IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	MARAGANORE *et al.*	Confirmation No.:	9190
Patent No.:	5,196,404	Issue:	March 23, 1993
Application No.:	07/549,388	Filed:	July 6, 1990
Title:	INHIBITORS OF THROMBIN		

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.183

Dear Sir:

The Medicines Company ("Petitioner"), the applicant in the captioned application for patent term extension, hereby petitions the United States Patent and Trademark Office ("PTO") to suspend the requirements of § 1.750 to the extent they limit requests for reconsideration of patent term extension applications to a single submission within the times specified in the rule. Petitioner is concurrently filing a Request for Reconsideration of the PTO's denial of its patent term extension application. It petitions the PTO to enter and to act upon that Request for Reconsideration.

This petition requires payment of the fee specified in § 1.17(f) ($400). Petitioner requests that the Director debit that amount from our Deposit Account No. 08-0219. Any additional fee required for entry or consideration of this paper or the concurrently-filed Request for Reconsideration may be debited from the same account.

BACKGROUND

1. On Friday, December 15, 2000, the Food and Drug Administration ("FDA") faxed a letter to Petitioner communicating that it had approved its drug product, Angiomax, for marketing in the United States. The fax was not transmitted, however, until after normal business hours, at 6:17 p.m. EST. The next business day was Monday, December 18, 2000.

2. On February 14, 2001—61 days after December 15, 2000, but only 58 days after December 18, 2001—Petitioner filed the captioned application to extend the term of U.S. Patent No. 5,196,404 based on the approval of Angiomax.

3. After consultations with the FDA, and following the PTO's then-customary practice, the PTO concluded that the first day of the 60-day period specified in 35 U.S.C. § 156(d)(1) for filing patent term extension applications was Saturday, December 16, 2000—the first day after the FDA's December 15, 2000 approval for Angiomax. The PTO therefore determined that the application would have been timely if it had been filed by February 13, 2001—one day before the application was in fact filed—and dismissed the application as untimely. *See* Corrected Notice of Final Determination mailed March 4, 2002.

4. Petitioner sought reconsideration in a request filed on October 2, 2002.

5. The PTO referred the request for reconsideration to the FDA, which reiterated its view that Angiomax was approved on December 15, 2000. *See* Letter from FDA dated November 2, 2006.

6. On January 26, 2007, Petitioner filed a petition requesting that the PTO stay proceedings in this application in view of legislative activity that could have rendered the basis for the PTO's original determination moot. On February 12, 2007, the PTO granted the petition in part and afforded Petitioner the opportunity to supplement its arguments.

7. On March 13, 2007, Petitioner filed an amended patent term extension application and an Amended Request for Reconsideration arguing (among other things) that the PTO had an independent obligation to determine the timeliness of the application and that, in the unique circumstances of this matter, the period under § 156(d)(1) should be found to run from December 18, 2000.

8. In a decision dated April 26, 2007, the PTO denied reconsideration. In that decision, the PTO stated for the first time that the patent term extension application had been filed "two days late." *See* Decision mailed April 26, 2007, at 7 n.3.

ARGUMENT

To the extent § 1.750 prohibits the filing of successive requests for reconsideration and imposes a time limit for the submission of any such request, Petitioner respectfully requests that the PTO suspend such restrictions and consider the concurrently-filed Request for Reconsideration. 37 C.F.R. § 1.183 provides:

> In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed.

The provisions of § 1.750 implicated by the present request are not requirements of the statute. In particular, 35 U.S.C. § 156 does not specify or otherwise limit the number of requests for reconsideration that an applicant may file, and it does not address the question of when such requests must be filed. Accordingly, the PTO has the authority to suspend its rules in these respects. For the reasons discussed below, Petitioner submits that this is an extraordinary situation within the meaning of § 1.183 and that the interests of justice require the PTO to consider and respond to the arguments set forth in the Request for Reconsideration.

Reconsideration is necessary to take into account a new development since the filing of Petitioner's prior request for reconsideration—the PTO's new approach to calculating the 60-day period under § 156(d)(1). In communications in this proceeding before the decision mailed on April 26, 2007, the PTO interpreted the deadline in § 156(d)(1) the same way most court filing deadlines are calculated: with the day count starting on the day *after* the event triggering the deadline. Thus, in its initial determination, the PTO concluded that the Angiomax patent term extension application had been filed a single day late. *See* Corrected Notice of Final Determination mailed March 4, 2002. But in its 2007 decision, the PTO asserted for the first time that the application was actually filed not one, but two, days late.

Subsequently, the PTO has applied this new interpretation in other matters. In denying one application that would have been timely under the former approach, the PTO explained its shift in position:

> Applicant is correct that the USPTO has changed the way in which it makes the timeliness count between 2004 and 2008. The agency has done so because it realized that it was erroneously beginning the sixty-day count on the wrong day. By not counting the date of FDA approval as one of the sixty days included in the time period for filing a PTE application, the USPTO was failing to comply with section 156 and case law. The FDA made the same error as the USPTO and also corrected itself.

In re Patent Term Extension Application for U.S. Patent No. 5,817,338, 2008 WL 5477176 (Com'r Pat. Dec. 16, 2008) (Prilosec, *see* chart below).

The chart below shows that the PTO and/or the FDA have taken the position that at least seven applications for patent term extensions were untimely, even though each of those applications would have been timely under the PTO's prior interpretation of § 156(d)(1).

Drug/Product	Patent No.	FDA Approval Date	PTE App. Date	Date of Denial
AbioCor Heart	5,084,064	9/5/2006	11/6/2006	6/29/2007 (PTO letter to FDA)
Bextra	5,633,272	11/16/2001	1/15/2002	3/20/2008
Isolex 300	4,714,680 4,965,204 5,035,994 5,130,144	7/2/1999	8/31/1999	4/1/2008
A180	4,861,779	9/20/2002	11/19/2002	4/4/2008 (order to show cause)
Decapinol Rinse	4,894,221	4/18/2005	6/17/2005	6/5/2008 (FDA letter to PTO)
Symbicort	5,674,860	7/21/2006	9/19/2006	6/13/2008
Prilosec OTC	5,817,338	6/20/2003	8/19/2003	12/16/2008

None of these decisions had been rendered at the time Petitioner filed its prior request for reconsideration in this matter. As a result, Petitioner has not previously had the opportunity to address the new interpretation of § 156(d)(1).

Petitioner contends that when the FDA transmits a new drug application approval after normal business hours, the product should be deemed to have "received permission" for commercial marketing on the *next* business day. The change in the PTO's interpretation of § 156(d)(1) provides further support for Petitioner's position. Under the PTO's new interpretation, an approval transmitted late in the evening could eliminate an entire day of the statutorily-mandated 60-day period in § 156(d)(1). The PTO's new interpretation therefore affords a basis for the PTO to revisit the question of which day is the first day of the 60-day period for filing an application for patent term extension when the FDA's approval is transmitted after normal business hours.

Because the PTO first announced its revised interpretation of § 156(d)(1) in the decision mailed on April 26, 2007, Petitioner has had no opportunity to present arguments that take account of the PTO's shift in policy. Accordingly, the PTO should reopen its consideration of this matter to afford Petitioner the opportunity to address the issue on this administrative record.

Consideration of this successive request for reconsideration is also in the interests of justice because—as Petitioner explained in its prior request for reconsideration—the consequences of depriving Petitioner of a patent term extension are severe. Without such an extension, the commercial incentive for Petitioner to develop new indications for Angiomax, a unique and important medicine, will be significantly diminished. The patent term restoration provisions of the Hatch-Waxman Act are essentially remedial in nature. It is therefore proper for the PTO to administer these provisions with sufficient flexibility to give applicants for term extension a full opportunity to present all of their arguments.

Finally, reconsideration is appropriate to permit the PTO to address the merits of Petitioner's proposed next business day rule. The PTO did not substantively respond to Petitioner's contentions because it felt bound to adhere to the FDA's view that the 60-day period under § 156(d)(1) began on December 15, 2000—the day the FDA has indicated that it approved Angiomax. *See* Decision mailed April 26, 2007, at 9-11. If the PTO agrees with Petitioner that, in fact, it was not required to defer to the FDA, then it is appropriate for the PTO to grant reconsideration to address Petitioner's arguments on the merits.

CONCLUSION

Petitioner respectfully requests that the PTO suspend the provisions of 37 C.F.R. § 1.750 to the extent that they would preclude consideration of a further request for reconsideration of

the PTO's decision concerning its application for patent term extension, and enter and address the concurrently-filed Request for Reconsideration.

Respectfully submitted,

/Donald R. Steinberg/

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REQUEST FOR RECONSIDERATION OF APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Dear Sir:

The Medicines Company ("Applicant") hereby seeks reconsideration of the denial of its application for an extension of the term of U.S. Patent No. 5,196,404 under 35 U.S.C. § 156. Applicant is concurrently filing a petition under 37 C.F.R. § 1.183 to request that the United States Patent and Trademark Office ("PTO") suspend any provisions of § 1.750 that might otherwise bar consideration of this request.

Under 35 U.S.C. § 156(d)(1), a patent term extension application must be submitted "within the sixty-day period beginning on the date the product received permission … for commercial marketing or use." Applicant respectfully submits that the PTO can and should determine that, when the Food and Drug Administration ("FDA") transmits notice of approval of a drug product after the close of the FDA's normal business hours,[1] the product has not "received

[1] Normal business hours of the FDA close at 4:30 p.m. *See* Center for Drug Evaluation and Research, *Manual of Policies and Procedures* § 4657.1 at 2 (Oct. 3, 2007) ("CDER's business hours are 8:00 a.m. to 4:30 p.m., Monday through Friday."), *available at*

permission" for commercial marketing under § 156(d)(1) until the next business day. Under this proposed "next business day" rule, the present application for patent term extension based on the approval of Angiomax was timely filed because it is undisputed that the FDA's approval letter was not faxed to Applicant until after the close of business, at 6:17 p.m., on December 15, 2000.

As explained below, the PTO is responsible for determining under § 156(d)(1) whether an application for patent term extension was filed within the 60-day period after the drug product "received permission" for commercial marketing. Although related, this determination is distinct from the question of when a new drug application is "approved" for various purposes under the Food, Drug, and Cosmetic Act ("FDCA"), and from the FDA's determination of the end of the regulatory review period under 35 U.S.C. § 156(g)(1)(B)(ii). Those distinct dates are phrased in different statutory language, have distinct purposes, and are properly determined by the FDA. Specifically, provisions in the FDCA refer to the "effective" date of "approval" of a new drug application and generally concern the legal effect of approval of a new drug application and FDA obligations regarding review of those applications. Section 156(g)(1)(B)(ii) similarly refers to the date a new drug application was "approved" and serves to define the end of the regulatory review period of that application.

Considering the distinct language and purpose of § 156(d)(1), Applicant submits that the PTO can and should interpret the language of § 156(d)(1) to conclude that the present application was timely filed. The PTO can do this by concluding that this application was filed within 60 days of the first business day on which the product had "received permission … for commercial marketing." Recognizing that the notice of approval of Angiomax was sent after the close of the FDA's normal business hours, it is reasonable for the PTO to conclude that the first day of the

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http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffPoliciesand Procedures/ucm079530.pdf.

period specified in § 156(d)(1) was the first business day after Friday, December 15, 2000—namely, Monday, December 18, 2000. Employing this rule of construction would not affect the manner by which the FDA determines the date of approval of a new drug application for other purposes under the FDCA and would not alter how the FDA determines the length of the regulatory review period under § 156(g)(1)(B)(ii).

Reconsideration is particularly appropriate in this case in view of the PTO's newly announced approach to counting days under § 156(d)(1). At the time Applicant filed its previous request for reconsideration, the PTO took the position that the first day of the 60-day period was the day *after* the drug received permission for commercial marketing. Since that time, the PTO has revisited its interpretation of § 156(d)(1) and now takes the position that the statute requires that date the new drug application is approved by the FDA be considered the *first* day of the 60-day period. Absent adoption of the proposed next business day rule, application of this new interpretation in cases where the FDA transmits notice of approval of the drug product *after normal business hours* would impermissibly shorten the period for filing a § 156 application to less than the 60 days the statute requires.

Applicant proposes that the PTO can and should employ a rule of construction whereby the 60-day period of § 156(d)(1) commences on the first business day after the day the FDA transmits notice of approval of the drug product if that transmittal occurs after normal business hours. This next business day rule would further the purposes of § 156(d)(1) and would make its application more transparent and predictable. Such a construction is also the only one that is consistent with the language and intent of § 156(d)(1) because it will ensure that all applicants enjoy no less than the full 60 days prescribed by § 156(d)(1) to prepare and file a patent term restoration application. By focusing on *receipt* of permission, not the FDA action of signing an

approval letter, the PTO will better protect the interests of innovators and more faithfully implement the statutory intent.

The proposed rule of construction, moreover, would provide an objective standard that is easy to administer. The PTO could readily determine if the FDA's transmittal of the new drug approval occurred before or after the close of the FDA's ordinary business hours by inspecting the date and time of the transmission. Such information is readily available to both the § 156 applicant and the FDA. The inquiry would not—and should not—turn on actual receipt of the after-hours approval. Indeed, it is and should be immaterial and irrelevant to the determination of compliance with § 156(d)(1) whether a person affiliated with the new drug applicant actually read an approval letter or spoke to an FDA official after normal business hours on the date of transmittal.

Because the PTO is statutorily charged with determining whether the requirements of § 156(d)(1) have been met and because § 156(d)(1) does not expressly address how to account for FDA approvals transmitted after normal business hours, the PTO has both the authority and responsibility to interpret that provision. Applicant respectfully submits that adopting a next business day rule is faithful to Congress' intent, furthers the PTO's purpose of promoting innovation, and would create a standard that is easy to administer and would not interfere with other PTO or FDA functions.

BACKGROUND

Applicant filed an Amended Request for Reconsideration and an amended patent term extension application in this proceeding on March 13, 2007. On April 26, 2007, the PTO denied Applicant's requested extension. The decision acknowledged that "USPTO is charged with determining whether an application meets the statutory requirements for extension," including whether it is timely under § 156(d)(1). *See* Decision mailed April 26, 2007, at 9. But the PTO

relied on the FDA's determination that the Angiomax new drug application was approved on December 15, 2000 and consequently denied the Applicant's extension request. *See, e.g., id.* at 5 (The FDA "has made clear three times that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000.").

In its April 26, 2007 decision, the PTO raised a new issue concerning how the first day of the 60-day period under § 156(d)(1) should be determined. Before the decision, the PTO had interpreted the 60-day deadline the same way most filing deadlines are calculated: with the first day of the period being the day *after* the event that triggers the running of the period. Thus, in the initial determination mailed November 20, 2001 and in its March 4, 2002 Corrected Notice of Final Determination, the PTO concluded that the Angiomax extension application had been filed a single day late. But in its April 26, 2007 decision, the PTO changed its view about how to interpret the relevant provision and asserted for the first time that the Angiomax extension application was filed *two* days late. *See* Decision mailed April 26, 2007, at 7 n.3. In other words, the PTO adopted a new interpretation of the statutory language of § 156(d) that defines the start of the 60-day period within which an applicant must submit an application. The PTO has since applied its new interpretation to other applications under § 156. *See, e.g.*, *In re Patent Term Extension Application for U.S. Patent No. 5,817,338*, 2008 WL 5477176 (Com'r Pat. Dec. 16, 2008).

The combined effect of treating the day a product receives permission for commercial marketing as the first day of the 60-day period allotted to file a patent term extension application and concluding that a product may be deemed to "receive permission" even after the close of the normal business day effectively shortens the 60 days provided by Congress to 59 days. The PTO's new interpretation of § 156(d)(1) thus provides additional reason to adopt Applicant's

proposed rule of construction that the 60-day period under § 156(d)(1) commences on the next business day when the notice of FDA approval is transmitted after the close of the FDA's normal business hours.

REQUEST FOR RECONSIDERATION

I. PTO CAN AND SHOULD MAKE ITS OWN DETERMINATION REGARDING WHEN ANGIOMAX "RECEIVED PERMISSION" FOR COMMERCIAL MARKETING WITHIN THE MEANING OF § 156(d)(1)

As the PTO has recognized, § 156 carefully allocates responsibility for administering the patent term extension application process between the Director of the PTO and the Secretary of Health and Human Services ("HHS") (acting through the FDA). *See* Decision mailed April 26, 2007, at 9; *see also Aktiebolaget Astra v. Lehman*, 71 F.3d 1578, 1581 (Fed. Cir. 1995) (noting division of responsibility). The statute requires the PTO Director to determine whether an application meets the statutory requirements for a patent term extension. 35 U.S.C. § 156(e)(1) ("If *the Director determines* that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, *the Director* shall issue …." (emphasis added)); *see also id.* § 156(d)(1)(C) (an application must contain "information to enable *the Director to determine* . . . the eligibility of a patent for extension" (emphasis added)). By contrast, the Secretary of HHS—and the FDA by delegation—is charged with calculating the "regulatory review period," which affects the length of the extension that is available if the Director determines that the patent is eligible. *See id.* § 156(d)(2) (requiring the Secretary to "determine the applicable regulatory review period [and to] notify the Director of the determination").

The statute thus expressly assigns the PTO Director—not the FDA—responsibility for determining whether an application has been "submitted within the sixty-day period beginning on the date the product received permission . . . for commercial marketing or use" as required by

§ 156(d)(1). This requires the Director to interpret the phrase the "date the product received permission … for commercial marketing or use" and then apply that interpretation to the relevant facts.

The "FDA's access to drug approval records, information outside the purview of the USPTO," Decision mailed April 26, 2007, at 9, provides no basis for deferring to the FDA with respect to the *legal* question of how the PTO should construe and apply § 156(d)(1) in this unique context. It is, of course, perfectly appropriate for the PTO to obtain relevant facts from the FDA concerning that Agency's activities. In this case, the only relevant facts—the date and time of the FDA's fax transmittal of the letter approving the Angiomax new drug application—are not disputed. It is clear that officers of Applicant did not read—and could not have read—the FDA's approval letter until the evening of Friday, December 15, 2000, after the close of business. The only issue here is whether, in light of the fact that the fax was transmitted after normal business hours, "the date [Angiomax] received permission . . . for commercial marketing or use," 35 U.S.C. § 156(d)(1), should be treated as Friday, December 15, or Monday, December 18. This application of law to fact in no way requires deference to the FDA.

The 1987 Memorandum of Understanding ("MOU") between the PTO and the FDA regarding procedures for reviewing patent term extension applications, *see* 52 Fed. Reg. 17,830, is not to the contrary. The MOU recognizes, consistent with the statutory division of authority, that "it is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied" the timeliness requirement under § 156(d)(1). *Id.* at 17,831. The FDA's job under the MOU is to "convey to PTO … information," *id.*, not to make the legal determination regarding timeliness under § 156(d)(1). Although the MOU asks the FDA to "inform" the PTO whether the application "was submitted within 60 days after the product was

approved," the MOU does not purport to bind the PTO. *Id.* By contrast, under the MOU, the FDA does not just provide information about the period of regulatory review, it issues a "determination" of that period, consistent with the statutory mandate. *Id.*; *see* 35 U.S.C. § 156(d)(2) (requiring the Secretary to "determine the applicable regulatory review period [and to] notify the Director of the determination").

In any event, the MOU could not authorize FDA to make determinations the PTO is required to make under § 156. When Congress directs an agency to make a particular determination, the agency must itself carry out that responsibility.[2] The 1999 statute creating the PTO as an agency within the Department of Commerce and transferring its existing functions provides that "an official to whom functions are transferred under this subtitle (including the head of any office to which functions are transferred under this subtitle) may delegate any of the functions so transferred to such officers and employees *of the office of the official* as the official may designate."[3] This limited authorization bars any delegation *outside* the PTO.[4]

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[2] *See New York Cross Harbor R.R. v. Surface Transp. Bd.*, 374 F.3d 1177, 1186 (D.C. Cir. 2004) ("The Board cannot abdicate its responsibility to make an independent assessment of the relevant factors. . . ."); *Achernar Broad. Co. v. FCC*, 62 F.3d 1441, 1447 (D.C. Cir. 1995) (setting aside an FCC order in light of the FCC's "blind acceptance" of objections raised by National Radio Astronomy Observatory); *Idaho ex rel. Idaho Pub. Utils. Comm'n v. ICC*, 35 F.3d 585, 595 (D.C. Cir. 1994) (rejecting agency decision where, "[i]nstead of taking its own hard look, the Commission deferred to the scrutiny of others").

[3] Patent and Trademark Office Efficiency Act, Pub. L. No. 106-113, § 4745, 113 Stat. 1501, 1501A-587 (1999) (35 U.S.C. § 1 note) (emphasis added).

[4] *See Halverson v. Slater*, 129 F.3d 180, 184–85 (D.C. Cir. 1997) (holding that 46 U.S.C. § 2104(a), which authorizes the Secretary of Transportation to delegate certain powers and duties "to any officer, employee, or member of the Coast Guard," was "intended to exclude delegations to non-Coast Guard officials").

II. THE DATE A DRUG "RECEIVE[S] PERMISSION" FOR COMMERCIAL MARKETING UNDER § 156(D)(1) IS DISTINCT FROM THE DATE THE NEW DRUG IS "APPROVED"

To exercise its authority to decide whether a patent term extension application was timely filed, the PTO must first construe the relevant language of § 156(d)(1) to determine when the 60-day period for filing an application for term extension begins. When the PTO most recently consulted the FDA in connection with the present application, the FDA reiterated its conclusion that "Angiomax was approved on December 15, 2000." Letter from FDA dated November 2, 2006. But that conclusion does not address the issue in dispute in this application. Section 156(d)(1) provides that an application for patent term extension must be filed within the 60-day period "beginning on the date the product received permission … for commercial marketing or use." Although the date a "product received permission … for commercial marketing" under § 156(d)(1) might, in many cases, be the effective date of "approval" of the new drug application under the FDCA and § 156(g)(1)(B)(ii), nothing in the statute compels this result. Ample reasons exist to conclude that, where an FDA approval is transmitted after normal business hours, the PTO may determine that these dates are different.

First, the relevant statutory language is different. Section 156(d)(1) calls for the PTO to decide "the date the *product received permission* … for commercial marketing or use." 35 U.S.C. § 156(d)(1) (emphasis added). This is not the same language used in the FDCA or in the subsection of § 156 that addresses the start and end of the regulatory review period.

Under the FDCA, it is *approval of a new drug application*, not effective *receipt* of approval, that is legally relevant. For example, the FDCA prohibition on marketing an unapproved drug provides that:

> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless *an approval* of an application

> filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

21 U.S.C. § 355(a) (emphasis added). Similarly, § 355(c) mandates that "[w]ithin one hundred and eighty days after the filing of an application … [the FDA] shall … *approve* the application if [it] then finds that none of the grounds for denying approval specified in subsection (d) of this section applies" or afford the applicant a hearing. *Id.* § 355(c)(1)(A) (emphasis added).

The statutory language of § 156(d)(1) ("received permission") also stands in contrast to that in § 156(g)(1)(B)(ii), which defines the regulatory review period to be "the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date *such application was approved* under such section." (Emphasis added.) The date of *approval* of a new drug application marks the end of the period of regulatory review under § 156(g)(1)(B)(ii) that is used to calculate the period of patent term restoration.

Thus, while § 156(d)(1) focuses the PTO on the *product* and *receipt* of permission, § 355 and § 156(g)(1)(B)(ii) focus the FDA on the FDA action of *approving* a new drug application. The fact that Congress used two different formulations in the same statutory section reinforces the conclusion that these two date references do not have the same meaning. *Sosa v. Alvarez-Machain*, 542 U.S. 692, 711 n.9 (2004) ("[W]hen the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended." (internal quotation marks omitted)).

Second, and even more importantly, the relevant provisions serve distinct purposes. The function of § 156(d)(1) is to establish the period of time during which an extension application may be prepared and filed. This section identifies an *interval* of time during which an extension application may be prepared and filed ("within the sixty-day period") and the first day of that

interval ("beginning on the date the product received permission"). The structure of this provision conveys the intent of Congress that applicants should have the 60-day period to file an application for an extension of patent term.

An essential purpose of § 156(d)(1) is to provide a trigger that starts the interval of time during which the applicant must act. In this context, it makes no sense to look to the date that appears on the face of an FDA approval letter. What matters is when the applicant should be deemed to be on notice of the approval. Indeed, a standard that disregards the circumstances of transmittal of this notice serves no purpose other than to unduly shorten the period the applicant is given to prepare and file the § 156 application. Certainly, the statutory language does not compel a conclusion that the 60-day clock must start on the "effective" date of approval of the new drug application—if that were the case, the same terms used in § 156(g)(1)(B)(ii) and throughout the FDCA would have been employed in § 156(d)(1). Moreover, it is common to apply rules of constructive receipt when a party is required to act in a specified interval of time following an event. For example, the Federal Rules of Civil Procedure provide that "[w]hen a party may or must act within a specified time after service and service is made [by certain means including mail], 3 days are added after the period would otherwise expire." Fed. R. Civ. P. 6(d).[5] Similarly, a PTO rule of practice in trademark cases provides that "[w]henever a party is required to take some action within a prescribed period after the service of a paper upon the party by another party and the paper is served by first-class mail, 'Express Mail,' or overnight courier, 5 days shall be added to the prescribed period." 37 C.F.R. § 2.119(c).

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[5] *See also, e.g.*, 2 U.S.C. § 394(b) (statute governing contested congressional elections providing that "[w]henever a party has the right or is required to do some act or take some proceeding within a prescribed period after the service of a pleading, motion, notice, brief, or other paper upon him, which is served upon him by mail, three days shall be added to the prescribed period"); Fed. R. Crim. P. 45(c); Fed. R. App. P. 26(c); Fed. R. Bankr. P. 9006(f).

The statutory language in the FDCA and § 156(g)(1)(B)(ii)—unlike that in § 156(d)(1)—makes no reference to receipt of the FDA's action, and with good reason. Those dates establish rights or consequences without the necessity of notice to the new drug applicant. In particular, the date the FDA's "approval" of a new drug application becomes "effective" marks the period when an applicant may begin to market the drug without prohibition. *See* 21 U.S.C. § 355(a). That date also marks the end of the period of regulatory review under § 156(g)(1)(B)(ii). Notice to the new drug applicant is not necessary to further either of these statutory purposes. It is the fact that the FDA has actually approved a new drug application—after concluding the drug specified in it to be safe and effective—that matters under the FDCA.[6] Similarly, in § 156(g)(1)(B)(ii), Congress chose to delimit the period of "regulatory review" using the date of FDA approval of the new drug application. No corresponding or similar language is used in § 156(d)(1).

The decision in *Norwich Eaton Pharmaceuticals, Inc. v. Bowen*, 808 F.2d 486 (6th Cir. 1987), is fully consistent with this distinction. *Norwich* did not involve a patent term extension application under § 156 or an interpretation of § 156(d)(1). Rather, in *Norwich*, the date of FDA approval determined whether a drug was eligible for a 10-year (instead of 5-year) period of *non-patent* exclusivity under a transitional provision of the Hatch-Waxman Act. It was perfectly reasonable and appropriate in that context to look to the date an approval letter was mailed, not the date it was received, since notice of approval was not relevant to the proper treatment of the drug under the transitional provision. *See id.* at 491.

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[6] It is therefore entirely appropriate for the FDA to use the date of actual approval for purposes of administering the FDCA. *See, e.g.*, 21 C.F.R. § 314.108(a) (defining the date a product was "approved" for establishing new chemical entity regulatory exclusivity).

Unimed, Inc. v. Quigg, 888 F.2d 826 (Fed. Cir. 1989), is also inapposite. *Unimed* concerned an application for patent term extension based on the approval of the drug product Marinol, which contains the active psychoactive substance found in marijuana. *See id.* at 827. The applicant argued that the period for filing an application under § 156 should not have commenced until the Drug Enforcement Agency ("DEA") rescheduled the drug, almost a year after the FDA approved the Marinol product under the FDCA. *Id.* at 828. The case thus turned on whether the 60-day period in § 156(d)(1) started running, not from the date the product received permission for commercial marketing from the *FDA*, but from the date the DEA took action to allow it to be sold as a Schedule II drug under the Controlled Substances Act. *Id.* at 827-28. Rejecting the applicant's position, the Court held that the Hatch-Waxman Act "takes into account only the regulatory review carried out by the FDA and no other government obstacles to marketing new drugs." *Id.* at 828.

A couple of sentences in *Unimed* could be read to suggest that the date of FDA approval under the FDCA is the same date on which the 60-day clock under § 156(d)(1) begins to run. *See id.* at 829. But that issue was not even remotely presented in the case. Indeed, this is not even a situation where a court in non-binding *dicta* considers and addresses an issue not strictly necessary to its decision.[7] The snippets in *Unimed* "are not even dicta." *United States v. Anderson*, 885 F.2d 1248, 1251 (5th Cir. 1989) (en banc). The question of whether a product

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[7] *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998) ("drive-by jurisdictional rulings" not binding where issue "made no substantive difference," "had been assumed by the parties, and was assumed without discussion by the Court"); *Palm Beach Isles Assocs. v. United States*, 231 F.3d 1354, 1360 (Fed. Cir. 2000) ("[T]hough the court addressed the issue, the statement must be considered non-binding dictum, since it was not essential to a holding . . . ."); *In re McGrew*, 120 F.3d 1236, 1238 (Fed. Cir. 1997) ("[D]ictum consists, inter alia, of statements in judicial opinions upon a point or points not necessary to the decision of the case."); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1189 n.6 (Fed. Cir. 1995) ("[T]he court's discussion . . . was not necessary to the resolution of the issue and is, therefore, dicta.").

"receive[s] permission" for commercial marketing under § 156(d)(1) on the date of an FDA approval letter—where the letter is transmitted after the close of business that day—was not relevant to the decision, was not briefed by the parties, and was not addressed by the Court. The Court had no reason to consider this issue because *Unimed* filed its extension application "fourteen days after DEA rescheduled the drug, but more than a year after the FDA's final approval letter." *Unimed*, 888 F.2d at 827. Indeed, the appellate briefs in *Unimed* give no indication that the timing of the FDA's letter was at issue. In its brief, *Unimed* stated the issue as:

> Whether an application for a human drug patent term extension under 35 U.S.C. Section 156 filed within 60 days of the rescheduling of that drug product by the Drug Enforcement Administration (DEA) is timely, where (1) the drug product was legally barred from any commercial marketing or use prior to the action taken by the DEA, and (2) the Food and Drug Administration (FDA) expressly indicated in its approval letter with respect to the New Drug Application (NDA) for the product that it could not be legally marketed prior to rescheduling by the DEA.

Brief for Unimed, Inc. and Theodor Petrzilka at 1, *Unimed*, 888 F.2d 826 (No. 89-1430).

No court has ever relied on the few sentences in *Unimed* suggesting that the date of FDA approval is the same as the date a product "received permission" for commercial marketing under § 156(d)(1). The holding of *Unimed* is that the controlling regulatory event under § 156 is receipt of permission *from the FDA*, rather than action by *other government agencies* to remove legal impediments to the commercial marketing of the product. *Unimed* did not decide whether the effective date of FDA approval of a new drug application must *always* be the same as "the date the product received permission" under §156(d). In the ordinary case, where FDA approval is transmitted during normal business hours, the dates will be the same, as *Unimed* observes. But *Unimed* did not address the narrow question presented here—whether a product "received

permission" for commercial marketing on the date of FDA approval where the transmission of the approval letter *occurred after normal business hours.* Thus, no inference may be drawn from *Unimed* with respect to this issue. *See, e.g., Webster v. Fall*, 266 U.S. 507, 511 (1925) ("Questions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, are not to be considered as having been so decided as to constitute precedents").

Because the language and purpose of § 156(d)(1) are distinct from the language and purpose of provisions of the FDCA and § 156(g) relating to new drug "approval," the PTO can and should give § 156(d)(1) independent meaning, at least where FDA approval is transmitted after normal business hours.[8]

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[8] If the PTO rejects Applicant's contention and concludes that the "received permission" language of § 156(d)(1) must be equated with "approval" under § 156(g)(1)(B)(ii) even in the circumstances of this case, then the PTO will be required to interpret § 156(g)(1)(B)(ii) in order to administer § 156(d)(1). As Applicant has previously explained, the FDA's practices treat "the date" that marks the beginning of the period of regulatory review under §156(g)(1)(B)(ii) differently than "the date" that marks the end of that period. The FDA considers new drug applications submitted after 4:30 p.m. EST to have been received on the next business day, *see infra* n.10, but considers approvals transmitted after hours to be effective on the date the letter is issued, *see, e.g.*, 21 C.F.R. § 314.105. This inconsistent approach is contrary to the "normal rule of statutory construction" that "identical words used in different parts of the same act are intended to have the same meaning." *Sorenson v. Secretary of Treasury*, 475 U.S. 851, 860 (1986) (internal quotation marks omitted); *see also Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007). This rule applies with particular force where, as here, the words appear *in the very same sentence*. *Brown v. Gardner*, 513 U.S. 115, 118 (1994); *see also Buckeye Check Cashing, Inc. v. Cardegna*, 546 U.S. 440, 448 (2006). Where Congress has used the same term in related statutory provisions, courts presume that Congress intended for agencies to "define [the term] consistently." *SKF USA Inc. v. United States*, 263 F.3d 1369, 1382 (Fed. Cir. 2001); *see also Butterbaugh v. DOJ*, 336 F.3d 1332, 1338-39 (Fed. Cir. 2003) (rejecting inconsistent interpretation of the word "date"); *NSK Ltd. v. United States*, 390 F.3d 1352, 1357–58 (Fed. Cir. 2004); *National Org. of Veterans' Advocates, Inc. v. Secretary of Veterans Affairs*, 260 F.3d 1365, 1379–80 (Fed. Cir. 2001). In its prior determination in this matter, the PTO cited *Unimed*, 888 F.2d 826, *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332 (D.C. Cir. 1988), and *Norwich*, 808 F.2d 486, for the proposition that the "approval date" of a drug "is the date appearing on the FDA approval letter." Decision mailed April 26, 2007, at 6. But none of those cases addressed the FDA's inconsistent treatment of after-hours incoming communications and outgoing approvals.

III. THE PTO SHOULD CONCLUDE THAT IF FDA APPROVAL IS TRANSMITTED AFTER NORMAL BUSINESS HOURS, THE PRODUCT "RECEIVED PERMISSION" FOR MARKETING THE NEXT BUSINESS DAY

As explained above, the PTO can and should independently construe the meaning of the phrase "date the product received permission . . . for commercial marketing" in § 156(d)(1) as specifying a date that may, at least in certain circumstances, be distinct from the effective date of FDA "approval" of a new drug application under the FDCA and § 156(g)(1)(B)(ii). For the reasons set forth below, in doing so, the PTO should conclude that if notification of approval of a new drug product is transmitted after normal business hours, then the date that the drug product "received permission" under § 156(d)(1) should be deemed to be the next business day following that after-hours communication.[9]

A. Treating An After-Hours Approval As Effective For Purposes Of § 156(d)(1) The Next Business Day Comports With The Language And Purpose Of The Statute

Congress charged the PTO with determining the date on which Angiomax "received permission . . . for commercial marketing or use." 35 U.S.C. § 156(d)(1). This language is best construed to mean that, where the FDA sends notice of an approval decision after the close of business, the product "receive[s] permission" for purposes of § 156(d)(1) on the next business day.

Applicant's proposed reading of the statute comports with its plain language and background norms regarding the date an after-hours event is deemed to occur. As discussed above, § 156(d)(1) focuses on the date the product "*receive[s]* permission … for commercial

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[9] An agency's authority to formulate *procedural* standards is broad. In the absence of a statutory limitation, procedural standards "are generally within the discretion of the agency." *American Trucking Ass'ns, Inc. v. United States*, 627 F.2d 1313, 1321 (D.C. Cir. 1980); *see also National Whistleblower Ctr. v. Nuclear Regulatory Comm'n*, 208 F.3d 256, 264 (D.C. Cir. 2000) (noting "the wide latitude an agency has in designing its own procedures").

marketing." (Emphasis added.) It would be anomalous to adopt a general rule that permission is deemed received on the date sent even if the transmittal is after the close of business. The more sensible construction is that an after-hours communication should be deemed to have been received on the next business day.

A next business day rule would be consistent with the FDA's own practice with regard to recognizing receipt of a communication concerning a new drug application. Specifically, the FDA considers new drug applications submitted after 4:30 p.m. EST to have been received on the next business day.[10] Moreover, the FDA has a general policy of treating after-hours submissions to the agency as having been received the following business day.[11] The FDA's practices are not unique; other agencies follow this practice with regard to a number of their regulatory functions. *See*, *e.g.*, 7 C.F.R. § 1.612(c) (Department of Agriculture); 10 C.F.R. § 501.7(a)(3) (Department of Energy); 10 C.F.R. § 1004.4(a) (Department of Energy); 19 C.F.R. § 201.3(c) (International Trade Commission); 30 C.F.R. § 210.103(b) (Minerals Management

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[10] *See* FDA, *Electronic Submissions Gateway, Frequently Asked Questions*, *available at* http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114807.htm ("If your submission was received . . . after 4:30 PM EST, the official receipt date for the submission is the next government business day."); Bronwyn Collier, FDA, *eCTD: Module 1* 14 (2006), *available at* http://www.fda.gov/downloads/AboutFDA/CenterOffices/CDER/ucm118815.pdf ("Official receipt time 8:00–4:30 EST"; "Submissions received outside of official hours—next business day.").

[11] *See, e.g.*, Center for Drug Evaluation and Research, FDA, *Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products* 4 (2000), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079744.pdf; *see also* Center for Biologics Evaluation and Research, FDA, *Manual of Standard Operating Procedures and Policies* § 8113, *available at* http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079472.htm (providing that an incoming facsimile "must be received before 4:30 PM (16:30) EST(DST) on a regular business day in order for the received date to be the same date" and that "[i]f the facsimile is received after that time or on a non-business day, the receipt date will be the next business day").

Service); 18 C.F.R. § 385.2001(a)(2) (Federal Energy Regulatory Commission); 43 C.F.R. § 45.12(c) (Department of the Interior).[12]

A contrary interpretation would deprive applicants of the full 60-day period Congress intended them to have to prepare their patent term extension applications. This is especially true in light of the PTO's most recent interpretation of § 156(d)(1). As noted above, since Applicant's Amended Request for Reconsideration was filed, the PTO has changed the way it calculates the 60-day period under § 156(d)(1). The PTO initially calculated the deadline the same way deadlines are determined in federal civil litigation: by starting counting the day after the triggering event. *Cf.* Fed. R. Civ. P. 6(a)(1)(A) ("exclude the day of the event that triggers the period"). But the PTO now "count[s] the date of FDA approval as one of the sixty days included in the time period" for filing a patent term extension application. *In re Patent Term Extension Application for U.S. Patent No. 5,817,338*, 2008 WL 5477176; *see id.* ("Applicant is correct that the USPTO has changed the way in which it makes the timeliness count between 2004 and 2008.").

At the time Applicant filed its Amended Request for Reconsideration, the PTO had not yet changed its approach to counting the 60-day period under § 156(d)(1). As a result, Applicant was unable to raise—and the PTO was thus unable to consider—the important interaction between this interpretation and the treatment of after-hours approvals. The PTO's new approach

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[12] Notably, the two cited Department of Energy regulations implement statutory provisions requiring certain action within a specified period after *receipt* of a document. *See* 42 U.S.C. § 8311(d)(1) ("Within 15 days after *receipt* of a certification submitted pursuant to this paragraph, the Secretary shall publish in the Federal Register a notice reciting that the certification has been filed." (emphasis added)); 5 U.S.C. § 552(a)(6)(A) ("The 20-day period under clause (i) shall commence on the date on which the request is first *received* by the appropriate component of the agency, but in any event not later than ten days after the request is first *received* by any component of the agency that is designated in the agency's regulations under this section to receive requests under this section." (emphasis added)).

makes even clearer why, for purposes of § 156(d)(1), treating an after-hours communication as effective on the following business day better serves the intent of Congress to give patent owners a 60-day period within which to file their applications for patent term extension. For example, an approval sent late in the evening would start the 60-day clock and leave the applicant 59 days to complete its extension application. This is surely not the result Congress envisioned.

The PTO has the right and the duty to interpret the patent laws so as to avoid results that "would serve no useful purpose, would frustrate the constitutional objective, [or] would exalt form over substance . . . to the injury of the patent system and to him to whom it must appeal, i.e., the inventor." *In re Bennett*, 766 F.2d 524, 527 (Fed. Cir. 1985) (internal quotation marks omitted); *see also Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 877 (Fed. Cir. 1985) (the purpose of the patent system is to "encourage[] innovation and its fruits" (internal quotation mark omitted)), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). Accordingly, the PTO has historically developed policies to avoid the unnecessary loss of patent rights. Indeed, if Applicant had filed an application that did not comply with the requirements of 37 C.F.R. § 1.740, it would have been given two months, or such other time set by the PTO in its notice, in which to correct the problem and could have sought an extension of that period. 37 C.F.R. § 1.740(c). The PTO can and should bring this perspective to bear in interpreting § 156(d)(1).

A standard that deems an FDA communication received on the first business day following the date it is transmitted—if the transmission was outside the normal business hours of the agency—would provide an objective and straightforward bright-line rule. Indeed, it is precisely the same standard that the FDA employs for communications submitted to it by applicants after the close of business. *See supra* p. 17. It is also the standard applied in other

administrative proceedings. *See supra* p. 17-18. This standard would allow an unambiguous determination of timeliness with reference only to the FDA's date-stamped approval notification letter, including the fax header.

Applicant does not propose that the PTO look to *actual* receipt of the FDA's notification. Such a standard would be difficult to administer, calling for both potentially burdensome fact-finding that the PTO is not equipped to undertake and, often, the recovery of evidence after the fact. It would also raise other difficult issues, such as whether actual receipt by a member of the administrative staff is sufficient and, if not, who among the professional staff is "qualified" to receive the actual notice. Section 156(d)(1) therefore should be understood to impose a standard of *constructive* notice.

B. Adopting A "Next Business Day" Rule Under § 156(d)(1) Would Have No Impact On The FDA Or On Other Determinations By The PTO

The standard Applicant proposes for purposes of the PTO's administration of § 156(d)(1) would have no effect on the date a drug is approved for purposes of the FDCA or have any impact on the timing requirements set forth in the FDCA or the Prescription Drug User Fee Amendments (PDUFA).[13] It also would not affect the FDA's calculation of the period of

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[13] The FDA has 180 days to "approve" a new drug application or provide the applicant with notice of a hearing on whether the application is approvable. *See* 21 U.S.C. § 355(c)(1); *see also* 21 C.F.R. §§ 314.100, 314.101(f)(1). Congress set additional goals for the FDA in PDUFA. *See* Prescription Drug User Fee Amendments of 2007, Pub. L. No. 110-85 ("PDUFA IV"), Title I, § 101(c), 121 Stat. 823, 825. For example, the FDA must review and act on 90% of non-priority new drug applications within 10 months of receipt and 90% of priority new drug applications within 6 months of receipt. *See* PDUFA Reauthorization Performance Goals and Procedures, Fiscal Years 2008 Through 2012, § I.A, *available at* http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm. And it must report to Congress each year on the progress it has made toward meeting these goals. *See, e.g.,* PDUFA IV, § 105(a), 121 Stat. at 840.

regulatory review under § 156(g)(1)(B)(ii).[14] All of these provisions turn on the date of the FDA's "approval" of a new drug application without regard to when transmittal of notice of the FDA action occurs. It is Applicant's position that the date of "approval" for these purposes can be distinct from the date a "product received permission … for commercial marketing" under § 156(d)(1) in some circumstances. The next business day rule Applicant proposes would apply only to the unique standard in § 156(d)(1) administered by the PTO.

The PTO's decision on this request would affect the FDA only if the PTO rejected Applicant's contentions and concluded that the standards under § 156(d)(1) and § 156(g)(1)(B)(ii) are identical, even in the unique circumstances of this case. If the PTO reaches this conclusion—notwithstanding Applicant's arguments to the contrary—then the PTO will be required to interpret § 156(g)(1)(B)(ii). And as explained above, interpreting the "date" of approval under § 156(g)(1)(B)(ii) to mean the date of an *after-hours* transmittal of approval raises serious concerns. *See supra* n.8. If, however, the PTO agrees with Applicant that, in the narrow context of an after-hours approval, the standards in § 156(d)(1) and § 156(g)(1)(B)(ii) can diverge, then it will have no reason to consider this issue.

Similarly, the proposed standard would not affect the PTO's calculation of any time period under title 35 *except* for that under § 156(d)(1). The language of that paragraph is structured in a way that is different from every other timing provision in the Patent Act. Accordingly, the effect of the proposed standard would be confined to the administration of § 156(d)(1).

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[14] Accordingly, Applicant does not dispute that the period of regulatory review under § 156(g)(1)(B)(ii) ended on December 15, 2000.

CONCLUSION

For the reasons set forth in this submission, Applicant respectfully requests that the PTO (1) reconsider its Decision mailed April 26, 2007, (2) conclude that, for purposes of applying § 156(d)(1), a drug does not "receive[] permission … for commercial marketing" until the next business day after receiving notice of FDA approval if that notice was transmitted after normal business hours, and (3) accept the amended patent term extension application for Angiomax as timely and begin consideration thereof.

Finally, if the Director grants this Request for Reconsideration, Applicant respectfully requests that the Director extend, pursuant to 35 U.S.C. § 156(e)(2), the term of this patent for such period necessary to permit the Director to make the necessary determinations under § 156 concerning this application.

Respectfully submitted,

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