

WILMER, CUTLER & PICKERING

2445 M STREET, N.W.
WASHINGTON, D.C. 20037-1420

TELEPHONE (202) 663-6000
FACSIMILE (202) 663-6363

May 8, 1997

GARY D. WILSON
DIRECT LINE (202) 663-6279
INTERNET GWILSON@WILMER.COM

100 LIGHT STREET
BALTIMORE, MD 21202
TELEPHONE (410) 685-2800
FACSIMILE (410) 685-2828

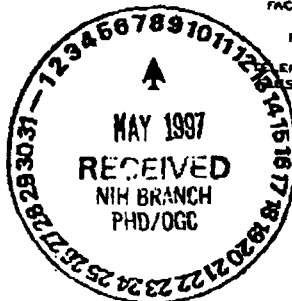
4 CARLTON GARDENS
LONDON SW1Y 5AA
TELEPHONE 011 441711874000
FACSIMILE 011 441711836-3637

RUE DE LA LOI 15 WETSTRAAT
B-1040 BRUSSELS
TELEPHONE 011 3221 288-4800
FACSIMILE 011 3221 288-4849

FRIEDRICHSTRASSE 95
D-10117 BERLIN
TELEPHONE 011 49301 3022-8400
FACSIMILE 011 49301 2022-6600

By Hand

Robert B. Lanman, Esquire
NIH Legal Advisor
National Institutes of Health
31 Center Drive
Building 31, Room 2B50, MSC 2111
Bethesda, Maryland 20892-2111



Dear Mr. Lanman:

As we discussed, I am enclosing copies of the reply papers filed by Baxter and the other plaintiffs in support of their motion for a permanent injunction in the ongoing patent litigation. Also enclosed is a copy of the hearing transcript of April 30, 1997, on the subject of that motion.

A few comments are in order.

First, Baxter's reply papers provide more information about its recent filing at the FDA. As is clear from the declaration of the Assistant Director of Clinical Research in Baxter's Immunotherapy Division, the February 24, 1997, filing was based on clinical trials using its Isolex 300SA System: "Baxter expects to amend or supplement the PMA to cover the 300i, or else to file a separate PMA for the 300i later this year." Declaration of Bonnie J. Mills, ¶ 4. The same declaration explains Baxter's belief "that the PMA is on track for approval by the end of 1997." *Id.*, ¶ 7. However, given that the only application on file is for the obsolete Isolex 300SA product, it seems likely that the FDA approval process will not be completed for at least two or three years, even if future clinical trials succeed in showing that the new Isolex 300i product is safe and effective.

Second, Baxter submitted with its reply brief a new form of proposed injunction which would modify its proposed stay of the injunctive relief it is seeking. As amended, the proposed stay would allow for continuation of clinical trials that have already been approved by the FDA and the relevant institutions. It would, however, prohibit any such trials that have not yet been so approved.

This modification and the other provisions of Baxter's proposed stay that would allow continued sales of CellPro's CEPRATE System in effect acknowledge that there are significant health needs that can only be met by CellPro's FDA approved product. Because of those health needs and for the other reasons we have previously addressed, the conditions set forth in the Bayh-Dole Act have plainly been satisfied. Accordingly, under the Act, the Department should

- 2 -

issue CellPro a license on reasonable terms and conditions. With that license, CellPro will be in a position to maximize the use and benefits of technology originally developed at taxpayers' expense. Baxter, however, continues to seek an injunction to bar further distribution of the CellPro CEPRATE System, subject only to its limited "health needs" stay and on grossly unreasonable terms and conditions. The whole purpose of Baxter's proposed terms and conditions is to minimize use of CellPro's technology — regardless of the adverse impact on cancer victims and others.

The differences between the Bayh-Dole license CellPro seeks and the "health needs" stay Baxter has proposed are dramatic and include the following:

- With a Bayh-Dole license, CellPro could and would deliver its CEPRATE System to additional transplant centers in the United States and supply disposable antibody kits to use with that System for use by patients regardless of their location. As of March 12, 1997, the CEPRATE System was in use at only some 40 of the more than 300 transplant centers in the United States, and CellPro anticipates that it will be able to place its product in a large number of additional centers unless it is enjoined from doing so.

Under Baxter's proposed stay, CellPro could only sell antibody kits to transplant centers which had already acquired the CEPRATE System before March 12, 1997. Cancer victims not located near such facilities would have to forego the potentially lifesaving benefits of the new process or (if able) travel to a distant center. Baxter's expert economist recognizes that placement of additional CEPRATE devices would "increase demand" for the product (i.e., more patients would benefit from its use) but urges against allowing additional placements to avoid providing CellPro any "economic benefit." Declaration of Dr. Jerry A. Hausman, ¶ 13.

- With a Bayh-Dole license, CellPro would pay reasonable royalties to Johns Hopkins, which in turn would use those funds to further its medical research programs.

Under Baxter's proposed stay, CellPro would be required to pay Baxter punitive and unreasonable royalties of at least \$2,000 per antibody kit, or a royalty of between 45 and 50 percent of the current \$4,000 to \$4,300 price per kit. We are unsure what portion of that royalty would flow through to Johns Hopkins since we have not been given information concerning the license agreement between Johns Hopkins and Becton-Dickinson. However, at the 5.5% royalty rate in its license agreement, Baxter would owe Becton-Dickinson less than \$250 (and would thus retain more than \$1,750) for each kit sold. Baxter's proposed royalty is thus more than eight times the royalty it pays — and indeed approximately five times the 8% to 10% Baxter's expert testified at the recent trial was, in his opinion, a "reasonable royalty" under the patent laws. It may be that CellPro could justify selling some antibody kits pending appeal even under the terms of Baxter's proposed stay, but the proposed royalty upon which a stay of the injunction would be conditioned can only be designed to provide the strongest possible incentive to CellPro to

- 3 -

minimize the promotion and sale of its CEPRATE System, notwithstanding the clear public interest in making it widely available to all those who would benefit from it.

- With a Bayh-Dole license, CellPro and the investigators using the CEPRATE System would have every incentive to seek out new potential uses for the device and to continue to develop second and later generation products. The benefits in terms of advancing the treatment and possible cure of a multitude of diseases are clear.

Under Baxter's proposed stay, all research would come to a halt except that involved in clinical trials that have already been approved. Baxter's theory is that any investigator interested in doing stem cell research could simply switch from CellPro's CEPRATE System to Baxter's Isolex 300i system. But even if Baxter's system were suitable for all future trials and could simply be substituted without cost or delay -- which it clearly could not be -- there is no reason whatever to believe that Baxter (or whoever purchases Baxter's Immunotherapy Division) will provide all interested investigators with the same level of support they would get from CellPro. Indeed, the contrary would almost certainly be the case for the reasons summarized in CellPro's preliminary injunction opposition (Exhibit 2 to CellPro's April 21, 1997, submission at 13-16) and addressed further in the enclosed Declaration of David F. Weeda which was filed therewith. Moreover, Baxter does not have second generation tumor cell depletion and T-cell depletion products. Those products are only available from CellPro. Baxter's proposed injunction is designed to stop -- and would stop -- future clinical trials of these promising new developments, the effect of which would surely be to set back progress in the treatment of leukemia and other diseases.

- With a Bayh-Dole license, CellPro would be in a position to continue manufacturing products in the United States -- one of the objectives of the Bayh-Dole Act. See 35 U.S.C. § 204. In this way, United States industry would satisfy the health needs of cancer victims not only in this country but also in Canada, Europe, and throughout the world.

Under Baxter's proposed stay, the court has been asked to effect an unprecedented extension of the United States patent laws to countries where Johns Hopkins did not even seek a patent. It is apparent, however, that the patent laws do not have extraterritorial reach, and Baxter has been forced to rely on "trade secret" case authority to seek an injunction against sales abroad. CellPro believes the court should recognize considerations of international comity and existing precedent and deny the relief Baxter seeks with regard to foreign sales. In that event, the result of the injunction Baxter seeks would simply be that the investment and jobs needed to satisfy health needs in other countries would be moved abroad.

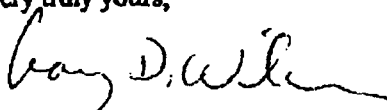
With regard to the schedule of proceedings on the injunction, we have been advised that Baxter has not yet filed its proposed motion for summary judgment against CellPro's claim that

- 4 -

Baxter engaged in patent misuse when it attempted to condition a license to the Johns Hopkins patents on exclusive distribution rights to CellPro products in Europe and Japan and subsequently refused to grant a license on reasonable terms. Given that CellPro has not yet received Baxter's filing, it is difficult to anticipate the schedule of court proceedings. CellPro's position is that it is entitled to a jury trial on its misuse claim and that no injunction could properly issue if, as it believes it will, CellPro prevails in such a trial. When the court will rule on Baxter's forthcoming motion and what the result will be is, however, impossible to say.

I hope that this letter and accompanying materials are of assistance. Please let us know if you have any further questions.

Very truly yours,



Gary D. Wilson

Enclosures