

IN THE MATTER of an application  
under Section 46(3) by  
Harris Pharmaceuticals Ltd for  
settlement of terms of a licence  
of right in respect of Patent No 1285038  
and Patents of Addition Nos 1312095  
and 1312610 all in the name of ICI

STATEMENT OF REASONS FOR PRELIMINARY DECISION

Harris Pharmaceuticals, who are the applicants for settlement of the terms of a licence of right in respect of patent no 1285038 and of patents of addition nos 1312095 and 1312610 all in the name of ICI, requested an urgent preliminary hearing to settle the terms of an 'interim' licence pending the ~~settlement of the terms of a licence of right pursuant to the provisions of Section 46(3)(a) at a substantive hearing.~~ These patents are treated as endorsed licences of right under the provisions of paragraph 4(2)(c) of Schedule 1 of the Patents Act 1977.

At a preliminary hearing held on 20 May 1986 Mr H Laddie QC and Mr H Carr appeared as counsel for the applicants and Mr A Wilson appeared as counsel for the patentees.

Having heard counsel I decided that I would not grant an 'interim' licence. I promised to issue a statement of reasons as soon as possible.

The particular nature of the invention to which the main patent in suit (no 1285038) relates is not relevant to this statement of reasons. I need only mention that the patent relates to a pharmaceutical which is known by the generic name of atenolol and which is clearly an important drug since a number of firms, apart from the present applicants, have applied to the Comptroller

to settle the terms of a licence of right in respect of this patent. The licence which the applicants sought at the hearing was only in respect of this main patent.

The reason for the applicants' request is that they do not wish to be at a disadvantage compared with Generics (UK) Ltd (hereinafter called Generics) because of a recent High Court action. Generics are one of the other firms which have applied for settlement of terms in respect of this patent. In the High Court proceedings the patentees sued Generics for infringement and the parties agreed that until the terms of the licence are settled Generics will pay £1,333 per kilo of the drug atenolol as security for damages. Generics are therefore able to sell atenolol before the terms of their licence are settled. The hearing in respect of Generics application for settlement of terms was subsequently held on 22 and 23 May 1986 but no decision is likely to arise until at least four weeks from that decision as further evidence is to be filed by the patentees.

The licence in that case as in all these cases cannot take effect until the decision is issued. Mr Laddie explained that the applicants do not want to infringe the patent by operating under it without a licence. However if his clients wait until their application has run its normal course before a licence is granted the licence would, he submitted, be of little commercial value because Generics would already be established in the market place.

There was some argument between counsel as to whether the licence which the applicants sought at the hearing should be termed an 'interim' licence. Mr Laddie made it clear that the licence he sought was not to conclude these proceedings but should only last until the terms of a substantive licence be settled at a full hearing. In this circumstance I consider

the term 'interim' licence appropriate and I will use it in this statement.

For the 'interim' licence the applicants propose that the terms of the draft licence accompanying the patentees counterstatement be adopted with some amendments. The main amendments are (i) the introduction of a most favoured licensee clause (so if Generics are given a lower royalty rate than that proposed by the patentees the present applicants will receive the same rate under the "interim" licence) (ii) the introduction of a clause permitting sub-contracting, and (iii) the introduction of a clause specifying that the grant of the licence is until the terms of a further licence of right are settled by the Comptroller pursuant to the Act. .

The relevant parts of Section 46(3) read as follows:

"(3) Where such an entry is made in respect of a patent-

- (a) any person shall, at any time after the entry is made, be entitled as of right to a licence under the patent on such terms as may be settled by agreement or, in default of agreement, by the comptroller on the application of the proprietor of the patent or the person requiring the licence;
- (b) the comptroller may, on the application of the holder of any licence granted under the patent before the entry was made, order the licence to be exchanged for a licence of right on terms so settled;
- (c) if in the proceedings for infringement of the patent (otherwise than by the importation of any article) the defendant or defender undertakes to take a licence on such terms, no injunction or interdict shall be granted

against him and the amount (if any) recoverable against him by way of damages shall not exceed double the amount which would have been payable by him as licensee if such a licence on those terms had been granted before the earliest infringement;"

Much of the argument at the hearing was concerned with whether I could and should grant an interim licence. Mr Laddie pointed out that the grant of an interim licence was not expressly precluded by the wording of Section 46(3)(a) and that Rule 63 which deals with the procedure for the settlement of terms under this sub-section specifically provides that after a counter-statement has been filed the Comptroller may give such directions as he may think fit with regard to the subsequent procedure - ie there are no mandatory rounds of evidence before a decision can be reached as there are in some proceedings before the Comptroller. Mr Wilson in reply on this point submitted that paragraph (a) of sub-section 46(3) did not on the other hand expressly include the granting of an interim licence while paragraph (c), which prescribes for the consequences of infringement before the terms of a licence are settled, does not contemplate the grant of an interim licence.

Counsel for both parties referred for support to the House of Lords judgment in Gist-Brocades [1986]WLR 51 which extensively considered the procedures under Section 46(3)(a). Mr Laddie stated that according to the judgment the procedures under this sub-section must not be used to prevent the grant of licences and he referred me to Lord Diplock's comments on pages 61 and 62 that the Comptroller had a wide discretion in settling terms and that there are only two fetters on his discretion. The two fetters are that no positive obligation can be imposed on the licensee to do any of the acts licensed, and that terms cannot be incorporated which would have the effect of debarring future applicants from applying for a similar licence. He emphasised this reference to future

applicants being able to apply for a similar licence. On the other hand Mr Wilson submitted that while the question of an interim licence was not canvassed in the House of Lords there is no support in the judgment for such a licence and that the judgment found a different solution to the problem of how to allow an applicant to obtain a licence for the whole of the 4 year licence of right period. The House of Lord's solution is that an applicant can apply to the Comptroller for settlement of terms sufficiently in advance of the start of the period to permit the terms to be settled in time.

Mr Laddie drew my attention to a provision in the Interpretation Act to the effect that words in the singular shall include the plural unless the contrary intention appears and argued that in Section 46(3)(a) the reference to a licence must be taken to read a licence or licences. This argument, I felt, begged the question of whether there is an intention that the Comptroller should settle interim licences and this had to be decided on the interpretation of the Act as a whole assisted by the House of Lords' judgment and any other relevant case law.

Mr Laddie also argued that not to give an "interim" licence would be to give rewards to those who infringe and have the benefit of Section 46(3)(c). Mr Wilson countered this argument by pointing out that Generics were taking a great risk in infringing before a licence is granted since they would be liable in damages up to an amount of double the royalty rate to be set in the licence. The royalty rate proposed by the patentees is over 50% of their selling price. I found this argument of Mr Laddie a moral rather than a legal one and this matter had to be decided on what the present law is and not on what the law might be in an ideal world. Moreover, we cannot be certain that at the end of the day Generics will in fact benefit from their actions.

Mr Wilson on behalf of the patentees in arguing against the grant of an interim licence referred to the practice under Section 41 of the Patents Act 1949 with respect to the grant

of compulsory licences. He submitted that that legislation did not expressly preclude interim licences being granted but none, to his knowledge, ever were, and that the logic expressed in the Hoffman-La Roche and Geigy case, [1965] RPC 226, also applied to the present situation. The logic, as I understood Mr Wilson, was that it was wrong to grant a temporary licence, and he again drew my attention to the fact that Section 46(3)(c) does not take the interim licence approach. Mr Laddie in reply submitted that the Section 41 situation was not equivalent because under Section 41 there was no automatic entitlement, as there is under the present Section 46(3), to the grant of a licence. I did not therefore find the Section 41 analogy of much assistance in this matter.

Mr Wilson also sought to rely by analogy on Moore v Assignment Courier Ltd [1977] WLR 638. In an action for possession of demised premises on the ground of forfeiture the landlord sought orders for payment of mesne profits payable at the rate of the rents due under leases on the grounds that on the worst situation for the landlord, as far as the outcome of the actions were concerned, he would be entitled to such sums. It was held in that case that inter alia the court had no inherent jurisdiction to make the orders sought which went beyond procedural matters and were matters of substantive right. Sir John Pennycuik in his judgment commented that there would be very considerable practical difficulty from such an application since the court would have to go into the facts of the particular case and that the proposed procedure would work only in very simple cases. Again I did not find this analogy of much assistance in interpreting the Section before me though I noted that Sir John Pennycuick's comments would be applicable if the Office were to consider applications for interim licences.

Mr Laddie also drew some comfort from Section 46(3)(b). He argued that once somebody had got a licence he can come along and say "Look, you have now endorsed your patent 'Licences of right', and somebody else has got better terms: Can I have the terms

which have been settled under the licence of right". As I understood him he considered that all licensees should have more or less the same terms once one set of terms have been settled. Firstly I do not accept that premise and in this particular case it could have very strange results. Mr Laddie has argued that I have the power to settle the terms of an 'interim licence' in accordance with Section 46(3)(a). On Mr Laddie's line of argument it would be possible, if no other settlement has intervened, that when he returns to this tribunal to get his full licence that the Comptroller could settle terms which include a royalty at the rate of £1,333/kilo since this was a term settled in the 'interim' licence. On the other hand, if the 'interim licence' is not a licence settled pursuant to Section 46(3)(a) then I have no power to grant such a licence in any event. Secondly, and more importantly, I consider that Section 46(3)(b) simply means that once a patent is endorsed 'licences of right' an existing licensee is entitled to apply to have the terms settled according to the full procedure of Section 46(3)(a) and Rule 63 and not just have his licence exchanged for one identical to that settled for some other applicant.

In coming to the decision not to grant an "interim" licence I relied on the straightforward wording of Section 46(3)(a). The Comptroller is empowered to settle the terms of a licence if an application is made. Once the terms of a licence are settled that is the end of the application and if the applicants want the terms varied then he has to make a further application. Therefore a possibility of an interim licence does not arise. I found support for this view both in Mr Wilson's arguments on Section 46(3)(c) and in the House of Lords' judgment in Gist-Brocades. In their Lordship's thorough review of Section 46(3)(a) procedure there is no suggestion about the possibility of the grant of an interim licence. It is made clear in the judgment that a licence only takes effect from the settlement of terms. The granting of an 'interim licence' before the terms are settled would seem to run counter to that

judgment. I also considered that if parliament had intended that the Comptroller should grant 'interim' licences pending the settlement of terms either the Act or the Rules would have made this clear and not left the matter open to judicial interpretation. Moreover, even if the wording of Section 46(3)(a) was such as to leave this matter entirely open to me, in the light of the House of Lords' judgment and of other recent judgments of superior courts on the working of this section I felt that I should hesitate before establishing a new procedure by acceding to the request to grant an interim licence. The Patent Office is of course very conscious of the need for swift settlement of terms in these applications under Section 46(3)(a) of which there are a large number at present, and attempts to settle terms as quickly as the judicial process allows. If requests for interim licences were acceded to this would not only, in many cases, delay the settlement of the substantive licence on those cases but would also be likely to delay the settlement in cases in which no request for an interim licence is made. Many of the parties involved in these cases, including their counsel and other advisers, are highly stretched at the moment and it seems an unnecessary burden for the terms of interim as well as final licences to be settled. As I mentioned above the House of Lords decided that if an applicant wished for a licence to take effect from the earliest possible date he should apply for it sufficiently early. I noted that the present application was made over two months after Generics made their application under this same patent. Finally on this particular matter I would mention that Mr Laddie admitted, in effect, that the applicants were taking advantage of the patentees having put in a licence with their counter-statement. I was conscious of the fact that had I granted an interim licence in these circumstances future patentees would likely to be less forthcoming in their counter-statements and this would only be to the disadvantage of future applicants in being a hindrance to the resolution of



future applications under Section 46(3)(a).

Dated this 29<sup>th</sup> day of May 1986

M F VIVIAN

Superintending Examiner, acting for the Comptroller



THE PATENT OFFICE