

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: U.S. PATENT NO. 6,410,550 :
ISSUED: JUNE 25, 2002 :
TO: JOTHAM W. COE AND PAIGE R.P. BROOKS :
FOR: ARYL FUSED AZAPOLYCYCLIC COMPOUNDS :
FROM: SERIAL NO. 09/402,010 :
OF: Nov. 13, 1998 :

Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

**TRANSMITTAL OF REQUEST FOR EXTENSION OF
PATENT TERM UNDER 35 U.S.C. §156**

Transmitted herewith are the application papers of PFIZER INC., dated June 28, 2006, for extension of the term of U.S. Patent No. 6,410,550 under 35 U.S.C. §156, based on the regulatory review period for CHANTIX™ (varenicline) Tablets, together with two duplicate copies as required under 37 C.F.R. §1.740(b) and two additional duplicate copies of the application pursuant to M.P.E.P. §2753, for a total of four copies and one original.

As set forth under 37 C.F.R. §1.20(j), please charge the sum of \$1,120.00 to Deposit Account No. 16-1445 for the filing of this application for extension of patent term. Also, please charge any underpayment, or any additional fees that may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two copies of this paper are enclosed.

Respectfully submitted,
PFIZER INC.



A. David Joran
Attorney for Applicant
Reg. No. 37,858

Date: June 28, 2006

PFIZER INC.
Legal Division
150 East 42nd Street
New York, NY 10017-5755
Tel.: (212) 733-3381
Fax: (212) 573-1939

2007 E-0010

APP 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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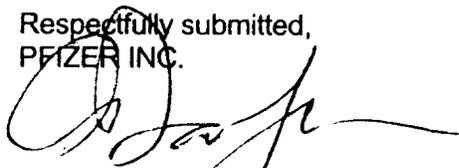
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New York, NY 10017-5755
Tel.: (212) 733-3381
Fax: (212) 573-1939

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: Pfizer Inc.Application No./Patent No./Control No.: 09/402,010 Filed/Issue Date: September 28, 1999Entitled: ARYL FUSED AZAPOLYCYCLIC COMPOUNDSPfizer Inc

(Name of Assignee)

, a Corporation

(Type of Assignee: corporation, partnership, university, government agency, etc.)

states that it is:

1. the assignee of the entire right, title, and interest; or
2. an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is _____ %)

in the patent application/patent identified above by virtue of either:

- A. An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 012920, Frame 0128, or a true copy of the original assignment is attached.

OR

- B. A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

- Additional documents in the chain of title are listed on a supplemental sheet.

As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Grover F. Fuller Jr.
Signature

Date

Grover F. Fuller Jr., Reg. No. 31,760
Printed or Typed Name

(212)-573-1390
Telephone Number

Senior Corporate Counsel of Pfizer Inc
Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**POWER OF ATTORNEY
 and
 CORRESPONDENCE ADDRESS
 INDICATION FORM**

Application Number	09/402,010
Filing Date	September 28, 1999
First Named Inventor	Jotham Wadsworth Coe
Title	ARYL FUSED AZAPOLYCYCLIC COMPOUN
Art Unit	
Examiner Name	
Attorney Docket Number	

I hereby revoke all previous powers of attorney given in the above-identified application.

I hereby appoint:

Practitioners associated with the Customer Number: 23913

OR

Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

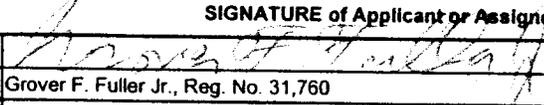
Please recognize or change the correspondence address for the above-identified application to:

The address associated with the above-mentioned Customer Number:
 OR
 The address associated with Customer Number:

<input type="checkbox"/> Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone	Email		

I am the:
 Applicant/Inventor.
 Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature		Date	
Name	Grover F. Fuller Jr., Reg. No. 31,760	Telephone	212-573-1390
Title and Company	Senior Corporate Counsel of Pfizer Inc		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

*Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN RE: U.S. PATENT NO. 6,410,550
ISSUED: JUNE 25, 2002
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FROM: SERIAL NO. 09/402,010
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Commissioner for Patents
Mail Stop Patent Extension
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Alexandria, Virginia 22313-1450

Sir:

**APPLICATION FOR EXTENSION OF THE TERM OF
UNITED STATES PATENT NO. 6,410,550 UNDER 35 U.S.C. §156
FOR CHANTIX™ (VARENICLINE) TABLETS**

Your applicant, PFIZER INC., a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, NY 10017, United States of America, represents that it is the owner of the entire right, title and interest in and to Letters Patent of the United States No. 6,410,550 granted to JOTHAM W. COE and PAIGE R.P. BROOKS on the 25th day of June, 2002, for ARYL FUSED AZAPOLYCYCLIC COMPOUNDS, by virtue of assignments, recorded in the United States Patent and Trademark Office (hereinafter referred to as "the Patent Office") on the 20th day of May, 2002 at Reel 012920, Frame 0128. A copy of the Notice of Recordation is enclosed as Exhibit A.

Pursuant to the provisions of 37 C.F.R. §1.730, your applicant hereby applies for an extension of the term of Patent No. 6,410,550 under 35 U.S.C. §156 of 545 days, based on the materials set forth herein and in the accompanying papers.

In the materials which follow herein, numbered paragraphs (1) through (15) correspond to paragraphs (1) through (15) of 37 C.F.R. §1.740(a).

- (1) The approved product is the active ingredient, including any salt of the active ingredient, in CHANTIX™, *i.e.*, varenicline, varenicline tartrate, and any other pharmaceutically acceptable salt of varenicline, which is the generic name of the chemical compound. CHANTIX™ tablets consist of varenicline as the varenicline tartrate salt and pharmaceutically-acceptable carriers. Varenicline and varenicline tartrate are further identified as follows:

Varenicline:

Chemical Name

7,8,9,10-tetrahydro-6,10-methano-6*H*-pyrazino[2,3-*h*][3]benzazepine

Alternate Chemical Name

5,8,14-triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]hexadeca-2(11),3,5,7,9-pentaene

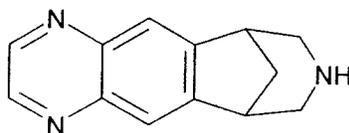
Molecular Formula

C₁₃H₁₃N₃

Molecular Weight

211.27

Chemical Formula



Varenicline tartrate:

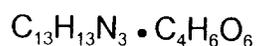
Chemical Name

7,8,9,10-tetrahydro-6,10-methano-6*H*-pyrazino[2,3-*h*][3]benzazepine, (2*R*,3*R*)-2,3-dihydroxybutanedioate (1:1)

Alternate Chemical Name

5,8,14-triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-hexadeca-2(11),3,5,7,9-pentaene tartrate

Molecular Formula



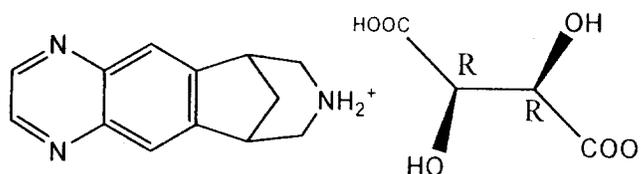
Molecular Weight

361.35

Physical Description

CHANTIX™ tablets are supplied for oral administration in two strengths: a 0.5 mg capsular biconvex, white to off-white, film-coated tablet debossed with "Pfizer" on one side and "CHX 0.5" on the other side and a 1 mg capsular biconvex, light blue film-coated tablets debossed with "Pfizer" on one side and "CHX 1.0" on the other side. Each 0.5 mg CHANTIX tablet contains 0.85 mg of varenicline tartrate equivalent to 0.5 mg of varenicline free base; each 1mg CHANTIX™ tablet contains 1.71 mg of varenicline tartrate equivalent to 1 mg of varenicline free base. The following inactive ingredients are included in the tablets: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, Opadry® White (for 0.5 mg), Opadry® Blue (for 1 mg), and Opadry® Clear.

Chemical Formula



(2) CHANTIX™ (varenicline) tablets was subject to regulatory review under section 505(b) of the Federal Food, Drug and Cosmetic Act, which is codified at 21 U.S.C. §355(b).

(3) CHANTIX™ (varenicline) tablets received permission for commercial marketing or use under section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355(b), on May 10, 2006. It was approved as an aid to smoking cessation treatment.

(4) The active ingredient in CHANTIX™ tablets is varenicline, as its salt varenicline tartrate (5,8,14-triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-hexadeca-2(11),3,5,7,9-pentaene tartrate). Neither varenicline nor any salt thereof has 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.

(5) This application is being submitted within the sixty day period permitted for its submission pursuant to 37 C.F.R. §1.720(f). The last day on which this application could be submitted is July 10, 2006.

(6) The patent for which an extension is being sought is identified as follows:

Inventors: JOTHAM W. COE AND PAIGE R.P. BROOKS
Patent No.: 6,410,550
For: ARYL FUSED AZAPOLYCYCLIC COMPOUNDS
Issued: JUNE 25, 2002
Expires: NOVEMBER 13, 2018

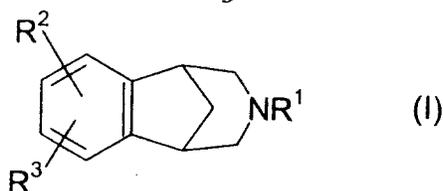
(7) A copy of Patent No. 6,410,550, the patent for which an extension is being sought, is attached hereto as EXHIBIT B.

(8) A maintenance fee payment for Patent No. 6,410,550 has been made to keep the patent in force beyond four years from its issue date. A copy of the official receipt for such payment is attached hereto as EXHIBIT C. Patent No. 6,410,550 has no disclaimers or re-examination certificates.

(9) Patent No. 6,410,550 claims the approved product, pharmaceutical compositions including the approved product, and a method of using the approved product. Claims 1 and 8 claim the approved product *per se*; claim 12 claims a pharmaceutical composition which contains the approved product and is useful for the approved use; and, claims 13 and 14 claim the approved use of the approved product. A showing that lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product, a pharmaceutical composition containing the approved product, or a method of using the approved product is as follows:

Claim 1 of Patent No. 6,410,550 reads as follows:

" A compound of the formula



R^1 is hydrogen, (C_1-C_6) alkyl, unconjugated (C_3-C_6) alkenyl, $XC(=O)R^{13}$, benzyl or $-CH_2CH_2-O-(C_1-C_4)$ alkyl;

R^2 and R^3 , together with the carbons to which they are attached, form a four to seven membered monocyclic, or ten to fourteen membered bicyclic, carbocyclic ring that can be saturated or unsaturated, wherein from one to three of the nonfused carbon atoms of said monocyclic rings, and from one to five of the carbon atoms of said bicyclic rings that are not part of the benzo ring shown in formula I, may optionally and independently be replaced by a nitrogen, oxygen or sulfur, and wherein said monocyclic and bicyclic rings may optionally be substituted with one or more substituents that are selected, independently, from (C_1-C_6) alkyl optionally substituted with from one to seven fluorine atoms; (C_1-C_6) alkoxy optionally substituted with from one to seven fluorine atoms; nitro, cyano, halo, (C_2-C_6) alkenyl, (C_2-C_6) alkynyl, hydroxy, amino, (C_1-C_6) alkylamino and $((C_1-C_6)alkyl)_2$ amino, $-CO_2R^4$, $-CONR^5R^6$, $-SO_2NR^7R^8$, $-C(=O)R^{13}$ and $-XC(=O)R^{13}$;

wherein each R^4 , R^5 , R^6 , R^7 , R^8 and R^{13} is selected, independently, from hydrogen and (C_1-C_6) alkyl, or R^5 and R^6 , or R^7 and R^8 together with the nitrogen to which they are attached, form a pyrrolidine, piperidine, morpholine, azetidine, piperazine, $-N-(C_1-C_6)alkyl$ piperazine or thiomorpholine ring, or a thiomorpholine ring wherein the ring sulfur is replaced with a sulfoxide or sulfone; and

each X is, independently, $(C_1-C_6)alkylene$;

or a pharmaceutically acceptable salt thereof."

When R_1 is hydrogen; and, R^2 and R^3 , together with the carbons to which they are attached, form a six-membered monocyclic carbocyclic ring that is unsaturated, wherein two of the nonfused carbon atoms of said monocyclic ring are replaced by a nitrogen, and wherein the monocyclic ring is not substituted, the compound claimed is varenicline. Therefore, claim 1 reads on the approved product.

Claim 8 of Patent No. 6,410,550 claims the compound according to claim 1 which is 5,8,14-triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]hexadeca-2(11),3,5,7,9-pentaene, which is varenicline. Claim 8 also claims a pharmaceutically acceptable salt 5,8,14-triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]hexadeca-2(11),3,5,7,9-pentaene, which encompasses varenicline tartrate. Therefore, claim 8 reads on the approved product.

Claim 12 of Patent No. 6,410,550 claims a pharmaceutical composition comprising an amount of a compound according to claim 1 and a pharmaceutically acceptable carrier. Since claim 1 claims a compound which encompasses varenicline, claim 12 reads on a pharmaceutical composition comprising the approved product.

Claim 13 of Patent No. 6,410,550 claims a method for reducing nicotine addiction or aiding in the cessation or lessening of tobacco use in a mammal, comprising administering to said mammal an amount of a compound according to claim 1 that is effective in reducing nicotine addiction or aiding in the cessation or lessening of tobacco use. Since claim 1 claims a compound which encompasses varenicline, claim 8 reads on a method of using the approved product for the approved use.

Claim 14 of Patent No. 6,410,550 claims a method for treating a disorder or condition selected from a grouping of indications which recites dependencies on, or addictions to, nicotine and tobacco products, comprising administering to a mammal in need of such treatment an amount of a compound according to claim 1 that is effective in treating such disorder or condition. Since claim 1 claims a compound which encompasses varenicline, claim 14 reads on a method of using the approved product for the approved use.

(10) The relevant dates and information pursuant to 35 U.S.C. §156(g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

- An exemption under subsection (i) of section 505 of the Federal Food, Drug and Cosmetic Act became effective for varenicline tartrate October 14, 1999, following receipt by the Food and Drug Administration of Investigational New Drug ("IND") Application No. 58,994 on September 15, 1999.
- A New Drug Application ("NDA") under section 505(b) of the Federal Food, Drug and Cosmetic Act for CHANTIX™ was initially submitted on November 10, 2005, as NDA No. 21-928.
- NDA No. 21-928 was approved on May 10, 2006.

(11) A brief description 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 is attached hereto as EXHIBIT D.

(12) Applicant is of the opinion that Patent No. 6,410,550 is eligible for an extension under 35 U.S.C. §156. The length of extension claimed is 545 days.

The eligibility requirements of 35 U.S.C. §§156(a) and 156(c)(4) have been satisfied as follows:

- Patent No. 6,410,550 claims a product (the active ingredient, including any salt of the active ingredient) in CHANTIX™, *i.e.*, varenicline, varenicline tartrate and any other pharmaceutically acceptable salt. Patent No. 6,410,550 also claims pharmaceutical compositions including the product CHANTIX™ and a method of using the product CHANTIX™.
- Patent No. 6,410,550 is currently set to expire on November 13, 2018 (*i.e.*, the term of the patent has not yet expired).
- The term of Patent No. 6,410,550 has never been extended under subsection (e)(1) of 35 U.S.C. §156.
- This application for extension is being submitted by PFIZER INC, the owner of record of Patent No. 6,410,550, in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. §156(d).
- The product (the active ingredient, including any salt of the active ingredient) in CHANTIX™, *i.e.*, varenicline, varenicline tartrate and any other pharmaceutically acceptable salt, has been subject to a regulatory review period under section 505(b) of the Federal Food, Drug and Cosmetic Act before its commercial marketing or use, and the permission for said commercial marketing or use is the first permitted commercial marketing or use of the product under section 505(b) of the Federal Food, Drug and Cosmetic Act.
- No patent has to this date been extended, nor has any other extension been applied for, under subsection (e)(1) of 35 U.S.C. §156, for the regulatory review period which forms the basis for this application for extension of the term of Patent No. 6,410,550.

The length of extension of the term of Patent No. 6,410,550 of 545 days claimed by applicant was determined according to the provisions of 37 C.F.R. §1.775 as follows:

- According to 37 C.F.R. §1.775(b), the length of extension is equal to the regulatory review period for the approved product, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of 37 C.F.R. §1.775.
- According to 37 C.F.R. §1.775(c), the regulatory review period is the sum of: (A) the number of days in the period beginning on the date the exemption under subsection 505 of the Federal Food, Drug and Cosmetic Act became effective for the approved product and ending on the date the NDA was initially submitted under subsection 505 of the Federal Food, Drug and Cosmetic Act; and (B) the number of days in the period beginning on the date the NDA was initially submitted under subsection 505 of the Federal Food, Drug and Cosmetic Act and ending on the date the NDA was approved. The exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act became effective on October 14, 1999; the NDA was initially submitted on November 10, 2005; and the NDA was approved on May 10, 2006. Hence, the regulatory review period under 37 C.F.R. §1.775(c) is the sum of the period from October 14, 1999 to November 10, 2005 and from November 10, 2005 to May 10, 2006. This is the sum of 2,219 days and 180 days, which is 2,399 days.
- According to 37 C.F.R. §1.775(d)(1)(i), the number of days in the regulatory review period which were on and before the date on which the patent issued must be subtracted. Patent No. 6,410,550 issued on June 25, 2002. Subtraction of the period on and before June 25, 2002 leaves a reduced regulatory review period from June 26, 2002 to November 10, 2005 and from November 10, 2005 to May 10, 2006. This is the sum of 1,234 days and 180 days, which is 1,414 days.
- 37 C.F.R. §1.775(d)(1)(ii) does not apply.
- According to 37 C.F.R. §1.775(d)(1)(iii), the regulatory review period must then be reduced by one-half of the days remaining in the period defined in 37 C.F.R. §1.775(c)(1). This is one-half of 1,234 days, which is 617 days. After subtraction, this now leaves a reduced regulatory review period of 617 days plus 180 days, which is 797 days.

- According to 37 C.F.R. §1.775(d)(2), the reduced regulatory review period of 797 days must be added to the expiration date of Patent No. 6,410,550 (*i.e.*, November 13, 2018). This gives a date of July 22, 2020. According to 37 C.F.R. §1.775(d)(3), 14 years must be added to the date of approval of the approved product. This gives a date of May 10, 2020. According to 37 C.F.R. §1.775(d)(4), the earlier of these dates must be selected. The earlier of these dates is May 10, 2020 (*i.e.*, 545 days beyond the expiration date of the 6,410,550 patent).
- The provisions of 37 C.F.R. §1.775(d)(5) apply to this application, because Patent No. 6,410,550 issued after September 24, 1984. Pursuant to 37 C.F.R. §1.775(d)(5)(i) five (5) years are added to the expiration date of Patent No. 6,410,550 (November 13, 2018) giving a date of November 13, 2023. According to 37 C.F.R. §1.775(d)(5)(ii), the dates obtained pursuant to 37 C.F.R. §1.775(d)(5)(i) and 37 C.F.R. §1.775(d)(4) are compared and the earlier date is selected. The date calculated according to 37 C.F.R. §1.775(d)(4) above is May 10, 2020. Therefore, the earlier of these dates is May 10, 2020. Applicant is entitled to an extension of term of Patent No. 6,410,550 until May 10, 2020, *i.e.*, an extension of 545 days from the original expiration date of November 13, 2018.
- 37 C.F.R. §1.775(d)(6) does not apply because Patent No. 6,410,550 issued on June 25, 2002, after September 24, 1984.

(13) Applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office 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 of 545 days which is being sought to the term of Patent No. 6,410,550.

(14) The prescribed fee under 37 C.F.R. §1.20(j) for receiving and acting on this application for patent term extension is to be charged to Deposit Account No. 16-1445, as requested in the enclosed transmittal letter.

(15) Please direct all inquiries and correspondence relating to this application for patent term extension as follows:

(16)

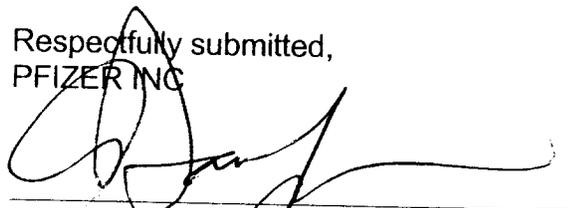
A. David Joran
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150 East 42nd Street
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Pursuant to 37 C.F.R. §1.740(b), two duplicate copies of these application papers are enclosed herewith. Pursuant to M.P.E.P. §2753 an additional two copies of the application are also enclosed herewith. Accordingly, a total of four copies of the application and one original application for patent term extension of Patent No. 6,410,550 are submitted herewith.

Applicant respectfully requests prompt and favorable action on the merits of this application for extension of the term of Letters Patent No. 6,410,550 of 545 days, based on the regulatory review period for CHANTIX™ (varenicline) Tablets.

Respectfully submitted,
PFIZER INC



Date: June 28, 2006

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