

NAPM



NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS

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June 28, 2000

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BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00D-1197, 180-Day Generic Drug Exclusivity

Dear Sir or Madam:

This comment is submitted by the National Association of Pharmaceutical Manufacturers (NAPM). NAPM is a national, not-for-profit trade association representing generic drug manufacturers and suppliers of bulk active drug substances and related goods and services to the pharmaceutical industry. NAPM submits this comment in response to the "Guidance for Industry, Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act" (hereafter "Guidance"), which the Food and Drug Administration (FDA) published in the Federal Register on March 30, 2000. 65 Fed. Reg. 16922 (March 30, 2000).

In the Guidance, FDA provides information to regulated industry regarding the timing of approval of Abbreviated New Drug Applications (ANDAs) following a court determination that a patent covering a reference listed drug is invalid, unenforceable, or not infringed. The Guidance further addresses the 180 days of marketing exclusivity that may be granted to the holder of a Paragraph IV ANDA. On the whole, NAPM welcomes FDA's efforts to clarify the 180-day exclusivity issues. With the exception of FDA's decision to apply the Guidance only prospectively, NAPM agrees with and supports FDA's positions as set forth in the Guidance.

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This Guidance is another step in FDA's ongoing revision of its 180-day exclusivity policies and regulation. In August 1999, FDA issued a proposed rule to amend the 180-day exclusivity provisions set out in 21 C.F.R. § 314.107. 64 Fed. Reg. 42873 (Aug. 6, 1999). In comments submitted to that Docket, Dkt. 85N-0214, NAPM stated its support for many aspects of FDA's proposed rule. Among other things, NAPM urged adoption of the proposed "triggering periods" to prevent indefinite blockage of the generic market. NAPM further supported heightened FDA scrutiny of the first Paragraph IV ANDA to determine eligibility for 180-day exclusivity. FDA states in the March Guidance and Federal Register notice announcing its availability that the Guidance will be incorporated into the final rule which FDA will issue. NAPM urges FDA to adopt the changes set forth below and those previously expressed in its comments to Dkt. 85N-0214. NAPM further urges FDA to publish a final rule as soon as reasonably possible. The Guidance and its incorporation into the much-needed regulation will bring desirable predictability to the generic drug industry. Prompt publication of a final rule will also benefit American consumers, taxpayers, and third-party payors by speeding the availability of generic versions of brand name drug products.

* * *

The Guidance sets forth FDA's new definition of the term "court." FDA has long interpreted "court" to mean "the court that enters final judgement from which no appeal can be or has been taken," 21 C.F.R. § 314.107(e)(1), which is usually the Court of Appeals for the Federal Circuit in the case of contested patent litigation. Court decisions have slowly chipped away at the definition of "court" in existing § 314.107(e)(1). See TorPharm, Inc. v. Shalala, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sept. 15, 1997), appeal withdrawn and remanded, 1998 U.S. App. LEXIS 4681 (D.C. Cir. Feb. 5, 1998), vacated, No. 97-1925 (D.D.C. April 9, 1998); Inwood Laboratories, Inc. v. Young, 723 F. Supp. 1523 (D.D.C. 1989), vacated as moot, No. 89-5209 (D.C. Cir., Nov. 13, 1989). In January 2000, in Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp.2d 30 (D.D.C. 2000), the United States District Court for the District of Columbia again found FDA's interpretation of "court" invalid, as inconsistent with the plain meaning of the Hatch-Waxman Amendments. In the Guidance, FDA states that it will follow that court's interpretation of the statute and decided not to appeal the January 2000 Mylan district court decision. The Guidance concludes that "court," for purposes of date of ANDA approvals and 180-day exclusivity, means "the first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed." Guidance at 4.

As the Guidance states, the definition is important to two provisions of section 505(j) of the Federal Food, Drug and Cosmetic (FDC) Act. Guidance at 2. First, FDA approval of a Paragraph IV ANDA can be made effective from the date of a "court" decision finding the challenged patent invalid or not infringed, 21 U.S.C. § 355(j)(5)(B)(iii)(I). Second, the first Paragraph IV ANDA applicant is also entitled to 180 days of marketing exclusivity from the

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earlier of either the date of first commercial marketing, or the date of a "court" decision holding the challenged patent invalid or not infringed, 21 U.S.C. § 355(j)(5)(B)(iv).

Under the Guidance, once there is a district court decision of patent invalidity, unenforceability, or noninfringement, the 180-day period of exclusivity begins to run. A subsequent stay or reversal of that court decision will have no effect on ANDA approval or 180-day exclusivity. If the New Drug Application (NDA) holder or patent owner wants to prevent an ANDA applicant from marketing its product during the course of an appeal, the NDA holder or patent owner must obtain an injunction.

NAPM recognizes, as FDA does, that this new interpretation of "court" may eliminate much of the value which inured to a generic company entitled to 180-day marketing exclusivity. Unless there is a significant assurance that the district court's decision will not be reversed on appeal, few companies are likely to take the enormous risk and avail themselves of the 180-day exclusivity by going to market on the strength of a district court finding of patent validity, unenforceability, or noninfringement. Because of the possibility of treble damages for patent infringement, ANDA applicants typically decide to wait until they receive a Federal Circuit decision of patent invalidity, unenforceability, or noninfringement. Thus, FDA's new definition of "court" will adversely impact those generic applicants that have made the appropriate business decisions and investments in submitting an ANDA to be the first Paragraph IV applicant in connection with a particular reference listed drug, thereby achieving eligibility for 180-day exclusivity. Going forward, ANDA applicants will more carefully consider their investment decisions, because these business decisions will now have to take into account not only ANDA development and patent litigation costs, but also the possibility of treble damages to the patent holders.

As a practical matter, however, the value of the 180-day period to a generic company was greatly diminished even before the issuance of the March Guidance. Its value has fluctuated wildly with the conflicting and ever-changing FDA and court interpretations of the 180-day generic drug exclusivity provisions. The litigation to determine the meaning and extent of the 180-day exclusivity has been costly as one generic company after another challenged pieces of the exclusivity provisions, and other companies scrambled to intervene in those cases to protect their own interests in pending or approved ANDAs.

As expensive and burdensome as 180-day exclusivity litigation has been to industry, substantial harm has also resulted from the uncertainty which litigation has injected into business planning, drug development, and marketing plans. Of paramount concern to the generic industry now is restoration of confidence and predictability. FDA's adoption of the definition of "court"

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as set out in the Guidance and Mylan decision will hopefully give the generic industry what it has lacked for over three years -- a clear path by which it can bring generic drugs to market.

* * *

The Guidance contains one significant infirmity to this attainment of greater certainty in the generic industry. FDA states that its new interpretation of the term "court" will apply only prospectively, and only in those situations where the ANDA cites a reference listed drug for which no other Paragraph IV ANDA has been submitted. FDA states this "bright line" implementation plan will help minimize disruptions and litigation. Guidance at 5.

NAPM respectfully urges FDA to reconsider this point. In NAPM's view, further litigation is virtually assured if FDA does not apply the definition of "court" to all pending ANDAs. In particular, presented with the right factual scenario, a subsequent Paragraph IV ANDA applicant that finds itself blocked by the first applicant's 180-day exclusivity under the old "court" means "court of appeals" interpretation will most certainly sue FDA, challenging FDA's refusal to apply its new "court" means "district court" interpretation to existing Paragraph IV ANDAs. Litigation will again entangle industry and FDA, and ultimately could delay publication of the much needed final rule.

As history demonstrates, further litigation on the definition of "court" is almost inevitable. For example, in a decision filed one day after FDA announced the availability of March Guidance in the Federal Register, another Judge of the United States District Court for the District of Columbia rejected FDA's former view that "court" means "court of appeals." Mylan Pharmaceuticals, Inc. v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000).

FDA attempts to minimize the disruption and hardship to industry by not applying "court" means "court of appeals" to pending applications. However, no one can seriously argue that this change to 21 C.F.R. § 314.107 is unexpected. The definition of "court" has been under attack since the Inwood Laboratories decision in 1989. Moreover, with the weight of court authority holding that the language of the Hatch-Waxman Amendments unambiguously provides that "court" means "district court," FDA does not have the discretion to interpret the statute otherwise and carve out an exception for pending applications. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984) (if Congress has spoken directly to the question at issue, agency must give effect to the unambiguously expressed intent of Congress).

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As temporarily painful as the transition may be, FDA has no authority or discretion to do other than begin applying the "court" means "district court" definition immediately, to all pending ANDAs.

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NAPM urges the agency to publish a final rule as soon as possible. The final rule should be based on the proposed rule and Guidance, with the changes suggested above. NAPM appreciates this opportunity to comment.

Sincerely yours,

A handwritten signature in cursive script that reads "Robert S. Milanese" followed by a stylized flourish or initials.

Robert S. Milanese

President