BLO/049/87

PATENTS ACT 1977

IN THE MATTER OF an application under Section 46(3) by Generics (UK) Limited for settlement of terms of a licence of right in respect of patent no. 1,291,631 in the name of The Upjohn Company

AND

IN THE MATTER OF an application under Section 46(3) by Generics (UK) Limited for settlement of terms of a licence of right in respect of patent no. 1,298,364 in the name of Takeda Chemical Industries Limited

DECISION

I have considered it convenient for ease of understanding to deal with the decision on each of these applications for settlement of terms in one document. Where I am dealing with matters concerning only one of the patentees I have said so. The licences granted are, of course, entirely separate.

BACKGROUND

Patent No 1,291,631 in the name of The Upjohn Company (Upjohn) is dated 5th February 1970 and by virtue of Schedule 1 of the 1977

Patents Act its maximum term was extended from 16 to 20 years and licences under the patent became available as of right after the end of the sixteenth year; that is from 5th February 1986.

The applicants Generics (UK) Limited (GUK) wish to obtain a licence under the Upjohn patent in order to market pharmaceutical formulations containing triazolam as active ingredient and have applied to the Comptroller under Section 46(3) for settlement of the licence terms.

During the course of proceedings on the Upjohn patent, GUK discovered from evidence provided by Upjohn that in order to manufacture and sell triazolam formulations they would also require a licence under patent no. 1,298,364 in the name of Takeda Chemical Industries Limited (Takeda). The Takeda patent is dated 27th October 1969 and is similarly subject to Schedule 1 of the Act. Accordingly, GUK applied to the Comptroller under Section 46(3) on 8 August 1986 for settlement of licence terms under this patent also.

At a preliminary hearing before me on 5 November 1986 it was decided that the two applications should be heard together. The joint hearing took place before me on 29th-31st July 1987.

GUK were represented by their solicitor Mr S D Kon, Upjohn by their counsel Mr A Watson Q.C. and Takeda by their agent Mr J J Laredo.

Of the two patents involved in these proceedings, the Takeda patent is the earlier and also claims the earlier priority date, this claim being accepted by Mr Armitage for Upjohn in paragraph 91 of his first declaration. Claim 1 of the Takeda patent claims per se a wide range of benzodiazepine compounds, including triazolam, but there is no specific claim to that compound, neither is it disclosed in the body of the specification. But the Takeda patent does specifically disclose and claim two other commercially significant benzodiazepine compounds, namely estazolam (claimed in claim 4) and alprazolam (claimed in claim 5).

Claim 1 of the Upjohn patent is a generic per se claim of similar, but not identical, scope to claim 1 of the Takeda patent. Triazolam, estazolam and alprazolam are each covered generically by the Upjohn Patent and are also claimed specifically: triazolam in claim 4, estazolam in claim 14 and alprazolam in claim 2.

The priority and publication dates of the two patents are such that neither prior publishes the other, but the Upjohn patent was amended in 1976 so as to reduce, though not it would seem to eliminate, overlap of claim under Section 8 of the 1949 Act. Takeda and Upjohn also signed a series of agreements, beginning with a general agreement dated 9th May 1972 and culminating in a specific agreement on triazolam dated 29th December 1977. Under this agreement Upjohn undertook to pay Takeda a 4% royalty on sales of triazolam in the UK and, as I understand it from the

parties, they are still paying this royalty, notwithstanding paragraph 4(2)(b) of Schedule 1 of the 1977 Act, because the agreement is subject to Japanese and not UK law (see Rosenbergs' declaration paragraph 6 in the Upjohn proceedings).

Certain intermediates useful in the preparation of triazolam are covered by a third patent no 1291632 which is held by Upjohn. This patent is also the subject of a licence of right application by GUK, but, since this application is proceeding separately, I need not make further mention of it here.

Triazalam is marketed by Upjohn under the brand name HALCION and is not marketed by Takeda. It is a sleeping pill of short duration with a relatively short half-life. This means that when the patient awakes in the morning he has less of a hangover. The drug is also stated by Upjohn to have a minimal effect on intellectual performance.

HISTORY OF PROCEEDINGS

GUK's application under the Upjohn patent was filed on 26th September 1985 and has thus taken 22 months to come to hearing. The reasons for this will emerge from the following chronology.

The application initially proceeded according to the usual timetable with the patentees evidence-in-chief, including their first reference to the Takeda patent being filed on 11th April 1986. GUK filed their application under the Takeda patent on

8th August 1986 together with their evidence-in-chief. A preliminary hearing was requested by Takeda to consider (a) alleged inadequacies in GUK's evidence, (b) a provisional direction by the Office that Takeda file their counterstatement and evidence-in-chief within the same two month period and (c) the relationship between the Takeda and Upjohn proceedings. At this hearing on 21st October 1986, I held (a) that deficiencies in the applicants' evidence be made good, (b) that Takeda should file their counterstatement and evidence within the same 3 month period beginning on the date on which the applicants' evidence was made good and (c) that GUK, Upjohn and Takeda could attend a joint preliminary hearing on 5th November to consider whether the main Upjohn and Takeda proceedings should be heard together.

At the 5th November hearing I upheld the view of the two patentees and decided that the two proceedings should be heard together at a joint hearing beginning on 23rd February 1987.

On 23rd January 1987 Upjohn filed "rebuttal" evidence in reference to GUKs reply evidence in the Upjohn proceedings. On 13th February a third preliminary hearing was convened to consider (a) postponement of the main hearing until after the Court of Appeal had given its decision on the Allen and Hanbury's case (Allen and Hanbury's Patent, Court of Appeal, 26 March 1987) (b) the admissibility of certain parts of Upjohn's evidence in rebuttal and (c) whether Takeda's evidence-in-chief should be amplified. At that hearing I decided (a) that the main hearing

should not be postponed, (b) that parts of Upjohn's rebuttal evidence were inadmissible (thereby finding for GUK and against Upjohn on these questions) and (c) that Takeda would not be directed to amplify their evidence (thereby finding for Takeda against Upjohn).

At a fourth preliminary hearing on 18 February 1987, Upjohn indicated that they intended to appeal my decision of 13 February and I accordingly postponed the main hearing until 13th April. At the appeal before the Patents Court on 26th March, Takeda consented to amplifying their evidence and Mr Justice Falconer allowed Upjohn time to file reply evidence. In consequence the date of 13th April had to be vacated and the main hearing was reset first for 10 June and later for 29th July 1987.

LATE FILED EVIDENCE

During the hearing I was requested to examine two further pieces of evidence, both in the Upjohn proceedings. They were a fourth declaration by Mr Tabatznik of GUK in response to Upjohns "rebuttal" evidence and a declaration by Mr Rosenberg for Upjohn to correct an error in their earlier evidence which had only recently come to light. There being no objection to either declaration from any of the other parties, I agreed that both could be admitted. I also allowed GUK and Upjohn to file two further declarations after the hearing, GUK's declaration to show the appearance of the Halcion tablet and Upjohns'

declaration to show whether they had included patent department costs in their research and development costs. The reasons for this will emerge from later parts of this decision.

BASIS OF ROYALTY

I now come to the substantive issues to be decided on these applications and I turn first to the basis on which the royalty is to be calculated. The leading case on this subject now seems to be the salbutamol case and my attention was drawn to the judgement of Mr Justice Whitford at page 20 D to page 23 B (Allen and Hanbury's patent, Patents Court, 17 March 1987). The salient points that emerge from that decision are as follows:-

(1) A royalty expressed as a percentage of the patentee's selling price would not be agreed to by a willing licensee since it would leave him in a position that he was unable to forecast his liability to royalty.

(2) As to whether one goes for a royalty expressed as (a) a fixed price per unit quantity sold or (b) a percentage of the licencees selling price, this depends on the circumstances of the particular case.

(3) Where there is a temptation to cut prices a fixed price per unit quantity is the better option and more in the interests of both parties so that they can have some better idea where

they stand. Mr Justice Whitford elaborated on this at page 15 at G of his decision in the Syntex case ([1986] RPC 585 at page 603) where he said:-

> "I think there is much to be said for the view that, if one relates the royalty to the selling price of either of the parties, particularly in circumstances where one is dealing with the run up to a free market, in which very substantial alterations in price may, for market reasons, be made on either side with a view to establishing their position at the time when the monopoly under the patent comes to an end, it is much better and more in the interests of both parties, so that they can have some better idea where they stand, to fix royalty on the basis of a price per kilo."

That seems to me to be a summary of the law as it now stands. I will now turn to the facts of the Upjohn case to see if there are any special factors in that case which would lead me away from the better option referred to by Mr Justice Whitford ie a fixed price per unit quantity sold.

Mr Kon sought to persuade me that there were such special factors. He drew attention to the fact that as of 1 April 1985 triazolam was placed on the NHS "White List" as a generic product only (see Mr Tabatznik's second declaration in the Upjohn proceedings, paragraph 3.1). This means that in an NHS prescription the doctor has to prescribe triazolam and cannot use

option in the Takeda case. Under an agreement dated 29 December 1977 (Exhibit RAA5) Upjohn pay a royalty to Takeda for any triazolam which they sell and, according to Article 4 of that agreement the royalty is a percentage of the licensee (Upjohns) selling price. Moreover, under this agreement Upjohn could have sublicenced GUK and in this case the royalty would again have been based on a percentage of the licensees selling price. In the light of this agreement, and the basis that I have determined in the Upjohn case, I consider that the basis of the royalty in the Takeda patent should be a percentage of the licensees selling price.

I should just mention before leaving the question of basis of royalty in respect of both the Upjohn and the Takeda patent, the possibility of using the drug tariff price for this purpose. An alternative put to me by Mr Watson as a possibility which avoids some of the problems of using the patentees selling price. It would, as I understand it from Mr Watson's submission, provide a more stable basis, because the drug tariff price, which tends to shadow the market price, is less liable to sudden or repeated changes. It also has the advantage of taking the level of licensees royalty liability out of the direct control of the patentee. But it still leaves the figure variable and uncertain. Accordingly, it would still leave the licensee with a liability, the future level of which it would be difficult to predict. This alternative was opposed by the applicants and I am not persuaded that it offers sufficient advantages to warrant further consideration.

PUBLIC ADVANTAGE/INTEREST

Mr Kon has suggested, that, in setting the royalty rates, I should have regard to the public interest in obtaining drugs at the lowest possible price. He reminded me that in his judgment on the Gist Brocades case ([1986] RPC 203), Lord Diplock indicated that, in view of the terms of Section 53(4), guidance on royalty rates in Section 46(3) proceedings can be found in Sections 48 to 51.

Section 50(1)(a) refers to the public interest in working the invention in this country, while Section 50(2)(b) says that in granting a licence under Section 48, the Comptroller should take into account the ability of the potential licensee to work the invention to the public advantage. In Mr Kon's submission those sections, though of limited compass themselves, demonstrate that this part of the patent legislation should generally be operated to the public advantage. I do not accept Mr Kon's arguments. As pointed out by Mr Watson the public advantage/interest talked about in these sections is not clearly related to the lowering of drug prices as was Section 41(2) of the 1949 Act, but is directed in the main to public interests other than price, eg questions of importation or non importation.

Mr Laredo for Takeda suggests that there is a public interest in ensuring that those pharmaceutical companies which develop new drugs derive sufficient income from them to finance their very

expensive research. Mr Kon has, as I have mentioned in another context, pointed to a report in Hansard of a speech by the Secretary of State for Health and Social Security where the minister seems to imply that the object of "white listing" drugs such as triazolam is to reduce their cost to the National Health Service. Mr Watson, on the other hand, referred me to a letter from the Secretary of State to the Pharmaceutical Services Negotiating Committee which is couched in somewhat different terms. Nevertheless I will accept, for the sake of argument, Mr Kon's hypothesis that the purpose of "white listing" is to reduce prices. However it does not necessarily follow that Section 46(3) should also be used for the same purpose. To my mind if the object of "white listing" is itself to reduce the NHS drugs bill then the intervention of Section 46(3) for this purpose is not necessary and to reduce prices by virtue of Section 46(3) would be to get involved in a price reduction exercise twice over. There is certainly no evidence to suggest that the minister, the Government or anyone else had Section 46(3) in mind when the "White list" was drawn up. It would be wrong, therefore, to make a separate and additional adjustment for this factor. Accordingly I reject Mr Kon's submission on this point.

INADEQUACY OF REMUNERATION (Upjohn Case)

Mr Watson has suggested that in setting the royalty rate in the Upjohn Case I should take into account that the patentees, as such, have made little or no profit out of the invention during

the 16 years term of the patent under the 1949 Act. In support of this he referred me to accounts prepared by Mr Jameyson somewhat on the lines of those considered in applications for extension of term under Section 23 of the 1949 Act. Mr Kon opposed admission of this argument on the ground that it was not contained in the pleadings. I note that paragraph 6 of Upjohn's counterstatement reads "..... it is denied that they (Upjohn) would not have been entitled to an extension under Section 23 of the Patents 1949. In any case Upjohn contend that the question of whether such an extension would have been granted is irrelevant to the questions arising in this application." Mr Watson contends that his present argument is based on inadequacy of remuneration per se, without reference to Section 23, and is not therefore inconsistent with the pleadings. Even if I were to accept this I am still unable to find any positive basis in the pleadings for Mr Watson's argument. However, I do not propose to go into this further. This is because I do not consider inadequacy of remuneration a relevant factor in this case for the reasons set out below.

Mr Watson sought to find a legal basis for his argument that inadequacy of remuneration is relevant in the decision of Mr Tarnofsky in the salbutamol case (Allen and Hanbury's, Patent Office, 5 September 1985). In that case the applicants suggested that, as the patentees had already made a considerable profit from the invention in the 16 year term under the 1949 Act, they would not have qualified for an extension under Section 23 and accordingly were not entitled to any licence royalty under

Section 46(3). Mr Tarnofsky rejected this argument but observed (see page 16) -

> "To my mind, whilst I would not altogether dismiss the possibility that in some circumstances adequacy of remuneration might indeed be a factor to be taken into account in settling royalty terms, to conclude that it could ever provide a reason for rendering the four year extension of no effective value whatsoever to the patentee makes nonsense of those provisions of the 1977 Act which extended the terms of new existing patents."

Mr Watson interpreted these observations as meaning that whilst the patentee should not be penalized if he has made a great deal of money out of his invention, in the opposite situation where he has made little or no money or a loss he is entitled to an element of compensation in the royalty payable by the licensee.

It seems to be accepted on both sides that if the patentee has been adequately remunerated that fact should not affect the royalty set in the sense that it should be lower than it otherwise would be. In my opinion it would be quite inequitable if in contrast inadequcy of remuneration were to be considered as a factor which would cause the royalty to be higher than it otherwise would be. It seems to me that the correct view is that in general neither adequacy or inadequacy of remuneration alone are of themselves relevant in deciding that the royalty should be respectively lower or higher than it otherwise woud be. What I

do consider relevant, and I shall deal with this in the next section, is the commercial and medical value of the drug. In this context the remuneration received by the patentee is simply one amongst many items of evidence to be taken into account in determining these values. However, in this sense a low remuneration or loss could work against Upjohn and suggest a low royalty on the basis that it is one indicator of a low commercial or medical value.

All that Mr Tarnofsky, I think, was doing in his decision was allowing the possibility that there may be some, as yet unthought of, special circumstances in which adequacy of remuneration may have some relevance but I do not regard the present circumstances as in any way special in this respect.

COMMERCIAL AND MEDICAL VALUE OF TRIAZOLAM

A factor, which in Mr Kon's submission, has a bearing on the level of royalty applicable in this case is the range of royalties set in other Section 46(3) decisions and the value of the drug to which each of these decisions applied. He referred me, on the one hand to the Bayer decision (Bayer's Patent, Patent Office, 17 April 1986) in which a 30% royalty was set for a life-saving drug which had 70% of the market and compared this with the Harris application (Tanabe Seiyebu's Patent, Patent Office 16 September 1986) concerning diltiazem, a drug with a low market share and for which a royalty of 20% was set. It was common ground that such an approach was used in the Office

decision on metoprolol (Hassles Patent, 30 April 1987), but Mr Watson, for Upjohn, suggested that the approach was not valid and the metoprolol decision was inconsistent with other decisions of the Office and courts. I can accept Mr Watson's submission that the value of the drug was not a factor taken into account by the Patents Court or the Court of Appeal, for example, in the salbutamol case. It was not endorsed, but nor was it rejected and it is this not precluded from consideration here. Moreover, I do not accept the submission that, amongst Office decisions, the metoprolol decision is one on its own. I note, for example, that in Mr Tarnofsky's second office decision on the Bayer case (24 April 1986) he had this to say (page 5): "Nevertheless it" (the existence of another licence)" does provide some sort of marker which, together with the royalties which have been found for other pharmaceuticals, rules out of court the sort of figures proposed by Mr Watson." In my own decision on cephalexin (Eli Lilly's Patent, Patent Office, 15 April 1987), I said (pages 45-46)". "Taking all the factors into account that have been put before me and with due regard to the royalties which have been fixed for other pharmaceuticals I consider ..." (in each case the underlining has been done only for the purposes of the present decision). It is established that the royalty rate set in Section 46(3) proceedings should be that which would be agreed between a willing licensee and a willing licensor. The Section 41 type of calculation, of the licensors costs seems to me to lay slightly greater emphasis on what a willing licensor would wish to charge. To follow this pointer alone would be to substantially overlook the view of the

willing licensee. His view is more likely to be coloured by the commercial value of the drug and this in turn will depend to some extent on its medical value. I am satisfied therefore that both commercial and medical value are factors which I should take into account in these proceedings.

Turning now to the facts in this case, I note that triazolam is a sleeping pill and is one of a very large number of sleeping pills on the market. No less than twenty-five competitors of triazolam are listed in Mr Rogers' exhibit GRR19 and by its nature this is not an exhaustive list. Moreover a good indication of the competitors in the field is given in Mr Rogers' first declaration at paragraphs 16-26. Mr Tabatznik for GUK in his second declaration in the Upjohn proceedings, para 7.2 calls triazolam a "me too" drug, implying that it has no advantage over other sleeping pills.

This is contested by Mr Rogers in his second declaration, para 61, but he fails to point to any particular distinguishing property. Earlier, in his first declaration, para 21, Mr Rogers pointed to the short-half life of the drug and the attendant reduction in after-effects on waking, but I note that other drugs listed by Mr Rogers in this part of his evidence are also claimed to have minimal after-effects. The market for triazolam is estimated by Mr Tabatznik in his second declaration in the Upjohn proceedings, para 3.1, to be about £4 million. This is in broad agreement with sales figures in dollars given by Mr Jameyson for Upjohn. When compared with other drugs which have been the

Upjohn's brand name Halcion. Mr Tabatznik goes on to say that because of this "GUK and Upjohn will be competing in this market head-on, on a price basis only; there is no brand protection for "Halcion". This means that if a fixed sum royalty were imposed Upjohn could undercut GUK and would". Mr Watson, in argument, acknowledged that virtually 100 per cent of the market is now open to competition, but pointed out that in other cases where a brand name existed there was a free hospital market which in some cases was quite large (see, for example, the timolol case - Charles E Frossts Patent, Patent Office 27 May 1987). Mr Kon also made great play of the evidence given in Mr Rodgers' second declaration and, in particular, paragraphs 12-14 and 15 where Mr Rodgers says that "In order to preserve market share, Limited" (ie Upjohn)" will be forced to undercut Generics' price to wholesalers." However, as Mr Watson points out, this comment must be seen in context. Sofar as that is concerned I note that Mr Rodgers goes on to say that there will then be a price spiral and in paragraph 18 he finishes by saying that "I believe that the only way to prevent this spiral is to award a fixed rate royalty based on Limited's selling price." This, of course, is only a belief of Mr Rodgers and not a fact. It is, therefore, worthwhile to see whether there is any independent evidence as to whether there is likely to be a reduction in price through progressive lowering of prices by either party. I think there is a little. In another context Mr Kon referred me to the remarks of the minister, Mr Fowler, when speaking of the so called "white list" or "limited list", ie those drugs which can only be

prescribed generically, in Parliament on 21 February and 18th March 1985 (see Mr Tabatznik's fourth declaration in the Upjohn proceedings paragraph 3(a) and 3(d)).

I do not use Mr Fowler's statement as evidence of the Governments' intention when introducing the "white list". Merely as evidence of the opinion of the Secretary of State for Social Services, opinion which must be regarded at least as well-informed, of what the likely effect of the "white list" would be.

It seems to me to be that, having regard to the ministers' observations and to the fact that the drug cannot be prescribed by its brand name under the NHS, this is a case in which the temptation for the patentee Upjohn to get involved in price cutting is greater than in any other case that has come before this office even if a fixed rate royalty were to be imposed. Moreover, if the patentee does start to undercut the licensee and the royalty is a fixed price per unit quantity sold which has traditionally been based on the patentees current selling price, the licensee could be left high and dry with a high royalty that no willing licensee would accept. In reaching this conclusion I have due regard to the remarks of Lord Justice Dillon in the salbutamol case (Allen and Hanbury's Patent, Court of Appeal, 26 March 1987, page 24 H) where he said this

> "In this regard Lord Justice Dillon made the following comments: 'It is submitted by the Applicants, in relation

to the amount of the royalty as settled by the judge that it is unreasonably high and effectively means that they have acquired a licence of no practical use to them at all. Reference is made to the commentss of May LJ in his judgment on the earlier hearing in this Court in (1986) RPC at page 214 at lines 16-18. Whether or not, however, the Applicants can operate profitably under a licence on the terms settled by the judge must depend on the price at which they will sell their Salbutamol formulation. They cannot insist on a licence which will be profitable to them however low they may choose to fix their selling price, and however much they may choose to undercut the patentees, even, eg to the extent of fixing a price so low that they can sell profitably to the patentees' own licensees'".

I take this passage to mean that if, having considered all matters which can properly be taken into account, I arrive at a royalty level which is too high for the licensees to operate profitably, that is their misfortune. The level of royalty should not be lowered for this reason. But the situation which I have before me goes beyond this. In this case if I were to set a fixed price royalty at a level which I see as being fair and equitable in all normal circumstances, there is a distinct possiblity that it may not remain fair and equitable throughout the term of the licence. I have, therefore, considered maintaining the fixed price royalty as a means of providing certainty and stability in the run up to the end of the patentees monopoly but introducing a measure of protection for the

applicants as well. I have considered a regime wherein so long as the patentees selling price remains above that of the licensees' the royalty should be based on a fixed price per unit quantity sold but if at any time it should equal or go below that of the licensee then the royalty should, whilst the patentees selling price remains at that level, be based on a percentage of the licensees selling price. I arranged for this proposal which I was considering to be put to the patentees and the applicants in an official letter dated 28 August 1987 inviting comments on the drafting of appropriate clauses. In their responses dated 10 and 11 September 1987 respectively it was clear that such a compromise was not entirely acceptable to either party and moreover the patentees raised in my mind sufficient doubts about the effectiveness of such a proposal in achieving my desired objective, and its legality, that I decided not to pursue it further. In any event it was not an option fully argued at the hearing. I am nevertheless left with my finding of fact that the temptation for the patentees to get involved in a price cutting exercise is greater than in any other case of this type which has come before the office even if a fixed rate royalty were to be imposed. I therefore have concluded that the royalty should be based, as in the old Act Section 41 cases, on the licensees selling price, an uplift being applied to allow for any price differential between licensee and patentee. I am aware that I differ from Mr Justice Whitford in that he regarded a fixed price royalty as the better option. However, as I have indicated above I regard the circumstances of this case as different from any other case that has come before the office and Mr Justice

Whitford did comment in his salbutamol decision that the choice between fixed price royalty and a royalty based on the licensees selling price was one that "depends on the circumstances of each particular case".

Having now dealt with the Upjohn case I turn to the Takeda patent. Takeda do not have a selling price as they have not marketed triazolam. Thus it is not possible to set a royalty based either on a percentage of the patentees selling price or a fixed price per unit quantity sold which as I have said has traditionally been based on the patentees current selling price. Takeda are willing for the Upjohn selling price to be used but GUK may well not be. They are certainly not arguing for a fixed rate royalty based in the traditional manner in the Upjohn case or I assume in the Takeda case. I have also some doubts as to whether it would be right to fix a royalty base for Takeda which is in some way related to figures derived from Upjohn's current selling price. As was made clear by Mr Justice Falconer in his decision on this case dated 26 March 1987 at page 6,F-G the Office has to settle the terms of the licence in respect of each application. No precedent for determining the basis of royalty in one application on figures provided in another application has been brought to my attention.

What therefore is open to me? There is, of course, the option of a percentage of the licensees selling price, but what evidence or argument is there to support the view that I should adopt this

subject of Section 46(3) proceedings it represents a relatively small market, but it is to be noted that because triazolam is "white listed" by the DHSS and can therefore only be prescribed generically, the whole of this market is open to the generic companies. My conclusion is that triazolam is not a drug of any great medical value. It is not a life-saving drug as was nifedipine. It is a satisfactory sleeping draught with certain advantages. It is of short duration and, has a short half-life and is stated by Upjohn to have a minimal effect on intellectual performance. Looking at the properties of the sleeping draughts set out in Mr Rogers' first declaration it seems to me that which one you select may well depend on the circumstances. Some of the advantages put forward in triazolam's favour are not necessarily significant in particular types of patient eg elderly patients. There are other drugs which have a comparatively short half life and thus produce no hangover (see, for example, Hernineverin and Rohypnol Rogers first declaration paragraphs 18 and 23). Commercially triazolam has a relatively small market even though the whole of this is now generic. The evidence shows that to date Upjohn profits in this country have been very small by the standards of many drugs. Nevertheless I am faced with the fact that GUK wish to enter the market, which is an indication that the drug does have commerical value.

Taking matters in the round I conclude that triazolam is in the lower half of the scale of drugs measured in terms of its commercial and medical value which, were these the only factors to be considered, would suggest to me a royalty of about 22-24%,

that is in the lower half of the range set in other cases. This of course would represent the total royalty payable to a hypothetical single patentee who had sole rights in triazolam. I have yet to deal with the setting of a royalty independently for Takeda and Upjohn. For reasons that will emerge from the section headed "UPJOHN ROYALTY" this range of 22 to 24% will have to be lowered to 18-20% to take account of the relationship between the Takeda and Upjohn patents when one is assessing the royalty to be paid to Upjohn.

TAKEDA ROYALTY

These proceedings relate to only one drug, but their are two patents and two patentees. At the end of the day each of the patentees will have to grant the applicants a licence to market triazolam and I am therefore obliged to set a royalty rate independently for each patent. I will consider the Takeda royalty first.

Takeda are not in the usual situation of a patentee in Section 46(3) proceedings in that they do not market triazolam themselves in this country, although I note Mr Laredo's submission that they have taken steps to see that the patent is worked here by their licence agreement with Upjohn. In this country the Takeda patent has an earlier priority date than the Upjohn patent and so the Japanese company may reasonably claim to be the inventor of the whole of the group of compounds covered by the patent and to have appreciated their value as drugs of a sedative and traquilising

nature. Clearly they have incurred research and development costs in doing so and I have no evidence to suggest other than that they have made a valuable contribution to the understanding of that group of compounds. But I note that, although triazolam is one of the group, neither the compound nor its specific pharmaceutical activity is mentioned in the Takeda specification. Clearly, therefore, Upjohn or any other company or individual provided with the Takeda patent would have to do a very great deal of chemical, pharmacological and clinical research to arrive at a marketable triazolam formulation. Moreover, as Takeda have not sold the drug, they have not incurred any promotional expenditure. There can be no doubt that they have contributed to the development of the drug, triazolam, and the benefits which the public have derived from it, but their contribution must be seen as a fairly modest one, which would seem to merit a lower royalty figure than those normally set in Section 46(3) proceedings. There are four pointers as to what this figure might be. First there is the 4% royalty which Upjohn are presently paying Takeda under the licensing agreement between them. This coincides with the second pointer, the 4% already offered by GUK in their draft licence and supported by Mr Kon at this hearing. Then there are two higher pointers: the range of 23-42% calculated by Mr Nakamura of Takeda from his companies sales, R+D and promotional costs and the figure of around 14-15% submitted by Mr Laredo on the basis of a Section 41 calculation by Mr Allen for GUK, though I should make it clear that Mr Allen submits this calculation very much as a fall-back

position and does not concede its relevance to the facts of this case.

I have considerable difficulty in understanding Mr Nakamura's calculation. He uses a formula which, as far as I am aware, has never previously been used in Section 46 preceedings or Section 41 proceedings under the 1949 Act and seems to provide little justification for doing so. The formula differs from the traditional Section 41 calculation in several respects, but most notably in multiplying the percentage of R+D expenditure with respect to sales by a factor of 3, which, as far as I can see, he justifies on two grounds: (1) that it provides a royalty figure which is in line with those set in other licence decisions and (2) that it allows for the fact that research and development may be spread over several years. Neither of these reasons seems adequate to me. As indicated above, Takeda's position in these proceedings is quite different from that of the usual patentee and I see no reason to assume that their royalty should fall within the usual limits. The spread of R+D expenditure over several years seems to be adequately catered for by the spread of licence royalty income over several years and in my opinion needs no additional accounting. I do not think that I need say any more about Mr Nakamura's calculation, except to point out that it contains a figure for promotional expenses and this would not seem to be justified. Takeda have incurred no promotional expenses on triazolam.

Mr Laredo's Section 41 calculation, based on the evidence of Mr Allen, contains three elements: 10% for R+D expenditure, 2% (that is 20% of 10%) for loss of return on capital invested on those expenses and a further uplift of about 28% to account for the fact that the sales and R+D figures given by Takeda are for all activities of the company. Had figures been given for pharmaceutical sales and pharmaceutical R+D the ratio would have been higher. Although Mr Kon has questioned the basis of some of these figures I do not think that any of them is very surprising or is in question to any great extent. What is questioned is whether they are relevant to the circumstances of this case. Mr Laredo concedes that having calculated a royalty figure for Takeda in isolation I may wish to make a reduction to allow for the presence of the Upjohn patent and suggests a figure of 1% for this purpose.

I see Mr Laredo's calculation as being somewhat on the generous side. It may be that the R+D figures have been understated in the way that he has suggested, but it seems to me that they have also, and more significantly, been overstated because they relate to total R+D up to and after the production of a marketable product. In the present case Takeda have not produced a marketable product; that has been done by Upjohn. Takeda have carried out chemical and some pharmacological research to provide a patent for a group of chemical compounds and brief details of their pharmaceutical activity. But Upjohn have had to find the most marketable compound and take it through animal experiments and clinical trials etc to obtain a product licence from the

DHSS. I do not have sufficient evidence to put a precise figure on the percentage of research and development expenditure normally incurred by Takeda before and after patenting of a drug, but bearing in mind the relative time periods involved and the high cost of clinical testing towards a product licence, it seems unlikely to me that more than a third or a quarter of R+D expenditure would be incurred before patenting. A quarter would closely correspond to the figures actually incurred by Upjohn in their research and development figures for triazolam (see Exhibit RAJ2). A third or a quarter of Mr Laredo's figure of 14-15% would give a royalty figure in the range 3½ to 5%.

Beyond this I have little to go on. Mr Kon, Mr Watson and Mr Laredo, for different reasons, all agree that Upjohn should get a higher royalty than Takeda, but neither GUK or Upjohn have provided any detailed evidence to support any particular figure. I note that GUK have already offered 4% and it would not seem reasonable to me to settle below this figures. Although the licence agreement between Upjohn and Takeda is not in any way comparable with the situation between GUK and Takeda, the 4% figure under this agreement does seem relevant. First it is the figure which Upjohn would have had to pay Takeda if Upjohn had granted GUK a sublicence pursuant to their agreement with Takeda, which Upjohn could have done, if they had so wished (see Article 3 licence agreement dated 29 December 1987 Exhibit RAA5). Secondly, at the moment all triazolam sold in the UK is sold by Upjohn, who pay Takeda a 4% royalty on their sales. Entry of GUK into the market may increase the market size and/or replace some

of Upjohn's sales with GUK sales. In time the market may shrink because of factors not directly connected with this application but it will not shrink simply as a result of GUK's receiving a licence. Accordingly Takeda, unlike most patentees in Section 46(3) proceedings have nothing to loose by the granting of a licence, provided they receive from GUK a royalty which is at least as great as they are receiving at present from Upjohn. As they have nothing to lose, it is difficult to see how they can reasonably expect to gain an increased royalty. Takeda have made great play of the fact that they have priority over Upjohn. In the context of the present case and insofar as Takeda's royalty is concerned I do not consider this to be of any greater significance than to give Takeda the right to a royalty. The measure of that royalty is determined by the contribution that they have made to the development of triazolam formulations and the extent to which they must receive compensation from the licensee for that contribution. In the event I see the 4% figure in the Takeda Upjohn agreement as being in one respect the smallest royalty which I can award and in another respect the greatest. It matches the 4% offered by GUK and roughly accords with the 3½ to 5% which I derived above from the R+D calculation. As I have decided to base the Takeda royalty on GUK's selling price I do consider it appropriate to uplift the royalty to allow for the difference between the licensees selling price and the patentees selling price as was done in the old Section 41 calculations. The only difficultly is that the patentees do not have their own selling price. However, since the existing royalties that Takeda receive are from Upjohn I must take account

of the likely extent to which GUK may undercut Upjohn I therefore propose an uplift of 20%. Accordingly, I conclude that 4.8% (4%X1.2) is the royalty which GUK should pay Takeda for a licence to market triazolam under patent no. 1298364, the royalty to be calculated on the basis of the licensees selling price.

UPJOHN ROYALTY

I now turn to the royalty to be paid to Upjohn. The general arguments as to level of royalty in the Upjohn case I have referred to earlier. The detailed argument centered around the Section 41 approach under the 1949 Act following the decision in Geigy's Patent [1964] RPC 391. Both parties accept that such an approach can give an indication of the appropriate level of royalty though I think Mr Kon felt that I should place rather less reliance on it than did Mr Watson. No doubt the fact that the Section 41 calculation as set forth in Mr Jameyson's declaration gave figures for royalty of anywhere between and 40-50 per cent, figures far in excess of any awarded following full argument at a hearing either by the Office, the Patents Court or the Court of Appeal, had some influence upon Mr Kon's and Mr Watson's view of the relevance of this approach.

In accordance with the Section 41 approach Mr Jameyson put forward in his first declaration three elements which are to be added together in order to arrive at a royalty rate, and which cover contributions to the patentee's research costs, promotional

expenses and allow for a return on capital employed in these activities.

Research costs -

In these calculations the contribution made by this element is expressed as worldwide R&D as a percentage of world-wide sales. Argument in these cases usually centres around the question of whether or not certain items should be included in world-wide R&D and world-wide sales and whether like is being compared with like and this case is no exception. Mr Kon conceded on the basis of existing precedent that products licensed-in from third parties should be excluded from sales. On the basis of the figures given in confidential exhibit RAJ6 to Mr Jameyson's first declaration this would mean that the contribution made by research costs should be 20.3%.

The first area of real contention centered on the extent to which agricultural products, that is anything from seeds through to veterinary products, should be included in sales figures. Mr Jameyson says in his second declaration at paragraph 4 -

> "Whilst I accept, of course, that the veterinary or 'Animal health aspects' of the agricultural division have benefited from research and development in the human pharmaceutical field, agricultural research and development and sales are regarded by Upjohn as separate fields, and for this reason I did not feel it appropriate to include these figures. Only

a proportion of agricultural sales can be regarded as relating to animal health.."

Since it is conceded by Upjohn that animal health has benefited from human pharmaceutical research I think in this case it would be right to include veterinary sales but at the same time an element for veterinary R&D should be included in order that like may be compared with like. The necessary figures are provided in confidential exhibit RAJ8 and the contribution for R&D in the overall Section 41 calculation is reduced from 20.3% to 19.2%. Mr Kon did criticize the veterinary figures in that it was not clear as to which veterinary products benefit from human research but the effect is likely to be small and I regard the recalculation provided in exhibit RAJ8 as sufficient for the purpose.

The next area of contention is the sales figures "for bulk pharmaceutical chemicals". Mr Jameyson makes clear in paragraph 3 of his second declaration that he has excluded the sales figures for "bulk pharmaceutical chemicals, fine chemicals and contract manufacturing sales. Such sales, although set out in the Report as attributable to the Human Health Care group, relate primarily to using excess manufacturing capacity to manufacture in bulk for third parties .... No more than 30-40% are of products developed from Upjohn's overall research and development. However, as I excluded from the research and development figures in RAJ6 all research and development relating to these sales I submit that such sales are irrelevant." I am of the opinion that it is by no

means clear that bulk pharmaceutical products do not make a contribution to R&D. This is consistent with the view that Mr Tarnofsky took in the nifedipine case (Bayers Patent, Patent Office 17 April 1986) and that I took in the cephalexin case (Eli Lilly's Patent, Patent Office 15 April 1987). I have therefore decided to increase the world-wide sales figures given in confidential exhibit RAJ8 by 30% of the bulk chemical sales given in confidential exhibit RAJ7. The effect of this is to reduce the R&D contribution to royalty from 19.2% to 18.9%.

The next matter of dispute is the question of whether formulation costs should be included in the world wide R&D costs. In a number of cases such costs have been excluded from R&D on the basis that the licensee has to develop his own formulations and thus does not benefit from the patentees R&D work in this area. Mr Watson in argument suggested that there was no evidence to show that GUK are carrying out independent formulation work and suggested that the onus was upon GUK to show that they are not benefiting from the formulation work of Upjohn. I cannot accept this argument if anything it seems to me that the onus is the other way around. The normal rule in the Section 41 precedents (see Hoffman-La-Roche & Co AG's Patent [1973] RPC at page 610) is that formulation costs are not included. It seems to me that in the normal situation the licensee does not take the benefit of the patentees formulation costs and that is perhaps the reason why GUK's evidence is couched as it is in terms of what normally happens (see, for example Mr Tabatznik's second declaration in the Upjohn proceedings at paragraphs 7.1 and 7.2 and in

particular the statement at 7.2 that the best kept secrets of the pharmaceutical industry are the patent holder's formulations). There is certainly no evidence to suggest that Upjohn have made this know-how available. Some R&D will need to be done by GUK in this field in order to get their product licence. I do not accept the argument of Mr Watson based on Mr Rodgers' declaration para 53 which reads "From a simple analysis of Upjohn's Halcion tablets, Generics could readily ascertain the identities and proportion of all materials used. If Generics were to use similar excipients in similar proportions, it is likely that any DHSS preformulation study requirements would be waived." Firstly Mr Rodger's has only put forward an opinion as to what the DHSS might do. Secondly if what he has said is true then in many other cases formulation costs would not have been excluded and such is not the case. I consider that the normal rule should be followed and formulation costs should be excluded from R&D costs.

Having reached this conclusion the next matter I must deal with is how much I allow for formulation costs. Mr Jameyson at paragraph 52 of his first declaration suggests that a reduction of the research and development costs of 5 per cent would account for this and that is the only evidence we have. Such a figure is not out of line with the 4% allowed in the timolol case, (Charles E Frossts Patent, Patent Office 27 May 1987) per cent. I therefore propose to adopt the 5 per cent figure. This reduces the percentage allowance for R&D to 17.9%

Mr Kon finally drew my attention to the fact that no mention was made in the figures for research and development costs as to whether patent department costs, licensee income and world-wide information services have been included. The only evidence that I have on licensee income is that in 1985 licensee income was 7.2 million dollars. Mr Watson did offer and subsequently provided evidence to the effect that patent department costs were not included. He took issue that the matter of world wide information services had not been challenged by GUK in evidence. These items have been traditionally excluded from R&D costs but I do not think they amount to much and in view of the fact that patent department costs have already been excluded I am only prepared to round the figure of 17.9%, (arrived at by taking into consideration the other areas of dispute that I have dealt with), down to 17% in order to take these into account.

It is at this juncture that I consider that I should look at the effect of the Takeda patent in the Section 41 type calculation of the Upjohn royalty. In determining the allowance to be made in the Takeda calculation for R&D I suggested that so far as triazolam itself was concerned Takeda had only been involved in R&D up to patenting of the drug. Thus in order to allow for this I looked at the effect of lowering the royalty in proportion to the amount of time spent by Upjohn before and after patenting on triazolam R&D (see Exhibit RAJ2). I consider that this is the point at which Takeda's argument, on priority which they put very strongly, should be taken into account. Takeda do have the prior patent and up until the point in time at which Upjohn filed their

convention applications which established their priority, March and October 1969, Takeda were the leading patentee in this field of drugs and prior to that date much of what Upjohn was doing was duplicating research efforts already made by Takeda. It seems reasonable to me that GUK should not have to pay for the duplication of effort. I have no figures for what Upjohn normally spend on R&D pre-and post-filing of their patent applications over the whole field of their world-wide pharmaceutical activity. This would be what I would need if I were to look at this matter in exactly the same way as R&D in normal Section 41 calculations. However, unusually in this case I do have the specific figures for triazolam (see exhibit RAJ2) and these show approximately 25% of R&D costs arising before filing of their basic patent applications and 75% after. Thus in making an allowance for R&D in the normal Section 41 calculation I propose to take only 75% of the figure arrived at above namely 75% of 17% ie 12.75%.

Promotion expenditure element -

The main submission of Upjohn on this element of the calculation is that in the circumstances of the present case the patentees should get all their promotion costs and that their should be no discount for promotion of the brand name since almost the entire market is now generic and therefore open to GUK because of the existence of the "limited list". In confidential exhibit RAJ3 in detailing promotion costs over the period 1981-1985 Mr Jameyson distinguishes between "direct medical promotion" concerned with

educating the medical profession as to the merits of the drug and "other promotion" which he indicates at paragraph 50 of his declaration are the costs "of that which could be regarded as promoting the brand." These figures show approximately 77% of promotion costs devoted to "direct medical promotion" and 23% to "other promotion".

Mr Kon sought to persuade me that, despite the fact that the market for triazolam is now entirely generic, I should, nevertheless, not allow Upjohn all their promotion costs. Mr Kon relied on some observations of Mr Tollerfield in J R Geigy SA's Patent ([1964] RPC at page 400 line 44 - page 401 line 33) and he relied, I think, particularly on the passage at lines 18-32 on page 401:-

> "In deciding the question of to what extent the licensees should contribute to the cost of the promotion of the drug it must be remembered that the patentees' promotion activities are directed to two separate and distinct ends, the first is to educate the medical profession in the advantages, properties and use of imipramine as a drug, and this is an operation which is peculiar to the drug industry. The other consideration is the publicity campaign necessary to promote sales of the drug, which of course is the normal sales promotion common in any industry. The publicity campaign as distinct from medical promotion is one to which, in my view, the licensees should not be required to make a contribution. As to the medical promotion, the licensees

get the benefit of expenditure incurred in establishing the drug as such before they appeared on the scene. They must, therefore, make some contribution towards this, but although they find the drug established they must still convince the medical profession that their drug is medically the same, at least as good and a cheaper product than that of the patentees, and they must sell in competition with them. Apart from the fact that the drug is established as being suitable for the treatment of depression, the licensees also get some small benefit from the continuing activities of the patentees on the medical side."

However this passage must also be read in the light of Mr Justice Whitford's remarks in the more recent case Hoffman La Roche AG's Patents [1973] RPC beginning at page 625 line 42. He observes:-

"In so far as the advertising draws the attention of the relevant public to the fact that diazepam is an effective tranquilizer, it is a promotion of the invention for which no doubt the licensees should pay. In so far as it draws the attention of those who may wish to make purchases to the fact that a particular drug under a particular trade mark made by a particular manufacturer is the drug that they ought to get, the patentees are building up for themselves, very properly and very sensibly, a monopoly interest which will extend beyond the existence of these particular patents covering this particular product and, although the patentees are to be allowed to derive a reasonable advantage from

their patent rights, I cannot myself see any particular reason why licensees should be expected to pay for the building up of the patentees' reputation in the same field under a different guise or in a more general field.

The practice as illustrated by the cases shows that in considering the terms appropriate to the grant of licences under this subsection it has heretofore been thought right that those fixing the terms, when considering costs of promotion, should, if in any particular instance they thought it was appropriate, make some deduction on promotion costs put forward. I reject entirely the submission of the patentees that this approach is a wrong approach."

Mr Watson argued that in Mr Justice Whitford's decision in the Syntex case [1986] RPC at page 606, line 38 to page 607, line 4 he said that all promotion costs should be counted. I do not agree that that is the correct interpretation of that passage for the reasons given in Mr Tarnofsky's timolol decision (Charles E Frossts Patent, Patent Office 27 May 1987) pages 10 and 11 and that the Hoffman-La-Roche approach still applies. The difficult question, I think, so far as GUK is concerned is that now that prescription under the NHS by brand name is forbidden does this mean that GUK should make a contribution by way of increased royalty rate to the costs of promoting the brand name in a market formerly exclusive to the patentee and now open to GUK. I do not think they should. The patentees in fact get their contribution by virtue of the fact that this market is now

open to the applicant and if the applicant does make sales in it the patentees will get an increased amount of royaltly to the extent that GUK penetrate that market. Although white-listing reduces the value of brand name promotion to the patentees; it does not, so far as I can see, bestow any benefit on the licensee and therefore GUK should not have to pay for it.

Mr Kon at a late stage was permitted to put in evidence consisting of a sample of the Upjohn Halcion tablets (Exhibit SDK5 to Mr Kon's second declaration). This I believe, was I to show that it was distinctive and thus that if a patient prescribed triazolam was given a GUK tablet he would reject it and say "this is not the drug I usually have" ie. Mr Kon wished to show by this evidence and certain other evidence which he referred to, that despite the existence of the "limited list" there was some residual good will and reputation attached to Halcion packaging and presentation. Whatever he was trying to show the evidence, as Mr Watson implied, is very thin and I would need a lot more to show me what the actual situation is. However I do not think any of this matters as, in view of what I have said above, on brand name promotion I propose to allow GUK a 23% reduction on promotion which I understand from Exhibit RAJ3 to be that part of the promotion costs directed towards the brand name. Thus the percentage element in the royalty for promotion costs will be $\frac{77}{100} \times 16.6 = 12.8\%$

Before leaving the question of promotion costs I should deal with the "Van der Kroef" difficulty (see Rodgers first declaration paragraphs 27-34). In essence Upjohn have had to spend a very large amount of money on promotion particularly in the years 1980 and 1982 due to an adverse press. In the event the criticisms of the drug, at least at dosage levels promoted in this country, were unfounded. Mr Allen in his second declaration in the Upjohn proceedings suggests that this problem and the high costs consequently incurred could have been avoided, but evidence in support of this view is scant. On balance I consider that extra expense was unavoidable. It is in this very area of promoting the medical value and efficacy of a drug that the patentee is entitled to recover his promotion costs. The fact that due to circumstances beyond Upjohns control the costs have been high is GUK's misfortune but if Upjohn had not spent this money it is I think not unreasonable to suggest that GUK would not be here asking for a licence at all.

Return on capital and calculated Section 41 royalty rate -

I think both parties accepted that I was not likely to depart from the 20% uplift for the capital invested in the R & D costs and promotion costs now customary in office decisions in this field, although Mr Watson still maintained that it should be 22½%. I reject that submission and applying the figure of 20% I arrive at a royalty rate for Upjohn of 30.6% on the basis of a Section 41 calculation, $((12{\cdot}15 + 12{\cdot}8) \times 1{\cdot}2)\%$.

Effect of commercial and medical value of drug on royalty rate -

As I indicated earlier I consider that in assessing royalty rate the commercial and medical value of a drug should be taken into account and I concluded that triazolam was in the lower half of the range and that on previous awards this would indicate a royalty for a triazolam of the order of 22-24%, which represent a royalty of 18-20% to Upjohn when Takeda's royalty is taken into account. However, having determined a royalty for Takeda of 4% and on a Section 41 basis a royalty of almost 31% for Upjohn, this means that GUK would be paying a total royalty of almost 35%, about 5% higher than any other hitherto awarded by the office in the pharmaceutical field. This cannot be right. I consider this a case where Mr Justice Whitford's endorsement of Mr Tarnofsky's observation that "Section 41 cases can be said to give some sort of guidance" (my emphasis) must come into play. I also think it must be right that the figure of 18-20% for Upjohn is too low. The Section 41 calculation does properly give emphasis to the problems created by the Van der Kroef difficulty. I would therefore expect the figure of 18-20% to be exceeded but by how much?

A survey of previous office decisions in these licence of right cases in which a Section 41 calculation has been used and a specific figure for the promotion element percentage given shows that the average contribution of promotion costs is about 9.2%. In this case a figure of 12.8% was arrived at which no doubt was in large measure due to the Van der Kroef difficulty. This is

roughly 3.6% higher than the average contribution in past cases and when multiplied by the factor of 1.2 to allow for return on capital would give an additional royalty of 4.3%. When added to my estimated royalty on an average case, 18-20% allowing for commercial and medical value, this gives a royalty figure of 22.3 to 24.3%. This is still short of my actual figure achieved by a Section 41 calculation of 30.6%.

This is the stage at which I consider that what I will call the Takeda factor, comes into play a second time. I am of the opinion that a willing licensee would say "Yes 30.6% is fine if you were still having to pay Takeda a royalty of 4% on your selling price - but you are not - since you decided not to sub-licence and I have got to pay that money to Takeda myself". In these circumstances I consider that a willing licensor would agree to a reduction in royalty of 4% and would thus agree to 26.6%. It is for exactly the same reason that I lowered my estimated value for an average drug of comparitively low commerical and medical value to 18-20%.

Thus I now have my own estimated royalty taking into account commerical and medical value of the drug and the Van der Kroef difficulty of 22.3 to 24.3% and a royalty arrived at by carrying out a Section 41 calculation and not taking specific account of the commercial and medical value of the drug of 26.6%. Since both are really guides as to the correct level of royalty I don't think it would be unreasonable to split the difference. I therefore set the royalty at $\frac{24.3 + 26.6}{2}\%$ = 25.5%. Since I have

decided upon a royalty based on the licensees selling price, as with the Takeda royalty, I propose to give an uplift of 20% to allow for a possible differential between the patentees and licensees selling price of 20%. The net result is to give a royalty rate for Upjohn of 30.6% based on the licensees selling price.

IMPORTATION

The question of importation can be dealt with fairly shortly. In Mr Rogers first declaration paragraphs 11 and 12, it is made clear that the triazolam which Upjohn (UK) is selling at home and abroad is manufactured as raw material in France, formulated into tablets in Belgium and only packaged in the United Kingdom. Mr Tabatznik in his third declaration in the Upjohn proceedings indicates that his company, GUK, wishes to import triazolam both as bulk raw material and in final dosage form from Italy and also, possibly, Australia. This is opposed by the patentees (see Armitage first declaration paragraph 136) except for EEC countries where Upjohn has parallel patent protection. Importation from countries such as Italy (and, Mr Watson added in argument, Spain and Portugal) where drug patent protection was not available at the relevant time, is opposed on the ground that the importer has not had to pay R&D costs and, in consequence, can unfairly undercut Upjohn's UK selling price. Importation from outside the EEC was opposed by Mr Watson on the ground that it would discriminate against an EEC manufacturer. According to Mr Watson, Upjohn are to be considered as an EEC manufacturer,

not only because they make triazolam in France, but also because they are a large UK manufacturer of other drugs, employing labour and contributing to the UK economy. These arguments were considered by Mr Tarnofsky in the timolol case (Charles E Frosst, Patent, Patent Office, 27 May 1987) and were rejected. For the same reasons I reject them in this case. Mr Laredo did not argue the importation point. The same reasoning applies to the Takeda licence with the additional factor that Takeda do not manufacture triazolam anywhere. Accordingly I propose to allow GUK to import triazolam and triazolam formulations into the UK under both licence agreements.

OTHER LICENCE PROVISIONS

Upjohn -

I will now move on to the remaining licence provisions in the Upjohn case. At the hearing GUK and Upjohn consented to file a draft licence agreed between them. Where they could not agree two alternative forms would be submitted. This draft licence would contain two options for royalty basis (i) a fixed price per unit quantity sold and (ii) a percentage of the licensee's selling price. The remaining points of difference between the parties I deal with briefly as follows using the draft submitted by the parties on 17 August 1987.

(1) The first point that arises is whether GUK are entitled to sell, supply or otherwise dispose of triazolam, the compound, as

opposed to pharmaceutical formulations containing it. Such a requirement first appeared in the alternative draft licence put forward by GUK on 17 August 1987 and Upjohn have not had the opportunity to put forward any arguments or evidence on this point. Such a requirement was not hinted at either in the pleadings or the evidence. I therefore do not propose to grant GUK a licence including such a provision. I therefore adopt Upjohn's draft for the grant clause save that GUK also asked that in the grant clause they be permitted to conduct trials and experiments incidental to their licensed activities. This was foreshadowed in paragraph 4 of their pleadings coupled with clause 2 of their originally filed draft licence. Despite Upjohns objections I propose to accede to this request.

(2) Upjohn have asked for a clause seeking the licensees cooperation in seeking an agreement with the Inland Revenue that royalty payments should be made without deduction of tax. Such a clause has not been included in licences previously granted by the Office and I do not propose to include it. The parties can settle this point quite independently with the Inland revenue.

(4) Clause 4.1 concerning quality control I reject for the reasons given in my cephalexin decision (Eli Lilly's Patent, Patent Office 15 April 1987). I also reject clauses 4.4 to 4.7 for similar reasons. The licensor has his protection under existing law and should not demand in these proceedings more than the law gives him. Clause 4.2, however, I do consider necessary if only as a warning to the purchaser. It should nevertheless be

simplified so that it merely requires the licensee to indicate the patent number and the fact that he manufactures under licence.

(5) Mr Watson did seek a payment guarantee clause but he acknowledged that the Office had not to date granted such a clause and was unlikely to do so. He therefore did not press the matter.

(6) In the latter part of Clause 7.1 Upjohn seek to prevent GUK from selling formulations to another party where they know or suspect they are to be resold outside the UK. GUK oppose this limitation as being contrary to EEC law. I am not aware of such a clause being inlcuded in other Section 46(3) licences and I have omitted it from the present licence.

Takeda -

Takeda indicated that subject to the removal of certain clauses which I have not included in any event they will accept a similar licence subject to appropriate amendment to reflect the fact that a different patent is concerned.

Taking into account the various matters set out in this decision, I order the grant of licences to Takeda and Upjohn in the terms set out in the two licences appended to this decision.

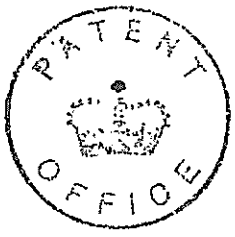
None of the parties has asked for costs and I therefore make no award.

Dated this 28th day of September 1987

M F Vivian

Superintending Examiner, acting for the Comptroller

PATENT OFFICE



UPJOHN LICENCE

T H I S A G R E E M E N T is made the day of 1987

B E T W E E N:

(1) THE UPJOHN COMPANY a corporation incorporated under the laws of the State of Delaware, USA, whose principal place of business is at 7000 Portage Road, Kalamazoo, Michigan 49001, USA, ("the Licensor") and

(2) GENERICS (UK) LIMITED a company incorporated under the laws of England whose registered office is at Station Close, Potters Bar, Herts EN6 1TL, England ("the Licensee")

W H E R E A S

(A) The Licensor is the registered proprietor of the Patent which covers the active ingredient referred to herein as Compound

(B) The Patent is a new existing patent under Schedule 1, Patents Act 1977 and the Licensee has made application to the Licensor for a licence of right under the Patent pursuant to Schedule 1 and Section 46, Patents Act 1977.

(C) The Licensor has agreed to grant this licence of right to the Licensee to manufacture, use and sell the Formulations under the Patent in the United Kingdom upon the terms and conditions of this Agreement.

N O W IT IS HEREBY A G R E E D as follows:-

1. Definitions

In this Agreement and in the Recitals and Schedules hereto the following words shall have the meanings following, namely:-

1.1 "the Patent" means United Kingdom patent number 1,291,631

1.2 Compound means 8-chloro-1-methyl-6-phenyl-4H-s-triazolo [4, 3-a] [1,4] benzodiazepine

1.3 "the Formulations" means the following pharmaceutical formulations:-

1.3.1 "Low Dose" : tablets containing approximately 0.125 mg of Compound

1.3.2 "High Dose" : tablets containing approximately 0.250 mg of Compound

1.4 "Holding Company" and "Subsidiary" shall have the meanings ascribed to them by Section 736, Companies Act 1985

1.5 "the Takeda Patent" means United Kingdom patent number 1,298,364

1.6 "Commencement Date" means 28th September 1987 being the date upon which Comptroller General of Patents and Trade Marks issued his decision in the application by the Licensee for a licence of right under the Patent

1.7 "Accounting Period" means the period of three calendar months commencing on the Commencement Date and at three monthly intervals thereafter

1.8 "Net Invoice Price" means

(a) in respect of Formulations sold by or on behalf of the Licensee in the ordinary course of business to an independent customer at arm's length, the total amount invoiced by the Licensee in respect of the product, less sales and excise taxes (including value added tax) and duties, if any, as are included in the invoice price; and

(b) in the case of Formulations disposed of in any other way, the gross invoice price, less only the relevant deductions set out above, which would have been charged on an equivalent sale at arm's length.

1.9 It is hereby declared that any sales or other supplies by the Licensee to any of its holding companies from time to time and any subsidiaries of its holding companies [the terms "holding company" and "subsidiaries" being as defined in section

736 Companies Act 1985] shall not be treated as sales or supplies to an independent customer at arm's length within Clause 1.8 (a) above.

2. Grant

2.1 The Licensor hereby grants to the Licensee the non-exclusive right and licence under the Patent to manufacture, import and use Compound or the Formulations in or into in the United Kingdom and to sell supply or otherwise dispose of Formulations in the United Kingdom during the currency of this Agreement. The Licensee is also permitted to conduct trials and experiments incidental to these licensed activities.

2.2 Nothing in this Licence shall be construed as granting any right to the Licensee to do any act under the Takeda Patent or as granting any right to the Licensee to sell supply or otherwise dispose of Compound in the United Kingdom.

2.3 The Licensor makes no warranty or other representation that manufacture use and sale of the Formulations in the United Kingdom by the Licensee will not infringe the Takeda Patent.

3. Royalty and Accounting

3.1 The Licensee shell pay in sterling to the Licensor a royalty on each tablet of the Formulations imported, manufactured, used or sold by the Licensee during the currency of the Agreement.

3.2 Subject to Clause 6.4(d), the royalties shall be at the rate of 30.6% of the Net Invoice Price.

3.3 No more than 15 days within the end of each Accounting Period and Licensee shall give the Licensor a full account:

(1) of all importation of Compound
(2) of all importation of Formulations
(3) of all manufacture of Compound
(4) of all manufacture of Formulation
(5) of all Formulation sold in, supplied in, removed from the United Kingdom or otherwise disposed of

in respect of that Accounting Period together with a statement of the royalty due in respect of that Accounting Period, such statement to be accompanied by a remittance to the Licensor in pounds sterling for the sum shown to be due.

3.4 If the Licensor fails to make payment of any royalty when due the Licensor may require the Licensee to pay interest calculated on a daily basis at the rate of Lloyds Bank plc base rate from time to time plus 2% per annum until payment in full whether before or after Judgment.

3.5 The Licensee shall if so required by the Licensor permit the Licensor upon reasonable notice at its own expense to have an independent chartered accountant of its own selection examine all relevant books and records of accounts (including information contained in computer readable form) and to take copies of such books and records to determine whether all appropriate accounting and payments have been made.

3.6 The Licensee shall keep at its usual place of business in the United Kingdom complete and accurate books and records of all dealings in Compound and Formulations including, without prejudice to the generality of the foregoing, full particulars of:

(1) all Compound and Formulations manufactured under this Licence and manufacturing batch numbers thereof and all batch records relating thereto.

(2) all Compound and Formulations imported under this Licence and importation batch numbers thereof and batch and importation records relating thereto.

(3) all the Formulations sold in, supplied in, removed from the United Kingdom or otherwise disposed of and where such sales, supplies, removals or disposals are not at full arms' length, the actual terms of transactions and any associated transactions.

4. Formulations

4.1 All packaging of the Products sold by the Licensee hereunder shall be marked with the Patent number and a statement that the Products are manufactured and sold by the Licensee under licence from the Licensor.

4.2 The Licensee shall indemnify and hold the Licensor harmless from all claims, demands, liabilities costs and expenses which may be made or alleged against or incurred by the Licensor arising out of the manufacture, use and sale of Compound and the Formulations by the Licensee and this indemnity shall continue in full force and effect notwithstanding the termination or expiry of this Agreement.

5. Formal Licence

5.1 The Licensor shall upon request from the Licensee execute a formal licence under the Patent in the form set out in Schedule 1 hereto which shall be registered at the United Kingdom Patent

Office. Any such formal licence shall operate subject to the terms of this Agreement.

6. Term and Termination

6.1 Subject to the remaining sub-clauses of this clause, this Agreement shall commence on the Commencement Date and continue in force until the expiry of the Patent.

6.2 The Licensor may terminate this Agreement by serving written notice on the Licensee:

(a) if the Licensee shall have failed to pay royalties due within 60 days of the due date or shall have acted in breach of this agreement and in the case of a breach capable of remedy shall have failed to cure the same within 30 days after receiving a written notice specifying the breach and requiring its remedy, or

(b) if the Licensee shall have entered into liquidation (otherwise than for the purposes of reconstruction or amalgamation) or shall have had a receiver appointed over any part of its assets, or

(c) come under the direct or indirect or de facto direction or control of any other company operating in the pharmaceutical field.

6.3 On termination of this Agreement under Clause 6.2(a) or (b) the Licensee shall not sell, supply, remove from the United Kingdom or otherwise dispose of any Compound or Formulations in its possession, custody, power or control. Within 14 days of such termination the Licensee shall deliver up to the Licensor for destruction all Compound and Formulations in its possession, custody, power or control.

6.4 On termination of this Agreement under Clause 6.2(c) above or on expiry of the Patent the Licensee.

(a) may sell, supply, remove from the united Kingdom or otherwise dispose of any Formulations which are in stock at the date of termination

(b) shall account to the Licensor within 30 days of the date of termination in respect of Formulations

(i) sold, supplied, removed from the United Kingdom or otherwise disposed of save by way of destruction since the end of the last Accounting Period; and

(ii) in stock at the date of termination whether or not sold [such Formulations in stock hereinafter referred to as "Stock Formulations"]

(c) account to the Licensor for all Compound not converted into Formulations and either

(i) deliver up such Compound to the Licensor for destruction or

(ii) convert such Compound into Formulations [such converted Compound hereinafter also referred to as "Stock Formulations"]

(d) shall pay to the Licensor within 30 days of termination royalty in respect of Stock Formulations of 30.6 per cent of the mean average Net Invoice Price charged by the Licensee during the period of 6 months prior to termination. Such mean average Net Invoice Price to be calculated by dividing the total amount invoiced by the Licensee [less such deductions as are described in Clause 1.8(a)] in respect of each of High Dose Formulations and Low Dose Formulations during such period by the number of tablets of High Dose Formulations and Low Dose Formulations respectively sold by the Licensee during such period.

6.5 The provisions of Clause 3 shall survive termination for so long as may be necessary to allow proper accounting for all royalties due and any rights or remedies accrued up to the date of termination shall not be affected by termination.

7. General

7.1 The Licensee shall not sell the Formulations outside of or export the same from the United Kingdom to any country in which a patent corresponding to the Patent shall be in force.

7.2 This Licence is personal to the Licensee and the Licensee shall not assign, mortgage, charge or make over this Agreement or any part hereof without the express prior written consent of the Licensor and the Licensee shall not grant or purport to grant any sublicence hereunder or subcontract any of its rights or obligations hereunder without the prior express written consent of the Licensor.

7.3 Clause headings are for reference only and do not form part of this Agreement for the purposes of construction.

7.4 No relaxation forbearance delay or indulgence by the Licensor in enforcing any of the terms and conditions of this Agreement or the granting of any time by the Licensor shall prejudice affect or restrict the rights and powers of the Licensor nor shall any waiver by the Licensor of any breach hereof operate as a waiver of any subsequent or any continuing breach hereof.

7.5 No amendment or other variation to this Agreement shall be effective unless it is in writing is dated and is signed by an authorised representative of each of the parties hereto.

7.6 Any notice or other document to be given hereunder shall be given by sending the same by personal delivery, registered post, cable, telex or telecopier to the address of the relevant party set out in this Agreement or to such other address as such party may have notified to the other and notices posted to an address in another country shall be sent by air mail. Any notices sent by post shall be deemed (in the absence of any evidence of early receipt) to have been delivered 72 hours after dispatch and in proving the fact of dispatch it shall be sufficient to show that the envelope containing such notice was properly stamped, addressed and posted. Any notice delivered personally or sent by cable, telex or telecopier shall be deemed to be delivered on the day of its dispatch.

7.7 This Agreement shall be governed by and construed in accordance with the laws of England.

A S W I T N E S S the hands of the duly authorised representatives of the parties hereto the day and year first above written.

signed by }

}

in the presence of:- }

for and on behalf of }
THE UPJOHN COMPANY in }
the presence of:- }

Signed by }
}
for and on behalf of }
GENERICS (UK) LIMITED }

SCHEDULE 1

(Form of Patent Licence)

BY THIS LICENCE The Upjohn Company of 7000 Portage Road, Kalamazoo, Michigan 49001, USA ("the Licensor") HEREBY GRANTS to GENERICS (UK) LIMITED of Station Close, Potters Bar, Herts EN6 1TL ("the Licensee") in respect of Patent No 1291631 of which it is the registered proprietor the non-exclusive licence as from 28th September 1987 to manufacture, use and sell Formulations incorporating the product described in Claim 4 of the Patent to the intent that such licence shall endure (unless sooner determined by or pursuant to an agreement between the Licensor and the Licensee) until the date of expiry of the Patent SUCH LICENCE being SUBJECT to and with the BENEFIT of an Agreement dated the day of 1987 and made between the Licensor and the Licensee.

I N W I T N E S S whereof this Licence is executed to this day of One thousand nine hundred and eighty-seven.

SIGNED, SEALED AND }
DELIVERED by }
}
for and on behalf of }
THE UPJOHN COMPANY }
in the presence of:- }

SIGNED, SEALED AND }
DELIVERED by }
}
for and on behalf o }
GENERICS (UK) LIMITED }
in the presence of:- }

TAKEDA LICENCE

MV3AAF

T H I S A G R E E M E N T is made the day of 1987

B E T W E E N:

(1) TAKEDA CHEMICAL INDUSTRIES LIMITED a corporation incorporated under the laws of Japan, whose principal place of business is at 17/85 Jusohonmachi 2-chome, Yodogawu-Ku, O-aka 532, Japan, (the Licensor) and

(2) GENERICS (UK) LIMITED a company incorporated under the laws of England whose registered office is at Station Close, Potters Bar, Herts EN6 1TL, England ("the Licensee")

W H E R E A S

(A) The Licensor is the registered proprietor of the Patent which covers the active ingredient referred to herein as Compound.

(B) The Patent is a new existing patent under Schedule 1, Patents Act 1977 and the Licensee has made application to the Licensor for a licence of right under the Patent pursuant to Schedule 1 and Section 46, Patents Act 1977.

(C) The Licensor has agreed to grant this licence of right to the Licensee to manufacture, use and sell the Formulations under the Patent in the United Kingdom upon the terms and conditions of this Agreement.

N O W IT IS HEREBY A G R E E D as follows:-

1. Definitions

In this Agreement and in the Recitals and Schedules hereto the following words shall have the meanings following, namely:-

1.1 "the Patent" means United Kingdom patent number 1,298,634

1.2 Compound means 8-chloro-1-methyl-6-phenyl-4H-s-triazolo [4, 3-a] [1,4] benzodiazepine

1.3 "the Formulations" means the following pharmaceutical formulations:-

1.3.1 "Low Dose" : tablets containing approximately 0.125 mg of Compound

1.3.2 "High Dose" : tablets containing approximately 0.250 mg of Compound

1.4 "Holding Company" and "Subsidiary" shall have the meanings ascribed to them by Section 736, Companies Act 1985

1.5 "the Upjohn Patent" means United Kingdom patent number 1,291,631

1.6 "Commencement Date" means 28th September 1987 being the date upon which the Comptroller General of Patents and Trade Marks issued his decision in the application by the Licensee for a licence of right under the Patent

1.7 "Accounting Period" means the period of three calendar months commencing on the Commencement Date and at three monthly intervals thereafter

1.8 "Net Invoice Price" means

(a) in respect of Formulations sold by or on behalf of the Licensee in the ordinary course of business to an independent customer at arms' length, the total amount invoiced by the Licensee in respect of the Product, less sales and excise taxes (including value added tax) and duties, if any, as are included in the invoice price; and

(b) in the case of Formulations disposed of in any other way, the gross invoice price, less only the relevant deductions set out above, which would have been charged on an equivalent sale at arms' length.

1.9 It is hereby declared that any sales or other supplies by the Licensee to any of its holding companies from time to time and any subsidiaries of its holding companies [the terms "holding company" and "subsidiaries" being as defined in section 736 Companies Act 1985] shall not be treated as sales or supplies to an independent customer at arm's length within Clause 1.8 (a) above.

2. Grant

2.1 The Licensor hereby grants to the Licensee the non-exclusive right and licence under the Patent to manufacture, import and use Compound or the Formulations in or into in the United Kingdom and to sell supply or otherwise dispose of Formulations in the United Kingdom during the currency of this Agreement. The licensee is also permitted to conduct trials and experiments incidental to these licensed activities.

2.2 Nothing in this Licence shall be construed as granting any right to the Licensee to do any act under the Upjohn Patent or as granting any right to the Licensee to sell supply or otherwise dispose of Compound in the United Kingdom.

2.3 The Licensor makes no warranty or other representation that manufacture use and sale of the Formulations in the United Kingdom by the Licensee will not infringe the Upjohn Patent.

3. Royalty and Accounting

3.1 The Licensee shall pay in sterling to the Licensor a royalty on each tablet of the Formulations imported, manufactured, used or sold by the Licensee during the currency of this Agreement.

3.2 Subject to Clause 6.4(d), the royalties shall be at the rate of 4.8 per cent of the Net Invoice Price.

3.3 No more than 15 days within the end of each Accounting Period - the Licensee shall give the licensor a full account:

(1) of all importation of Compound

(2) of all importation of Formulations

(3) of all manufacture of Compound

(4) of all manufacture of Formulations

(5) of all Formulations sold in, supplied in, removed from the United Kingdom on otherwise disposed of

in respect of that Accounting Period together with a statement of the royalty due in respect of that Accounting Period, such statement to be accompanies by a remittance to the Licensor in pounds sterling for the sum shown to be due.

3.4 If the Licensor fails to make payment of any royalty when due the Licensor may require the Licensee to pay interest calculated on a daily basis at the rate of Lloyds Bank plc base rate from time to time plus 2% per annum until payment in full whether before or after Judgment.

3.5 The Licensee shall if so required by the Licensor permit the Licensor upon reasonable notice at its own expense to have an independent chartered accountant of its own selection examine all relevant books and records of accounts (including information contained in computer readable form) and to take copies of such books and records to determine whether all appropriate accounting and payments have been made.

3.6 The Licensee shall keep at its usual place of business in the United Kingdom complete and accurate books and records of all dealings in Compound and Formulations including, without prejudice to the generality of the foregoing, full particulars of:

(1) all Compound and Formulations manufactured under this Licence and manufacturing batch numbers thereof and all batch records relating thereto.

(2) all Compound and Formulations imported under this Licence and importation batch numbers thereof and batch and importation records relating thereto.

(3) all the Formulations sold in, supplied in, removed from the United Kingdom or otherwise disposed of and where such sales, supplies, removals or disposals are not at full arms' length, the actual terms of transactions and any associated transactions.

4.1 All packaging of the Products sold by the Licensee hereunder shall be marked with the Patent number and a statement that the Products are manufactured and sold by the Licensee under licence from the Licensor.

4.2 The Licensee shall indemnify and hold the Licensor harmless from all claims, demands, liabilities costs and expenses which may be made or alleged against or incurred by the Licensor arising out of the manufacture, use and sale of Compound and the Formulations by the Licensee and this indemnity shall continue in full force and effect notwithstanding the termination or expiry of this Agreement.

5. Formal Licence

5.1 The Licensor shall upon request from the Licensee execute a formal licence under the Patent in the form set out in Schedule 1 hereto which shall be registered at the United Kingdom Patent Office. Any such formal licence shall operate subject to the terms of this Agreement.

6. Term and Termination

6.1 Subject to the remaining sub-clauses of this clause, this Agreement shall commence on the Commencement Date and continue in force until the expiry of the Patent.

6.2 The Licensor may terminate this Agreement by serving written notice on the Licensee:

(a) if the Licensee shall have failed to pay royalties due within 60 days of the due date or shall have acted in breach of this agreement and in the case of a breach capable of remedy shall have failed to cure the same within 30 days after receiving a written notice specifying the breach and requiring its remedy, or

(b) if the Licensee shall have entered into liquidation (otherwise than for the purposes of reconstruction or amalgamation) or shall have had a receiver appointed over any part of its assets, or

(c) come under the direct or indirect or de facto direction or control of any other company operating in the pharmaceutical field.

6.3 On termination of this Agreement under Clause 6.2(a) or (b) the Licensee shall not sell, supply, remove from the United Kingdom or otherwise dispose of any Compound or Formulations in its possession, custody, power or control. Within 14 days of such termination the Licensee shall deliver up to the Licensor for destruction all Compound and Formulations in its possession, custody, power or control.

6.4 On termination of this Agreement under Clause 6.2(c) above or on expiry of the Patent the Licensee.

(a) may sell, supply, remove from the united Kingdom or otherwise dispose of any Formulations which are in stock at the date of termination

(b) shall account to the Licensor within 30 days of the date of termination in respect of Formulations

(i) sold, supplied, removed from the United Kingdom or otherwise disposed of save by way of destruction since the end of the last Accounting Period; and

(ii) in stock at the date of termination whether or not sold [such Formulations in stock hereinafter referred to as "Stock Formulations"]

(c) account to the Licensor for all Compound not converted into Formulations and either

(i) deliver up such Compound to the Licensor for destruction or

(ii) convert such Compound into Formulations [such converted Compound hereinafter also referred to as "Stock Formulations"]

(d) shall pay to the Licensor within 30 days of termination a royalty in respect of Stock Formulations of 4.8 per cent of the mean average Net Invoice Price charged by the Licensee during the period of 6 months prior to termination. Such mean average Net Invoice Price to be calculated by dividing the total amount invoiced by the Licensee [less such deductions as are described in Clause 1.8(a)] in respect of each of High Dose Formulations and Low Dose Formulations during such period by the number of tablets of High Dose Formulations and Low Dose Formulations respectively sold by the Licensee during such period.

6.5 The provisions of Clause 3 shall survive termination for so long as may be necessary to allow proper accounting for all royalties due and any rights or remedies accrued up to the date of termination shall not be affected by termination.

7. General

7.1 The Licensee shall not sell the Formulations outside of or export the same from the United Kingdom to any country in which a patent corresponding to the Patent shall be in force.

7.2 This Licence is personal to the Licensee and the Licensee shall not assign, mortgage, charge or make over this Agreement or any part hereof without the express prior written consent of the Licensor and the Licensee shall not grant or purport to grant any sublicence hereunder or subcontract any of its rights or obligations hereunder without the prior express written consent of the Licensor.

7.3 Clause headings are for reference only and do not form part of this Agreement for the purposes of construction.

7.4 No relaxation forbearance delay or indulgence by the Licensor in enforcing any of the terms and conditions of this Agreement or the granting of any time by the Licensor shall prejudice affect or restrict the rights and powers of

the Licensor nor shall any waiver by the Licensor of any breach hereof operate as a waiver of any subsequent or any continuing breach hereof.

7.5 No amendment or other variation to this Agreement shall be effective unless it is in writing is dated and is signed by an authorised representative of each of the parties hereto.

7.6 Any notice or other document to be given hereunder shall be given by sending the same by personal delivery, registered post, cable, telex or telecopier to the address of the relevant party set out in this Agreement or to such other address as such party may have notified to the other and notices posted to an address in another country shall be sent by air mail. Any notices sent by post shall be deemed (in the absence of any evidence of early receipt) to have been delivered 72 hours after dispatch and in proving the fact of dispatch it shall be sufficient to show that the envelope containing such notice was properly stamped, addressed and posted. Any notice delivered personally or sent by cable, telex or telecopier shall be deemed to be delivered on the day of its dispatch.

7.7 This Agreement shall be governed by and construed in accordance with the laws of England.

A S W I T N E S S the hands of the duly authorised representatives of the parties hereto the day and year first above written.

signed by }
}
for and on behalf of }
TAKEDA CHEMICAL }
INDUSTRIES LIMITED }
in the presence of:- }

Signed by }
}
for and on behalf of }
GENERICS (UK) LIMITED }

SCHEDULE 1

(Form of Patent Licence)

BY THIS LICENCE Takeda Chemical Industries Limited of 17/85 Jusohonmachi 2-chome, Yodogawa-Ku, Osaka 532, Japan ("the Licensor") HEREBY GRANTS to GENERICS (UK) LIMITED of Station Close, Potters Bar, Herts EN6 1TL ("the Licensee") in respect of Patent No 1298634 of which it is the registered proprietor the non-exclusive licence as from 28th September 1987 to manufacture, use and sell Formulations incorporating the product described in Claim 4 of the Patent to the intent that such licence shall endure (unless sooner determined by or pursuant to an agreement between the Licensor and the Licensee) until the date of expiry of the Patent SUCH LICENCE being SUBJECT to and with the BENEFIT of an Agreement dated the day of 1987 and made between the Licensor and the Licensee.

I N W I T N E S S whereof this Licence is executed to this day of One thousand nine hundred and eighty-seven.

SIGNED, SEALED AND }
DELIVERED by }
}
for and on behalf of }
TAKEDA CHEMICAL }
INDUSTRIES LIMITED }
in the presence of:- }

SIGNED, SEALED AND }
DELIVERED by }
}
for and on behalf o }
GENERICS (UK) LIMITED }
in the presence of:- }