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March 19, 2004

**VIA FACSIMILE and FIRST CLASS MAIL**Eugene M. Gelernter, Esq.  
Patterson, Belknap, Webb & Tyler LLP  
1133 Avenue of the Americas  
New York, New York 10036-6710**Re: Reliant Pharmaceuticals Paragraph IV Certification to Abbott  
Laboratories and Laboratories Fournier, S.A.**

Dear Mr. Gelernter:

This is in response to your letter dated March 16, 2004.

We note that you continue to refuse Reliant's offer to produce additional information potentially relevant to an analysis of infringement under the '726 patent, despite our willingness to compromise on the issue of the extent of permissible disclosure, and allow in-house legal personnel from Abbott to review the information.

Contrary to the "concerns" expressed in your letter, Reliant has followed, and will continue to follow, all applicable FDA laws, regulations and guidances in connection with its 505(b)(2) application for RP1824. In fact, it is Abbott itself that is seeking to broaden its inquiry far beyond that contemplated under relevant law.

FDA's draft Guidance for Industry titled *Applications Covered by Section 505(b)(2)* provides, in relevant part,

Unlike a full NDA for which the sponsor has conducted or obtained a right of reference to all the data essential to approval, the filing or approval of a 505(b)(2) application may be delayed due to patent or exclusivity protections covering an approved product. Section 505(b)(2) applications must include patent certifications described at 21 CFR 314.50(i) and must provide notice of certain patent certifications to the NDA holder and patent owner under 21 CFR 314.52.

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21 C.F.R. § 314.50(i)(1), in turn, provides that a 505(b)(2) application is required to contain a patent certification with respect to each patent that, "in the opinion of the applicant and to the best of its knowledge, claims a drug (the drug product or drug substance that is a component of the drug product) on which investigations that are relied upon by the applicant . . . were conducted . . . ."

Under these applicable regulatory and guidance provisions, Reliant was only obligated to address patents listed with respect to the *drug product* with respect to which Reliant has relied upon reports of investigations of safety and efficacy, or the *drug substance* fenofibrate itself.

Similarly, FDA's 505(b)(2) Guidance makes clear that patent certifications are only required to be filed with respect to the "listed drug or drugs" on which the applicant seeks to rely for previous findings of safety or efficacy.

If the 505(b)(2) seeks to rely on the Agency's previous finding of safety or efficacy for a listed drug or drugs, identification of any and all listed drugs by established name, proprietary name (if any), dosage form, strength, route of administration, name of the listed drug's sponsor, and the application number (21 CFR 314.54(a)(1)(iii)). . . . If there is a listed drug that is the pharmaceutical equivalent to the drug proposed in the 505(b)(2) application, that drug should be identified as the listed drug.

There are no listed patents that claim the *drug substance* fenofibrate. Fenofibrate itself has been in the public domain for many years.

There is no listed drug that is the pharmaceutical equivalent of RP 1824.

Reliant's NDA only makes reference to clinical data contained in NDA 19-304, for the *drug product* fenofibrate (micronized) capsules. We note that NDA 21-203, which is referenced in your letter, is for a *tablet* dosage form. We reiterate that Reliant's proposed RP 1824, like the product described in NDA 19-304, is itself a capsule dosage form containing 130 mg, 87 mg or 43 mg of micronized fenofibrate.

Based on the foregoing, Reliant continues to believe that it was only required to file a certification of non-infringement with respect to the '726 patent. Hence, our belief, which we continue to hold, that the '726 patent is the only patent that needs to be addressed *within the 45-day period*.

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*Marion Merrill Dow, Inc. v. Hoechst-Roussel Pharm.*, a 1994 opinion marked by the court as "not for publication," does nothing to alter this fact. Nor, incidentally, does the *Marion Merrill Dow* case reflect current law, FDA regulation or guidance with respect to this matter.

We reiterate that Reliant does not practice the claims of the '726 patent, and remains willing to produce the relevant portions of its 505(b)(2) application and unredacted information with respect to its supplier of fenofibrate API to demonstrate that fact. We cannot accede to Abbott's other demands, which are wholly without statutory or regulatory justification.

Very truly yours,



Andrew M. Berdon

AMB/elf

cc: Michael J. Lerner, Esq. (via facsimile)