



PATENT
ATTORNEY DOCKET NO.: 061635-0007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 4,937,078)
Granted: June 26, 1990)
Patentees: Michael MEZEI and Adrienn)
GESZTES)
Assignee: Mezei Associates Limited)
FOR: LIPOSOMAL LOCAL ANESTHETIC)
AND ANALGESIC)

Commissioner for Patents
U.S. Patent and Trademark Office
220 20th Street S.
Customer Window, **Mail Stop Patent Ext.**
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Date: July 7, 2004

FEE COVER SHEET FOR
REQUEST FOR EXTENSION OF PATENT TERM
PURSUANT TO 35 U.S.C. § 156

Sir:

1. Transmitted herewith is a REQUEST FOR EXTENSION OF PATENT TERM PURSUANT TO 35 U.S.C. § 156 including Exhibits 1-7 (Original + 4 sets).

2. Constructive Petition

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

3. Fee Calculation (37 C.F.R. §1.16)

Fee for <u>Patent Term Extension</u>	\$ 1,120.00
Reduction by ½ for filing by a small entity	\$ 0.00
TOTAL FEE =	\$ 1,120.00

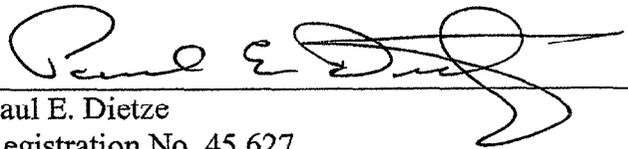
4. Fee Payment

- The Commissioner is hereby authorized to charge \$1,120.00 to Deposit Account No. 50-0310 for Extension of Term of Patent (37 C.F.R. §1.20(j)(1) (PTO Fee Code 111).
- The Commissioner is hereby authorized to charge any additional fees which may be required, including fees due under 37 C.F.R. §§ 1.16 and 1.17, or credit any overpayment to Deposit Account 50-0310.

Respectfully Submitted,
Morgan Lewis & Bockius LLP

Date: July 7, 2004
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**REQUEST FOR EXTENSION OF PATENT TERM
PURSUANT TO 35 U.S.C. § 156**

Sir:

Applicant, Mezei Associates, Ltd. (“Mezei”), a corporation created and existing under the Laws of Canada, represents that it is the owner of the entire interest in and to United States Patent No. 4,937,078 for LIPOSOMAL LOCAL ANESTHETIC AND ANALGESIC PRODUCTS granted to Michael MEZEI and Adrienn GESZTES on June 26, 1990 by virtue of an assignment from Michael MEZEI to Mezei, recorded at frame 005044, reel 0743, and an assignment from Adrienn GESZTES to Mezei, recorded at frame 005044, reel 0741. A copy of the assignments are attached hereto as **Exhibit 1**. A Grant of Power of Attorney, authorizing the registered practitioners of Morgan, Lewis & Bockius LLP to act of behalf of Mezei for the purposes of obtaining a patent term

extension for United States patent no. 4,937,078, with correspondence and communications to be directed as set forth therein and in section (15) of this Application, is being filed concurrently herewith. A copy of the Grant of Power of Attorney is attached hereto as **Exhibit 2**.

The following information is submitted in accordance with 35 U.S.C. § 156(d) and 37 C.F.R. § 1.710 *et seq.*, and follows the numerical sequence and format as set forth in 37 C.F.R. § 1.740(a):

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics.

The approved product is SURPASS[®], which is further identified as follows:

Chemical Name:

sodium [o-(2,6-dichloroanilino)phenyl]acetate, as set forth in the approved label insert.

Generic Name:

Diclofenac sodium

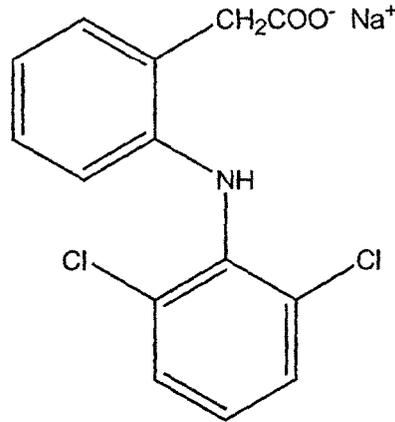
Molecular Formula:

$C_{14}H_{10}Cl_2NNaO_2$

Molecular Weight:

318.13

Structural Formula:



Diclofenac sodium, as described above, is the active ingredient of the approved product, SURPASS[®], as can be seen from the approved labeling for SURPASS[®]. A copy of the approved labeling for SURPASS[®] is attached hereto as **Exhibit 3**.

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred.

SURPASS[®] was subject to regulatory review under Section 512(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §360(b)).

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred.

SURPASS[®] received permission for commercial marketing or use under Section 512(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §360(b)) upon approval of NADA 141-186 on May 13, 2004.

(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or

use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.

The active ingredient of SURPASS[®] is diclofenac sodium. Diclofenac sodium has been approved for commercial marketing and use in humans under section 505(b) of the Federal Food, Drug and Cosmetic Act. Diclofenac sodium, has not been approved for commercial marketing and use in animals under section 512(b) of the Federal Food, Drug and Cosmetic Act prior to approval of NADA 141-186 on May 13, 2004.

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted.

SURPASS[®] was approved on May 13, 2004, and the last day within the sixty day period permitted for submission of an application for patent term extension is July 13, 2003. Accordingly, this application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f).

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration.

The complete identification of the patent for which an extension is being sought is as follows:

Inventor:	Michael MEZEI and Adrienn GESZTES
U.S. Patent No.:	4,937,078
Issue Date:	June 26, 1990
Expiration Date:	August 26, 2008

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings.

A full copy of U.S. Patent No. 4,937,078, for which extension is being sought, is attached hereto as **Exhibit 4**.

(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.

A copy of the maintenance fee statement showing timely payment of each maintenance fee when due is attached as **Exhibit 5**.

No disclaimer, certificate of correction, or reexamination certificate has been filed and/or issued for U.S. Patent No. 4,937,078.

(9) A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:

- (i) The approved product, if the listed claims include any claim to the approved product.**
- (ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and**
- (iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product;**

Claim 14 of U.S. Patent 4,937,078 reads on the method of using the approved product, as detailed below.

Claim 14 of U.S. Patent 4,937,078 reads as follows:

14. A method for providing local anesthesia or analgesia to a mammal which comprises topically applying to said mammal a composition containing phospholipid vesicles encapsulating 0.1 to 10% by wt. of an anesthetic or analgesic agent, wherein said composition is applied in an amount between about 0.005 to 0.5 g/cm² of surface to be anesthetized.

As set forth on page 1 of the labeling for the approved product, **Exhibit 3**, SURPASS[®] is indicated for control of pain and inflammation associated with osteoarthritis in the joints of horses by applying a 5" ribbon of SURPASS[®] topical cream twice daily over the affected joint. As also set forth on page 1 of the labeling, SURPASS[®] is a topical cream containing 1% diclofenac sodium in a base composed of Phospholipoin 90H (a phospholipid), propylene glycol, alcohol, vitamin E acetate,

benzethonium chloride, and purified water in a liposomal formulation, *i.e.*, a phospholipid vesicles. As set forth on page 2 of the labeling, SURPASS[®] is a non-steroidal anti-inflammatory drug with analgesic properties, *i.e.*, an analgesic agent. Applying a 5" ribbon of SURPASS[®] to the joint of a horse corresponds to applying the composition in an amount between about 0.005 to 0.5 g/cm². For example, the surface area of the knee joint of a horse is about 730 cm² and a 5" ribbon of SURPASS[®] corresponds to about 7.3 g of SURPASS[®] (this is because a 5" ribbon of SURPASS[®] contains about 73 mg of diclofenac sodium at a concentration of about 1% (*See*, package insert page 2, section on effectiveness))¹. Therefore, applying a 5" ribbon of SURPASS[®] to the knee joint of a horse corresponds to applying the composition in an amount of about 0.01 g/cm² (7.3g / 730 cm²). The largest joint of a horse for which SURPASS[®] is intended to be applied is the hock, which has a surface area about 1.5 times larger than the surface area of the knee. Accordingly, applying SURPASS[®] to the hock of a horse corresponds to applying the composition in an amount of about 0.007 g/cm². The smallest joint of a horse for which SURPASS[®] is intended to be applied is the interphalangeal joint, which has a surface area about 0.5 times smaller than the surface area of the knee. Accordingly, applying SURPASS[®] to the interphalangeal joint of a horse corresponds to applying the composition in an amount of about 0.02 g/cm². Or, considered another way, applying 7.3 g of SURPASS[®] in an amount between about 0.005 to 0.5 g/cm² corresponds to covering a surface of an area between about 14.6 cm² and 1,460 cm². The area of the joints of a horse for which SURPASS[®] is intended to be applied all fall within this range. Therefore, claim 14 reads on a method of using the approved product.

¹ The area of the knee joint of a horse can be estimated by approximating that the knee joint is a cylinder 15.24 cm (6 inches) high and 15.25 cm (6 inches) in diameter and using the formula for the area of the sides of a cylinder (area of sides of a cylinder = circumference x height, wherein circumference is π x diameter) to calculate the area of the knee joint.

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(ii) For a patent claiming a new animal drug:

(A) The date a major health or environmental effects test on the drug was initiated, and any available substantiation of that date, or the date of an exemption under subsection (j) of section 512 of the Federal Food Drug and Cosmetic Act became effective for such animal drug;

On January 11, 1999 the FDA granted IDEXX's request for a categorical exclusion from preparing an environmental assessment. A copy of the FDA letter granting the request for categorical exclusion is attached hereto as **Exhibit 6**. This establishes the beginning of the "regulatory review period" under 35 U.S.C. 156(g)(4) as January 11, 1999.

(B) The date on which a new animal drug application (NADA) was initially submitted and the NADA number; and

The initial submission constituting NADA 141-186 for SURPASS[®] was on December 27, 2000 (**Exhibit 7**). The FDA acknowledged receipt of the initial submission and assigned the submission NADA number 141-186 on January 2, 2001 (**Exhibit 8**). This establishes the "initial" submission date of NADA 141-186 under 35 U.S.C. 156(g)(4) as January 2, 2001.²

² This is consistent with FDA's policy, as stated in FDA's proposal to amend 21 C.F.R. § 60.1, Patent Term Restoration Regulations, that the date "a NADA will be considered to have been initially submitted with respect to the animal drug product under section 512(b) of the act will be the date of FDA's official acknowledgement letter assigning a number to the NADA" (*See*, FDA's proposal to amend 21 C.F.R. § 60.1, Patent Term Restoration Regulations, 56 Fed. Reg. 5784, February 13, 1991, (**Exhibit 9**)).

(C) The date on which the NADA was approved.

The NADA was approved by the FDA in an approval letter sent May 13, 2004. A copy of this FDA approval letter is attached as **Exhibit 10**. This establishes the end of the “regulatory review period” under 35 U.S.C. 156(g)(4) as May 13, 2004.

(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

The regulatory activities undertaken to obtain approval of SURPASS[®] commenced with the submission of an Investigational New Animal Drug (INAD) Application by Blue Ridge Pharmaceuticals, Inc. ("Blue Ridge", now IDEXX Pharmaceuticals, Inc. ("IDEXX")) on March 6, 1998 to study the use of 1% topical diclofenac in a liposomal base for the relief of pain and inflammation in horses. On March 11, 1998, the FDA acknowledged receipt of the INAD application and assigned the submission INAD number 10-294.

Although, Mezei, the applicant for this patent term extension, did not undertake activities for marketing approval before the FDA, Mezei is authorized to rely upon the activities of Blue Ridge before the FDA as evidenced by a letter from IDEXX specifically authorizing such reliance. A copy of the letter from IDEXX is attached hereto as **Exhibit 11**.

A developmental conference with the FDA was requested on June 30, 1998 and a developmental conference was held on August 14, 1998. Minutes of the developmental conference were provided by the FDA on August 17, 1998.

Protocols for the clinical study and target animal safety studies were submitted on September 8, 1998 and the FDA completed review of the clinical study and target animal safety studies on January 11, 1999. On January 11, 1999 the FDA also granted Blue Ridge's request for categorical exclusion from the requirement to prepare an environmental assessment.

Pivotal clinical studies began in December 16, 1998 and ended on April 15, 1999. Clinical studies were initiated prior to receiving the January 11, 1999 letter from the FDA, providing the FDA's review of the clinical study and target animal safety studies, since the FDA provided their comments to Blue Ridge in an earlier teleconference.

The Chemistry Manufacturing and Controls section was submitted to the FDA on April 30, 1999.

A teleconference was held with the FDA on May 11, 1999 to discuss the statistical methodology for the pivotal clinical study.

The Clinical Efficacy section was submitted to the FDA on October 1, 1999.

The Proposed Labeling section was submitted to the FDA on October 1, 1999.

The Target Animal Safety section was submitted to the FDA on November 23, 1999.

On January 21, 2000, the FDA provided comments on the Clinical Efficacy section.

On February 11, 2000, the FDA provided comments on the Chemistry Manufacturing and Controls section.

On March 23, 2000 Blue Ridge requested a teleconference to discuss the Clinical Efficacy section. The teleconference took place on May 2, 2000 and the FDA provided minutes from the teleconference on June 12, 2000.

On June 14, 2000, the FDA provided comments on the Proposed Labeling section.

On August 31, 2000, the FDA provided comments on the Target Animal Safety section.

On December 27, 2000, IDEXX submitted a complete NADA that addressed all of the comments provided by the FDA. On January 2, 2001, the FDA assigned the NADA number 141-186.

IDEXX filed amendments to NADA 141-186 on February 19, 2001; October 3, 2001; October 4, 2001; and December 14, 2001.

On February 26, 2002, the FDA mailed a letter indicating that NADA 141-186 was incomplete.

On February 27, 2002, IDEXX had a teleconference with the FDA to discuss the labeling. Minutes from the teleconference were provided by FDA on March 26, 2002.

On April 16, 2002, IDEXX had a second teleconference with the FDA to discuss labeling. Minutes from the second teleconference were provided by the FDA on May 13, 2002.

IDEXX re-submitted NADA 141-186 on May 31, 2002.

IDEXX filed amendments to NADA 141-186 on August 28, 2002 and October 11, 2002.

On June 6, 2003, the FDA mailed a letter indicating that NADA 141-186 was incomplete.

IDEXX re-submitted NADA 141-186 on August 26, 2003.

IDEXX filed amendments to NADA 141-186 on December 2, 2003; February 23, 2004; February 24, 2004; March 3, 2004; and March 19, 2004.

NADA 141-186 was approved by the FDA on May 13, 2004.

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined.

Statement That The Patent Is Eligible For Extension:

Applicant is of the opinion that U.S. Patent 4,937,078 is eligible for extension under 35 U.S.C. 156(a) because it satisfies all of the requirements for such extension as follows:

(1) 35 U.S.C. 156(a)

U.S. Patent 4,937,078 claims a method of using the approved product, as detailed in section (9) above.

(2) 35 U.S.C. 156(a)(1)

U.S. Patent 4,937,078 granted on June 26, 1990 from U.S. application no. 07/236,724, filed on August 26, 1988. Accordingly, the expiration date of the patent is August 26, 2008.³ This application, therefore, has been submitted before the expiration of the patent term.

(3) 35 U.S.C. 156(a)(2)

The term of this patent has never been extended.

(4) 35 U.S.C. 156(a)(3)

This application is submitted by the owner of record in accordance with the requirement of 35 U.S.C. 156(d) and rules of the U.S. Patent and Trademark Office. Mezei is the owner of record of the patent by virtue of an assignment from inventor Michael MEZEI to Mezei, recorded at frame 005044, reel 0743, and an assignment from inventor Adrienn GESZTES to Mezei, recorded at

³ The term of a patent in force on June 8, 1995 is the greater of the date that is 20 years from the date on which the application was filed, if the application does not claim priority to any earlier filed application, or 17 years from the patent grant. 35 U.S.C. § 154(c) and MPEP 2701. Accordingly, the expiration date of U.S. Patent 4,937,078 is August 26, 2008, i.e., 20 years from the date on which the application was filed.

frame 005044, reel 0741. Copies of these assignments are attached hereto as **Exhibit 1**.

(5) 35 U.S.C. 156(a)(4)

As evidenced by the May 13, 2004 approval letter from the FDA (**Exhibit 10**), SURPASS[®] was subject to a regulatory review period under Section 512(b) of the Federal Food, Drug, and Cosmetic Act before its commercial marketing or use.

(6) 35 U.S.C. 156(a)(5)(A)(i)

The permission for commercial marketing of SURPASS[®] after this regulatory review period is the first permitted commercial marketing of SURPASS[®] under a provision of the Federal Food, Drug and Cosmetic Act (Section 512(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §360(b)) under which the regulatory review period occurred, as confirmed by the absence of any approved NADA for the approved product prior to May 13, 2004.

(7) 35 U.S.C. 156(c)(4)

No other patent has been extended for the same regulatory review period for the product SURPASS[®].

Statement as to Length of Extension Claimed:

The term of U.S. Patent No. 4,937,078 should be extended by **1590** days, from August 26, 2008 to January 3, 2013. This extension is calculated on the following basis:

Title 35 U.S.C. 156(c) provides that the term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that -- (1) each period of the regulatory review period shall be reduced by any period during which the applicant for the patent extension did not act with due diligence; (2)

after any such reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the period under section 156(g)(4)(B)(i) (the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the new animal drug product); and (3) the total of the period of extension plus the period remaining in the term of the patent after the date of approval shall not exceed fourteen years. The “regulatory review period” is defined in section 156(g)(4), for a new animal drug product, as being the sum of (i) the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal product under section 512, and (ii) the period beginning on the date the application was submitted for the approved animal drug product under section (b) of section 512 and ending on the date such application was approved under such section. Section 156(g)(6) further provides that if the patent involved was issued after the date of the enactment of this section (September 24, 1984), then the period of extension may not exceed five years.

In context of the implementing regulations of 37 C.F.R. 1.778 with respect to patent term extensions for an animal drug product, the term extension of U.S. Patent No. 4,937,078 based on the regulatory review for SURPASS[®] was determined as follows:

Sec. 1.778 Calculation of patent term extension for an animal drug product.

(a) If a determination is made pursuant to Sec. 1.750 that a patent for an animal drug is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (§ 1.321).

U.S. Patent No. 4,937,078 was issued on June 26, 1990 from U.S. application no. 07/236,724, filed on August 26, 1988. Pursuant to 35 U.S.C. 154(c), this patent is entitled to an original term of 20 years from August 26, 1988, which provides an original expiration date of August 26, 2008.

(b) The term of the patent for an animal drug will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for an animal drug will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(4)(B), it is the sum of--

(1) The number of days in the period beginning on the earlier date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved animal drug product and ending on the date an application was initially submitted for such animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved animal drug under subsection (b) of section 512 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.

The number of days in the period beginning on the earlier date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved animal drug product and ending on the date an application was initially submitted for such animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act, *i.e.*, the period defined under 37 C.F.R. § 1.778(c)(1), extends from January 11, 1999 (the date an exemption under subsection (j) of section 512 became effective for the approved animal drug product (**Exhibit 6**)) to January 2, 2001 (the date an application was initially submitted for such animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act, (**Exhibit 8**)) and is **723** days.

The number of days in the period beginning on the date the application was initially submitted for the approved animal drug under subsection (b) of section 512 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section, *i.e.*, the period defined under 37 C.F.R. § 1.778(c)(2), extends from January 2, 2001 (the date application was initially submitted for the approved animal drug under subsection (b) of section 512 of the Federal Food, Drug, and

Cosmetic Act (**Exhibit 8**) to May 13, 2004 (the date such application was approved under such section (**Exhibit 10**)) and is **1228** days.⁴

The regulatory review period is the sum of the periods of defined under 37 C.F.R. § 1.778(c)(1),and (c)(2) and is **1951** days.

(d) The term of the patent as extended for an animal drug will be determined by--

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction;

With respect to 37 C.F.R. § 1.778 (d)(1)(i), **0** days of the periods defined in paragraphs (c)(1) and (c)(2) were before the June 26, 1990 date on which U.S. Patent 4,937,078 issued.

With respect to paragraph 37 C.F.R. § 1.778(d)(1)(ii), there were **0** days during which applicant did not act with due diligence during the periods defined in 37 C.F.R. § 1.778 (c)(1) and (c)(2), as detailed in section (11) above.

⁴ We note that the approval letter for NADA (**Exhibit 10**) suggests that NADA 141-186 was initially submitted on August 26, 2003. It is our understanding, however, that the FDA considers the date an NADA is initially submitted to be “the date of FDA’s official acknowledgement letter assigning a number to the NADA” (See, FDA’s proposal to amend 21 C.F.R. § 60.1, Patent Term Restoration Regulations, 56 Fed. Reg. 5784, February 13, 1991, (**Exhibit 9**)). Accordingly, the August 26, 2003 appears to be the incorrect designation of the filing date for the purposes of determining the patent term extension. Applicant’s of this Request for Patent Term Extension consider January 2, 2001 (the date application was initially submitted for the approved animal drug under subsection (b) of section 512 of the Federal Food, Drug, and Cosmetic Act, *i.e.*, “the date of FDA’s official acknowledgement letter assigning a number to the NADA” (**Exhibit 8**)) to be the filing date for the purposes of determining the patent term extension.

With respect to 37 C.F.R. § 1.778 (d)(1)(iii), one-half of the number of days remaining in the period defined by paragraph 37 C.F.R. § 1.778(c)(1) after that period is reduced in accordance with 37 C.F.R. § 1.778(d)(1) (i) and (ii) is one-half of 723 days, which is 361 days.

Subtracting from the regulatory review period of 1951 days as determined above pursuant to 37 C.F.R. § 1.775(c) the number of days determined above with respect to 37 C.F.R. § 1.778(d)(1)(i), (ii), and (iii), the term of patent extension is 1951 days minus 0 days, minus 0 days, minus 361 days, for a sum total of 1590 days.

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

The original term of U.S. Patent No. 4,937,078 is August 26, 2008 and is not shortened by terminal disclaimer. Adding the 1590 days as determined in 37 C.F.R. § 1.778(d)(1) to the original term of the patent results in an extended term to January 3, 2013.

(3) By adding 14 years to the date of approval of the application under section 512 of the Federal Food, Drug, and Cosmetic Act;

Adding 14 years to the May 13, 2004 date of the approval of the NADA results in a date May 13, 2018.

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

The earlier of January 3, 2013 and May 13, 2018 is January 3, 2013.

(5) If the original patent was issued after November 16, 1988, by--,

(i) adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

U.S. Patent No. 4,937,078 issued after November 16, 1988. Adding 5 years to the original expiration date of the patent (there was no terminal disclaimer) of August 26, 2008 gives a date of August 26, 2013. The earlier of January 3, 2013 and August 26, 2013 is January 3, 2013.

- (6) If the original patent was issued before November 16, 1988, and**
- (i) If no major environmental effects test on the drug was initiated and no request was submitted for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act before November 16, 1988, by--**
- (A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and**
- (B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or**
- (ii) If a major environmental effects test on the drug was initiated and no request was submitted for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act before November 16, 1988, and the application for commercial marketing or use of the animal drug was not approved before November 16, 1988, by--**
- (A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and**
- (B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.**

U.S. Patent No. 4,937,078 issued after November 16, 1988. Accordingly, this section is not applicable to determining the patent term extension.

Thus, as calculated above, the term of U.S. Patent No. 5,770,599 is eligible for a 1590 day extension until January 3, 2013.

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (see § 1.765).

Applicant acknowledges a duty to disclose to the Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to any determination of entitlement to the extension sought.

(14) The prescribed fee for receiving and acting upon the application for extension (see § 1.20(j)).

As noted in the letter of transmittal submitted with this application, the Patent and Trademark Office is authorized to charge the filing fee of \$1,120.00 and any additional fees which may be required by this or any other related paper, or to credit any overpayment to Deposit Account No. 50-0310.

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed.

In accordance with the Grant of Power of Attorney, filed concurrently herewith, authorizing the registered practitioners of Morgan, Lewis & Bockius LLP to act of behalf of Mezei for the purposes of obtaining a patent term extension for United States patent no. 4,937,078 (copy attached as **Exhibit 2**), please address all inquiries and correspondence relating to this application for patent term extension to:

Paul E. Dietze
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Telephone: 202-739-5667
Facsimile: 202-739-3001

Respectfully Submitted,
Morgan, Lewis & Bockius LLP

Date: July 7, 2004

By:



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