

IN THE HIGH COURT OF JUSTICE
COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION (PATENTS COURT)
The Hon Mr Justice Arnold
[2010] EWHC 1487 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 18/11/2010

Before:
THE RT HON LORD JUSTICE LONGMORE
THE RT HON LORD JUSTICE JACOB
and
THE HON MR JUSTICE KITCHIN

Between:

- (1) KCI Licensing Inc
(2) KCI Medical Resources
(3) KCI Medical Limited

Claimants/
Respond-
ents/
Appellants
by cross-
appeal

- and -

- (1) Smith & Nephew plc
(2) Smith & Nephew Inc
(3) Smith & Nephew Medical Limited
(4) Smith & Nephew Healthcare Limited

Defendants/
Appellants/
Respond-
ents to
cross-
appeal

Michael Tappin QC and Henry Ward (instructed by Olswang LLP)
for the Claimants/Respondents
James Mellor QC and Andrew Lykiardopoulos (instructed by Bristows)
for the Defendants/Appellants

Hearing dates: 18/19 October 2010

Judgment

Lord Justice Jacob:

1. This is the judgment of the Court.
2. By the judgment under appeal, [2010] EWHC 1487 (Pat), Arnold J held that S&N (as we will call all the defendants) have infringed KCI's (as we call the claimant patentees) EP (UK) patents Nos. 0 777 504 ('504) and 0 853 950 ('950) (collectively "the Patents"). The Patents are for apparatus to be used for negative pressure wound therapy ("NPWT"). '950 is a divisional of '504. They have the same priority date (22.8.1994) and virtually the same specification.
3. More specifically the judge held:
 - 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 failed;
 - 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 pursuant to section 60(2) of the Patents Act 1977 by sales of the GO pumps and canisters;
 - v) S&N have infringed claims 7 and 8 of '950 pursuant to section 60(2) of the Act by sales of the EZ canisters, but not by sales of the GO canisters.
4. The judge gave permission to appeal on all these points save for the obviousness points. S&N have not pursued an appeal on priority and, at a late stage, abandoned their appeal against the finding of infringement in respect of the EZ canisters.
5. The issues we have to decide are:
 - i) Does the GO system infringe claim 5 of '504 and, in particular, does it have:
 - a) "means for detecting when the canister is substantially filled with liquid and generating a signal which causes the pump to be deactivated", and
 - b) "a guide for aligning the container in a recess in the housing such that the suction port is connected to the pump"?
 - ii) Were sales of the GO canisters intended to put the inventions of claims 7 and 8 of '950 into effect within the meaning of section 60(2)?
 - iii) In relation to obviousness:
 - a) whether it was obvious in 1994 to use reticulated foam as the dressing for NPWT - the invention of claim 5 of '504 and claim 8 of '950. S&N sought permission to appeal.

- b) whether it was obvious in 1994 to put a gel-forming substance in the canister to prevent spillage of liquid – the invention of claim 7 of ‘950. Again, S&N sought permission to appeal.

Applicable legal principles

6. It is not contended that the judge misstated the law. He accurately set out the law as to common general knowledge (“cgk”) at [105]-[112]. It is worth re-repeating what he said about information which is available but not immediately in the head of the notional skilled person:

[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.

7. As to obviousness, the judge stated the principles at [139]-[140]. Neither side quarrels with that. As to claim construction, again there is no dispute as to the principles, the judge having properly referred to them at [170]-[171].
8. All we need to add are two matters concerning the approach on appeal, both of which were also uncontroversial. First there is the well-known approach of the Court of Appeal as to appeals on obviousness, the so-called *Biogen* principle, namely that:

Where the application of a legal standard such as negligence or obviousness involves no question of principle but is simply a matter of degree, an appellate court should be very cautious in differing from the judge’s evaluation *per* Lord Hoffmann in *Biogen v Medeva* [1997] RPC 1 at p.45

9. Secondly there is the approach of the Court of Appeal to questions of fact. The Court will only interfere with a finding of fact by a judge where there was no proper material upon which the finding could be based – the legal term for this is “perverse” although in this context the word does not carry with it the overtone of personal criticism which it is apt to carry in other contexts.

The skilled team, prior art and common general knowledge

10. The skilled team to which the Patents are addressed includes a clinician and a design engineer but the team would be led by the clinician. The clinical evidence was given

by KCI's expert, Dr Téot, whose first language was not English. The engineering evidence was given by Mr Wood for S&N and Mr Buckley for KCI. S&N chose not to call their own clinical expert, Dr Gordon.

11. The Patents present the inventions as improvements over the disclosure of a prior published patent application called "Argenta" (WO 93/09727). The judge sets out material passages of this at [8]-[14]. The basic idea is to treat large open wounds by the use of a screen over the wound, covering this with a larger material such as a flexible polymer sheet so to provide a seal and applying a vacuum. The vacuum increases the blood flow which speeds up healing.

12. Argenta says this about the screen which is applied to the wound:

"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 [sic] 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." (8₃₋₁₉).

13. As to the vacuum means, all Argenta says is this:

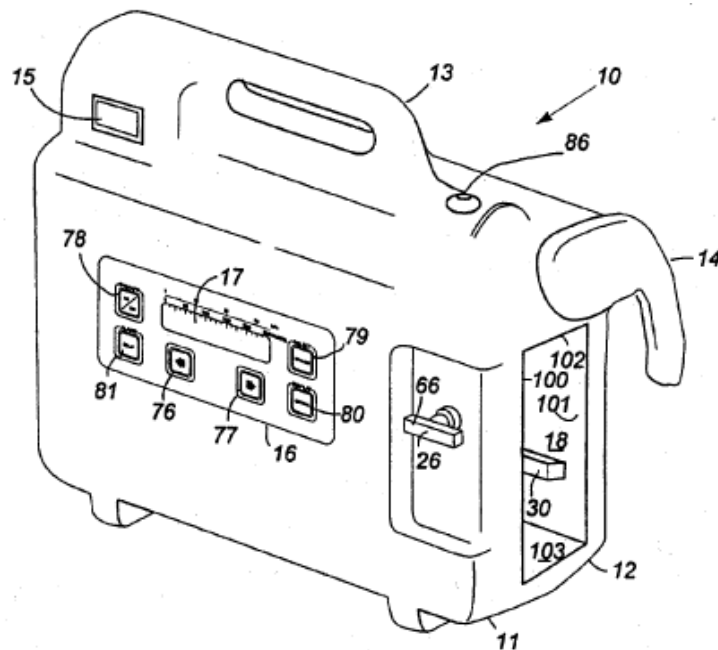
"Suitable vacuum means includes any suction pump capable of providing at least 0.1 pound suction to the wound, and preferably up to 3 pounds suction, and most preferably up to 14 pounds suction, and a flexible hose that leads from the pump to a point within the pressurized volume created by the sealing 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." (8₃₆₋₉₁₃).

Patent '504

14. The judge sets out all the material portions of this at [15]-[32]. Because the issues of construction and infringement involve no question of principle we will not lengthen

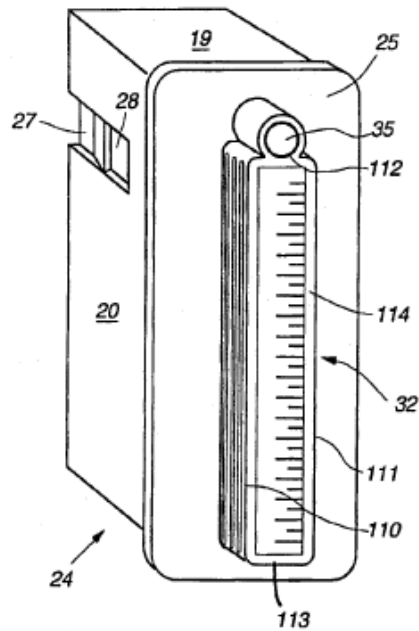
this judgment by setting them out all over again in detail. We will confine ourselves to the figures and passages relevant to the issues as we get to them.

15. In summary, the main idea of the patent as set out in claim 1 is to use a disposable canister and tubing to collect exudate from the wound. This prevents any contamination of the pump. KCI do not resist the contention that that idea is old or obvious so that the main claims of the patents are not valid. But, say KCI, certain of the sub-claims of the patents are valid and infringed. In particular we are concerned with claim 5 of '504 and, in due course, claims 7 and 8 of '950.
16. The specific embodiment of the pump apparatus looks like this:

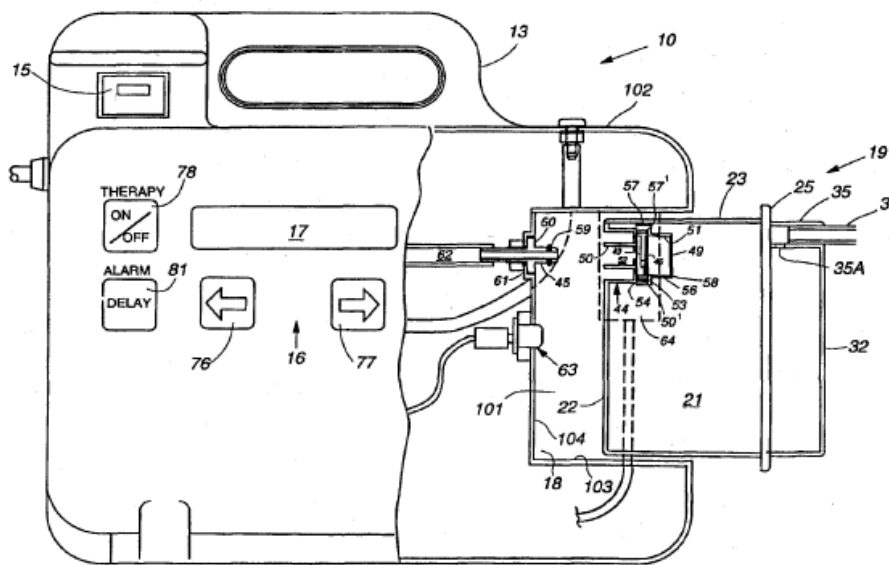


The removable canister slides into the aperture on the right.

17. The canister looks like this:



18. One can see the canister fitted into the chamber in fig. 6:



It does not go wholly in – part sticks out.

19. The specification, before it gets to the specific embodiment, says this about the canister and body:

“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.” (158-27).

20. The patent teaches something about control of the pump speed so as not to allow the pump to apply too much vacuum to the wound. It says this:

“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.” (11₃₆₋₅₂).

Note that the passage is also concerned with what happens if the desired pressure is not reached (in the example after 5 minutes). The motor is “deactivated” and an alarm sounded. Clearly here and in all other contexts in the body of the specification, as the judge accepted, “deactivated” means switched off.

21. The specific embodiment is fitted with a means to operate when the canister is “completely filled”. The specification says this:

“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.” (12₇₋₁₄)

22. We can now turn to the claims of ‘504 relevant to this appeal. Claim 1, broken down into elements, reads 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.

23. Claim 4 adds the element:

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

24. Claim 5 adds the element:

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

25. KCI did not seek to defend the validity of claim 1. It was only claim 5 which was said to be independently valid (the dependent claim 6 was also said to be valid but it was agreed it stands or falls with claim 5). All the issues of claim construction and whether the S&N GO system falls within the claims as properly construed, turn on elements of claim 1, namely elements [8] and [10].

Patent '950

26. As in the case of '504, KCI did not seek to defend the validity of the broader claims of '950. The only claims upon which they relied were claims 7 and 8. Claim 7 is dependent on claim 1. Broken down into elements, claim 1 reads:

[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.

27. Claim 7 adds the element:

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

28. 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.

Issue (i)(a) – The meaning of element [10] of ‘504 and does the GO device fall within that meaning?

29. Element [10] of ‘504 calls for a “means” for three things, (1) *detecting ...* (2) *generating a signal* and (3) *which causes the pump to be deactivated*.

30. Mr James Mellor QC for S&N contends that GO has none of these means. Mr Tappin QC for KCI objected to Mr Mellor taking all of these points. He said that counsel for S&N below (not Mr Mellor) had conceded that the first two elements were present. He showed us the transcript, which he said showed that. We do not think it clearly shows the suggested concession. The discussion was about the fact that the GO device is set to sound an alarm when the motor speed falls below a predetermined level.

31. Furthermore, all three points were clearly taken in the Amended Grounds of Appeal (“the GO product has no means for detecting when the canister is substantially filled, does not prevent over-filling of the canister and the pump is not deactivated”) and in S&N’s skeleton argument. Moreover, Mr Tappin only raised his objection after Mr Mellor had fully opened his appeal and developed all three points. Finally we can see no prejudice to KCI if the points are taken now, even if they were not so fully developed below. There is nothing in Mr Tappin’s objection.

32. The judge held that the requirement of “deactivation” was satisfied if the pump ceased to pump fluid for whatever reason. He differed from the Landgericht, Mannheim on this point (Case No. 7 O 114/9). S&N contend that was wrong, that if the pump stops pumping fluid into the canister for the simple reason that the canister is full, that is not “deactivation” as called for by the claim.

33. We agree. The specific embodiment of the patent shows the sort of thing contemplated by the element. It has an actual detector. It detects when the fluid has reached a certain level and sends a signal which switches the pump motor off. Nothing like that happens with the GO device. The way GO works is quite different. The apparatus is set so as to achieve a pre-set negative pressure and the motor is turned on. The motor causes the pump to operate. The pressure is detected and the motor speed controlled so as to maintain the pre-set pressure. It continues to operate at all times, keeping the pressure at the pre-set level. As the canister fills up, the head of air diminishes until the canister is completely full. The motor slows down as the canister fills. When it is full the motor slows right down but does not stop. It continues to maintain the originally set negative pressure – which by then is only on the other side of the filter. For by then the fluid will be wetting the filter and it is only the filter which prevents fluid from being sucked through into the pump. By contrast in the device of the specific embodiment, the pump motor is simply turned off. That is what “deactivated” in the claim means.
34. Moreover the GO device has no relevant “full” detector at all, that is to say no detector which responds to a full condition so as to deactivate the pump. It does have a detector which detects when the motor speed falls below a pre-set level. But all that detector does is to sound an alarm. It does not cause any change in the operation of the pump or its motor.
35. One is reinforced in this view by consideration of the way the patentee uses “deactivated” in other parts of the specification, for instance the passage about what happens if the necessary negative pressure is not achieved within 5 minutes. The pump is turned off. There are other passages, listed in S&N’s skeleton argument, which also show that “deactivated” means turned off.
36. The judge considered that the purpose of the element was to “stop the canister being over-filled with fluid” at [186]. And so it is. So the element should, using purposive construction, be construed as limited to a means which does just that. There is nothing in the GO device which stops over-filling. The canister fills to the brim. It fills no more because there is no room, not because the pump is deactivated.
37. Accordingly we think the judge erred in relation to element [10] of claim 1. The GO device is not within it.

Issue (i)(b): The meaning of element [8] of ‘504 and does the GO system fall within it?

38. Element 8 of ‘504 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.” Although it uses “container” that obviously means “canister”, not least because there is no antecedent for “container.”
39. In the specific embodiment of the patent, the canister goes partially inside a recess, as shown in the pictures. The judge held that the claim was not limited to the case where the canister is wholly or partially accommodated by a recess in the housing. It was sufficient if the housing had something which could be called “a recess” and the canister fitted over that. What really mattered was a guide for aligning the canister so that the suction port is connected to the pump, that being the real purpose of the integer.

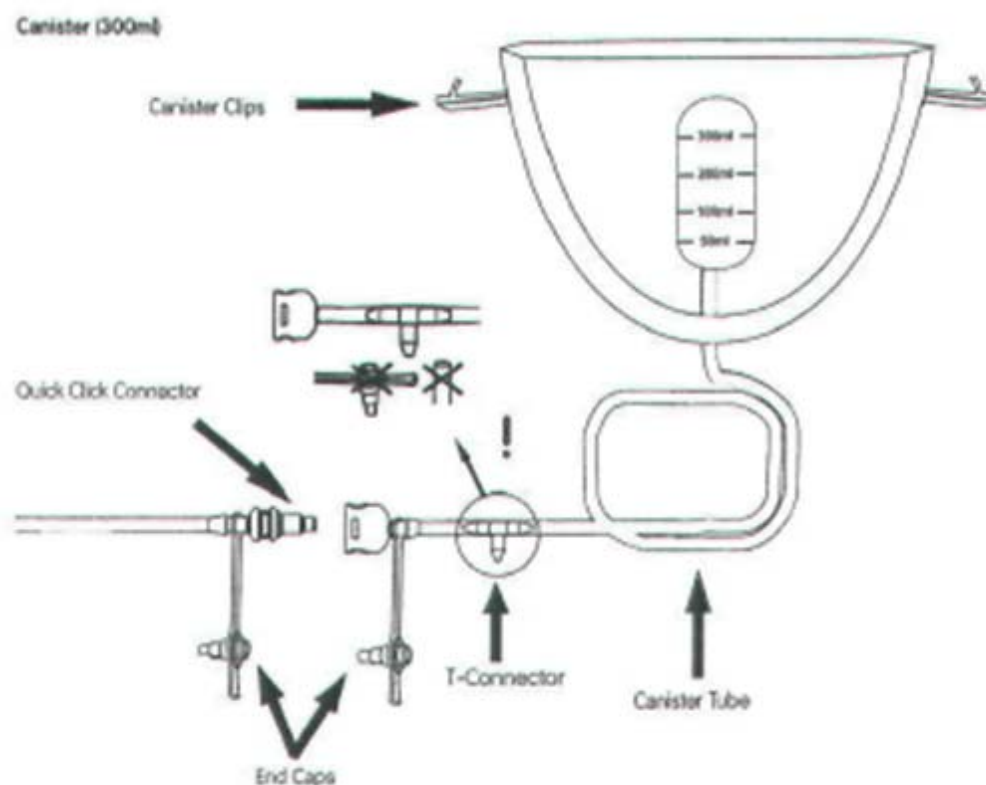
40. The housing of the GO device has a small rebate running around the portion where the canister is fitted. The canister fits snugly over this rebate (aided by some small guides described by the judge at [181]) so as to connect the suction port to the pump.
41. Accordingly the judge held that the GO device complied with element [8]. We do not agree. The claim requires a “recess in the housing” and that the “container” be aligned “in” (our underlining) that recess. The language of the claim simply does not extend to a case where the container is fitted over the housing, even if the “rebate” can properly be called a “recess” at all, which we doubt. As Mr Mellor put it, the recess in the GO device is in the canister and the housing is aligned in that. Although the purpose of the claim (connection) is achieved, it is achieved in a different way from that called for by the claim.

Issue ii) – Were sales of the GO canister intended to put the invention of claims 7 and 8 of ‘950 into effect?

42. The issue arises because it was common ground that the GO canister as sold by S&N does not include a clamp means on the inlet tube as required by integer [4] of claim 1. So KCI alleged indirect infringement under s.60(2). This reads:

"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."

43. KCI contended at trial that S&N knew or it was obvious to a reasonable person in the circumstances that the GO canisters were intended to put the invention into effect by hospital practitioners adding a clamp to the tube to avoid the risk of leakage. S&N countered that the tube had a stopper or end cap which was to be used to close it off after disconnection. So the GO system dealt with the problem of leakage in a different (and better) way.
44. The arrangement is shown below, with the inlet tube identified as the “Canister Tube”.



45. The judge made the following findings of fact at [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.”

46. These findings are the subject of a respondent’s notice. S&N say that if the judge meant only that the possibility of some practitioners adding a clamp could not be ruled out, then the findings might not be objectionable. If, on the other hand, the judge was holding that there was more widespread use of clamps with the GO product and that it was therefore obvious to S&N that their product was intended to be used with a clamp, then the evidence did not support such a finding.
47. In our judgment it is plain that the judge was not considering speculative, maverick or unlikely use. Moreover that finding was inevitable on the evidence before him.
48. Dr Téot said this in paragraph 93 of his report:

“...I understand the GO canisters are only provided with a cap and are not provided with a separate clamp. I have explained the importance of disposing of infected material safely. Without a clamp on the tube, fluid could and would be likely to

seep out before that tube was capped. This would lead to infected material potentially being spread around the hospital or treatment environment. In my view, given that clamps are cheap and very easily available in hospitals, it is overwhelmingly likely that a large number of hospital practitioners using the GO device would add a clamp to the tube. Indeed, as I described in paragraph 77 above, clamping tubes when changing a canister has been routine practice in hospitals for many years. I believe that anyone selling that device would be aware of that likelihood.”

49. As the judge recorded at [209], this met only limited challenge:

“..... 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. ”

50. Further, although Mr Wood said that the point of the cap was to stop fluid escaping, he accepted in cross examination there was a risk of that happening before the cap could be fastened and that some medical staff might well apply a clamp to avoid that risk. Moreover S&N knew it was being said that some nurses would clamp – if that was unlikely they surely would have been able to call someone like a nurse to say that clamping would never happen.

51. The judge nevertheless rejected the allegation of infringement. He reasoned at [212]-[213]:

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. ”

52. It seems the judge here drew a distinction between the persons supplied (the medical institutions) and the actual users (the medical personnel). The claim failed because, at

the time of supply, the medical institutions (including their staff) had no intention to put the invention into effect because they had not, at that stage, decided to use clamps. That decision was only made at the time the devices were actually used.

53. After the decision of the judge and shortly before the hearing of this appeal, this Court gave judgment in *Grimme v Scott* [2010] EWCA Civ 1110 and clarified the scope and proper interpretation of s.60(2), including the requirement of knowledge. So far as relevant to this appeal, it held:
- i) The required intention is to put the invention into effect. The question is what the supplier knows or ought to know about the intention of the person who is in a position to put the invention into effect – the person at the end of the supply chain, [108].
 - ii) It is enough if the supplier knows (or it is obvious to a reasonable person in the circumstances) that some ultimate users will intend to use or adapt the “means” so as to infringe, [107(i)] and [114].
 - iii) There is no requirement that the intention of the individual ultimate user must be known to the defendant at the moment of the alleged infringement, [124].
 - iv) Whilst it is the intention of the ultimate user which matters, a future intention of a future ultimate user is enough if that is what one would expect in all the circumstances, [125].
 - v) The knowledge and intention requirements are satisfied if, at the time of supply or offer to supply, the supplier knows, or it is obvious to a reasonable person in the circumstances, that ultimate users will intend to put the invention into effect. This has to be proved on the usual standard of the balance of probabilities. It is not enough merely that the means are suitable for putting the invention into effect (for that is a separate requirement), but it is likely to be the case where the supplier proposes or recommends or even indicates the possibility of such use in his promotional material, [131].
54. It follows the judge misdirected himself on the law. There is no requirement that the ultimate users must have decided to use the means to put the invention into effect at the time they first take possession of the means. The relevant intention may be formed at a later time. But the supplier must know (or it must be obvious to him in all the circumstances) that some ultimate users will indeed form that intention.
55. Application of these principles to the facts as found by the judge leads to only one conclusion. S&N have infringed because 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. Further, it would have been obvious to a reasonable person supplying GO canisters that that this would be likely to occur.
56. Accordingly the appeal on this issue must be allowed.

Obviousness

57. As we have mentioned, S&N sought permission to appeal on two issues: first, whether it was obvious in 1994 to use reticulated foam as the dressing for NPWT - the alleged invention of claim 5 of '504 and claim 8 of '950; second, whether it was obvious in 1994 to put a gelling agent in the canister to prevent spillage of liquid – the alleged invention of claim 7 of '950. Having heard Mr Mellor, we gave permission to appeal on both issues, but limited in the case of claim 7 to the allegation of obviousness over US Patent No 4,748,069 (“Karakelle”).

Issue (iii)(a) - Reticulated foam

58. Reticulated foam is an open-celled foam with an extremely open structure. It was described by KCI's expert, Mr Buckley, as being like a three dimensional spider's web. Methods of reticulation have been used for very many years and involve dissolving or melting away the cell walls of an open or closed cell block. S&N's case at trial was that the use of reticulated foam was an obvious way to implement the teaching of the principal item of prior art, Argenta.

59. Before elaborating upon KCI's case, we must first record the relevant findings of the judge as to the common general knowledge and the general approach of the skilled team, none of which was challenged before this court.

60. As we have said, the skilled team to which the Patents are addressed includes a clinician and a design engineer but the team would be led by the clinician. This has an important consequence. The choice of dressing would never simply be handed over to the engineer.

61. The judge found that it was universally accepted that in order to promote wound healing, the wound must be kept moist and free from infection. Moist wound healing was achieved by the application of dressings and these were changed frequently to prevent them from becoming a focus for infection.

62. Gauze was the most commonly used dressing material and it was used extensively in surgery. However, by 1994, new dressings were being introduced and, in specialist wound care centres, foam dressings were replacing gauze as the dressings of choice. Two such foams, Allevyn and Lyofoam, had been medically approved and were commercially available. They were designed to keep wounds moist and also to avoid tissue ingrowth, another important consideration. Lyofoam was an open-celled foam, and perhaps Allevyn too. Neither was reticulated.

63. As for reticulated foams, the judge found the *existence* of such foams would have formed part of the design engineer's common general knowledge. But the judge was not satisfied that any use of reticulated foam in connection with the treatment of patients was common general knowledge. Indeed the only application in the medical context which would have formed part of the designer's common general knowledge was for packaging. The clinician would have known of “prep” sponges, commonly used for swabbing and other external uses. These are made of reticulated foam though this is not something the clinician would have appreciated.

64. That brings us to Argenta. This teaches the use of NPWT for the treatment of wounds and the preferred dressing is an open-celled foam. So the only difference between Argenta and claim 5 is the use of reticulated open-celled foam. The question for the judge was whether this was obvious. He recorded S&N's main case as being that the design engineer would have appreciated from Argenta that reticulated foam was suitable because of its mechanical properties, in particular because it was uniform so as to allow uniform distribution of pressure, porous so as to allow oxygen to reach the wound and allow exudates to be removed, yet sufficiently rigid to prevent tissue in-growth. The judge rejected this case for two reasons at [152] and [153]:

“152. 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.”

65. Mr Mellor's vigorous attack on these findings proceeded by a number of steps. First, he took us to Dr Téot's acceptance in cross examination that despite concerns about open-cell foams expressed in his report, the examples in Argenta were sufficiently striking to the average clinician that he would give them a try. But the problem, as Dr Téot also accepted, was that there was nothing on the wound care market suitable to use as the open-celled foam. Neither Allevyn nor Lyofoam could be used without any modification. So the clinician would have to go to his design engineer and ask him for assistance.
66. The question, continued Mr Mellor, was what would the skilled engineer then do faced with this request from the clinician? On this, he said, the evidence was all one way because both Mr Wood and Mr Buckley thought reticulated foam would do the job. Further, he submitted, there was no reason not to use it. The only concerns advanced by Dr Téot were those which he had given in relation to the use of open-celled foams generally and they did not withstand cross examination.
67. Attractively though these submissions were developed, we are unable to accept them. As a starting point, the judge found at [123] that reticulation was a process by which a

very open-celled foam could be made. This was a finding he was plainly entitled to make on the evidence. For example, Mr Wood explained it is possible to identify a reticulated foam by looking at the cell walls on the surface of the foam, ideally with a microscope. One sees not cells with walls but “struts” or “strands”.

68. Turning to clinical concerns, these were keeping the wound moist and avoiding tissue ingrowth, as the judge recorded at [114] and [148]. Now it is true to say that Dr Téot accepted in cross examination they would not have led the clinician to reject open-celled foam altogether in implementing Argenta. But a reticulated foam has a *very* open-celled structure and so its use would have made these concerns particularly acute, as Dr Téot explained in paragraph 92 of his report:

"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."

69. This paragraph was not tested in cross examination. Nor, as Mr Tappin fairly submitted, was it ever suggested to Dr Téot that there was no distinction between his concerns about reticulated foams and other open-celled foams.
70. This evidence must also be seen in light of the following further findings as to which there was no effective challenge. First, as we have mentioned, the skilled team would be led by the clinician. Second, 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. Third, the clinician would approach the task of implementing Argenta, and in particular the choice of the foam dressing, with great caution and, if pushed, would select one of the medically approved foams such as Allewyn and Lyofoam, but appropriately modified. This latter finding was amply supported by Dr Téot’s evidence under cross examination when read as a whole.
71. In all these circumstances the judge was entitled to find the clinician would not simply relinquish the task of selecting an appropriate material to the design engineer and that even if the engineer had come up with the idea of using reticulated foam, the clinician would have rejected it. It follows that the judge had proper material upon which to base his finding of non obviousness and the appeal against this aspect of his judgment and order must be dismissed.

Issue (iii)(b) – Gel-forming substance

72. Karakelle came into the case in a most unusual way. It was originally relied upon by S&N solely in support of their case on cgk. But, perhaps anticipating that they might fail to prove that the use of gelling agents was cgk, on the second day of the trial S&N applied to re-re-amend their Grounds of Invalidity to plead Karakelle as a specific item of prior art against ‘950. After an adjournment, it was apparently 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 in relation to it nor cross examine either Dr Téot or Mr Buckley upon it. The judge duly allowed the amendment and the trial proceeded on that basis.

73. Karakelle describes a new composition for converting a liquid to a gel which is said to be useful in the prevention and clean up of spills. It was filed in 1990 and published in 1992.

74. In the description of the background to the invention, Karakelle explains spills are a concern in the medical area and particularly so in surgical procedures which often require body fluids to be drained from the patient. There follows (at col.1, lines 25-62) a description of the use of suction canisters for the drainage of fluids. It is said that upon the completion of 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 process fraught with the possibility of leaks and spills. So, it continues (at lines 45-49):

“It has become common practice in the art to add a material to the canister to convert the liquid to a solid or a semisolid so that, if an accident should occur, any spill will be confined to the immediate area and cleanup will be quicker and safer.”

75. Karakelle then says that for this purpose gelling agents have been used. They may come in packets and comprise sodium acrylate with the result that (at lines 55-58):

“When placed in a suction canister containing body fluids, the packet degrades so that the polyacrylate comes into contact with and immobilises the fluid as a gel.”

76. The invention of Karakelle is a gelling composition including starch which has been chemically modified by a silane coupling agent so as to confer upon it a very high capacity for liquid absorption. In the examples, the gelling composition is sprinkled in powder form onto the surface of test fluid so as to demonstrate its gel formation properties.

77. At trial, S&N’s case based upon Karakelle was straightforward. They contended it taught the skilled reader of the concern of spillages in suction canisters, if he did not already share it, and that a gel-forming substance can be added to the canisters to avoid the problem.

78. This argument did not find favour with the judge. He summarised the disclosure and identified a difference between Karakelle and claim 7 of ‘950 in these terms (at [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.”

79. The judge then turned to consider whether this was an obvious step to take. In light of what he perceived to be an absence of relevant expert evidence, he concluded, somewhat reluctantly, that the claim was not obvious (at [167]-[168]):

“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.”

80. On appeal, S&N contended the judge wrongly held Karakelle only discloses the addition of a gel-forming substance to the canister *after* it has been filled with fluid; wrongly construed claim 7 as being directed to a canister to which a gel-forming substance has been added *before* it is filled with fluid; and wrongly thought there was no relevant expert evidence.
81. We believe, like the judge, there is no specific disclosure in Karakelle of the addition of a gel-forming substance to a canister before it has been filled with liquid. But, as we have explained, there is a clear general teaching of the common practice of adding such a substance to a canister.
82. As for the interpretation of claim 7, we are content to proceed on the basis that it is directed to a canister suitable for use in a wound dressing treatment apparatus and so it must contain the gel-forming substance before it is filled with fluid.
83. That brings us to the crucial question whether it was obvious to add the gel-forming substance to the canister before putting it to use. We have to say that this does seem to us a trivial step but have resisted our inclination to find it inherently obvious since the skilled team to which the patent is addressed consists of persons with specialist expertise. Nevertheless, we have no doubt there was ample evidence before the court to justify the conclusion it was indeed obvious to that skilled team.

84. Mr Wood explained in paragraph 37 of his first report that whether or not gel-forming substances would have been used by the engineer and medical scientist depended upon the application in question and the preferences of the medical advisor. If there was a concern over leakage or spillage, they were an obvious tool and readily available.
85. Mr Wood referred to the disclosure of Karakelle in his second report and then said this at paragraph 22:
- “If the container is disposable, it would clearly be preferable to immobilise the exudate by turning it into a gel so that it may be hygienically discarded with the container with no risk of the contents escaping during that process. I believe, therefore, that it would be immediately evident to at least the engineers and medical scientists in the skilled team in 1994 that it would be a beneficial and obvious option to use a gel-forming substance on drained wound exudates in a container.”
86. None of this evidence was challenged.
87. As for Mr Buckley, he was not aware of gel-forming substances but, on the assumption he had known of them and their use in suction canisters for the prevention of spillage, accepted they were an option to be discussed with the clinical member of the team.
88. This evidence all points one way; it was obvious to put a gel-forming substance in the canister before use in order to prevent spillage. The judge fell into error on this issue and the appeal must be allowed.

Conclusion

89. We conclude on the issues argued before us:
- i) the GO system does not infringe claim 5 of ‘504; S&N’s appeal on this issue is allowed;
 - ii) S&N have infringed claim 8 of ‘950 pursuant to section 60(2) by sales of the GO canisters; KCI’s appeal on this issue is allowed;
 - iii) S&N’s appeal against the finding of validity of claim 5 of ‘504 and claim 8 of ‘950 (the reticulated foam issue) is dismissed;
 - iv) S&N’s appeal against the finding of validity of claim 7 of ‘950 (the gel-forming substance issue) is allowed; the claim is invalid for obviousness over Karakelle.