Miss Durow
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THE PATENTS ACT 1977 BL O/068/95.

IN THE MATTER of an application under Section 46(3) by Chance Propper Ltd for the settlement of the terms of a licence of right in relation to Patent No 1539101 in the name of PyMah Corporation.

DECISION

Patent Number 1539101, originally in the name of Bio Medical Sciences Inc ("BMS") but now proceeding in the name of PyMah Corporation ("the proprietors"), is dated 29 March 1976. Under the terms of paragraph 3(1)(b) of Schedule 1 to the Patents Act 1977 it is a "new existing patent" which, by virtue of paragraph 4(2)(c) of that Schedule, became subject to licences of right on 29 March 1992. Chance Propper Ltd ("the applicants") applied on 24 February 1993 under section 46(3) of the 1977 Act, asking the Comptroller to settle the terms of a licence of right. The proprietors opposed the terms suggested in the application in a statement filed on 1 June 1993 and the applicants' counterstatement was filed on 28 July 1993.

As a result of the subsequent filing of the proprietors' evidence in chief and the applicants' evidence in answer, a number of preliminary matters arose which were dealt with at a preliminary hearing, my written decision from which is dated 11 October 1994. In that decision, I granted in part a request from the proprietors for discovery of documents from the applicants relating to financial matters, and made orders under rule 94 for certain documents to be treated as confidential. I also allowed the applicants two weeks to file additional evidence arising from documents voluntarily supplied by the proprietors and set a time for the filing of the proprietors' evidence in reply. That evidence was subsequently filed together with further requests for certain items to be treated as confidential under rule 94.

The proprietors' evidence in chief included a statutory declaration by Robert Hardy Falk, an attorney acting for PyMah in the USA, giving details of the re-examination process undertaken in the USA and of the US litigation which is underway for infringement of a US patent equivalent to the patent in suit, a statutory declaration by Robert Wilkinson, a registered pharmacist, and a statutory declaration by Bernard M Hanafin, the President of PyMah.

The applicants' evidence in answer included a statutory declaration by Philip Richard Maries, a senior sales representative for the applicants, a statutory declaration by Thomas Anthony Augurt, the Vice President for Planning of the applicants' American parent company, Propper, a statutory declaration by Kenneth Summer, the President of Propper, a statutory declaration by John David Emanuel, the Managing Director of Pax Technology Transfer and the applicants' licensing expert, a statutory declaration by Michael Williamson, the General Manager of the applicants, and a statutory declaration by Marina T Larson, a US attorney acting for Propper in the US litigation.

Following the preliminary hearing the applicants filed additional evidence in the form of second and third statutory declarations by Mr Emanuel with which he exhibited certain documents from among a number voluntarily supplied by the proprietors, specifically certain agreements and licences dating from 1975 between Akzo and Akzona and BMS, all of which companies have subsequently been taken over by the proprietors. I have since made orders under rule 94 that all these documents, including Mr Emanuel's second and third statutory declarations, should be treated as confidential.

The proprietors then filed their evidence in reply under cover of a letter from their solicitors dated 16 December 1994. This evidence included a statutory declaration by Richard Guy Reeves, a senior partner of a licensing consultancy and the proprietors' licensing expert, a second statutory declaration by Bernard M Hanafin, a statutory declaration by Patrick Francis Dillon, the proprietors' sales manager, a second statutory declaration by George Robert Wilkinson, a statutory declaration by Brian G Fitzpatrick who previously worked for the proprietors' parent company in the USA but later set up his own distribution company, a statutory declaration by James Bernard Sumpter, the proprietors' corporate manager for

quality and assurance, second and third statutory declarations by Robert Hardy Falk, a statutory declaration by David Harriss, the proprietors' patent agent, a statutory declaration by Robert J Witonsky, a scientist with BMS and co-inventor of the patent in suit, and a statutory declaration by Robert B Polak, formerly vice-president of Akzona.

When filing their evidence in reply the proprietors asked that two of the exhibits to Mr Reeves' declaration, specifically RGR-1 and RGR-3, two of the exhibits to Mr Hanafin's second declaration, specifically BMH2-1 and BMH2-2, and the statutory declarations by Mr Witonsky and Mr Polak should be treated as confidential under rule 94. In a letter dated 15 December from their solicitors, the proprietors had also sought to amend their statement of objections. The applicants objected to the amendment and it was agreed that this question, and the requests under rule 94 to which the applicants had also objected, would be taken as preliminary matters at a hearing which was fixed for 6 March 1995. Subsequently, in a letter dated 22 February, the proprietors' solicitors wrote seeking to re-amend the proprietors' statement of objections and this issue was also taken as a preliminary matter at the hearing before me, which commenced on 6 March 1995 when counsel for the proprietors was Mr Michael Silverleaf instructed by Bird & Bird, and the applicants were represented by Mr Keith Percy of Lucas & Co.

I should perhaps say at this point that the applicants changed their representative only a matter of a few weeks before the hearing and that although three days had been set down for the hearing, Mr Percy's instructions were that he was only to appear for one day. This gave rise to a number of difficulties during the hearing, not the least of which was that Mr Percy was not present when Mr Silverleaf replied on the morning of the 7 March. I shall refer to certain other difficulties later.

At the hearing Mr Silverleaf told me, and Mr Percy agreed, that the applicants had withdrawn their earlier objections to the proprietors' requests under rule 94 and were now content for the appropriate orders to be made. In these circumstances, I am satisfied that I should make the orders requested and consequently I hereby order that exhibits RGR-1 and RGR-3 to Mr Reeves' statutory declaration, exhibits BMH2-1 and BMH2-2 to Mr Hanafin's

second statutory declaration, and the statutory declarations by Mr Witonsky and Mr Polak should be treated as confidential under rule 94(1).

Although the applicants had previously made a request under rule 94(1) in relation to their list of documents arising from the discovery that I ordered following the preliminary hearing, Mr Percy did not pursue this request and I shall therefore make no order under rule 94 in relation to the applicants list of documents.

As to the proprietors' requests to amend their statement of objections, the first such request accompanied their solicitors' letter of 15 December 1994. This proposed the addition to the licence of provisions concerning the keeping of books and records, specifically the addition of a requirement that full particulars of the identity of the manufacturer and country of manufacture should be recorded for all products imported under the licence. It also proposed the addition of provisions relating to the policing of the licence which would oblige the licensee to provide the licensor with "all such information as may be material for establishing the proper fulfilment of all terms of the licence", and an independent third party not only with all the information which is recorded in the books and records under the licence, but also with all the information which ought to have been contained in the books and records and which might reasonably be required to enable that independent party to inform the licensor of any breach of the terms of the licence.

The second request to re-amend the statement of objections sought to add a provision for terminating the licence in the event that the licensee acts in breach of any term of the licence which is incapable of remedy, and further very detailed provisions on the policing of the licence and of exports made under the licence.

In pressing me to allow the amendments, Mr Silverleaf argued that provided there was no unfairness to the other side, amendments to the pleadings should be allowed at any stage in order to allow all the arguments to be exposed, especially since the other side could be compensated in costs if this were necessary. In response to my question as to the effect of the Comptroller's practice in cases involving the settlement of licence of right terms which was not to make any costs awards at all, Mr Silverleaf argued that it was within the

Comptroller's power to make any order as to costs as he saw fit so the issue of costs was quite separate from the question of whether an amendment of the pleadings should be allowed. Mr Percy on the other hand argued that it was quite unreasonable to be making changes of the sort proposed so late in the day. The provisions set out in the re-amended statement of objections in particular were highly technical and would involve third parties, such as accountants, and his clients had simply had no opportunity to seek advice on the workability of the provisions proposed. Cost awards, particularly the small awards by way of a contribution to costs typically made by the Comptroller, could not compensate his clients. Mr Silverleaf replied by saying that while the second request to re-amend the pleadings had indeed been made rather late, the first had been made almost three months ago giving plenty of time for its proper consideration.

Having heard the submissions, I decided that while I was prepared to accept the first amendment to the pleadings which had been proposed on 15 December 1994 and which would allow the general issue of policing of the licence to be aired, I was not prepared to allow the second amendment which had only been proposed on 22 February, less than three weeks before the hearing, and which involved a number of very complex and detailed provisions. In my view, one of the main objects of the procedures adopted by the Comptroller is to ensure that all the issues are exposed in writing as fully as possible at as early a stage in the proceedings as is possible so that the proceedings can be brought to a conclusion rapidly and efficiently. I am conscious of the fact that this is often not easy to achieve in applications to settle licence of right terms, largely, I am bound to say, as a result of the judgment of the House of Lords in *Allen & Hanburys Ltd v Generics (UK) Ltd et al* [1986] RPC 203 where it was held that the licence does not come into effect until the Comptroller has settled the terms. Nevertheless, in my view that is no reason to make matters worse by allowing late changes to the pleadings. I agreed with Mr Percy that it would have been quite unreasonable to introduce such a major amendment at such a very late stage in the proceedings and I was not prepared to allow that to be done.

Turning now to the substantive matters, the patent is suit relates to a sterility indicator which is used to check whether sterile conditions are obtained in a steam sterilization process. An organic compound with a melting point which is just above the desired sterility temperature

but which is depressed in the presence of moisture is used in conjunction with a wick and a strip controlling the rate of transmission of water vapour to the organic compound and the wick. An integrated measure of time, temperature and the presence of steam over a range of temperatures is obtained from the distance the dyed organic compound migrates along the wick during sterilization; in practice the measurement is by visual inspection against a scale showing safe and unsafe degrees of sterility. Leaving aside the fact that by its very nature the invention is used in situations, *eg* in hospitals, where there is an element of public safety at stake, and the submissions from the proprietors that the invention was revolutionary relative to what went before, the technical details of the invention have no bearing on the case and I shall not therefore describe them further.

It was agreed by both Mr Silverleaf and Mr Percy that there are four main areas of dispute, *viz* the appropriate basis and level of royalty payments, whether there should be any quality control provisions in the licence, whether there should be any provisions in the licence preventing the licensee from adopting a confusingly similar get up or trade dress to that of the proprietors, and whether there should be any provisions on the policing of the licensees working of the licence. Beyond these main issues however there is still a disappointingly large number of relatively minor issues on which the parties have been unable or unwilling to agree and which therefore remain for me to determine as best I can. I am bound to say that I regret the particularly unhelpful, uncooperative relationship which seems to have prevailed between the parties throughout this case. One outcome of this was that while the proprietors were prepared to accede to my suggestion that I should give two weeks after the hearing for the parties to try to agree on the minor terms, failing which I would settle them in my decision, the applicants by this time had decided that they would no longer pursue their application beyond appearing for one day at the hearing and then, in Mr Percy's words, submitting to judgment. This is doubly unfortunate not only because agreed terms are I think always to be preferred to imposed terms, but also because the settlement of a large number of minor terms on which there has been little or no argument or evidence inevitably poses difficulties for the Comptroller. It also inevitably means that it takes a disproportionate additional amount of time for me to go through all the details before reaching a final decision. One outcome, of course, as a result of the *Allen & Hanburys* judgement, is that the licence will have less time to run than had the applicants been prepared to cooperate in

the manner I suggested. Whilst I have done my best to arrive at a fair, reasonable and rational result in a timely fashion, the nature of many of the details is such that there is almost bound to be an element of arbitrariness involved.

Before coming to the substantive details, I should also refer to the difficulties which arose from Mr Percy's apparently rigid instructions that he could only attend the hearing on one day, and from the nature of the case he presented at the hearing. When opening his case, Mr Percy sought to undertake oral examination-in-chief of one of his witnesses, Mr Williamson. Whilst I pointed out to him that this was most unusual before the Comptroller since it was assumed that all the evidence had already been adduced in writing prior to the hearing, I allowed Mr Percy to proceed on the basis that he would be seeking to clarify certain points in Mr Williamson's written evidence. However, it emerged that the purpose of the examination was to bring in new evidence, whereupon Mr Silverleaf argued that if the applicants were to rely on this new evidence, it would be necessary to adjourn to give the proprietors an opportunity to consider the evidence, to apply for discovery of associated documentation if they felt this were appropriate, and to prepare to cross-examine Mr Williamson. As Mr Silverleaf said, having been confronted with new evidence at the hearing itself, he was in no position effectively to cross-examine Mr Williamson. I indicated to Mr Percy that we could not operate on the basis of having rabbits produced from hats, since the purpose of the evidential procedures before the Comptroller was to ensure that each party knew in advance of all the evidence adduced by the other side. I stated that if he wished to rely on the new evidence, I would be bound to grant Mr Silverleaf an adjournment. In my view the main reason for the giving of oral evidence before the Comptroller is cross-examination in which the evidence which has already been given in writing is tested. This is an important function and I felt it was essential that Mr Silverleaf should be given the opportunity to take advice and to prepare to cross-examine Mr Williamson on the new evidence. However, since Mr Percy's instructions did not allow him to accept any such delay, he decided after some discussion that he would not rely on Mr Williamson's new evidence, and I have therefore taken no account of it other than in relation to the narrow issue of trade dress which Mr Silverleaf was content should be admitted.

This matter and the subsequent cross-examination by Mr Silverleaf of Mr Williamson on his written evidence occupied all but about forty minutes of the remainder of the day which had already been extended by an hour and a half at Mr Percy's request. Mr Percy's problem then was that he had not at that stage made any submission to me nor had his other witness, Mr Emanuel, been put up for cross-examination. Though Mr Percy seemed to suggest that his difficulty had been caused in some way by the actions of the proprietors and by inflexible, pedantic procedures followed by the Comptroller, I must state that I do not accept this. In particular, I consider that Mr Silverleaf's conduct of the hearing was entirely proper and correct throughout. Equally, I do not accept that the procedures followed are to blame. The new evidence which Mr Percy sought to introduce by examining Mr Williamson must have been available to the applicants for some time in advance of the hearing, and it was always open to them to seek leave to introduce the matter in a proper form which would have given the proprietors a fair chance to consider the evidence and their response to it before we came to the hearing. In seeking to introduce the matter at the hearing, Mr Percy in effect wasted about an hour which would I think have been sufficient for Mr Silverleaf to cross-examine Mr Emanuel and which would then have left Mr Percy time to make his own submissions. As it was, Mr Silverleaf argued that he had given notice that he wished to cross-examine Mr Emanuel whose expert evidence on licences and royalties was central to the matter in hand. Mr Silverleaf argued that if Mr Emanuel were not put up for cross-examination, none of his evidence could be relied upon. I initially suggested to Mr Silverleaf that if Mr Emanuel were not put up for cross-examination, the proper course would not be to rule out all of Mr Emanuel's evidence altogether, but for me to put an appropriate weight on that, in effect untested, evidence. Mr Silverleaf argued, however, that the evidence given by Mr Emanuel concerned issues which were central to the settlement of the licence but which he did not accept. The only way of resolving this disputed evidence would be for Mr Emanuel to be cross-examined, and if this were not done it would be quite wrong for any of the disputed evidence to be admitted.

Having considered this, I accepted Mr Silverleaf's submission because, in the absence of any cross-examination of Mr Emanuel, I would have absolutely no basis on which to decide on the appropriate weight to give to the matters covered in his evidence. Since these matters are indeed of central importance to the settlement of the major terms of the licence, I decided

that if Mr Emanuel were not put up for cross-examination, Mr Percy should not be allowed to rely on any of his evidence.

Again, resolving this matter took up more valuable time at the hearing and Mr Percy eventually decided that he would not put Mr Emanuel up for cross-examination but would use his remaining time to make his submissions. I have therefore not taken account of Mr Emanuel's evidence in settling the licence. As will become apparent, this presents some potential difficulties in settling the terms of the licence.

Turning now to the main areas of dispute, I shall take the four major issues in order before coming to the other, minor matters.

Royalty

It is clear from the authorities that, as Mr Silverleaf submitted, the licence terms in general should be those agreed between a willing licensee and a willing licensor, as established for example in *Allen & Hanbury's Patent* [1987] RPC at page 376. As to royalties, it is also clear, in particular from *Smith Kline & French Laboratories Ltd's (Cimetidine) Patent* [1990] RPC 203, that the preferred way of determining the amounts payable is by using comparable agreements willingly entered into.

However, the only potentially comparable agreements adduced in evidence were those of 5 February 1975 between BMS and Akzo and Akzona respectively (the "Akzo agreements"), which were set out in the three exhibits to Mr Emanuel's third statutory declaration. Whilst I have decided that I should take no account of Mr Emanuel's evidence, the Akzo agreements are also referred to in the evidence in reply from Messrs Hanafin and Reeves, where it is argued that the agreements are not at all comparable with the licence I am settling. Essentially, the confidential evidence of Messrs Hanafin and Reeves shows that the Akzo agreements included very substantial initial payments and a low royalty rate. The result was that Akzo/Akzona put substantial amounts of capital into BMS in the form of large, up-front payments and BMS set Akzo/Akzona up in business as a competitor selling a range of their products. Thus, the circumstances appear very different from those applying to the licence

I must settle, which is based on a willing licensee and willing licensee approach. Mr Hanafin's and Mr Reeves' evidence also shows that of the wide range of products covered by the Akzo agreements, some were developed and some were no more than undeveloped concepts. So far as sterility indicators are concerned, at the time of the agreements in 1975 the patent in suit had not been applied for, and the technology was fledgling and not fully developed and recognised as is now the case. On this basis, I agree that it would be inappropriate to try to use the Akzo agreements as a comparable basis on which to settle the terms of the present licence.

Another way of settling terms may be to use the so called section 41 approach. This too stems from the judgment of the Court of Appeal in *Allen & Hanburys Ltd's Patent* [1987] RPC 327 at page 376 where the court decided that the approach adopted for determining royalty payments under compulsory licences granted under section 41 of the Patents Act 1949 was of use in settling royalties under licences of right. Section 41 gave the Comptroller discretion to grant compulsory licences under patents relating to foods, medicines and surgical and curative devices and, following *Geigy's Patent* [1964] RPC 391, it became well established that pharmaceutical royalties should cover three elements, namely (a) an allowance for the recovery by the patentees of the cost of discovering the drug and establishing its efficiency, (b) an allowance for the recoupment of the promotional expenses incurred in creating and maintaining the market for it, and (c) a reward for the patentees for their contribution to the art secured by an appropriate measure of profit upon the capital investment in the project. The sum of the first two elements uplifted by the third element represents the royalty payable, expressed as a percentage of the patentee's selling price. Formulae were established for determining elements (a) and (b). The uplift element (c) in *Geigy's Patent* was set at 22.5%, and in later cases it has been derived from the level of profit on the sales or costs of the patentee or of the industry as a whole.

In *Shiley Inc's Patent* 1988 [RPC] 97 the Patents Court ruled that the section 41 approach was appropriate to assist in the settlement of terms of a licence of right in respect of a heart valve, and in *Smith & Nephew Limited's Patent* (unreported - SRIS O/126/87) the Hearing Officer concluded that a surgical dressing also came within the category of subject matter for which section 41 provided a guide as to royalty. Although on appeal in *Smith & Nephew*

Falconer J disagreed with the Hearing Officer as to the manner of application of the section 41 considerations, he did not dissent from the view that the approach was appropriate for such subject matter. Mr Silverleaf contended that similar considerations applied to the sterility indicator of the present case, and therefore that I could regard section 41 as in principle offering a possible guide to determination of the royalty in this case. However, he conceded that the evidence I would require to carry out a section 41 calculation had not been put into the proceedings. The necessary evidence would, of course, primarily have been from the proprietors, so it is incompleteness of evidence from his own side which leaves Mr Silverleaf without data upon which to base a section 41 calculation. The applicants might have sought discovery of such data, but Mr Percy's position on their behalf was that the invention was not such as to justify a section 41 approach. My view is that the sort of questions of design, processing, testing and control, and the need to meet exacting standards and to satisfy a selective and cautious category of user, which contributed to Whitford J's judgement that section 41 was applicable to a heart valve, and which also caused the Hearing Officer in *Smith & Nephew* to come to the same view in relation to a surgical dressing, apply also in some measure to a sterility indicator, and I therefore share Mr Silverleaf's view that section 41 could in principle assist me in royalty determination in this case.

I note that in *Shiley* the limited amount of evidence directly applicable to section 41, certainly as compared with the copious financial evidence which from personal experience I know was commonplace in settlement of terms on a section 41 basis in respect of pharmaceutical inventions, did not deter Whitford J from seeking to apply the principles involved to assist in his determination of royalty. This requires me to look very carefully at the evidence before me to see whether it provides any indication as to how I might apply the section 41 principles to this case. Having done this I am forced to the conclusion that, even as compared with the limited evidence available in *Shiley*, there is very little in the present evidence which has any direct bearing on how I might apply the section 41 approach. I will nevertheless attempt to draw whatever I can from the evidence in this regard.

In connection with element (a) of the section 41 formula, Mr Witonsky gives some confidential evidence of the investment made in connection with the invention of the patent in suit, and Mr Silverleaf suggested that the evidence, such as it is, pointed to this being the

product of extensive research. However, the research and development element of the conventional section 41 formula is based upon the established R&D record of the patentee organisation as a whole, rather than on its concentration on a particular product, and there is nothing in the evidence to enable me to judge whether the present proprietors are more or less R&D based than, say, the patentee companies in *Shiley* or *Smith & Nephew*.

On element (b), although Mr Hanafin's confidential evidence gives figures for the American, European and UK sales of the product to be licensed, there is no evidence on the expenditure incurred by the proprietors in promoting in the United Kingdom the product to be licensed, as is required by element (b) of the conventional section 41 formula. Comparison of a limited kind might be attempted with *Shiley* and *Smith & Nephew*, in both of which the decisions appear to suggest that there was some evidence of substantial promotional effort by the patentees contributing to a relatively large element (b) in the section 41 equation. The principle UK promotional effort of the proprietors in relation to the invention in suit appears to have been directed towards persuading the Department of Health authorities of the desirability and acceptability of the product for general use. Although it is clear from the evidence that this has been a time-consuming and frustrating exercise, it is not apparent that it has been in any way unusually costly, for example in terms of commitment of sales representatives to promoting the product - in fact I am left with the clear impression that the proprietors have so far felt themselves baulked by official conservatism from being in a position to launch any major selling campaign in the United Kingdom. In this respect there is a suggestion, then, that the promotional element of the section 41 formula may properly be set at a somewhat lower level than for *Shiley* or *Smith & Nephew*.

I believe that this is much guidance as I can usefully draw from the section 41 approach, and I shall return later to this very limited conclusion.

Another method of royalty determination which has been given limited approval by the courts is the profits available approach, which involves making an estimate of the likely profit available to the licensee and deciding how that profit might be divided between the licensee and the patentee. In *Smith Kline & French Laboratories Ltd's (Cimetidine) Patents* [1990] RPC 203 Falconer J split the profit available into two shares, one which gave the applicants

a return on sales equal to their general level of profitability in all their trading, and another which represented the residue to be returned to the patentees as royalty. This approach was however criticised in the Court of Appeal because it made the royalty dependent on the licensee's reasonable remuneration rather than on that of the patentee as required by section 50(1)(b). It is therefore clear to me that the profits available approach should only be used as a last resort, though it may be used as a cross-check on results derived in other ways by showing their consequences in terms of the profit shares the parties will receive.

In the present case, since I have so far not found a suitable way of determining the royalty payable, the profits available approach may yet take on "last resort" status, and I will therefore consider the extent to which there is evidence relating to it. A major difficulty, however, is that there is no evidence of the applicants' likely, let alone their actual, level of costs or profit in relation to the product to be licensed. The only generally applicable evidence relating to profit margins is that of Mr Reeves, which shows that average profit margins on goods of a similar type to the sterility indicator of the invention are around 45%. Giving equal shares to the proprietors and the licensees, as has been usual in cases where the profits available approach has been used, would thus produce a relatively high royalty of 22.5%. On the other hand, whilst I have not taken any account of Mr Emanuel's evidence as such, I note that his statutory declaration includes an argument (as distinct from evidence) that it would be reasonable to presume that 25% of profits result from the financing and general management of the business, 25% from efficient marketing, and 25 % from efficient manufacture, leaving the remaining 25% to form a royalty relating to intellectual property and payable to the proprietors. Applying this approach to the 45% average profit margin would produce a royalty of 11.25%. However, there seems to me to be an arbitrariness in Mr Emanuel's reasoning which does not give me any confidence that it would form a justifiable basis for settling the royalty rate in this case.

Mr Silverleaf made a calculation using figures given by Mr Reeves in an exhibit to his evidence which I have ordered should be treated as confidential. In this evidence figures are given for the proprietors' costs in producing the product and their selling prices, both to dealers and to hospitals as the final end user. Unfortunately, none of the prices given are entirely consistent with those on the proprietors' published price list also provided with

Mr Reeves' evidence, so there must be some residual doubt over the precise figures. In any event, Mr Silverleaf's arithmetic was based on an assumption that the applicants' selling price would be 30% less than the proprietors' dealer price. Then, in the absence of any evidence on the point, Mr Silverleaf assumed that the applicants' costs would be the same as those of the proprietors as set out by Mr Reeves. He then subtracted these costs from his assumed selling price to arrive at a profit which he divided equally between the applicants and proprietors. Expressed as a percentage of the proprietors' selling price this produced a royalty figure of 20%. However, as Mr Silverleaf subsequently pointed out, Mr Williamson indicated under cross-examination that the applicants' likely selling price would be around 8½ to 10 pence per unit dependent upon whether sales were to distributors or direct to the end users, with the average price being around 9 pence. On this basis the applicants' profit, and hence the calculated royalty, would in fact be significantly higher than the one Mr Silverleaf had calculated using a lower selling price.

I have to conclude that there is nothing in this case to suggest that the profits available approach is of any value to me in settling a appropriate royalty. Apart from the criticisms levelled at this approach in general by the courts, and the consequent limitations on its use, the figures I have been given involve a good deal of assumption, not to say guess work, on both the applicants' costs and their selling price.

In the absence of a better guide as to royalty Mr Percy and Mr Silverleaf seemed to agree that the way forward was to look at the royalties which had been set in previously decided cases of a broadly similar nature. However, they could not agree on the outcome of such an exercise, and it is therefore necessary for me to look carefully at the cases which have been cited.

In this respect Mr Percy referred me to the judgments in *Shiley* and in *Fairfax (Dental Equipment) Ltd's Patent* (unreported - SRIS O/7/93), to which Mr Silverleaf added *Cabot Safety Corp's Patent* [1992] RPC 39. At the hearing I also drew attention to *Smith & Nephew* and *Cyprane's Patent 1224478* (unreported - SRIS 0/108/88).

As I have already noted, *Shiley* related to a heart valve, and an index-linked fixed unit price royalty of 15% of the patentee's selling price was settled. *Smith & Nephew* related to a medical dressing, and a royalty of 11.25% of the licensee's price (the agreed basis) was set using existing voluntary licences as guidance. *Fairfax* concerned a dental pin which the Hearing Officer regarded as not solely mechanical in nature, but as a surgical, or at the very least a health, product, setting a fixed unit price royalty equivalent to 14.5% of the patentee's overall selling price. *Cabot* involved an ear plug which the Hearing Officer regarded as having similarities with surgical inventions and, having considered the commercial value of the invention, set a fixed sum royalty equivalent to almost 18% of the patentee's price. Finally, *Cyprane* involved an anaesthetic vaporiser which the Hearing Officer held was not a surgical or curative device under the terms of section 41 of the 1949 Act, but for which a section 41 approach was nevertheless still applicable because of the invention's similarities with pharmaceutical and surgical products, particularly its high promotion costs. Although the resulting royalty of 7.2% of the patentee's price was substantially uplifted, this was an agreed measure to take account of allegedly infringing activities which occurred prior to the settlement of the licence.

The first thing I note from these cases is the common use made of a fixed royalty per unit. Mr Percy and Mr Silverleaf agreed that this provided the best approach in the present case, and I also agree that this is indeed the right way to proceed. It can also be seen from the cases cited above that the royalties vary from 18% for an ear plug, which was regarded as being similar to surgical inventions, through around 15% for a dental pin, which was regarded as being a surgical or a health product, and a heart valve, which on any footing must be regarded as a life critical piece of medical or surgical equipment, to 11.25% for a medical dressing and 7.2% for an anaesthetic vapouriser, which was held not to be surgical or curative but to be a mechanical device with some similarity to surgical and pharmaceutical products. The present invention concerns a sterility indicator which, whilst it probably may not properly be described as a surgical or curative device, is certainly a health product in much the same way as the *Fairfax* dental pin and the *Smith & Nephew* medical dressing. Indeed, in my view the *Smith & Nephew* medical dressing provides probably the closest technical analogue to the present invention inasmuch as it concerns an item which clearly has public safety implications but which is not of itself directly life critical in the same way, for

example, as is the *Shiley* heart valve. This consideration taken alone might suggest that the appropriate royalty in this case would not be in the upper part of the range spanned in the cited cases, though the position of the ear plug at the very top of the range does not encourage me to believe that I am justified in approaching the range on the basis simply of the relative medical or surgical content of the various inventions.

In fact in each of these five prior cases a royalty figure was set in accordance with the particular circumstances of the case, so it would not I think be right for me simply to regard these cases as indicative of a range of royalties appropriate for different categories of product in a range of products and to set the royalty on the present case in accordance with where I consider the product of the present invention to lie within that range. Rather, I think that these cases provide me with no more than broad guidance as to what is generally appropriate in the way of royalties for cases of the kind I am considering, and that I must go on to set a specific royalty consistent with that broad guidance by having regard to the particular circumstances of the present case.

In this respect, Mr Percy argued that starting from the basis of the 15% royalty which was set in the *Fairfax* and *Shiley* cases, I should lower the rate because the products in *Fairfax* and *Shiley* were good, medical products which provided a tremendous advance on what had gone before. He noted that the confidential sales figures in Mr Hanafin's evidence showed that the UK sales of the present product were very low, so, he argued, it would be unreasonable to regard the present invention as commercially valuable. He also argued that the present licence was a bare patent licence with no know-how, so the applicants would have costs in developing the product. On this latter point I do not see how the situation is any different from that in any of the cases to which I was referred, all of which concerned bare licences of right.

Mr Silverleaf, on the other hand, argued that the evidence showed that the invention had great technical and commercial value and should therefore command a higher royalty. On the technical front, he pointed out that Mr Williamson had accepted under cross-examination that the present invention was the only available steam integrator. Thus, almost twenty years after it was invented, it still represents the state of the art. As to commercial value, he

argued that the commercial value had been shown by high sales at premium prices in the USA. The small sales figures in the United Kingdom arose from very special circumstances. The evidence showed that the Department of Health's guidance in the form of Health Technical Memorandum (HTM) - 10 was still in force and that this stated that the use of steam integrators as a means of testing for sterility was not recommended. Correspondence from a Dr Hoxey of the Medical Devices Directorate of the Department of Health exhibited with both Mr Hanafin's and Dr Augurt's evidence showed that the Department was planning to withdraw the existing specifications for chemical indicators and to publish advice to the Health Service recommending that sterility indicators complying with the appropriate British standard (implementing a European standard when appropriate) should be purchased. This is I think a reference to the new guidance HTM - 2010 which Mr Silverleaf conceded had been promised by the Department of Health for about two years but which had still not at the time of the hearing replaced HTM - 10, which latter Memorandum still therefore appears to constitute the official guidance in force. In the face of this evidence, Mr Silverleaf argued that given that the nature of the National Health Service is such that the guidance from the Department of Health was critical, the present rules set out in HTM - 10 would be taken as a positive prohibition on the use of chemical sterility indicators, but that as soon as the existing prohibition was removed and replaced by a positive recommendation that such indicators should be used, the market for the present invention would immediately take off without there being any need for a marketing exercise. Moreover, given that there would only be two sources of supply, from the proprietors and the licensees, the only choice would be which of the two sources to use. Thus there would be an instantly established market for the product and, far from warranting a discount because of the need for marketing effort and expenditure, the royalty for the present invention should be set at the higher end of the range of royalties suggested by the cases referred to.

On this basis, Mr Silverleaf argued that using Mr Reeves' figure for an appropriate royalty of 16% of the proprietors' selling price, and taking as the appropriate selling price that of 12.97 pence per unit, which from Mr Reeves' evidence was the middle price for purchases of between 6,000 and 15,000 units, pointed towards a royalty of 2 pence per unit. However, as I pointed out to Mr Silverleaf, there appears to be nothing in the evidence to indicate that the middle price is necessarily the most appropriate one to use. Certainly, there is nothing

at all to imply that this is the "average" price, as was suggested by Mr Silverleaf, because that would need evidence on the numbers of purchases of different quantities which has not been adduced. In the absence of any such evidence, the middle price quoted is no more that exactly that - a middle price. Indeed, it seems to me that I would be much more justified in taking the lowest price applicable to large purchases of more than 16,000 units on the basis that the most important customers will be hospitals or Health Authorities who are likely to buy in large quantities.

Mr Percy had also pointed out that there were no guarantees that the Department of Health would stick to its plans to recommend sterility indicators within the relatively short timescale of the present licence. On the other hand, as Mr Silverleaf observed, the advantage of a running royalty figure in this situation is that for so long as the Department of Health stick to their present prohibition there will be no sales at all to hospitals, and if there are no sales, no royalty will be payable regardless of the rate set for the royalty. If, however, the Department of Health do change their posture and sales take off as a result, then and only then will royalties be payable. These circumstances, he contended, are ideally suited to the setting of a relatively high running royalty which is only paid if and to the extent that there are sales.

Having considered this, I find that the evidence favours Mr Silverleaf's argument that the present invention should be regarded as a technically valuable invention with a high potential market in the United Kingdom, but that development of that market has been inhibited by the absence so far of a Department of Health recommendation for the use of sterility indicators. I note, however, that Mr Hanafin's evidence in the proprietors' evidence-in-chief submitted in November 1993 suggested that the UK market was about to take off, but Mr Dillon's evidence in the proprietors' evidence-in-reply, which was submitted more than 12 months later, said much the same thing. The licence has only about a year to run, and the evidence does not establish whether the new Department of Health guidance HTM - 2010, issue of which appears to me to be a prerequisite to expansion of the UK market for the invention, will even appear within that time. I am satisfied that I must judge the commercial value of the invention in the context of the UK market as established in the evidence, rather than as it might become at some indeterminate point in the future. Thus, although I am persuaded

of the invention's high technical value, I cannot conclude other than that its commercial value in the context of the UK market is not outstanding. This would tend to suggest that I should settle the royalty at a figure in the lower part of the range spanned by the prior cases, and certainly that it should be well below the highest level of 18% set in *Cabot* for the ear plug of high commercial value.

This is not inconsistent with my earlier conclusion, in considering the section 41 approach, that the promotional element in the royalty formula for the present invention should be set at a somewhat lower level than had been adopted in *Shiley* or *Smith & Nephew*. Unfortunately, however, the limited evidence and guidance available to me in the proceedings do not direct me very clearly towards any particular figure for the royalty level, and I regret therefore that an element of arbitrariness in my choice of a figure seems unavoidable. Subject to that caveat, therefore, and in all the circumstances of the case as I have reviewed them, I conclude that a royalty equivalent to a percentage in the region of 10% of the proprietors' lowest selling price is appropriate.

As I indicated above, the detailed evidence is not entirely consistent as regards the proprietors' selling price, even allowing for the different price figures which are applicable to different quantities purchased. In the circumstances, I do not consider that I would be far wrong to use the figure of 10 pence which was quoted in Mr Dillon's evidence as the proprietors' minimum selling price. It is true that Mr Dillon accepted in cross-examination that this figure was an approximation which was convenient for the purpose of calculation and that it did not agree with PyMah's published price list which showed a price of 11.34 pence per unit for purchases of more than 16,000 units. However, different figures are shown in the proprietors' confidential evidence relating to their selling prices to dealers and to hospitals, and I believe that it is sensible and fair to use Mr Dillon's figure of 10 pence per unit. Applying 10% to this gives me a royalty of 1 penny per unit, and I conclude that this is the royalty which should apply in the licence the terms of which I am required to settle.

I was not given any assistance at the hearing in relation to a dispute which arises concerning the acts to which the royalty should attach, there being a clause proposed by the applicants

stating that royalty should be payable only once in respect of any product. I regard it as self-evident that royalty should only be payable once in respect of any product, and a convenient way to achieve this, and the one I shall adopt, is to provide that royalty is payable on any disposal of the product in the territory, disposal to include disposal for export, but to include the proprietors' proposal that royalty shall be due on all unsold stock at expiry or on termination.

Quality Control

The question of the Comptroller's jurisdiction to include quality control provisions in a licence of right arose at the preliminary hearing, when I was referred to the judgement in *Allen & Hanburys Limited v Generics (UK) Limited and others* [1986] RPC 203, and in particular to the contrasting views of Lord Diplock, who considered that the Comptroller had a wide discretion as to the terms he could include in a licence of right, referring specifically to a quality control clause, and of Lord Templeman, who came to the opposite conclusion. In my preliminary decision I noted that subsequent judgements, for example in *Hilti AG's Patent* [1988] RPC 51, had tended to follow Lord Diplock's approach. I left the matter open at that stage, stating that I assumed that there would be further argument at the full hearing. In the event, however, I heard no further argument of substance as to the matter of jurisdiction at the full hearing. I am bound to conclude, therefore, that since in *Hilti*, which was settled in the light of *Allen & Hanburys v Generics*, the need to take account of the public interest persuaded the Hearing Officer to include a quality control provision, and this was not altered by the Patents Court (albeit that it was not challenged on appeal), I too am empowered to include such a provision if the circumstances of the case are appropriate. I will therefore proceed to consider whether a quality control clause should be included, on the basis of whether there is a demonstrated need for such a clause in the public interest on the facts of this case.

Mr Percy made much of the fact that the international and European standards for sterility indicators had not yet been finalised, and this was effectively confirmed by Mr Dillon under cross-examination. Mr Dillon explained that the ISO standard relating to the technical specification of the indicators had been agreed and was shortly to issue, but that the standard

relating to the technical standards and setting out the procedures by which the question of whether an indicator complies with the various standards can be checked was proving more controversial and had not so far been agreed. Nevertheless, whilst Mr Percy objected to the proprietors being given the final say as to whether the applicants' products were of a suitable standard, as would be required by the proprietors' proposed quality control provisions on the basis that internaional standards had not yet been settled, he indicated that he would have no objection to a requirement that samples of the applicants' products should be submitted to an independent testing authority for compliance with ISO standards. Mr Silverleaf did not accept that this was sufficient, arguing that Mr Sumpter's evidence showed that the ISO standard does not set actual quality standards but only concerns overall systems.

Moreover, Mr Williamson accepted under cross-examination that the testing procedures the applicants were proposing would result in 6.5% of their products giving a false indication that sterilization was satisfactory. Although Mr Williamson seemed not to be completely at home with the meaning of the various figures exhibited with his written evidence and used to describe the testing procedures the applicants intended to use, to an extent which cast some doubt in my mind as to the precise meaning of the evidence he gave, he was quite unequivocal in accepting that the applicants' proposal would result in a 6.5% failure rate. I am bound to say that this admission gives me pause for thought. I find it hard to accept that a false safety indication in 6.5% of cases could be regarded as acceptable, given that the widespread use of sterility indicators with such a failure rate in hospitals would surely give rise to serious questions of public safety, notwithstanding the possible continued usage of the present Bowie-Dick test strips once at the start of each day to test that each sterilizing autoclave is operating correctly.

Mr Silverleaf also argued that because there is presently only one source of sterility indicator according to the present invention, and there will only be two sources when the present licence comes into effect, there would be a great temptation for any user confronted with a faulty indicator to blame the indicator system rather than the particular producer of the indicator in question. This tendency, he argued, would severely damage the proprietors' reputation and business. He was therefore very concerned to see that all indicators according to the invention were of the highest quality. In this connection, I see similarities with the

situation in *Hilti*, where a quality control term was included not only because the issue of public safety arose, but also because the licensees' nail gun cartridge could be used in the licensors' gun so that any quality problems with the licensees' cartridges would be likely to rebound to some extent on the licensors and their reputation. I agree that this is a relevant consideration, and I therefore consider it right, for all the reasons given above, that I should include some quality control provision in the licence. This leaves the question of what form that provision should take.

In this connection, the only real assistance I was given was by Mr Silverleaf, who indicated that the proprietors would provide a list of Department of Health approved testing laboratories from which the applicants could pick one to whom samples of their product would be sent for approval on the basis of procedures and standards set out in exhibits to Mr Sumpter's evidence. In fact, in a letter dated 21 March 1995, the proprietors only provided the name of one testing body. On the basis that the applicants have not objected, I see no reason not to use this body, and I shall therefore include a provision requiring that the applicants may only sell products under the licence following the periodic submission to, and approval by, the specified testing body of samples of the applicants' product. However, I do not accept that the testing should be for compliance with Mr Sumpter's evidence, since much of this evidence concerns machinery specific to the proprietors and particular dimensions particular to the proprietors' product.

This leaves me in some difficulty as to precisely what standards should be set, and I would observe that this is an example of an area in which I regret that a degree of arbitrariness inevitably follows from the relative lack of assistance which I have received from the parties to these proceedings. That this should arise in particular in an area where there is a strong public interest is especially unsatisfactory. Having given careful consideration to the matter, drawing as much guidance as I can from the evidence available to me, I conclude that the best solution would be for the tests to be carried out on the basis of the applicants' proposals as set out in the exhibit MW-4 to Mr Williamson's evidence, but using as the specified Acceptable Quality Level the figure of 0.4 quoted by Mr Sumpter in his exhibit JSB-3 as that to be used by the proprietors for an eighteen minute test at 250°F.

Trade Dress

The question of whether there should be any provision in the licence prohibiting the licensee from using a confusingly similar trade dress seems to have arisen because of what the proprietors' US parent company consider to be the confusingly similar labelling and appearance of the applicants' US parent's sterility indicators in the USA, and because of the proprietors' fear that the same will happen in the United Kingdom under the licence. On the other hand, Mr Percy argued that the situation was analogous to that in *Fisons Ltd v E J Godwin Ltd* [1976] RPC 653 in which, as Mr Percy put it, the judge took one look at the products in question and found that they were not at all the same. In Mr Percy's view, the American products from the proprietors', and from the applicants', US parent companies were not at all similar and there was nothing to indicate any need for a provision preventing confusion in this country.

Mr Silverleaf argued that the inclusion of terms prohibiting passing-off had been approved in principle by Whitford J in *Syntex Corporation's Patent* [1986] RPC 585. Moreover, under examination and cross-examination, Mr Williamson had said that the applicants intended only to produce a so-called "Vaporline" product which Mr Silverleaf seemed to accept was distinct from the proprietors' product and would be acceptable. This was the aspect of the new evidence introduced during Mr Williamson's examination to which Mr Silverleaf raised no objection, and which I therefore admitted. Indeed, on the basis of that evidence Mr Silverleaf argued that a term in the licence restricting the applicants to producing only the "Vaporline" product would suffice, and that there was every reason to include such a provision and no reason not to.

For my part, I am not as confident that Whitford J's approval of the principle of anti-passing off provisions in *Syntex* was anything like as clear as Mr Silverleaf seemed to suggest. I note from the judgement at page 607 that the most that was said was that in the event that passing off were to occur, the inclusion of a term in the licence might save some money by avoiding the need for large amounts of evidence. Nevertheless, Whitford J remarked that such a provision would be most unusual and decided that it should not be included. As to Mr Silverleaf's suggestion that the fact that Mr Williamson had clearly indicated that the

applicants would only be producing a product of a form acceptable to the proprietors was good reason to include a provision to this end, it seems to me that one could equally well say that Mr Williamson's evidence on this point and Mr Silverleaf's apparent acceptance that the "Vaporline" product was distinct showed there was no need for such a provision. Either way, I do not think that any provision of this nature should be included. Legal remedies exist to deal with passing off, and I do not consider that it should be for the Comptroller to include provisions in a licence which would in some way add to or subtract from those rights unless the circumstances were such as to provide a very good reason for so doing. Whilst I confess that the point made by Mr Silverleaf in connection with quality control that the very specialised and rare nature of the product in question meant that it was likely that customers would tend to confuse products made by the proprietors and by the applicants did cause me to wonder whether some provision to avoid confusion might be needed, on reflection I think that this is an entirely separate issue which is properly dealt with as a quality control matter, because the argument hinges on the confusion stemming from the inherent nature of the product itself and has nothing to do with packaging or labelling or trade dress. I therefore conclude that I should not include any provisions on trade dress and passing off.

It is also I think convenient to deal here with the question of trade marks, where I note that the applicants themselves originally suggested provisions in their draft clauses 6,1 and 6.2 and 6.3, though they did subsequently agree to the proprietors' suggestion that clauses 6.2(i) and (ii) should not be included.

The proprietors on the other hand proposed an addition to the effect that the applicants' trade dress must not only include their own name and that of their distributor, but also that it must state that the product is not from the proprietors and is not sold with the proprietors' consent and, moreover, that the applicants must mark the product with a distinctive number and a legend indicating that the product is manufactured under a licence of right and that no licence has been granted for sale or distribution outside the UK. In their clause 6.3 and associated Appendix A the proprietors would impose some very stringent requirements on the applicants as regards packaging and trade dress, and in their clause 6.4 they would prevent "knocking-copy" promotions.

It is clear to me that trade mark law and the law on passing-off are quite separate issues and will give the proprietors rights to counter any abuses which might occur, independent of and additional to any terms I may settle in the licence of right. As in *Syntex*, therefore, I do not consider that there is any demonstrated need to include any of the provisions proposed by the proprietors on trade marks *etc* in the licence. However, there is agreement between the parties on the applicants' clauses 6.1, 6.2 (as revised) and 6.3, and on that basis I shall include these terms in the licence, subject to a small change to clause 6.3 to bring it into line with the rights given in clause 2.1(iv).

Policing

The proprietors proposal to include what they term a policing provision was first made in their amended statement and has two parts. The first would add to the provisions on book keeping a requirement that records be kept of the manufacturer and country of origin of all imports of the licensed product. The second part is a new provision which would oblige the licensee to give to the proprietors all such information as may be material for establishing the proper fulfilment of all terms of the licence and at all reasonable times to produce to an independent third party all information contained, and all information which ought to be contained, in the books as shall be reasonably be required. All the information provided would be confidential to the third party and would be used only for establishing proper fulfilment of the licence terms and reporting this to the proprietors. In essence what is being proposed here is an extension of the normal, commonly used provision which has also been proposed for this licence and which provides for an independent inspection of the books for the purpose of verifying the royalties owed. The new proposal would extend this into a general provision allowing an independent third party to check that the licensee is complying with all the terms of the licence.

The only parallel for such a general policing provision to which Mr Silverleaf was able to refer me was an agreed term in a licence settled by the Patent Office in *Smith Kline & French Laboratories' Patent* (unreported - SRIS 0/46/88). In the present case there is no such agreement, and I see no justification for such a provision in this case and will not include it.

Miscellaneous matters

Turning now to the remaining clauses, I shall deal only with matters still in dispute at the hearing, the first item concerning the Net Sales Price introduced in clause 1.3 of the applicants proposed licence. Given that I have decided to impose a fixed price royalty per unit, the issue of Net Sales Price is no longer relevant and can be ignored.

In clauses 2.1 and 2.2 of the licence proposed by the applicants, apart from a wholly inconsequential drafting difference, the only issue of dispute is whether the word "lawful" together with a definition should be included in relation to the manufacture of goods to be imported under the licence. The proprietors proposed inclusion of the word, and the applicants objected on the basis that the licence relates to the United Kingdom and that it is inappropriate to include extraterritorial questions of lawfulness, which is in any event not clearly defined in the proprietors' proposal. I do not think that it is appropriate to include the requirement that overseas manufacture must be lawful, since this is a matter which would properly be decided by the appropriate authority in the country concerned and is not something with which this licence should concern itself. I shall therefore not include the word "lawful" in clauses 2.1 or 2.2.

Although an earlier dispute in relation to the applicants' proposed clause 2.3 was resolved at the hearing, I note there remain two variants of the final sentence of the clause, one from the applicants expressly denying third parties the right to manufacture under the licence, and the other from the proprietors expressly denying third parties the right to manufacture and to sell or use the product outside the Territory. I do not see why either is necessary. Since the licence is expressly between two particular parties, I find it impossible to see how there could be any question of third party rights to manufacture the product, especially given that sub-licensing and sub-contracting are prohibited by clause 11. In any event, I do not think the proprietors' proposed addition withholding the right for third parties to use or sell products overseas could be accepted, since such questions are entirely outside the Comptroller's jurisdiction. I shall not therefore include either of these proposals.

There are disputes over provisions proposed on payment in clause 4 on which I was given no assistance at the hearing. These are made more complex by having been linked in various ways by conditional acceptance by the applicants of certain of the proprietors' proposals, but not of others. The first outstanding issue here concerns the additional information requested by the proprietors in their clause 4.1. I must assume that the applicants are still formally contesting this, even though it was not referred to at all at the hearing. That said, the applicants have in fact accepted a proposal from the proprietors in relation to clause 5 that the books should contain full particulars of all the product manufactured both within and without the European Community, and imported into the Territory. In fact, the proprietors' proposed clause 4.1 goes too far in requiring details of all the Product manufactured in the Community even if it is not subsequently imported into the Territory. I shall therefore restrict this clause to limit it to Product which is made in or imported into the Territory and shall include it together with the agreed provisions of similar effect in clause 5.

Clause 4.2 refers to the proprietors' bank account into which royalties are to be paid. Details of the account were provided in a letter from the proprietors' solicitors after the hearing, accompanied by a request under rule 94 that the account number should be kept off the public file. Although the applicants have not had an opportunity to comment on this, I believe that the request is reasonable, and I therefore order that the proprietors' bank account number be treated as confidential under rule 94. If they have not already done so, I order also that the proprietors inform the applicants of the account number.

Clause 4.3 concerns the proprietors' right to inspect the books and to have records kept, to which the proprietors proposed the addition of a requirement that the records should be kept for a period of years after the expiry of the patent and the licence for possible further inspection. The proprietors proposed additions in relation to keeping records were accepted by the applicants subject to a disagreement as to whether the additional period should be four years or two years. The applicants had supplied an amended clause for the licence to give effect to their partial acceptance of the proprietors' proposal and, although again this issue was not raised at the hearing, I have decided to include a clause based on the applicants' amended clause including the period of two years which is I think enough for the purpose which the clause is intended to achieve.

The proprietors' proposed clauses 4.4 and 4.5 concern who pays for the inspections of the books and was subject to a compromise proposal from the applicants which would relax the conditions set out in the proprietors' proposal as to when responsibility for the payment of costs shifts from the proprietors to the applicants in favour of the applicants and adds a provision for arbitration if the applicants consider the costs they are being asked for are unreasonable. Again I was given no assistance at the hearing with this matter, but I do not think it is unreasonable, and I shall therefore include a provision incorporating the applicants' additional suggestions.

Clause 5 of the applicants' proposed licence which concerns book keeping requirements has been dealt with above. However, the proprietors also put in an additional proposal for clause 5 in their amended statement of objections which would require the provision of full particulars of the identity of the manufacturer of Product imported into the Territory and the country from which the Product has been imported. This is yet another provision on which I have had no assistance, but I do not see that such a provision is necessary or justified. To my mind, the details which the licensee will be required to provide under clauses 4 and 5 are sufficient. In any event it seems to me possible that a requirement to state the country of origin of imports could perhaps be contrary to European law for countries which are Member States of the European Union, and I would not wish to include such a provision without hearing submissions on this possibility. I shall therefore not include the additional provisions sought by the proprietors.

The next area of dispute concerns clause 9 and the termination of the licence, specifically the various periods involved, whether termination may be triggered following a challenge to the patent by the applicants, and whether the applicants should pay royalties on all product in stock on termination of the licence and in possession of the applicants on expiry of the patent. In this connection, the normal period for termination in the event of a breach of the licence is 30 days from receipt, or deemed receipt, of notice of the breach, as decided in *Hilti*. Here, however, the applicants proposed a period of 60 days and the proprietors countered with periods of 14 days in relation to non-payment of royalties and 30 days in relation to any other notified breach. I see no reason to depart from the accepted norm of 30 days and shall use this for all the circumstances covered here. On the other time periods

for delivering up or destroying product in the event of termination and for paying outstanding royalties on termination, again I see no reason why 30 days is not appropriate and I shall use this period.

The provision allowing the proprietors to terminate the licence in the event that the applicants challenge the patent was formally resisted by the applicants in their counterstatement even though it has been approved by the courts in both *Schering's Patent 1193998 (ABM Chemical Ltd's Application)* (unreported - SRIS O/133/87) and *E.I. Du Pont de Nemour's (Blade's) Patent* and *E.I. Du Pont de Nemours & Co v Enka BV* [1988] RPC 479 & 497 respectively. This matter was not raised at the hearing so all I can say is that, in the light of the authorities, I cannot see how the applicants can succeed in their opposition to this provision, which I shall include.

Clause 12 concerns infringement. The applicants' proposed clause builds on sections 46(4) and (5) of the Patents Act 1977 and goes on to give details of the manner in which any requests under section 46(5) should be made. It would also oblige them to assist the proprietors in infringement actions against third parties at their own expense. The proprietors on the other hand have proposed that the licensee must notify them of any infringements and, in effect, that sections 46(4) and (5) should be overridden in that it would be entirely up to the proprietors whether to proceed with an infringement action against third party whilst the licensee would be obliged to provide such assistance as may be required at their own expense.

Although this matter was not argued at the hearing, Mr Percy did indicate that he was prepared to accept the proprietors' proposal. Nevertheless, I think I must still address the question of whether the parenthetical reference in section 46(4) to that sub-section being applicable "unless, in the case of a licence the terms of which are settled by agreement, the licence otherwise expressly provides" is met in a case such as this where only some, but not all, of the terms of the licence are agreed. If the terms of the parenthesis are not met in these circumstances, and the reference to "a licence the terms of which are settled by agreement" does suggest that the whole licence must be agreed, then notwithstanding that there was agreement on the very issue in question, I could not accept the proprietors'

proposal since to do so would be to override a statutory right. However, it seems to me that since the statute clearly admits of a variation in its provisions by agreement, it would be contrary to its intention to refuse to allow an agreed variation on the grounds that some other, unrelated terms of the licence were disputed. I shall therefore include the provision proposed by the proprietors.

Finally, there are the proprietors' proposals that there should be provision in the licence to the effect that the licence is a bare licence under the patent and excludes any other rights, and to the effect that the licence embodies the whole undertaking between the parties and overrides any other agreements between them. Neither of these proposals was referred to at the hearing, but they have previously been resisted by the applicants on the ground that neither provision is necessary or appropriate. I am not aware of any authorities on provisions such as these, but even if the provisions were felt to be perfectly appropriate, I agree with the applicants that they are not necessary. The licence stands on its own feet as a bare licence and this does not need to be stated. Similarly, while it may well be that the licence does constitute the whole undertaking between the parties, this need not necessarily be so and in any event, it is not a matter for the Comptroller to decide. Therefore, I shall not include either of these provisions.

Thus, in the light of the above, I order that the proprietors, PyMah Corporation, shall grant to the applicants, Chance Propper Limited, a licence under patent number 1539101 in the terms appended to this decision, to take effect from the date of this decision.

This then leaves only the matter of costs. At the conclusion of the hearing on the 7 March when Mr Percy was not present, Mr Silverleaf asked me to reserve my decision on costs until after the proprietors had had an opportunity to see and consider my decision on the terms of the licence. He indicated that certain offers had been made by both sides to settle the dispute in this case which had also proceeded in an unusual way and he would wish to have an opportunity to address me on the nature of any cost award in the light of the terms of the offer(s) which had been made and of the terms I settled in my decision. Mr Silverleaf suggested that this would be a good opportunity to consider how the practice of the Comptroller in this matter should develop in this respect.

Having considered this matter, I have decided that I should not defer the question of costs. It is not the general practice of the Comptroller to follow the practice of the Courts in relation to costs, certainly in the absence of a full and clear argument as to why an exception to the Comptrollers' normal practice should be made. I understand that the Courts' approach is intended to provide an incentive to settle matters without action in court on the basis that if an offer to settle is made on terms which are refused by the eventual winning party but which turn out to be better that those of the subsequent decision of the court, no costs are awarded to the winning party from the time the offer was made. That is of course a perfectly sensible approach where the costs awards reflect the actual costs incurred. However, this is not the position before the Comptroller, so the justification for following this procedure falls away. I therefore see no reason for me to reserve my decision on costs.

As to costs in this case, whilst there have been some delays and some ill feeling between the parties, it is clear to me that both sides are responsible in some measure for this state of affairs. For example, though Mr Percy has complained that the licence will only have around 12 months to run when it is finally settled, I am aware that his clients contributed significantly to a delay of several months in fixing the date of the preliminary hearing last year. In these circumstances, I see no reason to depart from what has become the normal practice in licence of right cases, and make no order as to costs.

Any appeal from this decision must be lodged within six weeks from the date of the decision.

Dated this 7 day of April 1995.

DR P FERDINANDO

Superintending Examiner, acting for the Comptroller.

THE PATENT OFFICE

LICENCE OF RIGHT

BETWEEN:-

1. PYMAH CORPORATION, INC, a corporation incorporated under the laws of the State of New Jersey, United States of America and having its principal place of business at PO Box 1114, Somerville, New Jersey 08876, United States of America (hereinafter referred to as "PY") and

2. CHANCE PROPPER LTD (Company No 1010297) a company whose registered office is PO Box 53 Spon Lane South, Smethwick, Warley, West Midlands, B66 1NZ (hereinafter referred to as "CH").

WHEREAS

1. PY is the proprietor of United Kingdom Letters Patent No 1 539 101 - "Sterility Indicator" which by virtue of the Patents Act 1977 is deemed to be endorsed "licences of right" under Section 35 of the Patents Act 1949 as from 29 March 1992.

2. Upon application by CH the Comptroller has settled the terms of a Licence of Right as herein set forth commencing on the date of the decision to which this Licence of Right is appended.

NOW THIS LICENCE IS GRANTED AS FOLLOWS :

1. **DEFINITIONS**

In this licence of right the following expressions shall have the meanings set out below.

1.1 The Patent - United Kingdom Letters Patent No 1 539 101;

1.2	The Product	-	a sterility indicator falling within the scope of any of the claims of the Patent;
1.3	The Territory	-	the United Kingdom of Great Britain, Northern Ireland and the Isle of Man;
1.4	Accounting Period	-	the period of 3 (three) calendar months commencing on the commencement date and each three month period thereafter and, in the last period, the period terminating on the date of expiry of the patent.

2. GRANT

2.1 PY grants to CH a non-exclusive licence of right under the Patent to:

(i) import into the Territory Product manufactured wholly within the European Community;

(ii) import into the Territory Product manufactured wholly outside the European Community;

(iii) make the Product in the Territory;

(iv) use, offer to dispose of, dispose of and keep the Product.

2.2 No other or additional licence is granted by implication or otherwise except as set out in Clause 2.1. In particular CH shall not export the Product from the Territory or sell or dispose of the Product for export from the Territory to any country in which a patent corresponding to the Patent shall be in force.

3. **ROYALTY**

3.1 In consideration of the rights granted under Clause 2.1, CH shall pay to PY a royalty at the rate of 1 penny per unit of Product disposed of in the Territory, including for export.

4. **PAYMENT**

4.1 Within 30 days of the end of each Accounting Period, CH shall provide to PY a full and accurate account in writing of :

(i) all importation into the Territory from within and outside the European Community of the Product;

(ii) all the manufacture in the Territory of the Product and all the manufacture elsewhere of the Product imported into the Territory ;

(iii) all the Product used, sold or otherwise disposed of within the Territory in respect of the Accounting Period.

such statement to be accompanied by a cheque in pounds sterling for the sum shown to be due without any deductions of whatever nature.

4.2 The written accounts shall be sent to PY via air mail to the following address: PyMaH Corporation, PO Box 1114, Somerville New Jersey 08876. Attention: Accounting Department and the royalty payments shall be made by bank wire transfer to PY's bank account No [******], Philadelphia National Bank, PO Box 7618, Philadelphia, PA, USA.

4.3 If any sum payable by CH under the licence of right shall not have been paid to PY by the due date then (without prejudice to any other claim or remedy of PY, including the right to terminate this licence of right pursuant to Clause 9), CH shall pay interest thereon at an annual rate of 3 percent above the base lending rate of Barclays Bank PLC

from time to time published in respect of the period commencing with the due date and ending on the actual date of payment.

4.4 CH shall permit PY, upon reasonable notice, at any time during normal business hours to have an independent Chartered Accountant of its own selection, but who shall be a member of the Institute of Chartered Accountants (England and Wales) and at its costs examine all relevant documents, books and records of accounts (including information contained in computer readable form) and to take copies of all such documents, books and records to determine whether all appropriate accounting of royalties hereunder and payments thereof have been made. Any information so obtained by PY's chartered accountant shall be used by the chartered accountant solely for the purposes of verifying CH's accounting to PY and shall be dealt with on the basis of strictest confidence and not disclosed to PY otherwise than to report the results of its examination. Prior to proceeding with the examination, the Chartered Accountant shall provide to CH a written and signed undertaking to maintain confidential all information coming to his attention in the course of carrying out the examination, save for such information as may reasonably be necessary to disclose to PY on a need to know basis, for purposes of reporting on the outcome of the examination. One copy only shall be made by the accountant of any copies supplied by CH and shall be kept at the office of the accountant for the purposes of the examination and determining whether all appropriate accounting of royalties and payments have been made, and two years after the expiry of the Patent or termination of this licence if earlier the accountant shall return to CH all copies supplied by them.

4.5 The examination in accordance with sub-clause 4.4 shall be at PY's cost, except that in the case where the examination shall show that CH owes PY more than 10% of the amount payable for any one Accounting Period, the costs of the examination will be borne by CH provided that the costs of such an examination are reasonable. In default of agreement between the parties in respect of whether the such cost is reasonable the matter shall be submitted to and decided by a single arbitrator ("the Arbitrator"), such arbitration to be held in the City of London. The Arbitrator shall be appointed by agreement between the parties or, failing agreement within fourteen days of a party requesting such agreement,

by the then President of the Institute of Chartered Accountants. The decision of the Arbitrator shall be final and binding on the parties.

4.6 Inspection of the records or audit may take place notwithstanding the termination or expiration of this Licence whilst any claim relating to payment under this licence remains unsettled.

5. BOOKS AND RECORDS

CH shall at all times keep at its usual place of business in the United Kingdom complete and accurate books and records of all dealings in the Product, including, without prejudice to the generality of the foregoing, full particulars of:

(i) all of the Product imported into the Territory , including manufacturing batch records and batch numbers insofar as these form part of CH's manufacturing records;

(ii) all of the Product manufactured in the Territory and all of the Product manufactured elsewhere and imported into the Territory, including manufacturing batch records and batch numbers insofar as these form part of CH's manufacturing records;

(iii) all of the Product used, sold or otherwise disposed of in the Territory, including for export.

6. SALES/PROMOTION

6.1 CH shall not make any reference to PY or its trade marks in any promotion of Product nor in any advertising literature, packaging or other material.

6.2 CH shall not use a trade mark on or in relation to the Product the same as or substantially similar to any trade marks owned or used by PY or any associated company or import any reference to any such trade marks.

6.3 CH shall use, offer to dispose of, or dispose of the Product to third parties under their own trade name and/or marks only.

7. REGULATORY APPROVAL

It shall be CH's responsibility to obtain all necessary governmental approvals and permissions which may be required to sell in the Territory the Products and to comply with all applicable laws and governmental regulations in this respect.

8. INDEMNITIES

8.1 PY shall not be responsible for any damages or losses suffered by CH arising directly or indirectly out of any activity undertaken pursuant to this licence of right. CH shall indemnify and hold PY harmless from any claims, including legal fees made in respect of the exercise of any rights by CH under this licence.

8.2 PY shall not be responsible for, and CH shall indemnify and hold PY harmless from any claim, action or damages asserted by any third party on the grounds that the use, sale or disposal of the Product by CH infringes upon the patent, trade mark or any other intellectual property owned or controlled by such third party. CH shall immediately notify PY of any assertion of infringement by such third party.

9. TERM AND TERMINATION

9.1 Subject to the provisions set out below, this licence of right shall commence on the date of the decision of the Comptroller settling the terms of this licence of right, and shall continue in force until the expiry of the Patent.

9.2 PY may terminate this licence of right with immediate effect against CH:

(i) by serving written notice on CH if CH shall have failed to pay any and all royalties due within 30 days of the due date; or

(ii) if CH shall have failed to cure a breach of any term of this licence of right within 30 days after receiving a written notice specifying the breach and requiring its remedy. It is confirmed between the parties that any infringement or alleged infringement by CH of any rights held by PY under the laws of a country, other than the United Kingdom, shall not give rise to a breach under this Licence.

(iii) if CH shall seek to challenge the validity of the Patent or shall procure, cause or allow any other individual, firm or company so to do.

9.3 This licence of right shall terminate with immediate effect if CH shall enter into liquidation (otherwise than for the purposes of reconstruction or amalgamation) or shall have a Receiver or Administrator appointed over any part of its assets, or at any time control (as defined in section 840 of the Income and Corporation Taxes Act 1988) of CH is acquired by any person or group of connected persons (as defined in section 839 of the Income and Corporation Taxes Act 1988) not having control of CH at the date of this Agreement.

9.4 On termination of this licence of right under Clause 9.1 or 9.2 or 9.3, CH shall account to and pay PY a royalty of 1 penny per unit in respect of Product in stock and in possession of CH at the date of termination of the licence.

9.5 On termination of this licence under Clause 9.2 or 9.3:

(i) CH shall not use, or otherwise dispose of the Product in its possession, custody, power or control and shall immediately cease all importation and manufacture of the Product;

(ii) within 30 days of such termination, CH shall deliver up to PY or destroy, confirmed by affidavit, all the Product in its possession, custody, power or control;

(iii) within 30 days of such termination, CH shall account to and pay PY all royalties due in respect of the Product sold to a party other than PY since the end of the last Account Period.

9.6 The provisions of clauses 1,3,4,5 and 9 shall survive termination for so long as may be necessary to allow proper accounting for all royalties due in relation to the Product prior to termination.

9.7 Any rights or remedies accrued up to the date of termination shall not be affected by termination.

10. WAIVER

The failure by PY to enforce at any time or for any period any one or more of the provisions of this licence of right shall not be a waiver of them or of the right at any time subsequently to enforce all the provisions of this licence of right.

11. ASSIGNMENT AND SUB-LICENCE

This licence is to be personal to CH and CH shall not assign or sub-licence or sub-contract any of the benefits or obligations under this licence of right and CH shall not be entitled to grant to any third party a right to do any act which would otherwise be an infringement of the Patent.

12. INFRINGEMENT

CH shall give notice to PY of any actual infringement or threatened infringement of the

Patent which shall at any time come to CH's notice. It is in PY's discretion whether or not to institute such proceedings and CH shall, at its expense, provide such co-operation and assistance in the preparation and prosecution of the proceedings as may reasonably be required.

13. QUALITY CONTROL

CH shall only dispose of Product under this licence in any accounting period if at their own expense at least twenty five samples have been submitted to and approved by BSI : TESTING, Maylands Avenue, Hemel Hempstead, Hertfordshire, HP2 2SQ as having provided an Acceptable Quality Level of 0.4% on the basis of the tests specified in the exhibit MW - 4 to the evidence of Michael Williamson.

14. NOTICE

14.1 Any notice from CH under the Licence shall be addressed to:-

PyMaH Corporation
PO Box 1114
Somerville
New Jersey 08876
Unites States of America
Attention: The President.

Notice to CH shall be addressed to:-

Chance Propper Ltd
PO Box 53
Spon Lane South
Smethwick Warley
West Midlands B66 1NZ
Attention: The General Manager

14.2 Any notice required or provided for by the terms of this licence of right shall be in writing delivered by hand or sent by first class post. Notices given by post shall be deemed to have been received seven (7) days after posting. Either party may, by notice in writing, change the address to which notices are to be given.

15. GOVERNING LAW

This licence of right shall be interpreted by and be construed according to the laws to England and the parties hereto submit to the jurisdiction of the English Courts.

16. MISCELLANEOUS

16.1 The headings in this licence of right are for convenience of reference only and shall not affect its interpretation.

16.2 The singular shall include the plural and vice versa.