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

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

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

A. Factual Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23. On March 16, 2010, the district court issued a memorandum opinion and order vacating the denial of the PTE application and remanding the case to the agency for reconsideration "as to the date of approval under § 156." *The Medicines Co. v. Kappos*, Civ. Act. No. 01:10-cv-81, slip op. at 18 ("District Court Decision"). The district court explained that the USPTO erroneously believed that its construction of the term "date" in section 156(d)(1) to mean "calendar day" was compelled by the statute and that it lacked any discretion to adopt Applicant's proffered "business day" construction. *Id.* at 10. The district court also identified four argument that Applicant made to support its "business day" construction, including: "§ 156(d)(1)'s focus on the date approval was received, the purpose of § 156(d)(1), the need to ensure that all applicants received the 60 days to file extension applications that Congress required[,] and the ways in which its interpretation of date in combination with its new counting rule is inconsistent with that requirement." *Id.* at 11. The

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

B. Decision

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

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

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

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

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

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

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

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

35 U.S.C. § 156(d)(1) (emphases added). To determine what the term "date" means, the USPTO looks to the words surrounding that term, namely the phrase "the product received permission . . . for commercial marketing or use." A drug product "receive[s] permission . . . for commercial marketing or use" when the FDA approves the drug. Section 355(a) of Title 21 makes this clear. It provides: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." 21 U.S.C. § 355(a). The requirement that all "new drugs" obtain approval from FDA before they may be distributed in interstate commerce is the linchpin of drug regulation under the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. §§ 331(d).

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

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

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

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

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