NOTE

AUTHORIZED GENERICS: A PRESCRIPTION FOR HATCH-WAXMAN REFORM

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INTRODUCTION

AUTHORIZED generics are brand-name drugs sold under generic labels, manufactured by the pioneer drug firm but marketed and distributed through a subsidiary or outside generic partner.[1] Although identical to the brand-name drug, they are priced at

[1] See Notice of Authorized Generic Drug Study, 71 Fed. Reg. 16,779, 16,780 (Apr. 4, 2006), available at http://www.ftc.gov/os/2006/03/P062105AuthorizedGenericDrugStudyFRNotice.pdf.

the same level as other generics, allowing pioneers to sell the same drug product in both the brand-name and generic drug markets.[2]

Competition in these markets is regulated by the Hatch-Waxman Act,[3] which governs regulatory approval and market entry for both pioneer and generic drugs. Paragraph IV is a particularly important aspect of the Hatch-Waxman Act, designed as a patent quality-control mechanism that accelerates generic market entry. Under this system, generic drug firms are encouraged to challenge pioneers' drug patents in court. If successful, the prevailing generic firm obtains a 180-day marketing exclusivity period as the economic reward for its litigation efforts, and consumers benefit from earlier access to low-cost generic alternatives to the brand-name drug.[4]

In recent years, pioneer drug firms have increasingly deployed authorized generics as a controversial response to patent invalidation during Paragraph IV litigation.[5] Whereas successful generic challengers previously enjoyed complete dominance over the generic market for 180 days, authorized generics are now entering the market during this time to capture market share and reduce the economic bounty of Paragraph IV entrants.[6] Critics condemn this strategy as a deliberate violation of Hatch-Waxman's 180-day exclusivity provision, designed to discourage generic drug firms from pursuing Paragraph IV entry.[7] Proponents highlight the benefits of increased price competition during the exclusivity period and deny any deterrent effects.[8]

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[2] See id. at 16,780.

[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.).

[4] See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1075 (D.C. Cir. 1998) ("The purpose of [21 U.S.C.] § 355(j)(5)(B)(iv) is to provide a reward, in the form of an exclusivity period, to generic drug companies that are the first to file paragraph IV ANDAs.").

[5] See Jenna Greene, Big Pharma's Big Leap, IP L. & Bus., Jan. 2006, at 40, 40, available at http://www.law.com/jsp/article.jsp?id=1137665110733; see also Gregory Glass, Authorized Generics, 4 Nature Rev. Drug Discovery 953 (2005).

[6] See Glass, supra note 5, at 953.

[7] Greene, supra note 5, at 48 (noting that Congressman Henry Waxman, coauthor of the Hatch-Waxman Act, has criticized authorized generics as "a distortion of what was intended in the law," and "an effort by major pharmaceutical companies to find loopholes in the law").

[8] See Glass, supra note 5, at 953.

Thus far, courts have relied solely on a textual analysis of the Hatch-Waxman Act to uphold the authorized generics practice.[9] However, on April 4, 2006, the Federal Trade Commission (FTC) announced it would investigate the likely short-term and long-term economic impact of authorized generics.[10] The FTC investigation is a welcome development—the courts' exclusive reliance on textual analysis is an incomplete approach that ignores important antitrust considerations. This Note advances a new perspective by providing a detailed theory of how authorized generics will likely operate in the pharmaceutical market, followed by an analysis of the legal issues at the intersection of the antitrust, regulatory, and patent law regimes. Part I will provide a brief overview of the relevant Hatch-Waxman provisions potentially affected by authorized generics. Part II will summarize the current literature and case law pertaining to the authorized generics controversy. Part III will explore the nature of the pharmaceutical marketplace, laying a foundation for the theory of competitive harm set forth in Part IV. Parts V, VI, and VII will analyze authorized generics from the antitrust, Hatch-Waxman, and patent law perspectives, respectively. Finally, Part VIII will suggest potential solutions to the authorized generics controversy, including Hatch-Waxman legislative reform.

I. HATCH-WAXMAN OVERVIEW

A. Historical Background and Previous Regulatory Problems

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act,[11] "emerged from Congress's efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic cop-

[9] See Mylan Pharm. v. FDA, 454 F.3d 270, 275–76 (4th Cir. 2006); Teva Pharm. Indus. v. Crawford, 410 F.3d 51, 53 (D.C. Cir. 2005).

[10] See Notice of Authorized Generic Drug Study, 71 Fed. Reg. 16,779, 16,779 (Apr. 4, 2006), available at http://www.ftc.gov/os/2006/03/P062105AuthorizedGenericDrugStudyFRNotice.pdf.

[11] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.).

ies of those drugs to market."[12] Congress recognized that the earlier regulatory regime established by the Food and Drug Administration ("FDA") was unduly burdensome to both pioneer and generic drug firms. Previously, generic drug firms were required to replicate the pioneer's clinical trials to demonstrate safety and efficacy before obtaining FDA approval.[13] Moreover, they could not begin this extremely lengthy and expensive testing process until *after* the relevant drug patent had expired because clinical testing beforehand would have constituted patent infringement.[14] These entry barriers created an undesirable de facto extension of drug patents, ultimately delaying consumer access to affordable drugs.[15]

Pioneer drug firms also faced their own difficulties. Drug patent applications filed early in the drug discovery process often issued long before FDA approval of the corresponding New Drug Application ("NDA"), leaving only a few years of effective patent life once a drug entered the market.[16] This situation threatened to undermine pioneers' innovation incentives and deprive consumers of important advances in drug therapy.

B. Hatch-Waxman: A New Regulatory Framework

Hatch-Waxman created a streamlined regulatory system to alleviate these problems. The newly designated Abbreviated New Drug Application ("ANDA") adopted "bioequivalence" as the new standard for generic drug approval in order to facilitate and accelerate FDA review.[17] A generic drug manufacturer is now only required to demonstrate that its product contains the same active ingredient and basic pharmacokinetics as the brand-name drug.[18]

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[12] Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990).

[13] See FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study 3 (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf [hereinafter FTC Generic Drug Study].

[14] Id. at 4; see Roche Prods. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

[15] See *Roche Prods.*, 733 F.2d. at 864.

[16] See FTC Generic Drug Study, supra note 13, at 4.

[17] 21 U.S.C. § 355(j)(2)(A)(iv) (2000); FTC Generic Drug Study, supra note 13, at 5.

[18] An active ingredient is the chemical compound that produces the drug's intended therapeutic effect. In contrast, inactive ingredients, also called "excipients," do not elicit any therapeutic response but are used instead to provide attributes such as bulk, color, or flavor. See Huba Kalász and István Antal, Drug Excipients, 13 Current Medicinal Chemistry 2535, 2535 (2006).

The generic manufacturer can otherwise rely on the pioneer's clinical trial data to satisfy the FDA's safety and efficacy requirements.[19] This standard simultaneously ensures generic drug quality while eliminating duplicative research costs, and it has greatly accelerated consumer access to affordable medications. Additionally, Hatch-Waxman created an experimental use exception, which insulates ANDA-related clinical research from patent infringement liability.[20] This allows generic drug manufacturers to begin bioequivalence testing even while the drug patent remains in force, often leading to generic drug availability immediately upon patent expiration.

To balance these progeneric provisions, Hatch-Waxman provides pioneers with patent term restoration to offset certain losses caused by FDA regulatory delays.[21] Patent term restoration is subject to various restraints, however. The entire restoration may not exceed five years,[22] and the remaining patent life following FDA market approval may not exceed fourteen years.[23] Additionally, delays caused by the pioneer's lack of due diligence during the regulatory review period will reduce the restored patent term accordingly.[24] Despite these limitations, the patent term extensions ultimately confer significant economic benefits, which provide the necessary incentive for further research and development.

Hatch-Waxman employs a unique procedural framework to manage the interplay between pioneer NDAs and their generic ANDA counterparts. Upon filing an NDA, a pioneer firm must provide a list of relevant patents, which are then listed in an FDA

[19] FTC Generic Drug Study, supra note 13, at 5.

[20] 35 U.S.C. § 271(e)(1) (2000) provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

[21] See generally 35 U.S.C. § 156 (2000).

[22] Id. § 156(g)(6)(A).

[23] Id. § 156(c)(3).

[24] Id. § 156(c)(1).

publication known as the "Orange Book."[25] Subsequent ANDAs must reference these Orange Book listings and make one of four "certifications" for each patent:[26]

> (I) the required patent information has not been filed;
>
> (II) the patent has already expired;
>
> (III) the patent has not yet expired, but will do so prior to FDA approval of the ANDA; or
>
> (IV) the patent is invalid or will not be infringed by the ANDA.

The most significant and contentious of these is the Paragraph IV certification, because a generic firm is seeking market entry prior to patent expiration, whereas the other certifications simply confirm there are no extant patent rights that would prevent generic entry. Generic applicants making Paragraph IV certifications must notify the pioneer firm, which then has forty-five days to initiate a patent infringement lawsuit.[27] Pioneers typically pursue litigation, automatically triggering a thirty-month stay that prevents FDA approval of the ANDA until the earliest of the following dates: patent expiration, a final resolution of the patent litigation, or expiration of the thirty-month period.[28]

If the generic drug manufacturer prevails in the Paragraph IV patent litigation, it is rewarded with a 180-day marketing exclusivity period, during which the FDA cannot approve subsequent generic versions of that drug.[29] This 180-day "monopoly" can be immensely profitable, and it thus rewards the first Paragraph IV filer for bearing the risks and expenses of patent litigation, which typically costs $10 million.[30] Hatch-Waxman originally provided for two events that would trigger the 180-day exclusivity period: (1) commercial marketing of the drug, or (2) a final court decision holding

[25] See U.S. Dep't of Health & Human Servs. et al., Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, http://www.fda.gov/cder/ob (last visited Jan. 29, 2007).
[26] See 21 U.S.C. § 355(j)(2)(A)(vii) (2000).
[27] See id. § 355(j)(5)(B)(iii) (Supp. III 2003).
[28] Id.
[29] See id. § 355(j)(5)(B)(iv).
[30] See Greene, supra note 5, at 42, 44.

the relevant drug patent(s) invalid or not infringed.[31] Once the exclusivity period has been triggered and expires, the FDA may approve subsequent generics to enter the market.

In summary, Paragraph IV has created the following generic industry paradigm: generic drug firms frequently race to file the first Paragraph IV certification in hopes of successfully challenging drug patent(s) in litigation and obtaining the profits of 180-day exclusivity. This process serves as an important patent quality-oversight mechanism that exposes invalid patents and accelerates consumer access to generic drugs.

C. Previous Hatch-Waxman Abuses

Paragraph IV entry can be quite dramatic, generating sizable profits for generic firms, often at devastating expense to the pioneer. Consequently, pioneer firms have engaged in strategic manipulations and abuses that have attracted FTC scrutiny and enforcement. The "first generation" of FTC enforcement targeted anticompetitive settlement agreements between pioneer and generic drug firms.[32] Under these collusive arrangements, the first Paragraph IV applicant would agree to refrain from entering the market to exploit its 180-day exclusivity in return for substantial monetary payments.[33] The result was that a pioneer could block all subsequent generic competitors, whose market entry was contingent upon the triggering and expiration of 180-day exclusivity, which had now been "parked" indefinitely.[34] These arrangements are sometimes referred to as reverse settlements or exit payments,

[31] See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1589 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv) (Supp. III 2003)). Subsequent Hatch-Waxman amendments eliminated the court-decision trigger for ANDAs filed after December 8, 2003. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(1)(I), (b)(1), 117 Stat. 2066, 2457, 2460 (2003).

[32] See Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the S. Comm. on Commerce, Science & Transportation, 107th Cong. 23–24 (2002) (statement of Timothy J. Muris, Chairman, Fed. Trade Comm'n), available at http://www.ftc.gov/os/2002/04/pharmatestimony.htm [hereinafter Muris].

[33] Id.

[34] Id. at 24; see also Larissa Burford, Note, In re Cardizem & Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform, 19 Berkeley Tech. L.J. 365, 369 (2004).

because the patentee pays an alleged infringer to exit the generic market in order to forestall the onset of generic competition.[35]

The FTC directed its "second generation" of enforcement at fraudulent Orange Book listings, in which pioneer firms frivolously listed additional and often irrelevant drug patents in the Orange Book in order to delay generic firms' Paragraph IV entry.[36] Generic firms wishing to proceed with market entry were forced to file additional Paragraph IV certifications for each of the newly listed patents, allowing the pioneer to trigger a cascade of successive thirty-month stays to delay generic market entry.[37]

A combination of persistent FTC enforcement and public concerns over escalating health care costs led to legislative reform with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[38] Title XI of the Act, "Access to Affordable Pharmaceuticals," introduced several changes to the original Hatch-Waxman Act designed to eliminate the dilatory effects of anticompetitive settlements and fraudulent Orange Book listings.[39] To reduce "first generation" anticompetitive settlements, Title XI requires pioneer and generic firms to notify the FTC and Department of Justice within 10 days of any agreements involving the 180-day exclusivity period.[40] Furthermore, Paragraph IV generics must exploit their exclusivity period within certain time limits or risk forfeiture of their reward.[41] To limit "second generation" fraudulent Orange Book listings, Title XI generally allows only one automatic thirty-month stay[42] and also provides generics with the

[35] Muris, supra note 32, at 24; see also Daniel A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications, 54 Fla. L. Rev. 747, 748 (2002).

[36] Muris, supra note 32 at 25.

[37] Id.; see also Natalie M. Derzko, The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation, 45 IDEA 165, 176 (2005).

[38] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 26 U.S.C. and 42 U.S.C.).

[39] See John R. Thomas, Pharmaceutical Patent Law 23–25 (2005).

[40] See Medicare Prescription Drug, Improvement, and Modernization Act §§ 1111–13.

[41] See 21 U.S.C. § 355(j)(5)(D) (Supp. III 2003).

[42] See Medicare Prescription Drug, Improvement, and Modernization Act § 1101(a)(2)(A)(ii)(I) (amending 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. III 2003)); see also id. § 1101(b)(2)(B)(ii)(I) (amending 21 U.S.C. § 355(c)(3)(C) (Supp. III 2003)).

option of filing counterclaims to de-list allegedly improper Orange Book patents.[43]

The question now presented by authorized generics is whether this new practice constitutes a "third generation" of Hatch-Waxman abuse that warrants FTC scrutiny and further legislative reform.

II. THE AUTHORIZED GENERICS DEBATE

Authorized generics have generated intense controversy because they operate during the 180-day exclusivity period, which had traditionally been the exclusive domain of the Paragraph IV generic ("ANDA IV"). The ANDA IV would typically price its product just below the pioneer's brand-name drug in order to capture tremendous profits. The advent of authorized generics has altered this landscape, permitting two generic competitors to operate during the exclusivity period: the ANDA IV and the authorized generic.

A. Basic Arguments: Short Versus Long Term Effects

Critics contend that authorized generics violate Hatch-Waxman's award of 180-day exclusivity to successful patent challengers.[44] They also argue that in the long term, authorized generics will reduce the profitability of Paragraph IV entry and ultimately eliminate the incentive to pursue such patent challenges.[45]

Proponents respond by noting the immediate benefits of increased price competition during the exclusivity period. They further maintain that authorized generics will not deter Paragraph IV entry, because even with the presence of authorized generics, the profits to be gained from Paragraph IV entry still far outweigh the costs, and therefore remain an adequate entry incentive.[46] Moreover, 180-day exclusivity only bars other ANDA generics—not authorized generics, which rely on the pioneer's original NDA for market approval.[47]

[43] 21 U.S.C. § 355(j)(5)(C)(ii) (Supp. III 2003); id. § 355(c)(3)(D)(ii).
[44] See Greene, supra note 5, at 42.
[45] Id.
[46] Id. at 44.
[47] See Mylan Pharm. v. FDA, 454 F.3d 270, 276 (4th Cir. 2006); Teva Pharm. Indus. v. Crawford, 410 F.3d 51, 53, 55 (D.C. Cir. 2005).

B. Limited Economic Literature

Authorized generics remain controversial because there have been no conclusive empirical studies to assess their economic impact. By necessity, the studies published to date have been limited to speculative economic projections, because the practice is so recent and the relevant inquiry is long term in nature. Different studies have generated differing conclusions, with some suggesting that authorized generics will harm competition,[48] and others concluding they will not.[49] Thus, there remains no consensus as to whether authorized generics will deter Paragraph IV entry. This deficiency was one reason behind the FTC's recent decision to investigate authorized generics.[50]

C. Authorized Generics Case Law

Thus far, courts have relied on statutory interpretation in rejecting challenges to the practice of authorized generics. In *Teva Pharmaceutical Industries v. Crawford*, the Court of Appeals for the District of Columbia affirmed the legality of Pfizer's authorized

[48] Professor Hollis has studied pseudo-generics, the equivalent of authorized generics in the Canadian pharmaceutical market, and concludes that pseudo-generics are likely to increase prices of both generic and brand-name drugs. See Aidan Hollis, How do Brands' "Own Generics" Affect Pharmaceutical Prices?, 27 Rev. Indus. Org. 329, 348–49 (2005). He also concludes they deter generic entry in certain markets. See Aidan Hollis, The Anti-Competitive Effects of Brand-Controlled 'Pseudo-Generics' in the Canadian Pharmaceutical Market, 29 Can. Pub. Pol'y 21, 28–29 (2003). While both of Professor Hollis's papers provide useful guidance, the extent to which his conclusions apply to the U.S. market remains unclear due to potential differences between the two countries' regulatory and patent regimes.

[49] See, e.g., Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition and Consumers' Welfare 1 (Am. Enter. Inst. for Pub. Policy Research, Working Paper, 2005), available at http://www.aei.org/docLib/20051103_GenericsDraft.pdf. The authors conclude that authorized generics are unlikely to harm consumer welfare, noting that generic entrants already face competition in the race to file the first Paragraph IV certification and that an additional disincentive should not discourage many patent challenges. Id. at 14. The authors also observe that even if some generics are deterred, overall Paragraph IV entry will remain unaffected so long as at least one generic firm continues to file as early as those that have been deterred and otherwise devotes similar resources to the litigation effort. Id. at 15.

[50] See Notice of Authorized Generic Drug Study, 71 Fed. Reg. 16,779, 16,780 (Apr. 4, 2006), available at http://www.ftc.gov/os/2006/03/P062105AuthorizedGenericDrugStudyFRNotice.pdf.

generic version of gabapentin.[51] The FDA had denied Teva's citizen petition requesting a prohibition of authorized generics during the 180-day exclusivity period, concluding that Hatch-Waxman contained "no statutory basis for imposing categorical approval requirements for the marketing of authorized generics, as a means to prevent their marketing during a 180-day exclusivity period applicable to the drug under an ANDA."[52] Both the trial and appellate courts agreed. In conducting a *Chevron* analysis of the relevant Hatch-Waxman provision,[53] the D.C. Circuit concluded that the statutory language was unambiguous and that 180-day exclusivity applied only to FDA approval of other ANDAs.[54] The court held that, because authorized generics rely on the pioneer's previously approved NDA, they are beyond the reach of the exclusivity provision and are free to enter the market during that 180-day period.[55] In *Mylan Pharmaceuticals v. FDA*, the only other authorized generics case to date, the Fourth Circuit adopted the *Teva* court's rationale.[56] Although the *Teva* and *Mylan* courts correctly decided the narrow issue of whether the language of Hatch-Waxman Section 355(j)(5)(B)(iv) prohibits authorized generic entry during the 180-day exclusivity period, the broader conclusion that authorized generics are legal is unwarranted, given the absence of antitrust scrutiny in the courts' analyses.

D. Future Directions

The authorized generics debate has largely been an exchange of unsupported generalities, with both sides simply offering sweeping conclusions unsupported by empirical data or detailed theory. Critics merely assert that authorized generics will deter Paragraph IV entry, while proponents maintain they will not. The recently announced FTC investigation will gather empirical evidence to augment the economic literature. Briefly stated, this Note asserts that authorized generics operate by targeting and exploiting various

[51] 410 F.3d at 52, 55.
[52] Id. at 53.
[53] See 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003).
[54] *Teva*, 410 F.3d at 52–55.
[55] Id. at 54.
[56] See 454 F.3d 270, 276 (4th Cir. 2006).

imperfections in the pharmaceutical marketplace, in order to deter Paragraph IV challenges.

III. PHARMACEUTICAL COMPETITION

Authorized generics present a new factual scenario not previously encountered under the Hatch-Waxman regime. Whereas previous abuses, such as exit settlements and fraudulent Orange Book listings, harmed competition by withholding generic products from the market, authorized generics do the opposite—they *introduce* an additional generic market participant. Therefore, exploring the nature of pharmaceutical competition is central to understanding the competitive impact of authorized generics.

A. The Pharmaceutical Supply Chain

The pharmaceutical supply chain is peculiar in that the physical distribution of drug products is relatively straightforward, while the flow of funds is much more complex.[57] Naturally, physical distribution of the drug product originates with the drug manufacturer. Wholesale distributors then purchase the drugs and distribute them to a variety of pharmacies, including retail, mail-order, and hospital pharmacies.[58] These pharmacies then serve as the final distribution point prior to delivery to the ultimate consumer, the patient.[59]

The financial axis of the pharmaceutical supply chain is far more complicated, comprising an intricate web of commercial relationships through which competing drug manufacturers vie for market share.[60] Generally, drug manufacturers offer financial incentives, such as retroactive rebates based on market share, to encourage supply chain members to work toward increasing a given drug's market share.[61] For instance, manufacturers frequently give phar-

[57] See Thomas E. Getzen, Health Economics: Fundamentals and Flow of Funds 256 (2d ed. 2004).

[58] See Health Strategies Consultancy LLC, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain 4, 8–9 (Mar. 2005) (unpublished report prepared for the Kaiser Family Foundation on file with the Virginia Law Review Association), available at http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf.

[59] Id. at 9.

[60] Id. at 24.

[61] Id. at 19.

macies volume discounts when their drugs achieve certain market share targets, creating a significant incentive for pharmacies to work with patients and physicians to switch to those drugs and away from substitutes.[62]

Likewise, manufacturers negotiate with other price-influencing entities, such as Pharmacy Benefit Managers ("PBMs"), for preferred placement on drug formularies.[63] PBMs work with health insurers to create drug formularies that manage patient drug utilization and currently process an estimated two-thirds of all drug prescriptions each year.[64] These drug formularies influence market share by imposing multi-tiered copayments for selected drugs; the purpose is to alter consumers' drug choices by funneling price-sensitive customers toward lower copay formulary drugs.[65] In this respect, the pharmaceutical industry is particularly unique, since other industries lack this financial mechanism for managing consumer choice.

Thus, the pharmaceutical supply chain provides more than a means for physically distributing drug products; it is also a critical mechanism for competition between rival manufacturers of the same drug in their quest for increased market share.

B. Prescription Drug Consumption

Pharmaceuticals are unique not only in their distribution mechanisms but also in their consumption patterns. Drug consumers exercise much less free choice over consumption decisions than do consumers of other products. Prescription drug utilization is heavily regulated by a unique network of three consumer groups: physicians, pharmacists, and insurers. Physicians serve as the primary gatekeepers who control drug access by writing the necessary prescriptions. Pharmacists influence drug selection more subtly: generic substitution laws allow them to dispense generics even when

[62] Id.
[63] Id. at 14.
[64] Id. at 13–14.
[65] Id. at 14; see also Julie M. Ganther-Urmie et al., Consumer Attitudes and Factors Related to Prescription Switching Decisions in Multitier Copayment Drug Benefit Plans, 10 Am. J. Managed Care 201, 201 (2004) (noting that "a typical structure has the lowest copayment for generic drugs, the middle copayment for brand name formulary drugs, and the highest copayment for nonformulary drugs").

the physician has prescribed a brand-name.[66] Patient choice is further constrained by insurers' multi-tiered drug formularies, which encourage selection of drugs with lower copayments.

An important implication of this interpersonal network is that prescription drug consumption, and thus market share competition, is largely a function of the behavioral interactions among these consumer groups. Authorized generics deliberately target and manipulate the behavioral tendencies of these groups as part of a strategy to suppress generic drug competition.

1. Patient Perceptions and Behavior

Ample evidence suggests that many patients harbor irrational brand loyalties, because they unreasonably believe that generic drugs are of inferior quality. A study in 2000 found that "[t]he percentage of respondents who perceived that generic prescription drugs were riskier than brand name products varied from 14.2% to 53.8%, depending on the medical condition being treated."[67] A more recent study in 2005 found that "37% of patients expressed general skepticism towards generic drugs because of their lower price."[68] As a result, many consumers forego the cost savings offered by generic drugs and opt for more expensive alternatives. For instance, a 2004 study found that 53.6% of survey respondents, when told that a prescribed medication was not on their plan's formulary, paid extra to purchase these non-formulary medications,[69] in part because of beliefs that managed care plans design formularies "solely to save the health plan money."[70]

Ironically, it is managed care that allows consumers to maintain their irrational preferences for higher-priced drugs. Because drug expenses are partially reimbursed by insurers, pharmaceutical demand is stronger and less sensitive to price changes than it might

[66] For further discussion of state generic substitution laws, see generally Jillena A. Warner, Note, Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws, 67 Ky. L.J. 384 (1979).

[67] Julie M. Ganther & David H. Kreling, Consumer Perceptions of Risk and Required Cost Savings for Generic Prescription Drugs, 40 J. Am. Pharm. Ass'n 378, 378 (2000).

[68] W. Himmel et al., What do primary care patients think about generic drugs?, 43 Int'l J. Clinical Pharmacology & Therapeutics 472, 472 (2005).

[69] Ganther-Urmie et al., supra note 65, at 203.

[70] Id. at 202.

otherwise be.[71] The result is a phenomenon known as "moral hazard," in which patients spend more on drugs than is socially optimal because the "existence of insurance means they do not directly bear the full marginal cost of care."[72]

2. Physician Perceptions and Behavior

There is also evidence that physicians, and to a lesser extent pharmacists, may behave in similar ways that create market imperfection. For instance, Judge Posner has noted that

> [T]hough the patent may have expired, the physicians who prescribe the drug may continue to prescribe the branded version rather than the generic substitute, whether out of inertia, or because they think the branded version may be produced under better quality control (the rationale for trademarks), or because the patient may feel greater confidence in a familiar brand.[73]

Another observer has noted that "individual physicians tend to be risk-averse, insensitive to cost, and creatures of habit, prescribing drugs by brand name even when much less expensive generic substitutes exist."[74]

Physicians may therefore continue prescribing brand-name drugs for reasons of convenience and habit. Moreover, agency imperfections within the doctor-patient relationship—specifically, the failure of physicians to capture any of the cost savings associated with lower-price prescriptions—frequently cause physicians to underinvest in gathering information about generic drugs.[75] This reality was an implicit motivation for the passage of generic substitution laws.[76] The problem is further exacerbated because "[g]eneric drug manufacturers do very little advertising," such that "it may take

[71] See Nick Liddell, The valuation of pharmaceutical brands, *in* Brand Medicine: The Role of Branding in the Pharmaceutical Industry 27, 27 (Tom Blackett & Rebecca Robins eds., 2001).

[72] Judith K. Hellerstein, The importance of the physician in the generic versus trade-name prescription decision, 29 RAND J. Econ., 108, 112 (1998).

[73] In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 787 (7th Cir. 1999).

[74] F.M. Scherer, Pricing, Profits, and Technological Progress in the Pharmaceutical Industry, J. Econ. Persp., Summer 1993, at 97, 101.

[75] Hellerstein, supra note 72, at 111.

[76] Id.

time for information to diffuse about the existence and name of the generic."[77] Even when generic versions become well known, "there is evidence that physicians have little knowledge of actual drug prices"; physicians, accordingly, are not fully price-sensitive on behalf of their patients.[78]

Physicians may also perceive medical and legal reasons for prescribing brand-name drugs rather than generic versions. For instance, over time, the size, shape, and color of drug pills may develop a useful role for identifying the medication, particularly for pharmacists and elderly patients, who must regularly identify and distinguish multiple medications.[79] Because generic drugs frequently differ in trade dress, physicians may continue to prescribe brand-name drugs in order to avoid misidentification and dispensing errors by patients and pharmacists.[80] Physicians themselves may also suffer from misperceptions about generic drug quality. One recent study found that only seventeen percent of physicians could correctly identify the FDA standards for bioequivalency.[81]

Moreover, the scientific literature suggests that in very limited circumstances, generic drug quality may be a legitimate medical concern. Of greatest concern are drugs with a narrow therapeutic index, in which the drug response is particularly sensitive to even small changes in blood concentrations.[82] In recent years, a number of state legislatures, pharmacy boards, and drug utilization review committees have expressed concern that generic substitution for these narrow therapeutic index drugs may jeopardize safety and ef-

[77] Id.

[78] Id.

[79] See Jeffrey Church & Roger Ware, Trade Dress and Pharmaceuticals: Efficiency, Competition and Intellectual Property Rights, Pol'y Options, Oct. 1997, at 9, 10, available at http://www.irpp.org/po/archive/oct97/church.pdf.

[80] The term "trade dress" refers to a product's overall image and appearance, including its color, size, shape, packaging, and label. See Joel W. Reese, Defining the Elements of Trade Dress Infringement Under Section 43(a) of the Lanham Act, 2 Tex. Intell. Prop. L.J. 103, 104 (1994).

[81] Benjamin F. Banahan III & E.M. Kolassa, A Physician Survey on Generic Drugs and Substitution of Critical Dose Medications, 157 Archives of Internal Med. 2080, 2085 (1997).

[82] See Peter R. Kowey, Issues in Bioequivalence and Generic Substitution for Antiarrythmic Drugs, http://www.americanheart.org/presenter.jhtml?identifier=3015266 (last visited Dec. 6, 2006).

ficacy when switching from brand-name to bioequivalent generics, prompting the FDA to assure the medical community otherwise.[83]

Organic chemistry considerations such as "polymorphism" have also appeared in the scientific literature. Polymorphism describes the ability of drugs to exist in multiple crystalline phases, which may have different reactivities.[84] FDA scientists have indicated that these altered chemical properties may affect drug product stability and bioavailability, which suggests that polymorphism warrants careful attention during drug development and regulatory review.[85]

Generic substitution has also been raised as a concern for elderly patients. Individual pharmacokinetic variations become particularly troublesome for these patients because many suffer from multiple medical conditions and therefore consume several drugs simultaneously, a phenomenon known as "polypharmacy."[86] Furthermore, "physiologic changes associated with age may affect drug absorption, distribution, metabolism, and excretion," causing some medical practitioners to remain wary that pharmacokinetic differences may exist "in this patient population that might not be detected in younger, healthy subjects" who are typically tested in FDA bioequivalence studies.[87]

The point here is not to evaluate the scientific merits of these concerns but rather to highlight their potential to affect physician prescribing behavior. To the extent that physicians remain wellread and are aware of these issues, they may choose to err on the side of caution and continue to prescribe brand-name drugs, or the chemically identical authorized generic, rather than the "merely" bioequivalent generic. This could occur for one of two reasons. First, busy physicians may simply adopt a blanket policy of prescribing the brand-name or authorized generic, rather than incur the sub-

[83] See Letter from Stuart L. Nightingale, Assoc. Comm'r for Health Affairs, FDA, to Health Practitioners (Jan. 28, 1998), http://www.fda.gov/cder/news/nightgenlett.htm ("To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug.").

[84] See Lawrence X. Yu et al., Scientific Considerations of Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications, 20 Pharm. Res. 531, 531 (2003).

[85] See id.

[86] See Peter Meredith, Bioequivalence and Other Unresolved Issues in Generic Drug Substitution, 25 Clinical Therapeutics 2875, 2885 (2003).

[87] Id.

stantial search costs of assessing the generic substitution concerns for each individual drug. Second, risk-averse physicians may choose to prescribe brand-name drugs to avoid potential calculation errors.

Defensive medicine may also reinforce this tendency. Defensive medicine describes the phenomenon in which treatment is driven by malpractice liability concerns rather than purely medical considerations.[88] Studies show that some risk-averse physicians continue "to prescribe higher-priced brands that are trusted on the basis of experience or reputation rather than risking an ineffective treatment or adverse reaction from a poor-quality drug."[89] Even physicians who are confident in bioequivalent generic drug quality from a medical perspective may for *legal* reasons simply choose to err on the side of caution and prescribe a chemically identical authorized generic to avoid potential tort liability, especially when so many patients remain skeptical of generic drug quality.

3. Implications for Generic Drug Competition

Whereas generic substitution laws and multi-tier drug formularies are designed to shift market consumption toward generics, the combination of patients' irrational brand loyalty, physician risk aversion, and moral hazard serves as a forceful counterweight. Both physicians and patients are susceptible to preferences for brand-name drugs over bioequivalent generics.

Two important observations about generic drug supply chain economics underscore the immense competitive impact of these behavioral tendencies. First, pharmacies typically stock only one generic version for a given prescription drug.[90] Second, at least one major pharmacy, and presumably others, has expressed an inclination to "choose to stock the generic product that *most closely re-*

[88] See David M. Studdert et al., Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment, 293 J. Am. Med. Ass'n 2609, 2609 (2005).

[89] Mark A. Hurwitz & Richard E. Caves, Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals, 31 J.L. & Econ. 299, 305 (1988).

[90] Anna Cook, Am. Enter. Inst. Panel, Authorized Generics: Part of the Solution or Part of the Problem? (Oct. 31, 2005) (summary available at http://www.aei.org/events/filter.economic,eventID.1177/summary.asp).

sembles the branded product."[91] Taken together, these observations demonstrate that the battle for generic market share is to be won by competing for exclusive shelf space, and victory is achieved based on similarity to the brand-name drug. Authorized generics are designed to leverage their status as identical versions of brand-name drugs, to distinguish themselves from bioequivalent generics and to obtain an insurmountable competitive advantage that deters Paragraph IV generic entry. The precise anticompetitive mechanism by which this occurs is elaborated below.

IV. THEORY OF COMPETITIVE HARM

So far, this Note has described how behavioral tendencies of patients and physicians interact to influence supply chain economics and generic market share. The analysis now presents a theory of competitive harm that explains the precise mechanism by which authorized generics strategically target and exploit these market imperfections to suppress Paragraph IV entry. Briefly, authorized generics constitute a "divide and conquer" strategy whereby first-mover advantages are used to generate insurmountable switching costs to protect drug patents from Paragraph IV challenges.

A. First-Mover Advantages

Generic drug competition is essentially a race in which the first entrant receives a disproportionately large first prize,[92] while the

[91] Shire US, Inc. v. Barr Labs., 329 F.3d 348, 355 (3d Cir. 2003) (emphasis added). This was a trade dress infringement case involving brand-name and generic drugs used for treating ADHD. The trial court had found that the identifying characteristics of pills used to treat ADHD were an important functional consideration that affected patient drug therapy and the pharmacy's generic stocking decision, and this finding was upheld on appeal. Id. at 359. Because ADHD patients were easily confused if their generic drugs were of a different color and general appearance than their previous brand-name drug, Rite Aid's policy was to select the generic version whose appearance was most similar to the brand-name. Id. at 355. This illustrates how consumer behavioral tendencies can influence supply chain economics and market share. Since secondary considerations, such as visual similarity, can favorably influence a pharmacy's inventory decision, it is likely that chemical similarity will be looked upon even more favorably, given that drugs are prescribed primarily for their therapeutic effects, which are a function of their chemical composition.

[92] David Reiffen & Michael R. Ward, "Branded Generics" as a Strategy to Limit Cannibalization of Pharmaceutical Markets 4 (May 2005) (unpublished manuscript,

benefit "of being second as opposed to third is not nearly as large."[93] This disproportionate order-of-entry effect is known as a "first-mover advantage," and 180-day exclusivity is highly prized precisely because it confers first-mover advantage.

Professors Lieberman and Montgomery, in their landmark paper on first-mover advantage, explain that one source of first-mover advantage is the ability to preempt rivals' acquisition of scarce assets.[94] One such scarce asset is retail shelf space,[95] which is critical to generic competition, because pharmacies typically stock only one generic version of a prescription drug.

Authorized generics are virtually guaranteed to enjoy first-mover advantage and secure this exclusive shelf space, because they rely on the pioneer's original NDA to enter the market, whereas ANDA generics must await FDA review and approval.[96] This effectively relegates ANDA IVs to second place. Because second place is only marginally better but immensely more expensive than third place, there is no incentive to bear the risks and costs of a pre-expiration patent challenge. The result is that rational generic firms may forego potential Paragraph IV challenges when faced with this unfavorable cost-benefit calculus.

Supply contracts are a related first-mover advantage that may discourage Paragraph IV entry. An increasingly common practice, partially in response to managed care pressures, is to develop contractual relationships that serve to "lock in" customers to a given product line.[97] Professor Liang describes this result as "entry lag," in which brand-name firms contractually extend patent exclusivity to create a de facto delay of actual generic market entry.[98] Authorized generics may enter the market prior to the ANDA IVs, and they may negotiate exclusive supply contracts that extend well into

on file with the Virginia Law Review Association), available at http://www.uta.edu/faculty/mikeward/brandedgenerics.pdf.

[93] Aidan Hollis, The importance of being first: evidence from Canadian generic pharmaceuticals, 11 Health Econ. 723, 732–33 (2002).

[94] Marvin B. Lieberman & David B. Montgomery, First-Mover Advantages, 9 Strategic Mgmt. J. 41, 44 (1988).

[95] Id.

[96] See Reiffen & Ward, supra note 92, at 3–4.

[97] See Getzen, supra note 57, at 267.

[98] See Bryan A. Liang, The anticompetitive nature of brand-name firm introduction of generics before patent expiration, 41 Antitrust Bull. 599, 622–23 (1996).

the 180-day exclusivity period. This practice would reduce both the profitability of the 180-day exclusivity period and the incentives for generic firms to bring Paragraph IV challenges.[99] Because authorized generics can invariably implement these strategies before ANDA generics can enter the market, rational generic firms may wisely aim for other markets not already occupied or imminently threatened by authorized generics.[100]

B. Switching Costs: Imposing Switching Costs by Exaggerating the "Identical" Versus "Bioequivalent" Distinction

Authorized generics can also use their virtually guaranteed first-mover advantage to impose substantial switching costs as a barrier to entry; this is perhaps their greatest potential for anticompetitive harm. Switching costs can deter subsequent entry by forcing later entrants to invest extra resources to attract customers away from the first-mover firm.[101]

By targeting the irrational brand loyalties of patients and physicians, authorized generics seek to lock in consumers and thereby create substantial switching costs that deter later entrants. There are two primary sources of switching costs that lock in consumers. First, authorized generics are chemically "identical" to the brand-name drug, whereas ANDA generics are "bioequivalent." Second, authorized generics are presumably free to mimic the brand-name's trade dress without fear of infringement liability. By promoting themselves as both chemically and visually identical to the brand-name drug, authorized generics manipulate patient and physician concerns over generic drug quality and appearance, which imposes significant switching costs as an entry barrier.

Professors Lieberman and Montgomery note that switching costs frequently arise "due to supplier-specific learning by the buyer. Over time, the buyer adapts to characteristics of the product and its supplier and thus finds it costly to change over to another brand."[102] For pharmaceuticals, trade dress can present a significant

[99] See Roy Levy, Bureau of Econ., FTC, The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change 93 (Mar. 1999), www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

[100] See Liang, supra note 98, at 617.

[101] See Lieberman & Montgomery, supra note 94, at 46.

[102] Id.

switching cost, because "[o]nce patients, health care workers and others have developed a familiarity with a medicine packaged in a particular style of capsule," the size, shape, and color of the pill may present "switching costs if there is a change to the same medication 'packaged'" in different trade dress.[103] This is partly because of consumers' irrational associations of the brand-name product (and its trade dress) with superior quality and partly because of the potential medical consequences of trade dress alterations, since "[t[he signal or information provided by the trade-dress is socially useful in identifying the medication and its dosage."[104] Misidentification due to differing trade dress may lead to harmful double-dosing and dispensing errors by careless patients and pharmacists.

Based on interviews with Canadian pharmacists, Professor Hollis summarizes the impact of switching costs presented by generic drug use:

> [Pharmacists] prefer to continue selling whichever generic arrives first since it is troublesome explaining bio-equivalence to patients, many of whom feel uncomfortable being switched to a new medication. While patients may accept the first generic on the market because it is less expensive than the brand name product, they are less willing to be switched again to yet another product which does not offer any cost-saving. . . . At the same time, if a prescription is filled with a second product with a different name and markings, there is a risk that the patient may mistake the two drugs for different products. This could lead to double dosing, which is a serious risk and concern to pharmacists. This is to say, there is a switching cost for the patient (discomfort with receiving a different medication) and therefore a switching cost for the pharmacist, who has to spend time consulting with the patient and assuring him that the difference between generics is insignificant . . . .[105]

Physician prescribing behavior may also generate additional switching costs. Physicians may share pharmacists' concern that patients will misidentify pills, and recommend authorized generics because they are chemically and visually identical to the brand-

[103] Church & Ware, supra note 79, at 10.
[104] Id.
[105] Hollis, supra note 93, at 724; see also Church & Ware, supra note 79, at 10.

name drug. Additionally, physicians are risk-averse, busy professionals. Risk-averse attitudes towards generic substitution due to concerns about narrow therapeutic index drugs, drug polymorphism, and geriatric polypharmacy may lead many physicians to opt for authorized generics in place of ANDA bioequivalent generics, whether motivated by scientific concerns or defensive medicine. Physicians may believe that prescribing authorized generics simultaneously protects patients' medical well-being and reduces potential legal liability. Adopting a blanket policy of prescribing authorized generics would eliminate potentially cumbersome drug-by-drug information search costs and calculation errors.

C. Authorized Generics: A "Divide and Conquer" Strategy

Authorized generics use their first-mover advantage to generate switching costs to "divide and conquer" the generic market. First, authorized generics seek to "divide" the generic market into two segments: identical authorized generics and bioequivalent competitors. Targeting patient irrationality and physician risk-aversion allows them to translate those behavioral tendencies into insurmountable switching costs. The ultimate effect of this strategy is to "tip" the generic market towards chemically and visually identical authorized generics, to eliminate the competitive threat of ANDA generic entry.

It bears repeating that FDA-approved generic drugs are therapeutically indistinguishable and equal to their brand-name counterparts in terms of safety, efficacy, dosage, and quality.[106] Bioequivalence testing ensures that the generic drug delivers the same active ingredients into the body at virtually the same speed and dosage as the brand-name drug.[107] Generics only differ in their inactive ingredients, which are harmless substances that do not affect the body.[108] Furthermore, both generics and brand-name drugs are

[106] See FDA, Facts About Generic Drugs, available at http://www.fda.gov/cder/consumerinfo/generic_FactsAbout_text.htm.

[107] See Harold Silverman, Trade-Name and Generic Drugs, *in* The Merck Manual of Medical Information 88, 91 (Mark H. Beers ed., 2d ed. 2003).

[108] See id. ("Inactive ingredients are added for specific reasons—for example, to provide bulk so that a tablet is large enough to handle, to keep a tablet from crumbling between the time it is manufactured and the time it is used, to help a tablet dissolve in the stomach or intestine, or to provide a pleasant taste and color.").

held to the same federal manufacturing standards, known as Good Manufacturing Practices.[109] The ultimate result is that bioequivalent generics are therapeutically equivalent to and perfect substitutes for brand-name drugs.[110]

Thus, authorized generics' divide and conquer strategy is a deceptive marketing ploy designed to capture market share by exaggerating trivial differences between brand-name and bioequivalent generic drugs. By doing so, authorized generics seek to exploit the market imperfections caused by patient irrationality and physician risk aversion. This strategy is predatory in both its intent and impact. Predatory behaviors commonly operate by putting competitors at a competitive disadvantage, which "can be accomplished by *raising the rival's costs* or by *impairing its ability to generate demand* for its product."[111] Authorized generics' divide and conquer strategy simultaneously does both. Dividing the market into identical versus bioequivalent allows authorized generics to conquer the generic market by both impairing demand for ANDA generics and raising rivals' costs.

1. Impairing Demand for Bioequivalent Generics

By promoting the inconsequential differences between identical and bioequivalent generics, authorized generic drug manufacturers hope to impair demand for ANDA generics. ANDA generic firms can respond by slashing prices to make their products even cheaper and more affordable. However, this may not succeed, due to the combination of irrational consumer beliefs and health insurance benefits, which reduce patient price sensitivity. These market imperfections may allow consumers to maintain an irrational preference for authorized generics and make it difficult for ANDA IV

[109] Id.

[110] See Letter from Roger L. Williams, M.D., Deputy Ctr. Dir. for Pharm. Sci. Ctr. for Drug Evaluation and Research, to Carmen A. Catizone, Executive Dir./Sec'y, Nat'l Ass'n of Bds. of Pharmacy (Apr. 16, 1997), http://www.fda.gov/cder/news/ntiletter.htm (citing an FDA study of over 220 generic drugs which revealed an "observed mean bioavailability difference between the generic and innovator products of only 3.5%").

[111] Janusz A. Ordover & Garth Saloner, Predation, Monopolization, and Antitrust, *in* 1 Handbook of Industrial Organization 565 (Richard Schmalensee & Robert D. Willig eds., 1989) (emphasis added).

firms to generate demand and compete effectively for market share.

2. Raising Rivals' Costs

Authorized generics may also raise rivals' costs. Raising rivals' costs ("RRC") is a strategic behavior designed to force upon smaller firms higher costs than those borne by the predatory firm.[112] In the authorized generics context, the likely goal is to force ANDA generic manufacturers to engage in their own advertising to counteract the misleading myths about identical versus bioequivalent drugs. The underlying strategy of RRC advertising is to force a smaller competitor to engage in a similar amount of advertising that is distributed over a much smaller amount of revenue or output.[113] Thus, ANDA generics must wage an equally expensive advertising campaign. Because they lack the first-mover rents of authorized generics, however, these costs will be distributed across much smaller revenues and are therefore more burdensome for ANDA generic firms than for their authorized generic counterparts.

Moreover, the differing cost structures and advertising capabilities of pioneer drug firms and their generic competitors will further impose relatively greater harm on ANDA generic manufacturers. Authorized generic manufacturers are more capable of sustained advertising campaigns, because they capture first-mover advantages and therefore enjoy correspondingly higher revenue streams with which to fund their ads. They also enjoy lower costs, because they rely on the pioneer's NDA and avoid the high costs of bioequivalence testing and Paragraph IV patent litigation that must be incurred by ANDA IV generic firms.

It is also conceivable that pioneer drug firms may deploy their considerable sales and marketing capabilities toward authorized generics promotion. This would provide authorized generics with a capability that ANDA generic firms would be unable to match. Advertising capacity, like innovation, is one of the hallmark characteristics that distinguish pioneer firms from their generic coun-

[112] Herbert Hovenkamp, Antitrust Policy After Chicago, 84 Mich. L. Rev. 213, 274 (1985).

[113] See id. at 278.

terparts. In 2001, brand-name firms spent approximately twenty-three billion dollars promoting and marketing their drugs with a sales force 87,000 strong; large brand companies typically maintain a sales staff of as many as 7,000 people.[114] In contrast, the generic industry spent less than one billion dollars, and a large generic company typically employs fewer than 500 salespeople.[115] Thus, it is unlikely that ANDA generic manufacturers could effectively compete in advertising, even if they wanted to, because they simply lack the necessary capacity.

Furthermore, pioneer firms' superior marketing prowess could simply preempt any ANDA advertising counter-campaigns. Commentators have suggested that drug promotion is designed to jam communication lines between physicians and subsequent entrants by saturating the market with the first-mover's product promotions.[116] According to this theory, major pharmaceutical companies purposely provide more information than physicians are willing or able to absorb. By saturating this communication line, first-movers foreclose subsequent entrants from effectively reaching their target audience.[117] Pioneer manufacturers may work with authorized generics to engage in similar promotion efforts, if they believe such efforts could defeat subsequent generic competitors.

Even assuming that ANDA generic manufacturers are able to mount effective advertising counter-campaigns, the RRC strategy may still remain successful in one of two ways. First, ANDA IV generic manufacturers might maintain previous price levels, but their newly increased advertising costs would reduce profit margins and undermine the economic incentives of 180-day exclusivity. Second, ANDA IVs might choose to maintain profit margins by increasing prices, which would defeat their inherent low-price appeal and undermine Hatch-Waxman's purpose of providing low-cost generic drugs. Neither option is particularly attractive to a generic company contemplating a risky and expensive Paragraph IV certi-

[114] Nat'l Inst. for Health Care Mgmt. Research & Educ. Found., A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace 24 (June 2002) (unpublished manuscript, on file with the Virginia Law Review Association), available at www.nihcm.org/GenericsPrimer.pdf.

[115] Id.

[116] See William S. Comanor, The Political Economy of the Pharmaceutical Industry, 24 J. Econ. Literature 1178, 1197 (1986).

[117] Id.

fication; their entry may be deterred altogether or substantially delayed in hopes that another generic competitor will bear the burden instead.

Overall, RRC is a plausible anticompetitive mechanism, because, as a practical matter, "raising rivals' costs can be both more profitable and less risky" than predatory pricing.[118] Predatory pricing requires an incumbent to sustain losses via below-cost selling in hopes of driving a rival from the market. This strategy is not only expensive in the near term, but recouping losses in the long-term is unlikely because new entrants will inevitably replace the dispatched rival.[119] In contrast, RRC is potentially more beneficial precisely because it is subtle and requires no immediate losses.[120] The subtlety of RRC is central to the authorized generics debate: proponents disingenuously focus on the near-term procompetitive benefits, while ignoring the long-term anticompetitive effects.

D. Prasco Authorized Generics: Divide and Conquer in Action

Already, there is evidence that authorized generics are indeed engaging in a divide and conquer strategy that targets consumers' irrational beliefs about generic drug quality. Prasco Laboratories[121] is a four-year-old authorized generics specialist based in Ohio.[122] Since 2004, Prasco has launched seventeen authorized generics with brand partners,[123] including the blockbuster allergy drug Allegra.[124] Prasco is believed to be the only authorized generics specialist in the industry, and their CEO claims the company is "'talking with virtually all of the major companies and expect agreements

[118] Hovenkamp, supra note 112, at 275.

[119] Id.

[120] Id.

[121] See Prasco Authorized Generics, http://www.authorizedgenerics.com (last visited Jan. 10, 2007).

[122] See James Ritchie, Prasco's market share Rx: authorized generic drugs, Cincinnati Bus. Courier, Feb. 3, 2006, at 6, available at http://cincinnati.bizjournals.com/cincinnati/stories/2006/02/06/story7.html?page=1.

[123] See Prasco Authorized Generics, Prasco Background, http://www.authorizedgenerics.com (follow "Marketplace Imapact" hyperlink; then follow "Prasco Background" hyperlink) (last visited Mar. 17, 2007).

[124] See Prasco Authorized Generics, Prasco Product Profile, http://www.authorizedgenerics.com/files/Branded_Site_Products/07.5.2_AG_Product Profile_Web.pdf (last visited Mar. 17, 2007).

soon.'"[125] The company does not manufacture any drugs; instead, it markets and distributes drugs supplied by the brand company, using the Prasco private label.[126]

Prasco's competitive strategy is immediately clear from its website, which greets visitors with the slogan, "It's Hard to Differentiate Between Identical."[127] Unquestionably, Prasco's approach is to highlight the identical nature of authorized generics to distinguish them from bioequivalent generics. The homepage states:

> Authorized Generics have the idnetical [sic] product characteristics that the patient is used to taking. Generic products can differ in qualities such as taste, the sensation in the mouth, and even the packaging. A Prasco Independent Authorized Generic provides patients with the identical experience they have with the brand product.[128]

Other sections of the website devote equal attention to emphasizing the identical nature of authorized generics. For instance, the website includes a page entitled "Authorized Generics, Providing Patients with Brand Sameness," which states:

> The Authorized Generic is the same as the brand name drug.
>
> . . . [I]t has the identical dosage, safety, strength, quality, performance, intended use, color, shape, taste, smell and mouth feel, and is identical in how it is taken . . . . *AND UNLIKE* a standard generic product, Authorized Generics contain the identical inactive ingredient(s) as the brand.[129]

To further illustrate this message, Prasco provides a side-by-side image comparing a white brand-name pill to a blue generic pill.[130]

This advertising strategy, which emphasizes that authorized generics are *identical* and the *same* as the brand-name drug, particularly for functional criteria such as "safety," "quality," and "performance," clearly implies that bioequivalent generics are inferior,

[125] Ritchie, supra note 122, at 6.
[126] Id.
[127] Prasco Authorized Generics, supra note 121.
[128] Id.
[129] Prasco Authorized Generics, About Authorized Generics, http://www.authorizedgenerics.com (follow "About Authorized Generics" hyperlink) (last visited Mar. 17, 2007).
[130] Id.

notwithstanding the FDA's regulatory assurances to the contrary. It appears that this strategy has already succeeded in manipulating consumer attitudes. A recent 2005 study commissioned by Prasco found that "87 percent of Americans say they want the option of taking an Authorized Generic version of a prescription drug made by the original manufacturer. Nearly all Americans (90 percent) say they would like to be told specifically by their pharmacist when an Authorized Generic is available."[131] Most significant are the study's findings that

> [I]f given the choice, three in four Americans say they would be more comfortable taking an Authorized Generic prescription drug as opposed to a standard generic. Even consumers who say authorized versions make "no difference" in their comfort with generics would still feel more comfortable with an Authorized Generic drug than with another manufacturer's copy. Most significantly, eight in ten would prefer the authorized generic if the price of an Authorized Generic and a standard generic were the same.
>
> "This data demonstrates that patients want brand sameness as long as they can also get generic prices," said E. Thomas Arington, Chairman and CEO of Prasco Laboratories. "Consumers have more confidence in their prescription drug when they have the identical experience that is offered to them by authorized generics."[132]

Prasco's competitive strategy thus embodies the divide and conquer anticompetitive strategy in action. The company seems to have already succeeded in its effort to divide consumer perceptions of identical and bioequivalent generic drugs. Clearly, they hope to conquer the generic marketplace by exploiting consumers' misunderstandings and irrational fears regarding bioequivalence and generic drug quality. The next Part provides an antitrust analysis of this authorized generics strategy.

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[131] Business Wire, BioPortfolio News: Prasco Laboratories: Over 80 percent of Americans Want the Option of Authorized Generic Prescription Drugs; Research Underlines Consumer Demand to Have Authorized Generic Prescription Drugs Available (Aug. 29, 2005), http://www.bioportfolio.com/aug_05/30_08_2005/Prasco_Laboratories_Over_80.html (last visited Feb. 25, 2007).

[132] Id.

V. ANTITRUST ANALYSIS

As a preliminary matter, the antitrust inquiry should focus on the differences that separate authorized generics from their ANDA IV counterparts. It should be acknowledged that ANDA IV generics are not entirely benign, as they too capture first-mover advantages and create potential switching costs that harm subsequent generic competitors. However, this is a result that Hatch-Waxman not merely tolerates, but actually encourages as an incentive to challenge patents and accelerate generic entry. Thus, the mere fact that authorized generics impose competitive harms does not itself warrant antitrust scrutiny; to the extent that they simply replace the role of ANDA IVs, social welfare remains unchanged.

There is cause for antitrust alarm, however, to the extent that authorized generics are capable of imposing *greater* competitive harms than ANDA IVs. Indeed, authorized generics present a greater anticompetitive threat, because their divide and conquer strategy is entirely premised on exploiting unique product characteristics such as identical chemistry and trade dress. This strategy is unavailable to ANDA IVs, and for this reason authorized generics should be viewed with greater suspicion.

A. Antitrust Standard: Rule of Reason

Authorized generics should be analyzed under the rule of reason. As a general matter, *per se* analysis has become increasingly disfavored; it is typically reserved for inherently anticompetitive behaviors with which courts have sufficient experience to condemn without further analysis. In contrast, authorized generics have never been confronted by the antitrust laws, and they do not closely mimic any previously established *per se* illegal conduct. For these reasons, a rule of reason analysis is the more comprehensive and appropriate antitrust approach.

Under a rule of reason analysis, anticompetitive harms are weighed against potential procompetitive justifications in order to assess whether, on balance, the challenged conduct is more anticompetitive than not. The procompetitive benefits of authorized generics are marginal. During the 180-day exclusivity period, authorized generics do introduce additional price competition. Conversely, authorized generics impose substantial anticompetitive

harms on generic competitors via their divide and conquer strategy. This strategy deters generic competition by exaggerating insubstantial product differences and contributes little, if anything, to consumer welfare. At best, the medical benefits of having an "identical" generic drug are limited to situations involving narrow therapeutic index drugs, polypharmacy, and misidentification caused by trade dress differences. Exploiting drug trade dress in this manner is itself of questionable social value. In the overwhelming majority of cases, highlighting the identical versus bioequivalent distinction serves no useful purpose and confers little social welfare because FDA standards ensure that all generic versions are therapeutically interchangeable with the brand-name drug. The deliberate and strategic misrepresentation of bioequivalence by authorized generic manufacturers warrants FTC scrutiny because deceptive advertising adversely affects market performance and tends toward market failure.[133]

1. DOJ/FTC IP Licensing Guidelines

Because authorized generics are essentially patent licenses between a pioneer firm and a generic partner, the DOJ and FTC Antitrust Guidelines for the Licensing of Intellectual Property ("Licensing Guidelines")[134] provide useful guidance. First, the Licensing Guidelines indicate that most "intellectual property licensing arrangements are evaluated under the rule of reason,"[135] which suggests that authorized generics licensing should likewise be held to the same standard. Importantly, the Licensing Guidelines state that IP licenses can be procompetitive when they allow a more efficient exploitation of intellectual property rights, particularly where the licensee provides an efficient source of production, such as manufacturing and distribution capabilities not possessed by the licen-

[133] Paul L. Joskow, Comments on Peltzman, 24 J.L. & Econ. 449, 449 (1981) (describing FTC efforts to reduce market failures resulting from false or misleading advertising); Cass R. Sunstein, Paradoxes of the Regulatory State, 57 U. Chi. L. Rev. 407, 424 (1990) (noting that "[s]ometimes markets fail because people are deceived or lack information").

[134] See Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property, 4 Trade Reg. Rep. (CCH) ¶ 13,132, at 20,733 (Apr. 11, 1995).

[135] Id. at 20,740.

sor.[136] However, authorized generics licenses are not procompetitive in this respect because they are largely unnecessary. Pioneer drug firms possess their own production, distribution, and marketing capacity and do not need authorized generics partnerships to deliver their products to market.

Conversely, the Licensing Guidelines note that anticompetitive potential arises when "a licensing arrangement affects parties in a horizontal relationship" because this may "increase the risk of coordinated pricing, output restrictions, or the acquisition or maintenance of market power."[137] Furthermore, "[t]he potential for competitive harm depends in part on the degree of concentration in, the difficulty of entry into, and the responsiveness of supply and demand to changes in price in the relevant markets."[138] Authorized generics licenses are indeed horizontal in nature, and because their divide and conquer strategy is designed to deter entry by horizontal ANDA competitors, they also increase the risk of price coordination, reduced output, and market power. Moreover, the nature of the pharmaceutical marketplace is problematic, because it is highly concentrated, difficult to enter, and somewhat price inelastic due to the combined effects of consumer brand loyalty, physician risk-aversion, and moral hazard. Overall, the rule of reason approach endorsed by the Licensing Guidelines suggests that authorized generics present anticompetitive concerns, without any offsetting procompetitive justifications.

B. Nature and Purpose of Authorized Generics: Monopoly Leveraging

Typically, absent significant market imperfections, monopoly rents will attract new entry that restores competition. Authorized generics represent a form of monopoly leveraging behavior, whereby a monopolist leverages its monopoly power in a primary market into a secondary market.[139]

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[136] Id. at 20,735, 20,741.

[137] Id. at 20,742.

[138] Id.

[139] See Jennifer M. Clarke-Smith, The Development of the Monopolistic Leveraging Theory and Its Appropriate Role in Antitrust Law, 52 Cath. U. L. Rev. 179, 179 (2002).

1. Primary Purpose: Defensive Leveraging

Defensive leveraging theory describes behavior whereby a monopolist responds to nascent competitive threats by leveraging into the new market, in order to prevent monopoly erosion and preserve rents in the original market.[140] Authorized generics are clearly a defensive leveraging measure, designed to extend drug patent monopolies by eliminating generic competition, particularly Paragraph IV entry. Hatch-Waxman regulation influences drug monopoly life cycles by encouraging Paragraph IV patent challenges, which prematurely terminate invalid drug patents. Because of widespread generic substitution laws and managed-care drug formularies, successful Paragraph IV challengers enjoy immense profits at the expense of pioneer firms. Paragraph IV entry is therefore an important strategic concern for pioneer drug firms, because although patent expiration is inevitable and unavoidable, Paragraph IV entry is not. Pioneer firms thus have every incentive to deter or delay such entry, especially for blockbuster drugs, where each day of patent exclusivity generates millions in sales. For instance, in 2005, Pfizer's Lipitor generated annual sales over $12 billion,[141] or nearly $33 million in sales each day. Prolonging drug patent monopolies by insulating them from Paragraph IV challenges is therefore highly desirable and lucrative for pioneer drug firms.

Previous Hatch-Waxman abuses such as exit settlements and multiple 30-month stays achieved this objective and prompted legislative reform designed to curb such behavior. Authorized generics are simply a more subtle but equally anticompetitive strategy that undermines the Hatch-Waxman Paragraph IV mechanism. Strategic manipulations of the Hatch-Waxman regime warrant heightened antitrust scrutiny, because "when a firm secures monopoly power through the regulatory system, no natural competitive force can displace it."[142] Defensive leveraging to protect pharmaceutical patents is especially suspect, given that generic challengers historically enjoy a seventy-three percent success rate

[140] See Robin Cooper Feldman, Defensive Leveraging in Antitrust, 87 Geo. L.J. 2079, 2114 (1999).

[141] Jerry Avorn, Torcetrapib and Atorvastatin—Should Marketing Drive the Research Agenda?, 352 New Eng. J. Med. 2573, 2574 (2005).

[142] David A. Balto, We'll Sell Generics, Too, Legal Times, Mar. 20, 2006, at 39, available at http://www.law.com/jsp/dc/pubarticleDC.jsp?id=1142601433226.

in Hatch-Waxman patent litigation.[143] This statistic suggests that pharmaceutical patents are often of questionable validity, and maintaining Paragraph IV challenges serves the important social function of eliminating unwarranted monopolies.

2. Likelihood of Success: A Monopoly Leveraging Analysis

Monopoly leveraging theory has been widely debated in the antitrust literature. The basic concern of traditional leverage theorists is that "if one monopoly is bad, surely two monopolies are worse."[144] Chicago school scholars have heavily criticized the traditional theory and assert that offensive leveraging is impossible: monopoly rents are a fixed sum that cannot be increased by leveraging into an additional market.[145] According to the Chicago school, leveraging into another market does not increase monopoly rents or competitive harm but simply redistributes them.

Defensive leveraging theory is a newer approach to the monopoly leveraging debate and asserts that leveraging into another market is not for the purpose of obtaining additional rents from the secondary market but rather to prevent monopoly erosion in the primary market.[146] Thus, where nascent threats arise in a secondary market, a monopolist will leverage into that market to eliminate them. Pioneer drug firms clearly have no true interest in monopolizing the generic market for its own sake, as this clearly cannibalizes far more lucrative brand-name drug sales. Instead, they deploy authorized generics as leverage into the generic market, only as a mechanism to deter Paragraph IV entry. The antitrust inquiry should therefore focus on the ability of authorized generics to insulate drug monopolies, especially those derived from patents of questionable validity.

Professor Kaplow has articulated four criteria for assessing monopoly leveraging conduct.[147] First, it is important to consider the potential cost to the monopolist who employs the restrictive prac-

[143] See FTC Generic Drug Study, supra note 13, at 13.
[144] See Feldman, supra note 140, at 2080.
[145] Id.
[146] Id. at 2088.
[147] See Louis Kaplow, Extension of Monopoly Power Through Leverage, 85 Colum. L. Rev. 515, 526 (1985).

tice.[148] Cheaper strategies enable more aggressive pursuit of even speculative strategic behavior.[149] Authorized generics agreements are relatively cheap to implement, in that most of the operational costs are borne by the licensee who actually markets and distributes the authorized generic product. Although the costs of brand-name cannibalization are quite high, it should be remembered that authorized generics are typically only released after the pioneer has lost during Paragraph IV litigation and the prevailing ANDA IV generic is poised to enter the market. As a result, cannibalization of brand-name sales is not a true cost of implementing an authorized generic strategy, because those same costs would have otherwise been imposed by the ANDA IV generic. Thus, authorized generics are a low-cost strategic behavior with potentially immense long-term payoffs.

Second, Professor Kaplow distinguishes between static and dynamic markets to focus on short- versus long-term effects.[150] Excessive focus on the short-term effects of a restrictive practice will fail to capture the potentially more important long-term motivations. A firm may be willing to forego profit-maximizing behavior in the near term if it believes that its conduct will achieve greater overall profits in the long run.[151] Authorized generics proponents, who focus exclusively on the short-term procompetitive benefits such as price competition during the exclusivity period, thus fall victim to the "static market fallacy," because they assume that markets remain constant and fail to appreciate the dynamic nature of real-world markets.[152] In assuming that the market for Paragraph IV entry will remain unchanged, proponents ignore the possibility that over time authorized generics may destroy the incentive to pursue patent challenges. Post-Chicago school theorists take a more long-term and dynamic view of markets and accept the possibility that monopoly leveraging may generate additional profits in some circumstances by reducing competition over time.[153] This more accurate approach to the authorized generics problem mirrors critics'

[148] Id.
[149] Id.
[150] Id.
[151] Id.
[152] See Hovenkamp, supra note 112, at 261.
[153] See Clarke-Smith, supra note 139, at 198–99.

concerns that authorized generics will ultimately harm generic drug competition by eliminating long-run Paragraph IV incentives. In the short term, authorized generics are unlikely to deter Paragraph IV entry, because they are typically released concurrently with the Paragraph IV generic. By that time, the Paragraph IV entrant has already sunk significant costs into bioequivalence testing and patent litigation. Accordingly, there is little incentive to exit the market at that time. Instead, the ANDA IV is likely to proceed with market entry in hopes of recouping entry costs and perhaps even generating profit by competing for whatever revenues it can obtain. It is the long-term activity of authorized generics that create anticompetitive harm. Over time, as the authorized generics strategy is repeated over several iterations, Paragraph IV entrants will become frustrated and will begin questioning the value of pursuing patent challenges only to see authorized generics consistently arrogate the lion's share of first-mover rents. Some pioneer firms may develop reputations for aggressively deploying authorized generics, which may encourage potential Paragraph IV entrants to target other markets or even vie to become the pioneer's authorized generics partner instead.[154] If successful, this could create a domino effect, in which all pioneer firms begin turning to authorized generics to shield their drugs from Paragraph IV challenges. Professor Kaplow's second factor thus weighs heavily in the authorized generics analysis.

Third, Professor Kaplow warns of free rider problems, which often prevent self-correcting market mechanisms from restraining monopoly power.[155] In the generic drug context, Paragraph IV entry is a policymaker-imposed market correcting mechanism designed to restrain monopoly power derived from questionable patents. Authorized generics present significant free-rider concerns, because generic competitors may eventually seek to free ride rather than bear the costs of the market-correcting Paragraph IV mechanism. On the one hand, as David Balto, a former FTC attorney, notes, authorized generics could completely deter Paragraph IV entry. This would shift the generic business model away from a race to Paragraph IV filing and toward a race to become pioneer

[154] See Balto, supra note 142, at 40.
[155] See Kaplow, supra note 147, at 526, 531.

firms' authorized generic partners.[156] Thus, rather than taking the initiative to pursue Paragraph IV entry, generic manufacturers may instead seek to free ride the pioneer's NDA and become an authorized generic distributor, allowing them to capture the same benefits, minus the substantial costs of bioequivalence testing and Paragraph IV litigation. Authorized generics, however, may not entirely deter—but could still delay—the Paragraph IV entry decision. This is because the authorized generic is virtually guaranteed to win the race to market and capture first-mover advantages, and the difference between second place (the first ANDA IV applicant) and third place benefits is marginal while the costs of second place (Paragraph IV litigation and bioequivalence testing) far outweigh the costs of third place (bioequivalence testing only). Thus, would-be ANDA IV applicants may seek to free ride one another by delaying and stalling their ANDA IV filings in hopes that another competitor will file first and bear the burdens of litigation for them. Ultimately, as a defensive leveraging strategy, these authorized-generics-induced free rider effects may either substantially delay monopoly erosion or prevent it altogether.[157] From an antitrust perspective, Professor Areeda notes, "the distinction between [delayed entry and permanent exclusion] is generally irrelevant to antitrust policy."[158] Both results harm competition and consumer welfare.

Fourth, and finally, Professor Kaplow notes that market imperfections may create additional opportunities for monopoly leveraging to modify market structure.[159] As discussed previously, authorized generics are a defensive leveraging strategy, which employs a divide and conquer tactic designed to exploit the market's imperfections in order to modify its structure. The substantial market imperfections arising from consumer irrationality, physician risk-aversion, and moral hazard will make it much more difficult for later generic entrants to restore competitive equilibrium. These imperfections may alter market structure if authorized generics ef-

[156] See Balto, supra note 142, at 40.

[157] Feldman, supra note 140, at 2093.

[158] Id. (quoting 2A Phillip E. Areeda & Herbert Hovenkamp, Antitrust law ¶ 420c, at 60–61 (revised ed. 1995)).

[159] See Kaplow, supra note 147, at 526.

fectively dominate the generics market and deter Paragraph IV entry.

3. Secondary Consequences: Increased Generic Drug Prices

The switching costs incurred by the divide and conquer strategy also have the potential to increase generic drug prices. Prior to the advent of authorized generics, the generic drug market was a homogeneous one, where all products were fungible and thus perfect substitutes for one another. In such markets, price differentiation is the primary means of competition. This drives prices downward towards marginal cost, and consumers benefit from lower prices.[160]

In a world with authorized generics, the divide and conquer strategy promotes the identical versus bioequivalent distinction to create a differentiated product market. Because sellers can compete on more dimensions than just price, there is often a wider price range in such markets.[161] Authorized generics, by establishing themselves as the sole identical generic on the market, can presumably raise prices without losing marginal buyers to bioequivalent competitors.

This occurs because the divide and conquer strategy reduces the cross-elasticity of both supply and demand. Cross-elasticity of demand is reduced because the combination of patients' skepticism toward bioequivalent generics, physician risk aversion, and moral hazard results in price-insensitivity. Cross-elasticity of supply is potentially decreased because competing suppliers may be hesitant to mimic drug trade dress due to infringement liability concerns. Thus, because they may increase prices, authorized generics may be a more socially harmful form of defensive leveraging than previous behaviors such as the Microsoft browser wars,[162] because browsers are distributed for free whereas drugs can be quite costly.

[160] See United States v. Oracle Corp., 331 F. Supp. 2d 1098, 1121 (N.D. Cal. 2004).

[161] Id.

[162] See Steve Lohr & John Markoff, How Software's Giant Played Hardball Game, N.Y. Times, Oct. 8, 1998, at A1 (describing the browser wars between Microsoft and Netscape).

C. Antitrust Case Law Parallels

1. Microsoft Java "Embrace and Extend"

There are several defensive leveraging behaviors that have been previously challenged under the antitrust laws and closely parallel the authorized generics strategy. Authorized generics' divide and conquer approach closely parallels Microsoft's "embrace and extend" strategy against Java.[163] In *In re Microsoft Corp. Antitrust Litigation*, Sun contended that their Java application threatened Microsoft's operating systems monopoly by eroding an application's software barrier to entry.[164] To protect its operating system monopoly, Microsoft responded with an "embrace and extend" strategy designed to eliminate Java as a competitive threat.[165] First, Microsoft "embraced" the Java technology by licensing it from Sun.[166] Second, it "extended" the Java platform by strategically incorporating technical incompatibilities to create its own different and unique version of Java.[167] Finally, Microsoft used its distribution channels to flood the market with this new version of Java in order to dominate the market for Java technology.[168] The alleged outcome of this strategy was referred to as "market tipping," in which Microsoft's version would emerge as the dominant product or standard, firmly entrenched and difficult to unseat.[169]

Authorized generics' divide and conquer approach is essentially the same strategy. First, pioneer drug firms embrace the generic drug market, albeit by granting licenses to authorized generics partners rather than taking them. Second, authorized generics extend the generic drug concept by promoting themselves as identical to the brand-name drug and thus different than their bioequivalent competitors. Finally, authorized generics firms such as Prasco seek to flood the market with messages about identical versus bioequivalent generics in an effort to manipulate consumer preferences. The final outcome is essentially a preemptive market tipping in which authorized generics, by virtue of their identical nature,

[163] See In re Microsoft Corp. Antitrust Litig., 333 F.3d 517, 520–21 (4th Cir. 2003).
[164] Id. at 523.
[165] Id.
[166] Id.
[167] Id.
[168] Id.
[169] Id. at 527.

emerge as the dominant standard and become difficult to displace, due to patient misperceptions about bioequivalence, physician risk-aversion, and moral hazard.

Although the appellate court in *Microsoft* never reached the merits of Microsoft's embrace and extend strategy due to an inadequate market definition, the opinion clearly articulates a convincing theory of competitive harm, which closely parallels the strategy adopted by authorized generics. Both tactics are clearly defensive leveraging behaviors that seek to hijack and tip secondary markets containing a nascent threat in order to preserve a primary monopoly.

2. Vaporware

Authorized generics may be used as a "vaporware" strategy, which has also been described as "preannouncing," "ambush marketing," and "FUD-factor marketing" (where "FUD" stands for "Fear, Uncertainty, and Doubt").[170] In *United States v. Microsoft Corp.*, "vaporware" was described as the public announcement of a product before it is ready for market, for the purpose of discouraging consumers and competitors from pursuing competing products.[171]

Vaporware announcements may deter future entrants altogether, or they may delay entry by introducing uncertainty into the Paragraph IV decision. Pioneer firms that aggressively and consistently deploy authorized generics may develop a reputation for authorized generic release, and they may use preannouncements to deter would-be ANDA IV applicants from targeting their markets. Likewise, pioneer firms that release authorized generics in a less predictable fashion may still delay ANDA IV entry by virtue of their erratic behavior. In other words, pioneer firms that regularly make vaporware preannouncements but do not regularly follow through may generate a guessing game among ANDAs as they try to assess the likelihood of actual authorized generic entry, its precise timing, and the resulting competitive environment they would face upon their own Paragraph IV entry. This uncertainty intro-

[170] See Robert Prentice, Vaporware: Imaginary High-Tech Products and Real Antitrust Liability in a Post-Chicago World, 57 Ohio St. L.J. 1163, 1172–73 (1996).

[171] 56 F.3d 1448, 1453 (D.C. Cir. 1995).

duces an additional variable into the entry decision, the result of which is likely to create delays as cautious entrants engage in additional market surveillance to make a more informed decision prior to Paragraph IV filing.

The potential impact of such product preannouncements is not insignificant, given the nature of the pharmaceutical industry. ANDA IV applicants already face significant uncertainty in their Paragraph IV decision. They must face the uncertainty of the race to file, and even if they succeed, they then face the uncertainties of patent litigation. Assuming they prevail in court, even the most thorough ANDA IV entrants will still remain uncertain of the potential profits that await them. The market that existed at the time of their entry decision may be unrecognizable compared to the market that exists at the conclusion of Paragraph IV litigation and actual market entry. This is because significant time will have passed between the initial entry decision and actual market entry, typically at least thirty months.[172] Industry experts have estimated that the generic drug development process can take three to five years, with drug formulation requiring six to eighteen months, bioequivalence testing another six to twelve months, and FDA approval an additional eighteen to thirty months.[173] During this substantial intervening time period, market circumstances may change drastically for the worse. Perhaps the greatest concern is that creative destruction may occur and destroy an initially attractive blockbuster drug market. A recent study of the pharmaceutical industry examined the effects of within-patent competition (generic entry) and between-patent competition (newly discovered drugs) and found that "between-patent competition accounts for at least as much erosion of innovator returns as within-patent competition caused by patent expiration, and often considerably more."[174] Creative destruction is one of the rare instances in which a pioneer and generic drug firm have mutually aligned interests; both firms hope

[172] See FTC Generic Drug Study, supra note 13, at iii ("Thirty months historically has approximated the time required for FDA review and approval of the paragraph IV ANDAs of generic applicants that were not sued, and for district and appellate court resolutions of ANDA-related patent infringement litigation.").

[173] See Christopher-Paul Milne & Catherine Cairns, Generic Drug Regulation in the US Under the Hatch-Waxman Act, 1 Pharmaceutical Dev. & Reg. 11, 12 (2003).

[174] Tomas J. Philipson & Carolanne Dai, Between- vs. Within-Patent Competition, Reg., Fall 2003, at 42, 43.

that the specific drug remains a dominant market player that will not be displaced by a newer, better drug. However, if such creative destruction does occur, to the extent that any rents remain available in that market, they are likely to be absorbed by the authorized generic, which invariably enjoys first-mover advantage.

Thus, authorized generics may be used as vaporware either to deter Paragraph IV entry altogether or to complicate and delay the entry decision by introducing additional uncertainty. The potential for creative destruction to fundamentally alter the market and render entry decisions unprofitable always lurks in the background. The virtual guarantee that authorized generics can move first to absorb whatever leftover sales may remain after creative destruction occurs will tend to further deter or delay ANDA IV entry.

3. Liggett Generic Cigarettes

Authorized generics also resemble the competitive strategy previously challenged in *Brooke Group v. Brown & Williamson Tobacco*.[175] There, Liggett had introduced a line of black and white generic cigarettes, priced roughly thirty percent lower than branded cigarettes, and achieved significant success in attracting price-sensitive customers at the expense of brand-name competitors.[176] Brown & Williamson responded by introducing its own generic. Like generic drugs, the generic cigarettes were "more or less fungible," so "wholesalers had little incentive to carry more than one line."[177] Liggett accused Brown & Williamson of predatory pricing, and their theory of competitive injury involved a complex chain of events, in which they alleged that Brown & Williamson engaged in predatory price wars that forced Liggett to raise its generic prices, until a narrowing price gap between branded and generics "would make generics less appealing to the consumer, thus slowing the growth of the economy segment and reducing cannibalization of branded sales."[178] Ultimately, the Supreme Court rejected the predatory theory in part because the recoupment mechanism would have required "conscious parallelism of oligop-

[175] 509 U.S. 209, 212 (1993).
[176] Id. at 214.
[177] See id. at 215.
[178] Id. at 230–31.

oly" relying upon "uncertain and ambiguous signals to achieve concerted action."[179] The Court thought this was an infeasible strategy, expressing doubt that Brown & Williamson could recoup their losses incurred during predatory pricing. Accordingly, the Court did not find an anticompetitive threat.

Authorized generics, by contrast, are quite similar to the theory of competitive harm alleged by Liggett, but even more likely to succeed. Both industries exhibit fungible generic products in which retailers stock only one version. Although Liggett alleged predatory pricing, and authorized generics act instead by raising rivals' costs, the net result is potentially the same. The victim must raise prices in order to maintain profit margins, which decreases its primary low-cost appeal to consumers, allowing the branded segment to recapture market share. More importantly, authorized generics do not require complex oligopoly signaling for the strategy to be worthwhile. As a result, authorized generics are more capable of imposing anticompetitive harm than their generic cigarette counterparts.

Thus, both antitrust theory and case law support the notion that authorized generics are an anticompetitive strategic behavior designed to undermine Paragraph IV incentives and suppress generic competition. Examining the Hatch-Waxman Act and patent laws will also reveal that authorized generics are normatively and doctrinally inconsistent with both regimes.

VI. HATCH-WAXMAN NORMS

Examining the structure and legislative history of the Hatch-Waxman Act provides further normative support to corroborate the antitrust analysis set forth above. Hatch-Waxman was a delicate compromise between the pioneer and generic segments of the pharmaceutical industry: Title I provides pro-generic concessions while Title II is pro-pioneer.

Authorized generics manufacturers, with their divide and conquer strategy to deter Paragraph IV entry, clearly undermine the original intent of Title I, which was designed to accelerate generic market entry. The reduced bioequivalence threshold, which allows generics to rely on pioneers' clinical trials, was clearly intended to

[179] Id. at 227.

reduce the time and money required for generic entry. Likewise, the research exemptions, Paragraph IV entry, and 180-day exclusivity were all attempts to facilitate earlier generic market entry to benefit consumers.

Examining the legislative history provides specific support for these general observations. The House Report indicates that the regulatory regime prior to Hatch-Waxman "had serious anticompetitive effects" because it created the "practical extension of the monopoly position of the patent holder beyond the expiration of the patent," in large part because of the "enormous expenditures of money for duplicative tests."[180] Likewise, authorized generics also present serious anticompetitive effects, because the divide and conquer strategy seeks to extend monopolies by deterring paragraph IV entry. Whereas the pre-Hatch-Waxman regime required enormous expenditures for duplicative clinical trials for generics to gain market entry, authorized generics impose enormous advertising expenses on generics who hope to gain market share. Thus, by prolonging drug patent monopolies and increasing costs for generic competitors, authorized generics reintroduce previous problems which Hatch-Waxman was purposely designed to overcome.

Because authorized generics defy the pro-generic provisions of Title I, any justification for the authorized generics strategy must be found within Title II of the Hatch-Waxman Act, which provides for patent term extension to compensate for FDA regulatory delay.[181] The basic premise was that in return for suffering the prospect of cheaper and accelerated generic market entry, the government would reward pioneers with patent term restoration to offset losses caused by FDA regulatory delay. However, a close examination of the relevant provisions and their legislative history suggests that the intent of the patent term restoration provisions was to avoid *penalizing* pioneer firms for government *inaction* that was *beyond* the pioneer's control. In contrast, authorized generics represent unilateral attempts to extend patent monopolies; condoning them would *reward* strategic *action* that is *within* the pioneer's con-

[180] H.R. Rep. No. 98-857, pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2688.

[181] See generally 35 U.S.C. § 156 (2000).

trol. Specifically, the legislative history reveals that Title II places "several limits on the period of patent extension."[182] Many of these limits simply state that the cumulative total of patent term restoration is subject to absolute caps and may not exceed a certain number of years.[183] More importantly, the legislative history indicates that "any time that the product's manufacturer did not act with due diligence during the regulatory review period would be subtracted" from the patent term restoration.[184] Taken together, these observations suggest a very cautious approach to patent term restoration, as Congress deliberately placed absolute caps on patent term restorations and only awarded them when regulatory delay was caused by *unintentional government inaction.* In contrast, authorized generics represent intentional action by private actors to extend their drug monopolies indefinitely.

Ultimately, discerning Hatch-Waxman's legislative intent is an ambiguous exercise, and it is likely that none of its drafters ever contemplated the concept of authorized generics. However, the legislative history supports numerous inferences that suggest that authorized generics contravene the original purpose of the legislation. At the very least, the entry of authorized generics into the market shifts the delicate balance originally achieved by the Hatch-Waxman Act and warrants serious attention regarding whether such behavior violates the statute. On balance, the legislative history, when combined with antitrust and patent law analyses, suggests a potential need for statutory reform.

VII. PATENT LAW NORMS

A. The Nexus Requirement: The Proper Role of Business Acumen

In addition to violating antitrust and Hatch-Waxman norms, authorized generics also conflict with well-established patent law doctrine and statutory amendments. There is a tension between the patent and antitrust laws regarding the appropriate role of business

[182] H.R. Rep. No. 98-857, pt.1, at 15 (1984).

[183] See id. ("First, the period of extension may not exceed two years for products either currently being tested or awaiting approval . . . . Second, the period of patent extension when added to the patent time left after approval of the product may not exceed fourteen years.").

[184] Id.

acumen and commercial success. In *United States v. Grinnell Corp.*, the Supreme Court offered the following statement of monopolization:

> The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, *business acumen*, or historic accident.[185]

In other words, under the antitrust laws, the acquisition or maintenance of monopoly is acceptable if it is the consequence of superior business acumen.

Conversely, the patent law suggests that business acumen is *not* an acceptable justification for obtaining a patent monopoly. Coincidentally, in the same year as *Grinnell*, the Supreme Court decided *Graham v. John Deere Co.*, articulating the "*Graham* factors" for assessing nonobviousness.[186] The Court stated that "[s]uch secondary considerations as *commercial success*, long felt but unsolved needs, failure of others, etc." could serve as relevant indicia of nonobviousness.[187] For a secondary consideration such as commercial success to reflect nonobviousness, there must first be a "nexus" between the commercial success and the technical merits of the claimed invention.[188] Thus, the nexus requirement reflects the judgment that patent law only rewards monopolies for technical innovation rather than business acumen. The important underlying policy implication is that if a claimed invention is obvious, then it is not patentable and lies within the public domain, and applicants cannot monopolize this public domain simply by using superior business acumen to generate commercial success. This inherent tension between antitrust, which privileges monopoly power acquired through business acumen, and patent law, which prohibits patent monopolies obtained through business acumen, becomes crucial when evaluating authorized generics, which are essentially the use of business acumen to prolong drug monopolies.

[185] 384 U.S. 563, 570–71 (1966) (emphasis added).
[186] 383 U.S. 1, 17–18 (1966).
[187] Id. (emphasis added).
[188] Roger E. Schechter & John R. Thomas, Principles of Patent Law 163–64 (2004).

The historically questionable validity of pharmaceutical patents renders the obviousness inquiry and its nexus requirement especially relevant. Generic challengers typically prevail in seventy-three percent of Hatch-Waxman Paragraph IV patent litigations, with many of these drug patents presumably being found invalid.[189] Moreover, "nonobviousness is the most significant hurdle to patentability," and therefore obviousness is the most commonly asserted validity defense raised by accused infringers.[190] Taken together, these observations suggest that a significant percentage of invalidated pharmaceutical patents will fail for obviousness reasons. Because patent law prohibits the use of business acumen to *obtain* patent monopolies on obvious inventions, by logical extension the antitrust law should prohibit the use of business acumen to *prolong* drug monopolies, especially in light of their frequent invalidation on obviousness grounds.

Superimposed upon this inherent tension between the antitrust and patent laws is the Hatch-Waxman regime, which reinforces the notion that business acumen should not be used to prolong patent monopolies. Provisions such as the bioequivalence standard and research exemption were designed to eliminate previous de facto monopoly extensions caused by regulatory delay. If patent extensions caused by unintentional regulatory delay were undesirable, then the intentional use of predatory business acumen to achieve the same result is an equally undesirable departure from Hatch-Waxman's legislative intent. Furthermore, Hatch-Waxman was designed as a prolitigation statute, to encourage Paragraph IV litigation as a post-grant quality control mechanism for unmasking weak

[189] See FTC Generic Drug Study, supra note 13, at vi–vii. This statistic most likely reflects the combined effect of generic firms' adeptness in identifying and attacking weak patents, in addition to the baseline error rates by the Patent Office when issuing patents, due to its limited time and financial resources. See John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents, 26 AIPLA Q.J. 185, 205 (1998) (describing an empirical study finding that forty-six percent of litigated patents were found invalid); see also Kimberly A. Moore, Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box, 99 Mich. L. Rev. 365, 391 (2000) (finding that judges and juries invalidate patents in thirty-six percent and twenty-nine percent of cases, respectively). Assuming these statistics apply similarly to Hatch-Waxman litigation, a significant percentage of generic firms will prevail in part or whole by invalidating the asserted drug patents.

[190] Schechter & Thomas, supra note 188, at 143.

patents. Using business acumen to deter Paragraph IV entry, as authorized generics do, undermines this purpose.

Ultimately, authorized generics constitute a form of predatory business acumen that, on balance, must be condemned. Despite antitrust's suggestion that superior business acumen can immunize monopolists from antitrust liability, the patent law nexus requirement, combined with Hatch-Waxman legislative intent, provide a more convincing counterargument that the use of business acumen to prolong monopolies is improper, especially when they are derived from empirically questionable patents.

B. Submarine Patenting: The Chilling Effects of Secrecy

Authorized generics not only mimic vaporware in the antitrust context, but they potentially function like "submarine patents" in the patent context. Whereas vaporware can be used as a deterrent by regularly preannouncing a pioneer firm's authorized generics intentions, "submarine generics" may arise if a pioneer firm purposely *withholds* its authorized generics intentions. "Submarine authorized generics" could mimic submarine patents by relying on secrecy to "surface unexpectedly and take competitors by surprise" at the last minute.[191]

Submarine patents relied on continuation applications to maintain a pipeline of secret patent applications whose issuance was delayed indefinitely.[192] Applicants often amended or drafted claims to target competitors who were unaware of these pending applications. Once the patent issued, they demanded royalties from those firms already in the market, which—faced with the threat of injunction—had little choice but to pay. The result of previous submarine patenting was to "extend the effective life of patents, permit patentees to hold-up competitors who have made investments in plant capacity, and upset the settled expectations of manufacturers . . . ."[193]

Congress, in recognition of the chilling effects of submarine patents, amended the patent laws to make submarine patenting more

[191] See Mark A. Lemley & Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. Rev. 63, 79 (2004).

[192] Id.

[193] Id. at 80.

difficult. Submarine patentees relied on secrecy and the fixed nature of patent terms, which allowed them to delay issuance without sacrificing patent duration.[194] Subsequent amendments to the patent statute discouraged this strategic behavior. In 1995, Congress changed the patent term from seventeen years after issuance to twenty years from the earliest filing date.[195] As a result, every year of delayed prosecution reduces effective patent life by a year and discourages secretive continuation pipelines.[196] Additionally, in 1999, Congress provided that the great majority of patent applications would be published eighteen months after filing, in order to remove the cloak of secrecy that was necessary for submarine patenting.[197] The combined effect of these amendments was to reduce the ability and incentive to engage in submarine patenting, allowing firms to compete aggressively without fear of unanticipated patent infringement liability.

Like submarine patents, unannounced "submarine authorized generics" may have a chilling effect by introducing uncertainty that deters competitors from investing in generic entry. Generic manufacturers may be hesitant to file Paragraph IV certifications if they fear the prospect of an unannounced authorized generic surfacing at the last second and entering the market prior to the 180-day exclusivity period. Given that Congress specifically amended the patent statutes to eliminate these chilling effects in the patent context, it should also consider amending Hatch-Waxman to eliminate similar effects in the antitrust context.

VIII. POTENTIAL SOLUTIONS

There are several possible approaches to solving the authorized generics problem. Reducing the market imperfections and switch-

[194] Id.

[195] Id.; see 35 U.S.C. § 154(a)(2) (2000) ("[A] grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed . . . or, if the application contains a specific reference to an earlier filed application or applications . . . , from the date on which the earliest such application was filed.").

[196] See Lemley & Moore, supra note 191, at 80.

[197] See id.; see also 35 U.S.C. § 122(b)(1)(A) (2000) ("[E]ach application for a patent shall be published . . . promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title.").

ing costs may help alleviate the anticompetitive consequences of the divide and conquer strategy.

A. Prior Suggestions for Reform

Already, it has been suggested that the FDA require authorized generics labeling to clearly identify their brand-name connection.[198] The basic idea is that "[i]f consumers were aware that the authorized generic's product is actually the same as the brand-name product, they would be less willing to pay the premium price for the brand-name drug."[199] Ultimately, this labeling requirement could decrease pioneers' incentives to release authorized generics.[200]

Another strategy would be to reduce or even eliminate authorized generics' ability to perpetuate identical versus bioequivalent myths. Consumer education regarding bioequivalence, combined with FTC regulation of advertising, may be helpful in reducing the danger of manipulating consumer beliefs regarding generic drug *quality*. However, this could be administratively difficult, and fails to address concerns regarding generic drug *misidentification.*

Standardized drug trade dress may adequately address this misidentification concern. This approach has previously been suggested as a general remedy, but would be particularly useful in combating authorized generics. Commentators have noted that because drug trade dress is socially useful in identifying medications, "[s]tandardization of trade-dress for a dosage and medication is beneficial because it allows both patients and health care workers to identify dispensing errors and reduces the probability of the wrong medicine or dosage being administered."[201] In addition to these medical benefits, standardization could be particularly helpful for protecting generic competition, because it would eliminate

[198] See Beth Understahl, Note, Authorized Generics: Careful Balance Undone, 16 Fordham Intell. Prop. Media & Ent. L.J. 355, 391–92 (2005).

[199] Id. at 392.

[200] See id.

[201] Church & Ware, supra note 79, at 10. See also SK&F, Co., v. Premo Pharm. Labs., Inc., 625 F.2d 1055, 1060 (3d Cir. 1980) (quoting the affidavit of pharmacist Edward Stemple: "I believe it is exceptionally important that all drug products of the same ingredients and strengths have the same color, size, and shape so that there is a standard means of identifying the drug product").

many of the patient switching costs currently targeted and exploited by authorized generics. Mandatory standardization is logical, because these trade-dress-induced switching costs provide no offsetting social value.[202] The useful signaling and informational value of drug trade dress "arises only because the brand of the innovator is the only one available during the tenure of the patent, not because of any innovative effort" by the patentee.[203] Since all FDA-approved generic drugs are bioequivalent and fungible, the "social value of product differentiation, certainly in many if not all cases, is not worth the cost of market power associated with intellectual property rights in trade-dress."[204] These arguments are particularly persuasive in the authorized generics context, where trade dress concerns become the source of switching costs, which undermine the competitive stance of Paragraph IV entrants. If all generic drug pills were required by law to mimic the brand-name drug in terms of size, shape, and color, this would eliminate the use of drug misidentification as an anticompetitive strategy.

There is case law that supports this approach. In *Shire US, Inc. v. Barr Laboratories*, the Third Circuit allowed a generic manufacturer of ADHD medicine to mimic the pioneer's drug pill trade dress, holding that the trade dress was functional and thus ineligible for protection.[205] The court noted the two tests for functionality. First, trade dress is functional and cannot serve as a trademark if it is "essential to the use or purpose of the article or if it affects the cost or quality of the article."[206] Second, functionality exists where the exclusive use of a feature "would put competitors at a significant non-reputation-related disadvantage."[207] Noting that ADHD patients overuse visual cues, the district court recognized—and the Third Circuit affirmed—that generic pills with similar visual recognition properties conferred a "substantial degree of clinical functionality."[208] Therefore, the drug trade dress was held to be functional and unprotected, because the "generic drug's similar

[202] See Church & Ware, supra note 79, at 11.
[203] Id. at 12.
[204] Id.
[205] 329 F.3d 348, 359 (3d Cir. 2003).
[206] Id. at 354 (internal citations omitted).
[207] Id. (internal citations omitted).
[208] Id.

appearance to the branded product enhance[s] patient safety and compliance with the medically prescribed dosing regimen."[209] Extending this concept universally to all generic drugs would serve the twin purposes of enhancing patient safety and eliminating anticompetitive exploitation of trade dress, and therefore merits serious consideration.

B. New Suggestions for Reform

Ultimately, an effective solution must simultaneously address both generic drug quality and misidentification concerns. Labeling and trade-dress standardization only resolve misidentification concerns and do not alleviate patients' skepticism regarding generic drug quality. It remains unclear whether consumer education and/or FTC advertising regulations can unseat consumers' deeply entrenched irrational beliefs that bioequivalent generics are of inferior quality.

Therefore, the most comprehensive solution must go beyond mere trade dress and educational considerations. Ultimately, lawmakers should consider the possibility of Hatch-Waxman reform to prohibit authorized generic entry during the 180-day exclusivity period. An encouraging development has been the recent introduction of bills seeking to ban authorized generics during the exclusivity period, sponsored by a number of Senators whose Democratic party now holds the majority in Congress.[210] Expanding 180-day exclusivity to prohibit entry by any firm except the Paragraph IV generic would effectively eliminate authorized generics as an anticompetitive strategy. This would assure potential ANDA IV applicants of first-mover advantages and an adequate economic prize in return for bearing the risks and costs of patent litigation. Combined with standardized trade dress, absolute 180-day exclusivity would allow the ANDA IV generic to establish a foothold in the marketplace and presumably reduce consumer fears regarding bioequivalent generic quality and misidentification.

However, authorized generics should remain legal in two scenarios. First, they should be allowed to enter the market upon expira-

[209] Id. at 355 (internal citations omitted).

[210] See Fair Prescription Drug Competition Act, S. 438, 110th Cong. (2007); S. 3695, 109th Cong. (2006).

tion of the exclusivity period. After this time, authorized generic entry would increase price competition and be less capable of manipulating consumer beliefs regarding generic drug quality and identification because the ANDA IV generic will have presumably gained consumer acceptance during its 180-day exclusivity period. Second, as a related corollary to absolute 180-day exclusivity, authorized generics should be prohibited only after an ANDA IV application has been filed. In other words, authorized generics should be banned as a strategic *response* to impending Paragraph IV entry but should be allowed in their absence or after 180-day exclusivity expiration. In the unlikely event that a pioneer firm should choose to release an authorized generic absent the threat of Paragraph IV entry, the law should allow this, because it accomplishes the same outcome as Paragraph IV entry: earlier consumer access to cheaper generic drugs. However, to safeguard against the strategic use of "vaporware" authorized generics *prior* to ANDA IV filings as an entry deterrent, it may be helpful to institute a predetermined time window during which a pioneer can decide to release an authorized generic prior to any ANDA IV filings. Subjecting authorized generics to such a fixed-window requirement, in combination with an industry-wide public notification scheme, would simultaneously eliminate the possibility of vaporware or submarine authorized generics, allowing ANDA IV applicants to plan their entry decision with maximal certainty.

CONCLUSION

Authorized generics operate at the intersection of the antitrust, patent, and Hatch-Waxman regimes. Antitrust theory and case law suggest that the divide and conquer approach constitutes predatory behavior that is anticompetitive in both intent and operation and should be condemned. This conclusion is corroborated by normative and doctrinal support found within the Hatch-Waxman and patent law regimes.

Given the historically questionable nature of pharmaceutical patents tested by Hatch-Waxman litigation and previous patterns of exploitation and abuse of this system, continuing scrutiny of strategic behavior in this context remains critically important. This is particularly true given the unique interaction between pharmaceutical supply chain economics and market imperfections such as

consumer irrationality, physician risk aversion, and moral hazard. These forces interact in a way to render the pharmaceutical market susceptible to strategic manipulations that threaten the original intent and operation of the Hatch-Waxman system, particularly with respect to Paragraph IV entry. To prevent this outcome, Hatch-Waxman should be revised to prohibit authorized generics during the 180-day exclusivity period, and standardized drug trade dress should be required by law.