IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re	:	Patent Term Extension Application for US 5,817,338
Issued	:	October 6, 1998
To	:	Pontus J.A. Bergstrand Kurt I. Lövgren
For	:	Multiple Unit Tableted Dosage Form of Omeprazole

CERTIFICATE OF EFS-WEB TRANSMISSION
I hereby certify that this paper is being transmitted via the Electronic Filing System to the U.S. Patent and Trademark Office on the date indicated below.
/John M. Genova/ June 10, 2008
Signature Date

Mail Stop Petition
Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

RENEWED PETITION TO THE DIRECTOR
(37 C.F.R. §1.181)

Sir:

Applicant, AstraZeneca AB timely filed a Petition to the Director under 37 C.F.R. §1.181 ("Petition") and a supporting Declaration in the name of John M. Genova ("Declaration"), both by express mail in accordance with 37 C.F.R. §1.10, on May 30, 2008 in connection with its application for extension of the patent term of the referenced patent. The Petition and Declaration have both been loaded into the image file wrapper system of PAIR.

The Petition was submitted in response to a letter dated April 1, 2008 ("Letter"), which the Office of Patent Legal Administration, U.S. Patent & Trademark Office ("PTO"), sent to the Office of Regulatory Policy, Food and Drug Administration ("FDA") and copied the Applicant, in connection with its application for extension of the patent term of US 5,817,338 (the "'338

patent") (hereinafter, "PTE Application"). Applicant is herewith filing, by EFS, this Renewed Petition ("Renewed Petition") to correct the originally filed Petition in a limited number of instances to ensure that the record is accurate and free of ambiguity.

Firstly, the second page of the Petition has been changed by the deletion of a header that should have been removed but was overlooked at the time of filing. Secondly, in Paragraph 9, page 4 of the Petition, it is stated that the FDA's Guidelines entitled "Frequently Asked Questions on the Patent Term Restoration Program", which is posted and available on the FDA's website, were last updated on July 22, 2005. The Guidelines were in fact last updated on May 12, 2008. The correct date of the last update is reflected in Paragraph 9 and throughout this Renewed Petition. A copy of the FDA Guidelines at Exhibit F of the Declaration contains a copy of the May 12, 2008 update. Finally, in Paragraph 12, page 5 of the Petition, the number of the so-called Angiomax patent is incorrectly given as "US 5,916,404". Paragraph 12 of this Renewed Petition provides the correct number -- US 5,196,404 --. The same correction is made on page 10, line 3, of the Renewed Petition.

No other changes have been made to the Petition as originally filed. The Petition and this Renewed Petition remain supported by the Declaration as filed May 30, 2008.

Applicant authorizes the Director to charge any fee required in connection with this Petition to Deposit Account No. 23-1703.

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I. INTRODUCTION

In its April 1, 2008 Letter, the PTO reversed its long-held position that the subject PTE Application was timely and eligible for a patent term extension. This Petition now seeks to have this *ex post facto* decision withdrawn so that the PTO returns to the position it has held since 2004 that the subject PTE Application was timely filed. Like any other administrative agency, the PTO should not be permitted to retroactively apply a new standard to a pending application when the result would have unduly prejudicial and detrimental consequences for the Applicant.

Almost four years ago, both the PTO and FDA determined that the subject PTE Application was timely filed pursuant to 35 U.S.C. §156(d)(1) because Applicant had filed it within 60 days after FDA approval (the "Original Method"), just as Applicant had for its patent term extension for Foscavir® granted on May 20, 1993. From at least 1986 until relatively recently, the PTO had consistently applied to numerous other PTE applications the Original Method of determining timeliness, which had been enunciated in a PTO-FDA interagency memorandum as requiring submission of a PTE application "within 60 days after the product was approved." Indeed, Applicant can find no evidence that the PTO has ever dismissed a PTE application as one day late when the application was filed on the sixtieth day under the Original Method.

For these reasons and the others set forth herein, Applicant petitions under 37 C.F.R. §1.181(a)(3) (alternatively, 37 C.F.R., §1.182) to invoke the supervisory authority of the Director to prevent the PTO from retroactively applying to the subject PTE Application an apparently new method of determining timeliness that has not yet even been announced to the public.

II. STATEMENT OF FACTS

A. The Subject PTE Application and the Prior 2004 PTO/FDA Correspondence

1. The subject PTE Application was filed with the PTO on August 19, 2003, by express mail in accordance with 37 C.F.R. §1.10. (*See* Genova Decl. Ex. A.) Applicant seeks a patent term extension under 35 U.S.C. §156 for the human drug product known by the trade name Prilosec OTC®.

2. In 2004, the PTO and FDA exchanged correspondence stating that the subject PTE Application would be eligible for PTE under 35 U.S.C. §156, based upon a review of that application by each agency. (Genova Decl. Exs. B & C.)

3. Specifically, in a letter dated July 19, 2004, the PTO (Karin Ferriter) stated that "[o]ur review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. §156 of [sic] the active ingredient is omeprazole magnesium, not omeprazole." (Genova Decl. Ex. B.) The PTO requested the FDA's assistance in confirming, inter alia, that the PTE application "was filed within the sixty-day period ***after*** the product was approved," i.e., the Original Method. (Id. (emphasis added).) With this letter, the PTO provided the FDA with a copy of the subject PTE Application, which it stated was filed on August 19, 2003. (Id.)

4. In a response dated October 19, 2004, the FDA (Jane A. Axelrad) wrote, *inter alia*, that "[t]he NDA was approved on June 20, 2003, which makes the submission of the patent term extension application on August 19, 2003, timely within the meaning of 35 U.S.C. §156(d)(1)." (Genova Decl. Ex. C.) This conclusion was based on application of the Original Method.

5. On April 1, 2008, almost four years after the two 2004 favorable agency letters, the PTO (Mary C. Till) sent a second request to the FDA for assistance with the subject PTE

Application but reversed its position stated in 2004 and concluded that the subject PTE Application was not timely filed. (Genova Decl. Ex. D.) This 2008 PTO Letter did not refer to the prior favorable PTO and FDA letters of July 19, 2004, and October 19, 2004. To date, the FDA has not replied to the PTO's Letter of April 1, 2008.

6. In its Letter of April 1, 2008,[1] the PTO stated that "the subject patent term extension application was not timely filed based on a plain reading of the statutory language of 35 U.S.C. §156(d)(1) and the PTO's implementing regulations at 37 C.F.R. §1.720(f)." (Genova Decl. Ex. D at 1.) In reliance thereon, the PTO stated that "[t]he absolute deadline for filing a PTE application was sixty days from June 20, 2003, starting the count of that sixty-day period on June 20, 2003." (Id. at 2.) Therefore, according to the PTO, "[t]he sixtieth day of that time period was August 18, 2003 (a Monday)." (Id.) And "[s]ince the PTE application was filed on August 19, 2003," the PTO concluded that the PTE Application was untimely. (Id.) For Applicant, this April 1, 2008 Letter marked the first time that the PTO had described such an approach to determining whether or not a PTE application was filed — here termed the "2008 Method."

B. PTO's Past Policies and Long-Standing Practices – the Original Method

7. In each of two publications, which have not been superseded or withdrawn, the PTO and FDA interpret the timeliness provision of 35 U.S.C. §156(d)(1) to mean that a PTE application must be filed within 60 days ***after*** FDA approval, i.e., the Original Method. It is clear from the plain language of these publications that the PTO and FDA interpret the "sixty-day period" of 35 U.S.C. §156(d)(1) to begin on the first day after FDA approval.

[1] The April 1, 2008 PTO letter also set forth its new position on eligibility, which issue is not addressed here, but to which Applicant also strongly objects as a change of position from the PTO's letter of July 19, 2004. (*See* Genova Decl. Ex. D.)

8. To establish the procedures by which the FDA was to assist the PTO to determine eligibility under 35 U.S.C. §156, the PTO and FDA entered into an interagency agreement of understanding, entitled *Memorandum of Understanding Between The Patent and Trademark Office and The Food and Drug Administration* (the "*1987 Memorandum of Understanding*"), MOU 225-86-8251, 52 Fed. Reg. 17830 (May 12, 1987), signed by John M. Taylor for the FDA and Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, both in September 1986. (Genova Decl. Ex. E.) In response to a PTO request for assistance in making a PTE determination, the *1987 Memorandum of Understanding* provides that the FDA will provide a written reply, "informing the [PTO] whether the patent term extension application was [inter alia] submitted **within 60 days *after* the product was approved**." (Id. at 2 (emphasis added).)

9. The FDA's "Frequently Asked Questions on the Patent Term Restoration Program" (hereinafter "2008 FDA Guidelines"), last updated May 12, 2008, which is still posted and available on the FDA's website at http://www.fda.gov/cder/about/smallbiz/patent_term.htm, provides similar guidance to small business owners and the general public. Question 5 provides:

> **5. When is a patent extension application submitted and where is it submitted?**
>
> Application for patent extension must be filed ***within 60 days of FDA approval*** of the drug product even if the product cannot be commercially marketed at that time.... The patent extension application is filed with the PTO.

(Genova Decl. Ex. F (emphasis added).) These 2008 FDA Guidelines provide contact information for both the FDA and PTO contact persons for patent term extensions. (Id. at 5.)

10. In 1993, Applicant itself was granted a patent term extension for its approved Foscavir® drug product, based on a PTE application filed on the sixtieth day as determined by the Original Method. (Genova Decl. Ex. G.) Thereafter, this patent term extension was the subject of litigation over the length of the regulatory review period, which was first brought in a

federal district court and then decided by the U.S. Court of Appeals for the Federal Circuit in *Astra* v. *Lehman*, 71 F.3d 1578 (Fed. Cir. 1995). Although 35 U.S.C. §156(d)(1) was the focus of the legal analysis by both courts (*see, e.g., Astra* at 1580-1581), the timeliness of Applicant's PTE application was not questioned. Moreover, Applicant's attorney was the same law firm as for the subject PTE Application.

11. The PTO has granted at least thirteen other patent term extensions, beginning in 1986, based on third-party PTE applications filed on the sixtieth day according to the Original Method. The patents enjoying the benefits of these patent term extensions are US 3,721,687; 3,732,340; 4,407,288; 4,513,006; 4,702,253; 4,830,010; 4,836,217; 4,874,794; 4,941,093; 5,441,745; 5,532,221; 5,639,639; and 5,827,937; this last patent term extension was granted on October 7, 2007. This long-standing practice, from at least 1986 through at least October 2007, is evident from a review of relevant portions of the prosecution history for each of these patents. (Genova Decl. Ex. H, tabs 1-13, respectively.)

12. The long-standing practice of the PTO and FDA using the Original Method is also apparent from a review of the prosecution history concerning the PTE application submitted in connection with US 5,196,404 for the human drug product known by the trade name Angiomax®. The original PTE application of US 5,196,404 (the "'404 application") was filed with the PTO on February 14, 2001. (Genova Decl. Ex. I.) In its Notice of Final Determination dated March 4, 2002, the PTO indicated that the '404 application was untimely (when determined by the Original Method) because it was filed on the sixty-first day after FDA approval, thus suggesting that it would have been timely had it been filed on the *sixtieth day after FDA approval.* (Genova Decl. Ex. J at 1.) However, notwithstanding several preliminary and final determinations of untimeliness and requests for reconsideration, the PTO stated in a

footnote in its Decision Denying PTE, dated April 26, 2007 (Genova Decl. Ex. K at 7 fn3), i.e., more than six years after the PTE filing date of February 14, 2001, that, upon reconsideration (and using the 2008 Method for the first time in that case), the PTE application was actually filed on the sixty-second day of the period beginning on the date of FDA approval.

III. POINT TO BE REVIEWED

13. The point to be reviewed by this Petition is whether the PTO may reverse its previously held position by retroactively applying the 2008 Method of determining the timeliness of a PTE Application that had already been deemed timely by the PTO and FDA in 2004 (applying the Original Method), while ignoring the unduly prejudicial and deleterious consequences for the Applicant. The PTO's pronouncement that the subject PTE Application is untimely when determined by the 2008 Method represents an abrupt departure from the well-established practices of both the PTO and the FDA in carrying out their responsibilities under 35 U.S.C. §156(d)(1) by applying the Original Method for over twenty years, which is impermissible in view of U.S. Supreme Court precedent.

IV. IT IS IMPROPER FOR THE PTO TO CHANGE ITS POSITION ON THE TIMELINESS OF THE SUBJECT PTE APPLICATION AFTER DETERMINING IT TO BE TIMELY IN 2004 AND IN VIEW OF 20+ YEARS OF A WELL-ESTABLISHED PRACTICE

A. Balancing Test Strongly Favors Applicant Over PTO

In *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947), the United States Supreme Court held that an agency may give retroactive force to a new standard of conduct in a case of first impression, but "[the] retroactivity must be balanced against the mischief of producing a result which is contrary to a statutory design or to legal and equitable principles." *SEC* v. *Chenery Corp.*, 332 U.S. 194, 203 (1947); *see also Miguel-Miguel* v. *Gonzales*, 500 F.3d 941, 951 (9th

Cir. 2007); *Retail, Wholesale and Dep't Store Union, AFL-CIO* v. *NLRB*, 466 F.2d 380, 390 (D.C. Cir. 1972).

To perform the balancing analysis required by the *Chenery* Supreme Court decision, the following five (5) factors should be considered:

(1) whether the particular case is one of first impression;

(2) whether the new rule represents an abrupt departure from well-established practice or merely attempts to fill a void in an unsettled area of law;

(3) the extent to which the party against whom the new rule is applied relied on the former rule;

(4) the degree of the burden which a retroactive order imposes on a party; and

(5) the statutory interest in applying a new rule despite the reliance of a party on the old standard.

Retail, Wholesale and Dep't Store Union, 466 F.2d at 390; *see also Miguel-Miguel* v. *Gonzales*, 500 F.3d at 951 (holding that a new standard for determining whether a drug trafficking offense is "particularly serious," adopted in an unrelated proceeding while an alien's removal proceedings were already pending, could not be applied retroactively to the alien's removal proceedings); *Montgomery Ward & Co., Inc.* v. *FTC*, 691 F.2d 1322, 1333 (9th Cir. 1982) (holding that the Federal Trade Commission could not retroactively apply a new interpretation of a rule regarding the placement of warranty binders in retail stores to conduct that occurred prior to the Commission's articulation of its new standard, where retroactive application would impose a significant burden on a party); *Chang* v. *United States*, 327 F.3d 911, 928 (9th Cir. 2003) (holding that a new policy regarding an immigrant investor program, announced by an agency in an unrelated decision subsequent to the agency's approval of immigrants' first petitions, could not be applied retroactively to those immigrants with respect to the immigrants' second petitions related to the program); *Gilbert* v. *Federal Mine Safety & Health Review Comm'n*, 866 F.2d

1433, 1442 (D.C. Cir. 1989) (holding that a change in policy could not be retroactively applied). Retroactive application cannot be countenanced when its inequity is not counterbalanced by sufficiently significant statutory interests. *Retail, Wholesale and Dep't Store Union*, 466 F.2d at 390. Analysis of the five factors leads to the inevitable conclusion that the PTO should be precluded from retroactively applying the new 2008 Method to the subject PTE Application filed in 2003.

1. Whether the particular case is one of first impression

This is not a case of first impression. Applicant itself and at least thirteen other PTE applicants have been granted patent term extensions for applications submitted on the sixtieth day after FDA approval according to the Original Method. Therefore, this first factor favors Applicant. Retroactivity is disfavored "where the [agency] ha[s] confronted the problem before, ha[s] established an explicit standard of conduct, and now attempts to punish conformity to that standard under a new standard subsequently adopted." *Miguel-Miguel* v. *Gonzales*, 500 F.3d at 951, *quoting Retail, Wholesale and Dep't Store Union, AFL-CIO* v. *NLRB*, 466 F.2d at 391.

2. Whether the new rule represents an abrupt departure from well-established practice or merely attempts to fill a void in an unsettled area of law

The PTO's Letter of April 1, 2008, regarding its determination of untimeliness represents an abrupt departure from long-standing policies and practices, dating back to at least September 1986, when the interagency *1987 Memorandum of Understanding* was signed by the FDA and PTO Commissioner Donald Quigg. This public pronouncement of the PTO's and FDA's joint interpretation of 35 U.S.C. §156(d)(1) is helpful to the general public and PTE applicants in particular because its implementing regulation, 37 C.F.R. §1.720(f), merely recites the statutory provision.

The *1987 Memorandum of Understanding* is still in force and, to the best of Applicant's knowledge, the terms of the *1987 Memorandum of Understanding* have not been modified. Under this agreement, the FDA, upon receipt of a written request from the PTO, will convey to PTO, *inter alia*, whether the PTE application was submitted ***within 60 days after the product was approved***. (Genova Decl. Ex. E at 2 (emphasis added).) The 2008 FDA Guidelines provided a similar interpretation of the statute and the regulations: "Application for patent extension must be filed ***within 60 days of FDA approval***...." (Genova Decl. Ex. F at 2 (emphasis added).) Applicant is not aware of any other public pronouncements by the PTO and/or FDA on the interpretation of 35 U.S.C. §156(d)(1).

The PTO's letter of July 19, 2004, to the FDA followed the language of the *1987 Memorandum of Understanding* and requested the FDA to confirm that "the application for patent term extension was filed ***within the sixty-day period after the product was approved.***" (Genova Decl. Ex. B (emphasis added).) In its reply of October 19, 2004, the FDA confirmed that Applicant's PTE application on August 19, 2003, was timely within the meaning of 35 U.S.C. §156(d)(1). (Genova Decl. Ex. C.)

Applicant's own success in obtaining a patent term extension for Foscavir® in 1993 from a PTE application filed on a date according to the Original Method is relevant to this Petition. Since that success, the PTO has not issued any public notice that it intended to replace the Original Method with the 2008 Method. In fact, at least thirteen other PTE applicants have been granted patent term extensions based on PTE applications filed on the sixtieth day according to the Original Method, as recently as October 7, 2007. (*See* Genova Decl. Ex. H-13.)

Applicant is also aware of other instances where the PTO and/or FDA have deemed timely PTE applications filed on the sixtieth day per the Original Method but rejected the

application on substantive grounds. (*See* U.S. Patent Nos. 3,419,578; 4,674,505; 5,545,403; 5,808,665; 4,710,532; 4,824,893.)

The PTO history of the Angiomax PTE application for US 5,196,404 demonstrates the PTO's abrupt departure from well-established precedent for determining timeliness using the Original Method. The Angiomax PTE application was filed with the PTO on February 14, 2001, *61 days after FDA approval* on December 15, 2000.[2] For more than six years, the PTO determined that the Angiomax PTE application was untimely by only one day based on the Original Method. For example, the PTO Corrected Notice of Final Determination, dated March 4, 2002, states:

> 35 U.S.C. §156(d) requires that an application for patent term extension be filed "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. ***Sixty days after the approval date***, December 15, 2001 [sic] is February 13, 2001. Since February 13, 2001 was a regular business day, the application must be dismissed as untimely.

(Genova Decl. Ex. J (emphasis added).) By stating that "[s]ixty days ***after*** the approval date of December 15, 2001 [sic] is February 13, 2001," the PTO explicitly used the Original Method in calculating the deadline. However, the PTO decided more than six years after the PTE application filing date that, upon reconsideration, the PTE application was filed on the sixty-second day of the period beginning on the date of FDA approval. This statement, wherein for the first time in the case the PTO applied the 2008 Method of counting, appears in footnote 3 on page 7, of the PTO's Decision, dated April 26, 2007, denying PTE for the '404 patent. (Genova Decl. Ex. K at 7.) Even after this April 2007 determination, the PTO subsequently granted term

[2] The actual issue in the Angiomax PTE application was not how to count the 60-day period but rather when the FDA approved the NDA for Angiomax. Whether the Original Method or 2008 Method was used, the PTE application was untimely.

extension to a PTE application filed on the sixtieth day according to the Original Method. (*See* Genova Decl. Ex. H, tab 13, re US 5,827,937.)

Applicant acknowledges that the Manual of Patenting Examining Procedure ("MPEP") in effect when it filed the subject PTE Application contained a section entitled "Deadline for Filing an Application Under 35 U.S.C. §156(d)(1)." (*See* MPEP §2754.01 (8th ed. Rev. 1, Feb. 2003).) This section merely recites the language in the statute and provides no guidance on how to calculate the deadline. The section refers to US 4,486,425, but the PTE application in that case was filed many weeks after the deadline under any method. Therefore, to the extent that PTO practice can be used to illuminate how to calculate the deadline, it was using the Original Method, as already discussed, in addition to the *1987 Memorandum of Understanding.*

In sum, more than 20 years of a publicly stated policy based on the Original Method and its implementation, as evidenced by approval of PTE applications filed according to the Original Method, defines without question a "well-established practice." Applicant had no basis to believe that the Original Method of determining timeliness was no longer in effect when it filed the subject PTE Application in 2003, particularly when its timeliness was confirmed by both the PTO and FDA in 2004.

Thus, by now deeming Applicant's PTE Application filed in 2003 as untimely based on the new 2008 Method, the PTO has impermissibly decided to apply a new standard to an already pending PTE application, with extremely prejudicial and detrimental consequences to the Applicant. Such conduct is arbitrary, capricious and an abuse of discretion. *E.g.*, *Chang* v. *United States*, 327 F.3d at 929; *Gilbert* v. *Federal Mine Safety & Health Review Comm'n*, 866 F.2d at 1441-1443.

3. The extent to which the party against whom the new rule is applied relied on the former rule

The third factor also favors Applicant. In filing the subject PTE Application when it did, Applicant relied on its experience in filing a successful PTE application, as well as the *1987 Memorandum of Understanding* and the 2005 FDA Guidelines (as published at the time), as confirmed by both the PTO and FDA in favorable eligibility letters of 2004 and the ensuing three years of silence. There are no new facts, changes in the law, or any public notice to the contrary that should have precluded Applicant's reliance on the PTO's use of the Original Method of determining timeliness under 35 U.S.C. §156(d).

4. The degree of the burden which a retroactive order imposes on a party

The fourth factor also favors Applicant. If the PTO's new 2008 Method is applied retroactively to Applicant's PTE Application, Applicant would lose the opportunity for its PTE Application for an extension of 623 days to be considered on the merits. After all, in 2004 the PTO had determined that the subject PTE Application was also substantially eligible for a patent term extension. (Genova Decl. Exs. B & C.) Such a loss represents a financial penalty that is inordinately egregious to Applicant. In *NLRB* v. *Majestic Weaving Co.*, 355 F.2d 854, 860-861 (2d Cir. 1966), the court said:

> "Although courts have not generally balked at allowing administrative agencies to apply a rule newly fashioned in an adjudicative proceeding to past conduct, a decision branding as "unfair" conduct stamped "fair" at the time a party acted; raises judicial hackles...And the hackles bristle still more when a financial penalty is assessed for action that might well have been avoided if the agency's changed disposition had been earlier made known, or might have even been taken in express reliance on the standard previously established."

The PTO's change from the Original Method to the 2008 Method for determining the timeliness of Applicant's PTE Application effects a change in PTO policy from a favorable to a

negative determination regarding the timeliness of the PTE Application and thereby amounts to deprivation of Applicant's rights. In view of the long-standing intrepretation by the PTO in applying the Original Method to calculate the deadline under 35 U.S.C. 156(d)(1), there is no basis for applying the 2008 Method. Such a change would be akin to a retroactive rule change that may divest applicants of valuable rights to which, but for the change in PTO method, they were entitled. *See In re Henriksen*, 399 F.2d 253, 261-262 (C.C.P.A. 1968). Even assuming the PTO had authority to adopt a new method of calculating the deadline for submitting a PTE application, an administrative agency cannot impose a penalty or forfeiture without providing appropriate notice. *U.S.* v. *Chrysler Corp.*, 158 F.3d 1350 (D.C. Cir. 1998).

5. The statutory interest in applying a new rule despite the reliance of a party on the old standard

Finally, the fifth factor favors Applicant. There cannot be a sufficiently significant statutory interest that outweighs the foregoing factors in these circumstances where the PTO has applied the Original Method for more than 20 years.

The PTO administered the patent term extension statute, 35 U.S.C. §156, essentially since its enactment in 1984 by applying the Original Method for determining whether or not a PTE application was timely filed. Applicant could find no evidence of any inconsistency with which the Original Method was applied to PTE applications. In fact, more than 15 years ago, in 1993, Applicant was granted a patent term extension based on an application filed on a date under the Original Method. The 2008 Method that the PTO now seeks to apply retroactively against Applicant appears to represent a different interpretation of the statute correlated with a change in personnel in the Office of Patent Legal Administration, which occurred in the third quarter of 2005, that is, after the August 19, 2003 filing date of the subject PTE Application and favorable agency letters of 2004. The 2008 Method does not implement any change in the

governing statute, is not the result of a rule-making process that was subject to public comment, and does not represent a procedure by which public notice was first given so that new PTE applicants would be aware of how to determine when to file their PTE applications. In fact, no public notice of this change has yet been issued. Accordingly, as an equitable matter, whatever interest there may be to interpret the statute differently more than 20 years after its enactment is far outweighed by the interests of Applicant and its reliance on the Original Method.

V. ACTION REQUESTED

Applicant respectfully requests that the PTO maintain its original position that Applicant's PTE Application was submitted timely for all the foregoing reasons and exhibits in support thereof.

Respectfully submitted,

Dated: June 10, 2008

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