

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

THE MEDICINES COMPANY,

Plaintiff,

v.

DAVID KAPPOS, in his official capacity as
Under Secretary of Commerce for Intellectual
Property and Director of the United States
Patent and Trademark Office; UNITED
STATES PATENT AND TRADEMARK
OFFICE; MARGARET A. HAMBURG, in
her official capacity as Commissioner of the
United States Food and Drug Administration;
UNITED STATES FOOD AND DRUG
ADMINISTRATION; KATHLEEN
SEBELIUS, in her official capacity as
Secretary of Health and Human Services;
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Defendants.

No. 1:10-cv-81-CMH/TCB

MEMORANDUM OF LAW
IN SUPPORT OF
PLAINTIFF'S MOTION FOR
SUMMARY JUDGMENT

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INTRODUCTION

Under the Hatch-Waxman Act, a patent covering a new drug may be extended to compensate the patent holder for the years of effective patent life lost while the drug awaited approval from the Food and Drug Administration (“FDA”). *See* 35 U.S.C. § 156. To secure the extension, an application must be filed “within the sixty-day period beginning on the date the product received permission” from the FDA. *Id.* § 156(d)(1). In this action, The Medicines Company (“MDCO”) challenges the denial of its application to extend the term of the patent¹ covering its drug ANGIOMAX® on the ground that the application was not timely filed. The FDA faxed MDCO the approval of ANGIOMAX after normal business hours, and MDCO indisputably filed its application within the 60-day period beginning on the first business day following transmission of that notice. Nonetheless, the Patent and Trademark Office (“PTO”)—and the FDA—incorrectly concluded that the application was untimely.

The PTO initially found that MDCO’s extension application was filed a single day late. On reconsideration, interpreting the same statute, the PTO changed its view and concluded that MDCO had filed the application *two* days late. Both decisions rested on the PTO’s conclusion that the “date” that ANGIOMAX “received permission” must be the *calendar day* on which the FDA sent its after-hours fax. But this is flatly inconsistent with the government’s interpretation of the *same word*—“date”—in another provision of § 156, which addresses submissions to the FDA and defines the length of the “regulatory review” period during which an application has been under FDA consideration. Specifically, the government takes the “heads-I-win, tails-you-lose” position that a new drug application submitted *to* the FDA after normal business hours is

¹ U.S. Patent No. 5,196,404 (“’404 patent”) (attached as Ex. 1 to MDCO’s Complaint). All references to numbered exhibits are to the exhibits attached to MDCO’s filed Complaint.

deemed to be submitted on the *following* business day, whereas an after-hours approval sent *from* the FDA is deemed received on the *same* day. Neither the PTO nor the FDA could articulate *any* justification for this glaring contradiction. The government's position here is thus directly at odds with the Federal Circuit's decision in *Butterbaugh v. DOJ*, 336 F.3d 1332 (Fed. Cir. 2003), which held that the government could not construe "day" to mean "workday" in one statute but "calendar day" in a closely related provision.

Even more remarkably, in denying MDCO's application as untimely the PTO asserted that the word "date" can *only* be interpreted to mean "calendar day." The PTO thus takes the position that "date" *cannot* mean "business day"—yet that is precisely how the FDA has construed "date" in the very same section of the statute. And the PTO failed even to address the fact that its interpretation will often mean that an applicant will not receive the 60-day period Congress mandated.

The PTO's decision is also at odds with the canon that the patent laws must be interpreted 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). As the PTO has itself recognized, the patent term extension statute is "remedial in nature" and thus "should be liberally construed so as to carry out its purpose to the end that justice may be done to both the patentees and the public." *In re Patent No. 4,146,029* at 3 (Comm'r Pat. July 12, 1988) ("SynchroMed Decision") (attached as Addendum A).

Here, as in the SynchroMed Decision, these considerations weigh heavily in favor of considering MDCO's extension application on the merits. MDCO spent over \$200 million to develop ANGIOMAX, which had sales of more than \$300 million in 2009. These sales

accounted for substantially all of MDCO's revenues. Even more important than the harm to MDCO are the public health consequences of the PTO's flawed interpretation. Without an assured period of exclusivity, neither MDCO nor any other company will have the incentive to conduct research into new uses of ANGIOMAX to treat life-threatening conditions like heart attack and stroke. *See* Ex. 18 at 21-23.

This result is not dictated by either the statute or common sense. The process of developing, testing, and obtaining regulatory approval for ANGIOMAX took over a decade, and consumed more than seven years of MDCO's patent term. Recognizing that this type of regulatory delay substantially diminishes the effective life of a patent, Congress mandated that patent terms be extended to compensate companies for the economic value lost during the review period, thereby preserving the incentive to create, develop, and secure regulatory approval for innovative new drugs. There is no dispute that MDCO has met the substantive requirements of the Hatch-Waxman Act and is entitled to an extension as long as its application is found to be timely filed. For the reasons set forth below, the PTO's decision that MDCO's application was untimely should be set aside and the matter remanded to the PTO with instructions that it accept MDCO's patent term extension application as timely filed.

BACKGROUND

I. STATUTORY FRAMEWORK

A new drug cannot be commercially marketed or used until the FDA approves it under § 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See* 21 U.S.C. § 355(a). The process of securing FDA approval is extraordinarily time consuming and expensive. A new drug applicant must conduct clinical studies and submit detailed information. *Id.* § 355(b)(1); 21 C.F.R. § 314.50. The FDA must then determine whether the drug is safe and effective. During

this process, the applicant receives no commercial benefit from any patents on the drug.

Concerned that this shortening of the effective patent term was diminishing the incentive to develop innovative new drug products, Congress enacted Title II of the Hatch-Waxman Act, which is codified in relevant part at 35 U.S.C. § 156. Under § 156, the holder of a drug patent or its agent is entitled to apply for a patent term extension “to compensate for the delay in obtaining FDA approval.” *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996); *see also* SynchroMed Decision at 3 (“Since § 156 was intended to restore a part of the effective patent life ... , § 156 can be viewed as remedial in nature.”); *Hoechst-Roussel Pharm., Inc. v. Lehman*, No. 95-650-A, 1995 U.S. Dist. LEXIS 22485, at *8 (E.D. Va. Oct. 25, 1995) (Section 156 “was intended to compensate those patent owners who lost time to market a patented product while that product awaited FDA approval.”), *aff’d*, 109 F.3d 756 (Fed. Cir. 1997). The purpose of the Act is to “encourage[] drug manufacturers to assume the increased costs of research and development of certain products which are subject to premarketing clearance.” H.R. Rep. No. 98-857, pt. 2, at 11 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2695.

The length of the extension depends on how long the product was under review. The review period is divided into a “testing phase” followed by an “approval phase.” The approval phase “begin[s] on the date the application was initially submitted ... and end[s] on the date such application was approved.” 35 U.S.C. § 156(g)(1)(B)(ii). Subject to specified caps and adjustments, the lengths of these phases determine the length of the extension. *See id.* § 156(c).

A different provision in the same statute governs when requests for patent extensions must be filed. *Id.* § 156(d)(1). Although Congress could have keyed the time for seeking an extension directly to the end of the “approval phase” specified in § 156(g)(1)(B)(ii) (*i.e.*, “the date [the] application was approved”), it did not. Instead, Congress used a different term to

begin the time period for requesting an extension: The patent holder or its agent must submit an application to the PTO “within the sixty-day period beginning on the date the product *received* permission ... for commercial marketing or use.” *Id.* § 156(d)(1) (emphasis added).

If a patent relates to a human drug (as does the ANGIOMAX patent), responsibility for reviewing an extension application is shared by the Director of the PTO and the Secretary of Health and Human Services, who has delegated her authority to the FDA.² The PTO is responsible for determining “that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d)”—including the timeliness requirement of (d)(1) at issue here—“have been complied with.” 35 U.S.C. § 156(e)(1). The FDA is responsible for determining the length of the applicable regulatory review period. *Id.* § 156(d)(2)(A). In so doing, it must determine “the date the [new drug] application was initially submitted” to the FDA and “the date such application was approved.” *Id.* § 156(g)(1)(B)(ii). A 1987 Memorandum of Understanding between the PTO and the FDA sets forth procedures for their joint review of applications. *See* 52 Fed. Reg. 17,830-02 (May 12, 1987).

II. THE DEVELOPMENT AND APPROVAL OF ANGIOMAX

MDCO is an innovative pharmaceutical company that specializes in developing acute care medicines that larger pharmaceutical companies have chosen not to pursue. This case involves one such drug, a life-saving anticoagulant called ANGIOMAX. This drug works by directly inhibiting a key contributor to the formation of blood clots. *See* Product Monograph: Angiomax 4-6, *available at* http://www.themedicinescompany.com/pdf/ANG-PMN-011-06_Product_Monograph.pdf. The drug has the potential to become the leading replacement for

² *See* 2 FDA Staff Manual Guides § 1410.10(1)(A)(25), *available at* <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm>.

heparin, an animal-based anticoagulant that was discovered almost 100 years ago. A recent study demonstrated that using ANGIOMAX instead of heparin in severe heart attack patients reduces bleeding by about 50%. *See* Daniel P. Kessler, *The Effects of Angiomax on Health Care Costs and Outcomes* (Nov. 5, 2009).

The active ingredient in ANGIOMAX—a chemical called bivalirudin—is covered by the '404 patent. The rights to the '404 patent were initially assigned to two companies other than MDCO, one of which became the exclusive licensee in June 1990. That company decided not to clinically pursue bivalirudin. MDCO subsequently obtained an exclusive license under the '404 patent in 1997 and proceeded to invest over \$200 million to clinically develop ANGIOMAX for use in angioplasty procedures. Absent extension, the '404 patent will expire on March 23, 2010.

MDCO filed a new drug application for ANGIOMAX on December 23, 1997. The FDA approved that application in December 2000. The FDA's approval was set forth in a letter faxed to MDCO after the close of business—at 6:17 p.m.—on Friday, December 15, 2000.³ *See* Ex. 2. The FDA then published the approval date for ANGIOMAX as December 19, 2000 on one page of its website. *See* Ex. 4.

III. ADMINISTRATIVE PROCEEDINGS

A. MDCO's Application And Initial FDA And PTO Decisions

MDCO filed its patent term extension application on February 14, 2001. *See* Ex. 6. The application demonstrated that, because of the lengthy period that had been necessary for testing and FDA review of ANGIOMAX, MDCO was entitled to the maximum extension permitted

³ The following week MDCO received a second copy of the letter by U.S. mail. That copy did not include a date stamp, but appended an electronic signature page indicating that the letter was signed at 5:18 p.m. on December 15, 2000. *See* Ex. 5. Thus, not only was the letter faxed to MDCO after normal business hours, but it was also signed after the close of business.

under the Hatch-Waxman Act. Such an extension would change the expiration date of the '404 patent from March 23, 2010 to December 2014. There is no dispute that MDCO satisfied all of the *substantive* requirements of 35 U.S.C. § 156.⁴

On September 6, 2001, in response to a request from the PTO, the FDA asserted that ANGIOMAX “was approved on December 15, 2000” and that MDCO’s application was “untimely within the meaning of 35 U.S.C. § 156(d)(1).” Ex. 10. Although it had been called to the agency’s attention, the FDA did not address the fact that a page on its website listed December 19 as the approval date for ANGIOMAX.

On December 18, 2001, MDCO received an undated “Notice of Final Determination” from the PTO denying MDCO’s application. *See* Ex. 11. The Notice accepted the FDA’s view that ANGIOMAX “was approved on December 15, 2000” and that the “extension application [was] untimely” because it was filed a *single day* late. On March 4, 2002, the PTO issued a corrected decision that was in relevant respects identical to the original. *See* Ex. 12.

B. FDA’s Inconsistent Treatment Of Submissions And Notifications After Normal Business Hours

It is undisputed that the FDA treats submissions *to* the FDA received after its normal business hours differently than it treats communications *from* the agency after normal business hours. In particular, the agency considers the date of submission of a new drug application

⁴ MDCO’s initial application incorrectly stated that ANGIOMAX received permission for commercial marketing on December 15, 2000 and omitted a certification of timeliness. The PTO referred the matter of the application’s timeliness to the FDA. *See* Ex. 7. Before the FDA replied, MDCO filed a supplemental submission explaining that the certification of timeliness in its application had been crossed out by counsel by hand before filing “out of an abundance of caution” based on “uncertainty as to what the approval date really was.” Ex. 8. The submission noted that a page on the FDA’s website listed the approval date as December 19, 2001, and included an updated certification of timeliness. The PTO forwarded MDCO’s supplemental submission to the FDA. *See* Ex. 9.

received after 4:30 p.m. EST to be the next business day.⁵ The FDA has never disputed that it follows this practice. Accordingly, if an applicant submits an electronic application or sends a fax to the FDA at 6:17 p.m. on a Friday night, the FDA will deem that application to be submitted on the following Monday (or Tuesday, if the Monday is a federal holiday). This FDA practice has the consequence of making the regulatory review period defined in § 156(g) commence days later than if the application was considered submitted on Friday and can operate to reduce the overall length of the patent term extension granted.

By contrast, for communications *from* the FDA, the agency takes the position that whether the communication is sent after the close of business is irrelevant. For example, if the FDA faxes an approval letter at 11:59 p.m., it will treat the letter as if it had been issued earlier that day during business hours. Accordingly, although the approval letter in this case was sent after the close of business, the FDA concluded that the approval was made that day.

C. MDCO's Request For Reconsideration And Second FDA Decision

On October 2, 2002, MDCO filed a timely Request for Reconsideration with the PTO. *See Ex. 14.* Among other things, MDCO pointed out that the FDA approval letter for ANGIOMAX was faxed after business hours on a Friday evening, and that “under FDA’s practices, facsimiles submitted to FDA after the close of business are considered received by the

⁵ *See* FDA, 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.”); *see also, e.g.*, Center for Drug Evaluation and Research, FDA, *Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products 4* (2000) (Ex. 13); *see also* Center for Biologics Evaluation and Research, FDA, *Manual of Standard Operating Procedures and Policies* § 8113 (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”).

Agency on the next business day.” *Id.* at 2-3. For that reason, MDCO asked the PTO to “treat December 18, 2000 as the effective approval date of ANGIOMAX®,” *id.* at 3—which would have made MDCO’s February 14, 2001 application unquestionably timely.

On March 24, 2003, the PTO sent the FDA a copy of MDCO’s request and asked the FDA to determine whether the application was timely. *See* Ex. 15. More than *three years* later, on November 2, 2006, the FDA issued a terse reply “reiterat[ing] that ... Angiomax was approved on December 15, 2000.” Ex. 16. Although the FDA noted MDCO’s position that the approval was not effective until December 18, 2000 because the December 15, 2000 letter was transmitted after normal business hours, the FDA failed to provide any explanation why it found that contention unpersuasive. *See id.* Notably, the FDA did not dispute that when calculating the length of regulatory review periods under 35 U.S.C. § 156(g), it deems submissions to the agency after normal business hours as having been filed on the next business day, but deems an approval transmitted from the agency after normal business hours to be effective as of the date on the letter.

On February 12, 2007, before the PTO issued a decision on MDCO’s Request for Reconsideration, the agency granted MDCO’s request to file an amended extension application and amended request for reconsideration. MDCO filed the amended papers on March 13, 2007. *See* Amended Application Pursuant to 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.740 for Extension of Patent Term (Ex. 17) and Amended Request for Reconsideration (Ex. 18). MDCO again demonstrated, among other things, that the FDA’s determination that approval occurred on December 15, 2000 was arbitrary and capricious and contrary to law, particularly in light of the FDA’s inconsistent treatment of after-hours submissions *to* the agency and after-hours communications *from* the agency.

D. PTO's First Reconsideration Decision

On April 26, 2007, the PTO denied MDCO's Request for Reconsideration. *See* Decision Denying Application for Patent Term Extension for U.S. Patent No. 5,196,404 ("2007 Decision") (Ex. 19). The PTO offered no defense of what it acknowledged was the FDA's "seemingly inconsistent" approach to determining the effective date of submissions to the agency and communications from the agency. *Id.* at 11. Rather, it indicated that any challenge to the FDA's approach must be raised with the FDA. *See id.* at 5-6, 10-11. Using the FDA's December 15, 2000 approval date, the PTO also determined that MDCO's application was filed *two days* after the 60-day period expired—contrary to its initial decision finding the application *one day* late. The change in the PTO's calculation was due to a change in the agency's interpretation of § 156(d)(1) that was apparently announced for the first time in its reconsideration decision in this case. *See* 2007 Decision at 7 n.3.

For years, in applying § 156(d)(1)'s 60-day deadline, the PTO followed the general rule of starting the count on the first day *after* the triggering event. In its 2007 Decision, however, the PTO for the first time concluded that it had been misreading § 156(d)(1). It then abruptly changed course and announced that it would "count[] the date of FDA approval as one of the sixty days included in the time period for filing a PTE application." *In re Patent Term Extension Application for U.S. Patent No. 5,817,338*, 2008 WL 5477176 (Comm'r Pat. Dec. 16, 2008) ("Prilosec Decision"). Applying this new interpretation, the PTO or the FDA has taken the position that at least seven applications for patent term extensions were untimely, even though they would have been timely under the PTO's prior interpretation of § 156(d)(1). *See* Compl. ¶ 44. Moreover, as this case demonstrates, the PTO takes the view that the "date" of FDA approval counts as the first day of the 60-day period even where the application is not approved

until after the close of business—that is, as late as 11:59 p.m.—and the PTO’s interpretation can thus mean that an applicant is afforded only 59 days rather than the 60 days Congress directed.

E. MDCO’s 2009 Petition And Second Request For Reconsideration

On December 4, 2009, MDCO submitted a petition for leave to file a second request for reconsideration (Ex. 20) and a second request for reconsideration (Ex. 21). MDCO demonstrated that further reconsideration was appropriate because it had not previously had an opportunity to address the effect of the PTO’s new method of counting the 60-day period under § 156(d)(1) on the interpretation of the “date” on which that period begins.

On the merits, MDCO explained that the PTO had the authority to treat new drugs approved by the FDA after business hours as having “received permission” for purposes of § 156(d)(1) on the following business day. MDCO demonstrated that the date a product “receive[s] permission ... for commercial marketing and use” under § 156(d)(1) (a date determined by the PTO) need not in all circumstances be the same as the date a new drug is “approved” for purposes of marking the end of the regulatory review period under § 156(g)(1)(B)(ii) (a date determined by FDA). *Id.* at 9-15. It also explained that where the FDA transmits notice of approval after normal business hours, a “next business day” rule comports with the statute’s text and purpose. *Id.* at 10-11, 16-21. This is especially so given the recent decision of the PTO to count “the date of FDA approval” as the first day of the 60-day period, as opposed to its previously established practice of starting the counting period on the first day after the triggering event. Thus, MDCO demonstrated that unless the PTO adopted a “next business day” rule for after-hour approvals, it would effectively deprive many patent applicants of one of the 60 days Congress granted them for seeking extensions under § 156. Finally, MDCO observed that if the PTO rejected a “next business day” rule for § 156(d)(1) and

concluded that it was bound to give § 156(d)(1) the same meaning that the FDA has given § 156(g)(1)(B)(ii), then it would be required to reconcile its decision with the FDA's inconsistent interpretation of the word "date" in § 156(g)(1)(B)(ii). *Id.* at 15 n.8.

F. PTO's Denial Of MDCO's Second Request For Reconsideration

On January 8, 2010, the PTO agreed to consider MDCO's request for further review but denied reconsideration on the merits. *See* Ex. 22 ("2010 Decision"). The PTO agreed that its decision to change the way it counted days under § 156(d)(1) was an "extraordinary" situation that supported waiving its regulation prohibiting successive reconsideration requests. *Id.* at 3. On the merits, however, the PTO did not even consider the effect of this change and concluded that it lacked authority under § 156 and its regulations to treat new drugs approved after business hours as having "received permission" on the following business day. The PTO thus believed that it lacked any discretion to adopt such a construction even if it wanted to do so, and that the contrary construction was compelled by the statute.

In reaching this conclusion, the PTO first rejected MDCO's argument that the date a drug "receive[s] permission ... for commercial marketing or use" can in some circumstances be distinct from the date the drug was approved for purposes of the FDA's calculation of the period of regulatory review. *Id.* at 6-7. It therefore held that "the date stamped on a NDA approval letter"—which the FDA terms the "effective date" of an approval—"is the appropriate trigger date for § 156(d)(1)." 2010 Decision at 6. The PTO also held that MDCO's submission was foreclosed by the text of § 156 because "[a] particular 'date' spans the course of 24 hours; it does not end with the close of business." *Id.* at 8. The PTO made no attempt to reconcile this position with the FDA's own practice of treating submissions to the agency after the close of business as being received the next business day. The PTO also did not address § 156(d)(1)'s focus on the

date approval was “received,” the purpose of § 156(d)(1), or the need to ensure that all applicants receive the 60 days to file extension applications that Congress required and the ways in which its interpretation of “date” in combination with its new counting rule is inconsistent with that requirement.

STATEMENT OF UNDISPUTED FACTS

Despite the lengthy procedural history of this case, the Court need consider only three facts, all undisputed, to grant MDCO summary judgment:

1. The FDA’s approval of ANGIOMAX was set forth in a letter faxed to MDCO after the close of business—at 6:17 p.m.—on Friday, December 15, 2000. *See* Ex. 2. The approval letter was also signed after the close of business on December 15. *See* Ex. 5.
2. MDCO filed its application for an extension of the ’404 patent under the Hatch-Waxman Act on February 14, 2001. *See* Ex. 6.
3. February 14, 2001 falls within the 60-day period beginning on December 18, 2000, the first business day after the FDA’s after-hours transmittal of the ANGIOMAX approval letter.

ARGUMENT

The Administrative Procedure Act (“APA”) requires the Court to “hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A); *see Arnold P’ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004) (APA applies to denial of patent term extension application). Agency action is arbitrary and capricious “if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*,

463 U.S. 29, 43 (1983). Agency action resting on an inconsistent or self-contradictory explanation is, by definition, arbitrary and capricious. *See, e.g., Lee Lumber & Bldg. Material Corp. v. NLRB*, 117 F.3d 1454, 1460 (D.C. Cir. 1997); *Air Line Pilots Ass'n v. FAA*, 3 F.3d 449, 453 (D.C. Cir. 1993).

The Court's review here is further shaped by the "remedial nature" of the statute at issue. SynchroMed Decision at 3. As the PTO itself has explained, § 156 is "intended to restore a part of the effective patent life that had been diminished through the delays which are necessary in regulatory review and approval of the product." *Id.*; *see also Merck*, 80 F.3d at 1547 (§ 156 is designed to "compensate for the delay in obtaining FDA approval"). The PTO thus previously held that the timing provisions of § 156(d) should be "liberally construed ... to carry out its purpose" so that "justice may be done to both the patentees and the public." SynchroMed Decision at 3; *see United States v. Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (it is a "well-accepted principle that remedial legislation ... is to be given a liberal construction consistent with [its] overriding purpose").⁶

Under these well-established principles, the PTO's decision should be set aside. There is a strong presumption that when Congress repeats the same word in the same statute, it intends for that word to be given the same meaning. In this case, the PTO and the FDA interpreted the word "date" to have *two different meanings* in the *very same provision*, and the PTO offered *no* explanation for that inconsistency. That failure alone requires that the PTO's decision be set

⁶ *See also Samish Indian Nation v. United States*, 419 F.3d 1355, 1367 (Fed. Cir. 2005) ("It is of course true that courts are to construe remedial statutes liberally to effectuate their purposes." (citation and internal quotation marks omitted)); *Hogar Agua y Vida en el Desierto, Inc. v. Suarez-Medina*, 36 F.3d 177, 181 (1st Cir. 1994) (employing the "traditional tool[] of statutory interpretation" that "ambiguous language in a remedial statute is entitled to a generous construction consistent with its reformative mission").

aside. But the PTO also compounded its error by misperceiving the scope of its authority. The PTO believed that it was *precluded* from adopting a “business hours” interpretation of the word “date” in § 156(d)(1). But in fact, neither the statutory text nor any other authority forecloses that reading. To the contrary, while the PTO believed that the term “date” can only be construed to mean “calendar day,” the statute *cannot* be so inflexible because the FDA interprets the same word in the same section to mean “business day.”

Indeed, the best interpretation of the text, structure, and purpose of the statute is that a product approved in an after-hours fax should not be deemed to have “received permission” from the FDA for purposes of § 156(d)(1) until the next business day. Only that reading preserves the full period for requesting an extension and the remedial character of § 156. Therefore, this Court should require the PTO to adopt a “business hours” reading of the statute. At an absolute minimum, given that the PTO incorrectly thought a “business hours” interpretation was foreclosed and did not even consider central arguments MDCO advanced, let alone offer a persuasive reason for rejecting them, the Court should return the matter to the agency. It should further instruct that the agency has authority to adopt a “business hours” interpretation of § 156(d)(1) and must *consider* MDCO’s arguments and render a decision on the matter that is free from the legal errors that infected its previous determinations.

I. THE PTO’S INCONSISTENT INTERPRETATION OF THE WORD “DATE” IN § 156 IS ARBITRARY AND CAPRICIOUS

The PTO’s decision denying MDCO’s patent term extension should be set aside because it rests on an inconsistent and arbitrary construction of the word “date” in § 156. The Hatch-Waxman Act provides that the approval phase of the “regulatory review period” should be calculated by reference to “the period beginning on *the date* the application was initially submitted ... and ending on *the date* such application was approved.” 35 U.S.C.

§ 156(g)(1)(B)(ii) (emphasis added). It also sets the deadline for filing an extension application by reference to the “date” a product receives permission for commercial marketing. *Id.*

§ 156(d)(1). Although Congress used the same word in all three instances, the PTO and the FDA interpret the “date” that marks the beginning of the regulatory period *differently* from the “date” that marks the end of that period and the “date” that begins the 60-day period for filing an extension application. It is undisputed that the government treats submissions to the FDA after normal business hours as being effective on the next business day, and thus shifts the regulatory review period set by the statute forward by one or more days. *See supra* pp. 7-8. Yet in this case the PTO held that it was somehow *precluded* from construing § 156(d)(1) similarly to take into account the fact that the FDA’s approval of ANGIOMAX was sent after normal business hours.

This inconsistent approach contradicts basic principles of statutory interpretation. The “normal rule of statutory construction” is 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); *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005); *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990). “Without an explanation sufficient to rebut this presumption,” an agency may not adopt inconsistent definitions of identical statutory terms. *SKF USA Inc. v. United States*, 263 F.3d 1369, 1382 (Fed. Cir. 2001).⁷

⁷ *See also NSK Ltd. v. United States*, 390 F.3d 1352, 1357-1358 (Fed. Cir. 2004) (remand required because agency’s interpretation of statute was “internally inconsistent” and agency “fail[ed] to explain the inconsistency”); *National Org. of Veterans’ Advocates, Inc. v. Secretary of Veterans Affairs*, 260 F.3d 1365, 1379-1380 (Fed. Cir. 2001) (remand required because agency’s interpretation of a term was “inconsistent with the agency’s interpretation of another virtually identical statute” and the agency had not “explain[ed] the rationale for the different interpretations”).

The Federal Circuit's decision in *Butterbaugh* makes just this point. In that case, the government took the position that the term "days" in 5 U.S.C. § 6323(a)(1) meant "calendar days," rather than "workdays." Noting the Office of Personnel Management's declaration that "day" means "workday" for purposes of another provision in the same subchapter (§ 6326), the Federal Circuit rejected the government's inconsistent interpretation. The court explained:

While consistency is not necessarily the paramount imperative of statutory interpretation, we ... expect that administrative agencies ordinarily will construe the same term in closely related statutes consistently. The government, despite invitations from this court, cannot offer any rationale why "day" should mean "workday" for purposes of 5 U.S.C. § 6326 but not for 5 U.S.C. § 6323(a)(1). Absent such a rationale, it would seem arbitrary and capricious for the government to count non-workdays when computing military leave, but not when computing other kinds of leave.

Butterbaugh, 336 F.3d at 1338-1339 (citations omitted).

Just as it was arbitrary and capricious for the government to adopt inconsistent definitions of the word "day" without any explanation in *Butterbaugh*, it was arbitrary and capricious for it to adopt inconsistent definitions of the word "date" here without providing some basis for doing so. As explained above, MDCO repeatedly objected to the agencies' inconsistent approach. But the government never provided *any* meaningful response, much less an explanation sufficient to overcome the presumption in favor of consistency. That failure independently requires that its order be vacated. *See infra* n.12.

The FDA altogether failed to offer any support for its reading of the statute, which appears designed simply to maximize the agency's own convenience. *See* Ex. 16. Its letter to the PTO merely reiterated the FDA's view that "Angiomax was approved on December 15, 2000" without giving *any reason* for rejecting MDCO's argument. *Id.* The PTO similarly failed to provide any rationale for giving the word "date" two conflicting meanings in the same statute. In its 2007 Decision, the PTO initially stated that it lacked authority to second-guess the FDA's

approach even if that approach was “inconsistent” and “contrary to congressional intent.” 2007 Decision at 5-6, 10-11. It explained that “the determination of the date of approval is within the exclusive purview of the FDA. Accordingly, the USPTO *cannot entertain* Applicant’s arguments regarding what date should be considered to be the effective approval date of ANGIOMAX® (bivalirudin).” *Id.* at 6 (emphasis added). It added that the PTO “has no control over any of the FDA’s business practices” and that MDCO was “complaining to the wrong agency regarding the late day notice it received in this case.” *Id.* at 10. Indeed, the PTO appeared to acknowledge the inconsistency of the FDA’s approach to after-hours communications but took the untenable position that it was bound even by an erroneous FDA decision:

Applicant likewise takes issue with the *seemingly inconsistent* manner in which the FDA treats facsimile correspondence when FDA is the receiver as opposed to the transmitter. *Even if Applicant is correct that the FDA’s method of counting days is contrary to congressional intent, that is not for the USPTO to decide.*

Id. at 11 (emphasis added); *see also id.* at 5-6.

The PTO later asserted that it was not, in fact, completely deferring to the FDA. *See* 2010 Decision at 4-5. But the PTO still treated the date that the FDA placed on the face of the approval letter as dispositive of the question when the period for MDCO to file its extension application began to run—even though the letter was signed and sent after normal business hours. Thus, the PTO did not, despite its assertions, make an independent determination of the pertinent date, and it has been unable to articulate any rationale to support the government’s inconsistent reading of the word “date.” Strikingly, in discussing what it considered to be the plain and unambiguous meaning of the word “date,” the PTO did not even attempt to explain how its conclusion could be squared with the fact that the FDA interpretation it was following gave the same word in the same statute two different meanings. *See id.* at 7-8.

II. THE PTO INCORRECTLY CONCLUDED THAT IT LACKED THE AUTHORITY TO INTERPRET THE WORD “DATE” IN § 156(d)(1) TO MEAN “BUSINESS DAY”

The PTO adopted an inconsistent interpretation of the word “date” because it erroneously believed that it was compelled to follow the FDA’s interpretation of the provision of § 156(g)(1)(B)(ii) marking the end of the regulatory review period. That was just one respect in which the PTO misapprehended the scope of its own authority. The agency also incorrectly believed that a “business hours” interpretation of § 156(d)(1) was foreclosed by the plain text of the statute, Federal Circuit precedent, and its own regulations. Because it believed its hands were tied, the PTO never even considered whether it should exercise its discretion to adopt a “business hours” rule. Indeed, the PTO must have believed it had no option but to construe the statute as it did: Had the PTO recognized *any* statutory ambiguity, its own precedents would have required it to apply the interpretive rule that “a remedial statute should be liberally construed so as to carry out its purpose to the end that justice may be done to both the patentees and the public.” *SynchroMed Decision* at 2-3 (rejecting what PTO described as the more natural reading of the statute in favor of a liberal construction).⁸

But, as explained below, none of the authorities cited by the PTO actually constrain its authority to adopt such a rule in this case. The PTO’s determination thus must be set aside because an agency decision “cannot be sustained where it is based not on the agency’s own judgment but on an erroneous view of the law,”⁹ or is otherwise inconsistent.¹⁰

⁸ As evidence of the statute’s ambiguity in the *SynchroMed Decision*, the PTO cited the fact that applicants had offered inconsistent interpretations. *Id.* at 2. The evidence here is far stronger: another government agency, the FDA, has interpreted the word “date” to bear multiple and inconsistent meanings. *See supra* pp. 7-8.

⁹ *Sea-Land Serv., Inc. v. DOT*, 137 F.3d 640, 646 (D.C. Cir. 1998) (internal quotation marks omitted); *see also FEC v. Akins*, 524 U.S. 11, 25 (1998) (“If a reviewing court agrees that the

First, the PTO erred in believing that its interpretation of § 156(d)(1) was compelled by the plain meaning of the word “date.” The agency asserted, without citation or explanation, that “[a] particular ‘date’ spans the course of 24 hours; it does not end with the close of business.” 2010 Decision at 8. Accordingly, the PTO believed that MDCO’s proposed “business hours” interpretation was “contrary to statute” and would require it to “put[] words into the statute that are not there.” *Id.* at 7-8.

This does not even come close to fulfilling the PTO’s obligations under the APA. The PTO provided no analysis of the putative plain meaning it assigned to the term, the ways in which the term is used throughout § 156, the differing contexts of the usage, or the regulatory impact of competing alternative interpretations. It merely asserted *ipse dixit* that the term “date” in § 156(d)(1) must be a calendar day and could not be a business day. The agency’s interpretation is entitled to no weight because it “reflects no consideration of other possible interpretations, no assessment of the statutory objectives, no weighing of congressional policy, [and] no application of expertise.” *Alarm Indus. Commc’ns Comm. v. FCC*, 131 F.3d 1066, 1069 (D.C. Cir. 1997).

agency misinterpreted the law, it will set aside the agency’s action and remand the case—even though the agency ... might later, in the exercise of its lawful discretion, reach the same result for a different reason”); *Secretary of Labor v. National Cement Co.*, 494 F.3d 1066, 1074-1075 (D.C. Cir. 2007) (“[B]oth of the relevant statutory terms are ambiguous and the Secretary therefore erroneously interpreted them as bearing a plain meaning. In the event of such ambiguity, it is incumbent upon the agency not to rest simply on its parsing of the statutory language—it must bring its experience and expertise to bear in light of competing interests at stake.” (internal quotation marks omitted)).

¹⁰ *See, e.g., Lee Lumber*, 117 F.3d at 1460 (“There is a clear and fundamental inconsistency between the standard the Board announced ... and the Board’s application of that standard in this case. The Board’s failure to explain this inconsistency is arbitrary.”); *Air Line Pilots Ass’n*, 3 F.3d at 453 (“The [order under review] must be remanded because of a basic inconsistency in its reasoning....”).

Most fundamentally, the PTO's assertion about the plain meaning of "date" plainly conflicts with the FDA's interpretation of the *same word* in the *same statute* to mean precisely what the PTO says it cannot mean. As explained above, when a new drug application is filed with the FDA after normal business hours, the FDA deems the "date" the application was submitted to be the next business day. The PTO, however, did not provide any rationale to reconcile these competing constructions of the statute. At a minimum, the FDA's interpretation of the word "date" to mean "business day" precludes the government from arguing that "date" can have only one meaning. If the government is going to interpret the word "date" two different ways in the same statute, it must at least acknowledge that the statute does not compel one meaning over the other. *See also infra* pp. 26-27 (citing agency rules interpreting similar provisions as adopting "next business day" rule).

Second, the PTO also incorrectly concluded that *Unimed, Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989), controlled this case. The PTO believed that *Unimed* held that the "date [a] product received permission" under § 156(d)(1) must be "the date stamped on the [FDA] approval letter," even if that letter was sent after business hours. 2010 Decision at 6-7. But *Unimed* never even purported to address the question presented here. Rather, it concerned an application for patent term extension based on the approval of a drug product that contained the psychoactive substance found in marijuana. *See* 888 F.2d 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 product under the FDCA. *Id.* at 828. 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.*

A few sentences in *Unimed* could be read to suggest that the “date” that starts the 60-day period in § 156(d)(1) is the date stamped on the FDA approval letter. *See* 888 F.2d at 829. But the question at issue here—the proper treatment of an after-hours letter—was not even remotely presented in *Unimed* because the extension application at issue there was filed “*more than a year* after the FDA’s final approval letter.” *Id.* at 827 (emphasis added). Moreover, in *Unimed* there was no reason to believe that the letter was transmitted after the close of business. Accordingly, the Federal Circuit’s decision in *Unimed* has no bearing on the timeliness of MDCO’s application.

Third, the PTO’s decision was also flawed because the Office erroneously concluded that a “‘next business day’ rule” would be “contrary to regulations.” 2010 Decision at 8. To support that contention, the PTO noted only that “[n]o USPTO regulation ... requires a PTE applicant to state at what time of day the FDA transmitted the approval.” *Id.* The mere fact that the PTO’s regulations do not *require* something hardly means that the governing statute *prohibits* the agency from taking it into consideration. Moreover, the only PTO regulation cited by the agency simply parrots the statute, requiring an applicant to specify the “date on which the product received permission.” 37 C.F.R. § 1.740(a)(3). But if a business-hours interpretation would otherwise be consistent with § 156(d)(1), it can hardly be foreclosed by a regulation that repeats the relevant statutory language verbatim.¹¹

¹¹ The PTO’s reliance on the Manual of Patent Examining Procedure (“MPEP”) and its own past practice is equally unavailing. The agency explained that it has “never considered the time of day that the NDA was approved” in interpreting § 156(d)(1). 2010 Decision at 8. But that appears to be because the issue has never arisen: The MPEP does not address the proper treatment of after-hours approvals, and the PTO has not pointed to an instance in which an applicant was denied a patent term extension based on the PTO’s determination that a “next business day” rule did not apply.

Finally, the PTO incorrectly believed that in interpreting § 156(d)(1), it was bound to follow the FDA’s interpretation of § 156(g)(1)(B)(ii). *See* 2010 Decision at 6-7. Specifically, although the PTO asserted that it was independently interpreting § 156(d)(1) and relying on the FDA only to provide it with “facts” regarding the drug approval process, the PTO effectively determined that the 60-day period under § 156(d)(1) must necessarily start to run whenever the FDA determined that the regulatory review period under § 156(g)(1)(B)(ii) ends. Consistent with the FDA’s interpretation, the PTO concluded that “the date stamped in a NDA approval letter is the appropriate trigger for section 156(d)(1)” —regardless of the time the FDA letter is transmitted to the applicant. 2010 Decision at 6. The PTO’s position, however, ignores material differences between § 156(d)(1) and § 156(g)(1)(B)(ii).

Most obviously, the relevant statutory language is different. Section 156(d)(1) calls for the PTO to determine when the “product received permission,” while § 156(g)(1)(B)(ii) calls for the FDA to determine when the new drug application was “approved.” Congress’s use of different words suggests that the two terms do not necessarily 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)).

Moreover, as explained in more detail below, *see infra* pp. 25-27, the two provisions serve distinct purposes. Section 156(g)(1)(B)(ii) defines the period of time that the FDA has taken to review a new drug application. In that context, the FDA employs a “business day” rule to define the start of the period and then looks to when it has finished its internal review of the new drug application to define the end of that period. By contrast, § 156(d)(1) refers to the time given to an applicant to prepare and file its patent term extension application. In that context, the

focus is on when the product “receive[s] permission,” such that it would be fair for the applicant’s filing period to begin. In light of the distinct language and purposes of § 156(d)(1) and § 156(g)(1)(B)(ii), the PTO erred in concluding that it was compelled to follow the FDA’s interpretation of § 156(g)(1)(B)(ii).

* * *

Because the PTO had the authority to adopt a “business hours” interpretation of § 156(d)(1) but failed to recognize or exercise that authority, this Court must set aside the PTO’s decision and remand the matter to allow the agency to “reconsider [the] matter free from its erroneous conception of the bounds of the law.” *Prill v. NLRB*, 755 F.2d 941, 942 (D.C. Cir. 1985); *see also, e.g., Akins*, 524 U.S. at 25.

III. IN LIGHT OF THE STATUTORY TEXT, STATUTORY PURPOSE, AND CONGRESSIONAL INTENT THAT THE PTO IMPROPERLY FAILED TO CONSIDER, THE WORD “DATE” IN § 156(d)(1) IS BEST READ TO MEAN “BUSINESS DAY”

For the reasons discussed above, the PTO should be required, at a minimum, to reconsider the timeliness of MDCO’s application because neither the statutory text nor any other authority *precludes* the agency from adopting a “business hours” interpretation of § 156(d)(1). As explained below, however, a “business hours” rule is not merely a *permissible* reading of the statute, but also the *best* reading. The PTO failed to consider or offer a reasoned response to the arguments MDCO made that supported that reading.¹²

¹² The PTO’s failure even to respond to MDCO’s central arguments is reason alone to vacate the PTO’s decision. *See PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (“An agency’s failure to respond meaningfully to objections raised by a party renders its decision arbitrary and capricious.” (internal quotation marks omitted)); *see also Timken U.S. Corp. v. United States*, 421 F.3d 1350, 1354-1356 (Fed. Cir. 2005); *Canadian Ass’n of Petroleum Producers v. FERC*, 254 F.3d 289, 299 (D.C. Cir. 2001); *Frizelle v. Slater*, 111 F.3d 172, 177 (D.C. Cir. 1997).

First, the PTO's rigid interpretation of § 156(d)(1) failed to consider the context in which the word "date" appears.¹³ Section 156(d)(1) does not say that the 60-day period to file an extension application begins on the date the FDA signs an approval letter or even, as in § 156(g)(1)(B)(ii), on the date the "application was approved." Rather, it focuses on the date a product "received permission ... for commercial marketing or use." 35 U.S.C. § 156(d)(1) (emphasis added). The distinction is important. By using the word "received" rather than the word "approved," Congress broadened the focus from the FDA's act of approval, viewed in isolation, to the product's receipt of that approval. In doing so, Congress indicated that the way the FDA communicates its approval to an applicant is a relevant consideration under § 156(d)(1). For example, if the FDA signs an approval letter but then forgets to send it to the applicant for 60 days or faxes it to the wrong number, no one could seriously argue that the applicant was precluded from filing a timely extension application because the drug "received permission" on the date the FDA signed the letter.

Because the purpose of § 156(d)(1) is to provide a trigger that starts the interval of time during which an applicant must act, it makes no sense to rely solely on the date that appears on the face of an FDA approval letter. For purposes of calculating such a date, what matters is when the applicant should be deemed to be on notice of the triggering action, and an applicant cannot reasonably be said to be on notice of an after-hours transmittal of approval until the next business day.

¹³ Because "[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000), it is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme," *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989).

Indeed, this commonsense approach explains the FDA's own "business hours" interpretation of the "date" on which a new drug application is submitted to the agency. An application's submission date triggers deadlines *for the FDA*. The FDA must make an initial determination "[w]ithin 60 days after [it] receives an application" as to whether the application is "sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a)(1). If it is, the FDA must act on the application "[w]ithin 180 days." *Id.* § 314.101(f)(1); *see also* 21 U.S.C. § 355(c)(1). As explained above, *see supra* pp. 7-8, the FDA's position therefore is that the "date" on which an after-hours application is filed—and thus the date on which its first response period begins—is the next business day. This is entirely sensible: Any other interpretation would start the FDA's response clock before the agency could reasonably be deemed to be on notice of the application. But the same logic suggests that a "business hours" rule should also apply when, as in § 156(d)(1), the parties' positions are reversed and an *applicant* must act within a specified period after a letter from the *FDA*.

Moreover, the FDA's "business hours" rule is hardly an outlier. To the contrary, other agencies likewise take the position that when they are required to act within a specified period after receipt of a document, an after-hours filing should be deemed to have been submitted on the next business day. For example, the Powerplant and Industrial Fuel Use Act of 1978, 42 U.S.C. §§ 8301 *et seq.*, requires the Department of Energy to publish notice in the Federal Register "[w]ithin 15 days after *receipt* of a certification" submitted by the operator of a new power plant. *Id.* § 8311(d)(1) (emphasis added). The regulation implementing this requirement states: "Documents that are to be considered filed upon receipt ... and that are received after regular business hours are deemed filed on the next regular business day." 10 C.F.R. § 501.7(a)(3). The Department has similarly implemented the provision of the Freedom of Information Act that

states that an agency's "20-day period" to respond to a FOIA request "shall commence on the date ... not later than ten days after the request is first *received* by any component of the agency" designated to receive such requests. 5 U.S.C. § 552(a)(6)(A). The Department's regulations state that "[r]equests delivered after regular business hours of the Freedom of Information Office are considered received on the next regular business day." 10 C.F.R. § 1004.4(a). These regulations reflect a broader agency practice of determining the date a document is received based on whether it was submitted during normal business hours. *See, e.g.*, 7 C.F.R. § 1.612(c) (Department of Agriculture); 19 C.F.R. § 201.3(c) (International Trade Commission); 30 C.F.R. § 210.103(b) (Minerals Management Service); 18 C.F.R. § 385.2001(a)(2) (Federal Energy Regulatory Commission); 43 C.F.R. § 45.12(c) (Department of the Interior).

Second, the PTO did not even consider MDCO's showing that, by declining to apply a "next business day" rule, the agency would deprive many applicants of the 60-day period Congress intended them to have to prepare their patent term extension applications. This failure to consider MDCO's argument on the merits is especially stark given that the PTO simultaneously recognized that its decision to change the way in which it counted days under § 156(d)(1) was an "extraordinary" situation that warranted a waiver of the PTO's rule prohibiting successive reconsideration petitions. 2010 Decision at 3.

Specifically, for years, 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. *Cf.* Fed. R. Civ. P. 6(a)(1)(A) ("exclude the day of the event that triggers the period"). Consistent with this practice, in its initial review of MDCO's application, the PTO concluded that the ANGIOMAX patent term extension application had been filed a single day late. *See* Ex. 12. But in its 2007 Decision, the PTO asserted for the first time that MDCO's

application was actually filed not one, but two, days late. Subsequently, the PTO applied this new interpretation in other matters, holding that the first day of the 60-day period is the date the product received FDA approval. *See* Prilosec Decision, 2008 WL 5477176.

Particularly in light of the PTO's new approach, § 156(d)(1) must be read to incorporate a "next business day" rule in order to further Congress's intent to give applicants 60 days in which to prepare and file their patent term extension applications. Under the normal rule for calculating deadlines, the time of day that a triggering event occurs is less significant because the clock does not begin to run until the next day and, therefore, the party required to take action will always enjoy the full period allocated to it by statute in which to take action. By contrast, the government's interpretation of the statutory language in § 156(d)(1) makes the timing of the FDA's approval important because it means that, unless a "business day" interpretation is adopted, an approval sent late in the evening—and as late as 11:59 p.m. under the PTO's reading of the statute—effectively gives the applicant fewer than the statutorily defined number of days to complete its extension application.

Third, as the PTO itself has recognized in a similar case, § 156 is "remedial in nature" and thus governed by the "well established principle of statutory construction that a remedial statute should be given a liberal interpretation in order to carry out its purposes." *SynchroMed* Decision at 3. In that case, the PTO considered whether the 60-day period in § 156(d)(1) should be deemed to include the day on which a drug receives FDA approval. The agency noted that the statutory language "appears to be clear" and "unambiguous" in requiring that the first day be included. *Id.* at 2. The PTO, however, also noted that this reading would require the denial of an otherwise valid application on the basis of a technicality. The PTO therefore invoked the canon

favoring liberal construction to conclude that Congress had not departed from “the general rule” that the first day should be excluded when calculating a statutory deadline:

[A] remedial statute should be liberally construed so as to carry out its purpose to the end that justice may be done to both the patentees and the public.... Under the circumstances of this application, the patent owner has lost several years of patent protection due to the regulatory review process in FDA. This loss reduces the period of time during which the patent owner may attempt to recover the expenses of creating, developing, and placing a useful medical device in possession of the public.

Id. at 3-4.¹⁴

The same logic applies here: There is no reason to think that Congress intended to foreclose a “business hours” rule for § 156(d)(1), and concluding that it did so would frustrate the purposes of the Hatch-Waxman Act by denying MDCO years of patent protection on the basis of a technicality. Such a result cannot be squared with the established principle favoring liberal construction of remedial statutes like § 156, nor does it account for the fundamental principle that patent laws must be interpreted 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.” *Bennett*, 766 F.2d at 527 (internal quotation marks omitted). The PTO, however, wholly failed to consider these principles.

Finally, the PTO asserted in passing that a “business hours” interpretation would be difficult to administer because “[b]oth applicants and the USPTO would be placed in the position of having to track not only the date of NDA approval but also the exact time of day that approval was given.” 2010 Decision at 9. This objection is wholly insubstantial. In those rare cases

¹⁴ This decision is inconsistent with the PTO’s current position that the day on which a product receives approval *is* included in the 60-day period. *See supra* pp. 10-11.

when the time of transmission is relevant, the PTO can require the applicant to establish the precise date and time of transmission in the extension application. *See* 35 U.S.C. § 156(e)(1) (eligibility decision “may be made by the Director solely on the basis of the representations contained in the application”). Indeed, it is not uncommon for the PTO to make important determinations based solely on an applicant’s assertion. *See, e.g.,* 37 C.F.R. § 1.137(b)(3) (permitting patent revival in some cases based solely on statement by counsel that delay was “unintentional”). Moreover, as this case illustrates, the time of transmission is not difficult to establish: It is plainly reflected in the date stamp on the faxed approval letter. Finally, the FDA does not appear to have any problem administering a “business hours” rule for *incoming* transmissions. The PTO gave no reason to think that applying the same rule to *outgoing* transmissions would be any more difficult.

CONCLUSION

For all of these reasons, MDCO respectfully requests that the Court vacate the PTO’s denial of MDCO’s patent term extension application and hold that the PTO is required to treat after-hours approvals the same way the FDA treats after-hours new drug application filings—by applying a “next business day” rule. At a minimum, the Court should confirm that the PTO has authority under § 156 to adopt such an interpretation—if it chooses to do so—and remand the matter for further *expedited* consideration freed of the legal errors that infected its prior orders. The Court should also order the PTO to take such actions as necessary to ensure that the ’404 patent does not expire pending further resolution of these proceedings.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of January, 2010, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system. In addition, I have served the following counsel by hand:

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