MEMORANDUM

TO: Dr. R. Perry
    Dr. A. Macleod
    Dr. J. D. Cash

FROM: Dr. P. Foster

DATE: 19th June, 1984

SUBJECT: Pasteurisation of Coagulation Factors Patent Protection

Sorbitol was first used as a stabilising agent at PFC in October 1982 by Alex Macleod after reading papers by Gekko et al (J. Biochem 90, 39-50, 51-60, 1981) sent to myself by D. Pepper.

We had not at that time seen the Behringwerke patent (US patent 4297344, 1981) but we had a good idea of their process from a paper by Heimburger et al (Drug research 31, 619-622, 1981) translated for Alex by W. Zolg.

All of the Behringwerke data (papers and patent) concerns saccharose as the only sugar used, but in the patent the claims cover:-

"...from 20-60 w/w percent of a carbohydrate selected from a group consisting of monosaccharides oligosaccharides and sugar alcohols".

"...then heating the resulting heat-stabilised aqueous solution at a temperature from 30°C to 100°C for a period of time from 1 minute to 48 hours...".

Points where the PFC process may lie out with this patent are:

1) The specific use of sorbitol.

2) The sorbitol concentration used by us is 65%. (This is possible because sorbitol has a higher solubility than saccharose. This possibility is alluded to in the introduction to the patent but is not included in their "claims").

3) The use of calcium to improve stabilisation.

4) The patent does not cover FIX.

We approached NRDC/BTG in November 1982 to explore the possibility of filing our own patent. Although NRDC did think this was possible they felt it would not be easily enforceable and they did not wish to pursue it on our behalf.

I discussed this situation with Alan Johnson last week and he is seriously concerned that we are allowing Behringwerke the opportunity to close a potential loophole in their patent. We have published our work in abstract form (Thromb. Haemost. 50, 432, 1983) and have drawn attention to this in a letter to the Lancet concerning pasteurisation of IgG.
Alan Johnson believes that Behringwerke could apply for an extension to their patent and that this will not be prevented by our publications in abstract or letter form (from his own experience). This may not be the case in the UK (I was unable to fully patent our thawing process because of an earlier Lancet letter from myself) but it could well be the situation elsewhere (especially in the USA).

Alan argues forcefully that the SNBTS has a moral and ethical responsibility to patent this work to ensure that the technique is freely available to the rest of the world. He also believes that if the BTG will not patent this (because it will not make money for them) then the SNBTS should hire its own patent lawyer to do the job.

He may well have a case that you would want to consider. However, we are bound by UK rules and I believe that our abstract will be held to be a valid publication. If we do wish to file a patent this must therefore be done within 12 months of the publication of this abstract (ie before 3rd July 1984).