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Hollie L. Baker
Donald R. Steinberg
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

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

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[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

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[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 USTPO 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.

Further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

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

John J. Love

John J. Love
Deputy Commissioner for Patent Examination Policy
Commissioner for Patents
United States Patent and Trademark Office