

ARTICLE

THE FDA AND PATENT, ANTITRUST, AND PROPERTY TAKINGS LAWS: STRANGE BEDFELLOWS USEFUL TO UNBLOCK ACCESS TO BLOCKED DRUGS

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ABSTRACT

Generic drugs play an integral part in national healthcare cost policy. Manufacturers of generics offer products containing the same active ingredients as their brand-name counterparts at significantly reduced prices. This dramatic price discrepancy incentivizes consumers to switch from expensive brand-name products to generic lower-priced “copies,” spelling disaster for brand-name manufacturers.

Generic-drug legislation requires comparative studies between the brand drug and the future generic drug product. So without access to samples of the brand drug, comparative studies cannot be done. Yet current legislation impedes the abilities of generic manufacturers to access these samples. This Article examines this problem of controlled access to brand drug samples spurred by drug companies’ efforts to deprive generic manufacturers of these samples and proposes how antitrust law, patent law, and real property Fifth Amendment “takings” law may help compel that access.

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INTRODUCTION

New Food and Drug Administration (“FDA”) legislation is imperiling the abilities of generic drug companies to obtain brand drug samples in order to conduct the necessary studies to bring generics to the market. Because of the newness of the FDA legislation and these access controls, no case law or body of precedent currently exists to help solve this critical problem in providing access to affordable health care.

Spiraling health care costs have put increased pressure on governments, payors, insurers, and consumers to control these costs. Despite the significant cost of prescription drugs, this cost is still only a subset of overall health care costs.³ To help control drug costs, payors, whether individual consumers or insurance companies, are increasingly buying generic drugs because of their significantly reduced prices.⁴

Consumers see these reduced prices when they purchase over-the-counter cough, cold, pain, and allergy medicines. At pharmacies, generic drug equivalents of ibuprofen are shown beside the brand bottle of Advil, generic acetaminophen beside the Tylenol bottle, generic guaifenesin beside the Robitussin cough syrup bottle, and loratadine beside its branded brother Claritin.⁵ Although generic drugs account for eighty percent of prescriptions filled in the United States, they only account for about twenty-seven percent of overall prescription drug costs.⁶

³ Health care costs include doctor visits, in-office procedures, blood tests, out-patient services (e.g., mammograms, x-rays, colonoscopies, fracture repair, etc.), in-hospital care (room charges, medication charges, devices, operations, physician charges, etc.) and ancillary services (e.g., physiotherapy, occupational therapy, in-home nursing care, etc.). If a patient has a simple ailment, the health care cost might be the cost of the doctor office visit plus the cost of the ultimate prescription drug prescribed. In evaluating the cost of healthcare, it is unfair to single out prescription drug charges as the culprit when myriad costs, if controlled, could result in overall healthcare cost reduction.

⁴ It is beyond dispute that generic drug costs are significantly less than brand drug costs. When fully commoditized, a generic drug may cost ten to twenty percent of the original brand drug price. See FDA, *Facts about Generic Drugs*, FDA.GOV (last updated Sept. 19, 2012); see also Generic Pharm. Ass’n, *Economic Analysis Generic Pharmaceuticals 1999-2008: \$734 Billion in Health Care Savings* (May 7, 2009), http://multivu.prnewswire.com/mnr/GPhA/38110/docs/38110-734_Billion_in_Generic_Savings_GPhA.

⁵ Drugs usually are known by two different names, the brand name and the “generic” molecule name adopted under the appropriate naming convention, which any manufacturer can use. Most consumers know a drug by virtue of its marketing or advertising brand name, which is usually trademarked by the brand drug company. In addition to the listed examples, Viagra for erectile dysfunction has a generic name of sildenafil; Lipitor for cholesterol control is named atorvastatin; Zoloft, the anti-depressant, is named sertraline; and Imitrex for migraines is named sumatriptan. A doctor can write a prescription using either name.

⁶ Lynne Taylor, *US FDA plans generics “Super Office,”* PHARMATIMES (Sept. 12, 2012),

A cursory review shows that even though the active ingredients in generic drugs are and must be the same as those in brand drugs, the price differential is large. In the prescription market, the price is less visible to the public but nonetheless noticeable at the point of purchase. For the insured retail purchaser, a typical generic drug co-pay may be \$5.00, whereas the brand drug co-pay may be \$25.00 or more.⁷ In this regard, for the same \$25.00 potentially spent on a brand drug, a consumer may purchase four more generic drugs and perhaps achieve a better overall health result.

Insurers, as payors, may control their costs by ensuring that generic counterparts are substituted for prescriptions for brand drugs. At the counter, different payor dynamics are at play. If the insurance company payor does not cover a specific drug in its drug plan, the pharmacist may call the doctor to rewrite the prescription for a covered drug. If not, the patient may be forced to pay the full price.⁸

Automatic substitution laws exist in most U.S. states.⁹ When a patient

http://www.pharmatimes.com/article/12-09-12/US_FDA_plans_generics_Super_Office.aspx.

⁷ Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U. L. REV. 33, 34 (2007) (“A common structure is the three-tier plan. The first tier of co-payment, which is the lowest, typically provides for a copay of around \$10 for generic drugs. The middle tier, with a slightly higher copay, allows for the purchase of brand-name drugs that have been determined by the PBM to be the preferred brand drugs in the formulary for treating a particular disease or condition. The third tier, allows plan participants to purchase non-preferred brand drugs with the payment of the highest copay.”).

⁸ *Astrazeneca AB v. Apotex Corp.*, 2013 WL 6244425, at *8 (S.D.N.Y. Dec. 3, 2013) (“One methodology that third party payers or TPPs have adopted for managing their reimbursement of prescription drug costs is the creation of a ‘formulary,’ or list of covered drugs. During the time at issue in this litigation, formularies often placed drugs into three tiers. Tier I was generally reserved for generic drugs and required the patient to pay nothing or the smallest co-pay. Tier II usually contained the preferred branded drug and required a higher co-pay by the patient. Tier III usually included non-preferred branded drugs and required the highest co-pay. ‘Closed’ formularies excluded certain drugs altogether.”); *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 2696916, at *11 (E.D.N.Y. July 2, 2008) (“To manage the UFCW Fund’s pharmacy benefits, NMHC uses a formulary containing a list of preferred drugs. Many of the drugs on the preferred list are those for which the NMHC has rebate contracts with the manufacturers. The UFCW Fund pays the cost, minus a co-pay, regardless of whether the drug is included in the formulary. The co-pay is a percentage of the drug cost or a fixed amount per prescription paid by the actual user; it may vary depending on whether the particular drug is on-formulary or off-formulary.”).

⁹ Jesse C. Vivian, *Generic-Substitution Laws*, 33(6) U.S. PHARMACIST 30, 30-34 (2008), available at <http://www.uspharmacist.com/content/s/44/c/9787/>) (“These disclaimers aside, many states have elevated the Orange Book lists to legal status by indicating that drugs the FDA deems to have equivalencies may be substituted or, conversely, that drugs the FDA

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submits a prescription, these laws require a pharmacist to substitute and dispense a generic drug whenever the generic drug is available, irrespective of whether the doctor wrote the brand name or generic name.¹⁰ This means that if a generic drug is available, the brand drug essentially becomes unmarketable.¹¹ It is indisputable that brand companies lose tremendous revenue when a generic substitute for a brand drug enters the market. If a brand company loses too many brand drugs to market genericization too soon (and before any new brand drugs can fill the gap, if possible), the brand company may lose some or all of its value, which is no inconsequential event. Indeed, some brand companies have reported losses in the hundreds of millions or billions of dollars when genericization occurs.¹² To this end, it is understandable that brand companies may wish to use any available tool to either block generic drugs entirely or at least delay their entry to the market. Arguments for delaying market entry of generic drugs include that generic drugs are not the

does not list as having equivalencies cannot be substituted. All states in the U.S. have laws addressing generic substitution to one degree or another. There are ‘positive formulary’ states, which identify generics that can be substituted, and there are ‘negative formulary’ states, which list drugs that cannot be substituted. There are also states that do not refer to Orange Book standards and have neither a positive nor a negative formulary, and where pharmacists are permitted to perform generic substitution so long as the drugs are pharmaceutically equivalent.”).

¹⁰ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011) (“But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits.”) (citations omitted); *see Hill Dermaceuticals, Inc. v. FDA*, 826 F. Supp. 2d 252, 261 (D.D.C. 2011) (“Because pharmacists will substitute the generic product for the brand-name drug—and are often required to substitute generic products under state law—a generic drug company will automatically capture a sizeable portion of the sales of the drug, even if the generic is only marginally less costly and not as safe as the branded drug.”).

¹¹ A brand drug is not entirely worthless, however. Despite automatic substitution laws that require pharmacists to substitute brand name versions for generic versions if available, a pharmacist can still dispense a brand version if the physician writes that no substitution is permitted (usually denoted as “dispense as written”) or if the patient is willing to pay the higher price. *See Foster v. Am. Home Prod. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994) (“Although generic manufacturers do not advertise, they still are able to generate sales, as pharmacists often substitute generic drugs for name brand prescriptions because the generics cost less. Unless a physician affirmatively indicates that a prescription is to be dispensed as written, the pharmacist may substitute a lower priced generic equivalent for the name brand drug actually prescribed.”).

¹² C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 635 (2009) (“For a blockbuster drug with billions of dollars in annual sales, a brand-name firm has billions to lose from generic competition. Moreover, entry hurts the brand-name firm more than it helps the generic firm.”).

same as brand names, that generic drugs are counterfeits, and that generic drugs lack the same therapeutic effects as brand drugs.¹³

Generic drugs, however, are not counterfeits of original brands. The FDA extensively reviews generic drugs to ensure that they are the same as the original brand drugs.¹⁴ Though generic drug companies do not replicate the expensive drug candidate searches, animal testing, and later full clinical trials in humans that brand companies do to obtain initial drug approval, generic companies rely on the FDA's decision to approve a particular branded drug to establish the safety and efficacy profiles. Generic drugs undergo abbreviated testing and review. Essentially, generic drug companies conduct bioequivalency studies ("BE") to show that their versions will behave in the same way as brand drugs do.¹⁵ To prove this, generic drug companies compare the behavior of their versions to the brand drugs' behavior.

What would happen if a brand drug's distribution was so tightly controlled that a generic drug company could not even obtain the brand drug to run comparative studies? Without comparative study data, the FDA will not

¹³ See Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 260 (2012) ("Citizen petitions have been filed by three types of filers. First, brand firms file petitions, often to request denial of a generic's ANDA. These petitioners raise issues related to safety and efficacy of the generic drug. And they question whether generics are bioequivalent, such that the body can absorb the drug similarly."); see also *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999); *Sanofi-Aventis U.S. L.L.C. v. FDA*, 842 F. Supp. 2d 195, 198-99 (D.D.C. 2012) ("On February 19, 2003, Sanofi submitted a Citizen Petition urging FDA to withhold approval of any ANDA for generic enoxaparin '[u]ntil such time as enoxaparin has been fully characterized . . . unless the manufacturing process used to create the generic product is determined to be equivalent to [Sanofi's] manufacturing process for enoxaparin, or the application is supported by proof of equivalent safety and effectiveness demonstrated through clinical trials.' [The] FDA ultimately rejected this request to forestall the marketing of a generic.").

¹⁴ See 21 U.S.C. § 355(j) (2006).

¹⁵ See *id.* (A generic drug will be deemed bioequivalent to the Reference Listed Drug if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the [Reference Listed Drug] when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either single dose or multiple doses."); *Mylan Labs. Ltd. v. FDA*, 910 F. Supp. 2d 299, 301 (D.D.C. 2012) ("[I]t can submit an abbreviated new drug application ('ANDA') showing that the generic drug is 'bioequivalent' to the approved drug and meets certain chemistry and labeling requirements."); SHASHANK UPADHYE, *Abbreviated New Drug Application (ANDA) Approval Process*, in *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 7:6 (6th ed. 2013) ("A generic drug is BE when the rate and extent of absorption is not significantly different from the rate and extent of absorption of the branded drug (the branded drug is also known as the Reference Listed Drug (RLD)). It essentially means that if the patient absorbs X amount of the drug in Y amount of time and Z amount reaches the location, then within the realm of statistical deviation, so will the generic product.") (citations omitted).

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approve a generic drug and, thus, drug costs will remain high. Therein lies the rub!

New FDA laws require brand companies to promulgate drug safety and distribution controls to ensure ultimate patient safety. These are known as Risk Minimization Action Plans (“RiskMAPs”) and Risk Evaluation & Mitigation Strategies (“REMS”). REMS are used to control brand drug access so that generic drug companies cannot obtain the products in order to run comparative BE studies.¹⁶ The Hatch Waxman Act of 1984, which was specifically enacted to modernize the drug approval process for both brand and generic drug companies and facilitate early generic drug entry,¹⁷ potentially stands in conflict with REMS. The well-intended REMS, which were meant to enhance patient safety, have led to the questionable blocking of early generic drug entry. The policy rationales behind REMS and the Hatch Waxman Act conflict.

This Article discusses the impact of REMS on generic drug development. This issue continues to plague the industry and create uncertainty for both brand and generic drug manufacturers because the following market dynamics are in conflict:

- more new brand drugs becoming subject to REMS controls;¹⁸
- decrease in the overall number of new drugs being discovered;¹⁹

¹⁶ See discussion *infra* Section B.3.

¹⁷ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (“Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug. As we have previously recognized, this process is designed to speed the introduction of low-cost generic drugs to market.”) (citations omitted); *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002) (“Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§355, 360cc, and 35 U.S.C. §§156, 271, (the ‘Hatch Waxman Amendments’ to the Federal Food, Drug and Cosmetic Act (‘FFDCA’)), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”); *Mylan Labs.*, 910 F.Supp. at 311 (“Mylan is correct that in enacting the Hatch–Waxman Act Congress sought to promote generic competition.”).

¹⁸ See Theresa Toigo, Assoc. Dir. for Drug Safety Operations, FDA, Opening Remarks at FDA Public Meeting: Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS) 11 (July 25, 2013), available at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM363676.pdf>.

¹⁹ The FDA’s new Molecular Entity Chart shows a decrease in new drug applications from 1995 to 2011: 1995 (28); 1996 (53); 1997 (39); 1998 (30); 1999 (35); 2000 (27); 2001 (24); 2002 (17); 2003(21); 2004 (36); 2005 (20); 2006 (22); 2007 (18); 2008 (24); 2009

- increased pressures on brand companies to protect residual and future revenues and profits; and
- desires of payors to control spiraling drug costs.²⁰

This Article explores new territory; no precedent yet exists and no theory has been tested in court. There is a gap in the law governing pharmaceuticals that needs to be filled. This Article borrows from the diverse subjects of patents, FDA regulations, antitrust, and real property in developing cross disciplinary theories to determine which laws, if any, can work to provide generic drug manufacturers access to information needed to enter the market. Without some type of access to generic drugs, payors will not realize the savings associated with those generic drugs. Yet requiring one party to develop REMS that are then used by another, perhaps free of charge, creates a free rider problem.²¹

Importantly, this Article does not take the position that brand drug controls are inherently bad and generic utilization is good. Rather, this Article explores whether brand controls currently exist, and if so, whether a legal remedy exists for generic drug manufacturers to overcome those controls. Therefore, we ask a simple question: “Does anyone have the ability or authority to obtain access to samples or REMS, and if so, how?” We will see that the answer is not so simple.

Accordingly, this Article discusses two themes. First, assuming certain REMS block generic manufacturers’ access to certain brand drugs to run comparative studies, do any laws allow generic manufacturers initial access to the brand drugs? Second, once an Abbreviated New Drug Application (“ANDA”)²² is on file, if REMS exist and the FDA requires the ANDA applicant to have REMS, do any laws permit the ANDA applicant to have its

(26); 2010 (21); 2011(30). FDA, *Summary of NDA Approvals & Receipts, 1938 to the present*, available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SummaryofNDAAApprovalsReceipts1938tothepresent/default.htm> (last updated Jan. 1, 2013).

²⁰ Since the U.S. government is the biggest buyer of prescription drugs, it has every motivation to control future drug costs. See Brian Fung, *The World’s Impending \$1.2 Trillion Drug Bill, in Two Charts*, ATLANTIC (July 12, 2012, 12:29 PM), available at <http://www.theatlantic.com/health/archive/2012/07/the-worlds-impending-12-trillion-drug-bill-in-two-charts/259746/>.

²¹ Eric Boyd, *Compensating Manufacturers Submitting Health and Safety Data to Support Product Registrations After Ruckelshaus v. Monsanto*, 61 IND. L.J., 189, 190 (1986) (discussing the free rider problem arising when one party creates data for the use by another party).

²² An ANDA is filed under 21 U.S.C. § 355(j). Essentially, it can be thought of as the generic drug approval application.

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own REMS or force the brand company to share its REMS?

Part A of this Article discusses the origins and substance of REMS. This Part also discusses the effect of new statutory language on REMS. Part B discusses the antitrust implications of depriving generic manufacturers access to brand drug samples and REMS. Further, this Part discusses whether antitrust law can compel brand drug manufacturers to give generic manufacturers access. In particular, it discusses whether the essential facilities doctrine applies. Part C discusses patent law and whether courts can compel brand drug manufacturers to give generic manufacturers access to a patented drug. Specifically, it discusses whether patent law shields brand companies from compelled access or whether patent law provides a remedy for generic manufacturers. Part D discusses whether Fifth Amendment real property “takings” law can apply to compel access as a taking. It discusses how to adapt real property takings to REMS and whether these takings are constitutionally justified. This Article concludes that these different legal theories, individually or cumulatively, can compel access to brand drug samples and brand drug manufacturers’ REMS.

A.1. REMS - WHAT ARE THEY?

The FDA’s authority to regulate drugs has significantly evolved over recent years. Initially, the FDA did not regulate drugs or at least was lackadaisical in its enforcement of regulatory authority.²³ The Pure Food and Drugs Act of 1906 failed to give the FDA any inspection authority, and it deprived the FDA of the ability to police any misleading claims about pharmaceuticals.²⁴ In 1911, the Supreme Court held that the 1906 Act did not allow the FDA’s predecessor to police misbranded products.²⁵ After more than 100 people died in a sulfanilamide tragedy in 1937,²⁶ Congress enacted the 1938 Food Drug and

²³ Though drug regulation existed in the early 1900s, the FDA was not formally created until much later. The term “FDA” is used to include those previous agencies that had regulatory authority.

²⁴ Pure Food and Drugs Act of 1906, ch. 3915, §§ 1-13, 34 Stat. 768 (repealed 1938). Initially, the 1906 Pure Food and Drugs Act vested regulation in the Department of Agriculture’s Bureau of Chemistry. In 1927, the Bureau of Chemistry changed its name to the Food Drug and Insecticide Administration. In 1931, the name of the agency was shortened further to the Food and Drug Administration. In 1940, the Federal Security Agency took control over the FDA from the Department of Agriculture. The Federal Security Agency became the Department of Health & Human Services.

²⁵ *United States v. Johnson*, 221 U.S. 488, 497 (1911).

²⁶ See H. A. WALLACE, REPORT OF THE SEC’Y OF AGRIC. ON DEATHS DUE TO ELIXIR SULFANILAMIDE-MASSENGILL, S. DOC. NO. 75-124, at 1-3 (1937). In this disaster, the Massengill company wanted to sell the drug sulfanilamide in liquid form. *Id.* The drug was stubbornly insoluble, and hence the company needed a good solvent to solubilize the drug.

Cosmetic Act (“FDCA”) to give the FDA more regulatory authority.²⁷

The FDCA required drug manufacturers to prove the safety of new drugs but not their efficacy and allowed the FDA to police for false and misleading therapeutic claims.²⁸ Drug companies fought against the FDCA because they did not want to be subject to safety regulations. Today, drug companies may take the opposite position and instead demand compliance with REMS. In 1962, Congress amended the FDCA to require drug companies to prove both safety and efficacy of new drugs.²⁹ From 1962 to 2007, Congress amended the FDCA periodically but implemented its most significant drug safety and distribution control system in September of 2007 with the passage of the Food and Drug Administration Amendments Act (“FDAAA”).³⁰ The FDAAA was a comprehensive bill that concerned various aspects of the FDCA, including enacting 21 U.S.C. § 355-1.³¹

Newly enacted § 355(p)³² through § 355-1 required a proposal and implementation of certain REMS.³³ Though various components of REMS were already in place, the new statute created a more structured REMS system. Under the new law, the specific type of REMS required would depend on the programs and protocols that the drug companies implemented, ensuring that the FDA could correctly evaluate whether the benefits of a drug outweigh the

Id. The company chose diethylene glycol as the solvent without investigating its safety, despite literature showing it was toxic. *Id.* The company rationalized its decision on the basis that diethylene glycol was derived from glycerine, which was used in medicines. *Id.* After 107 people died, authorities seized the products, not because the solvent was toxic, but on the grounds that it was misbranded because it was marketed as an Elixir, which required the use of alcohol and the product did not have an alcohol. *Id.*

²⁷ See Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 et seq. (2006)).

²⁸ *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-13 (1973) (“The 1938 Act, which established a system of premarketing clearance for drugs, prohibited the introduction into commerce of any ‘new drug’ unless a new drug application (NDA) filed with the Food and Drug Administration (FDA) was effective with respect to that drug. Under the 1938 Act a ‘new drug’ was one not generally recognized by qualified experts as safe for its intended use.”).

²⁹ See Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (1962).

³⁰ Food & Drug Administration Amendments Act (FDAAA) of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).

³¹ See 21 U.S.C. § 355(p) (2006), which requires the implementation of REMS, with reference to newly enacted § 355-1, which governs the details of the REMS plan.

³² For the purposes of this Article, any statutory section is presumed to be in 21 U.S.C. unless otherwise noted.

³³ Food & Drug Administration Amendments Act § 102 (adding 21 U.S.C. § 355-1). See Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112-144126 Stat. 993 (Supp. 2012), which further amended 21 U.S.C. § 355-1.

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risks.³⁴ A failure to implement REMS may result in a drug being deemed “misbranded,” causing the drug company to potentially face future administrative, civil, or criminal penalties.³⁵ The FDA may require a drug maker to develop REMS prior to approving the underlying drug (a preapproval REMS) or require REMS after the drug is marketed openly (a post-approval REMS).³⁶

A.2. REMS AND THEIR COMPONENTS

Since the purpose of REMS is to inform either doctors or patients about safety and educational concerns regarding a specific drug, the various components of REMS range from strict to relaxed. The spectrum of REMS components are shown here in Figure 1:

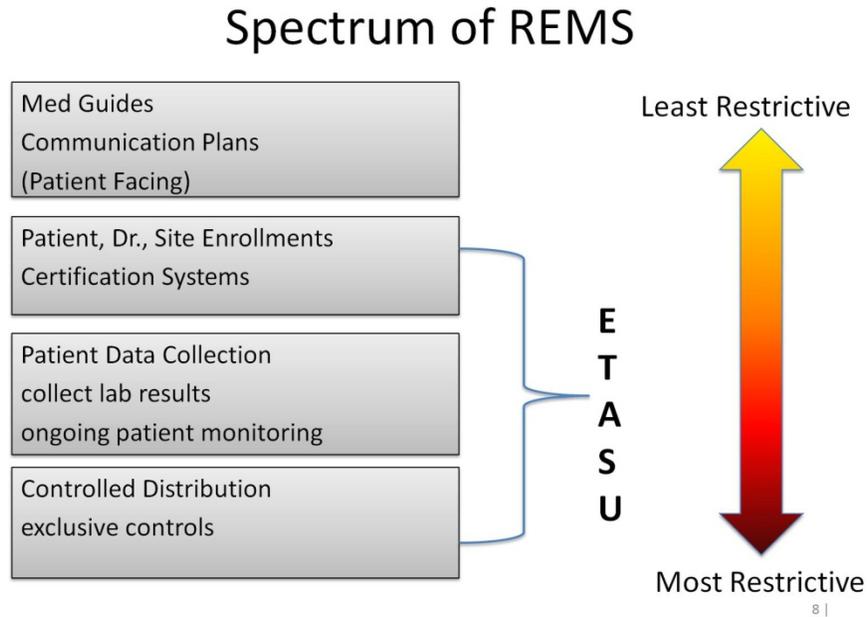


Figure 1: Spectrum of REMS Indicating the Degree of Restrictiveness

³⁴ § 355-1(a)(1).

³⁵ 21 U.S.C. § 352(y) (2006) (indicating that a drug may be deemed misbranded if it is subject to an REMS program and the drug manufacturer fails to comply with any REMS requirements). A misbranded drug cannot be introduced, delivered, or received into interstate commerce. 21 U.S.C. §§ 331(a), (c) (2006).

³⁶ § 355-1(a).

The least restrictive are low-level REMS, which can include medication guides for patients or communication plans for healthcare practitioners. The FDA must approve all literature meant for patients as medication guides.³⁷ These guides are included when patients need certain information about drugs to prevent serious adverse events, about serious adverse events in order to make informed decisions, or about directions for drug use or compliance so that the effectiveness of the drugs is not compromised.³⁸ Accordingly, medication guides are usually patient-facing.

Communication plans are practitioner-facing. The practitioner may be a doctor, nurse, or pharmacist. These plans usually include, but are not limited to, “Dear Doctor/Health Care Practitioner” letters, web-based tutorials or lessons, and in-person Continuing Medical Education programs.³⁹ The purpose of these plans is to educate the practitioner on the safe and appropriate use of the drug. These plans describe how the drug maker will inform practitioners about a drug’s risks and the components of REMS.⁴⁰

High-level REMS are more restrictive. The FDA may require the implementation of Elements to Assure Safe Use (“ETASUs”).⁴¹ ETASUs are strict controls or systems that enforce the appropriate distribution and use of drugs.⁴² ETASUs include doctor certifications, patient registration,⁴³ use of specialized pharmacies for controlled distribution (e.g., specialized mail-order or in-hospital pharmacy), patient co-testing and lab tests,⁴⁴ and patient

³⁷ 21 C.F.R. § 208.1 (2013).

³⁸ *Id.* Note that a medication guide is not solely a function of REMS. Rather, the FDA may require medication guides outside of REMS, although a drug manufacturer is not required to assess them if medication guides are outside of REMS. *Id.*

³⁹ See Gary H. Slatko et al., FOOD & DRUG L. INST., *Utilizing REMS to Mitigate the Safety Risks of Pharmaceuticals: Perspectives on FDA Guidance, Lifecycle Management and Creating a New Scientific Discipline*, 2 FDLI MONOGRAPH SERIES 13 (2010), available at <http://www.fdpi.org/docs/default-document-library/fdpi-monograph-vol2no2-preview.pdf?sfvrsn=0%29>.

⁴⁰ § 355-1(e)(3).

⁴¹ § 355-1(f).

⁴² FDA, GUIDANCE FOR INDUSTRY: FORMAT AND CONTENT OF PROPOSED RISK EVALUATION AND MITIGATION STRATEGIES (REMS), REMS ASSESSMENTS, AND PROPOSED REMS MODIFICATIONS 11 (2009), available at <http://www.fda.gov/downloads/Drugs/Guidances/UCM184128.pdf>.

⁴³ § 355-1(f)(3).

⁴⁴ For example, general cholesterol-reducing medicines do not require the patient to continuously get blood tests done to see if cholesterol is actually being reduced. On the other hand, for the drug REMICADE, not only must the patient go to a specialized I.V. clinic to have the drug administered by I.V. injection over the course of a few hours, but the patient also must have blood tests conducted to ensure that adverse side effects in the liver are not occurring. The patient’s blood test is not to monitor the effectiveness of the

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monitoring. In very strict REMS, the system may only permit certain certified doctors to submit prescriptions online to a central database. The central database then checks the information and sends the patient educational materials that the patient must complete and re-submit to the pharmacy database before the drug is delivered directly to the patient using specialized couriers.⁴⁵

Despite the benefits of REMS, REMS may end up harming consumers because they challenge the ability of generic companies to obtain brand product samples. Normally, a generic drug company could obtain brand drug samples through the supply chain, usually by purchasing the drug from wholesalers or distributors. Rarely will the generic company procure the product at a local retail level. Theoretically, if REMS are strict, a generic drug company could simply try to pay a patient or physician to manipulate the REMS system and retrieve the sample from that patient or physician. However, this would not result in enough samples for reverse engineering, testing, and required sample retention.⁴⁶ Accordingly, a generic manufacturer would need to employ this scheme an impracticable number of times before obtaining the requisite amount of the brand drug.

A.3. THE PROHIBITION ON BLOCKING REMS - APPLICATION OF § 355-1(F)(8)⁴⁷

The FDA statute seemingly provides for a remedy against illicit REMS control. Particularly, 21 U.S.C. § 355-1(f)(8) states:

(8) Limitation

No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) [a/k/a a 505(b)(2) “Paper NDA” application] or (j) [a/k/a an ANDA] of this title or to prevent application of such element under subsection (i)(1)(B) to a drug that is the

REMICADE drug for its therapeutic use, but to monitor for hepatic side effects. *See* JANSSEN BIOTECH, INC., MEDICATION GUIDE, REMICADE (2013), *available at* <http://www.fda.gov/downloads/Drugs/DrugSafety/ucm089023.pdf> (example of patient-directed REMS). The label also includes doctor-facing instructions to monitor for safety by testing for tuberculosis prior to the first administration and then periodically testing for latent infections. JANSSEN BIOTECH, INC., PRESCRIBING INFORMATION §§ 2.9, 5.1 (2011), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103772s52951bl.pdf.

⁴⁵ *See XYREM Success Program for Patients*, <http://www.xyrem.com/patient-success-program> (last visited Dec. 15, 2013) (discussing the REMS system for the drug Xyrem).

⁴⁶ Companies are obligated to maintain samples so that they can be evaluated. 21 C.F.R. § 314.50(e) (2013).

⁴⁷ § 355-1(f)(8).

subject of an abbreviated new drug application.⁴⁸

Only the FDA can expressly enforce this provision because private parties do not have private rights of action to enforce provisions of the FDCA.⁴⁹ Usually the FDA predicates enforcement authority on one of the Prohibited Acts listed under 21 U.S.C. § 331.⁵⁰ But a close review of the Prohibited Acts reveals that the list does not include any explicit enforcement authority or parallel references to § 355-1(f)(8)'s prohibition.⁵¹

Perhaps in enacting § 355-1(f)(8), Congress thought that because it included explicit affirmative prohibitory language there was no need to further include any enforcement language in § 331's list of Prohibited Acts. Perhaps Congress intended that § 355-1(f)(8) be policed under the FDA's enforcement authority to regulate aspects of the FDCA.⁵² Or perhaps Congress intended other areas of law to provide the enforcement mechanism.

At first reading, it would appear that the language explicitly prohibits a brand company from using REMS to block approval of either a § 505(b)(2) Paper New Drug Application ("NDA") or an ANDA.⁵³ The statute, however, is silent on the enforcement mechanism and any penalties for failure to comply.

The plain language of § 355-1(f)(8) can be separated into three prohibitions regarding ANDA applications, namely that no holder of REMS can use REMS to:

1. block approval of an ANDA (a 21 U.S.C. § 355(j) application);
2. delay approval of an ANDA; or
3. prevent application of any REMS subject to an ANDA.⁵⁴

⁴⁸ *Id.*

⁴⁹ *Morris v. PLIVA, Inc.*, 713 F.3d 774, 778 (5th Cir. 2013) ("First, the Federal Food, Drug, and Cosmetic Act ('FDCA') provides no private right of action for these violations. '[A]ll such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States.'").

⁵⁰ *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988) ("As noted at the outset, 21 U.S.C. § 331 lists the acts which constitute criminal violations of the Act.").

⁵¹ *See* 21 U.S.C. § 331 (2006).

⁵² The FDA may also possess general enforcement authority to regulate any provision of the Food Drug and Cosmetic Act. *Nutritional Health Alliance v. FDA*, 318 F.3d 92, 97-98 (2d Cir. 2003) ("The FDC Act provides the FDA with broad authority to regulate food, drug and dietary supplement products to ensure public health and safety.").

⁵³ An § 505(b)(2) application is governed by 21 U.S.C. § 355(b)(2) and is a hybrid between an NDA and an ANDA. *See* § 355(b)(2). The ANDA is governed by 21 U.S.C. § 355(j). *Id.* at § 355(j). The similarities and differences are more fully described in UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW*, *supra* note 15, at §§ 7-8.

⁵⁴ § 355-1(f)(8).

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Of course, lawyers for both brand and generic companies can read the statute's plain language to suit their own purposes. For example, does "block", broadly interpreted, preclude *any* activity that could block approval? Could this mean that failing to fulfill a generic drug manufacturer's requests for brand samples qualifies as blocking approval?

Or perhaps a narrower construction is merited; the language may imply that there must be an ANDA already *on file* before the brand company will be prohibited from engaging in REMS-related activity that blocks the pending ANDA's approval. Similarly, does the word "delay" apply to pre-ANDA filing activity or does it only apply to post-ANDA filing activity? In one sense, the word "delay" implicitly refers to something that already exists (such as the ANDA), which is then delayed to prolong its pendency. It might belabor the word "delay" to interpret it as an act of thwarting the progress of an ANDA that does not yet exist.

In certain cases, the FDA may require all companies to participate in the same REMS program. This is often called Shared REMS.⁵⁵ Shared REMS come in different forms, but generally this means that information is shared amongst the relevant drug companies. Accordingly, the last phrase of § 355-1(f)(8) could be interpreted as forcing drug companies to participate in Shared REMS.⁵⁶ In fact, § 355-1(i)(1) requires that in certain situations there must be a

⁵⁵ According to the FDA's website, the FDA has imposed shared REMS for the following drug products: Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) REMS, Extended-Release and Long-Acting (ER/LA) Opioid Analgesics REMS, Isotretinoin iPLEDGE REMS, Mycophenolate REMS, Rosiglitazone REMS, and Transmucosal Immediate-Release Fentanyl (TIRF) Products REMS. *Approved Risk Evaluation and Mitigation Strategies (REMS)*, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm> (last updated Sept. 24, 2013).

⁵⁶ A drug company recently filed a Citizen Petition asking the FDA to clarify how companies should mutually negotiate Shared REMS programs. The petition alleges that although the FDA requires companies to discuss, the FDA gives no guidance whatsoever on the scope and content of the process. *See* FDA Citizen Petition 2013-P-0572, submitted by Prometheus Laboratories Inc., 6-17 (May 10, 2013). The Prometheus Citizen Petition also states that without guidance from the FDA on negotiated REMS, Prometheus suggests it might be the target of FTC antitrust scrutiny. *Id.* at 12-14. The allegations would be that Prometheus failed to negotiate a successful Shared REMS program when required to do so by statute, that any negotiation was done in bad faith, or that any successful negotiation could also in parallel be construed as a "reverse payment" as consideration to settle patent lawsuits. *Id.*

The FDA denied in part and granted in part the Petition. Letter from Janet Woodcock, Docket No. 2013P-0572, Dir. of Ctr. for Drug Evaluation, FDA (Oct. 7, 2013). In the decision, the FDA stated that companies must cooperate to agree on a Shared REMS

single Shared REMS and that a waiver of the sharing requirement should rarely be given.⁵⁷ The waiver allows a generic drug company to obtain final ANDA approval with its own parallel REMS that are not shared.⁵⁸

If the brand company could limit access to its drug and be immune from any liability for doing so, the deprivation would essentially gut the purpose of the Hatch Waxman Act, which is to provide access and expedited approval pathways for generic drugs. If Congress intended to gut the Hatch Waxman Act, then it could have done so in a more clear and drastic fashion, rather than in the more back-handed manner just noted.⁵⁹ If the Hatch Waxman Act is deemed to have no force, then why promulgate it? Congress chose to include REMS, therefore presumably giving the provision force.⁶⁰

A brand company could argue that REMS prohibit it from selling samples to a generic company as such a sale would be outside of the REMS guidelines and thus barred by the FDAAA. However, nothing in the FDAAA prohibits the sale of REMS-controlled drugs to qualified generic companies that will use those drugs in controlled FDA-required BE. The provision only prevents brand companies from using REMS to block or delay the ANDA process.⁶¹ The FDA has even stated that it would not consider it an illegal REMS diversion if a brand company sells branded samples to a generic company.⁶²

A.4. EFFECT OF OMITTED LANGUAGE

Assuming that the statute's plain language is unclear, can we divine some

program. *Id.* The FDA stated that Prometheus was incorrect in saying that a brand company need not cooperate with a generic company in Shared REMS. *Id.* Rather, companies are statutorily required to work together. *Id.* Moreover, the FDA demonstrated how companies in the past have cooperated, such as convening industry-working groups to manage the cooperation process. *Id.* The FDA punted the question of whether the FTC would consider any Shared REMS as inter-party collusion that violated the antitrust law. The FDA referred Prometheus to the FTC to discuss whether such cooperation was tantamount to collusion. *Id.* In granting part of the Petition, the FDA granted Prometheus its usual rights to be part of any new process. *Id.*

⁵⁷ § 355-1(i)(1)(B)(i) .

⁵⁸ The FDA appears to have granted a partial Shared REMS waiver relating to buprenorphine products for opioid dependence. *See* FDA, Decision Letter 2012-P-1028, to Reckitt Benckiser Pharmaceuticals, 12 n. 45 (Feb. 22, 2013), *available at* <http://www.regulations.gov#!documentDetail;D=FDA-2012-P-1028-0011>.

⁵⁹ *Whitman v. Am. Trucking Ass'n.*, 531 U.S. 457, 468 (2001) (Congress does not hide “elephants in mouseholes.”).

⁶⁰ *Stone v. INS*, 514 U.S. 386, 397 (1995).

⁶¹ § 355-1(f)(8).

⁶² Letter from Gary J. Buehler, Dir., FDA Office of Generic Drugs, to John Ryman, Lannett Corp. (Feb. 12, 2007).

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meaning or intent from its legislative history?⁶³ Brand companies may argue the legislative history reflects that Congress contemplated certain language providing for direct enforcement but never enacted it, indicating that the promulgated language has no enforcement value. H.R. 2900 included the House of Representatives' more explicit enforcement provision, namely:

(6) BIOEQUIVALENCE TESTING.- 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.⁶⁴

This proposal unequivocally created the mechanism of enforcement.⁶⁵ No Senate counterpart existed.⁶⁶ According to one source, various disagreements arose that blocked joint House and Senate conferences regarding their respective versions of the bill.⁶⁷ Congress eventually struck a compromise; the

⁶³ *United States v. Williams*, 659 F.3d 1223, 1225 (9th Cir. 2011), *cert. denied*, 132 S. Ct. 1951 (2012) ("In statutory construction, our starting point is the plain language of the statute. We examine not only the specific provision at issue, but also the structure of the statute as a whole, including its object and policy. If the plain meaning of the statute is unambiguous, that meaning is controlling and we need not examine legislative history as an aide to interpretation unless the legislative history clearly indicates that Congress meant something other than what it said. If the statutory language is ambiguous, then we consult legislative history.").

⁶⁴ H.R. 2900, 110th Cong. § 505-1(f)(6) (as passed by House, July 11, 2007), 153 CONG. REC. 18,580 (2007).

⁶⁵ Similarly, the Patent Clause of the U.S. Constitution is unique among the Constitutional provisions because it sets forth not only the purpose of the patent law (i.e., to promote the progress of science and useful arts) but also the mechanism for doing so (i.e., by securing certain exclusive rights for limited times). U.S. CONST. art 1, § 8, cl. 8. The House bill contained the same structure. H.R. 2900.

⁶⁶ See Food and Drug Administration Revitalization Act, S. 1082, 110th Cong. (2007).

⁶⁷ 66 C. Q. WEEKLY 48 (2008).

drug-user fee reauthorization was deemed the most important provision, and many other provisions were dropped. Importantly, no discussion arose as to why any other provision was dropped.

A Senate version of what would become the Food and Drug Administration Safety and Innovation Act of 2012 contained a more benign provision that prohibited REMS blockage of brand samples:

(k) Drug Development and Bioequivalence Testing - (1) IN GENERAL- 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 developing, or conducting bioequivalence 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.⁶⁸

No House counterpart to this bill existed, and the Senate dropped this provision when it adopted the House's version. Nothing in the Senate's legislative history makes any mention that Congress dropped the provision.

Omitted language from a previous legislative draft can be interpreted in two ways: (1) Congress intended to drop the provision because lawmakers opposed its inclusion, or (2) Congress's intent cannot be gleaned from the dropped provision unless there are clear and unequivocal reasons for the omission. The Supreme Court has stated that unexplained disappearances of language from a previous draft are rarely a reliable indicator of intent.⁶⁹ In the context of the Hatch Waxman Act, for example, the Supreme Court noted that a provision in a bill might be proposed and rejected for any number of reasons.⁷⁰

In summary, to certain readers, § 355-1(f)(8) is plain and unambiguous in that it explicitly prohibits illicit use of REMS to block generic companies' access to brand drug samples. To others, the statute is clear in what it prohibits but explicitly fails to denominate a penalty. The legislative history is unhelpful. So if we assume that no enforcement exists in the plain language, do other legal theories help?

B.1. REMS AND THE ANTITRUST CONCERN:
THE ESSENTIAL FACILITIES DOCTRINE

Antitrust law supports generic manufacturers' efforts to compel brand drug

⁶⁸ Food and Drug Administration Safety and Innovation Act, S. 3187, 112th Cong. § 1131(k) (passed by Senate, May 24, 2008).

⁶⁹ *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989).

⁷⁰ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1686 (2012).

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companies to provide access to brand drug samples and to REMS systems or components. U.S. case law generally recognizes the right of a firm to unilaterally refuse to deal with competitors.⁷¹ The Supreme Court, however, has recognized certain limited exceptions to this broad right.⁷² Lower courts have woven these sparse threads together to form the so-called “essential facilities” doctrine, which states that when certain products or “facilities” are under the control of a monopolist, an exception to the refusal-to-deal rule may exist.⁷³ Most courts have employed a test similar to one used in the Seventh Circuit’s *MCI Communications Corp. v. AT&T* decision, which held that a firm with monopoly power violates § 2 of the Sherman Act when:

1. the monopolist controls access to an essential facility,
2. the facility cannot be reasonably duplicated by a competitor,
3. the monopolist denies access to a competitor, and
4. it was feasible to grant access.⁷⁴

⁷¹ *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408 (2004) (“Thus, as a general matter, the Sherman Act ‘does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal.’ (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919))”).

⁷² *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) (involving denial of access to a previously shared multi-facility ski pass program); *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973) (involving a refusal by a regulated power utility to either transport or wholesale electricity to municipalities within its territory); *Associated Press v. United States*, 326 U.S. 1 (1945) (involving denial of entry into an affiliation of newspapers to competitive newspapers operating in the same markets as existing members); *United States v. Terminal R. R. Ass’n of St. Louis*, 224 U.S. 383 (1912) (involving denial of access to railroad terminal facilities to railroad companies lacking an ownership stake in the facilities).

⁷³ The essential facilities doctrine has been recognized and applied in every Circuit. *See, e.g.*, *Interface Group v. Mass. Port Auth.*, 816 F.2d 9, 12 (1st Cir. 1987); *Twin Labs. v. Weider Health & Fitness*, 900 F.2d 566, 568-69 (2d Cir. 1990); *Ideal Dairy Farms v. John Labatt*, 90 F.3d 737, 748 (3d Cir. 1996); *Laurel Sand v. CSX Transp.*, 924 F.2d 539, 544 (4th Cir. 1991); *Mid-Tex. Commc’ns Sys. v. AT&T*, 615 F.2d 1372, 1387 n.12 (5th Cir. 1980); *Directory Sales Mgmt. v. Ohio Bell Tel.*, 833 F.2d 606, 612 (6th Cir. 1987); *MCI Commc’ns Corp. v. AT&T*, 708 F.2d 1081, 1132-33 (7th Cir. 1983); *Willman v. Heartland Hospital*, 34 F.3d 605, 613 (8th Cir. 1994); *Ferguson v. Greater Pocatello Chamber of Commerce*, 848 F.2d 976, 983 (9th Cir. 1988); *McKenzie v. Mercy Hosp.*, 854 F.2d 365, 369-370 (10th Cir. 1988); *Covad Commc’n v. BellSouth*, 299 F.3d 1272, 1286-88 (11th Cir. 2002); *Caribbean Broad. v. Cable & Wireless*, 148 F.3d 1080, 1088 (D.C. Cir.1998); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1356-57 (Fed. Cir. 1999).

⁷⁴ *MCI Commc’ns Corp.*, 708 F.2d at 1132-33.

The essential facilities doctrine is generally used to prohibit a monopolist from using its position to create a “bottleneck” in the market. A monopolist, for example, may have a bottleneck over actual things such as railroad stations and tracks, utilities, airport terminals, or the sole newspaper in town. While theoretically possible, it may be impractical or too costly to build a new airport terminal adjacent to an existing one or to run a separate set of railway tracks alongside preexisting ones. Though a cognizable essential facility claim may exist, it is difficult to prove. To prove that a facility is essential, a plaintiff must show that the facility is so indispensable to market entry and competition that it would be impossible for smaller firms to compete with the monopolist without access.⁷⁵ To ensure a level playing field, a plaintiff must also show that the competitor’s use of the facility would not interfere with the monopolist’s ability to serve its own consumers.⁷⁶

In a seminal article, the late antitrust expert Professor Phillip Areeda urged courts to apply principled limits to the application of such an extreme remedy.⁷⁷ Areeda generally proposed a very tight and strict set of factors to consider before declaring something an “essential facility.” Due to his expertise, courts uniformly have heeded his cautions.⁷⁸ The courts’ deference

⁷⁵ Calling a product or facility essential is not enough. The facility must be so necessary that competition could not exist without compelling it. *See City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1380 n.5 (9th Cir. 1992) (“[A] facility ‘controlled by a single firm will be considered ‘essential’ only if control of the facility carries with it the power to eliminate competition . . .’ (quoting *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 544 (9th Cir. 1991))”); *see also Twin Labs., Inc. v. Weider Health & Fitness*, 900 F.2d 566, 568, 569 (2d Cir. 1990); *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 992 (D.C. Cir. 1977) (“To be ‘essential’ a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants.”); *Am. Online, Inc. v. GreatDeals.net*, 49 F. Supp. 2d 851, 862 (E.D. Va. 1999) (“An ‘essential facility’ is one which is not merely helpful but vital to the claimant’s competitive viability.” (quoting *Cyber Promotions, Inc. v. Am. Online, Inc.*, 948 F. Supp. 456, 463 (E.D. Pa. 1996)); *TCA Bldg. Co. v. Nw. Res. Co.*, 873 F. Supp. 29, 39 (S.D. Tex. 1995); *Driscoll v. New York*, 650 F. Supp. 1522, 1529 (S.D.N.Y. 1987).

⁷⁶ *MCI Commc’ns Corp.*, 708 F.2d at 1133 (“Nor was MCI asking that AT & T in any way abandon its facilities.”).

⁷⁷ Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST 841 (1989).

⁷⁸ *See e.g.*, *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1072 (10th Cir. 2013); *TKO Energy Servs., LLC v. M-I L.L.C.*, 2013 WL 789458 (N.D. Okla. Mar. 4, 2013) *aff’d*, 13-5028, 2013 WL 4767813 (10th Cir. Sept. 6, 2013); *Cyber Promotions, Inc.*, 948 F. Supp. at 460 (“Areeda & Turner caution that the doctrine should at most extend to facilities that are a natural monopoly, facilities whose duplication is forbidden by law, and perhaps those that

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to Areeda is not surprising as courts have a long history of heeding Areeda's warnings on matters of antitrust law. Even Justice Breyer once said that most lawyers would prefer to have on their side "two paragraphs of Areeda on antitrust [rather] than four Courts of Appeals and three Supreme Court Justices."⁷⁹

Breyer's words have proved prophetic; although the Supreme Court has expressly refused to adopt or repudiate the essential facilities doctrine,⁸⁰ the Court nonetheless used *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko* to approve of Areeda's considerations on the doctrine.⁸¹ Moreover, even where the Court did not address the doctrine per se, the *Trinko* Court's discussion of the right of refusal-to-deal and its characterization of appropriate exceptions to it closely paralleled Areeda's considerations for limiting the use of the doctrine.⁸² Since any prediction of the Supreme Court's position on a monopolist's right of refusal-to-deal does well to consider Areeda's formulation, one must examine the Court and Areeda in conjunction.

Both the *Trinko* Court and Areeda identify a number of concerns with liberal application of judicially compelled access in the antitrust context. Collectively, these concerns reflect the idea that antitrust law should impose sharing upon a monopolist only when readily available facts indicate that forced sharing is likely to benefit the consumer and that this benefit can be realized through the discreet and isolated interventions amenable to judicial decision-making.⁸³ In other words, the essential facilities doctrine should be used sparingly, in unique circumstances, and only when one can show that there is a larger consumer benefit.

Under this view, Areeda points out that cases such as *United States v. Terminal Railroad Ass'n of St. Louis* and *Associated Press v. United States*

are publicly subsidized and thus could not practicably be built privately.").

⁷⁹ David Binder, *Phillip Areeda, Considered Top Authority on Antitrust Law, Dies at 65*, N.Y. TIMES, Dec. 27, 1995.

⁸⁰ *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 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.").

⁸¹ After the Court indicated that it sees insufficient grounds to compel access, it cites Areeda for both the proposition that "[t]his conclusion would be unchanged even if we considered to be established law the 'essential facilities' doctrine crafted by some lower courts, under which the Court of Appeals concluded respondent's allegations might state a claim," and for the proposition that "essential facility claims should . . . be denied where a state or federal agency has effective power to compel sharing and to regulate its scope and terms." *Id.*

⁸² *Id.* at 409, 412.

⁸³ "We have been very cautious in recognizing such exceptions, because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm." *Id.* at 408.

were sensible interventions because they involved the concerted action of a number of competitors.⁸⁴ Concerted action on the part of some number of competitors demonstrates the value of cooperative action in general. Forced opening of membership to a group requires nothing more than an order to include a previously excluded plaintiff in the relevant joint activity.⁸⁵ The *Trinko* Court embraced the idea that concerted action more easily justifies judicial intervention because it clearly indicates the benefits of shared access and is amenable to judicial remedy.⁸⁶

Single actors, such as brand drug manufacturers, present a more difficult case. Unilateral actors may exclude others for a myriad of reasons, the consideration of which strains a court's ability to substitute its own judgment for that of the market.⁸⁷ As a preliminary matter, merely obtaining a monopoly or profiting from it cannot be enough to trigger antitrust liability.⁸⁸ Instead, only abusive or unreasonable conduct for anti-competitive purposes is actionable.⁸⁹ Areeda says this baldly stated limitation is insufficient, because

⁸⁴ *Terminal Railroad* concerned the consolidation of all railway-related products and services in the St. Louis area. *United States v. Terminal R. R. Ass'n of St. Louis*, 224 U.S. 383 (1912). Though competing railways were permitted to use the terminal, the prices charged were high. Similarly, in *Associated Press*, the issue involved the association's ability to gather and distribute news more easily. See John T. Soma et al., *The Essential Facilities Doctrine in the Deregulated Telecommunications Industry*, 13 BERKELEY TECH. L.J. 565, 583 (1998).

⁸⁵ "Recognizing that the combination had obtained a monopoly through joint purchase, the Supreme Court wisely concluded that the most efficient remedy was to admit nonmember competitors to the consortium." Areeda, *supra* note 77, at 842 (discussing *Terminal Railroad*, 224 U.S. at 383). "The basic rationale for the venture was to achieve economies of scale, which goal the addition of members served . . . [E]xisting members essentially were allowed to block the admission of competitors, but no one else . . . The remedy was to enjoin this discrimination." *Id.* (discussing *Associated Press v. United States*, 326 U.S. 1 (1945)).

⁸⁶ See *Trinko*, 540 U.S. at 410 n.3 ("These cases involved *concerted* action, which . . . is amenable to a remedy that does not require judicial estimation of free-market forces: simply requiring that the outsider be granted nondiscriminatory admission to the club.").

⁸⁷ "Innumerable firms engage in unilateral action every day. We have to be very wary about examining the decisions of each of those firms in our economy, particularly when anything one has that another wants may be called an 'essential facility.'" Areeda, *supra* note 77, at 844.

⁸⁸ "If the monopoly was not improperly obtained or maintained, then exploiting the monopoly – to charge whatever monopoly price the market will bear – does not violate the statute" *Id.* at 847. "[T]he mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system." *Trinko*, 540 U.S. at 407.

⁸⁹ "The possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Id.*

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most of a would-be monopolist's conduct is undertaken with the specific intent of excluding competitors but is nonetheless desirable.⁹⁰ Areeda and the courts give the example of the natural monopoly market where investment in an appropriately scaled manufacturing facility delivers the lowest possible cost to the consumer but simultaneously forecloses further entry into the market.⁹¹

Instead, courts should only intervene against single actors when, as with the concerted action cases, clear facts make the harm suffered by the consumer as a result of the refusal apparent. The *Trinko* Court identified *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.* and *Otter Tail Power Co. v. United States* to be exactly these types of cases. In *Aspen Skiing*, it was not past conduct per se – an element stressed by many commentators and litigators – that rendered the defendant's subsequent refusal-to-deal actionable.⁹² Rather, the defendant's previous participation in a profitable ski pass scheme that benefitted consumers and the ski industry alike enabled the Court to conclude that access for the plaintiff was a worthwhile end.⁹³ Drug manufacturers have relied upon the prior cooperative conduct element of *Aspen Skiing* when opposing current litigation to compel access for generic companies.⁹⁴

In the broad sense of past prior conduct, one could argue that the brand pharmaceutical industry and its supply chain have engaged in prior conduct that permitted open access to the generic industry en masse. Accordingly, because the brand pharmaceutical industry has known and accepted that supply chain diversion existed, it would expectedly continue. The narrow sense could be equally true. A brand drug manufacturer could argue that the past prior

⁹⁰ “But that adds little help, because, in the lay sense, almost anything can be said to exclude. If I build a better mouse-trap that deprives you of customers, you might say I have excluded you from the market. Of course, you have an equal opportunity to invent a better mousetrap of your own. Yet, where the market is a natural monopoly -- that is to say, it will only sustain one producer of optimum, low-cost size -- the first person to build an optimum sized plant is likely to be the last person in that market.” *Id.* at 846.

⁹¹ *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 548 (9th Cir. 1991) (“A firm that creates a valued service or product should not be punished with treble damages and criminal sanctions merely because the firm finds itself to be the holder of a natural monopoly.”).

⁹² *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).

⁹³ “The defendant . . . had cooperated for years in the issuance of a joint, multiple-day, all-area ski ticket. After repeatedly demanding an increased share of the proceeds, the defendant canceled the joint ticket . . . We upheld a jury verdict for the plaintiff, reasoning that “[t]he jury may well have concluded that [the defendant] elected to forgo these short-run benefits because it was more interested in reducing competition over the long run by harming its smaller competitor.” *Trinko*, 540 U.S. at 408-09.

⁹⁴ See *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-5743 NLH/AMD, 2013 WL 5524078 (D.N.J. Sept. 6, 2013).

conduct under antitrust law meant showing (1) that this particular brand manufacturer and (2) this particular generic drug company (3) had a prior course of dealing with (4) this particular underlying product. That is, industry wide knowledge and acceptance of the diversion of generalized drug products is not enough to show a past prior conduct pattern for antitrust purposes.⁹⁵ It has to be specific. In sum, generic companies would argue that the brand company's prior knowledge and conduct toward the generic industry as a whole shows the requisite prior conduct. Brand companies would argue that it must be more narrowly tailored, consistent with the narrow application of the essential facilities doctrine.

Areeda and the Supreme Court, however, have made it clear that prior conduct is no litmus test.⁹⁶ Instead, the question is whether, as in certain cases of concerted action, the facts make clear that a firm's conduct in refusing to deal is detrimental to the consumer or the market.⁹⁷

Otter Tail presented another case that did not depend on past dealing but on the potential for future abuse. In *Otter Tail*, a utility company possessed the only means of delivering power to certain municipalities but refused to transmit power through its lines.⁹⁸ The utility company also refused to wholesale power to municipalities wishing to sell power directly to residents.⁹⁹

⁹⁵ Richards v. Neilsen Freight Lines, 810 F.2d 898, 904 (9th Cir. 1987).

⁹⁶ SolidFX, LLC v. Jeppesen Sanderson, Inc., 935 F. Supp. 2d 1069, 1083 (D. Colo. 2013) ("Specifically, Plaintiff contends that, because the parties were previously engaged in a cooperative and profitable venture, from which Defendant unilaterally withdrew, Defendant's conduct was anti-competitive. However, the Court finds this argument unpersuasive. The Supreme Court has recognized that Aspen Skiing was an exceptional case that lies "at or near the outer boundary of § 2 liability." Unlike the relationship in Aspen Skiing, the parties here had been in business together for less than one year when the issue regarding the development of an iPad app arose. Additionally, and of greater importance here, Aspen Skiing did not involve a party's copyright, nor was the subject matter of the dispute there intellectual property owned by one of the parties. Thus, the Court finds that this case does not fall within the narrow purview of Aspen Skiing and that Plaintiff has not shown that Defendant's refusal to license its Terminal Charts and/or JIT was anticompetitive.") (citations omitted).

⁹⁷ Alaska Airlines, Inc. v. United Airlines, Inc., 948 F.2d 536, 544 (9th Cir. 1991) ("A facility that is controlled by a single firm will be considered 'essential' only if control of the facility carries with it the power to eliminate competition in the downstream market.").

⁹⁸ *Otter Tail Power Co. v. United States*, 410 U.S. 366, 369-71 (1973).

⁹⁹ *See id.* at 368. The Otter Tail Power Company's general practice was to supply both "wholesale" and "retail" electrical services in its operating area. However, a number of municipalities decided that they would prefer to supply the retail component of these electrical services and sought to contract with Otter Tail Power for only "wholesale" electrical services. Otter Tail Power, whose wholesale electrical services could not be duplicated feasibly, refused to supply only wholesale electricity, thereby eliminating the

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Although the utility company was a unilateral actor with no history of prior dealing with the plaintiff municipalities, the facts clearly indicated to the Court that consumers would suffer from the utility company's decision to exclude the municipalities from the market.¹⁰⁰ Additionally, although a federal regulator existed to facilitate dealings between the parties, the regulator did not possess the power to compel access.¹⁰¹ The Court, however, did have authority to compel access.¹⁰² Thus, *Otter Tail*, although involving neither concerted action nor prior dealing, is a case amenable to Areeda's view on compelled sharing.

More recently, the Court revisited the refusal-to-deal law in *Trinko*. *Trinko* has been cited as a death knell for the essential facilities doctrine.¹⁰³ The *Trinko* Court explicitly acknowledged that some sets of facts may permit or even require forced sharing.¹⁰⁴ Additionally, as previously discussed, the *Trinko* Court couched its analysis within the framework of its prior decisions along lines closely parallel to Areeda's more extended analysis. Therefore, the best way to understand *Trinko* is not by considering whether forced sharing exists in law after *Trinko*, but instead to see why the facts in *Trinko* made such a particularly poor case for forced sharing.

In *Trinko*, Verizon was a unilateral actor, comprehensively regulated by a government agency with the express authority to mandate competitor access to certain services.¹⁰⁵ The nature of the services requested would have required complicated multi-faceted interactions between the defendant and any successful plaintiff.¹⁰⁶ Furthermore, the proposed deal between Verizon and the plaintiffs offered no obvious benefit to the eventual consumer, only a

possibility of competition in the provision of "retail" electrical services.

¹⁰⁰ "Although it is not completely clear from the [*Otter Tail*] decision, it appears that transmission (wheeling) charges and wholesale prices were regulated by the Federal Power Commission, the predecessor of the Federal Energy Regulatory Commission. Retail charges to consumers were regulated, if at all, by local authorities in Minnesota. If *Otter Tail* wheels or sells power wholesale, regulators will force it to charge less than the monopoly price. If *Otter Tail* is in the retail distribution business, which is not very effectively regulated, it can charge monopoly prices. Thus, in the peculiar circumstances of *Otter Tail*, a duty to deal may benefit consumers." Areeda, *supra* note 77, at 848 n.34.

¹⁰¹ *Otter Tail*, 410 U.S. at 373.

¹⁰² *Id.* at 382 (affirming the district court's decision to compel access).

¹⁰³ See Spencer Waller, *Areeda, Epithets, and Essential Facilities*, 2008 WISC. L. REV. 359, 365 (2008).

¹⁰⁴ "However, '[t]he high value that we have placed on the right to refuse to deal with other firms does not mean that the right is unqualified.'" *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408 (2004) (quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985)).

¹⁰⁵ *Id.* at 402-05.

¹⁰⁶ *Id.*

benefit to Verizon's competitors.¹⁰⁷ Given the absence of a clear market benefit, the inadequacy of the judicial remedy to the task at hand, and the presence of an informed regulator who could better understand and fulfill plaintiffs' needs should they prove meritorious, the Court's refusal to compel access in *Trinko* should not be seen so much as a turn in the Court's refusal-to-deal jurisprudence, but as a confirmation of the state of that law as of Areeda's writing in 1989.

Whether an essential facilities doctrine exists as such, the Supreme Court has made it clear that it will consider intervening to compel access against a single actor when situations arise that are similar to those narrow circumstances present in *Otter Tail* and *Aspen Skiing*, as explained by Areeda and confirmed by the Court in *Trinko*. When the various cases are considered together, several factors emerge for compelled access analysis. First, there must be clear evidence that the refusal complained of is substantially likely to harm competition or increase prices.¹⁰⁸ Second, the judicial remedy available must be limited, must not require extensive judicial oversight, and must be outside the scope of authority of any relevant regulatory entity.¹⁰⁹ Finally, there must be no other justification for the complained of refusal, such as a valid patent right or acknowledged business justification.¹¹⁰

With this legal underbrush cleared away, it is now possible to take a more informed look at the arguments for and against compelled access in the REMS context. At first glance, brand manufacturers' argument to avoid compulsory access to their products for generic manufacturers appears strong. First, they

¹⁰⁷ *Id.*

¹⁰⁸ "No one should be forced to deal unless doing so is likely substantially to improve competition in the marketplace by reducing price or by increasing output or innovation." Areeda, *supra* note 77, at 852.

¹⁰⁹ "No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise. The problem should be deemed irremediable by antitrust law when compulsory access requires the court to assume the day-to-day controls characteristic of a regulatory agency. Remedies may be practical . . . when, as in *Otter Tail*, a regulatory agency already exists to control the terms of dealing." *Id.* at 853.

¹¹⁰ "Even when all these conditions are satisfied, denial of access is never per se unlawful; legitimate business purpose always saves the defendant. What constitutes legitimacy is a question of law for the courts. Although the defendant bears the burden of coming forward with a legitimate business purpose, the plaintiff bears the burden of persuading the tribunal that any such claim is unjustified." *Id.* at 852. "[I]n *SCM* the Second Circuit held that, under general patent principles, a patent monopolist is absolutely privileged to keep its invention to itself." *Id.* at 850 (citing *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981)). It is worth nothing that this raises a question as to the rights of a drug manufacturer as a patent holder. Although the manufacturer holds the patent, to use the patent to block access to a process Congressionally created in order to permit challenges to the validity of that patent creates a circular reference that may be problematic.

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argue there is no history of past dealing, as in *Aspen Skiing*, that might demonstrate the benefit of shared access in a single actor case. At best, they contend, they are merely respecting FDA-mandated safety protocols; at worst, they are exercising their right to determine the market channels through which they distribute their products.¹¹¹ This argument goes to whether a clear market benefit exists for mandating cooperation with generic manufacturers.

Second, as in *Trinko*, the need for generic drug manufacturers to have access to the branded drugs arises as part of a complicated regulatory structure overseen and intimately managed by a federal regulatory body, which in this case is the FDA.¹¹² Manufacturers imply, even if they do not directly state, that if compelling access is necessary to the effective operation of the Hatch Waxman generic drug regime, then the FDA, not the antitrust courts, should be the actor to do so. Who better to determine the scope and effect of the access given that the FDA reviews and approves REMS? In the same way courts give deference to a governmental agency because of its expertise, the courts should not circumscribe a federal regulator with its own remedy.¹¹³

Finally, brand drug manufacturers argue that as patent holders, the statutory grant of monopoly over their products includes the absolute authority to decide whether, how, and to whom to sell their products.¹¹⁴ This argument, together with the notion that brand drug manufacturers' refusal to provide access is merely compliance with mandated REMS programs, establishes a legal or business justification. Thus, brand manufacturers' primary arguments for limiting generic manufacturers' access to brand drugs are market benefit, judicial amenability, and business justification. Whether antitrust-based challenges of a brand drug manufacturer's refusal-to-deal are successful may likely turn on how each of these three arguments is resolved. Thus, it is helpful

¹¹¹ Following the law of REMS and restricting access ought to be a valid legitimate rationale for depriving access. Though recall the FDA already stated that it will not criminalize or penalize a brand company for allowing generic company access outside of REMS to reference samples. Accordingly, the argument that the brand company must follow the law or otherwise be in violation is no longer valid. *See* Letter from Gary J. Buehler, *supra* note 62.

¹¹² The FDA maintains authority to approve drugs into the marketplace. 21 U.S.C. § 355(a), (b), (j) (2006).

¹¹³ *Astrue v. Capato ex rel. B.N.C.*, 132 S. Ct. 2021, 2033-34 (2012) (“*Chevron* deference is appropriate ‘when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.’”).

¹¹⁴ *Carbice Corp. of Am. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 31 (1931) (“If the patent is valid the owner can, of course, prohibit entirely the manufacture, sale, or use of such packages . . . Or it can grant licenses upon terms consistent with the limited scope of the patent monopoly.”); *see Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405 (1908); *see also United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926).

to address each of them in turn.

B.2. CLEAR MARKET BENEFIT

As discussed previously, refusal-to-deal jurisprudence has often taken a dim view of the clear market benefit necessary to compel unilateral actors to open up to competitors. This can best be seen in Areeda's analogy of the would-be monopolist who seeks to create facilities or assets essential to all his competitors and to exclude them to his benefit, but in doing so provides the consumer with the lowest priced product.¹¹⁵ This tendency might support companies in defending claims of impropriety related to their refusal to sell products covered by REMS to generic companies.

Generic companies, on the other hand, are not left entirely without a response. Cases such as *Otter Tail*, where a single actor has been found to improperly exclude competitors, have rested on readily ascertainable facts that remove from courts' hands the difficult task of deducing the ultimate effect the behavior in question had on the market.¹¹⁶ Generic companies may argue that Congress's decision to incentivize generic drug market entry under the Hatch Waxman Act does exactly that. By enacting Hatch Waxman, Congress made a clear determination that consumers of pharmaceutical substances were best served by accelerated generic entry to the market.¹¹⁷

Additionally, this conclusion is bolstered by language specific to the statutes creating REMS plans.¹¹⁸ This language speaks to delaying or blocking the

¹¹⁵ For example, if a new entrant is required to duplicate the facility with investment and manufacture, then those costs are passed along to the consumer thereby leading to future higher prices. On the other hand, if the prices are already high by the initial monopolist, then that would encourage new entrants. So a balance can be struck between the monopolist's desire to maintain the monopoly and the price it charges. If its charges are priced right (e.g., the lowest consumer price), then there is no incentive to other competitors to expend resources to duplicate the facility just to chase an already low price. If the price is too high, it creates the incentive for competitors to enter. Accordingly, the monopolist may choose to preserve the monopoly by actually offering the lowest price.

¹¹⁶ *Otter Tail Power Co. v. United States*, 410 U.S. 366, 373 (1973).

¹¹⁷ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) ("Once the FDA has approved a brand manufacturer's drug, another company may seek permission to market a generic version pursuant to legislation known as the Hatch-Waxman Amendments. Those amendments allow a generic competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA. Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug. As we have previously recognized, this process is designed to speed the introduction of low-cost generic drugs to market."); see *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

¹¹⁸ "No holder of an approved covered application shall use any element to assure safe

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approval of an ANDA filed under Hatch Waxman.¹¹⁹ To the extent that access to a product is required for BE, and BE are, in turn, required for approval of an ANDA, the use of REMS to block access would appear to qualify as prohibited “blocking” or “delaying.”¹²⁰ Therefore, courts considering a unilateral actor essential facility case can look to the Hatch Waxman Act and assume that blocking a generic manufacturer’s access to drug samples or REMS is obstructing a clear market benefit.

In no uncertain terms, the brand drug is essential because without it, a generic company cannot compete.¹²¹ Intent may also play a role in whether to impose essential facility liability. Precedent indicates that brand drug companies may be liable if there is no legitimate interest at stake in excluding access to generic drug manufacturers.¹²² Some courts have taken “legitimate”

use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) of this section to a drug that is the subject of an abbreviated new drug application.” 21 U.S.C. § 355-1(f)(8) (2006).

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ We leave for another day whether the brand drug constitutes the “relevant market” in a typical antitrust analysis. If relevant market analysis is required for essential facilities doctrinal application, then a further step would be to evaluate whether that market is the brand drug or broader (e.g., all drug products in that same therapeutic class) and whether generics exist in parallel markets. *See, e.g., Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (“The district court ruled that the entire warfarin sodium market, including Coumadin, was the appropriate market. It had noted the chemical equivalence between Coumadin and generics, found that customers and vendors viewed the products as competing, and concluded that generics took market share from Coumadin. We have performed our own analysis of the Brown Shoe factors and we conclude to the contrary that in this case generics alone constitute the relevant market . . . It may seem paradoxical to believe that Coumadin and generic warfarin—which have been certified by the FDA as therapeutically equivalent—are nevertheless in separate markets for antitrust analysis.”).

¹²² *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 894 (N.D. Cal. 2011) (“Here, in its motion to dismiss, Abbott argued, based on *Trinko* and *MetroNet*, that Plaintiffs’ antitrust duty-to-deal claims did not fall within the scope of *Aspen Skiing*. The Court denied the motion, holding that liability under Section 2 could arise if a defendant unilaterally alters a voluntary course of dealing and ‘anticompetitive malice’ motivates the defendant’s conduct. The Court noted *MetroNet*’s observation that *Aspen Skiing* could apply in cases involving a practical refusal-to-deal, in which a defendant offered its competitors only on unreasonable terms and conditions. In opposition to Abbott’s motions for summary judgment, Plaintiffs provide evidence that creates a genuine issue of fact with respect to the three factors of significance identified in *MetroNet* and the elements outlined by the Court in its order on Abbott’s motions to dismiss.”).

to include a subjective intent component.¹²³ It is debatable whether courts can measure legitimacy on purely objective grounds or if a subjective intent is needed. Even assuming *arguendo* that a subjective intent component exists, does this mean that intent is balanced by the essentiality of the facility? Said another way, is the essentiality of the facility easier to prove if a high level of culpable intent exists? Or if there is less intent to squeeze out competition, should a plaintiff be required to show a higher level of need for the facility?¹²⁴

As one can imagine, a brand drug company will argue that if any reason is legitimate, then there is no antitrust liability.¹²⁵ A brand company may rely on the inequitable conduct law that says that if multiple inferences can be drawn about whether a patentee specifically intended to deceive the patent office, then there is no specific intent to deceive because there is no sole inference of deceit.¹²⁶ As such, if other inferences exist, there is no deceit.¹²⁷ Similarly, if

¹²³ See *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1356, 1358 (Fed. Cir. 1999) (“A ‘refusal-to-deal’ may raise antitrust concerns when the refusal is directed against competition and the purpose is to create, maintain, or enlarge a monopoly.”). The Supreme Court reached the same conclusion. *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 483 n.32 (1992) (The right to refuse to deal “exists only if there are legitimate competitive reasons for the refusal.”) (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602-05 (1985)); see also *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1211 (9th Cir. 1997) (citing Supreme Court precedents which limited the right to refuse to deal to situations where there was no “purpose to create or maintain a monopoly”); *Aspen Skiing*, 472 U.S. at 604 (“[Aspen Skiing] Co’s decision to terminate the all-Aspen ticket was thus a decision by a monopolist to make an important change in the character of the market.”); *Sunshine Cellular v. Vanguard Cellular Sys., Inc.*, 810 F. Supp. 486, 497 (S.D.N.Y. 1992) (“[A monopolist] may not refuse to deal with [its competitor] if its refusal is motivated by anticompetitive animus.”).

¹²⁴ In the patent law context concerning fraud in the patent process, precedent does not allow for a sliding scale of bad subjective intent balanced against the materiality of the malfeasance. Rather, precedent requires that both the materiality of the malfeasance and the bad subjective intent rise to the level of clear and convincing evidence. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

¹²⁵ *High Tech. Careers v. San Jose Mercury News*, 996 F.2d 987, 990 (9th Cir. 1993) (“If there is a valid business reason for [the defendant’s] conduct, there is no antitrust liability.”).

¹²⁶ *Therasense*, 649 F.3d at 1290.

¹²⁷ *Id.* at 1290-91 (“However, to meet the clear and convincing evidence standard, the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence’ (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008)). Indeed, the evidence ‘must be sufficient to require a finding of deceitful intent in the light of all the circumstances’ (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988)). Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.”); see *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable

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antitrust law requires that a specific intent to deny access for anticompetitive purposes be the sole inference, and if other rationales exist, then there is legitimacy to its actions.

Finally, without access to a brand drug, there can be no comparison. No alternative drugs exist, for if an alternative existed, then that brand drug (facility) is not essential.¹²⁸ As noted previously, an FDA-approved brand product must be accessed and studied. Foreign reference product is not allowed.¹²⁹ Even if a brand company manufactures one drug for global distribution from just one plant, a generic company is not permitted to obtain that drug in a foreign market to run the comparison even though it is exactly the same formulation as the U.S. product. Accordingly, if access to the brand drug is easier in other countries due to relaxed REMS, this access could not form the basis for any U.S. BE trials.

Even if a generic company has the exact recipe of a brand formulation (e.g., elucidated from the brand company's patents or other technical literature), the generic company cannot manufacture its own version of the brand product then run comparisons against it. In other words, the product must be the brand company's U.S. product, and nothing else will do. Therefore, by definition, no alternatives can exist.

B.3. JUDICIAL AMENABILITY

It is clear that the FDA's role in regulating interactions between generic and brand manufacturers weighs heavily in courts' evaluations of antitrust claims brought against brand manufacturers on account of refusal-to-deal.¹³⁰ It is not

inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”).

¹²⁸ The brand drug cannot be available from other sources or capable of duplication by the firm seeking access. “[A] facility will not be deemed essential if equivalent facilities exist or where the benefits to be derived from access to the alleged essential facility can be obtained from other sources.” *The Apartment Source of Pa., L.P. v. Phila. Newspapers, Inc.*, Civ. A. No. 98-5472, 1999 WL 191649, at *7 (E.D. Pa. Apr. 1, 1999) (holding that hospital could not be essential facility where there were eight other hospitals with a forty-mile radius); *Soap Opera Now, Inc. v. Network Publ'g Corp.*, 737 F.Supp. 1338, 1349 (S.D.N.Y.1990) (advertising in a particular magazine not an essential facility because the target audience could be reached in other ways and some of plaintiff's competitors did not advertise in the magazine).

¹²⁹ To file an ANDA, the generic company will file the application under 21 U.S.C. § 355(j). The reference product is defined in § 355(j)(7), which itself refers to drug products approved under § 355(b) and (c). Foreign approved products are approved under that country's law, not under § 355(b) and (c). As such, without a U.S. counterpart approved under § 355(b) and (c), there is no U.S. based reference product.

¹³⁰ While the FDA has not yet had the occasion to discuss the impact of REMS and antitrust, making this Article's discussion one of first impression, we note that courts are

so clear which way this regulatory presence cuts more strongly.

If, as part of a sweeping authority to regulate the brand and generic drug markets, the FDA possesses the authority to compel brand manufacturers to provide generic manufacturers access to drugs for the purposes of testing and elects not to exercise this authority, *Trinko* seems to strongly imply that antitrust courts should step back. Consistent with Areeda's understanding of *Otter Tail*, when a regulator is competent to mandate any necessary interaction between the parties, antitrust remedies should be avoided. The *Trinko* Court noted that "essential facility claims should . . . be denied where a state or federal agency has effective power to compel sharing and to regulate its scope and terms."¹³¹

If the FDA lacks the authority to compel access, however, the case begins to look more like *Otter Tail*. In *Otter Tail*, it was precisely the fact that a regulatory body existed to monitor the relationship between the parties that justified judicial intervention.¹³² Taken together, a narrow window for judicial intervention may exist not *despite* regulation, but *because* of it. In a scenario of limited judicial intervention, it is only appropriate for courts to intervene in regulated commerce where the remedy sought is outside the authority of the regulatory agency and an opportunity for one party to exploit the consumer exists as a result.¹³³ That is the lesson of *Otter Tail*.¹³⁴

sensitive to antitrust concerns when the industry is also highly regulated. *Town of Concord, Mass. v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) ("Thus, where regulatory and antitrust regimes coexist, antitrust analysis must sensitively 'recognize and reflect the distinctive economic and legal setting' of the regulated industry to which it applies.").

¹³¹ *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004) (quoting PHILLIP AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶ 773e (2003 Supp.)).

¹³² "Very importantly, there was already in place a regulatory agency . . . [t]hus the court could airily require *Otter Tail* to deal, but never burden itself with administrative details . . ." Areeda, *supra* note 77, at 848.

¹³³ *MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1133 (9th Cir. 2004) ("The third fact the Court emphasized in *Verizon* was that the defendants in *Aspen Skiing* and *Otter Tail* refused to provide to their competitors' products that were already sold in a retail market to other customers. The importance of this fact relates to the Court's concern about the administrability of a judicial remedy. One of the reasons for a general 'no duty to deal' rule is that enforced sharing requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill-suited. If the defendant already sells the product in an existing market to certain customers but merely refuses to sell to its competitors, the court can impose a judicial remedy that does not require the court to assume the day-to-day controls characteristic of a regulatory agency. The court can simply order the defendant to deal with its competitors on the same terms that it already deals with others in the existing retail market, without setting the terms of dealing. In contrast, if the defendant does not already provide the product in an existing market or otherwise make it available to the public, the court will have to delineate the defendant's

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Having already considered the potential consumer benefit, we may focus now on the competence of the FDA to mandate access. Generic drug companies may be able to argue that the intent and scope of 21 U.S.C. § 355-1 have placed them in similar circumstances to those of the municipalities in *Otter Tail*.¹³⁵

Accordingly, from an antitrust perspective, perhaps a different way to look at § 355-1(f)(8) is not for what it says, but rather for what it implies. We discussed earlier whether § 355-1(f)(8) expressly grants the FDA enforcement authority. We now examine its effect under antitrust law. Perhaps a different way to look at the provision is that whereas the provision may not explicitly provide for a *basis* of an enforcement right, the provision should be read as providing *evidence of* illicit behavior. The enforcement right then can be found in other statutes, namely the general antitrust laws. Said another way, the provision does not provide the express basis for an antitrust violation; rather it provides for a categorical, and possibly dispositive, factor to consider in proving generalized antitrust violations or in other FDA enforcement statutes.

Much attention has been paid to the question of the FDA's authority to compel access and the effect of omitted statutory language on that authority. The so-called omitted language has played a large role in the briefs for antitrust cases filed so far.¹³⁶ Due to the various procedural postures and fora in which the disputes over refusal-to-deal REMS covered drugs have taken place, the parties have taken various, and possibly counterintuitive, positions. For example, in a citizen's petition urging the FDA to act on behalf of generic drug manufacturers, Dr. Reddy's Laboratories attempted to locate FDA authority to compel access within the FDA's broad power to regulate drug labeling.¹³⁷ Dr.

sharing obligations, and an antitrust court is unlikely to be an effective day-to-day enforcer of these detailed sharing obligations.") (citations omitted).

¹³⁴ "Retail charges to consumers were regulated, if at all, by local authorities . . . If *Otter Tail* is in the retail distribution business, which is not very effectively regulated, it can charge monopoly prices. Thus, in the peculiar circumstances of *Otter Tail*, a duty to deal may benefit consumers." Areeda, *supra* note 77, at 848.

¹³⁵ As with any enforcement attempt, it is important to determine if a plaintiff has standing. A brand company may argue that its activities policing REMS are not anticompetitive. Rather, it is the FDA's statutes and regulations that require a generic company to have REMS. As such, a generic company does not have standing to sue under antitrust law because there is no causal connection and the FDA's own conduct precludes a generic company from obtaining final ANDA approval. *See Shionogi Pharma Inc. v. Mylan, Inc.*, 2011 WL 3860680, at *5 (D. Del. Aug. 31, 2011) (denying motion to dismiss for lack of standing and rejecting lack of regulatory approval as basis for dismissing action).

¹³⁶ Memorandum of Law in Support of Plaintiffs' Motion for Judgment on the Pleadings and to Dismiss Counterclaims at 20, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-5743 NLH/AMD, 2013 WL 5524078 (D.N.J. Sept. 6, 2013) (No. 12-CV-05743).

¹³⁷ "If FDA finds that a 'deemed REMS' product sponsor has violated FDC Act §505-1

Reddy's Laboratories pointed out that a failure to comply with § 355-1(f)(8) may render a drug misbranded under the terms of the FDAAA, thus creating the possibility for sanctions.¹³⁸ It is worth noting, however, that the language requiring adherence to § 355-1(f) was drawn primarily to ensure safe use; speedy generic entry was not part of appropriate branding. Additionally, the enforcement authority that Dr. Reddy's Laboratories refers to includes only the ability to levy fines and not a clear right to compel access.¹³⁹

Actelion, a brand manufacturer defending itself against antitrust claims related to its refusal to sell to generic companies, attempted to convince a court that no legal authority exists to mandate sales to generic companies.¹⁴⁰ Actelion argued that the omitted language should be read as a decision by Congress to deny the FDA the authority to compel access.¹⁴¹ A Commissioner of the Federal Trade Commission ("FTC") has even gotten involved, implicitly suggesting in a letter to the Senate Committee tasked with studying 2012 amendments to the FDCA that both the FDA and FTC lack the required authority to compel access.¹⁴² Apotex, one of the generic firms challenging

[by using an element of a REMS to delay an ANDA application in violation of 21 U.S.C. §355-1(f)(8)], then the Agency should take other appropriate enforcement action not specifically precluded by FDAAA §909(b)(2)(B) to influence the sponsor's anti-competitive commercial activities." Citizen Petition of Dr. Reddy's Laboratories, Inc., No. FDA-2009-P-0266 at 12 (June 10, 2009).

¹³⁸ "FDAAA also amended the FDC Act to create new provisions for the enforcement of §505-1. Specifically, under new FDC Act §502(y), a drug is deemed to be misbranded '[i]f it is a drug subject to an approved [REMS] pursuant to section 505(p) and the responsible person (as such term is used in section 505-1) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 505-1.' In addition, FDAAA amended the law to add new § 303(f)(4), which states that '[a]ny responsible person (as such term is used in section 505-1) that violates a requirement of section 505(o), 505(p), or 505-1 shall be subject to a civil monetary penalty' of up to \$10 million for all violations adjudicated in a single proceeding." *Id.* at 7 (citations omitted).

¹³⁹ 21 U.S.C. § 355-1(f)(8) (2006).

¹⁴⁰ Statements in various cases abound that support the notion of a refusal-to-deal as perfectly permissible. *See, e.g.,* Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC, 148 F.3d 1080, 1088 (D.C. Cir. 1998) ("A monopolist has no general duty to share his essential facility, although there are certain circumstances in which he must do so.").

¹⁴¹ "Congress's rejections of these proposals [to permit forcing access onto brand manufacturers] demonstrates [sic] that there is no special exception to the general right to choose with whom to deal merely because a drug product is subject to restricted distribution in a REMS." Memorandum of Law in Support of Plaintiffs' Motion for Judgment on the Pleadings and to Dismiss Counterclaims, *supra* note 136, at 20. Plaintiff's motion was denied. Order Denying Motion to Dismiss, *Actelion Pharm. Ltd.*, 2013 WL 5524078.

¹⁴² The Commissioner's letter recognized the importance of creating authority for some regulator to compel brand manufacturers to permit generic access to compounds covered under REMS but urged the committee to hold off on what he considered substantial

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Actelion's refusal-to-deal, has, in responding to Actelion, perhaps wisely made a meal out of Actelion's insistence that the FDA lacks authority and attempted to use this conclusion to support its argument that the case is more like *Otter Tail* than *Trinko*.¹⁴³

However this issue is resolved, it has strong implications for the validity of antitrust claims against brand drug manufacturers. If the FDA has the authority to mandate access for generic drug manufacturers yet elects not to, the case looks very much like *Trinko*, and it is difficult to see potential plaintiffs prevailing on antitrust claims. If, however, the authority to compel sharing is not within the FDA's regulatory authority, the matter begins to more closely resemble *Otter Tail*. Although the *Trinko* Court's reticence to embrace compelled access makes it far from certain that generic manufacturers would win under these circumstances, at the very least, this would squarely present a tough case that exists right at the boundary of current refusal-to-deal jurisprudence and possibly throw into doubt the notion that cases of an essential facilities nature, whether or not they are referred to under that title, are in decline.

In summary, the essential facilities doctrine exists and can be used as a basis for compelling access to brand samples and subsequent REMS. The Supreme Court has had the opportunity to debunk the doctrine but failed to do so.¹⁴⁴ The anticompetitive effect of denying access is clear. Congress promulgated a statute that appears to state a purpose, and the antitrust laws do exist to give

legislation as a rider on an otherwise procedural bill. Letter from Thomas Rosch, Comm'r, Federal Trade Comm'n, to Harry Reid, Senate Majority Leader, and Mitch McConnell, Senate Minority Leader (May 4, 2012), *available at* <http://www.ftc.gov/speeches/rosch/120504payfordelayletter.pdf> ("The REMS legislation advocated by staff at the Federal Trade Commission (FTC) would give the FTC jurisdiction to challenge the refusal of a pioneer drug company to provide product samples to generic manufacturers if the FDA determined that the generic company's protocols were safe.").

¹⁴³ "Unlike the Federal Communications Commission and state public utility commissions (the agencies at issue in *Trinko*), however, the Food and Drug Administration ('FDA'), which implements Hatch Waxman, has no authority to regulate the competitive process or compel a course of dealing. Actelion readily concedes as much through its repeated insistence that Hatch Waxman does not impose a mandatory requirement that brand-name drug manufacturers make samples available to generic manufacturers." Memorandum of Law in Support of Defendants/Counterclaim Plaintiffs' Opposition to Plaintiffs/Counterclaim Defendants' Motion for Judgment on the Pleadings and to Dismiss Counterclaims at 4, *Actelion Pharm. Ltd.*, 2013 WL 5524078 (No. 12-CV-05743).

¹⁴⁴ *Verizon Comm'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 410-11 (2004) ("This conclusion would be unchanged even if we considered to be established law the 'essential facilities' doctrine crafted by some lower courts, under which the Court of Appeals concluded respondent's allegations might state a claim. We have never recognized such a doctrine, and we find no need either to recognize it or to repudiate it here.").

meaning and enforcement to that purpose. Whether the omitted language in legislative drafts debunk the enforcement authority remains for the courts to decide.

C.1. PATENT RIGHTS AND REMS

A brand company may defend antitrust claims by asserting that it has a patent. We now examine whether that matters. Sometimes the REMS system or components might be subject to patent rights. If patent rights exist in one or more components of REMS or in the REMS system entirely, then there are antitrust provisions within patent law that might provide relief to generic drug companies.

Manufacturers believe that as patent holders, they hold an absolute right to determine whether and how to distribute their inventions and that regardless of the disposition of other claims, this independently permits their behavior in refusing access to generic manufacturers.¹⁴⁵ In other words, patentees believe that because of their patents, they have an immutable right to exclude. This is not true.¹⁴⁶

Under the U.S. Constitution, patent rights are creatures of statute and as such, Congress may create statutory exceptions to patent rights.¹⁴⁷ For example, Congress created mechanisms for invalidating patents.¹⁴⁸ Congress also passed laws to transfer patent rights from one person to another via march-in rights or through correction of inventorship.¹⁴⁹ More relevant here, Congress created a statutory exemption to infringement in the amendments to the Hatch Waxman Act.¹⁵⁰ Thus, this argument must exist only in the realm of the rights

¹⁴⁵ *SolidFX, LLC v. Jeppesen Sanderson, Inc.*, 935 F. Supp. 2d 1069, 1083-84 (D. Colo. 2013) (“None of the cases cited by Plaintiff in support of its essential facility theory involve intellectual property. As one court has noted: ‘To find a patent an “essential facility” to which [the patentee] must provide access would subvert the plain meaning and purpose of the Patent Act.’”).

¹⁴⁶ *Id.* at 1080-81.

¹⁴⁷ See, for example, 35 U.S.C. §§ 101-03 (2006 & Supp. 2012), involving statutory subject matter as to what can qualify for patenting and what cannot; *see also* *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012) (patentability of a method of diagnosing); *Bilski v. Kappos*, 130 S. Ct. 3218, 3229 (2010) (patentability of business method program); *Diamond v. Diehr*, 450 U.S. 175, 191-93 (1981) (patentability of a method of curing rubber that uses mathematical formulae as part of the process); *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980) (patentability of microbial organism).

¹⁴⁸ 35 U.S.C. § 282 (2006 & Supp. 2012).

¹⁴⁹ *Id.* at § 261 (ownership and assignment); *id.* at § 262 (joint ownership); *id.* at § 256 (correction of inventorship); *id.* at § 203 (march-in rights).

¹⁵⁰ This is the so-called Bolar amendment. *Id.* at § 271(e)(1). The statute provides: It shall not be an act of infringement to make, use, offer to sell, or sell within the United

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of patent holders to exert dominion over their creations. The mere existence of a patent, however, is hardly an ironclad shield against judicial examination of potentially anti-competitive behavior.¹⁵¹

Simply arguing that one has a patent is not enough. A patent is meaningful and valuable based on what it claims (how broad) and its enforceability. To this end, before a brand company can use a patent as a basis for legitimizing its exclusionary conduct, the first step is to determine the scope of the patent right and whether the underlying product being sought is actually covered by the patent. This inquiry would measure the degree of nexus between the patent right and the underlying product. Similarly, if the patent right covers the REMS system or components thereof, the same inquiry exists. It makes no sense to insulate a patentee from antitrust liability based on the existence of a patent if the patent does not protect the underlying access or product. If the patent does not indeed cover the underlying product or access at issue, then perhaps there is yet another anticompetitive claim of patent misuse present.

Finally, some courts have recognized that bad faith might exist.¹⁵² For example, a brand company may argue it made bona fide offers to negotiate or license its product or access, but that no deal consummated. Accordingly, the absence of a deal could exculpate any ulterior motive. Courts have held, however, if the terms of an offer are so unreasonable, such an offer is tantamount to bad behavior.¹⁵³ As such, it cannot be that an overt but unreasonably termed offer is anticompetitive, but an absolute exertion of the patent-based right to exclude provides a complete defense. So the categorical

States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. *Id.*

This amendment overturned *Roche Products, Inc. v. Bolar Pharmaceutical. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984), which held that such conduct constituted infringement.

¹⁵¹ 35 U.S.C. § 211 (2006) (“Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law.”); *id.* at § 271(d) (explaining certain limited conduct as not qualifying as patent misuse). As Justice Harlan explained in his landmark concurrence in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, in cases where a patent holder is accused of anti-competitive behavior, the patent holder’s conduct must be examined in light of the intent of patent law and antitrust law to promote innovation and competition respectively. 382 U.S. 172, 179-80 (1965) (Antitrust analysis requires weighing the impact of the conduct defended under the patent’s exclusionary power on the patent system’s incentive to induce innovation). If the patent holder’s conduct does not further either of those objectives, application of the antitrust laws to the patent holder’s conduct does not undermine patent law because the conduct is inconsistent with both legal theories.

¹⁵² *MetroNet Servs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1132 (9th Cir. 2004).

¹⁵³ *Id.* (“An offer to deal with a competitor only on unreasonable terms and conditions can amount to a practical refusal-to-deal.”).

and absolutist position that patent law offers patent holders the right to exclude others and not share access is meritless.

Patent rights may cover the REMS system. For example, the XYREM Success Program is the system of REMS covering the drug Xyrem and is ostensibly claimed by U.S. Patent No. 7,895,059.¹⁵⁴ Xyrem has some serious side effects in legitimate use and is also commonly abused.¹⁵⁵ To control the drug distribution, the REMS system monitors patients to avoid single patients ordering more Xyrem than required. Additionally, the system alerts the police to doctors who are over-prescribing and thereby potentially participating in trafficking and other diversions. The patented system processes all the prescriptions written into a central database, checks and reconciles patient and doctor information in the database, sends patient educational information, and then under strict distribution arranges for the drug to be sent to patients. Obviously, Xyrem is not available at any regular retail pharmacy. The drug is only obtainable via a prescription and only sent from one central pharmacy.

Patent law also provides for the right to “take” patented subject matter, which usually occurs in the contexts of both private and public property transfer.¹⁵⁶ For public property transfer, the government usually compels a license for patent rights to the government.¹⁵⁷ This can be in the context of allowing the government to practice the patent rights, such as in the case of national security. Also, if the government is acting more like a traditional infringer, the government can compel a license as opposed to being enjoined from practicing the invention further.¹⁵⁸ It should be noted, however, that as

¹⁵⁴ The Xyrem drug product is also the subject of traditional Paragraph IV patent litigation between Jazz Pharmaceuticals and Roxane Laboratories. Complaint of Plaintiff at 1, *Jazz Pharm., Inc. v. Roxane Labs., Inc.*, 2:10-CV-06108 ES-CLW, 2012 WL 3133943 (D.N.J. July 30, 2012) *aff'd*, CIV.A. 10-6108 ES, 2013 WL 785067 (D.N.J. Feb. 28, 2013) (No. 10-06108). In this case, it remains to be seen how the FDA will, if at all, allow Roxane to have its own REMS system or share with Jazz Pharmaceuticals. See also the U.S. Patent No. 6,045,501 col. 2-3 l. 10 (filed Aug. 28 1998) (issued Apr. 4, 2000) owned by Celgene Inc. Celgene’s patent ostensibly covers Celgene’s S.T.E.P.S program that polices whether pregnant women should take the drug Lenalidomide, a drug related to Thalidomide. The patent claims a method of conducting a patient pregnancy registry to police that pregnant women do not take the drug to avoid the known birth defects.

¹⁵⁵ *United States v. Caronia*, 703 F.3d 149, 155 (2d Cir. 2012) (“Xyrem’s active ingredient is gamma-hydroxybutyrate (‘GHB’). GHB has been federally classified as the ‘date rape drug’ for its use in the commission of sexual assaults.”).

¹⁵⁶ 28 U.S.C. § 1498 (2006); *Zoltek Corp v. United States*, 672 F.3d 1309 (Fed Cir. 2012).

¹⁵⁷ § 1498.

¹⁵⁸ *Zoltek*, 672 F.3d at 1318-19 (holding that 28 U.S.C. § 1498 provides the sole remedy for U.S. government infringement, and only money damages are available). Injunctive relief to prevent future infringement is not permitted as the U.S. government may infringe and

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opposed to so-called compulsory licensing, which by its terms is a license, a taking of a patent right would take the title to that patent right.

In the private patent context, it is usually the case that a patent infringer, upon a plaintiff establishing liability, is not only liable for some amount in damages but is also enjoined from further infringement.¹⁵⁹ It may happen, though, that a court may instead order a compulsory license that provides for ongoing royalties in exchange for patent license rights.¹⁶⁰ It is beyond the scope of this Article to debate whether a patent exclusion right is antithetical to a compulsory license, and much debate exists as to whether a compulsory license is jurisprudentially allowable.¹⁶¹

What is being taken within the patent right? A patent may claim more subject matter than the actual underlying tangible property. And so the question remains, depending on the facts of each case, whether a taking of any REMS system or component thereof even implicates the whole patent right. As

continue to infringe. *Id.*

¹⁵⁹ 35 U.S.C. § 283; *see eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006) (“In doing so, we take no position on whether permanent injunctive relief should or should not issue in this particular case, or indeed in any number of other disputes arising under the Patent Act. We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.”).

¹⁶⁰ § 283 (“The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.”). A permanent injunction is not the only remedy as a compulsory license may be appropriate in certain circumstances. *See, e.g.,* *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1341 (Fed. Cir. 2012) (“We vacate the grant of a permanent injunction in this case and remand for the district court to consider an appropriate ongoing royalty rate for future infringement by Verizon.”); *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1314-1315 (Fed. Cir. 2007) (agreeing that compulsory license may be needed but remanding to district court to re-evaluate sufficiency of ongoing royalty rate); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 628 (Fed. Cir. 1985) (“LOF also criticizes the court-ordered 5% royalty for the compulsory patent license for continuing operations. This royalty is based on sales, measured as defined in the order, and we do not find the amount of the royalty or its method of measurement to be clearly erroneous or an abuse of judicial discretion.”).

¹⁶¹ A finding of patent infringement does not per se mandate a permanent injunction. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). Indeed, the Supreme Court rejected the Federal Circuit’s presumptive rule that permanent injunctions are mandated after infringement. *See eBay Inc.*, 547 U.S. at 394 (“We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.”).

such, if the patent covers the system but only a component is taken, then the taking may not implicate the patent right. For example, in the case of the Xyrem patent mentioned previously, if the government or a court grants compelled access to the actual data in the database only (i.e., the patient and physician names), but allows a generic drug company to have its own controlled REMS system (such as the reconciliation database, educational system, and distribution system), then the patent is not implicated at all because the Xyrem patent covers the system *completely*. To this end, it is critical that any compelled access question evaluates the nexus between what is actually being taken and what the patent right is. It is too trite to simply say that REMS may be patented and as such, no system or component may be taken.¹⁶²

So, it appears that during the scope of a traditional infringement case, a compulsory license may be available.¹⁶³ It also shows that some form of compensation should to be paid to the patentee in the event of infringement and ongoing royalty.¹⁶⁴ The nature of how much compensation should to be paid is likely case specific.¹⁶⁵ In the end, the government may compel access through a compulsory license or through a taking of the patent itself (including title). Additionally, private individuals may obtain a compulsory license to the patent through a court-ordered mandate.

C.2. ESSENTIAL FACILITIES DOCTRINE AND INTELLECTUAL PROPERTY

Section B.1. discussed the role of the essential facilities doctrine. This Section discusses whether the doctrine applies in the context of intellectual property, since the doctrine is normally associated with tangible property as opposed to intangible property.

Courts have held that the doctrine can apply to intangible items like services.¹⁶⁶ There is no per se barrier to applying the essential facilities

¹⁶² Furthermore, that a patent exists does not answer any question of what might be taken. A patent is an exclusion right but there need not be any underlying tangible product or process existing. That is, just because a patent exists that covers a product does not at all mean that the underlying product exists and is in use.

¹⁶³ See, e.g., *ActiveVideo Networks*, 694 F.3d at 1341.

¹⁶⁴ See *id.*

¹⁶⁵ See 28 U.S.C. § 1498 (2006); *Leesona Corp. v. United States*, 599 F.2d 958, 973 (Ct. Cl. 1979) (The reasonable royalty is the preferred method to quantify the compensation paid to patentees.).

¹⁶⁶ *Sunshine Cellular v. Vanguard Cellular Sys., Inc.*, 810 F. Supp. 486, 497-498 (S.D.N.Y. 1992) (finding cause of action where essential facility alleged to be roaming agreement to provide billing services for competitor cellular telephone service carrier); *Am. Tel. & Tel. Co. v. North Am. Indus. of N. Y., Inc.*, 772 F. Supp. 777, 785 (S.D.N.Y. 1991) (Plaintiff “adequately alleged that the central office services refused it by [defendant] are

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doctrine to intellectual property. As one court noted, “Although the doctrine of essential facilities has been applied predominantly to tangible assets, there is no reason why it could not apply, as in this case, to information wrongfully withheld. The effect in both situations is the same: a party is prevented from sharing in something essential to compete.”¹⁶⁷ Many of the cases involving essential facilities and intellectual property are in the copyright realm.¹⁶⁸ That said, compulsory licensing of patent pools could be considered analogous.¹⁶⁹

A benefit of pursuing compelled access to brand drugs and compelled access to REMS systems (if patented) is that the plaintiff is a private party. The government agency does not need to be the enforcer. As such, traditional antitrust law permits a private party and private remedy.

D.1. ACCESS TO REMS AS A “TAKING” UNDER THE FIFTH AMENDMENT – REAL PROPERTY LAW

We previously discussed how to gain access to brand drug samples and subsequent REMS under FDA and antitrust laws. We now examine whether real property law provides a complementary or supplemental basis for access.

essential within the meaning of the federal antitrust laws.”). Courts have also applied the doctrine to health care referral services. *See* *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150-51 (4th Cir. 1990) (Supplier of home health care products adequately alleged that access to hospital patients for patient referrals constituted essential facility.); *see also* *Poster Exch., Inc. v. Nat’l Screen Serv. Corp.*, 431 F.2d 334, 338-40 (5th Cir. 1970) (Exclusive licensee of movie promotional materials, such as posters, could constitute essential facility required to supply additional materials to competitor distributor); *Tri-Tech Mach. Sales, Ltd. v. Artos Eng’g Co.*, 928 F. Supp. 836, 839 (E.D. Wis. 1996) (“The essential facilities doctrine does not unequivocally require that a facility be of a grand nature as suggested by the defendant, nor is the doctrine specifically inapplicable to tangibles such as a manufacturer’s spare parts.”); *Montgomery Cnty. Ass’n of Realtors, Inc. v. Realty Photo Master Corp.*, 878 F. Supp. 804, 817 (D. Md. 1995) (considering essential facilities claim as to copyrighted real estate listing service and dismissing claim because no evidence presented that service constituted an essential facility).

¹⁶⁷ *Bellsouth Adver. & Publ’g Corp. v. Donnelley Info. Publ’g, Inc.*, 719 F. Supp. 1551, 1566 (S.D. Fla. 1988) *aff’d*, 933 F.2d 952 (11th Cir. 1991) *reh’g granted and opinion vacated*, 977 F.2d 1435 (11th Cir. 1992) *and on reh’g*, 999 F.2d 1436 (11th Cir. 1993) *and rev’d*, 999 F.2d 1436 (11th Cir. 1993).

¹⁶⁸ *See* *Rural Tel. Serv. Co., Inc. v. Feist Publ’ns, Inc.*, 737 F. Supp. 610, 617-20 (D. Kan. 1990) (essential facilities doctrine in relation to copyright of telephone listings), *rev’d on other grounds*, 957 F.2d 765 (10th Cir. 1992), *rev’d*, 499 U.S. 340 (1990); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 761 F. Supp. 185, 191-92 (D. Mass. 1991) (relating to copyrighted diagnostic software), *aff’d in part*, 36 F.3d 1147 (1st Cir. 1994); *Serv. & Training, Inc. v. Data Gen. Corp.*, 737 F. Supp. 334, 343-44 (D. Md. 1990) (allowing monopolization claim to proceed based on computer manufacturer’s unwillingness to license diagnostic software to competitor computer repair service provider).

¹⁶⁹ *See* *Standard Oil Co., Ind. v. United States*, 283 U.S. 163, 168 (1931).

If one accepts, for the moment, that a brand company's drugs are its private property, and that private property is sacred, then no agency or court could compel a forced divestiture of drugs from a brand company to a generic company.¹⁷⁰ There is no doubt that drugs in possession of a brand company remain the brand company's private property. With some compensation to the owner, however, private property may be taken. Other property theorists say that property is not sacrosanct, that it can be taken and should be taken for the public good.¹⁷¹ This Section examines the nature of a taking under the Fifth Amendment as applied to private non-real estate property, recognizing at the outset that most takings jurisprudence happens within the context of real estate land use.¹⁷²

The Fifth Amendment does not bar the government from a private property taking; rather it only limits the exercise of that power.¹⁷³ Takings take two forms: (1) a direct appropriation or physical invasion of the private property or (2) a regulatory taking, done by virtue of government regulation of the private property.¹⁷⁴ A physical invasion or actual appropriation is akin to a full possession or ouster of the owner from the property.¹⁷⁵ For regulatory taking,

¹⁷⁰ Michael J. Offenhiser, *Is the Right to Private Property More Sacred Than the Right to Life? The Case of Terri Schiavo*, 3 AVE MARIA L. REV. 705, 722 (2005) ("Under the common law and natural law philosophy, the right to own private property is sacred. An analysis of Blackstone's Commentaries reveals that its sacred character can be accredited on two grounds under the natural law: first, that property is a gift of the Creator God, with which man is entrusted and given dominion, and second, that the right to own private property accords with right reason and the nature of man."). The Lockean theory of sacrosanct property rights existed when the Framers drafted the Constitution. RICHARD A. EPSTEIN, TAKINGS: PRIVATE PROPERTY AND THE POWER OF EMINENT DOMAIN 16 (1985).

¹⁷¹ Myrl L. Duncan, *Property As A Public Conversation, Not A Lockean Soliloquy: A Role for Intellectual and Legal History in Takings Analysis*, 26 ENVTL. L. 1095, 1142-43 (1996) ("By 'public rights,' Scheiber and others who refer to the same concept of what I will call 'the common good' do not simply mean the power of government to act in the public interest. Rather, 'public rights' signify government's positive obligation to act, its duty to provide those things that the community 'has a right to claim of its government.'").

¹⁷² See *Phillips v. Wash. Legal Found.*, 524 U.S. 156, 169-70 (1998) (regarding the "taking" of interest money earned on legal trust accounts, more commonly known as IOLTA funds); *Eastern Enterp. v. APFEL*, 524 U.S. 498, 500 (1998) (distinguishing between physical invasion of property and economic regulations); see also *Heats Bluff Game Ranch v. United States*, 669 F.3d 1326, 1328 (Fed. Cir. 2012) ("Real property, tangible property, and intangible property all may be the subject of takings claims.").

¹⁷³ *Lingle v. Chevron U.S.A.*, 544 U.S. 528, 536-37 (2005).

¹⁷⁴ *Id.* at 537-38.

¹⁷⁵ *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 426 (1982) ("Our cases further establish that when the physical intrusion reaches the extreme form of a permanent physical occupation, a taking has occurred.").

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the regulation of the property becomes so onerous that it is tantamount to a taking.¹⁷⁶

Within regulatory takings jurisprudence, there are generally three categories of takings, of which two categories qualify as per se takings. The first is when government regulators require the private property owner to suffer an invasion of the property.¹⁷⁷ The second category of per se regulatory taking is when the regulatory burden has deprived the property owner of all economically beneficial use of his or her property.¹⁷⁸ The third and only non-per se category of regulatory taking governs all other takings under the test articulated in *Penn Central Transportation Co. v. New York City*.¹⁷⁹ Under *Penn Central*, to determine whether a regulatory taking occurs, the court should evaluate: (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action.¹⁸⁰

Accordingly, with respect to regulatory takings, the permanent physical invasion under *Loretto v. Teleprompter Manhattan CATV Corp.* makes it unnecessary for a court to consider economic impact because the total ouster of the property is a per se taking.¹⁸¹ Similarly, under *Lucas v. South Carolina Coastal Council*, the regulatory burden totally deprived the owner of the property's value and was a per se taking.¹⁸² The catchall *Penn Central* test relies mostly on the magnitude of the regulatory economic impact and the degree to which it interferes with the property interest.¹⁸³

The *Penn Central* factors may also be stated in the form of a three-part test: (1) purpose; (2) means; and (3) impact. For the purpose prong, the taking must pass a valid police power purpose. For the means prong, the means used for the taking must be reasonably related to accomplishing the valid police power purpose. For the impact prong, the taking must not have an undue impact on

¹⁷⁶ *Lingle*, 544 U.S. at 537 (“Beginning with *Mahon*, however, the Court recognized that government regulation of private property may, in some instances, be so onerous that its effect is tantamount to a direct appropriation or ouster—and that such “regulatory takings” may be compensable under the Fifth Amendment.”).

¹⁷⁷ *Id.* at 538 (citing *Loretto*, 458 U.S. at 419).

¹⁷⁸ *Id.* (citing *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1019 (1992)); see *Stop the Beach Replenishment v. Fla. Dept. of Environ. Prot.*, 560 U.S. 702, 713 (2010) (reaffirming that regulatory takings occur with either permanent physical occupation or a deprivation of all economically viable use).

¹⁷⁹ *Lingle*, 544 U.S. at 538.

¹⁸⁰ *Id.* (citing *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978)).

¹⁸¹ *Loretto*, 458 U.S. at 419; see *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994); *Nollan v. Cal. Coastal Comm.*, 483 U.S. 825, 830-836 (1987).

¹⁸² *Lucas*, 505 U.S. at 1019.

¹⁸³ *Lingle*, 544 U.S. at 539-40.

the regulated entity.¹⁸⁴ Typically, the purpose prong is easily satisfied because takings are usually related to public health, safety, or welfare. For the means prong, the question is whether there is a rational or reasonable relationship between the means chosen and the purpose. For the impact prong, it is not enough that there is an impact on the regulated entity. Any taking has some impact on the entity. Rather, the proper scope balances the impact or harm to the regulated entity with the societal harms it would cause if left unregulated.¹⁸⁵

The Fifth Amendment states that private property may not be taken for a public use without just compensation.¹⁸⁶ The courts subsequently interpreted this clause to require a two-part test: (1) the taking must be for a public use; and (2) just compensation must be paid.¹⁸⁷ It is elementary that to challenge a taking, one can assert that the taking is not for any reasonable public use (that is for purely private use), or that the private use dominates over any incidental public use. Additionally, a property-holder can argue that any compensation is inadequate. Notably, a property owner's consent is not required.¹⁸⁸

The 2005 Supreme Court case *Kelo v. City of New London* raised a possible new ground for private property taking.¹⁸⁹ As to the public use, *Kelo* represented a change in the law of takings. Most relate takings of private property to truly public enterprises wherein the public retains ownership of the property, such as for roads, hospitals, military bases, or airports¹⁹⁰ or to other private entities that use the taken property for public uses, such as building a

¹⁸⁴ See *Agins v. City of Tiburon*, 447 U.S. 255 (1980) (discussing the purpose and impact prongs); see also *Keystone Bituminous Coal Assoc. v. DeBenedictis*, 480 U.S. 470, 491 (1987) (key case on the purpose prong); *Village of Belle Torre v. Borrás*, 416 U.S. 1 (1974) (discussing the expansive reach of the police power regulation of public health, safety, and welfare); *Nollan*, 483 U.S. at 836 (discussing the means prong and the requirement for a clear nexus between the restriction and purpose sought to be protected); *Dolan*, 512 U.S. at 391 (discussing the requirement to show "rough proportionality" between the impact and the purpose).

¹⁸⁵ In 2010, the Supreme Court added a new theory of non-real property taking where the government recharacterizes private property as public property. *Stop the Beach Replenishment v. Fla. Dept. of Environ. Prot.*, 560 U.S. 702, 713 (2010) (The government cannot simply recharacterize private money as public money so as to take it. Here, when the government took the money, it committed a taking).

¹⁸⁶ U.S. CONST. amend. V.

¹⁸⁷ *Brown v. Legal Found. of Wash.*, 538 U.S. 216, 231-232 (2003).

¹⁸⁸ *Rex Realty Co. v. City of Cedar Rapids*, 322 F.3d 526, 528 (8th Cir. 2003) ("Eminent domain is the power of a governmental entity to take private property for a public use without the owner's consent.").

¹⁸⁹ *Kelo v. City of New London*, 545 U.S. 469 (2005).

¹⁹⁰ See e.g., *Old Dominion Land Co. v. United States*, 269 U.S. 55 (1925); *Rindge Co. v. Cnty. of L.A.*, 262 U.S. 700 (1923).

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public stadium, running public utility pipes, laying private land rail lines.¹⁹¹ *Kelo* suggests that the government may take private property and then transfer it to yet another private party if there is a public purpose at hand.¹⁹² That is, whereas government takings of private property from one owner to another private party was allowable if the recipient pledged the property for public use, *Kelo* suggests that public purpose in private use is also an allowable grounds for a takings.

For a *Kelo*-type taking of a brand company's REMS, one must determine what kind of taking it is, as well as the basis for the taking. *Kelo* did not change the kinds of takings that can occur. Recall that takings generally come in two forms: legislatively authorized takings and administrative agency regulatory takings. Legislatively authorized takings are those in which the statute authorizes the takings and usually are reserved for actual physical takings. Regulatory takings are those conducted by administrative agencies as part of their regulatory regime.¹⁹³

Legal challenges to takings usually fall into well-accepted categories: (1) alleged procedural errors; (2) insufficient or zero legal authority for the taking; (3) constitutional rights violations; and (4) individualized complaints. Constitutional rights violations may include issues related to due process, equal protection, separation of powers, or even civil rights violations. For individualized complaints, property owners may challenge a takings decision on grounds such as abuse of discretion, decision makers' conflicts of interest, mistakes in procedure, incorrect interpretations or uses of any data or criteria, lack of substantial factual bases, decision makers acting beyond the scope of any reasoned jurisdiction, violations of other laws or regulations, or the catch-all arbitrary and capricious behaviors or decisions.

¹⁹¹ See e.g., *Nat'l R.R. Passenger Corp. v. Boston & Me. Corp.*, 503 U.S. 407 (1992); *Mt. Vernon-Woodberry Cotton Duck Co. v. Ala. Interstate Power Co.*, 240 U.S. 30 (1916).

¹⁹² *Kelo*, 545 U.S. at 489-90.

¹⁹³ *Brown v. Legal Found. of Wash.*, 538 U.S. 216, 233 (2003). ("Before moving on to the second condition, the 'just compensation' requirement, we must address the type of taking, if any, that this case involves. As we made clear just last term: 'The text of the Fifth Amendment itself provides a basis for drawing a distinction between physical takings and regulatory takings. Its plain language requires the payment of compensation whenever the government acquires private property for a public purpose, whether the acquisition is the result of a condemnation proceeding or a physical appropriation. But the Constitution contains no comparable reference to regulations that prohibit a property owner from making certain uses of her private property. Our jurisprudence involving condemnations and physical takings is as old as the Republic and, for the most part, involves the straightforward application of per se rules. Our regulatory takings jurisprudence, in contrast, is of more recent vintage and is characterized by "essentially ad hoc, factual inquiries" designed to allow "careful examination and weighing of all the relevant circumstances."'") (citations omitted).

D.2. TAKINGS AS APPLIED TO REMS

When a brand company engages in the NDA process and then develops a particular REMS program, the brand company has entered into an area that, from the start, is subject to pervasive governmental regulation. With the FDA controlling almost every aspect of drug development, submission, and approval, it may be difficult to argue that a brand company has a cognizable property interest that could be the subject of a taking. If there are no cognizable property interests capable of being taken, then any takings claims fail and courts need not even proceed to the *Penn Central* factors to evaluate whether property was in fact taken.¹⁹⁴ Because the existence of REMS is a requirement of government regulation, REMS systems may not be the subject of any private property right.¹⁹⁵

Even if a brand company successfully argues that it has a property right, Fifth Amendment takings jurisprudence only deals with the relationship of the property right and its owner.¹⁹⁶ It does not deal with any collateral interest that may be incident to that ownership.¹⁹⁷

Accordingly, is there a case for REMS taking? First, some government agency would have to instigate the taking because private parties cannot. Even in *Kelo*, the real intended beneficiary, Pfizer Inc., could not instigate the taking; the government did. The discussion of the language of § 355-1(f)(8) showed that this language is supposed to provide some meaning. To the extent that it might not provide for an actual enforcement right to compel access under the general FDA enforcement authority, it might perhaps be construed as to provide a legislative authority for a taking.¹⁹⁸

Presuming it is the FDA that conducts any taking, it would then have to determine what is being taken. In its simplistic form, the government would take the actual brand samples and pay fair compensation to the brand company. The FDA may already possess the ability to obtain the samples in the first

¹⁹⁴ *Hearts Bluff Game Ranch, Inc. v. United States*, 669 F.3d 1326, 1330 (Fed. Cir. 2012).

¹⁹⁵ *Id.* at 1331 (citing *Mitchell Arms, Inc. v. United States*, 7 F.3d 212, 216 (Fed. Cir. 1993)).

¹⁹⁶ *Mitchell Arms*, 7 F.3d at 217.

¹⁹⁷ *Id.*; *United States v. Gen. Motors Corp.*, 323 U.S. 373, 378 (1945) (“But it is to be observed that whether the sovereign substitutes itself as occupant in place of the former owner, or destroys all his existing rights in the subject matter, the Fifth Amendment concerns itself solely with the ‘property,’ i.e., with the owner’s relation as such to the physical thing and not with other collateral interests which may be incident to his ownership.”).

¹⁹⁸ It appears that for general takings, there need not be an express legislative authority that mandates a taking. Rather, an underlying statute may simply authorize the legislature or agency in general terms.

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place under its current regulations wherein the FDA may command samples in order to test them or undertake other investigations.¹⁹⁹

The obstacle lies in transferring those samples from the FDA's possession to a generic company, because administering that sample distribution program may itself prove problematic. To which generic companies would the FDA transfer the samples? Would that permit the FDA to play favorites among generic companies? Would it become first-come, first-served? Would the FDA take enough samples at one time or would the FDA take sufficient samples each time it is requested?²⁰⁰ We assume that if the FDA were to take samples, it would not play favorites and simply work under a first-come, first-served basis.

The rationale for this taking is clear. Healthcare of the citizenry falls squarely within the well-established police power of the government. It is not credible to say that healthcare is not a traditional police power. As to satisfying the purpose, means, and impact test of *Penn Central*, the purpose is well established and likely indisputable.²⁰¹ As to the means, simply diverting a certain quantity of samples from a brand company through the FDA to a generic company is not problematic. Furthermore, the transfer of brand samples is the only way to get the samples to the generic company and thus is rationally related to accomplishing the result. The FDA is unable to conduct a taking by simply ordering the samples be transferred and must resort to taking physical possession of them.

The impact can be measured at the micro or macro scales. At the micro level, measurements consider only that a certain number of bottles were taken by the government. The impact of taking these bottles is usually insignificant in the grand scheme. For BE purposes, perhaps only 100 or fewer bottles may be needed, and usually this represents only a fraction of the manufacturing output. A brand company is not deprived in any meaningful way, especially in that just compensation will be paid for the bottles. Accordingly, in its narrowest sense, the simple taking of a bottle will have negligible impact.

On the other hand, at the macro level, the impact inquiry would include incidental and consequential effects and potentially the market end

¹⁹⁹ 21 C.F.R. § 314.50(e) (2013). The FDA may also possess general enforcement authority to regulate any provision of the Food, Drug and Cosmetic Act. *Nutritional Health Alliance v. Food & Drug Admin.*, 318 F.3d 92, 97-98 (2nd Cir. 2003) (“The FDC Act provides the FDA with broad authority to regulate food, drug and dietary supplement products to ensure public health and safety.”).

²⁰⁰ The FDA may not be so inclined to take all the required samples at once. Generic companies must test “fresh” brand samples (those that have not expired), and it may be that samples obtained could be old or stale.

²⁰¹ *See Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).

consequence to the brand company. At one end of the spectrum, the taking could lead to disastrous and crippling effects for the brand company. Imagine that the brand company sells just this one REMS controlled product. If the result of the taking would be that generic products enter the market, it is clear that price erosion and market share loss would result. The brand company's residual market share could be less than ten percent. Even if the brand drug product stayed at the same price, the resulting market share loss might not be sustainable, and the brand company might have to declare bankruptcy. In other words, the taking could cripple the brand company. Even later on, the just compensation may be inadequate. For companies that are not one-product manufacturers, the decline in revenue on one drug product may result in lost capital to invest in the pipeline for other product developments. This depletion of revenue has the collateral effect of a spiral downward.

So the question becomes whether consequential damages downstream from the taking can be included in the effects. Generally because the Fifth Amendment only deals with the property taken, takings jurisprudence usually limits the consequences to the effect of that property taken. Moreover, for just compensation calculations, consequential damages are usually not included.²⁰² It may seem unfair that crippling damages can occur without recompense. As such, in cases where real property takings jurisprudence is applied to REMS takings, courts may then be asked to expound further on whether incidental and consequential damages are calculable.

By extension, the same analysis may be applied to the REMS system (as opposed to the actual drug product) that is used to block access to drug products. For most REMS systemic components, the actual property to be taken is usually a document. The FDA maintains copies of REMS documentation by virtue of the NDA approval process. In this regard, the FDA has already approved each document that might face the public. Accordingly, one need not physically take documents out of a brand company's hands, as copies exist with the FDA. These documents may therefore be obtained quite easily.

Sometimes the REMS system contains patient data. The FDA does not possess that data. For example, in those REMS systems where patients or doctors register into a database, that data usually resides only with the brand company. Is data a property interest? If so, what is the precise property interest at stake? Is the raw data itself or the compilation of the data into useable form a trade secret?

The Supreme Court in *Ruckelshaus v. Monsanto Co.* discussed the use of

²⁰² *Gen. Motors*, 323 U.S. at 379-80 (“[I]t has generally been held that that which is taken or damaged is the group of rights which the so-called owner exercises in his dominion of the physical thing, and that damage to those rights of ownership does not include losses to his business or other consequential damage.”).

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trade secret data by competitors.²⁰³ There, to actually market certain agricultural pesticides, federal law required sellers to generate health and safety data as part of their applications. The law allowed an applicant to maintain trade secrets protection, and if a subsequent applicant wanted access, the two parties were forced into a mandatory data-licensing regime. The trial court ruled in Monsanto's favor that the use of Monsanto's data was a Fifth Amendment taking in that Monsanto had a protectable property right in its data. The effect of the taking was substantial because it pushed all the development costs onto Monsanto yet provided for a free-rider benefit to the later applicant. Furthermore, the property would be destroyed once the public used it. Finally, the trial court ruled that the mandatory arbitration provisions to effectuate the licensing regime were illegal.

The Supreme Court affirmed that to the "extent that Monsanto ha[d] an interest in its health, safety and environmental data cognizable as a trade-secret property right under [State] law, that property right is protected by the Taking Clause of the Fifth Amendment."²⁰⁴ The Court also stated that the taking of data most implicated the third *Penn Central* factor, the interference of reasonable investment-backed expectations.²⁰⁵ The Court said that because amendments to the law required the Environmental Protection Agency ("EPA") to consider submitted data, data submitted after the amendments were not protectable as trade secrets. The Court grounded its holding on the fact that the applicant subjected itself to the new regulatory regime requiring data be submitted and then allowed the EPA to use that data in regulating subsequent applicants.²⁰⁶

Monsanto also complained that it was creating data that another company could use unfairly. The Court, however, dismissed this argument, suggesting Monsanto subjected itself to that regulatory regime by seeking permission to market products under that regime. Monsanto could hardly have the right to complain about its own voluntary actions.²⁰⁷ Finally, the Court rejected the argument that the true beneficiaries of the data submission and sharing would be later applicants who would not have to generate their own data.²⁰⁸ The

²⁰³ *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).

²⁰⁴ *Monsanto*, 467 U.S. at 1003-04.

²⁰⁵ *Id.* at 1005.

²⁰⁶ *Id.* at 1006.

²⁰⁷ *Id.* at 1007-08.

²⁰⁸ But see *Philip Morris, Inc. v. Reilly*, 267 F.3d 45 (1st Cir. 2001), which reversed the trial court's decision that the cigarette disclosure requirement was a taking as it forced Philip Morris to disclose its trade secret formula. The First Circuit held that no taking per se occurred because Philip Morris was not asked to bear a burden that should be shared by state citizens. Also, it was not a regulatory taking because the disclosure of formula ingredients was a valid exercise of police power to protect the public health of state citizens.

Court stated that the takings for public use could have public purpose or public benefit, even if many benefactors were private parties.²⁰⁹

In applying *Monsanto* to the REMS area, takings jurisprudence appears to be an available tool to obtain access to REMS-controlled drug products. In sum, there seems to be a governmental basis for doing so. Even the language of § 355-1(f)(8) may support the takings. For governmental action, it is not necessary that the underlying statute provide explicitly for a taking. Rather, and more often, the underlying statute states the purpose and desires, and underlying regulations provide more granularity to the details of the tools and vehicles to implement the statute. Here, § 355-1(f)(8) may be read as providing the statutory desires to not have REMS block access to generic development and hence, the FDA has within its general enforcement authority to implement that statute. The counterargument is that the statute only provides a goal but no actual enforcement, and that any enforcement authority the FDA has explicitly only resides in the enforcement statutes.²¹⁰

The quantum of compensation can be based on the economic impact prong of the *Penn Central* test. Courts may consider multiple factors while assessing a property owner's losses to determine what the property owner is owed. This would include, as discussed previously, how far downstream damages can be calculated (e.g., incidental and consequential damages).

However, to again melt together patent law and real property law, one could theorize that patent damages could be a factor in the quantum of compensation. Patent law allows for patent damages in the form of lost profits or reasonable royalties.²¹¹ To prove entitlement to lost profits, courts usually require a but-for analysis.²¹² To determine lost profits, courts consider what the patentee's profits would have been with no infringement. Said another way, courts consider the compensatory value of the infringement to the patentee. Compensating the patentee for lost property is analogous to compensating traditional property owners for lost property. In the event that REMS are patent protected in some form, a hypothetical infringement analysis might infer the value of REMS if they were the subject of a taking. Patent law provides for damages that are likely beyond the allowable compensation under takings

²⁰⁹ *Monsanto*, 467 U.S. at 1014-15. We again note that we do not take any position on whether this or any other case was fairly or correctly decided. The scope of this Article is whether any jurisprudential tools exist to obtain access to REMS controlled drug products.

²¹⁰ See generally 21 U.S.C. § 331 (2006).

²¹¹ 35 U.S.C. § 284 (2006); see *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995).

²¹² *Rite-Hite Corp.*, 56 F.3d at 1545 (“To recover lost profits damages, the patentee must show a reasonable probability that, ‘but for’ the infringement, it would have made the sales that were made by the infringer.”).

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law.²¹³ On the other hand, if the government would exact a compulsory license under 28 U.S.C. § 1498, then usually the quantum of damages is a reasonable royalty.²¹⁴

In sum, *Kelo* and more traditional Fifth Amendment real property law may provide a basis for a taking. First, § 355-1(f)(8), though not explicitly providing for a taking, may provide a generalized statutory authority to take the samples and subsequent REMS. As a government agency, the FDA (and likely the FTC under its general enforcement authority) may compel a taking. That the samples are taken ultimately for a private party, here a generic drug company, does not automatically negate the taking. Rather *Kelo* expressly states that private property may be transferred from one private party to another if there is a public purpose. Here, the transfers of drug samples and subsequent REMS are not purely for the generic company's use. Rather, the benefit is for the public in having greater access to medication at a lower cost. Indeed, the Hatch Waxman Act effectuates this purpose. Compensation can be paid to the brand company either by the FDA or by the generic company. Even though collateral effects may be devastating, takings law currently does not concern itself with collateral or ancillary effects. Courts may later decide how much compensation must be paid, but the fact that compensation may be difficult to calculate at a later date does not negate the taking in first instance.

CONCLUSION

In this Article, we analyzed REMS legislation and the problem with access to brand drug samples, and we then hypothesized how the government or private individuals may use disparate legal theories to obtain access to samples and subsequent REMS systems. We saw that a particular statute, namely § 355-1(f)(8), may provide express or implied enforcement authority under FDA law, antitrust law, and Fifth Amendment real property law.²¹⁵ If no power is ascribed to § 355-1(f)(8), it becomes a statutory provision with no power to carry out its stated purpose. We also saw that in using antitrust law, the essential facilities doctrine may apply, although many have debunked the theory. Similarly, we saw real property Fifth Amendment law may apply using the *Kelo* case, despite many taking offense to it.

²¹³ For example, patent law allows for consequential damages and so-called convoyed sales. *Id.* at 1550 (“[W]hen recovery is sought on sales of unpatented components sold with patented components, to the effect that the unpatented components must function together with the patented component in some manner so as to produce a desired end product or result. All the components together must be analogous to components of a single assembly or be parts of a complete machine, or they must constitute a functional unit.”).

²¹⁴ See 28 U.S.C. § 1498 (2006).

²¹⁵ It may not be the most elegant way to shoehorn enforcement authority into a statute, but one must play the cards that one is dealt.

So in the end, many parties may have the basis for compelling access to a brand drug. As discussed in this Article, governmental enforcement authorities such as the FTC, the FDA as the regulator, and private parties may compel access. Under the current body of antitrust case law, the essential facilities doctrine is alive and well. Further, because the scope of REMS legislation has not been tested, it remains a viable source for authorizing the compelled access. Finally, under the regulatory takings regime, private property may be taken for a public use by the government.