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DR. STRANGE DRUG, OR: HOW I LEARNED TO STOP WORRYING AND LOVE AUTHORIZED GENERICS
John M. Rebman*

INTRODUCTION

An "authorized generic" is chemically identical to the brand-name drug product, but authorized by the brand-name manufacturer to be marketed in a generic version. The brand-name manufacturer either sells the authorized generic through a subsidiary or licenses it to another independent generic company. The practice has generated considerable debate within the pharmaceutical industry and drawn the attention of Congress and government regulators.

The controversy stems from certain provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, which regulates the entry and approval of both brand-name and generic pharmaceuticals. One of the primary purposes of the Act is to encourage generic entry into the market after patent expiration and through patent validity challenges. Under certain circumstances, the first generic entrant is awarded a 180-day marketing exclusivity period as an economic reward. Because the authorized generic ordinarily enters the market during this exclusivity period, controversy has arisen concerning the legality and competitive effects of the new market entrant.

Proponents argue that authorized generics are a legal practice that benefits consumers with increased competition. The argument

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1 Agency Information Collection Activities; Comment Request, 71 Fed. Reg. 16779, 16780 (Apr. 4, 2006).
2 Id.
4 See In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 901 (6th Cir. 2003).
5 See 21 U.S.C.A § 355(j)(5)(B)(iv) (Supp. 2007). This period is exclusive in the sense that no later generic applicant may enter the market; however, the brand-name pharmaceutical remains in the market. See infra notes 35–37 and accompanying text. See also infra note 35 and accompanying text (describing three other situations where this exclusivity period is shared between generic manufacturers).
6 See Richard E. Coe and M. Howard Morse, Authorized Generics Are Good for You: Competition from drug pioneers shouldn't trouble the FTC, LEGAL TIMES, Apr. 10, 2006, at 37 ("There is little doubt that authorized generics benefit consumers by
stems from the fact that authorized generics increase competition in a period of exclusivity, which may, in turn, lower the short-term prices of the drugs. Opponents, however, argue that authorized generics exploit loopholes in the Hatch-Waxman Act and likely violate antitrust laws. The critics, particularly the Generic Pharmaceutical Association ("GPhA"), further speculate that the sale of authorized generics during the exclusivity period "reduces the value of the 180-day exclusivity" and diminishes the incentives for generic entry.

The courts have thus far upheld the legality of the practice under Hatch-Waxman; however, commentators and opponents of authorized generics have suggested that the practice is anti-competitive and harms consumer welfare. As a result, the critics have encouraged driving down prices for generic drugs. They are legal under the current regulatory scheme, and the suggestion that their introduction somehow violates antitrust law is baseless."

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7 David A. Balto, We'll Sell Generics Too: Innovator drug makers are gaming the regulatory system and harming competition, LEGAL TIMES, Mar. 20, 2006, at 39.
9 This article will only address the competitive and economic policy issues associated with authorized generics and omit an antitrust analysis. By addressing the competitive and economic policy issues, this article will, by necessity, provide an antitrust policy analysis; however it will omit an analysis detailing how current antitrust law does not prevent the use of authorized generics. There are many theories under Section 1 and Section 2 of the Sherman Act, as well as state law trade practices claims, which could be brought to bear. See, e.g. Mylan Pharmaceuticals, Inc. v. Procter & Gamble Co., Plaintiff’s Sec. Amended Complaint, Case No. CGC-04-429860 (Cal. Super. Ct. 2004) (alleging fraudulent business practices violations); SmithKline Beecham Corp. v. Apotex Corp., 383 F. Supp. 2d 686 (E.D. Pa. 2004) (alleging antitrust violations and tortious interference); Eon Labs Mfg., Inc. v. Watson Pharmaceuticals, Inc., 164 F. Supp. 2d 350 (S.D.N.Y. 2001) (alleging violations of the Sherman Act, Lanham Act, and state deceptive practices statute); Thomas Chen, Authorized Generics: A Prescription for Hatch-Waxman Reform, 93 VA. L. REv. 459, 471-502 (2007). Antitrust law, however, recognizes that price competition benefits consumers and has restricted competitor’s ability to make predatory pricing claims when the goods are sold above cost. See Coe & Morse, supra note 6 at 1. The allegation that the mere introduction of a product can be predatory has long been rejected. Id. FTC Commissioner Jon has publicly stated that he is not persuaded by the arguments that authorized generics violate antitrust laws. Jon Leibowitz, Comm’r, Fed. Trade Comm’n, Health Care and the FTC: The Agency as Prosecutor and Policy Wonk, Remarks at the Antitrust in HealthCare Conference (May 12, 2005) available at http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf. For a further criticism of the antitrust allegations, see Mike Cowie and Melissa K. Jensen, Misguided Attempts to Restrict Competition From Authorized Generics Drugs,
Congress to propose legislation and for the Federal Trade Commission ("FTC") to investigate the competitive effects of authorized generics.

This Comment provides a detailed analysis of the FTC study and economic policy issues associated with authorized generics and the likely impact of previously proposed legislation and other offered "solutions." Part I briefly describes the procedural aspects of the drug approval process and the relevant provisions and history of the Hatch-Waxman Act. Part II provides a detailed discussion of the practice of authorized generics and analyzes the differing views of the legality of the practice under recent case law. Part III addresses the FTC’s recent announcement to investigate the economic impact of authorized generics. Part III specifically addresses the goals of the FTC study and the views of both the generic and brand-name manufacturers. Part IV provides an economic analysis of the short-term and long-term effects of authorized generics to demonstrate the likely outcome of the FTC study. This section argues that authorized generics ultimately benefit consumers with lower prices during the 180-day exclusivity period and that significant incentives remain for generic manufacturers to enter the market, regardless of exclusivity. Finally, Part V draws on the pro-competitive nature of the practice of authorized generics and the benefits received by consumers to demonstrate the unintended consequences that will result from any prohibition of the practice.

I. THE HATCH-WAXMAN BACKGROUND AND FRAMEWORK

A. The Previous Framework under the Original Federal Food, Drug, and Cosmetic Act

The Food and Drug Administration ("FDA") is the governing body responsible for regulation of pharmaceutical manufacturing and approval to ensure public health and safety.\(^\text{10}\) In order for a new drug to be approved by the FDA, the manufacturer must demonstrate that the pharmaceutical product is safe and effective.\(^\text{11}\) To achieve this end, Congress passed the 1962 Amendment to the Federal Food, Drug, and


\(^{11}\) Id.
Cosmetic Act ("FFDCA"), which requires the FDA to positively determine that a drug is safe before it enters commercial distribution and to consider whether new drugs are effective for the purposes for which they are intended.12

A pharmaceutical manufacturer seeking to market a new drug that has not been approved by the FDA is required by the FFDCA to submit a New Drug Application ("NDA").13 Typically, these applications are very lengthy and detailed. Among the requirements, the NDAs must include a full investigative report regarding the drug's safety and effectiveness, detailed description about the method and composition of the drug, and pertinent information about any patents which claims the drug under the NDA.14 Specifically, the application must contain "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."15

The 1962 Amendments contained no separate provisions for approval of generic versions that were identical to previously approved drugs.16 As a result, if a drug manufacturer wished to make a generic version of a brand-name drug, the generic manufacturer was forced to file its own NDA and demonstrate the safety and efficacy of the drug.17 The generic drug manufacturers were thus required to prove that the drug was safe and effective, even though the generic version was chemically identical to the previously approved brand-name drug. Additionally, a generic manufacturer possibly risked infringing the brand-name manufacturer by conducting clinical testing prior to the brand-name's patent expiration.18

The separate approval process

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14 Id.
15 Id.
17 See id. at 396–97.
18 See 35 U.S.C.A § 271 (Supp. 2007); Chen, supra note 9, 465. But see, Engelberg, supra note 17, at 396 (arguing that "it was not an act of patent infringement to make or use a patented drug solely for the purpose of seeking approval to market a generic copy of the patented drug").
proved to be unnecessary, duplicative, and expensive for the generic manufacturers.\textsuperscript{19}

The brand-name manufacturers also faced difficulties under the 1962 Amendments. Because brand-name manufacturers often obtained patents years prior to FDA approval of the drug, the effective patent term of the drug was shortened due to the lengthy approval process.\textsuperscript{20} As a result, it was more difficult for the brand-name manufacturers to recoup the significant investments made for research and development.

B. The Hatch-Waxman Act

In response to the concerns of both the brand-name and generic manufacturers, Congress enacted the Hatch-Waxman Act. The Act has been described as an effort “to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”\textsuperscript{21} In other words, the Hatch-Waxman Act was designed as a compromise to appease the conflicting viewpoints of the brand-name and generic manufacturers, striking a delicate balance.

The new framework created an efficient generic approval process to bring generic drugs to the market more quickly and increase consumer access to affordable medications. The new generic proposal known as an Abbreviated New Drug Application (“ANDA”) requires a generic manufacturer to demonstrate only that its drug is the “bioequivalent” of the previously approved brand-name drug.\textsuperscript{22} Thus, the ANDA applicant is no longer required to perform the duplicative and costly safety approval procedure previously required. Additionally, under the Hatch-Waxman Act, an ANDA applicant is


\textsuperscript{21} Abbott Labs v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds) (citations omitted).

\textsuperscript{22} See 21 U.S.C.A § 355(j) (Supp. 2007). Bioequivalence is met if the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the Orange Book-listed drug when administered at the same dosage. FTC Study, supra note 20, at 5.
able to perform the preliminary application steps without fear of a potential patent infringement action.\(^2\)

The Hatch-Waxman Act also provided brand-name manufacturers with certain favorable provisions to counter the benefits to the generic manufacturers. As noted above, the delay in the FDA approval process essentially decreased the term of the patent and made it difficult for brand-name pharmaceutical manufacturers to recoup the significant cost of research and development. To offset any delays caused by the NDA regulatory review process and increase the effective time available to recoup investments, the Hatch-Waxman Act provides for an extension of patent terms.\(^2\)

In addition to being the holder of an FDA-approved NDA, the brand-name manufacturer typically owns patents directed towards that particular drug.\(^2\) Upon approval of the NDA, the FDA lists these patents in a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” which is commonly referred to as the “Orange Book.”\(^2\) The Hatch-Waxman Act provides a unique, specialized procedure for generic manufacturers wishing to produce a brand-name’s Orange Book-listed pharmaceutical. The ANDA applicant must reference each of the Orange Book-listed patents and certify one of the following for each patent: (i) the brand-named firm has not filed any patent information; (ii) the patent has already expired; (iii) the generic manufacturer will not market the drug until after the

\(^2\) See 35 U.S.C.A § 271(e)(1) (Supp. 2007) (“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 . . . 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.”).


\(^2\) Patents provide their owner with the ability to exclude others from making, using, selling, offering to sell or importing the patented invention into United States. 35 U.S.C.A § 271(a) (Supp. 2007). While generally the term of the patent is twenty years after the patent filing date, 35 U.S.C.A § 154 (Supp. 2007), pharmaceutical patents may be extended in order to compensate for a portion of the patent term that was lost during the FDA approval procedures. 35 U.S.C.A § 156 (Supp. 2007); see supra note 24 and accompanying text. Patent owners are permitted to file a civil suit in federal court to enjoin infringers and obtain monetary damages. 35 U.S.C.A § 281 (Supp. 2007). Although issued patents enjoy a presumption of validity, accused infringers may assert that the patent is invalid or not infringed. 35 U.S.C.A § 282 (Supp. 2007). See also, John R. Thomas, Authorized Generic Pharmaceuticals: Effects on Innovation, CONGRESSIONAL RESEARCH SERVICE, at 4 n. 21 (Aug. 8, 2006)

The determination of the effective approval date of an ANDA application depends on the type of certification filed. Both Paragraph I and II ANDA certifications meeting the necessary scientific and regulatory requirements receive immediate effective approval. An ANDA certification filed under a Paragraph III application may not be approved until after the brand-name’s patent expires. The Paragraph IV certification, however, is a much more difficult approval process, whereby a court must determine issues of the validity and/or infringement of the brand-name patent.

Generic manufacturers filing a paragraph IV ANDA certification must give an opinion notice to the patentee detailing the factual and legal basis that the patent is invalid or will not be infringed. The patent owner then has forty-five days to file an action for infringement, during which time the ANDA applicant is barred from filing a declaratory judgment action. If the patentee chooses to file an action for infringement, an automatic thirty-month stay is triggered which prevents the FDA from approving the ANDA until the suit is resolved or the patent expires.

If the generic manufacturer prevails in the infringement action, they may launch their generic product with a 180-day marketing exclusivity period, during which the FDA may not approve a subsequent generic manufacturer’s ANDA application for the same drug.

28 Id. at § 355(j)(5)(B)(i).
29 Id. at § 355(j)(5)(B)(ii).
30 See id. at § 355(j)(5)(B)(iii).
31 As noted above, the patent directed towards the particular drug is typically held by the brand-name manufacturer, the holder of an FDA-approved NDA.
33 See 21 U.S.C.A § 355(j)(5)(B)(iii) (Supp. 2007). Although the generic manufacturer can perform the preliminary application and testing steps without fear of infringement, see supra, note 23 and accompanying text, the Hatch-Waxman Act provides that the filing of an ANDA is an act of infringement. See 35 U.S.C.A § 271(e)(2)(A) (Supp. 2007). This “highly artificial act of infringement” was created to enable a patentee to bring an action against the ANDA filer. Eli Lilly Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).
This exclusivity period provides an economic incentive for generic manufacturers to challenge and "design around" a brand-name company's drug product. This is an incentive to incur the expenses involved in filing such an application, trying to create a non-infringing version of the drug, and facing a likely patent infringement lawsuit from the brand-name manufacturer. Under the original Hatch-Waxman Act, the commencement of the 180-day exclusivity period could be triggered by either the first commercial sale of the generic drug by the ANDA filer or a court decision finding the patent invalid or not infringed.

In essence, the Hatch-Waxman Act was the result of negotiations between brand-name and generic pharmaceutical manufacturers. Generally speaking, it was implemented to increase competition in the pharmaceutical marketplace, by providing incentives to both generic and brand-name pharmaceutical manufacturers. Certain provisions encourage brand-name competition by rewarding the innovative efforts of brand-name manufacturers. Other provisions, of which exclusivity is but one, were enacted to increase generic competition in the pharmaceutical marketplace, thereby providing consumers with affordable access to drugs.

C. Medicare Modernization and Improvement Act

Congressional enactment of the Medicare Modernization and Improvement Act of 2003 ("Medicare Act") implemented several changes to the Hatch-Waxman framework. Of particular importance, the Medicare Act allows for multiple ANDA applicants to share the

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35 Id. at § 355(j)(5)(B)(iv); Teva, 395 F.3d at 1328. While this period is referred to as "exclusive", multiple or shared exclusivity between generic manufacturers can arise in three situations:

1) multiple generic applicants submit ANDAs with paragraph IV certifications to the same patent(s) on the same first day; 2) multiple ANDA applicants submit ANDAs with paragraph IV certifications for different dosage forms or strengths of the same innovator drug product; and 3) multiple ANDA applicants submit ANDAs with paragraph IV certifications to different listed patents for the same innovator drug product.


36 Teva, 395 F.3d at 1328 (citing FTC Study, supra note 21, at 57).


180-day exclusivity period, under certain circumstances. This Act entitles "any first applicant" to the 180 days of exclusivity. The statute further defines "first applicant" as any applicant who, on the first day on which a substantially complete application containing a paragraph IV certification is submitted, did themselves submit a substantially complete application with a paragraph IV certification. Thus, if multiple generic applicants file a "substantially complete" application with a paragraph IV certification on the same day, each applicant shares the 180-day exclusivity period.

II. AUTHORIZED GENERICS

A. The Practice of Authorized Generics

The FDA defines an authorized generic as "any marketing by an NDA holder or authorized by an NDA holder, including through a third-party distributor, of the drug product approved under the NDA in a manner equivalent to the marketing practices of holders of an approved ANDA for that drug." Thus, authorized generics are manufactured by the holder of an NDA and marketed through a subsidiary or a licensing agreement with an affiliate rather than being manufactured and marketed by an independent generic firm holding an approved ANDA.

39 See 21 U.S.C.A § 355(j)(5)(B)(iv) (Supp. 2007). Previously, ANDA applicants would literally camp outside the FDA office in order to be the first generic applicant to file after the brand-name exclusivity period. See FDA, Guidance For Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (July, 2003), at 4 available at http://www.fda.gov/cder/guidance/5710fnl.pdf. The FDA, though, adopted a policy to allow for multiple first applicants, see id. at 1, which the Medicare Act ultimately codified. The Medicare Act also provides a new, more complex set of events that trigger the 180-day exclusivity period, see 21 U.S.C.A § 355(j)(5)(D) (Supp. 2007), places restrictions on brand-name manufacturers’ thirty month stay, see id. at § 355(j)(5)(B)(iii), and provides new remedies for generic manufacturers “to obtain patent certainty,” see id. at § 355(j)(5)(C) (allowing the ANDA applicant to file a declaratory judgment action against the patentee if the patentee does not bring an infringement action within the required forty-five days).

40 Id. at § 355(j)(5)(B)(iv)(I) (emphasis added).

41 Id. at § 355(j)(5)(B)(iv)(II)(bb).

In the early 1990s, many brand-name manufacturers created subsidiaries to market their own generic copies upon expiration of the patented brand-name drug. However, due to lack of profitability, the brand-name manufacturers abandoned the practice. In recent years, though, authorized generics have reemerged. Beginning around 2003, brand-manufactures starting licensing their drugs to the generic companies; thus, reducing the expenses of starting a subsidiary and allowing for a greater return of investment. Furthermore, generics currently own a much larger share of the market than in the early 1990s and the brand-name manufacturers entered the market to capture a portion of this increased share.

This resurgence of "authorized generics" has created quite a controversy in the pharmaceutical industry. Whereas previously the authorized generics were launched upon patent expiration, now, the brand-name manufacturers, mostly through licensing agreements, generally launch the product during the 180-day exclusivity period, subsequent to Paragraph IV challenges. Because the exclusivity period only applies to ANDA applications containing Paragraph IV certifications, the Hatch-Waxman Act does not bar authorized generics issued under an NDA application from entering the market. Although, authorized generics are utilized in other less controversial situations, the primary area of concern arises with authorized generics during the exclusivity period. The opponents thus began to argue that

43 Milt Freudenheim, All About/Generic Pharmaceuticals; Now the Big Drug Makers Are Imitating Their Imitators, NEW YORK TIMES, Sept. 20, 1992 at F5. Because these generic copies were introduced after patent expiration, they competed with ANDA applications containing paragraph III certifications. See supra note 29 and accompanying text.


45 Id.

46 Id.

47 While authorized generics are primarily introduced during the exclusivity period, it is important to note that authorized generics may also be introduced at a variety of times and under differing circumstances. For example, they may be marketed after the exclusivity period has run, after patent expiration, or even in situations where no patent was awarded.

authorized generics undermine the legislative intent of the exclusivity period.

B. Recent Case Law – the FDA and Federal Courts Support Authorized Generics

Over the past few years, generic manufacturers have challenged the legality of the authorized generics before the FDA and the courts. On July 2, 2004, the FDA rejected citizen petitions submitted by Mylan Pharmaceuticals Inc. ("Mylan") and Teva Pharmaceuticals USA, Inc. ("Teva"). In its petition, Mylan requested that the FDA prohibit the marketing and distribution of authorized generics during the 180-day exclusivity period. Teva asked that the FDA (1) require the NDA holder to submit supplemental NDAs ("sNDAs") if they wish to market or distribute an authorized generic, and (2) delay approval of these sNDAs until after the exclusivity period. The FDA did not find either argument persuasive and in denying the requests found that it had no authority to delay the entry of authorized generics; and even if it did have authority, the marketing of authorized generics "appears to promote competition in the pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch-Waxman amendments." Subsequently, both Teva and Mylan filed suits against the FDA.

In Teva Pharmaceuticals Industries, Ltd. v. Crawford, the Court of Appeals for the District of Columbia agreed with the FDA that nothing in the Hatch-Waxman Act prohibits NDA holders from marketing authorized generics during the exclusivity period. Generic manufacturer Teva entered into an agreement with Purepac Pharmaceutical Co. ("Purepac"), the first ANDA applicant to challenge the patent for gabapentin, under which Purepac agreed to share the

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50 FDA Ruling, supra note 42, at 1.
51 Id.
52 See 21 U.S.C.A § 356a (Supp. 2007) (describing the circumstances under which a manufacturer is required to submit a supplemental application).
53 FDA Ruling, supra note 42, at 8. In essence, Teva's argument is identical to that of Mylan, with the end result being that an NDA holder would be prohibited from marketing or distributing authorized generics during the exclusivity period.
54 Id. at 2. The FDA also found that the Hatch-Waxman Act neither countenances delaying entry of authorized generics nor prohibits an NDA holder's use of alternative marketing practices. Id. at 3, 6.
56 Id. at 53.
exclusivity period with Teva. During the term of the agreement, Pfizer sold its own "generic" version, which was priced substantially below its brand-name version of the drug. Because this was prior to the enactment of the Deficit Reduction Act, Pfizer’s "authorized generic" competed directly under HMO formularies with Teva’s drug during the exclusivity period.

After having the FDA’s rejection of its citizen petition confirmed by the district court, Teva appealed to the Court of Appeals for the D.C. Circuit. The Court began by noting that the Hatch-Waxman Act says nothing about the marketing practices of a NDA holder. Furthermore, prior to the Hatch-Waxman Act, "nothing in the [Federal Food, Drug, and Cosmetic] Act prohibited the holder of an approved NDA from marketing a ‘brand-generic’ version of its drug" and the subsequent Hatch-Waxman Act said nothing about the practice.

According to Teva, the practice of authorized generics could not have been anticipated by Congress and thus a "functional" interpretation was needed to preserve the statutory purpose. Specifically, Teva argued that "adhering to the ‘literal’ terms of the statute would lead to an absurd result, namely, that [the Hatch-Waxman Act] grants only a ‘meaningless’ exclusivity against subsequent ANDA filers rather than a ‘commercially effective’ exclusivity that runs against the NDA holder as well."

The Court, though, reasoned that the incentive to challenge brand-name drug patents, namely the exclusivity period, is not without limitation. Rather, Congress sought to "strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market." The means chosen by Congress for this incentive to challenge patents, the Court found, was unambiguous: "The FDA may not approve a second or later ANDA . . . until 180 days after the first filer . . . begins commercially

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57 Id. at 52.  
58 Id. (internal quotes omitted).  
59 See infra note 91 and accompanying text for a discussion of the possible effects of the Deficit Reduction Act on the practice of authorized generics.  
60 Teva, 410 F.3d at 52.  
61 Id. at 53.  
62 Id.  
63 Id. at 53–54.  
64 Id. at 54.  
65 Teva, 410 F.3d at 54.  
66 Id.
marketing the drug or wins a court decision against the patent holder.”67 Thus, the practice of authorized generics does not render the exclusivity period “meaningless.”68 The Court therefore affirmed the FDA’s interpretation of the Hatch-Waxman Act concerning authorized generics.69

In Mylan Pharmaceuticals, Inc. v. FDA,70 the second and only other authorized generics case to date, the Court similarly concluded that Hatch-Waxman “does not grant the FDA the power to prohibit the marketing of authorized generics during the 180-day exclusivity period . . . .”71 After the FDA approved Mylan’s Paragraph IV ANDA application to sell a generic version of the brand name Macrobid, Procter & Gamble, the brand name manufacturer, licensed a third party to sell a competing generic version.72 According to Mylan, they lost “tens of millions” of dollars as a result of the authorized generic.73

The Fourth Circuit Court of Appeals affirmed the district court’s and FDA’s approval of authorized generics. In concluding that the 180-day exclusivity period applied only with respect to other Paragraph IV ANDA applicants, not authorized generics, the Fourth Circuit followed and approvingly cited the rationale of the D.C. Circuit.74 The Court ultimately concluded “authorized generic[s] may reduce the economic benefit of the 180 days of exclusivity awarded to the first paragraph IV ANDA applicant, [but] § 355(j)(5)(B)(iv) gives no legal basis for the FDA to prohibit the encroachment of authorized generics on that exclusivity.”75

Both these two decisions correctly decided that nothing in the language of the Hatch-Waxman Act prohibits the practice of authorized generics during the exclusivity period. The pharmaceutical manufacturers were free to, and did, license authorized generics before the enactment of the Hatch-Waxman Act,76 and “Hatch-Waxman did

67 Id.
68 Id.; see also note 35 and Section I.C. a discussion of “shared exclusivity” between multiple generic applicants under the Medicare Modernization and Improvement Act.
69 Id. at 55.
70 454 F.3d 270 (4th Cir. 2006).
71 Id. at 271.
72 Id.
73 Id. at 273.
74 Id. at 275–76.
75 Mylan, 454 F.3d at 276.
76 See supra Section II-A for a historical discussion of the practice of authorized generics.
not purport to restrain that freedom.’’ Thus, if the practice of authorized generics is to be prohibited, it must come through other means, such as legislation or FTC enforcement actions. In its ruling, however, the FDA found that the marketing of authorized generics “furthers the Hatch-Waxman objective of enhancing competition overall among drug products” and “is a long-standing, pro-competitive practice . . . .”

As a result of these decisions, much of the debate has turned on economic policy, specifically the short-term versus long-term effects. Generally speaking, the opponents argue that authorized generics deter Paragraph IV entry in the long run, while the proponents assert that authorized generics provide short-term competitive benefits, with no long-term harms. Although some empirical studies exist, the FTC has noted that there is no publicly available, comprehensive economic study; thus, the FTC has proposed to undertake such a study. This Note will discuss the information sought, as well as the concerns of the FTC study. Doing so will shed light on the previous empirical studies and demonstrate the positive competitive impact of authorized generics on the pharmaceutical market.

III. THE FTC STUDY AND CONFLICTING VIEWPOINTS

As the FDA and courts have thus far upheld the legality of authorized generics, the issue has become one of policy. Given the possible implications on consumer health care costs, in May of 2005, Senators Grassley, Leahy, and Rockefeller urged the FTC to study the competitive effects of authorized generics. The FTC responded by announcing “a study of the use, and likely short- and long-term competitive effects, of authorized generics in the prescription drug marketplace.” The study will essentially attempt to determine the extent, if any, to which the expectation of competition from authorized generics during the exclusivity period decreases the entry of generic

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77 Mylan, 454 F.3d at 276; Teva Pharmaceuticals Industries, Ltd. v. Crawford, 410 F.3d 51, 53 (D.C. Cir. 2005).
78 FDA Ruling, supra note 42, at 12–13.
79 First Notice, supra note 1, at 16780.
drugs in the market and weigh this against any short-term benefits from the increased competition—all in an effort to ultimately determine whether authorized generics benefit or harm consumers.

There are primarily four factors the FTC announced it will examine in the proposed study:

[1] actual wholesale prices (including rebates, discounts, etc.) for brand-name and generic drugs, both with and without competition from authorized generics; [2] business reasons (including profitability assessments) that support authorized generic entry; [3] factors (including product development and litigation costs) relevant to the decisions of generic firms about whether and under what circumstances to seek entry prior to patent expiration; and [4] licensing agreements with authorized generics.\(^8\)

To analyze these factors, information will be sought from approximately 80 brand-name manufacturers, 10 authorized generic companies, and 100 independent generic manufacturers.\(^3\) The study proposed to examine drug information for every NDA product that received an ANDA notification since January 1, 1999, as well as the corresponding ANDA data.\(^4\)

The notice provided a very lengthy and detailed description of the information that the FTC plans to request from pharmaceutical manufacturers in order to evaluate these factors. In brief, the information requested is as follows:

a) detailed sales, cost, and price information for NDA products, including authorized generics, and the corresponding ANDA product;

b) any documents dated after January 1, 1998 prepared or received by any senior officer concerning generic competition, generic entry, patent expiration, and license agreements;

c) IMS Health Data, if obtained in the regular course of business.\(^5\)

In order to obtain the relevant data, the FTC will issue special orders pursuant to Section 6(b) of the FTC Act\(^6\) to the brand-name,

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\(^{82}\) First Notice, supra note 1, at 16780 (emphasis added).

\(^{83}\) Id. at 16781.

\(^{84}\) Id.

\(^{85}\) Id. at 16781–82; See also, Roberti, supra note 9, at 22. IMS Health is the world's leading provider of information, research, and analysis to the pharmaceutical industry.
generic, and authorized generic companies. The FTC economists and lawyers will then analyze the data and begin to reach preliminary conclusions—such as recommending legislation or enforcement actions, or finding no harm. However, before requesting any data, the FTC invited any interested party to submit comments on the proposed study.

A. First Request for Comments

In response to the FTC’s request for comments, 13 commentators submitted written statements. Generally speaking, most of the comments agreed with the practical utility of the study; however, one commentator, speaking on behalf of an undisclosed client, argued that the recent enactment of the Deficit Reduction Act could sufficiently change the incentives to market authorized generics, rending the study virtually moot.

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87 First Notice, supra note 1, at 16780.
88 See, Roberti, supra note 9, at 22.
89 First Notice, supra note 1, at 16779.
90 See e.g., GPhA I, supra note 8, at 1 (stating that GPhA “commend[s] the FTC’s decision to issue the Study”); PhRMA Comments On Proposed Information Requests 2 (June 5, 2006), available at http://www.ftc.gov/os/comments/genericdrugstudy3/060605pharma.pdf [hereinafter PhRMA I] (noting that the study “should enhance public understanding of how authorized generics impact consumers”); Letter from Alex Sugerman-Brozan, Director, Prescription Access Litigation Project, to Office of the Secretary, Federal Trade Commission 6 (June 5, 2006), available at http://www.ftc.gov/os/comments/genericdrugstudy3/060605pal.pdf [hereinafter PAL] (stating that the “information will be particularly useful as a tool for Congress to make an informed decision on whether further legislation needs to be adopted surrounding the marketing of authorized generics”).
91 Comments on Proposed Information and Document Requests, Authorized Generic Drug Study, submitted by Ronald W. Davis 2 (June 4, 2006), available at http://www.ftc.gov/os/comments/genericdrugstudy3/060604davis.pdf [hereinafter Davis]. Although Section 6003 of the Deficit Reduction Act (“DRA”) did not specifically address authorized generics, the legislation requires a manufacturer that “approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under 505(c) of the Federal Food, Drug, and Cosmetic Act,” to include all such drugs in the manufacturer’s average manufacturer’s price [AMP] and best price, a requirement that includes authorized generics. Pub. L. No. 109–171, 120 Stat. 4 (2006) (amending Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)). Thus, DRA requires that authorized generics be included when calculating AMP and best price for Medicaid rebates. According to Davis, the effect of DRA will “fundamentally reduce the
While agreeing with the overall utility, commentators, representing both brand-name and generic manufacturers, as well as public interest groups, offered various suggestions on the scope of the information requested. Specifically, recommendations were made to limit the time period covered,\textsuperscript{92} reduce the number of drugs,\textsuperscript{93} and focus document request on those relating to authorized generics.\textsuperscript{94} Also, an unnamed generic manufacturer urged the FTC to specifically request pricing information of drugs at the \textit{retail} level.\textsuperscript{95}

Most notably about the comments received, though, were the differing views of the brand-name and generic manufacturers about the primary source of information. Brand-name manufacturers, through their organization Pharmaceutical Research and Manufacturers of America ("PhRMA"), expressed support of the use of quantitative data, rather than qualitative documents requests, to determine the effects on consumers. PhRMA asserted that pricing data and output data "will show most clearly and directly whether authorized generics have benefited consumers by increasing availability of prescription drugs at lower prices."\textsuperscript{96} Furthermore, documents relating to brand-name manufacturers subjective future plans are not well suited to assess the incentives of branded firms to introduce authorized generics." Davis, \textit{supra} note 91, at 3. There may be some support for this argument. \textit{See} Christopher Stromberg, \textit{Will Medicaid Reform Affect Brand-Name Manufacturers' Choices to Market Authorized Generic Versions of Their Drugs}, 20 \textit{ANTITRUST HEALTH CARE CHRONICLE} 2 (2006) (providing an in depth analysis of possible effects of DRA and its impact on the economic viability of authorized generics). The FTC though, found that the inclusion of authorized generics in the best price calculation is unlikely to decrease revenues for authorized generics in most cases. \textit{Agency Information Collection Activities; Comment Request}, 72 Fed. Reg. 25304, 25308–10 (May 4, 2007) [hereinafter Second Notice].

\textsuperscript{92} \textit{See} \textit{GPhA I, supra} note 8, at 4 n. 5; \textit{Letter from William M. Rubenstein, Actavis Group, to Office of the Secretary, Federal Trade Commission 2} (June 5, 2006) \textit{available at} http://www.ftc.gov/os/comments/genericdrugstudy3/060605actavisgroup.pdf [hereinafter Actavis].

\textsuperscript{93} \textit{See} \textit{Actavis, supra} note 92, at 2–3; Davis, \textit{supra} note XX, at 91.

\textsuperscript{94} \textit{See} \textit{PhRMA I, supra} note 90, at 8; \textit{Actavis, supra} note 92, at 2–3.

\textsuperscript{95} \textit{Letter from Tim Gilbert, Gilbert's LLP, to Office of the Secretary, Federal Trade Commission 3} (June 5, 2006) \textit{available at} http://www.ftc.gov/os/comments/genericdrugstudy3/060605gilberts.pdf. As noted above, the study had only requested pricing information on the \textit{wholesale} level. The difference between the two types of pricing data becomes especially important in performing an economic analysis of the impact of authorized generics. \textit{See, infra} Part IV.B.

\textsuperscript{96} \textit{PhRMA I, supra} note 90, at 2–3.
impact of authorized generics on the market and "are of little utility for a long-term empirical study." The support for quantitative data was further reiterated by Eli Lilly and Company.

Generic manufacturers (and some public interest groups), on the other hand, stressed the importance of, and need for, qualitative information. The evaluative decision concerning generic entry with Paragraph IV filings is typically a three-to-seven year proposition. As authorized generics only began to resurface around 2003, the decision to market a generic was made before authorized generics became so prevalent. Thus, GPhA argues, the quantitative data requested will not fully demonstrate the effects that authorized generics have on generic entry. While recognizing the usefulness the quantitative data, GPhA stressed the need for evidence of the decision-making processes of both generic and brand-name manufacturers.

B. Second Request for Comments

In response to the submitted comments, the FTC amended the study and issued a second notice and request for further comments. The FTC accepted the numerous recommendations to limit the scope; specifically, they reduced the number of drugs and time period covered and focused the document request on those relating to authorized generics only.

97 Id. at 3.
98 Letter from Robert A. Armitage, Senior Vice President and General Counsel, Eli Lilly and Company, to Office of the Secretary, Federal Trade Commission 1 (June 5, 2006) available at http://www.ftc.gov/os/comments/genericdrugstudy3/0606051illy.pdf [hereinafter Lilly] (supporting the comments of PhRMA as to the need to tailor the information requests to the objectives of the study).
99 GPhA I, supra note 8, at 4.
100 Id.
101 Id.; see also, Letter from David A. Balto, on behalf of the American Antitrust Institute, Consumer Federation of America, Families USA, and US PIRG, to Donald S. Clark, Secretary, Federal Trade Commission 6 (June 6, 2006) available at http://www.ftc.gov/os/comments/genericdrugstudy3/060606balto.pdf [hereinafter Balto] ("Authorized generics began only 2 years ago. Since the decision by a generic firm to enter is typically made several years before entry, the more significant long-term effects will not be identified by current quantitative data.").
102 GPhA I, supra note 8, at 4–5. In addition to stressing the importance of qualitative data, GPhA and other commentators suggested that the FTC hold hearings to gain more insight into the decision-making process and to evaluate the long-term competitive effects of authorized generics. Id. at 6–7; Balto, supra note 101, at 6; PAL, supra note 90, at 6.
generics.\textsuperscript{103} Notably, the FTC accepted the invitation to request pricing data at the retail level, in addition to the previously requested wholesale data.\textsuperscript{104} However, the FTC declined to evaluate authorized generics, in conjunction with other possible strategies brand-name manufacturers might use to adversely affect generic competition, as an expansive strategy to delay generic entry.\textsuperscript{105}

The FTC expressed the need for both quantitative and qualitative data to fully analyze the short- and long-term competitive effects of authorized generics on the pharmaceutical marketplace.\textsuperscript{106} Of the quantitative data that the FTC is seeking, price data will likely show the short-term effects on consumers, whereas data on sales, market share, and return on investment are more significant in evaluating the long-term effects of authorized generics on generic manufacturers’ incentives to file ANDAs and challenge patents.\textsuperscript{107} The number of recent filings of Paragraph IV certifications should also be relevant to the long-term effects.\textsuperscript{108} However, the FTC noted, qualitative information is also essential to assess the long-term impact of authorized generics on generic manufacturers’ decisions to file Paragraph IV certifications.\textsuperscript{109} Generic manufacturer documents are necessary to understand how authorized generics actually affect generic manufacturers’ decision-making.\textsuperscript{110} According to the FTC, brand-name manufacturer documents could “further elucidate the likely effects of authorized generics on generic company decisions to challenge patents, and aid in the interpretation of the quantitative data.”\textsuperscript{111}

One of the previous commentators, PhRMA, responded to the Second Notice, primarily asserting their arguments in opposition to the practical utility of document requests. PhRMA reiterated its previous position that the study should focus on quantitative data and that brand-name company documents will not be of any practical utility to the

\textsuperscript{103} Second Notice, \textit{supra} note 91, at 25308–10.
\textsuperscript{104} \textit{Id.} at 25311. In order to evaluate the retail level prices, the FTC will obtain the data directly from IMS. \textit{Id.}
\textsuperscript{105} \textit{Id.} at 25312.
\textsuperscript{106} \textit{Id.} at 25310.
\textsuperscript{107} \textit{Id.}
\textsuperscript{108} Second Notice, \textit{supra} note 91, at 25310. The diminishing number of brand products available for Paragraph IV challenges will also be taken into account when analyzing the current trends in Paragraph IV filings. \textit{Id.} at 25312.
\textsuperscript{109} \textit{Id.} at 25310.
\textsuperscript{110} \textit{Id.} at 25311. The generic company documents requested will be those prepared before the First Notice for this study was published. \textit{Id.} at 25310.
\textsuperscript{111} \textit{Id.} at 25311.
The brand-name company documents about generic entry decisions are "pure speculation" and will not "reliably show whether generic drug company entry has become unprofitable as a result of authorized generics."113

GPhA and Gilbert's, representing a generic manufacturer, also each submitted a second set of comments about the study, primarily arguing generally against the practice of authorized generics. GPhA asserted that most authorized generic licensing agreements provide that the authorized generic may not be marketed until after a generic has been approved (i.e. during the exclusivity period).114 According to Gilbert's, when authorized generics are permitted, brand-name manufacturers are essentially being rewarded for invalid or non-infringed patents during the exclusivity period, because the brand-name manufacturer prevents generic entry and competition and benefits from inappropriate monopoly prices.115 Thus, GPhA argues, brand-name firms are intentionally diminishing generic incentives and therefore "more brand-name patents will go unchallenged (because the value of the diluted exclusivity makes patent challenges less cost effective), generic competition will be diminished, and consumers will be denied lower-cost generic drugs."116

In addition to asserting arguments against authorized generics, GPhA detailed the level of involvement of generic manufacturers in the pharmaceutical industry. Generic drugs account for over 56% percent of all prescriptions filed.117 Much of this generic entry is likely the

113 Id. at 6–8.
115 Letter from Tim Gilbert, Gilbert's LLP, to Office of the Secretary, Federal Trade Commission 2 (June 4, 2007) available at http://www.ftc.gov/os/comments/genericdrugstudy3/529613-00004.pdf [hereinafter Gilbert's II] (asserting that while the brand-name manufacturer is being rewarded, the generic manufacturer is being punished for exposing the invalid patent).
116 GPhA II, supra note 114, at 3.
117 Id. at 2. GPhA reported on their website that generics account for 63 percent of all prescriptions dispensed. GPhA Statistics, http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm.
result of the enactment of the Hatch-Waxman Act. Furthermore, an estimated $78 billion in pharmaceutical sales are expected to go off-patent in the next few years.118 Thus, GPhA argues, generics play a significant role in health care savings.119

C. Concluding Observations

Based on commentator’s suggestions and the FTC responses, certain conclusions can be drawn regarding the factors to be used in evaluating the effects of authorized generics. The business decisions of both brand-name and generic manufacturers are important in determining the reasons for both generic and authorized generic entry.120 Company documents from the manufacturers will primarily be used in evaluating this factor. Secondly, the short-term effects on consumers must be determined using both wholesale and retail pricing data.121 Finally, sales, market share, and return on investment data must be analyzed to determine the long-term competitive impact of authorized generics.

118 See GPhAII, supra 114, at 2.
119 Id.
120 For generic entry, this also includes an assessment of “whether and to what extent consumers benefit from the accelerated generic entry due to patent challenges; whether 180-day exclusivity undermines those benefits by delaying competition; and whether 180-day exclusivity is a necessary incentive for generic companies to undertake patent challenges.” Second Notice, supra note 91, at 25312. An evaluation of the exclusivity period is especially important when analyzing the alleged reduction in generic incentives. Authorized generic entry will also be compared and contrasted with shared exclusivity. Id.
121 It is unclear which, if any, of the pricing data will be more heavily weighted. Interestingly, in the First Notice, the FTC only requested wholesale prices. It is also the position of a PhRMA supported study that economists, including the FTC, prefer the use of wholesale prices in determining competitive effects. See infra note 144 and accompanying text.
IV. COMPETITIVE IMPACT—A QUALITATIVE AND QUANTITATIVE ECONOMIC POLICY ANALYSIS

This Note has previously established the factors needed to evaluate the likely impact of authorized generics. This Section begins by analyzing the reasons for generic and authorized generic entry, particularly analyzing the role that exclusivity plays in generic entry. The analysis proceeds with an examination of these factors, using previous economic studies to demonstrate the likely effects of authorized generics on consumers. As the FTC noted, there is no comprehensive economic study on authorized generics; however, current studies provide an insight into the likely impact of the practice on consumers.

A. Generic and Authorized Generic Entry

1. Generic Entry and Exclusivity

Generic manufacturers have argued that authorized generics decrease the incentives to file ANDAs. Their primary assertion is that the introduction of authorized generics reduces the value of the exclusivity period. The underlying assumption of such an argument is that the exclusivity period is the primary, and necessary, incentive for generic entry. Thus, an evaluation of generic manufacturers' entry decisions would not be complete without an analysis of the degree of incentive of the 180-day exclusivity period and how it factors into the generic entry decision-making process. This was the view expressed by Eli Lilly and Co. and adopted by the FTC in their study. It has even been suggested that the 180-day exclusivity period is unnecessary as an incentive to induce generic entry and thus may even harm consumers in some situations. The FDA often sees as many as five

122 It is the goal of this Section to provide more of a summary of the differing economic studies on authorized generics, rather than a through dissecting and analysis of the studies. However, this Section will “analyze” the economic studies in light of the comments to the FTC study, and the subsequent responses. In doing so, it is the aim of this section to determine the likely competitive impact of authorized generics on the pharmaceutical market, particular the impact on consumers.

123 See Lilly, supra note 98, at 2; Second Notice, supra note 91, at 25312.

ANDAs for a single drug, even without the prospect of the exclusivity period.\textsuperscript{125} Furthermore, there is also the possibility that the exclusivity period will be “shared” with other manufacturers, thus increasing the likelihood that multiple generics will be awarded the exclusivity period.\textsuperscript{126} If multiple ANDAs are still being filed, and risking the likelihood of an expensive patent infringement suit without the possibility of exclusivity as an incentive, how can authorized generics really affect the decision of a generic to enter the market?\textsuperscript{127} These arguments are not meant to suggest that the exclusivity period should be eliminated, as there are clear benefits to the exclusivity period, particularly in smaller market drugs when fewer ANDAs are likely to be filed. However, the incentive of exclusivity is not the primary factor in generic entry and likely plays a smaller role in generic decision-making than many commentators assume.

So if the exclusivity period is not the primary reason, or maybe not even a large factor, in the decision-making process, why do generics enter the market? First and foremost, it goes without saying, that the pharmaceutical market, including generics, is profitable. As GPhA has noted, generic drugs account for approximately 63 percent of all pharmaceuticals and over $78 billion in pharmaceutical sales will go off patent in the coming years. Many consumers, and their insurers, prefer the lower cost generics to costly brand-name drugs.\textsuperscript{128} Thus, there is clearly a profitable market to enter.

\textsuperscript{125} Coe & Morse, supra note 6, at 2. The authors likely even underestimated the number of ANDA filers for many drugs. The FDA often sees as many as fourteen generic manufacturers enter the market. U.S. Food and Drug Administration, Center for Drug Evaluation and Approvals, First-Time Generics – April 2007, http://www.fda.gov/cder/ogd/approvals/1stgen0407.htm (approving fourteen applications to market generic versions of Ambien CR\textsuperscript{TM} (Zolpidem)).

\textsuperscript{126} See supra note 35 and accompanying text. Marketing an authorized generic during the exclusivity period is no different than the “shared exclusivity” between multiple generic manufacturers. If generics manufacturers are willing to file with the likelihood that exclusivity will be shared with another generic, then so too are they likely to file when an authorized generic is anticipated.

\textsuperscript{127} See Jerry Swindel, Senior Counsel, Johnson & Johnson, Whose Drug Is It Anyway? Authorized Generics, Their Role In The Pharmaceutical Marketplace, And The FTC Study, Address Before the Intellectual Property, Healthcare and Federal Civil Enforcement Committees of the American Bar Association’s Antitrust Section (Sept. 14, 2006).

\textsuperscript{128} According to GPhA, the average generic prescription drug cost $28.71, compared to $95.54 for the branded version. GPhA II, supra note 114, at 2.
One of the primary incentives, and reasons for generic entry, is the ANDA application created under the Hatch-Waxman Act. Prior to enactment, a generic manufacturer was required to conduct clinical trials to demonstrate the safety and efficacy of the drug and file its own NDA. Conducting the clinical trials and demonstrating the safety and efficacy of the drug is a lengthy, expensive process, consuming years and hundreds of millions of dollars. A study conducted in 2003 estimated an average out-of-pocket clinical period cost per approved new drug to be US$ 282 million with a capitalized cost of US$ 467 million. As a result of the Hatch-Waxman Act, the generic manufacturers need only demonstrate bioequivalence, rather than duplicate these costly clinical trials. While the cost to demonstrate bioequivalence is not insignificant, it is much less expensive than NDA clinical trials, with cost estimates for preparing and submitting an ANDA ranging from US$ 300,000 to US$ 1 million. By establishing the ANDA process, the Hatch-Waxman Act decreased a major barrier to generic entry—cost—and increased the incentives for generic manufacturers.

129 The Congressional Budget Office noted two other factors driving generic entry, namely: (1) "states had passed drug-product substitution laws that allowed pharmacists to dispense a generic drug even when the prescription called for a brand-name drug;" and (2) "government health programs, such as Medicaid, and many private health insurance plans have actively promoting such generic substitution." CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998) [hereinafter CBO Study] available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

130 Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, The Price of Innovation: New Estimates of Drug Development Costs, 22 J. HEALTH ECON. 151, 165 (2003). The study surveyed the research and development cost of 68 randomly selected new drugs to determine the average costs in 2000 dollars. Id. at 151. The capitalized cost took into account the timing of investment and returns. Id. at 160. The authors inferred from the out-of-pocket and capitalized clinical cost per new approved drug that the preclinical cost would be US$ 121 and 335 million, respectively. Id. at 166. Summing the preclinical and clinical cost estimates, the total out-of-pocket cost per approved new drug was found to be US$ 403 million, with a fully capitalized cost of US$ 802 million. Id.

131 Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003); See also David Reiffen & Michael R. Ward, Generic Drug Industry Dynamics, 87 REV. ECON. & STAT. 37, 38 (2005) [hereinafter Reiffen & Ward I] (estimating the cost of applying for an ANDA, including bioequivalency testing, to be approximately $603,000 in the early 1990s).
2. Authorized Generic Entry

In evaluating the reasons for the marketing of authorized generics, it is important to note a few important statistics about the generic pharmaceutical industry. As noted above, generics account for about 63 percent of all pharmaceuticals dispensed in the United States. This translates into sales of $58.5 billion. In recent years, the generic pharmaceutical industry has been growing at rates between 10 percent and 50 percent. When these generics enter the market, brand-name drug sales drop by as much as 80-90 percent in a matter of weeks, adversely affecting the brand-name manufacturers’ profits.

So why do brand-name manufacturers market authorized generics? In the words of a representative of a brand-name manufacturer: “Because its profitable.” As a way to retain some of the 80 to 90 percent in lost profits, brand-name manufacturers introduce authorized generics. In addition, brand-name manufacturers have spent a considerable amount of time and money for the research and development of these drugs. Authorized generics act as a means to utilize the excess capacity resulting from their investment and continue the income stream. Thus, authorized generics are particularly likely to be introduced in markets with large sales revenue, when the profits are the greatest.

By allowing brand-name firms to continue their revenue stream and utilize their excess capacity, authorized generics increase the incentives to innovate. As a matter of policy, such efforts should be encouraged. For example, a brand-name firm may invest as much as $800 million into developing an innovator drug. Many times, a monopoly is awarded, by means of patent protection, enabling the brand-name manufacturer to recoup their investment. However, if the patent on that drug is found invalid or non-infringed, and a generic enters the market, the brand-name manufacturer may lose a large percent of its pre-generic entry profits. With the authorized generic, the

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132 Generic Pharmaceutical Association Statistics, supra note 117. Although the brand-name sales account for about four times as much the generic market, $58.5 billion represents a very large market.
135 Swindel, supra note 127.
136 Id.
brand-name manufacturer is able to retain an income stream, a return on their large investment, and compete with generic entry. Because Paragraph IV certifications have been increasing rapidly in recent years, brand-name manufacturers may be fearful of abruptly losing profits on these innovator drugs. Authorized generics help quell these concerns and encourage innovation. Furthermore, as discussed below, the introduction of the authorized generic lowers prices for consumers during the exclusivity period.

B. Short-Term Effects

It is a fundamental principle of economics that increasing competition leads to lower prices. This was one of the goals driving the enactment of Hatch-Waxman: consumer access to affordable drugs by increased competition. It thus seems axiomatic that increasing competition with the introduction of authorized generics during a period of generic exclusivity will lead to lower generic drug prices in the short-term.

Two recent empirical studies, though, using the same market and data sets, reached different conclusions on the short-term effects of authorized generics on pharmaceutical prices. Both studies employed the same basic methodology: analyzing nine drug data sets, the average discount between brand-name and generic drugs in which there was authorized generic competition during the exclusivity period was compared to the average discount between brand-name and generic drugs for which there was no authorized generic. Ultimately, this comparison would be used to determine the effects of authorized generics on pharmaceutical pricing. As noted above, though, the two studies reached conflicting conclusions.

Using wholesale prices, the IMS study found as follows: when an authorized generic was present during the exclusivity period, the

137 See IMS Consulting, Assessment of Authorized Generics in the U.S. 6–7 (Spring 2006) available at http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf; Aidan Hollis & Bryan A. Liang, An Assessment of the Effect of Authorized Generics on Consumer Prices 9 (July 31, 2006) available at http://www.gphaonline.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=2647. The conflicting findings are not surprising as the IMS study was sponsored by PhRMA and the second study was sponsored by GPhA. The GPhA study was conducted by Aidan Hollis, Associate Professor of Economics at the University of Calgary, and Bryan Liang, Executive Director & Professor of Law at California Western School of Law. Id.
average discount between generic and brand was 38.8 percent; when an authorized generic was not present, however, the average discount was only 23.0 percent. 138 Comparing the two scenarios, the average wholesale discount between generic and brand was 15.8 percent greater in the scenarios when an authorized generic was present.139 Using retail prices, the Hollis & Liang study, on the other hand, found as follows: with an authorized generic marketed during the exclusivity period, the price discount for generic products averaged 20 percent over the pre-entry brand price; when an authorized generic was not present, the average discount was found to be 15 percent.140 Thus, the difference between discounts in the authorized generic sample and the no-authorized generic sample was found to be 5 percent.141 The discounts found in the IMS study are much larger than those of the Hollis & Liang study (16.8 percent compared to 5 percent). According to Hollis & Liang, one of the primary reasons for these divergent findings is IMS’s use of wholesale level price data.142

A subsequent study led by Howrey LLP antitrust partner Mike Cowie and CapAnalysis economist Oliver Grawe (and supported by PhRMA) substantiates the previous IMS study and refutes the findings of Hollis & Liang.143 Cowie & Grawe provide an extensive defense of the IMS’s use of wholesale prices and criticism of retail prices. They

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138 IMS Consulting, supra note 137, at 9–10. Wholesale prices are the costs to outlets such as pharmacies and hospitals and were used to determine savings at any level of the drug distribution channel (i.e. “savings to the healthcare system”). Id. at 7 n. 5.
139 Id. at 11.
140 Hollis & Liang, supra note 137, at 12–14.
141 Id. at 14. Hollis & Liang also calculated a volume-weighted average discount and found that the impact on price appeared to be approximately zero. Id. In another study, Professor Hollis also concluded that in the Canadian market “pseudo-generics” increase prices of both generic and brand-name drugs. Aidan Hollis, How do Brands’ “Own Generics” Affect Pharmaceutical Prices?, 27 REV. INDUS. ORG. 329, 346-348 (2005). However, because the Canadian pharmaceutical market and its regulations are very different from the United States, it is not likely to provide much guidance for the U.S. pharmaceutical market.
142 Hollis & Liang, supra note 137 at 15. According to Hollis & Liang, the retail level prices used reflect the “price[s] consumers face.” Id at 5. They also asserted a number of other criticisms of the IMS study, including the following: comparison of brand to generic prices at a given time and use of simple rather than weighted averages. Id. at 15.
allege that the use of retail prices do not actually reflect the prices consumers pay. In reaching this conclusion, Cowie & Grawe focused on the structure of the industry and Hollis & Liang’s failure to consider the role that insurance plans play in retail level pricing. While a detailed description of the pharmaceutical industry and its structure is beyond the scope of this article, it is important to note that the structure of the pharmaceutical industry plays a vital role in determining pricing and competition issues. Thus, because of the multifarious and multi-tiered aspects of the pharmaceutical industry, data sets can easily be manipulated (with regards to price level) in order to obtain the end result sought. Neither wholesale nor retail price reduction directly results in lower consumer prices. Instead, both wholesale and retail reductions result in savings to the drug distribution network, which indirectly result in consumer savings. As a result, and noted above, the FTC will investigate both wholesale and retail level prices in order to determine the effects of authorized generics.

Regardless of which price level data set (wholesale or retail) accurately measures consumer welfare, a comparison of the findings leads to the conclusion that authorized generics result in short-term generic price reductions between 5 and 17 percent. FTC

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144 Id. at 3. Furthermore, economists at both the Federal Trade Commission and the Department of Justice focus on manufacturer level prices, rather than retail. Id. at 12–14.

145 Id. at 3–9 (noting that about 85% of retail pharmacy transactions relate to insurance plans and the study’s failure to focus on expenditures borne by individuals). Insured patients merely pay a co-pay regardless of the retail price. Specifically, Cowie & Grawe allege that the retail level prices used by Hollis & Liang measured total pharmacy reimbursement. Id. at 7. The large difference in price discounts between wholesale and retail level seems to suggest problems may exist with the distributional aspects of the pharmaceutical market. It has been suggested that when analyzing the effects of authorized generics, the distributional and regulatory concerns must be addressed. See Zain, supra note 134, at 760–75.


147 Another independent study reviewed data on generic entry generally and concluded that “authorized generics benefitting consumers of drugs sold during 180-day exclusivity periods, by introducing additional competition that places downward pressure on overall generic prices.” Ernst R. Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parece, and Edward Tuttle, Authorized Generic Drugs, Price
Commissioner Leibowitz has even publicly stated that authorized generics likely benefit consumers in the short-term. Several other studies, focusing though exclusivity on the generic market, have found that the introduction of a second generic further reduces drug prices. In addition, generic manufacturers themselves have brought actions alleging that authorized generics have resulted in excessively low prices for consumers. Thus, in conclusion, authorized generics will clearly benefit consumers in the short-term by lowering either retail or wholesale prices for generic drugs during the 180-day exclusivity period.

C. Long-Term Competitive Effects on Generic Manufacturers

Authorized generics are clearly taking profits from the generics, but is this transfer of profits from one competitor to another competitor a problem? This depends on whether or not authorized generics decrease the incentives of the exclusivity period to such a degree that they delay generic entry and harm consumers. Thus, much of the controversy surrounding authorized generics turns on their likely impact on future generic entry and pharmaceutical prices. Although evaluations of their effects have been relatively limited, the available studies demonstrate that authorized generics are unlikely to deter future Paragraph IV filings and even if some filings are deterred, there will be no net harm for the consumers.

Opponents argue that authorized generics, or the threat of, reduce expected profits during the exclusivity period, which in turn reduces the incentives to file Paragraph IV certifications. Because the incentives are reduced, fewer Paragraph IV certifications will be filed, generic entry will be delayed, and consumers will pay higher prices.

\[\text{Competition, And Consumers' Welfare: On balance, authorized generics are likely to benefit consumers, 26 HEALTH AFFAIRS 790, 797 (2007) [hereinafter Berndt I].}\]

148 See, e.g., Reiffen & Ward I, supra note 131; CBO Study, supra note 129.

149 Cowie & Grawe, supra note 143, at 19; see also, supra note 9.

150 Generic entry may actually be accelerated in cases where the generic manufacturer launches an “at-risk” strategy. Under this strategy, the generic manufacturer launches the generic drug prior to resolution of the patent litigation and thus subjects itself to triple damages. John Carreyrou & Joann S. Lublin, Emergency Room: How Bristol-Myers Fumbled Defense of $4 Billion Drug, WALL ST. J., Sept. 2, 2006, at A1. This strategy was employed by Apotex when it launched an at-risk version of Plavix in 2006. Id. Thus, in some cases, the threat of authorized generics encourages generic manufacturers to enter the market earlier. See Yana Pechersky, To Achieve Closure of the Hatch-Waxman Act's Loopholes, Legislative Action is Unnecessary: Generic Manufacturers Are Able to Hold Their Own, 25 CARDOZO ARTS & ENT. L.J. 775
Generic manufacturers, though, have acknowledged that it will be difficult for any empirical study to demonstrate the impact of authorized generics on long-term generic entry.\textsuperscript{151}

The few economics studies that have been conducted thus far reached slightly conflicting conclusions. A recent study conducted by David Reiffen of the U.S. Commodity Future Trading Commission and Michael R. Ward, Associate Professor of Economics at the University of Texas, concluded that “the anticipation of [authorized] generic entry in Paragraph IV cases can dramatically change the incentives of generic firms, perhaps eliminating the incentive to litigate the validity of patents in some cases.”\textsuperscript{152} Using an economic mechanism based on an indirect approach, Reiffen and Ward determined the effects of authorized generic entry on generic prices after patent expiration.\textsuperscript{153} Applying these results to Paragraph IV cases, the authors concluded the following:

\[P\]rice changes resulting from [authorized] generics are largest in relatively small markets. Conversely, the estimates indicate that such introductions are least problematic (from the standpoint of social welfare), but most profitable in relatively large markets. As such, government policy targeting [authorized] generic entry

\textsuperscript{151}See supra notes 100–03 and accompanying text.
\textsuperscript{152}David Reiffen & Michael R. Ward, ‘Branded Generics’ as a Strategy to Limit Cannibalization of Pharmaceutical Markets, 28 MANAGE. DECIS. ECON. 251, 262 (2007) (emphasis added) [hereinafter Reiffen & Ward II]; see also, Aidan Hollis, The Anti-Competitive Effects of Brand-Controlled “Pseudo-Generics” in the Canadian Pharmaceutical Market, 29 CANADIAN PUBLIC POLICY – ANALYSE DE POLITIQUES 21 (2003) (concluding that the threat of “pseudo-generics” deters generic entry in smaller markets). As the title implies, this study was conducted in the Canadian pharmaceutical market, with deferring regulations, and thus has limited applicability to the US market. While arguments such as these have been advanced in the past, they have proven false. See Bryan A. Liang, The Anticompetitive Nature of Brand Name Firm Introduction of Generics Before Patent Expiration, 41 ANTITRUST BULLETIN 599, 634 (1996) (arguing in 1996 that change was needed “so that the generics industry [would not be] overcome” by authorized generics).
\textsuperscript{153}Reiffen & Ward II, supra note 152, at 252–53. The impact of authorized generics could not be measured directly because the decision to file an ANDA takes well prior to patent expiration. \textit{Id.} at 252. For the hypothetical small market, authorized generic entry resulted in generic price increases between 1.6 percent and 2.7 percent, depending on how high the switching costs. \textit{Id.} at 260. For the larger markets, on the other hand, the price increases ranged between 0.1 percent and 0.3 percent. \textit{Id.}
would be most appropriate if branded generic drugs were most often introduced in small markets.154

Stated different, the size of the market will have a direct impact on both the deterrent effect and profitability of authorized generics. In the case of smaller markets, authorized generics are likely to be less profitable, but generate greater long-term effects on generic entry. For larger markets, though, authorized generics will generate greater profits for brand-name manufacturers and be insufficient to increase generic prices.

A previous study, while reaching some similar findings to Reiffen and Ward, concluded overall that authorized generics are unlikely to harm long-term prices.155 For many drugs, the generic profits are sufficient to recoup the cost of patent challenges and ANDA expenses, even with authorized generics on the market.156 Similar to the Reiffen and Ward, Berndt found the size of the market to be an important factor when determining the effects of authorized generics. For the larger markets, even if authorized generics may deter generic entry, consumers are unlikely to be harmed because of the number of generics willing to file Paragraph IV certifications.157 Generally, drugs with high pre-generic entry sales are more likely to have both authorized generic entry and generic manufacturers filing Paragraph IV certifications.158 Furthermore, to the extent that generics are deterred,
they will likely be in situations when the generic has the least likelihood of success in prevailing in the patent challenge. Thus, while authorized generics may reduce the gains of generic manufacturers during the 180-day exclusivity period, substantial incentives for filing Paragraph IV certifications remain and consumer welfare is unlikely to be harmed.

D. Conclusion

In determining the overall net impact of authorized generics on consumer welfare, it is necessary to weigh the short-term benefits against any long-term harms. Authorized generics provide consumers with increased competition during the period of generic exclusivity, reducing pharmaceutical prices. The price discount differs depending on whether retail or wholesale prices are measured. Regardless, though, consumer welfare is advanced, either through savings to the healthcare network or through pharmacy reimbursements. This direct evidence of savings should not be taken lightly when balancing with the long-term impact. As noted by many commentators, an empirical study of the long-term effects will have difficulty reaching a definitive conclusion. The recent studies, though, suggest that for large market drugs, when authorized generics are most likely to enter, independent generics are unlikely to be deterred from entering the market. In the smaller markets, the introduction of an authorized generic potentially decreases the incentives of generic entry. However, these potential harms are offset by the benefits of short-term price discounts.

V. POSSIBLE SOLUTIONS AND UNINTENDED CONSEQUENCES

With generic exclusivity as the primary concern expressed by opponents of authorized generics, options are limited for possible

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R. Berndt, Richard Mortimer, and Andrew Parece, Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence 14–15 (Analysis Group, Working Paper, 2007), available at http://www.analysisgroup.com/analysisgroup/uploadedFiles/Publishing/Articles/PhRMA_Authorized_Generic_Entry.pdf. The authors also found an increase in the rate of Paragraph IV filings in recent years. Id. at 11.

159 Berndt, supra note 147, at 794. Because this litigation is less likely to lead to improved consumer access to generic drugs, any potential deterrence due to authorized generics is unlikely to impact competition or consumer welfare. Thomas, supra note 25, at 18.
solutions. The generics manufacturers have, in the past, sought Congressional action, discussed below; however, these bills failed to pass in Congress. Commentators have also suggested other alternative approaches. Having demonstrated that the only area of concern arises in small market drugs, this Section will analyze these proposed solutions and demonstrate the unintended consequences likely to result should any of these proposed solutions be enacted.

A. Previously Proposed Legislation

An example of a possible “solution” to the alleged “problem” of authorized generics can be seen in previously proposed legislation. On January 30, 2007, members of the Senate introduced the “Fair Prescription Drug Competition Act” to restrict the marketing of authorized generics.160 According to Senator Rockefeller, authorized generics “shut[] true generics out of the market, limit[] consumer choice and eliminate[] billions of dollars in prescription drug savings for people . . . across the country.”161 The bill would have amended the Federal Food, Drug, and Cosmetic Act to provide that an NDA may not “manufacture, market, sell, or distribute an authorized generic drug, direct or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.”162 Thus, the bill would have made the practice of authorized generics per se illegal, even during periods of non-exclusivity.

Because the opponents of authorized generics are primarily concerned with their effects on Paragraph IV certifications and generic incentives (namely, the exclusivity period), such a broad, over-inclusive bar on authorized generics would clearly have unintended consequences. Upon expiration of the exclusivity period, there has been no disagreement that authorized generics would increase price competition in the generic marketplace. In a sense, the authorized generics would be acting merely as another generic. The same can also be said of the beneficial effects of authorized generics upon patent expiration, when there is no generic exclusivity. Thus, even if one

160 S. 438, 110th Cong. (2007). The bill was introduced by Senators Rockefeller (D-WV), Schumer (D-NY), Kohl (D-WI), and Leahy (D-VT).
assumes, for the sake of argument, that authorized generics deter
generic entry during the exclusivity, a complete prohibition would
place a ban on authorized generics during periods that offer unarguable
consumer benefits.

B. Other Possible Solutions

Given the commentators concerns over exclusivity (and the
economic data suggesting a potential concern in small markets), the
most obvious solution would be to bar authorized generics during the
exclusivity period. To achieve this end, Congress could amend Hatch-
Waxman to prohibit the marketing of authorized generics during the
180-day exclusivity period. However, by doing so, Congress would
harm consumer welfare. During the 180-day exclusivity period, a
single generic entrant essentially operates as a monopoly in the generic
market. With the introduction of an authorized generic, the generic
manufacturer is faced with competition and forced to lower its price.
As a result of this increased competition, pharmaceutical prices are
lowered. Opponents of authorized generics rationalize a ban because of
the potential deterrent effect in low volume markets. However,
by eliminating this potential harm to low market pharmaceuticals,
Congress would be denying consumers the clear price benefits of
authorized generics seen in the majority of drugs.

Altering the Hatch-Waxman balance by prohibiting authorized
generics during the exclusivity period reduces brand-name
manufacturers' profits and the incentives for new drug development as
well. Generic drug entry, particularly during exclusivity, drastically
reduces brand-name sales. Brand-name manufacturers must match this
competition and they do so with the entry of authorized generics.
Placing a restriction on authorized generics would force brand-name
manufacturers to find other ways to compete with generics. They may
choose to lower the price of the brand-name drug, which in turn may
again decrease the incentives of generic entry. Would opponents then
petition Congress to prohibit brand-name manufacturers from lowering
their prices during the exclusivity period? By eliminating the brand-
name manufacturers' introduction of a lower priced alternative,
Congress would be walking a slippery slope.

163 See Chen, supra note 9, at 511 (concluding that a ban during the exclusivity period
would eliminate authorized generics as an anticompetitive strategy and ensure an
adequate reward for Paragraph IV litigation).
164 Coe & Morse, supra note 6, at 3.
Another possible area of reform involves the use of authorized generics in the context of settlement, when brand-name manufacturers promise to forgo introducing an authorized generic in exchange for the first-filer agreeing to push back its entry date. In such cases, there may be a violation of the antitrust laws and it may be appropriate to prohibit the use of authorized generics in the context of litigation settlement. The implication of this proposal and its legality, though, is beyond the scope of this article and is more in line with the controversy surrounding the so-called “reverse payment settlements.”

CONCLUSION

Authorized generics operate within the delicate balance of the Hatch-Waxman Act. Courts have thus far upheld their legality because they promote competition in furtherance of fundamental Hatch-Waxman objectives. Economic studies suggest consumers benefit with price discounts in the short-term.

Given the clear benefits resulting from authorized generics, Congress should restrain from placing any restrictions on the practice. In many ways, authorized generics represent the best of both worlds of the Hatch-Waxman balance: lower priced generic drugs and rewarding innovative efforts. Because authorized generics reduce short-term prices of pharmaceuticals, their introduction is very valuable to consumer access to affordable drugs. Significant incentives remain to encourage generic manufacturers to enter the market. Authorized generics also reward the innovative efforts of brand-name manufacturers following generic entry by allowing them to continue a declining revenue stream and utilizing excess capacity. Removing this

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165 See Gilbert's II, supra note 115, at 4.
166 See Jon Leibowitz, Comm’r, Fed. Trade Comm’n, Exclusion Payments to Settle Pharmaceutical Patent Cases: They’re B-a-a-a-ck! (The Role of the Commission, Congress, and the Courts), Remarks at the Second Annual In-House Counsel’s Forum on Pharmaceutical Antitrust (Apr. 24, 2006) (“[S]uch settlements may raise interesting questions regarding whether accepting delay in exchange for an assurance from the brand that the generic can enjoy its exclusivity period – without fear of competing with an authorized generic – constitutes a violation of the FTC Act.”).
167 These have been analyzed by multiple courts and numerous commentators. See e.g., In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); Schering-Plough v. FTC, 402 F.3d 1056 (11th Cir. 2005); In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Christopher M. Holman, Do Reverse Settlement Payments Violate the Antitrust Laws?, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489 (2007); C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553 (2006).
reward for innovation would deny consumers access to a lower cost alternative and lead to new attempts to compete in the generic market.

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