Intellectual Property Office

BL O/243/15
27 May 2015

PATENTS ACT 1977

CLAIMANT	Norbrook Laboratories Ltd
DEFENDANT	Bimeda Research & Development Ltd
ISSUE	Application under section 72 for revocation of UK patent GB2429159
HEARING OFFICER	H Jones

Ms Anna Edwards-Stuart of 11 South Square appeared for the Claimant
Mr Tom Alkin of 11 South Square appeared for the Defendant
Hearing dates: 25 & 26 March 2015

DECISION

Introduction

1 This decision relates to an application under section 72 of the Patents Act 1977 ("the Act") for revocation of UK patent GB2429159 in the name of Bimeda Research & Development Ltd ("Bimeda"). The patent relates to a method and device for treating a teat canal of an animal, and it derives from PCT application WO 2005/072644 filed on 2 February 2005 and having an earliest priority date of 2 February 2004. The patent was granted with effect from 30 September 2008.

2 The application for revocation was filed by the claimant ("Norbrook") on 8 November 2013. In their initial statement of case, Norbrook set out the grounds on which the application for revocation is based, namely that the invention is not new and does not involve an inventive step, i.e. under section 72(1)(a) of the Act. This statement was subsequently amended on 2 May 2014 to also include an application under section 72(1)(d) that matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent.

3 Bimeda subsequently applied to amend the patent unconditionally under section 75(1) of the Act by deleting all of claims 2-39, thus leaving the patent with a single independent claim in the form of claim 1 as granted. These amendments were advertised on 25 February 2015 in accordance with section 75(1) and there has been no opposition.

4 Both sides have filed evidence, including witness statements and video evidence. The matter came before me at a hearing on 25 and 26 March 2015, where Norbrook were represented by Ms Anna Edwards-Stuart of 11 South Square and Bimeda were represented by Mr Tom Alkin also of 11 South Square.

The invention

5 The invention relates to a single injector device for the delivery of two components into the teat canal of a non-human animal and has particular application in the treatment of bovine mastitis (an inflammatory disease in the udder of an animal, e.g. a dairy cow). The patent specification explains that the conventional way of treating bovine mastitis is through the use of a twin injector pack, whereby an antibacterial formulation is delivered first using a one of the twin injectors and then a seal or barrier formulation that forms a physical barrier in the teat canal against the entry of bacteria into the udder is delivered using the other injector. The single injector of the invention is perhaps best illustrated in figures 10-16 of the specification, with figures 14(a)-14(c) reproduced below for reference:

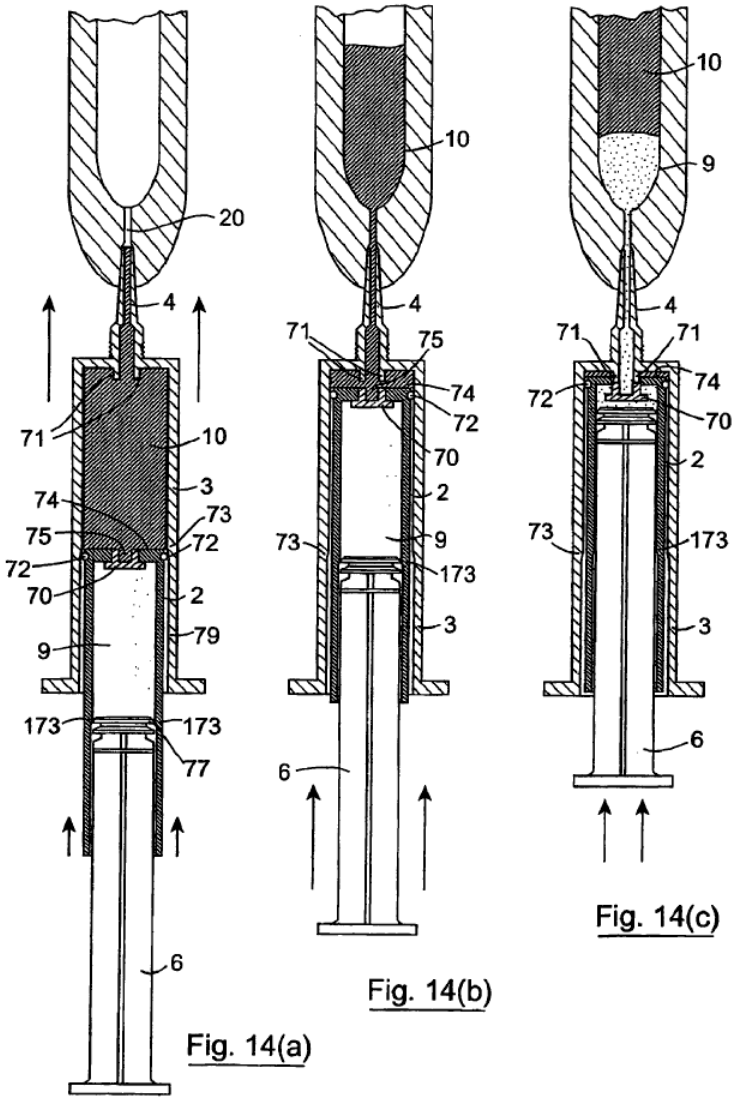


Fig. 14(a)

Fig. 14(b)

Fig. 14(c)

6 The single injector device comprises a barrel (3) containing a first component (10), e.g. an antimicrobial or anti-inflammatory formulation, and an internal receptacle (2) containing a second component (9), e.g. a seal formulation. In use, a nozzle (4) of the injector device is inserted into the teat canal (20) of the udder and a delivery means (6), e.g. a plunger, is depressed to expel the first component into the udder.

When the first component has been expelled from the barrel into the teat canal, a valve (70), which separates the first component and the second component, is opened through engagement with an activator (71) and the second component is sequentially expelled and delivered from the internal receptacle into the teat canal. Thus, in the treatment of bovine mastitis, the injector device allows an antibiotic to be delivered first into the teat canal followed sequentially by delivery of a seal formulation using a single injector device.

7 The granted patent as proposed to be amended contains a single claim, claim 1, which reads as follows (broken down into the same integers used by the parties in their respective statements):

1A An injector device for delivery of components into the teat canal of a non-human animal comprising -

1B a barrel for containing a first component;

1C an outlet nozzle configured for insertion into a teat canal at one end of the barrel;

1D an internal receptacle within the barrel for containing a second component to be injected into the teat canal;

1E a valve for separating the first component from the second component;

1F an activator for opening the valve to allow the second component to be released from the internal receptacle; and

1G a delivery means for delivery of a first component from the barrel, and, on engagement of the valve with the activator to open the valve, sequential delivery of a second component from the internal receptacle through the outlet nozzle.

The case for revocation

8 The following grounds for revocation were pursued by Norbrook at the hearing:

a) Lack of novelty

9 The invention defined by claim 1 of the patent is anticipated by:

US3680558 (“Kapelowitz”), published on 1 August 1972;
JPH8-294532 (“JPH8”), published on 12 November 1996; and
US4702737 (“Pizzino”), published on 27 October 1987.

10 Norbrook argue that claim 1, when correctly construed, relates to any injector device capable of delivering two components sequentially into the teat canal of an animal, e.g. an injector with a hypodermic needle, and which has a barrel and space within the barrel for separately containing the two components. The injector device is required to have some sort of valve, membrane or barrier within the injector in order

to separate the two components, in addition to any means that facilitates the opening of the valve.

11 Kapelowitz discloses a syringe with an inner barrel and outer barrel, and an outlet in the form of a hypodermic needle. The inner barrel is provided with a valve comprising a flange portion of the inner barrel and a seal member slideably and rotationally mounted to one another. A plug is also provided to prevent rotation of part of the valve, thus allowing the valve to open/close.

12 JPH8 discloses a syringe with an external cylinder, a needle, and front and rear gaskets. The gaskets define an area “X” for a first liquid component and an area “Y” for second liquid component, with the first and second liquid areas separated by a valve in the front gasket.

13 Pizzino discloses a syringe with an inner barrel and outer barrel, and an outlet in the form of a needle. The inner barrel is provided with a membrane which is punctured to release fluid from the outer barrel.

b) Lack of inventive step

14 The invention defined by claim 1 of the patent is obvious in the light of Kapelowitz, JPH8 and Pizzino, and also:

WO03/022245 (“McHardy”), published on 20 March 2003; and
Common general knowledge

15 McHardy discloses an injector device with a barrel, and an outlet in the form of a nozzle; a burstable membrane is provided in the barrel to provide separation between sealant and sterilising agent. The common general knowledge is based on evidence provided by Dr Stephen Dunne, who is an expert witness on behalf of Norbrook.

16 Norbrook say that it was well known at the priority date of the invention that mastitis could be treated by delivering anti-bacterial formulation and seal formulation sequentially into the teat canal of a mammal, and that the two formulations could be delivered using a twin injector pack. They argue that any adaptation or modification of the prior art “double formulation”/”single injector” devices for use in the treatment of bovine mastitis would have been obvious to a person skilled in the art.

c) Added matter

17 Norbrook say that the application as originally filed discloses only two specific embodiments that include valves. Each of these embodiments discloses a particular valve in a specific configuration and each valve needs to interact with the other components of its respective injection device in a particular manner for the embodiments to work. Norbrook argue that claim 1 covers valves in general and that this amounts to an intermediate generalisation because it results in the skilled person being presented with information that he could not have derived from the original application.

Witnesses

18 Evidence from Norbrook takes the form of an expert report from Dr Stephen Dunne and witness statements from Mr Francis O'Sullivan and Mr Tim Kirby. Dr Dunne and Mr O'Sullivan were cross-examined at the hearing but unfortunately the planned cross-examination of Mr Kirby had to be abandoned due to technical difficulties.

19 Dr Stephen Dunne is a mechanical engineer who has been involved in the design and manufacture of a wide range of delivery systems for drugs, cosmetics and food since the 1980s. At present, he is the principal of Dunne Consultancy Services and the sole shareholder of New Injection Systems Ltd. In his report, Dr Dunne considers the features and functioning of different types of syringes in use in February 2004 and what the skilled person would understand from Kapelowitz, JPH8 and McHardy. He also considers whether and how the skilled person would have implemented or improved the systems in each of Kapelowitz, JPH8 and McHardy for the purpose of delivering antibiotic and seal components into a teat canal in order to treat bovine mastitis.

20 In an annex to his report, Dr Dunne also reviews information provided by Norbrook regarding the twin injector pack treatment of bovine mastitis and was asked to design an alternative or improvement whilst assuming the position of a skilled, unimaginative and non-inventive person. The annex sets out four possible improvements.

21 Under cross-examination, Dr Dunne explained that he had been consulted in relation to veterinary products and possibly products for the treatment of bovine mastitis, but confirmed that he was not an expert in the treatment of bovine mastitis. Dr Dunne also confirmed that he was the named inventor on nearly seventy patent applications and that he was a "naturally inventive person", with many of his patent application relating to devices for delivering drugs. I believe that he was a fair and credible witness.

22 Mr Francis O'Sullivan is an experienced veterinary practitioner who has extensive experience in the treatment and prevention of bovine mastitis. He currently sits on the mastitis technical working group for Animal Health Ireland. In his witness statements, he describes the process of treating bovine mastitis using the twin injector pack, i.e. where the antibiotic is administered first and massaged up into the udder, followed by the seal that would act as a physical block in the teat canal to prevent ingress of bacteria. The procedure would usually be carried out by a farmer, who would disinfect the teat area before inserting the first injector into the teat canal and then infusing the antibiotic into the teat. The farmer would then massage the antibiotic up into the udder, remove the first injector from the teat and then insert the second injector in order to infuse the seal formulation into the antibiotic-treated teats. Although not essential, he states that the massaging step was good practice and that it could be done while pinching the teat around the nozzle of the first injector or by withdrawing the nozzle first and pinching the teat closed before massaging. He considers both techniques acceptable and confirms that he has seen farmers use both.

23 During cross-examination, Mr O'Sullivan was shown a training video directed at farmers in which Mr O'Sullivan could be seen infusing antibiotic into a teat and taking the nozzle out before performing the massage step. Mr O'Sullivan then explained

that he did not formally train in either technique of taking the nozzle out before the massage step or leaving the nozzle in: he considered both acceptable, and did not discourage farmers from either technique. Mr O'Sullivan was a fair and credible witness, and was sufficiently experienced on the matters on which he gave evidence.

24 Mr Kirby is a veterinary practitioner and is the head of Research & Development for Norbrook. He provided evidence in the form of a witness statement and a video exhibit (TK1) which shows the use of a dual-barrel syringe for infusing antibiotic and seal components into the udder of a cow. He is shown performing the massaging step while pinching the teat around the nozzle of the syringe. Unfortunately, due to the abandonment of the cross-examination due to technical reasons, little can be said about the evidence of Mr Kirby; as Ms Edwards-Stuart said in her closing statements, the less said about the video link the better. Mr Kirby had been called for cross-examination in order to clarify various aspects about the video evidence, namely the location, the nature of the dual-barrel syringe and the identity of the person shown using the syringe in the video. In the event, it was possible for Norbrook to provide the necessary clarification at the hearing.

25 Bimeda provided evidence in the form of an expert report from Mr William Meaney and a witness statement from Mr Padraig Hyland. Mr Meaney was cross-examined at the hearing while Mr Hyland's evidence was not challenged.

26 Mr William Meaney is currently Director of Fermoy VetLab Services which provides laboratory microbiological analyses to the equine industry, and consultancy to the veterinary pharmaceutical and Irish dairy industries. He also has experience in bovine mastitis research. In his witness statement, Mr Meaney outlines the treatment of bovine mastitis at February 2004 and the use of the twin injector pack. He then goes on to consider the skilled person's reaction to Kapelowitz, JPH8 and McHardy. Mr Meaney notes that he is not an engineer and his comments are based on his experience of mastitis treatment and research. He says that when using a device such as those in Kapelowitz or JPH8, massaging the antibiotic component up the udder while the device was still inserted in the teat canal would be very difficult, it could result in the nozzle becoming dislodged and would likely lead to reaction from the cow. Mr Meaney also says that not performing the massage step would result in unacceptable mixing of the antibiotic and teat seal within the teat.

27 When questioned, Mr Meaney confirmed that he had no background in engineering and that his research involved the contents of the injector device rather than the device itself. Mr Meaney also stated that he had never, from his own experience, seen the technique of massaging the udder with the nozzle in place. Mr Meaney was handed extracts from two textbooks which disclosed a sharp needle being inserted into the teat canal of a cow. Although Mr Meaney was at pains to point out that the extracts showed a surgical procedure and that he could see no reason to insert a hypodermic needle into a teat canal in the context of treatment for bovine mastitis, he accepted that you could insert a hypodermic needle into the teat canal of a cow. I believe that Mr Meaney was a fair and credible witness

28 Mr Hyland's witness statement describes using the device of figures 10-13 of the patent to introduce various antibiotics and seals into the udders of a cow. He did not perform a massaging process. X-rays were then taken of the treated udders which showed the seal to be in place and with the antibiotic located above the seal.

The law

29 The Comptroller's powers to revoke a patent on the application of another person are set out in section 72(1) of 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) ...*
> *(d) the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent, as filed, or, if the patent was granted on a new application filed under section 8(3), 12 or 37(4) above or as mentioned in section 15(9) above, in the earlier application, as filed;*
> *(e) ...*

30 An invention is patentable if it meets the conditions set out in section 1(1) of the Act, namely that the invention is new, it involves an inventive step, it is capable of industrial application and is not excluded.

31 Sections 2 and 3 of the Act define what is meant by "new" and "inventive step" respectively. Section 2 states that an invention shall be taken to be new if it does not form part of the state of the art, and goes on to define the state of the art as comprising anything made available to the public before the priority date of the invention. Section 3 states that an invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art.

32 Also relevant is section 125 of the Act, which specifies that an invention shall be taken to be defined by the claims as interpreted by the description and any drawings in the patent specification. Section 125(3) says that the extent of protection conferred by a patent or application for a patent shall also be determined in accordance with 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.*

Novelty

33 The current test for novelty was set out by Lord Hoffman (sitting in the Court of Appeal) in *H Lundbeck A/S v Generics (UK) Ltd*[1]:

> *"In order to anticipate a patent, the prior art must disclose the claimed invention and (together with common general knowledge) enable the ordinary skilled person to perform it."*

34 In order to "disclose the claimed invention" the prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent (paragraph 22, *Synthon BV v SmithKline Beecham plc*[2]*).*

35 In order to decide whether claim 1 is novel it is first necessary to determine its scope and meaning. The established authority on claim construction is found in *Kirin-Amgen*[3], where Lord Hoffman held that:

> *"When applying a 'purposive construction', the question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean". I shall begin by identifying the skilled person and the common general knowledge of that person."*

The skilled person

36 According to the relevant authorities, 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 some cases the patent may be addressed to a team of persons with different knowledge and experience.

37 Norbrook argue that the relevant art is the design and manufacture of injection systems for veterinary use, and the skilled addressee would be a team comprising a designer and manufacturer of injection devices together with a veterinary practitioner. Bimeda argue that the patent is addressed to a reader interested in the development of treatments for bovine mastitis; in other words, the person skilled in the art is an expert in bovine mastitis.

38 It should be noted that claim 1 of the patent is to an injector device and not to a method or way of treating bovine mastitis, and therefore the skilled person is at least in part an engineer or designer of injector devices. As noted by Norbrook, the specification provides no general teaching regarding the construction of injector devices, which points towards the requirement of a skilled engineer or designer in order to perform the invention. Furthermore, since the invention is generally concerned with the treatment of bovine mastitis, then I consider that the skilled engineer would also require a knowledge of such physical properties as the viscosity,

[1] [2008] RPC 19, para 19
[2] [2006] RPC 10
[3] Kirin-Amgen v Hoechst Marion Roussel Ltd [2005] RPC 91

density, reactivity and volume of treatment doses to be delivered into the teat canal in order for the invention to be put into practice. It is likely, therefore, that the skilled person will be a team comprising a designer and manufacturer of injection devices together with a veterinary practitioner or researcher of bovine mastitis.

The common general knowledge of the skilled person

39 The law as to what constitutes common general knowledge is set out by the Court of Appeal in *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd*[4] (paragraphs 482-483) and *Beloit Technologies Inc v Valmet Paper Machinery Inc*[5] (paragraphs 494-495). 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*[6] (paragraph 40) when he said that the common general knowledge includes all material in the field that the skilled person is working and which he knows exists, "which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work".

40 It seems to me that the common general knowledge of the skilled person can be split into two distinct parts: the engineering considerations and the treatment of bovine mastitis.

a) Engineering considerations

41 It is common ground that the skilled engineer or designer of injector devices would have a good understanding of the basic single-barrel/single-chamber syringe and its operation as described in paragraphs 20-24 Dr Dunne's witness statement.

42 Dr Dunne says that a number of other types of syringe were in use in February 2004, in particular the "double-syringes" consisting of two separate, unconnected barrels, and the "multi-needle" syringes with more than one needle from the same chamber. He also identifies a third type of syringe, the "dual-chamber" syringe, of which two subsets are described: the first subset is a "two-chamber" syringe, of the type described in JPH8; and the second subset is a "dual-barreled" syringe, of the type described in Kapelowitz. He cites the "Caverject Impulse" and the "Vetter Lyoject" as two examples of commercially available "dual-chamber" syringes.

43 Dr Dunne states that while some of these syringes might not specifically have been known to the skilled person, he is confident that "they are examples of types of syringe that would have been found in any routine search". When asked about this in cross-examination, i.e. which of the syringes would not have been known to the skilled person, Dr Dunne confirmed that what he was referring to was the dual-chamber syringes and, in particular, the JPH8 and Kapelowitz examples of dual-chamber syringes.

44 Bimeda argue that the only pre-2004 dual-barreled syringe in evidence in the case is Kapelowitz, although I note that figures 1 and 2 of Pizzino also show a dual-barreled

[4] [1972] RPC 457
[5] [1997] RPC 489
[6] [1998] RPC 31

arrangement. They say that Norbrook has adduced no evidence of any other type of dual-barreled syringe being common general knowledge, nor evidence that dual-barrelled syringes generally, as distinct from the broader class of dual-chambered syringes, were common general knowledge. Dr Dunne says that some of the double-chamber syringes, i.e. the JPH8 and Kapelowitz type of syringes, would not have been known to the skilled person but could have been found upon routine search, which begs the question of what motivation would there have been to undertake such a routine search in order to place such devices in the common general knowledge. Dr Dunne's witness statement is silent on this.

45 On the basis of Dr Dunne's written evidence and his testimony at the hearing, I find that the common general knowledge of the skilled engineer or designer of injector devices would have included a general awareness of dual-chamber syringes but not the particular dual-barreled syringe shown in Kapelowitz.

b) Treatment of bovine mastitis

46 It is common ground that the skilled veterinary practitioner or researcher of bovine mastitis would be well aware of various formulations for the treatment of intra-mammary infections. He would know that the formulations could be used to treat existing infections and be used to protect against the risk of new infections. Also, he would be familiar with various teat seal formulations and their use in protecting against infection by creating a physical barrier.

47 The skilled person would also be familiar with the twin injector pack and the general process of inserting the nozzle of the first syringe into the teat to infuse the antibiotic, massaging the antibiotic upwards into the mammary gland, and then inserting the second syringe to infuse the teat seal.

48 There is disagreement between the parties as to whether the process of massaging the antibiotic formulation up into the udder with the nozzle in place was common general knowledge. The evidence of Mr Meaney is that he had never seen it happen, whereas Mr O'Sullivan had seen it and felt that it was acceptable. I do not think that this is an issue of particular importance since the claim is not limited to the treatment of bovine mastitis, and I think it is enough to conclude that the person skilled in the art would simply be aware of the need of a massaging step.

Claim construction

49 A summary of the law in relation claim construction can be found in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd*[7], which emphasises that claims are not construed alone or in the abstract but within their context in the specification of the patent, that purposive construction is vital, and that one is in the end concerned with the meaning of the language used. Meticulous verbal analysis is to be eschewed.

50 There are several features in the claim that need to be construed, namely 1A and 1C, 1D, 1E, and 1F. I will consider each of these claim integers in turn. Before I do so, I will first consider a general point of construction that arises in relation to the context in which the wording of a claim is to be construed. Norbrook say that claim 1 is drafted very broadly using general terms that are not contended to be terms of the

[7] [2009] EWCA Civ 1062, [2010] RPC 8

art nor are they expressly defined in the specification. They argue that the claim should be construed according to its ordinary English language meaning, by reference to all the embodiments described in the specification and the teaching of the patent as a whole. The say that it is highly relevant that on the natural and wide reading of the claim, all of the embodiments described in the specification fall within claim 1 of the patent, which is precisely what the skilled addressee would expect. Bimeda argue that the claim should be construed in the light of particular embodiments and that the relevant embodiments are those shown in figures 10-16 of the specification. They say that the skilled person would realise that the scope of the claim has been narrowed during processing to grant and that the features of claim 1 have been amended to correspond with the embodiments of figures 10-16. They say that the specification at grant makes clear that only figures 10-16 show an injector device "according to the invention".

51 As in all questions of claim construction, the law says that the answer will lie somewhere between these two positions, the precise point being dependent on the specific facts of the case.

52 Turning to integers 1A and 1C of claim 1, i.e. an injector device for delivery of components into the teat canal of a non-human animal (1A) and an outlet nozzle configured for insertion into a teat canal at one end of the barrel (1C), the issue at hand is essentially the same. Norbrook argue that a hypodermic needle can be considered to be "an outlet nozzle configured for insertion into a teat canal" and similarly that an injection device fitted with a hypodermic needle is an injector device capable of delivering components into the teat canal of a non-human animal. Bimeda consider the injector to be limited to a nozzle which is specifically adapted for insertion into a teat canal, and they note the deliberate limitation and use of the term "configured". It is also submitted that, in ordinary English, "a nozzle is not a needle and a needle is not a nozzle".

53 The question I need to answer is what would the person skilled in the art have understood the patentee to have meant by integers 1A and 1C? The first point of consideration is the term "nozzle". The term nozzle would normally be taken to mean any means for controlling the direction and flow of a fluid, and there is nothing in the specification to provide any further limitation on the term. Thus, an outlet nozzle is of broad meaning which encompasses many different types and shapes. Also, the person skilled in the art would not think that the nozzle of claim 1 was necessarily limited in context to the embodiments of figures 10-16 because many of the other injector devices described in the specification also have very similar nozzles, and the significance of the shape and size of the nozzles is simply not explained. The nozzle in figure 17, for example, has an end that comes to a point or a very close approximation of one, which would appear at first glance to approximate to a needle. However, in the context of the specification as a whole, I don't think any significance can be derived from this. Therefore, I conclude that the person skilled in the art would construe the term "nozzle" as being any means for controlling the direction and flow of a fluid, and that a "nozzle" may take the form of a needle.

54 Bimeda argue that the phrase "configured for" insertion into a teat canal in integer should be construed as meaning "specifically adapted" for insertion into a teat canal. They suggest that Norbrook's construction of integer 1C, i.e. an outlet nozzle capable of being inserted, writes the term "configured for" out the claim altogether, which is contrary to the guideline in *Virgin* that a deliberate limitation must have a

meaning. However, I can find nothing in the specification to indicate that the meaning of “configured for” insertion into a teat canal is anything other than simply capable of insertion: there is nothing to indicate how the nozzle is specifically adapted, and figures 9 and 17, for example, show two quite distinct nozzles with no obvious adaption for insertion into a teat canal in common between them.

55 Therefore, I find that the person skilled in the art would take integer 1A to mean an injector device suitable for delivery of components into the teat canal of a non-human animal and would take integer 1C to mean an outlet means for controlling the direction and flow of a fluid which is capable of insertion into a teat canal at one end of the barrel.

56 Turning to integer 1D, i.e. an internal receptacle within the barrel for containing a second component to be injected into the teat canal, Norbrook argue that the term “internal receptacle” should be construed simply as something containing a second component, and that this can encompass any defined and enclosed space within the main barrel. Bimeda argue that the term means a discrete container within the barrel.

57 Although the term “internal receptacle” is not defined explicitly in the specification, the embodiments discussed and shown in figures 1-16, 19 and 20 each have a receptacle in the form of an inner barrel, and the injector devices shown in figures 17 and 18 have a receptacle in the form of a free floating bag. The question then is what the person skilled in the art would have understood the patentee to mean by the term “internal receptacle”. It seems to me that when the application was first published, it would have been understood that the patent intended to cover the types of internal receptacle shown in all of the embodiments shown in figures 1-20. Even though additional integers have been added to the claim and some of the original integers have been specified in more detail during the examination process to grant, the term “internal receptacle” has not been amended and so must mean the same as it meant originally, i.e. a distinct and separate item within the barrel for containing the second component to be injected into the teat canal.

58 Next I will consider integers 1E and 1F, i.e. a valve for separating the first component from the second component (1E) and an activator for opening the valve to allow the second component to be released from the internal receptacle (1F). Norbrook argue that the terms “valve” and “activator” should be construed as they are read. They say that the term “valve” is simply a means to separate the first component from the second component, and encompasses the valves, membranes and barriers in the specification. They also say that the term “activator” is simply a means for opening the valve so as to allow the second component to be released from the internal receptacle, with no limitation on how this is achieved. Bimeda argue that the terms expressly reference the specific features of injectors shown in figures 10-16 of the drawings.

59 So what would the person skilled in the art have understood the patentee to mean by these terms? The term “valve” clearly has a specific mechanical meaning and is generally understood to be more than just a membrane or barrier. If the person skilled in the art did not know this beforehand, he would certainly know this from reading the patent specification, which shows a number of different injector devices having either a membrane, a valve or a barrier for separating the first component from the second component. The injector device shown in figure 9 has an inner and outer barrel and a barrier separating the first component in the outer barrel from the

second component in the inner barrel. The barrier has a portion 51 that is punctured by an activator (defined by a number of spikes 50) to allow ejection of the second component. The specification does not use the word “valve” to describe this portion 51, but does use the term in respect of the arrangements shown in figures 10-16, where a valve element 60 is lifted by activator 61. The valve is shown in more detail in figures 14-16, and is described as comprising a series of channels that become exposed when the valve is released to allow the second component to pass out through the valve. The channels define a passageway for the second component and are open when the valve is released by the activator. The specification states that one advantage of the valve-type barrier is that there is no risk of any of the barrier becoming mobile and that it is retained within the injector, i.e. fragments of membrane/barrier cannot enter the nozzle and into the teat canal. In the injector devices shown in figures 17-20, the second component is released either by puncturing or rupturing a barrier/membrane, and again the term “valve” is not used.

60 I note that in the annex to his report submitted in evidence, Dr Dunne discusses two types of valves for his solutions (1) and (2) for providing sequential delivery of two fluids into a teat canal, the first being a pressure release valve and the second being a mechanical release valve. This is relevant in demonstrating how the skilled person uses the word “valve” and what he takes it to mean. In other words, it lends weight to the argument that the term “valve” clearly has a specific mechanical meaning and is generally understood to be more than just a membrane or barrier. I can find nothing in the specification that would lead the skilled person to think the word was being used otherwise.

61 The term “activator” would mean very little to the skilled person absent the context of the specification. The term is described in relation to the injector devices shown in figures 9-16, where in figure 9 it comprises a series of spikes acting directly on the membrane/barrier in order to puncture an opening in the membrane/barrier, and in figures 10-16 the activator acts directly on the valve to lift it from its original position and to open up passageways for the flow of fluid. Integer 1G in claim 1 refers to the activator “engaging” with the valve in order to open it, which suggests that the activator has a direct interaction with the element it is intended to activate.

62 Taking all of this into account, I believe that the skilled person would have understood the patentee to be using integers 1E and 1F in the context of the injector device shown in figures 10-16, i.e. a mechanical valve arrangement for separating the first component from the second component; and an activator which directly and actively effects the opening of the valve to allow the second component to be released from the internal receptacle.

63 Having construed the scope and meaning of claim 1 of the patent, I will now consider the issue of novelty in light of the prior art documents.

The prior art

a) Kapelowitz

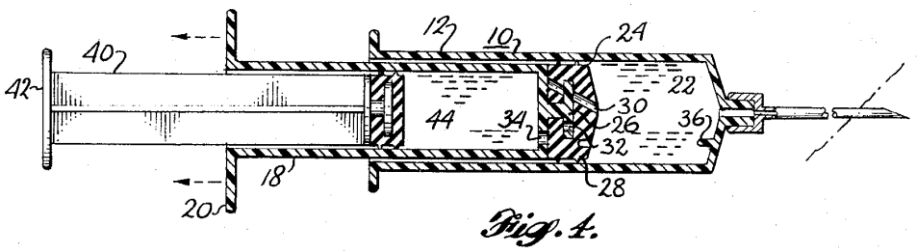


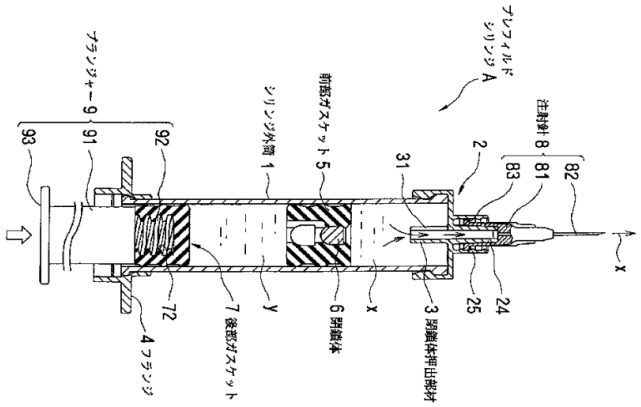
Fig. 4.

64 Kapelowitz discloses a syringe (10) with an inner barrel (18) and outer barrel (12), and an outlet in the form of a hypodermic needle. The inner barrel is provided with a valve (24) comprising a flange portion (26) of the inner barrel and a seal member (28) slideably and rotationally mounted to one another. In use, the plunger (42) is depressed and a first component in the outer barrel (12) is released. When the first component has been discharged, a recess in the seal member (28) of the valve engages a plug (36). The knob (20) of the inner barrel is then turned and the valve (24) is opened by aligning orifices (30) and (34). The seal member (28) cannot rotate with the flange (26) due to the plug (36) and recess preventing rotation. The second component in the inner barrel can then be discharged.

65 Bimeda do not dispute that Kapelowitz discloses a barrel, an internal receptacle and a valve as required by integers 1B, 1D and 1E of claim 1. With regard to integers 1A and 1C as construed above, i.e. an injector device suitable for delivery of components into the teat canal of a non-human animal and having an outlet means for controlling the direction and flow of a fluid which is capable of insertion into a teat canal at one end of the barrel, the issue is whether the hypodermic needle of Kapelowitz is capable of insertion into a teat canal. Norbrook argue, and I agree with them, that it does not matter whether or not the syringe and its components are for the treatment of bovine mastitis because this requirement is not specified in the claim. Thus Mr Meany's concerns as to why one would insert a needle into the teat canal are irrelevant. Furthermore, from the cross-examination of Mr Meaney it is clear that a hypodermic needle could be inserted into the teat canal of a cow, and therefore I find that Kapelowitz does also disclose integers 1A and 1C.

66 The remaining integers of claim 1 to consider are 1F and 1G, i.e. whether Kapelowitz discloses an "activator" that engages with and opens the valve. Norbrook argue that plug (36) engages with a recess in the seal member and that, once engaged, the flange can be rotated relative to the seal member to open the valve to allow the second component to be released from the inner barrel. The syringe is provided with a delivery means in the form of knob (20) and plunger (40), and the knob is advanced to deliver the first component from the outer barrel followed by the second component from the inner barrel. However, given the way I have construed the term "activator" above, I do not consider that plug (36) of Kapelowitz directly and actively effects opening of valve (24). I consider that plug (36) has at best an indirect and passive role in the opening of valve, with its role or functionality in the opening of the valve reliant on the active, direct and distinct user action of turning the barrel. It is not the engagement of the activator with the valve that opens the valve. Kapelowitz does not disclose integers 1F and 1G of claim 1. As a consequence, claim 1 of the patent is not anticipated by Kapelowitz.

b) JPH8



67 JPH8 discloses a syringe with an external cylinder (1), needle (8), and front (5) and rear gaskets (7). The gaskets (5) and (7) define a first liquid area “X” and a second liquid area “Y”, with the first and second liquid areas separated by a valve (6) in gasket (5). The rear gasket (7) also accommodates a moveable plunger (9). In use the plunger (9) is depressed and the liquid “X” is released via needle (8). When liquid “X” is almost finished being released the valve (6) makes contact with projection (3) and opens such that the liquid “Y” in the second liquid area can be released via the needle (8).

68 Bimeda do not dispute that JPH8 discloses a barrel, a valve, and an activator for opening the valve to provide sequential delivery of two separate components as required by integers 1B, 1E, 1F and 1G. As with Kapelowitz, I consider that the needle (8) of JPH8 is capable of being inserted into the teat canal of a cow and that it therefore also discloses integers 1A and 1C of claim 1.

69 The remaining integer of claim 1 to consider is 1D and, in particular, whether JPH8 discloses an “internal receptacle” within the barrel. Norbrook argue that the second chamber containing liquid “Y”, which is bounded by the gaskets (5) and (7) within barrel 1, meets the requirement of an “internal receptacle” within the barrel. However, as I have construed this feature, the area bounded by the gaskets and barrel wall does not provide a distinct and separate item within the barrel for containing the second component to be injected into the teat canal. Therefore, JPH8 does not disclose integer 1D. As a consequence, claim 1 of the patent is not anticipated by JPH8.

c) Pizzino

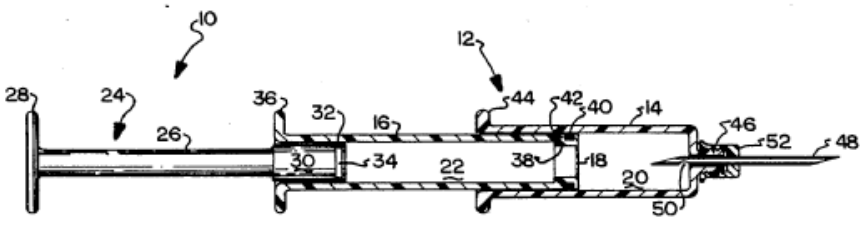


FIG. 1

70 Pizzino discloses a syringe with an inner barrel (16) and outer barrel (14), and an

outlet in the form of a needle (48). The inner barrel (16) is provided with a membrane (18). In use the plunger (24) is depressed and the liquid from a first chamber (20) is released via double ended needle (48). When the inner barrel (16) approaches the forward limit of its travel, the needle (50) inside chamber (20) punctures membrane (18) and the liquid from second chamber (22) is released via needle (48).

71 Put simply, Pizzino does not disclose a valve as I have construed in integer 1E of claim 1. Therefore, claim 1 is not anticipated by Pizzino.

Inventive step

72 The Court of Appeal in *Windsurfing*[8] formulated a four-step approach for assessing whether an invention is obvious to a person skilled in the art. This approach was restated and elaborated upon by the Court of Appeal in *Pozzoli*[9]. Here, Jacob LJ reformulated the *Windsurfing* approach as follows:

> *(1)(a) Identify the notional "person skilled in the art".*
> *(1)(b) Identify the common general knowledge of that person.*
> *(2) Identify the inventive concept of the claim in question or if that cannot be readily 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 claim as construed.*
> *(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the person skilled in the art or do they require any degree of invention?*

73 Both sides have referred to a number of authorities I should bear in mind in relation to obviousness. I shall summarise the salient points very briefly.

74 In *Conor v Angiotech*[10], Lord Hoffman approved the following statement of Kitchin J made in *Generics v Lundbeck*[11]:

> *"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."*

75 Hindsight must be avoided, especially where an allegation of obviousness is based on common general knowledge (Kitchin J in *Ratiopharm v Alza Corporation*[12], paragraph 105):

> *"I must also avoid hindsight. This is particularly important where, as here, there is an allegation of obviousness based upon the common general knowledge. I put it this way in Abbott v Evysio [2008] EWHC 800 (Pat) at [180]:*

[8] *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd, [1985] RPC 49*
[9] *Pozzoli SPA v BDMO SA [2007] EWCA Civ 588*
[10] [2008] UKHL 49
[11] [2007] RPC 32
[12] [2009] EWHC 213 (Pat)

> *"It is also particularly important to be wary of hindsight when considering an obviousness attack based upon the common general knowledge. The reason is straightforward. In attacking a patent, attention is focussed upon the particular development which is said to constitute the inventive step. With this development in mind it may be possible to mount an attack which is unencumbered by any detail which might point to non obviousness [...]. It is all too easy after the event to identify aspects of the common general knowledge which can be combined together in such a way as to lead to the claimed invention. But once again this has the potential to lead the court astray. The question is whether it would have been obvious to the skilled but uninventive person to take those features, extract them from the context in which they appear and combine them together to produce the invention."*

76 The pleaded prior art must be read properly and with interest, and the public has the right to make anything which is an obvious development of what is disclosed. However this does not mean that the prior art is deemed to have any relevance to the problem that the skilled person is considering or necessarily forms a realistic starting point for further development. An undue focus on one prior publication to the exclusion of the prior art as a whole is misconceived and itself tainted with hindsight (paragraphs 106 and 107, *Ratiopharm v Alza Corporation).* This reflects the comments of Aldous LJ in *Asahi Medical Co v Macopharm*[13] (paragraph 22):

> *"...a decision on obviousness does not require a conclusion as to whether or not the skilled person would be slightly, moderately or particularly interested in any document. The court has to adopt the mantle of the skilled person. That mantle will include the prejudices, preferences and attitudes that such persons had at the priority date. Thereafter the court has to decide whether the step or steps from the prior art to the invention were obvious. That decision has to be taken without the invention in mind and through the eyes of the skilled person. Of course any prior art document relied on must be deemed to be read properly and in that sense with interest. To conclude otherwise would deprive the public of their right to make anything which is an obvious modification of a published document. By obvious I mean that which would be obvious to the skilled person."*

77 The question of whether a skilled person "could" or "would" have made the step from the prior art was considered in *Asahi Medical* and also by Birss J in *Hospira v Genentech*[14] (paragraphs 229 to 231):

> *"Second, the law of obviousness cannot be accurately summarised simply by stating that the question is whether the skilled person would have arrived at the claimed invention, not whether they could have. The issue is multifactorial and based closely on the particular circumstances.*
>
> *Third, the word "would" is not always straightforward. Sometimes asking simply if a skilled person "would" do something risks placing too much weight on what are really minor or irrelevant factors like cost, instead of focussing on*

[13] [2002] EWCA Civ 466
[14] EWHC 3857 (Pat)

the technical issues. Moreover, the well known 9 ½ inch plate is not something a skilled person would make. It is more accurate to say that it is not patentable because the skilled person could make it without any inventive step.

In other cases the difference between could and would is important. If the outcome rides on the result of a single experiment, the fact the skilled person could carry it out does not usually mean the invention is obvious. One often needs to ask if they would carry out the test in the expectation of a positive result."

78 The relevance of an expectation of a positive result to the question of obviousness was summarised by Floyd J in *LEO Pharma v Sandoz Ltd* [15]:

"98. In St Gobain v Fusion Provida [2005] EWCA Civ 177 Jacob LJ explained the role of "obvious to try" in the assessment of inventive step:

> *"Mere possible inclusion of something within a research programme on the basis you will find out more and something might turn up is not enough. If it were otherwise there would be few inventions which were patentable. The only research which would be worthwhile (because of the prospect of protection) would be in areas totally devoid of prospect. The "obvious to try" test really only works where it is more-or-less self evident that what is being tested ought to work"*

99. This and other authorities on "obvious to try" were considered in the judgment of Jacob LJ in Conor v Angiotech [2007] RPC 20; [2007] EWCA Civ 5. In the House of Lords, [2007] UKHL 49; [2008] RPC 28 at [42] Lord Hoffmann explained:

> *"In the Court of Appeal, Jacob LJ dealt comprehensively with the question of when an invention could be considered obvious on the ground that it was obvious to try. He correctly summarised the authorities, starting with the judgment of Diplock LJ in Johns-Manville Corporation's Patent [1967] RPC 479, by saying that the notion of something being obvious to try was useful only in a case in which there was a fair expectation of success. How much of an expectation would be needed depended upon the particular facts of the case. As Kitchin J said in Generics (UK) Ltd v H Lundbeck A/S [2007] RPC 32, para 72 [see quote above]:*

100. Lord Justice Jacob's phrase "more-or-less self-evident that what is being tested ought to work" is explained by Lord Hoffmann as a "fair expectation of success", with the degree of expectation depending on the facts of the case. I have had these principles in mind when approaching the question of obviousness in this case."

79 With these authorities in mind, I shall next address the question of whether the invention of claim 1 involves an inventive step by following the structure approach set out in *Pozzoli*.

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[15] EWHC 996 (Pat)

80 I have already identified the skilled person and the common general knowledge of that person in paragraphs 36-48 above.

What is the inventive concept?

81 The inventive concept of claim 1 lies in an injector device for the sequential delivery of first and second components into the teat canal of a non-human animal and comprises an outlet suitable for insertion into the teat canal, a first barrel for the first component, a distinct and separate internal receptacle within the barrel for the second component, a mechanical valve and an activator for directly and actively opening the valve for the sequential delivery of the second component.

82 I shall address the third and fourth steps of *Pozzoli* separately for each of the prior art documents.

a) Kapelowitz

83 The difference between the disclosure in Kapelowitz and the inventive concept of claim 1 is that Kapelowitz does not disclose an activator which directly and actively effects opening of the valve to allow the second component to be released from the internal receptacle. Given the construction I have given to the term "activator" above, Norbrook say that they do not advance a positive case that it would be obvious to amend Kapelowitz so as to bring it within the scope of claim 1.

b) JPH8

84 The difference between the disclosure in JPH8 and the inventive concept of claim 1 is that JPH8 does not disclose an internal receptacle which is a distinct and separate item within the barrel for containing the second component. Norbrook argue that such a modification to JPH8 is technically obvious based on Dr Dunne's evidence that there were two equally obvious modifications that could be made to JPH8 for the purposes of using it to inject the mastitis treatment into a teat canal. The two modifications would be required to take account of the higher viscosity of seal formulation that was known to be used in the treatment of bovine mastitis. The first modification would have been to vary the dimensions of the passageway so as to ensure that the viscous formulation could pass through. Dr Dunne says that this would not have caused the skilled person any difficulty. The second modification would have been to introduce an inner barrel. As Dr Dunne explains in his report, if the more viscous seal member was kept in a narrower channel in an inner barrel, then that would result in a higher pressure in that chamber, which would in turn result in an easier delivery of the seal formulation. He says that the dual-barrel solution would have been one that the skilled person would have come up with in February 2004 and there was no technical consideration that would have prevented the skilled person from introducing the inner barrel into the JPH8 system. Norbrook argue that there is no challenge to Dr Dunne's evidence that both of his proposed solutions were technically obvious.

85 In cross-examination Dr Dunne accepted that the second modification was "more significant" and that it would require "some motivation". Bimeda say that there is no evidence that dual-barreled syringes were common general knowledge and also point out that Dr Dunne does not say in his evidence that that the skilled person would undertake a routine literature search when considering possible modifications

to JPH8. Hence, they say, there is no basis for saying that the skilled person would have dual-barreled syringes in mind when considering JPH8; if the skilled person did not have them in mind as a result of his common general knowledge then the idea of introducing an inner barrel would have to occur to him independently, i.e. it would be an invention. Dr Dunne does say in the annex to his report that he was aware of dual-barreled syringes in February 2004, which he relied upon to form the basis of his solution (2).

86 Bimeda contend that the fundamental difficulty with the introduction of an inner barrel into JPH8 is that the document itself teaches that no such modification is necessary; they say that it specifically teaches that a viscous fluid can be expelled from the rear chamber without modification of the device. In cross-examination Dr Dunne accepted that JPH8 does not provide a specific motivation to introduce an inner barrel, he qualified this by explaining that the motivation to introduce an inner barrel was dependent on the viscosity of the seal formulation.

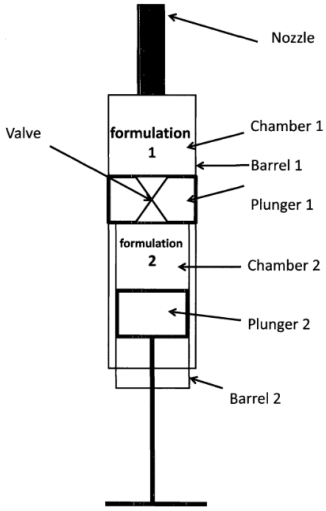
87 I have already found that the "dual-barreled' type of syringe does not form part of the common general knowledge of the person skilled in the art, so there is nothing to indicate that the use of an inner barrel is inherently or technically obvious. If I am wrong on this point, I find that the specific reference in JPH8 (paragraph 12) that the second component "Y" can be a "high viscosity drug solution" teaches the skilled reader away from any need to alter the "dual chamber" syringe to one of a "dual-barrel" because the syringe of JPH8 is already designed to administer a high viscosity fluid via the second chamber. Norbrook argue that modifications would be dependent on the viscosity of the teat seal, however they have provided no particular evidence or arguments that the viscosity of a teat seal formulation necessitates or leads to modification of JPH8. I must conclude, therefore, that the person skilled in the art would have no motivation to alter the syringe of JPH8 for the purpose of treating bovine mastitis. Claim 1 involves an inventive step in light of JPH8.

c) Pizzino & McHardy

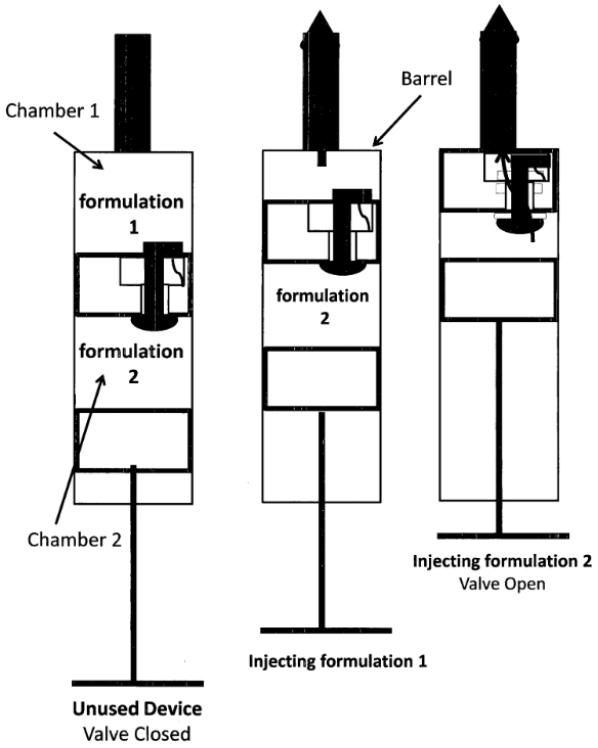
88 The difference between the disclosures in Pizzino and McHardy and the inventive concept of claim 1 is that Pizzino and McHardy do not disclose a valve. Both these documents disclose the use of a membrane barrier rather than a valve barrier. Given the construction I have given to the term "valve" above, Norbrook say that they do not advance a positive case that it would be obvious to amend Pizzino and McHardy in order to bring them within the scope of claim 1.

d) Inventive step in light of common general knowledge

89 Norbrook argue that the invention as defined in claim 1 is obvious in light of common general knowledge alone. Dr Dunne was tasked by Norbrook with designing an improvement or alternative to the twin injector pack as at February 2004 without any knowledge of the patent whatsoever, and set out his improvements in the annex to his report. He was asked to assume the position of the unimaginative and non-inventive person skilled in the art, and after clarifying a few points, provided two initial solutions. Solution (2), with two chambers and an inner and outer barrel, is illustrated below:



90 When he presented solutions (1) and (2) to Norbrook, Dr Dunne was asked to "complete" them as far as he could, in particular with regard to how the valves in solutions (1) and (2) would work. He then suggested using valves he considered to be widely used at the time, namely pressure valves and mechanical valves. He arrived at the use of mechanical valves for solution (1), as seen in his figures 6 and 7 of the annex. The solution of figure 6 is produced below:



91 He also considered that the use of mechanical valves would be perfectly suitable for solution (2).

92 The question thus arises whether Dr Dunne's evidence indicates a lack of inventive step in claim 1 of the patent on the basis of common general knowledge alone.

93 At paragraph 11 of the annex, Dr Dunne says in relation to his solution 1 (single-barrel, double-chamber) that the delivery of both formulations is "therefore effected

by one continuous step taken by the user". It was suggested to Dr Dunne in cross-examination that by proposing a solution in which the two components were delivered sequentially in "one continuous step" that he had overlooked the need to massage the udder after administration. However, as Norbrook subsequently pointed out, claim 1 of the patent is to an injector device and does not require a pause or break between the administration of the first and second formulations to permit massaging of the antibiotic.

94 Bimeda argue that there are three fundamental problems with Dr Dunne's evidence. The first is that it is not established that dual-barreled syringes were part of the common general knowledge of the skilled person, which I have already dealt with above. The second problem is that Dr Dunne is, by his own admission, a naturally inventive person, and so the task he was set was not consistent with providing an understanding of the content and extent of the common general knowledge of the unimaginative skilled person. The third problem is that when Dr Dunne was asked to identify advantages and disadvantages of any device he came up with, he was positively steered toward a single device solution.

95 I have a great deal of sympathy with Bimeda's argument that Dr Dunne's evidence does not provide me with an accurate understanding of the extent of the common general knowledge of the skilled person. This is not intended as a criticism of Dr Dunne's expertise in the field of injector design nor of the careful approach he took in setting out his knowledge of the subject matter in his report, but is more a consequence of the nature of the task he was asked to complete. Norbrook's case is that claim 1 must lack inventive step because Dr Dunne was able to devise the exact same device from his own common general knowledge. I have serious doubt as to whether Dr Dunne was truly able to distance himself from his own inventive nature when required to assume the mantle of the notional skilled unimaginative person. My view is that Dr Dunne's evidence has been helpful in establishing what was and wasn't common general knowledge of the skilled person at the time the invention was made, e.g. in relation to the double-barrel, but I cannot rely on Dr Dunne's solutions as an indication of obviousness in the light of common general knowledge.

96 Double-barrel syringes were not a part of the common general knowledge of the skilled person at the time of the invention. Consequently, I conclude that the invention defined in claim 1 is inventive in light of common general knowledge.

Added Matter

97 Norbrook contend that claim 1 of the patent contains added matter, such that the specification of the patent extends beyond that disclosed in the application for the patent. As filed in PCT application WO 2005/072644, the device claim (claim 25) was as follows:

> *An injector device for delivery of components into the teat canal of a non-human animal comprising:*
> *a barrel for containing a first component;*
> *an outlet nozzle at one end of the barrel;*
> *an internal receptacle for containing a second component;*
> *a barrier for separating a first component and a second component; and*
> *a delivery means for delivery of a first component from the barrel and sequential delivery of a second component from the internal receptacle*

through the outlet nozzle.

98 During prosecution, the claim was amended such that the "barrier" feature was limited to a "valve" along with the feature of an activator. None of the original claims refer to valves but, as discussed above, two embodiments shown and discussed in figures 10-16 clearly show mechanical valves as a particular type of barrier. Norbrook allege that the amendment to claim 1 results in the claim covering valves in general rather than the two specific valve embodiments in the specification, and thus the claim adds matter through an "intermediate generalisation". In particular, Norbrook note the two embodiments are different and each has a specific valve arrangement.

99 Amendments which limit the scope of a claim by the introduction of one or more features from the description may in certain circumstances add matter through what is known as "intermediate generalisation". The concept of "intermediate generalisation" was explained by Pumfrey J in Palmaz's *European Patents (UK)*[16]:

> *"If the specification discloses distinct sub-classes of the overall inventive concept, then it should be possible to amend down to one or other of those sub-classes, whether or not they are presented as inventively distinct in the specification before amendment. The difficulty comes when it is sought to take features which are only disclosed in a particular context and which are not disclosed as having any inventive significance and introduce them into the claim deprived of that context. This is a process sometimes called "intermediate generalisation"."*

100 Floyd J summarised the concept of "intermediate generalisation" in *Nokia v IPCom*[17] as follows (paragraph 132):

> *"....it is sought to add to the claim features only to be found in the specification as part of the description of a specific embodiment, and where they are technically or functionally connected to other features which are not sought to be claimed."*

101 So did the amendment of claim 1 add matter? Although the term "valve" did not appear in the claims as originally filed, I consider that the person skilled in the art would readily identify the valves in the two embodiments in figures 10-16 as being a distinct sub-class of the inventive concept of a barrier as disclosed in the application as filed (see page 17 line 11 of WO 2005/072644). Thus the fact that claim 1 has been amended to a "general" valve does not matter; the feature of a valve introduced to claim 1 is a distinct subclass of the barrier feature identified as being of inventive significance. Furthermore, the claims were not simply amended down to a valve from a barrier; the feature of the activator was also included in claim 1. Thus the context of the valve feature and the features it is "functionally connected" to were also introduced into claim 1. I agree with Bimeda's argument that the amendment of claim 1 to the valve type barrier was a simple limiting amendment which contributes no new technical information over and above that disclosed in the original application in respect of the embodiments shown in figures 10-16.

102 Therefore, I conclude that the specification of the patent does not extend beyond that

[16] *Palmaz's European Patents (UK) ([1999] RPC 47, upheld on appeal [2000] RPC 631*
[17] *Nokia v IPCom [2011] EWHC 1470*

disclosed in the application for the patent.

Conclusion and order

103 Bimeda have applied to amend the patent unconditionally by deleting all of claims 2-39, thus leaving the patent with a single independent claim, claim 1. Claim 1 of the patent is both novel and inventive in light of the cited prior art and also common general knowledge. Furthermore, the specification of the patent does not extend beyond that disclosed in the application for the patent. I therefore:

- allow Bimeda's application to amend the patent under section 75(1) and direct that clean amended pages be incorporated in the specification; and

- refuse Norbrook's application for revocation.

Costs

104 Both sides have asked for costs in their favour. Bimeda have been successful in defending this application for revocation and are entitled to costs. In proceedings before the comptroller, costs are usually awarded on a standard scale. In view of the duration of the hearing and the relatively straightforward nature of the statements and evidence, I order that Norbrook pays Bimeda the sum of £4000 as a contribution to their costs in these proceedings, this sum to be paid within seven days of the expiry of the period for appeal.

Appeal

105 Any appeal must be lodged within 28 days.

H Jones
Deputy Director, acting for the Comptroller