

## Legal Alert:

# Significant Changes for Prescription Drug Patent Holders, NDA Holders, and Generics

January 30, 2004

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act). Pub. L. 108-173, 117 Stat. 2066. Title XI of the Act, entitled “Access to Affordable Pharmaceuticals,” represents the first significant legislative changes to the Hatch-Waxman Act since its enactment in 1984. The legislation directly affects both patent and regulatory aspects of pre-market approval of drugs by the Food and Drug Administration (FDA). Except as noted below, the changes discussed here<sup>1</sup> apply to any proceeding under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 355, that is pending at the time of enactment of the Act. Certain changes also apply to drug applications filed under §§ 505(b)(2) (505(b)(2) applications) and 505(j) (Abbreviated New Drug Applications or ANDAs)<sup>2</sup> that were submitted on or after August 18, 2003. The Act amends both the FDCA (codified in Title 21 of the U.S. Code) and the Patent Code (codified in Title 35 of the U.S. Code).

### I. Amendments to the Federal Food, Drug, and Cosmetic Act

#### A. *Abolition of Multiple 30-Month Stays of Approval*

A full NDA holder or patent owner is now entitled only to a single 30-month stay of FDA approval of a generic drug application with a ¶ IV certification while the courts determine whether the generic drug infringes the patent that is the subject of the certification. The 30-month stay does not preclude the FDA from reviewing the drug application. The 30-month stay terminates with the first court decision finding invalidity or non-infringement. The new

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<sup>1</sup> The Act makes other statutory changes that are outside the scope of this Legal Alert.

<sup>2</sup> For purposes of this Legal Alert, both § 505(b)(2) and § 505(j) drug applications will be characterized as generic drug applications.

limitation to a single 30-month stay supersedes a recent FDA rule change that also addressed concerns voiced by the Federal Trade Commission (FTC) regarding potentially anticompetitive practices associated with multiple 30-month stay periods. The new limitation will prevent stacking of multiple 30-month stays and should satisfy at least some of the FTC's antitrust concerns. Section F below details how the Act further addresses other antitrust concerns that have arisen in recent years.

**B. *Twenty-Day Period to Notify NDA Holder and Patent Owner of a Paragraph IV Certification***

Until now, the statute has been silent as to when generic drug applicants filing an application with a ¶ IV certification must provide notice to the full New Drug Application (NDA) holder and patent owner of the filing.<sup>3</sup> The new statute specifies that the notice of the ¶ IV certification must be given within 20 days after the postmark on FDA's notice to the generic applicant that the application has been accepted for filing. Notice of an amendment of a generic application to include a ¶ IV certification must be given to the NDA holder and patent owner "at the time" at which the amendment is submitted to the FDA. As before, the notice must include a detailed statement of the legal and factual basis why the applicant believes the Orange Book-listed patent to be invalid or not infringed. The notice must also include an offer of confidential access, as will be discussed in section C below, if the generic drug applicant wishes to establish its right to file a declaratory judgment action in the absence of a patent infringement suit filed against it in response to the notice.

**C. *Declaratory Judgment in Absence of Infringement Suit***

The new statute codifies, with one significant change, the availability of the declaratory judgment remedy to generic applicants that file ¶ IV certifications but are not sued for patent infringement within the statutory 45-day period. After the 45-day period has expired, the generic applicant may file a declaratory judgment action seeking a judicial determination that the patent that is the subject of the certification is either invalid or will not be infringed by the product for which the applicant seeks approval. The generic applicant is now required, however, to have offered confidential access to its application at the time that notice of the ¶ IV certification was sent to the NDA holder and patent owner.<sup>4</sup> As before, a declaratory judgment action can only be

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<sup>3</sup> FDA regulations have provided only that notice must be sent "when [the generic applicant] receives" notice from the FDA that its application has been accepted for filing. 21 C.F.R. § 314.95(b).

<sup>4</sup> The generic drug applicant must allow confidential access to its entire application, except those parts not relevant to any issue of patent infringement, subject to protective-order-type conditions, for the sole purpose of evaluating possible infringement of the patent challenged in the ¶ IV certification.

filed after expiration of the 45-day period, and only if the generic applicant was not sued for infringement within that period. Furthermore, the declaratory judgment still may be sought only in a judicial district where the defendant has its principal place of business or a regular and established place of business.

**D. *Counterclaim to Infringement Action – Orange Book Listing***

The new statute also provides, for the first time, a limited mechanism by which a generic applicant may directly pursue a court challenge to the listing of a patent in the Orange Book. The challenge may occur, however, only within the context of a patent infringement suit against the generic applicant. Specifically, the infringement defendant may assert a counterclaim seeking an order that would require the NDA holder to correct or delete patent information listed in the Orange Book if the patent (1) does not claim the drug for which the NDA was approved or (2) does not claim an approved method of using the drug. Although the legislation thus creates a new avenue by which a NDA holder can be compelled to correct its Orange Book listing, it does not itself authorize generic applicants to recover any damages caused by erroneous listings or incurred in seeking corrections.

**E. *180-Day Exclusivity Changes***

The new statute changes the 180-day exclusivity scheme in two basic respects.

1. The first ANDA applicant to file an application containing a ¶ IV certification continues to be entitled to 180-day market exclusivity, but is now subject to six new potential “forfeiture events.”<sup>5</sup> The most significant change concerning 180-day exclusivity is that the statute no longer provides a “court decision” trigger to begin the exclusivity period.<sup>6</sup> One consequence of this change is that a subsequent ANDA filer no longer can “leapfrog” past the first ANDA filer to enter the market. Absent one of the six forfeiture events detailed below, even a subsequent ANDA filer who does not infringe an Orange Book-listed patent is barred

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<sup>5</sup> As before, 180-day market exclusivity is not available to applicants under § 505(b)(2) of the FDCA.

<sup>6</sup> However, prior law remains in force for post-enactment ANDAs for listed drugs for which there was a pre-enactment ¶ IV certification. Additionally, the new statute preserves the “court decision” trigger for ¶ IV ANDA filers whose 180-day exclusivity period had not yet been triggered as of the date of enactment. But for such cases, the new statute modifies prior case law by providing that only a final, unappealable court decision will constitute a “trigger,” not appealable district court decisions as under pre-enactment law.

from entering the market prior to expiration of the first ANDA filer's 180-day market exclusivity.<sup>7</sup>

The first ¶ IV ANDA filer's 180-day market exclusivity may be lost if any one of six forfeiture events occurs. Market exclusivity may be lost if (1) the first filer fails to market the drug within, essentially, 75 days after it becomes legally free to do so; (2) the first filer withdraws its ANDA containing a ¶ IV certification; (3) the first filer drops its ¶ IV certification; (4) the first filer fails to receive tentative FDA approval of its application within 30 months; (5) the first filer has entered into an agreement with another ANDA applicant, the NDA holder, or patent owner, *and* the FTC or the Department of Justice (DOJ) has filed a complaint, *and* a final, unappealable judgment of antitrust violation has been entered; or (6) all the patents that are the subject of the ¶ IV certification have expired.

2. Under the prior statute, FDA's policy was to recognize 180-day exclusivity on a patent-by-patent basis. That is, a ¶ IV ANDA filer that was the first to challenge a particular listed patent might have to share its exclusivity with other ¶ IV filers that were the first to challenge other listed patents for the same drug. Now, only one ANDA filer can be entitled to 180-day exclusivity as to any given drug, *i.e.*, the first filer of a ¶ IV ANDA as to *any* listed patent for that drug.<sup>8</sup> On a related issue, the new statute codifies FDA's policy of requiring 180-day exclusivity to be shared among all ¶ IV applicants filing on the same day as the first ¶ IV filer.

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<sup>7</sup> According to one of the original sponsors of the Hatch-Waxman Act, this is contrary to Congress's original intent in the 1984 Act. Senator Hatch stated in the Congressional Record the day after the new statute became law that the original intent was to reward the first successful challenger of a pioneer firm's patents, not the first generic applicant merely to file a ¶ IV application with the FDA. Arguably, the 2003 amendments move the statute still further away from Senator Hatch's stated intent.

<sup>8</sup> While this Legal Alert was being drafted, the U.S. District Court for the District of Columbia orally ruled that FDA's prior "shared exclusivity policy" was unlawful even under the former statute.

F. *Reporting of Agreements to the FTC and DOJ*

The new statute also requires notice to the FTC and the DOJ of any agreement between competing ANDA filers involving 180-day exclusivity<sup>9</sup> or between an ANDA filer and a brand-name drug company involving the brand-name or generic drug that is the subject of the ANDA submission or the 180-day exclusivity period.<sup>10</sup> The Act details the procedures by which the agreeing parties must provide both the FTC and DOJ with copies of the agreement. Routine commercial dealings in the ordinary course of trade are exempt from the reporting requirement.<sup>11</sup>

**II. Amendment to The Patent Code**

The sole amendment to Title 35 of the U.S. Code confirms that a ¶ IV ANDA applicant may seek a declaratory judgment in the absence of a patent infringement suit by the NDA holder or patent owner within the 45-day statutory period. As the DOJ testified in Congressional hearings on the bill prior to its enactment, however, federal courts have jurisdiction only if there is a “case or controversy” within the meaning of Article III of the Constitution. In an effort to avoid a question raised by the DOJ as to the constitutionality of the new declaratory judgment provision, the caveat “to the extent consistent with the Constitution” was added. The federal courts likely will be called upon to determine whether and under what circumstances a declaratory judgment action by a ¶ IV generic applicant meets the “case or controversy” requirement, considering that the generic product cannot legally be marketed prior to FDA approval.<sup>12</sup>

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<sup>9</sup> In an apparent printer’s error, the subparagraph requiring notification of “agreements” between generic applicants does not explicitly say that it is the parties to the agreement that must report it. While Congress’s intent may not be hard to discern, the omission may well create controversy when the FTC promulgates regulations implementing this provision of the statute.

<sup>10</sup> The notification requirement applies only to agreements entered into on or after January 7, 2004.

<sup>11</sup> Specifically, agreements related to purchase orders of raw materials, equipment or facility contracts, employment or consulting contracts, and packaging and labeling contracts are exempt.

<sup>12</sup> This issue will require the courts to consider how the traditional “reasonable apprehension of suit” requirement applies in this context, and whether, as construed, the requirement is constitutionally compelled.

Please contact any of the following members of our Intellectual Property or FDA practice if you have any questions concerning these changes implemented by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

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