

THE NEW YORK BLOOD CENTER



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January 21, 1990

Dr. C.V. Prowse
Scottish National Transfusion Service
S.E. Regional Centre and
Department of Transfusion Medicine
Royal Infirmary
Edinburgh EH3 9HB
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Dear Dr. Prowse:

Bernard Horowitz sent your letter of January 5 regarding the licensing of the solvent/detergent (S/D) technology to me for response. We are pleased that the Scottish Blood Transfusion Service is interested the use of the technology for its products and I have attempted to answer the questions posed in your letter below.

1. Disclosure of the technology is accomplished through a two-day workshop at the New York Blood Center (NYBC) and a handbook. The workshop is designed to transmit all information necessary for adoption of the TNBP method, including discussions of blood-borne viruses, virus inactivation data, implementation in a production environment, quality control, toxicology, and regulatory approval. The comprehensive workshop handbook, which provides the information in written form, is sent to you in advance of the workshop. The workbook is sent immediately upon execution of the License Agreement and payment of the Disclosure and Evaluation fee and a workshop is usually held semi-annually. We expect to hold the next workshop in March 1990.
2. In order to be assured that the technology is used in compliance with NYBC standards and procedures, we review each licensee's use of the technology prior to their commercialization of an S/D-treated product. Our preferred method of accomplishing this review is to have Dr. Horowitz or Dr. Cundell visit the licensee's production facility to observe the implementation of the technology. NYBC bears all costs related to this review.
3. NYBC is committed to sharing with its licensees any improvements or additions to the technology. This is done by additions to the handbook and by the Virex Newsletter. The Virex Newsletter is a confidential publication of NYBC which is meant to keep the licensees informed of updates to the

technology and to serve as a forum in which new applications of the technology as well as clinical results can be shared.

4. The fees associated with licensing the technology include a Disclosure and Evaluation fee, a License fee, and running royalties on net sales. The Disclosure and Evaluation Fee covers disclosure of the technology in the form of the workshop and handbook. This fee is paid when the agreement is executed.

From the date of execution of the agreement the licensee has two years to evaluate the technology. During this time members of NYBC's scientific staff are available to answer inquiries to facilitate the application of the technology to the licensee's products. Once an organization decides to use the process beyond evaluation, payment of the license fee is required. This license fee is recoverable by the licensee against the first year's royalties.

To enable all qualified fractionation centers access to the technology, the fees are set on a sliding scale. A not-for-profit organization with the capacity to fractionate 100,000 or more liters of plasma per year is required to pay a \$10,000 disclosure and evaluation fee and a \$15,000 license fee. The running royalty is 4% of net sales. As mentioned above, the licensee may recoup the license fee by keeping first year's royalties until they equal the amount paid for the licensee's fee.

5. Unfortunately, agreements signed in the past prevent us from offering more favorable terms to new licensees than those already set. However, Dr. Horowitz asked me to relay his interest in hearing from you regarding the possibilities of a collaboration between the Scottish Transfusion Service and NYBC.

I have enclosed a copy of the License Agreement for your review. Should you decide to license the technology, please return two signed copies of the agreement along with the disclosure and evaluation fee to my attention. I will have the copies executed at NYBC and return a copy to you along with the workshop handbook. Should you have any questions, please do not hesitate to contact me. Our telefax number is 212 570 3195.

Sincerely,

Christine Watklevicz

Christine Watklevicz
Licensee Affairs

P.S. Bernie asked that I send his best regards!!