Patents Act 1977 **Opinion Number** **01/17**

OPINION UNDER SECTION 74A

Patent	EP 2568928 B1
Proprietor(s)	Privelop-Spine AG
Exclusive Licensee	
Requester	Derek Jackson Associates
Observer(s)	
Date Opinion issued	06 April 2017

The request

1. The comptroller has been requested by Derek Jackson Associates ("the Requester") to issue an opinion as to whether claim 1 of EP 2568928 B1 ("the Patent") is novel in light of three documents.

2. The request was received on 13 January 2017. It was accompanied by a statement supporting the request as well as copies of the cited documents. Also provided was a copy of a review article ("Interbody fusion cages in reconstructive operations on the spine", P.C. McAfee, Journal of Bone & Joint Surgery, Vol. 81A, Issue 6, pp 859-80, June 1999), as a summary of the early history of the subject matter of the Patent.

Observations & Observations in reply

3. No observations were received.

The Patent

4. The Patent entitled "Surgical Implant" is an EP(UK) patent derived from PCT application PCT/EP2011/003715 filed on 25 July 2011 with an earliest claimed priority date of 23 July 2010. The PCT application entered into the European phase as EP11758375.7. The Patent was granted on 23 September 2015 and is still in force in the UK.

5. The Patent relates to a surgical implant or so-called fusion cage to be introduced between two adjacent vertebrae of the spine to be fused. The implant acts as a placeholder until the formation of new bone through the implant has taken place. A key feature of the invention is a number of vertical and horizontal holes or tubes that

pass from one side of the implant to the other. The tubes facilitate blood flow and therefore the transport of bone cells into the implant, supporting and accelerating the through growth of the implant. The horizontal tubes have the additional function of allowing monitoring of bone in-growth by X-ray spectroscopy.

6. The Patent has 15 claims including a single independent claim, claim 1. Claim 1 reads as follows with the features for convenience separated out in a manner adopted by the Requester:

> ***1*** *(i) An intervertebral implant for the fusion of two adjacent vertebrae*
> *(ii) with an upper plane (3A) for contacting an upper vertebral body*
> *(iii) and a lower plane (3B) for contacting a lower vertebral body*
> *(iv) and a tubular structure,*
> *(v) wherein the tubular structure is formed by a plurality of vertical tubes (5) running from the upper plane (3A) to the lower plane (3B)*
> *(vi) and by a plurality of horizontal tubes (7,7',7'') running in substantially horizontal direction*
> *(vii) throughout one side of the intervertebral implant straight to the opposite side of the intervertebral implant,*
> *(viii) characterized in that the horizontal tubes (7,7',7'') of the tubular structure are parallel to each other*
> *(ix) or the horizontal tubes (7,7',7'') of the tubular structure are grouped into groups of parallel tubes.*

7. The Requester has specifically stated that no opinion is requested regarding the novelty of any other claim of the Patent apart from claim 1, or the inventive step of any claim of the Patent. I will therefore limit this opinion to whether claim 1 is novel in light of the three cited documents.

Novelty – the law

8. Section 1(1)(a) of the Act reads:

> *1(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –*
> *(a) the invention is new;*

9. The relevant provisions in relation to novelty are found in section 2(1) and section 2(2) which read:

> *2(1) An invention shall be taken to be new if it does not form part of the state of the art.*
>
> *2(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.*

10. The three documents cited in support of the request are: WO 96/40015 A1 (X1); US 2003/0040798 A1 (X2); and US 2005/0177238 A1 (X3). Each of the three documents was published before the earliest priority date for the Patent and therefore forms part of the state of the art.

Construction of claim 1

11. In order to determine whether claim 1 of the Patent is novel in light of the three documents, I first need to construe claim 1 following the well-known authority on claim construction which is Kirin-Amgen and others v Hoechst Marion Roussel Limited and others [2005] RPC 9. This requires that I put a purposive construction on the claim, interpret it in the light of the description and drawings as instructed by section 125(1) of the Act and take account of the Protocol to Article 69 of the EPC. Simply put, I must decide what a person skilled in the art would have understood the patentee to have used the language of the claim to mean.

12. I consider the person skilled in the art to be a person skilled in the design and manufacture of surgical implants particularly those intended for insertion between spinal vertebrae.

13. Claim 1 is generally straightforward to construe. There are, however, some terms that require particular consideration.

14. Claim 1 specifies that the implant has an upper plane for contacting an upper vertebral body and a lower plane for contacting a lower vertebral body. Regarding the term ‘plane’ the Requester has suggested that this does not imply any degree of flatness or geometrical character but rather only a distinct and identifiable contact surface. I agree with this assessment. From the Patent particularly paragraph [0035] the skilled person would realise that the upper and lower planes provide contact surfaces with the corresponding vertebral bodies. It would also be clear to the skilled person that the planes need not be flat (paragraph [0154]) but may be arched (paragraph [0076]) or not necessarily even (paragraph [0075]). Moreover, from paragraph [0073] and Figures 5 and 7 the planes may be ‘jagged’ or ‘rippled’ to stimulate bone growth and to achieve a better anchoring at the adjacent vertebral body (caption corresponding to Figure 5).

15. The Requester has directed me to paragraph [0040] regarding the terms ‘upper’ and ‘lower’. I agree that the skilled person would interpret these terms according to this paragraph so that they correspond to the upper and lower vertebral bodies in a frame of reference when the implant is implanted.

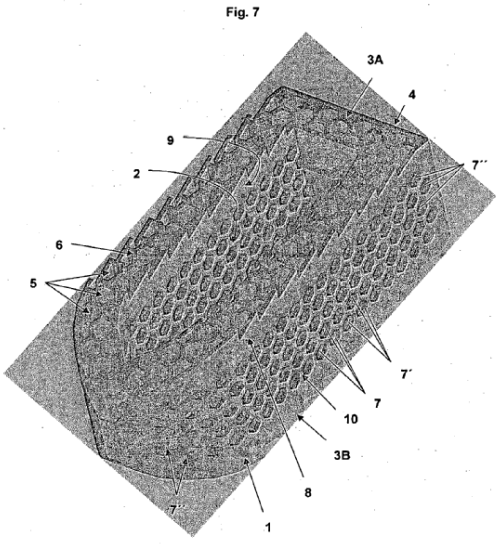
16. Similarly, as the Requester suggests, the skilled person would interpret the terms ‘horizontal’ and ‘vertical’ to refer to a frame of reference when the implant is implanted i.e. ‘vertical’ corresponds to a direction from one contacting vertebra of the spine to the other along the longitudinal axis of the spine and ‘horizontal’ to a direction perpendicular to the longitudinal axis crossing the spine (see for example paragraph [0098]).

17. I shall now move onto the term ‘tube’. In the Patent the implants are characterized by a plurality of horizontal tubes and a plurality of vertical tubes which are holes that

pass from one side of the implant to the other. As discussed above the tubes provide a high surface area for the adhesion of bone cells and make use of capillary action to suck blood and therefore bone cells into the implant. The horizontal tubes have an additional function to allow X-ray spectra to be conducted through them to monitor for example bone growth (paragraph [0061]). From the Patent, the skilled person would understand that the tubes may have any cross-sectional shape (paragraph [0039]). Further, the vertical tubes need not be straight but may take a more curved or random-like path (paragraph [0032]). The Requester has suggested the term 'tube' to be interpreted to include any elongate structure having an elongate void. From the considerations outlined above I agree that the skilled person would interpret the term broadly in this way.

18. Regarding further the construction of the term 'tube', the implant may have an inner cavity 2 (see for example Figure 7 reproduced below). Vertical tubes 5 pass through the boundary layer 1 surrounding the cavity. There are two species of horizontal tubes 7: horizontal tubes 7'' that pass exclusively through the boundary layer and horizontal tubes 7' that 'cross the inner cavity' paragraph [0033]. In other words as the Requester points out the horizontal tubes may have an 'imaginary' portion running though the space of the inner cavity. In an extreme case from paragraph [0042] the ratio of the height of the implant to the thickness of the boundary layer surrounding the cavity could be 15:1 i.e. the length of the portion of imaginary tube can be large in comparison to the overall length of the tube. Although from the Patent only the horizontal tubes cross the inner cavity, I think the skilled person would consider a tube more generally to have this capability.

Fig. 7



19. The skilled person would interpret the term 'tubular structure' to mean simply a number of tubes. From paragraph [0104] the term does not necessarily refer to the entirety of the tubes of the implant. In particular there may be groups of tubular structures present in the implant.

20. In feature (vii) the expression "throughout one side of the intervertebral implant straight to the opposite side of the intervertebral implant" refers to the additional requirements for the horizontal tubes. The skilled person would realise from

paragraphs [0033] and [0034] that firstly this means that the horizontal tubes run from one side of the implant to the other. The key word in feature (vii) is ‘straight’. The skilled person would also realise from these paragraphs and throughout the Patent that the horizontal tubes must be sufficiently straight so that X-ray measurements could be conducted through them. Moreover, the skilled person would understand from paragraph [0038] that the horizontal tubes must not show any ‘curves, kinks, bends or the like’. As paragraph [0038] specifies, a light beam may run through the implant along a straight line. From paragraph [0161] the horizontal tubes must also take a straight path when crossing an inner cavity. Therefore the skilled person would realise that feature (vii) imposes a strict requirement on the horizontal tubes so that X-ray measurements could be carried out through them.

21. In features (viii) and (ix) the horizontal tubes are either parallel to each other or grouped into groups of parallel tubes. As the Requester points out, the skilled person would appreciate from for example paragraphs [0161] – [0162] that this allows X-ray measurements to be made across a number of tubes. From paragraph [0037] the term ‘parallel’ appears to have its standard meaning within certain tolerance margins.

Novelty - arguments

22. I will now deal with each of the documents in turn.

23. **X1, WO 96/40025 A1**, is directed to interbody spinal fusion implants configured to restore and maintain two adjacent vertebrae (page 1 lines 14-18) and therefore meets the terms of feature (i) of claim 1. The Requester directs me to two particular embodiments in X1. I will consider them one at a time.

24. **In the first embodiment,** the implant 100 featured in Figures 1-7 (see Figure 1 reproduced below) has a general rectangular configuration having an upper surface 112 and lower surface 114 (page 12 lines 12-14). The surfaces may be flat or curved to conform to the shape of the end plates of the adjacent vertebrae (page 12 lines 27-29). Therefore this meets the terms of features (ii) and (iii) as construed above.

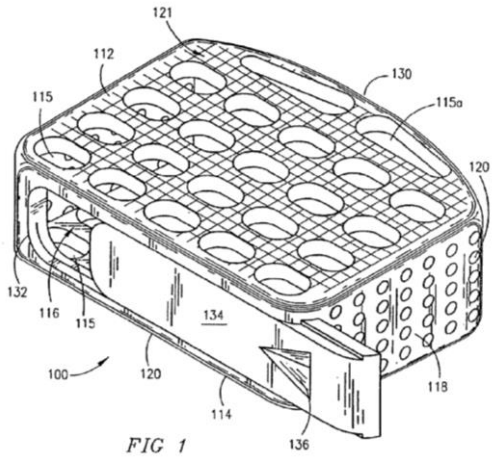


FIG 1

25. The implant is hollow and comprises a plurality of openings 115 that pass through the upper and lower surfaces 112 and 114 and into a central hollow chamber 116

(page 13 lines 19-22). The upper and lower surfaces of the implant are supported and spaced apart by side wall 118 which may also comprise a plurality of openings 122 (sentence bridging pages 13 and 14). I first need to decide whether these openings can be considered to form 'tubes' as construed above. There is clearly a cavity in the centre of the implant. From the discussion above, a tube can still exist if there can be considered to be an imaginary portion of tube that passes through the cavity connecting the two portions on either side.

26. The text is silent regarding whether there is any correspondence between holes on opposite sides of the implant. I must therefore rely on the drawings. The Requester has emphasized that the principle to be applied is whether the drawings, interpreted through the eyes of the skilled person, would disclose the relevant geometrical features. I agree that this is the principle to apply. From Figure 1, 22 openings 115, 115a can be seen in the upper surface 112 and two openings can be viewed in the lower surface. Figures 3 and 4 (reproduced below) further illustrate the left hand side and right hand side of the implant respectively. From these 35 holes appear on each side. I think it reasonable to assume that the skilled person would realise that the implant is intended to have a significant number of holes on each of these four sides. Taking a broad interpretation of the term 'tube' as construed above, they would appreciate further that both horizontal and vertical tubes could be identified that find their way from one side of the implant to the other even if they have to take a slight deviation in their path as they cross the cavity. Therefore I consider this embodiment to meet further features (iv)-(vi).

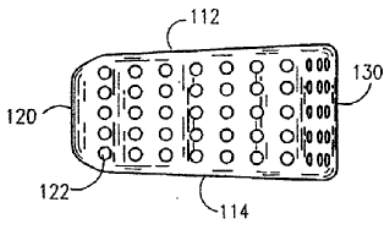


FIG 3

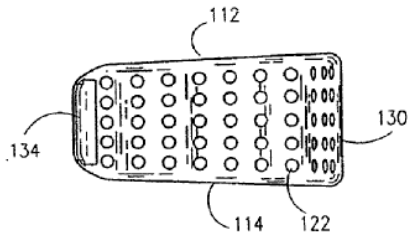


FIG 4

27. Feature (vii) requires the horizontal tubes to pass 'straight' from one side of the implant to the other. As discussed above the tubes should be straight so that X-ray radiation could pass through in a straight line. There is no mention in X1 of using the holes to perform X-ray investigations or any further assistance from the text regarding the positioning or nature of the holes. I must therefore rely again on the drawings.

28. However, I must be careful when deriving specific features from a drawing. It was held by the EPO Board of Appeal in Decision T204/83 (OJ EPO 1985, 310) that features shown solely in a drawing form part of the state of the art when a person skilled in the art is able, in the absence of any other description, to derive a technical teaching from them. The authority, although only persuasive in UK law, goes on to caution that dimensions obtained merely by measuring a diagrammatic representation in a document do not form part of the disclosure.

29. The Requester has made the assertion that, "when dealing with the human body, which has generally bilateral symmetry, where an express disclosure of asymmetry of structure is absent, symmetry of structure can be inferred". They further submit

that, “the structures in each of the relevant embodiments of X1 to X3, which are intended for insertion on a spinal axis and between vertebrae of a spinal column, would be understood to exhibit bilateral symmetry as a matter of course”. They conclude that, “The skilled person, putting the disclosures of these documents into effect, would therefore not deviate from the exemplary symmetric structures depicted therein, even if such symmetry is not expressly noted in the text, unless explicitly instructed in the disclosure so to do.”

30. Returning to the specific embodiment in question, the Requester claims that “Comparison of Figures 3 and 4 makes clear that opposing openings 122 of the horizontal tubes are aligned and in one-to-one correspondence. A light beam dimensioned as the opening and shone through one opening perpendicular to the side wall will pass out through the correspondingly aligned opening on the opposite side of the implant”. From Figures 3 and 4 it certainly appears that the holes are symmetrically positioned on each side which I agree would result in ‘straight’ horizontal tubes. However, from the guidance above, I cannot assume symmetry by simply measuring the positions of the holes in the Figures. There is no technical reason provided in the description of X1 to position the holes symmetrically. In fact, I note that a general lack of symmetry has been introduced to the implant due to a sliding door 134 (see Figures 1 and 4) which slides onto the right but not the left hand side. It would appear to be possible for example for the holes on the right hand side to be shifted slightly to allow for the sliding door. The only reason for symmetry, as the Requester appears to be suggesting above, is that this would be the most likely scenario for spinal structures. When considering novelty (rather than obviousness) the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented. In this case I think the skilled person would also be presented with an alternative possibility, that of asymmetry. Therefore I do not consider the disclosure sufficient to meet the terms of feature (vii). For similar reasons features (viii) and (ix) are also not anticipated.

31. **In the second embodiment** featured in Figures 8 – 12 the implant 200 is solid and has an upper and lower surface 212 and 214 (page 17 lines 1-4). A plurality of ‘ratchetings’ 250 are located on these surfaces for engaging the bone of the adjacent vertebrae (page 18 lines 2-4). As discussed above the term ‘plane’ in features (ii) and (iii) encompasses a potentially jagged surface and therefore implant 200 meets the terms of these two features.

32. The implant 200 from page 17 lines 1-4, comprises a plurality of channels 215 passing from the upper surface 212 to the lower surface 214 through the implant 200. Further, from lines 14-16, the implant 200 may have small openings 222 on the side wall 218 which may or may not pass through the entire implant 200. Therefore the implant has a series of tubes as construed above passing in both the horizontal and vertical directions. This is sufficient to anticipate features (iv), (v) and (vi).

33. Regarding feature (vii), as considered above, the horizontal tubes must pass ‘straight’ from one side to the other. From page 17 lines 16-20 of X1 the holes are intended to promote bone ingrowth. There is no mention of how straight or otherwise the holes should be. Figure 9 (reproduced below) provides a left hand view of the implant showing the holes 222. There is no right hand view. In this embodiment for the horizontal tubes to be straight the skilled person would realise that the holes must not only be symmetrically placed on each side but must also be bored through

the solid structure without any ‘curves, kinks, bends or the like’. The skilled person would not be able to infer such a requirement from the Figures. There is no reason provided in the text for such precision to be involved. Presumably the holes in X1 need only be formed fairly roughly to meet their purpose of promoting bone ingrowth. I therefore do not consider this embodiment to provide clear and unmistakable directions to carry out this feature. Similarly features (viii) and (ix) are not anticipated.

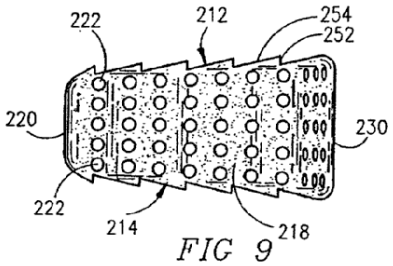


FIG 9

34. **X2, US2003/0040798 A1**, as the Requester points out is related to X1 and contains much of the same disclosure including the two embodiments discussed above. I do not need to repeat the same arguments again for these two embodiments.

35. The Requester notes that X2 includes additional disclosure in the form of Figure 32 (reproduced below) which appears to show a variant of the embodiment described with reference to Figure 31 which does appear in both documents. Figure 31 is also discussed in the description of each document but there is no explicit mention of Figure 32 in the description of either document. In the embodiment of Figure 31, the implant 700 is rectangular in shape with a top and bottom surface 702, 704 (paragraph [0094]). Therefore this embodiment meets the terms of features (i) - (iii) of claim 1 of the Patent.

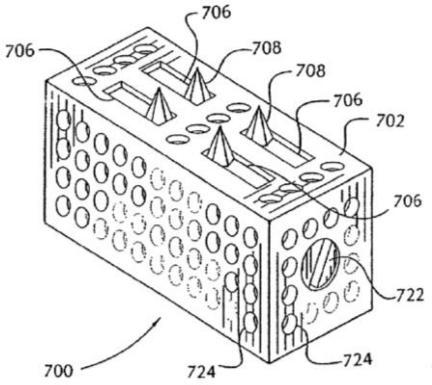


FIG 32

36. Regarding any possible tubes, a short statement is provided in paragraph [0095] of X2, “The implant 700 may comprise a series of holes in the upper and lower surfaces 702 and 704 for promoting bone ingrowth and fusion.” This appears to be illustrated at least in part in Figure 32. Holes can be seen in the upper surface but cannot be seen in the lower surface. Similarly holes can be seen in two adjacent sides but not the corresponding opposite sides. Therefore it seems that the skilled person would identify vertical tubes from a combination of the text and Figure 32, thus meeting the

terms of features (iv) and (v). Regarding horizontal tubes, it is not possible for the skilled person to ascertain with any certainty whether there are holes in opposite sides of the implant. Holes in the sidewalls are not mentioned in the text and only seen in adjacent (not opposite) walls in the Figure. I am not convinced that the skilled person would necessarily assume the implant of Figure 32 to have bilateral symmetry. Therefore this disclosure is not sufficient to anticipate feature (vi) and similarly the remaining features of the claim.

37. **X3, US 2005/0177238 A1**, relates to spinal fusion cages of the type designed for human implantation between adjacent spinal vertebrae (paragraph [0002]) and therefore meets the terms of feature (i) of claim 1. The Requester has directed me to the embodiment illustrated in Figures 10-13 and described in particular in paragraph [0047]. The implant 610 clearly has upper and lower surfaces for contacting the adjacent vertebrae (see Figure 11 reproduced below). The implant has 'external serrations' on the upper and lower surfaces as discussed for example in paragraph [0050] but these surfaces can be considered 'planes' using the construction above. Therefore this meets the terms of features (ii) and (iii).

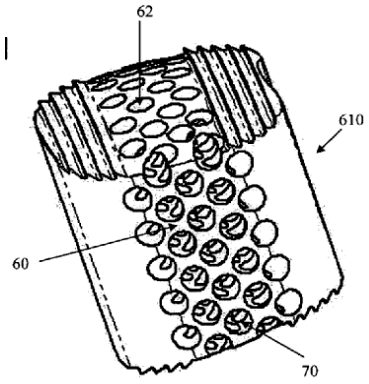


FIG. 11

38. The implant 610 has a porous structure 60 created by 'drilling or boring a plurality of macro-pores 62 into the superior, inferior and lateral faces of the device' in order to promote bone ingrowth (paragraph [0047]). The skilled person would realise that 'superior' and 'inferior' correspond to 'upper' and 'lower' in the Patent. We are told further in paragraph [0047] that the macro-pores extend either from one face of the device to the opposite face or are terminated after a certain depth. This can be seen in Figure 12 (reproduced below) which is a sectional view of the device and shows two holes in the horizontal direction passing completely through the device and four holes in the vertical direction that do the same. These holes that pass completely through the device can be considered to be 'tubes' and therefore this device meets the terms of further features (iv), (v) and (vi).

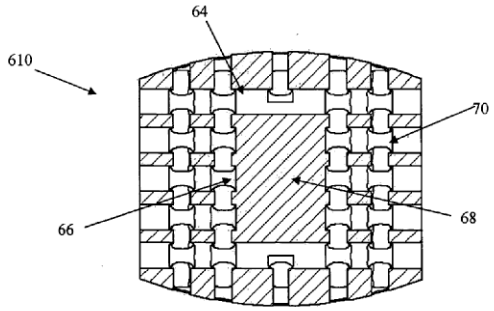


FIG. 12

39. As discussed above feature (vii) requires the horizontal tubes to run ‘straight’ through the implant. From Figure 12 the horizontal tubes certainly appear to be straight. However, as discussed above I have to be careful when deriving features solely from the drawings. The question is whether the skilled person would appreciate that the holes have been bored with sufficient precision without any ‘curves, kinks, bends or the like’ so that X-ray measurements could be carried out through them. There is no mention in the text of X3 of performing any X-ray measurements. This of course is not required. However, there is also no mention of any precision requirements when boring the holes. Presumably, it is likely as above that the holes need only be drilled fairly roughly to meet their stated objective of promoting bone ingrowth. Therefore I do not consider the skilled person to have received clear and unmistakable directions to carry out this feature. Similarly features (viii) and (ix) are not anticipated.

Opinion

40. It is my opinion that claim 1 of the Patent is novel in light of the three cited documents.

Susan Dewar
Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.