FILED by _____ D.C.
INTAKE
DEC 10 2007
CLARENCE MADDOX
CLERK U.S. DIST. CT.
S.D. OF FLA. – MIAMI

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 07-61800

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

CIV-MORENO

MAGISTRATE JUDGE
SIMONTON

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Apotex Inc. and Apotex Corp., hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned

subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff sanofi-aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

Acts Giving Rise to this Action

Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a

proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j)(2)(A)(vii)(IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '491 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex Inc.'s ANDA identified in this Complaint shall not be earlier than the expiration date of the '491 patent, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently

enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated this 10th day of December, 2007.
Miami, Florida

Respectfully submitted,

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EXHIBIT A

United States Patent [19]

Regnier

[11] **Patent Number: 4,661,491**

[45] **Date of Patent: Apr. 28, 1987**

[54] **ALFUZOSINE COMPOSITIONS AND USE**

[75] Inventor: **François Regnier**, Nancy, France

[73] Assignee: **Synthelabo**, Paris, France

[21] Appl. No.: **867,031**

[22] Filed: **May 27, 1986**

[30] **Foreign Application Priority Data**

May 28, 1985 [FR] France 85 07950

[51] **Int. Cl.**[4] **A61K 31/505**

[52] **U.S. Cl.** **514/260**

[58] **Field of Search** 514/260

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,315,007 2/1982 Manoury 514/259

Primary Examiner—Allen J. Robinson

Attorney, Agent, or Firm—Wegner & Bretschneider

[57] **ABSTRACT**

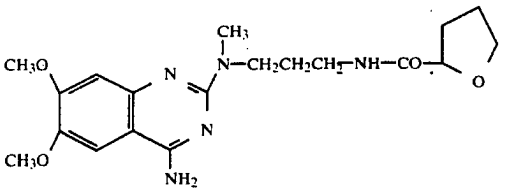
A method for treating humans or non-human animals for dysuria comprising administering an effective non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human animal suffering dysuria.

5 Claims, No Drawings

ALFUZOSINE COMPOSITIONS AND USE

The present invention relates to pharmaceutical compositions containing alfuzosine and the use of alfuzosine in the treatment of dysuria.

Alfuzosine, the compound of formula



is known for its antihypertensive activity. It is an antagonist of vascular α_1-adrenergic receptors which possesses direct muscle-relaxant properties.

In many patients manifesting dysuria, an exceptionally high cervico-urethral pressure is observed, which is related to a relative hyperactivity of the α-adrenergic receptors.

It has now been found that alfuzosine has activitity in altering the phenylephrine-induced contractions on preparations of smooth muscle originating from the base of the bladder (trigone muscle) and the urethra of rabbits and that alfuzosine can be used for the treatment of conditions of the lower urinary apparatus, in which hyperactivity of the alpha-adrenergic receptors of the vesicosphincter system disturbs the continence/micturition cycle.

Accordingly the present invention provides a method for treating dysuria in humans or non-human animals comprising administering a therapeutic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or animal suffering dysuria.

Patients who may be treated are, for example, men and women who have bladder neck disease, or men who have benign hypertrophy of the prostrate with dysuria of alpha-adrenergic origin.

Other patients who may be treated include those suffering from neurological disorders such as paraplegia or multiple sclerosis, for whom the disturbance of micturition also responds to alfuzosine.

The daily dosage can range from 0.5 to 10 mg for adult humans.

The present invention also provides a pharamceutical composition for treating dysuria comprising an effective amount of alfuzosine or a pharmaceutically acceptable salt thereof and a pharmaceutical diluent or carrier therefor.

The pharmaceutical compositions of the invention containing alfuzosine or a pharmaceutically acceptable salt thereof in combination with any suitable excipient can be administered orally, parenterally or transdermally. They are presented in any suitable form such as gelatine capsules, tablets, solutions, and the like. The pharmaceutical compositions can also be presented in the form of delayed-release tablets or gelatine capsules.

The pharmaceutically acceptable salts include acid addition salts of a pharamceutically acceptable organic or inorganic acid such as mineral acids and mono-, di- or tri- carboxylic acids, especially the hydrochloride salt.

The invention will now be illustrated by the following Pharmacological Data and Formulation Examples.

PHARMACOLOGICAL DATA

Male rabbits (CEGAN) weighing 3 to 4 kg are sacrificed by exsanguination and cervical dislocation.

The bladder and urethra are rapidly removed and placed in lukewarm Krebs solution containing bicarbonate.

The composition of this Krebs medium is as follows, in mM: NaCl 114; KCl 4.7; $CaCl_2$ 2.5; KH_2PO_4 1.2; $MgSO_4$ 1.2; $NaHCO_3$ 25.0; glucose 11.7; ascorbic acid 1.1. Propranolol (1.0 μM) is added into the Krebs medium to block the β-adrenergic receptors.

The bladder is opened transversely and the "trigone" region of the muscle, located on the dorsal surface of the bladder and between the two ureters, is dissected out.

A 5 mm ring of urethra, from the region situated between the base of the bladder and the prostate, is also prepared.

The portions of trigone muscle and urethra are washed under a tension of 1 g in Krebs medium.

The contraction-response curve to cumulated concentrations of phenylephrine is determined.

Additions of the agonist are performed every 5 min. The tissues are washed until the original tension is reestablished, and are then incubated for 30 min with alfuzosine. A second response curve to phenylephrine is determined in the presence of alfuzosine.

The response curves to concentrations of phenylephrine in the presence or absence of alfuzosine are expressed as a percentage of the maximum response obtained relative to the control curve.

The power of alfuzosine is calculated in the form of pA_2 by Schild's method, where pA_2=negative logarithm of the molar concentration of alfuzosine which causes a rightward shift of the response curve to the agonist.

Alfuzosine (at a dose of 3.0 μM) causes a significant rightward parallel shift of the response curve to phenylephrine both in the trigone muscle and in the urethra. Alfuzosine causes a 20 to 30% reduction in the maximum contractile effects of phenylephrine.

By Schild analysis, the pA_2 can be determined, this being 7.05–0.17.

By means of clinical studies, it has also been possible to show the efficacy of alfuzosine in patients suffering from dysuria of neurological origin with urethral hypertonia.

5 mg of alfuzosine are injected intravenously continuously for a period of 20 min. Sphincterometric measurements were made using an electronic micro-sensor, before and after the injection of the drug, at the bladder neck and at the striated sphincter of the posterior urethra.

The results of these measurements enabled a 44% pressure decrease ($p<0.001$) to be noted at the bladder neck, and a 39% decrease ($p<0.001$) at the striated sphincter.

A clinical study was also performed in paraplegics.

The paraplegic, or spinal man, gives rise to an experimental model of the peripheral receptors, since he embodies a disconnection from the influence of the higher, diencephalic and cortical nerve centres.

Given the localization of the alpha-adrenergic receptors in the posterior urethra and the vesico-urethral segment or neck, alpha-adrenergic hypertonia is the

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source of dysuria and disturbances of micturition. The opening of the neck and the fall in the pressure gradient in the posterior urethra are the two conditions required for the production of effective micturition.

Alfuzosine was administered intravenously, and then orally if the first test is positive. 5 mg of alfuzosine are injected intravenously in the course of 20 min.

After injection of alfuzosine, the intra-urethral pressures decrease significantly. The test is considered to be positive if an initiation of micturition, that is to say, necessarily, opening of the neck, takes place.

For patients for whom the test is positive, the administration of alfuzosine was then performed orally at the rate of 9 mg/24 h/28 d.

In most cases, the treatment per os enabled micturition to be rendered easier to initiate.

FORMULATION EXAMPLES

Examples of pharmaceutical formulations are given below:

	mg
Tablet:	
Alfuzosine (as the hydrochloride salt)	5
Microcrystalline cellulose	36
Lactose	122
Sodium carboxymethylamide	7
Polyvidone excipient	9
Magnesium stearate	1
	180
Coating env.	8
Injectable Solution	
Alfuzosine (as the hydrochloride salt)	1
Sodium chloride	44.9
Water for injection qs	5 ml

I claim:

1. A method for treating humans or non-human animals for dysuria comprising administering an effective dysuria controlling, non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human animal suffering dysuria.

2. A method according to claim 1 comprising administering alfuzosine hydrochloride.

3. A method according to claim 1 comprising administering from 0.5 to 10 mg of alfuzosine or the corresponding amount of a pharmaceutically acceptable salt thereof.

4. A method according to claim 1 for treating dysuria in patients having bladder neck disease or a neurological disorder.

5. A method according to claim 1 for treating dysuria in male patients having benign hypertrophy of the prostrate of alpha-adrenergic origin.

* * * * *

JS 44 (Rev. 11/05)

CIVIL COVER SHEET

07-61800

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.) **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS
sanofi-aventi and
sanofi-aventis U.S. LLC

(b) County of Residence of First Listed Plaintiff France
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

DEFENDANTS
Apotex Inc. and
Apotex Corp.

County of Residence of First Listed Defendant Broward
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT LAND INVOLVED.

Attorneys (If Known) **CIV-MORENO**

(d) Check County Where Action Arose: ☐ MIAMI- DADE ☐ MONROE ☒ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST. LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE ☐ HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

☐ 1 U.S. Government Plaintiff
☒ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

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III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
[illegible]	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

MAGISTRATE JUDGE SIMONTON

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☒ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other	LABOR	☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability		☐ 710 Fair Labor Standards Act	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury			☐ 720 Labor/Mgmt. Relations	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability				☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise				☐ 740 Railway Labor Act	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		☐ 790 Other Labor Litigation	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence		☐ 791 Empl. Ret. Inc. Security Act	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:		SOCIAL SECURITY	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 861 HIA (1395ff)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 862 Black Lung (923)	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other		☐ 863 DIWC/DIWW (405(g))	☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights		☐ 864 SSID Title XVI	☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition		☐ 865 RSI (405(g))	
				FEDERAL TAX SUITS	
				☐ 870 Taxes (U.S. Plaintiff or Defendant)	
				☐ 871 IRS—Third Party 26 USC 7609	

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V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed- (see VI below) ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. RELATED/RE-FILED CASE(S).

(See instructions second page): a) Re-filed Case ☐ YES ☐ NO b) Related Cases ☒ YES ☐ NO

JUDGE Sleet Manning

DOCKET NUMBER 1:07-cv-00572-GMS (D. Del.) 1:07-cv-00574-GMS (D. Del.) 1:07-cv-00792 (D. Del.) 1:07-cv-5807 (N.D. Ill.)

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause **(Do not cite jurisdictional statutes unless diversity):**
35 U.S.C. Section 271
Patent Infringement

LENGTH OF TRIAL via _____ days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

SIGNATURE OF ATTORNEY OF RECORD

DATE Dec. 10, 2007

FOR OFFICE USE ONLY

AMOUNT 350- RECEIPT # 971492 IFP