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

**Re: Docket No. 85N-0214 - Court Decisions, ANDA Approvals, and
180-Day Exclusivity (the "Interim Rule"), and**

**Docket No. 00D-1197 - Guidance for Industry on Court
Decisions, ANDA Approvals, and 180-Day Exclusivity Under the
Hatch-Waxman Amendments to the Federal Food Drug and
Cosmetic Act (the "Guidance")**

Ladies and Gentlemen:

Andrx Pharmaceuticals, Inc. ("Andrx") writes in response to the referenced Interim Rule and Guidance as well as certain comments submitted with respect thereto.

The Interim Rule and Guidance attempt to respond to the recent Mylan and TorPharm court decisions construing the Hatch-Waxman Amendments, while also taking into consideration the commercial realities within the industry. Andrx absolutely believes that the FDA's 1994 regulations implementing the "court decision" triggers under 21 U.S.C. § 355(j)(5)(B)(iii) and (iv) were, and continue to be, a reasonable and legitimate exercise of the FDA's power to implement the Amendments. If FDA's regulatory interpretation is now to change, however, Andrx fully agrees with the agency that the new approach must be applied on a prospective basis only.

FDA's Historical Interpretation Is Reasonable and Legitimate

Since at least 1989, the FDA has consistently and expressly interpreted the statutory phrases "court decision" and "decision of a court" to mean a "final judgment from which no appeal can be or has been taken" by an affected party. 54 Fed. Reg. 28872, 28895 (July 10, 1989); see 21 C.F.R. § 314.107(e)(1) (1999). FDA reaffirmed in the Interim Rule and Guidance, and Andrx agrees, that 21 U.S.C. § 355(j)(5)(B)(iii) (early termination of 30-month statutory bar to approval of ANDA after commencement

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of infringement action following paragraph IV certification) and 355(j)(5)(B)(iv) (triggers for 180-day exclusivity period) were properly implemented by regulation § 314.107(e). The debates and reports surrounding the passage of the Amendments, and the drafting of section 355(j)(5)(B)(iii) and (iv) in particular, support the FDA's original view that the goal of these sections is best served by limiting the relevant "court decisions" to final — i.e. non-appealable — decisions concerning patent issues.

In the events leading up to the passage of the Amendments, all sides recognized that the "facts of life are that a generic drug manufacturer. . . ., as a practical matter", generally "would expect the [patent] litigation to be resolved" in a determinative fashion before proceeding to market. 130 Cong. Rec. 24, 427 (1984) (statement of Congressman Waxman). The debate among the relevant constituencies was not whether patent litigation finality should, as a general matter, be available before a generic drug product's 180-day market exclusivity would begin to run. That much was assumed. Rather, the question was whether a generic manufacturer would be required to wait until a "final decision" had issued, or should have the option of entering the market at some earlier point. Early on, the Committee on the Judiciary rejected a proposal to force generics to wait, reasoning that a bold manufacturer should have the option to go to market despite the lack of a "final decision." See, e.g., H.R. Rep. 98-857(II) at 9 (1984) (rejecting Sawyer amendment).

The debate then turned to the length of time that the parties would have to satisfactorily resolve patent issues. The generic manufacturers argued for 18 months, while the brands pushed for 30. Ultimately, the branded manufacturers prevailed. Contrary to the assumption underlying the Mylan opinion, however, the fact that generic and branded manufacturers differed as to the amount of time needed to obtain a final judgment does not discount the importance to the generics of preserving the 180-day period of exclusivity until a final judgment is entered, protecting a generic manufacturer against claims of infringement. See 130 Cong. Rec. 23, 765 (statement of Senator Hatch that extension of the no-approval period from 18 to 30 months "increases the likelihood that the litigation will be concluded within the time period during which ANDA's are not allowed.").

Prospective Application of Any New Interpretation is Fundamental

As the FDA has expressly acknowledged, the generic drug industry as we know it today was launched by the passage of the Hatch-Waxman Amendments. The entire structure of the industry is premised on the careful balance of incentives and protections built into the Amendments and elucidated through the agency's regulations and guidance. The 30-month ANDA approval "moratorium" and the 180-day market exclusivity periods related to "paragraph IV" patent certifications are perhaps the most delicately balanced aspects of the Amendments, and are the "cornerstones" to the business incentives for many generic manufacturers. It is no exaggeration to state that hundreds of business decisions have been made, and hundreds of millions of dollars

have been invested, on the understanding that the risks a generic manufacturer undertakes in accepting virtually “automatic” patent infringement litigation under 21 U.S.C. § 355(j)(5)(B)(iv) may be offset by the promise of 180-days’ exclusive marketing rights after the generic’s position is vindicated and marketing may begin without the threat of treble damage liability for infringement.

Given the well-considered and substantial reliance of the generic industry on FDA’s regulations, there is ample justification for the FDA to apply its new interpretation of § 355(j)(5)(B)(iii) and (iv) on a prospective basis only. As a general rule, retroactive rulemaking is disfavored. “[A] statutory grant of legislative rulemaking authority will not . . . be understood to encompass the power to promulgate retroactive rules unless the power is conveyed by Congress in express terms.” Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208, 109 S.Ct. 468, 471, L.Ed.2d 493 (1988) (emphasis added). Moreover, where, as here, the agency’s new take on an issue is inconsistent with its prior, long-standing regulations, the new regulations are “legislative”, not “interpretative” and generally may not be applied retroactively. First National Bank of Chicago v. Standard Bank & Trust, 172 F.3d 472, 478 (Bowen’s ban on retroactivity applies when agency makes substantive change in interpretation of statute); cf. U.S. v. Winstar Corp., 518 U.S. 839, 135 L.Ed.2d 964, 116 S.Ct. 2432 (1996) (holding that institutions that had invested in failing savings and loans based on then-existing accounting regulations could hold United States liable for breach of contract based on application of new accounting regulations).

FDA’s consideration of the inequities that would impact individual applicants (as well as the confusion that would result in the industry more generally) from a retroactive change to the understanding of “court decision” is not only appropriate, but mandatory. Questions of equity are not reserved solely for the courts, but are appropriately considered by administrative agencies as well. Retroactive regulations can cause considerable “mischief” “when parties rely on an admittedly lawful regulation and plan their activities accordingly.” Yakima Valley Cablevision, Inc. v. Federal Communications Commission, 794 F.2d 737, 745-46 (D.C. Cir. 1986). Given that the Mylan and TorPharm opinions themselves were not reviewed on appeal, it cannot be said that the rule articulated in Yakima is inapplicable to the circumstances here.

“The decision whether to make a new policy prospective or retrospective is ‘an important aspect of the problem’ that must be considered by an agency changing a longstanding policy.” Id. When an agency seeks to implement a stark change in policy, it must “give due consideration to the equities, if any, arising out of commitments based on previous rulings.” Consolidated Gas Supply Corp. v. Federal Power Commission, 520 F.2d 1176, 1187 (D.C. Cir. 1975); a drastic administrative change that “does not take account legitimate reliance on prior interpretation may be arbitrary, capricious, or an abuse of discretion.” Smiley v. Citibank (South Dakota), N.A., 116 S.Ct. 1730, 1734 (1996). Accordingly, it is well within an agency’s discretion to make a blanket determination to apply a new regulation on a prospective basis only. Methodist Hospital

of Sacramento v. Shalala, 38 F.3d 1225, 1235 (D.C. Cir. 1994) (upholding agency's decision to apply new, corrected wage index on a prospective basis only).

Andrx strongly endorses FDA's policy that, if there is to be a change at all, the new interpretation of "court decision" should be applied on a prospective basis only. The Mylan Court and FDA have both correctly recognized that giving immediate effect to this new interpretation "may substantially change the value of the 180-day exclusivity" provisions, and that well-noticed, prospective change will "lessen the likelihood that ANDA applicants will sue the Agency alleging that they ... relied in good faith on the Agency's regulation." Retroactive application would unfairly penalize ANDA applicants that relied, in good faith, on the government's longstanding regulatory interpretation.

"The longer and more consistently an agency has followed one view of the law, the more likely it is that private parties have reasonably relied to their detriment on that view." Clark-Cowitz Joint Operating Agency v. FERC, 826 F.2d 1074, 1082-83 (D.C. Cir. 1987) (en banc). The FDA's decision to bifurcate its approach to ANDAs with paragraph IV certifications demonstrates that the agency is aware of the above limitations and has acted appropriately in moving to change the longstanding regulatory scheme.

Waiver

The Interim Rule and Guidance correctly recognize that generic drug manufacturers have reasonably relied on the agency's regulations that established a clear-cut "final decision" trigger for 180-day exclusivity. However, neither legal nor equitable concerns prevent FDA from granting immediate, final marketing approval of a generic drug product when a favorable district court decision is obtained prior to expiration of the otherwise-applicable 30-month waiting period. Andrx believes that a generic applicant, having successfully maintained its position and defeated a patent holder's position at the district court level, might wish to "waive" its right to await a court decision which is final and non-appealable, and assume the risk of marketing its product immediately (assuming the product is otherwise deemed approvable by FDA).

Most generic pharmaceutical companies are loath to incur any infringement risk from marketing a product. However, a confluence of factors might lead a company to accept that risk, even before it has secured finality in patent litigation. Relevant factors might include: the relative "value" of the product vis-à-vis the company itself; the strength of the legal opinion the company received from its patent counsel; the company's analysis and comparison of the United States District Court opinion with the opinions expressed by counsel; the company's analysis of whether any reversible error occurred in connection with the trial; a "worst-case" financial analysis, looking at the projected remaining period of the appeal process, the projected sales of that product and the company's financial position; and the cost of not going to market while awaiting finality.

Andrx believes that FDA should permit a generic company that is subject to the “old” regulatory interpretation of “court decision” to voluntarily and affirmatively waive its right to finality if it desires to assume the risk of marketing a product after issuance of a favorable district court decision, but prior to expiration of the 30-month statutory period. FDA should not infer, however, that any applicant has waived its right to await a final, non-appealable court decision before beginning to market a drug product. Rather, the agency must require an express written statement demonstrating knowledge and voluntary relinquishment of the valuable protection that is being surrendered.

Neither the FDC Act nor FDA’s implementing regulations prohibit a generic manufacturer that has successfully defended patent infringement litigation at the district court level from waiving its right to the protection of a final court decision. In fact, FDA and at least one court have deemed waivers to be permissible under the Hatch-Waxman Amendments in two other contexts. First, FDA has established that a generic manufacturer qualifying for 180-day exclusivity may waive some or all of its exclusive marketing period in favor of a subsequent ANDA holder. See 64 Fed. Reg. 42873, 42881 (Aug. 6, 1999); Boehringer Ingelheim Corp. v. Shalala, 993 F. Supp. 1, 2 (D.D.C. 1997) (“The statute is simply silent on the point, and certainly does not clearly express a statutory policy precluding waivers”). Second, FDA has established that drug manufacturers may waive the benefit of market exclusivity under the non-patent exclusivity provisions of the Hatch-Waxman Amendments. 59 Fed. Reg. at 50359.

This waiver concept would permit FDA and affected companies to maintain the benefits and protections provided by the Hatch-Waxman Amendments, while also facilitating market competition. Moreover, since the patent holder could seek to obtain an injunction to prevent the generic company from marketing its product during the pendency of the appeal, the balance of interests clearly favors immediate recognition of a limited and express waiver concept.

Clarification Is Needed With Regard to Multiple Patents

Andrx believes that FDA needs carefully to consider and to clarify the meaning of “court decision” when multiple patents are at issue in litigation.

Current 21 C.F.R. § 314.107(b)(4) provides that, if an applicant submits a patent certification with regard to more than one patent, the date of approval will be calculated for each certification, and the approval will become effective on the last applicable date. A similar approach by FDA in patent litigation would reasonably permit an ANDA applicant to resolve all patent infringement claims raised against it before its exclusivity period would be triggered.

In August 1999, however, FDA stated in the preamble to a proposed rule that, if an ANDA applicant submits multiple Paragraph IV certifications with regard to multiple

patents listed for a reference drug, the first court decision finding one of the patents invalid, not infringed, or unenforceable would trigger running of the applicant's exclusivity entitlement. 64 Fed. Reg. 42873, 42875 (Aug. 6, 1999). This proposed approach, coupled with FDA's new "court decision" interpretation raises a number of critical questions, as well as potentially negative consequences. For example, if a District Court renders summary judgment on some, but not all, patent issues in a case would that be considered a "court decision"? If the answer is yes, the practical effect very well might be to discourage efforts that might streamline litigation and may unnecessarily lengthen litigation processes. This certainly cannot be what Congress or the agency intends.

Similarly, will (or should) the term "court decision" apply to a District Court decision in which the generic applicant prevails on one or more patents at issue, but loses on another? In this scenario, the generic product may not be marketed until the infringed patent expires or the District Court decision on the other patent(s) at issue is overturned on appeal. Andrx questions, and believes FDA should more clearly address, whether a court decision of this type will be deemed to be a district court finding that a patent is invalid, unenforceable or not infringed.

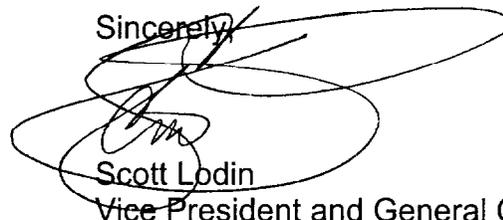
Conclusion

FDA should apply its new "bright line" interpretation of the term "court decision" only prospectively, thereby preserving the longstanding incentive of exclusivity which ANDA applicants, including Andrx, justifiably relied upon.

At the same time, the public interests of both (1) promoting the prompt availability of generic drug products, and (2) promoting industry incentives for innovation, points strongly in favor of permitting an ANDA applicant to waive a right created to protect it, for the benefit of consumers, on a case-by-case basis. While in many cases there is tension between these two legislative goals, here the goals are simultaneously served by permitting the applicant to waive the protection of finality after it has received a favorable District Court decision.

Lastly, the regulations should be clarified to provide a clearer "bright line" interpretation of the term "court decision" in situations where more than one patent is involved, either in the case at issue or in the decision itself.

Sincerely,



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