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COMMERCIAL-IN-CONFIDENCE

Elaine Webb
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Department of Health
Room 516
Eileen House
80-94 Newington Causeway
Elephant & Castle
London SE1 6EF

Your ref

Our ref

Date 27 February 1991

Dear Miss Webb

BIO PRODUCTS LABORATORY - SUPPLY OF BLOOD PLASMA DERIVATIVES

The Office has received a complaint about the activities of Bio Products Laboratory (BPL) of Elstree, Herts, a company who are subject to Crown Immunity and who supply blood plasma derivatives and, in particular, Factor VIII to the National Health Service. The complainant has also approached the Medicines Control Agency (contact: Dr J Purves). The basis of the complaint, which is explained in more detail below, is that BPL's Crown Immunity gives them specific advantages which are not open to commercial competitors.

It would be helpful to us in consideration of the complaint to have your views and any background information you can provide. Under the Fair Trading Act 1973 the Director General of Fair Trading has a duty to review commercial activities in the United Kingdom with a view to becoming aware of monopoly situations or uncompetitive practices. The Competition Act 1980 gives the Director General the power to investigate practices that may restrict, distort or prevent competition in the supply or acquisition of goods or services in the UK.

If I might first detail the specifics of the complaint, the points put to us are as follows:-

- (1) BPL is able to sell Factor VIII to district health authorities at lower prices than those at which competitors can supply. It is alleged that this price advantage is attributable solely to BPL's costs which may be 'subsidised' somewhat by being a state-owned organisation, rather than from any greater processing efficiency. Your confirmation of BPL's legal status would be appreciated.

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The complainant lists three possible explanations for BPL's low prices:-

- (a) The price at which BPL buys in blood from the National Blood Transfusion Service (NBTS) or the Regional Health Authorities is low; where the blood is sourced is not certain to the complainant.
 - (b) The alleged effective 'writing-off' of BPL's capital expenditure in relation to a new laboratory has helped reduce BPL's costs.
 - (c) BPL's selling price is fixed at or below cost.
- (2) BPL is allegedly able to produce and market a number of products without, apparently, needing to obtain product licences, manufacturing licences or wholesale dealer's licences required under Part II of the Medicines Act 1968. This position is said to be due to Crown Immunity.
- (3) BPL has allegedly been able to make available promotional literature which, it is claimed, contravene various regulations governing the advertising of medicinal products. It is claimed that this privilege would not be open to competitors. The relevant promotional activities have been notified by the complainant to the Medicines Control Agency.
- (4) It is further alleged that BPL has exported human plasma collected in the UK by the NBTS to the Kabi Company in Sweden, where Factor VIII is extracted and BPL propose to

import it back into the UK. The complainant says that both the product and the process are unlicensed and the manufacturing is carried out in a plant which is neither registered with your Department nor inspected by you.

The complainant tells us that section 60 of the National Health Service and Community Care Act 1990 will remove Crown Immunity from health service bodies with effect from 1 April 1991. However, the transitional provisions set out in Part III of schedule 8 to the Act will, they say, permit BPL to continue its present activities; under the schedule, BPL and other health authorities will for all purposes be regarded as holding any necessary licences provided that applications for such licences are submitted in respect of current activities by 1 April 1991, according to the complainant.

In order to consider this complaint we firstly need to understand the facts and it would be extremely useful to have your views and comments on the validity of the complainant's points. Additionally, any information you can provide by way of background would also be appreciated, particularly the significance and extent of BPL's Crown Immunity and how that will be affected after 1 April 1991.

I hope that this will not be too onerous a task and look forward to your reply.

Yours sincerely

GRO-C

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COMPETITION POLICY DIVISION 2A