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

FILED

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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. 1:10CV286
CMH/JFA

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 complaint is related to a case decided nine days ago by Judge Hilton of this Court. *See The Medicines Co. v. Kappos*, No. 1:10cv81 (CMH/TCB) (E.D. Va. Mar. 16, 2010)

(Docs. 26 & 27) ("March 16 Opinion" & "March 16 Order") (attached as Exhibits A & B). Judge Hilton's March 16 Order in Case No. 1:10cv81 vacated a decision by the PTO and remanded the case to the PTO for further consideration in light of the Court's decision. The PTO purported to undertake that further consideration in 65 hours, issuing a new decision on the morning of March 19, 2010. *Decision Denying Application for Patent Term Extension for U.S. Patent No. 5,196,404* (attached as Exhibit C) ("March 19 Decision"). Like the complaint in Case No. 1:10cv81, this suit challenges the PTO's action under the Administrative Procedure Act, 5 U.S.C. §§ 551-706 ("APA").

2. The PTO's March 19 Decision—like its prior decisions that this Court set aside—denied MDCO's application under 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. MDCO was entitled to the extension to compensate it for the years of effective patent term lost awaiting approval of its new drug by the Food and Drug Administration ("FDA"). A copy of the patent at issue—United States Patent No. 5,196,404 (the "'404 patent")—is attached as Exhibit D.

3. The dispute in this case—as in the prior case—turns on whether MDCO's patent term extension application was timely filed under 35 U.S.C. § 156(d)(1), which provides that a 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." The PTO previously took the position that the text of this provision and case law from the United States Court of Appeals for the Federal Circuit compelled it to reject a "business day" interpretation of the word "date." But this Court's March 16 Opinion held that the PTO erred and that "neither the statutory text nor any other authority foreclose[d]" MDCO's proposed

reading of the statute. The Court also explained that its review was "shaped by the remedial nature of the statute at issue," and it cited authority supporting the "well-accepted principle that remedial legislation ... is to be given a liberal construction consistent with [its] overriding purpose."

4. Almost immediately following remand, the PTO again rejected a "business day" interpretation of the word "date" in § 156(d)(1). Notwithstanding the Court's March 16 Opinion, the PTO's March 19 Decision concluded (among other things) (1) that the relevant statutory provision is not "remedial," (2) that Federal Circuit precedent "establishes" that "date" in § 156(d)(1) means the calendar day "stamped on the FDA approval letter," and (3) that the text of the statute itself "establish[es]" that the "date [a] product receives" permission for commercial marketing is the date of FDA approval. Each of these conclusions is directly at odds with this Court's decision.

5. During the exceedingly brief remand, the PTO also purported to consider and adopt additional rationales to support its seemingly predetermined decision. The PTO did not provide MDCO with any opportunity to address these newly minted arguments, and none withstands minimal scrutiny.

6. As alleged below, the PTO's March 19 Decision was arbitrary and capricious, an abuse of discretion, and contrary to law.

Parties

7. 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. MDCO manufactures and markets a drug called ANGIOMAX® that practices the invention claimed in the '404 patent.

8. 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.

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

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

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

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

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

Jurisdiction and Venue

14. 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.

15. There exists between the parties an actual, justiciable controversy as to which Plaintiff requires a declaration of its rights by the Court and other relief.

16. MDCO challenges final agency action.

17. 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.

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

Count 1

(Violation of the Administrative Procedure Act)

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

20. The '404 patent issued March 23, 1993, and its original patent term would have expired March 23, 2010. The patent covers a chemical called bivalirudin, which is the active ingredient in ANGIOMAX, a life-saving anticoagulant.

21. Following years of research and testing, MDCO filed a new drug application ("NDA") for ANGIOMAX on December 23, 1997. Almost three years later—by letter date-stamped Friday, December 15, 2000 and transmitted to MDCO by facsimile that day at 6:17 p.m. EST—the FDA sent written notice that the ANGIOMAX NDA had been approved.

22. On February 14, 2001, MDCO submitted its patent term extension application to the PTO. 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 to compensate for its lost patent term. 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).

23. The PTO referred the question of the application's timeliness to the FDA in a letter dated March 2, 2001. On September 6, 2001, the FDA asserted in response that ANGIOMAX "was approved on December 15, 2000" and 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)." In December 2001, MDCO's

extension application was initially denied by the PTO on the ground that it purportedly had not been timely filed.

24. Over the next eight years, there were protracted administrative proceedings for reconsideration of the PTO's determination that MDCO's extension application was untimely. As noted above, the pivotal issue in those proceedings was the interpretation of the statutory provision for commencing the 60-day period for filing an extension application—"the date the product received permission ... for commercial marketing or use," 35 U.S.C. § 156(d)(1).

25. MDCO took the position that in light of the text and purpose of the Hatch-Waxman Act, the word "date" should be read to mean "business day." Under this interpretation, if the FDA transmits notice of approval after business hours, the drug is deemed to have "received permission ... for commercial marketing or use" on the next business day. Under MDCO's proposed interpretation, the 60-day period for submission of the ANGIOMAX extension application began on Monday, December 18, 2000, and thus the February 14, 2001 application was timely.

26. Rejecting MDCO's interpretation, the PTO maintained that the language of the statute and Federal Circuit precedent required it to interpret "date" to mean "calendar day." It held that the 60-day period for filing an extension application commences on the same calendar day on which the FDA date-stamps an approval letter, regardless of whether that letter is transmitted after the close of normal business hours. Applying that definition, the PTO concluded that the 60-day period for filing the ANGIOMAX extension application commenced on Friday, December 15, 2000, the date stamped on the FDA approval letter. Indeed, the PTO took the position that the date stamped on the letter is controlling, regardless of when, how, and even whether the letter is "received" by the applicant. In a decision dated January 8, 2010, the

PTO issued a final denial, finding that the ANGIOMAX extension application had been untimely under the PTO's "calendar day" definition.

27. By complaint filed January 27, 2010, MDCO commenced an APA action seeking judicial review of that denial. *The Medicines Co. v. Kappos*, No. 1:10cv81 (CMH/TCB) (E.D. Va.) (Doc. 1). MDCO incorporates paragraphs 1-51 of the complaint in Case No. 1:10cv81 as if fully set forth herein. After expedited litigation, the District Court issued a memorandum opinion and order at 4:12 PM EDT and 4:18 PM EDT, respectively, on March 16, 2010. Exs. 1 & 2. As noted above, the District Court found (among other things) that the PTO erred in concluding that the "calendar day" definition it used was mandated by either the statute or Federal Circuit precedent. The Court also held that the Hatch-Waxman Act should be interpreted "liberally" in light of its "remedial" nature. The District Court thus vacated the PTO's denial and remanded the case to the PTO for reconsideration in light of the Court's decision. The Court also ordered that the PTO "take such actions as necessary to ensure [the] '404 patent does not expire pending resolution of these proceedings."

28. On March 18, 2010, the PTO entered an order granting an interim extension "for a period of 60 days from the original expiration date of the ['404] patent, to and including, May 23, 2010." Recognizing that it had made a counting error, the next day the PTO issued a "Correction" indicating that the interim extension "to and including May 23, 2010" was actually "for a period of 61 days."

29. Despite requests from MDCO, the PTO refused to discuss the process for reaching a decision on remand, including the process for receiving further submissions from MDCO.

30. On March 19, 2010, at 9:27 a.m. EDT—just 65 hours after the District Court's March 16 Opinion and without conducting any further proceedings on remand or receiving any further submissions from MDCO—the PTO issued its March 19 Decision.

31. The March 19 Decision:

(a) Disregards the District Court's March 16 Opinion;

(b) Disregards the text, structure, and purpose of 35 U.S.C. § 156(d)(1);

(c) Ignores and conflicts with the remedial purposes of the Hatch-Waxman Act;

(d) Adopts a statutory interpretation that would produce absurd consequences;

(e) Adopts a statutory interpretation that would deprive applicants of the full 60-day period provided by statute to prepare and file a patent term extension application;

(f) Fails generally to provide a reasoned explanation for the decision it reaches;

(g) Erroneously relies on inapposite cases;

(h) Fails to adequately explain the inconsistency between the interpretation of the phrase "beginning on the date" as applied by the FDA and PTO under the same statute;

(i) Fails to provide a reasoned explanation of the purported difficulties of administering a "business day" rule;

(j) Erroneously claims to be adhering to a "historic practice";

(k) Misconstrues and fails adequately to respond to MDCO's arguments;

(l) Fails to explain its departure from past PTO precedent; and

(m) Erroneously relies on irrelevant factors.

32. Accordingly, the March 19 Decision and the denial of MDCO's extension application are "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 MDCO prays that this Court:

A. Vacate and set aside the PTO's March 19 Decision denying MDCO's application for an extension of the term of U.S. Patent No. 5,196,404;

B. 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;

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

D. 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, following determination by the FDA of the regulatory review period;

E. Order the FDA to act expeditiously in determining the regulatory review period for ANGIOMAX and carrying out the FDA's other obligations related to MDCO's patent term extension application;

F. Order the PTO immediately to grant an interim extension of U.S. Patent No. 5,196,404 and to take any additional present or future actions as are necessary to enable MDCO to protect its rights and to ensure that U.S. Patent No. 5,196,404 does not expire prior to issuance of a certificate of extension;

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

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

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

Date: March 25, 2010

Respectfully submitted,

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