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JAN 08 2010

In re Patent Term Extension Application of	:
Maraganore et al.	: Decision on Petition to
U.S. Patent No. 5,196,404	: Suspend Requirements of
Issue Date: March 23, 1993	: 37 C.F.R. § 1.750 and 37 C.F.R. 1.181(f) &
Application No. 07/549,388	: Request for Reconsideration of Application
Filing Date: July 6, 1990	: for Patent Term Extension
For: Inhibitors of Thrombin	:

The patent term extension application containing a petition under 37 C.F.R. § 1.183 and a request for reconsideration, both filed on December 4, 2009, has been forwarded to the Office of the Associate Commissioner for Patent Examination Policy in the United States Patent and Trademark Office (the "USPTO") for consideration. The petition under 37 C.F.R. § 1.183 is being treated as a request to suspend not only the provisions of 37 C.F.R. § 1.750 regarding a "single" request for reconsideration, but also as a request to suspend the timeliness provisions of 37 C.F.R. § 1.181(f).

The petition under 37 C.F.R. § 1.183 to suspend 37 C.F.R. § 1.750 and suspend the provisions of 37 C.F.R. § 1.181(f) is **GRANTED**. The request for reconsideration of the application for patent term extension is **DENIED**.

Factual Background

1. On March 23, 1993, the USPTO granted U.S. Patent No. 5,196,404 (the '404 patent) to John M. Maraganore et al. who assigned their rights to, what is now, Biogen Idec MA, Inc.
2. On December 15, 2000, the FDA transmitted a letter via facsimile to The Medicines Company ("Applicant") explaining that Applicant's New Drug Application ("NDA") 20-873, seeking approval for ANGIOMAX® (bivalirudin), 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 pm. Applicant does not deny either that the FDA transmitted, or that it received, that letter on December 15, 2000, at approximately 6:17 pm by facsimile.

3. On February 14, 2001, Applicant filed its application for patent term extension (PTE) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO ("PTE Application"). Applicant does not claim any earlier date for its application. In the application, Applicant stated in paragraphs (3), (10), and (11) that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000. 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: "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."
4. 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® (bivalirudin) 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 the sixty day period beginning on the day the product received FDA approval as required by section 156(g)(1).
5. On March 9, 2001, Applicant filed a supplement to its PTE application, explaining that it struck through paragraph (5) based upon 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, 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."
6. On September 6, 2001, the FDA confirmed by letter to the USPTO that ANGIOMAX® (bivalirudin) was subject to a regulatory review period before its first commercial marketing or use and that ANGIOMAX® (bivalirudin) had been approved on December 15, 2000, making Applicant's PTE application untimely within the meaning of section 156(d)(1).
7. On March 4, 2002, the USPTO mailed a notice of final determination to Applicant stating that its PTE application was not timely filed as required by statute and regulation, and that the application consequently was dismissed.
8. On October 7, 2002, Applicant requested reconsideration of the dismissal, arguing that the date of approval for ANGIOMAX® (bivalirudin) should be effective on December 18, 2000, yet a third possible approval date.
9. 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® (bivalirudin) as December 15, 2000.

10. On November 2, 2006, the FDA replied, indicating for a second time that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000.
11. 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.
12. 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.
13. On March 13, 2007, Applicant filed an amended request for reconsideration and an amended PTE application.
14. On April 26, 2007, the USPTO denied Applicant's application for patent term extension ("Denial").
15. On December 4, 2009, Applicant filed a petition under 37 C.F.R. § 1.183 ("Petition").
16. On December 4, 2009, Applicant filed a request for reconsideration of the USPTO's denial of Applicant's application for patent term extension ("Request for Reconsideration").

DECISION

A. Petition under 37 C.F.R. § 1.183 to Suspend 37 C.F.R. § 1.750

Applicant requests, under 37 C.F.R. § 1.183, to suspend the provisions of 37 C.F.R. § 1.750 to the extent that the regulation mandates a single request for reconsideration within a specified time frame. Petition at 3. Applicant argues that section 156 does not set a limit on the number of requests for reconsideration of an application for patent term extension, nor does it set forth a time frame within which such requests for reconsideration must be filed. *Id.* Applicant thus argues that the requirements of Rule 750 are not requirements of the statute. Further, Applicant points out that the USPTO set forth a new methodology for counting the time period of section 156(d)(1) in the denial of its PTE application on April 26, 2007, and as a result, justice supports giving Applicant an opportunity to address that new counting methodology. *Id.* at 4.

The USPTO is persuaded by Applicant's argument for suspension of Rule 750 under the terms of Rule 183. That latter regulation states: "In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed." 37 C.F.R. § 1.183. Since the USPTO has corrected its methodology of counting the time period of 35 U.S.C. § 156(d)(1) to conform with the express language of the statute and first applied its corrected counting methodology in finally denying Applicant's PTE application, the USPTO finds that justice favors giving Applicant the opportunity to address the denial of its PTE application under the USPTO new counting methodology.¹ Accordingly, Applicant's petition

¹ Notably, Applicant does not actually challenge the application of the USPTO's new counting methodology in its Request for Reconsideration, but instead raises arguments focused only on the specific date that triggered the 60 day window for filing its PTE application, i.e., Applicant disputes whether the correct trigger date is December 15, 2000, as applied by the USPTO, or December 18, 2000, which Applicant asserts is correct.

filed under Rule 183 to suspend Rule 750 is **GRANTED**.

B. Petition under 37 C.F.R. § 1.183 to Suspend 37 C.F.R. § 1.181(f)

Any consideration of the petition filed under 37 C.F.R. § 1.183 is predicated upon a suspension of the timeliness requirement of 37 C.F.R. § 1.181(f). Rule 181(f) provides: “The mere filing of a petition will not stay any period for reply that may be running against the application; nor act as a stay of other proceedings. Any petition under this part not filed within two months of the mailing date of the action or notice from which relief is requested may be dismissed as untimely, except as otherwise provided. This two-month period is not extendable.” 37 C.F.R. § 1.181(f). Even though Applicant did not file a petition to suspend the timeliness provision Rule 181(f), the USPTO is nevertheless *sua sponte* considering Applicant’s petition under Rule 183 as a request to also suspend the timeliness provisions of Rule 181(f). For the reasons explained above — in short, because justice favors waiver — Applicant’s petition filed under Rule 183 to suspend Rule 181(f) is **GRANTED**.

C. Request for Reconsideration of Application for Extension of Patent Term Under 35 U.S.C. § 156

Applicant raises numerous arguments why the USPTO should consider its PTE application for the ’404 patent based on the regulatory review period for Angiomax®(bivalirudin) timely filed under section 156(d)(1). Distilling those arguments to their core, Applicant asserts that the 60-day time window of section 156(d)(1) should not commence until an applicant can “be deemed to be on notice” of the FDA approval. Request for Reconsideration at 11. Because the USPTO finds that the section 156(d)(1) expressly sets forth the trigger date for compliance with section 156(d)(1) as the date the applicant may commercially market or use the approved product, which is the date of NDA approval, and does not take an applicant’s receipt of such notice into consideration, the USPTO considers Applicant’s arguments to be unpersuasive. The present request for reconsideration of the denial of the PTE application for the ’404 patent therefore is **DENIED**. Each of Applicant’s arguments will be considered in detail in turn.

1. The USPTO Independently Determined Compliance with Section 156(d)(1)

Applicant argues that the USPTO should make its own determination regarding whether the timeliness requirement of § 156(d)(1) is satisfied and should not defer that determination to the FDA. Request for Reconsideration at 6-8. In support of its argument, Applicant points out that section 156 of Title 35 expressly assigns the USPTO Director with responsibility for determining compliance with section 156(d)(1). Request for Reconsideration at 6. Applicant contends that when Congress appoints a particular agency to administer a statute, the appointed agency cannot delegate such duties to a different agency. Request for Reconsideration at 8. As further support, Applicant points out that the USPTO and the FDA entered into a Memorandum of Understanding regarding the administration of section 156 wherein the USPTO acknowledged its responsibility for deciding compliance with section 156(d)(1). Request for Reconsideration at 7-8.

The USPTO agrees with Applicant that the USPTO — and only the USPTO — is assigned responsibility for determining compliance with section 156(d)(1) pursuant to the statute. Indeed, section 156 explicitly provides that “[a] determination that a patent is eligible for

extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension[.]" then the Director shall issue a certificate of extension. 35 U.S.C. § 156(e)(1). The USPTO also agrees with Applicant that the Memorandum of Understanding is evidence of the USPTO's appreciation for its statutory duty. To that end, the Memorandum of Understanding states:

This agreement establishes the procedures whereby the Food and Drug Administration (FDA) assists the Patent and Trademark Office (PTO) in determining a product's eligibility for patent term restoration under 35 U.S.C. 156. It also establishes *procedures for exchanging information between FDA and PTO* regarding regulatory review period determinations, due diligence petitions and informal FDA hearings under the law.

Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration, page 1 (executed September 1986) (emphasis added) (hereinafter "PTO-FDA MOU"). The USPTO disagrees with Applicant, however, that it deferred to the FDA for a determination of timeliness. In making such argument, Applicant misunderstands the process that the USPTO employed in deciding the timeliness of its PTE application.

The Director addressed the timeliness of Applicant's PTE application as early as March 2, 2001. At that time, the USPTO wrote a letter to the FDA, informing the FDA that it determined that Applicant's PTE application was not timely filed. The USPTO made its timeliness finding based solely on Applicant's statements in its PTE application that (i) "[t]he date the product received permission for commercial marketing was 15 December 2000," (ii) "[t]he date on which the NDA was approved was 15 December 2000;" and (iii) a table entry listing December 15, 2000 as the "Approval of Angiomax." See PTE Application at 1. This is exactly what the USPTO is obligated to do under section 156(e)(1). The USPTO repeated its independent determination regarding the untimeliness of Applicant's PTE application in its final determination of March 4, 2002 and its Denial on April 26, 2007. Finally, herein, the USPTO explains once more that Applicant's PTE application was not timely filed. See *infra* at page 9.

Focusing more specifically on the USPTO's interaction with the FDA to place the FDA's role in proper perspective, the USPTO wrote to the FDA on two occasions asking for the FDA to confirm that the Applicant correctly represented the date of NDA approval in its PTE application. The USPTO sought information about the NDA approval date from the FDA because the USPTO is not privy to such records; they are solely within the purview of the FDA. Thus, 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 NDA approval letter, enabling the USPTO to see the NDA approval date. But the FDA's assistance is limited exclusively to providing information to the USPTO; it does not mean that the USPTO defers any decisions on PTE eligibility to the FDA. Said differently, seeking assistance from the FDA regarding a factual inquiry, that is, the approval date of an NDA, and then using that fact to conclude that a PTE application was not timely filed in no way constitutes deferral to the FDA on compliance with section 156(d)(1). 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."). What is more, the Memorandum of Understanding even reflects the nature of the relationship between the agencies in this regard:

While it is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied these six conditions, FDA possesses expertise and records regarding the last four and has certain direct responsibilities under 35 U.S.C. 156 for determining the length of the regulatory review period. . . . Under this agreement, FDA, upon receipt of a written request from PTO, will convey to PTO the following information regarding eligibility for extension. . . . (3) whether the patent term extension application was submitted within 60 days after the product was approved

PTO-FDA MOU at 2 (emphases added). Thus, the FDA did not decide the timeliness of Applicant's PTE application for purposes of Applicant's satisfaction of section 156(g)(1); the USPTO did, exactly as it is required to do by statute.

2. The Date the Product Received Permission for Commercial Marketing or Use is the Date Stamped on the NDA Approval Letter

Applicant argues that the date a drug receives permission for commercial marketing under section 156(d)(1) is not required by statute to be the date the new drug application (NDA) is approved when the FDA transmits the NDA approval after normal business hours. Request for Reconsideration at 9. For support, Applicant points to section 355 of the Federal Food Drug and Cosmetic Act and section 156(g)(1)(B)(ii) of the Hatch-Waxman Act, both of which use different language than section 156(d)(1). *Id.* at 10-12. Applicant contends that "[t]he fact that Congress used two different formulations in the same statutory section reinforces the conclusion that these two dates do not have the same meaning." *Id.* at 10. Applicant misunderstands the Hatch-Waxman scheme.

Section 355(a) of Title 21 governs the approval of new drugs. 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." 35 U.S.C. § 355(a). In other words, the date that an NDA sponsor receives NDA approval is the date that the sponsor may commercially market or use the approved drug. This provision means that NDA approval constitutes the permission for commercial marketing or use of the new drug product, and in turn, that the date of NDA approval is the date a drug receives permission for commercial marketing or use. Accordingly, the date stamped on a NDA approval letter is the appropriate trigger date for section 156(d)(1). To be sure, the FDA defines an "approval letter" as "[a]n official communication from FDA to a new drug application (NDA) sponsor that allows the commercial marketing of the product."² The time of day of FDA approval in no way factors into the calculus. And Applicant does not point to any law, regulation, or case law precedent which compels that the NDA approval date is not the same date that a product receives permission for commercial marketing or use when the FDA transmits approval after normal business hours.

Applicant asserts that the Federal Circuit's discussion of the timeliness requirement of section 156(d)(1) in *Unimed, Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989), is "not even *dicta*" because timing was not at issue in that case. Request for Reconsideration at 13-15. Applicant reads that decision to resolve only the very narrow dispute of whether the triggering event for the time period of § 156(d)(1) is FDA approval or the removal of other government obstacles to marketing. *Id.* Applicant's reading is in error.

² See Drugs@FDA Glossary of Terms.<http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>.

Turning to the specific facts, Unimed sought FDA approval of a particular drug product that was a controlled substance. 888 F.2d at 827. The FDA approved Unimed's NDA on May 31, 1985. In its approval letter, the FDA reminded Unimed that the drug could not be legally marketed until the Drug Enforcement Administration ("DEA") rescheduled the drug, which DEA did on May 13, 1986. Unimed then filed a PTE application. The USPTO denied the PTE application as untimely filed under section 156(d)(1). Unimed challenged the USPTO's denial, arguing that the 60-day time period set forth in section 156(d)(1) did not begin until the date of DEA rescheduling because the drug could not legally be marketed until then. The Federal Circuit rejected Unimed's argument.

The Federal Circuit framed the issue as "whether the sixty-day period specified in section 156(d)(1) began, as the Commissioner argues, when the FDA sent its approval letter, on May 31, 1985 or, as Unimed argues, when the DEA rescheduled Marinol nearly a year later." 888 F.2d at 828. To answer the question, the Federal Circuit looked to express language of section 156(d)(1), which it concluded explicitly identified the FDA approval via the language "provision of law under which regulatory review occurred," referring to section 505 of the Federal Food Drug and Cosmetic Act. Applying that statutory construction, the Federal Circuit then explained: "The sixty-day period specified in section 156(d)(1) commenced on May 31, 1985, the date of the FDA's letter to Unimed giving notice of its final approval of Marinol and Unimed's application for extension of the patent term was untimely." *Id.* at 829. The Court's decision here not only addressed the triggering event — FDA approval versus DEA rescheduling, but also addressed the triggering date for section 156(d)(1) and whether the timeliness provision was satisfied based upon an NDA approval date of May 31, 1985, which the Court concluded it was not. Thus, the triggering date was integral to the Court's conclusion, and as a result, *Unimed* is instructive as to how to calculate the 60-day time period of section 156(d)(1).

3. A Product Receives Permission for Commercial Marketing or Use on the Date Stamped on the NDA Approval Letter, Regardless of the Time of Day the Letter is Transmitted

Applicant argues that Congress's intent to give an applicant a full sixty days within which to prepare and submit a PTE application is not followed if an "after hours" NDA approval is considered to trigger compliance with section 156(d)(1). Request for Reconsideration at 16. Applicant thus argues for a "next business day" rule to be applied when the FDA communicates NDA approval outside the FDA business hours of 8:00 AM to 4:30 PM. *Id.* Here, because the FDA transmitted NDA approval to Applicant by facsimile at 6:17 PM on December 15, 2000, Applicant asserts that the 60-day time period should begin on the next business day — December 18, 2000. In other words, Applicant argues that "what matters is when the applicant should be deemed to be on notice of the approval." Request for Reconsideration at 11. Applicant asserts that its "next business day" rule would not have any adverse impact on the FDA or on other determinations by the USPTO, but instead would result in an "objective and straightforward bright-line rule." Request for Reconsideration at 20-21. Applicant's arguments are unpersuasive.

Applicant's "next business day" rule is contrary to statute. Section 156(d)(1) does not consider the time of day that the FDA gives NDA approval, which opens the door for the NDA holder to commercially market the approved drug. Rather, the statute focuses only 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.” 35 U.S.C. 156(d)(1) (emphasis added). A particular “date” spans the course of 24 hours; it does not end with the close of business. Hence, for the USPTO to construe section 156(d)(1) to contain a “next business day” requirement for “after hours” NDA approval simply puts words into the statute that are not there.

Applicant’s “next business day” rule is also contrary to regulations. No USPTO regulation regarding patent term extension requires a PTE applicant to state at what time of day the FDA transmitted the approval. Like the language of the statute, the USPTO regulation focuses only on the “date” of NDA approval. *See* 37 C.F.R. 1.740(a)(3) (“A formal application for the extension of a patent term must include: . . . an identification of the *date* on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred.”) (emphasis added). The FDA’s regulations support the idea that the “date” of FDA approval of a NDA application runs for a 24 hour period. Specifically, 21 C.F.R. § 314.105, which governs the FDA’s approval of an NDA application, speaks in terms of the “date” of NDA approval as all day; it makes no mention of the time of day that the letter is transmitted from CDER to the NDA sponsor. That regulation states: “The approval becomes effective on the *date of the issuance* of the agency’s approval letter unless the approval letter provides for a delayed effective date.” 21 C.F.R. § 314.105(a) & (e) (emphasis added).

Additionally, Applicant’s “next business day” rule breaks with the USPTO’s historical practice in existence since the inception of the Hatch-Waxman Act of treating the trigger date of section 156(d)(1) as the NDA approval date when the product under regulatory review is a new drug product. The USPTO has never considered the time of day that the NDA was approved. The Manual of Patent Examining Procedure (“MPEP”) contains a section entitled: “Deadline for Filing an Application Under 35 U.S.C. – 2700 Patent Terms and Extensions.” In that section, the MPEP states:

The sixty-day period *begins on the regulatory agency approval date* which marks the end of the regulatory review period. The statute takes into account only the regulatory review carried out by the Food and Drug Administration or the Department of Agriculture and no other government obstacles to marketing or use. *See Unimed, Inc. v. Quigg*, 888 F2d 826, 828; 12 USPQ2d 1644, 1646 (Fed. Cir. 1989). For drug products *the approval date is the date of a letter by the Food and Drug Administration indicating that the application has been approved*, even if the letter requires further action before the drug can be marketed. *Mead Johnson Pharmaceutical Group v. Bowen*, 838 F2d 1332, 1336; 6 USPQ2d 1565, 1568 (D.C. Cir. 1988).

U.S. Patent & Trademark Office, Manual of Patent Examining Procedure § 2754.01 (emphases added). The MPEP says nothing about the time of day of NDA approval.

Finally, in terms of administration, Applicant’s “next business day” rule will not result in an “objective and straightforward bright-line rule.”³ It would instead result in much speculation

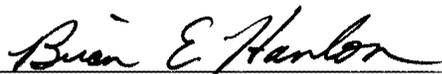
³Applicant does contend that PTE applicants should be required to submit PTE applications to the USPTO during “normal business hours,” perhaps because such submission are permitted up to 11:59PM on the last day of any time period for which a reply is due.

and confusion for PTE applicants as well as the USPTO. Both 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. Finally, it is not clear how the regular business hours of the approving agency affect the question of whether an applicant should be on notice of a communication it received from that agency.

4. Applicant Untimely Filed Its PTE Application for Angiomax® (bivalirudin) based on the Regulatory Review Period of NDA 20-873

Applying the statutory language to the facts here, “the date [Angiomax® (bivalirudin)] received permission . . . for commercial marketing or use. . .” was December 15, 2000, as indicated on the face of the FDA’s NDA approval letter, as stated by Applicant three separate times in its PTE Application, and as twice confirmed by the FDA upon a request for information from the UPSTO. Under the USPTO’s counting methodology of treating the date of approval as day one in conformity with the express language of the statute and case law, *see Unimed*, 888 F.2d at 828, Applicant’s PTE application was due by the last day of the 60-day period beginning on December 15, 2000, *i.e.*, February 12, 2001.⁴ Applicant filed its PTE application on February 14, 2001, two days late. Notably, even under the USPTO’s former counting methodology of treating the day after the date of approval as day one, Applicant still untimely filed its PTE application by one day. Thus, because Applicant filed its application for patent term extension on February 14, 2001, more than 60 days after receiving permission for commercial marketing or use for Angiomax® (bivalirudin), the present application for patent term extension is **DENIED**.

Telephone inquiries with regard to this communication should be directed to Mary C. Till at (571) 272-7755.



Brian E. Hanlon

Director

Office of Patent Legal Administration

Office of the Associate Commissioner
for Patent Examination Policy

⁴ As noted earlier, Applicant does not challenge the USPTO’s new counting methodology. A full discussion of the USPTO’s new counting methodology is set forth in the USPTO denial of Applicant’s PTE application on April 26, 2007, which is incorporated herein by reference and attached herewith.



APR 26 2007

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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 is in response to 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; the first request for reconsideration, filed October 2, 2002; and the amended request for reconsideration, filed on March 13, 2007. The application was filed by The Medicines Company (Applicant). Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of the human drug product known by the tradename ANGIOMAX®, having the active ingredient bivalirudin. Because the Food and Drug Administration (FDA) confirmed (more than once) that the approval date of NDA 20-873 for ANGIOMAX® (bivalirudin) is December 15, 2000, and because Applicant failed to timely file its patent term extension application within sixty days of that date as required by § 156(d)(1) and 37 C.F.R. § 1.720(f), Applicant's request for extension of the patent term of the '404 patent is **DENIED**.

A. Factual Background

On December 15, 2000, the FDA transmitted a letter via facsimile to Applicant explaining that Applicant's NDA 20-873, seeking approval for ANGIOMAX® (bivalirudin), 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 pm. Applicant does not deny either that the FDA transmitted, or that it received, that letter on December 15, 2000, at approximately 6:17 pm by facsimile.¹

¹ 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 pm 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.

On February 14, 2001, Applicant filed its application for patent term extension (PTE) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO. Applicant does not claim any earlier date for its application. In the application, Applicant stated in paragraphs (3), (10), and (11) that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000. 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: "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."

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® (bivalirudin) was subject to regulatory review within the meaning of § 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 § 156(g)(1).

On March 9, 2001, Applicant filed a supplement to its PTE application, explaining that it struck through paragraph (5) based upon 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, 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."

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

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

On October 7, 2002, Applicant requested reconsideration of the dismissal, arguing that the date of approval for ANGIOMAX® (bivalirudin) should be effective on December 18, 2000.

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® (bivalirudin) as December 15, 2000.

On November 2, 2006, the FDA replied, again indicating that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000, and not December 18, 2000.

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.

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

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

B. Applicable Statutes and Regulation

The following statute and regulation are relevant to the timeliness issue presented in Applicant's PTE application:

35 U.S.C. § 156 Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if -

(d)

(1) To 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 applicable regulatory review period occurred for commercial marketing or use. The application shall contain -

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of--

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on the date an application was initially submitted for such drug under section 351, 505, or 507, and

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

37 C.F.R. § 1.720 Conditions for extension of patent term

The term of a patent may be extended if:

- (a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;
- (b) The term of the patent has never been previously extended, except for extensions issued pursuant to §§ 1.701, 1.760, or 1.790;
- (c) An application for extension is submitted in compliance with § 1.740;
- (d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;
- (e) The product has received permission for commercial marketing or use and -
 - (1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or
 - (2) In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent, or
 - (3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.
- (f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

(g) The term of the patent, including any interim extension issued pursuant to § 1.790, has not expired before the submission of an application in compliance with § 1.741; and

(h) No other patent term has been extended for the same regulatory review period for the product.

C. Decision

This decision addresses arguments raised by Applicant in its first request for reconsideration filed on October 7, 2006, and in its amended request for reconsideration filed on March 13, 2007.

1. First Request for Reconsideration

Despite the unambiguous language of the FDA's December 15, 2000, approval letter stating that the date of that letter was the date of approval of ANGIOMAX® (bivalirudin), and despite the FDA's two subsequent confirmations of December 15, 2000, as the approval date, Applicant makes three arguments why December 18, 2000, or alternatively, December 19, 2000, should be treated as the effective approval date for ANGIOMAX® (bivalirudin): (1) it received the FDA approval letter late in the day on December 15, 2000, after normal business hours; (2) the FDA itself was confused as to the approval date, publishing two different approval dates on its website; and (3) fairness weighs in favor of granting the PTE application since ANGIOMAX® (bivalirudin) is Applicant's first commercial product and a denial of patent term extension is a disproportionately harsh penalty, counter to public policy, and counter to the intent of the Hatch-Waxman Act. The USPTO will address each argument in turn.

a) The FDA Approval Letter Plainly Sets Forth the Approval Date of ANGIOMAX® (bivalirudin)

Applicant asserts that because the approval of ANGIOMAX® (bivalirudin) was transmitted by facsimile after 4:30 pm on Friday, December 15, 2000, the approval should be considered to have occurred on the next business day, namely, Monday, December 18, 2000. Applicant's argument is misplaced. The FDA has made clear three times that the approval date of ANGIOMAX® (bivalirudin) is December 15, 2000. First, the original approval letter from FDA explicitly states: "Accordingly, the application is approved effective on the date of this letter." The approval letter is clearly date-stamped December 15, 2000, which Applicant does not dispute. Second, the FDA indicated in its first confirmation letter of September 6, 2001, that "[t]he NDA was approved on December 15, 2000," Third, in its second confirmation letter of November 2, 2006, the FDA reiterated that NDA 20-873 for ANGIOMAX® (bivalirudin) was approved on December 15, 2000.

Applicant would have the USPTO, which is responsible for determining eligibility of a patent for PTE, consider December 18, 2000 or December 19, 2000, as the approval date, but the USPTO cannot do so. The USPTO is not involved in the regulatory review process of new drugs and does not issue drug approvals. Although the USPTO can comprehend Applicant's arguments, the fact of approval date of a new drug product is solely within the written records of FDA. Furthermore, as the Federal Circuit has pointed out, the determination of the length of the regulatory review period is the responsibility of the regulatory agency, here, the FDA.

Aktiebolaget Astra v. Lehman, 71 F.3d 1578, 1580-81 (Fed. Cir. 1995). Because approval for a drug product occurs at the end of such period, it follows 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).

It is well settled that the approval date is the date appearing on the FDA approval letter. *Norwich Eaton Pharms., Inc. v. Bowen*, 808 F.2d 486, 491 (6th Cir. 1987); *Mead Johnson Pharm. v. Bowen*, 838 F.2d 1332, 1336 (D.C. Cir. 1988); *Unimed, Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989). In *Norwich*, the Sixth Circuit observed that the FDA adopted a regulation expressly providing that "[t]he date of the agency's approval letter is the date of the approval of the application." 808 F.2d at 491 (quoting 21 C.F.R. § 314.105(a)). The Sixth Circuit concluded that the FDA's regulation was reasonable and in line with its statutory mandate to review NDA applications and approve or disapprove them. *Id.* Accordingly, the Sixth Circuit concluded that FDA approval occurs when the FDA issues its approval letter and not when the FDA approves an applicant's labeling instructions or when the applicant receives the FDA approval letter. In *Mead*, the D.C. Circuit reached the same conclusion, also relying on the FDA regulation set forth in § 314.105(a) as well as the Sixth Circuit's decision in *Norwich*.

In *Unimed*, the Federal Circuit squarely addressed the issue in dispute here, *i.e.*, the timeliness of a PTE application which was filed nearly one year late due the applicant's belief that the sixty-day period set forth in § 156(d)(1) commenced after the Drug Enforcement Agency (DEA) rescheduled its narcotic drug to allow for commercial marketing. The Court reasoned that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date" and not the date of rescheduling by the DEA. *Unimed*, 888 F.2d at 828. Turning to consider what date qualifies as the approval date, the Federal Circuit then observed that "[a]ccording to the FDA, the date of marketing approval for all new drugs is the date appearing on its approval letters." *Id.* It also observed that both the Sixth Circuit in *Norwich* and the D.C. Circuit in *Mead* confirmed that the approval date for a new drug is the date of the FDA approval letter.

Given *Norwich*, *Mead*, and *Unimed*, there can be no doubt that the FDA approval date for ANGIOMAX® (bivalirudin) occurred on December 15, 2000, the date appearing on the FDA's approval letter for NDA 20-873 and subsequently confirmed twice by the FDA.

Turning to the time period triggered by FDA approval, § 156(d)(1) requires that an application for patent term extension of a patent which claims a product,² a method of using such product, or a method of manufacturing such product, wherein the product was subject to premarket regulatory review by a regulating agency, must be submitted, "within the sixty-day period beginning 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." 35 U.S.C. § 156(d)(1) (emphases added). Additionally, the implementing regulations mirror the language of §156 (d)(1): "[t]he application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the

² The term "product" is as defined in 35 U.S.C. § 156(f).

provision of law under which the applicable regulatory review period occurred” 37 CFR § 1.720(f) (emphases added). The phrases used in § 156 (d)(1) to define the time period, i.e., “within” and “beginning on,” are clear. See *Unimed*, 888 F.2d at 828 (characterizing the language used in § 156(d)(1) as “crystal clear”); see also *United States v. Inn Foods, Inc.*, 383 F.3d 1319, 1322 (Fed. Cir. 2004) (explaining, in the context of a statute of limitation, that terms such as “within [a particular time period]” and “beginning on” clearly specify a time period and need no further analysis). Thus, under both § 156(d)(1) and § 1.720(f), a PTE applicant has sixty days to submit a PTE application where the first day of that sixty-day period begins on the approval date.

In the present case, the FDA approved NDA 20-873 for ANGIOMAX® (bivalirudin) on December 15, 2000. The absolute deadline for filing the application for patent term extension was sixty days from December 15, 2000, starting the count of that sixty-day period on December 15, 2000. The sixtieth day of that time period was February 12, 2001. Applicant failed to meet that statutory deadline because it filed its patent term extension application on February 14, 2001, two days late.³ Consequently, Applicant’s PTE application was untimely filed under § 156(d)(1) and § 1.720(f), and the USPTO has no choice but to deny it.

b) The FDA Has Repeatedly Confirmed the Approval Date of ANGIOMAX® (bivalirudin) as December 15, 2000

Applicant argues that December 18, 2000, or alternatively, December 19, 2000, should be treated as the effective approval date for ANGIOMAX® (bivalirudin) because the FDA itself was confused as to the approval date, publishing two different approval dates on its website. Specifically, on its “NMEs Approved In Calendar Year 2000” webpage, the FDA listed the approval date for ANGIOMAX® (bivalirudin) as December 15, 2000. However, on its “NDA Approvals for Calendar Year 2000” webpage, it listed the approval date as December 19, 2000, as recently as March 23, 2002. Applicant’s argument is unavailing as the case law is quite clear. The FDA has consistently treated the date appearing on the FDA approval letter as the approval date. In fact, the FDA even promulgated a regulation, namely 21 C.F.R. § 314.105(a), to that effect. Thus, whether the FDA may have erroneously published the approval date as December 19, 2000, on its “NDA Approvals for Calendar Year 2000” webpage cannot alter the actual December 15, 2000, approval date found in the FDA approval letter. Additionally, the FDA has repeatedly informed the USPTO upon inquiry that the approval date for ANGIOMAX® (bivalirudin) is December 15, 2000.

Moreover, in Applicant’s original PTE application, Applicant indicated that the FDA approval date was December 15, 2000, in more than one location, as required by 37 C.F.R. § 1.740(a)(3), (10) and (11). 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 again stated: “The date on which the NDA was approved was 15 December 2000.” And, in paragraph (11), the chronology of regulatory events listed a communication from Julie

³ In the USPTO’s notice of final determination, it indicated that Applicant filed its PTE application for ANGIOMAX® (bivalirudin) on the sixty-first day after FDA approval. Upon reconsideration of the dates involved in this application, the USPTO notes that Applicant actually filed its PTE application on the sixty-second day after FDA approval. In other words, the USPTO observes that Applicant’s PTE application was not one day late, but instead two days late.

DuBeau to Sonja Loar on December 15, 2000, with the description, "Approval of Angiomax." Hence, even if the FDA was confused as to the approval date for ANGIOMAX® (bivalirudin), which it plainly was not given its two letters confirming an approval date of December 15, 2000, Applicant gave no indication that it was confused as to, or even questioned, the ANGIOMAX® (bivalirudin) approval date when it filed its PTE application on February 14, 2001.

Furthermore, that Applicant filed a supplemental application asserting that it was uncertain as to the approval date seven days after the USPTO sent a letter to the FDA requesting confirmation that the application was untimely filed does not change the fact that Applicant affirmatively listed the approval date as December 15, 2000, in its original PTE application. Thus, Applicant's "uncertainty" as to the approval date was first raised only after the USPTO revealed that it considered Applicant's PTE application to be untimely.

c) Fairness Considerations Cannot Alter the Statutory Language of § 156 as to the Deadline for Filing a PTE Application

Applicant argues that fairness weighs in favor of treating the effective approval date for ANGIOMAX® (bivalirudin) as December 18, 2000, since the drug is Applicant's first commercial product and since a denial is a disproportionately harsh penalty, counter to public policy, and counter to the intent of the Hatch-Waxman Act. While the USPTO appreciates the importance of ANGIOMAX® (bivalirudin) to Applicant and is aware of the impact a PTE denial may have on Applicant, the sixty-day statutory deadline is non-discretionary. That is, § 156(d)(1) neither provides for a grace period, nor gives the USPTO discretion to waive the sixty-day window. As such, the PTO is bound by statute to implement the provisions of § 156(d)(1), including the sixty-day deadline. What is more, fairness is not a factor in a statutory interpretation case such as this one. *See Unimed*, 888 F.2d at 829 ("[T]his is purely a case of statutory interpretation, so the equitable considerations raised by *Unimed* are inappropriate.").

2. Amended Request for Reconsideration

In its amended request for reconsideration, Applicant supplements the arguments it made in its first request for reconsideration, urging the USPTO to use its own judgment to determine the effective FDA approval date of NDA 20-873 for ANGIOMAX® (bivalirudin) instead of relying on the FDA for the approval date. More specifically, Applicant provides three arguments why the USPTO should not defer to the FDA's conclusion that the approval date is December 15, 2000. The USPTO will address these arguments in the order presented by Applicant.

a) The USPTO Independently Assessed the Timeliness of Applicant's PTE Application for the '404 Patent

Applicant asserts that the USPTO deferred to the FDA on the issue of whether the PTE application was timely submitted without question and that such deference runs afoul of basic principles of administrative law and statutory construction. Applicant also asserts that FDA's determination of the timeliness question is itself arbitrary, capricious, and contrary to law because the FDA failed to give a coherent reading to the statutory terms used in § 156(g)(1). Upon making an independent assessment of timeliness, Applicant asserts that the

USPTO should conclude that the effective approval date of ANGIOMAX®(bivalirudin) was December 18, 2000, or alternatively, December 19, 2000.

Applicant is correct that § 156 delineates the duties in the patent term extension process between the Director of the USPTO and the Secretary of Health and Human Services acting through the FDA. Additionally, Applicant is correct that FDA is charged with calculating the “regulatory review period,” and that the USPTO is charged with determining whether an application meets the statutory requirements for extension. That is, the USPTO must determine whether an application is in compliance with § 156(a)(1)-(5) and § 156(d). To determine compliance with § 156(d)(1), which requires a PTE application to “be submitted within the sixty-day period beginning 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,” the USPTO must ascertain the approval date of ANGIOMAX® (bivalirudin). Only then can the USPTO determine whether Applicant’s PTE application is timely filed within the meaning of § 156(d)(1). The USPTO, however, is not involved in the drug approval process; rather, the FDA approves new drugs via the IND and NDA processes. *See* Federal Food Drug & Cosmetic Act §§ 505(i) and 505(b), as codified in 21 U.S.C. § 355. And, while a PTE applicant includes the approval date in its PTE application, the USPTO has no way to verify that the date is accurate. Consequently, the USPTO must rely on the written records for drug approvals maintained by the FDA.

Here, the USPTO followed the above-described process in determining whether Applicant timely filed its PTE application for ANGIOMAX® (bivalirudin). In arguing that the USPTO failed to make an independent timeliness assessment, Applicant misapprehends the nature of the USPTO’s communications with the FDA. After reviewing Applicant’s original PTE application, the USPTO made an initial determination that the application was not timely filed based upon the December 15, 2000, approval date for ANGIOMAX® (bivalirudin) provided in paragraphs (3), (10), and (11) of Applicant’s PTE application. The USPTO communicated that independent initial determination to FDA via a letter on March 2, 2001, and requested the FDA’s assistance. Specifically, the USPTO stated in the letter:

The **assistance** of your Office is requested in confirming that the product identified in the application, Angiomax(bivalirudin), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. In addition, the **assistance** of your Office is requested in confirming that the application for patent term extension was NOT filed within sixty days after the product was approved. . . . **Our review** of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. 156.

(Emphases added). The use of the term “assistance” plainly shows that the USPTO made an independent decision over six years ago that Applicant’s PTE application was not timely filed in compliance with § 156(d)(1). It simply sought the FDA’s help in confirming that decision because of the FDA’s access to drug approval records, information outside the purview of the USPTO.

Then, after Applicant filed its first request for reconsideration on October 7, 2002, the USPTO wrote another letter to the FDA, again requesting the FDA's assistance: "The assistance of your Office is requested in preparing a reply to this request." In particular, the USPTO sought the FDA's help in addressing Applicant's argument that the approval date for ANGIOMAX® (bivalirudin) should be considered to be December 18, 2000, because the FDA gave its approval late in the day. Applicant's argument regarding the business practices of FDA with respect to communications relating to approvals of NDAs is misplaced. The USPTO has no control over any of the FDA's business practices. As such, Applicant is complaining to the wrong agency regarding the late day notice it received in this case.

Because the USPTO is informed of the approval date by a PTE applicant and has no independent knowledge of such date, the USPTO must avail itself of the approval records maintained by the FDA for confirmation of the date. Moreover, for nearly twenty years, it has been the USPTO's standard practice in processing PTE applications to request the FDA to confirm the approval date of an NDA as represented by an applicant in a PTE application. *See* 52 FR 17830, 17831 (May 12, 1987) (providing public notice of Memorandum of Understanding between USPTO and FDA and explaining that FDA is responsible for checking their records to determine whether the PTE application was timely filed). Consequently, Applicant's assertion that "[t]he PTO's approach thus far—its complete reliance on the FDA's view—raises the concern of arbitrary and capricious agency action" is false.

Applicant urges that the USPTO must engage in "reasoned decisionmaking" when it carries out its statutory obligation under § 156 of determining whether a patent is eligible for patent term extension. As pointed out above, the USPTO has engaged in reasoned decisionmaking throughout the patent term extension process for the '404 patent. First, it made an initial independent assessment of the eligibility of the '404 patent for patent term extension based on the regulatory review period for ANGIOMAX® (bivalirudin). After doing so, it confirmed that decision by letter on two occasions with the FDA, the agency having the official written records relating to approval of ANGIOMAX® (bivalirudin). More specifically, the USPTO asked the FDA to confirm Applicant's representation that the approval date of ANGIOMAX® (bivalirudin) was December 15, 2000, as represented, at least twice, in Applicant's PTE application. Following that confirmation from the FDA, the USPTO provided a notice of final determination and corrected notice of final determination that the '404 patent was not eligible for extension because the application for PTE was not timely filed. Finally, through the present decision, the USPTO is addressing Applicant's challenge to that determination and further explaining its reasoning for denying the extension. Accordingly, the USPTO has carried out its responsibility in deciding whether to grant Applicant's PTE application; it has not delegated that responsibility to the FDA, and is not merely sitting on the sidelines waiting for FDA's decision.

Next, Applicant argues that the USPTO's policies and rulemaking are designed to encourage and reward innovation, not produce an untimely and unnecessary loss of patent rights. In support, Applicant cites in a footnote to several sections of title 37 of the Code of Federal Regulations which permit late filings. The USPTO is not attempting to deny any patent rights to Applicant. As discussed earlier, the USPTO has no discretion under § 156 to waive the sixty-day time period for filing a PTE application. If an applicant fails to file its PTE application within this timeframe, then the USPTO is bound by statute to reject the application. Applicant's reliance on

late filing regulations sidesteps the fact that the patent term extension process is governed by statute. If an applicant is not satisfied with the provisions of that statute, then the fix lies with Congress.

Finally, Applicant points out that "there is simply no sound rationale for the [US]PTO to accept a contrary rule that would always deprive a patent holder of one or more days to commercially exploit its patent." The USPTO has not prevented Applicant from enforcing its patent rights in any way. Holding a patent does not give a patent owner an affirmative right to conduct commercial activities. Rather, it gives the patent owner the right to exclude another who, without authority, makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent.⁴ For the term of the '404 patent, Applicant may exclude another who seeks to make, use, offer to sell, or sell ANGIOMAX® (bivalirudin).

b) The USPTO Accepts the FDA's Determination of the Approval Date of ANGIOMAX® (bivalirudin)

Applicant asserts that the USPTO should not accept the FDA's conclusion with respect to the date of approval of the ANGIOMAX® (bivalirudin) because it is arbitrary, capricious, and contrary to law. Applicant's assertion is based on the statutory language "on the date," as found in § 156(g)(1)(B)(ii). That provision provides that the regulatory review period is to be calculated by reference to, *inter alia*, "the period beginning on the date the application was initially submitted for the approved product . . . and ending on the date the application was approved." Applicant claims that Congress, by using the term twice in the same sentence, intended for the date to be calculated in the same way for submissions and approvals. And, contrary to congressional intent, Applicant points out that the FDA treats submissions via facsimile to FDA, which are received after the close of business as received on the next business day, but considers approvals to occur on the calendar date that is stamped on the approval letter,⁵ regardless of the time of day such letter was faxed by FDA to the NDA applicant.

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. In the context of the patent term extension process, the USPTO must gather the necessary facts and apply the laws and regulations to assess the eligibility of an applicant's PTE application. Even though Applicant takes issue with FDA's business practice regarding communication of NDA approvals to NDA applicants, the USPTO cannot override the clear regulatory language of 21 C.F.R. §§ 314.105(a) and 314.108(a). Those provisions expressly provide that the date of approval is the date appearing on the letter to the NDA applicant. See 21 C.F.R. § 314.105(a) (providing in pertinent part that "[a]n approval becomes effective on the date of the issuance of the approval letter, except with regard to an

⁴ See 35 U.S.C. § 271.

⁵ Applicant accurately points out that 21 C.F.R. § 314.108 defines "date of approval" to mean the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. "Date of approval" refers only to a final approval and not to a tentative approval that may become effective at a later date.

approval under section 505(b)(2) of the act with a delayed effective date”) and 21 C.F.R. § 314.108(a) (providing in pertinent part that “[d]ate of approval means the date on the letter from FDA stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required. “Date of approval” refers only to a final approval and not to a tentative approval that may become effective at a later date). Here, the uncontested date of the approval letter was December 15, 2000. Accordingly, the USPTO must use that date as the trigger for the sixty day time period within which Applicant had to submit its PTE application.

**c) The Correct Date of Approval of ANGIOMAX® (bivalirudin)
is December 15, 2000**

Applicant challenges the way the FDA communicated approval of NDA 20-873 for ANGIOMAX® (bivalirudin) to Applicant and the date afforded the approval letter. Specifically, in the case of ANGIOMAX® (bivalirudin), Applicant contends that the FDA failed to follow its internal procedures for communicating approval of NDA 20-873, sending two approval letters with different time stamps, though both date-stamped December 15, 2000, and posting conflicting approval dates on its website.

Even if Applicant is correct that the FDA did not employ best practices in communicating approval of NDA 20-873 to Applicants, and that the FDA failed to follow internal procedures in the case of ANGIOMAX® (bivalirudin), the USPTO plays no role in those communications and is not in the position to change the FDA’s procedures. As repeatedly explained, the USPTO cannot ignore the plain language of the ANGIOMAX® (bivalirudin) approval letter that the USPTO independently reviewed and that states: “Accordingly, the application is approved effective on the date of this letter.” The letter was date-stamped December 15, 2000, which Applicant does not dispute. Thus, consistent with 21 C.F.R. § 314.105(a), there can be no doubt that the FDA approved ANGIOMAX® (bivalirudin) on December 15, 2000, triggering day one of the sixty-day period for filing a PTE application.

**d) Equity Considerations With Respect to Approval Date of
ANGIOMAX® (bivalirudin)**

Applicant largely repeats the equity arguments it made in its first request for reconsideration as reasons why the USPTO should consider the approval date of ANGIOMAX® (bivalirudin) to be December 18, 2000, or December 19, 2000, including that the denial of an extension is contrary to public policy and exacts a disproportionately harsh penalty. As Applicant is quick to point out, the USPTO is charged with the duty of administering patent term extensions under Title II of the Hatch-Waxman Act, codified in § 156. The provisions of that statute do not give the USPTO any discretion to permit late PTE application filings, a point repeated above more than once. Additionally, the facts and figures Applicant sets forth in the amended request for reconsideration regarding the time, money, and work involved in developing ANGIOMAX® (bivalirudin), although informative, are not relevant in the face of the statutory constraints of § 156. Accordingly, since the USPTO regards the approval date as December 15, 2000, based on the date stamped on the FDA approval letter, the USPTO must reject Applicant’s PTE application as filed two days after the sixty-day statutory window.

Applicant provides arguments relating to the life-saving potential of ANGIOMAX® (bivalirudin) under the heading, "The Public May Benefit Enormously From Angiomax's Life-Saving Potential." Speculation about possible additional indications for ANGIOMAX® (bivalirudin) is not relevant to whether Applicant complied with section 156(d)(1). Section 156 of the statute does not include any provisions for considering such issues. Therefore, the USPTO must administer the statutory provisions of § 156 without regard to the economics of drug development and regulatory requirements for marketing new drug products.

Moreover, Applicant is not left without any protection for new uses for ANGIOMAX® (bivalirudin) after the expiration of the '404 patent. When new clinical tests are required for approval of an additional indication for a previously marketed drug, the FDA provides data exclusivities for such information subject to the new clinical investigations.⁶

Applicant further adds that extension of the '404 patent will not harm the rights or legitimate interests of third parties. Contrary to this argument, a generic producer seeking to enter the market and sell a generic version of ANGIOMAX® (bivalirudin) would, without litigation, have to wait more than four years beyond the original expiration date of the '404 patent if the USPTO granted a certificate of extension for the amount of term sought by Applicant. Hence, Applicant's contention is unavailing.

e) USPTO Precedent Permits the USPTO to Make an Independent Determination of the Approval Date of the NDA for ANGIOMAX® (bivalirudin)

Applicant conducted research into the USPTO's past administration of § 156 and found that, although rare to deny a PTE because of a late filing, the USPTO has done so in the past on four occasions for the anti-nausea drug related to marijuana (litigated in *Unimed*) and the drug products Vantin®, Saraflox, and Kadian®. Applicant contends that the circumstances in those cases were different from those here. Because of those factual differences, Applicant appears to implicitly suggest that the USPTO should not deny a patent term extension in this case.

Just because the four prior PTE denials on timeliness grounds involved facts distinguishable from those here does not mean that the USPTO should grant Applicant's PTE application. The USPTO must evaluate each PTE application on the facts presented therein and in turn deny those applications that fail to comply with the provisions of § 156. Therefore, it is irrelevant how many times the USPTO has denied other PTE applications for different drug products based on considerations of timeliness under § 156(d)(1).

3. Amended Application for Patent Term Extension

On March 13, 2007, Applicant filed an amended application for patent term extension. This amended application has been entered into the records of the USPTO. In the amended application for PTE, Applicant indicates the approval date for NDA 20-873 for ANGIOMAX® (bivalirudin) should be considered December 18, 2000, or alternatively, December 19, 2000, in compliance with 37 C.F.R. § 1.740(3) and (10) and provides the calculation of term pursuant to 37 C.F.R. § 1.775 in paragraph (12) using the alternative dates. However, the amended

⁶ See 21 C.F.R. § 314.108.

application also indicates that on December 15, 2000, Julie DuBeau of FDA communicated to Sonja Loar of The Medicines Company, "Approval of Angiomax" in compliance with 37 C.F.R. § 1.740(11). As repeatedly explained above, the USPTO considers the approval date of the NDA 20-873 for ANGIOMAX® (bivalirudin) to be December 15, 2000.

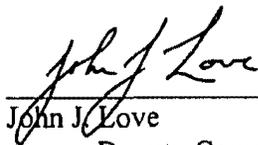
D. Conclusion

In sum, Applicant has accurately pointed out that the USPTO can and should make its own determination as to the appropriate approval date of ANGOMAX® (bivalirudin) for purposes of § 156(d)(1). As the USPTO explained in its letter of March 2, 2001, it relied on the approval date of December 15, 2000, a date presented in three places in Applicant's PTE application. Based upon that approval date, the USPTO determined that Applicant's PTE application was not timely filed. The USPTO then, consistent with its standard practice as set forth in its Memorandum of Understanding with the FDA, verified that determination by consulting with the FDA as to the approval date for ANGIOMAX (bivalirudin), since the FDA maintains all drug approval records. Moreover, regardless how the FDA communicated its approval of NDA 20-873 to Applicant, the FDA's approval letter clearly stated that the approval is effective on the date of the letter, and the letter was date-stamped December 15, 2000. Such treatment is consistent with § 314.105(a), which provides that the approval date of a drug product is the date of the approval letter, and with Federal Circuit precedent. Accordingly, because Applicant filed its PTE application two days late, the application for patent term extension under § 156 is denied. This decision may be viewed as a final agency action.

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