PATENTS ACT 1977

IN THE MATTER OF an application under section 71 by Owen Mumford Limited for a declaration of non-infringement of EP(UK) patent no. 0549694 in the name of Novo Nordisk A/S

DECISION

Introduction

1 The patent in suit, EP0549694, was granted to Novo Nordisk A/S in 1995. It concerns a pen syringe, of the sort commonly used by diabetics to administer insulin, in which a replaceable cartridge (or ampoule) containing the drug is insertable into a housing which both holds the cartridge and allows the drug to be delivered.

2 On 27 September 2000 Owen Mumford Limited wrote to Novo Nordisk seeking confirmation that a particular cartridge housing design they were proposing would not infringe Novo's patent. Novo were requested to make their assessment solely on the basis of some drawings supplied by Owen Mumford. On 23 February 2001, Novo replied that the drawings supplied by Owen Mumford did not provide sufficient information for them to be able to make such an assessment and that they would require a physical sample to do this. They also refused to grant Owen Mumford a license to use the technology covered by the patent. Not wishing to go to the expense of producing such a sample before they knew whether they would be free to manufacture their proposed housing, on 26 March 2001 Owen Mumford filed the present request for a declaration of non-infringement under section 71 of the Patents Act 1977.

3 The matter came before me at a hearing on 11 and 12 April 2002. Mr Richard Hacon (instructed by Messrs Wynne-Jones, Laine and James) appeared on behalf of the claimant and Mr Michael Tappin (instructed by Messrs J A Kemp) appeared on behalf of the defendant.

Background

4 In pen syringes the drug to be administered is contained in a cylindrical glass cartridge closed at one end by a piston which can be pushed along the length of the cartridge to expel the drug from the other end. That other end (the "neck") is sealed by a rubber diaphragm held on by a metal cover. In use the cartridge is placed in a housing and a needle is attached so that one end of it pierces the rubber diaphragm, thereby allowing the drug to be expelled through the needle when the piston is pushed. The patent specification explains that because housings of several different designs have been developed, each requiring a cartridge whose neck is of slightly different dimensions or design, it has been necessary to supply each drug in a number of different cartridges. The object of the invention, it says, is to provide a system of tops that allows a single

design of cartridge to fit any housing.

5 Claim 1 is in two-part form and reads as follows:

> 1. A pen syringe comprising a housing (14), an exchangeable cartridge (8) with a plastic top (1) having interlocking means (7) mating corresponding interlocking means in the housing, and having connecting means (5, 18) adapted to receive an exchangeable needle hub (13) carrying a needle (15), the cartridge being a standard cartridge of the kind having a neck part (9) with a flange and being closed by a rubber membrane sealingly secured against the flange by a metal cover (12) having its edge beaded behind the flange, characterized in that the plastic top has a bore with a diameter conforming the outer diameter of the metal cover of the cartridge, the inner wall of said bore being provided with protrusions (3), and that the plastic top is deformable allowing the protrusions to pass over the metal cover and grip behind the beaded edge of this cover when the neck part (9) of the cartridge is pressed into said bore.

6 There are four appendant claims, but for the purposes of this decision I need only recite claims 2 and 3:

> 2. A syringe according to claim 1, characterized in that the plastic top is provided with a thread (5, 18) coaxial with the bore as the connecting means to receive a threaded needle hub (13).
>
> 3. A syringe according to claim 1 or 2, characterized in that the interlocking means of the plastic top are knobs at the lower end of the top, these knobs having a triangular cross section with the apex of the triangle directed upwards, the interlocking means of the housing being corresponding triangular depressions in the end wall of this housing.

Proposed Acts

7 Given the object of the invention, there is a certain irony in the fact that what Owen Mumford want to do is not to make cartridges that can be adapted to fit a range of housings but to make a housing that can take a particular cartridge/plastic top combination made by Novo. Thus at the moment they only want to make one of the two components of the syringe claimed. However, the declaration they seek is in respect of both components jointly, ie the combination of the cartridge with its top and the cartridge housing. Such a declaration would, so far as the patent in suit is concerned, enable them not only to make their intended housing to take Novo cartridges but to supply the housing with their own Novo-like cartridges and tops. The latter is a possibility on which neither side has addressed me, no doubt because there are good commercial or legal reasons for Owen Mumford not wanting to do this, so I have not taken it into account. To put it another way, I have interpreted the declaration they seek as being for the combination of the Novo cartridge with its top and the Owen Mumford cartridge housing.

8 The Owen Mumford design is shown in the attached drawing. In the original drawing the various parts were clearly distinguished by the use of different colours. Inevitably

the greyscale reproduction below is not as clear, but it is sufficient for present purposes. The cartridge - which is, of course, the Novo cartridge - is shown at 8, with the plastic top 1 of claim 1 fitted to its neck. This top has small triangular projections (which I have labelled *TP*) which, in a Novo housing as described in the patent specification, engage corresponding recesses in the housing. The Owen Mumford design has no such recesses. Instead, it has a metal pressing *b* in the front end of the cartridge housing with an out-turned flange *c* at one end to prevent it moving axially to the left and an in-turned flange *a* at the other against which the tips of the triangular projections *TP* abut. The whole cartridge is urged towards the left hand end of the housing by a spring (not shown) at the right hand end. Finally, the plastic top 1 of the cartridge has a screw thread 5 on to which the needle carrier 13 can be screwed.

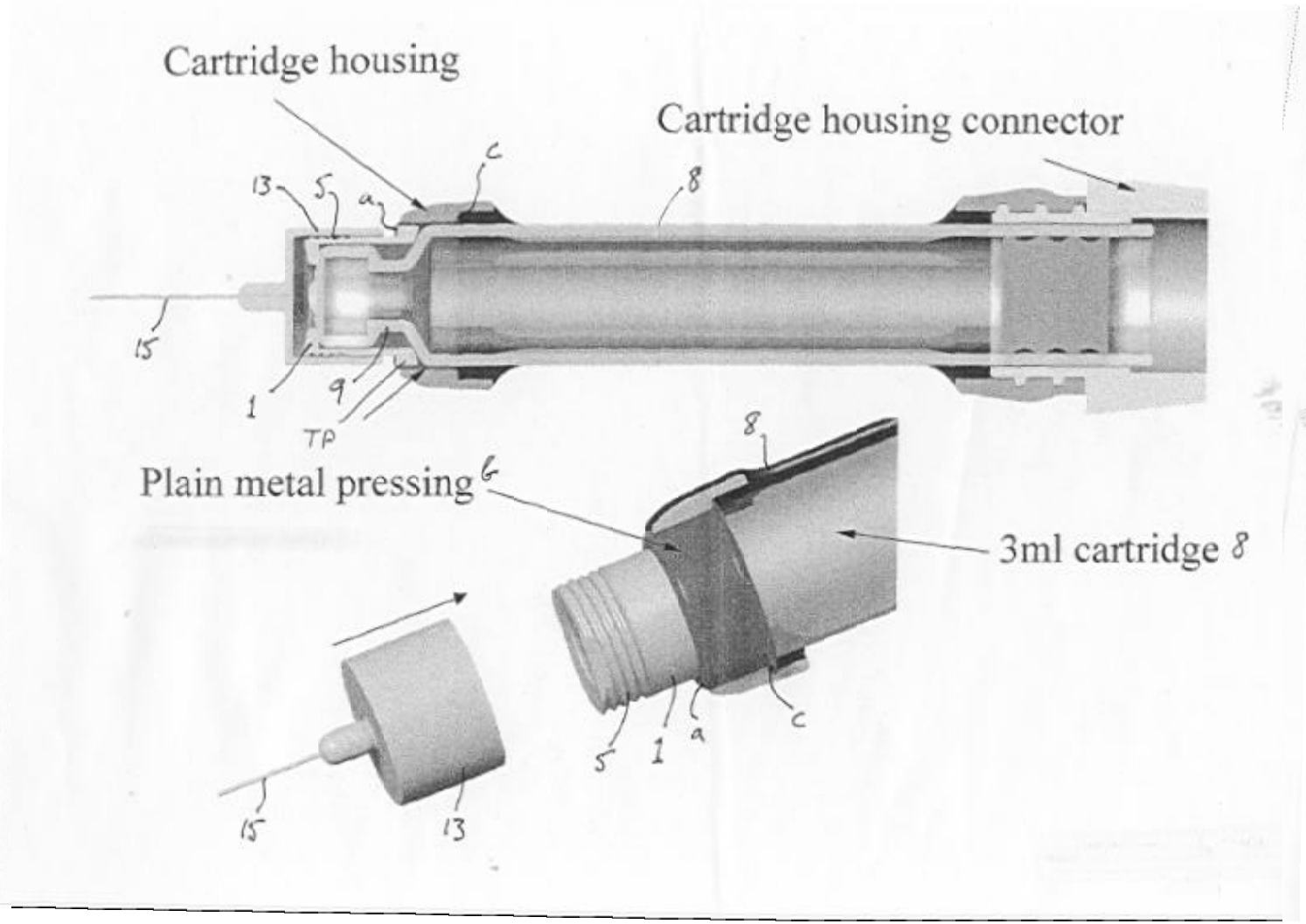
The Law

9 Section 71 of the Patents Act 1977 gives the Comptroller the power to make a declaration that an act (or proposed act) does not (or would not) constitute an infringement of a patent. Owen Mumford have asked for a declaration that the pen syringe illustrated in their drawings would not infringe any of the claims. Strictly under the terms of section 71 they should have identified specific acts that they wish to do, but I am not going to split hairs and neither, I am glad do say, did Novo attempt to do so. I shall construe Owen Mumford's request as seeking a declaration that carrying out any of acts specified in section 60(1)(a) in respect of the syringe - eg making, disposing or using the syringe - would not infringe.

10 As Mr Tappin rightly said, I have to be satisfied that nothing encompassed by the declaration sought (interpreted as I have indicated) could infringe the patent. Further, the onus of proving this rests on Owen Mumford.

11 As specified in subparagraphs (a) and (b) of section 71(1), a prerequisite of an application under section 71 is that the applicant must have sought a declaration from the patentee, furnishing full particulars of the act in question, and not been given one. As I mentioned at the outset, Owen Mumford had indeed written to Novo, and in declining to make such a declaration, Novo indicated that Owen Mumford had not provided them with sufficient information about the function of the metal pressing. If my understanding is correct, Owen Mumford had supplied the drawing but with no accompanying explanation. On that basis I think Novo had reasonable cause for complaint because it is not clear from the drawing alone what function the metal pressing performs. Novo are not, however, making an issue of this and I am grateful to them for that. When filing the application under section 71 Owen Mumford explained that friction between the projections TP and the in-turned flange of the metal pressing prevented rotation of the top when a needle was being screwed on, and on this basis Novo were able to confirm that they were still not willing to grant the declaration.

12 So much for section 71, but in any infringement-related proceedings determining the extent of protection conferred by the patent is often a central issue, and the present


Cartridge housing
Cartridge housing connector
13
5
a
c
8
15
1
9
TP
Plain metal pressing 6
8
3ml cartridge 8
5
1
a
c
15
13

proceedings are no exception. For the basis on which this should be done we have to turn to the Protocol on the Interpretation of Article 69 of the European Patent Convention. This Protocol is effectively embodied in the Patents Act 1977 by virtue of section 125(3). Article 69, much like our section 125(1), says that the extent of protection is determined by the terms of the claims, but the description and drawings can be used to interpret the claims. The Protocol says that the extent of protection is not limited to the strict literal interpretation of the claims, but equally the claims cannot be treated as providing no more than general guidelines to the scope of the monopoly. Rather, Article 69 defines a position between these two extremes which combines fair protection for the patentee with a reasonable degree of certainty for third parties.

13 The case law based on this Protocol is very well known. I do not think it is necessary for me to recite it in detail here, but in brief:

- *Catnic Components Ltd v Hill & Smith Ltd [1982] RPC 183* establishes that the claims must be given a purposive construction.

- *Improver v Remington [1990] FSR 181* re-phrased the *Catnic* approach in terms of three questions that could be asked if an alleged infringement fell outside the claims on a strictly literal interpretation:

  > (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -
  >
  > (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes -
  >
  > (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

  These have become known as the "Protocol questions" because they are intended to reflect the Protocol on Interpretation of Article 69.

- *Pharmacia Corp v Merck & Co Inc [2001] EWCA Civ 1610* (unreported) recognised that sometimes recourse to the Protocol questions was not helpful, and said that in such circumstances it was still necessary to go back and consider directly the balance between the patentee and third parties required by the Protocol to Article 69.

This is not the only case law to which the parties referred, but I will consider their other precedents when looking at the arguments in detail.

The Issues

14 In their statement of grounds, Owen Mumford highlighted a number of ways in which their proposed design allegedly differed from that covered in Novo's patent. Of these

the following fell away during the evidence rounds and were not relied upon at the hearing:

- that the abutment of the plastic top with the metal pressing in the Owen Mumford design occurs outside the housing, not in it as would be required to comply with claim 1;

- that Novo's cartridges are not "standard" and thus outside the scope of the claims;

- the Owen Mumford design allegedly has additional benefits including added strength, ease of cleaning, ease of use and added interchangeability of the metal pressing.

15 I think these arguments were rightly dropped. That leaves the question of whether the Owen Mumford design is infringement hinging on the interpretation to be given to what I shall call the interlocking clause in claim 1, ie that the "plastic top [has] interlocking means mating corresponding interlocking means in the housing". Mr Hacon and Mr Tappin both approached this question in three ways, looking at whether there is infringement firstly on a literal construction of the claims, secondly on a purposive construction using the Protocol questions and finally on the basis of the balance required by the Protocol to Article 69. Before I look at their arguments, though, I must say a word about the evidence.

Witnesses

16 Each party's case was supported by statements from expert witness, Professor Ian Sutherland for Owen Mumford and Dr Mark Kendall for Novo. Professor Sutherland and Dr Kendall were also cross examined at the hearing before me. They had both been well briefed in producing their witness statements and they were clearly conscious of their responsibilities as experts. Both were careful witnesses who thought about the questions put to them before offering answers. Both admitted that they did not have direct experience of working in the specific field of pen syringes although Professor Sutherland had worked on insulin infusion systems whilst at the Medical Research Council and Dr Kendall had worked on powder drug delivery (whose effectiveness is assessed against the needle syringe benchmark).

17 Both witnesses approached the issues put to them as a mechanical engineer, and despite the best endeavours of counsel to persuade me otherwise, I did not feel there was any fundamental conflict between their opinions. There was, though, a significant difference in emphasis in that Professor Sutherland concentrated much more heavily on the development and testing work that he would need to do to determine whether he could translate the Owen Mumford drawing into an accurate, marketable product, whereas Dr Kendall took it for granted that, given time, it would be possible to overcome the engineering problems. As a result Professor Sutherland was much more cautious in his assessment of what an engineer might recognise as being likely to be achievable in producing an accurate pen syringe based on the Owen Mumford drawings.

18 In the event, however, their evidence proved to be of little help to me in reaching my

decision. This was not because I felt either of them was in any way unreliable. Rather it is a consequence of the fact that the questions put to them in producing their reports and in cross examination were in the end of little assistance to me. Part of the time, for example, they were being asked to construe the patent specification and the meaning of non-technical words in it, and as counsel for both sides acknowledged, these are matters for me, not for expert evidence. They were also being asked to provide assistance in answering the first two Protocol questions, but in the event the first question was conceded and, as will be seen, I felt much of the questioning on the second Protocol question was misdirected.

Literal Infringement

19 I will now turn to the arguments as to whether the Owen Mumford design would infringe claim 1 on a literal interpretation of the claim. As I have said, this hinges on the interpretation of the interlocking clause. The underlying cause of the difficulty in interpreting this clause is the fact that the expression "interlock" is never used in the description. I have no doubt that is because this particular feature was introduced into claim 1 during prosecution of the application, and when that was done the description was not reviewed as well as, with hindsight, one might have liked, but that is by the way. The feature is now in claim 1. I do not need to concern myself with why it was introduced into a claim, but I do have to decide what it means.

20 Mr Hacon argued that the interlocking clause referred to the triangular projections and recesses on the cap and housing respectively of the preferred embodiment whose main purpose was to prevent rotation of the cap when the needle carrier was being screwed on. It follows, he said, that the clause must be interpreted as requiring at least one projection on one part fitting into a corresponding recess in the other part so as to prevent rotation. Mr Tappin, on the other hand, argued that the clause referred only to the means which locate the top correctly in the housing by helping to inhibit axial and lateral movement of the cartridge relative to the housing. It was not necessary for the interlock to prevent rotation - the clause referred simply to the features that adapted the cartridge to the housing. Two abutting flanges were sufficient to meet the clause. In the case of the Owen Mumford design, Mr Tappin said, the base of the plastic top interlocked with the in-turned flange on the metal pressing.

21 Counsel for both parties offered dictionary definitions to support their interpretation of the interlocking clause. The claimants relied on the meaning of "interlock" given in the New Oxford Dictionary of English and the defendants on the somewhat broader definition given in the Chambers English Dictionary (Edition 7). As I said at the hearing, dictionaries are rarely of any assistance in assessing the meaning of non-specialist words like "interlock" in a claim. Indeed, by rummaging through enough dictionaries each side can almost always find something that can be read as supporting their interpretation. It is for me to decide what it means, and that involves interpreting it in the context of this claim and this specification. The dictionary definitions do not help me in this and I have therefore paid no attention to them.

22 Both sides also got their witnesses to address the question of what the interlocking clause means. I shall make brief reference to some of their comments in a moment, but again, as with the dictionary definitions, I found their views on what the clause means of

very little assistance to me. Indeed, in the light of the comments of Hoffman J in *Societe Technique de Pulverisation Step [1993] RPC 513* ("*STEP*") at page 522, it is questionable whether their opinions on the meaning of this clause are even admissible, but I will let that pass.

23 In supporting his argument, Mr Tappin relied heavily on the stated aim of the invention as set out in column 2 lines 7-9, namely that:

> "It is the object of the invention to provide a system of tops making a standard cartridge usable in an optional pen syringe."

As the subsequent paragraphs explain, he said, that is achieved by using the plastic top to adapt the cartridge to the particular housing. He also relied on the optional character of another passage in the introductory part of the description at column 2 lines 46-54 which reads:

> "The plastic top may be provided with means for keyed engagement with corresponding means in a syringe to keep it unrotable (sic) when mounted with a cartridge in the syringe. This is of importance when a needle should be screwed onto the top."

He argued that it is not the purpose of the invention to prevent the cartridge rotating when a needle hub is screwed on, nor can it be given that a screw thread is merely one option for attaching the needle to the hub. This is evident, he insisted, because the provision of a screw thread on the plastic top to take a screw-on needle is relegated to a subordinate claim (claim 2), because the keyed engagement to prevent rotation is described in the second passage quoted above as optional, and because the description also refers to snap-on needles. Furthermore, he argued, even when screw-on needle hubs are used it is not always necessary to provide means to prevent rotation, because with some designs the user may be able to grip the top or cartridge to stop rotation. Taking all this into account, he argued, it is not reasonable to interpret claim 1 in such a way as to include in it a non-essential requirement, namely that rotation of the cartridge is prevented.

24 To reinforce this argument, during cross examination of Professor Sutherland, Mr Tappin produced a series of sketches A to D. Figure A showed an out-turned flange on the plastic cap simply abutting an in-turned flange on the housing, figures B and C showed different arrangements of triangular projections and fig. D simply showed two slightly-undulating or rough surfaces. The purpose of this little exercise was to attempt to get Professor Sutherland to agree that the figure A sketch met the requirements of the interlocking clause of claim 1 (he did not agree) and that in any case preventing rotation by friction was really no different from preventing rotation by projections and recesses (again, he did not agree).

25 In further support of his arguments, Mr Tappin sought to rely figure 5 of the patent specification. This shows an alternative to the main embodiment, and Mr Tappin correctly pointed out that no projections or recesses are shown in this figure. That, he said, further supported his assertion that the interlocking clause of claim 1 should be interpreted as covering abutting flanges.

26 I do not find Mr Tappin's submissions convincing, for several reasons. First, it is important to note that the phrase "interlocking means" is not used in isolation in claim 1. Rather it is one part of a clause whose total wording is very specific:

> ". . . with a plastic top (1) having interlocking means (7) *mating corresponding interlocking means* in the housing . . ." (my emphasis).

Mr Tappin argued two abutting flanges would comply with this clause because it was merely saying the two interlocking means had to correspond to and actually engage (rather than merely being capable of engaging) with each other. I disagree. Interlocking means on one member mating corresponding interlocking means on the other is not the way one would naturally describe two abutting flanges that are pressed together, even if the friction between them is sufficient to prevent rotation in use. To relate that more closely to the Owen Mumford design, it is also not a description one would naturally apply to projections on one member abutting an essentially smooth surface on the other. In saying that, I am well aware that when two surfaces are pressed together, any irregularities on one may create microscopic indentations on the other, but Professor Sutherland refused to accept that any engineer would regard that as interlocking means on one surface mating corresponding interlocking means on the other, and I am sure he was right. I have to say the low point of Mr Tappin's cross examination was reached when he tried to persuade Professor Sutherland that the triangular projections on Novo's plastic top would create indentations in Owen Mumford's metal pressing and that these would constitute the second "corresponding interlocking means".

27 Furthermore, I do not consider Mr Tappin is right to imply claim 1 must be construed as embracing snap-on needles, because the use of snap-on needle hubs is not disclosed in relation to the invention. Its only mention is in reference to a piece of acknowledged prior art which concerns a pen syringe of rather different design. Nowhere is there any suggestion that the present invention is for use with snap-on needles as well as screw-on ones. True, claim 1 is not limited to screw-on needles, but the fact that a claim is not limited to every feature of an embodiment does not mean it must be construed as including every possible variant of each unspecified feature. Moreover, as Mr Hacon reminded us, there may be other non-thread, options that require a twisting motion to attach the needle to the cartridge.

28 I do not accept that figure 5 can be relied upon to support Mr Tappin's argument either. The housing is not shown at all in figure 5 and in its absence it is not even possible to determine how the adaption of the cap to the housing is achieved in that embodiment. This is hardly surprising since the figure 5 embodiment is concerned with the way that the internal bore of the top can be modified to allow it to be attached to the neck of the cartridge, not with the way it is adapted to fit the cartridge holder. Thus the fact that no projections or recesses are depicted in figure 5 is not tantamount to a disclosure that the interlocking means of claim 1 does not require projections and recesses.

29 How, then, would the skilled reader construe the interlocking clause of claim 1? Mr Hacon submitted that on its plain meaning the skilled reader would assume it meant that

there is some sort of projection or projections on one part engaging a mating recess or recesses on the other, and I agree. However, I think the reader would also look at claim 3, because this is the only other part of the specification that refers to interlocking means. Claim 3 clearly relates to the preferred embodiment because this is the only support in the description for the claim. What it says is that the interlocking means are constituted by the triangular projections on the plastic top of the preferred embodiment and the corresponding triangular depressions in the housing.

30 Of course the skilled reader would not deduce that the interlocking means of claim 1 had to meet all the requirements of claim 3, because that would undermine the whole point of having claim 3 as a subordinate claim. However, I agree with Mr Hacon that the skilled reader would deduce from claim 3 that the interlocking means of claim 1 carry out the same function as the triangular projections and recesses of the preferred embodiment. That function is clearly stated in column 4 of the patent specification to be to prevent the top rotating when a needle is being screwed on.

31 Mr Tappin accepted that the knobs and depressions in claim 3 are the rotation-preventing "means for keyed engagement" of column 2, lines 46-51, but argued that in the claim 3 syringe preventing rotation was a function additional to the basic function of the interlocking means of claim 1. I do not think this is a tenable interpretation of the plain language used. Claim 3 does not say these are an additional interlocking means, nor does it suggest that interlocking means of this shape perform an additional function, either of which might have supported Mr Tappin's argument. It simply says they are **the** interlocking means.

32 The passage in column 2 goes on to say:

> "In some types of syringes such keyed engagement between cartridge and syringe is further used to ensure that only a certain type of cartridge is used in the syringe."

This suggests the projections and recesses may sometimes also have an additional function, but I observe this additional function does not support Mr Tappin's interpretation either.

33 Indeed, this passage in column 2 lends further support to my conclusion that the main purpose of the interlocking means of claim 1 is to prevent location. Whilst the passage in column 2 does not use the phrase "interlocking means", the way it is expressed - "means for keyed engagement with corresponding means in a syringe" - is so similar to the interlocking clause of claim 1 - "interlock means mating corresponding interlocking means in the housing"- that it strongly suggest the means for keyed engagement and the interlocking means are one and the same thing. This is not, as Mr Tappin submitted, using the description to cut down the claim. It is simply using the description to interpret the claim.

34 Taking all these things into account, I am satisfied that taking the specification as a whole the skilled reader would conclude that the interlocking clause of claim 1 requires inter-engaging projections and recesses which prevent rotation of the cap when a needle is being screwed on. For the avoidance of doubt, when I say the claim requires inter-

engaging projections and recesses I am not ruling out the possibility that there may be only one of each, or indeed that the recess could be itself constituted by an appropriately shaped projection.

35 If I still had any doubt about whether I am right to reject Mr Tappin's submissions - and I do not - there is one further factor that makes his that arguments even less plausible. Novo's own counterstatement states (at the bottom of page 3) that:

> "the interlocking means on the plastic top and in the housing can be any means which function to lock or clasp together the plastic top and housing so that the top does not rotate as the needle is screwed onto the syringe".

Clearly at that stage Novo interpreted the interlocking clause as referring to the means that prevented rotation, just as I have done. Mr Tappin's imaginative alternative had not even occurred to them. Since this is their own patent specification, this change in heart about what it is supposed to mean is singularly unconvincing.

36 Having interpreted the key clause in the claim, I now turn to the Owen Mumford design. It uses the Novo cartridge and this does indeed have projections on the plastic top. However, by no stretch of the imagination can they be said to mate "corresponding interlocking means" on the housing. The tips of the triangular projections on the Novo cartridge bear against the plain surface of the in-turned flange of the metal insert, with rotation being prevented by the friction between these tips and the surface, but there is no interlocking in the sense of claim 1. On this basis I find that there is no literal infringement of Novo's patent by the Owen Mumford design.

The Improver approach

37 Having decided there is no literal infringement, I must now look at the Mumford design as a variant on that defined in claim 1 and consider whether there is infringement of the patent when claim 1 is given its correct purposive construction. Both sides approached this primarily on the basis of the Protocol questions put forward in the *Improver* case. That I agree was appropriate because the present case is one where the Protocol questions constitute a helpful approach.

38 It was common ground that the variant to be considered when asking the Protocol questions is the provision of the metal pressing in the Mumford design and the absence of any recesses in the housing for receiving the triangular projections on the Novo cartridge top, rotation being prevented by friction between the tips of those projections and the metal pressing. That friction, of course, depends on sufficient axial force being applied.

39 Mr Tappin argued that the third question was the ultimate one since if no variants were allowed, the other two questions were academic. On that basis I think he was encouraging me to address the third question first, and indeed he said that is what Lord Diplock had done in *Catnic*. There is something in what he says, but with that approach one might end up asking question 3 in terms of the claim as a whole rather than asking it more narrowly in respect of the part of the claim which is relevant to the variant in question. If one asks the question of the claim as a whole, one will, by virtue

of the purposive construction required by *Catnic*, almost always coming up with the answer no. I note that, with one possible exception, the courts have always addressed the questions in the order in which they were set out in *Improver*. Indeed even in *Catnic*, whilst Lord Diplock quoted what we now call test 3 first, he then proceeded to refer to tests 1 and 2 in way that implied they had to be answered first. (The one possible exception I have in mind is *Lux Traffic Controls Ltd v. Pike Signals Ltd [1993] RPC 107*. I am mentioning it only in passing because it was not cited by either side. In this case Aldous J answered test 3 first, but I observe that he still tied the test to the material part of the claim.) This is reinforced by the comments he later made in paragraph 23 of *Wheatley (Davina) v Drillsafe Ltd [2001] RPC 4* where again he tied the third Protocol question to "such a variant". I shall therefore stick to the conventional order.

40 Mr Tappin and Mr Hacon were agreed on the level of generality of the invention that I should consider when addressing the questions. As stated by Hoffman J in *Improver* at page 193 and reinforced in paragraph 26 of *Wheatley*:

> "The right approach is to describe the invention at the level of generality with which it is described in the claim".

The 1st Protocol question

41 At the outset of the hearing Mr Hacon conceded (rightly in my opinion) that the variations in the Mumford design had no material effect on the way the invention worked. I can therefore pass straight to test 2.

The 2nd Protocol question

42 The parties have spent a considerable time addressing question 2, and indeed it was the subject of a good deal of the evidence and of the questioning during cross examination. However, I have to say I felt they were not always addressing the correct question. The test is not whether it would have been obvious to the skilled person that a variant could be used in place of particular feature, nor whether it would have been obvious that the particular variant would actually work or could actually be made. Hoffman J gave clear guidance on this in his judgement in *Improver*. The question to be asked is would it have been obvious that the variant under consideration had no material effect on the way the invention worked?

43 In the present case, addressing that question raised another issue: exactly what information should the skilled man be given in answering the second test? In particular, should he be given enough information to know that the variant does indeed work and how it works? This does not seem to be an issue which has been raised in many previous cases. It was considered relatively recently in *Kirin-Amgen Inc v Roche Diagnostics GmbH [2002] RPC 1* where I note Neuberger J also had difficulty with it. Neuberger J concluded that in the particular circumstances pertaining to that case, the skilled man must be told that the variant works, but the circumstances of *Kirin-Amgen* were unusual and I do not construe what Neuberger J said as concluding the skilled man must always be told this. Indeed, given the peculiarities of that case Mr Hacon and Mr Tappin agreed that there was nothing to be gained by trying to apply what

Neuberger J said to the current dispute, relating as it does to a much slower moving field of technology.

44 So what should the skilled person be told in the present case? Mr Tappin argued that I should assume the skilled person is given a working sample of the variant - "working" in the sense that there is indeed sufficient friction between the top and the in-turned flange on the metal pressing to prevent rotation when a needle is screwed on. After all, Mr Tappin says, if the skilled man is to answer questions about the variant he must know exactly what the variant is. Conversely, Mr Hacon argued that it cannot be right for the skilled man to be given a working sample to inspect because if he could see that the arrangement did work and how it worked, the answer to the second question would inevitably be 'yes'. Instead Mr Hacon proposed that the correct approach is for the skilled man to be furnished with the patent, told to consider a variant whereby interlocking means of the plastic top engage flat surfaces in the housing instead of mating corresponding interlocking means in the housing and then asked:

> "Would it have been obvious in June 1995 that abutting the smooth surfaces of the plastic top and the housing would still create sufficient friction to prevent the top rotating when the needle unit is screwed on?
>
> If so, would it have been obvious that in order to achieve sufficient friction, so much axial force would have to be used that the other problems identified by Professor Sutherland would prevent the syringe from being of any practical use?"

I should explain that Professor Sutherland identified a whole series of potential design problems arising from the need to provide an adequate axial force that would need to be addressed before he would be confident that the variant could be turned into a practical product.

45 In my opinion, Mr Hacon's suggested approach is tantamount to asking whether it is obvious that the variant would work, and that is not the correct question. However, I also consider that Mr Tappin's approach goes a little too far the other way, because Mr Hacon is right to point out that providing a working example could tip the balance rather too heavily towards a 'yes' answer on the grounds that the skilled man can see the variant does actually work. It may be that the correct approach is for the skilled man to be told of the variant but not actually given a working example. However, what the disagreement between Mr Hacon and Mr Tappin really shows is that in many instances if a variant passes test 1 it may more or less inevitably pass test 2 as well. If that were always the case, test 2 would be otiose. It is not because there are instances where the outcome of test 2 will not be so closely linked to the outcome of test 1. For example (and I quote this purely for illustrative purposes, as this case was not mentioned by either party), in *Sundstrand Corporation v Safe Flight Instrument Corporation [1994] FSR 599* at p 614 Judge Ford held that because of the state of technical knowledge at the time, even if the first test had been passed, the second would not because the skilled reader would not have expected the relevant changes to have had no material effect.

46 That said, in my opinion the present case is an example where a 'yes' answer to the second question follows almost automatically from a 'no' answer to the first. Part of the

information conveyed to the skilled man in informing him of the variant would in my opinion be that the variant relies on friction to stop rotation. I consider it would then be obvious to the skilled person that the variant has no material effect on the way the invention defined in the claim works so far as screwing on a needle is concerned. How difficult it might be to 'engineer' into an acceptable product is irrelevant. Thus the variant passes the second test.

The 3rd Protocol question

47 Having decided that the answers to the first and second tests as no and yes respectively, it now falls to me to decide the answer to the third test, namely:

> "Would the skilled reader in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes the variant is outside the claim."

48 In attempting to convince me that the answer to this 3rd question should be 'no', Mr Tappin sought to rely on much the same arguments as he had put forward in relation to the issue of literal infringement and with which I have dealt above. In summary he argued that even if the purpose of the interlocking means is to prevent rotation of the top, there is nothing in the patent to suggest it is essential for that means to include projections and recesses, particularly as this feature is only introduced in claim 3. Thus he asserted that it was entirely reasonable for the patentee to be protected from a party manufacturing a device differing only in this inessential feature and which variant was aimed at achieving the same purpose.

49 Mr Hacon sought to persuade me that the answer to the third question is 'yes' ie that the patentee did intend strict compliance with the primary meaning of the claim. He pointed out that an integer in a claim cannot be ignored simply because it does not affect the inventive concept, referring me to Hoffman J.'s comments in the *STEP* case where at page 522 he says:

> "The well known principle that patent claims are given a purposive construction does not mean that an integer can be treated as struck out if it does not appear to make any difference to the inventive concept."

Mr Hacon acknowledged that Mr Tappin was not arguing the interlocking clause could be ignored altogether, but he submitted that Mr Tappin's attempts - as he put it - to "improve" the claim under the guise of construction had much the same effect.

50 Mr Hacon also argued that it is not right to construe the claim with a view to making the monopoly effective. In support of his argument he referred me to Lady Justice Arden's statement in *Pharmacia Corporation v Merck [2001] EWCA Civ 1610* where she said at page 193 that the Protocol questions

> " make it clear that the touchstone for a variant to be within a patent is not that it is necessary so that the monopoly granted is effective. On the contrary the variant must be immaterial, obvious and consistent with the language of the patent"

51 Mr Hacon suggests that in his interpretation of the word "may" used in the passage in column 2 lines 46 - 54 quoted above, Mr Tappin was trying to use the description to extend the monopoly. That, he said, was impermissible, referring me to *Glaverbel SA v British Coal Corporation [1995] RPC 255* in which Staughton L.J said at page 269 that in interpreting a patent claim:

> "(4) The whole document must be read together, the body of the specification with the claims. But if a claim is expressed in clear language, the monopoly sought by the patentee cannot be extended or cut down by reference to the rest of the specification."

52 I find Mr Hacon's arguments persuasive. I do not accept Mr Tappin's argument that because claim 3 defines the precise form of the interlocking means described in the preferred embodiment, there can be no limitation on the interlocking means included in claim 1, and in particular, that the interlocking means do not need to include at least one projection and corresponding recess. That is plainly wrong. Claim 3 merely defines a specific form of interlocking means where the projections and corresponding recesses are triangular. Claim 1 covers other forms of projections and recesses.

53 As for the apparently-optional "may" in the paragraph in column 2, I have no doubt that it simply results from the fact that the paragraph relates to a feature on which claim 1 was initially silent but which was subsequently added to the claim. Had the appropriate consequential amendments been made to the description, I am quite sure this "may" would have changed to a "must", and I believe it should now be treated as a "must", since otherwise the patentee will simply be getting a windfall benefit from what one could describe as imperfect drafting of the specification.

The language of claim 1 is clearly very carefully chosen. In drafting the claim the patentee has chosen not to say "means to prevent rotation" which would be natural way to define the invention if anything achieving that function would do. He has chosen a much more specific form of wording in the form of the interlocking clause and I cannot ignore that fact.

54 I find that the answer to the final test is 'yes' in the context of the present variant. To express that in another way in the language of *Pharmacia*, the present variant is not consistent with the language of the patent.

The Protocol per se

55 In their submissions on non-literal infringement, both parties concentrated mainly on the Protocol questions of *Improver*. However, they did both briefly address me on applying the Protocol on Interpretation of Article 69 directly, as suggested in *Pharmacia*, but concluded that addressing the balance between the patentee and third parties would in the present case lead to the same results as they had respectively reached by considering the Protocol questions.

56 The problem in the *Pharmacia* case was, as Jacob J put it at first instance, that it the Protocol questions are not easy to apply:

> ". . . to a claim in which every term is unambiguous and devoid of any question of degree . . . but which would nonetheless be read as necessarily involving the presence of other species which are not mentioned but which would play a role in the chemical properties of the compound claimed."

In the present case we do not have such a claim, and I therefore agree with both counsel that the Protocol questions and direct consideration of the balance required by the Protocol itself point to the same end result. Of course that does not mean I agree with both of them as to what the end result is, and indeed, since they disagree on the end result, that would be impossible! In my view the conclusion I have come to by considering the Protocol questions does indeed combine fair protection for the patentee with a reasonable degree of certainty for third parties.

Conclusion

57 I have found there would be no infringement of claim 1 on its literal interpretation nor, by applying both the Protocol questions and the Protocol directly, on a purposive construction of the claim. The remaining claims are all subordinate to claim 1, so my finding necessarily extends to them too. Accordingly, I declare that carrying out any of the acts specified in section 60(1)(a) of the Patents Act 1977 in respect of the pen syringe illustrated in the drawings supplied by Owen Mumford Ltd, comprising the combination of the Novo cartridge with its top and the Owen Mumford cartridge housing and in which friction between the projections on the top and the in-turned flange of the metal pressing prevents rotation of the top when a needle is being screwed on, would not infringe any of the claims of Novo Nordisk's patent EP0549694B.

Costs

58 As the claimant has won, they are entitled to costs. At the hearing both sides agreed that I should award costs according to the Comptroller's standard scale. It is the new scale that applies since the proceedings commenced after 22 May 2000, and accordingly I order Novo Nordisk A/S to pay Owen Mumford Limited £3000 as a contribution towards their costs.

Appeal

59 As this decision does not relate to a procedural matter, any appeal should be filed within six weeks.

Dated this 27th day of June 2002

P HAYWARD
Divisional Director acting for the Comptroller

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