17/4/92 Clive 10/2 FCA
As requested.

Assistant Director/Patents 3

MINISTRY OF DEFENCE
Empress State Building London SW6 1TR

GRO-C: Ken G

Telephone 01-385 1244 ext
FAX ext GRO-C

Office of the Solicitor
Department of Health
New Court
Carey Street
LONDON WC2A 2LS
For the attention of: Mr J D Macdonald

Your reference IPR(P)

Our reference D/IPR 3G/C/3

Date 3 February 1992

Dear Mr Macdonald,

PROPOSED CROWN USE IN RESPECT OF CHIRON PATENT FOR HEPATITIS C TEST KITS

1. Your letter of 24 January to Mr Lockwood has been passed to me for action as Patents 3 are currently responsible for advice relating to Crown use by non-MOD departments.

2. As I understand the problem, Chiron have recently been granted a patent and are selling the test kits at a price above that which DoH regard as reasonable. As negotiations on price have failed, you are contemplating using the Crown Use provisions of the Patents Act 1977 to achieve competition. There are apparently proceedings in hand against one supplier, but you have no firm details of this.

3. I would suggest that the first course of action would be for us to advise you as to the validity of the patent and the scope of coverage. For this we would require a copy of the patent and also of any published material, dated before the application date of the patent, which describes anything similar. We would also require a contact with some technical knowledge in the area with whom we could discuss the matter. It is quite likely that we would recommend a further literature search.

4. If our analysis were to show that the patent is valid and not easily avoided, you would need to decide whether to issue an authorisation under the Patents Act. If you were to do this, any company supplying for "the services of the Crown" would be protected from action under the patent, but your department would become liable to pay compensation for the use of the patent and for any loss (eg of profit) resulting from the patentee not being awarded contracts for supply of the kits (the latter having been introduced by the Copyright, Patents and Designs Act 1988).

5. Supply to Health Authorities was found in the lithotryptor case (Dory vs. Sheffield Health Authority & Lothian Health Board; 1991 FSR 221) to be for "the services of the Crown". However, I am not aware of any decisions regarding self-governing trusts, and we would need to look at their statutory basis before forming a view whether they appear to be covered.

You indicated that the price appears to be some 18-20% above what your department considers reasonable. I have to advise that the compensation for use in this technical area could range from 7.5% up to 15% or even higher depending on the extent of clinical testing and approval required. For a test kit a figure around 10% would probably be reasonable if it shows high novelty. You would also be liable for lost profits. By virtue of Section 57A of the 1977 Act (introduced by the Copyright, Designs and Patents Act 1988 following the "genetic fingerprinting" case) this is in addition to the fair and reasonable royalty. Furthermore, I understand you are aware of the political sensitivity of invoking the Crown use provisions in cases where the price differential is large rather than clearly excessive.

7. All in all, I would counsel caution in invoking the Crown use provisions if the patent appears to be valid and unavoidable. However, firm advice would depend on a more detailed analysis of the circumstances. Of course, if an action is pending, you may be under some obligation, legal or moral, to the defendant to grant an authorisation, if indeed, such was not already in the relevant contracts.

8. I understand that the patentee is importing the kits into the UK. If the patents was granted 3 or more years ago, we also have the option of an action for compulsory licence on the grounds that demand in the UK "is being met to a substantial extent by importation" (1977 Act, Section 48(3)(b)(ii)) However this could also have political implications.

9. I confirm that we will advise on this matter on a repayment basis at our current rate of £60 per hour or £300 per whole day. (There will be no charge for this initial letter or for brief telephone advice) Should literature searching be required we would normally expect this to be contracted out and charged at cost unless you prefer to use your in-house facilities. The first step is for you to provide the details listed in para 3 for us to make a preliminary assessment of validity. If you require advice regarding the pending action we will also need details of this and a contact with the defendant.

10. I trust this is helpful and look foward to hearing from you.

Yours sincerely

GRO-C

A O Bowdery
Assistant Director/Patents 3