IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

THE MEDICINES COMPANY, Plaintiff,	)	
v.	)	Civil Action No. 01:10-cv-81
DAVID KAPPOS, et al., Defendants.	)	

MEMORANDUM OPINION

This is a civil action under the Administrative Procedure Act, 5 U.S.C. §§ 551-706, seeking to set aside the denial of an application - pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (commonly known as the "Hatch-Waxman Act") - to extend the term of a pharmaceutical patent exclusively licensed to Plaintiff. This matter comes before the Court on the parties' cross-motions for summary judgment.

The Medicines Company ("MDCO") is a pharmaceutical company that specializes in developing acute care medicines that larger pharmaceutical companies have chosen not to pursue. This case involves an anticoagulant called ANGIOMAX. This drug works by directly inhibiting a key contributor to the formation of blood clots.

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

A new drug cannot be commercially marketed or used until the FDA approves it under § 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"). See 21 U.S.C. § 355(a). The process of securing FDA approval is extraordinarily time consuming and expensive. A new drug applicant must conduct clinical studies and submit detailed information. Id. § 355(b)(1); 21 C.F.R. § 314.50. The FDA must then determine whether the drug is safe and effective. During this process, the applicant receives no commercial benefit from any patents on the drug.

Congress enacted Title II of the Hatch-Waxman Act, which is codified in relevant part at 35 U.S.C. § 156. Under § 156, the holder of a drug patent or its agent is entitled to apply for a patent term extension "to compensate for the delay in obtaining FDA approval." Merck & Co. v. Kessler, 80 F.3d 1543, 1547 (Fed. Cir. 1996); see also In re Patent No. 4,146,029 (Comm'r Pat. July 12, 1988)("SynchroMed Decision") at 3 ("Since § 156 was intended to restore a part of the effective patent life. . ., § 156 can be viewed as remedial in nature."); Hoechst-Roussel Pharm., Inc. v.

Lehman, No. 95-650-A, 1995 U.S. Dist. LEXIS 22485, at *8 (E.D. Va. Oct. 25, 1995) (Section 156 "was intended to compensate those patent owners who lost time to market a patented product while that product awaited FDA approval."), aff'd, 109 F.3d 756 (Fed. Cir. 1997). The purpose of the Act is to "encourage[] drug manufacturers to assume the increased costs of research and development of certain products which are subject to premarketing clearance." H.R. Rep. No. 98-857, pt. 2, at 11 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2695.

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

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

holder or its agent must submit an application to the PTO "within the sixty-day period beginning on the date the product received permission . . . for commercial marketing or use." Id. § 156(d)(1).

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

MDCO filed its patent term extension application on February 14, 2001 under the Hatch-Waxman Act. Such an extension would change the expiration date of the '404 patent from March 23, 2010 to December 2014. There is no dispute that MDCO satisfied all of

the substantive requirements of 35 U.S.C. § 156.

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

On December 18, 2001, MDCO received an undated Notice of Final Determination" from the PTO denying MDCO's application. The Notice accepted the FDA's view that ANGIOMAX was approved on December 15, 2000 and that the extension application was untimely because it was filed one day late. On March 4, 2002, the PTO issued a corrected decision that was in relevant respects identical to the original.

The FDA treats submissions to the FDA received after its normal business hours differently than it treats communications from the agency after normal business hours. The agency considers the date of submission of a new drug application received after 4:30 p.m. EST to be the next business day. If an applicant submits an electronic application or sends a fax to the FDA at 6:17 p.m. on a Friday night, the FDA will deem that application to be submitted on the following Monday (or Tuesday, if the Monday is a federal holiday). This FDA practice has the consequence of making the regulatory review period defined in §

156(g) commence days later than if the application was considered submitted on Friday and can operate to reduce the overall length of the patent term extension granted.

For communications from the FDA, the agency takes the position that whether the communication is sent after the close of business is irrelevant. If the FDA faxes an approval letter at 11:59 p.m., it will treat the letter as if it had been issued earlier that day during business hours.

On October 2, 2002, MDCO filed a timely Request for Reconsideration with the PTO. Among other things, MDCO pointed out that the FDA approval letter for ANGIOMAX was faxed after business hours on a Friday evening, and that under FDA's practices, facsimiles submitted to FDA after the close of business are considered received by the Agency on the next business day. For that reason, MDCO asked the PTO to treat December 18, 2000 as the effective approval date of ANGIOMAX®, and would have made MDCO's February 14, 2001 application timely.

On March 24, 2003, the PTO sent the FDA a copy of MDCO's request and asked the FDA to determine whether the application was timely. On November 2, 2006, the FDA issued a reply reiterating that Angiomax was approved on December 15, 2000. Although the FDA noted MDCO's position that the approval was not effective until December 18, 2000 because the December 15, 2000 letter was transmitted after normal business hours, the FDA

failed to provide any explanation why it found that contention unpersuasive. The FDA did not dispute that when calculating the length of regulatory review periods under 35 U.S.C. § 156(g), it deems submissions to the agency after normal business hours as having been filed on the next business day, but deems an approval transmitted from the agency after normal business hours to be effective as of the date on the letter.

On February 12, 2007, before the PTO issued a decision on MDCO's Request for Reconsideration, the agency granted MDCO's request to file an amended extension application and amended request for reconsideration. MDCO filed the amended papers on March 13, 2007.

On April 26, 2007, the PTO denied MDCO's Request for Reconsideration. The PTO offered no explanation of what it acknowledged was the FDA's seemingly inconsistent approach to determining the effective date of submissions to the agency and communications from the agency. Rather, it indicated that any challenge to the FDA's approach must be raised with the FDA. Using the FDA's December 15, 2000 approval date, the PTO also determined that MDCO's application was filed two days after the 60-day period expired. The change in the PTO's calculation was due to a change in the agency's interpretation of § 156(d)(1) that was apparently announced for the first time in its reconsideration decision in this case.

For years, in applying § 156(d)(1)'s 60-day deadline, the PTO followed the general rule of starting the count on the first day after the triggering event. In its 2007 Decision, however, the PTO concluded that it had been misreading § 156(d)(1). It then changed course and announced that it would count the date of FDA approval as one of the sixty days included in the time period for filing a PTE application. In re Patent Term Extension Application for U.S. Patent No. 5,817,338, 2008 WL 5477176 (Comm'r Pat. Dec. 16, 2008) ("Prilosec Decision"). Applying this new interpretation, the PTO or the FDA has taken the position that at least seven applications for patent term extensions were untimely, even though they would have been timely under the PTO's prior interpretation of § 156(d)(1). Moreover, as this case demonstrates, the PTO takes the view that the date of FDA approval counts as the first day of the 60-day period even where the application is not approved until after the close of business – that is, as late as 11:59 p.m – and the PTO's interpretation can thus mean that an applicant is afforded only 59 days rather than 60 days.

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

interpretation of the date on which that period begins.

MDCO contended that the PTO had the authority to treat new drugs approved by the FDA after business hours as having received permission for purposes of § 156(d)(1) on the following business day. MDCO argued that the date a product receives permission for commercial marketing and use under § 156(d)(1) need not in all circumstances be the same as the date a new drug is approved for purposes of marking the end of the regulatory review period under § 156(g)(1)(B)(ii). It also explained that where the FDA transmits notice of approval after normal business hours, a next business day rule comports with the statute's text and purpose. This is especially so given the recent decision of the PTO to count the date of FDA approval as the first day of the 60-day period, as opposed to its previously established practice of starting the counting period on the first day after the triggering event. Unless the PTO adopted a next business day rule for after-hour approvals, it would effectively deprive many patent applicants of one of the 60 days Congress granted them for seeking extensions under § 156. Finally, MDCO argued that if the PTO rejected a next business day rule for § 156(d)(1) and concluded that it was bound to give § 156(d)(1) the same meaning that the FDA has given § 156(g)(1)(B)(ii), then it would be required to reconcile its decision with the FDA's inconsistent interpretation of the word date in § 156(g)(1)(B)(ii).

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

In reaching this conclusion, the PTO rejected MDCO's argument that the date a drug receives permission for commercial marketing or use can in some circumstances be distinct from the date the drug was approved for purposes of the FDA's calculation of the period of regulatory review. It held that the date stamped on a NDA approval letter, which the FDA terms the effective date of an approval, is the appropriate trigger date for § 156(d)(1). The PTO also held that MDCO's submission was foreclosed by the text of § 156 because a particular date spans the course of 24 hours; it does not end with the close of business. The PTO made no attempt to reconcile this position with the FDA's own practice

of treating submissions to the agency after the close of business as being received the next business day. The PTO also did not address § 156(d)(1)'s focus on the date approval was received, the purpose of § 156(d)(1), or the need to ensure that all applicants receive the 60 days to file extension applications that Congress required and the ways in which its interpretation of date in combination with its new counting rule is inconsistent with that requirement.

The Administrative Procedure Act ("APA") requires the Court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); see Arnold P'ship v. Dudas, 362 F.3d 1338, 1340 (Fed. Cir. 2004) (APA applies to denial of patent term extension application). Agency action is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Agency action resting on an inconsistent or self-contradictory explanation is, by definition, arbitrary and

capricious. See, e.g., Lee Lumber & Bldg. Material Corp. v. NLRB, 117 F.3d 1454, 1460 (D.C. Cir. 1997); Air Line Pilots Ass'n v. FAA, 3 F.3d 449, 453 (D.C. Cir. 1993).

The Court's review here is further shaped by the remedial nature of the statute at issue. As the PTO has explained, § 156 is "intended to restore a part of the effective patent life that had been diminished through the delays which are necessary in regulatory review and approval of the product." In re Patent No. 4,146,029 (Comm'r Pat. July 12, 1988)("SynchroMed Decision") at 3 ; see also Merck, 80 F.3d at 1547 (§ 156 is designed to "compensate for the delay in obtaining FDA approval"). The PTO thus previously held that the timing provisions of § 156(d) should be "liberally construed . . . to carry out its purpose" so that "justice may be done to both the patentees and the public." SynchroMed Decision at 3; see United States v. Article of Drug . . . Bacto-Unidisk . . ., 394 U.S. 784, 798 (1969) (it is a "well-accepted principle that remedial legislation . . . is to be given a liberal construction consistent with [its] overriding purpose").

There is a strong presumption that when Congress repeats the same word in the same statute, it intends for that word to be given the same meaning. In this case, the PTO and the FDA interpreted the word date to have two different meanings in the very same provision, and the PTO offered no explanation for that

inconsistency. The PTO also misperceived the scope of its authority. The PTO believed that it was precluded from adopting a business hours interpretation of the word date in § 156(d)(1). But, neither the statutory text nor any other authority forecloses that reading. While the PTO believed that the term date can only be construed to mean calendar day, the statute cannot be so inflexible because the FDA interprets the same word in the same section to mean business day.

The PTO incorrectly thought a business hours interpretation was foreclosed and did not consider central arguments MDCO advanced, and gave no reason for rejecting them.

The PTO erroneously believed that it was compelled to follow the FDA's interpretation of the provision of § 156 (g)(1)(B)(ii) marking the end of the regulatory review period. The agency also incorrectly believed that a business hours interpretation of § 156(d)(1) was foreclosed by the plain text of the statute, Federal Circuit precedent, and its own regulations. Because it believed its hands were tied, the PTO never even considered whether it should exercise its discretion to adopt a "business hours" rule. Indeed, the PTO must have believed it had no option but to construe the statute as it did: Had the PTO recognized any statutory ambiguity, it should have addressed in its decision the issues raised by MDCO.

None of the authorities cited by the PTO actually constrain

its authority to adopt such a rule in this case. The PTO erred in believing that its interpretation of § 156(d)(1) was compelled by the plain meaning of the word date. The agency asserted, without citation or explanation, that a particular date spans the course of 24 hours; it does not end with the close of business. The PTO believed that MDCO's proposed business hours interpretation was contrary to statute and would require it to put words into the statute that are not there.

This does not fulfill the PTO's obligations under the APA. The PTO provided no analysis of the putative plain meaning it assigned to the term, the ways in which the term is used throughout § 156, the differing contexts of the usage, or the regulatory impact of competing alternative interpretations. It merely asserted that the term date in § 156(d)(1) must be a calendar day and could not be a business day.

The PTO's assertion about the plain meaning of date plainly conflicts with the FDA's interpretation of the same word in the *same* statute to mean precisely what the PTO says it cannot mean. When a new drug application is filed with the FDA after normal business hours, the FDA deems the date the application was submitted to be the next business day. The PTO, however, did not provide any rationale to reconcile these competing constructions of the statute.

The PTO also incorrectly concluded that Unimed, Inc. v.