

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FILED

AUG 18 2000

MICHAEL W. DOBBINS, CLERK
UNITED STATES DISTRICT COURT

ABBOTT LABORATORIES, an Illinois)
corporation, FOURNIER INDUSTRIE ET SANTÉ,)
a French corporation, and LABORATOIRES)
FOURNIER S.A., a French corporation,)

Plaintiffs,)

Civil Action No.)

vs.)

Judge)

000 5094

NOVOPHARM LIMITED, a corporation of the)
dominion of Canada,)

Jury Trial Demanded)

Defendant.)

CHIEF JUDGE ASPEN

NOTICE OF CLAIM INVOLVING PATENT

Pursuant to Rule LR3.4 of this Court, Plaintiff, Abbott Laboratories, submits this

Notice of Claim Involving Patent for this suit, stating that the parties are:

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064-3500;

MAGISTRATE JUDGE LEVIN

Fournier Industrie et Santé
42 Rue de Longvic
21300 Chenôve, France;

Laboratoires Fournier S.A.
42 Rue de Longvic
21300 Chenôve, France;

DOCKETED
AUG 23 2000

and

Novopharm Limited
30 Novopharm Court
Toronto, Canada M1B 2K9.

The patent upon which this action is brought is U.S. Patent 4,895,726, for which Bernard Curtet, Eric Teillaud and Philippe Reginault are the listed inventors.

Date: August 18, 2000

ABBOTT LABORATORIES

By: 

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James A. White

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ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation,

Plaintiffs,

vs.

NOVOPHARM LIMITED, a corporation of the dominion of Canada,

Defendant
DOCKETED

AUG 23 2000

Civil Action No.

00C 5094

Judge

CHIEF JUDGE ASPEN

Jury Trial Demanded

MAGISTRATE JUDGE LEVIN

COMPLAINT

Plaintiffs, Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier S.A., for their complaint against Defendant, Novopharm Limited, allege as follows:

THE PARTIES

1. Abbott Laboratories ("Abbott") is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at Abbott Park, Illinois 60064.

2. Fournier Industrie et Santé, formerly known as Fournier Innovation et Synergie, and Laboratoires Fournier S.A. (collectively "Fournier") are French corporations having their principal place of business at 42 Rue de Longvic, 21300 Chenôve, France.

3. Novopharm Limited ("Novopharm") is a corporation organized under the laws of the dominion of Canada, having its principal place of business at 30 Novopharm Court, Toronto, Canada M1B 2K9, doing business in the United States and in this district, and through

1-1

its wholly-owned subsidiary Novopharm, Inc., located at 165 Commerce Drive, Schaumburg, Illinois 60173.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this suit pursuant to 28 U.S.C. § 1338(a) as it arises under an Act of Congress relating to patents, Title 35, United States Code, §§ 1 et seq.

5. Venue properly exists in this judicial district pursuant to 28 U.S.C. § 1391 and § 1400(b) in that Novopharm is doing business in this district and therefore resides here.

6. This Court has personal jurisdiction over Defendant under 735 ILCS 5/2-209 because it transacts business within the State of Illinois.

FACTUAL BACKGROUND

7. Abbott is the exclusive licensee of U.S. Patent No. 4,895,726, ("the '726 patent"). A copy of the '726 patent is attached as Exhibit A.

8. The '726 patent, which issued on January 23, 1990, claims, *inter alia*, a novel dosage form of fenofibrate containing fenofibrate and a solid surfactant which have been co-micronized as well as a method for the preparation of this dosage form and its use for improving bioavailability *in vivo*. Fournier is the owner of the '726 patent, which expires on January 19, 2009.

9. Fenofibrate is useful as a lipid and cholesterol lowering agent for treatment of adults with increased triglyceride levels.

10. Abbott has approval from the United States Food and Drug Administration ("FDA") to market fenofibrate capsules under the name TRICOR®.

11. TRICOR® (fenofibrate) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's Abbreviated New Drug

Application ("ANDA") to obtain approval of the ANDA applicant's drug product under provisions of 21 U.S.C. § 355(j).

12. The FDA's "Orange Book" also lists patents associated with approved drugs. The '726 patent is listed in the "Orange Book" in association with TRICOR® (fenofibrate).

13. Abbott and Fournier received a letter from Novopharm dated July 6, 2000 stating that Novopharm had amended its ANDA, designated as No. 75-753, requesting FDA approval to market a generic version of Abbott's TRICOR® (fenofibrate) capsules in a 200 mg dosage before the expiration of the '726 patent.

14. 35 U.S.C. § 271(e)(2) provides that the submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Novopharm's submission of an ANDA for approval to sell fenofibrate capsules in a 200 mg dosage prior to the expiration of the '726 patent constitutes an act of infringement of one or more claims of the '726 patent under 35 U.S.C. § 271(e)(2). In addition, Novopharm's generic version of TRICOR® (fenofibrate), for which it has amended its ANDA, infringes one or more claims of the '726 patent.

15. Plaintiffs have no adequate remedy at law to redress Novopharm's infringement.

WHEREFORE, Plaintiffs pray for the following relief:

(a) a judgment that the '726 patent remains valid and enforceable, and is infringed under 35 U.S.C. § 271(e)(2) by Novopharm's filing and amendment of its ANDA No. 75-753;

(b) an order that the effective date of the approval of ANDA No. 75-753 be subsequent to the expiration date of the '726 patent;

(c) an injunction prohibiting Novopharm from commercially manufacturing, selling, using, or importing the fenofibrate claimed in the '726 patent or otherwise infringing one or more claims of the '726 patent;

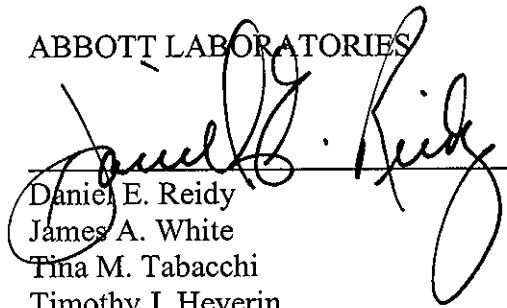
(d) damages and/or other monetary relief for any commercial manufacture, use or sale of the fenofibrate falling within the scope of one or more claims of the '726 patent by Novopharm;

(e) an award of Plaintiffs' costs and attorneys' fees pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and,

(f) such other and further relief as this Court may deem just and proper.

A TRIAL BY JURY IS DEMANDED FOR ALL COUNTS.

Date: August 18, 2000

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EXHIBIT A

United States Patent [19]
Curtet et al.

[11] Patent Number: **4,895,726**
 [45] Date of Patent: **Jan. 23, 1990**

[54] **NOVEL DOSAGE FORM OF FENOFIBRATE**

[75] Inventors: **Bernard Curtet, Marsanny la Cote;**
Eric Teillard, Talant; Philippe
Regisault, Fontaine les Dijon, all of
France

[73] Assignee: **Fournier Innovation et Synergie,**
Paris, France

[21] Appl. No.: **299,073**

[22] Filed: **Jan. 19, 1989**

[30] Foreign Application Priority Data
 Feb. 26, 1988 [FR] France 88 02359

[51] Int. Cl.⁴ **A61K 9/64**

[52] U.S. Cl. **424/456; 424/457;**
424/458

[58] Field of Search **424/456, 452, 458**

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,436,743 3/1984 Schönafinger et al. 514/364

4,558,058 12/1985 Schönafinger et al. 514/342
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82/01649 5/1982 European Pat. Off. .
 0179583 4/1986 European Pat. Off. .
 0239541 9/1987 European Pat. Off. .

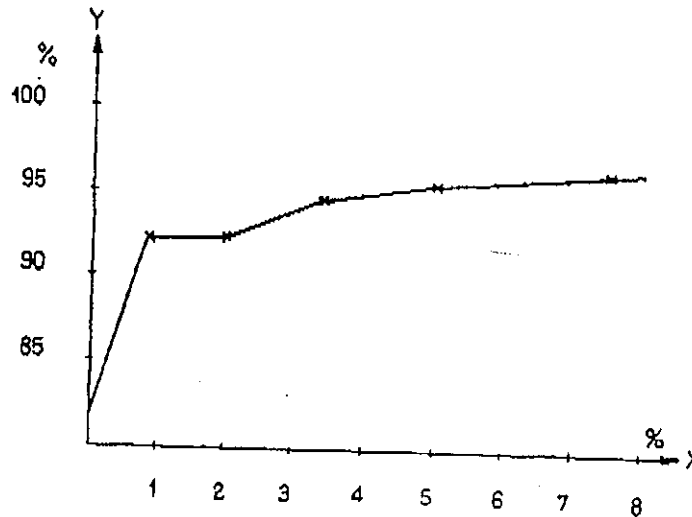
Primary Examiner—Ellis P. Robinson
Assistant Examiner—Leon R. Horne
Attorney, Agent, or Firm—Fleit, Jacobson, Cohn, Price,
 Holman & Stern

[57] **ABSTRACT**

The present invention relates to a novel dosage form of fenofibrate containing fenofibrate and a solid surfactant which have been co-micronized.

It also relates to the method for the preparation of this dosage form and its use for improving the bioavailability in vivo.

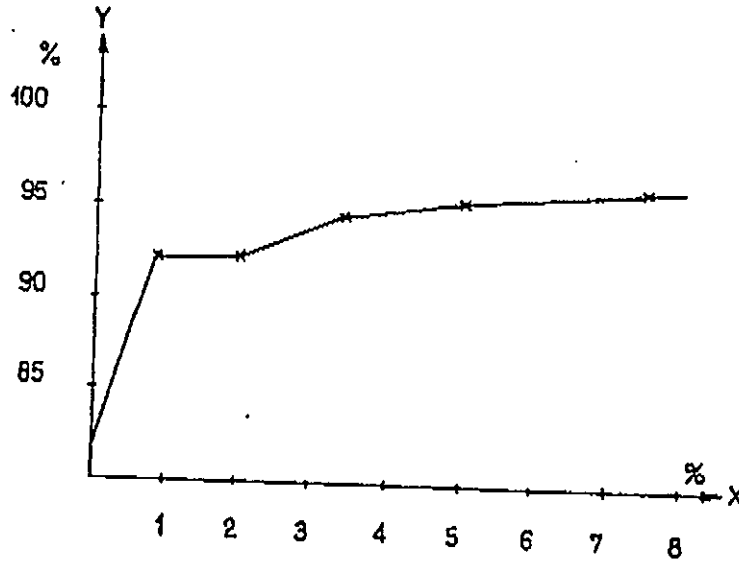
12 Claims, 1 Drawing Sheet



U.S. Patent

Jan. 23, 1990

4,895,726



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NOVEL DOSAGE FORM OF FENOFIBRATE

The present invention relates to a novel dosage form of fenofibrates. It relates more precisely to a therapeutic composition containing fenofibrate and ensuring an improved bioavailability, and to a method for the preparation of this composition.

Fenofibrate (international common name), which is recommended in the treatment of hyperlipidemia and hypercholesterolemia, corresponds to the nomenclature isopropyl 2-(4-(4-chlorobenzoyl)phenoxy)-2-methylpropionate. The customary adult dosage is three gelatin capsules per day, each containing 100 mg of fenofibrate.

For the patient's comfort, it is advantageous to try and find a dosage form which has to be taken only once a day and whose psychological effect is identical to that obtained when multiple doses are taken. A gelatin capsule containing 300 mg of fenofibrate has therefore been proposed, the dosage recommended in this case being only one administration per day.

However, it is possible to try and improve the dosage form still further. It is known, in fact, that the bioavailability of fenofibrate is not equal to 100%. It is therefore desirable to develop a dosage form in which the bioavailability of the fenofibrate is improved and which can be administered only once a day.

It is known that the micronization of an active principle is capable of improving the dissolution of the said active principle *in vivo*, and hence its bioavailability. It is also known that the addition of a surfactant excipient to a formulation of an active principle is capable of improving the absorption and consequently the bioavailability of the said active principle.

It has now been discovered that the co-micronization of fenofibrate and a solid surfactant (i.e. the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability of the fenofibrate to a significantly greater extent than that which would be achieved either by adding a surfactant, or by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant.

The present invention therefore proposes a novel therapeutic composition, prepared in the form of gelatin capsules, which is useful especially in the oral treatment of hyperlipidemia and hypercholesterolemia, the said composition containing fenofibrate and a solid surfactant which have been co-micronized.

The recommended amount of fenofibrate is about 200 mg per therapeutic unit.

The surfactant will be selected from solid surfactants so that it can be co-micronized with the fenofibrate. An alkali metal sulfate of lauryl alcohol, for example sodium lauryl-sulfate (alternative name: sodium dodecyl-sulfate), will be preferred. The recommended amount of sodium lauryl-sulfate will be between 0.5% and 7% by weight, relative to the total weight of the formulation. The weight ratio surfactant/fenofibrate will advantageously be between about 0.75/100 and 10.5/100.

The co-micronization of the fenofibrate and the solid surfactant will advantageously be carried out in an accelerated air-jet mill until the powder obtained is such that the mean particle size is less than 15 μm , preferably less than 10 μm and particularly preferably less than 5 μm .

To obtain a powder which can be formulated into gelatin capsules, conventional filling, dispersing and

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flow-enhancing excipients, for example lactose, starch, polyvinylpyrrolidone and magnesium stearate, may be added to the co-micronizate of fenofibrate and solid surfactant.

According to the invention, a method for the preparation of a therapeutic composition containing fenofibrate and a solid surfactant is recommended which comprises:

- (i) intimately mixing and then co-micronizing the fenofibrate and the solid surfactant,
- (ii) adding lactose and starch to the mixture obtained,
- (iii) converting the whole to granules in the presence of water,
- (iv) drying the granules until they contain no more than 1% of water,
- (v) grading the granules,
- (vi) adding polyvinylpyrrolidone and magnesium stearate to the graded granules, and
- (vii) filling gelatin capsules with the mixture obtained in stage (vi).

This invention will be understood more clearly from the description of the Preparative Examples which follow and from the description of the results obtained in comparative tests, which show that the invention is non-obvious.

PREPARATION I

For 100,000 gelatin capsules, each weighing 350 mg and containing 200 mg of fenofibrate, the amounts of products used are as follows:

fenofibrate	20.0 kg
sodium lauryl-sulfate	0.7 kg
α -lactose monohydrate	10.1 kg
pregelatinized starch	1.0 kg
crosslinked polyvinylpyrrolidone	0.7 kg
magnesium stearate	0.5 kg

The fenofibrate/sodium lauryl-sulfate mixture is co-micronized in an air-jet micronizer to give a powder with a median particle size of 3 μm . The lactose and the starch are then added to this powder and the whole is converted to granules in the presence of 8.9% of distilled water, relative to the total weight of the mixture. The granules obtained in this way are dried for one day at 50° C. and then graded so as to retain only the particles with sizes less than or equal to 1000 μm . The polyvinylpyrrolidone and the magnesium stearate are then added and the whole is mixed until homogeneous. The powder obtained is used to fill size 1 gelatin capsules on an automatic machine with the compression set to a maximum of 150N.

PREPARATION II

The procedure indicated in Preparation I is followed using a fenofibrate/sodium lauryl-sulfate mixture with a median particle size of 6-7 μm .

PREPARATION III

For 100,000 size 1 gelatin capsules, each weighing 297 mg and containing 200 mg of active principle, the amounts of products are as follows:

fenofibrate	20.0 kg
sodium lauryl-sulfate	0.7 kg
α -lactose monohydrate	6.8 kg
pregelatinized starch	1.5 kg

-continued

crosslinked polyvinylpyrrolidone	0.6 kg
magnesium stearate	0.5 kg

The procedure is analogous to that used for Preparation I, the co-micronization of the fenofibrate/sodium lauryl-sulfate mixture being such that the median particle size is 6-7 μ m and the granulation being carried out in the presence of 10% of distilled water, relative to the weight of the fenofibrate/sodium lauryl-sulfate/lactose/starch mixture.

PREPARATION IV

Following a procedure analogous to that described in Preparation I, using a co-micronized mixture of fenofibrate and sodium lauryl-sulfate with a median particle size of 6-7 μ m, the formulations collated in Table I below were prepared:

TABLE I
COMPOSITION (in mg) PER GELATIN CAPSULE

INGREDIENT	FORMULATION					
	A	B	C	D	E	F
Fenofibrate	200	200	200	200	200	200
Na lauryl-sulfate	0	3	7	12	17.5	26.5
Lactose	108	105	101	95	90.5	83.5
Starch	30	30	30	30	30	30
Polyvinylpyrrolidone	7	7	7	7	7	7
Mg stearate	5	5	5	5	5	5
Percentage of Na lauryl-sulfate	0	0.16	2	3.4	5	7.53

Taking these formulations, the dissolution curve shown in FIG. 1 was plotted, the percentage of dissolved fenofibrate (Y) being given as a function of the percentage of sodium lauryl-sulfate contained in the formulation (X). The dissolution kinetics are determined, as specified in the European Pharmacopocia, using a rotating-vane apparatus, the eluent consisting of water and 0.1M sodium lauryl-sulfate. The fenofibrate is determined by UV spectrophotometry at 282 nm. The curve in FIG. 1 is given by the values obtained after 20 minutes.

These results show that 82% of fenofibrate is dissolved at a sodium lauryl-sulfate concentration of 0%, 87% of fenofibrate is dissolved at a concentration of 0.5%, 92% of fenofibrate is dissolved at a concentration of 1% and a maximum dissolution of 95 to 96% of fenofibrate is obtained as from a sodium lauryl-sulfate concentration of 4%.

The dissolution curves were also plotted, in a continuous-flow cell with a flow rate of 20 ml/min of 0.1M sodium lauryl-sulfate, for formulations containing co-micronized fenofibrate and sodium lauryl-sulfate (NaLS), by comparison with micronized fenofibrate and with formulations obtained by intimately mixing separately micronized fenofibrate and lauryl-sulfate. The comparison is made by means of T 50%, i.e. the time required for 50% of the fenofibrate to dissolve. The results obtained are collated in Table II below:

TABLE II
VALUE OF THE T 50% TIMES (in minutes)

INGREDIENTS	A	B	C
Micronized pure fenofibrate	37.165	37.165	0
Fenofibrate + 1% of NaLS	18.01	3.62	-32.14

TABLE II-continued
VALUE OF THE T 50% TIMES (in minutes)

INGREDIENTS	A	B	C
Fenofibrate + 3% of NaLS	23.75	12.64	-46.61
Fenofibrate + 5% of NaLS	20.35	11.425	-43.86
Fenofibrate + 7% of NaLS	14.5	10.76	-25.79

10 Note
A mixture of micronization
B co-micronization of the mixture of ingredients
C variation $\frac{B-A}{A} \times 100$ (in %)

15 These results show that the T 50% of the fenofibrate is very significantly reduced (hence the dissolution rate of the fenofibrate is very significantly increased) when the fenofibrate and the sodium lauryl-sulfate are co-micronized, compared with the mixture of separately micronized fenofibrate and sodium lauryl-sulfate and compared with fenofibrate alone.

20 The dissolution rate of fenofibrate is correlated with the bioavailability of fenofibrate, which increases with the dissolution rate. The above results shown that it was not within the understanding of those skilled in the art to prepare a therapeutic composition characterized by the co-micronization of fenofibrate and a solid surfactant.

25 These results have been confirmed in clinical trials. Fenofibrate was administered to groups of healthy subjects, (a) in the form of a single administration (1 gelatin capsule) of 300 mg of non-micronized fenofibrate (marketed under the tradename "LIPANTHYL 300") and (b) in the form of a single administration of 200 mg of co-micronized fenofibrate obtained according to Preparation III described above. Blood samples are taken from the subjects at regular intervals and one of the active metabolites—2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropionic acid—is determined. The curve showing the concentration of this metabolite as a function of time is plotted and the area under the curve [AUC(0- ∞)], expressed in mg/l.h, is calculated.

The results obtained are shown in Table III below:

TABLE III

BIOAVAILABILITY PARAMETER	FENOFIBRATE 200 mg	FENOFIBRATE 300 mg
	(1)	(2)
AUC(0- ∞)(mg/l.h)	174.15 \pm 48.67	168.85 \pm 57.68
C max (m/l)	10.86 \pm 2.13	10.39 \pm 2.89
t max (h)	3.97 \pm 2.50	3.52 \pm 1.70
t 1/2 (h)	13.13 \pm 4.27	17.79 \pm 8.77

30 Note
(1) co-micronized fenofibrate (200 mg)
(2) non-micronized fenofibrate (300 mg)

35 The results in Table III show that there is not a statistically significant difference between the in vivo bioavailability of 200 mg of co-micronized fenofibrate according to the invention and 300 mg of non-micronized fenofibrate (which is currently the preferred dosage form for a single daily administration). In other words, co-micronized fenofibrate at a 200 mg dose is bioequivalent to non-micronized fenofibrate at a 300 mg dose.

40 According to another aspect of the invention, a method for improving the bioavailability of fenofibrate in vivo is recommended, the said method comprising co-micronization of the fenofibrate and a solid surfactant, the said co-micronization being carried out by

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microzonization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than 15 μm and preferably less than or equal to 5 μm .

What is claimed is:

1. A therapeutic composition, which is presented in the form of gelatin capsules and which is useful especially in the oral treatment of hyperlipidemia and hypercholesterolemia, said composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant, wherein the mean particle size of said co-micronized mixture is less than 15 μm .

2. The therapeutic composition according to claim 1 wherein the weight ratio surfactant/fenofibrate is between about 0.75/100 and 10.5/100.

3. The therapeutic composition according to claim 1 wherein the amount of fenofibrate is equal to 200 mg per therapeutic unit.

4. The therapeutic composition according to claim 1, wherein the solid surfactant is sodium lauryl-sulfate.

5. The therapeutic composition according to claim 4, wherein the amount of sodium lauryl-sulfate is between 0.5 and 7% by weight, relative to the total weight of the formulation.

6. The therapeutic composition according to claim 1, wherein said mean particle size is less than or equal to 10 μm and said solid surfactant is sodium lauryl-sulfate.

7. The therapeutic composition according to claim 1, which also contains excipients such as dispersants, fillers and flow enhancers.

8. A method for the manufacture of a therapeutic composition according to claim 1, which comprises:

- (i) intimately mixing and then co-micronizing the fenofibrate and a solid surfactant,
- (ii) adding lactose and starch to the mixture obtained,
- (iii) converting the whole to granules in the presence of water,
- (iv) drying the granules until they contain no more than 1% of water,
- (v) grading the granules,
- (vi) adding polyvinylpyrrolidone and magnesium stearate, and
- (vii) filling gelatin capsules.

9. The method according to claim 8, wherein the mean particle size of the co-micronized fenofibrates and sodium lauryl-sulfate is less than 15 μm .

10. A method for improving the bioavailability of fenofibrate in vivo, which comprises co-micronization of the fenofibrate and a solid surfactant, the said co-micronization being carried out by micronization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than 15 μm .

11. A method for treatment of hyperlipidemia or hypercholesterolemia comprising orally administering the therapeutic composition of claim 6 to a patient.

12. The method of treatment of claim 11, wherein said particle size is less than or equal to 5 μm .

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(Rev. 12/96)

CIVIL COVER SHEET

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.)

I. (a) PLAINTIFFS

Abbott Laboratories, Fournier Industrie et Sante, and Laboratoires Fournier S.A.

DEFENDANTS

Novopharm Limited

100 JOURNAL COPIES
MAILED
AUG 23 1999
U.S. DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
CHICAGO

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Lake
(EXCEPT IN U.S. PLAINTIFF CASES)

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)

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

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DOCKETED

CHIEF JUDGE ASPEN

AUG 22 2000

II. BASIS OF JURISDICTION

(PLACE AN "X" IN ONE BOX ONLY)

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

III. CITIZENSHIP OF PRINCIPAL PARTIES

- | | | | |
|---|---|--|---|
| <input type="checkbox"/> Citizen of This State
<input type="checkbox"/> Citizen of Another State
<input type="checkbox"/> Citizen or Subject of a Foreign Country | PTF DEF
<input type="checkbox"/> 1 <input type="checkbox"/> 1
<input type="checkbox"/> 2 <input type="checkbox"/> 2
<input type="checkbox"/> 3 <input type="checkbox"/> 3 | DEF
Incorporated or Principal Place of Business in This State
Incorporated and Principal Place of Business in Another State
Foreign Nation | PTF DEF
<input type="checkbox"/> 4 <input type="checkbox"/> 4
<input type="checkbox"/> 5 <input type="checkbox"/> 5
<input type="checkbox"/> 6 <input type="checkbox"/> 6 |
|---|---|--|---|

00C 5094

MAGISTRATE JUDGE LEVIN

IV. ORIGIN

(PLACE AN "X" IN ONE BOX ONLY)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from another district (specify)
- 6 Multidistrict Litigation
- 7 Appeal to District Judge from Magistrate Judgment

V. NATURE OF SUIT

(PLACE AN "X" IN ONE BOX ONLY)

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

VI. CAUSE OF ACTION

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.)

Patent infringement pursuant to 35 U.S.C Section 271 (e)

VII. 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

VIII. This case is not a refiling of a previously dismissed action.

is a refiling of case number _____, previously dismissed by Judge _____

DATE
August 18, 2000

SIGNATURE OF ATTORNEY OF RECORD

Daniel E. Reidy

UNITED STATES DISTRICT COURT

1-2

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

In the Matter of

Abbott Laboratories, Fournier Industrie et Santé and Laboratoires Fournier S.A. v. Novopharm Limited

Case Number:

00C 5094

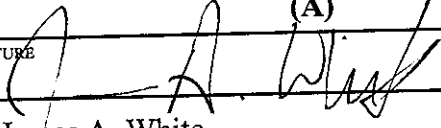
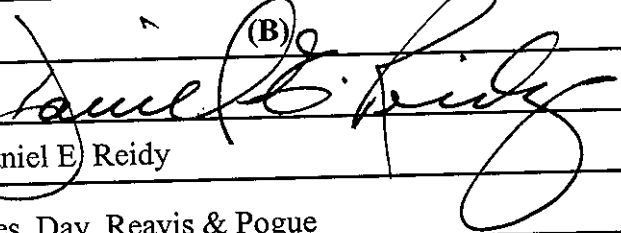
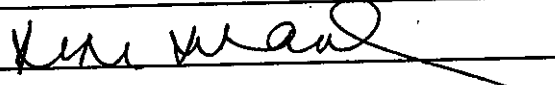
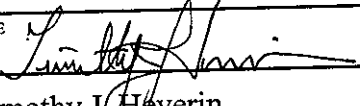
FILED-EDA
 00-5094-18 PM 3:31
 U.S. DISTRICT COURT

APPEARANCES ARE HEREBY FILED BY THE UNDERSIGNED AS ATTORNEY(S) FOR:

Abbott Laboratories

CHIEF JUDGE ASPEN

MAGISTRATE JUDGE LEVIN

(A)		(B)	
SIGNATURE 		SIGNATURE 	
NAME James A. White		NAME Daniel E. Reidy	
FIRM Jones, Day, Reavis & Pogue		FIRM Jones, Day, Reavis & Pogue	
STREET ADDRESS 77 West Wacker Drive, Suite 3500		STREET ADDRESS 77 West Wacker Drive, Suite 3500	
CITY/STATE/ZIP Chicago, Illinois 60601-1692		CITY/STATE/ZIP Chicago, Illinois 60601-1692	
TELEPHONE NUMBER (312) 782-3939		TELEPHONE NUMBER (312) 782-3939	
IDENTIFICATION NUMBER (SEE ITEM 4 ON REVERSE) 6190225		IDENTIFICATION NUMBER (SEE ITEM 4 ON REVERSE) 02306948	
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TRIAL ATTORNEY? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	TRIAL ATTORNEY? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	TRIAL ATTORNEY? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	TRIAL ATTORNEY? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
		DESIGNATED AS LOCAL COUNSEL? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
(C)		(D)	
SIGNATURE 		SIGNATURE 	
NAME Tina M. Tabacchi		NAME Timothy J. Heverin	
FIRM Jones, Day, Reavis & Pogue		FIRM Jones, Day, Reavis & Pogue	
STREET ADDRESS 77 West Wacker Drive, Suite 3500		STREET ADDRESS 77 West Wacker Drive, Suite 3500	
CITY/STATE/ZIP Chicago, Illinois 60601-1692		CITY/STATE/ZIP Chicago, Illinois 60601-1692	
TELEPHONE NUMBER (312) 782-3939		TELEPHONE NUMBER (312) 782-3939	
IDENTIFICATION NUMBER (SEE ITEM 4 ON REVERSE) 6210961		IDENTIFICATION NUMBER (SEE ITEM 4 ON REVERSE) 6253107	
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AUG 23 2000
 U.S. DISTRICT COURT

1-3

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

In the Matter of
ABBOTT LABORATORIES, et al.
 Plaintiffs,
 v.
NOVOPHARM LIMITED,
 Defendant

Case Number: **00C-5094**

APPEARANCES ARE HEREBY FILED BY THE UNDERSIGNED AS ATTORNEY(S) FOR:
 Plaintiffs Fournier Industrie et Sante and Laboratoires Fournier S.A.

CHIEF JUDGE ASPEN
 MAGISTRATE JUDGE LEVIN

(A)	(B)
SIGNATURE <i>Tracey L Wolfe</i>	SIGNATURE
NAME Tracey L. Wolfe	NAME
FIRM Clark & DeGrand	FIRM
STREET ADDRESS One South Wacker Dr., Suite 1495	STREET ADDRESS
CITY/STATE/ZIP Chicago, Illinois 60606	CITY/STATE/ZIP
TELEPHONE NUMBER (312) 425-0500	TELEPHONE NUMBER
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	DESIGNATED AS LOCAL COUNSEL? YES <input type="checkbox"/> NO <input type="checkbox"/>
(C)	(D)
SIGNATURE	SIGNATURE
NAME	NAME
FIRM	FIRM
STREET ADDRESS	STREET ADDRESS
CITY/STATE/ZIP	CITY/STATE/ZIP
TELEPHONE NUMBER	TELEPHONE NUMBER
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DESIGNATED AS LOCAL COUNSEL? YES <input type="checkbox"/> NO <input type="checkbox"/>	DESIGNATED AS LOCAL COUNSEL? YES <input type="checkbox"/> NO <input type="checkbox"/>

DOCKETED
 AUG 23 2000

PLEASE COMPLETE IN ACCORDANCE WITH INSTRUCTIONS ON REVERSE.

1-3