



-> S. Torname
P 7641 - 20 pages

Reliant Pharmaceuticals, LLC
110 Allen Road
Liberty Corner, NJ 07938
908-580-1200
Fax: 908-542-9405
www.ReliantPh.com

February 18, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

VIA FEDERAL EXPRESS

Abbott Laboratories
Attn: Chief Executive Officer
100 Abbott Park Road
Abbott Park, IL 60064
U.S.A.

Laboratories Fournier, S.A.
Attn: Chief Executive Officer
42 Rue de Longvic
21300 Chenove
France

Re: **Tricor[®]/Discontinued Fenofibrate Capsules, 200 mg**
NDA 19-304
United States Patent No. 4,895,726
Notice of Paragraph IV Certification

Dear Gentlemen:

We write to provide notice of certification on behalf of Reliant Pharmaceuticals, L.L.C ("Reliant" or "Applicant") pursuant to § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act ("the Act") and § 314.52 of Title 21 of the Code of Federal Regulations to the patent owner and the holder of the above-referenced discontinued New Drug Application. This information is provided to the owners of the patents that are the subject of the notice of certification and the holders of the approved applications under § 505(b) of the Act for the listed drug product.

1. To obtain approval to engage in the commercial manufacture, use or sale of micronized fenofibrate capsules, 43 mg, 87 mg, and 130 mg, Reliant submitted to the Food and Drug Administration ("FDA") a New Drug Application ("NDA") under § 505(b)(2) of the Act that contains the required bioavailability or bioequivalence data or information. FDA has received and accepted the filing of the NDA.
2. The NDA number is 21-695.
3. The name of Reliant's proposed drug product is RP 1824 fenofibrate (micronized) capsules ("RP 1824").
4. Reliant's application for approval of RP 1824 relies upon investigations conducted with respect to the discontinued drug product Tricor[®] 200 mg capsules marketed by Abbott Laboratories ("Abbott").

5. The active ingredient, strengths and dosage forms of RP 1824 are micronized fenofibrate, 43 mg, 87 mg, and 130 mg capsules for oral administration.
6. The NDA contains a certification that the Applicant intends to market RP 1824 before the expiration of U.S. Patent No. 4,895,726 ("the '726 Patent"), which expires on January 19, 2009. The '726 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for discontinued Tricor[®] brand of fenofibrate capsules, 200 mg.
7. The NDA contains a certification that in the Applicant's opinion and to the best of its knowledge, the '726 patent will not be infringed by the commercial manufacture, use, or sale of RP 1824.
8. Reliant hereby offers confidential access to its NDA for RP 1824 pursuant to § 505(c)(3)(D)(i)(III) of the Federal Food, Drug and Cosmetic Act to the patent owners and the holder of the listed drug application for the purpose of determining whether marketing of RP 1824 would infringe the '726 Patent ("the Evaluation").
9. A request for access by the patent owner or the holder of the listed drug application to Reliant's NDA under this offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in this offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract.
10. Confidential access shall be limited to outside counsel only who, aside from their responsibility in connection with the Evaluation, have no (and will have no) competitive decision making role or capacity concerning fenofibrate, including but not limited to involvement in prosecution of patent applications relating to fenofibrate.
11. A request for access to Reliant's NDA must be written, and received by Applicant within 14 days after receipt of this notice of certification. The request for access must include the names of proposed outside counsel that will have access to Applicant's NDA.
12. In the event Reliant objects to a person listed in the request for access, notice must be sent to the patent owners and/or the holder of the listed drug application in writing within 7 days. The patent owners and/or the holder of the listed drug application must provide name(s) of alternates in writing within 3 days.

13. In the absence of written permission from Reliant, any person provided confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph § 505(b)(2)(A)(iv) of the Act and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access.
14. The Evaluation will terminate upon the earlier of:
 - (a) receipt of written demand by Reliant for return of its NDA;
 - (b) expiration of the 45 day period provided for in section 505(c)(3)(C) of the Federal Food, Drug & Cosmetic Act; or
 - (c) the filing of a complaint for patent infringement.
15. Within 72 hours after termination of the Evaluation, the patent owners and the holder of the listed drug application shall, absent an agreement to the contrary, assemble and return to Reliant all materials produced in accordance with this Notice of Paragraph IV Certification, including all copies of such matter which may have been made. Copies containing notes or other attorney work product shall be destroyed and such destruction shall be certified in writing.
16. The patent owners and the holder of the listed drug application expressly agree not to disclose Applicants' NDA in a court filing unless an appropriate sealing/confidentiality order is in place.
17. This Agreement shall survive termination of the Evaluation.
18. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, without giving effect to conflict-of-law rules. The patent owner or the holder of the listed drug application further agree to jurisdiction and venue in the Southern District of New York in connection with any dispute arising from this Agreement

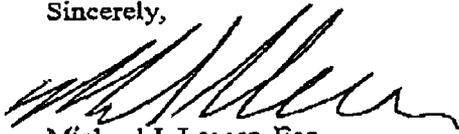
Attached is a detailed statement of the factual and legal basis of Reliant's patent certification. This information is supplied for the sole purpose of complying with the above-referenced statutes and regulations. Neither Reliant nor its attorneys waive any attorney-client privilege or attorney-work-product immunity or any other claims or privileges concerning the subject matter of this communication.

Reliant expressly reserves the right to develop and make other arguments and assert any defenses relating to non-infringement, invalidity and/or unenforceability of the claims of the '726 patent should grounds become apparent in the future.

Reliant appoints the following individual as an agent authorized, for the purposes of this matter only, to accept service of process in response to this letter:

Andrew M. Berdon, Esq.
QUINN EMANUEL URQUHART OLIVER & HEDGES, LLP
335 Madison Avenue, 17th Floor
New York, New York 10017
(212) 702-8100

Sincerely,



Michael J. Lerner, Esq.
Vice President, Legal Affairs
Reliant Pharmaceuticals, LLC
110 Allen Road
Liberty Corner, New Jersey 07938

ARNOLD & PORTER LLP

Donald O. Beers
Donald_Beers@aporter.com

202.942.5012
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

September 2, 2004

VIA FACSIMILE

Lyle Jaffe
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004P-0386

Dear Mr. Jaffe:

You have brought to my attention the fact that a document included in Tab 1 of the exhibits to this petition is labeled as confidential. This document was an enclosure in a letter from Reliant Pharmaceuticals to Abbott Laboratories and Laboratoires Fournier. It thus lost any confidential status it may ever have had when it was communicated to Abbott and Fournier. For FDA's purposes, this document should not be considered to be confidential and it may be appropriately placed in the public file.

Sincerely,



Donald O. Beers

20036 04 SEP -2 15 2004

ARNOLD & PORTER LLP

202.942.5000
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

Fax Transmittal

September 2, 2004

RECIPIENT NAME(S)	RECIPIENT FAX NUMBER(S)	RECIPIENT TELEPHONE NUMBER(S)	RECIPIENT ROOM #(S)
Lyle Jaffe	301-827-6870		
SENDER	SENDER'S TELEPHONE NUMBER	SENDER'S ROOM NUMBER	
Donald O. Beers	202-942-5012	1221	
CLIENT/MATTER NUMBER	TIMEKEEPER NUMBER	NUMBER OF PAGE(S)	
04275.023	3242	We are transmitting 2 page(s) (including this cover sheet)	
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This document must be transmitted no later than: September 2, 2004		Alternate telephone number at which the sender can be reached if there are difficulties with this fax:	
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MESSAGE			

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**DETAILED STATEMENT OF FACTUAL AND LEGAL BASES FOR RELIANT'S
OPINION THAT THE '726 PATENT IS NOT INFRINGED**

I. INTRODUCTION AND SUMMARY OF ARGUMENTS

Reliant's RP 1824 capsules do not infringe the '726 patent either literally or under the doctrine of equivalents. Specifically, the Federal Circuit in Abbott Laboratories v. Novopharm Ltd., 323 F.3d 1324 (Fed. Cir. 2003) construed the terms "co-micronized or co-micronization" in the claims of the '726 patent to mean micronizing fenofibrate and a solid surfactant together in the absence of other excipients. Abbott and Fournier (hereinafter sometimes referred to as the "Patentees") are precluded from relitigating the '726 patent claim construction.

RP 1824 does not literally infringe the '726 patent because it will be manufactured using fenofibrate that is micronized alone, and not in the presence of a solid surfactant. In addition, when, during the manufacturing process, the fenofibrate is combined with a surfactant, other excipients are present. Further, at all times during the process when the fenofibrate and the surfactants are mixed, the surfactant is dissolved in solution and not "solid" as claimed in the '726 patent. Accordingly, RP 1824 cannot be found to literally infringe any of the claims of the '726 patent.

Nor can the '726 patent be expanded to encompass RP 1824 under the doctrine of equivalents. More specifically, the Federal Circuit found that the Patentees relinquished coverage of compositions prepared by processes in which pre-micronized fenofibrate is combined with a pre-micronized or non-micronized solid surfactant without further co-micronization. Accordingly, Patentees are estopped from asserting that any claim of the '726 patent encompasses a composition in which fenofibrate is micronized alone, and then mixed with a surfactant in the presence of other excipients, without further micronization. As the process described in Reliant's NDA does not include any step in which fenofibrate and a solid surfactant are in a mixture, in the absence of other excipients, that undergoes a micronization step or any other step that could mechanically reduce particle size, RP 1824 does not infringe the claims of the '726 patent under the doctrine of equivalents.

Further, Reliant's process does not involve micronization of any mixture that includes fenofibrate and a solid surfactant, irrespective of the presence or absence of other excipients, as the surfactant used in Reliant's process is not solid but dissolved in an aqueous solution prior to mixing with fenofibrate and remains in solution throughout the drying steps.

Thus, there is no infringement of the '726 patent.

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II. RP 1824

Reliant proposes to manufacture and sell RP 1824 fenofibrate capsules that contain 43 mg, 87 mg, and 130 mg of micronized fenofibrate. The fenofibrate used to formulate these capsules is micronized alone. Further, the fenofibrate does not undergo further micronization, or any other step that could mechanically reduce particle size, during the formulation process. Rather, the pre-micronized fenofibrate is mixed in a solution including sodium lauryl sulfate ("SLS") and other excipients, and subsequently spray-dried onto inert cores.

More specifically, each capsule is filled with beads that comprise, micronized fenofibrate, neutral beads, hydroxypropylmethyl cellulose ("HPMC") 603, SLS, HPMC 606, talc, dimethicone and simethicone. RP 1824 will be manufactured by the following process: suspending fenofibrate in an aqueous mixture containing HPMC 603, SLS, dimethicone, simethicone and talc; spraying the above suspension onto inert cores; drying the coated cores; overcoating the dried, coated cores with an aqueous mixture of HPMC 606 and talc to form beads; and drying the overcoated cores. The dried beads will then be dispensed into gelatin capsules.

RP 1824 will be manufactured by a contract manufacturer using fenofibrate (hereinafter "Active Pharmaceutical Ingredient" or "API"), manufactured by a third party (the "API Supplier"). The API Supplier has certified to Reliant that the API is micronized alone and not in the presence of a surfactant; and that no additives are co-micronized with the API. (Attached as Exhibit 1). This statement is fully supported and evidenced by the certificate of analysis that accompanies each batch of API. (Attached as Exhibit 2). The certificate of analysis makes clear that the API is 98.5-100 percent pure, and that any substances other than fenofibrate present in the API are impurities related to the fenofibrate manufacturing process and not solid surfactants.

Finally, the chemistry, manufacturing and controls ("CMC") section of the RP 1824 NDA confirms that API does not undergo further micronization, or any other step that could mechanically reduce particle size, during the formulation process.

III. THE '726 PATENT

A. The '726 Patent Specification

The '726 patent was filed on January 19, 1989 and issued January 23, 1990. The '726 patent names Bernard Curtet, Eric Teillaud, and Philippe Reginault as inventors, and Laboratories Fournier, S.A. ("Fournier") as assignee. Abbott is Fournier's exclusive licensee under the '726 patent. The '726 patent expires on January 19, 2009 and claims priority from French Patent 88 02359, filed February 26, 1988.

The '726 patent is directed to compositions containing fenofibrate co-micronized with a solid surfactant. The specification states, "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

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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." ('726 patent, col. 1, lines 25-43).

The '726 patent specification includes data showing that the patented composition has improved properties relative to formulations in which: (1) a solid surfactant is added to fenofibrate (impliedly without co-micronization); (2) fenofibrate is micronized on its own; or (3) fenofibrate and surfactant are separately micronized and then intimately mixed ('726 patent, col. 1, lines 35-43). SLS is the only example of a solid surfactant provided in the '726 patent, and the method involving co-micronization of a fenofibrate/SLS mixture prior to the addition of excipients such as lactose or starch is the only detailed example of co-micronization disclosed in the '726 patent. No other excipient is identified as part of this mixture.

B. The '726 Patent Claims

The '726 patent concludes with 12 claims, which read as follows

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:

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surfactant, (i) intimately mixing and then co-micronizing the fenofibrate and a solid

- (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 fenofibrate 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 .

C. The '726 Patent's Prosecution History

The '726 patent issued from Application No. 07/299,073 ("the '073 application"), which was filed on January 19, 1989. The '073 application was filed with ten claims, the following of which are representative:

1. A therapeutic composition, presented 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.

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 .

('073 application file history, Paper No. 1, pp. 11-12).

The PTO issued a first Office Action on the merits on April 4, 1989. In the Office Action, all of the claims were rejected under 35 U.S.C. § 103 as obvious over U.S. Patent No.

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4,558,058 ("Schonafinger I") in view of U.S. Patent Nos. 4,629,624 ("Grouiller") and 4,436,743 ("Schonafinger II").

According to the Office Action, Schonafinger I "teaches loading of fenofibrate into gelatin capsules" but not "particle size and surfactant." (*Id.* at 2). Grouiller "teaches granulation of fenofibrate contained in a matrix having a particle size between 50 and 500 μm . . . the particles of fenofibrate in the matrix must be smaller than the matrix particles." (*Id.*) Schonafinger II "teaches that fenofibrate can be loaded into capsules to which can be added lubricants, wetting agents, stabilizers, emulsifiers, solubilizing agents etc." (*Id.* at 3). Thus, according to the Examiner,

[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a gelatin capsule as does Schonafinger (C) and fill same with fenofibrate of the particle size taught in Grouiller et al along with the usual materials for granulating a material to particle size, including excipients and other vehicles used by applicant.

(*Id.*).

Patentees filed a Response and Amendment Under 37 C.F.R. § 1.111 on July 5, 1989. ('073 application file history, Paper No. 7). Claims 1, 6 and 10 were amended as follows:

1. (amended) 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, [the] said composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant, [which have been co-micronized] wherein the mean particle size of said co-micronized mixture is less than 15 μm .

6. (amended) The therapeutic composition according to claim 1, wherein [the] said mean particle size is [of the co-micronized fenofibrate and sodium lauryl-sulfate is less than 15 μm , preferably] less than or equal to 10 μm [and particularly preferably less than or equal to 5 μm] and said solid surfactant is sodium lauryl-sulfate.

In claim 10, lines 6-7, please delete "and preferably less than or equal to 5 μm " immediately after "is less than 15 μm ".

(*Id.* at 1-2). In addition, claims 11 and 12 were added:

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

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or equal to 5 μ m.

(*Id.* at 2).

In response to the obviousness rejection, Patentees distinguished the claims from the cited art based on the increased bioavailability of co-micronizing a mixture of fenofibrate and a solid surfactant:

none of the cited references alone or in any combination thereof teaches or suggests that by co-micronizing a mixture of fenofibrate and a solid surfactant that the bioavailability of the fenofibrate is significantly and substantially increased compared to compositions containing mixtures of micronized fenofibrate and solid surfactant. This is clearly demonstrated in Table II of the specification in which the times for 50% (T50%) of the fenofibrate to dissolve when contained [in] compositions comprising a co-micronized mixture of fenofibrate and a surfactant (col. B, lines 2-5 of Table II) is compared with the T50% of fenofibrate in compositions containing mixtures of fenofibrate and a solid surfactant that had been micronized prior to mixing (col. A, lines 2-5). The T50% for micronized pure fenofibrate (cols. A and B, line 1), serves as a control to show that the observed results are not an artifact of mixing. It can be seen [sic] that in all instances fenofibrate in the co-micronized mixtures dissolves about 25-50% faster than fenofibrate that is micronized prior to mixing with micronized solid surfactant.

Further, the specification teaches that the above greater rate of dissolution of fenofibrate in co-micronized form correlates with greater bioavailability. In Table III data is presented which demonstrates that a dose of 200 mg. of co-micronized fenofibrate is equivalent to a 300 mg. dose of non-micronized fenofibrate as indicated by a comparison of blood levels of one of the active metabolites of fenofibrate as a function of time after administration in subjects administered either 300 mg. of non-micronized fenofibrate or 200 mg. of the co-micronized mixture.

Therefore, none of Grouiller et al. or Schonafinger (743) or ('058) teach or suggest that co-micronizing fenofibrate with a solid surfactant will increase the rate at which fenofibrate dissolves compared to the rate at which micronized fenofibrate mixed with micronized solid surfactant dissolves or that co-micronization increases the bioavailability of fenofibrate in vivo.

(*Id.* at 3-4) (Emphasis in original).

The PTO issued a Notice of Allowability and a Notice of Allowance and Issue Fee Due on September 12, 1989, allowing claims 1-12. ('073 application file history, Paper No. 8). The issue fee was paid on November 7, 1989, and the patent issued on January 23, 1990.

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Patentees filed a Request for Reexamination of the '726 patent in view of Boullay, "Microbroyage et dissolution," S.T.P. Pharma, 1(4): 296-99 (1985), on December 13, 1999. ('726 Reexamination File history, Paper No. 1, p. 1). The request was granted, and an Office Action issued on February 24, 2000. (Reexamination file history, Paper No. 5).

Patentees filed a response to the order granting the request for reexamination, with a Declaration Under 37 C.F.R. § 1.132 by Dr. Cutlet on April 24, 2000. (Reexamination file history, Paper No. 6). This response was later withdrawn because Patentees had discovered that Patentees' French patent counsel had falsified the declaration by Dr. Cutlet. (Reexamination file history, Paper No. 9). A new response, with Declarations Under 37 C.F.R. § 1.132 by Drs. Boullay and Reginault, was filed on April 6, 2001. (*Id.*).

In this response, Patentees argued that the claims of the '726 patent were nonobvious over Boullay. Specifically, Patentees distinguished compositions containing fenofibrate that had been "co-micronized" with a surfactant from compositions where fenofibrate and a surfactant that had been micronized separately, or pure micronized fenofibrate alone:

further evidence confirming the unpredictability of the impact of micronization with a surfactant on the dissolution characteristics of a substance is presented in the accompanying declaration of Dr. Philippe Reginault under 37 C.F.R. § 1.132 (hereinafter, "Reginault Declaration"). The Reginault Declaration presents a comparison of the dissolution characteristics of two other fibrates, bezafibrate and gemfibrozil, with the results reported in the '726 patent for fenofibrate. Specifically, the declaration presents a comparison of the dissolution speed of all three fibrates, both where the fibrate has been co-micronized with increasing levels of the surfactant sodium lauryl sulfate and where the fibrate and surfactant have been separately micronized and then mixed together. (Reginault Declaration at 8). The results of these experiments are expressed as $T_{50\%}$ (the time it takes for one-half of the substance to dissolve) and are listed in Table I of the Reginault Declaration. (Reginault Declaration at 8).

(*Id.* at 7).

Dr. Reginault summarized the results of these experiments in his declaration:

Contrary to the results observed for Bezafibrate and Gemfibrozil, the $T_{50\%}$ values for the co-micronized Fenofibrate and NaLS show a statistically significant improvement versus the $T_{50\%}$ values for pure micronized Fenofibrate. Additionally, the $T_{50\%}$ values for the co-micronized Fenofibrate and NaLS show a statistically significant improvement in the dissolution rates compared to the dissolution rates of the separately micronized Fenofibrate and NaLS at all concentrations of surfactant tested.

(Paper No. 9, Declaration by Dr. Reginault, p. 3).

Thereafter, the PTO issued a Reexamination Certificate on August 28, 2001.

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IV. LEGAL STANDARDS

A. INFRINGEMENT

Section U.S.C. § 271(e)(2) provides in pertinent part that "[i]t shall be an act of infringement to submit -(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2).

The patentee has the burden of proving infringement by a preponderance of the evidence. Amstar Corp. v. Envirotech Corp., 823 F.2d 1538, 1545 (Fed. Cir. 1987). Infringement may be literal or under the doctrine of equivalents. In each case the infringement analysis is a two-step process. First, the scope of the claims must be determined. The Supreme Court has held that this first step, sometimes referred to as claim interpretation, is an issue of law exclusively within the province of the court. Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) (Markman II); Cybor Corp. v. FAS/TECHS., Inc., 138 F.3d 1448, 1453 (Fed. Cir. 1998) (en banc). Thus, claim construction necessarily precedes a determination of whether the claims read on an accused product (or process) for infringement purposes. Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1562 (Fed. Cir. 1990); SmithKline Diagnostics, Inc. v. Helena Labs Corp., 859 F.2d 878, 882 (Fed. Cir. 1988).

The second step involves comparing the properly construed claims to the accused product or process to determine whether those claims "read on" the accused subject matter, i.e., whether all of the claim limitations are present in the accused device, either literally or by a substantial equivalent. Johnson Worldwide Assocs. Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1999); Renishaw PLC v. Marposs Societa per Azioni, 158 F.3d 1243, 1247 (Fed. Cir. 1998); Cybor, 138 F.3d at 1453. This second step is a factual determination and is thus submitted to a jury if the case is not tried to the court. Markman II, 517 U.S. at 385 (citing Winans v. Denmead, 15 How. 330, 338 (1854)).

1. Claim Interpretation

Claim interpretation involves consideration of the language of the patent claim itself, the specification, other claims, the prosecution history, and extrinsic evidence, if necessary. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996) (Markman I); Vitronics Corp. v. Conceptor, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Extrinsic evidence is any evidence which is external to the patent and prosecution history, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles. Vitronics, 90 F.3d at 1584. Finally, "the claims of [a] patent cannot be given a construction broader than the teachings expressed in the patent." Studiengesellschaft Kohle mbH v. Eastman Kodak, Inc., 616 F.2d 1315, 1324 (5th Cir. 1980). Thus, the scope of the claims can be no broader than the scope of the novel invention taught by the patentee in the specification.

Use of extrinsic evidence is endorsed by the Federal Circuit to understand an invention or

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to ensure that a claim construction is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field. This is especially the case with respect to technical terms." Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999). "[T]echnical treatises and dictionaries fall within the category of extrinsic evidence ... [but] are worthy of special note. Judges are free to consult such resources at any time in order to better understand the underlying technology." Vitronics, 90 F.3d at 1584 n. 6. However, extrinsic evidence must not be relied upon to contradict the plain meaning of claims discernible from the intrinsic evidence. Id. at 1593; Pitney Bowes, 182 F.3d at 1308.

The specification should be referred to when construing the limitations of patent claims. Indeed, usually, it is dispositive of the meaning of a term, and has been called "the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. Thus, the specification may act as a sort of dictionary, which explains the claimed subject matter and may define terms used in the claims. Markman I, 52 F.3d at 979; CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1153 (Fed. Cir. 1997). Where the specification contains nothing to indicate that phrases are to be given anything other than their ordinary meanings, then those are the meanings the court must give them. Enercon GmbH v. Int'l Trade Comm'n, 151 F.3d 1376, 1384 (Fed. Cir. 1998) (citing Vitronics, 90 F.3d at 1582); Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984). Thus, a technical term used in a patent document is given the same meaning that it would be given by persons experienced in the field of the patent, unless it is apparent from the patent and prosecution history that the patentee used the term with a different meaning. CVI/Beta Ventures, 112 F.3d at 1153, citing Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996) ("it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning").

While the specification should be used to interpret the meaning of terms in a claim, limitations should not be read from the specification into the claims. E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988), cert. denied, 488 U.S. 986 (1988) (citations omitted).

The Federal Circuit has also held that the prosecution history should be considered when construing the claims. The Court has cautioned, however, that "although the prosecution history can and should be used to understand the language used in the claims, it too cannot 'enlarge, diminish, or vary' the limitations in the claims." Markman I, 52 F.3d at 979-80 (citations omitted). The prosecution history may also be used to limit the interpretation of claim terms to exclude that which was intentionally and clearly disclaimed during prosecution. Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995).

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2. Literal Infringement

After claim interpretation, a determination is made whether the claims cover the accused products or methods. Johnson Worldwide Assocs., 175 F.3d at 988. In order to infringe a claim, the accused product or method must include every limitation of the claim, either literally or by a substantial equivalent. Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 397 (Fed. Cir. 1994).

To demonstrate literal infringement, a plaintiff must prove that the allegedly infringing product or method embodies every element of the asserted claim(s). Dolly, Inc., 16 F.3d at 397; Townsend Eng'g Co. v. Hitec Co., 829 F.2d 1086, 1090 (Fed. Cir. 1987). This follows from the principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." Lemelson v. United States, 752 F.2d 1538, 1551 (Fed. Cir. 1985) (explaining that "it is well settled that each element of a claim is material and essential" to the infringement inquiry). Thus, "[i]f even one limitation is missing or not met as claimed, there is no literal infringement." Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998).

3. The Doctrine of Equivalents

Even if a product or process does not literally infringe, there can still be infringement if there is "equivalence" between the elements of the accused product or process and the elements of the patent's claims. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605 (1950); Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997); We Care, Inc. v. Ultra-Mark Int'l Corp., 930 F.2d 1567, 1571 n.3 (Fed. Cir. 1991). Thus, infringement "may be found where those limitations of a claim not exactly found in the accused device are met equivalently." Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1568 (Fed. Cir. 1996). The doctrine of equivalents is intended to permit the patentee to protect the patent against what are essentially copies.

Thus, the doctrine of equivalents is invoked to prevent a "fraud on the patent," Graver Tank, 339 U.S. at 608, when an accused infringer is "stealing the benefit of the invention" by making insubstantial changes that avoid the literal scope of the claims. Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. at 34. Infringement by equivalents requires that "the accused product or process contain elements identical or equivalent to each claimed element of the patented invention." Id. at 40. For infringement of a process invention, all of the claimed steps of the process must be performed, either as claimed or by an equivalent step. EMI Group North America, Inc. v. Intel Corp., 157 F.3d 887, 896 (Fed. Cir. 1998).

One traditional standard or "linguistic framework" for applying the doctrine of equivalents rests on the substantiality of the differences between the claimed and accused products or processes. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1518 (Fed. Cir. 1995), rev'd on other grounds, 520 U.S. 17 (1997) (affirming the viability of the "insubstantial differences" test); Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996). The nature of the differences is assessed according to whether a person with ordinary skill in the relevant art would find the differences to be substantial. Id. at

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1519. If the accused and claimed elements are not known to be interchangeable, then one skilled in the relevant art may consider the change to be substantial. Id.; Graver Tank, 339 U.S. at 607.

Another traditional standard is to determine whether the elements of the accused process or product perform substantially the same function, in substantially the same way, to accomplish substantially the same result as each element of the claims. Warner-Jenkinson, 520 U.S. at 43; Graver Tank, 339 U.S. at 608 (1950); Wright Medical Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1444 (Fed. Cir. 1997).

There are, of course, limitations on the application of the doctrine of equivalents. Both the prior art and prosecution history estoppel limit the range of equivalents. Haynes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1579 (Fed. Cir. 1993), clarified on other grounds, 15 F.3d 1076 (Fed. Cir. 1994); Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934 n.1 (Fed. Cir. 1987) (en banc).

The range of equivalents afforded to a claim may not be so broad as to cover the prior art. Conair Group, Inc. v. Automatik ApMedichemate Maschinenbau GmbH, 944 F.2d 862, 866 (Fed. Cir. 1991), quoting We Care, Inc. v. Ultra-Mark Intern. Corp., 930 F.2d 1567, 1570-1571 (Fed. Cir. 1991). In addition, the doctrine of prosecution history estoppel precludes a patentee from recapturing through the doctrine of equivalents claim coverage given up during the prosecution of the patent. Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1424 (Fed. Cir. 1994), crt. denied, 513 U.S. 995 (1994); Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995). The application of prosecution history estoppel is a question of law. Id.

Prosecution history estoppel may apply to any claim amendment made to satisfy the requirements of the Patent Act, not just to amendments made to avoid the prior art, but estoppel need not absolutely bar the application of the doctrine of equivalents to the amended claim element. See Festo v. Shoketsu, 122 S. Ct. 1831 (2002). However, a patentee's decision to narrow its claims by amendment may be presumed to be a general disclaimer of the territory between the original and amended claim. Id. at 1842. To overcome the presumption, the patentee bears the burden of showing that the amendment does not surrender the particular equivalent in question. Id.

Another limitation of the doctrine of equivalents is that there can be no infringement if a claim limitation is totally missing from the accused device. London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1539 (Fed. Cir. 1991) (quoting Wahpeton Canvas Co., Inc. v. Frontier Inc., 870 F.2d 1546, 1552, n.9 (Fed. Cir. 1989)). "The doctrine of equivalents is not a license to ignore claim limitations." Dolly, Inc., 16 F.3d 394, 398 (Fed. Cir. 1994). A "court cannot convert a multilimitation claim to one with fewer limitations to support a finding of equivalency." Id. at 399.

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4. Inducement

Section 271(b) provides that, "Whoever actively induces infringement of a patent shall be liable as an infringer." To find inducement, there must first be an underlying direct act of infringement. Met-Coil Sys. Corp. v. Komers Unlimited, Inc., 803 F.2d 684 (Fed. Cir. 1986). While intent to induce infringement is not specifically mentioned in the statute, the Federal Circuit has held that intent and knowledge are critical in determining liability under 271(b). The inquiry determines whether the accused party "actively and knowingly" aided and abetted another's direct infringement. National Presto Indus., Inc. v. West Bend Co., 76 F.3d 1185, 1194-95 (Fed. Cir. 1996); Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988). In Minn. Min. & Mfg. v. Chemque, Inc., 303 F.3d 1294, 1304-05 (Fed. Cir. 2002), the Federal Circuit stated:

"In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement... and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement... In other words, the plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements" (emphasis in original).

The patent owner has the burden of proving that the alleged infringer encouraged others to follow the patented method. Plastering Dev. Ctr., Inc. v. Perma Glas-Mesh Corp., 371 F. Supp. 939, 950 (N.D. Ohio 1973). Mere sale of a staple item with knowledge of the buyer's intended use does not, however, constitute active inducement. Oak Indus. Inc. v. Zenith Elecs. Corp., 697 F.Supp. 988, 992 (N.D. Ill. 1988).

5. Contributory Infringement

Section 271(c) provides that, "Whoever sells... a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(c).

Like inducement, in order to find contributory infringement there must first be an underlying act of direct infringement. Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961). If direct infringement is present, it can then be determined whether another party's activities constitute contributory infringement. The courts would assess whether the product sold by the allegedly contributory infringing party is used to infringe a patented method, which use constitutes a material part of the invention, knowing that the product is especially made or adapted for use in infringing the patented method, and that the product is not a staple article or commodity of commerce suitable for substantial noninfringing use. See C.R. Bard v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 673 (Fed. Cir. 1990).

Even if a party is found to have the requisite knowledge that the product is or may be used to infringe a patented method, 35 U.S.C. § 271(c) specifically excludes from contributory

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infringement the selling of materials for use in practicing a patented process which materials are also "suitable for substantial noninfringing use." See Universal Elecs., Inc. v. Zenith Elecs. Corp., 846 F. Supp. 641, 651-52 (N.D. Ill. 1994) (noting that § 271(c) exempts from liability the manufacture, use, or sale of products suitable for noninfringing use); see also, C.R. Bard, 911 F.2d at 674-75 (whether the material has no use except through the practice of the patented method is the critical issue). Therefore, if a product has substantial noninfringing uses, there can be no contributory infringement.

The status of a material as a staple article or commodity of commerce suitable for substantial noninfringing use has been treated as a question of fact. See, e.g., Braintree Labs. v. Nephro-Tech, Inc., 31 F.Supp.2d 921, 924 (D. Kan. 1998). The courts have, however, provided guidelines to assessing whether a product has substantial noninfringing uses. See Reynolds Metal Co. v. Aluminum Co. of America, 457 F. Supp 482 (N.D. Ind. 1978, rev'd on other grounds, 609 F.2d 1218 (7th Cir. 1979), cert. denied, 446 U.S. 989 (1980) ("In assessing whether a product is a staple article of commerce, the quality, quantity, and efficiency of the suggested alternate uses are to be considered."); University of California v. Hansen, 54 U.S.P.Q.2d 1473 (E.D. Cal. 1999) (occasional aberrant use of a product clearly designed to be used in a particular matter does not make a device a staple article). Application of these guidelines can provide a good estimate of whether the sale of product could constitute contributory infringement. Title 35 of the United States Code, Section 271(a), states that "whoever without authority makes, uses, offers to sell or sells any patented invention within the United States . . . during the term of the patent therefore, infringes the patent."

B. Collateral Estoppel

"Collateral estoppel" precludes a plaintiff from relitigating identical issues by merely "switching adversaries" and precludes a plaintiff "from asserting a claim that the plaintiff had previously litigated and lost against another defendant." A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 702 (Fed. Cir. 1983). This doctrine may apply to a construction given a claim in a prior decision, so long as the determination of claim scope was essential to the determination of infringement. Molinaro v. Fannon/Courier Corp., 745 F.2d 651 (Fed. Cir. 1984) ("where a determination of the scope of patent claims was made in a prior case, and the determination was essential to the judgment there on the issue of infringement, there is collateral estoppel in a later case on the scope of such claims, i.e., the determined scope cannot be changed."); see also A.B. Dick, 713 F.2d at 704 ("judicial statements regarding the scope of patent claims are entitled to collateral estoppel effect in a subsequent infringement suit only to the extent that determination of scope was essential to a final judgment on the question of validity or infringement.")¹

For collateral estoppel to be applied, four elements must be met: 1) the issue at stake must have been identical to the one decided in the prior litigation; 2) the issue must have been actually litigated in the prior suit; 3) determination of the issue must have been essential to a

¹ These opinions were issued prior to Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384 (1996), which held that claim construction was an issue for decision by the court rather than a jury.

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final judgment; and 4) the party against whom the estoppel is invoked must have had a full and fair opportunity to litigate the issue in the earlier proceeding. A. B. Dick, 713 F.2d at 702.

V. RP 1824 DOES NOT INFRINGE THE '726 PATENT.

A. Abbott And Fournier Are Collaterally Estopped From Relitigating the Federal Circuit's Claim Construction of the '726 Patent Claims

Abbott and Fournier are collateral estopped from relitigating the Federal Circuit's claim construction of the '726 patent claims. See A. B. Dick, 713 F.2d at 702. Collateral Estoppel may apply to a construction given a claim in a prior decision, so long as the determination of claim scope was essential to the determination of infringement. Molinaro, 745 F.2d at 655.

The claims of the '726 patent were asserted by the Patentee, Fournier, and the exclusive licensee, Abbott Laboratories, in Abbott Laboratories v. Novopharm Ltd, 323 F.3d 1324 (Fed. Cir. 2003). This suit was filed in the United States District Court for the Northern District of Illinois, which construed the claims and found that the Defendant did not infringe the '726 patent. Fournier then appealed the District Court decision to the Federal Circuit, which affirmed the District Court's claim construction and found that the Defendant did not infringe the '726 patent. The Federal Circuit construed the terms "co-micronized" and "co-micronization of" in claim 1 and claim 10, respectively, to require the micronization of fenofibrate in the presence of a solid surfactant in the absence of other excipients.

Claim 1 of the '726 patent recites that the claimed composition contains "co-micronized mixture of particles of fenofibrate and a solid surfactant." Claims 2-9 depend from claim 1, directly or indirectly and, therefore include all of the limitations of claims 1. Similarly, Claim 10 recites that the claimed method "comprises co-micronization of the fenofibrate and a solid surfactant." Claims 11 and 12 depend from Claim 10, directly or indirectly and, therefore include all of the limitations of Claim 10. Thus, every claim of the '726 patent includes "co-micronized" or "co-micronization of" fenofibrate and a solid surfactant.

The Federal Circuit held that in order to infringe the '726 patent, a fenofibrate formulation must include a process step where fenofibrate and a surfactant are micronized together in the absence of any other excipients. Specifically, the Federal Circuit found that "'co-micronization of . . . fenofibrate and a solid surfactant' should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant." Id. at 1330.

More specifically, the Court in Abbott found that the '726 patent specification provides guidance as to the phrase "co-micronization of fenofibrate and a solid surfactant" and that the patentee had "chosen to be his own lexicographer". Id. at 1324. Further, "the inclusion of the word 'intimate' in the definition, together with the fact that fenofibrate and SLS are the only ingredients present in every co-micronized mixture described in the '726 patent's specification, makes it abundantly clear that 'co-micronization of . . . fenofibrate and a solid surfactant' should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant. Id.

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Accordingly, "[s]ince each of the claims of the '726 patent requires either 'a co-micronized mixture of particles of fenofibrate and a solid surfactant' or 'co-micronization of the fenofibrate and a solid surfactant' . . . carried out by micronization of a fenofibrate/solid surfactant mixture,' each of the claims requires co-micronization of a mixture consisting essentially of *only* fenofibrate and solid surfactant." Id. (Emphases in original).

In addition, the Federal Circuit held that Patentees relinquished coverage of compositions prepared by processes in which pre-micronized fenofibrate is combined with a pre-micronized or non-micronized solid surfactant without further co-micronization. Id. at 1331. More specifically, the Federal Circuit found that "[a]lthough Fournier distinguished its claimed composition from formulations prepared by combining pre-micronized fenofibrate with a pre-micronized or non-micronized solid surfactant without subsequent comicronization, and is accordingly estopped from asserting coverage of such formulations under the doctrine of equivalents, nothing in the '726 patent's specification, prosecution history, or reexamination record indicates that Fournier gave up coverage of compositions prepared by processes in which pre-micronized fenofibrate is later *further* micronized in the presence of a solid surfactant (that is, comicronized with the solid surfactant)." Id. (Emphases in original). Thus, co-micronizing or co-micronization cannot be construed to include mixtures obtained by adding a surfactant, micronizing fenofibrate by itself, or intimately mixing the separately micronized fenofibrate and surfactant.

In Abbott, the issue at stake was identical to the one here, *i.e.*, the meaning of "co-micronized" and "co-micronization" in the claims of the '726 patent and whether the claims encompass a composition in which the fenofibrate had been micronized apart from other ingredients. In addition, this issue was actually litigated in this prior suit. Further, a determination of the issue was essential to a final judgment, as the Federal Circuit would not have been able to reach a determination of noninfringement had it not construed the phrases "co-micronized" and "co-micronization". Finally, both Fournier and Abbott had a full and fair opportunity to litigate the issue of claim construction in the earlier proceeding, as both were parties to the suit. Thus, because of the Federal Circuit decision in Abbott Laboratories v. Novopharm, Fournier and Abbott are collaterally estopped from obtaining an alternate construction in other infringement suits in which the '726 patent is asserted.

Accordingly, Abbott and Fournier are collateral estopped from relitigating the claim construction of "co-micronized" and "co-micronization" and the finding that Patentees relinquished coverage of compositions prepared by processes in which pre-micronized fenofibrate is combined with a pre-micronized or non-micronized solid surfactant without further co-micronization. Further, the terms "co-micronized or co-micronization" in independent claims 1 and 10 do not encompass co-micronization of excipients other than fenofibrate and a solid surfactant, but instead is construed to mean micronizing fenofibrate and a solid surfactant together in the absence of other excipients.

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B. RP 1824 Does Not Literally Infringe the '726 Patent.

RP 1824, as specified and required by its NDA, does not contain a co-micronized mixture of particles of fenofibrate and a solid surfactant, and therefore does not infringe the '726 patent claims. "Literal infringement requires that the accused device contain each limitation of the claim exactly; any deviation from the claim precludes a finding of literal infringement." Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed. Cir. 1998). In order to infringe the '726 patent, an accused product must contain a co-micronized mixture of particles of fenofibrate and a solid surfactant.

RP 1824 does not literally infringe the claims of the '726 patent because RP 1824 contains fenofibrate that is micronized alone, and not in the presence of a solid surfactant; and when mixed with a surfactant other excipients are present. Further, during mixing, the surfactant is dissolved in solution and not "solid" as claimed in the '726 patent.

Specifically, Reliant's API Supplier will provide Reliant's Contract Manufacturer with the API. The API Supplier has certified to Reliant that fenofibrate is micronized alone and not in the presence of a surfactant; and that no additives are co-micronized with the fenofibrate. (See Exhibit 1). This statement is fully supported and evidenced by the certificate of analysis that accompanies each batch of API (See Exhibit 2). The certificate of analysis makes clear that fenofibrate is 98.5-100 percent pure with up to 0.5% impurities, which precludes the inclusion of a surfactant as claimed in the '726 patent. In addition, it is our understanding that the up to 0.5% total impurities in the API listed in the certificate of analysis are not surfactants but reaction by-products.

In addition, Reliant's process does not involve micronization of any mixture that includes fenofibrate and a solid surfactant, irrespective of the presence or absence of other excipients, as the surfactant used in Reliant's process is not solid, but dissolved in an aqueous solution prior to mixing with fenofibrate and remains in solution throughout the drying steps.

Thus, RP 1824 does not meet the elements "co-micronized" or "co-micronization" of independent claims 1 and 10. Accordingly, RP 1824 does not infringe the claims of the '726 patent.

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**C. RP 1824 Does Not Infringe the '726 Patent Under the Doctrine of
Equivalents.**

The claims of the '726 patent cannot be expanded beyond the claimed elements and therefore, cannot encompass RP 1824 under the doctrine of equivalents. Specifically, the Patentees are estopped from expanding the scope of the claims to cover RP 1824 for reasons relating to arguments made during prosecution of the '726 patent to avoid art rejections and because of narrowing amendments made for reason relating to patentability during the prosecution of the '726 patent, thereby creating the presumption that Patentees surrendered all subject matter between the broader and narrower claim language. Specifically, Patentees are estopped from expanding the scope of the claims to include a composition containing pre-micronized fenofibrate and a pre-micronized or non-micronized solid surfactant, without further micronization, as mentioned above. Abbott, 323 F.3d at 1331.

The process described in Reliant's NDA does not include any step in which fenofibrate and a solid surfactant are in a mixture, in the absence of other excipients, that undergoes a micronization step or any other step that could mechanically reduce particle size of RP 1824, which precludes any further micronization of fenofibrate during the formulation process, as evidenced by the API Supplier certification and the certificate of analysis that accompanies each batch of API.

Because of the arguments made during prosecution of the '726 patent and reexamination proceeding, and in view of the Federal Circuit Decision in Abbott Laboratories v. Novopharm Ltd, Patentees are estopped from asserting that any claim of the '726 patent encompasses a composition in which fenofibrate is micronized alone, and then mixed with a surfactant in the presence of other excipients, without further micronization, or a process in which fenofibrate is micronized alone, and then mixed with a surfactant in the presence of other excipients, without further micronization. Consequently, none of the claims of the '726 patent may be expanded under the doctrine of equivalents to encompass RP 1824.

Further, Reliant's process does not involve micronization of any mixture that includes fenofibrate and a solid surfactant, irrespective of the presence or absence of other excipients, as the surfactant used in Reliant's process is not solid, but dissolved in an aqueous solution prior to mixing with fenofibrate and remains in solution throughout the drying steps. Patentees cannot expand the scope of the claims to cover fenofibrate that is combined with a surfactant dissolved in solution. Significantly, Reliant's process does not involve micronization of any mixture that includes fenofibrate and a "solid" surfactant, irrespective of the presence or absence of other excipients, as the SLS is dissolved in an aqueous solution prior to mixing with fenofibrate, which is then spray-dried onto inert cores. Dissolved SLS is not a "solid surfactant". Under the "all elements rule," there can be no infringement under the doctrine of equivalents if even one element of a claim or its equivalent is not present in the accused device. To argue otherwise would vitiate the limitation in contravention of the all-elements rule. Abbott, 323 F.3d at 1331. Consequently, RP 1824 does not infringe any of the claims of the '726 patent under the doctrine of equivalents.

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**D. Reliant Will Not Induce Infringement and Will
Not Contribute to the Infringement of the '726 Patent**

In order to have inducement to infringe or contributory infringement there must be direct infringement, i.e., a claim in the '726 patent must be infringed either literally or under the doctrine of equivalents. For the reasons discussed above, the manufacture use or sale of RP 1824 in the United States does not directly infringe any of the claims of the '726 patent. Accordingly, there cannot be inducement to infringe or contributory infringement.

VI CONCLUSION

The marketing of RP 1824 in the United States will not infringe any claims of the '726 patent.

Reliant expressly reserves the right to develop and make other arguments and assert any defenses relating to non-infringement, invalidity and/or unenforceability of the claims of the '726 patent should grounds become apparent in the future.

REDACTED

REDACTED

c/o ;
Andrew Bordon
Frommer Lawrence & Haug

Re: - Non-Infringement Regarding U.S. Patent No. 4,895,726
Fenofibrate Micronization

Dear
REDACTED

REDACTED hereby certifies that it does not practice the invention claimed in U.S. Patent No. 4,895,726 (the '726 patent') in its manufacture of fenofibrate active pharmaceutical ingredient (API) for REDACTED Reliant Pharmaceuticals, LLC.

REDACTED In REDACTED fenofibrate micronizing process, no additives are co-micronized with the fenofibrate. Rather, the fenofibrate is micronized on its own. Co-micronization of fenofibrate with a solid surfactant is a chief limitation to the invention claimed in the '726 patent.

REDACTED Because REDACTED, micronizes the fenofibrate API on its own, REDACTED micronizing process fails to satisfy a necessary condition of all of the claims of the '726 patent. As a result, REDACTED does not practice the invention as claimed in the '726 patent. REDACTED

Very truly yours,

REDACTED

President

cc:

REDACTED

December 11th, 2003

REDACTED

REDACTED

FENOFIBRATE		
Batch No: 195008	ANALYSIS CERTIFICATE No.087	Man. date: February 2003
Date: February 20 2003		Retest before: February 2008
TESTS	SPECIFICATIONS	RESULTS
Characteristics	White or almost white crystalline powder. Practically insoluble in water, very soluble in methylene chloride, slightly soluble in alcohol.	Complies
Identification: A) Melting point B) IR spectrum	79° C to 82° C Confirms to Fenofibrate RS.	81.0 °C Complies
Appearance of solution.	A 5% solution in acetone R is clear and not more intensely coloured than reference solution BYe.	Complies
Acidity	According to the test	Complies
Halides	Not more than 100 ppm expressed as Cl	Complies
Sulphates	Not more than 100 ppm	Complies
Heavy metals	Not more than 20 ppm.	Complies
Loss on drying	Not more than 0.5%.	0.1%
Sulphated ash	Not more than 0.1%.	0.03%
Related substance (Ph.Eur): 4-chloro-4'-hydroxy benzophenone fenofibric acid Impurity G each unknown impurity	Not more than 0.05%. Not more than 0.05%. Not more than 0.2%. Not more than 0.1%. Not more than 0.5%.	Not detectable Not detectable Not detectable 0.02% 0.04%
Assay (HPLC)	Not less than 99.5% and not more than 101.0%, calculated with reference to U2 dried substance.	99.4%
Residual solvents isopropyl alcohol 2-bromopropane	Not more than 500 ppm Not more than 10 ppm	208 ppm Complies
Particle size	Not less than 90% < 10 microns	Complies
This material has been prepared following the current Good Manufacturing Practice (cGMP) according and conforms to the requirements of Ph.Eur. 4 th Ed. and		

REDACTED

Q.C. Manager

REDACTED

Technical Manager

REDACTED

Edition n°1

CERTIFICAT D'ANALYSE / CERTIFICATE OF ANALYSIS

Produit / Product: FÉNOFIBRATE / FENOFIBRATE

N° de lot / Batch No.: M0009042

Code ressource / Ressource code: A03234

Date de péremption / Expiry date: 02/2004

Fournisseur / Supplier: REDACTED

Lot fournisseur / Supplier reference: 135008

Date d'analyse / Date of analysis: 08/05/03

ESQUISSE / TESTS

SPÉCIFICATIONS / SPECIFICATIONS

RÉSULTATS / RESULTS

Caractères / Characters

Poudre cristalline blanche ou sensiblement blanche / White or almost white crystalline powder Conforme

Solubilités / Solubilities

Pratiquement insoluble dans l'eau, peu soluble dans l'alcool, très soluble dans le chlorure de méthylène / Practically insoluble in water, slightly soluble in alcohol, very soluble in methylene chloride Conforme

Identifications / Identifications

- A. Point de fusion / Melting point
- B. Spectre infrarouge / Infrared spectrum

79°C - 82°C 82°C
Conforme à la référence / Compliance with reference Conforme

Essais / Tests:

Aspect de la solution / Appearance of solution

Solution limpide et coloration ≤ JB6 / Clear solution and colouring ≤ JB6 Conforme

Acidité / Acidity

≤ 0,2 ml Na OH 0,1M Conforme

Substances apparentées / Related substances

- Impureté A / Impurity A
- Impureté B / Impurity B
- Impureté G / Impurity G
- Autres pics / Other pics
- Somme de tous (les pics autres que le fénofibrate / Sum of all impurities other than fenofibrate)

≤ 0,1 % < 0,1 %
 ≤ 0,1 % < 0,1 %
 ≤ 0,2 % < 0,2 %
 ≤ 0,1 % < 0,1 %
 ≤ 0,5 % < 0,5 %

Halogénures (exprimés en chlorures) / Halogenures (express in chlorides)

≤ 100 ppm < 100 ppm

Sulfates / Sulfates

≤ 100 ppm < 100 ppm

Métaux lourds / Heavy metals

≤ 20 ppm < 20 ppm

Perte à la dessiccation / Loss on drying

≤ 0,5 % < 0,5 %

Résidu à l'ignition / Residue on ignition

≤ 0,1 % < 0,1 %

Solvant résiduel / Residual solvent

- Alcool isopropylique / Isopropyl alcohol
- Bromopropane / 2-Bromopropane

≤ 500 ppm 208 ppm **
 ≤ 10 ppm < 10 ppm **

Dosage (sur produit sec) / Assay (on dried product)

98,5 % - 101,0 % 99,4 %

Granulométrie laser / Particle size laser distribution

D(0,5) ≤ 15,0 µm 11,8 µm **
 D(0,5) entre 2,0 et 7,0 µm / D(0,5) between 2,0 and 7,0 µm 5,6 µm **

** Résultats site de CET

** Résultats fournisseur

Résultats SGS

Réf. / Ref.: Pharmacopée Européenne 4^{ème} Edition

Conformité du lot / Batch compliance

CONFORME

Contrôle Qualité R&D

REDACTED

Acceptation du lot / Batch approval

ACCEPTÉ / RELEASED



NON ACCEPTÉ / REJECTED

Assurance Qualité

Version 8 - 08/10/03

Pierre DIEBOLT

20/02/04 15:23

Pour : Charles_Ossola@aporter.com, Donald_Beers@aporter.com,
Timothy_Bickham@aporter.com

cc : Steven.Crowley@abbott.com, royce.bedward@abbott.com

Objet : very urgent - new paragraph IV - Reliant

Taille : 2,0 Ko

We received today a Pargaraph IV certification from Reliant. I will telecopy you the paragraph IV straight away.

Reliant has filed a 505b2 application for a 43mg, 87mg and 130 mg capsule of feno.

Reliant's states that its application for approval relies upon investigations conducted with respect to the 200mg Tricor capsules.

Thus, Reliant based its non infringement analysis only on our '725 patent and not on our Ter patents.

Please let me have your comments as soon as possible on this new paragraph IV, and on the fact that Reliant should have discussed our Ter patents.

thanks

Pierre