BL O/326/12

24 August 2012

PATENTS ACT 1977

BETWEEN

Tip-top.com Ltd	Claimant
and	
Salvus Technology Limited	Defendant

PROCEEDINGS

Application under section 72 of the Patents Act 1977 for revocation of patent number EP(UK)1558311 B

HEARING OFFICER

MR. JULIAN CRUMP (for Messrs. Mintz Levin) appeared on behalf of the Claimant

DR. RICHARD GILLARD (for Elkington Fife LLP) appeared on behalf of the Defendant

Hearing date: 26-27 April 2012

DECISION

Introduction

1 Patent EP(UK)1558311 B ("P1") entitled "A safety needle" stands in the name Salvus Technology Limited ("Salvus"). The patent is derived from an earlier PCT application W02004/071560 which was filed on 9 February 2004, and claims an earliest priority date of 11 February 2003. The patent was then granted with effect from 6 December 2006.

2 An application for revocation was filed by the claimant, Tip-top.com Ltd ("Tip-top") on 16 July 2010. The claimant has applied under section 72(1)(a), on the grounds that the invention is not new and involves no inventive step, and as such is not a patentable invention; and under 72(1)(c), on the grounds that the specification is insufficient insofar as it does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art.

3 After the usual rounds of evidence, the matter came before me at a hearing on 26-27 April 2012. At the hearing, the Claimants were represented by Mr Julian Crump of Mintz Levin, and the Defendants were represented by Dr Richard Gillard of Elkington Fife LLP.

The invention

4 The invention relates to a “safety needle”, and in particular, to an attachment for rendering a needle, e.g. a syringe, safe after use in order to reduce the risk of so called “needle stick injuries”. The invention is perhaps best illustrated in figures 2 to 4 of the specification which have been reproduced below by way of reference:

FIG 2

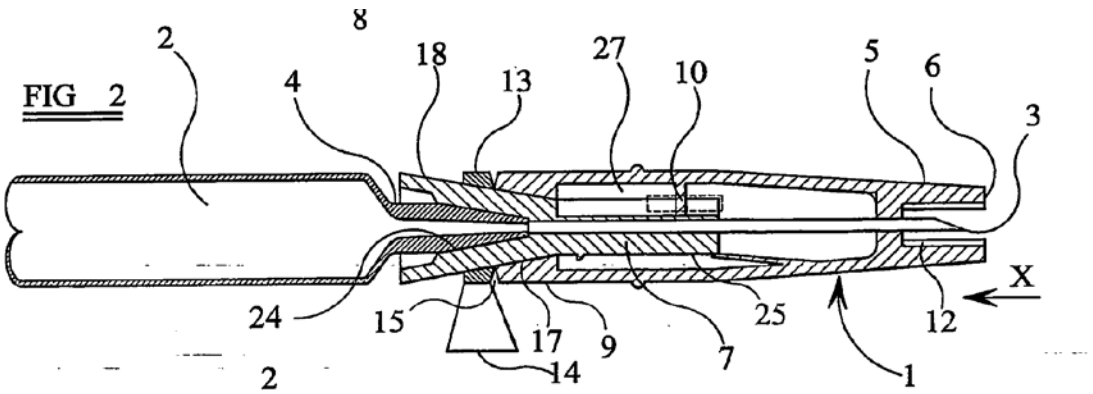


FIG 3

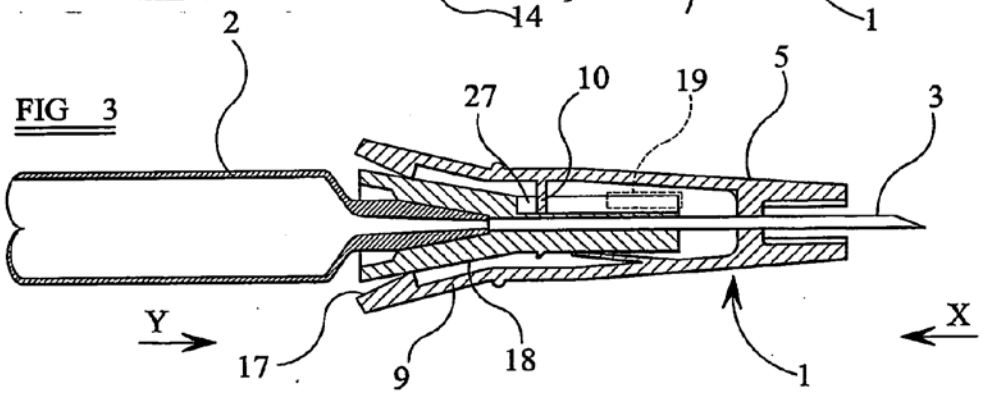
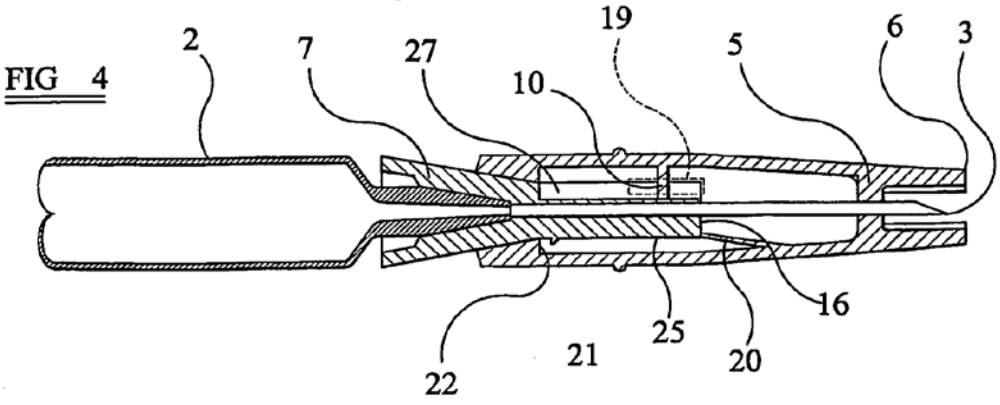


FIG 4



5 Fig. 2 is a cross-sectional view through the longitudinal axis of the safety needle 1. The needle hub 7 is cylindrical and terminates at the end which receives the syringe with a conical section 18, and is moulded onto the needle 3. The conical section 18 has an inner female Luer cone 24 which is shown frictionally attached to the male Luer cone 4 of syringe 2 (the Luer system for attaching the needle to the syringe has

two main forms, that is a taper friction fit and a screw thread and both are possible in the present invention).

6 The cylindrical slidable sleeve 5 shrouds the needle 3 and the needle hub 7, and is freely sliding on and guided by the needle hub 7. At the receiving end (i. e. the syringe end) of slidable sleeve 5, there are four cantilever arms 9 which bear resiliently upon the surface of the conical section 18. The slidable sleeve 5 is free to slide on the needle hub 7, but is temporarily prevented from doing so by the locking ring 13. Locking ring 13 is moulded integrally with the slidable sleeve 5 by a frangible joint 15, and may be partially or wholly detached by pulling on the tab 14 to break the frangible joint 15. It is preferred that the ring 13 remains attached to the slidable sleeve 5 to reduce the number of discarded parts. In addition, the frangible joint provides a tamper-evident lock. Alternatively, the locking ring 13 may be moulded to the needle hub 7 via a suitable frangible connection. When the locking ring 15 is removed, as shown in Fig. 3, the slidable sleeve 5 may be pushed in the direction of arrow X by acting on the face 6, when it will move relative to the needle hub 7 to expose the needle 3. As the slidable sleeve 5 moves, the cantilever arms 9 are forced outwards by the surface of the conical section 18. The cantilever arms 9 deform radially outward, and the reaction force against the surface 18 produces a resultant force Y (Figure 3) acting against arrow X, so that when the original force is removed, the slidable sleeve 5 returns to cover the tip of needle 3.

7 Since the restoring force is provided by the slidable sleeve 5 itself, no separate spring, e. g. a helical spring, is required

8 The specification also discloses a rotational locking mechanism for locking the sleeve after use to ensure the needle is covered and rendered safe.

9 The patent as granted contains a single independent claim which reads as follows:

> *1. A safety needle attachment (1) for surrounding a needle having a longitudinal axis, comprising:*
>
> *a hub (7);*
>
> *a sleeve (5) surrounding the hub (7) and slidable relatively to hub (7) in the axial direction;*
>
> *wherein the sleeve (5) has a radially elastically deformable portion (9), and the hub has a radially converging or diverging portion (18),*
>
> *and wherein the sleeve (5) is slidable in a first axial direction between a first position for fully or substantially fully surrounding the needle with the sleeve, and a second position for exposing the needle (3),* ***characterised in that*** *sliding between the first and second positions causes elastic radial deformation of the deformable portion (9) by sliding of the radially elastically deformable portion (9) of the sleeve (5) directly on converging or diverging portion (18) of the hub (7), and that the sleeve (5) is further slidable in a second, opposite, axial direction between the second position and a third position for fully surrounding the needle (3) by the sleeve (5), the force for*

sliding between the second and third positions being provided by the stored elastic energy in the radially deformable portion (9).

The Claimants' case

10 The claimants have identified three prior-art documents which they allege show that the invention as claimed is not novel and involves no inventive step. The documents which they rely on are as follows:

P2: US4553541 (BURNS)

P3: US5421347 (ENSTRÖM)

P4: US2002/0087180 A1 (SEARLE)

11 In summary, the claimant argues that claim 1, when correctly construed, relates to a safety needle attachment for ***any*** kind of needle having a longitudinal axis and is not limited in any way to hollow needles or syringes. Hence, claim 1 encompasses an attachment for a lancet, and lacks novelty over the disclosures in the above documents, each of which relate to safety mechanisms including a sleeve arranged to run along a surface equivalent to the hub in claim 1, which under the influence of a deformable elastic element, automatically returns to a position covering the tip of the needle after use.

12 Furthermore, they argue that even if the claims were deemed to be limited to an attachment for a syringe or other hollow needle, then the skilled person would be aware of these documents and would consider it obvious to incorporate the safety mechanisms disclosed therein into an attachment for a syringe.

13 The claimants also consider the specification to be insufficient to support the breadth of the invention as claimed. They allege that locking of the sleeve in a third position covering the tip of the needle after use is an essential feature of the invention. If the sleeve does not lock out in the third position, they argue that the attachment does not render the needle safe, and is not fit for purpose, in that it will not adequately protect the user from needle stick injuries. In their opinion, the fact that the specification discloses a single rotational locking mechanism and does not disclose how this could be achieved without rotation, is insufficient to support the breadth of the invention as claimed. The claimant goes as far as to say that the claims should be limited to a safety attachment in which the sleeve is locked in the third position, and in which movement between, first, second and third positions of the sleeve is accompanied by rotation of the sleeve relative to the hub.

The law

14 The Comptroller's powers to revoke a patent on the application of another person are set out in section 72(1) of the Patents Act 1977 ("the Act"), the relevant provisions of which read as follows:

> 72.-(1) Subject to the following provisions of the Act, the court or the comptroller may by order revoke a patent for an invention on the application of any person … on (but only on) any of the following grounds, that is to say –

(a) the invention is not a patentable invention;

(b) …

(c) The specification of the patent does not disclose the invention clearly enough and completely enough for it be performed by a person skilled in the art;

...

15 Also relevant is section 1 with the relevant portion stating:

1.-(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –

(a) The invention is new;

(b) It involves an inventive step;

…

16 Sections 2 and 3 define what is meant above by “new” and “inventive step” respectively:

2.-(1) An invention shall be taken to be new if it does not form part of the state of the art.

(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

(3) The state of the art in the case of an invention to which an application for a patent or a patent published on or after the priority date of that invention, if the following conditions are satisfied, that is to say -

(a) that matter was contained in the application for that other patent both as filed and as published; and

(b) the priority date of that matter is earlier than that of the invention.

(4) …

3. An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

17 Section 14 sets out the requirement for sufficiency:

14.-(3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

18 The claims of a patent are to be interpreted in the light of Section 125 subsections (1) and (3) of the Act, which read as follows:

125.-(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or

> patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.
>
> (2) It is hereby declared for the avoidance of doubt that where more than one invention is specified in any such claim, each invention may have a different priority date under section 5 above.
>
> (3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.

19 Section 125 (3) of the Act refers to the Protocol on the Interpretation of Article 69 of the European Patent Convention which reads as follows:

> Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

The skilled person

20 A patent specification is addressed to those likely to have a practical interest in the subject matter of the invention, and such persons are those with practical knowledge and experience of the kind of work in which the invention is intended to be used. The addressee comes to a reading of the specification with the common general knowledge of persons skilled in the relevant art, and he or she reads it knowing that its purpose is to describe and demarcate an invention. The skilled person is unimaginative and has no inventive capacity. In an appropriate case the patent may be addressed to a team of persons with different skills.

21 As I have already said above, the invention relates to a “safety needle”, and in particular, to an attachment for rendering a needle safe after use in order to reduce the risk of so called “needle stick injuries”. The claimant argues that when it comes to rendering a needle safe there is no distinction to be had between syringes and lancets, the safety requirements are the same, as are the potential solutions to the problem. Hence, the claimant argues that the skilled person is an engineer practising in the field of safety needles in general, including the design and development of safety features for both syringes and lancets. Indeed, the claimants have produced evidence to show that there were inventors working on both syringes and lancets at the priority date of the invention (see exhibits BPL20 & BPL21, BPL22 & BPL23 attached to Barry Liversidge’s witness statement of 19 January 2012).

22 The defendants on the other hand consider the skilled person to be an individual or a team working on the development of safety needles, and in particular needles for attachment to syringes. Whilst they accept that he may have been aware of the existence of lancets and their uses, he would not have had any particular expertise

in this area and would not seek out such expertise when designing a safety assembly for a syringe, for example, which includes a hollow needle.

23 To some extent, I agree with both parties. I think that the skilled man would be an engineer engaged in the development of safety needles with some general awareness and/or experience of both the design and development of syringes and lancets. The extent of his knowledge is something which will be addressed in subsequent paragraphs.

Common general knowledge

24 The law as to what constitutes common general knowledge is set out in the decisions of the Court of Appeal in *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd*[1] at paragraphs 482-483 and *Beloit Technologies Inc v Valmet Paper Machinery Inc*[2] at paragraphs 494-495. Counsel for the Patentees emphasised that, in order to constitute common general knowledge, it is not enough that information is generally known to the relevant skilled persons: it must also be, in the words of the Court of Appeal in *General Tire*, "generally regarded as a good basis for further action". Laddie J put the same idea in slightly different words in *Raychem Corp's Patents*[3] at paragraph 40 when he said "generally regarded as sufficiently reliable to use a foundation for further work".

25 At the hearing, and throughout the correspondence, there has been a significant amount of discussion as to the common general knowledge of the notional person skilled in the art. The question is basically whether or not the skilled person would consider lancets when designing a safety needle attachment. Is the problem a safer syringe for injection? Or is the problem one of preventing needle stick injuries from any kind of needle? Do lancets and hypodermic needles cross-over sufficiently for both to be considered by the skilled person?

26 The claimants argue that the person skilled in the art would be someone who is familiar with all types of safety needle device, including syringes and lancets, and as such, would have relevant knowledge of the design and construction of such devices, their principles of operation, the materials used in their manufacture, and their respective uses, advantages and disadvantages.

27 The defendants' position, as one might expect, is slightly different. In their opinion, the skilled person would be aware of conventional techniques for fabricating needles and will be familiar with their attachment to syringes and other injection devices. He will be aware of conventional fabrication techniques and materials including a basic knowledge of the mechanical aspects of such devices, and how they are intended to work. He may well be aware of related medical devices such as lancets and the like, but will appreciate that needles for injection and lancets have different applications and different associated problems. At the hearing, Mr Gillard drew my attention to the second of the witness statements provided by Mr Weston where he describes having carried out an extensive review of the patent literature relating to needles and lancets. In his witness statement Mr Weston concludes that:

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[1] General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd [1972] RPC 457
[2] Beloit Technologies Inc v Valmet Paper Machinery Inc [1997] RPC 489
[3] Raychem Corp's Patents [1998] RPC 31

"(18) By way of summary of our findings, it appears that lancets and safety needles/syringes have developed along different paths. In my view this is for the obvious reason that their functions are different. In the case of automatic lancets, the aim is to very quickly prick the skin to a shallow depth to obtain a capillary blood sample. Therefore such devices provide an impulsive action to the lancet blade, and it follows that the penetrative portion of the stroke of the lancet will be very short in the order of a couple of millimetres. It is desirable that the lancet blade is retracted into the housing to prevent subsequent injury and risk of contamination.

(19) Conversely, safety devices for hypodermic syringes are not generally required to be impulsive in operation – Indeed, the situation is quite the opposite. Therefore the development path for safety needles has been aimed at providing devices for inserting a needle much further into the tissue than would be needed for a lancet, holding the needle there during injecting of the drug, and then withdrawing the needle. Once the needle tip is out of the tissues, a mechanism ensures that it is made inaccessible. This is a significant difference between lancets and safety needles."

28 The point which the defendant is trying to make here is that there appear to be distinct differences in the function and operation of syringes and lancets which have resulted in them developing along different paths. This, the defendant argues, is supported by the fact that syringes for injection and lancets for penetrating the skin are included in completely separate International Patent Classification (IPC) codes. Mr Gillard has also provided evidence in the form of a number of nursing textbooks which are intended to show that, at least from the end users point of view, syringes and lancets are distinctly different in their use and operation and are dealt with separately, appearing in different chapters of the books.

29 The defendants argue therefore, that whilst the skilled man may well have been aware of lancet technology, it is quite different to that which is applicable to syringes, and that the skilled man would not have appreciated that lancet technology could be used to solve the problems associated with rendering a syringe safe after use.

30 The claimants disagree with this assertion and argue that the skilled person would be aware that all types of safety needle device share the common problem of the need to prevent needle stick injuries, because all such devices, be they pen needles, lancets, injectors etc., include a sharp needle which has the potential to deliver a needle stick injury. The legislation and guidelines, they argue, deal collectively with all kinds of sharps, indicating that at least in the terms of safety features they form a single group, and that it is therefore natural and unsurprising for engineers working in the field of safety needles to work on both syringes and lancets.

31 Having considered all of the evidence and arguments put before me, it is clear to me that the skilled person would have been aware of conventional techniques and materials used for fabricating needles and would have been familiar with their attachment to syringes and other injection devices. They would also have had knowledge of the mechanical aspects of such devices, and how they were intended to work. Furthermore, I think it is only reasonable to assume that the skilled person would have been aware of the relevant legislation and guidelines governing the use of safety needles, and the treatment of sharps in general at the priority date. The fact that the only legislation in force at that time was effective in the United States is irrelevant, as the market for safety needles is a global one, and any one working in the field would have been aware of that legislation. There is clearly some relationship between the fields of technology associated with syringes and lancets, and some

evidence to suggest that inventors were working in both fields at that time. However, I do not think it is necessarily the case that the skilled person would be as familiar with the design and development of lancets as they would with safety needles for injection, and I do not think it is reasonable to assume that they would have been working in both fields at the same time. However, I cannot escape the fact that the skilled person would be aware of lancet technology and that they may look to the field of lancets for a solution, although they would be aware of the differences in the function and operation of syringes and lancets.

Witnesses.

32 Witness statements were received from Barry Liversidge and Anne Campbell on behalf of the claimants. However, neither of these witnesses was cross-examined and therefore their evidence stands unchallenged.

33 Terence Weston and Richard Gillard supplied witness statements on behalf of the defendants, and both were cross-examined at the hearing. The defendants provided an additional witness statement in the name of John Davidson which also stands unchallenged.

34 Terence Weston is Managing Director of Salvus Technology Ltd and one of two inventors credited with having devised the invention subject of these proceedings. Mr Weston has some 25 years experience in the design and development of medical devices particularly in the field of drug delivery. His evidence highlights the apparent technical distinction between needles and lancets, and in particular how they appear to have developed along different paths.

35 When questioned, Mr Weston agreed that a lancet could be regarded as a type of needle and that it could give rise to needle stick injuries as could any other sharp needle. During cross-examination, Mr Weston was presented with an example, post-dating the invention, which he acknowledged showed a lancet having a hollow needle (TEW1). However, he did not appear to accept that it was common place for lancets to have hollow needles. Indeed, when questioned by Mr Gillard, Mr Weston said that he could not understand why a lancet would have a hollow needle as this would tend to suck up the blood, which would then need to be expelled in some way.

36 Mr Weston confirmed his view that the term “hub” was a well know term in the art, and that the conventional hub has two ends, one for connecting to a hollow needle and the other to a syringe body or other injection device. Mr Weston was somewhat hesitant and unsure when asked whether the embodiment shown in figure 8 was consistent with his interpretation of a hub, and appeared to agree that in this embodiment there was no separate hub, but that the hub was integral with the syringe body. When questioned as to whether a lancet could have a hub?, Mr Weston was again somewhat hesitant in his response stating that *“For a while I thought it could, but I am not sure now”.* He felt that it would be more appropriate to call the equivalent part of a lancet a rod or plunger as this was more representative of the pushing action required to activate the lancet. When presented with an additional document US8016847 B2 (TEW2), he was reluctant to accept that the lancet shown in figure 27A could be considered to include a hub. Again, I note that the exhibit TEW2 post-dates the invention.

37 Mr Weston's third witness statement includes a description of an alternative locking mechanism which does not rely on rotation for its operation, but which is intended to show that there are other ways envisaged in which locking of the sleeve could be achieved that would fall within the claim. However, he appeared to agree that the patent itself discloses only one way, which requires rotation of the assembly.

38 Mr Weston is clearly an expert in his field, and his responses when questioned, reflected his many years of experience. They were generally factual and to the point but on occasion he was a little hesitant and unsure of himself.

39 Mr Gillard is a qualified European Patent Attorney with a postgraduate background in chemistry. He is not expert in the field of medical devices. His evidence takes the form of a number of nursing textbooks and associated FDA guidelines relating to the use and operation of medical devices including syringes and lancets. Mr Gillard acknowledged having received this information from Mr Weston. He confirmed under cross-examination, that this was intended to show that the term hub was known in the art at the priority date, and would have been understood by the end-user e.g. a nurse to have had a specific meaning. Mr Gillard also confirmed that his intention was that the evidence would also show that the syringes and lancets were considered to be different things by the end-user requiring different considerations. He appeared to accept that the end-user would have a limited knowledge of how these types of devices worked from a technical point of view, but from a practical point of view, it was the end-user who selected the appropriate device for the right procedure e.g. selecting a lancet for blood sampling.

40 **Claim construction**

41 Before addressing the issue of novelty and inventive step it is important to ascertain the true scope of the invention as claimed. To do this, I must apply an appropriate construction to the claims.

42 It is well established that the approach that I must adopt in construing the claim is as set out by Lord Hoffman in his judgment in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd*[4]. At paragraph 34 he said:

> *"The question is always what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meaning with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document inter rusticos for which broad allowances must be made."*

43 Further guidance on construction can be found in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd*[5]. I remind myself that claims are not construed alone or in the abstract but in their context in the specification; that purposive construction is vital (there may be several purposes and several embodiments) and that one is in the end concerned with the meaning of the language used. Meticulous verbal analysis is eschewed.

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[4] Kirin-Amgen Inc v Hoechst Marion Roussel Ltd [2005] RPC 9

[5] Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd [2009] EWCA Civ 1062, [2010] RPC 8

44 There are a number of features in claim 1 which I think need to be addressed, namely what is meant by the terms “safety needle and/or attachment, and hub”. I will address these in turn.

Safety needle and/or attachment

45 The claim relates to a safety needle and in particular to a safety needle attachment. Both parties seem to accept that a safety needle is a needle which when used is rendered safe i.e. it cannot be reactivated, and in the present case this is achieved by locking the sleeve in its final position covering the needle tip. Locking is achieved by a rotation of the assembly. However, the claim is silent regarding this aspect.

46 The claimants argue that the purpose of the invention as a whole is to render a needle safe after use, and to prevent the risk of needle stick injuries, and that the claim is in no way limited to syringes or hollow needles, and encompasses other forms of solid needle including lancets designed to penetrate the skin which can also give rise to needle stick injuries. They argue that a “needle” is a common everyday term used to describe a “long sharp pointy thing”, and that there is nothing in the specification to suggest that the invention was intended to be limited to syringes or hollow needles, and that the skilled man would read the claim to include all forms of needle. They referred in their submissions to two specific passages in the specification which tend to support their argument. The first of which is paragraph [0004] which states that *“Another drawback of prior art safety needles (which in the present context includes safety syringes)”*. This they say would indicate to the skilled person reading the patent that the term *“safety needles”* is rather broader than *“safety syringes”* and therefore must embrace other types of needle. Similarly, paragraph [0094], whilst not a reference to lancets, does indicate that the invention has application beyond the use of a syringe, as it could be used in an intravenous giving set.

47 In my opinion, whilst it may have been the intention of the patentee to limit the invention to its use in safety syringes or other drug delivery systems such as intravenous giving sets, there is no such limitation in the claim which I think would be read by the skilled person to include all forms of needle including lancets, and not just hollow needles for injection.

48 There was some discussion at the hearing regarding the meaning of the word *“attachment”*. The defendants argue that the attachment is considered to be an “*item of commerce*” which can be sold separately to the needle. However, figure 8 appears to disclose an embodiment in which the hub is integral with the barrel of the syringe. If claim 1 covers this embodiment then the “*attachment*” of claim 1 could not be sold separately. I therefore believe the correct construction of claim 1 is that the “*attachment*” is simply an attachment for a needle as such, and one or more parts of the attachment may, or may not, be integral with the body of the device to which the needle is connected in use.

Hub

49 The safety needle attachment as claimed is said to include a *“hub”* which provides a radially converging or diverging surface on which a protective sleeve is said to slide which causes its elastic deformation and which ultimately creates the restoring force

required to return the sleeve to a position covering the needle after use. The defendants argue that the hub is more than just a surface on which the sleeve is arranged to slide, it is a recognised term in the art and defines the part of the attachment which connects to a hollow needle at one end and to a syringe or injection device at the other. Mr Gillard referred to two textbooks in support of this argument, *"Pharmacology and Drug Management for Nurses, Second Edition, ED. G. Downie et al., Churchill Livingstone, 1999, pages 499-511* and the FDA's *"Guidance on the Content of Premarket Notification [510(K)] Submissions for hypodermic Syringe Lumen Needles", April 1993.* Both textbooks, he alleges show that the word *"hub"* was a recognised term in the field of medical devices at the time of the invention and would have been known to the skilled person in the art as a reference to an assembly for attaching a hollow needle to the body of a syringe. This then is what the patentee meant when using the term hub in the specification and claims. The defendants conclude that as a minimum, the hub in claim 1 must therefore comprise two ends, a first end to receive a needle and a second end to receive a syringe or injection device. The two ends must be in fluid communication to permit fluid to be drawn up into the syringe or for fluid in the syringe to be expelled. This they argue is further evidence to support the fact that the invention as claimed is limited to hollow needles.

50 The claimants disagree with the defendants' interpretation of the term *"hub"*, stating that it is inconsistent in particular with the embodiments of the invention shown in figures 7 and 8 of the specification. In particular, they refer to figure 8 where there appears to be no hub at all, it is merely an integral part of the nose of the syringe. They allege that the skilled person would realise that once the notion of an integral hub is disclosed in the patent e.g. in figure 8, the idea that the hub could be the same as a conventional hub vanishes. The claimants argue therefore that the skilled person when reading the claims would interpret the term hub to be nothing more than the part of the attachment which provides the complimentary surface on which the sleeve is intended to slide, causing subsequent deformation of the sleeve which provides the necessary restoring force to return the sleeve to a position covering the needle.

51 I must admit, I have some degree of sympathy with the claimants' arguments when it comes to interpreting the term hub. The defendants' definition of a hub requires it to have two ends, a first end to receive a needle and a second end to receive a syringe or injection device, the two ends being in fluid communication. This would suggest that the hub would sit between the syringe body and the needle and that fluid would pass through the hub. However, this does not appear to be the case in the embodiments disclosed. Indeed, in the embodiment described above in relation to figures 2 to 4 of the specification, the hub 7 does not lie between the syringe body and the needle as such, but partially surrounds the needle and the nose of the syringe. Furthermore, I do not think the hub as claimed is intended to pass fluid as would be the case in a conventional hub, as the needle is connected directly to the nose of the syringe in these embodiments.

52 I would also like to add, that where the attachment is fitted to a conventional syringe assembly, itself including a hub, it is difficult to see how the hub of the attachment can be considered a conventional hub in the true sense of the word.

53 I therefore do not accept the defendants' interpretation of the term hub. I do not think the hub as defined in claim 1 is intended to connect the needle to the syringe body, nor do I think its purpose is to provide fluid communication between the syringe and the needle to which it is attached.

54 As I have said previously, the purpose of the hub appears to be to provide a radially converging or diverging surface on which the sleeve is positioned to slide in a longitudinal direction parallel to the axis of the needle. This causes a portion of the sleeve to deform which provides the restoring force required to return the sleeve to a safe position covering the needle. I think this is what the skilled person would have understood the term hub to have meant, and therefore I intend to construe it in that way.

Novelty

55 I would have to say from the outset, that I am very grateful to Mr Liversidge for having supplied what I consider to be very useful, well engineered working models of the devices shown in documents P2, P3 and P4 which have made my understanding of these various devices, and how they would operate, that much easier.

Document P2 - US4553541

56 Document P2 discloses an "automatic retractable lancet assembly" intended for single-use operation in which the lancet needle 108 is automatically returned to a position inside the lancet housing after use, and hence could be consider a safety needle. The operation of the lancet is probably best illustrated by considering figures 15, 17 and 18 of the specification reproduced below:

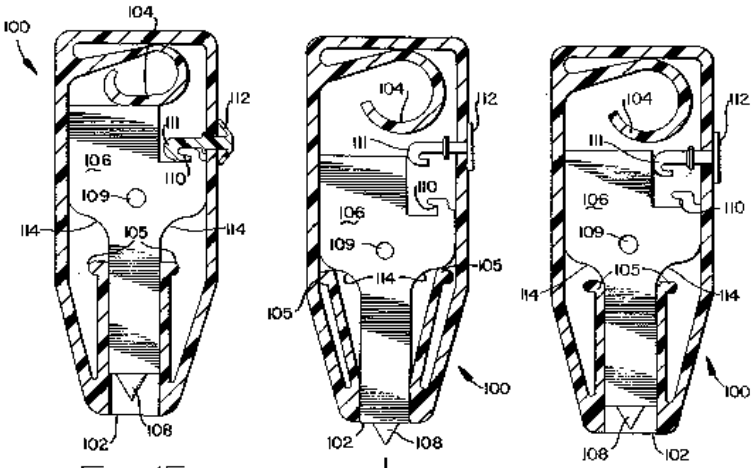


Fig. 15 Fig. 17 Fig. 18

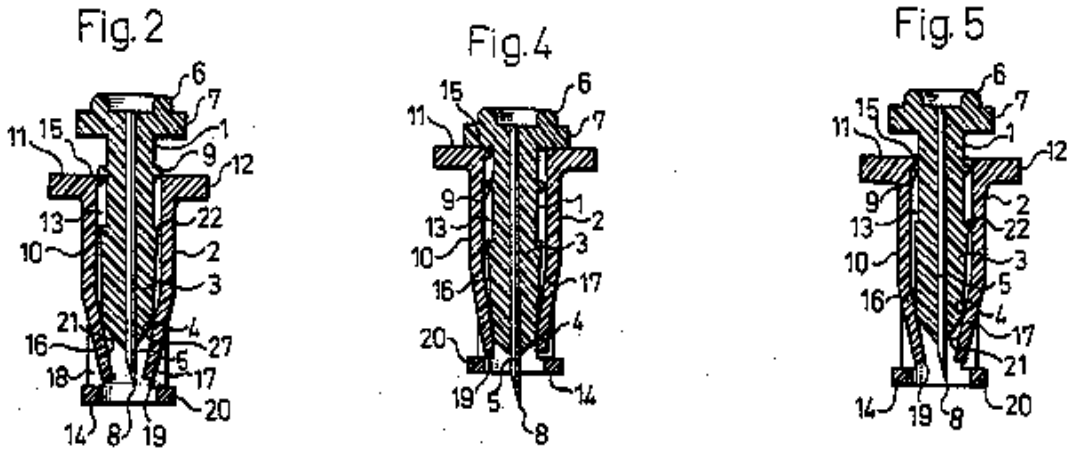
57 The lancet assembly 100 includes what could be regarded a "hub" in the form of a slidable plunger 106 which carries a lancet needle 108. The hub or plunger includes a pair of inclined surfaces 114. In figure 15, the plunger is held in a first position by

undercut notch 110 engaging hook 111, on depression of button 112 the plunger is forced downwards under the action of a coiled flat spring 104 to a second position outside of the housing or sleeve 101 thus exposing the needle. The housing or sleeve also includes a pair of deformable leaf springs 105. Contact with the inclined surface 114 of the hub causes the leaf springs to be deflected outwardly which biases them under tension, as shown in figure 17. Deflection of the leaf springs causes the lancet needle to return to a third position fully within, and surrounded by the housing, as shown in figure 18. I am grateful to the claimants for having provided me with a very useful summary of how the features of P2 correspond to those in the claims (see Annex 1, attached to the claimants' skeleton arguments of 23 April 2012, and Attachment A1 to their amended statement of 11 March 2011)

58 Given the construction I have given to the various integers within the claim, I consider the disclosure in P2 sufficient to anticipate claim 1.

Document P3 – US5421347

Document P3 also relates to a lancet in which the needle is automatically returned to a safe position with the lancet body following its use, the operation of which is best illustrated in figures 2, 4 and 5 of the specification below:



59 The lancet shown in P3 comprises a rod 1 which is equivalent to the hub, carries the lancet needle 5, and has conical end surfaces 27. The rod or hub is surrounded by a sleeve 2 arranged to slide in the longitudinal direction parallel to the axis of the needle. The sleeve has fingers or tongues 16, 17 which are radially deformable and which engage with the conical surfaces of the rod and move outwardly when the rod is pushed into the sleeve thus moving the lancet needle from a first position where it is covered by the sleeve (figure 2) to a second position where it is exposed (figure 4).The purpose of the tongues is to return the lancet to a third position where it is covered by the sleeve and is rendered safe (figure 5). I am again grateful to the

claimants for having provided me with a very useful summary of how the features of P3 correspond to those in the claims (see Annex 2, attached to the claimants' skeleton arguments of 23 April 2012, and Attachment A2 to their amended statement of 11 March 2011)

60 Again, I consider this disclosure to anticipate claim 1.

Document P4 – US2002/0087180

61 Document P4 is yet another example of a lancet having a base 12 ("sleeve") which carries a lancet needle 14, and has a deformable portion in the form of cantilever springs 26. There is a cap 16 ("hub") which has a radially diverging surface 46 along which the cantilever springs 26 of the sleeve run so as to be deformed radially outwardly on exposure of the needle. The cantilever springs storing sufficient elastic energy to apply a restorative force to the sleeve so that following use the original position of the device is restored. This is again illustrated well in Annex 3, attached to the claimants' skeleton arguments of 23 April 2012, and Attachment A3 to their amended statement of 11 March 2011. It is important to note that paragraph [0036] of the specification appears to envisage that an alternative arrangement is possible where the needle is mounted on the hub rather than on the sleeve, and the sleeve fully surrounds the needle in the first and third positions as required by claim 1. In this case the device of P4 would look like the drawing inset in Attachment A3 supplied by the claimants.

62 I therefore consider the disclosure in P4, given the reference to switching the various complimentary structures in paragraph [0036] of the specification, to read onto claim 1.

63 Having found claim 1 to lack novelty, I do not now need to consider whether it would also be lacking of an inventive step. However, for the sake of completeness, I will consider whether the claim is sufficient.

Sufficiency

64 A patent is said to invalid "if the specification does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art" (section 72(1)(c) of the 1977 Act). The patent will be insufficient if the skilled person is unable to carry out the claimed invention given the description of it in the specification and common general knowledge (sometimes called "classical insufficiency").

65 I think both parties would agree that the disclosure is sufficient enough for a person skilled in the art to work the invention i.e. there is sufficient information contained within the embodiments for him to manufacture a functioning device within the scope of claim 1, and that therefore there is no question that claim 1 is sufficient from a "classical" point of view. The issue is one of adequacy of disclosure to support the apparent breadth of the claim.

66 Unlike section 32(1)(i) of the Patents Act 1949, the 1977 Act does not provide that it is a ground of invalidity that "the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is

not fairly based on the matter disclosed in the specification". This is because no such ground is provided for by the European Patent Convention. Nor has the position changed in this respect following the coming into force of EPC 2000. This has given rise to repeated attempts by parties seeking to revoke patents to argue that a patent may be invalid on the ground of insufficiency as a result of either ambiguity or excessive breadth of the claims, so called "Biogen Insufficiency", rather than as a result of classical insufficiency. It is this latter, excessive breadth of claim which the claimant is relying upon here.

67 In *Medimmune Ltd v Novartis Pharmaceuticals UK Ltd, Medical Research Council,* [2011] EWHC 1669 (Pat) the extent to which a patent may be invalid on the grounds of insufficiency as a result of excessive breadth of claims, rather than a result of an inability on the part of the skilled person to carry out the invention was considered with reference to *Biogen Inc v Medeva plc* [1997] RPC 1, Kirin-Amgen Inc v Hoechst Marion Roussel [2004] UKHL 46 [2005] RPC 9 and *Generics (UK) Limited and others v H Lundbeck A/S* [2009] UKHL 12, [2009] RPC 13.

68 What conclusions do I draw from the above cases? Namely, that a claim will be invalid for insufficiency if the breadth of the claim exceeds the technical contribution to the art made by the invention. It follows that it is not necessarily enough to disclose one way of performing the invention in the specification.

69 The breadth of the claim will exceed the technical contribution if the claim covers ways of achieving the desired result which owe nothing to the patent or any principle it discloses. Two classes of this are where the patent claims results which it does not enable, such as making a wider class of products when it enables only one and discloses no principle to enable the others to be made, and where the patent claims every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention.

70 So what is the technical contribution? Does the breadth of claim 1 extend beyond that contribution?

71 The defendants argue that the contribution is a safety needle attachment as claimed in claim 1, which provides a simple, low cost arrangement for rendering a needle safe after use. The arrangement including a sleeve having a radially deformable portion which undergoes deformation when sliding over the surface of a hub such that the stored elastic energy in the radially deformable portion provides sufficient force to return the sleeve to a safe position, shielding the needle after use.

72 The claimants on the other hand argue that the contribution extends beyond that to include the locking mechanism which is an essential feature of the invention, for without it the needle is not safe. Furthermore, they do not consider it sufficient for the claim to be restricted to a locking mechanism in general, as the disclosure they say is insufficient to support such a level of generality as only a single rotational locking mechanism is enabled. In their view, the claims should be limited to a safety needle in which a rotational mechanism is provided for locking the sleeve in the third position after use.

73 I have some sympathy with the defendants' position here, as the claimants seem to be using sufficiency as a disguised attempt to limit the claims. It is clear to me that

what we have here is a claim to a safety needle which includes a simple mechanism for returning the sleeve to a safe position shielding the needle, and I think there is a degree of agreement between both parties that it would be implicit in the meaning of a safety needle per se that it would lock in that position. However, the claim is silent regarding the locking mechanism, perhaps because the patentee did not regard it as being an essential part of the invention, and as such I do not think the contribution as claimed extends that far. Given that there would appear to be adequate disclosure pertaining to the mechanism for returning the sleeve to the locking position, I do not think the breadth of the claim extends beyond the technical contribution and consider the disclosure sufficient to support the claim.

74 If I am wrong and the technical contribution includes the locking mechanism, then I still think it is sufficient for the specification to have disclosed one way of providing the locking function i.e. by rotation of the assembly.

Amendments

75 The defendants have offered a number of conditional amendments which I have been asked to consider should I find claim 1 to be invalid. I will consider these in turn.

Amendment – Proposal 1

76 The form of amended claim 1 (proposal 1) is as follows where the amendments are shown in bold:

> *1. A safety needle **assembly** comprising:*
> ***a hollow needle (3) having a longitudinal axis;***
> *a hub (7);*
> *a sleeve (5) surrounding the hub (7) and slidable relatively to hub (7) in the axial direction;*
> *wherein the sleeve (5) has a radially elastically deformable portion (9), and the hub has a radially converging or diverging portion (18),*
> *and wherein the sleeve (5) is slidable in a first axial direction between a first position for fully or substantially fully surrounding the needle with the sleeve, and a second position for exposing the needle (3), characterised in that sliding between the first and second positions causes elastic radial deformation of the deformable portion (9) by sliding of the radially elastically deformable portion (9) of the sleeve (5) directly on converging or diverging portion (18) of the hub (7), and that the sleeve (5) is further slidable in a second, opposite, axial direction between the second position and a third position for fully surrounding the needle (3) by the sleeve (5), the force for sliding between the second and third positions being provided by the stored elastic energy in the radially deformable portion (9).*

77 The purpose of this amendment is clear enough. By limiting the claim to a safety needle assembly incorporating a hollow needle, the claim is novel over the disclosures in P2, P3 and P4 which relate to lancets having solid needles. I am satisfied that this amendment is supported by the original description and does not add matter, and is therefore prima-facie allowable. However, does the claim as amended involve an inventive step?

Inventive step

78 A patent will be invalid for lack of inventive step if the invention as claimed was obvious to a person skilled in the art having regard to the state of the art at the priority date. There was no issue between the parties as to the applicable law. The correct structured approach to the assessment of allegations of obviousness first articulated by the Court of Appeal in *Windsurfing International Inc v Tabur Marine* [6]was re-stated by Jacob LJ in *Pozzoli*[7] as follows:

> *(a) Identify the notional 'person skilled in the art';*
>
> *(b) Identify the relevant common general knowledge of that person;*
>
> *(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;*
>
> *(3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed;*
>
> *(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"*

79 In *Conor v Angiotech*[8], the House of Lords considered the issue of obviousness. There Lord Hoffmann (with whom the others of their lordships agreed) approved the following statement of Kitchin J made in *Generics v Lundbeck*[9]:

> *"The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."*

The skilled person and the common general knowledge

80 I have already identified the skilled person and their common general knowledge above.

What is the inventive concept?

81 Before going on to consider the inventive concept, I must consider what is meant by a *"safety needle assembly"* comprising a *"hollow needle"*? Clearly, a safety needle assembly within the meaning of the patent is an assembly which includes an arrangement for rendering a needle safe after use. The fact that it includes a hollow needle would suggest that it is limited to arrangements including syringes or other injection devices including intravenous giving sets, both of which are envisaged by the patentee in the specification. Whilst there has been some discussion throughout these proceedings as to whether lancets can have hollow needles, I have not seen sufficient evidence to suggest that this was the case at the priority date of the invention.

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[6] in Windsurfing International Inc v Tabur Marine (Great Britain) Ltd [1985] RPC 59
[7] Pozzoli v BDMO SA [2007] EWCA Civ 588, [2007] FSR 37
[8] Conor v Angiotech [2008] UKHL 49, [2008] RPC 28
[9] Generics v Lundbeck [2007] RPC 32

82 The inventive concept would therefore seem to lie in a safety needle assembly including a hollow needle such as that used in a syringe which has a simple low cost mechanism for rendering the needle safe after use. The assembly including a sleeve having a radially deformable portion which undergoes deformation when sliding over the surface of a hub such that the stored elastic energy in the radially deformable portion provides sufficient force to return the sleeve to a safe position, shielding the needle after use.

What differences exist between the cited prior-art, documents P2, P3 & P4 and the inventive concept?

83 All of the cited documents disclose lancets with various mechanisms for sliding a sleeve relative to the needle in such a way as to shield the needle after use. However, none of these documents to syringes or other injection devices having hollow needles. That then is the difference between the invention as claimed and the cited prior-art.

Viewed without any knowledge of the alleged invention as claimed, would this difference have been obvious to the person skilled in the art or does this require any degree of invention?

84 Firstly, I have to ask myself whether it would be obvious for a person skilled in the art of safety needles for preventing needle stick injuries to turn to the field of lancets when considering how to effect axial movement of a protective sleeve over a hollow needle in such a way as to render the needle safe after use. I have already said that the skilled person would be aware of lancet technology, and that they may well look to that field for a solution. However, I have also said that the skilled person would be aware of the fact that syringes and lancets differ in their function and operation.

85 At the hearing, the defendant argued that the mode of operation of lancets and injection devices were distinctly different. The purpose of a lancet being very different to that of a needle for injection, even if the danger of needle stick injury is similar in both cases. In the case of automatic lancets, the aim is to very quickly prick the skin to a shallow depth to obtain a capillary blood sample. Therefore, such devices provide an impulsive action to the lancet blade, and it follows that the penetrative portion of the stroke of the lancet will be very short, of the order of a couple of millimetres. It is desirable that the lancet blade is then retracted into the housing to prevent subsequent injury and risk of contamination. Conversely, safety devices for hypodermic syringes are not generally required to have an impulsive operation. Indeed, the situation is quite the opposite. Safety needles for syringes are required to insert the needle much further into the tissue than would be needed for a lancet, holding the needle there during injection of the drug, and then withdrawing the needle. Once the needle tip is out of the tissue, a mechanism ensures that it is made inaccessible. This is the most significant difference between lancets and syringes. The key point with these injection devices is that the needle has to be in the tissue long enough for the drug to be expelled from the syringe. With a lancet, without a hollow needle, all it has to do is make a prick in the skins surface to draw a small sample of blood, it does not have to stay there, and so a lancet has an impulsive rapid fire mechanism and a needle for injection does not. A needle for injection has to be much more carefully placed, and has to be in the tissue for longer than a lancet and this difference in operation is considered to be quite critical.

86 This distinction leads me to conclude that whilst the person skilled in the art when seeking a simple, low cost mechanism to prevent needle stick injuries from a hollow needle assembly may look to lancets for a solution, it is likely that they would dismiss any such solution as their purpose and mode of operation (and consequently circumstances giving rise to the risk of needle stick injuries) are quite different to those of a syringe.

87 I would add, that the arrangements disclosed in P2, P3 and P4 are quite complicated, and do not readily lend themselves to adaptation for use with a hollow needle such as would be found in a syringe or other injection device. I do not think therefore that the skilled person would be in any way motivated to modify the teaching in these documents in such a way as to make them suitable for use with a hollow needle. It is also my view, that this would require a degree of ingenuity and invention on the part of the skilled man to achieve.

88 I conclude therefore that the invention as claimed in amended claim 1 (proposal 1) involves an inventive step over the cited prior art.

89 All that is left for me to decide is whether the specification is sufficient to enable the invention as claimed. I think this is an easy question to answer, the technical contribution associated with the invention as is now claimed is much the same as in claim 1 as granted, albeit it now limited to a safety needle assembly including a hollow needle. I therefore consider this claim to be sufficiently enabled by the specification, and do not consider the breadth of this claim to extend beyond the technical contribution.

90 Having found the amendment as proposed in proposal 1 to be both novel and inventive, I have no need to consider the other amendments being put forward by the defendant.

Conclusion

91 I have found that claim 1 as granted is not novel.

92 Claim 1 as amended (Proposal 1) is both novel and inventive, and the specification is sufficient to support the breadth of the invention as claimed.

93 The conditional amendment proposed by the defendants (Proposal 1) is governed by section 75 of the Act (having been proposed in the course of revocation proceedings before the Comptroller). I order that the proposed amendments should be formally requested within four weeks of the date of this decision and that they are then advertised in accordance with section 75(1). If the amendments are not formally requested within that period the patent will be revoked unless there is an appeal of this decision lodged within the time period for appeal.

Costs

94 At the hearing, both parties wished to deal with the issue of costs separately. I therefore give both parties two weeks from date of this decision to make written submissions on the award of costs.

Appeal

95 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

P R SLATER
Deputy Director acting for the Comptroller