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1st August, 1983

Professor A. J. Johnson
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Dear Alan,

I must tell you that I was much excited by the prospect that Peter brought back from Stockholm. The association between this Centre and yourself has been one of the most fruitful that we have enjoyed. It is no accident that, built into the product lot numbering system for our factor VIII standard product, we add the Prefix NY as recognition of the fact that the product was devised by you or at least only marginally changed from your original concept. The Supernine concentrate, now through clinical trial, is also your product to a large degree.

For me, your relationship with Speywood was a great disappointment because it caused some relaxation in the mutual sharing situation we had enjoyed since, after all, Speywood was a commercial threat to the state fractionators in the U.K. You may notice that I use the past tense; I think Speywood is all washed up as originally conceived. Whether or not the new direction of the company will work remains to be seen.

My decision that it is time for me to leave the PFC is multifactorial but, for the moment, suffice to say that it is the right time for me to change the direction of my career. However, it does have an effect on my ability to take the Centre into new collaborative situations unless they can be progressed effectively before the end of March 1984 or they can be shown to be in the long-term interest of the SNBTS.

Your own situation is also altered but one accepts that the concept, of Universities and industry (financial interests) entering into arrangements to exploit the commercial possibilities of a group of workers within the University, is well understood and becoming commonplace. This may affect the way we handle information arising out of collaboration but would not markedly affect the way we work together.

At this stage I am at something of a disadvantage because I know little of your development beyond your claim of simplicity of performance, high yield and very high purity. Such a process for recovery of factor VIII is bound to interest an organisation such as the PFC. I believe that the correct course of/

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of action to follow would be in at least two stages.

First we should meet and exchange letters of confidence in which we should agree that a limited number of people, myself and Peter Foster perhaps, be allowed in confidence to see a description of the procedure you have devised and data in support of your claims. Such a disclosure would be without undertaking by either party. This would allow Peter and I to assess the interest which PFC should take in your project and the degree of difficulty we might have to cope with in the incorporation of such technology into a comprehensive fractionation programme.

From past experience I feel certain that this stage would be formal rather than a source of real difficulty but I feel sure that you will appreciate the peculiar position of the PFC at present. We have spent considerable time and effort in development of a new factor VIII process which may not be as good as yours appears to be but is still a considerable advance on the general state of the art in terms of yield, purity and safety. Naturally we would hope that some, at least, of this effort would be applicable to your process also.

If, as is likely, we find your process of interest I propose that we continue the process of maintaining confidentiality in that we agree the terms of a collaboration in which we can examine your process at scale, making all data available to yourself and your principals, in return for a royalty-free licence to use the process. One area for discussion may be that, in making a reduction to practice, my colleagues and I may discover new information which is of a patentable nature and in which our employing authority may wish to retain interest. There are two ways of handling such a situation. In the first we would give a royalty-free licence to yourself and your principals to use the technology and any sale of the total process to a third party would be the subject of two royalty agreements, with your principals and our employing authority. In such an arrangement it would be likely that the employing authority would give the right of negotiation to your principals to allow unhindered sale of a complete process and it would be for your principals to negotiate and collect royalty of both organisations. The second means of tackling such eventuality would be for outright purchase by your principals of the knowledge and experience resulting from reduction to practice.

I mention this matter specifically because, as you are aware, a means of active reduction of the risk of disease transmission has become an essential feature of modern coagulation factor concentrates. At PFC we have spent already a considerable effort in material and manpower (I estimate about \$60,000 at this time) in discovering means of rendering factor VIII stable and in establishing virucidal conditions for such products without material loss of biological activity. In this we are not unique but we believe that our loss level is much lower than that of other manufacturers despite the fact that our virucidal stage is applied to the liquid preparation rather than to the dried final product and for that reason is more likely to be effective.

We would require to discuss priority in publication but I would imagine that your principals would agree that publication is possible provided that you and they have prior sight of the proposed publication, say thirty days before it is sent to a publisher or presented at a scientific meeting.

I enclose a copy of an agreement entered into recently with University Patents Inc. This is the granting of royalty free licence where the patentable process is held by the University of Arizona and where we have not added materially to the procedure so all patentable rights are with UPI. If new knowledge comes to light/

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light subsequently we would have UPI handle the patent but there would have to be some form of later agreement.

I've written at length trying to cover the salient points and giving an opinion of their solution. You may wish to discuss these further or to introduce further matters for discussion. I hope that, as proposed, you can visit Edinburgh shortly so that we can arrange to move quickly.

With kind regards.

Yours sincerely,



JOHN G. WATT
Scientific Director