



# Bristol-Myers Squibb Company

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## **VIA HAND DELIVERY**

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

**RE: Docket No. 85N-0214 (July 13, 2000 Interim Rule on Court Decisions, ANDA Approvals, and 180-Day Exclusivity)**

Dear Sir/Madam:

Bristol-Myers Squibb Company (BMS) submits these comments on FDA's Interim Rule on Court Decisions, ANDA Approvals, and 180-Day Exclusivity (Interim Rule).

### **I. THE INTERIM RULE IS BASED ON A FLAWED INTERPRETATION OF THE STATUTE**

The Interim Rule, and the Guidance which preceded it<sup>1</sup>, is based on the Mylan and TorPharm<sup>2</sup> decisions from the United States District Court for the District of Columbia. Interim Rule at 2. However, those decisions, and consequently the Interim Rule and the Guidance, are based on a flawed interpretation of the governing statute.

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<sup>1</sup> Guidance for Industry: *Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, March 2000.

<sup>2</sup> TorPharm was briefed, argued, and decided in a rapid two-week preliminary injunction proceeding, and FDA was appealing the decision when it later became moot. Its relevance is therefore questionable.

85N-0214

**A. The Interim Rule Ignores The “Last Applicable Date” Requirement of 21 U.S.C. § 355(j)(5)(B)**

Mylan and TorPharm both held that a district court decision of patent invalidity or noninfringement is a “court decision” under subparagraph (I) of 21 U.S.C. § 355(j)(5)(B)(iii). Interim Rule at 3-4. Mylan used this holding to conclude that the 180-day period of a related provision, 21 U.S.C. § 355(j)(5)(B)(iv), can be triggered by a district court decision, while TorPharm used it to determine that the 30 month period provided for in the introductory part of 21 U.S.C. § 355(j)(5)(B)(iii) can be ended by a district court decision. Id. However, these cases ignored the unambiguous language of 21 U.S.C. § 355(j)(5)(B), which does not allow this result in the case of district court decisions for which the time for appeal has not yet run.

The language in 21 U.S.C. § 355(j)(5)(B) is lengthy and complex. In relevant part, it provides that:

The approval of [an ANDA] shall be made effective on the last applicable date determined under the following:

- I. \* \* \*
- II. \* \* \*
- III. If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(I) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—
  - (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision.
  - (II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code . . .

The cases and the Interim Rule ignore the “last applicable date” language at the beginning of this provision. Instead, they focus on only one of the potentially “applicable dates” in the provision, that found at 21 U.S.C. § 355(j)(5)(B)(iii)(I). They read the date described in this subparagraph (“subparagraph I”) to unambiguously allow an ANDA approval on the date of a district court decision of invalidity for which the time for appeal has not yet run.

The fatal flaw in this reasoning is that in many cases the date described in subparagraph I will not be the “last applicable date” under 21 U.S.C. § 355(j)(5)(B). As such, the subparagraph I date cannot be the date of ANDA approval, because an ANDA approval can only “be made effective on the last applicable date” under 21 U.S.C. § 355(j)(5)(B) (emphasis added).

An example illustrates the point. Consider the case of a district court ruling of patent invalidity which occurs in the tenth month of the 30-month litigation period. In month twenty-five, the court of appeals overturns the district court and rules that the patent has been infringed. In this scenario, the “last applicable date” under the statute is the date of the appellate court ruling. This is because although under subparagraph I there was an initial ruling of invalidity, on a later date, there was a ruling of infringement under subparagraph II. Both subparagraphs define relevant dates under 21 U.S.C. § 355(j)(5)(B), so the later appellate ruling is the “last applicable date” for purposes of determining when to grant ANDA approval.

Of course, in some circumstances the earlier district court ruling will become the “last applicable date” under 21 U.S.C. § 355(j)(5)(B). For example, if the district court ruling is not appealed and the time for appealing it has run, an appellate reversal is no longer possible, so the district court ruling, pursuant to subparagraph I, becomes the “last applicable date.” Similarly, the underlying rule of 21 U.S.C. § 355(j)(5)(B)(iii) is that the ANDA is approved if the litigation continues for more than 30 months. Subparagraphs I and II are exceptions to that rule. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, if the 30 month period runs without any of the exceptions coming into play, the ANDA will be approved upon expiration of the 30 months.

The FDA regulations, 21 C.F.R. § 314.107(e)(1) and (e)(2)(i)-(iii), adequately implemented this complex, but unambiguous statutory language.<sup>3</sup> Nonetheless, in ruling against the regulation, the Mylan and TorPharm courts did not take into account the “last applicable date” requirement. As a result, their holdings, and by extension the Interim Rule, are flawed because they do not allow FDA to accurately determine what the “last applicable date” is under 21 U.S.C. § 355(j)(5)(B). Instead, FDA is forced to approve the ANDA before it can know whether or not the district court ruling will be appealed, or, if it is appealed, what the appellate court’s ruling might be.

The scenario above again illustrates the point. When the district court rules in the tenth month that the patent is invalid, under the Interim Rule, FDA must approve the ANDA upon the date of that ruling. Interim Rule at 4. FDA’s approval, however, would not be authorized under the plain terms of the statute, because the appeals court’s subsequent reversal of the district court provides a later “applicable date.” FDA would have approved the ANDA based not on the “last applicable date” as required by 21 U.S.C. § 355(j)(5)(B), but on an earlier date not authorized by the statute. The virtue of the pre-existing regulation, by contrast, is that, in accordance with the statute, it requires FDA to wait until the “last applicable date” has been clearly determined by the course of proceedings in the infringement litigation.

The Interim Rule fails to apply the “last applicable date” requirement of 21 U.S.C. § 355(j)(5)(B). As a result, it should be rescinded and FDA should return to applying 21 C.F.R. § 314.107(e) as it existed before the Guidance and the Interim Rule.

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<sup>3</sup> 21 C.F.R. § 314.107(e) does not define Supreme Court rulings (certiorari denials or decisions on the merits) as relevant court decisions. To be completely faithful to the statutory language, that would probably be required. The change would probably have little real-world effect, however, as the 30-month period would be likely to run before a Supreme Court decision.

## **B. The Interim Rule Is Flawed For Other Reasons**

In addition to ignoring the “last applicable date” provision, the Interim Rule is flawed for a number of other reasons. FDA is already familiar with these reasons, because they have been used by the Agency and others as justification for 21 C.F.R. § 314.107(e) as originally promulgated, whether in rulemaking or litigation. Consequently, these reasons are merely summarized here.

The statute is ambiguous. When the term “court” is used in 21 U.S.C. § 355(j)(5)(B), whether it is referring to a district or appellate court is never specified. By contrast, other provisions of the statute do use the specific terms “district court” or “appellate court.” See, e.g., 21 U.S.C. §§ 332, 334(a)(1) (“district court”); 21 U.S.C. §§ 335a(j)(1), 335b(c), 335c(d), 346a(h)(1), 348(g)(1), 355(h), 360g(a) (“appellate court”). Consequently, it is argued that the unqualified term “court” is ambiguous in 21 U.S.C. § 355(j)(5)(B). This is true as far as it goes. However, as explained above, in light of the “last applicable date” language of 21 U.S.C. § 355(j)(5)(B), the stronger argument seems to be that the statute unambiguously requires FDA to wait until a district court ruling of invalidity or noninfringement is either affirmed on appeal, or the time for its appeal has run.

Legislative History. The early Hatch-Waxman proposals discussed an 18 month, rather than 30 month period, and in some instances seemed to refer to the district court as the court making the relevant decision. See, e.g., Mylan, 81 F. Supp.2d at 40-41. However, once the period was expanded to 30 months, the references shifted to allowing the litigation to “conclude,” which, if the case is appealed, can only take place at the appellate level. Id. Consequently, the legislative history supports the interpretation that Congress meant appellate court decisions to be the relevant “court” decisions in cases which were appealed.

Congressional Intent. In 21 U.S.C. § 355(j)(5)(B)(iv), Congress intended to give ANDA applicants a significant incentive to challenge pharmaceutical patents and thereby speed generic competition. Interpreting “court” to always mean district court, however, severely undermines this incentive, in some cases rendering it useless, or worse (e.g., if an ANDA applicant is bankrupted by an appellate judgment of infringement when it had marketed based on a district court ruling of invalidity). FDA’s original regulation, 21 C.F.R. § 314.107(e), maintained the value of the incentive, in particular for prudent ANDA applicants who wait for appellate affirmation of their district court victories before venturing into the market. It thereby preserved congressional intent. To avoid a radical rebuff to Congress’ intent, FDA’s original regulation should be preserved.

## **II. THE MYLAN AND TORPHARM DECISIONS NEITHER NECESSITATE NOR ALLOW THE INTERIM RULE**

FDA asserts that the Interim Rule is “necessitated by recent court decisions.” Interim Rule at 1. FDA then refers to two District Court decisions—Torpharm, Inc. v. Shalala, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sept. 15, 1997) and Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp.2d 30 (D.D.C. Jan. 4, 2000)—which FDA apparently believes necessitate repeal of 21 C.F.R. 314.107(e)(1) through (e)(2)(iii).

The cited decisions neither necessitate nor allow the Interim Rule. It is undisputed that agencies like FDA must follow the law of the circuit. See Singh v. Ilchert, 63 F.3d 1501, 1508 (9<sup>th</sup> Cir. 1995) (“A federal agency is obligated to follow circuit precedent in cases originating within that circuit.”) (citing NLRB v. Ashkenazy Prop. Management Corp., 817 F.2d 74, 75 (9<sup>th</sup> Cir. 1987)). This principle has been interpreted to mean the law of an appellate court of the circuit. See Spraic v. United States R.R. Retirement Bd., 735 F.2d 1208, 1211 (9<sup>th</sup> Cir. 1984) (“An agency is bound to follow precedent established by an unappealed decision of a

*circuit court* on any matter within that court’s jurisdiction.”) (citations omitted) (emphasis added). Therefore, barring an appellate court decision affirming the Mylan or Torpharm holdings, it is not “necessary”, as FDA claims, for the agency to amend its regulations in favor of these two district court holdings.

In fact, the agency has ignored the importance of the Fourth Circuit’s holding in Granutec, Inc. v. Shalala, 1998 U.S. App. LEXIS 6685 (4<sup>th</sup> Cir. Apr. 3, 1998).<sup>1</sup> Unlike the two district court cases (one of which is of questionable authority because of mootness) on which FDA relies, the Granutec holding is of considerable precedential value. In Granutec, the Fourth Circuit found FDA’s definition of “court” to be a “reasonable interpretation of a complicated legislative framework that reflects a considered balance of competing statutory goals.” 1998 U.S. App. LEXIS 6685 at \*28. Therefore, the Granutec court, a federal appellate court, held that FDA’s position advocated in § 314.107(e) is compatible and consistent with the Congressional intent of the Hatch-Waxman Amendments. Inexplicably though, while passively acknowledging that the Granutec decision has affected 180 day exclusivity, FDA has fashioned this Interim Rule as a response to merely the Mylan and Torpharm decisions.

Taking into account the Granutec decision is especially important since the agency still maintains that its definition of “court” is the proper one. See Interim Rule at 4 (“Although the agency believes that the statutory provisions at issue may properly be interpreted as FDA set out in § 314.107(e), the agency nonetheless . . . accept[s] the interpretation of the *Torpharm* and *Mylan* courts.”). FDA has a legitimate basis for upholding its interpretation of the

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<sup>1</sup> Although Granutec is an unpublished decision in the Fourth Circuit, the rules of the Fourth Circuit do not prohibit the citation of this decision in other circuits and simply disfavor the citation in the Fourth Circuit if a published decision would serve equally. USCS Ct. App. 4<sup>th</sup> Cir., Local R 36(c) (2000). It is important to note that the Agency, in the Interim Rule, is relying on Torpharm, which is also an unpublished decision.

exclusivity statute and is choosing convenience and predictability over its own expertise.

Therefore, the agency is following an interpretation of its governing statute that it is not bound to follow and that it explicitly disagrees with. This is clearly an arbitrary and capricious agency action.

### **III. FDA'S FAILURE TO FOLLOW NOTICE-AND-COMMENT RULEMAKING HAS ALREADY CAUSED AN ARBITRARY AND CAPRICIOUS RESULT**

FDA's failure to use comprehensive notice-and-comment rulemaking in forming the Interim Rule has already resulted in a significant, arbitrary and capricious outcome. By foregoing proper administrative procedure, FDA has repealed a regulation governing 505(b)(2) applications<sup>2</sup> without once presaging or even acknowledging that result. In other words, FDA has eliminated part of the 505(b)(2) regulatory structure without any procedure whatsoever, despite the fact that the 505(b)(2) regulations were promulgated through notice-and-comment rulemaking.

The problem stems from the fact that the "court" definition repealed by the Interim Rule addresses both ANDAs and 505(b)(2) applications. 21 C.F.R. § 314.107. By repealing it, FDA has therefore changed the "court" definition for both ANDAs and 505(b)(2) applications. However, neither of the court decisions on which the Interim Rule is based, nor the Guidance, nor the Interim Rule itself, ever addressed 505(b)(2) applications -- they only addressed ANDAs. This result is clearly inconsistent with FDA's claim of judicial invalidation used to justify passage of the Interim rule. FDA has not and may not claim that the referenced court decisions also addressed 505(b)(2) applications. Consequently, FDA cannot now assert that Mylan and Torpharm "necessitated" repeal of the "court decision" regulation as regards 505(b)(2) applications. FDA's failure to engage in such rulemaking renders the wholesale repeal of the regulation arbitrary and capricious.

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<sup>2</sup> 505(b)(2) applications are a type of generic drug application where the generic applicant submits a New Drug Application which relies on study data to which the generic applicant has no right. 21 U.S.C. § 355(b)(2).

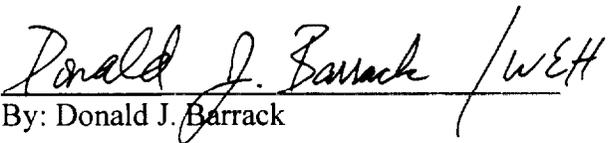
**IV. IF FDA STILL INTENDS TO FOLLOW MYLAN, THE DECISION TO ONLY APPLY MYLAN PROSPECTIVELY IS CORRECT**

If, despite the analysis above, FDA insists on adopting Mylan, the Agency's decision to apply Mylan only prospectively is correct. The Mylan court's equitable determination that application of its ruling to the parties before it would upset their settled expectations, founded on the pre-existing regulation, was correct. Mylan, 81 F. Supp. 2d at 44. Similarly, until the date of the Guidance, regulated industry had no inkling that the Agency would abandon its long-established regulation. Thus, as the Interim Rule states, the same equitable considerations that motivated the Mylan court require that the Interim Rule only be applied prospectively. Interim Rule at 5.

**V. CONCLUSION**

FDA's Interim Rule and its predecessor Guidance should be rescinded. They are contrary to the unambiguous requirements of the statute and its legislative history, undermine the statute's purpose, and are not judicially mandated. If not rescinded, the Interim Rule should only be applied prospectively, and as part of a re-promulgation of FDA's August 6, 1999, proposed rule on 180-day exclusivity prospectively.

**BRISTOL-MYERS SQUIBB COMPANY**

A handwritten signature in black ink that reads "Donald J. Barrack" followed by a large, stylized flourish that appears to be "JWBH". The signature is written over a horizontal line.

By: Donald J. Barrack