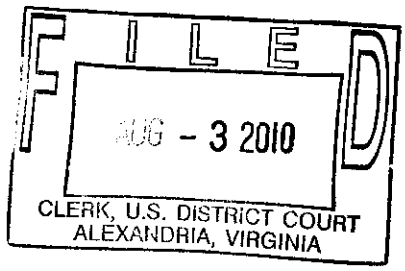
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division



THE MEDICINES COMPANY, Plaintiff,	)	
v.	)	Civil Action No. 01:10-cv-286
DAVID KAPPOS, et al., Defendants.	)	

MEMORANDUM OPINION

This matter comes before the Court on the parties' cross-motions for summary judgment.

The Medicines Company ("MDCO") is a pharmaceutical company that specializes in developing acute care medicines. This case involves an anticoagulant called ANGIOMAX, that works by directly inhibiting a key contributor to the formation of blood clots.

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

A new drug cannot be commercially marketed or used until the FDA approves it under § 505 of the Federal Food, Drug, and

Cosmetic Act ("FDCA"). See 21 U.S.C. § 355(a). The process of securing FDA approval is time consuming and expensive. A new drug applicant must conduct clinical studies and submit detailed information. Id. § 355(b)(1); 21 C.F.R. § 314.50. The FDA must then determine whether the drug is safe and effective. During this process, the applicant receives no commercial benefit from any patents on the drug.

Congress enacted 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") Title II of which is codified in relevant part at 35 U.S.C. § 156. Under § 156, the holder of a drug patent or its agent is entitled to apply for a patent term extension "to compensate for the delay in obtaining FDA approval." Merck & Co. v. Kessler, 80 F.3d 1543, 1547 (Fed. Cir. 1996); see also In re Patent No. 4,146,029 (Comm'r Pat. July 12, 1988)("SynchroMed") at 3 ("Since § 156 was intended to restore a part of the effective patent life. . ., § 156 can be viewed as remedial in nature."); Hoechst-Roussel Pharm., Inc. v. Lehman, No. 95-650-A, 1995 U.S. Dist. LEXIS 22485, at *8 (E.D. Va. Oct. 25, 1995) (Section 156 "was intended to compensate those patent owners who lost time to market a patented product while that product awaited FDA approval."), aff'd, 109 F.3d 756 (Fed. Cir. 1997). The purpose of the Act is to "encourage[] drug manufacturers to assume the increased costs of research and

development of certain products which are subject to premarketing clearance." H.R. Rep. No. 98-857, pt. 2, at 11 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2695.

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

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. See § 156(d)(1).

If a patent relates to a human drug, responsibility for reviewing an extension application is shared by the Director of the PTO and the Secretary of Health and Human Services, who has delegated her authority to the FDA. The PTO is responsible for determining that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d), including the timeliness requirement of (d)(1), have been complied with. 35 U.S.C. § 156(e)(1). The FDA is responsible for determining the length of

the applicable regulatory review period. Id. § 156 (d)(2)(A). In so doing, it must determine the date the application was initially submitted to the FDA and the date such application was approved. Id. § 156(g)(1)(B)(ii). A 1987 Memorandum of Understanding between the PTO and the FDA sets forth procedures for their joint review of applications. See 52 Fed. Reg. 17,830-02 (May 12, 1987).

MDCO filed its patent term extension application on February 14, 2001 under the Hatch-Waxman Act. Such an extension would change the expiration date of the '404 patent from March 23, 2010 to December 2014. There is no dispute that MDCO satisfied all of the substantive requirements of 35 U.S.C. § 156.

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

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

identical to the original.

The FDA treats submissions to the FDA received after its normal business hours differently than it treats communications from the agency after normal business hours. The agency considers the date of submission of a new drug application received after 4:30 p.m. EST to be the next business day. If an applicant submits an electronic application or sends a fax to the FDA at 6:17 p.m. on a Friday night, the FDA will deem that application to be submitted on the following Monday (or Tuesday, if the Monday is a federal holiday). This FDA practice has the consequence of making the regulatory review period defined in § 156(g) commence days later than if the application was considered submitted on Friday and can operate to reduce the overall length of the patent term extension granted.

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

On October 2, 2002, MDCO filed a timely Request for Reconsideration with the PTO. Among other things, MDCO pointed out that the FDA approval letter for ANGIOMAX was faxed after business hours on a Friday evening, and that under FDA's practices, facsimiles submitted to FDA after the close of

business are considered received by the Agency on the next business day. For that reason, MDCO asked the PTO to treat December 18, 2000 as the effective approval date of ANGIOMAX®, and would have made MDCO's February 14, 2001 application timely.

On March 24, 2003, the PTO sent the FDA a copy of MDCO's request and asked the FDA to determine whether the application was timely. On November 2, 2006, the FDA issued a reply reiterating that Angiomax was approved on December 15, 2000. Although the FDA noted MDCO's position that the approval was not effective until December 18, 2000 because the December 15, 2000 letter was transmitted after normal business hours, the FDA failed to provide any explanation why it found that contention unpersuasive. The FDA did not dispute that when calculating the length of regulatory review periods under 35 U.S.C. § 156(g), it deems submissions to the agency after normal business hours as having been filed on the next business day, but deems an approval transmitted from the agency after normal business hours to be effective as of the date on the letter.

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

On April 26, 2007, the PTO denied MDCO's Request for

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

For years, in applying § 156(d)(1)'s 60-day deadline, the PTO followed the general rule of starting the count on the first day after the triggering event. In its 2007 Decision, however, the PTO concluded that it had been misreading § 156(d)(1). It then changed course and announced that it would count the date of FDA approval as one of the sixty days included in the time period for filing a PTE application. In re Patent Term Extension Application for U.S. Patent No. 5,817,338, 2008 WL 5477176 (Comm'r Pat. Dec. 16, 2008) ("Prilosec Decision"). Applying this new interpretation, the PTO or the FDA has taken the position that at least seven applications for patent term extensions were untimely, even though they would have been timely under the PTO's prior interpretation of § 156(d)(1). The PTO takes the view that

the date of FDA approval counts as the first day of the 60-day period even where the application is not approved until after the close of business, even as late as 11:59 p.m. This interpretation can mean that an applicant is afforded only 59 days rather than 60 days.

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

MDCO contended that the PTO had the authority to treat new drugs approved by the FDA after business hours as having received permission for purposes of § 156(d)(1) on the following business day. MDCO argued that the date a product receives permission for commercial marketing and use under § 156(d)(1) need not in all circumstances be the same as the date a new drug is approved for purposes of marking the end of the regulatory review period under § 156(g)(1)(B)(ii). That where the FDA transmits notice of approval after normal business hours, a next business day rule comports with the statute's text and purpose. This is especially so given the recent decision of the PTO to count the date of FDA approval as the first day of the 60-day period, as opposed to its previously established practice of starting the counting period on the first day after the triggering event. Unless the PTO

adopted a next business day rule for after-hour approvals, it would effectively deprive many patent applicants of one of the 60 days Congress granted them for seeking extensions under § 156. Finally, MDCO argued that if the PTO rejected a next business day rule for § 156(d)(1) and concluded that it was bound to give § 156(d)(1) the same meaning that the FDA has given § 156(g)(1)(B)(ii), then it would be required to reconcile its decision with the FDA's inconsistent interpretation of the word date in § 156(g)(1)(B)(ii).

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

The PTO rejected MDCO's argument that the date a drug receives permission for commercial marketing or use can in some

circumstances be distinct from the date the drug was approved for purposes of the FDA's calculation of the period of regulatory review. It held that the date stamped on a NDA approval letter, which the FDA terms the effective date of an approval, is the appropriate trigger date for § 156(d)(1). The PTO also held that MDCO's submission was foreclosed by the text of § 156 because a particular date spans the course of 24 hours; it does not end with the close of business. The PTO made no attempt to reconcile this position with the FDA's own practice of treating submissions to the agency after the close of business as being received the next business day. The PTO also did not address § 156(d)(1)'s focus on the date approval was received, the purpose of § 156(d)(1), or the need to ensure that all applicants receive the 60 days to file extension applications that Congress required and the ways in which its interpretation of date in combination with its new counting rule is inconsistent with that requirement.

On March 16, 2010, this Court ordered a remand to the PTO for reconsideration based on its finding that § 156(d)(1) was a remedial statute and that it should be liberally construed. The Court also found that the PTO was not bound by the statute or case law to reject the business day interpretation of the word date in § 156(d)(1).

On March 19, 2010, without any additional hearings, the PTO released a new decision which again rejected the business day

interpretation of the Plaintiff. It held that the timing provision of § 156 was not remedial; that Federal Circuit case law establishes that the word "date" in § 156(d)(1) means the calendar day stamped on the FDA approval letter; and the text of the statute itself establishes that the date a product receives permission for commercial marketing is the date of FDA approval. Plaintiff now challenges the PTO's March 19, 2010 decision under the Administrative Procedure Act, 5 U.S.C. §§ 551-706.

As a threshold matter, this Court must determine what, if any, deference it must give to the March 19 decision of the PTO. The two types of deference that this Court can apply are taken from Skidmore v. Swift & Co., 323 U.S. 134 (1944) and Chevron, U.S.A., Inc. v. National Resource Defense Council, Inc., 467 U.S. 837 (1984), respectively. United States v. Mead, 533 U.S. 218, 231-234 (2001), made clear that Chevron deference is generally reserved for agency interpretations set forth after notice-and-comment rulemaking or a formal adjudication under 5 U.S.C. §§ 556-557. The government does not deny that PTE decisions are informal adjudications. It also appears to agree that to overcome the Federal Circuit's "ordinary reluctance to accord Chevron deference to informal agency interpretations," Butterbaugh, 336 F.3d at 1342, it must show (1) that PTE decisions result from a relatively formal administrative procedure, (2) that Congress has provided for deferential judicial review of those decisions, and

(3) that the PTO gives its own decisions precedential effect, Pesquera Mares Australes Ltda. v. United States, 266 F.3d 1372, 1380 (Fed. Cir. 2001).

Congress authorized the agency to grant or deny an extension in an ex parte proceeding solely on the basis of the representations contained in the application. 35 U.S.C. § 156(e)(1). The agency's procedures are set forth in a single regulation, which specifies only that the Director or other appropriate officials may exercise their discretion to require from an applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. 37 C.F.R. § 1.750. There are no hearings of any kind to determine eligibility for an extension. And apart from a request for reconsideration, there is no mechanism for additional administrative review within the PTO. This is not the relatively formal process envisioned in Pesquera. The Federal Circuit has already spoken on this matter: "PTO proceedings are not formal adjudications governed by [5 U.S.C. §§ 556 and 557]." Brand v. Miller, 487 F.3d 862, 867 (Fed. Cir. 2007).

The government argues that the mere fact that PTE proceedings are ex parte does not, by itself, preclude Chevron deference citing NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co., 513 U.S. 251 (1995). But the ex parte

nature of PTE proceedings is simply one relevant factor in assessing their formality. And, although the Supreme Court granted Chevron deference to an ex parte informal adjudication in NationsBank, the Mead opinion explained that this result was based on longstanding precedent according deference to the Comptroller of the Currency's interpretation of the banking laws. 533 U.S. at 231 n.13. The PTO cannot point to any similar tradition of deference to its views.

The government also argues that the PTO's proceedings in this case were sufficiently formal to warrant deference because MDCO filed several requests for reconsideration. But the relevant question under Mead is the formality of the category of administrative decision at issue, not the formality of the particular decision under review. In Mead itself, the Court held that the Customs Service's tariff classifications were not sufficiently formal to warrant deference even though the particular classification under review in that case was unusually formal. 533 U.S. at 225, 233-234.

Second, MDCO argues that Congress has provided for de novo review of PTE determinations in infringement proceedings under 35 U.S.C. § 282. In response, the government quotes a Federal Circuit decision stating that PTE determinations are given "'great deference.'" Pfizer, Inc. v. Ranbaxy Labs., Ltd., 457 F.3d 1284, 1290 (Fed. Cir. 2006). This quotation is originally

from Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 399 (Fed. Cir. 1990). Glaxo held that due to the agency's scientific and technical expertise, "we will give great deference to the [PTO's] determinations as to which patented chemical compounds fall within Congress' definition of 'products' [in § 156]." Id. But the Glaxo court then expressly rejected the PTO's claim for deference to its statutory interpretations in PTE proceedings: "[W]e will give . . . little or no deference to the [PTO's] surmise of Congress' intent in framing its definition." Id. Neither Glaxo nor Pfizer establishes that Congress provided for deferential review of the PTO's legal interpretations.

The government also claims that its interpretation of § 156(d)(1) is entitled to Chevron deference in light of the PTO's authority to govern the conduct of proceedings in the Office. But, as the government acknowledges, the source of this authority is 35 U.S.C. § 2(b)(2), which provides that the PTO may establish regulations to govern the conduct of proceedings in the Office. This provision authorizes the PTO only to adopt procedural regulations. It cannot be a basis for deference where, as here, the PTO has interpreted statutory language not in a regulation, but rather in an informal adjudication. See Mead, 533 U.S. at 226-227 ("[A]dministrative implementation of a particular statutory provision qualifies for Chevron deference when it appears that Congress delegated authority to the agency generally

to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority."

The government argues that it has consistently applied a calendar day interpretation of § 156(d)(1) and thus the government claims that it stands to reason that USPTO shall give precedential treatment to its decision here. But, the PTO admits that it has never previously considered the choice between calendar day and business day interpretations of § 156(d)(1), and it can not claim to give precedential effect to decisions that do not exist. And the government's assertion that it stands to reason that the PTO will adhere to its position in this case in the future hardly establishes that PTE decisions as a category are given precedential effect. To the contrary, the PTO has stated that its "[u]npublished adjudicatory decisions are not binding precedent." Def.'s Opp. to Pl.'s Cross-Mot. for Summ. J. at 6, SprinGuard Tech. Group v. PTO, No. 08-12119 (D. Mass. July 31, 2009); see also In re Zacharin, 1 U.S.P.Q.2d 1413, 1415 n.2 (Comm'r Pat. 1986) (same); Ex parte Vangompel, No. 98-1314, 1998 WL 1736077, at *2 n.2 (Bd. Pat. App. & Interf. 1998) ("unpublished Board opinions are not binding as precedent").

The government contends that PTO's PTE decisions are precedential because the PTO is obligated to give a reason for changing its practice. But the APA requires that all agency

decisions either be consistent with past decisions or give a reasonable explanation for any departure and this obligation applies even to non-precedential decisions. See Davila-Bardales v. INS, 27 F.3d 1, 5-6 (1st Cir. 1994). An agency thus cannot claim to give decisions precedential effect unless it accords them some additional weight beyond the minimum required by the APA. And there is no indication that the PTO does so here. To the contrary, many of its PTE decisions are not even published. Cf. Estrada-Espinoza v. Mukasey, 546 F.3d 1147, 1156-1157 (9th Cir. 2008) (collecting cases holding that "Chevron deference does not apply to unpublished, non-precedential [Board of Immigration Appeals] decisions"). For these reasons, the Court finds that Chevron deference is not appropriate for the PTO's March 19, 2010 decision and will instead treat the PTO's March 19 decision with only Skidmore deference.

It is well established that "[d]eviation from [a] court's remand order in . . . subsequent administrative proceedings is itself legal error, subject to reversal on further judicial review." Sullivan v. Hudson, 490 U.S. 877, 886 (1989). If an agency is dissatisfied with any part of a district court's order, the remedy is to appeal the case and not, under the guise of a hearing, to relitigate a question already finally decided by the district court. Hooper v. Heckler, 752 F.2d 83, 88 (4th Cir. 1985). When a case returns to a court for a second time after the

court has remanded it with explicit instructions to the agency, the court examines with care the order of the agency to ensure that its earlier decision has been followed. Guillen-Garcia v. INS, 60 F.3d 340, 344 (7th Cir. 1995).

In its March 16 Memorandum Opinion, this Court emphasized the "remedial nature of the statute at issue" and the "'well-accepted principle that remedial legislation . . . is to be given a liberal construction consistent with [its] overriding purpose.'" (quoting United States v. Article of Drug . . . Bacto-Unidisk . . ., 394 U.S. 784, 798 (1969)). It was noted that the PTO had followed that principle with respect to this very statute in SynchroMed, where it previously held that the timing provisions of § 156(d) should be liberally construed to carry out its purpose so that justice may be done to both the patentees and the public. Id. On remand, the PTO declined to apply this interpretive principle. It also did not acknowledge its own prior precedents applying this principle to § 156. The PTO asserted that even though § 156 is generally remedial, the specific timing provision at issue, § 156(d)(1), is not.

Section 156 provides a remedy: an extended patent term to offset the loss of effective patent life during the period of regulatory review of a new drug product. The timing provision of § 156(d)(1) is an integral part of the mechanism Congress enacted to remedy this harm.

All of the provisions of a remedial statute (other than exceptions created by the statute) should be construed liberally. See, e.g., 3 N. Singer & J.D. Singer, *Statutes and Statutory Construction* § 60:1, at 263 (7th ed. 2008). Courts have held that the rule in construing remedial statutes is that everything is to be done in advancement of the remedy that can be done consistently with any fair construction that can be put upon it. See, e.g., White v. Cotzhausen, 129 U.S. 329, 341 (1889). For these reasons, courts have broadly construed timing provisions in remedial statutes, making clear that "[a] generous reading, in favor of those whom Congress intended to benefit from the law, is also appropriate when considering issues of time limits and deadlines." Kelley v. Alamo, 964 F.2d 747, 750 (8th Cir. 1992).

The government argues that the fact that Congress did not provide a mechanism for USPTO to prevent the loss of an applicant's patent when the applicant misses a deadline necessarily compels the rejection of the position that § 156(d)(1) should be construed liberally. The absence of a grace period says nothing about whether the statute is remedial or how it should be interpreted.

The PTO's failure to acknowledge its prior relevant practices is an independent violation of the Administrative Procedure Act ("APA"). SynchroMed and other PTO decisions establish that, to the extent § 156(d)(1) is ambiguous, the PTO

must construe it to further the statute's remedial purpose. "An agency may not . . . depart from a prior policy sub silentio or simply disregard rules that are still on the books." FCC v. Fox Television Stations, Inc., 129 S. Ct. 1800, 1811 (2009); see also Dillmon v. NTSB, 588 F.3d 1085, 1089-1090 (D.C. Cir. 2009).

The PTO plainly made a decision in the SynchroMed matter: it accepted the PTE application at issue as timely filed because it construed § 156(d)(1) liberally. The fact that the explanation for this "Final Determination" was set forth in a letter to the FDA is immaterial. Finally, all three cited authorities each conclude that § 156 should be construed liberally in light of its remedial purpose. SynchroMed holds that the timing provision of § 156(d)(1) at issue here had to be so construed.

The PTO's decision was also at odds with this Court's conclusion that there are "material differences between § 156(d)(1) and § 156(g)(1)(B)(ii)." The relevant statutory language is different and the provisions serve distinct purposes. Section 156(d)(1) calls for the PTO to determine when the product received permission such that it would be fair for the applicant's filing period to begin, whereas § 156(g)(1)(B)(ii) calls for the FDA to determine when the new drug application was approved in order to define the period of time that the FDA has taken to review a new drug application. The PTO never sought to determine when it would be fair for the applicant's filing period

to begin. The PTO instead asserted that no such inquiry was necessary because the language Congress adopted in § 156(d)(1) was merely intended to capture all of the various types of permissions for commercial marketing or use for all of the various products discussed in § 156(g). Indeed, the PTO claimed the statute foreclosed it from even considering the issue of constructive notice. But the PTO has shown only that Congress needed to use language broad enough to cover all these events; it has not explained why Congress needed to use the particular phrase "the product received permission . . . for commercial marketing or use" instead of "commercial marketing or use of the product was permitted." Congress could have keyed the time for seeking an extension directly to the end of the approval phase but it did not. The PTO's interpretation fails to give meaning to Congress's actual language.

The government repeats the PTO's assertion that the statute cannot be read to require notice because the triggering event for food or color additive PTE applications is the effective date of a regulation, not any notice to the sponsor. This argument merely assumes its conclusion. In fact food and color additive applicants receive notice of the agency's approval and thus MDCO's reading of "received permission" accommodates these applications as easily as new drug applications ("NDAs").

The government also argues that the word "received" has

nothing to do with notice because § 156(d)(1) refers to the product's receipt of permission, rather than receipt by the NDA sponsor. But an inanimate product, considered in isolation, cannot "receive[ ] permission" to market itself, since "permission" is a "license or liberty to do something." *Black's Law Dictionary* 1255 (9th ed. 2009). It is the NDA applicant that "receives permission" to market the product.

Finally, in concluding that the date in § 156(d)(1) and the approval date in § 156(g)(1)(B)(ii) are one and the same. The government ignores the fact that § 156(d)(1) defines the date on which "the applicant's filing period [should be deemed] to begin," whereas § 156(g)(1)(B)(ii) "define[s] the end of [the regulatory review] period." The PTO still has not identified any reason why the date that defines the end of one period must necessarily, and in all cases, be the same as the date that defines the beginning of a different period. The PTO continues to rely on the Federal Circuit's decision in Unimed even though Unimed does not govern here. The PTO argues that 21 U.S.C. § 355(a) demonstrates that the two dates must be the same. But § 355(a) merely limits the commercial use of a product prior to its approval date; it provides no guarantee that the NDA sponsor will receive notice such that it would be fair for the PTE applicant's filing period to begin.

The government concedes that Unimed did not involve the same

facts and issues presented here, yet it does not deny that the PTO relied on Unimed. The government asserts that Unimed is highly instructive and persuasive precedent that indicates that the Federal Circuit would endorse the PTO's reading of the statute in examining the precise facts and legal issue presented here. The government also cites Unimed as foreclosing MDCO's argument that a business day interpretation of § 156(d)(1) is the only reading consistent with the statute's purpose.

In defending the PTO's reliance on Unimed, the government asserts that the Court's decision simply held that Unimed did not unilaterally control the ultimate result here. Although a few sentences in Unimed could be read to suggest that the date that starts the 60-day period in § 156(d)(1) is the date stamped on the FDA approval letter the question at issue here – the proper treatment of an after hours letter – was not presented in Unimed.

Even if the PTO were writing on a blank slate without the benefit of the Court's prior opinion, its decision still could not stand. In numerous respects, the decision violates the APA and advances an interpretation of § 156(d)(1) that is unreasonable even under the most deferential standard of review, let alone the more exacting review that applies to the appeal of a remanded order. Chamber of Commerce v. SEC, 443 F.3d 890, 899 (D.C. Cir. 2006).

The government does not deny that under the PTO's

interpretation, the date stamped on the FDA approval letter starts the 60-day period for filing an application, even if the FDA never sends the letter, sends it to the wrong address, delays in sending it, or sends it by means that would take multiple days to reach the applicant. Nor does the government deny that the PTO's decision failed to address this issue. That failure, by itself, renders the PTO's decision arbitrary and capricious. The government asserts that the absurd consequences resulting from the PTO's interpretation of the statute would not, in actuality, occur due to procedural safeguards FDA has put into place. As an initial matter, this argument may not be considered by the Court because the PTO did not rely on it in its decision. Chenery, 332 U.S. at 196. In any event, the issue is not that the FDA would intentionally fail to send or confirm notification of an NDA approval, but rather that over time mistakes are inevitable. An interpretation that imposes such drastic consequences when the government errs could not be what Congress intended.

Indeed, it is the opposite of the construction presumptively to be given to a remedial statute. The FDA guidance document cited by the government does not diminish the risk that under the PTO's interpretation an applicant could lose a substantial portion, if not all, of its time for filing a PTE application as a result of mistakes beyond its control. The document does not

specify what, if any, procedures are in place to ensure that a new drug applicant gets notice of an approval decision, nor does it require the FDA to verify receipt of the approval letter contemporaneously with its transmission. The FDA's internal policies suggest that even if an approval letter is properly sent, there can be substantial delays between when the FDA approves the NDA and when the notice of that approval can be expected to reach the applicant. FDA staff are permitted to mail the approval letter via the postal service, and this mailing can occur the next business day after the "signing of the approval letter." In combination, these delays between FDA approval and constructive receipt would, under the PTO's reading of § 156(d)(1), cause a PTE applicant to lose a substantial portion of the 60-day filing period.

The government does not dispute that there is a strong presumption that when Congress repeats the same word in the same statute, it intends for that word to be given the same meaning, but the PTO still has not provided an adequate explanation for the inconsistency between its calendar day interpretation of the phrase "beginning on the date" in § 156(d)(1) and the FDA's business day interpretation of the same phrase in § 156(g)(1)(B)(ii). The PTO has maintained the inconsistency is unavoidable because the word "date" appears twice in § 156(g)(1)(B)(ii), and the FDA interprets the word differently in

each instance. But § 156(d)(1) refers to the 60-day period beginning on the date the drug receives approval, and this same phrase appears not twice in § 156(g)(1)(B)(ii), but once – in reference to the period beginning on the date an NDA is initially submitted to the FDA.

Instead of attempting to achieve consistency between the two identical phrases, the PTO instead linked the meaning of "beginning on the date" in § 156(d)(1) to the meaning of "ending on the date" in § 156(g)(1)(B)(ii).

The government contends that doing so yields no logical result. But the government, like the PTO, continues to ignore the fact that the phrase day period does not start until applicants are deemed to have received notice of the FDA's approval – which, in the case of after-hours approvals, occurs on the next business day, "beginning on the date" serves the same purpose in § 156(d)(1) and § 156(g)(1)(B)(ii): in both instances, it defines the start of a period in which a party is required to take some action. Just as a PTE applicant must submit its application during the 60-day period "beginning on the date" the product received permission for commercial marketing, the FDA must determine whether an NDA is complete (which in turn starts the clock for the FDA to consider the application's merits) "[w]ithin 60 days after [it] receives" the application. 21 C.F.R. § 314.101(a)(1); see also id. § 314.101(f)(1); 21 U.S.C. §

355(c)(1). The logic that led the FDA to adopt for itself a business day construction – that the clock should not start to run before the party needing to act can reasonably be deemed to be on notice – applies with equal force to the construction of § 156(d)(1).

The two phrases the PTO has linked - "beginning on the date" in § 156(d)(1) and "ending on the date" in § 156(g)(1)(B)(ii) – have very different purposes. There is no reason why the beginning of a filing period must always coincide exactly with the end of the regulatory approval period, without regard to notice. To the contrary, it is commonplace for filing periods to take constructive notice into account. Perhaps most prominently, the Federal Rules of Civil Procedure provide that whenever a party may or must act within a specified time after service, that party automatically receives three additional days if service is made by means other than hand delivery, such as by mail or facsimile. Fed. R. Civ. P. 6(d), see also Fed. R. Civ. P. 5(b). The Federal Rules thus recognize that time periods should not start to run until a party can reasonably be deemed to be on notice. See, e.g., 4B Wright & Miller, *Federal Practice and Procedure* § 1171 (3d ed. 2002) (the rule "is thought to represent a reasonable transmission time[ ] and a fair compromise between the harshness of measuring time strictly from the date of mailing and the indefiniteness of attempting to measure from the date of

[actual] receipt"). This principle applies with equal force here, and the PTO has identified no reason why it should not.

The government does not deny that when notice of FDA approval is sent after normal business hours, the combination of the PTO's calendar day interpretation and its new counting method effectively deprives applicants of a portion of the 60-day filing period that Congress expressly granted them. It does not contest that the PTO would count the day of approval as an entire day of the filing period even if the approval letter were sent as late as 11:59 p.m. Nor does it dispute that the PTO's interpretation could deprive an applicant of several days of the period if, as here, an approval is issued late on a Friday.

Congress is presumed to have enacted § 156 against the backdrop of traditional rules of statutory construction, including the well-established interpretive canon that remedial statutes should be liberally construed. McNairy v. Haitian Refugee Ctr., Inc., 498 U.S. 479, 496 (1991) ("It is presumable that Congress legislates with knowledge of our basic rules of statutory construction."). And the government points to no evidence suggesting Congress intended to give PTE applicants effectively less time than the period it specified in § 156.

The government concedes that the PTO has never previously addressed the specific question of whether the term "date" that is utilized in § 156(d)(1) means a calendar day or a business

day. The government concedes that the PTO's historic practices include a business day rule in patent interference proceedings that accords certain filings a submission date based on the time of day they are received.

The government asserts the difficulty of administering a business day interpretation of the statute. However, the government simply repeats the PTO's reasoning without addressing that a business day rule would, in fact, be easy to administer. The government does not deny that in those rare cases where the time of transmission is an issue, the PTO could easily place the burden on applicants who rely on the next business day rule to establish the time the FDA's notice was transmitted. Given an applicant's duty of candor to the PTO, see, e.g., 37 C.F.R. § 1.56(a), the PTO could rely on the applicant's representations, as it routinely does in applying the patent laws. Indeed, the PTO gives no explanation for why it is able to accept the representations of applicants in other contexts — including representations that satisfy other requirements of § 156, see 35 U.S.C. § 156(e)(1) (eligibility decision "may be made by the Director solely on the basis of the representations contained in the application") — but cannot do so in this one area. Moreover, the PTO's contention is refuted by the PTO's assertion below that it was able to identify all PTE applications that were approved after business hours. Finally, the government's concern with

certainty, cannot justify the PTO's narrow interpretation. In light of the extreme consequences of missing the deadline for filing a PTE application the remedial nature of § 156 requires the statute's timing provision to be interpreted liberally, see, e.g., Rettig, 744 F.2d at 155.

The Court finds the proper interpretation of § 156(d)(1) is a business day construction of the phrase "beginning on the date." Of the parties' competing interpretations the business day construction is consistent with the statute's text, structure, and purpose.

"'[T]he courts are the final authorities on issues of statutory construction'" and "'must reject administrative constructions of [a] statute . . . that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement.'" Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1425 (Fed. Cir. 1988) (quoting FEC v. Democratic Senatorial Campaign Comm., 454 U.S. 27, 32 (1981)).

A business day interpretation is consistent with the remedial nature of § 156(d)(1) by limiting the unnecessary and arbitrary loss of property rights. A business day construction is consistent with the notice function of § 156(d)(1), which focuses on when the product receives permission, such that it would be fair for the applicant's filing period to begin. Just as the FDA and numerous other agencies apply a business day rule when

required to act within a specified time period after receiving a document, an applicant's period to file a PTE application should not begin running until the first business day following the FDA's after-hours transmission of an approval letter. Moreover, if § 156 is to serve its remedial purpose, it must be construed to require notice to applicants seeking to remedy their losses by filing extension applications.

Section 156(d)(1)'s use of the word "received" supports a business day interpretation. It reinforces the distinction between the act of FDA approval and the point at which an applicant is deemed to have received constructive notice of that approval. A business day interpretation ensures that the phrase "beginning on the date" is given the same meaning in both § 156(d)(1) and § 156(g)(1)(B)(ii). See Brown v. Gardner, 513 U.S. 115, 118 (1994) (noting the "presumption that a given term is used to mean the same thing throughout a statute"). The parallel language and purposes of these two provisions show that Congress wanted the respective dates to be calculated in the same way.

A business day interpretation ensures that, under the PTO's new method of counting days, applicants do not lose a portion of the period Congress granted them. Congress intended for the applicant to have sixty days. The PTO interpreted the statute in a manner that deprives an applicant the sixty days that Congress intended for them to receive.

For the forgoing reasons, summary judgment should be awarded to the Plaintiff. An appropriate order shall issue.

/s/
Claude M. Hilton
United States District Judge

Alexandria, Virginia
August 3, 2010