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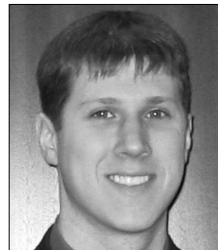
FOOD AND DRUG LAW

Hatch-Waxman Changes

ON DEC. 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act, described by some as the most significant restructuring of Medicare since its enactment. Along with a sweeping overhaul of many aspects of Medicare, this act includes lesser-known sections, which implement significant changes to the Hatch-Waxman Act, the 1984 law that governs the approval process for generic drugs. While these amendments are a small part of the act, they will need to be taken into account by those involved in promoting and opposing the introduction of new generic drug products.

The Hatch-Waxman Act amended the Food, Drug, and Cosmetic Act in order to expedite approval of generic drugs, while protecting the patent rights necessary to spur innovation by brand-name drug manufacturers. Under its provisions, a therapeutic equivalent of a previously approved drug can be approved pursuant to an abbreviated new drug application (ANDA) in which the generic applicant “piggybacks” on the safety and efficacy information that supported the previously approved new drug application (NDA). The ANDA, however, must include a certification—such as a “Paragraph IV certification”—that the patents listed in the Food and Drug Administration’s (FDA) Orange Book as patents claiming the drug or method of using the drug are either invalid or not infringed by the proposed generic

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product. If the NDA holder or patent owners challenge the Paragraph IV certification by bringing a patent infringement action within 45 days, they are entitled to an automatic 30-month stay of FDA approval of the generic ANDA product.

As an additional incentive to encourage generics to undertake the burdens and expense of Paragraph IV patent litigation, the act provided a 180-day period of marketing exclusivity to the first to file an ANDA with a Paragraph IV certification for a given drug. The recent amendments clarify these procedures and make significant changes to ensure that the process will serve the purposes of the act.

Now only one 30-month stay is permitted

Under the new law, only one 30-month stay per ANDA is allowed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, §§ 1101, 1102 (codified as amended at 21 U.S.C. 355(j)(2) and (5)). Under prior law, if an additional patent were added to the Orange Book after an applicant filed an ANDA, that applicant

would need to make a new Paragraph IV certification and the NDA holder or patent owners could then file a second patent infringement action, which would automatically result in a new 30-month stay of approval. The amendments eliminate this possibility by providing that ANDA applicants need only certify to patents that were listed in the Orange Book at the time the ANDA was filed.

At the same time, the amendments make it clear that an ANDA applicant cannot effectively shorten the 30-month stay by amending a previously filed ANDA to include a different drug. An ANDA applicant may, however, amend or supplement its application to seek approval of different strengths of the listed drug.

Under the amendments, an ANDA applicant that makes a Paragraph IV certification must give notice of its application to the NDA holder and the patent owners within 20 days of receiving notice from the FDA that its application has been filed. Previously, the law was silent as to when the ANDA applicant was required to give such notice so that the applicant could file its ANDA without immediately risking patent litigation. Notice must be given within 20 days, thereby triggering the 45-day period during which the NDA holder or patent owners must sue in order to obtain the 30-month stay of approval.

Further, the amendments clarify that if a Paragraph IV certification is included in a subsequent amendment or supplement, notice must be given when the amendment or supplement is submitted, regardless of whether the applicant had previously provided notice. The U.S. Circuit Court for

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the District of Columbia recently upheld an FDA decision that failure to provide simultaneous notice will not result in invalidation of the certification, but will cause the application to be deemed filed for priority purposes on the date the notice was mailed, rather than the date the application was submitted. *Purepac Pharmaceutical Co. v. Thompson*, 354 F.3d 877, 888-89 (D.C. Cir. 2004).

Under the recent amendments, an ANDA applicant may bring a declaratory judgment action against an NDA holder if the NDA holder does not institute a patent infringement lawsuit within the required 45-day time period. Previously, if the NDA holder did not bring suit, the applicant would have to complete the approval process with the FDA and proceed to market its drug before a court would determine if the generic product violated the listed patents. The new procedure affords the ANDA applicant the opportunity to obtain legal certainty while it seeks FDA approval, before it takes the risk of selling a potentially infringing product.

The declaratory judgment action will generally be available, however, only if the ANDA applicant makes an offer of confidential access to its application so that the NDA holder and patent owners may determine whether to bring a patent infringement suit. Without such an offer of confidentiality, a declaratory judgment action is available to the ANDA applicant only if its Paragraph IV certification is based solely on invalidity of the patent, and does not claim noninfringement.

The practical significance of this provision is uncertain because the amended act provides only that district courts will have jurisdiction to hear declaratory judgment actions on these issues "to the extent consistent with the Constitution." § 1101(d) (codified as amended at 35 U.S.C. 271(e)(5)). Courts had previously declined to hear declaratory judgment actions because they did not present an actual case or controversy as required by the Constitution.

The new law gives an ANDA applicant the ability to bring a counterclaim seeking an order requiring the NDA holder or patent owners to delete a patent from the Orange Book on the grounds that the patent does

not claim the approved drug or an approved method of using the drug. Previously, the courts held that there was no private right of action for such a claim. The ability to bring this counterclaim may provide an avenue for expedited resolution, as the issue on such a counterclaim (whether the listed patents claim the NDA drug or a method of using the NDA drug) is different from and potentially simpler than the issue in the Paragraph IV litigation (whether the proposed ANDA product violates any valid claims of the listed patents).

This new right, however, is strictly limited. The propriety of the Orange Book listing can be challenged only as a counterclaim, not as an independent cause of action. Further, the only relief available is an

The new Medicare act implements significant changes to the law that governs the approval process for generic drugs.

order requiring the patent owner to de-list the wrongfully listed patent. Money damages are prohibited.

Clarifications to the 180-day exclusivity period

The amendments clarify that the 180-day exclusivity period does not begin until the date of first commercial marketing. This amendment allows an ANDA applicant to ramp up after obtaining a favorable ruling without sacrificing part of its exclusivity period. The amendments further clarify that the exclusivity period begins upon the applicant's marketing of either the NDA product or the ANDA product. This subtlety takes care of the situation in which a first applicant agrees to market the brand-name

product instead of its own ANDA product. Previously, such an agreement would block later applicants from gaining FDA approval, since the first applicant would never trigger its exclusivity period.

This redefined exclusivity period is subject to forfeiture if the first ANDA applicant fails to market its drug in a timely fashion. See § 1102(a)(2). Moreover, the exclusivity period will be available only if tentative FDA approval is granted within 30 months of filing the application. Similarly, the exclusivity period is forfeited if the first applicant's ANDA is withdrawn or deemed withdrawn by the FDA for substantive reasons, the first applicant amends or withdraws its Paragraph IV certification, the Orange Book listed patents expire or the ANDA applicant is found to have entered into an agreement that violates the antitrust laws.

The new law also clarifies that if more than one applicant files a "substantially complete" ANDA application on the same day for a previously unchallenged drug, each will be entitled to share the 180-day exclusivity period, but there will only be one such period, and it begins on the first day of marketing by any of the first applicants. This provision moots any question of which application was filed first on any particular day.

The new law further clarifies that the first applicant to file an ANDA with a Paragraph IV certification is entitled to the exclusivity period, and will not have to share exclusivity with a later applicant that is the first to file a Paragraph IV certification on a later-listed patent.

Agreements among ANDA applicants and brand-name drug companies or other ANDA applicants as to the exclusivity period, or the manufacturing, marketing or sale of the brand-name or generic drug must be filed with the Federal Trade Commission and the Department of Justice within 10 days of execution. **NLJ**

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