PATENTS ACT 1977 BL O/049/86

IN THE MATTER OF an application under Section 46(3) by Generics (UK) Ltd for settlement of terms of a licence of right in respect of Patent No 1173862 in the name of Bayer AG.

DECISION

Patent No 173862 is dated 20 March 1968 and is therefore a new existing patent as defined by paragraphs 3(1)(a) and (b) of Schedule 1 of the Patents Act 1977. According to paragraphs 4(1) and 4(2)(c) of the Schedule the term of the patent is extended from 16 to 20 years and, during the extension, licences under the patent are available as of right. The parties have been unable to agree the terms of a licence and the prospective licensees have therefore made the present application for settlement of terms by the comptroller.

The matter came to a hearing before me on 17, 18, 19 and 20 December 1985 when Mr R Jacob QC and Mr H Laddie appeared as counsel for the patentees, and Mr A Walton QC appeared as counsel for the applicants.

The patent in suit covers an active ingredient known by the generic name nifedipine which is formulated into

soft gelatine capsules or slow release tablets sold by Bayer under the proprietory names Adalat and Adalat Retard respectively. I shall for convenience refer to both as Adalat. Nifedipine is a vasodilator of the type known as calcium antagonists and was first marketed for the treatment of angina pectoris, but has more recently turned to be useful in the treatment of hypertention and Raynaud's disease. The evidence makes clear that nifedipine is a highly effective drug, indeed so much so that Adalat sales now account for close to 70% of the turnover of Bayer UK. It took a considerable time however for this result to be achieved. After synthesis of nifedipine in 1966 and patent application in Germany in 1967 followed by application for the present patent in 1968, it was not until 1975 that the drug was launched in Germany with the passing of another two years before its introduction into the UK.

At the hearing and with the consent of the parties I admitted further evidence filed by both parties before the hearing and by the patentees at the hearing itself. Furthermore, I agreed that the patentees should be allowed to file evidence relating to the time at which drug prices enter the NHS Drug Tariff, conditional upon the evidence being filed by 16 January 1986 and subject to the right of the applicants to file further evidence in reply. In the event, the patentees filed further

evidence and the applicants in turn filed further evidence in reply. The patentees then challenged a request made by the applicants that all their further evidence should be accorded confidential treatment under Rule 94(1). Since in the view of the office the further evidence from both sides went well beyond the matter on which I had agreed that further evidence could be filed, an official letter issued refusing to admit what I might perhaps call the superfluous evidence and proposing that it should be returned to the parties in view of the confidentiality dispute. The patentees objected and these matters therefore came to a further hearing before me on 17 March 1986 when Mr R Jacob QC again appeared as counsel for the patentees and Mr S Kon appeared as solicitor for the applicants.

In the decision which I gave at the further hearing, I affirmed the office view that on the patentees' side the evidence of Mr Cambridge is not admissible, but that since it has already appeared on open file in the office, it should remain there. On the applicants' side, all their evidence should be returned to them, on the understanding that they may refile that admissible part of it which relates to the time it takes for drug prices to enter the NHS Drug Tariff and which, as Mr Kon agreed, need not be subject to a request for confidential treatment. The decision given at the

further hearing was on a matter of procedure and therefore subject to a fourteen day appeal period. In the event no appeal has been lodged within that period.

I feel bound to acknowledge that the further evidence which I have ruled to be inadmissible might well have been useful had it been produced before or at the substantive hearing and discussed at that hearing. However, were I to have admitted it, I feel that I could not have taken it into account without in effect allowing the case to be re-opened with the need for further rounds of evidence together with the need for a further substantive hearing. That would have introduced yet more delay into a process in which time is of the essence, and in any case would not in my view have been appropriate given the substantial volume of late filed evidence which had already been admitted at the substantiave hearing. As it is, the dispute following the substantive hearing inevitably delayed issue of this decision on the substantive matters to the point where it has had to be reconsidered in the light of the recent decision of the Patents Court on the appeal from the Comptroller's decision relating to Generics UK Limited's application for settlement of terms of a licence of right under Patent No 1200886 in the name of Allen and Hanburys Limited covering the drug salbutamol. That reconsideration has occasioned

yet more delay.

It is as well to note at the outset that the relevant law at the time of the substantive hearing was in something of a state of transition. The comptroller had given few decisions on the settlement of disputed terms of licences of right arising out of the Schedule 1 provisions. Four of these decisions were the subject of appeals which at that time had not been heard. Between then and now, three of the appeals have been heard. I think the only one to which I need refer in this decision is the salbutamol case mentioned above. However, I shall also wish to refer to the comptroller's decision in the salbutamol case itself and in what I shall term the labetalol and naproxen cases, namely those relating to Generics UK Limited's applications for settlement of terms of licences of right under patent No 1266058 in the name of Allen and Hanburys Limited and under patent No 1211134 in the name of Syntex Corporation. The appeal on the former was taken with what in the salbutamol case; the appeal on the latter has not yet been heard.

A number of points raised by the parties in this case, together with similar points discussed in the salbutamol appeal decision are drawn from the 1985 decision of the House of Lords in the matters of Gist Brocades and others, and of Allen and

Hanburys Ltd v Generics UK Limited. I shall refer to this simply as the House of Lords case. It is primarily concerned with the freedom of the comptroller to impose an import ban when settling terms and with the time at which an applicant for settlement of terms by the comptroller may make his application. However, on the question of a ban on importation, which crops up in the present case, their Lordships referred some points to the European Court of Justice. Furthermore their Lordships discussed other matters beyond those which necessarily had to be decided, but without adopting any unanimous viewpoint.

One point of the latter kind concerned the extent to which the comptroller's discretion extends beyond matters of royalty rates and import restrictions to other limitations and conditions. I think I need not discuss the arguments in detail, but need simply say that I can see nothing in the House of Lords case to prevent me following the practice adopted by the comptroller in the cases so far decided, and settling whatever disputes about terms are put to me by the parties. Furthermore, subject to any statutory objectives which may be imposed on me (and that is something to which I shall return later), I shall continue as in the earlier cases to regard myself as acting as an arbiter between the parties. Thus if the parties adopt a common basic approach to the question

of royalty, as has happened to some extent in the present case, then I regard myself as free to follow that line rather than one which has been considered as appropriate in earlier cases. To behave in any other way would seem to me to cause great difficulty since, as matters stand, I have to decide the issues on the evidence the parties have chosen to put before me. That evidence may not seem to me entirely appropriate, but I think I have to seek such common ground as I can find in order to reduce the arbitrariness of my decision. As will appear, both parties have accepted that costs borne by the patentees form a basis on which the royalty is to be determined although, not unexpectedly, they differ strongly on what these costs should be.

In the present case the applicants made quite clear at the outset what they were seeking by filing a draft licence along with their statement on 19 October 1984. I think it fair to say that the patentees' counter-statement, although asserting in general terms that the applicants' draft licence was inappropriate, fore-shadowed no substantial dispute beyond the royalty rate. Equally, the patentees' voluminous evidence, in so far as it is relevant, appears to me to be relevant almost entirely to questions of royalty. However, on 11 December 1985, ie six days before the start of the hearing, the patentees filed their own draft licence

and thereby made clear that as well as disputing the requested royalty rate and several less significant licensing terms, they also sought export and import limitations. The import limitation would interfere with arrangements which were foreshadowed in the applicants' evidence and which the applicants turn out already to have made. I shall return to this later, but it seems to me right to say at the outset that a party launching a substantial dispute so late in the proceedings is being unfair both to the comptroller and to the other party. Although Mr Walton did not go so far as to say that I should automatically dismiss the patentees' request for restrictions because of its late filing, he protested and I think quite rightly so. Mr Jacob argued that the patentees wished to assess all the evidence before filing their draft licence. I think that argument has little merit and in any case it misses the main point which is that by whatever means, disputes or potential disputes between the parties should be both fully exposed and supported where appropriate by evidence as early in the proceedings as possible. That is the whole point of the proceedings prior to the hearing. If a party behaves otherwise, it inevitably attracts the suspicion that it has disguised its position for the sake of its own advantage.

Another point to which I shall return later is the matter of allegations on the part of Generics that

Bayer have, by delaying the proceedings, shut Generics out from part of the period during which they could have expected to enjoy rights under a licence. In very broad outline the position is this. During prosecution of the present application, Bayer tried to invoke Section 36 of the 1949 Act and on 17 December 1984 requested the cancellation of the endorsement which is treated as having been applied by paragraph 4(2)(c) of Schedule 1 of the present act. The comptroller refused to entertain the request and, on 30 January 1985 Mr Justice Whitford stayed the proceedings to allow Bayer to file an application for judicial review of the comptroller's action. Generics then applied for discharge of the order for a stay and, on 22 March 1985, Mr Justice Whitford lifted the stay. He then, on 9 May 1985, endorsed the comptroller's action. In this connection Mr Walton drew my attention to Mr A S Tabatznik's first declaration which discusses the negotiations which took place between Bayer and Generics prior to the latter's present application to the comptroller for the settlement of terms. Mr Tabatznik's declaration refers to two passages in the decision of Mr Justice Whitford which lifted the stay. The first runs from the foot of page 4 to the top of page 6 and reads:

> "The correspondence, to my mind, quite clearly shows that at all times Generics were actively

endeavouring to secure some indication from Bayer of the terms under which it might be possible to reach agreement. Of course, the principal issue on any licence is likely to be, as it always is in these cases, as to the royalty that might be appropriate. One other matter that is worth noticing from the correspondence is that although the correspondence started off on the footing of the possibility of a compulsory licence under the statutory provisions, there was a stage at which there was some discussion as to the possibility of a voluntary licence. But whatever the basis of the discussion, there is one thing that it quite apparent; that is, that Bayer on their side were holding back. In fact, the date upon which an application for a compulsory licence could have been made was allowed to pass and the correspondence continued through the months of May, June and July and up to a point in October when it came to an end with a letter from Bayer indicating that they were not prepared to grant Generics a voluntary licence under the British patent.

The complaint having been made on the side of Generics that there had been no disclosure of these matters, there was a reply by Mr Ehrenstein which is to be found in Volume 1 where his

affidavit starts at page 22. In this he has what I would describe as the effrontery to suggest that the discussions which had been taking place with Generics had not been about a licence of right at all, but only about a voluntary licence. It is quite plain that the discussions started and continued of the basis of terms for a licence under the endorsement and, although it is right to say that there was also discussion about a voluntary licence brought to an end by the letter at page 56 of Volume B, it is quite wrong to suggest (as Mr Ehrenstein in his second affidavit tries to do) that the failure to refer to any of this back history can be excused, because it was never concerned with compulsory licences at all".

The second passage occurs further down page 6 and reads:

"The correspondence to which I have made reference shows, as I see it, the plain desire on the side of Bayer to go slow upon this question of the grant of a licence. They have now made this challenge to the refusal of the comptroller to remove the endorsement. If that challenge is carried through the courts (certainly through the court of first instance, no doubt through the Court of Appeal, possibly even to the House of

Lords) and if even at the end of all that Bayer fail, provided the present application for a compulsory licence has been stayed, although no doubt their unsuccessful proceeding will have cost them something, it will have been money well spent if they are able to hold competitors out of their market".

According to Mr Tabatznik, Bayer were deliberately stringing Generics along. There is, of course, a world of difference between doing that and taking legitimate advantage of the then somewhat uncertain legal position. Bayer have argued that allegations of delay were irrelevant anyway, since Generics had no nifedipine product licence. However, it is now clear that Generics were granted such a licence in July 1985, so that any delay in the hearing of the present dispute after that date will have shortened the life of the licence. I am very reluctant to decide that Bayer have deliberately introduced delay in a manner amounting to mischief. However, bearing in mind the remarks of Mr Justice Whitford, I have decided that Mr Walton was right to suggest that if I find myself uncertain at some point as to whether I should adopt a higher or lower figure for some component of the royalty rate, then I should allow the matter of delay to influence me towards the lower figure. I have borne that in mind and will return to it in due course.

Before moving on to the royalty rate there is one preliminary point that I must decide. The patent in suit covers a group of compounds of which nifedipine is only one. Generics' draft licence seeks the freedom to do anything which would otherwise be an infringement of the patent. In contrast, Bayer's draft licence is restricted to nifedipine and products containing nifedipine. There was no hint either in the evidence or at the hearing that Generics have any interest in anything other than nifedipine or nifedipine products. It therefore seems to me to make no difference in practice if the licence is restricted as Bayer suggest. Therefore, bearing in mind that the evidence directed to royalty determination discusses only nifedipine and nifedipine products and nothing else falling within the scope of the patent, I decide that the licence shall be so restricted.

Turning then to the royalty rate, I must deal first with a number of points of general principle put to me by Mr Walton and Mr Jacob. In outline, I understood Mr Walton's position to be this. The correct royalty rate is that which would be agreed between a willing licensee and willing licensor. It may be that such a rate can be deduced from existing licences in the industry concerned. In the present case no useful evidence has been filed about existing pharmaceutical

licence rates and it is therefore incumbent upon the comptroller to make some kind of calculation to arrive at an appropriate rate. In so doing, he should assume that the notional willing licensee and willing licensor would agree a payment on the basis determined by the Court of Appeal in Patchett's Patent 1967 RPC 237. In other words, the patentee should be regarded only as patentee and not as manufacturer. To Mr Walton that meant that the licensee should pay the patentee nothing more than a return for the research that was necessary to arrive at the point at which he was able to apply for a patent, i.e. the licensee should pay a return to the patentee for making the invention and nothing more. Thus, in his view, in pharmaceutical cases of the present kind no regard should be paid to the very substantial costs of research, development, and promotion which are incurred after applying for the patent and which are necessary, amongst other things, to establish that the drug is safe and effective, and also to establish its credibility in the medical world.

Mr Walton mentioned a number of supports for this point of view. However, I think the one on which he laid most stress and the only one I need mention here was the decision in Monsanto v Stauffer Chemical 1985 FSR 55. I can make the point clear by quoting a passage from the headnote.

> "In Section 60(5)(b) of the Act, the phrase "Experimental purposes relating to the subject matter of the invention" limited the paragraph to experiments directed to the patented invention as such. It excluded tests or trials having as their purpose the achievement or extension of the acceptance of a commercial embodiment of the invention. All three categories of proposed trials would accordingly be acts of infringement not excluded by the section".

That seems to me to be of no help in the present case since it relates only to what counts as experiment when deciding whether or not infringement has taken place. I do not see its relevance when it comes to deciding an appropriate royalty as agreed between willing licensee and willing licensor.

When it came to figures, although Mr Walton did not seek to import Section 41 of the 1949 Act into the present law, he did argue that I should accept, at least as a rough guide, the kind of calculations usually performed when determining royalty rates for compulsory pharmaceutical licences under that section. Such calculations appear in the evidence of Mr Siddons for the patentees in the present case. On that basis,

Mr Walton argued, on the basis of a number of examples he produced, that the general run of settlements of royalty rates under Section 41 of the 1949 Act included a component of very roughly 10% as a fair contribution to the patentee for his research and development effort. To get, as it were, a cross-bearing on this figure, Mr Walton drew my attention to an exhibited item from The Times newspaper dated 5 December 1985 and relating to a drug which "is being developed" at the DHSS research centre at Porton Down. "The Government has signed an agreement with a commercial group to market the drug internationally", and "under the agreement Britain stands to earn 10% in royalties from sales of the drug". The article notes that human trials have not started, but talks of the possibility of the drug becoming available within five years. Mr Walton claimed that the figure of 10% supported his view of the sort of royalty that ought to be paid on the criteria he was putting forward. For the moment I shall leave the Porton Down agreement on one side, apart from noting the obvious hazards of regarding a fairly sketchy newspaper article as evidence which I should take into account, and also noting that on the face of it, the drug concerned is still at an early and uncertain stage of its development.

Mr Walton also drew my attention to an exhibited annual report of Newport Pharmaceutical International Inc

filed with the Washington Securities and Exchange Commission in 1985. That report includes a discussion of the patent and trade mark position of the company and mentions several royalty figures. However I do not propose to consider the document further. I simply note that I do not have enough information about the figures to allow them to influence me.

Finally, although Mr Walton argued that the applicants should pay no more to the patentees than a fair contribution to the latter's research costs, he further argued that if I were minded to allow a contribution for promotion costs, then I should still rely on calculation. Mr Walton pointed out that the precedents under Section 41 of the 1949 Act always fixed a rather smaller contribution to promotion than to research and development. He therefore argue that the right general area for royalties in cases of the present kind is 10 to 15%, although I think he made no attempt to specify whether this figure applies to the applicants' or to the patentees' selling price.

I should interpose here that much of the applicants' evidence was concerned to argue that the patentees have already received adequate remuneration under the protection of the nifidepine patent. It was consequently submitted that although the appropriate royalty for the present licence should therefore be

zero, the applicants would offer the 4% commonly awarded in Canadian compulsory licensing proceedings. At the hearing, Mr Walton explicitly abandoned the adequate remuneration argument, although he did suggest that the Canadian 4% might not be inconsistent with the figure of 10% which he was putting forward here. I need only note that I find nothing in the Canadian law and practice to assist me here, and that a zero royalty would clearly negate the intention of the 1977 Act that the patent should have an extra four years of life.

I should also note here that, no doubt in part as a response to the line taken by the applicants in their opening evidence, the patentees' evidence is largely concerned to establish that they were unable to get Adalat onto the UK market until quite late in the day; that that situation was in no way their fault, but due to the difficulty of gaining acceptance for such a radically new class of drug as the calcium antagonists; and that they have not therefore had sufficient time for the enjoyment of their patent rights. In other words, I should settle a high royalty in compensation. The applicants argue that the delay in coming to market was entirely Bayer's fault: they say basically that Bayer did not try hard enough to arrange clinical trials, and that they failed to work with a proper understanding of the UK product licensing system. Whatever the truth of the matter, and I am not

sure that the evidence establishes it, the facts show that it took about nine years after application for a UK patent for nifedipine products to reach the market.

I will now turn to what I understood to be Mr Jacob's view of the general principles by which I should be guided. He accepted that the royalty to be fixed is that which would be agreed between a willing licensee and a willing licensor, although he clearly preferred the adjective "reasonable" when discussing the behaviour of the licensee. Thereafter, he parted company with Mr Walton. Mr Jacob put forward a picture of the comptroller as a presence at the negotiating table between the particular parties involved where his function is to ensure the reasonable behaviour of the parties. Mr Jacob put forward a number of factors which the negotiators should be assumed to take into account. In the present case, those factors included the following. First, the profits expected to be made by the applicant. Mr Jacob asserted that the nature of Generics meant that they are a company making very high profits. Furthermore, the licence is of great commercial value to the licensee given the high and rising market that the evidence shows to exist for nifedipine products. Second, a reasonable licensee would take into account that nifedipine is a very good drug in the medical sense, and that the patentee has had only a very short effective patent life in which to

reap the benefits from such a drug. Third, any going rate established by existing licences for comparable drugs at comparable stages of development. Mr Jacob asserted that there is no help here in the present case. Fourth, the costs borne by the patentee in inventing, developing, and promoting the drug whose success has made the licence desirable, and also the loss of manufacturing profit the patentee will suffer because of the licensees' entry into the market.

Mr Jacob also argued that any doubts about the validity of the patent might affect the royalty to be agreed between the parties in some other case. I accept that that could be a factor taken into account by parties settling the terms between themselves but it is not one which I am prepared to consider. To decide otherwise would mean the introduction into these proceedings of an investigation into matters which are properly the subject of revocation proceedings. Otherwise, it will be seen that all Mr Jacob's factors point in the direction of a high royalty. To my mind, they involve a certain amount of double counting. To take one example, the expanding market is likely to be tied up with the medical merit of a drug. Furthermore, they clearly envisage the patentee as having the whip hand in the negotiations so that his earnings from the patent would diminish to a minimal extent as a result of the presence of the licensee in the market.

Although it goes beyond matters of general principle, I need to mention here that Mr Jacob put forward a number of fall-back positions if I should not be willing to settle a royalty at the highest figure of 60% which he put forward as appropriate. Looking first at the 60% figure, the evidence shows this to have been put forward by Bayer in the negotiations with Generics which preceded the present application. The offer covered a combination of the present patent and another patent No 1362627 which protects Bayer's soft gelatine capsule formulation. Mr Jacob drew my attention to exhibit SDK1 to the first affidavit of Mr Kon filed in the judicial review proceedings to which I referred earlier. The exhibit includes a record of a telephone conversation between Mr Kon, acting on behalf of Generics, and Dr Ehrenstein of Bayer AG. In Mr Jacob's view, the record shows that Generics were quite happy to continue negotiations following the offer of 60%. In other words, Generics' behaviour did not suggest that they believed the 60% to be absurdly high. Therefore 60% cannot be an unreasonable figure. In support, Mr Jacob argued that the evidence showed negotiations to have been broken off not so much because of differences about the royalty rate, but because Bayer feared that any agreed terms even for a Schedule 1 licence of right might rank as acknowledgement that nifedipine products sold in the UK

by Generics were circulating with Bayer's consent and thereby, under Community Law, disturb the protection given by Bayer's parallel patents in EEC countries.

Like Mr Walton, it seems to me that willingness to continue negotiations is in no sense to concede that any particular figure on the table is reasonable. And in the present case, the record shows no more than that Generics wished to continue negotiations. Furthermore, the evidence makes clear that, whatever the position earlier on, Generics are not now seeking a licence under the capsule patent. Mr Jacob appeared to argue that the royalty should be the same whether or not the capsule patent is covered by the licence. However, that seems to me to be no argument unless the capsule patent is a necessary complement to the nifedipine patent. That does not appear to be the case here. Therefore, even if 60% were a reasonable figure for the two patents, the removal of the capsule patent would reduce the benefit conferred by the licence and the royalty should therefore be lower.

Mr Jacob's fall-back positions were all based on Mr Siddons' calculations. Indeed he argued that a royalty based on these calculations should be regarded as a minimum since it was determined by principles established under Section 41 (1949 Act) which was designed to ensure the lowest

prices to the public, a requirement which is no longer present in the legislation. Before coming to these calculations, there is a further general point I must mention. Mr Jacob drew my attention to references to Sections 48 to 50 of the present Act in the speech of Lord Diplock in the House of Lords case. These sections relate to the granting of compulsory licences where an abuse of monopoly has occurred. Mr Jacob sought to persuade me that the objectives set out in Section 50 are to influence the comptroller not only when considering applications for compulsory licences in the case of monopoly abuse, but also in cases of what may fairly be called compulsory licence of right.

I think I need review this point no further since following the House of Lords decision and the appeal decision of Mr Justice Whitford in the salbutamol case it is clear that the comptroller is obliged in cases like this to have regard to the various criteria which are also relevant in cases of monopoly abuse. Furthermore, although I have set out at some length the approaches which the two sides in this case have asked me to adopt, I think that, particularly in the light of Mr Justice Whitford's salbutamol decision, I need only say that it is quite clear that research, development, and promotional costs of the kind and magnitude that are incurred by a patentee after applying for a patent cannot be excluded as factors which will be an

influence on the royalty rate. Therefore I am unable to accept either Mr Walton's general thesis or the relevance of the Porton Down 10%.

I also accept that the potential profits to be made under a licence are normally likely to be an influence on the royalty rate. In the present case the applicants have made no attempt to indicate the profit margins they expect to achieve under the licence. Indeed, Mr Walton quite explicitly said that the applicants had not filed such information since it had never been held to be relevant in decisions under Section 41 of the 1949 Act. Mr Jacob pointed to Generics' accounts appearing as exhibit PRS2 to Mr Siddons declaration and deduced from them that, in terms of return on capital employed, Generics were making very large profits indeed. However, I accept points put to me by Mr Walton about the assertion, namely that the figures to which Mr Jacob pointed are relevant to only a three month period. The accounts do not show a full twelve month period, and it would be wrong to extrapolate from any particular three months.

While I do not consider that I should be bound by the methods used under Section 41 of the 1949 Act I do accept that they can give a rough indication of appropriate levels, and in this I am clearly supported by Mr Justice Whitford in the salbutamol case.

Therefore, in the absence of clearly comparable licences and in the absence of information about relevant profit margins, I propose to come to a figure based on methods of the general kind used by Mr Siddons. In any case, if I were not to use methods of this kind, I would be failing to utilise the only common ground between the parties which is consistent with the general approach that I think should be adopted.

Mr Siddons' evidence follows the general pattern adopted in cases under Section 41 of the 1949 Act following the decision in Geigy's Patent 1964 RPC 391. Mr Siddons therefore puts forward three elements which are to be summed to come to a final royalty rate and which cover contributions to the patentees' research costs, to his promotional expenses, and which also allow for a return on the capital employed in those activities. On this basis the patentees propose a royalty rate of 49.4%. Mr Siddons has also included a fourth element which quite explicitly relates to the effect on Bayer's profits of Generics' entry into the market. For this, Bayer seek an extra 5% on the royalty rate. However, such an addition does not appear in the Section 41 procedents, nor was it specifically included in the royalty figure adopted by Mr Justice Whitford in the salbutamol appeal. I shall therefore not include it here.

Mr Siddons gives aggregate figures for the three years 1982 to 1984 as well as setting out figures for each of those years. The patentees' evidence says there is no reason to suppose that the aggregate figure will not be typical of the next few years, and that has not been contested by the applicants. I should also note that Mr Walton accepted the current spending basis of the figures and did not contend that any item e.g. launch costs, should instead be spread over a period.

Since Mr Siddons' figures are confidential and have been shown only to the applicants' professional advisers, the figure work involved in this decision will appear in a confidential annex to the decision and will be made available only to the patentees and to the professional advisers of the applicants.

For the first element, Mr Siddons compares Bayer's worldwide pharmaceutical research and development expenditure with the worldwide sales of all pharmaceutical products which are the fruits of Bayer's research. There is, I think, no substantial dispute over the figure for research and development spending, although I note that it includes a specified amount for the cost of Bayer's patent department and also includes the unspecified cost of Bayer's worldwide technical information services. The latter appear to me to be

more akin to promotion than to research, and the former was not allowed in full in the Section 41 precedents since these costs were regarded only in part as being of benefit to the licensee. These amounts are no doubt small; however, I have thought it right to take them into account by making a small adjustment in a manner which will appear in a moment.

There are a number of disputes about the size of the worldwide sales figure over which the research and development costs should be spread. Mr Walton, echoing Mr Allen's evidence for the applicants, was unhappy about the exclusion of veterinary products from both sales and research costs, bearing in mind the possible movement between veterinary and human applications as a drug is developed. On this point, I have decided to accept the assurance in Mr Siddons' second declaration that a different treatment of veterinary products would have produced a negligible change in the calculation of the royalty rate.

A second dispute centres around Mr Siddons' inclusion only of products which have been the subject of patent protection since 1970. In other words, the sales figure excludes products whose patents expired in or before 1970. I must also assume that products which for one reason or another have never been the subject of patent protection are not included. Mr Siddons has

also excluded, to my mind quite rightly, fully developed products licensed in from other pharmaceutical companies.

Mr Jacob put it to me that research and development is funded by those products which carry a price premium, for example, because of patent protection, and that the products excluded by Mr Siddons would not carry such a premium. I am unhappy about this argument on a number of counts. Nothing in the evidence indicates the sensitivity of the patentees' figures to the length of the apparently arbitrary off-patent period that Mr Siddons has chosen. I have no evidence that all products excluded by Mr Siddons are subject to the kind of competition that will prevent them carrying a price premium. Furthermore, I am not sure that it is right to look only at products which carry a price premium. I assume that by referring to a price premium, Mr Siddons and Mr Jacob are indicating products whose price is higher than it would be in a fully competitive market and which therefore make a larger contribution to gross profits. However, products not bearing such a premium presumably do make some contribution to profits and I think I should not therefore assume that they will never make any contribution at all to research and to development of similar pharmaceuticals. Having said that, I have to accept that, as indicated in the Hearing Officer's decision in Farbwerke Hoechst AG

(Sturm's) Patent 1973 RPC 253 at page 263, the link between research occurring a particularly long time ago and current sales of drugs which are the fruits of that research may become too tenuous for these sales to be included in calculations of the present kind. Even so, that does leave in some doubt the position of sales of old drugs like aspirin which should, according to the applicants, be included because Bayer is still conducting research into the uses of the drug. If that research has led to an increase in sales, it seems to me that there is at least a case for the inclusion of some of the sales of such drugs. Mr Stockham's fourth affidavit argues that Bayer's aspirin sales are so small that they can be ignored. That is certainly true of the figures produced by Mr Stockham, but they relate only to UK sales and not to the worldwide sales which are of concern here. I think I have no alternative but to leave the point unresolved; however, I work on the assumption that a different treatment of aspirin is unlikely to cause any great distortion to the figures.

As is clear from the Section 41 precedents, the main problem at this point in the royalty calculation has usually been to ensure that like is being compared with like when looking at the kind of products whose sales are to be included and the kind of products which are the subject of the research and development expenditure which is to be included. In the present case, subject

to the exclusions referred to above, Mr Siddons says that his figures relate to all pharmaceutical products. Bearing this in mind, Mr Walton added to the doubts I already feel by pointing to Mr Allen's second declaration for the applicants in which he sets out what he describes as the publicly available sales figures of Bayer's Pharmaceutical Division for the years 1983 and 1984. I think Mr Jacob effectively conceded that these figures were those to be found in Bayer's annual reports. The sales are broken down under the following lists of products: ethical products, OTC products, hospital products, diagnostics, consumer products, and fine chemicals. The sales of ethical products alone are considerably higher than the sales figures used by Mr Siddons, and Mr Walton in fact asked me to adopt the sum of sales of ethical, OTC, and hospital products on which to base the research and development element of the royalty. Mr Jacob's response was that such sales would include things like blood plasma, bed pans, and surgical stockings as well as old drugs and drugs licensed in. This is not fully covered by the evidence, and Mr Siddons does not define the class of products he is considering, although the inference to be drawn from what Mr Jacob said is that the Bayer figures relate only to ethical products.

To my mind, the evidence does not enable me to resolve

the various uncertainties outlined above, so that I cannot avoid coming to an arbitrary figure. I have decided that for the worldwide sales figures in 1983 and 1984 I will adopt figures half-way between those provided by Mr Siddons and those appearing in the published figures under the heading of Ethical Products. On this basis, I have calculated a percentage contribution to the royalty using the combined figures for 1983 and 1984. However, this excludes 1982 for which I have no published figures and for which the ratio of research and development spending to sales as given by Mr Siddons is higher than the same ratio for 1983 and 1984. An upward adjustment to my figure is therefore needed to compensate for the 1982 position. Bearing in mind the relative size of Mr Siddons' ratios for the three years 1982, 83 and 84, and also bearing in mind the need for a small downward adjustment for patent and information services mentioned earlier, I have simply rounded up the contribution to the royalty to the nearest full percentage point.

I turn now to the second element, namely promotion. Mr Siddons has again followed Section 41 precedent by comparing UK promotional spending on nifedipine products with sales of nifedipine products in the UK. The promotional spending is shown under two heads, ie medical representatives, which is calculated according

to the proportion of their time which Bayer instructs them to spend on nifedipine products, and other promotional spending. No further breakdown is given. Again Mr Siddons proposes a contribution based on aggregate figures for 1982 to 84 and also gives separate figures for those years. The patentees' evidence is again that those figures should be typical of the next few years.

It was common for Section 41 decisions to allow only part of the patentees' promotional spending. I hope I summarise the basis for this reasonably fairly by saying that part of the promotion was regarded as an ordinary commercial activity designed to promote the patentees' branded product, and clearly was therefore something from which the licensee would not benefit. The remainder of the promotional spending could be regarded as an activity more peculiar to the pharmaceutical industry of gaining and increasing the medical acceptance of the drug and thereby creating the educated market of which the licensee would gain a share. The second component was regarded as of benefit to the licensee, and therefore as something to which he should contribute.

In the present case, the patentees claim that their promotional spending should be allowed in full on the basis that it is all of benefit to the licensee since

the market has been created entirely by Bayer. I think this is clearly an unreasonable approach. However, I am in some difficulty when it comes to deciding just what proportion I should allow. I have no significant information about the way in which the medical representatives carry out their function or the instructions to which they work. I can therefore make no assessment of the extent to which their activities have the effect of reserving a market for the branded product rather than the drug in general. Furthermore, bearing in mind a point made in the naproxen decision, I can make no assessment of the extent to which this or other promotional activity may lay greater stress on the branded product as the patent life draws to its close, ie to the point at which it might in any case expect to face generic competition.

On other promotional spending, there is much more information in the evidence about the very wide variety of activities in which Bayer engage. I do not propose to detail them. As might be expected, Mr Jacob drew my attention to the many items of literature which discuss nifedipine and in which the name Adalat is given little mention, whereas Mr Walton drew my attention to advertisements in which the name Adalat is given much greater prominence that the name nifedipine, and pointed to international symposia organised by Bayer which have the name Adalat in their titles. I also

note that the professional testimonials quoted in Dr H V Allen's evidence for the patentees often refer to Adalat rather than to nifedipine.

Mr Walton, appealing to Mr Allen's evidence for the applicants, asked me to decide how much promotional spending to allow by reference to the market share that will be available to Generics. Mr Allen's evidence says that the hospital market, to which the patentees say that Generics will have unrestricted access, accounts for only 7% of the UK sales of nifedipine products. In the remainder of the market, generic products will be dispensed only if prescriptions are written for nifedipine rather than for Adalat. Mr Allen says that in 1984 13% of prescriptions were written for nifedipine rather than Adalat, and argues in effect that Bayer's promotion should therefore be judged to have reserved over 80% of the market for its own Adalat. Mr Stockham's confidential evidence for the patentees gives some indication of the rate of change over time of the proportion of prescriptions written generically. From this evidence, it is clear that there was a very substantial increase between 1982 and 1984 and that the figure for 1985 will also be somewhat higher than for 1984. Mr Stockham's evidence also gives figures for the proportions of prescriptions written generically for other drugs at specified periods after their launch. On the basis of these

figures, he fears that generic products could take as much as 40% of the nifedipine market. I should note that Mr Stockham has explicitly assumed that Government policy does not change in the direction of further encouragement of generic prescribing. If it were to do that, he assumes that generic products would achieve a much higher market penetration. On this point I have been given no reason to assume any change in Government policy and I must therefore take things as they are.

Mr Walton put it to me, so far as I am aware correctly, that evidence on the generic writing of prescriptions of the kind filed here was not available in the Section 41 cases and could not therefore have been taken into account in them. I think there is much to be said for Mr Walton's approach, which is in effect to judge the patentees' promotion not so much by its intent as by the effect that it achieves. I have therefore taken it into account as one of the factors to which I have given careful consideration in all the evidence about promotion, including the fact that Generics themselves employ no sales force to influence prescribing habits, and I have come to the conclusion that Generics should contribute a little over half the total figure put forward by Mr Siddons. A figure of 55% seems appropriate

The figures I have come to as appropriate contributions

to the royalty rate in respect of research, development and promotion add up to 24.9%. However, again following the Geigy case, I must now increase this figure to allow the patentees a fair return on the capital investment involved in those research, development and promotional activities to which the licensee should contribute.

The patentees have proposed an increase under this head of 22.5%, a figure which was adopted in the Geigy case and was commonly seen in other decisions under Section 41 of the 1949 Act. However, Mr Walton drew my attention to the exhibited tenth report of the Committee of Public Accounts which was published in 1983 and is entitled "Dispensing of drugs in the National Health Service". Having acknowledged the good reputation of the industry and its importance in the economy, the report says in paragraph 18:

> "However, notwithstanding these important factors, we believe that the PPRS has not ensured the reasonableness of drug prices generally. For example, in 1978 the 21% return on capital earned under PPRS was 5 percentage points above the return for UK industry generally, and in 1979 and 1980 the return under PPRS increased to 22% and 23.3% respectively. On the other hand, as we pointed out in our 16th Report of Session 1981 to

1982, since 1978 profit margins have been declining in industry generally and in our view the average rate for Government non-competitive contracts should have been reduced from 20% to 17% at the most".

On this basis, the applicants ask that I should use the figure of 17% rather than 22½%.

Although I think Mr Jacob acknowledged that the target figure for return on capital employed under the PPRS is now 17%, he argued that the 22½% increase in the Geigy case was not intended to be a figure identical to whatever was thought to be a fair percentage return on capital employed. It was rather a figure which was designed to increase the royalty rate to the extent where its effect on the patentees' income would ensure a fair return on capital. The relation- ship between the percentage increase in the royalty rate and the desired percentage return on capital would depend on other factors. I have read the Geigy decision carefully and I find it does not make the position fully clear. There is further discussion of this point on page 518 of the Hearing Officer's decision in Hoffman - La Roche's Patent 1969 RPC 504 which perhaps supports Mr Jacob's point of view but I am still left with some uncertainty. However it seems clear that a determining factor in arriving at the figure of 22½% in

the Geigy case was the return on the relevant capital which was considered reasonable at the time and from the general conclusion of the Public Accounts Committee it would appear that such a return on capital would now be considered excessive. I therefore think that a more appropriate uplift would be 20%. That figure, applied to the royalty contribution of 24.9% derived above, gives a figure of 29.9%. Thus, if I were determining a royalty under Section 41 of the 1949 Act, I would take as my starting point a rate of 29.9% of the patentees' own price or in round figures 30%.

I next have to decide the precise form in which the royalty should be expressed. There are four alternatives, namely a percentage of the patentees' price or of the applicants' price, a fixed sum per unit of weight, or a percentage of the NHS Drug Tariff Price. The latter suggestion was made by Mr Jacob to avoid the difficulties, to which I shall refer in a moment, of fixing a royalty as a percentage of the applicants' price and also to avoid any allegation that a royalty fixed on the patentees' price could be said to be under the unfair control of the patentees.

In broad outline, my understanding of the Tariff is this. At present, Bayer is the only supplier of nifedipine products and when a pharmacist dispenses those products, he will be reimbursed by the DHSS at a

price based on Bayer's price. However, once a certain number of Generic competitors are on the market, a price will be established by the DHSS for the generic product and will in due course be published in the NHS Drug Tariff, and I shall from now on refer to this price simply as the NHS Price. The NHS price will be a weighted average of the generic prices assumed to be charged to the pharmacist and will be up-dated from time to time. Mr Jacob put it to me that this price is fair and objective, it is not something which Bayer itself influences, and it overcomes Bayer's objections to the use of Generics' price. In terms of figures, Mr Jacob suggested that I should assume the NHS Price at first appearance to be 90% of Bayer's price and that I should therefore increase by 10% any royalty determined by Section 41 principles and apply that royalty to the NHS Price. Since there would be a time lag between Generics' product going on the market and the NHS price appearing, Mr Jacob proposed a clause in the licence which would charge the royalty on a provisional basis and then make retrospective adjustment once the NHS price has been published.

Mr Walton put forward several objections to these proposals including their complexity, the uncertain position of trade discounts, and the fact that the royalty would be levied on a price which is rarely if ever actually charged and would certainly not be the

price charged in the case of Generics' direct sales to hospitals. He also objected to the uncertainty of an arrangement in which Generics would have to fix its prices in ignorance of what the NHS price, and therefore the royalty, would turn out to be. There was considerable uncertainty at the hearing about the likely time lag before the NHS price for nifedipine products would appear, and it was on this point, as indicated earlier in this decision, that I agreed to the filing of evidence after the hearing. The evidence filed by the patentees in this respect is in the form of a fifth declaration from Mr Stockham and includes the following statement. "I believe it is likely that nifedipine will be listed within nine or at the most twelve months after the launch of the generic equivalent". However, it is clear from Mr Stockham's evidence that another drug, salbutamol, took fifteen months to enter the drug tariff. It thus appears that Mr Jacob's proposal would require Generics to decide prices for their nifedipine products as much as twelve months or more in advance of knowledge of the royalty those prices would have to bear. For that reason alone, I think I should not contemplate the use of the NHS price.

Mr Jacob insisted that it would be quite wrong for the royalty to be levied on Generics' own price. I think his argument was fairly straightforward. He presented

Generics as what he called "A middleman's middleman", namely as a company whose main business is supplying other generic companies who then sell on in what I understand to be the usual way. In view of the longer chain involved and the extra slice of profit that is therefore needed, Generics would in his view be selling at a very low price.

I am bound to say that there is little in the evidence to help me adjudicate on these points. Generics' evidence makes clear that their main business lies in supplying other generic companies, although I think there is nothing saying that this will necessarily be their main business in the case of the particular drug nifedipine. However, Generics' evidence also says that they supply hospitals and pharmacy chains. Beyond that, I have no evidence about the particular market to which Generics will supply nifedipine products, about the intended price of those products, or about the likely profit margins on those products. Looking at the other side of the coin, I have again been given no clear view of the manner in which Bayer market the same products, although Mr Walton alleged at the hearing that some of the generic companies supplied by Generics also act as wholesalers for Bayer.

Furthermore, Mr Walton put it to me that factors of this kind had not been taken into account in decisions

under Section 41 of the 1949 Act. Mr Jacob's counter was in effect that such factors had not needed to be taken into account because none of the Section 41 applicants was of the same character as Generics. All in all, I find myself unable to come to any firm conclusion about the right parallel to draw between the marketing activities of Bayer and of Generics.

Equally, there is nothing in the evidence to give me any indication at all of the price at which Generics may attempt to enter the market. I therefore find myself unable to take a course commonly adopted in section 41 decisions of setting the royalty on the applicants' price after first applying an uplift to take account of the likely price differential between the applicants' and the patentees' selling prices at the time when the applicant enters the market. In any event, following Mr Justice Whitford's decision in the salbutamol case, I doubt whether this is a course which should be contemplated.

In a letter written after delivery of Mr Justice Whitford's decision in the salbutamol case, the patentees ask that I follow that decision and set the royalty as a fixed sum per unit of weight. To that end, their letter was accompanied by a 1985 Bayer price list including the prices of Adalat capsules and tablets. This information was not in evidence at the

time of the hearing, in contrast to the situation in the salbutamol case and is something which I feel I should not now take into account without giving both sides a further opportunity to file evidence and to present argument. Again it seems to me wrong that I should follow that course since it would cause yet further delay in the issue of this decision.

In all these circumstances, I have decided that the best of a number of poor alternatives will be to fix the royalty as a percentage of Bayer's net selling price to wholesalers. So far as I am aware, this form of royalty was not adopted in the section 41 cases. Furthermore, in my own decision in the salbutamol case I rejected this form of royalty on the ground that it would leave Generics in a position where they are unable to forecast their liability to royalty. That rejection was supported by Mr Justice Whitford on appeal although he made use of a percentage of the patentees' selling price in arriving at a royalty in the form of a fixed sum per unit quantity sold. However, each case must be taken on its merits and I consider that I have insufficient evidence to allow me to fix a royalty on units of weight or on Generic's own price. I therefore decide that the royalty shall be 30% of Bayer's net selling price to wholesalers. I should note that this form of royalty appears in a licence to DDSA in respect of the Bayer drug

clotrimazole, which licence was exhibited in a case for settlement of terms of a compulsory licence of right heard at the same time as the present case. Although the DDSA licence is itself a compulsory licence of right which arose out of the Schedule 1 provisions and whose terms were formally ordered by the comptroller, it is my understanding that neither party opposed those terms.

I now turn to Bayer's request that the licence should include an export ban and a limited import ban and I shall begin with importation. So far as I can tell, the evidence nowhere makes clear where Bayer manufacture nifedipine and its formulations, or where Generics intend to manufacture them or have them manufactured. However, as I indicated earlier, Generics' statement made clear that they wished to cover importation, and Mr A S Tabatznik's first declaration admits that active ingredients used by Generics "are in general synthesised in countries such as Italy". At the hearing, each side alleged that the other would be importing formulations, in Bayers' case from Germany, and I think neither allegation was denied. I shall assume therefore that Bayer are not manufacturing in this country. In Generics' case, Mr Walton made clear that their product licence is in respect of an Italian source, although I am not clear whether this applies only to the active ingredient or

also to formulations.

Against this background, Bayer seek the inclusion in the licence of a clause which prevents Generics importing nifedipine or its products from "any country in which, within one year after the priority date of the patent, patent protection was not available for pharmaceutical inventions as such upon the like terms as for other inventions". Italy is, of course, such a country. However, from their letter dated 17 March 1986 to which I have already referred, Bayer now appear to be asking that there should be no right to import from any country.

Here again, the law may be in a transitional state. As I understand it, from the orders made by their lordships, the House of Lords decided that the comptroller has the discretion to ban imports from non-EEC countries. However, their lordships referred the question of a ban on imports from EEC countries to the European Court of Justice and also asked if the position is affected when importation of pharmaceutical products is to take place from a member state where such products are not patentable. From the decision of the patents court in the salbutamol case, it appears to me that if, bearing in mind the criteria of sections 48 and 50, I consider that a ban on imports from an EEC country is appropriate, then I must place the matter in

abeyance until the decision of the European Court of Justice is known. However, if I think an import ban is inappropriate, then I may decide the matter now.

In the present case, the patentees are manufacturing abroad and are meeting the demands of the UK market by importation. There is no commercial working in the United Kingdom not any indication that there is likely to be any. Importation will not prejudice any working of the invention in the United kingdom, and, since I can see no other factor arising from sections 48 and 50 which would speak against Generics' planned importation, it seems to me that on the basis of those sections I have no reason for imposing an import ban. I should note that this seems to me fully consistent with such section 41 precedents as Hoffman-La Roche 1971 RPC 326 and 1973 RPC 130.

However, Mr Jacob put it to me that failure to ban imports from Italy would be in effect to discriminate against Germany and therefore would be contrary to community law. In other words, I should not distinguish between manufacture here and manufacture in Germany. He also advanced two further arguments. First, since manufacturers in countries like Italy are able to manufacture without the costs of the research base that a company like Bayer must maintain, and since Bayer cannot prevent such manufacture by patent

protection, then the Italian manufacture is in effect expropriation of Bayer's invention. That should, in itself, be discouraged, and in the particular case, the comptroller should do nothing which would add to the profits of the Italian manufacturer.

Mr Jacob's second argument involves the doctrine of reciprocity and is based on the speech of Lord Templeman in the House of Lords case. I shall quote the relevant passage which concerns one of three reasons advanced by Lord Templeman for concluding that the comptroller has discretionary power in matters of importation:

> "Secondly, in domestic law and I would hope in community law and international law the proprietor of the patent is entitled to invoke the doctrine of reciprocity. Where a patented product has been made in a country which does not grant rights to the inventor similar to those granted in the United Kingdom, a patented product which has been made without the consent of the proprietor of the patent does not in my opinion, afford the owner of the product the right to pray in aid the provisions of the Patents Act 1977 which apply to licences as of right. In the present case, I understand that, certainly in Italy, no patent protection has been afforded to the proprietor but

> anyone in Italy has been free to use and exploit the invention without regard to the ingenuity, time and money which the inventor lavished upon the invention. In these circumstances, it seems to me the comptroller is not bound to grant a licence to the importer to infringe rights of the proprietor which the country of origin fails to accord to the inventor".

I think it as well to note that this is Lord Templeman's view and was neither supported nor denied by any of the other speeches. I should also note my understanding that in the particular case to which Lord Templeman refers, the patentee was manufacturing in the United Kingdom.

As far as discrimination between the United Kingdom and Germany is concerned, Mr Walton argued that the provisions of Sections 48 to 50 of the present act relating to abuse of monopoly quite clearly distinguish between manufacture in the United Kingdom and manufacture abroad. They make no further distinction and thus in effect recognise that discrimination between EEC countries is permitted under existing domestic law. On the matter of reciprocity, Mr Walton put it to me that in the case of the present dispute, to allow importation would have no practical effect on Bayer. Mr Walton's argument is that although

Bayer get no reward from the Italian manufacturers activity in Italy, they do get a reward once the material is imported into this country and are paid a royalty under the present licence of right. In other words, Bayer get a reward in just the same way as if Generics had themselves manufactured the material in this country. In each case, Bayer receives a royalty payment. While I can certainly see the force of Lord Templemen's point, it seems to me that Mr Walton's arguments are strong enough, particularly given that nothing here is hurting domestic manufacture, for me to impose no import ban.

On the matter of an export ban, I think Mr Jacob's argument was quite straightforwardly that if Generics want to export, then they should give good reason; otherwise, exports should not be permitted. In my view, that puts the boot on the wrong foot. As I see it, I cannot decide to allow exports. That is something which depends on the patentees' patent position elsewhere in the world. All I can do is decide whether or not to impose a ban on exports. And as in any case where I am asked to impose a restriction on the activities of an applicant, it seems to me that I must be given a reason by whoever is seeking the restriction. Bayer have given me no such reason and I therefore decline to impose a blanket export ban. However, it does seem to me right that the position should

be made clear in respect of exports to countries where Bayer or its affiliates hold parallel patents, and I therefore think that the licence terms should, as in the salbutamol and labetalol cases, make it clear that sales in those countries are excluded. In any case, as I understood him, that is not something to which Mr Walton had any objection.

I now turn to the remaining terms of the licence. Both Mr Walton and Mr Jacob asked me to fix all the terms of the licence and leave nothing for the parties to agree between themselves. At the hearing, Mr Walton made criticisms of Bayer's draft licence, although Mr Jacob said very little about Generics' own draft. However, the discussion was to my mind often of a somewhat cursory nature and, although a number of matters were clearly agreed, I am left to decide the terms and their drafting in a situation in which each side has generally asked me to prefer the terms of its own licence, but in which the differences have not been fully aired. I must therefore assume that the parties have accepted the risks inherent in what they have asked me to do.

Since there was discussion only of Bayer's licence, I have used it as a basis for the licence appended to this decision. Where the Bayer clauses appear to me to have much the same effect as Generics' clauses, or were

agreed by Mr Walton, or were subject to amendments agreed between Mr Walton and Mr Jacob, I have with one exception adopted them without further explanation. Furthermore, I have made a number of small alterations which seem to me uncontroversial and which again I have not detailed here since I assume the parties intended to give me that kind of latitude.

The exception referred to above relates to clauses 2(a) and 3(i) in the appended licence. Subject to the inclusion of importation rights, these terms are as proposed by Bayer. It will be noted that they give rights to sell nifedipine products, but not nifedipine itself. Even so, I have adopted the clauses since, although the Generics' draft sought the right to perform any infringing act, the terms and definitions in that draft relating to royalty payments and to termination make it clear that only the sale of nifedipine products is contemplated.

I have already decided the basis on which the royalty should be levied. To give it effect, I have incorporated in the licence terms a definition of net invoice price and a requirement for royalty payment which are modelled on the DDSA licence referred to above. I have also already settled the position on imports and exports. There is therefore no clause restricting imports, and the export limitation follows

from the earlier part of this decision.

At the hearing, amendments to the recitals were agreed at least to the extent that they became tolerable to the applicants. I have therefore adopted the amended recitals. The definitions were also acceptable to Mr Walton subject to the definition of the price on which the royalty is to be levied and also subject to the definition of Product. Bayer wished the latter term to mean any product comprising or containing nifedipine "in final consumer package form." Mr Walton objected to the quoted restriction on the basis that it had never appeared in Section 41 licences. Be that as it may, it seems to me that the restriction will give rise to difficulties when determining the royalty to be paid on, for example, supplies sold in bulk to a wholesaler. I have therefore omitted the restriction, feeling that the definition of the invoice price is sufficient in itself. However, I have otherwise thought it clearer to adopt a definition of Product based on that put forward by Generics. The latter reads "pharmaceutical formulations containing an active ingredient falling within the claims of the patent." I have used that definition subject to an amendment which limits it to nifedipine formulations.

The Bayer draft included a number of statements that

the licence does not give rights to other intellectual property, to know-how, or to help with obtaining product licences. Mr Walton objected to these terms as otiose. I agree, and have omitted them. Furthermore, the Bayer draft included a clause designed to prevent any passing-off by Bayer. Mr Walton argued that existing law is sufficient protection here. I agree and, following the decision on the same point in the naproxen case, have omitted the clause.

The Bayer terms relating to record keeping and accounting procedures required the applicant to keep and supply records "broken down according to customer, presentation and pack size." Mr Walton objected that onerous detail was being imposed on the applicants. I think that is possibly the case and have therefore removed the restriction without, I hope, interfering with the more general requirement that the relevant records shall be such as to allow the appropriate royalty to be calculated.

The Bayer draft included the following clause:

> "The applicant shall within 15 days of the last day of each calendar month deliver to Bayer or procure delivery to Bayer of a return giving full details of Compound manufactured or purchased and of dealings in the Product by the applicant during

the course of that month and the stocks held by the applicant on the last day thereof."

Mr Walton objected that the period of a month should instead be a quarter. I agree. However, the clause then in effect repeats much of the requirement which appears in the appended licence as clause 4(c). I have therefore thought it right to omit the quoted clause except for the requirement that stocks shall be reported, which requirement I have incorporated in clause 4(c).

The appended clause 4(d) relating to inspection rights is in the main as proposed by Bayer. I think Mr Walton raised no substantial objection, though he was concerned that Bayer might find out more than it was reasonable for them to know. I have therefore incorporated the requirement that the accountant performing the inspection shall report to Bayer nothing more than the amount of royalties due.

Bayer also put forward as part of clause 4(c) a term specifying the arrangements to be adopted in respect of taxation. Mr Walton again argued that the term was unnecessary and would not have any practical effect. This seems to me to be a specialist matter on which I was given little elucidation at the hearing. If, as seems to be the case, the proposed term merely sets out

what are the normal requirements of the Inland Revenue, I see no reason for its inclusion in the licence and I have therefore deleted it.

Bayer also proposed a clause requiring the applicant to place on their packaging and advertising material detailed wording indicating that the product falls within the scope of the patent and is sold under a licence without their consent. This was with a view to safeguarding their position under community law. My own view is that this would be an unduly onerous imposition, particularly since the situation is already made clear in the opening recital in the licence.

Clause 5(b) is in substance as originally proposed by Bayer. At the hearing, Mr Jacob suggested that the clause needed amendment because it was in fact Bayer's intention that Generics should not be free to take infringement action. However, that appears to me to be contrary to Section 46(4) and I have therefore adopted the clause as it was proposed except for one amendment. The final words of the clause as proposed required the applicant to render to Bayer "all assistance within its power." That seems to me somewhat open ended and I have therefore adopted the appended wording. I should add that I have not adopted the alternative clause put forward by Generics, largely because I feel it leans too far in the direction of requiring Bayer to

institute infringement proceedings.

Clause 6(i) and (ii) as proposed by Bayer specified a 21 day default period. Generics proposed 60 days in respect of royalty payments and 30 days for other breaches. I have decided that 30 days is appropriate in both cases.

The requirement by Bayer that the licence be terminated in the event that control of the applicant company should change hands is not one I accede to. The identity of the licensees is not a material factor in proceedings under the Schedule in the sense that one does not have to be satisfied as to their suitability and I see no reason why an asset of the company, which is what this licence becomes, should be excluded if the company changes ownership.

The termination clauses proposed by Bayer require Generics to dispose of any stocks of nifedipine or nifedipine products in a manner to be determined by Bayer. As I understand it, this is a reasonably standard requirement and I have therefore included the termination clauses unchanged, in spite of objection from Mr Walton.

The draft proposed by Bayer included a prohibition on assignment or sub-licensing in the following terms:

"The applicant shall not assign or purport to assign the benefit of any of its rights under the licence nor grant nor purport to grant any sub-licence in respect thereof to any party and shall exercise such rights only by itself, its servants and employees."

Mr Jacob argued that this wording rightly prevented Generics from using sub-contractors to manufacture nifedipine formulations. In his view, if sub-contractors were to be used, then they should themselves come forward and apply for a licence. Mr Walton argued that sub-contracting should be permitted. I have already decided this point in the salbutamol case, and I see no reason for departing from that decision here. Clause 9 of the appended licence therefore permits sub-contracting in the same terms as were settled in the salbutamol case.

Finally, Generics' draft asks for a most favoured licensee clause. Except when the clause has been undisputed, the comptroller has so far refused to allow such clauses when settling the terms of Schedule 1 licences of right on the basis that he should not settle terms which take into account the circumstances of the particular case only to allow the settled terms to be replaced by others without further reference to

him. I see no reason to depart from that practice, and the appended licence does not therefore include a most favoured licensee clause.

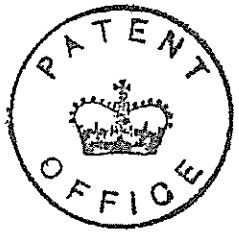
Taking into account the various matters set out in this decision, I order the grant of a licence in the appended terms.

The question of costs was raised at the hearing, but in all the circumstances of the case I think it inappropriate to award costs to either party.

Dated this 17th day of April 1986.

N G TARNOFSKY

Superintending Examiner, acting for the Comptroller



PATENT OFFICE

LICENCE OF RIGHT

Whereas Bayer AG (hereinafter called "Bayer") is the registered proprietor of United Kingdom letters patent no 1,173,862 (hereinafter called "the Letters Patent"),
And Whereas under the provisions of paragraph 4(2)(c) of Schedule 1 of the Patents Act 1977 any person is entitled as of right to a licence under the Letters Patent,
And Whereas Generics (UK) Limited (hereinafter called "the Applicant") and Bayer have not agreed to a licence or the terms of such a licence,
And Whereas the Applicant has applied to the Comptroller for such a licence,
And Whereas under the said provisions the Comptroller is empowered to settle the terms of such a licence,
The Comptroller has settled the terms hereinafter set forth.

1. DEFINITIONS

The following terms shall have the following meanings:

"Compound" shall mean 4-(2'-nitrophenyl)-2, 6-dimethyl-3, 5-dicarbomethoxy-1, 4-dihydropyridine) commonly known as Nifedipine

"Product" shall mean any pharmaceutical formulation

containing the compound

"Territory" shall mean the United Kingdom of Great Britain and Northern Ireland

"Net Invoice Price" shall mean in relation to each presentation of the product the price at which Bayer's corresponding presentation of the Product is actually invoiced by Bayer to wholesalers in the UK in the calendar quarter in question, less such sales and excise taxes (including value added tax) and duties as may be included in the invoice price. If Bayer has no presentation corresponding to the particular presentation sold by the applicant, then the net invoice price shall mean a price reasonably determined by Bayer by reference to the Bayer presentation most closely resembling the applicants' presentation in question.

"Affiliate" of a party shall mean an organisation which is directly or indirectly controlled by, in control of, or under common control with, such party. For the purposes of this definition control shall consist of the ownership of fifty one per cent (51%) or more of the voting stock of an organisation.

2. SCOPE OF LICENCE

(a) The Applicant is permitted to do the following things in the Territory:

(i) to make the Compound;

(ii) to import the Product and/or the Compound

(iii) to convert the Compound into Product;

(iv) to sell the Product.

(b) The licence does not grant to the Applicant any right whatsoever outside the Territory.

3. COVENANTS BY THE APPLICANT

Unless authorised to the contrary by Bayer in writing the Applicant shall not at any time during the continuance of the licence

(i) use Compound manufactured or purchased by the Applicant hereunder for any purpose other than for the purpose of compounding and converting the same into the Product hereunder and selling the Product in the Territory;

(ii) sell Product outside the Territory in countries where to do so would infringe patents equivalent to the present letters patent;

(iii) refer to Bayer or to any Affiliate of Bayer in any packaging, promotional or advertising materials relating to the Product;

4. ROYALTY AND PAYMENT BY THE APPLICANT

(a) For the rights granted under this licence, the Applicant will pay to Bayer on all sales of the Product a royalty at the rate of 30% of the Net Invoice Price;

(b) The Applicant shall keep true and accurate records of all the quantities of Compound manufactured or imported and the product sold hereunder the said records containing all such details as may be necessary for the calculation of the amount of any payment to be made hereunder;

(c) The Applicant shall within thirty (30) days of the last day of each calendar quarter (that is to say March 31st, June 30th, September 30th and

December 31st) despatch to Bayer a statement accompanied by a certificate in writing by an independent accountant qualified under the provisions of Section 389 of the Companies Act, 1985, certifying the truth and completeness of such a statement and showing the total quantities of Compound manufactured or purchased and of the Product dealt in hereunder by the Applicant during the preceding quarter and the stocks held by the Applicant on the last day thereof and shall within thirty (30) days of the last day of each quarter remit to Bayer in sterling and at such major clearing bank in the United Kingdom as Bayer shall indicate to the Applicant such amount of royalties as may be payable in respect of that quarter hereunder.

(d) Bayer shall have the right, upon reasonable notice and at any reasonable time, by any independent accountant authorised by Bayer, to inspect and audit the records and accounts of the Applicant and any other books, receipts, invoices, vouchers or other records relating to the manufacture or purchase of the Compound and dealings in the Product and of the make-up of the invoices therefor and all other facts or matters relating to the calculation of the payments due to Bayer and such representative shall be entitled to take

copies of, or extracts from, any such materials. In the case of such materials being stored in, on or by any computer, the Applicant will provide legible and comprehensible print-outs thereof. In the event that any examination of such materials reveals an error exceeding 0.5% of the total sum paid to Bayer in respect of any three months' period, then the cost of such inspection and audit shall be borne by the Applicant. Any inspection and audit may take place following expiration or termination of this Licence until all outstanding claims have been settled. Any accountant authorised under this clause shall report to Bayer only the amount of royalties due and payable to Bayer under this licence.

5. PROTECTION OF THE LETTERS PATENT

(a) If the Applicant at any time during the continuance of the licence shall become aware of an infringement or possible infringement of the Letters Patent it shall forthwith notify Bayer;

(b) Bayer shall be under no obligation to the Applicant to take any proceedings or other steps to prevent any infringement of the Letters Patent or of any other Letters Patent. If Bayer, in its own discretion, decides to take any proceedings or

other step to prevent any such infringement or otherwise to protect the Letters Patent the Applicant shall render to Bayer all reasonable assistance.

6. DURATION

The licence shall commence on 17th April 1986 and shall continue for the unexpired residue of the term of the Letters Patent provided, however, that Bayer may forthwith by notice in writing to the Applicant terminate the licence:

(i) if the royalties due hereunder or any part thereof shall at any time be in arrears or unpaid 30 days after the same shall have become due; or

(ii) if the Applicant shall commit any irremediable breach of any obligation herein contained or shall fail to correct any remediable breach within 30 days of being notified of it in writing by Bayer; or

(iii) if the Applicant shall compound or make arrangement with its creditors or go into liquidation or have a received appointed

for the whole or any part of its assets; or

(iv) if the Applicant shall challenge the validity of the Letters Patent.

7. TERMINATION

(a) Forthwith upon the termination of the licence for whatever reason other than normal expiry by effluxion of time the Applicant shall forthwith and at its expense dispose of all stocks of Compound and Product (whether partly finished ot otherwise) in such a manner as Bayer shall direct;

(b) Any termination of the licence shall be without prejudice to any right of action vested in Bayer or to any provision herein relating to accounting or payment or royalties or any other sums as may be due hereunder.

8. GENERAL

(a) Bayer is not to be deemed to warrant that any other letters patent or any other right of Bayer or any third party shall not be infringed by the exercise by the Applicant of any of the rights granted hereunder;

(b) Bayer shall be entitled to surrender or abandon the Patent at any time if it should so wish;

(c) The Applicant shall indemnify Bayer in respect of any costs, claims, demands or expenses incurred by or made against Bayer directly or indirectly as a result of the activities of the Applicant;

(d) The headings in this licence are for convenience of reference only and shall not affect its interpretation.

9. ASSIGNMENT OR SUBLICENCE

The Applicant shall not assign or purport to assign the benefit of any of its rights under the licence nor grant nor purport to grant any sublicence in respect thereof to any party without the prior written consent of Bayer provided that the Applicant shall be permitted to sub-contract the manufacture of the final dosage forms of the Product in accordance with the terms of its product licence.

10. NOTICES

Any notice required to be given hereunder shall be considered properly given if sent by first class post

with recorded delivery or by telex to such address as each party shall have indicated to the other.

11. GOVERNING LAW

The licence shall be governed in all respects by the law of England.