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STOPPING THE PRACTICE OF AUTHORIZED GENERICS: MYLAN’S EFFORT TO CLOSE THE GAPING BLACK HOLE IN THE HATCH-WAXMAN ACT

Brian Porter

Since the enactment of the Hatch-Waxman Act in 1984, brand name drug manufacturers have found many ways to use the provisions of the Hatch-Waxman Act to protect patented new drugs from generic competition. Using these provisions, brand name manufacturers have employed delay tactics and executed anti-competitive agreements with generic manufacturers in order to prevent generic manufacturers from entering the market. Although Congress, the FDA, and the courts have taken action to prevent brand name manufacturers from abusing the provisions of the Hatch-Waxman Act, brand name manufacturers have continued to find ways to do so.

Most recently, brand name manufacturers have marketed generic versions of their own patented drugs in order to prevent generic manufacturers from taking a large share of their market. These generic versions of brand name manufacturers’ patented drugs are called “authorized generics.” An authorized generic is chemically the same drug as the brand name

* J.D. 2005, The Catholic University of America, Columbus School of Law. The author wishes to thank Richard M. Volin for his guidance, the editors and staff of the Journal for all of their hard work, and his family for their love and support over the years.


3. See Shieber, supra note 2, at 75; The Stalling Game, supra note 2.
manufacturer's patented drug, but is relabeled and sold at a lower price like other generic versions of the patented drug.4

Authorized generics represent a new and unexplored area in the world of brand name and generic drugs. Indeed, Congress has not specifically addressed the issue since the Hatch-Waxman Act's inception, and only one court has ruled on the issue.5 However, this problem should be addressed soon. As one judge has stated in a case involving Mylan Pharmaceuticals Inc. ("Mylan"), a generic manufacturer, and the Federal Food and Drug Administration ("FDA"), a government agency responsible for pharmaceutical approval, authorized generics have exposed a "gaping black hole" in the Hatch-Waxman Act.6

Congress passed the Hatch-Waxman Act of 1984 in an effort to promote innovation and competition in the pharmaceutical industry.7 This Act attempted to strike a balance between allowing brand name drug manufacturers to bring new drugs to the market with patent protection and allowing generic manufacturers to compete with brand name manufacturers by marketing generic copies of the new drugs.8 In addition, Congress sought to make lower-priced generic drugs available to the public as an alternative to higher-priced brand name drugs.9

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), when a brand name drug manufacturer intends to market a new drug, it must submit a new drug application ("NDA") to the FDA for review.10 The FDA review of the NDA primarily determines: (1) whether the drug is safe and effective;

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8. Weiswasser & Danzis, supra note 7, at 590; see also H.R. REP. No. 98-857, pt. 2, at 4 (1984); Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (stating that "[t]he Act emerged from Congress' 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 copies of those drugs to market").
(2) whether the package labeling is appropriate; and (3) whether the methods used to manufacture the drug "are adequate to preserve the drug's identity, strength, quality, and purity." The brand name manufacturer must include in its NDA the drug's patent number and its expiration date, each of which is published by the FDA in the Orange Book. The Orange Book identifies and lists FDA approved drugs and provides details of their safety and effectiveness.

Under the Hatch-Waxman Act, a generic manufacturer can begin experimenting on a patented drug before its expiration and seek to market a generic version of the patented drug through the Abbreviated New Drug Application ("ANDA") process. Through the ANDA process, which will be described more fully in Part I, Section A of this comment, a generic manufacturer is able to rely on the safety and efficacy data of a patented drug and then manufacture and sell a generic version of the patented drug. The ANDA process allows for generic manufacturers to "piggyback on the proprietary safety and effectiveness data submitted by the innovator to obtain approval from the [FDA] for the pioneer drug." The Hatch-Waxman Act "substantially relax[ed] the testing requirements imposed on generic manufacturers" in order to create competition in the drug market. By permitting generic companies to avoid developing safety and efficacy data, these companies can spend significantly less money on research and

11. Id.
13. CTR. FOR DRUG EVALUATION AND RESEARCH, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, supra note 12.
16. Weiswasser & Danzis, supra note 7, at 585-86 (stating additionally that this process enables "generic manufacturers to avoid the costly and lengthy process of developing data establishing the safety and efficacy of their drugs and to obtain FDA approval merely by showing their drugs to be the 'same' as, and 'bioequivalent' to, the listed drug").
17. Id. at 590.
development, enabling them to develop and market a "lower cost alternative to brand-name drugs."18

To promote competition, the Hatch-Waxman Act gives the first generic manufacturer who files an ANDA with the FDA a 180-day period of exclusivity to market their generic version of the pioneer drug.19 During the 180-day exclusivity period, the generic copy is the only generic version of the pioneer drug allowed on the market.20 The 180-day exclusivity period can be utilized through the "commercial-marketing trigger"21 of the Hatch-Waxman Act, in which the period of exclusivity is "triggered" when the generic manufacturer first begins marketing its generic version.22 The Hatch-Waxman Act also has a "court-decision trigger" for the 180-day exclusivity period.23 The court-decision trigger has been subject to a great deal of dispute in the federal courts since the Hatch-Waxman Act’s enactment.24 Much of the dispute has involved FDA regulations interpreting the court-decision trigger to require generic manufacturers to successfully defend against patent infringement suits by the brand name manufacturers who patented the pioneer drugs, thereby making it more difficult to obtain the 180 days of exclusivity.25 Federal courts have stricken some these regulations,26 and in 2003, Congress practically eliminated the court-decision trigger, making the commercial-marketing trigger the primary trigger for the 180-day exclusivity period.27

In addition to striking down FDA regulations that have made it more difficult for a generic manufacturer to utilize the 180-day exclusivity period, courts have also had to deal with brand name manufacturers who have

25. See generally id. at 296-300.
27. Teva Pharm. USA, Inc. v. Pfizer Inc., 395 F.3d 1324, 1329 (Fed. Cir. 2005); see also Lietzan, supra note 12, at 310.
engaged in anti-competitive conduct. Although the Hatch-Waxman Act was enacted to promote competition by making it easier for generic manufacturers to obtain approval of their generics and rewarding them with the 180-day exclusivity period, brand name manufacturers have been finding ways to prevent generic manufacturers from coming to the market.28 For example, because the first generic ANDA applicant is entitled to 180 days of exclusivity without competition from other generic competition, some brand name manufacturers have paid the first generic ANDA applicants to not sell their generic version during the period, allowing the brand name manufacturers to continue reaping monopoly profits.29

In addition, some brand name manufacturers have used delay tactics, such as filing a citizen petition30 requesting the FDA not to approve the generic manufacturer’s ANDA.31 This tactic has been effective, because anytime “a citizen petition is filed, the FDA places a hold on approval of the generic while it investigates the complaint.”32

Another delay tactic used by brand name manufacturers is submitting new patents to the FDA, which are similar to an old patent that is about to expire.33 After the new patent is listed in the Orange Book, a brand name manufacturer would argue that the sale of a generic version of the old patented drug would violate the patent on the new listed drug.34 This would

28. Shieber, supra note 2, at 75.
29. Id.
30. Pursuant to 21 U.S.C. § 355 (2000) and 21 C.F.R. § 10.30 (2005), a citizen petition to the FDA is a petition requesting the Commissioner of the FDA to: (1) issue, amend, or revoke a regulation or proposed regulation; (2) issue, amend, or revoke an order or proposed order; or (3) take or refrain from taking administrative action. FDA, CITIZEN PETITION (1996), available at http://www.fda.gov/opacom/morechoices/smallbusiness/citizpet.html (last visited Nov. 10, 2005).
31. The Stalling Game, supra note 2.
32. Id.
33. See Shieber, supra note 2, at 75. The Hatch-Waxman Act’s thirty-month stay provision has allowed brand name manufacturers to delay a generic manufacturer’s coming to market by listing additional patents of doubtful validity in the Orange Book. Id. This is because every time a generic manufacturer submits an ANDA that infringes upon a listed patent, the generic manufacturer must provide notice of its ANDA to the brand name manufacturer. Id. When this notice is given, the brand name manufacturer has forty-five days after receiving notice to sue the generic manufacturer for patent infringement. An automatic thirty-month stay of approval of the ANDA by the FDA then takes effect. Id. See also The Stalling Game, supra note 2; In re Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 340, 350 (S.D.N.Y. 2002).
34. See In re Buspirone, 185 F. Supp. 2d at 343.
delay the approval of the generic manufacturer’s ANDA, allowing a brand
name manufacturer to continue reaping monopoly profits.\textsuperscript{35}

Although courts have invalidated many of the attempts by brand name
manufacturers to prevent generic competition,\textsuperscript{36} brand name manufacturers
have continued to find ways to do so. Over the past few years, many brand
name manufacturers have been creating generic versions of their own drugs
and marketing these generic versions in order to reduce competition from
generic manufacturers. These generic versions are called “authorized
generics.” An authorized generic is essentially the same drug as the brand
name manufacturer’s FDA-approved pioneer drug, or approved NDA, and it
is “then relabeled and marketed under the generic product name” and sold at
a lower price.\textsuperscript{37} The authorized generic is manufactured by the brand name
manufacturer, but it is distributed through a licensee, who packages the drug
with its own label and NDC number.\textsuperscript{38} Generic manufacturers and others
have opposed the marketing and sale of authorized generics, claiming that
brand name manufacturers are “trying to retain crucial market share through
partnerships for authorized generic versions of their products.”\textsuperscript{39}

\textsuperscript{35} See Shieber, supra note 2, at 75.
\textsuperscript{36} See, e.g., In re Buspirone, 185 F. Supp. 2d; In re K-Dur Antitrust Litig., 338 F.
\textsuperscript{37} Worrell, supra note 4. The FDA defines “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.” Letter from
William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Stuart
A. Williams, Chief Legal Officer, Mylan Pharmaceuticals, Inc., and James N. Czaban,
Heller Ehrman, at 2 n. 2 (Jul. 2, 2004) (on file with the author) [hereinafter FDA
Response to Mylan Citizen Petition]. Mylan defines “authorized generic” as “at term of
art commonly used in the pharmaceutical industry to describe a drug product, which is a
private label version of a brand name product supplied by the brand company.” Letter
from Stuart A. Williams, Chief Legal Officer, Mylan Pharmaceuticals, Inc., to Dockets
Management Branch, FDA, at 2 (Feb. 17, 2004) (on file with the author) [hereinafter
Mylan Citizen Petition] (requesting that “the FDA [] prohibit the marketing and
distribution of ‘Authorized Generics’ until the expiration of the first generic applicant’s
exclusivity period”).
\textsuperscript{38} Mylan Citizen Petition, supra note 37, at 3. NDC refers to the National Drug
Code Directory for prescription and a few selected over the counter (“OTC”) drugs. The
NDC number, a 10 digit, 3-segment number, allows for drugs to be identified in the
cder/ndc/ (last visited Feb. 24, 2005).
\textsuperscript{39} Steve Niles, Strike Against Generics: Marketing Authorized Generic
Formulations of Their Products Through Partnerships With Generic Companies Can
Help Branded Pharmaceutical Companies Hold on to Market Share, But These
Agreements Have Raised the Ire of Some in the Generic Pharmaceutical Industry as They
On February 17, 2004, Mylan, a manufacturer and distributor of generic drugs, filed a citizen petition with the FDA requesting that the FDA prohibit brand name manufacturers from marketing and distributing authorized generics until the end of the first generic ANDA applicant’s 180-day exclusivity period. Mylan claimed that authorized generics are the same as other generic versions of the pioneer drug because they are similarly priced and compete directly with other “true” generic versions of the pioneer drug. Therefore, Mylan argued that brand name manufacturers should not be able to market their authorized generics during the first-filing generic manufacturer’s 180 day period of exclusivity. If that were the case, brand name manufacturers would be treated like other generic manufacturers who file ANDAs subsequent to the first-filer and cannot market their generic versions during the exclusivity period. Mylan also argued that the marketing of authorized generics impeded competition and reduced the incentive for generic manufacturers to challenge the innovator’s patent through the ANDA process. The marketing of authorized generics reduces the incentive for generic manufacturers to file ANDAs, because it reduces the reward of the 180-day exclusivity period for the first ANDA filer. The effects of authorized generics, Mylan argued, were contrary to the intent of the Hatch-Waxman Act.

The FDA rejected Mylan’s petition on July 2, 2004, stating that it only had the power to regulate the safety and efficacy of new drugs for the benefit of public health and welfare, but did not have the power to regulate competition. Therefore, because the authorized generic has already received approval of the new drug from the FDA, the FDA cannot prohibit this practice. In addition, the FDA stated that authorized generics actually


41. Mylan Citizen Petition, supra note 37, at 3.
42. Id.
43. See id. at 2.
44. Id.
45. Id. at 3. When filing an ANDA with a paragraph IV certification, a generic manufacturer is challenging the validity of the branded manufacturer’s patent or stating that the patent will not be infringed by the generic manufacturer’s marketing of its generic version. Weiswasser & Danzis, supra note 7, at 600.
46. See Mylan Citizen Petition, supra note 37, at 3.
47. Id. at 1.
48. FDA Response to Mylan Citizen Petition, supra note 37, at 2.
49. Id.
"further[] the Hatch-Waxman objective of enhancing competition overall among drug products." 50

After the FDA rejected Mylan’s citizen petition, Mylan filed suit against the FDA in federal court in West Virginia. 51 Mylan asked the court to invalidate the FDA’s denial of Mylan’s petition to prohibit Proctor & Gamble from marketing an authorized generic version of Macrobid. 52 Mylan argued that the practice of authorized generics “stifles generic competition” and devalues the incentive to challenge pioneer patents through the ANDA process. 53

On August 30, 2004, Mylan asked for a dismissal of its complaint without prejudice so that it could later refile its case to include antitrust allegations. 54 Mylan has since refiled its lawsuit, this time asserting that Proctor & Gamble has violated antitrust laws. 55 Before the suit was dropped, U.S. District Judge Irene Keely, who presided over the dispute, made a statement implying that Congress was to blame for the problematic issue of authorized generics. 56 She said that under the current law, “any brand can go out and market its product as a generic at any time because it’s not covered in the law.” 57 Judge Keely further opined that “authorized generics look... like a gaping black hole that’s been ignored or avoided...” 58

Part I of this comment describes the ANDA process and the legislative history of the Hatch-Waxman Act. Part I also explains how Congress, the FDA, and courts have addressed the ways brand name manufacturers have attempted to prevent generic competition. It offers other interpretative issues that have arisen since the inception of the Hatch-Waxman Act. Part II analyzes the issue of authorized generics by examining Mylan’s citizen petition requesting that the FDA prohibit the marketing of authorized generics and the FDA’s subsequent rejection of that petition. Part III comments on how the Hatch-Waxman Act has not specifically addressed the issue of authorized generics, which has left the FDA and courts ill-equipped

50. Id. at 12.
53. Id.
56. Smith, supra note 6.
57. Id.
58. Id.
to stop this practice. Part III also explains how Congress must stop this practice by making new amendments to the Hatch-Waxman Act.

I. BACKGROUND OF THE HATCH-WAXMAN ACT AND THE 180-DAY PERIOD OF EXCLUSIVITY

In order to understand Mylan’s argument that the marketing of authorized generics by brand name manufacturers impedes competition from generic manufacturers and reduces the incentive for generic manufacturers to challenge an innovator’s patent through the ANDA process, it is necessary to understand the ANDA process and the Congressional intent underlying the Hatch-Waxman Act. It is also important to examine how the FDA has interpreted the Hatch-Waxman Act through its regulations.

A. ANDA Approval and Market Exclusivity

Under the Hatch-Waxman Act, the FDA will approve a generic manufacturer's ANDA only when the generic version of the pioneer drug is the “same” or the “bioequivalent” of the pioneer drug, which must have been already approved by the FDA.59 “The ‘sameness’ requirement provides that the active ingredient, route of administration, dosage form, strength, and labeling must all be the same as the pioneer product.”60

Under §505(j)(2)(A)(vii) of the FDCA, when a generic manufacturer files an ANDA, the generic manufacturer must include one of four certifications: (1) that the brand name manufacturer has not listed the patent information for its pioneer drug; (2) that the brand name manufacturer’s patent has expired; (3) that the brand name manufacturer’s patent will expire on a certain date, after which the generic manufacturer may market its generic version; (4) or that the patent, on which the ANDA is based, “is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.”61

The fourth certification is known as a paragraph IV certification, and when an ANDA is filed with a paragraph IV certification ("paragraph IV ANDA"), the generic manufacturer must give notice of its ANDA

59. Weiswasser & Danzis, supra note 7, at page 594.
application to the brand name manufacturer of the pioneer drug.\textsuperscript{62} Additionally, the ANDA filer must offer the innovator in its notice "an explanation as to why it believes the patent is invalid or not applicable."\textsuperscript{63} Therefore, this notice is essentially a challenge of the brand name manufacturer’s patent.\textsuperscript{64}

Once the brand name manufacturer has received notice of the generic manufacturer’s paragraph IV ANDA, the branded manufacturer has 45 days to bring a patent infringement suit.\textsuperscript{65} If suit is filed within this 45 day period, the FDA is barred from:

approving the [generic manufacturer’s] ANDA, or any subsequent ANDA, for thirty months or until the successful resolution of the patent infringement suit, whichever is earlier, at which time the first ANDA applicant is eligible for FDA approval and upon such approval is awarded a 180-day exclusivity period in which to market its generic version.\textsuperscript{66}

It is important to note that although the FDA cannot grant “final” approval until either the end of the 30-month period or successful resolution of the patent infringement suit, whichever is earlier, the FDA may grant “tentative” approval of the ANDA “if the FDA determines that the ANDA would

\textsuperscript{62} SmithKline Beecham Corp. v. Apotex Corp., 383 F. Supp. 2d 686, 691 (E.D.Pa. 2004); see also Shieber, supra note 2, at 75.

\textsuperscript{63} Shieber, supra note 2, at 75; see also SmithKline, 383 F. Supp. 2d at 691 (stating in its notice to the brand name manufacturer, the generic manufacturer must “[set] forth a detailed statement of the factual and legal basis for the applicant’s opinion that the patent is not valid or will not be infringed”); 21 U.S.C. §§ 355(b)(3)(B), (j)(2)(B)(ii)(2000).

\textsuperscript{64} SmithKline, 383 F. Supp. 2d at 691.

\textsuperscript{65} Andrx Pharms., Inc. v. Biovail Corp., Int'l, 256 F.3d 799, 802 (D.C. Cir. 2001).

\textsuperscript{66} Id.; see also 21 U.S.C. § 355(j)(5)(B)(iii)(2000). Section 505(j)(5)(B)(iii)'s thirty-month stay provision has had some anticompetitive effects. Shieber, supra note 2, at 75. Brand name manufacturers have an incentive to list patents of “doubtful validity” in order to prevent generic competition. Id. Moreover, “[e]ven if the patents are quickly declared by a court to be invalid or inapplicable, the automatic stay provision works in the branded manufacturer’s favor.” Id. The brand name manufacturer can also employ other techniques to prevent generic competition. Brand name manufacturers will also bypass the whole litigation process by settling the suit with the generic manufacturer who files the first ANDA. Id. Brand name manufacturers have settled suits and paid the generic manufacturer to not market its generic version of the pioneer drug and, therefore, not use its 180-day exclusivity period. Id. (stating that, “because the first filer is given 180 days of exclusivity whether or not it prosecutes the underlying patent case to its conclusion, [ ] such an agreement can create a bottleneck that effectively blocks generic competition”). This type of collusion between brand name manufacturers and generic manufacturers also has the effect of blocking all sales by subsequent ANDA applicants. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1067 (D.C. Cir. 1998).
otherwise receive final approval but for the thirty month stay." A tentative approval is an approval that has a delayed effective date. Tentative approval is not effective “until[the]FDA issues a letter granting final effective approval.”

Once approved, the first-filing generic manufacturer is entitled to the 180-day exclusivity period. The 180-day exclusivity period is governed by Sections 505(j)(5)(B)(iv) and 505(j)(5)(D) of the Hatch-Waxman Act. Section 505(j)(5)(B)(iv) states that the exclusivity period begins either when the generic applicant first markets the drug commercially, or on the date of a court decision holding that the brand name manufacturer’s patent is invalid or is not being infringed upon, whichever is earlier. Subsection (I) of Section 505(j)(5)(B)(iv) is the “commercial-marketing trigger” of the 180-day exclusivity period, and Subsection (II) is the “court-decision trigger.” During the 180-day exclusivity period, no other generic versions of the pioneer drug can come to market. This encourages generic applicants to challenge the patent on the innovator’s pioneer drug.

B. The Legislative History on the 180-Day Period of Exclusivity is Limited and Provides Very Little Guidance for the FDA and Courts

When Congress enacted the Hatch-Waxman Act in 1984, they failed to provide much guidance for interpreting the statutory provisions regarding the 180-day exclusivity period. Congress included the provisions in order

68. Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1277 (D.C. Cir. 2004).
69. Id.
71. Lietzan, supra note 12, at 288.
74. See Lietzan, supra note 12, at 288.
75. Id.

If an ANDA certifying patent invalidity or non-infringement is filed subsequent to an ANDA for the same listed drug that has made the same certification of invalidity or non-infringement, paragraph (4)(B)(iv) provides that the approval of the subsequent ANDA may not be made effective sooner than 180 days after
to promote the purposes of the Hatch-Waxman Act, which were to encourage competition by generic manufacturers and innovation of new drug products.\textsuperscript{77} The 180-day exclusivity period was created in contemplation that brand name manufacturers would bring patent infringement suits upon the filing of paragraph IV ANDAs by generic manufacturers.\textsuperscript{78} Congress recognized that first-filing generic manufacturers would be subject to costly patent litigation, and thus created the 180-day exclusivity period to "encourage the generic [manufacturer] to undertake this risky behavior."\textsuperscript{79} Congress' prediction has proved to be correct as generic manufacturers who file a paragraph IV ANDA are frequently sued for patent infringement, making the 180-day exclusivity period invaluable to generic manufacturers.\textsuperscript{80}

Although the Congressional intent behind the entire Act was clear, the legislative history for the provisions relating to the 180-day exclusivity period is limited.\textsuperscript{81} "Indeed, the provision is mentioned only twice in the final House Report."\textsuperscript{82} Therefore, "[w]hile seemingly a simple provision of the Act, the 180-day exclusivity has led to a number of controversies."\textsuperscript{83}

the previous applicant has begun commercial marketing, or the date on which the court holds the patent invalid or not infringed, whichever occurs first. In the event of multiple ANDAs certifying patent invalidity or non-infringement, the courts should employ the existing rules for multidistrict litigation, when appropriate to avoid hardship on the parties and witnesses and to promote the just and efficient conduct of the patent infringement actions.


79. Id.

80. Id. (stating that a 2002 study by the FTC found that "in nearly 75% of drug products studied, the pioneer company initiated patent infringement litigation against the first Paragraph IV applicant"); see also FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 13 (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf [hereinafter FTC STUDY].

81. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1065 (D.C. Cir. 1998); see also Lietzan, supra note 12, at 293.

82. Lietzan, supra note 12, at 293.

83. Weiswasser & Danzis, supra note 7, at 603.
C. Congress and the Courts Have Addressed Issues Involving Anti-Competitive Behavior by Brand Name Manufacturers and FDA Regulations that Have Impeded the Ability of Generic Manufacturers to Market Their Generic Versions

The Hatch-Waxman Act's market exclusivity provisions have been frequently litigated in federal courts since their enactment. Many cases have involved FDA regulations interpreting the statute, and others have involved the ways brand name manufacturers have abused the statutory provisions in their attempts to prevent competition from generic manufacturers. In order to curb these abuses and to clarify the 180-day exclusivity provisions, Congress amended the FDCA by enacting the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Act of 2003"). The FDA also amended some of its regulations to help curb these abuses.

In order to understand the amendments that Congress made to the Hatch-Waxman Act, the changes that the FDA also made, and the holdings of courts, it is necessary to understand the issues that gave rise to these changes. Below, this comment will address some of the significant changes that were made by Congress and the FDA and will give some of the background behind these changes. In addition, it will address some of the issues courts have faced involving FDA regulations and ways that brand name manufacturers have used the provisions of the Hatch-Waxman Act to prevent generic competition. Through understanding the issues that Congress, the FDA, and the courts have addressed with the Hatch-Waxman Act, the intents and purposes of the Act will be discussed and it will enable a better understanding of the gaping black hole that authorized generics have exposed.

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84. Although Congress, the FDA, and courts have addressed many interpretative issues since the enactment of the Hatch-Waxman Act, I will only focus on some of the key issues that are important to this comment.


1. The Thirty-Month Stay from Approval

In the 2003 Amendments, Congress mandated that when the first generic manufacturer files a paragraph IV ANDA and provides notice to the brand name manufacturer, the brand name manufacturer cannot obtain more than one thirty-month automatic stay of approval of the ANDA by the FDA. This amendment codified the FDA’s regulatory amendments earlier that year. The FDA’s regulatory amendments were made in response to Federal Trade Commission (“FTC”) studies that indicated that brand name manufacturers had been using the thirty-month stay provisions to delay market entry by the first-filing generic manufacturer.

Prior to these amendments by Congress and the FDA, brand name manufacturers had “a substantial incentive to list patents in the Orange Book, even if the listing is of doubtful validity.” In the case of In re Buspirone Patent & Antitrust Litig., a brand name manufacturer, Bristol-Myers Squibb, did just that. Right before its patent for the anti-anxiety drug BuSpar ("buspirone") was to expire, Bristol-Meyers Squibb submitted another patent application with the FDA, which subsequently listed the patent in the Orange Book, for a metabolite that buspirone naturally produces in the body when taking the drug. The generic manufacturer, Mylan, was about to begin marketing a generic version of buspirone, and as a result of Bristol-Myers Squibb's listing of the new patent, had to stop its shipment orders. Bristol-Myers Squibb argued that Mylan's sale of the generic version of the old patented drug would violate the patent on the new listed drug.

By listing another patent in the Orange Book, whether valid or not, the generic manufacturer with a paragraph IV ANDA may be subject to additional patent infringement lawsuits, which can significantly delay the generic manufacturer coming to market. These patent infringement "lawsuits can effectively give innovator companies up to another 30 months

88. See Smith, supra note 84, at 702.
89. See id. at 701; see also FTC STUDY, supra note 78, at v.
90. See Shieber, supra note 2, at 75.
92. Id. at 343.
93. The Stalling Game, supra note 2.
94. In re Buspirone, 185 F. Supp. 2d at 343.
95. The Stalling Game, supra note 2; see also Mark A. Lemley & Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. REV. 63, 82 (2004).
of market exclusivity under the Hatch-Waxman Act."96 Brand name manufacturers benefit from the thirty-month automatic stay provision through this delay tactic, "even if the patents are quickly declared by a court to be invalid or inapplicable...."97

Therefore, after FTC studies indicated that permitting only one 30-month stay "should eliminate most of the potential for improper Orange Book listings to generate unwarranted [30]-month stays," the FDA amended its rules, which Congress codified in the Medicare Act of 2003, to eliminate multiple thirty-month stays per ANDA.98

2. The First-Filing Generic Manufacturer’s Market Exclusivity Will Run Even If the Generic Manufacturer is Marketing and Selling the Brand Name Manufacturer’s Listed NDA

In the Medicare Act of 2003, Congress also “slightly altered” the 180-day market exclusivity provision to apply to situations where the first-filing generic manufacturer, who obtains the 180 days of market exclusivity, markets the brand name manufacturer’s listed drug.99 This amendment codified a 2001 decision by a district court in West Virginia, which held “that a generic manufacturer begins commercial marketing, and thereby starts the 180-day clock, even when it sells a private label version of the innovator’s product, rather than the product that is the subject of its ANDA.”100 In that case, Mylan, the first-filing generic manufacturer, filed suit against the FDA for denying its 180-day period of market exclusivity.101 Mylan had filed the first paragraph IV ANDA for 30mg generic version of Pfizer Inc.’s (“Pfizer”) nifedipine drug patent, after which Pfizer filed a patent infringement suit against Mylan.102

In 2000, Pfizer and Mylan executed a settlement agreement whereby the civil action would be dismissed, Pfizer would give Mylan a license to sell Pfizer’s drug in three different dosage levels, and Mylan would be able to

96. The Stalling Game, supra note 2; see also Shieber, supra note 2, at 75 (“Because every month that generic competition is kept off the market will result in significant additional sales for the branded product. . .”).

97. Shieber, supra note 2, at 75.

98. See Smith, supra note 86, at 701-02; see also FTC STUDY, supra note 78, at v; SmithKline, 383 F. Supp. 2d at 691 n.3; 21 U.S.C. § 355(c)(3)(C) (2000).


100. Lietzan, supra note 12, at 304; see also Mylan Pharm., Inc. v. Thompson, 207 F. Supp. 2d 476 (N.D.W.Va. 2001).

101. Id. at 483.

102. Id. at 481.
market its own generic version of Pfizer’s drug.\textsuperscript{103} Because of this agreement, the FDA denied Mylan its 180-day period of exclusivity, and then approved Biovail Laboratories, Inc.’s (“Biovail”) paragraph IV ANDA.\textsuperscript{104} The FDA denied Mylan the 180-day exclusivity period because the FDA concluded that the settlement agreement between Pfizer and Mylan, whereby Mylan would sell a private label generic version of Pfizer’s listed drug, effectively changed Mylan’s ANDA from paragraph IV certification to a paragraph III certification, making Mylan no longer eligible for market exclusivity.\textsuperscript{105} The FDA also held “that Mylan, by marketing its private label generic version of Pfizer’s [patented drug], as opposed to its own 30 milligram ANDA product, triggered the ‘commercial marketing’ provision of 21 U.S.C. § 355(j)(5)(B)(iv)(I) thereby commencing the running of the 180-day exclusivity period.”\textsuperscript{106}

Mylan filed suit, claiming that the FDA was required to withdraw its approval of Biovail’s later-filed paragraph IV ANDA, because Mylan’s exclusivity period had not commenced.\textsuperscript{107} Although the court did not agree with the FDA that the settlement agreement between Pfizer and Mylan changed Mylan’s ANDA from a paragraph IV certification to paragraph III certification, the court did agree with the FDA in holding that by marketing Pfizer’s listed drug as a licensee, Mylan’s 180-day period of exclusivity had commenced.\textsuperscript{108} Congress codified this holding in the Medicare Act of 2003, which states that the 180-day exclusivity period becomes effective upon the commercial marketing of the ANDA applicant’s generic version of the listed drug or a private label version of the listed drug.\textsuperscript{109}

3. Agreements to Not Enter the Market

In 2003, Congress also made amendments to the Hatch-Waxman Act in order to prevent brand name and generic manufacturers from entering into anti-competitive agreements that are designed to maintain market share in

\begin{itemize}
\item \textsuperscript{103} Id.
\item \textsuperscript{104} Id. at 482.
\item \textsuperscript{105} Id.
\item \textsuperscript{106} Id. The FDA claimed that “whether Mylan markets the produce [sic] approved in its ANDA or the produce [sic] approved is Pfizer’s NDA is [sic] of little import to the statutory scheme; Mylan has begun commercial marketing of genetic nifedipine, permitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.” Id. at 488.
\item \textsuperscript{107} Id. at 483.
\item \textsuperscript{108} Id. at 488.
\end{itemize}
the sale of a drug. Since the enactment of the Hatch-Waxman Act, brand name manufacturers have been able to use the first-filer and 180-day exclusivity provisions to their advantage by paying first-filing generic manufacturers to not market their generic versions during the exclusivity period. "Rather than face the risks of litigating the underlying patent suit, the branded manufacturer can settle the suit, pay the first filer not to come to market, and continue to reap its monopoly profits (less whatever is paid to the first filer)." This type of agreement has been successful in preventing generic competition, because under the original statute, if the first-filing generic manufacturer failed to enter the market, then the exclusivity period was not triggered, "and subsequently filed ANDAs [could not] be approved." This type of agreement is called "parking," in that it "parks" the 180-day exclusivity period, and it can have the effect of "infinitely delaying ANDA approvals and bottlenecks the market."

To prevent this practice, Congress enacted forfeiture provisions for the 180-day exclusivity period in the 2003 Amendments to the Hatch-Waxman Act. In enacting the forfeiture provisions, Congress also "replaced the traditional ['court decision trigger']." The forfeiture provisions create consequences for a generic manufacturer's failure to come to market. Under the new provisions, the 180-day exclusivity period is forfeited if the first generic manufacturer to file a paragraph IV ANDA fails to market the generic version of the pioneer drug by the later of: (1) 75 days after the effective approval of its application, or 30 months after it was submitted, whichever is earlier; or (2) 75 days after the date on which a court decision has held that the brand name manufacturer's patent is invalid or is not being infringed upon, a settlement has been approved by the court, or the brand name manufacturer has withdrawn its patent information.

The generic manufacturer also forfeits the 180-day exclusivity period if: (1) the first ANDA applicant withdraws its application; (2) the first ANDA applicant withdraws its paragraph IV certification; (3) the first ANDA applicant does not receive approval of its ANDA within 30 months after it was filed; (4) the first ANDA applicant enters into an agreement with another party, such as the patent holder, that the FTC or a court has found to

111. Shieber, supra note 2, at 75.
112. Id.
114. Id.; see also Shieber, supra note 2, at 75.
be in violation of the federal antitrust laws; or (5) the original patent, on which the paragraph IV ANDA was based, has expired.\textsuperscript{118}

Apart from the time-related forfeiture provisions, the statute states that if the settlement agreement violates the federal antitrust laws, then the exclusivity period will be forfeited.\textsuperscript{119} In addition, each party to an agreement involving the 180-day exclusivity period or the sale or marketing of a brand name or generic drug - whether the agreement is between a brand name manufacturer and a generic manufacturer or between generic manufacturers - must file the agreement with the FTC and the Attorney General within ten business days of the agreement’s execution.\textsuperscript{120}

Therefore, by expanding the forfeiture provisions in the Medicare Act of 2003, Congress intended to prevent the practice of “parking” the exclusivity period and “force generic manufacturers to market promptly.”\textsuperscript{121} In addition, Congress sought to prevent these anti-competitive agreements by employing FTC scrutiny of such agreements.\textsuperscript{122} It is clear that after the 2003 Amendments, “settlement agreements between drug manufacturers to resolve patent infringement litigation triggered by a paragraph IV certification, and that involve reverse payments, will be treated as highly suspect.”\textsuperscript{123}

4. Declaratory Judgment to Obtain Patent Certainty and Orange Book Listing Remedies

In the Medicare Act of 2003, Congress also included in its changes a provision directed to a “civil action to obtain patent certainty.”\textsuperscript{124} This provision allows a generic manufacturer to bring a federal suit for a declaratory action that the patent is either invalid or will not be infringed by the generic version if the brand name manufacturer does bring a timely

\begin{itemize}
  \item \textsuperscript{118} See 21 U.S.C. §§ 355(j)(5)(D)(2000); see also Lietzan, supra note 12, at 289.
  \item \textsuperscript{121} Lietzan, supra note 12, at 314; see Apotex, 385 F. Supp. 2d at 189-90.
  \item \textsuperscript{123} Id.
  \item \textsuperscript{124} Teva Pharm. USA, Inc. v. Pfizer Inc., 395 F.3d 1324, at 1329 (Fed. Cir. 2005); see also 21 U.S.C. § 355(j)(5)(C) (West Supp. 2004).
\end{itemize}
patent infringement suit. 125 The generic manufacturer must give the brand name manufacturer "confidential access to its ANDA application so that the [brand name manufacturer] can evaluate possible infringement." 126

In addition, a generic manufacturer that is sued for patent infringement may also bring a counterclaim to delist the patented NDA. 127 Although a counterclaim to delist the patent is not an independent cause of action and can only be brought if the generic manufacturer is sued for patent infringement, 128 it "may circumvent the need to confront the presumption of validity that a patent enjoys." 129 If successful on the counterclaim, a generic manufacturer may also be able to get its thirty-month stay of approval of its paragraph IV ANDA terminated. 130 At the very least, with the addition of the counterclaim and declaratory judgment provisions, Congress has given generic manufacturers a greater ability to challenge the listed patents of brand name manufacturers, and possibly speed up the approval of their paragraph IV ANDAs. 131

5. Courts have rejected the FDA's "Successful Defense" and "Involvement in a Patent Infringement Suit" Requirements

Since the enactment of the Hatch-Waxman Act, courts have not only addressed the ways that brand name manufacturers have used the provisions of the Act to prevent generic competition, but also have addressed FDA regulations governing ANDA approval and market exclusivity. The FDA did not implement finalized regulations governing the 180-day exclusivity period provisions until 1994, ten years after the Hatch-Waxman Act was enacted by Congress. 132 One of the FDA's regulations required that the first generic manufacturer to file a paragraph IV ANDA must "successfully defend against a suit for patent infringement" before it could obtain market exclusivity. 133 In addition to the "successful defense" requirement, the 1994

126. Id.
128. Id.
129. Id.
130. Id.
131. See id.
132. Lietzan, supra note 12, at 294.
133. Id.; see also Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1065 (D.C. Cir. 1998).
regulation maintained that "a generic applicant would be entitled to exclusivity only when it has itself been involved in a patent infringement lawsuit." Both of these requirements have been rejected by the courts.\(^{135}\)

\(\textit{a. The "Successful Defense" Requirement}\)

In \textit{Mova Pharm. Corp. v. Shalala}, the Court of Appeals for the DC Circuit rejected the FDA's requirement that the first generic manufacturer to file an ANDA with a paragraph IV certification had to successfully defend against a patent infringement suit in order to trigger the 180-day exclusivity period.\(^{136}\) Mova Pharmaceutical Corporation ("Mova") had filed an ANDA with a paragraph IV certification for a generic version of micronized glyburide, a drug used to treat diabetes that was created by Pharmacia & Upjohn Company ("Upjohn"). Upjohn brought a patent infringement suit against Mova.

During this litigation, Mylan filed an ANDA with a paragraph IV certification for a generic version of the same drug.\(^{138}\) The FDA subsequently approved Mylan's ANDA to market its generic version of micronized glyburide.\(^{139}\) Mova filed suit in the United States District Court for the District of Columbia attempting to "compel the FDA to delay the effective date" of the approval of Mylan's generic drug.\(^{140}\) Mova argued that, under section 355(j)(5)(B)(iv) of the Hatch-Waxman Act, the FDA was prohibited from approving Mylan's ANDA until the end of Mova's 180-day exclusivity period. This exclusivity period would start either when Mova first commercially marketed its generic version of the pioneer drug or when Mova had won its patent infringement suit against Upjohn.\(^{141}\)

The FDA argued that "Mova's exclusivity did not bar approval of the Mylan ANDA because Mova had not yet successfully defended against [Upjohn's] suit."\(^{142}\) Mova, however, claimed that the successful defense requirement was "inconsistent with the plain language of §
The district court agreed with Mova and granted a preliminary injunction requiring the FDA to stay approval of Mylan’s ANDA “until 180 days after Mova won its suit or began to market its product (whichever came first).”

On appeal, the D.C. Circuit affirmed, finding that the FDA’s successful defense requirement was “inconsistent with the literal language of the statute.” The court stated that under the statute, an ANDA filed after the first paragraph IV ANDA can only be approved 180 days after the commercial-marketing trigger or court-decision has been satisfied. The FDA’s “successful defense” requirement, however, allows subsequent ANDAs to be approved “even though neither trigger has been satisfied, simply because the first applicant’s litigation has not yet come to a successful conclusion.”

The court also held that the successful defense requirement was inconsistent with the purpose of the 180-day exclusivity provision, in that the requirement has the practical effect of “[writing] the commercial-marketing trigger out of the statute.” Therefore, the court invalidated the successful defense requirement, preventing the FDA from approving any subsequent ANDAs until after the first-filer’s 180 days of market exclusivity.

b. The “Involvement in a Patent Infringement Suit” Requirement

In Purepac Pharm. Co. v. Friedman, the D.C. Circuit held that the first generic manufacturer to file an ANDA does not have to be sued for patent infringement in order to benefit from market exclusivity. In this case, Torpharm was the first generic manufacturer to file a paragraph IV ANDA for a generic version of the drug ticlopidine hydrochloride, which had the brand-name “Ticlid.” Torpharm was not sued for patent infringement, and the FDA had not finally approved Torpharm’s ANDA when another generic manufacturer, Purepac Pharmaceutical Company (“Purepac”), filed a subsequent ANDA with the FDA. Although Purepac’s ANDA had become ready for approval, the FDA only tentatively approved Purepac’s...
ANDA, withholding "final approval pending Torpharm's final approval, commercial marketing, and expiry of its 180-day exclusivity."\footnote{152}

Purepac brought suit seeking a preliminary injunction and a declaratory judgment, arguing that Torpharm was not entitled to the 180-day exclusivity period, because it had not been sued for patent infringement.\footnote{153} After the \textit{Mova} decision, the FDA removed the "successful defense" requirement from its regulations governing the 180-day exclusivity period.\footnote{154} In addition, the FDA said that it would follow the \textit{Mova} court's more literal interpretation of the statute.\footnote{155} In doing so, the FDA also removed the phrase "if sued for patent infringement."\footnote{156} Therefore, the D.C. Circuit found that the FDA eliminated the requirement that a generic applicant must be sued for patent infringement in order to be entitled to the 180-day period of exclusivity, and thus had complied with the \textit{Mova} decision.\footnote{157} The D.C. Circuit also held that the FDA's decision to withhold approval of Purepac's ANDA until Torpharm's commercial marketing of their generic to be consistent with section 355(j)(5)(B)(iv).\footnote{158}

By rejecting the FDA's "successful defense" and "involvement in a patent infringement suit" requirements, courts have sustained the commercial-marketing trigger for the exclusivity period.\footnote{159} In the Medicare Act of 2003, Congress went even further than the courts in promoting the commercial-marketing trigger by practically eliminating the court decision trigger.\footnote{160}

\section*{II. MYLAN AND THE "AUTHORIZED GENERICS" PROBLEM}

Over the past few years, brand name manufacturers have been marketing authorized generics. Authorized generics are basically the same drug as the

\begin{footnotes}
\item[152] Lietzan, \textit{supra} note 12, at 299; see also \textit{Purepac}, 162 F.3d at 1202.
\item[153] \textit{Purepac}, 162 F.3d at 1202.
\item[154] \textit{Id.} at 1203; see also Effective Date of Approval of an Abbreviated New Drug Application, 63 Fed. Reg. 59,710 (proposed Nov. 5, 1998; interim rule effective Nov. 10, 1998) (to be codified at 21 C.F.R. pt. 314).
\item[155] \textit{Purepac}, 162 F.3d at 1203.
\item[156] \textit{Id.} at 1204 n.5; see also Effective Date of Approval of an Abbreviated New Drug Application, 63 Fed. Reg. 59,710, 59,712 (proposed Nov. 5, 1998; interim rule effective Nov. 10, 1998) (to be codified at 21 C.F.R. pt. 314).
\item[157] \textit{Purepac}, 162 F.3d at 1204.
\item[158] \textit{Id.} at 1205.
\item[159] See \textit{Mova Pharm. Corp. v. Shalala}, 140 F.3d 1060, 1076 (D.C. Cir. 1998); \textit{Purepac}, 162 F.3d at 1205.
\end{footnotes}
brand name manufacturer’s pioneer drug, but they are renamed and sold through a licensed distributor.\textsuperscript{161} Authorized generics are simply the new scheme that brand name manufacturers have employed to prevent generic competition, and the Generic Pharmaceutical Association has argued that this practice threatens the generic industry’s existence “by giving brand-name manufacturers total control of the market.”\textsuperscript{162}

\textcolor{red}{A. Mylan Filed a Citizen Petition Asking the FDA to Prohibit the Marketing of Authorized Generics During the Exclusivity Period}

On February 17, 2004, Mylan filed a citizen petition with the FDA requesting that the FDA stop the practice of authorized generics.\textsuperscript{163} This petition was filed after Proctor & Gamble had licensed its drug “Macrobid” to Watson Pharmaceuticals during Mylan’s 180-day exclusivity period.\textsuperscript{164} Through Watson, Proctor & Gamble began to market its authorized generic “around the same time that Mylan launched its generic version.”\textsuperscript{165} In its petition, Mylan argued that authorized generics “are the same as true ‘generic’ drugs, and therefore, should be prohibited from being marketed during the exclusivity period.”\textsuperscript{166} Mylan further argued that permitting authorized generics would be contrary to the intent of the law, and that Mylan is eligible for 180-days of market exclusivity.\textsuperscript{167}

Mylan argued that under the Hatch-Waxman Act, a generic manufacturer who first files a paragraph IV ANDA becomes eligible for a 180-day period of exclusivity to market that product.\textsuperscript{168} All subsequent paragraph IV ANDAs cannot be finally approved until the first applicant’s 180-day exclusivity period has expired.\textsuperscript{169} Mylan cited a U.S. Court of Appeals for the Federal Circuit’s opinion in arguing that the purpose of the Hatch-Waxman Act was to grant generic manufacturers that successfully challenge patents the right to sell generic versions of pioneer drugs “without competition for 180 days.”\textsuperscript{170} Mylan claimed that the marketing of authorized generics by brand name manufacturers reduces the incentive for

\begin{footnotes}
\item[161.] Smith, \textit{supra} note 6.
\item[162.] \textit{Id.}
\item[163.] Mylan Citizen Petition, \textit{supra} note 37, at 1.
\item[164.] \textit{Mylan Sues Over Authorized Generics Citing Antitrust Violations, supra} note 51.
\item[165.] \textit{Id.}
\item[166.] Mylan Citizen Petition, \textit{supra} note 37, at 1.
\item[167.] \textit{Id.}
\item[168.] \textit{Id.}
\item[169.] \textit{Id.}
\item[170.] \textit{Id.} at 2 (citing Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 878 (D.C. Cir. 2004)).
\end{footnotes}
generic manufacturers to challenge the brand name manufacturers’ patents. Mylan urged the FDA to treat authorized generics like all other generics by prohibiting the marketing of authorized generics until the first generic ANDA applicant’s 180-day period of exclusivity has expired.

Mylan described the “typical authorized generic scheme” as a situation where a brand name manufacturer licenses a generic version of its pioneer drug, “while continuing to market the same drug as a ‘brand’ drug.” The licensee packages the drug with its own label and NDC number, and the license agreement usually requires that the licensee wait to market the drug until the first generic manufacturer begins its 180-day period of market exclusivity. Mylan stated that this arrangement “cripple[s] the Paragraph IV ANDA applicant’s exclusivity.”

Mylan argued that the authorized generic is the “exact same drug” as the pioneer drug and that the authorized generic is not competing with the brand name drug, but rather, it is competing with the “true” generic drug, or the generic version of the pioneer drug marketed with 180 days of exclusivity. At the same time, the authorized generic is not subject to the same approval process as other generics under the Hatch-Waxman Act.

Mylan claimed that because authorized generics are directly competing with generic versions of the same drug, authorized generics should be subject to a separate approval process by the FDA. Mylan argued that the approval process did not have to be burdensome, and that the FDA “could require the authorized generic applicant to submit a one-page application to identify the distributor and manufacturer of the drug.” Mylan further stated that if “no other generic applicant is eligible for exclusivity, the FDA would grant final approval to the application.”

Mylan essentially suggests that when a generic paragraph IV ANDA applicant is the first to file with the FDA and becomes entitled to the 180-day exclusivity period, then the brand name manufacturer that markets an authorized generic should be treated like subsequent paragraph IV ANDA

171. Mylan Citizen Petition, supra note 37, at 2.
172. See id. at 1.
173. See id.
174. Id. at 2.
175. Id.
176. Id.
177. Id.
178. Id.
179. Id. at 3.
180. Id.
181. Id.
applicants. Like subsequent paragraph IV ANDA applicants, they should be prohibited from marketing their generic versions, the authorized generics, during the 180-day exclusivity period. Like subsequent paragraph IV ANDA applicants, brand name manufacturers would have to wait until the first generic applicant’s 180 days of market exclusivity expire before they can enter the market. Mylan’s argument is that this type of policy would ensure that the intent of Congress in passing the Hatch-Waxman Act is furthered.

B. The FDA Rejected Mylan’s Petition, Claiming That Not Only Does it Not Have the Authority to Prohibit Authorized Generics, But That Authorized Generics Further the Purposes of the Hatch-Waxman Act

On July 2, 2004, the FDA denied Mylan’s petition stating that under the Hatch-Waxman Act, it does not have the authority to regulate competition. The FDA said that it only has the authority to regulate issues of public health, and that it does not regulate drug prices. The FDA said that nothing in the Hatch-Waxman Act “authorizes [the] FDA to prohibit categorically the marketing of authorized generics during 180-day exclusivity periods.”

The FDA also stated that Mylan’s proposal, in which authorized generics would be subject to a separate approval process by the FDA, and therefore treated like other generics, is not persuasive because the Hatch-Waxman Act only forbids the marketing of a new drug that has not been approved. The FDA argued that the Hatch-Waxman Act does not prohibit the use of alternative marketing practices for an already-approved drug.

The FDA also stated that although it does not regulate competition under the Hatch-Waxman Act, competition is a fundamental objective of the Act. The FDA claimed that this objective is accomplished through the ANDA process, whereby generic manufacturers can challenge the innovator’s patent and gain market exclusivity before the end of the patent

182. See id. at 1, 3.
183. See id.
184. See id. at 1-3.
185. See id. at 1, 3.
186. FDA Response to Mylan Citizen Petition, supra note 37, at 13.
187. Id. at 2.
188. Id.
189. Id.
190. Id. at 6.
191. Id.
192. Id. at 12.
term. The FDA argued that competition from authorized generics during "the 180-day exclusivity period furthers the Hatch-Waxman objective of competition enhancing overall among drug products." Lastly, the FDA stated that "[i]f 180-day exclusivity were the sole incentive for ANDA submission, FDA would presumably not see, as we do, second, third, and fourth ANDAs filed by generic companies that are aware that they are not first to file an ANDA application... and cannot gain 180-day exclusivity."

After its citizen petition was denied, Mylan filed a suit against the FDA in the U.S. District Court for the Northern District of West Virginia. This suit was later dropped because Mylan believed that "additional potential claims may be available." Mylan has since refiled its complaint with additional antitrust claims.

C. Both Mylan and the FDA are Partially Correct in Their Arguments For and Against Authorized Generics

Mylan argued that brand name manufacturers who market authorized generics through a licensee are essentially acting like generic manufacturers. This argument is supported by the fact that brand name manufacturers are also often waiting until the first ANDA applicant actually markets the generic version before they market their authorized generic. Because of this, Mylan argued that Proctor & Gamble should have to wait until the end of Mylan's exclusivity period before it can market its authorized generic, as this result would be consistent with the purposes the Hatch-Waxman Act.

The problem with Mylan's position, as the FDA correctly stated in its rejection of Mylan's petition on July 2, 2004, is that the FDA does not have the power to regulate competition. The FDA only has the authority to

193. Id.
194. Id.
195. Id. at 13.
196. Id.
197. Mylan Sues Over Authorized Generics Citing Antitrust Violations, supra note 51.
198. Id.
199. Mylan Sues Over Authorized Generics Citing Antitrust Violations, supra note 55.
200. See Mylan Citizen Petition, supra note 37, at 2; Catherine Hollingsworth, FDA to Consider Ways to Implement Recently Enacted Hatch-Waxman Reforms, PHARMACEUTICAL L. & AND INDUSTRY REP. (Mar. 5, 2004), available at http://subscript.bna.com/SAMPLES/plp.nsf/0/12a29041c351a03e85256e4d007bd91e?OpenDocument (citing the "trend toward authorized generics just prior to the exclusivity period and essentially trumping the 180-day provision").
201. Mylan Citizen Petition, supra note 37, at 2.
regulate the safety and efficacy of new drugs for the public health and welfare. Since the FDA has already approved the brand name manufacturer's new drug application, thus approving the safety and efficacy of the new drug, public health and welfare is not harmed by the brand name manufacturer marketing its patented drug at a generic price.

In addition, because nothing in the Hatch-Waxman Act or its legislative history speaks to the practice of marketing authorized generics, the FDA does not have any guidance from the Act or any legislative history indicating how to deal with authorized generics. Therefore, as Proctor & Gamble's attorney argued, "Mylan's beef is really with Congress."204

Recently, a federal court has gone even further than this proposition, stating that the statute is clear and unambiguous in that the market exclusivity provisions of the Hatch-Waxman Act only apply to ANDA applications, not NDA applications.205 Using a Chevron analysis,206 the court stated that the plain language of the Hatch-Waxman Act is clear because "the statute only prohibits the FDA from approving subsequent ANDAs until after the 180 day exclusivity period has expired."207 The court further stated that nothing in the statute supports the argument "that the FDA can prohibit [brand name manufacturers] from entering the market with [an authorized generic] during the exclusivity period."208

In this case, Teva brought suit against the FDA after its citizen petition, in which Teva requested that the FDA prohibit brand name manufacturers from marketing authorized generics during the 180-day exclusivity period for generics, was rejected by the FDA.209 Teva, like Mylan in its citizen petition with the FDA, argued that the marketing of authorized generics during the first generic manufacturer's exclusivity period was contrary to the intent of

203. Id.
204. Smith, supra note 6.
206. See id. at 116-17; see Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842-43 (1984). Under the two-step Chevron analysis of an agency's determination, the court must first look at the statute to see if Congress directly spoke on the issue. If Congress did, then the court must give effect to the intent of Congress. Teva, 355 F. Supp. 2d at 117. If Congress has not spoken on the issue, and the statute is silent or ambiguous with respect to that issue, then the court must determine whether the agency's determination is a "permissible construction" of the statute. Id.
207. Teva, 355 F. Supp. 2d at 117.
208. Id.
209. Id. at 114-15. Teva's original citizen petition was for the drug Accupril. The Accupril petition was rejected by the FDA, but Teva took no action. Instead, Teva brought suit against the FDA to challenge the FDA's decision on the Accupril petition as it pertained to another Teva drug, Neurotin. Id.
the Hatch-Waxman Act. In finding for the FDA, the court found that the plain meaning of the statute is clear in that it "unambiguously on its face applies only to ANDA applications, not NDA applications" then deference should be given to the FDA’s interpretation of the statute. Therefore, the court held that the FDA’s decision to allow the marketing of authorized generics was consistent with the statute.

Not only did the FDA correctly state that it does not have the authority to regulate competition, but the FDA correctly noted that one of the main purposes of the Hatch-Waxman Act was to put cheaper drugs on the market. Marketing authorized generics helps serve this purpose by having two or more cheaper alternatives to the brand name drug from which consumers may choose. The absence of any guidance in the statute or legislative history on the issue of brand name manufacturers marketing their own generics does not necessarily mean that Congress did not anticipate this practice. Congress amended the Hatch-Waxman Act in 2003, and still there is nothing in the statute that speaks to this practice. As one court has interpreted the Hatch-Waxman Act, the fact that nothing in the statute speaks to the practice implies that authorized generics is not necessarily inconsistent with the intent of Congress. In addition, because the practice of authorized generics increases the amount of cheaper alternatives to the brand name drugs, it is possible that Congress would condone this practice because it is consistent with the Hatch-Waxman Act’s purpose.

On the other hand, however, another major purpose of the Hatch-Waxman Act was “to encourage generic manufacturers to challenge pioneer patent rights.” This incentive is rewarded through the Act’s market exclusivity provisions for generic ANDA applicants. The first generic ANDA

210. Id. at 115. Teva’s arguments will not be addressed in this paper, because they are similar to Mylan’s arguments against authorized generics, which have already been described.

211. Id. at 117.

212. Id. at 118-19.

213. Id. at 118.


218. See FDA Response to Mylan Citizen Petition, supra note 37, at 12.

219. Weiswasser & Danzis, supra note 7, at page 586.

220. Id.
applicants is given a 180-day exclusivity period to market their generic version of the pioneer drug. The Generic Pharmaceutical Association ("GPhA") has argued that if brand name manufacturers are able to market their own generic drugs through the practice of authorized generics, this reduces the incentive for generic manufacturers to challenge weak and questionable patents. "Authorized generics devalue the exclusivity provisions of the Hatch-Waxman Act" by reducing the incentive to challenge invalid patents.

Both Congress and the courts have placed significant value on the 180-day exclusivity period and the commercial marketing trigger for this exclusivity period. In Mova, the court rejected the FDA's requirement that the first generic ANDA applicant had to successfully defend against a patent infringement suit in order to trigger the 180-day exclusivity period. The court held to the literal language of the statute in that this exclusivity period began to run as soon as the generic ANDA applicant began to commercially market the drug. In addition, Congress deleted the "court decision" trigger in its 2003 amendments to the Hatch-Waxman Act leaving "commercial marketing" as the only trigger of the 180-day exclusivity period. Therefore, both Congress and the courts have not wanted to reduce or devalue the incentive for generic manufacturers to challenge weak or invalid patents as they have taken away many restrictions, both statutory and regulatory, to maintain this incentive.

Authorized generics reduce the incentive for generic ANDA applicants to challenge pioneer patents because it devalues the 180-day exclusivity period for generic ANDA applicants. This is because a generic manufacturer "has to be able to get a certain percentage of the market to come into the market at all." Although authorized generics do bring another cheaper alternative to the market in addition to the generic version of the pioneer drug, the GPhA has argued that "[a]uthorized generics in the long term could

223. Id.
224. See generally Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998); see also Lietzan, supra note 12, at 310.
225. Mova, 140 F.3d at 1076.
226. Id. at 1071-72.
227. Lietzan, supra note 12, at 310.
result in generic companies undertaking fewer patent challenges, which would result in higher drug costs for American consumers."\(^{230}\) Therefore, authorized generics do have some anticompetitive effects, contrary to the FDA’s opinion,\(^ {231}\) which may be inconsistent with the Hatch-Waxman Act’s purpose of promoting competition from generic manufacturers. In addition, brand name manufacturers have not hidden their intent to prevent generic competition as many wait until the first ANDA applicant actually markets the generic version before they market their authorized generic.\(^ {232}\) It is no surprise that a brand name manufacturer waits until the first generic manufacturer with market exclusivity comes to market, because “[d]uring the exclusivity period, generic drugs generally are priced at about 30 percent less than the branded drug.”\(^ {233}\)

### III. THE “GAPING BLACK HOLE”

Both Mylan and the FDA are partially correct in their arguments for and against authorized generics. The Hatch-Waxman Act does not give any specific guidance to the interpretative issue of authorized generics as it relates to a generic manufacturer’s ability to compete with brand name manufacturers through the Act’s 180-day exclusivity provision.\(^ {234}\) Indeed, as the statute stands, the market exclusivity provisions only apply to generic manufacturers.\(^ {235}\) In addition, the legislative history for the ANDA process and the 180-day exclusivity provisions is limited.\(^ {236}\) The issue of authorized generics has exposed a gaping black hole in the Hatch-Waxman Act that the FDA and courts have no ability to close.

The FDA was correct in its rejection of Mylan’s citizen petition. The FDA does not have the power to regulate competition as an agency, nor under the Hatch-Waxman Act.\(^ {237}\) The FDA only has the authority to regulate issues of public health and welfare, and a brand name manufacturer’s marketing its own, already-approved drug at a lower price...
does not harm the public health and welfare. In addition, the Hatch-Waxman Act does not provide authority for the FDA to prevent brand name manufacturers from marketing authorized generics. The FDA cannot write provisions into the statute, and it has no guidance from the statute or its legislative history to write rules to regulate authorized generics. As a result, Mylan’s argument that the FDA should create a separate approval process for authorized generics has no authority.

Courts also cannot effectively address this problem, because the Hatch-Waxman Act is silent on the practice of marketing authorized generics and the exclusivity provisions only apply to generic manufacturers who have submitted ANDA applications. The market exclusivity provisions only prohibit other generic manufacturers, who file paragraph IV ANDAs after the first-filing generic manufacturer, from marketing their generic versions during the first-filing generic manufacturer’s exclusivity period. The market exclusivity provisions do not prohibit brand name manufacturers from marketing authorized generics during the exclusivity period. Therefore, because nothing in the statute speaks to the practice, courts cannot effectively deal with this issue. They cannot enact provisions to fill this hole in the statute.

Although the FDA correctly dismissed Mylan’s citizen petition, the FDA’s argument that the practice of marketing authorized generics furthers Congress’ intent of promoting competition is weak. Marketing authorized generics, the FDA argued, brings additional cheaper alternatives to the market for consumers. Although one major purpose of the Hatch-Waxman Act was to bring cheaper drugs to the market, the effect of authorized generics is contrary to the intent of Congress, because brand name manufacturers are marketing authorized generics in order to prevent

238. *See id.*

239. *Teva*, 355 F. Supp. 2d, at 117. “Nothing in the statute provides any support for the argument that the FDA can prohibit NDA holders from entering the market with a brand generic drug during the exclusivity period.” *Id.*


241. *Id* at 118.

242. *Id* at 288; *see also Balto, supra* note 20, at 331.


244. *See FDA Response to Mylan Citizen Petition, supra note 37, at 12.*

cheaper drugs from entering the market.\textsuperscript{247} Brand name manufacturers are marketing authorized generics in order to prevent competition from the generic applicant entitled to market exclusivity.\textsuperscript{248} Brand name manufacturers often try to prevent this competition by only marketing their authorized generics when the generic ANDA applicants first begin to commercially market their generic versions.\textsuperscript{249}

In addition to the anticompetitive effects of authorized generics, this practice is also contrary to another major purpose of the Hatch-Waxman Act, namely to encourage generic manufacturers to challenge pioneer patents.\textsuperscript{250} Because marketing authorized generics devalues the 180-day exclusivity period for the first generic ANDA applicant, it reduces the incentive to challenge pioneer patents.\textsuperscript{251}

Congress and courts have placed significant value on the 180-day exclusivity period and the commercial marketing trigger for this period of exclusivity.\textsuperscript{252} The courts have removed the “successful defense” and “involvement in a patent infringement suit” requirements for approval of a generic’s ANDA.\textsuperscript{253} In addition, Congress practically eliminated the “court decision” trigger in the Medicare Act of 2003, keeping the “commercial marketing” trigger as the primary trigger for the 180-day period of market exclusivity.\textsuperscript{254} Therefore, both Congress and the courts have made sure that the right to market exclusivity has not been impeded in order to maintain the incentive for generic manufacturers to challenge the patents of pioneer drugs.

Furthermore, Congress, the FDA, and courts have tried to curb attempts by brand name manufacturers to prevent generic competition. In the Medicare Act of 2003, Congress attempted to curb some of these abuses by allowing only one thirty-month automatic stay per ANDA and enacting substantial forfeiture provisions for a generic manufacturer’s failure to come to market.\textsuperscript{255}

Brand name manufacturers have been marketing authorized generics as a new scheme to prevent generic competition. They have employed this

\begin{itemize}
\item \textsuperscript{247} See Mylan Citizen Petition, \textit{supra} note 37, at 2.
\item \textsuperscript{248} See id.
\item \textsuperscript{249} Id.
\item \textsuperscript{250} See Smith, \textit{supra} note 6.
\item \textsuperscript{251} \textit{Authorized Generic Drugs a Brand Windfall, GPhA Says, supra} note 230.
\item \textsuperscript{252} See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1076 (D.C. Cir. 1998); see also Lietzan, \textit{supra} note 12, at 310.
\item \textsuperscript{253} See Mova, 140 F.3d 1060, 1076 (D.C. Cir. 1998); see also Purepac Pharm. Co. v. Friedman, 162 F.3d 1201 (D.C. Cir. 1998).
\item \textsuperscript{254} Lietzan, \textit{supra} note 12, at 310.
\end{itemize}
practice to regain the market share that is taken away by generic manufacturers through the 180-day exclusivity period. However, the FDA, as stated above, does not have the authority to regulate competition. In addition, the Hatch-Waxman Act does not account for the practice of authorized generics by brand name manufacturers during the first-filing generic manufacturer’s market exclusivity period, as the market exclusivity provisions of the Hatch-Waxman Act only apply to generic manufacturers who have filed paragraph IV ANDAs.\textsuperscript{256} Congress needs to amend the Hatch-Waxman Act to account for the practice of authorized generics and to make changes in order to serve the purpose and intent of the original Act. Although brand name manufacturers should not be completely prohibited from marketing authorized generics, they should not be able to employ this practice during the exclusivity period in order to prevent generic competition. They should have to wait until the exclusivity period is over, and other generic manufacturers begin to market their generic versions. As it stands now, the practice completely devalues the incentive for generic manufacturers to challenge listed patents through the ANDA process. “Authorized generics are the biggest threat to the generic industry today[,]\textsuperscript{257} and if Congress does not address the issue, then it could result in higher drug costs for consumers in the long run if fewer generic manufacturers undertake patent challenges.\textsuperscript{258}

CONCLUSION

Congress did not account for authorized generics when it passed the Hatch-Waxman Act, and it has not accounted for this practice during the Act’s twenty-year lifespan. The FDA was correct in rejecting Mylan’s citizen petition on this issue, as the FDA does not have the power to regulate competition. In addition, the Hatch-Waxman Act gives no specific guidance for the FDA or courts in terms of how to properly address the issue of authorized generics. Mylan’s “beef” is with Congress, and it is up to Congress to fix the gaping black hole in the Act.


\textsuperscript{257} Kirsche, supra note 233.

\textsuperscript{258} Authorized Generic Drugs a Brand Windfall, GPhA Says, supra note 230.