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 ECF Case

***AMICUS CURIAE* TEVA PHARMACEUTICALS USA, INC.'S [PROPOSED] COMBINED BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

For the past four years, The Medicines Company ("MDCO") has been trying to evade the consequences of its negligence by begging the United States Congress for lenience. As the CEO of MDCO forthrightly explained to the House Judiciary Committee the first time MDCO sought legislation to change the patent laws so that PTO could accept the company's untimely request for a patent term extension ("PTE"):

> FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000. Under the Hatch-Waxman formula, we calculated that we were entitled to a restoration period of approximately 4-1/2 years. We quickly set about preparing our application for patent restoration, completing a first draft of the 100-plus page application package by the first week of January 2001 and then working steadily along with our counsel on further drafts. But then human error intervened.
>
> The current filing provision of Hatch-Waxman requires an application to be filed within 60 days of FDA's approval of the drug in question. Unfortunately, the 60-day requirement was evidently mistaken for a two-month requirement, and our patent restoration application was filed on February 14, 2001, within a two-month window, *but one day late for the actual 60-day deadline. Unlike other filing provisions of the patent laws, this provision of Hatch-Waxman does not allow for any discretion to accept late applications, no matter the reason and no matter how close to the actual deadline. So, the Patent and Trademark Office denied the petition as untimely. We filed a motion for reconsideration which is still pending, but the PTO lacks the authority to grant it.*

A Bill to Amend Title 35, U.S. Code, to Conform Certain Filing Provisions Within the Patent and Trademark Office: Hearing on H.R. 5120 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 109th Cong. (Sept. 14, 2006) (attached as Exhibit 1) (statement of Clive Meanwell, Chairman and CEO of The Medicines Company) (emphasis added) (hereinafter, the "Meanwell Testimony").

Time and again, however, MDCO's attempts to secure relief from Congress have fallen on deaf ears. To date, no fewer than *four bills* proposing to amend the statute so that MDCO could obtain a PTE for the Angiomax® patent have been introduced in Congress. Yet on each

occasion, Congress rejected MDCO's plea for relief—despite the company's seemingly contrite acknowledgement of "error," its unqualified concession that the patent-term application at issue here was filed "one day late for the actual 60-day deadline," its forthright admission that current law "does not allow for any discretion to accept late applications, no matter the reason and no matter how close to the actual deadline," and—perhaps most notably—its expenditure of well over than $10 million in lobbying fees and apparent willingness to pay an additional surcharge of $65 million to the U.S. Treasury in order to extend the '404 patent's term. *See* Responsive Government Act of 2008, H.R. 6344, 110th Cong. § 4 (2d Sess. 2008) (attached as Exhibit 2).

Undeterred by its repeated failure to obtain relief from Congress, MDCO now shamelessly seeks the very remedy the legislature has refused to grant—by asking this Court to do precisely what Congress consistently has declined and exactly what MDCO repeatedly has admitted the United States Patent and Trademark Office ("PTO") cannot do. This Court should not countenance MDCO's Janus-like representations, inconsistent arguments, and brazen invitation to error. As PTO explained each time it denied MDCO's requests for a patent-term extension, MDCO's sworn admissions to Congress were right: The plain language of the statute forecloses the very relief MDCO is seeking here, and even if it did not, the statute is—at the very least—permissibly interpreted the same way MDCO did when it pleaded with Congress to amend the law. Teva thus fully supports the PTO's motion for summary judgment, and submits the brief *amicus curiae* in order to emphasize three straightforward points.

First, this Court's scope of review is substantially limited by the Supreme Court's decision in *Chevron*. That makes this a very different case today than it was during the last round of this litigation. While this Court owed PTO no deference when MDCO challenged the Agency's decision *on procedural grounds* last time around, the fact that MDCO is now

challenging *the substantive statutory interpretation* embodied in PTO's latest decision means that this Court can displace PTO's interpretation only if the Agency's reading of the statute is unreasonable. Given MDCO's own pre-litigation admission that the plain language of the statute forecloses the company's current interpretation, and the company's unqualified pre-litigation concession that PTO cannot lawfully do precisely what MDCO now faults PTO for declining to do, it is hard to see how PTO's acceptance of MDCO's own pre-litigation interpretation of the statute fails that highly deferential test.

Second, PTO's interpretation of the statute closely tracks its text, which expressly provides that the sixty-day period for filing a PTE request begins to run "on *the date the product received* permission … for commercial marketing," 35 U.S.C. § 156(d)(1) (emphasis added), rather than on *the first business day after* the product received FDA permission for commercial marketing (or on the date *the product's sponsor receives constructive notice* that the product *previously received* permission for commercial marketing). To the extent there is any ambiguity in that statutory language, the fact that Congress has *four* times rejected legislation that would grant MDCO the very relief it seeks in this case is powerful evidence that PTO reasonably interpreted the existing law to deny such relief under the well-known circumstances of this case.

Finally, we wish to underscore that PTO's interpretation of the statute best reflects the realities of the pharmaceutical industry. Unlike the average consumer or *pro se* litigant, pharmaceutical companies like MDCO are highly sophisticated businesses that skillfully interact with their regulators and conduct their operations around the clock, especially when hundreds of millions of dollars are on the line. As a general matter, these companies know exactly when an FDA approval decision is coming, and they are more than prepared to turn on a dime and start shipping product as soon as FDA stamps an approval letter—whether that happens at 4:29 PM,

5:18 PM, or 6:17 PM, on a Monday or on a Friday. Wholly apart from that fact that MDCO does not allege *either* that it was unaware FDA's approval decision for Angiomax® would be issued on December 15, 2000 *or* that MDCO did not actually receive FDA's approval decision that day, the fact that the statute establishes quasi-jurisdictional constraints that govern the conduct of highly sophisticated corporations like MDCO is reason enough to dispense with the company's argument that PTO's interpretation of the statute somehow is not "fair."

Accordingly, Teva respectfully urges this Court to grant summary judgment in PTO's favor. If MDCO doesn't like that result, it is free to return to Congress and once again seek legislative relief. But this Court has no power to rewrite the statute in order to do what Congress repeatedly has refused.

ARGUMENT[1]

I. THE COURT'S SCOPE OF REVIEW IN THIS APA CHALLENGE IS SHARPLY CONSTRAINED BY *CHEVRON* AND ITS PROGENY.

When MDCO last filed suit against PTO, its challenge was essentially procedural—and this Court's review of MDCO's claims thus appropriately was non-deferential. In particular, MDCO's prior suit hinged on the company's arguments that PTO first erred by "never even consider[ing] whether it should exercise its discretion to adopt a 'business hours' rule" in construing § 156(d)(1), MDCO Memo. in Supp. of Mot. for Summ. Judg., No. 1:10-cv-00286-CMH, at 19, and that it next violated the APA's procedural requirements by failing "to respond to MDCO's central arguments." *Id*. at 24 & n.12; *see also id*. at 19-20 & n.9 (asserting that "an agency decision 'cannot be sustained where it is based not on the agency's own judgment but on

[1] The facts and procedural history of this case are well-known to the Court and not meaningfully in dispute. In the interest of judicial economy, Teva thus incorporates PTO's statement of the facts as set forth in its contemporaneously filed motion for summary judgment.

an erroneous view of the law," and collecting cases for the proposition that "[i]f a reviewing court agrees that the agency misinterpreted the law, it will set aside the agency's action and remand the case—even though the agency might later, in the exercise of its lawful discretion, reach the same result") (internal quotation and alteration omitted); *id.* at 24 ("Because the PTO had the authority to adopt a 'business hours' interpretation of § 156(d)(1) but failed to recognize or exercise that authority, this Court must set aside the PTO's decision and remand the matter to allow the agency to 'reconsider the matter free from its erroneous conception of the bounds of the law.'") (quoting *Prill v. NLRB*, 755 F.2d 941, 942 (D.C. Cir. 1985) (alteration omitted)); MDCO Rep. in Supp. of Mot. for Summ. Judg., No. 1:10-cv-00286-CMH, at 1 ("[W]hen an agency mistakenly believes a statute compels only one permissible reading and deprives it of authority to adopt any other, the reviewing court must remand the proceeding so that the agency can reconsider its position freed of its misapprehension of the law."); *id.* at 10 ("The PTO's decision must be remanded in light of its admitted failure to consider MDCO's arguments.") (alteration omitted).

Given the *procedural* nature of MDCO's arguments during the prior litigation, this Court owed PTO no deference in resolving MDCO's initial challenge to the Agency's administrative decisionmaking. As a general matter, courts defer neither to an agency's *Chevron* step one interpretation of a statute, *see, e.g.*, *Nat'l Org. of Veterans' Advocates v. Sec'y of Veterans Affairs*, 314 F.3d 1373, 1379 n.7 (Fed. Cir. 2003), nor on the question of whether a federal agency otherwise followed the proper procedures for considering matters arising under the APA (such as fulfilling its duty to respond to comments from interested parties). *See, e.g.*, MDCO Rep. in Supp. of Mot. for Summ. Judg., No. 1:10-cv-00286-CMH, at 18 ("The courts have made clear that the obligation of an agency to consider and respond to arguments raised in

administrative proceedings is independent and distinct from whether the agency's analysis is 'reasonable' under *Chevron*.") (collecting cases).

MDCO's current lawsuit, by contrast, is fundamentally distinct from its prior action. Rather than challenging PTO's failure *to proceed* to a *Chevron* step two analysis or contesting whether the Agency otherwise fulfilled the APA's *procedural* requirements, MDCO now takes direct aim at PTO's *Chevron* step two "construction of § 156(d)(1)." MDCO Mem. in Supp. of Mot. for Summ. Judg. at 5. Accordingly, this Court's scope of review of PTO's *Chevron* step two construction of the statute is exceptionally limited. As *Chevron* itself makes clear, where the reviewing court—as it did here—concludes "the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a *permissible* construction of the statute." *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984) (emphasis added). Critically, "[t]he court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Id*. at n.7. Instead, so long as the agency reasonably has interpreted the statute, the reviewing court may "'not disturb it unless it appears from the statute or its legislative history that the [interpretation] is not one that Congress would have sanctioned.'" *Id*. at 845 (quoting *United States v. Shimer*, 367 U.S. 374, 383 (1961)); *see also Timken Co. v. United States*, 354 F.3d 1334, 1342 (Fed. Cir. 2004) ("Under this second step of the *Chevron* analysis, any reasonable construction of the statute is a permissible construction. To survive judicial scrutiny, [the agency's] construction need not be the only reasonable interpretation or even the most reasonable interpretation. Rather, a court must defer to an agency's reasonable interpretation of a statute even if the court might have preferred another.") (internal citations, quotations, and

alterations omitted); *Akindemowo v. INS*, 61 F.3d 282, 284-85 (4th Cir. 1995) ("*Chevron* directs us not to impose automatically our own interpretation of the statute, but rather to apply the interpretation of the administrative agency charged with implementing the statute, provided the agency's interpretation 'is based on a permissible construction of the statute'…. Thus, if the agency's interpretation is 'rational and consistent with the statute,' we defer to that interpretation.") (quoting *Chevron*; *NLRB v. United Food & Comm. Workers Union, Local 23*, 484 U.S. 112, 123 (1987)) (internal citations omitted).

Against the weight of these long-established principles, MDCO now takes the position that "the appropriate construction of § 156(d)(1) is a legal issue for this Court to decide without deference to the agency." MDCO Mem. in Supp. of Mot. for Summ. Judg. at 5. It purports to justify that approach based on the Federal Circuit's generic, post-*Mead* test for reviewing informal agency adjudications that MDCO alleges are similar to a PTE determination. *Id*. at 30 (citing *Pesquera Mares Australes Ltda. v. United States*, 266 F.3d 1372, 1380 (Fed. Cir. 2001)). But whatever the merits of MDCO's argument that the Federal Circuit's generic post-*Mead* approach bears on the appropriate level of deference in this case, the key point here is that the Federal Circuit already (and quite specifically) has held that *Chevron*'s deferential two-part framework governs review of PTE determinations like the one in this case—as MDCO reluctantly admits. *Id.* at 30 n.19 (citing *Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 526 (Fed. Cir. 1990)).

MDCO offers two brief responses to that directly on-point precedent. It first asserts that *Hoechst*'s application of *Chevron* to a PTE decision like the one at issue here was "*dicta*." *Id.* MDCO does not explain *why* it believes that *Hoechst*'s application of the *Chevron* test was *dicta*, but that assertion appears to rest on the fact that *Hoechst* ultimately declined to defer to PTO's

PTE determination in that case because the court concluded that PTO's interpretation failed *at* Chevron *step one*. *Hoechst*, 917 F.2d at 526. *Hoechst*'s failure to reach the second step of the *Chevron* analysis, however, does not remotely demonstrate that its decision to follow *Chevron*'s approach in reviewing a PTE determination was *dicta*. Instead, the fact that the Court not only *framed* its stated standard of review by reference to *Chevron* but *actually applied the* Chevron test in analyzing the Agency's PTE decision demonstrates the Court's *holding* that *Chevron* supplies the proper lens for analyzing challenges to PTE decisions—whether the Court in that case needed to proceed to *Chevron*'s second step or not. *Id*. at 526-29. After all, had the Federal Circuit not *held* that *Chevron* supplies the proper framework for review of such determinations, it wouldn't explicitly have conducted a *Chevron* step one analysis in the first place.

Perhaps as a result, MDCO falls back on the argument that *Hoechst* "predates" the Supreme Court's decision in *United States v. Mead Corp.*, 533 U.S. 218 (2001), and thus that this Court somehow is free to ignore that directly on-point precedent. MDCO Mem. in Supp. of Mot. for Summ. Judg. at 30 n.9. There is no support in law or logic for that proposition. Just as it is the Supreme "'Court's prerogative alone to overrule one of its precedents' … even where subsequent decisions or factual developments may appear to have 'significantly undermined' the rationale for [the] earlier holding," *Roper v. Simmons*, 543 U.S. 551, 594 (2005) (quoting *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997); *United States v. Hatter*, 532 U.S. 557, 567 (2001)), only the Federal Circuit sitting *en banc* has authority to overrule one of *its* precedents. *George E. Warren Corp. v. United States*, 341 F.3d 1348, 1351-52 (Fed. Cir. 2003) ("[T]o overrule a precedent, the court must rule en banc."); *see also Nippon Steel Corp. v. United States*, 458 F.3d 1345, 1351 n.3 (Fed. Cir. 2006) (rejecting argument that one Federal Circuit panel should overrule the standard of review applied by a prior Federal Circuit panel in light of intervening

Supreme Court precedent, and observing that "[o]ur panel, of course, does not have authority to entertain this argument, as only the court *en banc* may overrule precedent").

Suffice it to say, if one panel of the Federal Circuit cannot overrule another panel of the Federal Circuit, then a federal District Court lacks the authority to effectively overrule a controlling decision of the Federal Circuit. This Court, in short, has no power to depart from *Hoechst*'s application of the *Chevron* framework to PTE decisions like the one challenged here. If MDCO wants to renew its argument that *Mead* fatally undermines *Hoechst*, it is free to do so in a petition for initial hearing *en banc* at the Federal Circuit or in a petition for rehearing *en banc* if and when a panel of the Federal Circuit rejects the company's strained construction of § 156(d)(1). But for now, *Hoechst* requires this Court to review the PTE decision at issue here through the *Chevron* lens, and PTO's interpretation of the statute thus can be vacated only if that interpretation flunks *Chevron*'s extraordinarily deferential standard of review.

II. PTO'S INTERPRETATION OF THE STATUTE CLOSELY TRACKS THE STATUTORY TEXT AND IS STRONGLY SUPPORTED BY CONGRESS'S REPEATED REJECTIONS OF MDCO'S EFFORTS TO SECURE RELIEF BY AMENDING THE CURRENT STATUTE.

As MDCO candidly conceded when it asked Congress to amend the law so that PTO could accept the company's untimely PTE request for the '404 patent, § 156(d)(1) is "unlike other filing provisions." Meanwell Testimony at 11. Rather than confer broad discretion on PTO to accept late submissions, *cf.* 35 U.S.C. § 41(c)(1), or (like the familiar rules that govern filing deadlines in this and other courts) extend the timeline for taking action based on a theory of constructive notice, *cf.* Fed. R. Civ. P. 6(d) (adding three days to the applicable deadlines where service is effectuated by mail), this statute plainly and unambiguously "requires a [PTE] application to be filed within 60 days of *FDA's approval of the drug in question*." Meanwell Testimony at 11 (emphasis added); *see also* 35 U.S.C. § 156(d)(1) ("[A]n application may *only*

be submitted within the sixty-day period beginning on *the date the product received permission* under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use.") (emphasis added). The proper interpretation of section 156(d)(1) thus hinges on two interdependent features of that statute: first, the fact that it defines the sixty-day period by reference to a *product-based* event (rather than an *applicant-based* event)—that is, that the start of the filing period is triggered when "*the product* received permission … for commercial marketing," 35 U.S.C. § 156(d)(1) (emphasis added), and not when the applicant receives "constructive notice" that FDA has approved the product—and second, that the statute incorporates by reference the Hatch-Waxman Act's provisions governing "commercial marketing [and] use" of regulated drug products. *Id*.

As PTO properly recognized in its final decision, the Hatch-Waxman Act and pertinent FDA regulations are clear on both of those key points: A regulated drug product "'receive[s] permission … for commercial marketing or use' when the FDA approves the drug," and that approval is legally effective the moment FDA "stamp[s] the FDA approval letter." *In re Patent Term Extension U.S. Pat. 5,196,404* at 6-7 (Mar. 19, 2010) [the "PTO Decision"]. MDCO notably does not contest—because MDCO could not credibly contest—that those are correct statements of the law governing FDA's marketing approval for new drug products. *See, e.g.*, 21 C.F.R. § 314.108(a) (noting that the "[d]ate of approval means the date on the letter"); *id*. at 314.105(a) ("An approval becomes effective on the date of the issuance of the approval letter."); *see also Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1336 (D.C. Cir. 1988) (upholding FDA's implementing regulations); *Norwich Eaton Pharms., Inc. v. Bowen*, 808 F.2d 486, 491 (6th Cir. 1987) (same). Given these long-settled and repeatedly reaffirmed regulatory provisions, then, any applicant for a new drug product is free to begin marketing that product

throughout the United States *the moment FDA stamps its approval letter*, and—as set forth below—sophisticated drug companies like MDCO thus *routinely* begin marketing their products before the proverbial ink dries on an FDA approval letter. *See infra* at 12-16. Given that PTO's interpretation of § 156(d)(1) thus *precisely* tracks that statute's explicit incorporation of FDA's Hatch-Waxman Act implementing regulations, it is impossible to conclude that the Agency's interpretation of § 156(d)(1) represents an impermissible construction of the statute that "'is not one that Congress would have sanctioned.'" *Chevron*, 467 U.S. at 845 (quoting *Shimer*, 367 U.S. at 383).

To the extent there is any doubt on this score, however, the fact that Congress repeatedly has refused to amend the statute in the face of MDCO's ongoing efforts to secure legislative relief settles it. Indeed, and as noted above, Congress has acquiesced not only in PTO's general interpretation of § 156(d)(1), but in the Agency's specific application of the statute *to this very case*. At MDCO's urging, no fewer than *four* bills have been introduced in Congress that would have allowed the PTO to accept untimely PTE requests like MDCO's. *See* H.R. 6344; Patent Reform Act of 2007, S. 1145 & H.R. 1909, 110th Cong. (2d Sess. 2008) (attached as Exhibit 3); H.R. 5120, 109th Cong. (2d Sess. 2006) (attached as Exhibit 4). And, importantly, the plain language and/or legislative history of each of those bills makes crystal clear that these pieces of proposed legislation were intended specifically to apply to MDCO's PTE request for the '404 patent. *See* H.R. 6344 § 4(b) (bill expressly drafted to apply to PTE applications involving "a drug intended for use in humans that is in the anticoagulant class"); S. 1145 § 13(b)(1)(B) (bill expressly made retroactive to cover cases in which the PTE application "is pending before the Director or is subject to judicial review"); H.R. 5120 § 2(c) (bill expressly made retroactive to cover cases in which the PTE application "is the subject of a request for reconsideration of a

denial of a patent term extension under section 156"); *see also* Meanwell Testimony on H.R. 5120.

Yet despite MDCO's expenditure of well over $10 million in lobbying fees between 2006 (when H.R. 5120 was introduced) and 2009 (when MDCO tried but failed to have similar legislation included as part of the recent healthcare reform effort),[2] Congress rejected every single one of these bills. Given the legislature's repeated refusal to pass any of these bills despite its "prolonged and acute awareness" of this very case, there is precious little doubt that "Congress acquiesced in" both PTO's interpretation of § 156(d)(1) and the Agency's application of that interpretation to this particular case—and even less doubt as to whether, in *Chevron*'s terms, the Agency's decision in this case "'is not one that Congress would have sanctioned,'" *Chevron*, 467 U.S. at 845 (quoting *Shimer*, 367 U.S. at 383). *See Bob Jones Univ. v. United States*, 461 U.S. 574, 600 (1983); *see also Dept. of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 16 n.7 (2001); *United States v. Rutherford*, 442 U.S. 544, 553-54 (1979); *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 170 -71 (4th Cir. 1998). Congress quite clearly *has sanctioned* PTO's interpretation and application of § 156(d)(1) in this case, and this Court has no authority to rewrite the statute in order to provide MDCO with the very relief Congress repeatedly has refused to grant.

III. PTO'S INTERPRETATION OF THE STATUTE BEST REFLECTS THE REALITIES OF THE PHARMACEUTICAL INDUSTRY.

PTO's interpretation of § 156(d)(1) not only comports with the statute's plain text and legislative history, but best reflects the realities of the industry that statute governs and the

[2] Data obtained from lobbying disclosures filed in Congress and compiled by the Center for Responsive Politics (*available at* http://www.opensecrets.org/lobby/clientsum.php?lname=Medicines+Co&year=all (last visited April 14, 2010)).

broader statutory context in which that statute is situated. In short, pharmaceutical companies like MDCO are highly sophisticated entities whose ultimate commercial success depends on regular interaction with their federal regulators. When a pharmaceutical company submits an application to FDA seeking approval to market a new drug product, its submission to FDA does not disappear into the ether—and companies like MDCO do not simply sit back and passively wait for FDA to act. To the contrary, these companies expend considerable energy helping shepherd their applications through the regulatory gamut—revisiting and revising the data in their initial submission, responding to inquiries posed by FDA's scientific review team, and interacting with the FDA Chief Counsel's office to resolve any legal issues that arise during review. Indeed, in this particular case, MDCO's FDA drug-approval package either contains or references dozens of letters between the Agency and the company and makes note of numerous in-person meetings between MDCO and FDA's Angiomax® review team during the time within which that drug® was under review by FDA. *See generally* Exhibit 5 (excerpt from FDA Drug Approval Package for Angiomax®, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20873_Angiomax_corres.pdf (visited Apr. 14, 2010)). As a result of these regular interactions, pharmaceutical companies like MDCO are well-positioned to gauge precisely where a given application stands in the review process—and exactly when that application is slated for approval.

Perhaps more important, Congress has taken a number of steps during the past twenty years in order to provide applicants with greater transparency and predictability in connection with FDA's new drug review and approval process. The Prescription Drug User Fee Act ("PDUFA"), first passed in 1992 and subsequently reauthorized in 1997, 2002, and 2007, is by far the most important of these measures. Pursuant to that statute, and during the time periods

relevant to this case, FDA committed to take final action on at least 90 percent of new drug applications within 12 months of the date the application was submitted for review, and FDA further developed an internal timetable for adjusting application-specific deadlines as issues arise during the review process. *See, e.g.*, Letter from Hon. D. Shalala to Hon. J. Jeffords, 11/12/97, *at* http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm143127.htm (last visited Apr. 14, 2010) (attached as Exhibit 6). Of note here, FDA consistently informs each new drug applicant of the specific PDUFA deadline for taking action on a pending application, and the Agency regularly follows up with the applicant when those dates must be adjusted in response to developments during the review process. Here, for instance, the publicly available correspondence between MDCO and FDA demonstrates that the Agency kept MDCO closely informed about the review deadlines throughout the Angiomax® review process, *see* Exh. 5 at 28 (Apr. 29, 1999 letter); *id*. at 20 (Dec. 2, 1999 letter); *id*. at 13 (July 20, 2000 letter), and, importantly, indicates that FDA informed MDCO by early December 2000 that Angiomax® would be approved imminently. *Id*. at 2 (soliciting a "*post-approval*" commitment from MDCO to complete an ongoing clinical trial and report the results to FDA).

Coupled with the otherwise routine interactions between applicants and the Agency, FDA's transparent communication of its statutory and regulatory review deadlines enables applicants to both time and plan for an immediate launch of their products. And sophisticated pharmaceutical companies like MDCO do just that, by producing launch-ready quantities of their drug products in the weeks leading up to expected approval; preparing distribution and marketing plans; and setting in place the mechanics necessary to execute a nationwide launch precisely so that they can begin shipping product to their customers—and, thus, profiting from their innovation—as soon FDA stamps their approval letter. With so much at stake, companies

anticipating an approval thus engage in a flurry of communication with the Agency in the days leading up to approval, and—in Teva's case—routinely station an employee by the fax machine so that the company can act as soon FDA's approval letter comes across the wires (be it at 4:29 PM or 6:17 PM). Indeed, just last Tuesday, FDA granted Teva marketing approval for two new drug products at 5:50 PM, and Teva had trucks moving that product to market the same day (and throughout the night).

These straightforward observations readily dispose of MDCO's two principal arguments in opposition to PTO's decision—first, that it would not be "fair" to adopt a plain-language approach to § 156(d)(1) because "an applicant should not be deemed to have 'received' notice after business hours" (even when they actually received such notice), *see* MDCO Mem. in Supp. of Mot. for Summ. Judg. at 13-14, and second, that PTO's interpretation of § 156(d)(1) somehow cannot reasonably be reconciled with FDA's interpretation of the word "date" in 35 U.S.C. § 156(g)(1)(B)(ii). *See id*. at 16-18. On one hand, there is simply nothing "unfair" about an interpretation of the statute that reflects the realities of this industry—where sophisticated pharmaceutical companies are well aware of the deadlines for FDA action, operate around the clock, and are well-prepared to act the moment FDA stamps an approval letter that authorizes them to make literally hundreds of millions of dollars by marketing their products. And on the other hand, the allegedly disparate interpretations that PTO gives to § 156(d)(1) (which in MDCO's view bears on outgoing correspondence *from FDA to applicants*) and that FDA gives to § 156(g)(1)(B)(ii) (which governs the treatment of incoming correspondence *to FDA from applicants*) are obviously and easily reconciled. In short, just as it is eminently reasonable for FDA to recognize that that non-profit governmental agency generally operates during normal business hours and is unprepared to take immediate action on unexpected correspondence that

arrives after 4:30 PM, it is eminently reasonable for PTO to recognize that sophisticated multinational pharmaceutical corporations like MDCO operate around the clock and are prepared to take immediate action with respect to highly anticipated FDA decisions worth hundreds of millions of dollars, regardless of whether FDA acts at 4:29 PM or 6:17 PM. *See* PTO Decision at 12 ("MDCO fails to articulate why its ability to receive notice is linked to the FDA's hours for accepting new drug applications. Instead, MDCO's ability to receive notice logically turns on whether *it* was closed for business when the FDA sent its courtesy facsimile on December 15, 2000. MDCO is careful to steer clear of urging actual notice because it has never asserted that it was not on actual notice of FDA approval on December 15, 2000.") (emphasis added).

The bottom line here is that MDCO blew its statutory deadline for filing a simple PTE request—as it candidly and repeatedly admitted to Congress when it sought a legislative fix, *see* Meanwell Testimony at 11—and now has manufactured a string of *post-hoc* rationales that contort the plain language of the statute, defy the legislative record, and ignore the realities of both the pharmaceutical industry and the broader statutory context within which § 156(d)(1) is situated. This Court should follow Congress's lead and deny PTO's brazen efforts to rewrite the statute in the face of the company's conceded "error" and longstanding admission—under oath, in sworn testimony to Congress—that "PTO lacks the authority to grant" precisely the relief it now faults PTO for refusing to grant. *Id*.

CONCLUSION

For the foregoing reasons, Teva respectfully submits that MDCO's motion for summary judgment should be DENIED and PTO's cross-motion for summary judgment GRANTED.

Dated: April 15, 2010

Respectfully submitted,

By: Elizabeth M. Locke

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 15th day of April, 2010, she electronically filed the foregoing **BRIEF *AMICUS CURIAE*** with the Clerk of Court using the CM/ECF system, which will send a notification of such filing ("NEF") to the following:

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