08/113320

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. 5,532,372
Issue date July 2, 1996
Inventors Ikutaro Saji et al.
For IMIDE DERIVATIVES, AND THEIR PRODUCTION AND USE

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

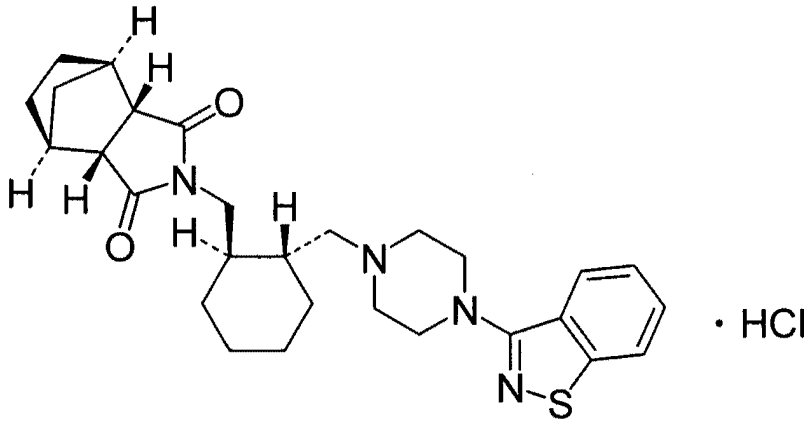
APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Applicant, Dainippon Sumitomo Pharma Co., Ltd., a Japanese Corporation, represents that it is the assignee of the entire interest in and to Letters Patent of the United States No. 5,532,372 granted to Ikutaro Saji, Masayuki Muto, Norihiko Tanno, and Mayumi Yoshigi on July 2, 1996. The assignment (for parent application US Application No. 07/726,172 to which U.S. Patent No. 5,532,372 claims priority), from the inventors to Sumitomo Pharmaceuticals Company, Ltd. was recorded on July 17, 1991 at Reel 5773, Frame 0144 and the conveyance from Sumitomo Pharmaceuticals Company, Ltd. to Dainippon Sumitomo Pharma Co., Ltd. was recorded on December 16, 2005 at Reel 017089, Frame 0420.

Information Required Under 37 C.F.R. § 1.740

Applicant hereby submits this application for an extension of patent term under 35 U.S.C. § 156 by providing the following information as required by § 1.740 of Title 37 of the Code of Federal Regulations (37 C.F.R. § 1.740).

1. The approved product is Latuda®, generic name being lurasidone hydrochloride, chemical name being (*3aR,4S,7R,7aS*)-2-{(*1R,2R*)-2-[4-(1,2-benzisothiazol-3-yl)piperazin-1-ylmethyl]cyclohexylmethyl}hexahydro-4,7-methano-*2H*-isoindole-1,3-dione hydrochloride, and having the following formula:



2. The approved product was subject to regulatory review under Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355.

3. The approved product Latuda® (lurasidone hydrochloride) received permission for commercial marketing or use under § 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, on October 28, 2010. A copy of the approval letter from the Food and Drug Administration is attached as Attachment "A".

4. The active ingredient in the approved product Latuda® is lurasidone hydrochloride, which 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.

No other active ingredients are contained in this product. A copy of the U.S. package insert for Latuda® (lurasidone hydrochloride) is attached as Attachment "B".

5. This application for extension of patent term under 35 U.S.C. § 156 is being submitted within the sixty (60) day period permitted for submission pursuant to § 1.720(f). The last day for submitting an application for extension is December 26, 2010 (a Sunday, so submission on Monday December 27, 2010, would be timely. 35 U.S.C. § 21(b)) .

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

Inventors	Ikutaro Saji, Masayuki Muto, Norihiko Tanno, and Mayumi Yoshigi
Patent No.	5,532,372
Issue date	July 2, 1996
Expiration date	July 2, 2013

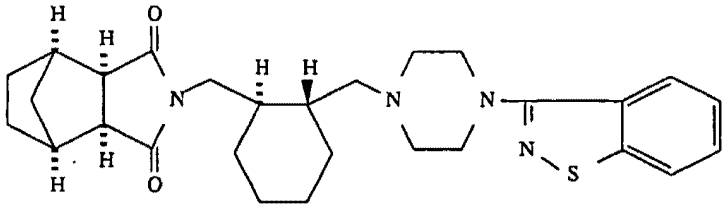
7. A copy of the patent for which an extension is being sought is attached hereto as Attachment "C".

8. Receipts for maintenance fee payments for this patent are attached hereto as Attachment "D". A certificate of correction issued November 24, 2009, is attached hereto as Attachment "E". No terminal disclaimer or reexamination certificate has been issued with respect to U.S. Patent No. 5,532,372.

9. The patent claims the active ingredient in the approved product Latuda® (lurasidone hydrochloride) in at least claims 1, 2, 5, 6, 8(6), 9(6), 10, 11, 12, 13, and 14.

In particular, Claim 14 reads on the approved product as follows:

14. The imide compound of the formula:



or an acid addition salt thereof.

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

(i) the effective date of the investigational new drug (IND) application was December 17, 2000;

(ii) the IND number was 61,292;

(iii) the date on which a new drug application (NDA) was initially submitted was December 30, 2009;

(iv) the NDA number was 200603; and

(v) the date on which the NDA was approved was October 28, 2010.

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