Neutral Citation Number: [2010] EWHC 1487 (Pat)

Case No: HC09C02624

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 23 June 2010

Before :

THE HONOURABLE MR JUSTICE ARNOLD

- -

Between :

(1) KCI LICENSING INC **(2) KCI MEDICAL RESOURCES** **(3) KCI MEDICAL LIMITED**	**Claimants**
- and -	
(1) SMITH & NEPHEW PLC **(2) SMITH & NEPHEW INC** **(3) SMITH & NEPHEW MEDICAL LIMITED** **(4) SMITH & NEPHEW HEALTHCARE LIMITED**	**Defendants**

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Michael Tappin QC and **Henry Ward** (instructed by **Olswang LLP**) for the **Claimants**
Simon Thorley QC and **Andrew Lykiardopoulos** (instructed by **Bristows**) for the **Defendants**

Hearing dates: 20-21, 24-27 May 2010

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE ARNOLD:

Contents

Introduction

1. The Claimants (who I shall refer to collectively as "KCI") claim that the Defendants (who I shall refer to collectively as "S & N") have infringed European Patents (UK) Nos. 0 777 504 B1 entitled "Wound drainage equipment" ("'504") and 0 853 950 B1 entitled "Wound drainage canister" ("'950") (which I shall refer to collectively as "the Patents"). '950 is a divisional of '504, and both have a claimed priority date of 22 August 1994. S & N deny infringement of either Patent and counterclaim for revocation of both Patents. At trial KCI did not defend the validity of the broader claims of the Patents, and therefore the issues are confined to the validity and infringement of claim 5 of '504 and claims 7 and 8 of '950.

Background to the dispute

2. The Patents concern apparatus for use in Negative Pressure Wound Therapy ("NPWT"). NPWT involves packing the wound with a dressing which is then covered by a film to create a seal. A partial vacuum is then applied to the area under the seal. NPWT has been found to reduce bacterial infection and to promote tissue growth, and thus to help heal wounds which were difficult to treat by previous methods. The development and use of NPWT has been pioneered by Dr Louis Argenta and Dr Michael Morykwas of Wake Forest University ("WFU"), although it turns out that they were not the first to devise such a technique.

3. NPWT was the subject of an International Patent Application by WFU, No. WO 93/09727 ("Argenta"), which is the principal item of prior art relied on by S & N in these proceedings. Argenta led to the grant of a family of patents, including European Patent No. 0 620 720 B2 ("'720"). KCI is the exclusive licensee under those patents.

4. This is the second patent action brought by KCI against S & N in respect of apparatus for NPWT in as many years. In the first action KCI and WFU sued S & N for infringement of '720 on 15 December 2008 and obtained an interim injunction from Lewison J on 13 January 2009: see *Wake Forest Health Sciences v Smith & Nephew plc* [2009] EWHC 45 (Pat), [2009] FSR 11. After a speedy trial, Roger Wyand QC held in a judgment dated 1 May 2009 [2009] EWHC 908 (Pat) that claims 1, 2 and 15 were anticipated by, and claims 8, 9, 13 and 17 were obvious in the light of, a short article written in Russian by N. A. Bagautdinov entitled (in translation) "Variant of External Vacuum Aspiration in the Treatment of Purulent Diseases of Soft Tissues" published in *Current Problems in Modern Clinical Surgery* by Chuvasia State University of the USSR in 1986. Nevertheless, Mr Wyand concluded that claims 4, 16 and 19 were valid and had been infringed by S & N. On 14 July 2009 the Court of Appeal allowed an appeal by S & N, holding that claims 4, 16 and 19 were obvious, and dismissed a cross-appeal by KCI and WFU against the finding that claim 1 was anticipated. The Court of Appeal gave its reasons for that decision in a judgment dated 31 July 2009 [2009] EWCA Civ 448.

5. Prior to the launch of KCI and WFU's claim against S & N, Mölnlycke Health Care AB had commenced a claim for revocation of '720. That claim came to trial just after the Court of Appeal had announced its decision, but Kitchin J nevertheless proceeded to hear and determine it since KCI and WFU intended to apply to the Supreme Court for permission to appeal against the Court of Appeal's judgment. In the event that application was refused. In the meantime Kitchin J concluded in a judgment dated 28

August 2009 [2009] EWHC 2204 (Pat) that '720 was invalid not only in the light of the Bagautdinov article, but also another item of prior art called Zamierowski. He also concluded that '720 was invalid as a result of an amendment after grant which extended the scope of the patent.

6. KCI also sought an interim injunction in these proceedings, but that application was refused by Mann J on balance of convenience grounds on 31 July 2009 [2009] EWHC 2143 (Pat).

Argenta

7. Since the Patents are for improved apparatus for use in the procedure disclosed in Argenta, it is convenient to consider the disclosure of Argenta before turning to the disclosure of the Patents.

8. The background to the invention is set out at page 1 line 6 – page 2 line 27 as follows:

> "The treatment of open wounds that are too large to spontaneously close has been a troublesome area for many years. Wound closure requires that epithelial and subcutaneous tissue adjacent to the wound migrate toward and eventually close the wound. Some wounds are sufficiently large or infected that they are unable to close spontaneously. In such instances, a zone of stasis, an area in which localized swelling of tissues restricts the flow of blood to these tissues, forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and accordingly is unable to close spontaneously.
>
> The most common techniques for closure of open wounds has long been the use of sutures or staples. These mechanical closure methods provide tension on the skin tissue at the wound border that encourages epithelial tissue to migrate toward the wound and cover it. While suturing and stapling of wounds is widely practiced, it has a major drawback: the tensile force required to achieve closure with sutures or staples causes very high localized stresses at the suture insertion points, resulting in the rupture of the tissue at these points. Substantial rupture will eventually cause dehiscence [*ie* tearing] in some wounds, which results in additional tissue loss. Moreover, some infected wounds harden and inflame to such a degree that closure by suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalisation, with its attendant high costs, and major surgical procedures, such as grafts of surrounding tissue. Examples of such wounds include large, deep, open wounds, pressure sores resulting from prolonged pressure, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

> To date, there has been no consistently satisfactory method for treating such wounds. What is needed is a method of closing the wound without the localized stresses that accompany suturing while at the same time treating any infection present in the wound along with a simple apparatus to carry out the method. Such a method and apparatus would reduce hospitalization and increase the probability of wound closure."

9. The invention is summarised at page 2 line 29 - page 3 line 37. The "fifth aspect" of the invention is described at page 3 lines 24-37 as follows:

> "an apparatus for facilitating the healing of wounds which comprises vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain the negative pressure on the, wound, and screen means for preventing overgrowth of tissue in the wound area. A preferred embodiment of the invention comprises a section of open-cell foam configured to be placed over a wound, a flexible tube inserted into the foam section for attachment to a suction pump, and a flexible polymer sheet overlying the foam section and tubing and configured to be adhered to the skin surrounding the wound."

10. The detailed description of the invention describes the apparatus in more detail at page 7 line 28 - page 10 line 2. At page 7 line 29 - page 8 line 2 Argenta says that the apparatus comprises (i) "vacuum means such as a pump", (ii) "sealing means such as an adhesive sheet" and (iii) "screen means such as an open-cell foam section".

11. The screen means is described at page 8 lines 3-19 as follows:

> "The screen means is placed over substantially the expanse of the wound to prevent its overgrowth. The size and configuration of the screen can be adjusted to fit the individual wound. It can be formed from a variety of porous semi-rigid materials. The material must be sufficiently porous to allow oxygen to reach the wound, and sufficiently rigid to prevent wound overgrowth. Most preferred is the use of an open-cell polymer foam, which permits direct connection of the screen means to the vacuum means through a flexible hose inserted into the foam. Such foam can vary in thickness and rigidity, although it is preferred that a spongy material be used for the patient's comfort if the patient must lay upon the device during its operation. It can also be perforated to reduce its weight. Another embodiment comprises a section of honeycombed polyethylene sheet cut to the shape of the wound."

12. The vacuum means is described at page 8 line 36 – page 9 line 13 as follows:

> "Suitable vacuum means includes any suction pump capable of providing at least 0.1 pound suction to the wound, and

> preferably up to 3 pounds suction, and most preferably up to 14 pounds suction, and a flexible hose that leads from the pump to a point within the pressurized volume created by the sealing means. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the neces[s]ary suction. The dimension [sic] of the tubing are limited only by the pump's ability to provide the suction level neede[d] for operation. A 1/4 inch diameter tube has proven suitable. The vacuum means may operate substantially continuously, or may operate cyclically with alternate periods of application and nonapplication of pressure to the wound."

13. A preferred embodiment of the apparatus is described at page 9 line 14 – page 10 line 2. In the preferred embodiment the screen means is made from "open cell polyester foam … (Fischer Scientific, Pittsburgh 15219)" and the vacuum means is "a Gast Vacuum pump (Fischer Scientific)".

14. Argenta includes eight examples. Examples 1-3 involve the treatment of pigs. Examples 4-8 involve the treatment of human beings. A number of the examples refer to use of open cell polyester foam and a vacuum pump supplied in both cases by Fischer Scientific.

'504

15. The specification of '504 begins at column 1 lines 3-7 by saying:

> "The present invention relates to the healing of wounds and, more particularly, but not by way of limitation, to an apparatus for closing wounds that is compact, self-contained, and includes a disposable wound fluids canister."

16. The specification then describes the background to the invention in almost identical terms to Argenta. It goes on at column 1 lines 44-52 to say that Argenta proposes a procedure for draining the wound by applying a continuous negative pressure to the wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound, but that the apparatus described has "certain practical shortcomings".

17. The specification continues at column 1 line 53 – column 2 line 45:

> "One problem with the apparatus described in [Argenta] is that no means are disclosed for avoiding spread of infection from one patient to another or re-infection of the patient being treated.
>
> The problem is solved by the features of claim 1.
>
> In accordance with the present invention, there is provided a therapeutic apparatus for stimulating healing of wounds, said apparatus including a housing that contains a vacuum pump and a chamber for holding a disposable wound drainage

> collection canister. The canister preferably resides within the chamber and connects at an outlet with the vacuum pump and at an inlet with a porous pad. The pad is placed over a wound and adhesively secured thereto to create a sealed environment at the wound. Thus, when the vacuum pump activates, it evacuates air from the canister and thence the wound environment, resulting in the application of negative pressure to the wound, which in turn tends to promote drainage of fluids flowing from the wound into the canister. After the canister is filled, it is removed from the chamber, disposed of, and replaced with another canister to continue therapy.
>
> Although the vacuum pump is designed to be reusable because of its more costly components, the apparatus utilizes a removable and disposable canister adapted to prevent contamination of the vacuum pump or the remainder of the apparatus. If the vacuum pump or other parts of the housing or the tubing leading to the pump from the canister became contaminated, the wound closure apparatus would have to be completely disassembled, thoroughly cleaned and possibly discarded. Disassembly and cleaning of the wound closure apparatus is extremely time and labour intensive, while disposal of the wound closure apparatus is expensive. Consequently, a removable and disposable canister prevents either of the above undesirable circumstances from occurring.
>
> It is, therefore, an object of the present invention to provide a wound closure apparatus that closes wounds without stressing the surrounding skin.
>
> It is another object of the present invention to render technology like that disclosed in [Argenta] available in a convenient, compact and self-contained, efficient and economically feasible system. It is also an object to optimize the safety and effectiveness of such a device, particularly from an infection control standpoint.
>
> It is a further object of the present invention to provide a wound closure apparatus that includes a removable and disposable wound fluids collection canister to protect the wound closure apparatus from contamination."

18. Thus '504 discloses apparatus for use in the technique described in Argenta the principal feature of which is that it comprises a removable and disposable canister for collecting fluids sucked from the wound. The apparatus also has certain other features. The specification goes on to describe the apparatus in considerable detail by reference to eleven drawings. Much of this detail is immaterial for present purposes, and it is only necessary to set out the teaching of the specification relating to three aspects of the claimed invention.

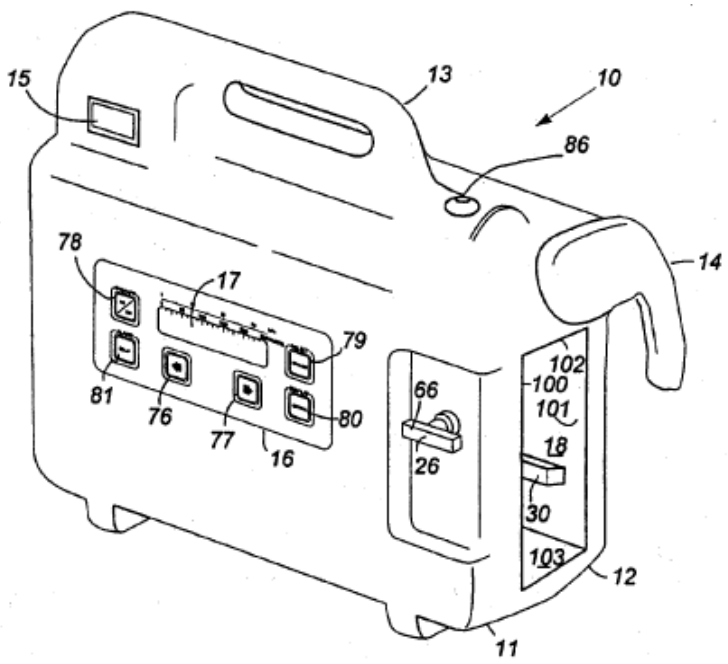
19. The first concerns the wound dressing, referred to as the pad. At column 5 lines 10-11 the specification states that the pad is "fabricated from open cell polyurethane or polyether foam". The specification goes on to say at column 5 lines 46-49:

> "A high degree of reticulation in the polymer foam is desirable to achieve good permeability when the foam is under suction. Foams having at least 90% and especially at least 95% of interconnecting cells are preferred."

20. The second concerns the spatial relationship between the disposable canister and the vacuum pump unit. At column 3 lines 39-48 the specification states:

> "Chamber 18 [in the vacuum pump unit] is defined by integrally formed interior walls 100 and 101, top wall 102, bottom wall 103 and rear wall 104. … The wound fluids collection canister, illustrated in Figures 3-5, is received within chamber 18. Side walls 100 and 101 each include a key 29 and 30, respectively, the [sic] aid in alignment of wound fluids collection canister 19 within chamber 18."

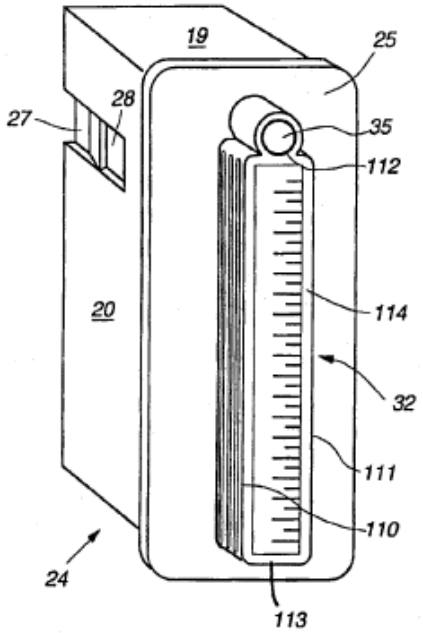
21. Key 30 can be seen inside chamber 18 in Figure 1, which I reproduce below:



22. The specification goes on at column 4 lines 6-13 to say:

> "As illustrated in Figures 3 to 6, canister 19 includes sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 that define the rectangular chamber for receiving blood, pus, and other fluids emitted from a wound. Sidewalls 20 and 21 include keyways 27 and 31 respectively, that receive a respective one of keys 29 and 30 to provide easy alignment of canister 19 within chamber 18."

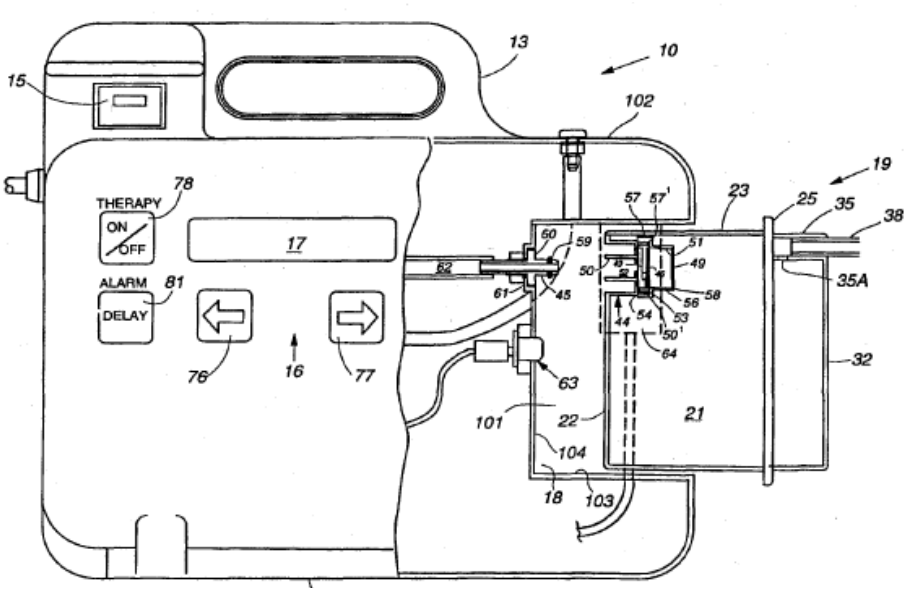
23. Keyway 27 can be seen in Figure 3, which I reproduce below:



24. At column 6 lines 11-25 the specification states:

> "As illustrated in Figures 2, 4 and 6, canister 19 includes outlet 44 that mounts over port 45 to permit wound closure apparatus 10 to draw wound fluids into canister 19. Outlet 44 is cylindrically shaped and formed as an integral part of back wall 22 by outer wall 33 and inner wall 50 which are interconnected by end wall 34. Passageway 52, defined in part by interior wall 50 and in part by filter cap 49, provides the actual conduit for outlet 44 between the interior and exterior of canister 19. The placement of canister 19 within recess 18 such that outlet 44 resides over port 45 couples canister 19 to a vacuum pump. The vacuum pump removes air from canister 19 to create vacuum pressure within canister 19. That vacuum pressure is then transmitted to a wound site through hoses 37 and 38…"

25. The relationship between outlet 44 and port 45 can be seen from Figure 6, which I reproduce below:



26. It can also be seen from Figure 6 that, even when the canister is placed in the recess so that the outlet 44 resides over the port 45, the part of the canister to the right of wall 25 will protrude beyond the housing of the vacuum pump unit.

27. The third aspect of the invention that is material for present purposes concerns the operation of the pump. At column 10 lines 33-37 the specification states:

> "After receiving and storing the user selected operational parameters and receiving an on signal due to the pressing of on/off button 78, microcontroller 72 activates pump motor 83 which, in turn, drives vacuum pump 84 to begin the removal of air from canister 19."

28. At column 11 line 36 to column 12 line 14 the specification states:

> "Microcontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83. That is, microcontroller 72 receives the 12V DC signal from DC power supply 71 and outputs a voltage between 0 and 12V DC to pump motor 83 to control its speed in accordance with the user selected vacuum pump pressure value. Accordingly, microcontroller 72 employs feedback to ensure that the wound experiences the user selected vacuum pump pressure. If the target pressure is not reached after a period of five minutes, microcontroller 72 deactivates motor 83 and sounds the audible alarm. Additionally, the feedback signal prevents maximum vacuum pump pressure from being exceeded. If the wound pressure measured by transducer 75 exceeds a maximum safe vacuum pump pressure, microcontroller 72 deactivates pump motor 83.
>
> Wound closure apparatus 10 includes fan 74 to cool pump motor 83 and printed circuit board or chassis 200 during the operation of the wound closure apparatus 10. In the preferred

> embodiment, microcontroller 72 controls fan 74 to always operate while power is being supplied. In alternative embodiments, however, microcontroller 72 controls fan 74 to operate only in relation to motor 83, because it is only necessary for fan 74 to operate if motor 83 is also operating. In such alternative, as long as pump motor 83 operates, microcontroller 72 runs fan 74. However, when microcontroller 72 deactivates pump motor 83 it also deactivates fan 74.
>
> Control system 70 includes fill sensor 64 to provide a signal to microcontroller 72 that indicates when canister 19 is completely filled with wound fluids. After receiving a signal from fill sensor 64, microcontroller 72 deactivates pump motor 83 and fan 74 and activates alarm 95 to signal the user that canister 19 must be replaced."

Claims of '504 in issue

29. As noted above, KCI do not seek to defend the validity of the broader claims of '504. The only claim which KCI contend is independently valid is claim 5. Claim 5 is dependent on claim 4, which is dependent on claim 1.

30. Broken down into integers and omitting reference numerals, claim 1 is as follows:

> "[1] A therapeutic apparatus for stimulating healing of a wound in mammals which comprises
>
> [2] a porous pad which is permeable to fluids for introduction into the wound,
>
> [3] a dressing for covering the wound and providing an air-tight seal therearound,
>
> [4] a drainage tube connecting the pad to a suction pump contained in a housing so that negative pressure can be applied to the wound, to draw fluids therefrom,
>
> [5] said tube being connected to the pump via a disposable canister for collecting fluids sucked from the wound,
>
> [6] said canister having an inlet connected to the drainage tube and a suction port connected to the pump,
>
> [7] said suction port incorporating a filter to prevent passage of liquid therethrough
>
> [8] and said canister and said housing having a guide for aligning the container in a recess in the housing such that the suction port is connected to the pump,
>
> [9] a latch for engaging with and releasably holding the canister in the

recess and

[10] means for detecting when the canister is substantially filled with liquid and generating a signal which causes the pump to be deactivated."

31. Claim 4 adds the integer:

"[11] wherein said pad is a polymer foam having interconnecting cells."

32. Claim 5 adds the integer:

"[12] wherein the foam is a reticulated foam having at least 90% of interconnecting cells"

'950

33. Since it is a divisional of '504, most of the specification of '950 is identical to that of '504 except that the paragraphs are numbered. There are certain differences in the passage quoted in paragraph 17 above, but these are not material for present purposes. The disclosure of '504 relating to reticulated foam quoted in paragraph 19 above is repeated in '950 at [0032] and [0034]. There are two additional passages in the specification that are relevant for the purposes of '950.

34. The first is to be found at [0031]:

> "In order to prevent liquids sucked into the canister from splashing directly onto cap 49, which masks the outlet 44, and to reduce foaming within the canister, inlet 35 has a blind inner end. … It is desirable to avoid foaming because this can give a false reading when a capacitance sensing device is used to sense when the canister is filled. An anti-foaming material, e.g. a silicone may be added to the canister, e.g. by coating the interior walls. It may also be advantageous to include a gel-forming substance, e.g. a polyacrylamide or modified starch in order to immobilise the drainage fluid. This is particularly useful if the apparatus is likely to be tilted."

35. The second is at [0038]:

> "In removing fluids from a wound utilizing wound closure apparatus 10, a major safety concern is preventing wound fluids from contaminating the vacuum pump. Accordingly, filter 46 mounts over outlet 44 utilizing filter carrier 48 and filter cap 49 to block the flow of wound fluids to outlet 44 so that wound fluids remain within canister 19 and do not flow into the vacuum pump. In this preferred embodiment, filter 46 is a 0.2 micron hydrophobic membrane filter providing a bacterial barrier, although other filters may be substituted as appropriate."

Claims of '950 in issue

36. As with '950, KCI do not seek to defend the validity of the broader claims of '504. The only claims which KCI contend are independently valid are claims 7 and 8. Claim 7 is dependent on claim 1.

37. Broken down into integers and omitting reference numerals, claim 1 is as follows:

> "[1] A disposable canister for use in wound dressing treatment apparatus comprising a wound dressing pad and a suction pump for applying negative pressure to the wound dressing pad,
>
> [2] said canister comprising a moulded plastics container having an inlet connected to a flexible inlet tube and an outlet for connection to the suction pump,
>
> [3] said outlet incorporating a bacterial filter and said inlet tube having a quick disconnect coupling device for connection to a flexible drainage tube leading to the wound dressing pad
>
> [4] and said inlet tube including clamp means for preventing escape of liquid from the container."

38. Claim 7 adds the integer:

> "[5] [the canister] includes a gel-forming substance which is capable of immobilising drainage fluids within the canister."

39. Claim 8 is as follows:

> "[1] A canister as claimed in any of the preceding claims in combination with a wound dressing pack,
>
> [2] the wound dressing pack comprising a reticulated open-celled foam pad having at least 90% of interconnecting cells
>
> [3] and being connected to a drainage tube terminating in a quick disconnect coupling device adapted to couple with coupling device, attached to the inlet tube which is attached to the inlet of the canister,
>
> [4] said drainage tube including clamp means to prevent the drainage tube leaking liquid when the coupling devices are disconnected."

The witnesses

40. KCI called two expert witnesses, Dr Luc Téot and Neil Buckley. S & N called one expert witness, Tim Wood. S & N served two expert reports from another witness, Dr Ian Gordon, but did not in the end call him.

41. Dr Téot received his MD from Montpellier University in 1980. After that, he trained in Paris and Montreal and at the Mayo Clinic in the USA. He qualified as a specialist in general surgery in 1986, as a specialist in orthopaedic surgery in 1988 and as a

plastic surgeon in 1991. He is presently head of the Plastic Surgery and Burns Unit at Montpellier General Hospital. In addition to his clinical work, he carries on research and has published a large number of articles and book chapters. In the early 1990s he became interested in wound healing. He started organising meetings about wound healing in Montpellier in 1992, leading to the foundation of the French Wound Healing Society in 1995. He was President of that Society from 1995 to 2004, President of the European Tissue Repair Society from 2002 to 2004 and President of the World Union of Wound Healing Societies from 2004 to 2008.

42. In addition to his other experience, Dr Téot has carried out clinical research on new medical devices in the field of wound healing. Indeed, as I will discuss in more detail below, he was one of the first surgeons in Europe to use KCI's VAC system, which implements Argenta and the Patents. He was thus as close to the hypothetical clinician on the skilled team to whom the Patents are addressed as one could hope to get. He was also a good expert witness.

43. Mr Buckley obtained a degree in Materials Science at the University of Bath. From 1978 to 1982 he was employed by Zimmer Ltd, a manufacturer of orthopaedic implants and instruments, as a materials technologist. From 1982 to 1985 he was employed by British Viggo, a manufacturer of sterile single-use medical devices, as a quality development engineer. From 1985 to 1998 he was again employed by Zimmer Ltd successively as Technical Manager, Director, Technical Operations and Director and General Manager, Operations. Since 1998 he has acted as a consultant in the medical device field, initially for Zimmer Ltd and then more widely. Although a materials scientist by training, he is a chartered engineer.

44. As counsel for S & N correctly pointed out, Mr Buckley had no relevant experience in wound care. Counsel also submitted that Mr Buckley's skills and experience were not those of a typical design engineer in the medical device field. I do not accept that submission. From the evidence in this case, it appears to me that design engineers in the medical device field are likely to have a range of backgrounds and experiences. Mr Buckley did have experience in the design of medical devices, which had often taken him into hospital theatres and had involved him working with orthopaedic surgeons on the design, development and testing of various devices. In my judgment Mr Buckley was appropriately qualified to act as a medical device design engineer forming part of the skilled team to whom the Patents are addressed. He was also a careful and fair witness.

45. Mr Wood obtained a degree in Production Engineering from Lanchester Polytechnic. Like Mr Buckley, he is a chartered engineer. Save for a brief interlude from 1987 to 1988 when he was employed by Cambridge Consultants, from 1982 to 2007 he worked for PA Consulting. During this time he worked on the development of a considerable number of new products and processes in the healthcare field. He did not specialise in that field, however, and indeed had experience in a number of sectors.

46. Mr Wood had little, if any, more experience of wound care than Mr Buckley. Although his background and experience was somewhat different to that of Mr Buckley, I consider that he was also appropriately qualified to act as a medical device design engineer forming part of the skilled team to whom the Patents are addressed. He too was a careful and fair witness.

47. Counsel for KCI made two criticisms of Mr Wood's evidence which were not really criticisms of Mr Wood, but of his instructions. First, he submitted that Mr Wood's evidence was tainted by hindsight since he had been given the Patents at an early stage. As a result, he approached a number of the issues in the case with the Patents in mind. He was not given a copy of Argenta and asked how he thought the skilled team would have implemented it without having had sight of the Patents. Secondly, it became clear during cross-examination that Mr Wood had not understood the concept of common general knowledge, and had included within that category almost any information that was reasonably accessible at the priority date. In my judgment there is force in both of these points, and in particular the second one. As I will discuss below, the issue of common general knowledge is an important one in the present case. Mr Wood's evidence on this topic must be treated with considerable caution.

48. In addition to the expert witnesses, KCI called Nadeem Bridi as a witness of fact on the priority issues discussed below. Mr Bridi is Chief Intellectual Property Counsel for Kinetic Concepts, Inc ("KC Inc"), which is the parent company of each of the Claimants. Mr Bridi was a straightforward witness whose evidence I accept. KCI also served a short witness statement from David Woodcraft, a retired UK and European Patent Attorney and formerly a partner of Brookes & Martin, who had responsibility for handing the international application from which the Patents derive. Mr Woodcraft was not required to attend for cross-examination.

Priority

49. KCI have admitted that apparatus as claimed in both Patents was sold during the priority year, and thus that the Patents are invalid if they are not entitled to the priority claimed. S & N deny that the Patents are entitled to priority. Unusually, the dispute does not concern the disclosure of the priority application, but the standing of the applicant or applicants to claim priority.

The right to priority

50. The right to priority is governed by section 5 of the Patents Act 1977, which is one of the provisions declared by section 130(7) to be "so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention … and the Patent Co-Operation Treaty". The corresponding provision of the EPC is Article 87 and the corresponding provision of the PCT is Article 8.

51. Prior to its amendment by the European Patent Convention 2000, paragraph 1 of Article 87 of the EPC provided:

> "Any person who has duly filed in or for any State party to the Paris Convention for the Protection of Industrial Property, an application for a patent or the registration of a utility model or for a utility certificate or for an inventor's certificate, or his successors in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application."

52. Article 8 of the PCT provides:

> "(1) The international application may contain a declaration, as prescribed in the Regulations, claiming the priority of one or more earlier applications filed in or for any country party to the Paris Convention for the Protection of Industrial Property .
>
> (2)(a) Subject to the provisions of sub-paragraph (b), the conditions for, and the effect of, any priority claim declared under paragraph (1) shall be as provided in Article 4 of the Stockholm Act of the Paris Convention for the Protection of Industrial Property.
>
> (b) The international application for which the priority of one or more earlier applications filed in or for a Contracting State is claimed may contain the designation of that State. Where, in the international application, the priority of one or more national applications filed in or for a designated State is claimed, or where the priority of an international application having designated only one State is claimed, the conditions for, and the effect of, the priority claim in that State shall be governed by the national law of that state."

53. Article 87(1) of the EPC and Article 8 of the PCT both give effect to Article 4(A)(1) of the Paris Convention, which provides:

> "Any person who has duly filed an application for a patent, or the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purposes of filing in the other countries, a right of priority during the periods hereinafter fixed."

54. In *Edwards Lifesciences AG v Cook Biotech Inc* [2009] EWHC 1304 (Pat), [2009] FSR 27 Kitchin J considered these provisions and concluded at [93]-[95]:

> "93. So art.4 specifies a person is to enjoy a right of priority if he has filed a relevant application for a patent or if he is the successor in title to such a person. Successor in title here must mean successor in title to the invention, as the parties before me agreed. Further, any person wishing to take advantage of the priority of such a filing must be required to make an appropriate declaration.
>
> 94. Both elements of art.4 are reflected in s.5 of the Act which requires a declaration made by the applicant which complies with the relevant rules and specifies one or more earlier relevant applications made by the applicant or a predecessor in title.

> 95. In my judgment, the effect of art.4 of the Paris Convention and s.5 of the Act is clear. A person who files a patent application for an invention is afforded the privilege of claiming priority only if he himself filed the earlier application from which priority is claimed or if he is the successor in title to the person who filed that earlier application. If he is neither the person who filed the earlier application nor his successor in title then he is denied the privilege. Moreover, his position is not improved if he subsequently acquires title to the invention. It remains the case that he was not entitled to the privilege when he filed the later application and made his claim. Any other interpretation would introduce uncertainty and the risk of unfairness to third parties. In reaching this conclusion I derive a measure of comfort from the fact that the Board of Appeal of the EPO has adopted the same approach to the interpretation of art.87 EPC in two cases: J19/87 and T62/05."

The applications

55. The application from which priority is claimed is United States Patent Application No. 08/293,854 filed on 22 August 1994 ("the Priority Document"). The Priority Document named Cesar Z. Lina as the sole inventor of the invention. As is required by US law, Mr Lina was therefore the sole applicant.

56. The application which led to the grant of the Patents was an international application under the PCT, No. PCT/GB95/01983, filed on 21 August 1995 ("the PCT Application"). I shall have to describe the PCT Application in more detail below, but it may be noted at this stage that (i) the applicant for the US was Mr Lina, (ii) KC Inc was an applicant for all designated states except the USA and (iii) Mediscus Products Ltd ("Mediscus") was an applicant for "GB only". Mediscus was, and remains, a wholly-owned subsidiary of KC Inc.

The issues

57. The issues which have arisen on priority are as follows:

    i) Did KC Inc have the right to claim priority at the date of filing the PCT Application by virtue of a confidentiality agreement signed by Mr Lina on 22 January 1990 ("the Confidentiality Agreement")?

    ii) If not, did KC Inc have the right to claim priority by virtue of a later specific assignment executed by Mr Lina?

    iii) Was Mediscus an applicant for purposes of the claim to priority?

    iv) If so, does that adversely affect the claim to priority?

Did KC Inc have the right to claim priority by virtue of the Confidentiality Agreement?

58. Given that the applicant for the Priority Document was Mr Lina, it is common ground that KC Inc only had the right to claim priority under Article 4(A)(1) of the Paris

Convention and Article 87(1) of the EPC if, at the time that the PCT Application was filed, KC Inc was Mr Lina's "successor in title". It is also common ground, as it was in *Edwards v Cook*, that "successor in title" means successor in title to the invention.

59. KCI contend that KC Inc was Mr Lina's successor in title by either or both of two routes, namely (i) the Confidentiality Agreement and (ii) a later specific assignment.

60. The Confidentiality Agreement is expressed to be entered into by Mr Lina "in consideration of employment with" KC Inc. Paragraph 3 provides:

> "I hereby assign and agree to assign to the Company [i.e. KC Inc] all right, title and interest in all confidential information, inventions and improvements conceived or developed by me, alone or in conjunction with others, during my employment and for a period of three (3) years after termination for whatever reason, which relate to any phase of the Company's business. In addition, I will communicate promptly to the Company all such inventions and improvements and will sign all documents reasonably requested by the Company to evidence the fact that such inventions and improvements are the sole and exclusive property of the Company and will do all things necessary to enable the Company to file patent applications on the inventions throughout the world."

61. Paragraph 5 of the Confidentiality Agreement provides that it is governed by the law of the State of Texas. There is no evidence as to Texas law before me, and accordingly it is common ground that it should be assumed to be the same as English law.

62. Counsel for S & N argued that neither the first sentence nor the second sentence of paragraph 3 was effective to assign Mr Lina's interest in the invention to KC Inc. So far as the first sentence is concerned, he submitted that it was not possible prospectively to assign a future invention, and accordingly this could only take effect as an agreement to assign. As to the second sentence, he submitted that Mr Lina had merely agreed to do whatever was necessary to enable KC Inc to file patent applications on the inventions, and that Mr Lina had neither assigned nor agreed to assign any such patent applications to KC Inc.

63. Counsel for KCI submitted that it was possible prospectively to assign a future invention, and accordingly the first sentence of paragraph 3 was effective to transfer Mr Lina's interest in the invention. He also submitted that the second sentence made it clear than KC Inc was entitled to file patent applications to the exclusion of Mr Lina. Either way, he submitted that paragraph 3 was sufficient to make KC Inc Mr Lina's successor in title within the meaning of Article 4A(1) of the Paris Convention and Article 87(1) of the EPC.

64. Neither counsel cited any authority in support of their respective submissions as to the effect of the first sentence of clause 3. As I understood his submissions, however, counsel for S & N was relying on the principle of English law which is stated in *Snell's Equity* (31st edition) at §3-28 as follows (omitting footnotes):

> "At common law assignments of future choses in action were void, for no one could assign what he had not got. But in equity any such purported assignment made for valuable consideration has always been treated as a contract to assign in the future if and when the chose comes into existence. The principle that equity regards as done that ought to be done is applied so that, once the assignor has received the valuable consideration and become possessed of the property, the beneficial interest in the property passes to the assignee immediately…"

This principle was applied to copyrights in songs yet to be written in *Performing Rights Society Ltd v London Theatre of Varieties Ltd* [1924] AC 1 (although section 91 of the Copyright, Designs and Patents Act 1988 now permits prospective assignments of copyright).

65. In my judgment, however, this principle does not apply to a patentable invention. Section 7(2) of the Patents Act 1977 provides:

> "A patent for an invention may be granted-
> (a) primarily to the inventor or joint inventors;
> (b) in preference to the foregoing, to any person or persons who, by virtue of an enactment or rule, or any foreign law or treaty or international obligation, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of making of the invention entitled to the whole of the property in it (other than equitable interests) in the United Kingdom;
> (c) in any event, to the successor or successors in title of any person or persons mentioned in paragraph (a) or (b) above or any person so mentioned and the successor or successors in title of another person so mentioned;
> and to no other person."

66. It is clear from section 7(2) that the statute proceeds upon the basis that a patentable invention is property, and that the inventor is the first owner of that property unless one of the circumstances mentioned in sub-subsection (b) applies. If one of those circumstances does apply, so that another person is entitled to the whole of the property in the invention before it is made, then that other person becomes entitled to apply for and be granted a patent by virtue of section 7(2)(b). For example, section 39(1) of the 1977 Act provides that an invention made by an employee belongs to his employer in the circumstances specified there. Similarly, if the inventor assigns the property in the invention to another person after making it, then that other person becomes entitled to apply for and be granted a patent by virtue of section 7(2)(c). It is this proprietary right to the invention which founds any claim to entitlement which the true owner may make under sections 8, 12 or 37 of the 1977 Act if someone else files an application to patent it: see *Yeda Research and Development Co Ltd v Rhone-Poulenc Rorer International Holdings Inc* [2007] UKHL 43, [2008] RPC 1 at [17]-[22].

67. Section 7(2)(b) proceeds on the basis that it is possible for a person other than the inventor to acquire "the whole of the property" in an invention by means of "an

enforceable term of any agreement entered into with the inventor before the making of the invention". In my view, this must mean that it is possible to assign the legal title (and not just the beneficial interest) in an invention before it is made. I do not consider that it matters for this purpose whether an invention is regarded as a chose in action or, as section 30(1) provides in the case of patents and patent applications, as "personal property (without being a thing in action)".

68. Accordingly, interpreting the Confidentiality Agreement in accordance with English law, I conclude that the first sentence of paragraph 3 was effective to assign legal title to the invention to KC Inc. Thus KC Inc was Mr Lina's successor in title as at the date of the PCT Application.

69. I would add that, even if it was not effective to convey the legal title to the invention, paragraph 3 of the Confidentiality Agreement was plainly effective to transfer the entire beneficial interest in the invention, including the right to file patent applications in respect of it, from Mr Lina to KC Inc. KC Inc would have been entitled to demand that Mr Lina convey the bare legal title to the invention to itself at any time, and to compel Mr Lina to do so if he failed or refused to do it. If necessary, I would hold that that was sufficient to make KC Inc Mr Lina's "successor in title" for the purposes of a claim to priority under Article 87(1) of the EPC and Article 4(A)(1) of the Paris Convention even if KC Inc had not acquired the bare legal title at the relevant date.

70. I am encouraged so to hold by the decision of the Legal Board of Appeal in Case J19/87 *Burr-Brown /Assignment* [1988] EPOR 350 that an assignment of an invention and a patent application from A to B with a covenant of further assurance was sufficient to entitle B to claim priority from an application filed by A even though the assignment of the patent application was ineffective because it was not signed by B contrary to section 30(6) of the 1977 Act as it then stood. In holding that the priority claim was a good one, the Board (two of whose members were Peter Ford, later His Honour Judge Ford, and Gerald Paterson, later the author of *The European Patent System*) accepted an opinion from English counsel (Nicholas Pumfrey, later Pumfrey J) stating that (i) the assignment of the invention (which post-dated the making of the invention) was effective in law even though the assignment of the patent application was not, and (ii) although the assignment was ineffective in law B had acquired an equitable interest in the patent application which was a proprietorial interest. Although it could well be argued that point (i) was enough, the Board seems to have regarded point (ii) as significant as well.

71. To my mind, this makes sense. Article 4(A) of the Paris Convention and Article 87(1) of the EPC are provisions in international treaties whose operation cannot depend upon the distinction drawn by English law, but not most other laws, between legal and equitable title. When determining whether a person is a "successor in title" for the purposes of the provisions, it must be the substantive rights of that person, and not his compliance with legal formalities, that matter.

72. For these reasons I conclude that KC Inc had the right to claim priority from the Priority Document at the date of the PCT Application by virtue of the Confidentiality Agreement.

Did KC Inc have the right to claim priority by virtue of a specific assignment?

73. The second basis upon which KCI say that KC Inc was Mr Lina's successor in title is that Mr Lina would also have executed a specific assignment of the invention to KC Inc shortly after the Priority Document was filed. KCI have been unable to produce any copy of such an assignment, however. S & N contend that the explanation for this is that no such assignment was executed even though one should have been.

74. I consider that it is more probable than not that Mr Lina did execute such an assignment for the following reasons:

    i) Mr Bridi's evidence was that it was standard practice for employees of KC Inc to sign specific assignments for each invention at the time that, or shortly after, the initial US application was filed.

    ii) Mr Lina agreed in the Confidentiality Agreement that he would sign any documents required.

    iii) Mr Lina did sign at least one other such document in a similar time frame, namely an assignment dated 31 October 1995 in respect of an invention for which a US application was filed on 22 August 1995.

    iv) Although KCI adduced no direct evidence from Mr Lina, Mr Bridi gave evidence that Mr Lina had told him that Mr Lina's recollection was that he had signed specific assignment documents for every invention with which he was involved at the time that, or soon after, the applications were filed.

    v) Mr Woodcraft gave evidence that it was his standard practice to check that an assignment had been entered into.

75. It is fair to say that it is surprising that KCI have not been able to produce a copy of the assignment, but explanations have been provided for this:

    i) Mr Bridi explained that many of KC Inc's files, including the file for the Priority Document, were damaged in a flood in the late 1990s. It was his belief that KC Inc's copy of the assignment was destroyed in this incident.

    ii) Mr Bridi also said that the United States Patent and Trade Mark Office had contacted KC Inc in about 2002 and 2003 for assistance in reconstituting certain files which had been found to be incomplete, including the file in question. KC Inc was unable to help as its own file had been damaged in the floods. Mr Bridi believed that this explained why the USPTO did not have a copy of the assignment.

    iii) Mr Woodcraft's evidence was that he did not usually obtain copies of such assignments. This explains why no copy can be found on his files.

    iv) According to Mr Bridi, Mr Lina told him that he did not keep copies of such assignments. Thus he does not have a copy either.

76. Counsel for S & N pointed out that, not only had no copy of the assignment been produced, but also no contemporaneous record of its existence had been produced. In

my view, this is the strongest point in favour of the contention that no assignment was executed. Again, however, explanations have been provided. In particular, it appears that any assignment would have been notarised before Will Quirk, Mr Bridi's predecessor. Mr Bridi has made enquiries as to the whereabouts of Mr Quirk's notary log books, but they cannot be found.

77. On balance, therefore, I do not consider that the absence of any copy of the document and the absence of any contemporaneous record of the document outweigh the factors listed in paragraph 74 above.

78. For these reasons I conclude that KC Inc had the right to claim priority from the Priority Document at the date of the PCT Application by virtue of a specific assignment executed by Mr Lina shortly after the Priority Document even if it did not do so by virtue of the Confidentiality Agreement.

Was Mediscus an applicant for the purposes of the claim to priority?

79. An important part of a PCT application is the request form. This is a standard form which contains various boxes which must be crossed and/or completed as appropriate. The request form filed by Mr Woodcraft in respect of the PCT Application ("the Request Form") identified KC Inc as "applicant for the purposes of … all designated States except the United States of America" and Mediscus as "applicant for the purposes of: … the State indicated in the Supplemental Box". It also identified Mr Lina and Keith Patrick Heaton, a resident and national of the United Kingdom, as inventors and as "applicant[s] for the purposes of: … the United States of America only". Box V of the Request Form, "Designation of States", contained crosses in all the check-boxes for designating states. Among the "regional patents" checked was "EP Patent" and among the "national patents" checked was "GB United Kingdom". The Supplemental Box contained the statement "Mediscus Products Limited GB only".

80. Counsel for KCI submitted that it is clear from the Request Form that "GB only" was a reference to the United Kingdom national patent, and not to a European patent (United Kingdom). I accept that submission. As is apparent from the request form, it is neither necessary nor possible for a PCT applicant who designates a European patent to designate particular Contracting States of the EPC in respect of the European patent. If a European patent is designated on the request form, the designation of EPC Contracting States will be made by the applicant when the application enters the regional/national phase.

81. This interpretation is supported by a letter which Mr Woodcraft wrote to KC Inc about the PCT Application on 31 August 1995. In the letter he said:

> "You will observe that in the PCT application, we designated all available states and that we designated Mediscus Products Limited as the applicant for the GB designation. The latter is a device to ensure that the British Patent Office can act properly as the Receiving Office for the PCT application and ensure that the requested filing date will be accorded.

> Once we have the filing receipt for the PCT application, we can assign the GB designation to KCI. However, since it is possible that the GB designation will lapse in favour of an EPO designation when we reach the national phase it may not be necessary to make any change in the applicants."

82. The explanation for the reference to the British Patent Office (now the United Kingdom Intellectual Property Office) being able to act as the receiving office for the PCT Application lies in rule 19 of the PCT Regulations, which provides *inter alia*:

> "19.1 *Where to File*
>
> (a) Subject to the provisions of paragraph (b), the international application shall be filed, at the option of the applicant,
>
> (i) with the national Office of or acting for the Contracting State of which the applicant is a resident
>
> (ii) with the national Office of or acting for the Contracting State of which the applicant is a national, or
>
> (iii) irrespective of the national Office of or acting for the Contracting State of which the applicant is a resident or national, with the International Bureau.
>
> …
>
> 19.2 *Two or More Applicants*
>
> If there are two or more applicants:
>
> (i) the requirements of Rule 19.1 shall be considered to be met if the national Office with which the international application is filed is the national Office of or acting for a Contracting State of which at least one of the applicants is a resident or national;
>
> (ii) the international application may be filed with the International Bureau under Rule 19.1(a)(iii) if at least one of the applicants is a resident or national of a Contracting State."

83. Although Mr Woodcraft did not say so in his letter, I infer that Mr Heaton, who was an employee of Mediscus, was named as an inventor in the Request Form for consistency with the naming of Mediscus of an applicant, in particular with regard to the position in the USA. As noted above, US law requires patent applications to be filed by the inventors. Since Mr Lina was named as the sole inventor in the Priority Document and since there is no dispute that the PCT Application disclosed the same invention as the Priority Document, it appears that Mr Heaton did not in fact contribute to the making of the invention.

84. Counsel for S & N submitted that it did not matter whether Mediscus was a co-applicant only for a GB national patent or also for a European patent (UK) since at that stage it was not yet known which of the regional/national phases would be

pursued by the applicants. He argued that KC Inc and Mediscus were co-applicants for the PCT Application, and accordingly priority could only be validly claimed in respect of the PCT Application if both co-applicants had the right to claim priority under Article 4(A)(1) of the Paris Convention.

85. I do not accept that submission. What matters for the purposes of this litigation is whether priority has been validly claimed for the Patents, both of which are European patents (UK), in accordance with Article 87(1) EPC. The PCT is simply a mechanism for the central filing of multiple patent applications. Once an international patent application enters the regional/national phase, it is treated as a regular regional or national application. Accordingly, the only part of the PCT Application that is material to the entitlement of the Patents to priority is the part that relates to the European patent. Provided that priority has been validly claimed in respect of the European patent, it does not matter whether priority was validly claimed in respect of the United Kingdom national patent, if any.

86. Counsel for S & N also submitted that either it had been intended that Mediscus should be a co-applicant for the European patent (UK) or the applicants' intentions had changed subsequently. In support of these submissions, he relied on the prosecution history of the Patents. On 21 February 1997 Mr Woodcraft completed and filed with the EPO the appropriate form to request entry of the PCT Application into the regional phase before the EPO as application No. 95929939.7, which subsequently led to the grant of '504. This form named KC Inc as the sole applicant. Subsequently divisional application No. 98200529.0, which subsequently led to the grant of '950, was filed.

87. On 8 April 1998 Mr Woodcraft wrote to the EPO saying:

> "I request the opportunity of correcting a clerical error in the request form which was filed with the divisional application. This application is made for correction under Rule 88. The correction required is to add Mediscus Products Limited of 10 Westminster Road, Wareham, Dorset BP20 4SP as a second applicant for GB. The error was a clerical one and was made at the time when the writer (the European representative) was absent from the office undergoing surgery.
>
> The applicant for the parent application was Kinetic Concepts, Inc for all designated European states, together with Mediscus Products Limited as joint applicants for GB.
>
> During the prosecution of the parent application, the name of the applicant was occasionally referred to as Kinetic Concepts, Inc for short without including a reference to the second applicant. For this reason, when the divisional application was prepared, the person who prepared the document erroneously entered the applicants on the request form as Kinetic Concepts, Inc only for all states. It is, however, clear on the face of the documents (see, for example, the published PCT application), that the applicants should have been Kinetic Concepts, Inc, and

> Mediscus Products Limited, and that nothing else could have been intended."

88. On 6 May 1998 the EPO notified Mr Woodcraft that this request had been allowed. Accordingly, '504 was granted naming KC Inc as the proprietor for all designated EPC Contracting States and Mediscus as a proprietor for the United Kingdom only. Through a clerical error on the part of the EPO, '950 was granted naming KC Inc as the proprietor for all designated EPC Contracting States except the United Kingdom and Mediscus as sole proprietor for the United Kingdom. Subsequently, both KC Inc and Mediscus assigned their rights to the First Claimant.

89. I do not accept that the letter dated 8 April 1998 shows that it had always been intended that Mediscus should be a co-applicant in respect of any application for a European patent (UK). Nor do I accept that it shows that the applicants' intentions had changed since the PCT Application was filed. In my judgment it is more likely that, as counsel for KCI submitted, three years after the event Mr Woodcraft had forgotten the reason why Mediscus was named as a co-applicant.

90. For these reasons I conclude that Mediscus was not a co-applicant in respect of the PCT Application in so far as it related to the European patent, and hence the Patents. The sole applicant in respect of the PCT Application in so far as it related to the European patent, and hence the Patents, was KC Inc. Since KC Inc was entitled to claim priority from the Priority Document as successor in title to Mr Lina for the reasons given above, the Patents are entitled to the priority claimed.

Would it adversely affect the claim to priority if Mediscus was an applicant?

91. Although I have concluded that Mediscus was not an applicant, in case I am wrong about that, I shall consider whether it would adversely affect the claim to priority if Mediscus was a co-applicant with KC Inc.

92. In *Edwards v Cook* the priority application had been filed by three individuals as joint inventors. Only one of those individuals was employed by Cook. A PCT application was filed by Cook. At the time of filing the only interest Cook had in the invention was that it owned its employee's share by virtue of the employee's contract of employment. Cook did not acquire the interests of the other two applicants until some time later. In these circumstances Kitchin J held that Cook was not entitled to claim priority from the priority application. He noted that this conclusion was consisted with that reached by the EPO Technical Board of Appeal in Case T788/05 *Terumo KK/Vascular catheter* (unreported, 8 May 2007).

93. In *Terumo* a prior art patent (D1) had been filed in the name of Terumo and Tokin as co-applicants. Terumo then filed a later application (A) to the same subject matter and claimed priority from A. Terumo distinguished D1 by way of a disclaimer. The opponent argued that priority could only be claimed from D1 and not A. The Board of Appeal did not accept this argument. Since D1 was filed jointly by Terumo and Tokin, priority from D1 could only be claimed by Terumo and Tokin jointly. Terumo alone had no right to claim priority from D1.

94. At §2 of the reasons, the Board held that:

> "The term 'a person' in Article 87(1) EPC (or 'an applicant' in Article 88(1) EPC) implies that the applicant be the same for 'the first application' (or 'previous application in Article 88(1) EPC) and for the later application for which a priority right is claimed. The required identity for the applicants originates in that the priority right is part of the applicants right.
>
> In the case of D1 in which two co-applicants (Terumo and Tokin) are present, this means that the priority right belongs simultaneously and jointly to the two applicants, who thus constitute a legal unity unless one of them decides to transfer his right to the other applicant, who then becomes his successor in title and this before the filing of the later application. Since no evidence for such a transfer was submitted to the Board, D1, independently of the question of the same invention, could only serve as a basis for claiming a priority right for the filing of a later application designating both applicants. But since the present application was only filed by one applicant (Terumo), D1 could not represent the 'first application' within the meaning of Article 87(1) EPC."

95. Counsel for S & N also relied upon the decision of the EPO Legal Board of Appeal in Case J2/01 *Trustees of Dartmouth College/Divisional application* [2004] EPOR 54, a decision concerning the right to file a divisional application under Article 76 of the EPC and Article 4(G) of the Paris Convention. In that case the Board held that where an application had been filed jointly by two applicants, a divisional application could not be filed by one of them alone. In my judgment, however, this does not advance S & N's case any further than *Terumo*.

96. Counsel for KCI submitted that the present case was to be distinguished from *Edwards v Cook* and *Terumo* because in those cases the priority application had been filed by joint applicants and priority had been claimed by only one of them, whereas in the present case the priority application had been filed by a single applicant. He submitted that it was possible for a single priority applicant to share its rights to the invention with another person so as to entitle both to claim priority for a later joint application.

97. Counsel for S & N accepted that it was possible for a single priority applicant A to assign part of its interest in an invention to another person B with the effect that A and B were both successors in title to A and both entitled to claim priority for a later joint application. He submitted, however, that there was no evidence of any assignment from KC Inc to Mediscus in the present case.

98. Counsel for KCI accepted that he could not point to any written assignment, or even an oral agreement, but argued that the correct inference to be drawn from the circumstances surrounding the filing of the PCT Application was that KC Inc had agreed by conduct to transfer part of its interest in the invention to its subsidiary Mediscus. He submitted that this was sufficient to make Mediscus a successor in title for the purposes of claiming priority, and that no greater degree of formality was required. I accept that submission.

99. For these reasons I conclude that it would not adversely affect the claim to priority if Mediscus was held to be a co-applicant.

Conclusion

100. I conclude that the Patents are entitled to the claimed priority date.

The skilled team

101. 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, once and for all, she) reads it knowing that its purpose is to describe and demarcate an invention. He is unimaginative and has no inventive capacity.

102. By the end of the trial there was little dispute between the parties that the Patents were addressed to a team consisting of a clinician with experience of wound care and a design engineer with experience of designing medical devices. Although Mr Wood suggested that the skilled team would also include a medical scientist, this suggestion was not pursued by S & N. In any event, it became clear during Mr Wood's cross-examination that the presence of a medical scientist would not add anything material to the skilled team's knowledge and expertise.

103. Dr Téot gave unchallenged evidence, which I accept, that the skilled team would be led by the clinician. In particular, the decision as to what would constitute an appropriate wound dressing is squarely within the remit of the clinician. The mechanical properties of candidate materials would be a matter on which the clinician would take advice from the design engineer, but those considerations would be secondary to clinical concerns as to efficacy and safety.

Common general knowledge

104. As I have already said, the issue of common general knowledge is an important one in this case.

The law

105. The classic modern exposition of the law as to what constitutes common general knowledge is contained in the following repeatedly-cited passage from the judgment of Aldous LJ, building on earlier authorities, in *Beloit Technologies Inc v Valmet Paper Machinery Inc* [1997] RPC 489 at 494-495:

> "It has never been easy to differentiate between common general knowledge and that which is known by some. It has become particularly difficult with the modern ability to circulate and retrieve information. Employees of some companies, with the use of libraries and patent departments, will become aware of information soon after it is published in a whole variety of documents; whereas others, without such

advantages, may never do so until that information is accepted generally and put into practice. The notional skilled addressee is the ordinary man who may not have the advantages that some employees of large companies may have. The information in a patent specification is addressed to such a man and must contain sufficient details for him to understand and apply the invention. It will only lack an inventive step if it is obvious to such a man.

It follows that evidence that a fact is known or even well-known to a witness does not establish that that fact forms part of the common general knowledge. Neither does it follow that it will form part of the common general knowledge if it is recorded in a document. As stated by the Court of Appeal in *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co. Ltd*. [1972] R.P.C. 457, at page 482, line 33:

> ‘The two classes of documents which call for consideration in relation to *common general* knowledge in the instant case were individual patent specifications and `widely read publications'.
>
> As to the former, it is clear that individual patent specifications and their contents do not normally form part of the relevant *common general* knowledge, though there may be specifications which are so well known amongst those versed in the art that upon evidence of that state of affairs they form part of such knowledge, and also there may occasionally be particular industries (such as that of colour photography) in which the evidence may show that all specifications form part of the relevant knowledge.
>
> As regards scientific papers generally, it was said by Luxmoore, J. in *British Acoustic Films* (53 R.P.C. 221 at 250):
>
> > “In my judgment it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates. A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is

> generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art."

And a little later, distinguishing between what has been written and what has been used, he said:

> "It is certainly difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in the art."

Those passages have often been quoted, and there has not been cited to us any case in which they have been criticised. We accept them as correctly stating in general the law on this point, though reserving for further consideration whether the words "accepted without question" may not be putting the position rather high: for the purposes of this case we are disposed, without wishing to put forward any full definition, to substitute the words "generally regarded as a good basis for further action".'"

106. Another frequently-cited passage is from the judgment of Laddie J in *Raychem Corp's Patents* [1998] RPC 31 at 40:

> "The court is trying to determine in a common sense way how the average skilled but non-inventive technician would have reacted to the pleaded prior art if it had been put before him in his work place or laboratory. The common general knowledge is the technical background of the notional man in the art against which the prior art must be considered. This is not limited to material he has memorised and has at the front of his mind. It includes all that material in the field he is working in 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 or to help understand the pleaded prior art. This does not mean that everything on the shelf which is capable of being referred to without difficulty is common general knowledge nor does it mean that every word in a common text book is either. In the case of standard textbooks, it is likely that all or most of the main text will be common general knowledge. In many cases common general knowledge will include or be reflected in readily available trade literature which a man in the art would be expected to have at his elbow and regard as basic reliable information."

107. As Floyd J noted in *Teva UK Ltd v Merck & Co Inc* [2009] EWHC 2952 (Pat), [2010] FSR 17 at [101]-[103], there is room for argument as to whether common general knowledge has a territorial dimension. What if, for example, a particular fact was commonly known by those skilled in the art in the USA at the relevant date, but not by those skilled in the art in the UK? At one stage I thought that an issue of this kind was emerging in the present case. In the end, however, neither side argued for a territorial approach to the question of common general knowledge. Both counsel submitted that, to be common general knowledge, information must be generally known and generally accepted by the bulk of those working in the field in question.

108. In several cases, notably *Nutrinova Nutrition Specialties & Food Ingredients GmbH v Scanchem UK Ltd* [2001] FSR 42 (Pumfrey J), *Novartis AG v Ivax Pharmaceuticals UK Ltd* [2006] EWHC 2506 (Pat) (unreported, Pumfrey J), and *Ivax Pharmaceuticals UK Ltd v Akzo Nobel NV* [2006] EWHC 1089 (Pat), [2007] RPC 3 (Lewison J), account has been taken of information that, while it was not part of the skilled addressee's common general knowledge, would have been acquired by him as a matter of routine before embarking on the problem to which the patented invention provides the solution.

109. In *Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd* [2008] EWHC 2413 (Pat), [2009] RPC 4, Kitchin J quoted passages from Pumfrey J's judgments in *Novartis v Ivax* and *Glaxo Group's Patent* [2004] RPC 43 and commented at [40]:

> "It seems to me that a subtle but potentially significant point of principle emerges from these passages. I can readily accept that, faced with a disclosure which forms part of the state of the art, it may be obvious for the skilled person to seek to acquire further information before he embarks on the problem to which the patent provides a solution. But that does not make all such information part of the common general knowledge. The distinction is a fine one but it may be important. If information is part of the common general knowledge then it forms part of the stock of knowledge which will inform and guide the skilled person's approach to the problem from the outset. It may, for example, affect the steps it will be obvious for him to take, including the nature and extent of any literature search."

110. In the Court of Appeal in that case [2009] EWCA Civ 646, [2009] RPC 23, Jacob LJ quoted the passage I have cited from *Raychem* and commented at [25]:

> "Of course material readily and widely to hand can be and may be part of the common general knowledge of the skilled person – stuff he is taken to know in his head and which he will bring to bear on reading or learning of a particular piece of prior art. But there will be other material readily to hand which he will not carry in his head but which he will know he can find *if he needs to do so* (my emphasis). The whole passage is about material which the skilled man would refer to 'as a matter of course.' It by no means follows that the material should be taken to be known to the skilled man if he has no particular reason for referring to it."

111. He went on to quote what Kitchin J had said at first instance in the passage I have cited and observed at [27]:

> "I agree with that although I personally do not find the point of principle 'subtle'. It would be wholly subversive of patents and quite unfair to inventors if one could simply say 'piece of information A is in the standard literature, so is B (albeit in a different place or context), so an invention consisting of putting A and B together cannot be inventive.' The skilled man reads each specific piece of prior art with his common general knowledge. If that makes the invention obvious, then it does. But he does not read a specific citation with another specific citation in mind, unless the first causes him to do so or both are part of the matter taken to be in his head."

112. It follows that, even if information is neither disclosed by a specific item of prior art nor common general knowledge, it may nevertheless be taken into account as part of a case of obviousness if it is proved that the skilled person faced with the problem to which the patent is addressed would acquire that information as a matter of routine. For example, if the problem is how to formulate a particular pharmaceutical substance for administration to patients, then it may be shown that the skilled formulator would as a matter of routine start by ascertaining certain physical and chemical properties of that substance (e.g. its aqueous solubility) from the literature or by routine testing. If so, it is legitimate to take that information into account when assessing the obviousness of a particular formulation. But that is because it is obvious for the skilled person to obtain the information, not because it is common general knowledge.

The common general knowledge of the clinician

113. Dr Téot gave undisputed evidence as to the common general knowledge of the clinician at the priority date as follows.

114. *The treatment of wounds.* It was universally accepted that, in order to promote healing of any wound, the wound should be kept moist (but not wet) and free from infection. Infected material was physically removed from wounds by cleaning and/or debridement. Cleaning involved irrigation with saline, followed by removal of the fluid through use of swabs or aspiration. Debridement involved either a surgeon cutting away infected tissue with a scalpel (often quite extensively), or mechanical debridement where infected material was enmeshed in gauze and then ripped away. Antibiotics were then used to treat more extensive infections.

115. Moist wound healing was achieved through the application of dressings to retain moisture at the wound site. Dressings had to be changed frequently (one to four times daily) to prevent build-up of excess fluid and resultant tissue maceration. Frequent changes also prevented the dressing from becoming a focus for infection. Sometimes drainage would be used to remove excess fluid and infection.

116. Smaller wounds would heal naturally if kept moist and free from infection. Larger wounds required physical intervention to close them. Such wounds were typically closed using sutures, staples or skin grafts. When closing wounds, it was known to be important not to seal in infection. Infected material was removed before closure using

the methods described above. Sometimes a drain would be applied to the closed wound to drain fluids that might build up and become infectious.

117. There were a significant number of wounds that in 1994 could not be healed readily, either because they were simply too large (so that the forces applied to sutures or staples would tear the wound edges, and there would not be enough underlying material in the wound to support a graft) or because of other complicating factors. The leading technique for dealing with difficult-to-heal wounds at that time was microsurgery.

118. *Dressings.* Gauze was the most commonly used dressing material. It was used extensively in surgery to mop up fluids (before being discarded), and similarly in wound care to absorb fluid. Fluid would soak through gauze placed on wounds quickly, which meant that dressings had to be changed frequently. These gauze dressings were taped in place and/or secured with gauze bandages. Gauze would never be sealed into a wound using a plastic waterproof film for fear that this would seal in infection.

119. By 1994 new dressings were being introduced which were designed to retain moisture, albeit not too much, at the wound site. These included dressings made from alginates, hydrocolloids and foams. In specialist wound care centres, foam dressings were replacing gauze as the dressing of choice.

120. *Prep sponges.* "Prep" sponges were commonly used for swabbing patients' skin prior to operations. In addition, sterilised prep sponges were sometimes used as bolsters externally on top of skin grafts. Prep sponges were only medically approved for external use.

The common general knowledge of the design engineer

121. The two key issues on common general knowledge concern the knowledge of the design engineer forming part of the skilled team. To what extent, if at all, did reticulated foam and gel-forming substances form part of his common general knowledge?

122. As counsel for KCI pointed out, S & N's case underwent a subtle, but significant, shift during the course of the trial. In opening, S & N's case was that the design engineer would know of the existence and use in medical applications of such materials as part of his common general knowledge. In closing, S & N's case was that this was information that the design engineer would either already know or, if not, would find out when seeking to implement Argenta. For the reasons explained above, the latter way of putting the case is really an allegation of obviousness and not an allegation of common general knowledge. At this stage I shall focus exclusively on what was common general knowledge.

123. *Reticulated foam.* Reticulation is a process by which a very open-celled foam can be made by removing most of the cell walls so that only a net-like structure remains. Two different methods of reticulation were developed in the late 1950s. In the first method, referred to as "zapping", foam is placed in a pressure vessel, a combustible mixture of gases is introduced and then ignited so that the foam membrane is melted leaving only the skeletal structure intact. In the second method, known as

"quenching", the cell walls of the foam are dissolved in a caustic solution to leave only the skeletal structure.

124. Claim 5 of '504 and claim 8 of '590 both require a reticulated foam which has "at least 90% of interconnecting cells". This additional requirement is of no significance, since the evidence is that any properly conducted reticulation process will result in a foam which has at least 90% of interconnecting cells.

125. There is little doubt that reticulated foams were well known at least in some contexts by August 1994. The *Handbook of Polymeric Foams and Foam Technology*, edited by Daniel Klempner and Kurt C. Frisch, a textbook which was published in 1991, includes a short section on reticulated foams which states that they are used as "air filters in engine exhaust systems, fibrous heat insulation and damping materials, etc.".

126. Mr Wood's evidence was that he personally was familiar with reticulated foams by 1994, that they were used in many applications and that he would have expected engineers with a decent background in materials to know about them. Mr Buckley's evidence was that he was not 100% sure whether he was aware of reticulated foams by that name in 1994, but he was certainly aware of open-celled foams which he now knew were made by reticulation. Having regard to the *Handbook* and this evidence, I conclude that the *existence* of reticulated foams would have formed part of the design engineer's common general knowledge. Indeed, I did not understand counsel for KCI to dispute this. Where he parted company with counsel for S & N was over the question of whether the *use* of reticulated foam *in medical applications* was common general knowledge.

127. In his second report, Mr Wood said that reticulated foams had been used in a number of medical applications, mentioning autoclave bags for medical instruments, medical packaging, hand scrubs and prep sponges. He mentioned some additional applications for the first time during cross-examination, namely for foot plasters, for blood filters in heart-lung machines and for membranes in anaesthetic gas machines. Not all of these examples were put to Mr Buckley, but he did say that he was aware of the use of foams which he now knew to be reticulated in some medical applications, in particular for packaging. The conclusion I draw from this evidence is that the design engineer would be likely to have came across the use of reticulated foams in the medical context, but possibly only to a very limited extent. The only application in the medical context which I feel confident would have formed part of his common general knowledge was for packaging.

128. S & N rightly disclaimed any suggestion that the use of reticulated foam in wound dressings would have formed part of the design engineer's common general knowledge. I would go further than this: I am not satisfied that any use of reticulated foam in connection with the treatment of patients was common general knowledge. The closest instance is prep sponges, which were in fact made from reticulated foam, but although Mr Wood was aware of this, Mr Buckley was not. (As it happens, Dr Téot was also aware of this; but there is no suggestion that he was typical of clinicians in that respect.)

129. *Gel-forming substances.* Get-forming substances are substances which react with liquids to form a gel. In this way they absorb and immobilise liquids. They have the

advantage over older absorbers, such as fabrics, sponges and granular materials, that they can soak up much larger volumes of liquids.

130. There is no dispute that gel-forming substances were widely available by 1994 and were in use in a variety of applications such as disposable diapers (nappies) and other incontinence products. The issue is whether gel-forming substances formed part of the common general knowledge of the design engineer with experience of designing medical devices. A striking feature of the present case is that the evidence of the experts on this question was diametrically opposed.

131. Mr Wood's evidence was that he was well aware of gel-forming substances in 1994, in particular a spillage absorber with added disinfectant called SaniSorb which was used in PA Consulting's laboratories. His opinion was that gel-forming substances would have been well known to design engineers, and indeed to anyone who had worked a hospital or clinical development facility.

132. By contrast, Mr Buckley's evidence was that he was not aware of them. He thought that, if gel-forming substances were being used in the medical field, he would have come across them. At that time he was in operating theatres several times a year, if not several times a month, and had witnessed spillages on a number of occasions, but he had not witnessed the use of gel-forming substances. Instead, he had seen people use cloths to mop up the spillage and then dispose of the cloth. (He acknowledged, however, that he had not spent much time in hospital wards or waste disposal facilities.) Furthermore, Mr Buckley said that, when preparing his report, he had undertaken some research into the use of gel-forming substances in the medical field in the UK at that time, and found nothing. As a result, he stated in his report that, so far as he was aware, gel-forming substances were not in use in the medical field in August 1994. (For what it is worth, Dr Téot was not aware of them either.)

133. In my judgment, Mr Buckley's evidence shows that gel-forming substances were not common general knowledge amongst design engineers with experience of designing medical devices. As counsel for KCI submitted, that conclusion is reinforced when one considers the materials produced by S & N in an attempt to support Mr Wood's evidence.

134. In his first report, the only material which Mr Wood relied on to support his opinion was a short article about SaniSorb from the *Buffalo News* dated 27 December 1992. As counsel for KCI pointed out, this is one column inch in a 204 page local newspaper published in the area of upstate New York where the manufacturer of SaniSorb was based on the Sunday after Christmas. In cross-examination, Mr Wood said that this has been provided to him. I infer that it was located by means of an electronic database search, but there is no evidence as to the nature or extent of the search. Mr Wood also said that he only relied on the article to confirm his recollection that SaniSorb was available in 1994. He accepted that, if SaniSorb had really been widely known in 1994, then there was no way that this article and the one referred to below would be the only references to it.

135. In his second report, Mr Wood exhibited and summarised a number of patents which he had found by means of a patent search. He explained in cross-examination that this again was intended to confirm that gel-forming substances were available and had applications in the medical field in 1994. As counsel for KCI submitted, this is no

way to establish common general knowledge. Furthermore, the results are unimpressive. The highlight from S & N's point of view is a statement in United States Patent No. 5,091,433 published on 25 February 1992 ("Karakelle") at column 1 lines 45-50 that:

> "It has become common practice in the art to add a material to the canister to convert the liquid to solid or semisolid so that, if an accident should occur, any spill will be confined to the immediate area and cleanup will be quicker and safer.
>
> For this purpose, gelling agents have been used…."

This does not get S & N very far however. There is no evidence that the statement is correct – Mr Wood did not know whether it was. One does not know what Karakelle means by "common practice" or which art he is referring to – it may be the art of hazardous waste disposal. Karakelle goes on to refer to US Patent No. 4,748,069 as supporting the proposition, but it does not. Karakelle also refers to two commercial products, but there is no evidence that they were widely used.

136. In addition to the patents exhibited to Mr Wood's second report, S & N relied upon various articles admitted under a hearsay notice showing that (i) a number of brands of commercial gel-forming substances in addition to SaniSorb were available in 1994 and (ii) such substances were being promoted or suggested for use in hospitals or other clinical environments. Again, these materials are unimpressive. The highlights are short advertorials for SaniSorb and another product published in *Nursing 93* magazine in October 1993 and for a third product published in *Nursing Homes* magazine in September 1993, in each case for disposal of bodily fluids. All these show, however, is that such products were commercially available and being promoted for that application.

137. To my eyes, a remarkable feature of these advertorials, and almost all the other materials relied upon S & N, is that they only evidence availability and use of gel-forming substances in the USA. Apart from Mr Wood's personal experience, there is almost no evidence about the availability and use of such substances in the UK (or elsewhere in Europe).

138. I conclude that it has not been shown that gel-forming substances were part of the design engineer's common general knowledge.

Obviousness

139. A patent will be invalid for lack of inventive step if the invention claimed in it was obvious to a person skilled in the art having regard to the state of the art at the priority date. The familiar structured approach to the assessment of allegations of obviousness first articulated by the Court of Appeal in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 was re-stated by Jacob LJ in *Pozzoli v BDMO SA* [2007] EWCA Civ 588, [2007] FSR 37 at [23] as follows:

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

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

140. In both *H. Lundbeck A/S v Generics (UK) Ltd* [2008] EWCA Civ 311, [2008] RPC 19 at [24] and *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49, [2008] RPC 28 at [42] Lord Hoffmann approved without qualification the following statement of principle by Kitchin J at first instance in the former case:

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

The skilled team and their common general knowledge

141. I have identified the skilled team and their common general knowledge above.

Would the skilled team implement Argenta?

142. As noted above, the principal item of prior art relied on by S & N is Argenta. A threshold question raised by KCI before one gets to the details of the individual claims in issue is whether the skilled team would try to implement Argenta. KCI accept that the skilled team is deemed to have read Argenta properly, and in that sense with interest, but contend that the skilled team would not have proceeded to implement Argenta.

143. In support of this contention KCI relied on the evidence of Dr Téot. This was that, as at August 1994, clinicians were very sceptical about the proposals of Argenta and Morkywas, which had been the subject of a number of presentations by then. Dr Téot was cross-examined at some length on this point, and he explained why this was so in detail. It was not simply due to conservatism, it was because the proposals went against conventional thinking in the field.

144. In my judgment, Dr Téot's evidence establishes that the clinician forming part of the skilled team would have approached implementing Argenta with scepticism, but not that he would have declined to try it at all. This is for two reasons. First, Dr Téot's

evidence was that the examples in Argenta, and in particular examples such as example 7 (the treatment of an ankle osteomyelitic ulcer), were very striking and would be of significant interest to the clinician. Secondly, Dr Téot was not himself deterred from trying the Argenta technique. On the contrary, in November 1995 he became one of the first surgeons in Europe to use it. Dr Téot eloquently explained that he had done so as a last resort when other treatments of a particular patient had failed and in the face of opposition from his superior. Furthermore, as counsel for KCI pointed out, he was able to gain access to an early commercial sample of KCI's VAC device for the purpose. In my view, none of this detracts from the fact that, when circumstances warranted it, Dr Téot was prepared to try the technique. This was not because of any change in attitudes amongst clinicians between August 1994 and November 1995. Nor was Dr Téot unique in being prepared to try the technique before it gained more general acceptance. Others did too.

145. On the other hand, I consider that Dr Téot's evidence shows that a clinician who did decide to implement Argenta in August 1994 would have done so with considerable caution. In particular, he would have been very cautious about placing a foam dressing in the wound, since this ran directly counter to accepted practice. In my judgment this is an important factor when considering what dressing the skilled team would select in order to implement Argenta.

Obviousness of claim 5 of '504 and claim 8 of '950 over Argenta

146. As noted above, KCI do not seek to defend the validity of the broader claims of '504. Accordingly, KCI do not contend that, if the skilled team did decide to implement Argenta, it would take an inventive step on their part to arrive at apparatus having the features of claims 1 and 4 of '504. The issue is whether it would be obvious to construct apparatus falling within claim 5. As set out above, Argenta teaches the use of an open-celled foam as the dressing. The difference between Argenta and claim 5 is that claim 5 requires the use of a reticulated foam. Given that I have concluded that the skilled team would implement Argenta, the question is whether it would have been obvious to the skilled team to select a reticulated foam for use as the dressing. As KCI accept, the position is the same with regard to the validity of claim 8 of '950.

147. As I have already said, the choice of dressing would be squarely within the remit of the clinician, although he would take advice on the mechanical properties of candidate materials from the design engineer. For the reasons given above, the clinician would approach the task of implementing Argenta, and in particular the selection of the foam dressing, with great caution.

148. Dr Téot's evidence was that the clinician faced with the task of implementing Argenta would prefer to use gauze to foam even though Argenta taught use of the latter. As I have noted above, it would be contrary to accepted practice at that time to place foam in a wound, and in particular to leave it there for prolonged periods. Furthermore, the use of polyurethane foam in the body had attracted a very bad reputation as a result of problems connected with its use in breast implants. If pushed to use foam, however, the clinician would select one of the existing medically-approved foam dressings that were available at that time. Dr Téot was not aware of any foam dressing supplied by Fischer Scientific at that time, and none was identified by S & N. Two particular medically-approved foam dressings which were both commercially available and starting to be used more frequently by clinicians in 1994 were those sold under the

brand names Allevyn and Lyofoam. These foam dressings were designed to keep wounds moist and to avoid tissue ingrowth, in accordance with received wisdom. Lyofoam was made from open-celled foam. It is not clear from the evidence before me whether Allevyn was open–celled or not. Accordingly, a clinician following the direction of Argenta to use an open-celled foam would have selected Lyofoam or possibly Allevyn. Neither was made from reticulated foam.

149. Dr Téot gave two specific reasons in his report as to why the clinician would not have chosen a reticulated foam, neither of which was directly challenged in cross-examination:

> "As I state in paragraph 23 above, clinicians in 1994 were concerned with keeping wounds moist and free from infection. When treating wounds, they would have looked for dressings that retained fluid to achieve the former. They would have looked for a dressing that could be changed easily to achieve the latter. It would not have been desirable from a clinical perspective to use a material with an extremely open structure such as reticulated foam (which would not retain fluid and into which tissue would grow, increasing the difficulty and pain of removal) in wound care."

150. It was put to Dr Téot that an obvious choice of material was the foam from which prep sponges were made (namely, reticulated foam). His answer to this suggestion was unequivocal:

> "… in 1994 applying a prep sponge on a wound would have affected your career definitively. … I am sure of that.
>
> …
>
> The prep sponge has nothing to do with the inside of the body."

151. S & N's main case on obviousness was that the design engineer would propose use of reticulated foam because he would appreciate from reading Argenta that reticulated foam was suitable due to its mechanical properties, in particular because it was (i) uniform so as to allow uniform distribution of pressure and (ii) porous so as to allow oxygen to reach the wound and allow exudates to be removed, yet (iii) sufficiently rigid to prevent tissue ingrowth. Thus Mr Wood's evidence that reticulated foam was an obvious choice was based upon its mechanical properties. He ignored the clinical issues, however. Moreover, this evidence was tainted by hindsight, since Mr Wood had concluded that the foam needed to be very porous from reading '504. The cross-examination of Mr Buckley again related to the mechanical properties of reticulated foam, and its suitability for use in implementing Argenta from that perspective.

152. In my judgment this case does not get off the ground for two reasons. The first is that I have concluded that, although the design engineer would be aware of the existence of reticulated foam as part of his common general knowledge, he would not be aware of the use of reticulated foam in connection with the treatment of patients. It follows that, if the clinician asked the design engineer to propose suitable foams *for use as a wound dressing*, the design engineer would not be conscious of reticulated foam as

being a suitable material. S & N's case is really that it would nevertheless be obvious for the design engineer faced with the problem of finding an open-celled foam to implement Argenta to search for a suitable foam and to select reticulated foam as a result. In my view, however, the evidence does not establish that the design engineer would as a matter of routine carry out a search which would lead him to reticulated foam.

153. The second reason is that, as I have said, the skilled team would in any event have regarded the mechanical properties of the foam as secondary to its clinical suitability. Even if the design engineer had come up with the idea of using reticulated foam, the clinician would have rejected it for the reasons explained above.

154. Accordingly, I conclude that it was not obvious to employ reticulated foam as the dressing for use in NPWT apparatus within claim 5 of '504 and claim 8 of '950.

Obviousness of claim 7 of '950 over Argenta

155. Again, KCI do not seek to defend the validity of the broader claims of '950. Accordingly, KCI do not contend that, if the skilled team did decide to implement Argenta, it would take an inventive step on their part to devise a disposable canister for use in NPWT having the features of claim 1 of '950. The issue is whether it would be obvious to devise a canister falling within claim 7. That is to say, would it be obvious to include within the canister a gel-forming substance which is capable of immobilising drainage fluids?

156. The problem to which this invention is addressed is the problem identified in '950 at [0031]. This is to stop fluid in the canister splashing on to the cap which masks the outlet from the canister to the pump. No doubt one can regard this as a specific aspect of a more general problem of how to minimise splashing within, and leakage from, the container.

157. By contrast with the issue over reticulated foam, this issue falls mainly with the province of the design engineer. Mr Wood's evidence was that putting a gel-forming substance in the canister would be an obvious way to solve this problem. That evidence was based, however, on the premise that gel-forming substances were common general knowledge. By contrast, Mr Buckley's evidence was that there were a variety of other well-known and obvious solutions to the problem, such as the use of baffles or a porous material. That evidence was based on the opposite premise.

158. Given my finding that gel-forming substances were not common general knowledge, it follows in my judgment that it would not have been obvious to employ a gel-forming substance to solve this problem.

159. In his closing submissions, counsel for S & N advanced an argument to the effect that a design engineer faced with the problem of preventing splashing within, and leakage from, the disposable canister would research the available solutions, and thus come up with a gel-forming substance even if he was not already aware of it. In my judgment, however, the evidence does not establish that the design engineer would as a matter of routine carry out a search which would lead him to gel-forming substances.

160. Accordingly, I conclude that it was not obvious to include a gel-forming substance in a disposable canister in accordance with claim 7 of '590 starting from Argenta.

Obviousness of claim 7 of '950 over Karakelle

161. Karakelle was pleaded by S & N as prior art in unusual circumstances, and upon an even more unusual basis. As indicated above, Karakelle was found by Mr Wood during his patent search and exhibited to his second report. At that stage it was being relied upon by S & N solely in support of their case on common general knowledge. On the second day of trial, however, S & N applied to re-re-amend their Grounds of Invalidity to plead Karakelle as prior art against '950. After an adjournment for KCI to consider their position, it was agreed between the parties that S & N should have permission to plead Karakelle, but only on the basis that S & N would neither adduce any further evidence nor cross-examine either Dr Téot or Mr Buckley on Karakelle itself as opposed to its support for common general knowledge.

162. At column 1 lines 26-40, Karakelle describes the drainage of body fluids during surgery using "suction canisters", saying:

> "Each canister generally includes a flexible line or hose connected to [a vacuum source such as a pump] so that vacuum can be applied to the interior of the canister. Another flexible line or hose extends from the canister to the source of body fluids in the patient. Once the vacuum is applied, a negative pressure gradient is communicated through the interior of the suction canister so that body fluids are drawn into the canister."

163. Karakelle goes on at column 1 lines 41-44 to say:

> "Upon completion of the surgery, the canister containing the waste fluids must be discarded in a safe and environmentally sound way. This often requires storing and transporting canisters filled with liquids, a procedure fraught with the possibility of leaks and spills."

164. It is in this context that Karakelle says, as discussed in paragraph 135 above, that it is common practice to add a gelling agent to the canister to convert the liquid to a solid or semi-solid. It is clear from column 1 lines 55-56 that Karakelle is talking about the gelling agent being added to the canister after it has been filled with body fluids, not before.

165. The problem addressed by Karakelle is to avoid clumping when gelling agents encounter water. The invention described and claimed by Karakelle is the use of a particular gelling agent which includes a chemically-modified form of starch.

166. Thus Karakelle discloses the addition of gelling agents to suction containers which have been filled with body fluids. The main difference between Karakelle and claim 7 of '504 is that Karakelle does not teach adding a gel-forming agent to a canister for use in applying negative pressure to a wound before the canister is filled with fluid.

167. While Karakelle seems like a promising starting point for an obviousness attack on claim 7 of '504, the difficulty which S & N face is that, due to the manner in which Karakelle came into the case, there is simply no evidence that this would be an obvious step to take. While it may seem obvious to a lay person with the benefit of hindsight, the law is clear that expert evidence is almost invariably required to establish that an invention was obvious to the person skilled in the art at the relevant date: see *Mölnlycke AB v Proctor & Gamble Co (No 5)* [1994] RPC 49 at 113 (Sir Donald Nicholls V-C, as he then was) and *Panduit Corp v Band-It Co Ltd* [2002] EWCA Civ 465, [2003] FSR 8 at [19]-[20] (Aldous LJ).

168. The dangers of making a finding which is not based on expert evidence are illustrated by the fact that in the present case counsel for KCI submitted in his closing submissions that there were clinical reasons why it would not be obvious to take the step from Karakelle to claim 7. To that counsel for S & N replied there was no evidence from the clinical experts as to such reasons. If, however, Karakelle had been pleaded at the outset and so addressed by the experts in their reports, there might well have been such evidence.

169. I am therefore driven to the conclusion that S & N have not proved that claim 7 is obvious over Karakelle.

Construction and infringement

170. The task for the court when construing a patent claim is to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean: see *Kirin Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9 at [30]-[35]. In that case the list of principles to be found in the judgment of Jacob LJ in *Technip France SA's Patent* [2004] EWCA Civ 381, [2004] RPC 46 at [41] was approved subject to one point.

171. In the present case the questions of construction which arise all relate solely to issues of infringement, and not to validity. Furthermore, they are somewhat intertwined with those issues. I shall therefore follow the course taken by counsel in argument of dealing with the two sets of issues together, while bearing firmly in mind that the true construction of the claims cannot depend on the nature of the alleged infringements.

The allegedly infringing products

172. KCI allege that S & N have infringed the Patents by sales of systems called RENASYS GO and RENASYS EZ respectively. These systems each consist of a re-usable vacuum pump unit and a disposable canister. Purchasers will buy multiple canisters for use with each pump unit. Both systems are compatible with each of two different types of dressing kit sold by S & N, namely RENASYS-F, which comprises a reticulated foam dressing, and RENASYS-G, which comprises a gauze dressing.

Construction and infringement of '504

173. KCI allege that '504 has been infringed by sales of RENASYS GO pumps and canisters. There are two issues as to the construction of the claims of '504 which are relevant to this allegation.

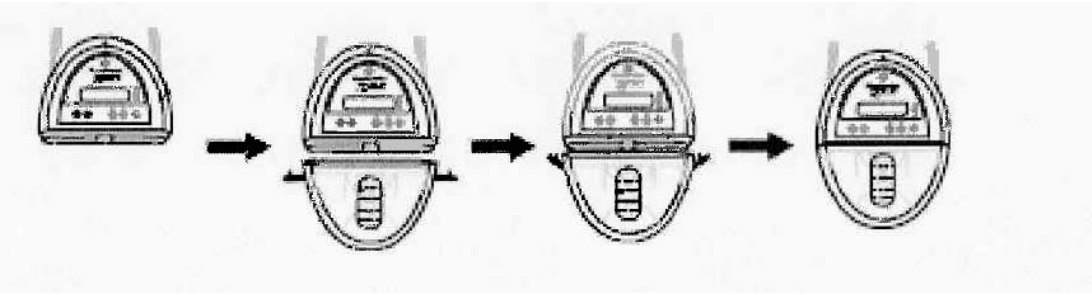
174. *Integer [8]*. Integer [8] requires "said canister and said housing having a guide for aligning the container in a recess in the housing such that the suction port is connected to the pump". The canister is the disposable canister for collecting fluids sucked from the wound first referred to in integer [5]. The housing is the housing which contains the suction pump first referred to in integer [4]. It can be seen from integer [8] that the canister is also referred to as the container. It can be seen from integer [6] that the canister has a suction port. Slightly confusingly, in the claim the term "suction port", denoted by reference numeral 52, refers to what the specification calls the "passageway" that provides the conduit for outlet 44, whereas the specification calls item 45 on the pump the suction port. The issue between the parties is as to the meaning of the words "in a recess in the housing".

175. It is common ground that integer [8] must be construed purposively, but the parties are divided as to its purpose. S & N focus on the requirement for a recess, and contend that the purpose of the recess is to ensure that the container (i.e. the canister) can be accommodated within, or mostly within, the housing so as to achieve a compact design. KCI focus on the requirement for a guide, and contend that the purpose of the guide is to align the canister and the housing so that (using the terminology of the claim, rather than the specification) the suction port of the canister is connected to the pump.

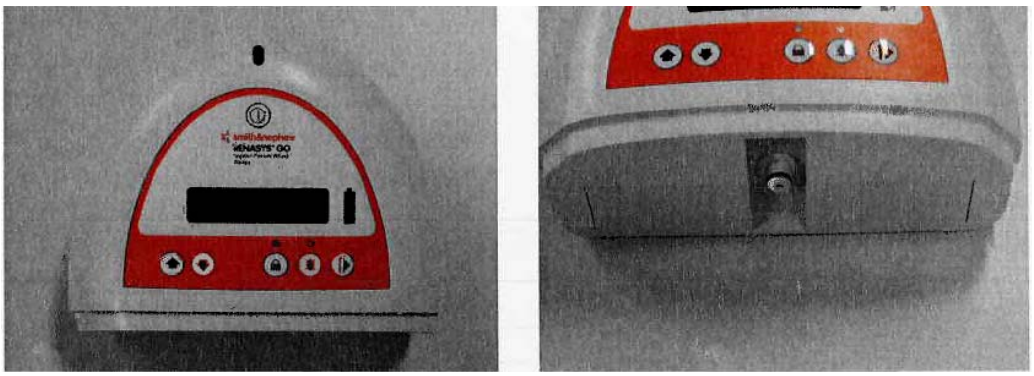
176. In support of their interpretation S & N point to the fact that the system is said at column 2 line 37 to be "convenient, compact and self-contained", to the fact that the specification uses the word "chamber" interchangeably with the word "recess" to describe item 18 and to the fact that there are several references in the specification to the canister being located, positioned or installed within the chamber. All that is true, but nevertheless I am not persuaded that the skilled reader would think that any importance attached to the canister being accommodated within the housing. The skilled reader would appreciate that the specification gives no technical reason why the canister should be accommodated within the housing, that in the specific embodiment the canister protrudes beyond the housing, and that a convenient, compact and self-contained design can be achieved in other ways.

177. By contrast, the skilled reader would appreciate both from the language of integer [8] itself and from the passage at column 6 lines 11-25 quoted in paragraph 24 above that the guide has an important function in ensuring that the canister is oriented vis-à-vis the housing so that the suction port is properly connected to the pump.

178. In the RENAZYS GO system the canister is not accommodated mostly within the pump housing. Instead, the canister is fastened to the side of the pump housing as shown in the following illustration:



179. KCI contend that the housing does have a recess, namely a peripheral recess round the side of the pump, which can be seen more clearly in the following photographs:



180. KCI also contend that the canister has a guide for aligning the container in this recess, namely a peripheral flange around the end of the canister which fits into the recess, and that the flange does align the canister with the housing so that the suction port is connected to the pump (via the nipple visible in the right-hand photograph which fits within a passageway on the canister).

181. Having regard to the purpose of integer [8] set out above, I accept that this integer reads on to the RENAZYS GO system in the manner contended for by KCI. Counsel for S & N submitted that the canister is not aligned "in" the recess, but the canister can fairly be described as aligned "in" the recess if integer [8] is not interpreted as requiring that most of the canister be accommodated within the recess. Counsel for S & N also submitted that, on KCI's case, the recess in the housing and the guide were the same thing. I disagree: the recess in the housing is the space into which the flange is received and the guide is the wall over which the flange slides. I would add that I have noticed when inspecting a sample of RENASYS GO system that there are in fact four small keys on the canister which mate with four keyways on the housing (two of the latter can just about be seen in the right-hand photograph above). In my judgment these clearly do amount to guides within the claim even if the wall does not.

182. *Integer [10]*. Integer [10] requires the presence of "means for detecting when the canister is substantially filled with liquid and generating a signal which causes the pump to be deactivated". The issue between the parties is as to the meaning of the word "deactivated".

183. Again there is a dispute as to the purpose of the integer. As can be seen from the final paragraph of the passage quoted in paragraph 28 above, the immediate purpose is to stop the canister being over-filled with body fluids. S & N contend that over-filling the container is to be avoided because it would be likely to lead to contamination of the pump. KCI contend that '504 teaches the reader that the filter protects the pump from contamination (see column 6 lines 43-52). In my view, it does not matter whether the skilled reader would think that the filter was the only way in which the pump is protected from contamination or whether he would think that integer [10] also helped to protect the pump.

184. S & N contend that the skilled reader would understand from the way in which the words "activated" and "deactivated" are used in the context of the specification that the patentee was using them to mean "switched on" and "switched off". In support of

this argument S & N rely in particular on the uses of those words in the passages quoted in paragraphs 27 and 28 above. S & N also pray in aid a judgment dated 23 October 2009 of the Landgericht Mannheim in Case No. 7 O 114/9 between the respective German affiliates of the parties. In that judgment the Landgericht dismissed KCI's claim that the GO system infringed the German counterpart of '504 on the ground that the requirement that the pump be deactivated was not satisfied. The Landgericht interpreted "deactivated" to mean what it described (in the translation provided to me) as "*definite* deactivation of pump motor [its emphasis]".

185. KCI contend that "deactivated" can refer to a state of reduced activity in which the pump is no longer actively pumping. KCI argue that this is sufficient to achieve the patentee's purpose. As to the decision of the Landgericht, KCI say that it is under appeal, and that the Landgericht does not appear to have considered a purposive interpretation of the word of the kind now advanced by KCI.

186. This is a classic issue of claim interpretation which I have not found easy to decide. I agree with S & N and with the Landgericht that, when describing the *specific embodiment* in the specification, the patentee appears to have used the words "activated" and "deactivated" to mean switched on and switched off. The key question, however, is how the skilled reader would understand the patentee to have been using the word "deactivated" to mean in the *claim*. The claim must, of course, be read in its context. On the other hand, it is not necessarily right to limit the scope of the claim to the specific embodiment. The verb "deactivate" can be used to mean either to render inactive or to render less active. As always, the touchstone is the technical purpose of the feature in question. The technical purpose here is to stop the canister being over-filled with fluid. The skilled reader would appreciate that that purpose can be achieved if the pump is rendered sufficiently less active that no more fluid is pumped into the canister. It is not necessary to achieve that purpose for the pump to be switched off. Accordingly, I conclude that KCI's interpretation is to be preferred.

187. Turning to the GO pump, this is controlled by a microprocessor. When the canister is full, the system detects that the vacuum level in the headspace is increasing and slows the pump motor down to below a predetermined (but unspecified) threshold level. After this, the pump just ticks over and no more liquid is pumped into the canister. In my judgment this amounts to the pump being deactivated as I have construed that term.

Construction and infringement of '950

188. KCI allege that '950 has been infringed by sales of S & N's RENASYS GO and RENASYS EZ canisters. There is one issue as to the construction of the claims of '950 which is relevant to these allegations.

189. *Integer [3]*. Integer [3] requires "said outlet incorporating a bacterial filter…". The outlet is the outlet for connection to the suction pump referred to in integer [2]. The issue here is the meaning of the word "outlet". S & N contend that the outlet must form part of the canister itself, so that the filter is located in the canister. KCI contend that the outlet can take the form of a length of tube, and hence the filter can be located anywhere along the length of tube.

190. It is common ground that the purpose of the bacterial filter is to protect the pump, as can be seen from paragraph [0038] quoted above. S & N contend that incorporating the filter in the outlet also meets two further objectives of the patentee. The first is to avoid the need for tubing from the canister to the pump. In support of this S & N rely upon the second sentence in the paragraph beginning "Although" quoted in paragraph 17 above. This merely says that it is desirable to avoid contamination of the pump and (non-disposable) tubing leading from the pump to the canister, however. It says nothing about the position of the filter. The second is to assist in making the apparatus small and compact. In support of this S & N point to a passage at column 3 lines 27-28 which says that the pump housing is small, compact and easily portable. It says nothing about the filter, however.

191. In my judgment there is no technical reason to interpret the word "outlet" as restrictively as S & N suggest. Accordingly, I prefer KCI's construction.

192. In the EZ canister the bacterial filter is located towards the end of a length of tubing which runs from the canister to the pump. I consider that the EZ canister does have an outlet incorporating a bacterial filter as I construe the claim.

The infringing acts alleged

193. In addition to the issues which turn on the construction of the claims, there are two issues concerning the infringing acts alleged against S & N.

Infringing acts in relation to claim 5 of '504 and claim 8 of '950

194. An issue on infringement of claim 5 of '504 and claim 8 of '950 arises out of the fact that, as KCI accept, a combination of pump, canister and gauze dressing does not fall within claim 5 of '504 and a combination of canister and gauze dressing does not fall within claim 8 of '950. KCI nevertheless allege that S & N's sales of pumps and canisters are infringing acts pursuant to section 60(2) of the Patents Act 1977.

195. Section 60(2) provides:

> "Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom."

196. Counsel for KCI submitted, and counsel for S & N did not dispute, that both the pumps and canisters constitute "means, relating to an essential element of the invention, for putting the invention into effect" and are "suitable for putting … the invention into effect". The issue therefore is whether at the time of the supplies in

question S & N knew, or it was obvious to a reasonable person in the circumstances, that the pumps and canisters were "intended to put the invention into effect".

197. As to that, KCI alleged in their Particulars of Infringement, and S & N admitted in their Defence, that S & N were marketing (i) the GO pump, GO canisters and both RENASYS-F foam and RENASYS-G gauze dressing kits and (ii) the EZ pump, EZ canisters and both RENASYS-F foam and RENASYS-G gauze dressing kits, in each case "together and/or separately but for use with each other". Furthermore, the manuals supplied with the GO and EZ systems both contain sections describing the "foam dressing application" as well as the "gauze dressing application".

198. The question which arises both here and in relation to the issue with regard to infringement of '950 discussed below is who must intend to put the invention into effect. Counsel for S & N argued that it was the supplier. Counsel for KCI argued that it was the person supplied or the user if different. Neither counsel suggested that it was necessary in this case to distinguish between the person supplied and the user if different, and so I will concentrate on the former.

199. In *Cranway Ltd v Playtech Ltd* [2009] EWHC 1588 (Pat), [2010] FSR 3 Lewison J held that an infringement was only committed under section 60(2) if the person supplied, as opposed to a user further down the supply chain, intended to put the invention into effect. In that case the claimant argued that the relevant intention could be that of the user, while the defendants argued that it had to be that of the person supplied. Neither party argued that the relevant intention was that of the supplier. It follows that Lewison J did not have to decide the precise point which arises in the present case. Nevertheless his reasoning at [156] is relevant to it:

> "Whether means are *suitable* for putting an invention into effect must be a purely objective test. But whether they are *intended* to put an invention into effect cannot be wholly objective. Only human beings can have intentions, although their intentions may be attributed to other legal persons, according to rules of attribution. Thus this limb of the test must depend on the subjective intention of someone. A supplier of essential means might reasonably be supposed to know what the intention of his immediate counter-party is. But it would be a far stronger thing to expect him to discern the intention of a person far down the supply chain. Moreover, at the time of the supplier's supply of the essential means the person who ultimately forms the intention to use the means to put the invention into effect may not be ascertainable and he may not have formed that intention. It thus seems to me to be more likely that s.60(2) was directed to a supply of essential means to a direct infringer rather than to another secondary infringer…. "

200. It is implicit in this reasoning that the relevant intention is not that of the supplier. In my judgment this is correct. Section 60(2) makes it clear that there can be infringement not merely if the supplier knows that the means are intended to put the invention into effect, but also if that would be obvious to a reasonable person in the circumstances. That is inconsistent with a requirement of intention on the part of the supplier. Thus the relevant intention must be that of the person supplied.

201. In the present case the persons supplied will begin by purchasing a combination of a pump, one or more canisters and one or more dressing kits. Thereafter they will purchase further quantities of both canisters and dressing kits. (It is possible that very occasionally a purchaser might buy a pump on its own for use with previously purchased canisters and dressing kits, but for present purposes I think that that possibility is sufficiently remote to be disregarded.)

202. There is no direct evidence as to what kinds of dressing kits purchasers buy or why. As noted above, S & N market both the GO and EZ pumps and canisters for use with both foam and gauze dressings which they also market. It appears to me from the following passage in the manuals that the decision as to whether to use a foam or gauze dressing lies with the medical professional treating the patient and will depend on the nature of the wound:

> "Prior to placement of RENASYS GO [EZ], the medical professional healing the wound must assess how to best use the system for an individual wound. It is important to carefully assess the wound and patient to ensure clinical indications for Negative Pressure Wound Therapy (NPWT) are met.
>
> All orders should include:
>
> - Wound location, size and type
> - Smith & Nephew Wound Dressing Kit type
>
> ..."

203. In the absence of direct evidence, I infer that pumps and canisters are purchased by medical institutions with the intention that they may be used with either foam or gauze dressings as appropriate, depending on both the individual preferences of their medical professionals and the nature of the wounds presented.

204. I also infer that S & N knew this, or at the very least it would have been obvious to a reasonable person in the circumstances, at the time that S & N made the sales in question.

205. That is sufficient for a finding of infringement. It is not necessary for me to decide, and I do not consider that I am in a position to decide, whether all sales of GO pumps and canisters and EZ canisters would infringe on this basis. It remains arguable that some might not, in particular if there are certain purchasers who always use gauze dressings. That is a matter to be explored on an inquiry or account.

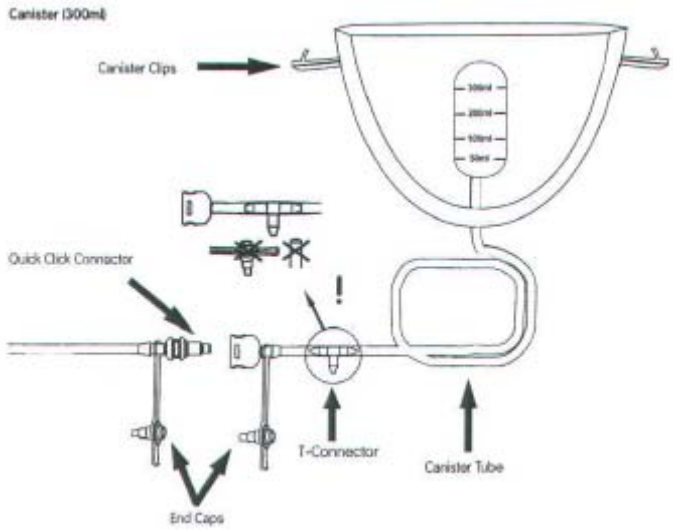
Infringing acts in relation to claims 7 and 8 of '950

206. An issue on infringement of claims 7 and 8 of '950 arises out of the fact that it is common ground that the GO canister as sold by S & N does not include clamp means on the inlet tube as required by integer [4]. KCI nevertheless allege that S & N's sales of canisters are infringing acts pursuant to section 60(2).

207. The basis for this allegation is rather different to that relied upon by KCI with regard to the foam dressing. KCI do not allege that S & N market the GO for use with a

clamp means on the inlet tube. It is not suggested, for example, that the manual recommends, or even mentions, use of a clamp on the inlet tube. By contrast, the manual does recommend that the end of the dressing tube be clamped. The basis for the allegation is that, notwithstanding the absence of any instruction or suggestion to do so by S & N, it is probable that at least on some occasions users of the GO canister will close the inlet tube with a clamp.

208. In considering this allegation, the starting point is the GO canister as supplied by S & N. This includes a length of tubing which terminates in the female half of a quick connector. The end of the tube is also equipped with an end cap. Near the end there is a T-connector:



209. KCI rely on evidence from Dr Téot that it is common practice to clamp tubes when changing canisters used for collecting fluids drained or sucked from wounds, and hence medical personnel would be very likely to clamp the tube when changing the GO canister in order to stop the fluid escaping before the tube was capped. It was put to Dr Téot in cross-examination that the T-connector was a bleed valve and that the vacuum in the tube would prevent fluid escaping. As counsel for KCI pointed out, however, there are two problems with this proposition. First, there is no evidence that the T-connector is a bleed valve. Dr Téot did not even know what the English expression "bleed valve" meant. Secondly, the manual tells the user to switch the pump off before disconnecting the tube to change a full canister. In those circumstances there would be no vacuum to stop fluid escaping.

210. Mr Wood pointed out that the purpose of the end cap supplied with the GO canister was to stop fluid escaping. He accepted in cross-examination, however, that there was risk of fluid escaping before the cap could be fastened and that some medical staff might well apply a clamp to avoid that risk.

211. In the light of this evidence I find that it is probable that from time to time some medical personnel using the GO system have clamped the end of the inlet tube when changing the canister. Moreover, I consider that it would have been obvious to a reasonable person supplying GO canisters that this would be likely to occur.

212. Importantly, however, the effect of the evidence is that, when medical personnel did this, they will have done it on their own initiative when faced with the need to change a filled canister without risking the escape of fluids. There is no evidence that GO canisters have been purchased by medical institutions with the intention that the canisters should be used in conjunction with a clamp on the inlet tube.

213. In my judgment it follows that S & N have not committed an infringement under section 60(2), because at the time the means in question were supplied they were not "intended to put the invention into effect". The invention has only been put into effect, on the occasions it was, as a matter of happenstance after the means were supplied.

Conclusions

214. For the reasons given above I conclude that:

i) the Patents are entitled to the priority date claimed;

ii) S & N's attacks on the validity of claim 5 of '504 and claims 7 and 8 of '950 fail;

iii) S & N's GO and EZ pumps and canisters fall within the scope of the relevant parts of claim 5 of '504 and claims 7 and 8 of '950;

iv) S & N have infringed claim 5 of '504 by sales of the GO pumps and canisters;

v) S & N have infringed claims 7 and 8 of '950 pursuant to section 60(2) by sales of the EZ canisters, but not by sales of the GO canisters.