PATENTS ACT 1977

BLO/140/86

IN THE MATTER OF an application
under Section 46(3) by Harris Pharmaceuticals Limited
for settlement of terms of a licence of right
under Patent 1236467 in the name of
Tanabe Seiyaku Company Limited

DECISION

Patent No 1236467 is dated 24 October 1986 and is therefore a new existing patent as defined by paragraph 3(1) of Schedule 1 of the Patents Act 1977. According to paragraphs 4(1) and 4(2)(c) of this Schedule the term of the patent is extended from 16 to 20 years and during the extension is treated as endorsed licences of right. The parties have been unable to agree the terms of a licence and Harris have therefore made the present application for settlement of terms by the Comptroller.

The matter accordingly came to a hearing before me on 11 August 1986 when Mr N Pumfrey appeared as counsel for the patentees and Mr H Carr appeared as counsel for the applicants.

The patent in suit is concerned with certain benzothiazepine derivatives including one known by the generic name diltiazem which is at present marketed in the UK under the brand name Tildiem by Lorex Pharmaceuticals under a licence granted to Synthelabo of France by the patentees. Diltiazem is a vasodilator of the type known as calcium antagonists and is effective in the treatment of angina pectoris.

The applicants filed a draft licence together with their statement of case on 5 September 1985. The proposed royalty rate was 5% of the applicants' selling price. The applicants have sought leave to amend these documents firstly to refer specifically to the right to import

the product, then to increase the proposed royalty rate from 5% to 10%, and finally to delete the prohibition on export of the product. The patentees in their counterstatement and accompanying schedule filed 13 December 1985 indicated that they found the terms unacceptable, that the royalty rate should be 30% of the applicants' selling price, that import and export should be prohibited, that the terms relating to "Affiliates" should be omitted, that the licence be restricted to pharmaceutical formulations in tablet form, and that the other financial terms should be as set out in paragraph 4 of the licence granted to Harris by Rhone Poulenc in respect of Patent 1164585.

Mr Carr began by referring at some length to the background of the application, observing that from January 1985, when Harris first approached the patentees, until August of that year, Harris were led to believe that a licence would be willingly granted, only to be told after eight months of fruitless correspondence that the patentees were, after all, not willing to oblige. It seems to me fairly clear from the evidence that the patentees were indeed guilty of delay and I would have considered it proper to introduce a compensatory factor into the royalty were it not for the fact that the applicants were not, even at the time of the hearing, in a position to exploit a licence since they had not yet obtained a product licence from the DHSS.

I thus proceed to the main considerations regarding the royalty rate. Both the applicants' offer of 10% and the patentees' demand of 30% are based on the applicants' selling price. This is at variance with the basis adopted by Whitford J in the salbutamol case (Generics UK v Allen & Hanburys) where the basis was taken to be the patentees' selling price and the royalty was expressed as a fixed amount per kilo. However Mr Pumfrey took the view that his clients had proceeded on the basis of a percentage of the applicants' selling price and he did not wish to depart from this approach at this late stage. Both parties therefore having agreed that the royalty should be calculated and expressed in this manner, I do not consider it necessary to depart from this basis.

This case has also differed from most other pharmaceutical cases in that the patentees have not pursued the approach established under Section 41 of the 1949 Act (see Geigy's Patent 1964 RPC 391). This took into account the expenditure by the patentees on research and development and promotion, and the various elements making up the royalty were calculated as percentages of these costs based on income from total sales. The patentees in this case have not provided any such information. The main basis for the figure of 30% appears to be that expressed by Mr Akira Yanagi, who is General Manager of the International Licensing and Development Division of Tanabe. In paragraph 10 of his affidavit he gives as his understanding that the royalty rates determined by the Comptroller have been 25% or above and he believes that the inherent value of diltiazem is such that a rate above the bottom of the range is appropriate. He then takes up the basis of calculation used by the applicants in deriving their figure of 10% and argues that on the contrary they can well afford to pay 30%. Mr Pumfrey pursued this approach and since both sides have followed it I see no reason to look for any other myself. Indeed, having regard to the paucity of evidence from the patentees as to their income and expenditure on this drug I have no alternative unless I were to assume a fixed going rate for pharmaceuticals and apply it regardless of the particular circumstances of this case. This is a course which I would be reluctant to follow in any case and more particularly here for this reason: the patentees repeatedly describe the drug as very valuable, an estimation endorsed by Mr C H Beck, Managing Director of Harris, yet its sales in the UK are surprisingly small. According to the undenied evidence of Mr Beck, in the period May 1984 to July 1985, sales amounted to a mere £194,000. It is true that there has subsequently been a marked increase, the figure for the first quarter of 1986, again provided by Mr Beck, being £330,000, which on an annual basis amounts to £1.32 million. Nevertheless even this figure, achieved after 17 years of the patent's life, is very small. The reasons for this advanced on behalf of the patentees by Dr B A Whittle, a Pharmaceutical Consultant, I do not find very convincing, in particular that there is resistance to a drug which is "not invented here". Numerous examples to refute this allegation come to mind. One need only

mention the tranquilisers diazepam and chlordiazepoxide invented abroad by Hoffman-La-Roche, and nifedipine, a calcium antagonist and thus in the same class as the present drug, invented in Germany and, as revealed in the proceedings of Generics (UK) application for settlement of terms of a licence of right under patent no. 1173862 (Bayer), achieving very considerable sales in the UK. Moreover, according to Mr Beck, diltiazem itself, launched in the United States around the same time as in the United Kingdom, reached a level of sales in that country of 123 million dollars in 1985. I conclude therefore that neither the patentees nor the exclusive licensees, Synthelabo, have made any appreciable efforts to promote the drug in this country, at any rate during the normal sixteen year life of the patent, and that a settlement of royalty on what may be regarded as the going rate would not be justified.

It is a question then of making an assessment of the profit which Harris might make on its sales and of a fair division of the profits to provide the royalty. The applicants have indicated that they intend to sell the product for £11 per 100 60 mg tablets. The production costs, including purchase of raw material, tabletting and packaging are said to amount to £3.10 and a sum of £4.05 is added for promotion and marketing. At the hearing the provision of a discount to distributors was also incorporated and assuming this to amount to about £1.50 the total cost per 100 tablets would come to £8.65 leaving a profit of £2.35. This is approximately 21% of the applicants proposed selling price and on the assumption that it should be divided equally between the two parties the applicants arrive at the figure of 10-11%.

The patentees' first attack on these figures was on the assumed selling price of £11. This compares with the Lorex price of £16.67, a price differential of £5.67, equivalent to 34%. The patentees' evidence was that it was usual for a generic product to be priced 5%-15% below the original branded product and taking the upper limit of 15% the applicants' price would be around £14 per 100 tablets. Mr Beck, on the other hand, said that it was not unusual for the price differential to be 25% or more. Mr Pumfrey alleged that the applicants put forward their figure of £11 in order to derive a low royalty and would, after a short period of pricing at £11, raise the

price by say £2, giving them a greater share of the profit relative to the patentees. In answer to Mr Pumfrey, Mr Beck agreed that he could make sales at £13 but did not agree that the amount would be the same as at £11. Nevertheless, as a counter to the possibility of a price rise, Mr Pumfrey introduced a fresh proposal, namely that the royalty should be 30% of the applicants' selling price where this was up to £13 but increased to 80 or 85% on the margin above this price. It was pointed out by Mr Carr that on the basis of a 30% royalty on a selling price of £13, on the costings figures provided by Mr Beck the profit remaining for the applicants would be 45p compared to the patentees royalty of £3.90, a distribution which he considered to be unacceptable.

Before deciding what might be a reasonable selling price for the applicants it is necessary to look at the costings provided by Mr Beck. Of these the only item which gave rise to dispute was the cost of marketing the products, which Mr Beck, in his first declaration, paragraph 9, stated to be "in the region of £4.05 per 100, more if we have to consider establishing a brand of our own for the product". In cross-examination he explained that the figure was provided by his costings department and he did not know exactly how it was arrived at but he accepted Mr Pumfrey's suggestion that it represented a certain proportion of the proposed selling price and was therefore more correctly described as an allowance. However, he also said that Harris would be marketing the drug as a branded product for which the price would be the same as for the generic product; and in answer to a question which I put to him in relation to the £4.05 promotion cost he replied: "No; this is for the ethical product. There is very little promotion needed for the generic product - the branded product" (page 17 of the transcript). Thus, a discrepancy has been introduced into his evidence. Further confusion arises from his statements under cross examination where at one point, on page 6 of the transcript, he says:- "We will not be able to sell it as a generic, because there is no generic prescription; it will be impossible", and lower down he says: "We intend to sell it as both" (ie generic and branded) and again "if there is a market for the generic product, we will sell it as a generic product". It would seem to me that whether or not there is a generic product will depend to a large extent on Harris themselves. To claim that it will be

impossible to sell the drug as a generic and at the same time to claim that it would cost more to market it as a branded product is a situation I find difficult to resolve. Nor do I accept the proposition that allowance should be made for the extra cost incurred by an applicant promoting his own branded product. Ultimately his purpose must be to facilitate his entry into the market and to gain advantage over other later competitors. While I take the view that royalties should be fixed at a level which will not prohibit a licensee from making use of the licence, I believe it would be improper for me to encourage an applicant in the manner which is in effect requested by the present applicants. I am thus left finally with serious doubts as to the validity of the figure of £4.05 for marketing costs. I do nevertheless accept that, since the drug has made such a minor penetration of the market, the applicants will be taking a greater risk and will need to spend more on its promotion, whether as a generic or branded product, than would be required for a well established product, such as salbutamol, with which comparisons were made at the hearing.

Taking all these matters into consideration I have come to the conclusion that the royalty rate should be computed as follows. I consider that a reasonable figure for the applicants' selling price is £13 per 100 tablets, this being approximately 20% below the price of Tildiem. I allow £1.70 for distributors' discount (approximately 12½%) and I assess for promotion and marketing the sum of £3. The production costs of £3.10 gives a total cost of £7.80 leaving a profit of £5.20. Mr Carr's proposal that the available profit should be shared equally was not, to my understanding, contested by Mr Pumfrey and I therefore take £2.60 as the royalty figure, which represents 20% of the sale price. The royalty is therefore set at 20% of the applicants selling price, this price being, in Mr Beck's words, the book price as listed in the "Chemist and Druggist". This is exclusive of VAT but the reference to other taxes in the proposed Clause 4.1, although not questioned by Mr Pumfrey, in my view introduces obscurity. I find Clause 4.2 even more open to objection on this account, particularly in its reference to the calculation of royalty, and I have made appropriate deletions in both cases. As a percentage of the net invoice price, the royalty equals 23%, which

was an average sort of figure set under Section 41 of the 1949 Act. It is appreciably below the standard set in the most recent cases but I believe it to be justified on two grounds: firstly the lack of effort by the patentees or the existing licensees in selling the drug in the UK, which I referred to earlier in this decision, which in turn means that the patentees stand to lose very little by the entry of Harris into the market; and secondly, the lack of information provided by the patentees, whether in relation to their costs and sales or the terms of the licence agreed with Synthelabo.

The second major matter is the question of allowance of importation. I was referred to the judgements of the House of Lords in the Allen and Hanburys v Generics case, and others, 1986 RPC, 203, in which Lord Diplock held that the Comptroller has a wide discretion to impose limitations and conditions on what a licence of right authorises the licensee to do and that recourse could be had to the provisions of section 48(3) and section 50 to identify the policy to be achieved. Sub-section 50(1)(a) states:-

> that inventions which can be worked on a commercial scale in the United Kingdom and which should in the public interest be so worked shall be worked there without undue delay and to the fullest extent that is reasonably practicable;

Mr Pumfrey argued that while section 48 provides as a ground for a compulsory licence the fact that the patentee is working his invention by importation, the purpose of the licence is to ensure working in the UK, not further importation. Both he and Mr Carr drew on the leading authority on this matter, at least under the 1949 Act, which is Hoffman-La-Roche and Company A.G.'s patent, 1969 RPC page 504. In that case too, the patentees imported the drug and the hearing officer's decision to allow importation by the licensees was upheld on appeal. Mr Pumfrey quoted Lloyd Jacob J at page 527, line 8, where he said: "The second point concerned the propriety of the inclusion in the licence of the right to import from abroad, a provision which in present circumstances is essential if competition with the patentees is to be made effective". This, argued Mr Pumfrey, followed from the requirement of section 41(2) of the

1949 Act that competition be introduced and it was found in that case that importation was essential to meet this requirement. In the present case, he contended, it was not essential. Mr Beck could manufacture but chose not to. I find myself unable to accept this argument. In the cited case, the applicants were, like Harris, also manufacturers and Lloyd Jacob J went on to say:

> "The applicants appear to have contemplated the establishment of a manufacturing source in this country, and by amendment of their application included the right so to manufacture in their request to the Comptroller-General but they acknowledge that the burden of initiating such manufacture within the realm must be dependent upon the economic factors which will emerge only after they have gained a market by distribution of the product. As no manufacture of diazepoxide has as yet taken place in the UK and the patentees do not suggest that they have any in contemplation, it is clear that the right to import from abroad cannot adversely affect any existing home manufacture, whilst it may conceivably provide an impetus to the setting up of such manufacture by the applicants".

The present case seems to be on all fours with the Hoffman-La-Roche case and bearing in mind the provisions of sections 48 and 50 of the Act I am in no doubt that the public interest is best served by allowing the licensees to import.

The patentees also objected to the inclusion of a provision allowing the export of the product on the grounds that this might be construed as a licence to export to countries in which parallel patent rights exist. The applicants made it clear that they had no intention of infringing foreign patents but they considered that this was a matter which should be dealt with under the laws of the states in which such patent rights exist. I take the view that where a licensee infringes a foreign patent it should not be necessary for the patentees to institute proceedings abroad but should have a cause for action under the licence in the United Kingdom. The words "or export" in the first passage of clause 3.3 of the applicants' draft licence should therefore be retained and I see no justification for the proviso at the end of this clause.

The patentees proposed that the licence should be restricted to sales of the finished product in the form of 60mg tablets, this being the only form at present available, on the grounds that there were no figures available for any other formulation so that it was not possible to calculate the proper royalty rate relevant to such formulations. Also they thought it unlikely that the applicants could develop and obtain a product licence for any other formulations within the remaining term of the patent. If the latter point is correct I can see no advantage to the patentees in the restriction they demand. On the other hand, if the applicants can produce and market other dosage forms it is clearly in the public interest that they should be allowed to do so. I consider therefore that it would not be unfair to the patentees to set the same royalty irrespective of the form of presentation of the product and consequently I decline to include any restriction in this respect in the licence.

An issue which gave rise to considerable dispute concerned the inclusion of 'Affiliates' in the licence. The patentees' fear was that there would be no redress against an affiliate if Harris ceased trading and Mr Pumfrey considered that since the subsidiary company, Norton, would be responsible for the sale of the drug they should be a party to the licence. After some argument Mr Carr intimated that the patentees would accept amendment of the application so as to associate Norton with Harris as co applicants and this I have done. It also became apparent that the presence of any other subsidiary was purely theoretical and I consider it unnecessary in the circumstances to include a reference to any other subsidiary or affiliate of Harris.

The patentees had asked in the Schedule appended to their Counter-statement that in addition to the royalty rate the financial provisions should be those contained in paragraph 4 of the licence granted by Rhone-Poulenc to Harris in respect of patent 1164585 (Ketoprofen). There was no argument at the hearing on this matter; indeed, there was no mention at all of this earlier licence, all of the discussion being based on the applicants' draft licence. As far as I can see the only significant points are the period for payment of royalties and the payment of interest on overdue royalties. I consider that the period of 90 days contained in clauses 5.1 and

9.1.1 of the applicants' draft licence is excessive and I have reduced this to 30 days. The matter of interest on overdue royalties was not pursued by Mr Pumfrey and since this provision in the licence on patent 1164585 seems to be the exception rather than the rule I have not included such a requirement in the present licence.

Finally, Harris's draft licence includes a most favoured licensee clause, 4.2. Although this clause was not disputed, I have come to the conclusion that such a clause should not be allowed. Since the settlement of terms has taken into account the circumstances of this particular case I believe it would be wrong to allow the terms to be altered without further reference to the Comptroller. The clause has therefore been removed from the licence.

That I believe disposes of all the matters which have either been in dispute or which in my view required review and I accordingly order that Tanabe Seiyaku grant to Harris and to Norton a licence in the form appended to this decision. The licence, in accordance with the judgment of the House of Lords, will take effect from the date of this decision.

Both sides asked for costs but I was not addressed on the matter at the hearing. In all the circumstances of this case I have decided to make no award as to costs.

Dated this 16th day of September 1986

N G TARNOFSKY

Superintending Examiner
acting for the Comptroller

GRANT OF LICENCE

WHEREAS TANABE SEIYAKU COMPANY LTD., of 21 Doso-Machi 3-chome, Higashi-ku, Osaka, Japan (hereinafter called "Tanabe") is the registered proprietor of Letters Patent No. 1236467 (hereinafter called "the Patent") dated 24th October 1968 and relating to an invention entitled "Benzothiazepine Derivatives".

AND WHEREAS under the provisions of paragraph 4(2)(c) of Schedule 1 of the Patents Act 1977 any person is entitled as of right to a licence under the Patent.

AND WHEREAS on the 28th August 1985 Harris Pharmaceuticals Ltd. and H N Norton & Co Limited have applied to the Comptroller for settlement of the terms of a Licence under the Patent.

The Comptroller in excercise of the powers conferred on him by the said Patents Act 1977 directs Tanabe to grant to the said Harris Pharmaceuticals Ltd., (hereinafter called "Harris") and to the said H. N. Norton & Co Ltd (hereinafter called "Norton") a non-assignable non-exclusive Licence within the United Kingdom of Great Britain and Northern Ireland and the Isle of Man, subject to the following terms and directions:-

1. Definitions

1.1 "subsidiary" of any party shall mean any company which is wholly owned and controlled by such party.

1.2 "the Product" shall mean the medicinal compound known as diltiazem.

1.3 "the Patent" shall mean the United Kingdom Letters Patent number 1236467.

2. Term

2.1 This Licence shall continue , subject to clause 9 hereof, until the patent ceases or expires.

3. Rights Granted

3.1 Tanabe hereby grants to Harris and to Norton the non-exclusive right under the Patent to make or have made, use and sell the Product in the United Kingdom, and to import the Product into the United Kingdom.

3.2 No other rights are granted or implied by this Licence beyond those expressly set forth herein and nothing contained in this Licence shall be deemed to convey to Harris or to Norton any right or rights under any Patents of Tanabe or its subsidiaries other than the Patent.

3.3 Without affecting the generality of the foregoing, neither Harris nor Norton shall make or have made, use or supply the Product in or export the Product to any country in which Tanabe or a subsidiary has a subsisting Patent for the Product corresponding to the Patent.

4. Royalty

4.1 In consideration of the rights herein granted Harris or Norton shall pay to Tanabe or to its order a royalty at the rate of twenty (20) per cent of the selling price of the Product manufactured or otherwise dealt in by Harris or Norton during the term of this Licence, this price being the price before deduction of any distributor's margin. Such royalty shall be exclusive of any VAT thereon which

shall be payable by Harris or Norton. The said royalty will accrue at the time of sale or disposal of the Product by Harris or Norton whether before or after the termination hereof.

5. Payment and Accounting

5.1 Harris or Norton shall render to Tanabe within thirty (30) days after the end of each calendar quarter during the period for which royalties accrue under this Licence an accounting of its sales or disposals of the Product hereunder for such calendar quarter or fraction thereof and shall accompany each such accounting with any royalties due hereunder for the accounting quarter. Royalty payments hereunder shall be accrued and payment made in sterling. For the avoidance of doubt it is confirmed that calendar quarters shall begin on 1st January, 1st April, 1st July and 1st October in each year.

5.2 Harris and Norton shall maintain records in sufficient detail to enable the royalty payments due hereunder to be readily determined for a period of six (6) years after the date of the sales or disposals in question and shall furnish annually, if requested by Tanabe and at Tanabe's expense, a certified statement prepared by an independent accountant selected by Tanabe and acceptable to Harris and Norton (such acceptance not to be unreasonably withheld) to verify the accuracy of the accounting of royalty bearing sales or disposals of the Product. Any examination of Harris' and Norton's books and records as may be necessary for the purpose hereof shall be made during normal business hours and at times and places convenient to Harris and Norton and the information thus obtained shall be regarded as confidential and shall not be disclosed to Tanabe except to the extent that any

such information should properly have been contained in Harris' and Norton's accounting to Tanabe.

6. Maintenance of Patent

6.1 Tanabe shall maintain the Patent in full force and effect through the remainder of its term and shall pay all annual renewal fees due thereon.

6.2 Harris and Norton shall notify Tanabe immediately upon apprehension of any infringement of the Patent actual or threatened which shall come to Harris' or Norton's attention and if Tanabe does not within ninety (90) days take steps to forestall further infringement, Harris and Norton shall have the full right in Tanabe's name to commence proceedings for infringement thereof. If Harris or Norton intends to commence such infringement proceedings it shall immediately notify Tanabe and Tanabe shall have the right to join in the prosecution thereof at its own expense. Harris and Norton will co-operate fully with Tanabe in any action in which Tanabe takes part. Any judgements or awards shall be the property or the liability of the party which instituted the litigation.

7. Regulatory Approvals

7.1 It shall be Harris' or Norton's responsibility to obtain all necessary governmental approvals and permissions which may be required for Harris or Norton to sell in the United Kingdom dosage forms of medicinal products containing the Product and to comply with all applicable laws and governmental regulations in this respect.

8. Indemnity by the Licensee

8.1 Harris or Norton shall indemnify and hold Tanabe harmless from and against any and all claims against Tanabe or losses and expenses incurred by Tanabe resulting from or attributable to the sale of the Product by Harris or Norton save to the extent that any such claims, losses or expenses are attributable in whole or in part to any act or default of Tanabe or its subsidiaries.

9. Termination

9.1 Tanabe shall have the right to terminate this Licence by written notice to Harris and Norton having immediate effect:-

9.1.1 if Harris or Norton fails to pay any royalties due hereunder within the time provided herein and continues in such default for more than thirty (30) days after receiving written notice of such dafault from Tanabe or if Harris or Norton shall be in breach of any of the terms or conditions of this Licence and, only where such breach is capable of remedy, fails to remedy such breach within thirty (30) days of written notice requiring such breach to be remedied; or

9.1.2 if Harris or Norton goes into liquidation whether voluntary or compulsory (except for the purpose of reconstruction or amalgamation), compounds or enters into an arrangement with its creditors, or suffers the appointment of a receiver of the whole or any part of its business.

9.2 Any termination of this Licence under clause 9.1 hereof shall not release Harris or Norton from the obligation to pay any royalties in accordance with clauses 4 and 5 hereof.

10. Notices

10.1 Any notice required to be given pursuant to this Licence shall be in writing and sent by telex and confirmed by first class pre-paid mail to the address set forth herein of the party receiving such notice or to such other address as either party may from time to time notify the other for this purpose.

11. Assignment

11.1 This Licence shall not be assigned or sublicensed in whole or in part by either party without the other party's prior written consent save that Tanabe shall at any time be entitled to assign the whole or any part hereof to any one or more of its subsidiaries without Harris' or Norton's consent.

12. Waiver

12.1 Failure by either party in any one or more instances to enforce its rights on account of any default or breach by the other party shall not be regarded as a waiver of such rights or the condonation of any such default or breach by the other party.

13. Applicable Law

13.1 This Licence shall be governed by and construed in accordance with the laws of England and the parties hereby submit to the jurisdiction of the English Courts for the determination of any question or dispute howsoever arising under or in connection with this Agreement.