A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act

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A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act

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I. INTRODUCTION

This article summarizes the history of the 180-day exclusivity provision in the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). Part II presents the statutory language, as amended in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and summarizes the law that applies to new abbreviated new drug applications (ANDAs) (those filed after December 8, 2003, provided there was no paragraph IV certification to the listed drug prior to December 8), as well as the law that applies to all other (“old”) ANDAs. Part III describes the legislative history of the original 1984 provision and traces its judicial and administrative history through the present. Part IV describes the history of the 2003 amendments and describes the key changes made in 2003. While Congress addressed in 2003 a number of the interpretive issues that had arisen since 1984, the new law is intricate and undoubtedly will give rise to new interpretive questions in the months and years ahead.

II. OVERVIEW OF THE LAW

Section 505(b)(1) of the FDCA requires a new drug applicant to include in its new drug application (NDA) 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.

The Food and Drug Administration (FDA) publishes these patent numbers and their expiration dates in an Addendum to the Orange Book. FDA explains in the preface to the Orange Book that “[p]atent information on unapproved applications or on patents beyond the scope of the Act (i.e., process or manufacturing patents) will not be published.” Section 505(j)(2)(A) of the FDCA requires a generic applicant to include in its ANDA, with respect to every “patent which claims the listed drug [on which the ANDA

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is based] or which claims a use for such listed drug for which the applicant is seeking approval under [subsection 505(j)] and for which information is required to be filed under [subsection 505(b) or (c)]" a certification that one of the following is true: 1) the patent information has not been filed by the NDA holder, 2) the patent has expired, 3) the date on which the patent will expire, or 4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted.5

Sections 505(j)(5)(B)(iv) and 505(j)(5)(D) of the FDCA govern the 180-day exclusivity available to the first generic applicant to file an ANDA challenging a patent held by the innovator. Congress enacted these provisions in 1984 and amended them substantially in 2003. Both the original and current language of these provisions are reproduced in the Appendix to this article. With one exception, the new rules apply only prospectively.6

The core concept of 180-day exclusivity is that the first generic applicant to challenge an innovator’s patent is entitled to six months of exclusivity against subsequent generic copies of the same innovator drug. This, it was thought, would encourage generic applicants.7 The concept was simple enough and the statutory language, described infra, was correspondingly brief. No one at the time anticipated the deluge of interpretive disputes and litigation that followed. No doubt, this in part explains the paucity of legislative history on the provision. FDA made a valiant effort to adopt reasonable implementing policies, but the agency was hampered by the lack of guidance in the legislative history and by inflexible statutory language. In an earlier era, the courts might have been more forgiving of FDA’s exercise of its discretion in this situation, but the 1990s were a time of searching review of agency decisionmaking,8 and, as discussed infra, the agency lost a number of cases involving its application of 180-day exclusivity.

A. The Current Legislative Language Governing 180-Day Exclusivity

As amended in 2003, section 505(j)(5)(B)(iv) provides that

[i]f the [abbreviated new drug] application contains a certification described in paragraph (2)(A)(vii)(IV) [otherwise known as a “paragraph IV certification”] and is a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.9

Put another way, the first generic applicant to file an ANDA containing a paragraph IV certification is awarded 180 days of marketing exclusivity, during which FDA may not approve a subsequent ANDA with a paragraph IV certification for the same drug prod-

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6 The new rules apply only to ANDAs filed after December 8, 2003, and only if there was no paragraph IV certification for the listed drug prior to December 8. See Pub. L. No. 108-173 § 1102(b). The exception relates to the “court decision” trigger for exclusivity, and it is explained infra at text accompanying n.29.
7 Apart from the so-called “paper NDA” process, FDA did not have a streamlined process for approval of generic copies of brand-name drug products whose patents had expired. According to the Federal Trade Commission (FTC), “[b]y 1984, the FDA estimated that there were approximately 150 brand-name drugs whose patents had expired for which there was no generic equivalent.” GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002) (citing H.R. REP. No. 98-857, Part 1, at 17 (1984)).
8 See Erika King & Elizabeth Walsh, FDA in Court: Statistics on the Agency’s Record in Recent Years, FDLI Update, July/Aug. 2002, at 34.
uct. The exclusivity period is calculated from the date of the first commercial marketing of the drug product (including the listed drug product) by the first applicant.

Under section 505(j)(5)(D), the 180-day exclusivity period is forfeited if the first applicant fails to market the drug by the later of: 1) 75 days after the date on which approval of its application is effective, or 30 months after its application was submitted, whichever is earlier, or 2) 75 days after the date on which, as to each patent that is the subject of a paragraph IV certification by the first applicant (qualifying it for exclusivity), a court has found the patent invalid or not infringed, a court signs a settlement order or consent decree finding the patent invalid or not infringed, or the patent information is withdrawn by the holder of the approved NDA.

The 180-day exclusivity period also is forfeited if any of the following occurs: 1) the first applicant withdraws its application or the Secretary considers it to have been withdrawn because it did not meet the requirements for approval; 2) the first applicant amends or withdraws all of the paragraph IV certifications that qualified it for exclusivity; 3) the first applicant fails to obtain tentative approval of its application within 30 months after it was filed (unless the failure is caused by a change in, or review of, the requirements for approval of the application imposed after it was filed); 4) the first applicant enters into an agreement with another ANDA applicant, the NDA holder, or a patent holder, and the Federal Trade Commission (FTC) or a court has found that the agreement violates the antitrust laws; or 5) all of the patents as to which the first applicant filed a paragraph IV certification qualifying it for exclusivity have expired. If all first applicants forfeit the 180-day exclusivity, any subsequent ANDA approval may be made effective immediately—that is, exclusivity does not “roll over” to a subsequent ANDA applicant.

B. The Prior Law Governing 180-Day Exclusivity

Between 1984 and 2003, section 505(j)(5)(B)(iv) of the FDCA provided that

If the [abbreviated new drug] application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) [otherwise known as a “paragraph IV certification”] and is for a drug for which a previous application has been submitted under this subsection continuing [sic “containing”] such a certification, the application shall be made effective not earlier than one hundred and eighty days after:—(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.10

Put another way, the first generic applicant to file an ANDA containing a paragraph IV certification was to be awarded 180 days of marketing exclusivity, during which FDA could not approve a subsequent ANDA with a paragraph IV certification for the same drug product. The exclusivity period was calculated from either the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever was sooner.

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C. The Rules Governing ANDAs Filed After December 8, 2003, If There Was No Paragraph IV Certification for the Listed Drug Prior to December 8 ("New" ANDAs)

The following are key interpretive questions about 180-day exclusivity and, after each, an explanation of the current law and the source for that law (whether statute, regulations, guidance, court decisions, legislative history, or some other document).

- **Who is entitled to 180-day exclusivity?** Exclusivity is awarded to the "first" applicant to file a "substantially complete" ANDA with a paragraph IV certification. A "substantially complete" ANDA is one that "on its face is sufficiently complete to permit a substantive review" and that contains all of the information required by section 505(j)(2)(A). 11 This was intended to continue prior FDA practice. 12

- **If several applicants file ANDAs on the same day, which is entitled to 180-day exclusivity?** If multiple applicants file substantially complete ANDAs with paragraph IV certifications on the same day as the first to do so, those applicants all are entitled to exclusivity. 13 This result also is required by the new statutory language, which precludes approval for 180 days after first commercial marketing by "any" first applicant, and which precludes rollover if "all first applicants" forfeit their exclusivity. 14

- **Must the ANDA applicant file its paragraph IV certification and send notice to the innovator on the same day?** Where notice is provided after the certification is received, agency policy under the statutory language in effect from 1984 to 2003 constructively moved the certification's submission date—which governs eligibility for exclusivity—to the day on which the applicant mailed the notice. This was sustained as a reasonable exercise of agency discretion. 15 Congress did not address this issue in 2003, and it is reasonable to assume FDA's policy has not changed. 16

- **Does 180-day exclusivity "roll over" to a second ANDA applicant in the event that the first does not perfect its rights?** No. In FDA's August 1999 draft regulations, which were never finalized, the agency confirmed that exclusivity would not roll to a second applicant, even if the first applicant withdrew its ANDA. 17 The new legislation requires this result as well: if all first applicants forfeit exclusivity, "no applicant shall be eligible." 18

- **Can there be separate exclusivity periods for different ANDA applicants who filed paragraph IV certifications as to different listed patents for the same innovator drug product, and for different applicants for different dosages of the same innovator drug product?** No. The new legislation abolished the patent-by-patent approach in favor of a product-by-product approach. If all first applicants forfeit exclusivity, approval of "any" application containing "a" paragraph IV certification may be made effective. 19

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12 See 21 C.F.R. § 314.101(b)(1).
14 See 149 CONG. REC. S15584 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) ("and the exclusivity is available to more than one generic applicant, if they all challenge patents on the same day").
18 Id. See also 149 CONG. REC. S15884 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) ("The Hatch-Waxman provisions in this bill also make the exclusivity available only with respect to the patent or patents challenged on the first day generic applicants challenge brand drug patents, which makes the exclusivity a product-by-product exclusivity rather than a patent-by-patent exclusivity.")
How do 180-day exclusivity and pediatric exclusivity interact? Under legislation enacted in 2002, if a pioneer applicant earns six months of pediatric exclusivity, the first generic applicant’s ANDA is approved effective the first day after conclusion of that exclusivity, and the 180 days begin at that point. The terms are consecutive. Congress did not address this issue again in 2003 so, presumably, the 2002 rule continues to apply.

Are 180-day exclusivity rights waivable and/or transferable? Under agency policy prior to 2003, the first generic may waive its 180-day exclusivity rights in favor of another generic applicant (or in favor of no generic), for consideration. In some instances, the consideration has been a royalty stream that would continue even after exclusivity expired. Congress did not address this issue in 2003, and, presumably, this continues to be agency policy.

Will marketing by the first generic of the pioneer’s product under a private generic label satisfy the commercial marketing trigger? Yes. Congress confirmed this in 2003 with the addition of the words “including the commercial marketing of the listed drug” in the sentence describing the trigger.

D. The Rules Governing All Other (“Old”) ANDAs

The rules are different for an ANDA filed before December 8, 2003, as well as an ANDA filed afterwards if a paragraph IV certification for the listed drug was filed before December 8.

Who is entitled to 180-day exclusivity? Exclusivity is awarded to the “first” applicant to file a “substantially complete” ANDA with a paragraph IV certification. The statute did not define “substantially complete,” but FDA has “received” an ANDA only if it is sufficiently complete to permit a substantive review. Among other things, the ANDA needs to contain “the results of any required bioequivalence studies or, if applicable, a request for a waiver of such studies.”

If several applicants file ANDAs on the same day, which is entitled to 180-day exclusivity? If multiple applicants file substantially complete ANDAs with paragraph IV certifications on the same day as the first to do so, those applicants all are entitled to exclusivity.

Must the ANDA applicant file its paragraph IV certification and send notice to the innovator on the same day? Where notice is provided after the certification is received, agency policy constructively moves the certification’s submission date, which governs eligibility for exclusivity, to the day on which the applicant mailed the notice. This has been sustained as a reasonable exercise of agency discretion.

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Does 180-day exclusivity “roll over” to a second ANDA applicant in the event that the first does not perfect its rights? No. In FDA’s August 1999 draft regulations, which were never finalized, the agency confirmed that exclusivity would not roll to a second applicant, even if the first applicant withdrew its ANDA.27

Must the generic applicant have itself prevailed in a patent infringement suit in order to obtain the benefits of 180-day exclusivity? No. There is no “successful defense” requirement. Another generic could prevail instead, or the case could be dismissed.28

What level court decision will trigger the 180-day exclusivity? This is the sole topic on which the 2003 legislation is retroactive. For ANDAs (i.e., those as to which the new rules do not apply), exclusivity begins when a decision is rendered by “the court from which no appeal (other than a petition of the Supreme Court for a writ of certiorari) has been or can be taken.”29

What kind of court decision will trigger the 180-day exclusivity? Exclusivity can be triggered by a decision in a declaratory judgment action brought by the generic manufacturer, including, for example, dismissal of that lawsuit for lack of case or controversy when the patent holder admits to noninfringement.30

Can there be separate exclusivity periods for different ANDA applicants who filed paragraph IV certifications as to different listed patents for the same innovator drug product, and for different applicants for different dosages of the same innovator drug product? Yes. One generic manufacturer may hold exclusivity for one dosage strength, while a different manufacturer holds exclusivity for a different dosage strength.31 Similarly, tablet forms and capsule forms of the same drug are eligible for separate 180-day exclusivity periods. If products are listed separately in the Orange Book, they are eligible for separate exclusivity periods.

How do 180-day exclusivity and pediatric exclusivity interact? If a pioneer earns six months of pediatric exclusivity, the first generic applicant’s ANDA is approved effective the first day after conclusion of that exclusivity, and the 180 days begin to run at that point. The terms are consecutive.32

Are 180-day exclusivity rights waivable and/or transferable? Yes. The first generic may waive its 180-day exclusivity rights in favor of another generic applicant (or in favor of no generic), for consideration.33 In some instances, the consideration has been a royalty stream that would continue even after exclusivity expired.

Will marketing by the first generic of the pioneer’s product under a private generic label satisfy the commercial marketing trigger? Yes.34

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30 Teva Pharm., USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999).
III. A History of the 1984 180-Day Exclusivity Provision

A. 1984: Enactment

There were no changes to the 180-day exclusivity provision between its introduction and the passage of the Hatch-Waxman Amendments.\(^{35}\) As enacted in 1984, the legislation provided that:

If the [ANDA] contains a certification described in subclause (IV) of paragraph (2)(A)(vii) [otherwise known as a “paragraph IV certification”] and is for a drug for which a previous application has been submitted under this subsection continuing [sic “containing”] such a certification, the application shall be made effective not earlier than one hundred and eighty days after—(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.\(^{36}\)

Put another way, the first generic applicant to file an ANDA containing a paragraph IV certification was to be awarded 180 days of marketing exclusivity, during which FDA could not approve a subsequent ANDA with a paragraph IV certification for the same drug product. The exclusivity period would be calculated from either the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever was sooner.

The legislative history of the provision is sparse. Indeed, the provision is mentioned only twice in the final House Report. Part 1 explains that:

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 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.\(^{37}\)

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\(^{35}\) The original language was introduced as part of Waxman’s amendment to H.R. 3605, as considered by the House Committee on Energy and Commerce, at 11. It can be found in S. 2926, as placed on the Senate Calendar, at 13-14, and in H.R. 3605, as placed on the House Union Calendar, at 14. The as-enacted version can be found at 98 Stat. 1589.

\(^{36}\) 21 U.S.C. § 355(j)(5)(B)(iv). The concept of a “court decision” was used in two places in section 505(j) of the FDCA. First, the patent-owner is entitled to a 30-month stay on approval of an ANDA that is the subject of patent infringement litigation except if “before the expiration of such period the court decides that such patent is invalid or not infringed, the approval will be made effective on the date of the court decision.” Id. § 355(j)(5)(B)(iii)(I). Second, 180-day generic drug exclusivity was to begin on either: 1) the date of first commercial marketing or 2) the date of a decision of a court holding the patent which is the subject of the paragraph IV certification to be invalid or not infringed, whichever is earlier. Id. § 355(j)(5)(B)(iv). Both provisions were amended by Congress in the MMA. The court decision trigger for 180-day exclusivity was dropped altogether.

Part 2 of the House Report essentially repeats the first sentence: 

If an ANDA certifying patent invalidity or non-infringement is filed subsequent to an ANDA for the same listed drug that has made a similar certification, clause (iv) provides that the approval of the subsequent ANDA can be made effective [no] sooner than 180 days after the previous applicant has begun commercial marketing, or the date on which the court rules the patent invalid or not infringed, whichever occurs first.\[38\]

Neither passage offers insight into the interpretive issues that arose between 1984 and 2003.

**B. 1994: FDA’s Implementing Regulations**

FDA was slow to issue regulations implementing the 180-day exclusivity provision. The agency proposed regulations to implement the 1984 legislation in 1989, but final regulations on the 180-day provision did not issue until October 1994.\[39\] Few changes were made between issuance of the proposed rule and issuance of the final rule.

The final regulation, printed at 21 C.F.R. § 314.107(c) (1994), stated that if an ANDA contained a paragraph IV certification and was for a generic copy of the same listed drug “for which one or more substantially complete abbreviated new drug applications were previously submitted” containing a paragraph IV certification, and “the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner’s receipt of notice,” then approval of the second ANDA would be made effective no sooner than the earlier of 1) the date the first applicant “first commences commercial marketing of its drug product” or 2) the date “of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.”\[40\]

The regulation clarified that the “applicant submitting the first application” is the applicant that submits an application that both 1) is substantially complete and 2) contains a paragraph IV certification, prior to the submission of any other application for the same listed drug that both is substantially complete and contains the same certification. A “substantially complete” application contains “the results of any required bioequivalence studies, or, if applicable, a request for a waiver of such studies.”\[41\] The regulation further stated that if the agency concluded that the first applicant was “not actively pursuing approval” of its ANDA, FDA would make the approval of subsequent abbreviated applications immediately effective if they were otherwise eli-

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\[39\] 54 Fed. Reg. 28,872 (July 10, 1989) (proposed rule); 59 Fed. Reg. 50,338 (Oct. 3, 1994) (final rule). Before 1992, however, FDA granted exclusivity to only three applicants, and from 1992 to 1998, FDA did not grant exclusivity to any applicants. GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 57 (July 2002). Each of the three applicants received exclusivity after successful defense of a patent infringement suit. Id. at 60. By way of contrast, 31 applicants obtained exclusivity between 1998 (when the “successful defense” requirement was invalidated) and the FTC’s 2002 report. Id. In 19 of these 31 instances, exclusivity was triggered by commercial marketing. Id. at 58, 60. See id. at 60-63 for a more detailed discussion of these statistics.

\[40\] The statute refers only to a decision holding the patent invalid or not infringed. FDA added “unenforceable.”

\[41\] In the preamble to the proposed regulation, FDA had added that a “required bioequivalence study is one that meets any FDA guidance document or is otherwise reasonable in design and purports to show that the drug product for which the applicant seeks exclusivity is bioequivalent to the listed drug.” 54 Fed. Reg. at 28,895. It does not include a protocol or a pilot study. Id.
gible for immediately effective approval. Finally, the regulation stated that the first applicant must, if sued for patent infringement, notify FDA of the date that it commences commercial marketing of its drug product. "Commercial marketing" was defined as "the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer of a drug product." It did not include shipment for investigational use or transfer of the drug product "for reasons other than sale within the control of the manufacturer or application holder." 

FDA clarified a number of important points in the preamble to the final regulations. First, FDA stated that a generic applicant would be entitled to exclusivity only when it has itself been involved in a patent infringement lawsuit. To provide otherwise "would provide a windfall to an applicant who has not devoted the considerable time and money necessary for patent litigation." After the FDA Commissioner signed the Federal Register notice of the proposed regulations, but before its publication in the Federal Register, a federal district court reached a contrary conclusion. The agency appealed that decision, however, and the case was dismissed as moot before FDA concluded the rulemaking. In its final regulations, the agency stood by its earlier position.

Second, in response to comments, FDA provided in the final rule that a generic applicant would be entitled to exclusivity only if it had successfully defended a patent infringement suit. Neither the court decision nor the commercial marketing trigger would apply, unless and until the first applicant won its patent infringement suit. To provide otherwise would "create[] an incentive for frivolous claims of patent invalidity or noninfringement." A federal district court invalidated the successful defense requirement in 1997, and FDA removed it from the regulation in 1998.

Third, as it had in the preamble to the proposed rule, FDA stated that the court decision activating the court decision trigger "must be a final decision from which no appeal can be or has been taken." A federal district court disagreed in 2000. For ANDAs filed after March 2000, therefore, "court" refers to the first court to decide the patent is invalid, not infringed, or not enforceable.

Fourth, rejecting concerns about so-called "file first fix later" practices on the part of generic manufacturers, FDA declined to establish criteria to determine whether changes to an ANDA have been so substantial that it can no longer be considered to have been the first filed. Instead, the agency would rely on its decision in 1992 to no longer accept

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43 Id. at 50,352-53.
45 Purepac Pharm. Co. v. Friedman, 162 F.3d 1201 (D.C. Cir. 1998).
ANDAs lacking complete bioequivalence study data (if such data are required for approval) and use a "case-by-case approach" to ANDA changes.\textsuperscript{53}

C. 1997: Mova and Boehringer

1. Mova (The "Successful Defense" Case)

In January 1997, a federal district court invalidated the successful defense requirement.\textsuperscript{34} The events leading up to that decision began in December 1994, when Mova Pharmaceutical Corporation filed an ANDA with a paragraph IV certification to market a generic version of micronized glyburide, a diabetes drug patented by Pharmacia & Upjohn. Pharmacia sued Mova for infringing its patent. In November 1995, while Mova was engaged in that litigation, Mylan Pharmaceuticals Inc. filed an ANDA for the same product. Although it originally included a paragraph III certification, Mylan amended its ANDA, in August 1996, to contain a paragraph IV certification. Pharmacia declined to sue, and FDA approved Mylan's application on December 19, 1996.\textsuperscript{11} FDA reasoned that Mova's exclusivity did not bar approval of the Mylan ANDA, because Mova had not yet successfully defended against Pharmacia's suit.

On December 26, 1996, Mova brought suit to compel FDA to delay the effective date of its approval of Mylan's product until 180 days after the earlier of the date Mova won its lawsuit or the date it began to market its product. Mova challenged the successful defense regulation as contrary to the plain language of the statute. The district court found that Mova had a very high likelihood of success on the merits of its claim and granted a preliminary injunction.\textsuperscript{5}

In 1998, the D.C. Circuit affirmed the district court's holding.\textsuperscript{56} Although FDA argued that its successful defense requirement furthered the intent of Congress, the court disagreed. The successful defense requirement, the court wrote, is "gravely inconsistent with the text and structure of the statute."\textsuperscript{58} FDA's construction of the statute meant that the first ANDA applicant could never benefit from that trigger. The D.C. Circuit explained,

The commercial-marketing trigger seems intended to insure that, if a first ANDA applicant chooses to begin marketing its product before it has won its patent-infringement suit, the 180-day exclusivity period will begin to run immediately. Under the FDA's regulation, however, the 180-day exclusivity period is only available to an applicant who has already "successfully defended against a suit for patent infringement."\textsuperscript{59}

Its practical effect, the court wrote, is "to write the commercial-marketing trigger out of the statute."\textsuperscript{60} The court recognized the problem, raised by Mylan, that the statutory

\textsuperscript{53} 59 Fed. Reg. at 50,354. Although FDA had been requiring complete study data since 1992, it commented in the preamble to the final rule that "[a] decision by the agency after receipt of an application that the bioequivalence information is inadequate for approval does not necessarily mean that the application was not substantially complete at the time of submission." Id. This effectively undermined the 1992 solution to what FDA itself referred to as a "significant and unwarranted expenditure of resources in reviewing applications that had little potential for approval." Id.


\textsuperscript{55} Id. at 130.


\textsuperscript{57} Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998).

\textsuperscript{58} Id. at 1069.

\textsuperscript{59} Id. at 1069-70.

\textsuperscript{60} Id. at 1069. The court reasoned that "if the first applicant begins marketing its product before it wins its infringement suit, the 180 days of exclusivity do not begin to run; other applicants remain eligible for FDA approval to begin marketing their products, at least up to the date that the first applicant wins the infringement action." Id. at 1070.
scheme might penalize a meritorious second ANDA applicant. Nevertheless, the court found that the successful defense requirement was too "blunt an instrument" to address that problem. Thus, the regulation was invalid. Mova accordingly established that the first generic need not successfully defend a patent infringement suit in order to enjoy the benefits of 180-day exclusivity.

2. Boehringer Ingelheim (The "Transfer of Exclusivity" Case)

In Boehringer Ingelheim Corp. v. Shalala, a federal district court upheld FDA's decision to approve an ANDA filed by a second applicant who had purchased 180-day exclusivity from the first applicant. The court noted that the Hatch-Waxman Amendments are silent on the question of transferability of 180-day exclusivity. FDA's decision to allow transfer in this instance, therefore, was well within the zone of the agency's discretion. FDA would restate its position that 180-day exclusivity rights are transferable for consideration in proposed regulations published in 1999, and the agency has continued to approve ANDAs filed by applicants who have purchased the exclusivity rights of the first to file. The availability of a transfer option and the lack of any sort of forfeiture provision led to absurd results, however, as in 2002 when the first applicant to file a substantially complete ANDA for generic Prilosec® (omeprazole) was found to infringe the sponsor's patents and was able, nevertheless, to block market entry by a noninfringing ANDA applicant until that second applicant agreed to pay a royalty stream for the life of its drug product.

D. 1998: Granutech, a Guidance to Industry, an Interim Rule, and Purepac I

1. Granutech (A "Successful Defense" Case)

After the district court in Mova found that FDA's successful defense regulation was invalid, FDA decided to cease enforcing the regulation pending appeal. During the pendency of that appeal, the Fourth Circuit, too, invalidated FDA's successful defense requirement.

61 Id. at 1072.
62 Id. at 1074.
63 In dicta, the court also approved as "elegant and textually persuasive" an argument made by Teva Pharmaceutical (as amicus curiae) that the court-decision trigger may be satisfied by any decision of a court holding the patent invalid or not infringed—including suits not brought by the patent holder, such as a declaratory judgment action by the second ANDA applicant. Id. at 1072-73. The court noted, however, that it "seems odd to reward the first applicant if some later applicant was the party that actually prevailed in the patent-infringement litigation." Id. at 1073.
64 993 F. Supp. 1 (D.D.C. 1997). Neither the court's opinion nor trade press disclosed the terms of the agreement, but it is reasonable to assume consideration was involved. See, e.g., Novopharm Marketing Generic Rantidine Through Agreement with Genpharm; Three-Week Delay Brings Glaxo $100 Mil. in Additional Zantac Sales, F-D-C REP. ("The Pink Sheet"), Aug. 4, 1997, at 3.
67 FTC STUDY supra note 7, at 36 ("For 6 out of 68 drug products in which there was more than one generic applicant, the first and second generic applicant entered into agreements related to generic market entry. In 4 of these agreements, one of the main provisions specified which generic applicant had or retained rights to the 180-day exclusivity."); id. ("In 1 agreement, the first generic applicant relinquished its rights to 180-day exclusivity for a $35 million license and royalty payment based on the second generic applicant's sales for a period of 7 years.").
68 See Andrx Altocor Sales Force Expanded 50%; Generic Prilosec Charge is $41 Mil., F-D-C REP. ("The Pink Sheet"), Nov. 4, 2002, at 4.
In this case, Genpharm Inc. had filed an ANDA with a paragraph IV certification for generic ranitidine (Form 2) in February 1991—the first to file. GlaxoWellcome, Inc., the owner of the patent for ranitidine, sued Genpharm and prevailed. In 1996, Genpharm filed an ANDA with a Paragraph IV certification for generic ranitidine (Form 1). GlaxoWellcome again sued, but that case was still pending when Granutec was decided. In April 1994, in the interim between the two Genpharm ANDAs, Granutec, Inc. filed a Paragraph IV ANDA for generic ranitidine (Form 1). GlaxoWellcome brought suit, but Granutec prevailed.

GlaxoWellcome and Granutec then entered into a licensing agreement for the final fifteen days of the patent on Zantac®, and Granutec sought FDA approval for its generic version beginning July 10, 1997. FDA refused approval, stating that the 180-day exclusivity period had been triggered on March 3, 1997, when the Federal Circuit had found, in an unrelated case, that Boehringer Ingelheim Corp.'s version of generic ranitidine did not infringe Glaxo's patent. Because Genpharm had filed the first ANDA for generic ranitidine, and because FDA had suspended the successful defense requirement after the district court decision in Mova, FDA concluded that Genpharm was entitled to exclusivity. (Genpharm, however, did not have final approval of its ANDA.).

Granutec then brought suit, arguing that FDA's refusal to enforce the successful defense requirement was arbitrary and capricious. The district court agreed and issued an injunction requiring FDA to adhere to the successful defense requirement. This would effectively mean that no company would be entitled to exclusivity. The Fourth Circuit reversed, finding that the statute did not require a successful defense against a patent infringement suit. Genpharm was entitled to exclusivity. The decision was not published, however, and under Fourth Circuit rules, the court of appeals could not cite it in any subsequent published opinion or unpublished disposition.

2. A Guidance to Industry and an Interim Rule ("Successful Defense")

In June 1998, shortly after the Granutec decision (April 3) and the appellate decision in Mova (April 14), FDA published a guidance for industry. This guidance detailed a new approach to 180-day exclusivity in light of the court decisions. FDA announced its intent to "formally" remove the successful defense requirement from the regulation and to conduct a rulemaking proceeding to issue new regulations. In the meantime, FDA stated, it would "regulate directly from the statute" and "make decisions on 180-day generic drug exclusivity on a case-by-case basis." Thus, the agency would inform the first applicant to submit a substantially complete abbreviated application with a paragraph IV certification that, as the first applicant, it was eligible for 180 days of market exclusivity, even though it had not been sued for patent infringement. In November,

71 Id. at *4.
72 Id.
73 Id.
75 1998 WL 153410 at *5.
76 Id. at *7.
77 See Court of Appeals for the Fourth Circuit Rule 36(b).
79 Id. at 4.
80 Id.
81 Id. at 5.
FDA published an interim rule, eliminating the successful defense requirement of 21 C.F.R. § 314.107(c)(1). The agency also made a conforming change to 21 C.F.R. § 214.107(c)(4), by deleting the phrase “if sued for patent infringement.”

3. Purepac I (The “First Generic Need Not Be Sued” Case)

In December 1998, the D.C. Circuit confirmed that the first generic need not be sued for patent infringement. TorPharm, a division of Apotex, Inc., was the first to file an ANDA for a generic version of Ticlid® (ticlopidine hydrochloride). TorPharm’s ANDA contained a paragraph IV certification. No one brought a patent infringement suit against TorPharm, however, and when the Purepac case was litigated, FDA had not yet finally approved TorPharm’s ANDA. Thus, the 180-day clock had not yet begun to run.

FDA tentatively approved Purepac Pharmaceutical Company’s subsequent ANDA, but withheld final approval pending TorPharm’s final approval, commercial marketing, and expiry of its 180-day exclusivity. Purepac sued for an injunction claiming that TorPharm was not entitled to exclusivity because it had not been sued for infringement. The court concluded that FDA’s “revised system for granting exclusivity” was consistent with the statute and the Mova decision. The statute does not require the first applicant to be sued in order to benefit from market exclusivity. Thus, FDA could withhold final approval of the Purepac ANDA until TorPharm had commercially marketed for 180 days.

E. 1999: The Apotex and Teva Decisions, a Response to Citizen Petitions, and Proposed Regulations

1. The Apotex Decision (“Separate Exclusivity Periods”)

In Apotex v. Shalala, the D.C. Circuit resolved the question whether different dosages of a drug are eligible for separate 180-day exclusivity periods. Glaxo held the patent and NDA for ranitidine hydrochloride, which it markets under the trade name “Zantac®.” Among the ranitidine hydrochloride products sold by Glaxo were 150 mg and 300 mg tablets, both prescription drug products intended for the treatment of ulcers, and 75 mg tablets, sold over-the-counter (OTC) for the treatment of heartburn. Genpharm was the first to file for the 150/300 mgs, and its exclusivity ran from March 3 to August 29, 1997. FDA had since approved additional ANDAs. NovoPharm Ltd. was the first to file on the 75 mg OTC product and was eligible for 180-day exclusivity. Apotex sought immediate approval of its own 75 mg tablets, however, on the theory that FDA may not grant exclusivity periods for ANDA applications that concern the same patents involved in previously-approved drugs of different strengths. The district court disagreed, holding that permitting separate exclusivity periods for separate drug strengths is consistent with the statute, which requires that an ANDA must contain, among other things, “information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug.” (Each strength has
For similar reasons, tablet forms and capsule forms of the same drug were to be eligible for separate 180-day exclusivity.  

2. The Teva Decision (Meaning of a “Court Decision”)

In Teva Pharmaceuticals,90 the D.C. Circuit ruled on the meaning of “court decision.” On June 20, 1997, Teva Pharmaceuticals, USA, Inc. filed an ANDA for ticlopidine tablets, a generic version of Ticlid91. Teva was a subsequent applicant, not the first generic applicant. Teva then sued the patent holder, Syntex (U.S.A.), Inc., in the Central District of California for a declaratory judgment of noninfringement.92 After Syntex admitted that Teva’s ANDA did not infringe its patent, the California court dismissed the suit for lack of subject matter jurisdiction.93

On October 29, 1998, FDA tentatively approved Teva’s ANDA. FDA informed Teva, however, that because there was a prior ANDA applicant, and neither commercial marketing nor a court decision had occurred, its application was ineligible for final approval. Teva argued, to no avail, that the California court’s dismissal of its declaratory judgment suit against Syntex satisfied the “court decision” requirement, triggering the other company’s exclusivity. Teva then brought suit in federal district court in the District of Columbia, seeking to have its ANDA approved effective 180 days after the California court dismissed the declaratory judgment suit. The district court upheld FDA’s decision and denied injunctive relief.94 The D.C. Circuit reversed, holding that the dismissal by the California court was the functional equivalent of a final decision of noninfringement. FDA’s unexplained refusal to recognize it as such was arbitrary. The refusal also was contrary to the FDCA, FDA’s guidance document, and FDA’s position in Granutec.95

The discussion in Teva addresses several points. First, any court decision with “preclusive effect,” even a dismissal of a declaratory judgment action, can trigger exclusivity. In this case, dismissal of the California case was a triggering court decision because it precluded the patent holder from suing Teva for patent infringement. “A ‘decision’ can take several forms,” the court wrote “including final judgment after a full trial, summary judgment or partial summary judgment, or even dismissal for failure to state a cause of action.”96 Second, although the statute provides that exclusivity dates to a decision that the patent is invalid or not infringed, FDA’s regulations, since 1994, have said “invalid, unenforceable, or not infringed.” The D.C. Circuit rejected the argument that unenforceability (in the regulation) and estoppel (in the case at hand) should be treated differently from invalidity and noninfringement.97 Third, the case confirms that

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90 See, e.g., Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d at 30, 35 n.8 (D.D.C. 2000) (“The tablet and capsule forms of the drug, however, are distinct products for FDA purposes and are thus each eligible for their own exclusivity.”) (citing Apotex).
91 Teva Pharm., USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999).
92 Id. at 1006.
93 Id.
94 Id. at 1007.
95 Id. at 1010-11.
96 Id. at 1007-08. Although Congress eliminated the court decision trigger for exclusivity in the MMA of 2003, it established a new court decision trigger for forfeiture of exclusivity, and confirmed this interpretation of “court decision” for the purposes of this new provision. See 149 Cong. Rec. $15885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) (“We do intend that a court decision like the one in the D.C. Circuit’s 1999 decision in Teva v. Shalala—a decision dismissing a declaratory judgment action for lack of subject matter jurisdiction because the patent owner has represented that the patent is not infringed—will count as a court decision under the new ‘failure to market’ provision.”). Elimination of the court decision trigger was prospective only. Congress also made a retroactive change, dictating that the relevant court for ANDAs subject to the old rules is the appellate court.
97 Teva, 182 F.3d at 1009.
the court decision that triggers exclusivity need not involve the first generic; instead, it may involve the patent holder and another ANDA applicant. Thus, if the pioneer has sued subsequent ANDA filers for patent infringement on the same drug, any decision of a district court finding the patent invalid, not infringed, or unenforceable in any of those cases will trigger exclusivity.

3. A Response to Citizen Petitions ("Multiple Exclusivity")

On August 2, 1999, in response to two citizen petitions, FDA decided that multiple generic applicants may hold exclusivity simultaneously. American Pharmaceutical Partners Inc. (APP) and Pharmachemie B.V. each requested that FDA stay approval of any ANDA other than their own for generic versions of Platinol-AQ®. Pharmachemie had filed the first substantially complete ANDA with a paragraph IV certification for the one patent. The patent holder did not file suit on this one, and it expired. APP filed the first substantially complete ANDA with a paragraph IV certification for a different patent. Pharmachemie then did the same thing. Bristol-Myers Squibb filed suit against both companies—each of whom argued that it had been the first to file a paragraph IV certification.

In response, FDA defined the controversy as "whether multiple ANDA applicants each can be eligible for 180-day exclusivity because each applicant was the first to file a paragraph IV certification as to a different patent for the listed drug." Although FDA intended to issue new proposed rules, "until such new regulations are final, FDA's determinations are governed by the existing regulations and the relevant provisions of the statute." FDA determined that both applicants could be entitled to exclusivity. The issue was "whether one or more substantially complete ANDAs were submitted that contained a certification that the same patent was invalid, not enforceable, or would not be infringed. Therefore, under the current regulations, eligibility for exclusivity is to be determined on a patent-by-patent basis." FDA's response makes it clear that the agency thought this result was unworkable and that FDA intended to address this issue in new regulations. In this particular instance, however, FDA granted exclusivity only to APP. The agency reasoned that Pharmachemie's exclusivity had terminated automatically when the patent in question expired. This theory was challenged in a citizen petition filed by TorPharm, but the company withdrew the petition before FDA answered.

4. Proposed Regulations

Four days later, on August 6, FDA proposed regulations to alter substantially the 180-day exclusivity rules. This proposal would be withdrawn in 2002, but FDA nevertheless implemented a number of the policies that the proposal represented.

First, the proposed regulations continued to state that, in order to be entitled to 180-day exclusivity, an ANDA applicant must be the first to file a substantially complete ANDA with a paragraph IV certification. An ANDA was not substantially complete if FDA determined that the required bioequivalence data failed to meet FDA standards. If FDA found the bioequivalence studies to be deficient, that applicant would lose its
exclusivity, and no other applicant would be granted exclusivity. As this suggests, there
was no “rolling exclusivity.” Thus, for example, if the first generic withdrew its applica-
tion, no subsequent applicant would be granted exclusivity. If the first generic did not
perfect its right to the 180-day period (e.g., if it lost the patent infringement case),
exclusivity would not roll over to the next-filed ANDA. This aspect of the August 1999
regulations was not new.

Second, multiple applicants could share exclusivity for a drug. All ANDAs for a
particular drug, with paragraph IV certifications, received on the same day would be
eligible for exclusivity, so long as no ANDAs were filed on a previous day. This aspect
of the August 1999 proposal continued to be agency policy after withdrawal of the
proposal and was restated in its July 2003 guidance.

Third, FDA proposed a new “triggering period” for 180-day exclusivity. Under this
proposal, once a subsequent generic received tentative approval for its generic drug
from FDA (such that the exclusivity was the only obstacle it faced for final approval), a
new 180-day triggering period (not to be confused with the 180-day exclusivity period)
would begin to run. Within 180 days, one of the two 180-day exclusivity period
triggering events would need to occur, or the first generic would lose its exclusivity.
Because FDA took the position that there was no rolling exclusivity, no other generic
would be eligible. This new triggering period would have served the same purpose as a
provision in the regulations stating that a first generic would lose its exclusivity if it did
not “actively pursue” approval of its ANDA. With the 2002 withdrawal of the proposed
regulations, this idea was never implemented.

Fourth, after occurrence of one of the triggering events—but only after that event—
a first generic would have been permitted to transfer its rights to another company.
FDA noted that transfer can be particularly useful when a subsequent generic wins its
patent suit with the pioneer before the first generic’s suit goes to trial. Prior to occur-
rence of a triggering event, however, the first generic would not have been permitted to
transfer its exclusivity rights. It could waive its exclusivity entirely, permitting FDA to
approve subsequent ANDAs, but it could not waive its rights in favor of a particular
generic manufacturer (i.e., sell its rights) until the occurrence of a triggering event.
FDA’s informal position to permit transfers of exclusivity already had withstood court
scrutiny, but with the 2002 withdrawal of the proposed regulations, the use of a
triggering event as a threshold requirement would not be implemented.

F. 2000: Mylan I, a Guidance for Industry and Interim Regulations,
and Mylan II

1. Mylan I (“Court Decision” and “Transfer of Exclusivity”)

In Mylan I, a federal district court rejected FDA’s position that the triggering event is
“either the date that a district court decision is affirmed by the Federal Circuit, or the date

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102 Id. at 42,873.
103 Same-day patent challenges generally occur when four years of a five-year new molecular
entity exclusivity period have expired, permitting the submission, on a particular date, of ANDAs
104 64 Fed. Reg. at 42,878.
105 Id.
106 Id. at 42,881.
107 Id.
approval of second ANDA filer who had purchased 180-day exclusivity from first generic).
on which the time for filing an appeal has lapsed." In other words, the court held that "decision of a court" includes "the decision of a United States district court regardless of whether that decision is appealed." The rule that resulted, therefore, was that the first generic's 180-day exclusivity period begins to run on the date of a district court decision finding invalidity, unenforceability, or noninfringement. The court also confirmed that exclusivity may be transferred separately from the ANDA, writing that "[e]xclusivity periods are a transferable commodity which can be waived in favor of another generic manufacturer for a substantial price."

2. A Guidance for Industry and Interim Regulations ("Court Decision")

In March 2000, FDA issued a guidance document responding to the Mylan I decision. In the guidance document, FDA stated that it would interpret the term "court" to mean "the first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed." After such a court decision, FDA would approve the first generic as of the date of the decision. Neither a stay nor a reversal of this decision would revoke approval of the first generic's ANDA or its 180-day exclusivity. If a district court found patent infringement, however, and that ruling was reversed by the Federal Circuit, the first generic's ANDA would be approved and the 180-day exclusivity would start "on the date the district court issues a judgment that the patent is invalid, unenforceable, or not infringed pursuant to a mandate issued by a court of appeals." FDA agreed that this could compromise companies that had developed marketing strategies in reliance on the old definition of court decision. FDA, therefore, would apply the new guidance prospectively. The new definition of court would apply only to ANDAs filed after March 30, 2000. In July 2000, FDA published interim regulations amending the definition of "court decision" as detailed in the March 2000 guidance and consistent with the Mylan decision.

3. Mylan II ("Court Decision" and "Loss of Exclusivity")

In Mylan II, the district court determined that a first generic could lose its exclusivity if it were obliged to amend its certification from a paragraph IV to a paragraph III. The Southern District of New York had invalidated the tamoxifen patent held by Imperial Chemicals Industries, PLC, but that decision was subsequently appealed and vacated pursuant to a settlement agreement between Imperial and the generic manufacturer (Barr Laboratories). Pursuant to the settlement, Barr amended its ANDA from a paragraph IV to a paragraph III certification. Barr also obtained a license to market the product prior to patent expiry. FDA declined to treat the New York decision as a "court decision" for purposes of exclusivity and instead agreed with Barr that its exclusivity was intact. In Mylan II, the D.C. District Court held that Barr had waived eligibility for 180-day exclusivity, explaining that once a company changes its certification, the ANDA is no

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110 Id. at 47.
111 Id. at 42.
113 Id. at 4.
114 Id.
115 Id.
longer considered to have “contained” a paragraph IV certification. This meant Barr was no longer eligible for exclusivity, so FDA could approve Mylan’s ANDA. The court also noted that “a decision of a court” meant all court decisions, whether subsequently vacated, settled, appealed, or otherwise mooted.

G. 2001: Mylan III and the Best Pharmaceuticals for Children Act

1. Mylan III (“Commercial Marketing Trigger”)

In Mylan III, a district court in West Virginia held, among other things, 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.

In April 1997, Mylan submitted an ANDA with a paragraph IV certification for 30 mg dosages of nifedipine. It was, therefore, the first generic. The pioneer company, Pfizer Inc., sued Mylan for infringement and the parties settled in February 2000. Although the settlement terms were not made public or given to the court, Pfizer apparently licensed Mylan to sell a private label version of its own 30 mg, 60 mg, and 90 mg nifedipine products. Pfizer also may have permitted Mylan to market its own 30 mg product under its own ANDA, but Mylan never did so. Mylan claimed the settlement allowed it to maintain its paragraph IV certification and never amended the paragraph IV certification to a paragraph III certification.

After the settlement, Biovail Laboratories, Inc., a generic manufacturer aspiring to market nifedipine, attempted without success to persuade Mylan to waive its 180-day exclusivity. When this failed, Teva Pharmaceuticals USA, Inc. (its licensee) submitted a citizen petition to FDA asking the agency to find either: a) the Mylan ANDA was not eligible for exclusivity or b) any exclusivity had expired. FDA responded in February 2001, agreeing on both grounds. The agency reasoned, first, that the settlement effectively turned Mylan’s paragraph IV certification into a paragraph III certification, and second, that the private label sales constituted commercial marketing and triggered exclusivity. Because the 180 days had expired, FDA approved Biovail’s ANDA.

Mylan brought suit. In the decision that resulted, Mylan III, the district court found that FDA had been unreasonable on the first issue and reasonable on the second. The court was not prepared to allow FDA unilaterally to deem the paragraph IV certification to be a paragraph III certification, particularly because Mylan had not amended the certification in its ANDA. (The court distinguished the earlier Mylan II case on this ground.) But the private label sales were commercial marketing, and thus the 180-day period had expired.

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118 Id. at 56-57. On May 24, 2001, Gary Buehler, Acting Director of FDA’s Office of Generic Drugs, confirmed this by telling the Senate Judiciary Committee that “Only an application containing a paragraph IV certification may be eligible for exclusivity. If an applicant changes from a paragraph IV certification to a paragraph III certification, for example upon losing its patent infringement litigation, the ANDA will no longer be eligible for exclusivity.” Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the Senate Comm. on the Judiciary, 107th Cong. 12 (2001) (statement of Gary Buehler, RPh).
119 Mylan II, 94 F. Supp. 2d at 54.
121 Id. at 482.
122 Id.
123 Id.
124 Id. at 488. In the MMA of 2003, Congress amended the FDCA to provide that the generic manufacturer’s marketing of the listed drug would trigger exclusivity. See 21 U.S.C. § 355(j)(5)(B)(iv)(I).
2. Best Pharmaceuticals for Children Act ("Relationship to Pediatric Exclusivity")

In May 2001, FDA sought public comment on whether pediatric exclusivity for an innovator runs concurrently or consecutively with 180-day exclusivity for the first generic.\(^{125}\) The agency evidently believed that the two exclusivity provisions run concurrently.\(^{126}\) At least one generic manufacturer challenged this assertion.

Barr was the first generic for Eli Lilly & Company’s drug Prozac®. A district court found infringement, but the Federal Circuit reversed and held the second of two challenged patents invalid, while upholding the first.\(^{127}\) The upheld patent was not set to expire until February 2001, followed by an additional six months of pediatric exclusivity. Had the appellate court ordered the district court to enter a judgment of invalidity on the second patent in September 2000, Barr’s exclusivity would have started to run and would have expired before Lilly’s pediatric exclusivity was due to expire. Barr prepared to challenge FDA’s interpretation, but it turned out never to be necessary. The timing of the Federal Circuit’s denial of a petition for rehearing and the district court’s resulting judgment of invalidity (triggering Barr’s 180 days) was such that pediatric exclusivity already had expired. Congress resolved the issue, however, with the passage of the Best Pharmaceuticals for Children Act (BPCA).\(^{128}\)

In the BPCA, Congress added section 505A(k) to the FDCA, which states that 180-day exclusivity does not begin until an innovator’s pediatric exclusivity has expired. This ensures that generic drug manufacturers entitled to 180-day exclusivity do not lose a portion of that exclusivity due to the overlap with the innovator’s pediatric exclusivity.

H. 2002: FTC Report and Withdrawal of Proposed Rule

1. The FTC Report

In July 2002, the FTC issued a report on its investigation of generic and innovator practices that were alleged to impede generic market entry.\(^{129}\) This report described antitrust law enforcement actions the FTC had taken against generic drug companies who had allegedly entered into anticompetitive agreements while taking advantage of 180-day exclusivity. For example, the FTC concluded that fourteen of twenty final settlements of ANDA-related patent litigation during the time period of the study had the potential to delay the start of the first generic’s 180-day exclusivity.\(^{130}\) In four instances, the FTC concluded that the innovator had paid the first generic not to waive exclusivity and not to enter the market during the life of the patent. This prevented the 180-day exclusivity from ever starting and therefore kept all generics off the market until patent expiry.\(^{131}\)

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129 FTC STUDY supra note 7.
130 Id. at 26.
131 Id. at 31. FDA had supported its “successful defense” requirement in 1998 on the ground that it would preclude results like this. An applicant that is not sued (e.g., because it signs an agreement with the pioneer) would not have “successfully defended” and thus, under FDA’s reasoning at the time, would not be entitled to exclusivity. Under FDA’s 1998 theory, this would permit, rather than preclude, approval of subsequent applicants.
subsequent ANDA applicant prevailed in a patent infringement case, of course, the 180-day period would start. But the pioneer simply would avoid filing suit against that subsequent applicant. FTC investigations in this area became public in 1999, and there have been no innovator-generic agreements of this nature since that time. As noted, one district court has held this *does* trigger exclusivity. In any event, the FTC recommended notification to the FTC and the U.S. Department of Justice (DoJ) of any innovator-generic agreement relating in any way to 180-day exclusivity or the manufacture, marketing, or sale of an innovator drug or its generic equivalent.

2. Withdrawal of Proposed Rule

In November 2002, FDA withdrew its August 1999 proposed rule. "After careful consideration of the comments," FDA wrote, "and the multiple court decisions affecting the agency’s interpretation of the provisions of the act relating to 180-day exclusivity and ANDA approvals," the agency concluded that "it is appropriate to withdraw the August 1999 proposed rule at this time." Thus, FDA “will continue to regulate directly from the statute and applicable FDA regulations to make 180-day exclusivity decisions on an issue-by-issue basis.”

I. 2003: Purepac II, a Guidance Document, TorPharm, and Purepac III

1. Purepac II ("Controlling Date for Exclusivity Purposes" and Little Section viii)

In Purepac v. Thompson, the U.S. District Court for the District of Columbia affirmed an FDA decision that clarified when a generic applicant has submitted its paragraph IV certification, for exclusivity purposes. Purepac mailed its certification to FDA on the patent in question on May 25, 2000, and FDA received the certification on May 26, 2000. Purepac waited until June 13, however, to send notice to the NDA holder. TorPharm, in contrast, mailed its certification on June 13, and FDA received TorPharm’s certification on June 16. TorPharm sent its notice to the NDA holder on the same day (June 13) that it mailed its certification to the agency. FDA concluded that the penalty for Purepac’s failure to provide notice simultaneously with its certification, as required by 21 U.S.C. § 355(j)(2)(B)(iii) and 21 C.F.R. § 314.95(d), should be postponement of the certification’s effective date—rather than nullification of the certification, as TorPharm had argued. That date was still earlier than the effective date of TorPharm’s certification, so FDA

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132 Arguably, the subsequent generic could file a declaratory judgment action after the 45-day window for a patent infringement suit, but it would be difficult to establish federal court jurisdiction if the pioneer did not intend to sue.

133 FTC STUDY, supra note 7, at viii.

134 Id. at 25.


136 Id. at vii. Congress would include in the MMA a provision requiring this notification. See Pub. L. No. 108-173, § 1112.


138 Id. at 66,594.

139 Id.


141 TorPharm v. Thompson, 260 F. Supp. 2d at 79-81.
found that only Purepac was eligible for exclusivity with regard to that patent. The district court found this to be a reasonable exercise of the agency's discretion. The court also sustained FDA's decision that the operative date for the filing of an amended certification is the day the certification is received by the agency, rather than the date the certification is mailed by the applicant. The D.C. Circuit affirmed on January 20, 2004.

Also at issue in this case was a patent that had been listed in the Orange Book and then, after litigation, deemed by FDA to be ineligible for listing. The generic applicant who had filed a paragraph IV certification on the patent brought suit, seeking to retain its exclusivity. The patent in question claimed a method of use of Neurontin® (gabapentin)—the treatment of neurodegenerative diseases—for which the innovator drug was not approved and for which the ANDA applicants could therefore not seek approval. After litigation, a federal court determined that Purepac's "section viii" statement as to this patent was appropriate. TorPharm, however, had submitted a paragraph IV certification on the patent. Under agency regulations, when a patent has been the "subject of a lawsuit" based on a paragraph IV certification, it may be delisted only if no ANDA applicant is entitled to exclusivity on the patent. Under well-established agency policy, however, where a section viii statement is proper, a paragraph IV certification is not. FDA determined that—in light of the federal court ruling that a section viii statement was appropriate—TorPharm's paragraph IV certification was improper; thus eliminating TorPharm's eligibility for exclusivity. FDA also removed the patent from the Orange Book, on the ground that it claimed a use the agency had not approved. No company was entitled, therefore, to exclusivity on the patent. The district court found FDA's actions to be reasonable and the D.C. Circuit affirmed.

2. A Guidance Document ("Multiple First Applicant")

In August 2000, Zenith Goldline Pharmaceuticals (now IVAX) petitioned FDA for a determination that "all [ANDAs] containing a paragraph IV certification delivered to FDA's Office of Generic Drugs (OGD) on the same business day are submitted at the same time for 180-day exclusivity purposes," each receiving 180 days of exclusivity without being subject to the other's exclusivity. In an accompanying petition, Zenith Goldline sought a stay of approval of a competitor's ANDA until its own product received approval. In a February 2001 response to the citizen petition, FDA indicated that it expected to conclude its evaluation shortly. In July 2003, FDA issued a guid-

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142 Id. at 79.
143 Id. at 80.
144 Id. at 81.
145 Purepac v. Thompson, 354 F.3d at 889.
146 TorPharm v. Thompson, 260 F. Supp. 2d at 82.
147 Id. at 75-76. A "section viii" statement states that the patent in question has been listed, but does not claim a use for which the applicant seeks approval. 21 U.S.C. § 355(j)(2)(A)(viii). It does not entitle the innovator to notice, and it does not entitle the ANDA applicant to exclusivity.
149 Id. at 84; Purepac v. Thompson, 354 F.3d at 888.
In the guidance document, FDA explained that when, on the same day, more than one applicant submits an ANDA for the same drug containing a paragraph IV certification to a listed patent, and no such certification was submitted previously, all such applicants will share exclusivity.\textsuperscript{5} Exclusivity would be triggered for all of the first applicants for a specific listed patent when one of them began to market its product (or on the date of a court decision finding that patent invalid, unenforceable, or not infringed, if earlier). The commercial marketing trigger would begin exclusivity as to all listed patents; a court decision would trigger it only as to patents addressed in the decision.

3. TorPharm ("Shared Exclusivity")

On November 19, 2003, TorPharm sued FDA challenging its "shared exclusivity" approach.\textsuperscript{156} TorPharm was the first applicant to file an ANDA for a generic version of Paxil\textsuperscript{10} (paroxetine hydrochloride). TorPharm also was the first to submit a paragraph IV certification challenging the only paroxetine patent listed at the time. On July 30, 2003, FDA approved TorPharm's ANDA. On the same day, FDA determined that Alphapharm, which had an ANDA pending, would be entitled to share exclusivity with TorPharm because it was the first to file a paragraph IV certification to a later-listed paroxetine patent. TorPharm launched its product on September 8, 2003—its 180-day exclusivity would expire, therefore, on March 6, 2004. TorPharm filed suit, seeking a declaration that FDA's shared exclusivity approach was unlawful and an order enjoining approval of any other ANDA for paroxetine until March 6, 2004. The sole focus of the complaint was FDA's decision to require TorPharm to share exclusivity with parties who were the first to certify to a later-listed patent. (The agency's "multiple first applicant" shared exclusivity policy was not at issue.) On January 2, the judge overturned FDA's decision.\textsuperscript{157}

4. Purepac III ("Controlling Date")

On October 29, 2003, Purepac Pharmaceutical filed suit against FDA, challenging the agency's view that when an ANDA applicant submits an amendment to certify to a newly-listed patent, the controlling date for exclusivity purposes is the date it sent notice to the patent-holder.\textsuperscript{158}
In July 2002, Purepac had filed an ANDA seeking to market a generic version of Glucophage XR® (metformin hydrochloride extended release). On November 5, the U.S. Patent and Trademark Office (PTO) issued another patent claiming metformin hydrochloride. FDA listed the patent in the Orange Book on November 21. On November 5, and on every subsequent business day through November 25, Purepac submitted a paragraph IV certification to that patent. On November 27, Purepac sent notice of the paragraph IV certification to Bristol-Myers Squibb (BMS), the patent-holder. BMS received that notice letter on December 3. IVAX filed its ANDA after Purepac amended its ANDA, but before Purepac sent notice to BMS. IVAX included a paragraph IV certification to the second patent, and notified BMS at that time. FDA awarded exclusivity to IVAX and not to Purepac, reasoning that the controlling dates for determination of “first applicant” status were Purepac’s notice date (because Purepac was amending its ANDA) and IVAX’s certification date (because IVAX was filing an original ANDA). FDA approved IVAX’s product on October 28, and the company began shipping the product that same day. Purepac immediately obtained a restraining order, and FDA suspended its approval on October 30. The parties settled the lawsuit by agreeing to share profits during the exclusivity period, and the judge dismissed the case on November 26.

IV. HATCH-WAXMAN REFORM IN 2003

A. Reform Bills

Numerous bills to amend the Hatch-Waxman Amendments were introduced in the 106th and 107th Congresses. Many were drafted and introduced in response to the generic industry’s complaint that generic market entry was being delayed in a manner not originally intended by Congress, by virtue of innovator practices as well as agency and judicial interpretation of the statute. Some bills purported to be limited to implementing the recommendations of the FTC in its 2002 report, others were considerably more sweeping in their scope.

1. S 812

An example of the latter was S 812, introduced by Senator Schumer (D-NY) and Senator McCain (R-AZ) in May 2001. Among other things, bill 812 would have required a patent owner to list its patent by a date certain or forever lose its right to sue an ANDA holder for patent infringement. Also, if a patent holder failed to bring an infringement action within forty-five days of receiving a paragraph IV notice, the patent holder would be forever barred from bringing that suit. Like many of the other bills introduced in the 106th and 107th Congresses, S 812 also would have made changes to the 180-day exclusivity provisions. For example, it would have effectively reinstated FDA’s “successful defense” requirement by requiring the ANDA holder to itself be sued for infringement of the patent in question and by making loss of litigation a forfeiture event, resulting in loss of exclusivity. Although S 812 contained provisions addressing 180-day exclusivity, these were not its primary feature. S 812 passed the Senate, on July 31,

161 See section III.C.1, above.
2002, by a vote of 78 to 21, but the House ignored the legislation entirely and the bill died in the 107th Congress.\textsuperscript{162}

2. \textit{S 1225}

On June 4, 2003, Senators Gregg (R-NH), Schumer (D-NY), McCain (R-AZ), and Kennedy (D-MA) announced that they had reached agreement on proposed legislation to amend the Hatch-Waxman Amendments. On June 10, 2003, Senator Gregg introduced the legislation in question—\textit{S 1225}, the “Greater Access to Affordable Pharmaceuticals Act.” The Senate Health, Education, Labor, and Pensions (HELP) Committee approved the bill on June 11 by unanimous consent.

Although this bill dealt with many other aspects of the Hatch-Waxman Amendments, one section specifically addressed 180-day exclusivity. In particular, the bill amended the “court decision” trigger for generic exclusivity from a trial court decision to an appellate decision (i.e., restoring the rule that had lasted from 1984 through 2000). It established several circumstances under which the first generic applicant would forfeit its 180-day exclusivity, including failure to market the drug within sixty days after the ANDA was approved or a favorable appellate court decision, whichever was later. If exclusivity was forfeited, it would not roll over to the next applicant.

\textit{S 1225} also provided that 180-day exclusivity would be available to the “first applicant submitting an application for a drug with respect to any patent without regard to whether an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.” This was intended to limit exclusivity to the first to challenge any patent claiming a drug, and to deny it to subsequent applicants who might challenge other patents claiming the same drug. Put another way, exclusivity would be product-by-product rather than patent-by-patent. The 180-day provisions of \textit{S 1225} would apply only to applications filed under section 505(j) after the date of its enactment, and only with respect to listed drugs for which no paragraph IV certification was made before the date of enactment. If, however, a generic applicant forfeited exclusivity under the new section 505(j)(5)(D)(i)(VI) (due to an anticompetitive agreement with the patent owner), the applicant would forfeit exclusivity “without regard to when” it made its paragraph IV certification.

3. \textit{S 1}

On June 19, 2003, the Senate adopted a narrowed version of the Gregg-Schumer bill as an amendment (amendment 945) to the Medicare prescription drug legislation (\textit{S 1}) by a vote of 94 to 1.\textsuperscript{163} The version of the bill passed by the Senate differed in several respects from the version marked up by the HELP Committee the prior week, including with respect to 180-day exclusivity. Notably, the “court decision” trigger was deleted, in favor of using only commercial marketing as the trigger. The provision for forfeiture for failure to market was much more complex than in the earlier bill. Exclusivity would be forfeited if the generic failed to market its drug within seventy-five days after at least one of the following with respect to each patent challenged by the generic: an appellate decision in the generic’s favor; a settlement finding the patent invalid or not infringed;

\textsuperscript{162} The companion bill in the House, \textit{HR 1862}, was referred on June 1 to the House Energy and Commerce Committee’s Subcommittee on Health. Neither the subcommittee nor the full committee considered the legislation, however, and it was never considered on the House floor.

\textsuperscript{163} Senator Hatch cast the sole dissenting vote.
THE HATCH-WAXMAN AMENDMENTS TO THE FDCA 311

patent expiry; or patent withdrawal. The new language added a provision for forfeiture if all patents qualifying the first applicant for exclusivity had expired. Exclusivity was to be shared among all first applicants who filed substantially complete applications on the same day, rather than belonging to the applicant who filed earliest on that day. Approval of subsequent ANDAs was to be permitted if all first applicants forfeited exclusivity; there was no rolling exclusivity.164

4. HR 1

Throughout most of June 2003, House leadership and the House Energy and Commerce Committee (the committee of jurisdiction) worked to prepare a scaled-back House alternative to S 1225. Following the Energy and Commerce Committee’s markup of the House Medicare bill (HR 1), the alternative language was perfected with input from relevant stakeholders and FDA. On June 26, the House Rules Committee met to consider HR 1 (the House Medicare bill that would meet up with S 1 in the ensuing conference) and reported out a rule for consideration of the bill on the floor. During Rules Committee consideration, an amendment in the nature of substitute was offered and adopted. The House alternative provisions to reform the Hatch-Waxman Amendments were included in Title XI of the adopted Rules Committee substitute. While other parts of the House alternative contained significant differences, the 180-day exclusivity language was identical to that in S 1.

On June 26, the House approved HR 1 by a vote of 216 to 215, and the Senate approved S 1 by a vote of 76 to 21.165 Thus began the historic House-Senate conference committee to fashion the final language of the Medicare reform legislation.

B. Conference

While the Medicare bills were in conference, a concern was raised about the interplay of several of the provisions relating to 180-day exclusivity. As noted above, exclusivity would begin only upon commercial marketing. Exclusivity would be forfeited if the generic failed to market its drug within seventy-five days after at least one of the following with respect to each patent challenged by the generic: an appellate decision in the generic’s favor; a settlement finding the patent invalid or not infringed; patent expiry; or patent withdrawal. The result, however, was that a generic had an incentive to file an

164 In another amendment (amendment 974) to S 1, the Senate approved language requiring generic drug applicants and brand name companies to notify the Department of Justice and the FTC of any agreement regarding 180-day exclusivity and that applicant’s ANDA or any other ANDA based on the same innovator drug. Senate Amendment 974 to S 1, available at http://thomas.loc.gov/cgi-bin/bdquery/z?d108:SP00974 (last accessed May 17, 2004).

165 On June 17, 2003, the Senate Judiciary Committee held a hearing on the FTC Report, the report’s relationship to FDA’s new Hatch-Waxman regulations (68 Fed. Reg. 36,676 (June 18, 2003)), and S 1225. The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the Senate Judiciary Comm., 108th Cong. 1st Sess (2003), available at http://judiciary.senate.gov/hearing.cfm?id=812 (last accessed May 17, 2004). The first panel consisted of the Chair of the FTC, the Chief Counsel of FDA, and a representative of the Department of Justice. Representatives of PhRMA, the Generic Pharmaceutical Association (GPhA), and the Consumer Federation of America spoke on the second panel. Several of the witnesses addressed 180-day exclusivity. The prepared statement of the FTC, for example, restated the findings of its 2002 report. Testimony of the Honorable Timothy J. Muris, Chairman, Federal Trade Commission (June 17, 2003), available at http://judiciary.senate.gov/testimony.cfm?id=812&wit_id=2251 (last accessed May 17, 2004).

Senate Judiciary Committee Chairman Hatch (R-UT) expressed concern that the 180-day provision would encourage more, and earlier, challenges of dubious merit.
early challenge to both the basic drug substance patent and the drug formulation patents. If the generic won on all of the patents, it could—indeed, must—market the drug early. If the generic lost on the basic patent—which usually is the case—and won on any of the others, it could wait until expiration of the basic patent to market the drug, which could be another eight or ten years. This is because the failure to market provision would not kick in until the last challenged patent had expired. No forfeiture would occur until seventy-five days after the basic patent expired. Arguments were made that this would encourage generic manufacturers to file speculative patent challenges very early in the process to market the drug. In short, the argument continued, the new legislation would transform early and speculative patent challenges from an intentionally high-risk uncertain-reward gambit to a virtually no-risk and guaranteed-reward proposition, effectively enabling the generic industry to adopt patent challenges as its business model.166

The conference committee issued its report on November 20.167 Under the new language, if an ANDA contains a paragraph IV certification and “is for a drug for which a first applicant has submitted an application containing such a certification” (i.e., is for a drug for which someone else submitted an ANDA earning it exclusivity), the application “shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.”168 The term “180-day exclusivity period” means “the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.”169 The term “first applicant” means “an applicant that, on the first day on which a substantially complete application containing a [paragraph IV] certification is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [paragraph IV certification].”170 A “substantially complete application” is “an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required” under section 505(j)(2)(A) of the FDCA.171

The first applicant forfeits exclusivity if it fails to market the drug by the later of (a) the earlier of 75 days after approval of the application of the first applicant is made effective under section 505(j)(5)(B)(iii), or 30 months after submission of the application of the first applicant; or (b) with respect to the first applicant or any other applicant (that has received tentative approval), 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a paragraph IV certification qualifying it for exclusivity, at least one of the following has occurred:

168 Id. at 400.
169 Id.
170 Id.
171 Id.
(1) in an infringement action brought against that applicant with respect to the patent, or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed;

(2) in an infringement action or a declaratory judgment action, a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed; or

(3) the patent information submitted under section 505(b) or (c) is withdrawn by the holder of the application approved under section 505(b).

Most of the changes in the conference report were minor. In the only real substantive changes, the conferees addressed the concern about interplay of the new forfeiture and trigger provisions. First, the conferees deleted the provision requiring forfeiture 75 days after every challenged patent expires. Second, to qualify as a “first applicant,” a generic manufacturer would be required to “lawfully maintain” a paragraph IV certification. Third, the failure-to-market forfeiture event applies only to patents for which a paragraph IV certification had been lawfully maintained. Thus, if an ANDA applicant loses a patent challenge (for example, to a basic patent), that patent challenge no longer qualifies the applicant for exclusivity. The 75-day forfeiture clock begins to run as soon as it prevails on a different patent. Put another way, if a generic company challenges a formulation patent but adds a frivolous challenge to the basic patent, prevails on the formulation patent and loses on the basic patent, then the 75-day clock begins to run. This precludes “parking” exclusivity by challenging two patents, knowing one will lose on the patent that is not due to expire for some time. Now the generic applicant forfeits exclusivity if it cannot market within 75 days of the appellate decision on a patent it successfully challenged.

The following scenario also would result in forfeiture.

Step 1. The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval.

Step 2. The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

Step 3. The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in, or a review of, the requirements for approval of the application imposed after the date on which the application is filed.

Step 4. The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the paragraph IV certification, the FTC or the Attorney General files a complaint, and there is a final decision of the FTC or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws.

Step 5. All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired. If all first applicants forfeited the 180-day exclusivity period, no applicant would be eligible for a 180-day exclusivity period. In other words, there would be no rolling exclusivity.

172 Id. at 401.

173 In a sense, in the new language forfeiture substitutes for the court decision trigger.
C. Passage

On November 22, the House approved the conference report by a vote of 220 to 215, and on November 25, the Senate approved the conference report by a vote of 54 to 44. There was no discussion of the bill's intellectual property provisions on the House floor. There was very little discussion on the Senate floor, and even less of the 180-day exclusivity portion. Senator Schumer, for example, briefly discussed the new forfeiture provisions as a means of ensuring that exclusivity “cannot be used as a bottleneck,” and Senator Frist noted that the bill took “steps to reduce or eliminate the delays in the movement of generic drugs to the marketplace.” The formal legislative history of the new language is sparse. The conference report contains no discussion of the new 180-day exclusivity provision in the bill reported out of the conference committee. President Bush signed the new Act into law on December 8.

V. Conclusion

The new law of 180-day exclusivity is quite different from the old. Chief among the differences are deletion of the court decision trigger, which had prompted so much litigation, and inclusion of forfeiture provisions to force generic manufacturers to market promptly. The conferees mooted or resolved a number of the issues that had arisen between 1984 and 2003, including whether there would be shared and multiple exclusivity, whether there could be rolling exclusivity, and what level court decision is required to trigger exclusivity. Some of these issues will remain, however, for “old” ANDAs. There will be new interpretive questions arising under both the new and the old language. A citizen petition filed on February 17, 2004, by Mylan Pharmaceuticals has raised one such issue. Mylan argues that so-called “authorized generics” (private label versions of the innovator product that are manufactured and supplied by the innovator) are “generic” drugs and therefore subject to (not permitted to market during) the exclusivity period awarded to the first generic applicant. The company also argues that the “emerging trend” of marketing authorized generics “will negatively affect the incentive given to generic manufacturers to challenge drug patents.”

The new scheme undoubtedly also will give rise to new interpretive questions. On December 9, 2003, Senate Judiciary Committee Chairman Hatch raised one such issue on the Senate floor. When the first-to-file has not yet marketed its product, and exclusivity has neither begun to run (the applicant has not gone to market) nor been forfeit (75 days have not elapsed since approval), and a second-to-file prevails in a challenge to the validity of the underlying patent, what result obtains?

Senator Hatch reported having been told by conferee staff that the successful challenge would cause forfeiture of the first-to-file’s exclusivity. Senator Hatch argued,

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175 149 Cong. Rec. S15746 (statement of Sen. Schumer); id. at S15761 (statement of Sen. Frist).

176 The sole exception, discussed supra at section II.D., is the issue of the “court decision” trigger, which Congress resolved retroactively.


178 Id. at 2.
however, that the successful challenge could effectively penalize the successful subsequent challenger. This would result as follows: ordinarily, the first applicant would have 75 days to come to market, after approval. If a second applicant prevailed in a patent challenge, however, forfeiture would not occur until the later of: 1) 75 days after the first applicant’s approval, or 2) 75 days after the second applicant’s successful appellate decision. The first applicant could wait, therefore, until day 74 after that second applicant’s victory, and then launch its product, thereby enjoying the 180 days of exclusivity. Senator Hatch argued that this would not be a sensible outcome, and suggested that in this case, it would even be preferable if the exclusivity were granted to the second-to-file. This, of course, would require a statutory amendment.\(^7\)

Further, the general policy in favor of maintaining 180-day exclusivity may continue to be questioned. A serious question remains, for example, whether the exclusivity incentive is even necessary in 2004, because there is ample evidence that generic manufacturers will file ANDAs even when they have no hope of exclusivity.\(^8\)

Another question is whether the incentive of 180-day exclusivity should be limited to generic manufacturers who prove the innovator’s patent is invalid, rather than also be given to generic manufacturers who simply design around the innovator’s patent, clearing the way to market only for themselves. On December 9, 2003, the day after President Bush signed the Medicare conference report into law, Hatch raised this issue on the Senate floor, pointing out the “incongruity” of “awarding 180 days both for a successful invalidity challenge and a noninfringement action.” The latter, he noted, benefits only a specific party, the noninfringing generic manufacturer, rather than clearing the way for generic market entry in general.\(^1^\) There may be good policy reasons to revisit the continued availability of exclusivity in this situation, and Senator Hatch may be well poised to introduce the necessary legislative amendments, but with several years’ worth of efforts to “reform” Hatch-Waxman finally off the table, policymakers may find they want several years to take stock of the new law, before returning to the drafting table.

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\(^8\) In the case of Prilosec®, for example, eight generic manufacturers filed ANDAs containing paragraph IV certifications of noninfringement even while Andrx’s exclusivity had not yet begun to run.

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<th>505(j)(5)(B)(iv) from 1984 to 2003</th>
<th>APPENDIX</th>
<th>505 (j)(5)(B)(iv) and (j)(5)(D) currently</th>
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<tr>
<td><strong>Changes made in 2003</strong></td>
<td><strong>(iv) 180 day exclusivity period.</strong> –</td>
<td><strong>(iv) 180-day exclusivity period.</strong> –</td>
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<td><strong>(I) Effectiveness of the application.</strong> –</td>
<td><strong>(I) Effectiveness of application.</strong> – Subject to paragraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a previous application first applicant has submitted under this subsection continuing an application containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.</td>
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<td><strong>Subject to the subparagraph (D), if the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii)(IV) and is for a drug for been a previous application first applicant has submitted under this subsection continuing an application containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.</strong></td>
<td><strong>(II) Definitions.</strong> – In this paragraph:</td>
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<td><strong>(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or</strong></td>
<td>(aa) <strong>180-day exclusivity period.</strong> – The term “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.</td>
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| **(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.** | (bb) **First applicant.** – As used in this subsection, the term “first applicant” means an applicant that, on the first day on which a substantially complete application
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<td>(II) Definitions.— In this paragraph:</td>
<td>containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.</td>
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<td>(aa) 180-day exclusivity period.— The term “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.</td>
<td>(cc) Substantially complete application.— As used in this subsection, the term “substantially complete application” means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).</td>
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<td>(bb) First applicant.— As used in this subsection, the term “first applicant” means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.</td>
<td>(dd) Tentative approval.— (AA) In general.— The term “tentative approval” means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (E) or section</td>
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<td>(cc) Substantially complete application.— As used in this subsection, the term “substantially complete application” means an application under this subsection that</td>
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<td>(AA) In general.—The term “tentative approval” means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (E) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.</td>
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<td>505A, or there is a 7-year period of exclusivity for the listed drug under section 527.</td>
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<td>(BB) Limitation.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.</td>
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<td>(D) Forfeiture of 180-day exclusivity period.—</td>
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<td>(i) Definition of forfeiture event.—In this subparagraph, the term “forfeiture event,” with respect to an application under this subsection, means the occurrence of any of the following:</td>
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<td>(I) Failure to market.—The first applicant fails to market the drug by the later of—</td>
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<td>(aa) the earlier of the date that is— (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or (BB) 30 months after the date of submission of the application of the first applicant; or (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred: (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.</td>
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<td>(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.</td>
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<td>(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).</td>
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<td>(II) Withdrawal of application.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).</td>
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<td>(III) Amendment of certification.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.</td>
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<td>(V) Agreement with another applicant, the listed drug application holder, or a patent owner.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).</td>
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### Table: 505(j)(5)(B)(iv) and (j)(5)(D) currently

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<th>Changes made in 2003</th>
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(VI) Expiration of all patents—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Exclusivity period—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant—If all first applicants forfeit the 180-day exclusivity period under clause (ii), approval of any application containing a certification described in paragraph (2)(A)(vi)(IV) shall be made effective in accordance with subparagraph (B)(iii);

(II) no applicant shall be eligible for a 180-day exclusivity period.