BLO/137/85

PATENTS ACT 1977

IN THE MATTER OF an application
by Generics (UK) Limited for
settlement of terms of a licence
of right in respect of
Patent No. 1266058 in the name of
Allen & Hanburys Limited.

DECISION

Patent No. 1266058 was granted pursuant to an application filed 29 June 1970 as a patent of addition to Patent No. 1200886 dated 15 September 1967. Both these patents are defined by paragraph 3(1) of Schedule 1 of the Act as new existing patents and as such their term is extended by paragraph 4(1) of the Schedule from 16 to 20 years, the term of the patent of addition by virtue of paragraph 3(1)(c) being reckoned from the date of the main patent. In accordance with paragraph 4(2)(c) of the Schedule, licences under the patents are available as of right during the extended term, i.e. from 16 September 1983.

The terms of a licence of right to the present applicants under the main patent have already been settled by me in a decision dated 5 September 1985. The main patent covers certain phenylaminoethanol derivatives and pharmaceutical compositions based thereon, and in settling the terms of the licence under that patent I decided that the licence should only cover one particular compound, namely that known under the generic name salbutamol, and pharmaceutical formulations containing salbutamol as the sole active ingredient. The patentees (hereinafter A & H) and their parent company, Glaxo Holdings plc (hereinafter Glaxo) market an ethical drug based on salbutamol under the trade mark "Ventolin" which is available in a number of formulations for treatment of asthma and related conditions.

Somewhat belatedly in the course of the application for a licence

under the main patent, it transpired that the applicants (hereinafter Generics) were also interested in another product known under the generic name labetalol (including labetalol hydrochloride) covered by the main patent, and more particularly, by the patent of addition, and since Glaxo would not agree either to amendment of that application to encompass the patent of addition or to grant a licence covering labetalol on terms acceptable to Generics, the latter filed the present application under Section 46(3)(a) on 10 April 1985 for settlement of terms of a licence under the patent of addition in respect of labetalol.

The matter came to a hearing before me on 29 and 30 July 1985 when Mr S D Kon appeared as solicitor for Generics and Mr William Aldous QC and Mr Guy Burkill appeared as counsel for A & H.

I should mention at the outset that in order to expedite the hearing of the present application Generics have relied entirely on the evidence filed by them in the salbutamol case, their view being that insofar as that evidence deals with general principles it is applicable mutatis mutandis to the present application. At the hearing, Mr Aldous expressed reservations as to the relevance of this evidence and submitted that Glaxo's evidence in this case (in particular the declaration of Mr R S Royston - who also gave evidence in the salbutamol case) was effectively unchallenged, but Mr Kon suggested in effect that Glaxo had ample opportunity before the hearing to comment on the propriety of Generics' evidence and that it was unreasonable to question its relevance at such a late stage in the proceedings. Whilst I cannot agree with Mr Kon that it was incumbent upon Glaxo to give prior notice of their views as to the relevance of Generics' evidence in this case, I would observe that having considered that evidence and the arguments advanced in relation thereto at the hearing, I have not experienced undue difficulty in determining in what respects it may be considered relevant to this application. That is not to say that it would not have been much more helpful if Generics' evidence had been specific to this application, but bearing in

mind the desirability of an early hearing it seems to me that some sort of compromise was necessary. Mr Kon did acknowledge that Glaxo in fact had been most helpful and cooperative in bringing this application to an early hearing, and to the extent that the present application does indeed involve general issues akin to issues arising in the salbutamol case, I have not been unduly inconvenienced by Generics' reliance on evidence filed in the latter case. Settlement of one significant term, however, namely the royalty to be paid under the licence, was complicated, for reasons which I mention below, due to the absence of evidence specific to labetalol.

Labetalol is a blood pressure lowering agent and is the active ingredient of an ethical drug marketed by Glaxo under the trade mark "Trandate", principally for the treatment of hypertension, although application has recently been made for a licence to cover the treatment of angina. On the evidence, this drug is of considerable therapeutic value which stems from its very special and beneficial blocking action on both alpha and beta adrenoceptors. It required, however, extensive studies and clinical trials when many problems were encountered and it was not marketed until 1977 when the first product licences were granted covering tablets and injections. In consequence, according to Mr Royston, sales of labetalol products have been slow to develop, the current annual sales being in the order of £4.5 million with the generic market representing about 20% of the total market.

At the hearing, Mr Kon made it clear that, as with salbutamol, Generics wanted a licence that would provide for manufacture of labetalol-based products in the UK and that would also give them right to import labetalol and to export to countries where there were no parallel patents. Mr Aldous on the other hand, submitted that in common with three other licences for labetalol already granted under the patent in suit without recourse to the Comptroller, these being exhibited by Mr Royston, Generics' licence should not include the right to import or export. In

regard to these rights, both sides basically relied on submissions made at the hearing of the salbutamol application, although there was some elaboration of those submissions at the hearing of the present application. Having given due consideration to the further arguments and the evidence filed by Glaxo in this case, particularly by Mr Royston, which I do not consider necessary to review in detail here, I am unable to come to any conclusion other than that Generics are entitled to the same rights in respect of labetalol as they are in respect of salbutamol. Thus, the licence granted to Generics in consequence of the present application, should not include any restriction on importation nor should it include any direct export ban, other than to countries where parallel patents are in force, or any indirect export ban.

I turn now to consider the question as to what royalty should be paid under the licence. In regard to the general approach to this question and the method of expressing the royalty, both sides again relied with some elaborations on submissions made at the hearing of the salbutamol application, and again having given due consideration to the further arguments and the evidence filed by Glaxo in this case, I am of the view that, as decided in the case of the salbutamol application, I should settle the question of royalty on the basis of what in my view a willing licensor and licensee would regard as reasonable, ignoring so far as is practicable the patentees' role as a manufacturer. Moreover, again for reasons given in my decision in the case of the salbutamol application, the royalty should be expressed as a percentage of Generics' selling price to arms length customers.

When it comes to determining what would be a reasonable royalty rate in this case, however, I find myself in some difficulty since there is no evidence as to the actual price differential between Glaxo's branded labetalol-based products and the equivalent generic products. The existing labetalol licences, like the other licences granted in respect of salbutamol, represent a royalty rate of about 30% of Glaxo's selling price to

wholesalers, but whereas in the case of salbutamol it was possible to establish that this represented a royalty rate of about 40% of Generics' likely selling price, in the present case I am unable to determine what Glaxo's proposed royalty rate represents in terms of a percentage of Generics' likely selling price. At the hearing, parts of which were held in camera, Mr Kon attempted to show in effect that the price differential was about 70%, but Mr Aldous questioned Mr Kon's assumptions and suggested that the price differential could be as low as 8%. I must say at this point that the failure to provide evidence on these matters adds to the difficulty in arriving at a rational figure for the royalty. Mr Kon's estimates and the disputations arising from them would seem to be unnecessary when the prices of the branded and of the generic products must be known to both parties. Arguments about wholesale prices, not to mention uncertainties as between wholesale selling price and selling price to wholesalers, would have been avoided. At this stage, however, I am not prepared to delay matters by calling for further evidence and the conflicting evidence will have to remain unresolved.

Mr Kon also referred to Mr Royston's evidence that Generics, if allowed to import, would be able to buy "unlicensed" labetalol from Italy at about £130/Kg, and on the assumption that Generics paid the same royalty as set in the existing licences and making certain allowances for their manufacturing overheads and packaging and handling costs he calculated that Generics' total costs would be considerably in excess of the price paid to Glaxo by the existing licensees under the terms of the supply agreements which they have negotiated with Glaxo, these agreements also being exhibited by Mr Royston. Mr Aldous questioned the allowance made by Mr Kon for Generics' manufacturing overheads and their packaging and handling costs, but even if Mr Kon's figures are adjusted along the lines suggested by Mr Aldous it still appears that Generics would be at a significant disadvantage compared with the existing licensees. It would thus appear that Mr Kon is justified in questioning the

accuracy of Mr Royston's predictions as to the likely consequences of Generics being allowed to import. However, I cannot quantify Generics' disadvantages on the evidence, and in any case Mr Kon was also concerned to distinguish the circumstances surrounding the grant of the existing licences from those surrounding the grant of Generics' licence. I do not feel able therefore to draw any further useful conclusions from these particular calculations.

Mr Aldous drew attention to the long period of costly research and development which had to be undertaken before the drug produced any financial return and submitted that a licensor would reasonably require some compensatory factor in the royalty agreed with a licensee. The contrast with the history of salbutamol is marked, the latter drug coming on the market after a mere two years of research and trials and still occupying a dominating position in its field, and in that case it was argued on behalf of the applicants that the patentees had already received very adequate remuneration. Conversely, a case exists for a higher royalty here. On the other hand, labetalol is, in terms of sales and financial returns, a much less profitable product than salbutamol and it could well be argued that in negotiating a sale of a licence the patentees would be disposed to settle at a lower price than in the case of salbutamol. I would not wish to lay down any general principles relating to these factors but I would not rule out the possibility that in certain circumstances one would outweigh the other. In the present case, however, I am of the view that the most equitable conclusion is to regard them as weighing equally in the balance.

In my decision in the case of the salbutamol application, I refer to attendance notes exhibited by Mr Kon in that case from which it was apparent that Generics originally considered that the royalty rate would be based on general principles applying to pharmaceuticals, and that, whilst it was difficult to conclude what royalty rate would be fixed by the Comptroller, on the authority of the Geigy case a guideline of 16-20% was thought to

be a reasonable rate. In that decision, I concluded that the figure of 16-20% could reasonably be construed as an opening bid, and that figures of 0-4% suggested elsewhere in the evidence and proposed at the hearing were unrealistic. The same attendance notes are exhibited by Mr Kon in this case, and on my understanding of them the remarks regarding royalty rate are equally applicable to labetalol. I have therefore assumed that in this case a willing licensor and willing licensee could reasonably be expected to settle for a royalty rate somewhere between 16% and a figure in the range of 33-51% which represents Glaxo's asking price expressed as a percentage of the licensees' selling price depending on whether one takes Mr Kon's or Mr Aldous' figures for the price differential between the branded and generic products.

Bearing in mind the various imponderable factors which it was also suggested that I should take into account when comparing Generics with existing licencees, and to which I refer in my decision on the salbutamol application, there is no wholly objective basis available to me to determine a royalty which a willing licensor and licensee would have finally negotiated. Nor is there any clear evidence as to the going commercial rate for licences in the pharmaceutical industry covering the working of patented inventions without compensation for manufacturing losses. Whilst recognising that labetalol and salbutamol are quite dissimilar, with different histories and markets, I must admit to having been predisposed to the view that it was likely that similar percentage royalties would be appropriate, particularly since in effect identical percentage royalties are specified in the existing licences exhibited in this case and in the salbutamol case. In the event, that view has not been displaced by the evidence and the argument in this case, and I therefore decide that Generics should pay royalty at the same rate as set in their salbutamol licence, namely 28% of their net arms-length selling price.

Finally, since Mr Kon indicated at the hearing that Generics' licence could be based on the draft licence exhibited by

Mr Royston, I propose to settle those terms in the draft licence which were the subject of dispute and which have not been effectively settled by the decisions arrived at above.

Firstly, concerning the definition of the "Product", Mr Kon was content to leave the re-drafting of this definition to the parties' legal advisors, indicating simply that reference to labetalol as developed by Glaxo or any affiliate and sold by them under the trade mark "Trandate" was inappropriate. Mr Aldous accepted that the "Product" could appropriately be defined as the various standard tablet formulations containing labetalol as the sole active ingredient. In the circumstances, it seems unnecessary to specify the precise form of a "Product" definition clause, but for the avoidance of doubt I should indicate that I consider Generics to be entitled to a licence covering labetalol and pharmaceutical formulations containing labetalol as the sole active ingredient.

Clause 3(d) of the draft licence concerns right of access of Glaxo's authorised representatives to Generics' premises to inspect the product and its manner of manufacture and generally ascertain that provisions of the licence agreement, other than accounting and payment provisions, are being complied with. Mr Kon submitted that where, as in this case, Generics are operating under their own DHSS manufacturer's product licence and are not taking supplies from Glaxo, there is no justification for allowing Glaxo such right of access. In Mr Aldous' submission, however, whilst specific reference to inspection of the product and its manner of manufacture was not needed the clause was otherwise reasonable. Since, in the light of arguments put to me, I can see no clearly useful or legitimate specific residual purpose behind the clause as proposed to be amended by Mr Aldous, I am of the view that it should not be included.

With regard to clause 3(e), which precludes establishment of depots and promotion of the product outside the UK, having decided that Generics are entitled to export to countries where

no parallel patents are in force, it follows that this clause cannot stand. In my view, given the right to export to certain countries, Generics are entitled to seek and promote sales in those countries and to service those markets by way of establishing storage depots.

As to whether the licence should specify that Generics are entitled to promote only certain indications for the product (clause 3(g) of the draft licence), Mr Kon was of the view that such a term was unnecessary, but Mr Aldous submitted that, since any promotion of indications not in the British Pharmacopoeia (BP) could reflect on Glaxo, the licence should restrict promotion. In the circumstances, and for the avoidance of doubt, my conclusion is that Generics' licence should include a clause restricting the promotion to indications set out in the BP.

Clause 3(h), which in the draft licence would allow Generics to sell the product to third parties only in its finished forms and under Generics' label and not in part finished form for use under a third party's label, was, in Mr Aldous' submission, absolutely necessary. Without it, according to Mr Aldous, Generics would be able to sell on imported labetalol in bulk and give somebody else the right to manufacture it into tablets and sell it on, leaving Glaxo unable to ascertain the royalty payable. As I understand it, however, Mr Aldous expressed no particular objection to Generics being allowed to sell the product in its finished form for repackaging and relabelling by Generics' customers which was Mr Kon's main requirement. According to Mr Kon, Generics would not be branding their product and in the main will be selling to other generic companies who must be free to repackage and label the product if necessary. In Mr Kon's submission, it is, moreover, quite impracticable to try to limit the chain since chemists must be free to adopt the common practice of repackaging the product. In the circumstances, it seems to me that whilst this particular clause may well be appropriate in the existing licences, it cannot be applied to Generics. In the light of the

Assignment clause considered below, I feel that Mr Aldous' fears are unfounded.

As far as the Assignment clause is concerned (clause 12 of the draft contract), as in the case of the salbutamol application the question arose as to whether this clause should provide for Generics to sub-contract manufacture of the final dosage forms of the product in accordance with the terms of its product licence. Since the same considerations apply in the case of labetalol as in the case of salbutamol, my decision is the same and therefore the Assignment clause in the labetalol licence should be equivalent to that in the salbutamol licence, ie the clause should include a proviso allowing sub-contract as aforesaid.

The draft licence itself does not include a most favoured licensee clause, although a supplementary side letter referring to the draft licence and supply agreements does include such a clause, albeit in a rather restricted form. In Mr Kon's view, since two of the existing licensees have the benefit of this clause it would be appropriate to extend the same benefit to Generics. In Mr Aldous' submission, however, Generics should not be entitled to renegotiate any of the terms settled by the Comptroller. I agree with Mr Aldous, since in my view if circumstances change to the extent that Generics consider that different terms are justified then they should make fresh application under Section 46(3). Accordingly, in my view Generics' licence should not include a most favoured licensee clause. I appreciate that this is not consistent with the salbutamol licence but in that case, operating from the draft proposed by Generics, the clause was not opposed.

As far as the remaining terms are concerned, both parties at the hearing agreed to the deletion of clauses 4, 5, 6 and 7 and the retention of clauses 8, 9, 10 and 11.

That I believe covers all the terms of the licence, and therefore I hereby order the patentees to grant a licence to Generics on

the agreed and settled terms, the licence to take effect from the date of this decision.

Neither side has asked for costs and I make no award.

Dated this 17th day of October 1985

N G Tarnofsky
Superintending Examiner, acting for the Comptroller

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