak patents, it does not address what brand manufacturers must do after their patents have expired. The companies who have disputed their duty to deal with a generic competitor have not explicitly tied their arguments to the drug patent, but instead rely heavily on a broader freedom to choose with whom they contract.¹⁰¹ Enhanced patent review is therefore an incomplete solution, and prosecutors of REMS abuses would have to supplement that structure with antitrust arguments that the freedom to refuse to supply generic companies with samples for bioequivalence testing ends at patent expiration. An enhanced patent review will be unsuccessful if patent life is indefinite, even if only strong patent applications pass the initial screening.

The patent review process is also imperfectly situated in the drug approval timeline as a means to address REMS abuses. Drug patents must be approved before the FDA approval process begins.¹⁰² Since the FDA can only determine whether product should have REMS restrictions after patent approval, a heightened standard of review necessarily requires the FDA to send the drug back to the PTO for further review once the patent has already been approved. What should the court make of a dispute over a patent that passed the standard review but later failed under heightened scrutiny once the FDA determined the drug was potentially hazardous? The FDA may also add a REMS to an existing, FDA-approved drug as new safety information becomes available.¹⁰³ It is likely not practical to expect the PTO to invalidate an eighteen-year-old patent on a product which has been marketed and sold for years after the FDA determines the drug might be dangerous?

101. See, e.g., Complaint for Declaratory Judgment at 10, Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743-NLH-AMD (D.N.J. Aug. 14, 2012).

102. See Fernandez et al., *supra* note 11, at 968.

103. See 21 U.S.C.A. § 355-1(a)(2)(A) (West 2013).

B. ANTITRUST SOLUTIONS

Prosecutors could alternatively rely on antitrust principles to limit REMS abuses. At the most extreme, brand drug companies might argue that Congress's implicit rejection of language prohibiting refusals to deal which prevent bioequivalence testing is evidence that antitrust liability is an inappropriate remedy for this conflict. The Supreme Court has held that some regulatory schemes necessarily preclude the application of antitrust law.¹⁰⁴ However, the brand companies would have to show that there was a "clear repugnancy" between the FDAAA and antitrust law or that the two are "clearly incompatible."¹⁰⁵ Congress's reluctance to explicitly include an antitrust provision in legislation is insufficient to demonstrate clear incompatibility, particularly where antitrust has recently played a significant role in other conflicts arising from the Hatch-Waxman Act.¹⁰⁶

1. Vertical Restraints

Generic drug manufacturers could allege that brand companies which prohibit their wholesalers from selling REMS-restricted products to generic competitors have imposed anticompetitive vertical restraints on those wholesalers. In response, brand drug makers will argue that restrictions on wholesale distribution are mandated by the REMS restrictions themselves and are therefore not imposed by the brand company at all.

Courts evaluate the anticompetitive effects of non-price vertical restraints under a rule of reason analysis.¹⁰⁷ In *Sylvania*, the court recognized that potential procompetitive benefits of vertical restraints in the interbrand market might outweigh the anticompetitive harm to the intrabrand market.¹⁰⁸ For example, geo-

104. See, e.g., *Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 279 (2007).

105. *Id.* at 275.

106. See *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

107. *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 59 (1977) ("[W]e conclude that the appropriate decision is to return to the rule of reason that governed vertical restrictions prior to *Schwinn*. When anticompetitive effects are shown to result from particular vertical restrictions they can be adequately policed under the rule of reason, the standard traditionally applied for the majority of anticompetitive practices challenged under § 1 of the Act.")

108. See *id.* at 51 (citing the stimulation of interbrand competition as a potential justification for the restriction of intrabrand competition).

graphic limitations on competing wholesalers might permit manufacturers to maximize the efficiency of their distribution system to minimize transportation costs and lower the final price of the product.¹⁰⁹ Generic competitors would have to show that 1) the agreement between brand manufacturers and wholesalers had a significant impact on price, 2) the agreement significantly harms competition in the market as a whole, and 3) that any procompetitive benefit is outweighed by the anticompetitive harm—or that the procompetitive benefit could have been achieved through less anticompetitive methods.¹¹⁰ The anticompetitive harm of blocking generic access to the drug market is apparent as a global matter, but the generic companies would have to demonstrate a market impact for the particular products at issue in their case. This overlaps significantly with the market power analysis addressed in Section III(b)(iv). A brand drug company might respond that they are refusing to provide their products to specific generic manufacturers in order to protect their brand and reputation from harm which could arise if a generic company misused the brand drug.¹¹¹ The validity of this claim will depend on a case-by-case analysis of the litigating parties.

Alternatively, brand manufacturers can argue that the language of the REMS restrictions prevents both wholesalers from selling the brand drugs to generic competitors. While this will depend on the specific terms of each REMS, there are two types of

109. The *Sylvania* court offered several other examples:

[N]ew manufacturers and manufacturers entering new markets can use the restrictions in order to induce competent and aggressive retailers to make the kind of investment of capital and labor that is often required in the distribution of products unknown to the consumer. Established manufacturers can use them to induce retailers to engage in promotional activities or to provide service and repair facilities necessary to the efficient marketing of their products. Service and repair are vital for many products, such as automobiles and major household appliances. The availability and quality of such services affect a manufacturer's goodwill and the competitiveness of his product. Because of market imperfections such as the so-called 'free rider' effect, these services might not be provided by retailers in a purely competitive situation, despite the fact that each retailer's benefit would be greater if all provided the services than if none did.

Id. at 55.

110. WILLIAM HOLMES & MELISSA MANGIARACINA, ANTITRUST LAW HANDBOOK § 2:14 (2012). The generic company must also show that there was an agreement, but the contract between the manufacturer and the wholesaler is sufficient to satisfy this requirement. *See id.* at § 2:4.

111. *See* Complaint for Declaratory Judgment at 10, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD, 2012 WL 4363827 (D.N.J. Sept. 14, 2012).

restrictions which might suggest a regulatory prohibition on wholesaler distribution to generic companies. First, a REMS may explicitly state that a wholesaler may only sell the drug to other registered wholesalers, registered pharmacies, and similarly limited entities (which do not include generic competitors).¹¹² In this case, it is unlikely that generic competitors overcome the language of the REMS to demonstrate that the manufacturer has taken unilateral anticompetitive action. Second, a REMS could specify that the product can only be distributed to a list of registered patients and pharmacies without specifically restricting wholesalers.¹¹³ In that case, it may be more difficult for the brand company to demonstrate that the REMS *requires* the manufacturer to restrict the wholesaler distribution. Where the REMS does not explicitly refer to wholesalers, the broader FDAAA provision preventing a brand manufacturer from delaying an ANDA weighs more heavily against the brand manufacturer's restraint. Therefore, vertical restraints offer a potential antitrust solution to REMS abuses, but the applicability of the theory may be limited based on the specific language in each REMS.

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112. For example, the Isotretinoin drug family is subject to the following restriction:
- 2.3(b) Isotretinoin sponsors will monitor wholesaler distribution data to ensure that only registered entities distribute isotretinoin. Wholesalers who distribute isotretinoin must be registered with iPLEDGE prior to distributing isotretinoin and must reregister annually thereafter. Wholesalers must register with iPLEDGE by signing and returning the iPLEDGE wholesaler agreement. By signing the agreement, wholesalers affirm that they will comply with all of the following iPLEDGE requirements:
- i. Distribute only FDA-approved isotretinoin product.
 - ii. Only ship isotretinoin to: 1) wholesalers registered in the iPLEDGE program with prior written consent from the manufacturer; and 2) pharmacies licensed in the US and registered and activated in the iPLEDGE program.
 - iii. Notify the isotretinoin manufacturer (or delegate) of any unregistered and/or non-activated pharmacy or unregistered wholesaler that attempts to order isotretinoin.
 - iv. Return to the manufacturer (or delegate) any undistributed product if registration is revoked by the manufacturer or if the wholesaler chooses to not reregister annually.

FDA, RISK EVALUATION AND MITIGATION STRATEGY (REMS): THE iPLEDGE PROGRAM: SINGLE SHARED SYSTEM FOR ISOTRETINOIN 8 (2010).

113. For example, consider Kynamro's restrictions: "1. Healthcare Providers (HCP) who prescribe KYNAMRO are specially certified 2. KYNAMRO will be dispensed only by specially certified pharmacies 3. KYNAMRO will be dispensed only to patients with evidence or other documentation of safe-use conditions." KYNAMRO RISK EVALUATION AND MITIGATION STRATEGY, *supra* note 67.

2. Refusals to Deal

Generally speaking, firms retain the freedom to decide whether or not they will contract with another party, including a competitor.¹¹⁴ In a select number of cases, the Supreme Court has held that firms with a significant market share abused their market power by refusing to deal with a competitor.¹¹⁵ However, a recent Supreme Court decision significantly limited the ability of the Sherman Act to address abuses of market power through refusals to deal. In *Trinko*, the Supreme Court held that the outer boundary for Sherman Act section two liability for refusals to deal lies where a firm with market power ceases cooperation with a competitor or when a firm acts against its own economic self-interest to exclude a competitor.¹¹⁶ Moreover, the Court held that antitrust liability is an unnecessary protection where a regulatory structure exists to protect competition.¹¹⁷

Trinko has the potential to foreclose a Sherman Act claim against a brand drug company based on either holding. First, brand drug companies act in their economic self-interest to maximize their monopoly profits by excluding generic competition. Generic companies seeking brand products for bioequivalence testing have also necessarily never purchased the product previously, so there is no cessation of cooperation when the brand company initially refuses to provide its product. Second, the drug approval and distribution processes are closely regulated through the Hatch-Waxman Act and the FDAAA. Brand companies would argue that antitrust liability adds no additional benefit to the regulation of drug competition where Congress has already regulated in detail.

Courts are unlikely to be swayed by plaintiffs charging a refusal to deal theory to prosecute REMS abuses. Single-firm refusals to deal are largely permitted outside of the narrow excep-

114. See *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 448 (2009); *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919).

115. See *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610–11 (1985); *Otter Tail Power Co. v. United States*, 410 U.S. 366, 380 (1973); *Lorain Journal Co. v. United States*, 342 U.S. 143, 144 (1951).

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

117. *Id.* at 412.

tions prescribed in *Trinko*,¹¹⁸ and REMS abuses do not fit neatly into one of those exceptions. However, plaintiffs could try an alternative path: the “essential facilities” doctrine.¹¹⁹ Essential facilities doctrine falls within the umbrella of refusals to deal, but there is a richer — and more hotly contested — legal history that disputes the validity and scope of the doctrine than other prongs of refusals to deal.

3. *Essential Facilities*

Instead of pursuing a general refusal to deal theory, generic companies could argue that brand manufacturers who refuse to provide sufficient REMS-restricted products for bioequivalence testing have denied them access to an essential facility. The doctrine derives from a 1912 Supreme Court decision requiring the owners of all river crossings in St. Louis to sell access to those bridges and ferries to railroads which needed to cross the river.¹²⁰ A few subsequent Supreme Court cases seem to have relied on essential facilities doctrine,¹²¹ but commentators have noted that essential facilities may have been merely the tool used in a broader monopolization argument.¹²² Most recently, however, the Supreme Court has questioned the validity of the essential facilities doctrine. In *Trinko*, the Court pointedly declined to either recognize or repudiate the essential facilities doctrine.¹²³ However, the essential facilities doctrine remains viable within the lower courts.¹²⁴

118. See, e.g., *In re Indep. Serv. Orgs. Antitrust Litig.*, 85 F. Supp. 2d 1130, 1153 (D. Kan. 2000) (holding that refusal to sell patented parts is not an antitrust violation); *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995) (arguing that preventing employees from “cross-covering” with independent physicians was not exclusionary).

119. The essential facilities doctrine is also known as the “bottleneck” doctrine. See *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 992 (D.C. Cir. 1977) (equating the two phrases).

120. *United States v. Terminal R.R. Ass’n of St. Louis*, 224 U.S. 383 (1912). See also *Hecht*, 570 F.2d at 992 (describing the contours of the doctrine).

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

122. David J. Gerber, *Rethinking the Monopolist’s Duty to Deal: A Legal and Economic Critique of the Doctrine of ‘Essential Facilities’*, 74 VA. L. REV. 1069, 1080-81 (1988).

123. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) (“We have never recognized such a doctrine and we find no need either to recognize it or to repudiate it here.” (citations omitted)).

124. See, e.g., *Loren Data Corp. v. GXS, Inc.*, 501 F. App’x 275, 277 (4th Cir. 2012), cert. denied, 133 S. Ct. 2835 (2013), reh’g denied, 134 S. Ct. 34 (2013); *Wellnx Life Scis.*

An “essential” facility is one for which “duplication of the facility would be economically infeasible and that denial of its use inflicts a *severe handicap* on potential or current market entrants.”¹²⁵ To win a restraint-of-trade claim based on the essential facilities doctrine, a generic drug company would have to establish “(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.”¹²⁶

A brand drug manufacturer’s abuse of a REMS through a refusal to provide generic competitors with access to sufficient samples for bioequivalence testing satisfies all of the elements of this test. First, brand manufacturers maintain absolute control over REMS-restricted products. The FDA can hold manufacturers who fail to conform to the REMS requirements liable for significant civil penalties.¹²⁷ Brand manufacturers therefore require wholesalers who distribute the product to strictly comply with the REMS to ensure compliance and to protect the brand manufacturer’s reputation,¹²⁸ which prevents generic competitors from accessing the drug further down the distribution chain. REMS abuses satisfy even the most restrictive definitions of control of an essential facility.¹²⁹

Second, generic competitors are unable to feasibly reproduce the expensive clinical trials executed by brand manufacturers.¹³⁰ Brand drug companies can recoup the development expenses of these trials during the period of exclusivity granted by their patents, but generic manufacturers receive no comparable protection. The remedies prescribed in the Hatch-Waxman Act to increase generic competition underscore a need to decrease the

Inc. v. Iovate Health Scis. Research Inc., 516 F. Supp. 2d 270 (S.D.N.Y. 2007) (entertaining “essential facilities” claims).

125. *Wellnx Life Scis.*, 516 F. Supp. 2d at 295 (S.D.N.Y. 2007) (quoting *Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 568 (2d Cir. 1990) (internal alterations and quotation marks omitted).

126. *Id.* at 295–96 (quoting *Twin Labs.*, 900 F.2d at 569).

127. See FDA GUIDANCE, *supra* note 52, at 7.

128. See Complaint for Declaratory Judgment at 7, 10, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD, 2012 WL 4363827 (D.N.J. Sept. 14, 2012).

129. See *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995) (implying 100 percent control of the market may be necessary for a monopolist to possess an essential facility).

130. See generally AUSTIN, *supra* note 39.

costs of entry to promote generic competition and lower the cost of drugs.¹³¹

Third, brand drug companies that prevent generic manufacturers from purchasing samples for bioequivalence testing are denying their competitors access to the essential facility.

Finally, the brand companies are capable of providing generic competitors with samples for bioequivalence testing — which they do (through wholesalers) for their other products.

4. *The Problem of Market Power*

Regardless of whether a generic company pursues a vertical restraint claim or an essential facilities claim, the company must establish that brand manufacturers have market power in the market relevant to the alleged REMS abuses to establish Sherman Act Section Two liability. While earlier cases held that a patent alone was sufficient for market power,¹³² the Supreme Court recently interpreted a Congressional amendment to the patent misuse statute to undo this presumption of market power.¹³³ Furthermore, the Court has held that patent holders may refuse to sell their patented products, even where such refusal is anticompetitive, so long as the refusal does not extend outside of the scope of the patent.¹³⁴ Plaintiffs seeking an injunction against a brand drug company's refusal to deal must show that the brand company holds market power in the relevant market, which includes the REMS-restricted product and other therapeutic competitors.

If the REMS-restricted product is a new molecular entity (NME), there is a greater likelihood that the brand company holding the NME patent possesses market power within the

131. See President Ronald W. Reagan, Remarks on Signing § 1538 Into Law (Sept. 24, 1984).

132. See *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 16 (1984) (“[I]f the government has granted the seller a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power.”).

133. See *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 31 (2006) (interpreting United States Patent Act, 35 U.S.C. § 271(d) (2006)).

134. See *In re Indep. Serv. Orgs. Antitrust Litig.*, 964 F. Supp. 1479, 1488 (D. Kan. 1997).

drug's therapeutic class.¹³⁵ NMEs are more likely to have fewer competitors because they are the first product approved by the FDA to have their specific 'active moiety,' which is the element of the drug which is "responsible for the physiological or pharmacological action of the drug substance."¹³⁶ In the alternative, a brand company can patent a new delivery system for a drug which uses a previously-approved active moiety by changing how the drug interacts with the body. For example, the newly patented drug might be a pill form of a drug that was previously approved for intravenous use, or an extended release pill which a patient can take less frequently than the previously approved pill. In that case, the new product necessarily has at least one competitor in its therapeutic class, and the brand drug company holding the new patent is less likely to have power in the relevant market.

While plaintiffs cannot rest solely upon the drug patent as a basis for market power, they could argue that the pharmaceutical industry shares sufficient similarities with other natural monopolies that holders of pioneer drug patents necessarily have market power. Congressional action favors this understanding of the drug industry. Through the Hatch-Waxman Act, Congress recognized (and tried to ameliorate) the elements of the FDA drug approval process which tend to create a regulatory natural monopoly.¹³⁷ Natural monopolies are characterized by high fixed costs for entry into the market and low marginal costs for production once the barrier to entry is overcome. Public utilities are a classic example of natural monopoly because of the high cost of developing a distribution network (laying pipes or wires across entire cities or states) and the relatively low cost of providing a unit of water or electricity once those networks are in place.¹³⁸ The regulations governing the FDA approval process have created a simi-

135. "A New Molecular Entity is an active ingredient that has never before been marketed in the United States in any form." *Glossary of Terms*, FDA (Feb. 2, 2012), <http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm>.

136. *Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm> (last updated July 1, 2010).

137. A natural monopoly exists where "the entire demand within a relevant market can be satisfied at lowest cost by one firm rather than by two or more . . . whatever the actual number of firms in it." Richard A. Posner, *Natural Monopoly and Its Regulation*, 21 STAN. L. REV. 548, 548 (1969).

138. *See id.*

lar market structure. The massive cost of developing a new drug, incurred in large part to ensure the safety and effectiveness of drugs, requires a significant investment, which would be inefficient for multiple firms to replicate.¹³⁹ The Hatch-Waxman Act solution, which permits generic companies to establish bioequivalence in lieu of expensive clinical trials, is an attempt to undo the effects of the stringent FDA approval process that lead towards natural monopoly.¹⁴⁰

Traditional natural monopolies might seem distinct from the biopharmaceutical industry as described above because in traditional natural monopolies, the initial high-cost investment is in a physical good which must be replicated by each market entrant. Where the initial investment develops intellectual property, future entrants can build upon those developments without replicating the first firm's high investments — there is no additional cost for other firms to use the same idea. Yet the Hatch-Waxman Act explicitly ties generic companies to the brand *product*, not the brand *patent*, through bioequivalence testing. Biopharmaceutical products differ from many other patented products because every pill or vial is subject to stringent safety testing and approval, so each market entrant necessarily has testing and development costs in excess of the costs of production.¹⁴¹ The explicit tie between the initial brand product and subsequent generic entry reflects the Hatch-Waxman Act understanding that the safety requirements of the FDA create a natural monopoly in a manner distinct from other industries which depend upon intellectual property. Brand companies which use REMS distribution restriction to refuse to supply generic companies with samples for bioequivalence testing frustrate the purpose of the Hatch-Waxman Act while maximizing the power of their natural monopoly.

*i. Market Conditions Surrounding Kynamro and Other
REMS-Restricted Products*

Patented REMS-restricted products are even more likely to command market power than typical patented drugs. The six

139. See ROY, *supra* note 39, at 1.

140. See 21 U.S.C.A. § 355 (West 2013).

141. See Hemphill & Sampat, *supra* note 9, at 617–18.

factors that the FDA must consider when determining whether to approve a product subject to a REMS imply a cost-benefit analysis which considers the universe of other drugs which treat the same disease.¹⁴² Where there is a much safer alternative already available (which might not be subject to a REMS), it seems unlikely that the FDA would approve a new, more dangerous product, even if a REMS could facilitate the safe use of the new drug. It is more likely that REMS-restricted products face competition only from similarly restricted and dangerous drugs. For example, Kynamro faced one other REMS-restricted competitor at the time of Kynamro's approval in January 2013.¹⁴³ Aegerion's Juxtapid has similar hepatotoxicity risk and potential to harm unborn babies as Kynamro.¹⁴⁴

There is some evidence that Kynamro and Juxtapid are competing on price. But even Kynamro's lower price poses a significant cost to consumers dependent on treatment for HoFH.¹⁴⁵ Broader evidence indicates that pharmaceutical companies are shifting their research towards drugs which treat high-risk diseases in small patient populations because of the significant profits available.¹⁴⁶ Prices for specialty "orphan" drugs which treat fewer than 200,000 patients at a time have risen 26% annually from 2001 through 2010, outstripping the growth of traditional pharmaceutical products.¹⁴⁷ The massive profits available are

142. See 21 U.S.C.A. § 355-1 (West 2013).

143. See *FDA Approved Drug Products*, FDA, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/> (last visited Nov. 26, 2013) (follow: "K" hyperlink; then follow "Kynamro" hyperlink) (last visited Mar. 16, 2013); *NDA 203858 JUXTAPID (lomitapide) capsules Risk Evaluation and Mitigation Strategy (REMS)*, FDA, <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM333438.pdf> (last updated August 2013); Tracy Stanton, *Genzyme's \$176K Kynamro price undercuts its \$250K-plus rival*, FIERCEPHARMA (Jan. 31, 2013), <http://www.fiercepharma.com/story/genzymes-176k-kynamro-price-undercuts-its-250k-plus-rival/2013-01-31#ixzz2Ne89YBST>.

144. See *Medication Guide: Juxtapid*, FDA, <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM333530.pdf>.

145. The \$176,000 price for a year of treatment of Kynamro undercuts the \$235,000–\$295,000 price per year for Juxtapid treatment. See Stanton, *supra* note 143.

146. "Drug companies have found that they can charge towering prices for such drugs, which often treat deadly conditions for which there are few or no options." Jonathan D. Rockoff, *Drug Makers See Profit Potential in Rare Diseases*, WALL ST. J. (Jan. 30, 2013), available at <http://online.wsj.com/article/SB10001424127887323926104578273900197322758.html>.

147. See Adam Feuerstein, *NPS Pharma: Controversy Over Super-Expensive Orphan Drug Prices*, THE STREET (Jan. 3, 2013), <http://www.thestreet.com/story/11803726/1/nps-pharma-controversy-over-super-expensive-orphan-drug-prices.html>.

circumstantial evidence of a lack of competition in an area where REMS-restrictions may proliferate. While courts will continue to determine on a case-by-case analysis whether brand companies holding patents on REMS-restricted products have market power, the market conditions surrounding drugs likely to be subject to REMS-restrictions suggest that REMS-restricted drugs are more likely to hold market power than traditional biopharmaceutical products.

IV. DESIGNING AN ESSENTIAL FACILITIES SOLUTION

Without legislation which creates a statutory requirement for brand manufacturers to provide generic competitors with sufficient samples for bioequivalence testing on products with REMS distribution restrictions, courts should use the essential facilities doctrine to presume such refusals to deal are anticompetitive absent a legitimate business reason. It is unlikely for brand companies to rely on an argument that they are withholding their product to prevent generic companies from reverse engineering the product in order to begin the ANDA process. Generic companies can reverse engineer products based on the patent alone.¹⁴⁸ However, if reverse engineering is faster or easier to do with the actual product on hand, it might support the argument that brand companies may refuse to supply their product until the generic has completed the reverse engineering process and is prepared for bioequivalence testing. Alternatively, a brand drug company could legally refuse to provide samples for bioequivalence testing if the generic company will not comply with the REMS restrictions.¹⁴⁹ Once a generic drug manufacturer has established that a brand company refused to provide sufficient samples for bioequivalence testing, a court should issue an injunction requiring the brand company to provide the samples unless the brand company can demonstrate that the generic company will not treat the sample safely or otherwise comply with FDA regulations.¹⁵⁰

148. See Arvind K. Bansal and Vishal Koradia, *The Role of Reverse Engineering in the Development of Generic Formulations*, Figure 2 PHARMTECH.COM (Aug. 2, 2005), <http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=173676>.

149. See, e.g., *Sports Ctr. Inc. v. Riddell, Inc.*, 673 F.2d 786, 791 (5th Cir. 1982).

150. Since a generic company attempting to reproduce a brand drug would necessarily be subject to the same REMS restrictions after market entry, it is unlikely that brand

Although some commentators have argued that true essential facilities are rare in the health care industry, most of the analysis in that area has focused on hospital resources and access to healthcare.¹⁵¹ From an economic perspective, requiring brand manufacturers to provide samples for generic bioequivalence testing serves as a check against inefficient patents and has the potential to significantly decrease the cost of drugs at a time when the cost of healthcare is of key importance to our nation. Alternatively, Seelen argues that the essential facilities doctrine should be rooted in public policy, not market concerns.¹⁵² This approach also favors labeling brand drugs as essential facilities for generic competitors since such bioequivalence testing is necessary for generic companies to take advantage of ANDAs. Both economics and broader public policy as articulated by the Hatch-Waxman Act favors increased generic access to the drug market and decreased prices.

Noted antitrust scholar Phillip Areeda has argued that the essential facilities doctrine has the potential to expand to ridiculous proportions, and that the “epithet” (he declines to describe essential facilities as a cohesive doctrine) needs more restrictive boundaries.¹⁵³ He proposes six limitations which have the potential to significantly narrow the scope of the essential facilities doctrine.¹⁵⁴ Yet even under Areeda’s limited approach, REMS abuses qualify as legitimate violations of the essential facilities doctrine.

First, Areeda affirms that essential facilities does not eliminate the general freedom to contract — or refuse to contract —

companies could consistently argue that generic companies would not handle the samples safely and in compliance with the REMS restrictions. It is important that brand companies retain the flexibility to protect the reputation of their products and the safety of their customers, but the exceptional situations in which generic companies would fail to comply with the REMS restrictions should be rare enough that this legitimate exception for refusing to deal will not swallow a more general rule requiring brand companies to deal with generic companies.

151. See, e.g., Scott D. Makar, *The Essential Facility Doctrine and the Health Care Industry*, 21 FLA. ST. U. L. REV. 913, 943 (1994). See also *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995) (holding that the Marshfield Clinic was not “an essential facility that any HMO may demand access to”).

152. See Christopher M. Seelen, *The Essential Facilities Doctrine: What Does It Mean to Be Essential?*, 80 MARQ. L. REV. 1117, 1133 (1997).

153. See Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841, 841 (1989).

154. *Id.* at 852–53.

with whoever a party wishes.¹⁵⁵ Similarly, this Note argues for the application of essential facilities solely in the instance of REMS abuses, an extremely limited exception to the broader freedom to control one's products.

Second, Areeda argues that the facility must be truly essential, meaning that the plaintiff "cannot compete effectively without it and that duplication or practical alternatives are not available."¹⁵⁶ This is largely the same definition of an essential facility from *MCI Communications*, which REMS abuses satisfy as previously discussed.¹⁵⁷

Third, Areeda argues that the essential facilities doctrine is only appropriate where it is "likely substantially to improve competition in the marketplace by reducing price or by increasing output or innovation."¹⁵⁸ Competition will almost certainly be enhanced by giving generic companies the opportunity to provide low cost drugs through the ANDA process.¹⁵⁹ Even in the cases in which the brand company successfully enjoins the ANDA by demonstrating that it infringes upon a valid patent, establishing bioequivalence will increase competition as soon as the patent expires.

Areeda's fourth and fifth principles argue that essential facilities doctrine should not reduce to a *per se* rule. Instead, defendants should bear the burden of offering legitimate business reasons which justify their refusal to deal.¹⁶⁰ Moreover, defendants should only be liable for using *improper* means to drive out competition.¹⁶¹ Similarly, this Note argues for a burden-shifting approach, where the plaintiff must establish an improper refusal to deal and may rebut the presumption of illegality by establishing a legitimate business purpose for the refusal.¹⁶² A *per se* ap-

155. *See id.* at 852.

156. *Id.*

157. *See supra* Part III.B.3; *see also* *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1132 (7th Cir. 1983).

158. *See* Areeda, *supra* note 153, at 852.

159. *See* Reagan, *supra* note 131.

160. *See* Areeda, *supra* note 153, at 852.

161. *See id.* at 852–53.

162. Because of the procedure for Paragraph IV challenges, Areeda's defendant (the alleged monopolist) is the same entity as the plaintiff that the author describes. In a Paragraph IV challenge, the generic company files its ANDA with the FDA and specifies that the brand company's patent is invalid. The brand company then has the burden of suing the generic company to seek an injunction of the generic's infringement of the brand patent. Therefore, the brand company is the plaintiff. In a more traditional essential facili-

proach eliminates the ability of a brand company to protect its reputation by ensuring that the generic competitor will use the drugs safely, as prescribed by the FDA. But other than a limited set of legitimate business purposes which ensure safety and compliance, a REMS abuse should be presumed to be illegal.

Finally, Areeda argues that a compulsion to provide access to an essential facility is only justifiable when a court can adequately explain and supervise execution of the duty.¹⁶³ This restriction exists to ensure courts order only discrete and verifiable action in reliance on the essential facilities doctrine. Where the competitor requires prolonged (perhaps indefinite) and uninterrupted access to an essential facility, courts may have a harder time monitoring the execution of that duty. In the case of REMS abuses, the court need only order a single transaction at the market price, which should be easy for the court to observe. Areeda also suggests that the existence of a regulatory agency which can monitor the execution of the required transaction weighs in favor of the use of the essential facilities doctrine,¹⁶⁴ and the FDA is perfectly situated to determine how much of the brand product would be sufficient for the generic company to complete bioequivalence testing and to monitor that the generic companies actually receive the brand product. Thus, a presumption of illegality for REMS abuses advocated for in this section satisfies even Areeda's restrictive criteria for the application of the essential facilities doctrine.

A. A REMEDY BOTH PRE- AND POST-PATENT EXPIRATION

The case for an essential facilities intervention is easier to make once the brand patent has expired. After patent expiration, the brand company has already enjoyed a long period of exclusivity during which it could more than recoup its research and development costs through monopoly pricing. Brand companies which refuse to provide REMS-restricted product to generic competitors would extend the exclusivity period indefinitely and destroy the balance between competition and innovation struck by the prescribed patent period.

ties suit, however, the brand company (or any company charged with refusing to provide its essential facility) would be the defendant.

163. See Areeda, *supra* note 153, at 853.

164. See *id.*

There is an argument that courts should grant greater discretion to patent holders to determine how to sell and withhold access to the patented product. In *In re ISO*, the court held that Xerox could lawfully withhold its patented parts from independent copy machine service companies, even though that refusal to deal might have anticompetitive consequences in the secondary market for copy machine repair.¹⁶⁵ In a similar case in which the copy machine parts were not patented, the court ruled that Kodak had taken exclusionary action by withholding parts it had a monopoly over and rejected Kodak's motion for summary judgment.¹⁶⁶ Patents are legal monopolies, and brand drug companies may argue that treating REMS-restricted products as essential facilities tips the balance too much in favor of generic competitors. Additionally, brand companies might argue that the application of essential facilities pre-expiration overlooks the fact that generic companies have multiple means to challenge brand patents. While Paragraph IV challenges remain the most common, generic companies could also challenge brand patents through the *inter partes* review process.¹⁶⁷ Patents are legally-protected monopolies, and generic companies retain alternative means to challenge brand patents even if Paragraph IV challenges are not possible.

However, these arguments fail to account for the legal and financial realities of generic drug competition. First, patents grant the holder the right to defend his monopoly in court, not an unassailable monopoly for the entire patent period. The REMS restrictions present an issue of process by providing brand manufacturers the means to prevent generic drug companies from challenging their patents at all. Process, in this case, outweighs any deference to patent holders. If the patent is legitimate, the brand company should be able to defend itself in court and continue to enjoy its period exclusivity. Courts should favor the use of essential facilities to shed light on the strength of patents and serve as a true appellate body for decisions of the patent office.

165. See *In re Indep. Serv. Orgs. Antitrust Litig.*, 85 F. Supp. 2d 1130, 1151 (D. Kan. 2000) ("A patentee may unilaterally exclude others from using its invention even if such conduct allows the patentee to obtain monopolies in multiple markets. The patentee's economic success is the reward for its invention.").

166. See *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 486 (1992).

167. 35 U.S.C. § 311 (2006).

Furthermore, the *inter partes* review process is an inadequate substitute for Paragraph IV challenges. Just as brand companies rely on the patent period to recoup development costs, generic companies depend upon the brief period of semi-exclusivity (where the brand and the first generic to enter the market are the only producers) after the FDA approves the first ANDA on a product.¹⁶⁸ A successful *inter partes* challenge to a brand patent would open a race to the FDA in which every generic company, not just the challenger, could request samples for bioequivalence testing with the hopes of filing the first successful ANDA and capturing the subsequent exclusivity period. It is unlikely that a generic company would incur the significant costs of litigation without assurances that it could not be beaten to the market by a freeriding competitor. Only the ANDA Paragraph IV process includes the safeguard that the challenging company necessarily is the first to submit an ANDA and is rewarded with the brief exclusivity period that follows.

V. CONCLUSION

By failing to require brand companies to provide generic drug manufacturers with sufficient product for bioequivalence testing, the REMS provisions of the FDAAA has the potential to undo the calculated market balance created by the Hatch-Waxman Act. Brand companies can lean on REMS distribution restrictions to prevent generic competitors from challenging their patents and entering the market. Courts should overcome Congress's apparent inability to prohibit brand refusals to deal by holding that such REMS abuses anticompetitively deprive a competitor of an essential facility in violation of section two of the Sherman Act. Where the brand company holds a legitimate patent on the drug, it will continue to enjoy monopoly profits for as long as patent law permits. However, where the patent has expired or litigation invalidates a weak patent, the essential facilities doctrine protects consumers by providing generic drug companies with the neces-

168. The expiration of several blockbuster drugs, or patent cliff, which occurred in 2012 poses issues for generic companies as well brand manufacturers hoping to maintain a steady revenue stream. Without brand products to challenge or to replicate immediately after the patent expires, many generic companies felt pressured to restructure to adjust to the loss of revenues. See Katie Thomas, *Generic Drug Makers See a Drought Ahead*, N.Y. TIMES, Dec. 3, 2012, at B1.

sary tools to challenge the brand company as anticipated, and promoted, by the Hatch-Waxman Act.