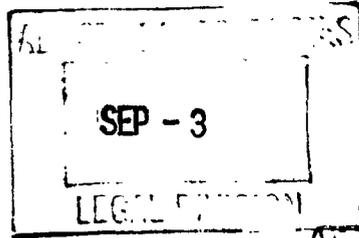


cipher
Pharmaceuticals Limited

To: SFW
RUB



August 18, 2003

General Counsel
Abbott Laboratories Inc.
Pharmaceutical Products Division
100 Abbott Park Road
Abbott Park
IL 60064-6400, USA

Re: Fenofibrate Capsules 50 mg, 100 mg, 150 mg, and 160 mg;
Notice of Paragraph IV Patent Certification Pursuant to
21 U.S.C. § 355(b)(3)(B) and 21 C.F.R. § 314.52.

Dear Sir or Madame:

This notice is provided pursuant to 21 U.S.C. § 355(b)(3)(B) and 21 C.F.R. § 314.52. Cipher Pharmaceuticals Ltd. ("Cipher") has submitted a New Drug Application pursuant to 21 U.S.C. § 355(b)(2) (a "505(b)(2) NDA"), NDA No. 21-612, and a statement has been filed with the Food and Drug Administration ("FDA"), for CIP-FENOFIBRATE (fenofibrate capsules 50 mg, 100 mg, 150 mg, and 160 mg). We have submitted a supplement to the NDA that includes a "paragraph IV certification" alleging that U.S. Patent No. 6,589,552 (expiration date January 09, 2018) (the '552 patent), will not be infringed by the manufacture, use, or sale of Cipher's fenofibrate capsules that are the subject of the NDA. This notification sets forth a detailed statement of the factual and legal bases for Cipher's opinion that no valid claims of these patents will be infringed.

I. The Facts

A. The Cipher Product and Process

The Cipher Product is a gelatine capsule containing fenofibrate. This product is prepared by the Cipher Process, namely, melting and blending at 80 degrees centigrade polyglyceride (Gelucire 44/14) and PEG 8,000 and 20,000, then adding fenofibrate to the hot mixture and mixing until the fenofibrate is dissolved. The Cipher Process also involves adding hydroxypropylcellulose and sodium starch glycollate and maintaining the mixture at 75 degrees centigrade. This molten mixture is filled in a liquid state into hard gelatine capsules, and when cooled sets as a "paste" in the capsule. Further details are set forth in U.S. Patent No. 5,545,628 to Deboeck et al.

B. '552 Patent

1. The Claims

The '552 patent contains 50 claims; the following three are the independent claims in the '552 patent:

1. A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate having a particle size below 20 μm , inert hydrosoluble carrier particles and at least 20% by weight of at least one hydrophilic polymer is from 1/10 to 4/1.

31. A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate having a particles size below 20 μm , inert hydrosoluble carrier particles, at least 20% by weight polyvinylpyrrolidone, and a surfactant in an amount of up to 10% by weight, and wherein the ratio of fenofibrate to polyvinylpyrrolidone is from 1/10 to 4/1.

57. A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate having a particle size below 20 µm, inert hydrosoluble carrier particles, at least 20% by weight of at least one hydrophilic polymer, and at least one surfactant; wherein the weight ratio of surfactant to hydrophilic polymer is from 1/500 to 1/10.

2. Analysis

The above claims require the fenofibrate product to have *granulates* comprising fenofibrate that has been *micronized* (less than 20 µm) and a hydrosoluble carrier in particulate form (specification at column 4, lines 14-24). The Cipher Product is not a granulate; it does not contain micronized fenofibrate alone or in combination with another ingredient; and, it does not contain a hydrosoluble carrier in particulate form. Because the Cipher Process involves dissolving fenofibrate into molten excipients, no particles of fenofibrate are present in the Cipher Product.

Claims 2 to 30 and 56 depend directly or indirectly from, and contain all the limitations of claim 1, and therefore include the requirement for a granulate comprising micronized fenofibrate and a hydrosoluble carrier in particulate form. Claims 32-55 depend directly or indirectly from claim 31, and likewise require a granulate comprising micronized fenofibrate and a hydrosoluble carrier in particulate form.

Because the Cipher Product does not contain these ingredients, it does not infringe any of the claims of the '552 patent.

II. The Legal Basis for Non-Infringement

Under U.S. law, a court would first interpret the scope and meaning of patent claims and then compare the properly construed claims to the allegedly infringing

product. The absence of even one claim element avoids literal infringement. Therefore, to establish literal infringement, every limitation set forth in a claim must be found in the accused product.

In the '552 patent, the claims must be interpreted as containing fenofibrate in a specific form, *i.e.* in *micronized form*. The independent claims recite this limitation and the dependent claims incorporate such limitation by virtue of dependency. Because the Cipher Process does contain a granulate and does not involve micronization of any of the fenofibrate alone or in combination with another ingredient, and the Cipher Product does not in fact contain micronized ingredients, this element is absent and the Cipher Product and Cipher Process, which therefore avoid literal infringement

Even where no literal infringement exists, a product may nevertheless infringe a patent under the doctrine of equivalents, which permits a court to extend the effective scope of patent protection beyond a claim's literal wording. However, even under the doctrine of equivalents, each element or equivalent of such element in a claim must be present. It is clear from the above analysis that the Cipher Product fails to contain many of the elements in the claims.

Therefore, the Cipher Product and Cipher Process avoid literal infringement and infringement under the doctrine of equivalents of all of the claims in the '552 patent.

I also enclose Cipher Pharmaceuticals U. S. Agent address and telephone and facsimile numbers.

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Yours sincerely,



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