Legal Backgrounder

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Ave., NW
Washington, D.C. 20036
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Vol. 19 No. 6 March 19, 2004

BETTER LATE THAN SORRY: MEDICARE REFORM USHERS IN NEW RULES ON GENERIC DRUGS

by

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On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[1] Title XI of this legislation, entitled "Access to Affordable Pharmaceuticals," culminates an effort to amend the Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984. The amendments address several important aspects of generic drug entry into the market.[2]

Since its inception, the Hatch-Waxman Act has stimulated tremendous growth of the generic drug industry by streamlining the process for generic drug approval by the Food and Drug Administration (FDA). A generic company typically files an Abbreviated New Drug Application (ANDA).[3] By demonstrating biological equivalence of its duplicate to the corresponding innovator drug, the generic company piggybacks on the innovator's safety and efficacy data obtained after the innovator had spent millions of dollars on lengthy and highly risky preclinical studies and clinical trials. If an innovator drug is protected by unexpired patents listed in the "Orange Book," the generic company may file an ANDA with a Paragraph IV certification asserting invalidity or non-infringement of the patents. The ANDA then gives the innovator a right to sue for patent infringement.[4]

This LEGAL BACKGROUNDER focuses on how the new legislation changed the rules governing the 180-day exclusivity available to certain generic companies,[5] namely "first [ANDA] applicants."[6] Unlike the old rules, the new law would not motivate generic companies to begin commercial marketing of their products immediately after a district court's favorable decision in the underlying patent infringement case.

The Old Rules Motivated Generic Companies to Enter the Market Early to Fully Benefit from the 180-day Exclusivity. Under the original Hatch-Waxman Act and rules promulgated by FDA, a generic company which was the first to file an ANDA with a Paragraph IV certification was eligible for the 180-day market exclusivity. During the exclusivity period, FDA could not approve any subsequent ANDAs. As a reward for the ANDA applicant who bore substantial costs associated with patent litigation, this potential exclusivity provided a strong

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financial incentive for generic companies to challenge the listed patents.[7] For up to 180 days, an eligible generic company could profit tremendously from lack of any other generic competition (or even competition from the innovator due tremendously from lack of any other generic competition (or even competition from the innovator due to pricing) and establish "brand" recognition in the market for its exclusive product.[8]

The events that triggered the running of the exclusivity period further drove an eligible generic company to enter the market as soon as a district court ruled in its favor. The 180-day period ran from the earlier of "the date . . . of the first commercial marketing of the drug under the [ANDA], or 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 . . . ."[9] FDA had interpreted "court" in this section as a court "that enters final judgment from which no appeal can be or has been taken."[10] In March 2000, FDA changed its position in response to two cases that challenged FDA's original interpretation.[11] Under the changed policy, the exclusivity period could start running immediately upon a district court's decision, regardless whether the generic company could obtain final approval by FDA and begin marketing.[12] To prevent loss of part or all of the exclusivity period, the generic company had to enter the market as soon as possible following a district court's favorable decision.

The New Law Creates an Incentive for Generic Companies to Wait for Appellate Decision Before Commercial Marketing. The new law creates a much more complex scheme regulating the 180-day exclusivity. In contrast to the two previous alternative triggers, only commercial marketing would start the running of 180 days.[13] Instead of allowing a generic company to potentially put off commercial marketing for a long time, the new law further identifies six categories of events that would cause an otherwise eligible generic company to forfeit the exclusivity.[14]

Failure to market as defined by the new law is arguably the most complex among the forfeiture provisions. A "first applicant" would be deemed to have failed to market if it does not market the drug by the earlier of 75 days after the final FDA approval or 30 months after submitting the ANDA.[15] But these dates would not control if the ANDA triggers a patent infringement action; the deadline for beginning commercial marketing would then be 75 days after a final court decision that cannot be appealed except to the Supreme Court, meaning in most instances a U.S. Court of Appeals for the Federal Circuit decision favorable to the ANDA applicant.[16]

Altogether, the new law gives eligible generic companies more time to prepare for market entry. Not entering the market following a favorable district court decision would no longer cause any loss of the exclusivity period. Should the Federal Circuit affirm the district court, the generic company would still have 75 days to begin commercial marketing. An eligible generic company, therefore, would have the time period between a favorable trial and the appellate affirmance, which is typically longer than one year, and additional 75 days to prepare for launching its product without losing any of the 180 days.

Further, the new law eliminates the risks of infringement damages associated with market entry following only a district court decision. If entering the market immediately after a favorable trial, the generic company would face the potential danger of reversal by the appellate court. Many have commented on the uncertainty of patent litigation; the Federal Circuit has been well known for its high reversal rate in patent infringement cases.[17] Because market entry of a generic drug usually causes staggering amount of lost profits to the innovator company,[18] a reversal

would be devastating to a generic company who rushed into the market and later became responsible for infringement damages.

Finally, the new law removes uncertainty in competition between the generic companies. The old rules did not clearly prohibit "rolling exclusivity," which meant that a subsequent ANDA applicant could become eligible for the 180-day exclusivity, if the first ANDA applicant lost it. The new law, however, clearly prohibits awarding exclusivity to any subsequent ANDA applicant, if the first applicant forfeits it. The new law further codifies the "drug-by-drug" instead of "patent-by-patent" approach in granting the generic exclusivity, so that multiple Paragraph IV challenges based on different patents covering a single drug would not lead to multiple exclusivity awards.

Conclusion. The new law is clear on when would be the best time for generic companies who have prevailed at trial to enter the market. Waiting for the Federal Circuit's affirmance not only gives the generic companies substantially more time to prepare for their product launch without compromising the important 180-day exclusivity, but also eliminates any of the enormous risks associated with a reversal.

ENDNOTES

1. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) [hereinafter Medicare Act].

2. Conference Agreement (Nov. 21, 2003), at 386, *available at* http://waysandmeans.house.gov/media/pdf/hr1/hr1jtexplstate.pdf (stating that the single 30-month stay provisions are "a centerpiece of this legislation").

3. *See generally* 21 U.S.C. § 355(j) (1994). For an introduction to the ANDA process, Paragraph IV certification, Orange Book listings, as well as the 180-day exclusivity, see FDA, 180-DAY GENERIC DRUG EXCLUSIVITY, *available at* http://www.fda.gov/cder/about/smallbiz/generic_exclusivity.htm (last updated Sept. 13, 2001).

4. 35 U.S.C. § 271(e)(2) (1994).

5. The new law is applicable only to ANDAs filed after December 8, 2003. Medicare Act, § 1102, 117 Stat. at 2460.

6. "First applicant" is "an applicant, that, on the first day on which a substantially complete [ANDA] containing [a Paragraph IV certification] is submitted, submits a substantially complete application that contains and lawfully maintains [a Paragraph IV certification]." *Id.* at § 1102, 117 Stat. at 2457.

7. FDA, GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY (July 2003), at 3, *available at* http://www.fda.gov/cder/guidance/5710fnl.pdf.

8. *See id.* (citing a July 1998 Congressional Budget Office report on decreases in generic drug price when more generic duplicates entered the market). The 180-day period also gives the generic company a head start to establish its product in prescription formularies.

  ISBN 1056 3059

9. 21 U.S.C. § 355(j)(5)(B)(iv) (1994).

10. 21 CFR 314.107(e)(1) (1999).

11. *See* FDA, GUIDANCE FOR INDUSTRY: COURT DECISIONS, ANDA APPROVALS, AND 180-DAY EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (Mar. 2000), *available at* http://www.fda.gov/cder/guidance/3659fnl.pdf ("FDA will interpret the term *court* as found in section 505(j)(5)(B)(iii)(I) and 505(j)(5)(B)(iv) to mean the first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed.") (citing *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30 (D.D.C., Jan. 4, 2000); *TorPharm, Inc. v. Shalala*, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C., Sept.15, 1997)). The Medicare Act, however, codified FDA's original interpretation of "court." Medicare Act, § 1102, 117 Stat. at 2460.

12. At least two generic drugs lost part of the exclusive period, because the district court ruled before FDA's final approval. FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), at 62, *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

13. Medicare Act, § 1102, 117 Stat. at 2457.

14. *Id.* at § 1102, 117 Stat. at 2458-59 (The occurrence of any of 1) failure to market; 2) withdrawal of application; 3) amendment of certification; 4) failure to obtain tentative approval; 5) agreement with another applicant, the listed drug application holder, or a patent owner; 6) expiration of all patents constitutes a "forfeiture event.").

15. *Id.* at § 1102, 117 Stat. at 2458.

16. *Id.* at § 1102, 117 Stat. at 2458-59 (Alternatively, the deadline would be 75 days after withdrawal of listed patents or a settlement order or consent decree entering a final judgment of invalidity or non-infringement of the patents.).

17. *See* Christian A. Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 BERKELEY TECH L.J. 1075, 1098-99 (2001), *available at* http://www.law.berkeley.edu/journals/btlj/articles/vol16/chu/chu.pdf, Figures A-1 and A-2 and associated text ("In fact, the reversal rate [of all cases decided by the Federal Circuit between January 1, 1998 and April 30, 2000 available in Lexis, excluding summary affirmances] hovers around 50% — to be exact, 47.3% — echoing the 53% reversal rate cited by Judge Rader in Cybor Corp. In other words, regardless of the issues appealed, a litigant has virtually as much chance of having his case reversed as having it affirmed.") (internal citation omitted); *see also* Ted D. Lee & Michelle Evans, *The Charade: Trying a Patent Case to All "Three" Juries*, 8 TEX. INTELL. PROP. L.J. 1, 11-20 (1999) (arguing that a patent litigator must prepare the record for appeal because the Federal Circuit "became a second jury [in addition to the traditional jury and the trial judge] by substituting its opinion for the jury verdict"); The Honorable Paul R. Michel, *The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1232-45 (1994).

18. An innovator drug patent holder would likely be able to demonstrate the *Panduit* factors that are required for calculating damages based on its lost profits, because in the absence of the infringement (the "but-for" world), the generic sales would have been captured by the patent holder. *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc*., 575 F.2d 1152 (6th Cir. 1978).

  ISBN 1056 3059