Exhibit C

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

DECISION DENYING APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 5,196,404

This decision is in response to the memorandum opinion and order of the United States District Court for the Eastern District of Virginia in Civil Action No. 01:10-cv-81, *The Medicines Company v. David Kappos, et al.*, issued on March 16, 2010. The district court vacated the USPTO's denial of the application for extension of the patent term of U.S. Patent No. 5,196,404 (the '404 patent) under 35 U.S.C. § 156, filed in the United States Patent and Trademark Office (USPTO) on February 14, 2001, and remanded the case to the USPTO for reconsideration. The USPTO has carefully reconsidered the issues raised in the district court's opinion as well as the arguments present in the Medicines Company's ("MDCO" or "Applicant") request for reconsideration. Because the USPTO again concludes that MDCO's application for patent term extension (PTE application) for the '404 patent was not timely filed as required by 35 U.S.C. § 156(d)(1), its request for a patent term extension of the '404 patent is **DENIED**.[1]

A. Factual Background

1. On March 23, 1993, the USPTO granted the '404 patent.
2. On December 15, 2000, the Food and Drug Administration (FDA) transmitted a letter via facsimile to Applicant explaining that Applicant's New Drug Application No. 20-873, seeking approval for Angiomax, had been approved. That letter stated: "[T]he application is approved effective on the date of this letter." The letter was dated December 15, 2000, in three places: (1) to the right of the address block by what appears to be a date stamp; (2) adjacent the signature on final page in handwriting; and (3) at the top of each of the three pages by what appears to be a facsimile machine imprint that also indicates the time of transmission as "18:17," i.e., 6:17 p.m. Applicant does not deny either that the FDA

[1] This decision incorporates the USPTO's decision dated January 8, 2010, regarding the grant of MDCO's petition under 37 C.F.R. § 1.183 to suspend 37 C.F.R. §§ 1.750 and 1.181(f).

transmitted, or that it received, that letter on December 15, 2000, at approximately 6:17 p.m. by facsimile.[2]

3. On February 13, 2001, Applicant, in their Annual Report for 2000, explicitly stated: "On December 15, 2000, the Company received FDA approval for Angiomax." The Medicines Company, Annual Report 2000 at 25-26 (issued Feb. 13, 2001) (Annual Report) (Attachment 1).

4. On February 14, 2001, Applicant filed its PTE application to extend the term of the '404 patent with the USPTO. In its application, Applicant stated in paragraphs (3), (10), and (11) that the approval date of Angiomax was December 15, 2000.

5. In paragraph (3), Applicant stated: "The date on which the approved product received permission for commercial marketing was 15 December 2000." In paragraph (10), Applicant stated: "The date on which the NDA was approved was 15 December 2000." And, in paragraph (11), Applicant identified significant activities undertaken as part of the regulatory review in a table. Applicant listed a communication from Julie DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Additionally, Applicant's counsel struck through paragraph (5), which set forth the last day for filing the PTE application, and initialed and dated the change. Specifically, Applicant's counsel struck through the following text: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. § 1.720(f). The last date upon which this application could be submitted is 15 February 2001."

6. On March 2, 2001, after receiving Applicant's PTE application, the USPTO wrote a letter to the FDA, indicating that the USPTO believed the PTE application to be untimely and requested the FDA's assistance in confirming that (1) Angiomax was subject to regulatory review within the meaning of section 156(g) before its first permitted commercial marketing or use and (2) the PTE application was not filed within sixty days after the product received FDA approval as required by section 156(g)(1).

7. On March 9, 2001, Applicant filed a supplement to its PTE application, explaining that it struck through paragraph (5) because of its "uncertainty as to what the approval date really was." Applicant then explained that it researched the approval date on the FDA web site and identified a document listing the approval date as December 19, 2000. Based upon that later approval date discovered months after their actual approval and weeks after the February 14, 2001 PTE application filing, Applicant restated paragraph (5) as follows: "This application is being submitted within the 60 day period permitted for submission pursuant to 37 C.F.R. 1.720(f). The last date upon which this application could be submitted is 17 February 2001."

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[2] Notably, Applicant claims that it received the FDA approval letter on December 15, 2000, by facsimile but that the letter did not include an electronic signature page. Applicant claims that it received a second copy of the FDA approval by regular mail the following week. According to Applicant, that second copy did not contain a date stamp, but instead included an electronic signature page with a 5:18 p.m. time stamp and a December 15, 2000, date stamp. Taking Applicant's claims as true, the bottom line is that the both copies of the approval letter contained a December 15, 2000, date stamp.

8. On May 21, 2001, Applicant filed a registration statement with the Security and Exchange Commission wherein it stated: "On December 15, 2000, the Company received FDA approval for Angiomax and any Angiomax bulk drug product to which the Company took title after that date is recorded as inventory." The Medicines Company, Form S-1 Registration Statement Under The Securities Act of 1933 at 84 (filed with Security Exchange Commission May 2001) (SEC Statement) (Attachment 2).

9. On September 6, 2001, the FDA confirmed by letter to the USPTO that Angiomax was subject to a regulatory review period before its first commercial marketing or use and that Angiomax had been approved on December 15, 2000, making Applicant's PTE application untimely within the meaning of section 156(d)(1).

10. On March 4, 2002, the USPTO mailed a notice of final determination to Applicant stating that its PTE application was not timely filed and that the application consequently was dismissed.

11. On October 7, 2002, Applicant requested reconsideration of the dismissal, arguing that the date of approval for Angiomax should be effective on December 18, 2000.

12. On March 23, 2003, the USPTO forwarded the request for reconsideration to the FDA, requesting the FDA's assistance in verifying the approval date of Angiomax as December 15, 2000.

13. On September 14, 2006, Applicant's Chairman and Chief Executive Officer, Clive Meanwell, testified before Congress about specific legislation it was lobbying Congress to pass, which would provide a legislative remedy for its untimely PTE application filing. Dr. Meanwell testified as follows:

> The FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000 . . . . But then human error intervened. The current filing provision of Hatch-Waxman requires an application to be filed within 60 days of FDA's approval of the drug in question. Unfortunately, the 60-day requirement was evidently mistaken for a two-month requirement, and our patent restoration application was filed on February 14, 2001, within a two-month window, but one day late for the actual 60-day deadline. Unlike other filing provisions of the patent laws, this provision of Hatch-Waxman does not allow for any discretion to accept late applications, no matter the reason and no matter how close to the actual deadline. So, the Patent and Trademark Office denied the petition as untimely. We filed a motion for reconsideration which is still pending, but the USPTO lacks the authority to grant it.

A Bill to Amend Title 35, U.S. Code, To Conform Certain Filing Provisions Within the Patent and Trademark Office: Hearing on H.R. 5120 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. On the Judiciary, 109th Cong. 11 (2006) (statement of Clive Meanwell, Chairman and CEO of the Medicines Company) (2006 Legislation) (Attachment 3). This was not Applicant's first or only attempt to secure a legislative fix for its untimely PTE application filing. Since September of 2005, Applicant's attempt to secure a legislative fix for its untimely PTE application filing resulted in at least four other bills, each of which provided relief to Applicant by providing a mechanism for the USPTO Director to accept

unintentionally delayed PTE application filings. *See, e.g.*, S. 1785, 109th Cong.; H.R. 1178, 110th Cong.; S. 1145, 110th Cong.; H.R. 6344, 110th Cong.

14. On November 2, 2006, the FDA replied to the USPTO March 2003 letter of inquiry regarding the approval date of Angiomax, again indicating that Angiomax was approved by the FDA on December 15, 2000, and not December 18, 2000.

15. On January 26, 2007, Applicant filed a petition under 37 C.F.R. §§ 1.182 and 1.183, requesting a stay of final action on its PTE application due to its pending legislation which, as explained earlier, would have provided an exception for Applicant's PTE to be considered timely.

16. On February 12, 2007, the USPTO granted-in-part and denied-in-part the petition under 37 C.F.R. §§ 1.182 and 1.183. The USPTO granted a limited stay of 30 days to permit Applicant to amend and supplement its request for reconsideration and PTE application.

17. On March 13, 2007, Applicant filed an amended request for reconsideration and an amended PTE application.

18. On April 26, 2007, the USPTO denied Applicant's application for patent term extension in final agency action.

19. On December 4, 2009, two years and eight months after Applicant could have brought suit to challenge the USPTO's final denial of its patent term extension application, Applicant filed a petition under 37 C.F.R. § 1.183 asking the USPTO to waive the requirements of 37 C.F.R. § 1.183, which limits an applicant to a single request for reconsideration within a specified time.

20. On December 4, 2009, Applicant also filed another request for reconsideration of the USPTO's denial of Applicant's application for patent term extension (Reconsideration Request).

21. On January 8, 2010, USPTO again denied Applicant's application for patent term extension in final agency action.

22. On January 27, 2010, Applicant filed suit against the USPTO, FDA, and Department of Health and Human Services in the United States District Court for the Eastern District of Virginia, Alexandria, Division under the Administrative Procedures Act, challenging the USPTO's denial of its PTE application.

23. On March 16, 2010, the district court issued a memorandum opinion and order vacating the denial of the PTE application and remanding the case to the agency for reconsideration "as to the date of approval under § 156." *The Medicines Co. v. Kappos*, Civ. Act. No. 01:10-cv-81, slip op. at 18 ("District Court Decision"). The district court explained that the USPTO erroneously believed that its construction of the term "date" in section 156(d)(1) to mean "calendar day" was compelled by the statute and that it lacked any discretion to adopt Applicant's proffered "business day" construction. *Id.* at 10. The district court also identified four argument that Applicant made to support its "business day" construction, including: "§ 156(d)(1)'s focus on the date approval was received, the purpose of § 156(d)(1), the need to ensure that all applicants received 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." *Id.* at 11. The

district court faulted the USPTO for not expressly considering these arguments, *id.* at 11, as well as for failing to provide an analysis of its plain meaning definition of "date" as "calendar day," *id.* at 14. Finally, the district court directed the USPTO "to take such actions as necessary to ensure that [Applicant's] patent does not expire pending further resolution of these proceedings." *Id.* at 18.

B. Decision

I. The USPTO Independently Determined that Applicant's PTE was Untimely Filed based on Information Supplied by the FDA

Applicant argues that section 156 expressly assigns the USPTO Director — not the FDA — responsibility for determining whether a PTE application has been timely filed as required by section 156(d)(1). Reconsideration Request at 6. Applicant also argues that just because the FDA has the approval date within their records, the USPTO must not defer to FDA's determination of compliance with section 156(d)(1). *Id.* at 7. Finally, Applicant argues that the Memorandum of Understanding between the USPTO and the FDA assigned certain duties to each agency, and USPTO is not authorized to delegate determination of compliance with the timeliness requirement of section 156(d)(1). *Id.* at 8. The USPTO agrees; it did not delegate a timeliness determination to the FDA here.

The USPTO wrote to the FDA on two occasions asking for the FDA to confirm that Applicant correctly represented the date of FDA approval of Angiomax in its PTE application. The USPTO sought this information from the FDA because the USPTO is not privy to such records; they are solely within the purview of the FDA. Because of this, the USPTO often requests the FDA's assistance with PTE applications, particularly since an applicant for a PTE application is not required to submit a copy of the FDA's approval letter to the USPTO. The USPTO's own regulation provides for the USPTO to make inquiries about the underlying facts when deciding a PTE application. *See* 37 C.F.R. § 1.750 ("The Director or other appropriate officials may . . . make independent inquiries as desired before a final determination is made on whether a patent is eligible for extension."). But the FDA's assistance is limited exclusively to providing information to the USPTO; it does not mean that the USPTO defers to the FDA on any decisions about timeliness or any other eligibility requirement. With information about the date that the FDA approved Angiomax as provided by the FDA in hand, the USPTO independently decided whether Applicant's PTE application satisfied the timeliness requirement of section 156(d)(1).

The USPTO's past practice indicates that it does not defer to the FDA for a determination of timeliness. For example, in considering a PTE application filed for U.S. Patent No. 4,911,920, the USPTO sent an inquiry to the FDA asking for confirmation of the drug approval date (Attachment 4). In response to the USPTO's inquiry, the FDA indicated that the approval date was February 23, 2000, and that the submission of the PTE application on April 26, 2000, was not timely filed under section 156(d)(1) (Attachment 5). In the USPTO's very next communication, the USPTO disagreed with the FDA's timeliness finding and stated: "The application was filed on April 19, 2000 under 35 U.S.C. § 156. The application was received by the undersigned on April 26, 2000, but was mailed by Express Mail on April 19, 2000, and is entitled to a filing date of April 19, 2000. As a result, the application was timely filed." (Attachment 6). Clearly, just as the USPTO did not defer to the FDA's timeliness determination in the PTE application for U.S. Patent No. 4,911,920, the agency did not defer to FDA here.

II. Construing the Term "Date" in Section 156(d)(1) to Mean "Calendar Day" is the Best Interpretation of the Text, Structure, and Purpose of the Statute

In its decision, the district court explained that section 156(d)(1) is not "so inflexible" as to admit of only one meaning, namely "calendar day," and implicitly found that the term "date" could have the "business day" definition that Applicant subscribes to it. District Court Decision at 13. In other words, the district court appears to find that the term "date" in section 156(d)(1) is open to more than one interpretation, freeing the USPTO to exercise its discretion in interpreting it. The USPTO finds that the best definition of "date" in section 156(d)(1) is "calendar day" based upon the text, structure, and purpose of the statute. In making this determination, the USPTO notes that section 156(d) squarely deals with the procedural requirements for obtaining a patent term extension. The USPTO's interpretation here is thus undertaken in the course of governing the conduct of its proceedings.

Beginning with the text and structure of the statute, section 156(d)(1) states:

> [t]o obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on *the date the product received permission* under the provision of law under which the regulatory review period occurred *for commercial marketing or use*.

35 U.S.C. § 156(d)(1) (emphases added). To determine what the term "date" means, the USPTO looks to the words surrounding that term, namely the phrase "the product received permission . . . for commercial marketing or use." A drug product "receive[s] permission . . . for commercial marketing or use" when the FDA approves the drug. Section 355(a) of Title 21 makes this clear. It provides: "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) is effective with respect to such drug." 21 U.S.C. § 355(a). The requirement that all "new drugs" obtain approval from FDA before they may be distributed in interstate commerce is the linchpin of drug regulation under the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. §§ 331(d).

The FDA approves a drug on the date stamped on the FDA approval letter. Various FDA regulations establish this. *See* 21 C.F.R. § 60.22(f) (explaining that "[a] marketing application . . . is approved on the date FDA sends the applicant a letter informing it of the approval"); 21 C.F.R. § 314.105(a) (stating that "[a]n approval becomes effective on the date of the issuance of the approval letter"); 21 C.F.R. § 314.108(a) (noting that "[d]ate of approval means the date on the letter"). It is likewise the FDA's long-standing practice — both before and after enactment of the Hatch-Waxman Act — to treat a drug as approved on the date of the approval letter. *See Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1336 (D.C. Cir. 1988) ("[21 C.F.R. § 314.105(a)] thus reflects a well-considered, long-standing policy."). To this end, FDA approval letters explicitly state that the "application is approved effective on the date of th[e] letter." *See, e.g.*, FDA Approval Letter to Applicant at 1 (Attachment 7). Additionally, three appellate courts have recognized the same. *See Mead Johnson*, 838 F.2d at 1336 (determining

that FDA's regulations which note that an approval is the date on the approval letter reflect a "well-considered, long-standing policy"); *Norwich Eaton Pharms, Inc. v. Bowen*, 808 F.2d 486, 491 (6th Cir. 1987) (noting that FDA approval was effective on the date of the approval letter, not the date the drug company received the approval letter), *cert. denied*, 108 S. Ct. 68 (1987); *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir. 1989) (concluding that the sixty day period mandated by 35 U.S.C. § 156(d) began on the date of the FDA approval letter). Accordingly, the date of approval is the date of the FDA approval letter.

The date stamped on the FDA approval letter covers a calendar day. Under Federal Food, Drug, and Cosmetic Act, there are no limits on what days (weekdays, weekends, or holidays) or at what times (business and non-business hours) that the FDA may approve a drug. *See* 21 U.S.C. §§ 355(a)-(d). Accordingly, Congress has implicitly authorized the FDA to approve drugs at any time of day. Said differently, Congress has not restricted the FDA to approve drugs before a certain time of day such as 4:30 p.m., the cut-off time that Applicant advocates here. Applicant's position that approval must occur on a business day, prior to 4:30 p.m. east coast time, in order to be deemed effective on that day is consequently not supported by statute. Nor does it make sense for the FDA to limit its approval window to a few hours in a day. Because Applicant essentially argues that FDA must stop official business at 4:30 p.m. east coast time, including halting the review of applications, Applicant's position could also prolong the approval process — to the detriment of industry and the public.

MDCO isolates the word "received" from section 156(d)(1) and contends that it shows that Congress intended for the patentee to have constructive receipt of the FDA approval before triggering the 60-day filing window. *See* Reconsideration Request at 16-17. In Applicant's view, "an after-hours communication should be deemed to have been received on the next business day." *Id.* at 17. The presence of the word "received" in section 156(d)(1), however, must be read in context. The statute speaks in terms of the "product receiv[ing] . . . permission for commercial marketing or use." The statute says nothing about the patentee actually or constructively receiving notice of the FDA approval. Hence, Applicant's argument is not fully consistent with the statutory language of section 156(d)(1). In fact, as explained more fully below, one reason why the term "received" in section 156(d)(1) cannot refer to the actual, or even constructive, receipt of an approval letter is because some permissions within the scope of section 156(d)(1) do not come in the form of approval letters at all. *See, e.g.*, 35 U.S.C. § 156(g)(2)(B)(ii) (specifying that the regulatory review period for a food or color additive ends on the effective date of a regulation).

Moreover, MDCO's argument that the date a human drug "receive[s] permission . . . for commercial marketing or use" is not the same day as the date that the new drug "application [i]s approved" because the language of section 156(d)(1) is distinct from the language of section 156(g)(1)(B)(ii) is unpersuasive. *See* Reconsideration Request at 9-10. Section 156(d) is simply using broader language to refer to the specific permission events that are also referred to in section 156(g). A review of the structure of section 156 reveals that the "receives permission . . . " language used in section 156(d)(1) covers various specific terms used in section 156(g). There are several different categories of products referenced in section 156(g): new drugs, food or color additives, medical devices, new animal drugs, and veterinary biological products. Section 156(d)(1) also explains that the "permission" that the various particular products "receive[]"

occurs pursuant to "the applicable regulatory review period" for that given product. Those applicable regulatory review periods are set forth in section 156(g). The nature of the "permission" that the FDA gives for the commercial marketing or use of a product depends upon what category the product falls under. Some are based on the date an "application was approved," while others are based on some other act by the FDA.

In reviewing the specific provisions of section 156(g), it becomes clear that section 156(d)(1) uses the broader language "permission ..." to encompass the various different acts of permission referred to by section 156(g). Thus, the date a new drug application is "approved" [156(g)(1)(B)(ii)], the date a regulation "became effective" for use of a food or color additive [156(g)(2)(B)(ii)], the date the protocol "was declared completed" for a medical device [156(g)(3)(B)(ii)], the date a new animal drug is "approved" [156(g)(4)(B)(ii)], and the date a license "was issued" for a veterinary biological product [156(g)(5)(B)(ii)], are all types of "permission" for commercial marketing and use contemplated in section 156(d)(1). Because of that, section 156(d)(1) does not use the same "date such application was approved" language that appears in section 156(g)(1)(B)(ii), and instead uses the broader, more generic "product received permission" language. Section 156(d)(1) necessarily uses language broader — and hence different — to encompass the specific approval or permission language particular to the various products referred to in section 156(g).

MDCO's argument that section 156(d)(1) and section (g)(1)(B)(ii) serve distinct purposes, and therefore must be construed to mean different things, is equally unpersuasive. *See* Reconsideration Request at 10-12. The USPTO agrees with MDCO's premise that the two provisions serve distinct purposes. Specifically, section 156(d)(1) serves to inform all patent term extension applicants of the trigger date which starts the sixty-day period for submission of a PTE application for his product, which could a human drug, food or color additive, medical device etc., whereas section 156(g)(1)(B)(ii) informs drug sponsors when a human drug product is approved, i.e., the regulatory review period ends, and commercial marketing may begin. Although these two provisions have different purposes, it does not follow that the specific temporal triggers that they include must be different. Title 21 of the Federal Food, Drug, and Cosmetic Act establish that the words "the date the product received permission . . . for commercial marketing or use" in section 156(d)(1) is synonymous with the language "the date [the drug] application was approved" in section 156(g)(1)(B)(ii). *See* 21 U.S.C. § 355(a). Moreover, as the Federal Circuit has made clear, it could "find no implication that the approval date that commences the 60-day application period under [section 156(d)(1)] should be different from the approval date that marks the end of the regulatory review period under [section 156(g)(1)(B)(ii)]." *Unimed*, 888 F.2d at 829.

Finally, it is critical that the "date" of section 156(d)(1) be certain because the consequence of missing the filing window is drastic. Indeed, the date of FDA approval is "of great concern to the FDA, the NDA applicant, and competing drug manufacturers, even before the Hatch-Waxman Amendments." *Mead Johnson*, 838 F.2d at 1336. Certainty is achieved under the calendar day definition only, which does not take time of day into account. Under a "business day" definition, by contrast, applicants for a patent term extension, the USPTO, the FDA, and the public must track down the precise time of day that the FDA approval is granted. But of the foregoing entities, only the FDA has access to that information. In many

circumstances, it is even possible that applicants for a patent term extension — the entities most in need of the information — do not have it since the FDA transmits the approval letter to the NDA sponsor, who may not be the patentee who will file the patent term extension application. *See, e.g.*, U.S. Patent No. 4,486,425 (decision denying PTE application where patent owner unaware of approval because patent owner and drug sponsor were distinct entities) (Attachment 8). Consequently, adopting a business day definition strains the purpose of section 156(d)(1).

III. The USPTO's Construction of the Term "Date" in Section 156(d)(1) to Mean "Calendar Day" is Consistent with Federal Circuit Precedent

Precedent establishes that the "date" in section 156(d)(1) means the date stamped on the FDA approval letter. In *Unimed*, the Federal Circuit considered whether the sixty-day period to file a patent term extension application for a patent claiming a drug product, which required DEA rescheduling, begins on the date the FDA sent the approval letter or on the date that the DEA rescheduled the drug product, which occurred nearly one year after FDA approval. 888 F.2d at 828. In answering this question, the Federal Circuit analyzed the statutory language of section 156(d)(1) and found that section 156(d)(1) is triggered by the date of the approval letter:

> According to section 156(d)(1), the sixty-day period begins "on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." Read in light of the definition of the "regulatory review period" in section 156(g)(1)(B), *this language is crystal clear*. In this case, "the provision of law under which the applicable regulatory review period occurred" is section 505 of the FFDCA, which governs the approval of new drugs by the FDA. There is no mention of DEA rescheduling or of 21 U.S.C. § 811(a), the statute under which rescheduling takes place. Therefore, *section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date.*
>
> *According to the FDA, the date of marketing approval for all new drugs is the date appearing on its approval letters.* Two circuit courts of appeals have confirmed this.

Id. (emphases added).

MDCO attempts to avoid *Unimed* by narrowly characterizing the case on its specific facts. Particularly, MDCO casts *Unimed* as concerning whether the 60-day filing window of section 156(d)(1) started from the date that the DEA rescheduled the drug as opposed to the date the product received permission for commercial marketing or use from the FDA and not whether transmission of the FDA approval letter by courtesy facsimile after 4:30 p.m. triggers the date of section 156(d)(1) — the issue here. *See* Reconsideration Request at 13-15. While *Unimed* did not involve the precise facts here, *Unimed* construed the word "date" in section 156(d)(1). The construction of the word "date" in section 156(d)(1) is central to deciding the issue here, and *Unimed*, thus is applicable precedent. Moreover, even if *Unimed* is factually distinguishable, the

USPTO's independent construction of the term "date," which the agency made exercising its discretion as ordered by the district court to do, is consistent with *Unimed*.

IV. The USPTO's Construction of "Date" as "Calendar Day" is Consistent with the USPTO's Historic Practice

Although the USPTO has not previously addressed a dispute over whether the term date means "calendar day" or "business day," the USPTO has in practice, since the enactment of the Hatch-Waxman Act, applied a "calendar day" definition for all PTE applications where the FDA issued what MDCO would characterize as an "after business hours" drug approval. *See Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 740 (1996) ("To be sure, agency interpretations that are of long standing come before us with a certain credential of reasonableness, since it is rare that error would long persist."). For example, when the FDA provided a courtesy facsimile of the drug approval letter for the drug Betaxon on February 23, 2000, at 4:44 p.m., the USPTO treated February 23, 2000, as the approval date for purposes of determining whether the PTE application was timely under section 156(d)(1). *See* U.S. Patent No. 4,911,920 (February 23, 2000 Approval Letter) (Attachment 9). The USPTO has done the same in connection with other PTE applications with similar facts. *See also, e.g.*, U.S. Patent No. 5,951,974 (January 19, 2001 Approval Letter) and U.S. Patent No. 5,565,447 (May 7, 2001 Approval Letter) (Attachments 10 and 11, respectively).

The patent law includes various time periods (other than the one at issue) that are measured from events or actions that do not take place in the USPTO, for example, the publication of a description of the invention, the public use of an invention, the placement of an invention on sale, the filing of an application in a foreign country. In all instances, the USPTO uses the calendar date for all trigger dates. Regarding the actions that the USPTO itself takes, the agency, like the FDA, is not limited to "business hours." For example, the USPTO grants patents on holidays. *See* Kenneth W. Dobyns, The Patent Office Pony 123 (1997) (". . .beginning in early 1848 and continuing to date, patents have issued at noon every Tuesday, and only on Tuesday, come fire, flood, war, riot or national holiday") (Attachment 12). The trigger date for periods measured from the grant of a patent (*e.g.*, the due dates in 35 U.S.C. § 41(b) for payment of maintenance fees, and the two-year period in 35 U.S.C. § 251 for filing a broadening reissue) is measured from the calendar date on which the patent is granted, and does not carry over to the next business day when a patent is granted on a federal holiday. The only instance when the USPTO considers business versus non-business days is when a time period for taking action before the USPTO ends on a non-business day. *See* 35 U.S.C. § 21(b).

Furthermore, it is the USPTO's practice to accept filings until midnight on the date a filing is due – thus a PTE application submitted to USPTO after "business hours" on the sixtieth day after FDA approval would be deemed timely. *See, e.g.*, Official Gazette Notice (Feb. 1, 2005) (Attachment 13); 37 C.F.R. § 1.10; 37 C.F.R. § 1.8; 37 C.F.R. § 1.6 (permits timely filing by facsimile so long as actual receipt by USPTO is by midnight EST); USPTO Legal Framework for EFS-Web 12, XXIII (Sept. 2008) (Attachment 14).

V. MDCO's Suggested Business-Day Interpretation of Section 156(d) Conflicts With the FDA's Interpretation of the Analogous Provision in Section 156(g)(1)(B)(ii)

MDCO argues that the USPTO should adopt a construction of section 156(d)'s date language—*i.e.*, "the date the product received permission . . . ," that mirrors the FDA's practice of considering new drug applications that are electronically submitted after 4:30 p.m. to have been received on the next business day (the 4:30 rule). Reconsideration Request at 15, n.8; 17-18.

The USPTO acknowledges that the FDA uses the 4:30 rule in the limited context of electronic submissions to determine when a new drug application is *submitted*,[3] but the FDA does not use that same rule when assessing the date that same application is *approved*. Critical to the question of whether the FDA and the USPTO are interpreting the term "date" similarly is the fact that while the word "date" only appears once in the provision interpreted by the USPTO, 35 U.S.C. § 156(d)(1), the word "date" appears *twice* in the provision interpreted by the FDA, 35 U.S.C. § 156(g)(1)(B)(ii):

> (ii) the period *beginning on the date* the application was initially submitted for the approved product under section 351, subsection (b) or section 505, or section 507 and *ending on the date* such application was approved under such section.

(Emphasis added). That provision defines a portion of the regulatory review period in terms of a beginning *date* and an ending *date*. The FDA only applies the 4:30 rule to the beginning date. That beginning date is not relevant to the 60-day filing window provided in section 156(d)(1) because the date an applicant submits a new drug application to the FDA is unrelated to a time period that turns on a subsequent approval of that application. Instead, it is the ending date in section 156(g)(1)(B)(ii) that is relevant to 60-day filing window of section 156(d)(1) because the conclusion of the review period marks the beginning PTE application filing window. By rule, the FDA considers the date of approval — which of course marks the end of the review period — to be the "date of issuance of the approval letter." 21 C.F.R. § 314.105(a). The USPTO cannot speak to whether the FDA's approach to interpreting section 156(g)(1)(B)(ii) is internally inconsistent, as MDCO argues. Reconsideration Request at 15, n.8. In any event, the USPTO should not compound that perceived inconsistency by applying the 4:30 rule to the ending date of the approval period, *i.e.*, to the date that the FDA *does not* apply the 4:30 rule. Thus, the USPTO concludes that the best approach is to interpret section 156(d)'s date language in harmony with the FDA's approach to interpreting the ending date language in section 156(g)(1)(B)(ii).

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[3] It is worth noting that MDCO does not assert that the FDA's 4:30 rule was used to determine the submission date of the ANGIOMAX application or that the ANGIOMAX application was even subject to the 4:30 rule, *i.e.*, MDCO does not assert it filed an electronic application. In other words, although MDCO implicitly makes the equitable argument that an outgoing approval should be treated like an incoming submission, it never asserts that *its* application should be subject to that equitable comity.

VI. MDCO's Suggested Interpretation of 156(g)(1)(B)(ii) Is Unpersuasive For Additional Reasons

Beyond the disharmony it would create with the FDA's interpretation of section 156(g)(1)(B)(ii), there are other problems with MDCO's arguments in favor of the 4:30 rule. First, the FDA's refusal to accept new drug application submissions after 4:30 p.m. bears no logical connection to whether a facsimile transmission sent after that time is received on the same calendar day. MDCO's concern is with notice. Reconsideration Request at 11. But MDCO fails to articulate why its ability to receive notice is linked to the FDA's hours for accepting new drug applications. Instead, MDCO's ability to receive notice logically turns on whether *it* was closed for business when the FDA sent its courtesy facsimile on December 15, 2000. MDCO is careful to steer clear of urging actual notice because it has never asserted that it was not on actual notice of FDA approval on December 15, 2000. MDCO candidly admits that any standard that turns on actual notice would be "difficult to administer" and involve "potentially burdensome fact-finding that the [USPTO] is not equipped to undertake." Reconsideration Request at 20.

Second, the FDA *was* conducting business after 4:30 p.m. on December 15, 2000, and any other time it takes action. The "business" of the FDA is drug approval, and MDCO agrees that the regulatory review period here "ended on December 15, 2000." Reconsideration Request at 21, n.14. Because MDCO also agrees that the FDA's act of approval is what ends the review period, *id.* at 20-21 (acknowledging that the end of the review period under section 156(g)(1)(B)(ii) is the date of FDA's approval), and because that approval occurred after 4:30 p.m., MDCO cannot seriously argue that the FDA was not conducting business when it sent the courtesy facsimile to MDCO. Although it might not have been accepting new drug applications at the time it approved Angiomax and almost immediately informed MDCO of that fact, it was clearly conducting the very business desired by MDCO. In addition, MDCO's permission for commercial market or use of Angiomax began on December 15, 2000, and was not delayed until the next business day (i.e., December 18, 2000) as a consequence of when, during the day on December 15, 2000, the FDA transmitted this courtesy facsimile to MDCO. The USPTO declines to adopt the *non sequitur* rule that a valid FDA approval should not count until the next business day just because the FDA was not accepting new applications at the time it issued its approval of an application that had been filed years earlier.

Third, MDCO fails to consider that a 4:29 p.m. approval would deprive an applicant for a patent term extension of the full 60-day period just as much as a 4:31 p.m. approval. Similarly, a facsimile transmission from the FDA of an approval at 4:35 p.m. east coast time to a drug sponsor in California, would, under MDCO's rationale, be outside the normal business hours of the FDA for purposes of triggering the 60-day filing window of section 156(d)(1) but would have provided many "business hours" for the California sponsor to commercially market or use its new drug.

Finally, MDCO's argument in favor of a 4:30 rule is made possible because the FDA provided a courtesy facsimile to Applicant. Nothing in the Federal Food, Drug, or Cosmetic Act or FDA regulations requires the FDA to facsimile notification of FDA approval to a drug sponsor. Had the FDA notified MDCO of the approval of its drug via postal mail only, MDCO could not allege that the term "date" in section 156(d)(1) means "business day" because there

would be no after business hours transmission of approval from the FDA to quibble over. Thus, this entire litigation was made possible solely because the FDA chose to extend a courtesy to MDCO and provide as prompt notification of FDA approval as possible.

VII. MDCO's Remaining Fairness Arguments Regarding Section 156

Urging that the USPTO should interpret section 156(d)(1) in a way that benefits it, MDCO argues that the USPTO "has historically developed policies to avoid the unnecessary loss of patent rights." Reconsideration Request at 19. MDCO fails to appreciate, however, that those policies are provided by statutory provisions absent here. For example, the USPTO allows filing on the next business day when a time period ends on a weekend or holiday, 37 C.F.R. § 1.7, and allows certain filing dates to be met by timely deposit of the filing with the U.S. Postal Service, 37 C.F.R. § 1.8. Both rules are specifically authorized by statute. *See* 35 U.S.C. § 21. Likewise, the USPTO will, under certain circumstances, allow revival of a patent that expires for failure to pay a fee, or revival of an application that is abandoned for failure to take action, but only because Congress authorized the USPTO to do so. 35 U.S.C. § 41(c) (patent maintenance fees) 35 U.S.C. §§ 41(a)(7) and 133 (application abandonment). Furthermore, the USPTO can even extend the time for appealing its Board decision to the U.S. Court of Appeals for the Federal Circuit, and accept late priority claims to earlier applications, but only because both practices are authorized by statute. 35 U.S.C. §§ 142 (Federal Circuit Appeal), 120 (priority).

The point is that there are indeed many instances where the USPTO prevents loss of rights due to an applicant, appellant, or patentee's failure to meet certain deadlines. But in all of those cases, Congress has provided the avenue for the relief available at the agency, and thus to the applicant or patentee. In light of that, it speaks volumes that Congress provided no avenue to allow the USPTO to accept a late PTE application filed under section 156. Given Congress's unquestionable awareness that lawyers make mistakes, and the various provisions it provided to redress those mistakes, Congress's failure to include a similar provision related to the section 156(d)(1) 60-day filing window compels the conclusion that Congress did not intend the provision to be remedial, or to be interpreted in a way that benefits late-filing PTE applicants.

Finally, although not specifically advanced in the Reconsideration Request, the USPTO notes that in its decision, the district court referred to section 156 as "remedial." While section 156, and more generally the Hatch-Waxman Act, in part, was certainly meant to remedy the loss of effective patent term due to lengthy regulatory delay, it does not follow that every provision within section 156 is "remedial." In section 156(d)(1), Congress provided a 60-day window within which a patentee can file its PTE application. No provision for extension of the time period is included. By creating such a non-extendable period, Congress provided a date-certain by which all players would know their future rights. Lastly, interpreting section 156(d)(1) "is purely a case of statutory interpretation, so the equitable considerations" are inappropriate. *Unimed*, 888 F.2d at 829.

VIII. MDCO's Situation is Not a Result of USPTO's "Calendar Day" Construction

At its core, MDCO's situation appears to turn on its failure to correctly docket the due date for filing the patent term extension application with the USPTO. That is, instead of

correctly docketing the 60-day filing window deadline as February 12, 2001 — 60 days from December 15, 2000, MDCO seemingly docketed the deadline as February 15, 2001 — 2 months from December 15, 2000. Because 60 days is not the same as two months in all instances due to the varying number of days in a month, MDCO's docketing mistake lead to its missed deadline. Dr. Clive Meanwell, Chairman and CEO of MDCO, admitted before Congress that MDCO's situation is the product of "human error" and not the USPTO long's standing "calendar day" definition of "date" in section 156(d)(1):

> The FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000 . . . . But then *human error intervened.* The current filing provision of Hatch-Waxman requires an application to be filed within 60 days of FDA's approval of the drug in question. *Unfortunately, the 60-day requirement was evidently mistaken for a two-month requirement, and our patent restoration application was filed on February 14, 2001, within a two-month window, but one day late for the actual 60-day deadline.*

A Bill to Amend Title 35, U.S. Code, To Conform Certain Filing Provisions Within the Patent and Trademark Office: Hearing on H.R. 5120 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. On the Judiciary, 109th Cong. 11 (2006) (emphases added). Dr. Meanwell made this admission under oath, not in a litigation-induced setting. And who better to know exactly why MDCO filed its PTE application on February 14, 2001, than the head of its company.

Furthermore, MDCO has made numerous attempts to secure legislation to remedy its situation rather than bring timely suit against the USPTO or the FDA. Specifically, the USPTO issued a final agency decision on April 26, 2007. MDCO could have brought suit immediately thereafter. But it did not do so. Instead, it spent at least the past three years lobbying Congress for a legislative fix to its problem. *See, e.g.*, S. 1785, 109th Cong.; H.R. 1178, 110th Cong.; S. 1145, 110th Cong.; H.R. 6344, 110th Cong. Thus, it was MDCO's choice to place itself on the courthouse steps on the eve of its patent expiration. Just as MDCO waited until the very last minute to file its PTE application, and then some, it likewise waited to the very last minute to seek redress of the USPTO's adverse patent term extension decision. MDCO's dire situation is therefore exclusively of its own making.

Finally, a PTE application is a relatively short filing. The statute requires only certain minimal items of information. *See* 35 U.S.C. § 156 (d)(1)(A)-(E). Consequently, it is not as if a patent owner needs a full 60-days to assemble all of the necessary information and/or prepare the application. In fact, all the information that MDCO needed, except for its FDA approval, was available well before December 15, 2000. And on December 15, 2000, MDCO received the missing FDA approval. Thus, MDCO was equipped on December 16, 2000, to file its PTE application. An applicant for PTE gains no advantage, nor does it receive any additional restored term, by waiting to the last minute to file its PTE.

IX. MDCO's Patent Term Extension Application Was Filed Two Days Late

As explained earlier, the trigger date for the 60-day filing window of section 156(d)(1) is the date stamped on the face of the FDA approval letter, here, December 15, 2000. MDCO has repeatedly acknowledged to various governmental bodies as well as the public that the date of FDA approval of its drug was December 15, 2000:

- In its patent term extension application to the USPTO, Applicant stated three times that the FDA approved its drug on December 15, 2000. For example, it stated: "The date on which the NDA was approved was 15 December 2000." PTE Application at 4.

- In testimony before Congress as part of its lobbying efforts for a legislative resolution to its untimely filing PTE application filing, Dr. Clive Meanwell, Chairman and CEO of MDCO, stated that "[t]he FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000." 2006 Legislation.

- In its filing to the Security and Exchange Commission, Applicant stated that "[i]n December 2000, the U.S. Food and Drug Administration (FDA) approved Angiomax(R) (bivalirudin), the Company's lead product, for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA)." SEC Statement at 84.

- In its Annual Report for 2000 to its shareholders and the public, Applicant notified stated that "[o]n December 15, 2000, the Company received FDA approval for Angiomax." Annual Report at 25-26.

With December 15, 2000, as the start of the 60-day filing window of section 156(d)(1), Applicant's patent term extension filing on February 14, 2001, was 2 days late. Thus, MDCO does not qualify for a patent term extension under section 156. Therefore, the application for extension of the patent term of U.S. Patent No. 5,196,404 under section 156 is **DENIED**. **THIS IS A FINAL AGENCY DECISION.**

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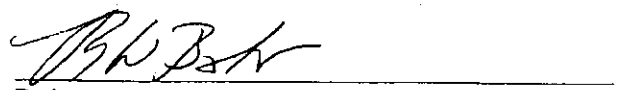

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