BL O/080/13

21 February 2013

PATENTS ACT 1977

APPLICANT	Christopher Blacklock
ISSUE	Whether patent application number GB0814285.3 complies with Section 1(1)(b)
HEARING OFFICER	Ben Buchanan

DECISION

Introduction

1 Patent application GB0814285.3 entitled "Gas diffuser for use in invasive medical procedures" was filed in the name of Mr. Christopher Blacklock on 5 August 2008. It was published as GB2462429A on 10 February 2010.

2 Following several rounds of correspondence, the applicant has been unable to convince the examiner, Bryony Barcelo, that the invention as claimed involves an inventive step over the prior art and so is patentable in terms of section 1(1)(b). There are also a number of unresolved clarity issues, which arise under sections 14(3) and 14(5).

3 The applicant therefore asked to be heard, and the matter came before me at a hearing held on 21 December 2012. Mr. Blacklock represented himself and the examiner was also present at the hearing.

The law

4 Section 1(1) deals with the conditions for grant of a patent, and states that:

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;

[other provisions not relevant]

5 Section 3 then sets out how the presence of an inventive step is determined:

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).

6 It is well-established that the approach to adopt when assessing whether an invention involves an inventive step is to work through the steps set out by the Court of Appeal in *Windsurfing*[1] and restated by that Court in *Pozzoli*[2]. These steps are:

(1)(a) Identify the notional "person skilled in the art"

(1)(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?

The invention

7 The invention is concerned with a gas diffuser for diffusing an inert gas, such as carbon dioxide, into an area of a patient's body undergoing an invasive medical procedure such as surgery. By displacing air, the invention reduces the risk of infection and air embolisms. Devices which do this are known. The stated advantage of the claimed invention is that the tip of the diffuser is 'non-wetting' and continues to diffuse gas across the majority of its surface even when immersed in fluid which may be present in the operational environment. It is therefore more effective in use and enables a reduced gas flow in operation.

8 Mr. Blacklock made some submissions at the hearing which focused on the advantages of his invention over the prior art. He supported his explanation by showing samples of both his invention and the prior art.

The claims

9 The most recent set of claims was filed on 21 June 2012. They are reproduced below:

1. A micro porous non wetting gas diffuser for use during invasive medical procedures to allow the delivery of gas to displace air or other gases from the surgical field, said diffuser comprising a micro porous hydrophobic tip for connection to a gas supply tube, said tip being sufficiently dense not to let fluid soak into it and to allow gas to diffuse through the majority of its surface when immersed in fluid.

2. A micro porous non wetting gas diffuser according to claim 1 wherein the tip is hollow.

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[1] *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd* [1985] RPC 59
[2] *Pozzoli SpA v BDMO SA* [2007] EWCA Civ 588, [2007] FSR 37

3. A micro porous non wetting gas diffuser substantially as hereinbefore described with reference to and as shown in figures 1 to 5 of the accompanying drawings.

Arguments and analysis

10 The examiner maintains that the latest claims filed on 21 June 2012 define an invention which does not involve an inventive step, when considered in light of certain identified prior art. Her position was set out most recently in her examination report of 12 September 2012.

11 What I must do is determine whether the invention does or does not involve an inventive step, within the meaning of the legislation. To do so, I will work through the *Windsurfing/Pozzoli* steps set out above.

Step 1 – identify the notional skilled person and their common general knowledge

12 In her examination report of 12 September 2012, the examiner considered the skilled person to be someone "with medical knowledge, particularly a doctor or surgeon and the common general knowledge of that person would be a knowledge of cardio thoracic surgery". At the hearing, Mr. Blacklock did not challenge this. I think it is a starting point for the ambit of the skilled person, but I note that it is well-established from case-law that the notional skilled person is a competent worker who has no inventive ingenuity but is able to make routine workshop developments.

13 Whilst I agree that the skilled person would possess sufficient medical knowledge to understand the need to control the environment during invasive medical procedures, and have an awareness of those procedures, I do not consider that they would be knowledgeable about surgery per se. Instead I consider that their knowledge would extend to the properties and advantages of devices operating within a surgical environment.

14 That is to say that I consider the skilled person to be a technician or trained operator of the equipment as part of a surgical team, and to be responsible for the preparation, testing and maintenance of that equipment. To that end I would credit them with keeping up to date with technical developments in the field, and with an awareness of the requirements of materials for use in that environment.

15 The common general knowledge of such a person would, it seems to me, include common mechanical and fluid engineering principles and techniques, and in particular would comprise knowledge of a variety of materials suitable for use in a medical environment, through which a pressurized gas may be forced to diffuse.

Step 2 – identify the inventive concept

16 In her examination report of 12 September 2012, the examiner summarised the

inventive concept as the use of a hydrophobic, micro-porous material for use as a diffuser tip. At the hearing, Mr. Blacklock agreed and repeatedly emphasized that the advatange of these features is to give the gas diffuser tip its 'non-wetting' characteristic, meaning that it will not soak up fluid like a sponge and become saturated when immersed in use, and will continue to diffuse gas evenly.

17 The inventive concept is defined by claim 1, although the claim as it stands gives rise to a number of clarity and support issues as set out in the examiner's report of 12 September 2012, including definition by result. The current authority on claim construction is found in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd*[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".

18 In practice this means that I must pay attention to the features defined in the claim, and can seek to understand them in the context of the description. In doing so I must read the specification as the skilled person would. What I cannot do is read into the claim any feature, even if it is present in the description, which is not clearly defined by the claim. To be clear, the claim should define the invention as precisely as the invention allows, and not by the result achieved, subject to the proviso in *No-Fume*[4] that the invention cannot be precisely defined independently of the result achieved.

19 Claim 1 defines 'a micro porous non wetting gas diffuser', comprising a 'micro porous hydrophobic tip'. Some discussion took place during the hearing about the meaning of the term 'hydrophobic'. In its conventional sense, 'hydrophobic' means 'lacking an affinity for water'. It is a physical property of a molecule reflecting the interaction of that molecule with water ions. Hydrophobic molecules may collectively form a surface and the surface may consequently exhibit a hydrophobic characteristic, but the term 'hydrophobic' is not conventionally used to describe the absorbency of materials. This latter point is key. When queried by the examiner whether in fact 'non-absorbent' would be a better descriptor of the property of the tip, Mr. Blacklock stated that he considered 'hydrophobic', 'non-absorbent' and 'non-wetting' to mean the same thing.

20 The description under the heading "Statement of Invention" describes the tip as 'micro porous hydrophobic' and 'micro porous non wetting'; and subsequently refers to a 'micro porous and hydrophobic' material. There is also a reference to the use of a 'micro porous hydrophobic membrane' for the tip. Subsequently under the heading "Detailed Description", there is a reference to the 'micro porous hydrophobic non wetting tip'. The specification uses the terms 'hydrophobic' and 'non wetting' apparently interchangeably (consistent with Mr. Blacklock's admission at the hearing) but also in conjunction with each other. This does not aid the reader in understanding what the patentee meant.

21 So what would the skilled person understand the claims to define? I think they

[3] *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9
[4] *No-Fume Ltd v Frank Pitchford Co Ltd* 52 RPC 231

would understand the patentee to use the language of the claim to mean that the tip is constructed from a material which is micro-porous and which exhibits a hydrophobic characteristic. To my mind a reader would not be much further enlightened having read the description. Given that the skilled person would be aware of materials used in the state of the art, and of the conventional meaning of the term 'hydrophobic', I believe they would not understand 'hydrophobic' and 'non-wetting' to mean the same thing. I think this leaves open in the mind of a reader what the term 'non-wetting' is intended to mean. It may be 'non-soaking' (i.e. 'non-absorbent'), or it may be 'hydrophobic'; it is not clear. If it is the former, it is defined by the result achieved. If the latter, it adds no additional constraint to the scope of the claim. In either case, the specification 'non-wetting' does not assist in construing the inventive concept and I make no further finding in respect of its definition in the claim.

22 Mr. Blacklock explained that the micro-porous and hydrophobic properties of the tip to gives rise to the 'non wetting' and other characteristics of the claimed invention – being 'sufficiently dense not to let fluid soak into it and to allow gas to diffuse through the majority of its surface when immersed'. This may be so, however in construing the claim I agree with the examiner as she sets out in her examination report of 12 September 2012 that these features are not clearly defined and in fact would appear to be defined by the result achieved. The claims should define the physical features of the invention as precisely as the invention allows. The requirement is that in describing what the invention achieves – its function – it should be clear *how* to achieve the desired result and not merely what the result is. Because this requirement is not satisfied in respect of these two features, I do not construe the inventive concept to be constrained by them.

23 Of course at the hearing I benefited from Mr. Blacklock's careful and patient explanation, but a reader of the patent would not. In construing the claim then I must be careful not to impart any teaching which is not clear in the description.

24 On balance, and given the conventional meaning of the term 'hydrophobic', I construe the inventive concept as the examiner did. It is a gas diffuser comprising a tip made from a micro porous material having a hydrophobic characteristic – a hydrophobic, micro-porous material.

<u>Step 3 – identify the differences between the state of the art and the inventive concept</u>

25 It is first necessary to consider the disclosures contained in the prior art documents cited by the examiner, which are listed in paragraph 2 of the examiner's report of 12 September 2012. Some explanation is needed here, in respect of the relation of the documents.

26 The documents are:

(a) A letter to the Editor of The Journal of Thoracic and Cardiovascular Surgery, entitled "A gauze sponge cannot act as a gas diffuser in cardiac surgery when it gets wet", by Jan van der Linden MD PhD and Mikael Persson MSc. This can be viewed at

http://jtcs.ctsnetjournals.org/cgi/content/full/125/5/1178.

(b) An article entitled “Efficiency of a gas diffuser and influence of suction in carbon dioxide deairing of a cardiothoracic wound cavity model”, by Jan van der Linden MD PhD, Mikael Persson MSc and Peter Svenarud MD, appearing in The Journal of Thoracic and Cardiovascular Surgery, Volume 125, Number 5, pp 1043-1049.

(c) WO 03/086220 A1 (CARDIA INNOVATION), which names the inventors as Jan van der Linden and Mikael Persson. This patent describes a gas diffuser having a porous tip.

27 Mr. Blacklock brought with him an example of what he referred to as “the CARDIA tip”. He explained that this was a gas diffuser of the type claimed in patent ‘220 (document (c)). Although this was helpful to demonstrate the claimed advantage of his invention in use, it is not a part of the prior art cited by the examiner and the specimen he provided cannot be definitively associated with any of the disclosures above. Neither can it be dated to lie in the section 2(2) field and so to be relevant for inventive step. For the avoidance of doubt, I do not consider that the sample provided by Mr. Blacklock at the hearing forms a part of the state of the art.

28 The examiner has relied upon each of the documents above to reveal different features of the claimed invention. I must then consider whether the skilled person would do the same. The question is whether it is likely that the skilled person would have considered those teachings together. In this respect, I am of the opinion that they would. The documents are all in the same technical field – indeed they all describe a similar, very possibly the same, device. They all have authors in common and reference each other in part (I note that (b) refers to (c) only as “the patented insufflations device, the gas diffuser (Cardia Innovation)”).

29 (a) describes a known device comprising a gauze sponge, which loses its function when it gets wet. The sponge is described as ‘hydrophylic’. The authors then describe their own device which overcomes this problem by using a hydrophobic soft polyurethane plastic foam. The device is specifically described as susceptible to being ‘soaked’, but that due to the supply gas pressure parts of the cell structure will remain clear. They state that even though it is hydrophobic, the foam material may become soaked if it is ‘drowned and at the same time compressed’… ‘just as a car wash sponge would’.

30 (b) also refers to a ‘soft cellular polyurethane diffuser’ in describing the patented device.

31 (c) also describes the porous body of the device as being manually compressible in the event that it gets filled with liquid. In one embodiment the device is a two-part device, comprising an attachment member to guide outlet gas flow through the porous body.

32 As I have said, Mr. Blacklock sought to differentiate his invention from the prior art on the basis that it was ‘non-wetting’. At the hearing I invited him to explain how this was achieved in terms used in his patent specification and he did so

referring to it as a “hydrophobic tip”. He explained that the CARDIA tip is not truly ‘hydrophobic’ as it is described in document (a) as capable of being soaked. I think confusion arises because the authors of document (a) use ‘hydrophobic’ in its conventional sense to describe the material (surface) characteristic, rather than the absorbency of the foam into which it is made.

33 Mr. Blacklock continued, explaining that it was the pore size (being ‘micro-porous’) of the tip of his invention which lent it its ‘hydrophobicity’, giving rise to its distinctive ‘non-wetting’ characteristic. He specified that micro-porous meant “very small holes” but acknowledged that his application did not teach specifically what size holes would be suitable. He also explained that the tip could be made hydrophobic or hydrophilic dependent on the pore size. Again, I think this illustrates that while the material used to construct the tip of the claimed invention is defined as hydrophobic, hydrophobicity is not the same the same thing as absorbency, which may be a function of pore size. The CARDIA device is made of a hydrophobic material, but it is compressible and absorbent. The sample of his invention that Mr. Blacklock produced at the hearing was incompressible and non-absorbent, but neither of these features are clearly defined in the claim.

34 Mr. Blacklock sought to distinguish his invention further on the basis of it being constructed from a micro-porous hydrophobic ‘membrane’. This too is not defined in the claims, although it may be supported by the description. Therefore it is not a feature of the inventive concept as I have construed it, and so it does not assist me in identifying the difference between the inventive concept and the state of the art.

35 In summary, Mr. Blacklock regards his invention as different from the state of the art because (i) it is non-absorbent by virtue of its pore size (‘non-wetting’, in his words) and (ii) that consequently this enables gas to diffuse over the majority of the tip surface when immersed (in his words, by using a micro-porous hydrophobic ‘membrane’).

36 Because I have not construed the claims to define the invention as Mr. Blacklock does, I cannot accept Mr. Blacklock’s argument. I agree with the examiner, in that the difference between the claimed inventive concept and the state of the art is that the tip of the claimed invention is made from a hydrophobic and micro-porous material.

Step 4 – is the difference obvious to the skilled person?

37 The examiner considers that it would be obvious to the skilled person to use a *micro-porous* hydrophobic material from which to construct the tip, in place of the known hydrophobic foam materials of the state of the art (of unspecified pore size). She reasons that the skilled person would be aware of micro-porous foams. In identifying the person skilled in the art, I have credited them with a knowledge of materials suitable for use in a medical environment, through which a pressurized gas may be forced to diffuse. Therefore it would seem an obvious modification to try a reduced ‘micro’ scale pore size of known hydrophobic material to address the problem of the tip ‘wetting out’, or of bubbles ‘jetting’ as the applicant’s patent application describes; as it would be

more difficult for liquid to enter smaller pores, given the characteristics of a hydrophobic surface.

38 I therefore find the difference to be obvious and the inventive concept defined by the claims as I have construed them to lack an inventive step, contrary to the requirements of section 1(1)(b).

Clarity and support

39 I have found that the claims are obvious under section 1(1)(b) and are not patentable on this basis. Consequently, I make no finding under sections 14(3) and 14(5) in respect of the clarity and support objections in the examiner's examination report of 12 September 2012.

40 However, having carefully considered the application, I have taken note of a number of features which give rise to the benefits Mr. Blacklock sought to emphasise, and which are not currently clearly defined in the claims. I make no finding in this respect, but in case there is basis in the application as filed to enable saving amendments, I remit the application to the examiner for re-examination and for Mr. Blacklock to have the opportunity to file amendments which might define a patentable invention.

Conclusion

41 I find that the claims, when properly construed, do not define an invention as required by section 1(1)(b). I make no finding under sections 14(3) and 14(5). Instead I remit the application to the examiner for further processing, to afford the applicant the opportunity to make amendments to the claims to attempt to define a patentable invention.

Appeal

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

Ben Buchanan

Deputy Director, acting for the Comptroller