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

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.	Case No. 1:10-CV-00286-CMH/JFA

BRIEF FOR *AMICUS CURIAE* APP PHARMACEUTICALS, LLC IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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APP Pharmaceuticals, LLC ("APP") respectfully submits this brief in support of Defendants' Opposition to Plaintiff's Motion for Summary Judgment and in support of Defendants' Motion for Summary Judgment.

I. INTEREST OF *AMICUS CURIAE*

APP is a leading manufacturer of generic and branded injectable pharmaceutical products for acute medical care both in ambulatory and in-patient settings. APP markets over 115 generic drug products. As such, APP has an interest in and relies on the promulgation, maintenance, and enforcement of consistent rules and procedures by the United States Patent and Trademark Office ("PTO") and by the United States Food and Drug Administration ("FDA").

APP also has a direct interest in the outcome of this case. APP made investments to develop a generic version of Plaintiff's Angiomax® product while relying on the published expiration date of United States Patent No. 5,196,404 ("the '404 patent"), the only patent Plaintiff had disclosed to the FDA as covering Angiomax® when APP filed its Abbreviated New Drug Application ("ANDA").

Plaintiff seeks a retrospective change to the PTO's long-standing and fair rules and procedures governing patent term extensions, resulting in an extension of the '404 patent's term by more than four years. APP would be directly and substantially prejudiced by this retrospective change. Retrospective patent term extension also could substantially delay the marketing of a safe and affordable generic version of Angiomax® to the public.

II. INTRODUCTION

The Hatch-Waxman Act is a carefully-considered framework that balances the interests of patent owners on the one hand, and the public on the other. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *Patent Case Management Judicial Guide* at 10-1 (Federal Judicial Center 2009). APP and other generic drug manufacturers enable Congress's intent to bring safe and affordable, life-saving drugs to the public as soon as possible. *Judicial Guide* at

10-2. Companies may develop generic versions of listed drugs[1] for purposes of submitting information to the FDA before patents covering the listed drugs ("listed patents") expire, without liability for infringement. 35 U.S.C. § 271(e)(1). However, liability for infringement may be based on the submission of "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

Thus, generic drug makers like APP rely on the expiration dates of listed patents to inform their business decisions about whether and when to invest in development of a given generic. These are significant strategic decisions in terms of time, money, and people. Investing money and assigning personnel to develop one drug means that opportunities to develop other generic drugs for the public are foregone. Unpredictable extensions of patent terms due to retrospective changes in PTO rules would undermine the ability of generic drug companies to make critical business decisions. Such extensions also could cause years of delay in marketing already-developed generic drugs, thus harming the public.

Before APP decided to develop a generic version of Angiomax®, the PTO had made a final determination that it would not extend the '404 patent's term, thus leaving the expiration date as March 23, 2010. APP filed its ANDA with the FDA in 2007, shortly after the PTO's final agency action denying Plaintiff's patent term extension. (*See* Exhibit 1, 11/21/2007 ANDA patent certification.) APP reasonably relied on the '404 patent's expiration date in deciding to begin and continue development of a generic version of Angiomax® without considering a concurrent challenge to the '404 patent. This work, of course, required time, money, and people that APP could have allocated to develop other generic drugs.

[1] Under the Hatch-Waxman Act, a drug becomes a "listed drug" on approval of its New Drug Application. 21 U.S.C. § 355(j)(2)(A)(i). Drug companies must disclose all patents covering a listed drug. 21 U.S.C. § 355(b)(1), (c)(2). The FDA provides a list of all such patents in a publication popularly known as the "Orange Book." *Judicial Guide* at 10-2.

Plaintiff asks this Court to change, after the fact, PTO rules and procedures that the rest of the pharmaceutical industry has followed and relied upon for many years. Plaintiff's requested change is an ad hoc contrivance to erase the consequence of its own failure to act in a timely manner under prevailing law. It serves no public policy purpose.

Plaintiff wants a retrospective change in the rules to extend the '404 patent term by more than four years. (D.I. 1, at 5.) For a product that has annual sales of almost $400 million, that is no small request. (*See* Exhibit 2, MDCO 4Q'09 and 2009 Conference Call Summary, http://www.themedicinescompany.com/pdf/MDCO-Earnings-Summary.pdf.) In addition to prejudicing APP, the extraordinary retrospective relief requested by Plaintiff could open the floodgates to litigation by prior patent term extension applicants who were rejected for untimeliness.

The PTO's denial of Plaintiff's request for a patent term extension has a rational basis and therefore is not arbitrary or capricious under the Administrative Procedures Act ("APA"). Moreover, under the APA and Supreme Court precedent, changes to the PTO's patent term extension rules must be prospective, not retrospective, to protect the interests of generic drug makers like APP who reasonably relied on the existing rules. The Court should affirm Defendant PTO's final agency action on the '404 patent because it upholds the law and is based on a rational, non-arbitrary, consistent, and fair procedure that protects the reliance interests of all regulated parties and the public. Accordingly, the Court should grant Defendants' motion for summary judgment, and deny Plaintiff's motion for summary judgment.

III. ARGUMENT

A. Standard Of Review.

While the parties dispute whether the standards of review set forth in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) and *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) should be applied here, there is no dispute that, *at a minimum*, the APA standard of review should apply.

Under the APA, a court may set aside an agency action, finding, or conclusion if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Put another way, agency decisions may be set aside only when they are irrational. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983) (requiring "a 'rational connection between the facts found and the choice made'" but allowing for "'less than ideal clarity if the agency's path may reasonably be discerned,'" *quoting Burlington Truck Lines v. U.S.*, 371 U.S. 156, 168 (1962) *and Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)). Thus, a court may not substitute its own judgment if an agency's decision can be supported by the law and the facts. *Motor Vehicle Mfrs.*, 463 U.S. at 43; *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 621 (1966).

B. The PTO's Rules And Procedures For Assessing Timeliness Of Applications For Patent Term Extension And Rejecting Untimely Applications, Were Longstanding And Well Known.

For many years, the PTO has used the date of FDA approval of a drug as the starting point for counting the 60-day time limit for filing an application for patent term extension. This rule was well known to the pharmaceutical industry, including to Plaintiff. For example, as explained by the PTO to the industry in 2001:

> An application for patent term extension under 35 U.S.C. 156(d)(1) may only be filed within the sixty-day period beginning on the date the product received permission . . . for commercial marketing or use. The statutory time period is not extendable and cannot be waived or excused. . . . For drug products *the approval date is the date of a letter by the [FDA] indicating that the application has been approved* . . . .

(Exhibit 3, Manual of Patent Examining Procedure § 2754.01 (8th ed. Aug. 2001) (emphasis added).)

Sworn testimony before Congress by Plaintiff's CEO, Clive Meanwell, on September 14, 2006, confirmed Plaintiff's understanding that (1) the FDA had approved Angiomax® on December 15, 2000, (2) the application for patent term extension had to be filed within 60 days

of that date, (3) Plaintiff missed the deadline for filing its application, and (4) the PTO did not have authority to extend the deadline. (*See* D.I. 17-3, at 11.)

The details of the events leading up to this lawsuit are set forth in the PTO's Decision Denying Application For Patent Term Extension For U.S. Patent 5,196,404, dated March 19, 2010, and will not be repeated here. (*See* D.I. 1, Exhibit C at 1-5.)

C. Defendant PTO Had A Rational Basis For Denying Plaintiff's Request For A Patent Term Extension Of The '404 Patent

1. Plaintiff's Proposed Change to PTO Rules and Procedures Violates Fundamental Principles Regarding the Uniform, Fair, and Prospective Application of Agency Rules.

a. Fundamental Fairness Requires that Any Change to Agency Rules and Procedures Not Be Applied Retrospectively.

"[A]gency discretion is limited not only by substantive, statutory grants of authority, but also by the procedural requirements which assure fairness and mature consideration of rules of general application." *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979) (internal quotation marks omitted). A corollary is that Congress designed the APA's deferential standard of review to promote uniform application of agency rules. *Consolo*, 383 U.S. at 620-21. This policy is "particularly important when a court is asked to review an agency's fashioning of discretionary relief." *Id.*

Consistent with fairness and uniformity "[r]etroactivity is not favored in the law" and "a statutory grant of . . . rulemaking authority will not . . . be understood to encompass . . . retroactive rules unless . . . conveyed by Congress in express terms." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988). As observed by one court, an agency's refusal to apply amended rules retrospectively is rational, not arbitrary or capricious, because retrospective application "would disturb settled agency decisions and increase administrative burdens." *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 75 (D.C. Dist. 2006), *aff'd*, 226 Fed. Appx. 4 (D.C. Cir. 2007).

The PTO's refusal to apply changed patent term extension rules retrospectively was a proper exercise of its discretion because the PTO uniformly applied its rules and regulations,

avoiding unfairness to APP and the public. Justice would not be done by ignoring public interests and instead furthering only Plaintiff's private interests.

b. Plaintiff's Proposed Change to PTO Rules and Procedures Would Amount to Rulemaking, Which Cannot Be Applied Retrospectively.

The APA recognizes that agency rules should be applied prospectively only. 5 U.S.C. § 551(4) (2008). According to the APA, a rule is "the whole or a part of an agency statement of . . . *future effect* designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements . . . ." *Id.* (emphasis added). The Supreme Court differentiated rulemaking from adjudication of facts, and confirmed that new rules can be applied only prospectively, absent express legislative authority to the contrary. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-214 (1988); *U.S. v. Florida E. Coast Ry. Co.*, 410 U.S. 224, 245-46 (1973).

(i) Plaintiff's Proposal Would Be Rulemaking.

The Supreme Court has explained that agency rulemaking is "a basically legislative-type judgment, for prospective application only," whereas agency adjudication (which may be retrospective) involves application of settled law to "a particular set of disputed facts." *Florida East Coast Railway*, 410 U.S. at 246.

Agency rulemaking includes how agencies implement existing law. In *Bowen*, the Medicare Act authorized the Department of Health and Human Services (HHS) to promulgate regulations setting limits on Medicare reimbursements to hospitals. 488 U.S. at 205-06. HHS attempted to apply a modified reimbursement schedule retroactively. *Id.* at 206-07. This required a group of hospitals to return over $2 million in reimbursement payments. *Id*. at 207. The Supreme Court held that "[r]etroactivity is not favored in the law. Thus, Congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." *Id.* at 208; *see also id.* at 220 (Scalia, J., concurring) ("A rule that has unreasonable secondary retroactivity — for example, altering future regulation in a manner

that makes worthless substantial past investment incurred in reliance upon the prior rule — may for that reason be 'arbitrary' or 'capricious', . . . and thus invalid.").

Plaintiff's proposed change to how the PTO determines timeliness would be rulemaking, not adjudication of facts. The PTO explained its procedures for implementing the patent extension provisions of the Hatch-Waxman Act in Section 2750 of the Manual of Patent Examination Procedure. (*See* Exhibit 3.) *See also* 37 C.F.R. §§ 1.720-1.750. This meets the definition of an agency rule under the APA — an agency statement that "implements" and "interprets" a statute and describes "procedures."

Plaintiff seeks to compel the PTO to change the PTO's interpretation of the statute and the procedure for implementing it, by requiring the PTO to read the starting "date" for the patent term extension time limit as a "business day." This is a "legislative-type" change of general applicability as described in *Florida East Coast Railway*, as opposed to an adjudication of specific disputed facts. Here, there is no dispute as to when Plaintiff filed its application for patent term extension, or when the FDA sent its approval letter for Angiomax®. The HHS in *Bowen* sought a changed rule for Medicare reimbursements by not counting government employees' salaries in a wage index. Similarly, Plaintiff here seeks a changed rule for calculating the patent term extension deadline by not counting a day when an FDA approval letter arrives after 4:30PM. Accordingly, Plaintiff's requested relief would amount to rulemaking.

(ii) Plaintiff's Proposed Rulemaking Cannot Be Applied Retrospectively.

Being rulemaking, Plaintiff's proposed change in patent term extension rules and procedures may be applied only prospectively, if at all. It may not be applied retrospectively, as Plaintiff desires. Here, Plaintiff missed the statutory sixty-day window for filing a simple patent term extension application for the '404 patent, and the PTO found Plaintiff's application untimely in a final decision based on long-standing PTO rules. Having sat on its rights, Plaintiff now urges a change to the PTO's rules and procedures for processing applications for patent

term extension that would remedy Plaintiff's untimeliness. Specifically, without statutory authority, Plaintiff urges application of a retrospective new rule that would permit a patent extension of more than four years (D.I. 1, at 5), prejudicing its generic drug competitors.

Defendant PTO properly denied Plaintiff's request, under the APA and under *Bowen.* Like the HHS in *Bowen,* which sought through retrospective rulemaking to reclaim moneys already paid out under a prior rule, Plaintiff here prays for retrospective rulemaking to revive an application for patent term extension that was untimely under the existing rules. In both cases the retrospective rulemaking would have prejudiced other regulated parties. As in *Bowen*, and despite Plaintiff's best efforts,[2] there is no statutory authority for a retrospective change of rules here. Thus the PTO properly rejected Plaintiff's proposal. The PTO's decision was not arbitrary or capricious because it upheld the law, protected settled PTO decisions, and avoided prejudice to the public and to regulated parties like APP who relied on the existing rules.

2. Defendant PTO's Denial of Plaintiff's Patent Term Extension was a Rational and Lawful Exercise of Agency Discretion.

This Court should uphold the PTO's decision because the PTO was rational, and not arbitrary or capricious, in rejecting Plaintiff's proposed retrospective rulemaking. *See* 5 U.S.C. § 706(2)(A) (providing that courts may set aside agency rules that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"). As we explain above, a retrospective rule change like the one Plaintiff desires would be improper under the law, would disturb the business expectations of APP and other third parties who reasonably relied on the existing rules, would prejudice the public interest, and would disturb settled PTO decisions. Plaintiff's proposal also could open the floodgates to litigation by previous applicants for patent term extensions who missed their filing deadlines, further jeopardizing the position of generic

[2] Plaintiff repeatedly attempted to obtain from Congress a change in the governing statute — and failed. (*See* D.I. 17-3; 17-4.) Notably, "the construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong, especially when Congress has refused to alter the administrative construction." *CBS, Inc. v. FCC*, 453 U.S. 367, 382 (1981) (internal quote and citation omitted).

drug makers who are already marketing products. Defendant PTO thus had good and lawful reasons to reject Plaintiff's application for a patent term extension of the '404 patent.

IV. CONCLUSION

For the foregoing reasons, this Court should affirm the PTO's action denying an extension of the '404 patent, grant Defendants' Motion for Summary Judgment, and deny Plaintiff's Motion for Summary Judgment.

Dated: April 22, 2010

Respectfully submitted,

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