

**OPINION UNDER SECTION 74A**

Patent	<b>GB 2379610</b>
Proprietor(s)	Smiths Group Plc
Exclusive Licensee	
Requester	Rocket Medical Plc, on 3 July 2009
Observer(s)	
Date Opinion issued	7 September 2009

**The request**

- 1 The comptroller has been requested to issue an opinion as to whether claims 1-20 of GB 2379610 (“the patent”) are valid over the following documents:

US 5,201,314 (Bosley *et al*) (US’314)

US 6,506,156 (Jones *et al*) (US’156)

US 3,605,750 (Sheridan *et al*) (US’750)

US 5,646,194 (Kobayashi *et al*) (US’194)

- 2 Although the request does not specifically distinguish between novelty and inventive step, it appears from the particulars of the request that Murgitroyd & Company (“the requester”) seeks an opinion as to whether claim 1 is novel and/ or inventive with respect to US’314 and US’156, and whether the remaining claims are inventive with respect to US’314 and US’156, either when read alone or in combination with either of US’750 and US’194.

**Observations**

- 3 Observations in response to the request were received from the patent holder’s attorney, Jonathan M Flint (“the proprietor”) on 16<sup>th</sup> July 2009. These maintain that the invention is novel over US’314 and US’156. The requester also provided a leaflet for the SureView<sup>RTM</sup> embryo replacement catheter to demonstrate that the invention defined in the patent is commercially available.

**Observations in reply**

- 4 Observations in reply were received from the requester on 4<sup>th</sup> August 2009 that countered the challenges of the proprietor and maintained the novelty and inventive step objections. The requester also provided three further documents in support of the inventive step arguments provided with the request:

US 5,383,466 (Partika) (US'466)

US 6,053,870 (Fulton III) (US'870)

WO 98/19713 (STS Biopolymers Inc) (WO'713)

- 5 WO'713 was cited during the prosecution of the patent at the Office and therefore will not form part of this Opinion.

### **The patent**

- 6 UK patent application number 0216145.3 was filed on 12 July 2002, claiming priority from GB 0120645, which itself was filed on 24 August 2001. The patent was granted on 12 January 2005 with the title "Medico-surgical device for ultrasound viewing", and is currently in force.
- 7 The patent provides a medico-surgical device of a plastics material, such as a catheter, that comprises gas bubbles through the major part of the plastic material. The gas bubbles improve the visibility of the device under ultrasound imaging. The device is exemplified as an embryo replacement catheter, which also allows an embryo to be viewed by the eye. Methods of making the device are also provided.

### **The claims**

- 8 Independent claims 1, 15, 17 and 18 read as follows:
1. *A medico-surgical device of a plastics material, wherein the material includes gas bubbles through the major part of the thickness of the material in at least a part of the device, said bubbles being regions of gas bounded by said plastics material, and wherein said bubbles are sufficient to increase the visibility of the device under ultrasound imaging.*
  15. *An embryo replacement catheter comprising a flexible, hollow, extruded shaft of a substantially transparent plastics material, wherein the shaft includes gas bubbles through the thickness of its wall, said bubbles being regions of gas bounded by said plastics material, wherein the density and size of the bubbles is selected to increase visibility of the catheter under ultrasound imaging whilst enabling an embryo within the catheter to be viewed by the eye, and wherein the bore of the catheter is smooth and uninterrupted by gas bubbles.*
  17. *A method of making a medico-surgical device comprising extruding a plastics material while incorporating a gas into the wall of the device such as to form gas bubbles through the major part of the thickness of the wall of the device, said bubbles being regions of gas bounded by said plastics material, and said*

*bubbles within the wall being sufficient to increase the visibility of the device under ultrasound observation.*

18. *A method of making a medico-surgical comprising forming a wall of plastics material containing a chemical foaming agent such as to form gas bubbles through the major part of the thickness of the wall of the device, said bubbles being regions of gas bounded by said plastics material, and said bubbles within the wall being sufficient to increase the visibility of the device under ultrasound observation.*

## **Novelty**

- 9 In my assessment of the novelty and inventive step of the claims I will make a purposive construction of the claims, following the judgement of Lord Hoffman in *Kirin Amgen*<sup>1</sup>. I will therefore interpret the claims in the way that I consider a person skilled in the art would have understood the patentee to mean by the language of the claim. The requester considers that claim 1, and claims appendent thereto, lack novelty in light of US'314 and US'156, and therefore I will limit my assessment under novelty to this claim.
- 10 Claim 1 defines a medical device of a plastics material, with gas bubbles bound within the plastics material. In my opinion, the term "of a plastics material" would be construed as "consisting of a plastics material", and therefore no other material would be present in the device. The gas bubbles are present through a major part of the thickness of the plastics material, which would be understood to be present through over half the thickness of the material, and are present in at least a part of the device. Therefore the bubbles need not be present along the whole length of the device. The claim also states that the bubbles are sufficient to increase the visibility of the device under ultrasound imaging, and whilst this is defined in terms of the result to be achieved, a skilled person would understand that this is the purpose of the bubbles in the device.
- 11 In considering the novelty of claim 1 in light of US'314 and US'156, I have taken into account the judgment of the House of Lords in *Smithkline Beecham PLC's (Paroxetine Methanesulfonate) Patent*<sup>2</sup>, where Lord Hoffman stated that anticipation requires a prior disclosure that necessarily infringes the patent when performed. In this judgment it was also held that the prior disclosure must be construed as it would have been by the skilled person at the date of the disclosure and not in light of the subsequent patent.
- 12 US'314 defines a medical device which is imageable with sonic imaging equipment. The device is comprised of a composite material consisting of a matrix material with sound reflective particles embedded therein. These particles are exemplified as glass microspheres, but the description at column 7 line 53-60 suggests a variety of materials that may be used as sound reflective particles: "*As indicated a variety of materials may be utilized for the sound reflective particles, such as aluminium, hard plastic, sand, metal particles and the like. Additionally, liquids, gases, gels,*

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<sup>1</sup> *Kirin Amgen v Hoechst Marion Roussel Ltd* [2005] RPC 9

<sup>2</sup> *Smithkline Beecham PLC's (Paroxetine Methanesulfonate) Patent* [2006] RPC 10

*microencapsulants, and/or coacervates suspended in the matrix may alternatively be used either alone or in combination, so long as they form a composite with ultrasonically reflective particles in the matrix*". It is this passage of the description that the requester considers anticipates the patent, and therefore I will consider this passage in detail.

- 13 The requester considers that this passage of US'314 discloses gas bubbles in the material that increases the visibility of the device under ultrasound imaging. In the observations in reply, the requester argues that for the gas to be suspended in the matrix it must inherently be in the form of gas bubbles, and with the matrix forming a large part of the device, the bubbles must be present in the major part of the wall of the device. The requester also refers to the figures, which demonstrate the sound reflective particles throughout the major part of the thickness of the device.
- 14 In the observations, the proprietor argues that the echogenicity of the device in US'314 is increased by the use of particles and not gas bubbles. The proprietor refers to the passage at column 7 line 53-60, emphasising the need for the formation of a composite between the liquids, gases, gels etc with the ultrasonically reflective particles in the matrix. The requester countered this argument by reference to the passage at column 5 lines 14-17, which defines the composite material as including a "*matrix material with discrete sound reflective particles embedded in matrix material*". In such a situation, according to the requester, the gas bubbles held within the matrix would inherently be within that composite material. The requester also refers to the passage at column 7 line 30-40, which states that the particles may comprise a "hollow spherical space therein", ie the particles might be hollow glass microspheres that may contain gas within them.
- 15 I agree with the assessment of the proprietor in that the echogenicity of the device in US'314 is provided by the use of sound reflective particles. A skilled person would understand the term "particle" in US'314 to mean a solid constituent that is distinct from the matrix. A particle would not be in the form of a gas bubble, and in my opinion a person skilled in the art would not interpret it as such. I have noted the requester's assertion that the glass microspheres might be hollow, and therefore filled with gas. However, this would not be considered to be a gas bubble; a hollow microsphere would still be interpreted as a solid constituent, it would simply have a space inside. Therefore, in my opinion, the sound reflective particles in US'314 are not in the form of gas bubbles.
- 16 The requester argues that if a gas is present within the matrix, even in the form of a composite with the ultrasonically reflective particles, then it would inherently be in the form of a gas bubble. I accept that if a gas is present within a solid material then it would form a cavity within that solid material, which could be considered to be a bubble. However, it is a necessary requirement of the patent that the gas bubbles are through the major part of the thickness of the material, and that the bubbles are sufficient to increase the visibility of the device under ultrasound imaging. The disclosure of US'314 does not suggest any use of the gas within the matrix other than to form a part of the matrix itself and there is nothing to suggest that the gas forms a significant part of the matrix material. Furthermore, whilst US'314 might direct a skilled person to mix a gas into the matrix of the medical imaging device, it does not disclose how or even if these gas bubbles are used to increase the visibility

of the device to ultrasound. In other words the disclosure of US'314, which the requester considers to anticipate the patent, is not enabling. Moreover, as the medical device of the patent necessarily has gas bubbles that are sufficient to increase the visibility of the device, and US'314 comprises reflective particles and not gas bubbles to perform this function, US'314 would not infringe the patent.

- 17 Therefore, in my opinion, as it is an essential requirement of claim 1 that the gas bubbles in the device are sufficient to increase the visibility of the device under ultrasound observation, claim 1 is novel in light of US'314.
- 18 The device of US'156 comprises an echogenic coating, wherein the echogenic layer comprises a polymeric matrix that may comprise a plurality of void spaces; the void spaces improve the ultrasonic reflective properties of the echogenic layer. The echogenic layer coats an electrically insulative material, and this is then applied to a substrate material, such as a medical device, including catheters. I agree with the assessment of the requester that the void spaces referred to in US'156 would be interpreted as gas bubbles within the polymeric matrix. I also agree that the echogenic layer can be the same as the electrically insulative material, and therefore might comprise a plastics material.
- 19 It is clear that US'156 discloses the presence of gas bubbles in a plastic material that coats a medical device. These gas bubbles would also be sufficient to improve the visibility of the device under ultrasound imaging. Therefore, I am of the opinion that the disclosure of US'156 would enable a skilled person to produce a plastic material comprising gas bubbles to enhance the visibility of a medical device, but I also need to consider whether the gas bubbles in the device of US'156 are through the major part of the thickness of the material in at least part of the device, and whether the device itself consists of a plastics material.
- 20 In the observations in reply, the requester argues that the claims of the patent do not exclude coatings, and moreover, as the thickness of the coating in US'156 can vary, there is no upper limit on the thickness of this layer. I agree with the requester that the echogenic part of the medical device of the patent may form a layer or coating; claim 1 of the patent states that the gas bubbles are through the major part of the thickness of the material. A plastic device coated with a plastic material comprising gas bubbles would therefore fall within the scope of this claim, provided that the coating comprising the bubbles was thicker than the device itself. It is clear from US'156 that the coating comprises two layers- an echogenic layer and an electrically insulating layer. Whilst the thickness of both layers can vary, the preferred thickness of the echogenic layer is 20-200 $\mu\text{m}$ , and the preferred thickness of the electrically insulative material is 100-300 $\mu\text{m}$ , with claim 10 of US'156 further defining the thickness of the echogenic and insulative layers as 20 $\mu\text{m}$  and 100 $\mu\text{m}$  respectively. It is therefore evident from this that the echogenic layer in the coating of US'156 is intended to be a minor part of the coating material itself.
- 21 I agree with the argument of the proprietor that the substrate material onto which the echogenic material of US'156 is layered is a metal substrate. The passage at column 3 line 57-61 states that the substrate material comprises any material that requires electrical insulation. In my opinion, this passage excludes plastic devices from use in US'156 as these would not require electrical insulation. Consequently, the medical

device of US'156, when coated with the echogenic coating, would not consist of a plastics material. In light of this, whilst US'156 enables a skilled person to produce a plastic coating comprising gas bubbles for increasing the visibility to ultrasonic equipment, it does not demonstrate how this can be extended to make a wholly plastic medical device comprising such bubbles. In addition, as the device of US'156 does not consist entirely of plastic, it would not infringe the claim. Therefore, I am of the opinion that claim 1 is novel over the disclosure of US'156.

22 I therefore conclude that claim 1 is novel over the disclosures of US'314 and US'156.

### **Inventive step**

23 In my assessment of the inventive step of the claims, I will use the four-step test formulated in *Windsurfing*<sup>3</sup>, as recently reformulated in *Pozzoli*<sup>4</sup>. The assessment of inventive step using the *Windsurfing/ Pozzoli* approach is as follows:

- (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?

24 Following the *Windsurfer/Pozzoli* test, I will first identify the person skilled in the art and the common general knowledge of that person; I note that neither the requester nor the proprietor has provided any suggestion as to who the person skilled in the art might be. The patent relates to a medico-surgical device for ultrasound imaging, and is exemplified as a catheter for use in embryo transfer. In my opinion, the person skilled in the art would be a medical technician, with knowledge of ultrasound imaging and the devices used in that method. They would also be aware of the necessity of visibility of these devices during the imaging process, and of the uses that can be made of such devices. It is clear from the prior art that the use of gas bubbles to improve the visibility of a device in ultrasonic imaging is known in the art. This is demonstrated, at least in part, by US'466, US'870 and WO'713 submitted by the requestor with the observations in reply. US'466 discloses a metallic medical instrument comprising a layer of plastic material with gas bubbles therein, and US'870 discloses a stainless steel needle comprising notches along its length, that entrap bubbles when the instrument is in use. US'156 discussed above also discloses the merits of the use of gas bubbles (or voids) in plastic echogenic coatings in order to enhance visibility. It is also known that catheters generally

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<sup>3</sup> *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59

<sup>4</sup> *Pozzoli SPA v BDMA SA* [2007] EWCA Civ 588

consist of a plastic material. This forms the basis of the common general knowledge at the priority date of the patent.

- 25 I will begin with the assessment of the inventive step of claim 1. I have construed claim 1 in my discussion under novelty in paragraph 10 above, and will use this construction in my assessment of the inventive step of the claim.
- 26 US'314 and US'156 were discussed in detail above. Briefly, the differences between US'314 and claim 1 is the presence of gas bubbles through the major part of the thickness of a plastic device to increase the visibility of the device under ultrasound imaging; the visibility of the plastic device of US'314 is enhanced by the presence of sound reflective particles, exemplified as glass microspheres. These particles may be hollow (ie contain air), and gases may be suspended in the matrix to form a composite with the sound reflective particles. US'156 differs as it defines an echogenic coating for a medical device to enhance the ultrasonic visibility. It is utilised in conjunction with an electrically insulative layer for coating a metallic medical device.
- 27 In my mind, the inventive concept of this claim lies in the use of gas bubbles in a substantially plastic medical device. Therefore, in light of the disclosures of US'314 or US'156, would it be obvious to a person skilled in the art to manufacture a substantially plastic medical device which includes gas bubbles throughout the major part of the thickness of the device, to increase the visibility under ultrasound imaging?
- 28 US'156 discloses a medical device with an echogenic coating, wherein the coating consists of a plastic material with gas bubbles dispersed therein. The coating is for improving the visibility of a metallic medical device, and there is no suggestion of the use of the coating in isolation. The addition of the electrically insulative layer between the echogenic coating and the medical device further demonstrates that the echogenic coating is not intended for use in isolation. Moreover, the echogenic layer does not form a large part of the thickness of the device when constructed, nor does it form the larger part of the plastic portion of the device (echogenic layer and electrically insulative layers combined). Therefore, in light of this it is my opinion that the skilled person would not consider the use of the echogenic layer of plastics material and gas bubbles as a major portion of the thickness of a medical device, and therefore would not be directed towards the manufacture of medico-surgical device consisting entirely of a plastics material which includes gas bubbles through the major part of the thickness of the device. Consequently, claim 1 does not lack inventive step in light of US'156.
- 29 The device of US'314 consists of a matrix material with discrete sound reflective particles embedded within the matrix. The matrix is preferably a plastic material. This demonstrates that plastic ultrasonically-detectable medical devices are known, and catheters are included within the list of devices proposed in US'314. The matrix is extruded and the particles are embedded within the matrix material. Although the glass particles may be hollow, there is no indication that gas bubbles could be substituted for the particles in US'314. Furthermore, in my opinion the gases that may be used to form a composite with the reflective particles are not intended to improve the visibility of the device to the ultrasound, and therefore a skilled person

reading US'314 would not consider gas bubbles to be a suitable alternative to the sound reflective particles. Therefore US'314 does not render claim 1 obvious.

- 30 Given that US'156 and US'314 are for use in the same area of technology, and both types of medical device would be familiar to a person skilled in the art, I consider that for completeness it would be appropriate to consider the inventive step of the claim in light of the combined teachings of these documents, even though this has not been raised as part of the inventive step arguments of the request.
- 31 Whilst US'314 and US'156 form part of the same area of technology, they disclose two distinct solutions to the problem of the visibility of instruments in ultrasonic imaging. In US'314 the entire medical device is composed of a plastics material which contains particles to improve the ultrasonic visibility; these particles are exemplified as solid microspheres. In US'156, a metallic medical device is coated with an insulative plastic layer, which in turn is coated with a thinner plastic layer that comprises gas bubbles to allow echogenic visibility. Therefore, would it be obvious to replace the sound reflective particles in the plastic device of US'314 with the gas bubbles provided in the coating of US'156?
- 32 I note that Figure 7 of US'314 discloses a medical device comprising an echogenic coating that comprises the sound reflective particles. Comparing this to the disclosure of US'156 I can see that a skilled person might use the coating of US'156 to coat the medical device of US'314, as shown in Figure 7, in order to improve ultrasonic visibility. However, in order to arrive at the invention of the patent, a skilled person would have to appreciate that the coating of US'156 could be extruded into a complete medical device, and moreover would need the motivation for doing so.
- 33 In the observations the proprietor argues that a skilled person would not appreciate that the ultrasonic visibility of a catheter could be improved by incorporating the bubbles without adversely affecting the clinical performance of the catheter. I agree with this argument; the sound reflective particles are solid and provide structure, rigidity and density to the medical device. Replacing these with gas bubbles would alter the structure, flexibility and the density of the device which may have an adverse effect upon the performance of the medical device. Therefore, on balance, it is my opinion that the disclosure of US'156 would not motivate a skilled person to replace the microspheres of US'314 with gas bubbles. Consequently I am of the opinion that a skilled person would not arrive at the inventive concept of claim 1 in light of the combined disclosures of US'314 and US'156.
- 34 Claims 17 and 18 are method claims, defining how the device of claim 1 is made. The methods include the steps of making a plastic medico-surgical device with gas bubbles through the major part of the thickness of the wall sufficient to increase the visibility to ultrasound observation. I have already found that the device itself is inventive over US'314 and US'156, and therefore it follows that the methods of making these devices is also inventive.
- 35 Claim 15 is an exemplification of the device of claim 1, in the form of a catheter suitable for embryo replacement. The catheter is defined as a flexible hollow extruded shaft of a substantially transparent plastics material, and a skilled person

would understand this to be in the form of a hollow tubular structure, which is for the most part plastic. The shaft includes gas bubbles through the thickness of the walls which again are bound within the plastic material (although the bubbles need not be through the major part of the thickness of the material). As in claim 1, the bubbles increase the visibility of the catheter under ultrasound imaging, but they also allow an embryo within the catheter to be viewed by the naked eye. The bore of the catheter is smooth and uninterrupted by gas bubbles. In other words, the internal surface of the tube is smooth and the gas bubbles do not penetrate it.

- 36 Neither US'314 nor US'156 disclose embryo replacement catheters, although it is simply a requirement of claim 15 that the catheter is suitable for embryo replacement. As discussed above, US'314 does not disclose a plastic device comprising gas bubbles to improve the visibility to ultrasound, and a skilled person would not replace the microspheres of US'314 with gas bubbles, and therefore in my opinion US'314 does not render obvious claim 15.
- 37 The gas bubbles in the catheter of claim 15 need not be through the major part of the thickness of the wall, and therefore the gas bubbles could simply be in the form of a coating of plastic, as in US'156. However, the catheter of claim 15 must allow the embryo to be viewed by the eye, and as the coating of US'156 is intended to improve the visibility of a metallic device, a skilled person would not consider the use of the device of US'156 in this manner. There is nothing in US'156 to suggest replacement of the metal part of the catheter with a transparent, ie plastic, material, and therefore a skilled person reading US'156 would not be directed towards the invention as defined in claim 15. Therefore claim 15 is considered to be inventive in light of US'156.
- 38 As I have found that independent claims 1, 15, 17 and 18 are inventive over documents US'156 and US'314, it is not necessary for me to consider the inventive step of the dependent claims over documents US'156 and US'314 when combined with documents US'750 and US'194.

### **Opinion**

- 39 I conclude that claim 1 is novel over the documents submitted by the requester.
- 40 I also conclude that claims 1, 15, 17 and 18 are inventive in light of each of the documents submitted by the requester. It therefore follows that dependent claims 2-14, 16, 19 and 20 are also inventive.

Rowena Dinham  
Examiner