FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

2010 JAN 27 P 3:20

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

THE MEDICINES COMPANY,

Plaintiff,

v.

DAVID KAPPOS, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office; UNITED STATES PATENT AND TRADEMARK OFFICE; MARGARET A. HAMBURG, in her official capacity as Commissioner of the United States Food and Drug Administration; UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

No. 1:10cv81-CMH/TCB

COMPLAINT

Plaintiff The Medicines Company ("MDCO"), for its Complaint against Defendants David Kappos, United States Patent and Trademark Office ("PTO"), Margaret A. Hamburg, United States Food and Drug Administration ("FDA"), Kathleen Sebelius, and United States Department of Health and Human Services ("HHS"), hereby alleges as follows:

Nature of Action

1. 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 MDCO. A copy of the patent at issue—United States Patent No. 5,196,404 (the "'404 patent")—is attached as Exhibit 1.

2. Under the Hatch-Waxman Act, a request for patent term extension ("PTE") must be filed within 60 days after a patented drug "received permission ... for commercial marketing or use." 35 U.S.C. § 156(d)(1). In this action, MDCO challenges the denial of its application to extend the term of the patent covering its drug ANGIOMAX®—a life-saving anticoagulant used in coronary angioplasty procedures—on the ground that the application was not timely filed. MDCO received notice of the FDA's approval of ANGIOMAX after business hours on Friday, December 15, 2000, and filed its patent term extension application on February 14, 2001—within 60 days after December 18, 2000, the first business day following receipt of the notice.

3. Nonetheless, the PTO initially contended that MDCO's lawyers had filed the application a single day late based on PTO's understanding of the "date" when the applicable 60-day period began to run. On reconsideration, interpreting the same statute, the PTO told MDCO that it had filed the application *two* days late. Both decisions interpreted the statutory deadline in a manner flatly inconsistent with the government's interpretation of the *same* word—"date"—in another provision of the *same* statutory section defining when a new drug application is "initially submitted." *See* 35 U.S.C. § 156(g)(1)(B)(ii). Thus, under the government's approach to this statute, an application for approval of a new drug received by the FDA after business hours is deemed to be filed on the *following* business day. By contrast, when a new drug application is approved after business hours, the government deems the approval to have occurred on the *same* business day and takes the position that this day starts the 60-day period for filing a patent term

extension application. Despite this inconsistency, the PTO somehow concluded that its interpretation was mandated by statute and regulation.

4. The PTO's decision is not merely arbitrary and capricious; it is profoundly unfair and undermines the remedial design of the patent term restoration system. The decision furthers no statutory purpose yet threatens to inflict enormous harm on MDCO. MDCO spent over $200 million to develop ANGIOMAX, and sales of ANGIOMAX account for substantially all of MDCO's revenue. But even more important are the public health consequences of the PTO's flawed interpretation. Without an extension of the ANGIOMAX patent, no company will have the financial means and incentive to conduct research into new uses of ANGIOMAX to treat life-threatening conditions like heart attack and stroke. Furthermore, by erecting an arbitrary barrier to obtaining patent term extensions, the PTO's position would erode the Hatch-Waxman Act's incentives designed to encourage the expensive, time consuming, and risky research and development necessary to bring a new drug to market.

5. Neither the statute, the regulations, nor common sense mandates such a result. The process of developing, testing, and obtaining regulatory approval for the use of ANGIOMAX took over a decade and consumed over seven years of MDCO's patent term. Recognizing that this type of regulatory delay substantially diminishes the effective life of a patent, Congress enacted remedial legislation specifically mandating that patent terms be restored to compensate companies for the economic value lost during the review period, thereby preserving the incentive to create, develop, and secure regulatory approval for innovative new drugs. There is no dispute that MDCO has met the substantive requirements of the Hatch-Waxman Act and, but for the question of its application's timeliness, is entitled to an extension. For the reasons set forth below, the PTO's decision that MDCO's application was not timely

filed should be set aside and the matter remanded to the PTO with instructions that it accept MDCO's patent term extension application as timely filed.

Parties

6. Plaintiff MDCO is a Delaware corporation headquartered in New Jersey that is engaged in the business of developing acute care medicines. It is the exclusive licensee of the '404 patent.

7. Defendant David Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the PTO. Mr. Kappos is sued in his official capacity as Director.

8. Defendant PTO is a federal agency within the Department of Commerce that is headquartered in Alexandria, Virginia.

9. Defendant Margaret A. Hamburg is the Commissioner of the FDA. Ms. Hamburg is sued in her official capacity as Commissioner.

10. Defendant FDA is a federal agency within the United States Department of Health and Human Services that is headquartered in Silver Spring, Maryland.

11. Defendant Kathleen Sebelius is the Secretary of Health and Human Services. Ms. Sebelius is sued in her official capacity as Secretary.

12. Defendant HHS is a federal agency headquartered in the District of Columbia.

Jurisdiction and Venue

13. This Court has jurisdiction over this action—which arises under 5 U.S.C. §§ 702 & 704, 28 U.S.C. § 2201, and 35 U.S.C. § 156—pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361.

14. There exists between the parties an actual, justiciable controversy as to which MDCO requires a declaration of its rights by the Court.

15. MDCO challenges final agency actions.

16. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1) because Defendants Kappos and PTO reside in the Eastern District of Virginia.

17. Venue is proper in this Division pursuant to Local Civ. R. 3(C) because Defendants Kappos and PTO reside in the Alexandria Division.

Statutory Framework

18. 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"), 21 U.S.C. § 355(a). The process of securing FDA approval for a new drug is extraordinarily time consuming and expensive. A new drug applicant must conduct clinical studies and submit detailed information to the FDA. *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.

19. Concerned that this shortening of the effective patent term was diminishing the incentive to create and develop innovative new drug products, 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). The Act is thus remedial, and its ultimate purpose 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. II, at 11 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2695.

20. 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 "begin[s] on the date the [new drug] application was initially submitted ... and end[s] on the date such application was approved." 35 U.S.C. § 156(g)(1)(B)(ii). Subject to specified caps and adjustments, the length of the testing phase and the approval phase determine the length of the extension. *Id.* § 156(c)(1)-(2).

21. In order to seek a patent term extension, the patent holder or its agent must file a detailed application with the PTO. *See id.* § 156(d)(1). Such an application must contain, among other things, "the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or method of using or manufacturing the approved product"; "information to enable the Director [of the PTO] to determine ... the eligibility of [the] patent for an extension"; detailed "information to enable [determination of] ... the period of the extension"; and a "brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities." *Id.*; *see also* 37 C.F.R. § 1.740.

22. The Hatch-Waxman Act also sets the time for filing an extension application. 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 different language to begin the time period for filing an extension application. To request a patent term 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." 35 U.S.C. § 156(d)(1) (emphasis added).

23. If a patent relates to a human drug product (as does the '404 patent), responsibility for reviewing an extension application is shared by the Director of the PTO and the Secretary of HHS. The Secretary has delegated her authority to the FDA. 2 FDA Staff Manual Guides § 1410.10(1)(A)(25), *available at* http://www.fda.gov/AboutFDA/Reports ManualsForms/StaffManualGuides/ucm080711.htm; *see also* 69 Fed. Reg. 17285-01 (Apr. 2, 2004). Under § 156, the Director 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) at issue here—"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).

24. A 1987 Memorandum of Understanding ("MOU") 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). "The MOU establishes procedures whereby FDA assists PTO in determining a product's eligibility for patent term restoration and procedures for exchanging information between FDA and PTO regarding regulatory review period determinations, due diligence petitions, and informal FDA hearings." *Id.* at 17,830. Among other things, the MOU asks the FDA to "[i]nform PTO whether [a] patent term restoration application was submitted within 60 days after the product was approved." *Id.* at 17,831.

The Development and Approval of ANGIOMAX

25. MDCO is an innovative pharmaceutical company that specializes in developing acute care medicines that larger pharmaceutical companies have chosen not to pursue. This case

involves one such drug, a life-saving anticoagulant called ANGIOMAX. ANGIOMAX works by directly inhibiting a key contributor to the formation of blood clots. *See* Product Monograph: Angiomax 4-6, *available at* http://www.themedicinescompany.com/pdf/ANG-PMN-011-06_Product_Monograph.pdf. The drug has the potential to become the leading replacement for heparin, an animal-based anticoagulant that was discovered almost 100 years ago. A recent study demonstrated that using ANGIOMAX instead of heparin in severe heart attack patients reduces bleeding by about 50%. *See* Daniel P. Kessler, *The Effects of Angiomax on Health Care Costs and Outcomes* (Nov. 5, 2009).

26. The active ingredient in ANGIOMAX—a chemical called bivalirudin—is covered by the '404 patent, which is exclusively licensed to MDCO. The rights to the '404 patent were initially assigned to two companies other than MDCO, one of which became the exclusive licensee in June 1990. After extensive testing and research beginning in 1990, that company decided not to develop bivalirudin for commercial use. MDCO obtained an exclusive license to the rights to bivalirudin in 1997. It then proceeded to invest over $200 million to develop the drug ANGIOMAX for use in angioplasty procedures.

27. 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 after the close of business—at 6:17 p.m.—on Friday, December 15, 2000. *See* Ex. 2. It was not until the next business day, Monday, December 18, 2000, that MDCO issued a press release announcing the FDA's approval of ANGIOMAX. *See* Ex. 3. The FDA then published the approval date for ANGIOMAX as December 19, 2000 in one place on its website. *See* Ex. 4. The week after the FDA faxed its approval letter, MDCO received a second copy of the letter by U.S. mail. That copy did not include a date stamp, but appended an

electronic signature page indicating that the letter was signed at 5:18 p.m. on December 15, 2000. *See* Ex. 5.

Administrative Proceedings

A. MDCO's PTE Application and Initial FDA and PTO Decisions

28. MDCO filed its patent term extension application on February 14, 2001. *See* Application Pursuant to 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.740 for Extension of Patent Term (Ex. 6 (with exhibits)). The application demonstrated that, because of the lengthy period that had been necessary for testing and FDA review of ANGIOMAX, MDCO was entitled to the maximum extension permitted 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(d).

29. MDCO's initial application incorrectly stated that ANGIOMAX received permission for commercial marketing on December 15, 2000 and omitted a certification of timeliness. The PTO referred the question of the application's timeliness to the FDA in a letter dated March 2, 2001. *See* Letter from Karin Tyson to David T. Read (Mar. 2, 2001) (Ex. 7). Before the FDA replied, MDCO filed a supplemental submission explaining that the certification of timeliness in its application had been crossed out by counsel by hand prior to filing "out of an abundance of caution" based on "uncertainty as to what the approval date really was." *See* Supplemental Submission for Application Pursuant to 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.740 for Extension of Patent Term (Ex. 8 (without exhibit)). The submission attached a printout of the page on the FDA's own website that listed the approval date for ANGIOMAX as December 19, 2001, and included an updated statement indicating that the application was

timely. The PTO forwarded MDCO's supplemental submission to the FDA. *See* Letter from Eric P. Schelin to David T. Read or Claudia Grillo (Mar. 9, 2001) (Ex. 9).

30. By letter dated September 6, 2001, the FDA asserted that ANGIOMAX "was approved on December 15, 2000." Letter from Jane A. Axelrad to Q. Todd Dickinson (Sept. 6, 2001) (Ex. 10). The FDA further asserted that "the submission of the patent term extension application on February 14, 2001"—61 days after December 15, 2000—was "untimely within the meaning of 35 U.S.C. § 156(d)(1)." *Id.* Although it had been called to the agency's attention, the FDA did not address the fact that a page on its own website listed the approval date for ANGIOMAX as December 19, 2000.

31. On December 18, 2001, MDCO received an undated "Notice of Final Determination" from the PTO denying MDCO's application as untimely. *See* Ex. 11. Rather than determine for itself the date ANGIOMAX "received permission" for marketing and use under § 156(d)(1), the PTO deferred to the FDA's view (contained in its September 6, 2001 letter) that ANGIOMAX "was approved on December 15, 2000" and that "the submission of the patent term extension application ... [was] untimely." In light of the FDA's conclusion, the PTO found that MDCO's application was a *single day* late and held that MDCO's "application must be dismissed as untimely."

32. Because the Notice misidentified the active ingredient of ANGIOMAX and was undated, MDCO asked the PTO to issue a corrected notice, which the PTO did on March 4, 2002. *See* Ex. 12. Other than changing the active ingredient information and adding a date, the Corrected Notice was identical to the original Notice.

B. The FDA's Inconsistent Treatment of Submissions and Notifications after Normal Business Hours

33. It is undisputed that the FDA treats submissions that it receives after normal business hours differently than it treats communications from the agency that occur after normal business hours. For submissions to the agency, the FDA considers whether the submission is received during or after normal business hours. Specifically, the agency considers new drug applications submitted after 4:30 p.m. EST to have been received on the next business day. *See* http://www.fda.gov/ForIndustry/ ElectronicSubmissionsGateway/ucm114807.htm ("If your submission was received ... after 4:30 PM EST, the official receipt date for the submission is the next government business day."). Thus, when the FDA determines the beginning of the regulatory review period specified in § 156(g)(1)(B)(ii), it deems an application received by the FDA after business hours to have been "initially submitted" on the next business day. Indeed, the FDA has never disputed that it has a general policy of treating after-hours submissions to the agency as having been received the following business day. *See, e.g.*, Center for Drug Evaluation and Research, FDA, *Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products* 4 (2000) (Ex. 13); *see also* Center for Biologics Evaluation and Research, FDA, *Manual of Standard Operating Procedures and Policies* § 8113, *available at* http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ ProceduresSOPPs/ucm079472.htm (providing that an incoming facsimile "must be received before 4:30 PM (16:30) EST(DST) on a regular business day in order for the received date to be the same date" and that "[i]f the facsimile is received after that time or on a non-business day, the receipt date will be the next business day"). Accordingly, 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

treat the submission as if it had been made on the following Monday (or Tuesday, if the Monday is a federal holiday).

34. By contrast, for communications *from* the FDA, the agency takes the position that whether the communication is sent after the close of business is irrelevant. For example, 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. Accordingly, although the FDA's approval letter in this case was sent after the close of the FDA's business day, the FDA concluded that the approval was made that day.

C. MDCO's Request for Reconsideration and Second FDA Decision

35. On October 2, 2002, MDCO filed a timely request for reconsideration with the PTO. *See* Request for Reconsideration (Ex. 14 (without exhibits)). Among other things, MDCO urged the PTO to make an independent determination regarding the timeliness of MDCO's extension application. *See id.* at 4-5. MDCO also pointed out that the FDA approval letter for ANGIOMAX was faxed after FDA 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." *Id.* at 2-3. For that reason, MDCO asked the PTO to "treat December 18, 2000 as the effective approval date of ANGIOMAX®," *id.* at 3—which would have made MDCO's February 14, 2001 application unquestionably timely.

36. On March 24, 2003, the PTO sent the FDA a copy of MDCO's Request for Reconsideration and again asked the FDA to determine whether MDCO's application was timely. *See* Letter from Karin Ferriter to David T. Read (Mar. 24, 2003) (Ex. 15). The letter noted MDCO's position "that the date of approval should be considered to have been December 18, 200[0], not December 15, 200[0] because the approval letter was signed after FDA's normal

business hours on December 15." The PTO's letter also said: "Although the applicant for patent term extension argues that the determination of eligibility is a matter for the United States Patent and Trademark Office to decide, the facts in support of that conclusion (i.e., the date of approval) in this matter are best decided by the Food and Drug Administration.... [T]his determination is wholly within the decision making authority of the Food and Drug Administration."

37. By letter dated November 2, 2006, the FDA issued a terse reply "reiterat[ing] that ... Angiomax was approved on December 15, 2000." Letter from Jane A. Axelrad to Jon Dudas (Nov. 2, 2006) (Ex. 16). 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 explain why it (apparently) found that contention unpersuasive. *See id.* Notably, the FDA did not dispute that when calculating the length of regulatory review periods under 35 U.S.C. § 156, it deems new drug applications submitted to the agency after normal business hours as having been filed on the *next* business day, but deems a new drug approval to be effective as of the date on the approval letter even if it is transmitted after normal business hours.

38. On January 26, 2007, before the PTO issued a decision on MDCO's Request for Reconsideration, MDCO filed a petition to stay final PTO action on its extension application in light of possible legislative activity and in order to permit MDCO to file an amended extension application and amended request for reconsideration. On February 12, 2007, the PTO denied in part and granted in part MDCO's stay application. The PTO declined to stay proceedings for six months, as MDCO had requested, but granted a stay of thirty days to permit MDCO to make the two requested amendments.

39. On March 13, 2007, MDCO filed an Amended Application Pursuant to 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.740 for Extension of Patent Term. *See* Ex. 17 (with Appendix K only). The amended application corrected the erroneous assertion in the original application that ANGIOMAX had received permission for commercial marketing on December 15, 2000.

40. MDCO also filed an amended request for reconsideration on March 13, 2007. *See* Amended Request for Reconsideration (Ex. 18 (without exhibits)). MDCO's Amended Request for Reconsideration again demonstrated (among other things) that the PTO was obligated to make an independent assessment of the timeliness of MDCO's application; that the FDA's determination that approval occurred on December 15, 2000 was arbitrary and capricious and contrary to law; and that the PTO ought to conclude that MDCO's application was timely because ANGIOMAX received permission for commercial marketing or use on December 18 or 19, 2000. In particular, MDCO again explained that the FDA's approach to determining the approval date for ANGIOMAX treated after-hours communications *from* the FDA differently than after-hours submissions *to* the agency. The request demonstrated that this inconsistent treatment was not only arbitrary and contrary to congressional intent but also required the word "date" to be given two different meanings in 35 U.S.C. § 156(g)(1)(b)(ii)—contrary to basic principles of statutory construction.

D. PTO's First Reconsideration Decision

41. On April 26, 2007, the PTO denied MDCO's Request for Reconsideration. *See* Decision Denying Application for Patent Term Extension for U.S. Patent No. 5,196,404 ("2007 Decision") (Ex. 19). The PTO concluded that ANGIOMAX received permission for commercial marketing or use on December 15, 2000 and that MDCO's application was filed two days late (contrary to its initial decision finding the application one day late).

42. In denying MDCO's application, the PTO conceded that it "can and should make its own determination as to the appropriate approval date of [ANGIOMAX] for purposes of § 156(d)(1)," *id.* at 14, but nonetheless accepted the FDA's determination as binding. The PTO noted that the "FDA has made clear three times that the approval date of [ANGIOMAX] is December 15, 2000." *Id.* at 5. The PTO further stated:

> 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.

Id. The PTO also indicated that it "must rely on the written records for drug approvals maintained by the FDA" in determining timeliness under § 156(d)(1). *Id.* at 9. In response to MDCO's showing that the FDA's position with respect to after-hours filings is contrary to law, wholly arbitrary, and self-serving, the PTO stated simply that it "has no control over any of the FDA's business practices," and that as a result, MDCO was "complaining to the wrong agency regarding the late day notice." *Id.* at 10. The PTO further took the position that even if "FDA's method of counting days is contrary to congressional intent, that is not for the USPTO to decide." *Id.* at 11. Using the date provided by the FDA, the PTO determined that MDCO's application was untimely.

E. MDCO's 2009 Petition and Second Request For Reconsideration

43. On December 4, 2009, MDCO filed a Petition Under 37 C.F.R. § 1.183 asking the PTO for permission to file a second request for reconsideration (Ex. 20) and a Request For Reconsideration of Application for Extension of Patent Term Under 35 U.S.C. § 156 (Ex. 21).

44. MDCO's petition for permission to file the successive request for reconsideration explained that MDCO had not previously had an opportunity to address a change in the way the

PTO calculates the due date under § 156(d)(1). Before its 2007 Decision in this case, the PTO had interpreted the 60-day deadline in § 156(d)(1) the same way most court filing deadlines are calculated: with the day count starting on the day *after* the event triggering the deadline. Thus, in its initial determination, the PTO concluded that the ANGIOMAX extension application had been filed a single day late. But without warning, in deciding MDCO's Amended Request for Reconsideration, the PTO apparently changed its view about how to interpret the relevant provision. It asserted for the first time that the ANGIOMAX application was actually two days late. 2007 Decision at 7 n.3. Subsequently, the PTO applied this new interpretation in other matters. In denying one application that would have been timely under the former approach, the PTO explained its shift in position:

> Applicant is correct that the USPTO has changed the way in which it makes the timeliness count between 2004 and 2008. The agency has done so because it realized that it was erroneously beginning the sixty-day count on the wrong day. By not counting the date of FDA approval as one of the sixty days included in the time period for filing a PTE application, the USPTO was failing to comply with section 156 and case law. The FDA made the same error as the USPTO and also corrected itself.

In re Patent Term Extension Application for U.S. Patent No. 5,817,338, 2008 WL 5477176 (Comm'r Pat. Dec. 16, 2008) (Prilosec, see chart below). The chart below shows that the PTO and/or the FDA have taken the position that at least seven applications for patent term extensions were untimely even though each of those applications would have been timely under the PTO's prior interpretation of § 156(d)(1).

Drug/Product	Patent No.	FDA Approval Date	PTE App. Date	Date of Denial
AbioCor Heart	5,084,064	9/5/2006	11/6/2006	6/29/2007 (PTO letter to FDA)
Bextra	5,633,272	11/16/2001	1/15/2002	3/20/2008
Isolex 300	4,714,680 4,965,204	7/2/1999	8/31/1999	4/1/2008

	5,035,994 5,130,144			
A180	4,861,779	9/20/2002	11/19/2002	4/4/2008 (order to show cause)
Decapinol Rinse	4,894,221	4/18/2005	6/17/2005	6/5/2008 (FDA letter to PTO)
Symbicort	5,674,860	7/21/2006	9/19/2006	6/13/2008
Prilosec OTC	5,817,338	6/20/2003	8/19/2003	12/16/2008

45. In its second Request for Reconsideration, MDCO explained 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 demonstrated that the date a product "receive[s] permission ... for commercial marketing and use" under 35 U.S.C. § 156(d)(1) (a date determined by the PTO) 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 35 U.S.C. § 156(g)(1)(B)(ii) (a period calculated by FDA). Ex. 21 at 9-15. MDCO noted that while § 156(d)(1) focuses the PTO on *the product* and *receipt* of permission, § 156(g)(1)(B)(ii) focuses on the FDA action of approving a new drug application. MDCO also explained that the relevant provisions serve distinct purposes. The function of § 156(d)(1) is to establish the period of time during which an extension application may be prepared and filed. Section 156(g)(1)(B)(ii), by contrast, establishes rights or consequences without the necessity of notice to the new drug applicant. MDCO observed that if the PTO rejected its contention and concluded that the "received permission" language of § 156(d)(1) must be equated with "was approved" under § 156(g)(1)(B)(ii), then the PTO would be required to interpret § 156(g)(1)(B)(ii) and to reconcile the FDA's inconsistent treatment of the "date" that marks the

beginning of the review period and the "date" that marks the end of the period of regulatory review. *See id.* at 15 n.8.

46. In light of the language and purpose of § 156(d)(1), MDCO asserted that the PTO should employ a rule of construction consistent with the FDA's practice, under which the 60-day period specified in § 156(d)(1) commences on the first business day after the FDA transmits notice of approval of a new drug application if that transmittal occurred after normal business hours. *See id.* at 16-20. MDCO explained that its interpretation furthered the Hatch-Waxman Act's remedial purposes of protecting the interests of innovators and promoting innovation. *Id.* at 19. MDCO further demonstrated that its interpretation comported with the statute's plain language and background norms regarding the date an after-hours event is deemed to occur. It also observed that its proposed construction was further supported by the PTO's new approach to counting days under § 156(d)(1)—counting the date a new drug application is approved by the FDA as the first day of the 60-day period. MDCO explained that absent adoption of its proposed next business day rule, application of the PTO's new interpretation in cases where the FDA transmits notice of approval of the drug product after normal business hours would impermissibly shorten the period for filing a § 156 application to less than the 60 days the statute provides.

F. PTO's Denial of MDCO's Second Request for Reconsideration

47. On January 8, 2010, the PTO granted MDCO's petition under 37 C.F.R. § 1.183 and agreed to consider MDCO's second Request for Reconsideration. The PTO agreed that its decision to change the way in which it counted days under § 156(d)(1) was an "extraordinary" situation that supported waiving its regulation prohibiting successive reconsideration requests.

See Decision on Petition to Suspend Requirements of 37 C.F.R. § 1.750 and 1.181(f) & Request for Reconsideration of Application for Patent Term Extension 3 ("2010 Decision") (Ex. 22).

48. In the same decision, however, the PTO denied MDCO's second Request for Reconsideration on the merits. The PTO first departed from its prior decisions to a degree and acknowledged that, although it seeks information from the FDA, it has the ultimate responsibility under § 156 to determine the timeliness of an application. *See id.* at 4-6. In practice, however, the PTO effectively deferred to the FDA.

49. The PTO 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 thus believed that it lacked any discretion to adopt such a construction even if it wanted to and that the contrary construction was compelled by the statute. *See id.* at 6-8.

50. In reaching the conclusion that it was statutorily foreclosed from treating drugs approved after business hours as having "received ... permission" the next business day, the PTO first rejected MDCO's argument that the date a drug "receive[s] permission ... for commercial marketing or use" can in some circumstances be distinct from the date a new drug "was approved" for purposes of marking the end of the period of regulatory review under § 156(g)(1)(B)(ii). *Id.* at 6-9. It held categorically that "*the date of NDA approval is the date a drug receives permission for commercial marketing or use*" and that "the date stamped on a NDA approval letter"—which the FDA contends is the effective date of an approval, *see* 21 C.F.R. § 314.105(a)—"is the appropriate trigger date for section 156(d)(1)." 2010 Decision at 6 (emphasis added). In doing so, the PTO did not respond to MDCO's arguments that the language and purposes of the provisions differ and that the PTO must avoid interpreting the

Hatch-Waxman Act in a way that results in the unnecessary loss of patent rights. Instead, the PTO relied almost exclusively on a case—*Unimed, Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989)—that did not address when a drug "receive[s] permission ... for commercial marketing" under § 156(d)(1) where approval of the drug is transmitted after normal business hours.

51. Additionally, the PTO concluded that MDCO's proposed "next business day" rule was foreclosed by the statute. *See* 2010 Decision at 7-9. Its analysis rested largely on the blanket proposition that "[a] particular 'date' spans the course of 24 hours; it does not end with the close of business." *Id.* at 8. The PTO took this position without even trying to reconcile it with the FDA's practice of deeming submissions to the agency after the close of business to have been received on the next 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 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 failed to honor that requirement. The PTO also asserted that a "next business day" rule is contrary to its regulations, *see id.*, but it pointed to nothing in its regulations foreclosing such an interpretation. Because the PTO had equated the date a product "receive[]s permission ... for commercial marketing" under § 156(d)(1) with FDA approval for purposes of § 156(g)(1)(B)(ii), which is administered by the FDA, the PTO relied on an FDA regulation governing the timing of FDA approvals. *See id.* (citing 21 C.F.R. § 314.105). The PTO also claimed support from its supposed "historical practice" and its policy manual for examiners, the Manual of Patent Examining Procedure. *See* 2010 Decision at 8. But the PTO does not appear ever to have previously addressed how to treat after-hours approvals. Finally, the PTO argued that the proposed "next business day" rule would be difficult to administer, *see id.* at 8-9, but it did not dispute that it could simply require

applicants to indicate the time of FDA transmission of approval in their applications or attach the approval letter containing the fax transmission header.

Count I

(Administrative Procedure Act)

52. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

53. The PTO's denial of MDCO's application for a patent term extension, the PTO's refusal to reconsider that determination, and the PTO's and the FDA's determinations that MDCO's application for an extension of the term of U.S. Patent No. 5,196,404 was not timely filed under 35 U.S.C. § 156(d)(1) misinterpreted § 156, failed to provide adequate explanations for their conclusions, failed to respond to significant arguments raised by MDCO, reflected a misapprehension of agency authority under § 156, and misinterpreted agency regulations and relevant case law.

54. Accordingly, these decisions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Prayer for Relief

WHEREFORE, Plaintiff prays that this Court:

A. Vacate and set aside the PTO's March 4, 2002, April 26, 2007, and January 8, 2010 decisions denying MDCO's application for an extension of the term of U.S. Patent No. 5,196,404;

B. Vacate and set aside the FDA's September 6, 2001 and November 2, 2006 determinations that MDCO's application for an extension of the term of U.S. Patent No. 5,196,404 was not timely filed under § 156(d)(1);

C. Declare that ANGIOMAX "received permission ... for commercial marketing or use" within the meaning of 35 U.S.C. § 156(d)(1) no earlier than December 18, 2000;

D. Declare that MDCO timely filed its application for patent term extension under 35 U.S.C. § 156;

E. Order the PTO to extend the term of U.S. Patent No. 5,196,404 for the full period required under 35 U.S.C. § 156, as determined by the FDA;

F. Expedite consideration of this case and grant any preliminary injunctive relief necessary to maintain the status quo pending resolution of this case;

G. Award MDCO its costs and reasonable attorney's fees as appropriate; and

H. Grant such further and other relief as this Court deems just and proper.

Date: January 27, 2010

Respectfully submitted,

Craig C. Reilly
VSB # 20942
111 Oronoco Street
Alexandria, Virginia 22314
Tel: (703) 549-5354
Fax: (703) 549-2604
craig.reilly@ccreillylaw.com

Peter D. Keisler*
Jeffrey P. Kushan+
C. Frederick Beckner III*
Lowell J. Schiller*
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel: (202) 736-8000
Fax: (202) 736-8711

Attorneys for Plaintiff THE MEDICINES COMPANY

* application for admission pro hac vice pending
+ application for admission pending