

OPINION UNDER SECTION 74A

Patent	EP 2667922 B1
Proprietor(s)	Prosys International Ltd
Exclusive Licensee	
Requester	Prosys International Ltd
Observer(s)	Priority IP Ltd
Date Opinion issued	29 October 2021

The request

1. The Comptroller has received a request from Prosys International Limited (the requester) to issue an opinion under section 74A(1)(b) in respect of infringement of patent EP 2667922 B1 (the patent) of which they are the proprietor. The product on which the opinion is requested is identified as the “Cath Dry HD”.
2. The Patent has a filing date of 27 January 2012, and it was originally a PCT application published as WO 2012/101265 A1. It was granted on 4 July 2017 and remains in force.
3. Observations were filed by Priority IP Limited (the observer) and observations in reply were subsequently received from the requester.

Preliminary issues

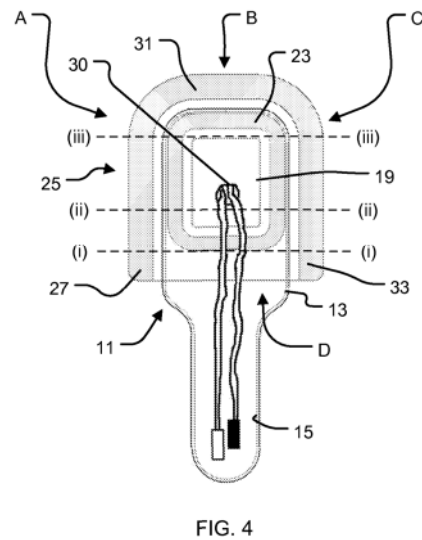
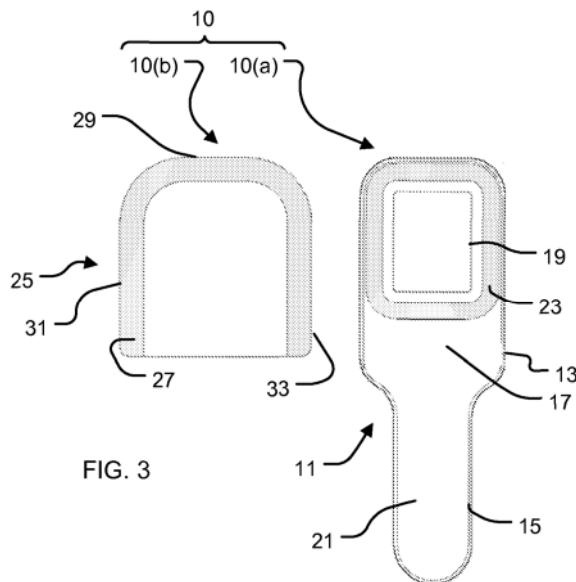
4. The observations include argument that the opinion request should be refused in the light of ongoing opposition proceedings before the EPO.
5. I consider however that the proprietor is entitled to an opinion on their validly granted patent without having to wait for opposition proceeding to conclude. I note that oral proceedings are not scheduled to take place until April 2022. The observations in reply also point to the fact that the preliminary view of the EPO is that *rejection of the opposition may be expected*.

The patent

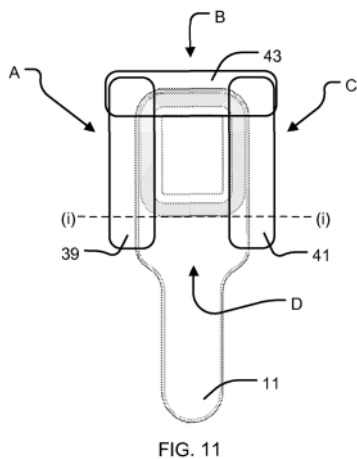
6. The patent relates to apparatus for shielding a catheter from contact with water. It

has particular utility in allowing a patient to shower whilst wearing the catheter, to protect the catheter and the aperture where the catheter exits the patient's body from getting wet. The apparatus is relatively simple comprising essentially a plastic bag for containing the catheter with a first seal surrounding the opening of the bag and a guard device comprising a second seal for protecting the first seal. The first seal seals against the patient's skin to create a watertight enclosure defining an internal volume for receipt of the catheter. The guard device also seals to the patients skin around the first seal to protect the first seal from ingress of water.

7. Figures 3 and 4 of the patent, reproduced below, illustrates an embodiment of the invention of the patent. The apparatus comprises the bag (11) with the first seal (23) surrounding the opening of the bag (19), and the guard device (25) having a U-shaped band of adhesive around the edge. The catheter exit aperture is referenced by numeral 30. The bag is identified as comprising two parts, the first part (13) surrounding the exit aperture and the second part (15) for receiving the distal part of the catheter.



8. Figure 11 illustrates a slightly different embodiment in which the guard device is formed of three separate cover components (39,41,43) which adhere to both the bag and the patient's skin.



9. It is worth noting that one of the particular problems the invention seeks to address is pooling of water between the top of the bag and the skin along the upper edge of the adhesive attaching the bag to the skin in prior art devices. This allegedly provides a mechanism for water to enter the bag. The guard device of the invention is intended to prevent water pooling in this way.

Claims

10. There is only one independent claim which reads as follows:
 1. Apparatus (10) for shielding a catheter from contact with water falling from a shower head of a shower, the apparatus comprising:

a first shield component (10a) having a first part (13) that is configured to form a first seal around an exit aperture (30) from which a catheter exits the patient's body, said first part (13) defining an internal volume (17) that opens to an internal volume (21) of a bag-like second part (15) that is configured to receive a distal part of said catheter, and

a second shield component (10b, 39, 41, 43) for adhering to the patient's body around at least part of the periphery of the first part(13) of said first shield component (10a) so as to provide a second seal against water contact with said exit aperture (30);

wherein said first (10a) and second (10b, 39, 41, 43) shield components cooperate, when the apparatus is worn by a patient, to provide two seals against contact between water falling from said shower head and said exit aperture (30) without obstructing access to an area of the patient's skin beneath said second part (15) of said first shield component.

The product

11. The requester seeks an opinion on whether the "Cath Dry HD" falls within the scope of the claims and consequently whether the importation into the UK of the product constitutes an infringement of their patent.
12. The product is identified in the request by a series of photographs, including photographs of the product itself and photographs of the instructions which accompany the product. The general arrangement is illustrated by the photograph reproduced below from which it can be seen that the product comprises a bag with a pair of O shaped adhesive liners surrounding an opening.



Infringement

13. Section 60 of the Act states:

(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say-

(a) Where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

(b) Where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent

(c) Where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

14. As the claims relate to apparatus only Section 60(1)(a) is relevant.

15. In the Supreme Court in *Actavis v Eli Lilly*¹ Lord Neuberger stated that the problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, i.e. the person skilled in the relevant art. Those issues are:

(i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not,

(ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

¹ *Actavis UK Limited and others v Eli Lilly and Company* [2017] UKSC 48

16. If the answer to either issue is “yes”, there is infringement; otherwise there is not.

Does the product infringe as a matter of normal interpretation?

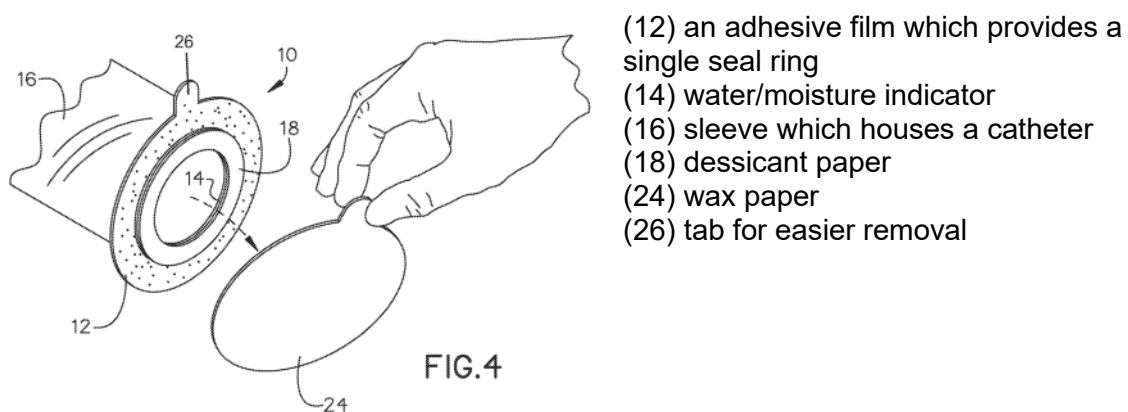
17. I shall start by considering whether the product infringes the patent as a matter of normal interpretation. This means interpreting the claims in the light of the description and drawings as instructed by Section 125(1). In doing so I must interpret the claims in context through the eyes of the person skilled in the art. Ultimately the question is what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. This approach has been confirmed in the recent decisions of the High Court in *Mylan v Yeda*² and the Court of Appeal in *Actavis v ICOS*³.
18. Although I consider that construction of claim 1 is mostly straightforward and that it may largely be construed as read, I do note that the seals are defined in part by a *result to be achieved*.
19. In particular, the first seal is required to seal around the aperture, the second seal must provide a *second* seal against water contact with the exit aperture and the first and second seals cooperate to provide *two* seals against contact between water and the exit aperture. There is no explicit statement that the first seal must in isolation provide a watertight seal. However, it may be considered implicit given the requirements for both a *second* seal against water and *two* seals against contact between water and the exit aperture. In order to resolve this issue, I have sought further guidance from the description.
20. As noted above, the second seal acts to provide a seal which stops water pooling adjacent the prior art first seal. I consider that the skilled person will interpret the first seal as being a watertight seal as known from the prior art.
21. The description also specifies:
- As will be appreciated from Fig. 4, the apparatus provides two seals against sideways water ingress (i.e. in directions A & C), and downwards water ingress (i.e. in direction B).*
22. I consider this passage would be interpreted as requiring both seals to be individually watertight in order to prevent sideways and downwards water ingress.
23. I therefore conclude that the claim should be construed to require both seals to individually provide a watertight seal against the body of a wearer in order that there are the requisite two seals against water ingress.
24. If the Cath-Dry HD is to infringe the patent as a matter of normal interpretation, then it must have all the features of claim 1 as I have construed it.
25. There is clearly a bag like part for receiving a distal part of a catheter which is connected to an internal volume surrounding the catheter exit aperture. There is also

² *Generics UK Ltd (t/a Mylan) v Yeda Research and Dev. Co. Ltd & Anor* [2017] EWHC 2629 (Pat)

³ *Actavis Group & Ors v ICOS Corp & Eli Lilly & Co.* [2017] EWCA Civ 1671

clearly a seal for forming a seal around the exit aperture and that seal is intended to prevent water reaching the exit aperture. The arrangement is fixed to the wearer so that the skin beneath the bag like part is accessible and not obstructed. The Cath-Dry HD thus has many of the features required to fall within the scope of claim 1. The issue as I see it is whether or not it has the first and second shield components defined in the terms required to fall within the scope of claim 1.

26. I start by considering the form of the seals of the Cath-Dry HD.
27. The photographs provided with the request do not provide much assistance in determining the nature or form of the seals. All that can be reasonably established is that there are two O shaped adhesive liners, with the inner ring apparently being formed of two semi-circular halves. It is not clear, for example, whether the liners cover a single ring of adhesive or whether there are in fact two separate rings of adhesive.
28. In the observations the observer makes the statement that figure 4 of US 10137292B2 shows the technical features of the Cath-Dry HD. This figure is reproduced below along with the features as identified in the observations.



29. It is apparent that there are differences between this arrangement and the photographs of the Cath-Dry HD provided by the requester. In particular, there is only a single circular wax paper cover over the adhesive rather than separate rings, which might suggest only a single ring of adhesive. Indeed, the observer indicates only a single outer ring of adhesive (12). No inner ring of adhesive (for adhering to the body of the wearer) is indicated or mentioned in the observations. Similarly, there is no suggestion in the specification of US 10137292B2 that there is an adhesive between the inner ring and the body of the user. It seems that the purpose of the circular wax paper cover is to maintain sterility of the sleeve as well as keep the outer adhesive ring clean.
30. In response, and to demonstrate that the Cath-Dry HD differs from the version illustrated in the observations, the observations in reply provide further photographs of the Cath-Dry HD and further details regarding its construction. It is clear from these that the O shaped liners both cover an adhesive as set out in following paragraph from the observations in reply:

For completeness, the image of exhibit IM_H shows the Cath Dry HD in a

state with both the release papers of the outer and the inner adhesive sealing rings removed. The inner adhesive sealing ring is coloured white and has an adhesive surface. The outer adhesive sealing ring is formed of a clear plastic material and has an adhesive surface. Both the inner and outer adhesive sealing rings have similar strength adhesive to one another.

31. Despite this notable difference between the Cath-Dry HD and the US 10137292B2 arrangement, the further features identified in the observations do seem to be in agreement. In particular, the desiccant ring and the water/moisture indicator ring are features of both.
32. The observations in reply continue as follows regarding the construction of the Cath-Dry HD:

As visible in those images, the inner and outer adhesive sealing rings have a gap between them and are formed of different materials to one another, such that they cannot be considered as a single seal. This can be seen in the image of exhibit IM_1, in which a radial cut has been made through the inner and outer adhesive sealing rings...

33. I reproduce part of the image of exhibit IM_1 below. It is very hard to discern anything about the construction from this image, it is certainly not clear from this image nor any of the other images provided that there is a gap between the adhesive of the sealing rings. I nevertheless accept that a gap of sorts exists.



34. I note also that whilst the underlying material (or at least that part which lies adjacent the skin in use) of the inner and outer seals differs, that is not to say that the adhesive differs. In any case, I do not consider that the inner and outer seals can be regarded as separate seals simply on the basis that the underlying material is not the same.
35. The observations in reply continue:

There is a gap between the seals of the inner and outer adhesive sealing rings when they are placed against the skin, at least due to the raised height of the inner sealing ring compared to the outer adhesive sealing ring, as seen at the very centre of the image of exhibit IM_1. Accordingly, the inner and outer adhesive sealing rings form/provide different seals to one another.

36. As suggested in this paragraph, much of the adhesive gap is considered to be attributable to the height of the material of the inner seal and its presumably adhesive free outer edge. I.e. the adhesive covers the entirety of the face of the seal region but the inner and outer adhesive rings are separated by the thickness of the inner ring. I do not consider that the seals can be said to form/provide first and second seals simply on the basis that there is a small gap between them as argued by the requester.

37. Aside from the reference to the somewhat different product, the observations merely argue that

There are not two distinct seal components which cooperate to provide two distinct seals or attachments which protect against contact between water falling from the shower head and the exit aperture of the catheter.

38. In my view, albeit that there are two distinct adhesive regions, they form only a *first seal* in use between the wearer's skin and the remainder of the device.

39. It is also apparent that the seals of the Cath-Dry HD are both on the same *part* of the device and that they surround the aperture. Claim 1 requires a *first part* that is configured to form a first seal around an exit aperture, and the seals of the Cath-dry HD are considered to fall within the scope of this requirement.

40. In particular, and using the language of the claim, I consider that both the inner and outer adhesive rings of the Cath-Dry HD form part of a *first shield component*. More particularly they form a *first part that is configured to form a first seal around an exit aperture (30) from which a catheter exits the patient's body, said first part (13) defining an internal volume (17) that opens to an internal volume (21) of a bag-like second part (15) that is configured to receive a distal part of said catheter.*

41. I consider that both of the inner and outer adhesive rings form the *first seal* and that they are both part of the *first part* of the claim. Accordingly, in the absence of any further seals, the Cath-dry HD lacks a second shield component as would be required to fall within the scope of the claims.

42. Claim 1 also requires that there are two seals to prevent water from a shower reaching the exit aperture, and I have construed this to require that both seals must individually provide watertight seals.

43. The requester has argued that there are two such watertight seals and the observer argues that the inner seal is not watertight. In view of the arguments presented I will analyse whether or not each of the seals (if they were considered to be separate seals) provides a seal between water and the exit aperture of the catheter.

44. It seems clear enough that the outer adhesive ring is intended to, and indeed does, form a watertight seal, sealing the exit aperture from contact with water.

45. With regards to the inner ring of the Cath-Dry HD, based upon the photograph reproduced above it can be seen to comprise two rings of material (as well as the adhesive layer). Based on the observations these are a larger diameter desiccant paper and a narrower diameter moisture indicator ring. The observations describe

the functions of these rings as follows:

The desiccant paper is there to absorb moisture, e.g. condensation or sweat, which may have accumulated or formed in the space surrounding the protected exit aperture of the catheter.

The desiccant paper may also incorporate a moisture indicator ring which turns red in colour when saturated with moisture. This change in colour indicates to the patient that a new dressing is needed otherwise sterility of the exit aperture of the catheter is compromised and infection could develop.

The desiccant paper feature (which could also incorporate the colourimetric indicator ring) does not form a seal nor does it attach firmly to the skin of the patient, in contrast to the strict requirement of the alleged invention and as argued by ProSys during examination.

The desiccant paper is certainly not integrated in the product in order to prevent against contact between water falling from the shower head and the exit aperture, but rather, as stated above, to absorb for example moisture from condensation or sweat, which are in themselves sterile fluids, in order to maintain sterility of the exit aperture of the catheter.

46. The requester provides the following comments in response:

The white material and its adhesive surface, which define the adhesive inner sealing ring, seal against water from passing between the skin of the human body and the white material.

The white material of the inner sealing ring is said to be a desiccant paper in the observations. We dispute whether "paper" is the correct term for the material. However, if it was a desiccant, then it would block water by absorbing the water rather than letting the water pass through the opening of the bag.

47. This issue is a little difficult to resolve, largely due to the definition by result form of the claim. Without experimental or observational data it is not entirely clear whether the inner ring will act as a seal between water and the exit aperture or not. However, I am persuaded by the points made in the observations that the purpose of the desiccant is to absorb residual moisture and it is neither intended to, nor does it form a seal. I consider that were it exposed to sufficient water then the desiccant would become waterlogged and would allow water to pass across it. On that basis I do not consider it to be a watertight seal.

48. I note also the following statement from US 10137292B2, included with the observations, which would also seem to suggest that the inner ring does not seal against water reaching the catheter exit aperture:

The desiccant paper 18 may absorb moisture and transmits the moisture to the water indicator 14, which may change color when exposed to water.

49. In any event, in the context of this opinion I do not consider sufficient evidence has

been provided that I can conclude that the inner ring acts as a watertight seal.

50. In my view the Cath-Dry HD does not provide two seals to seal against contact between water from a shower and the exit aperture as required by claim 1 in the manner I have construed it.
51. As the Cath-Dry HD does not possess all the features required to fall within the scope of claim 1, it does not infringe the patent based on a normal interpretation of the claims.

Is the product an immaterial variation?

52. I have not been provided with any argument regarding whether or not the product may be regarded as being an immaterial variation such that it infringes, despite not falling within the scope of the claim. I shall nevertheless consider this question briefly.
53. Claim 1 of the patent requires that there are two seals which both act to prevent water from a shower reaching a catheter exit aperture. I consider that the Cath-Dry HD has only a single seal for preventing water reaching the exit aperture. I do not consider that this amounts to an immaterial variation. One purpose of the additional seal is to prevent water pooling between an upper edge of the apparatus and the skin of the user. Without this additional seal water is still capable of pooling in this region in the Cath-Dry HD such that the variation is not immaterial. Additionally, having two watertight seals provides a degree of redundancy such that even if water were to breach one seal, it would be unlikely to also breach the second. Removing this redundancy is a further significant variation. In the language of the *Improver* questions, the Cath-Dry HD does not achieve the same result in substantially the same way as the invention of the patent.
54. In my opinion the Cath-Dry is not an immaterial variation on the invention of the patent.

Summary

55. I consider that the Cath-Dry HD does not provide a second shield component as required to fall within the scope of claim 1. Furthermore, there is only one watertight seal which acts to prevent water reaching the catheter exit aperture.

Opinion

56. It is my opinion that, based on the evidence and argument provided, the Cath-Dry HD does not fall within the scope of the claims of EP 2667922. Furthermore, it is not an immaterial variant or equivalent. Accordingly, any relevant acts in relation to it do not constitute infringement of the patent.

Application for review

57. Under section 74B and rule 98, the proprietor may, within three months of the date of issue of this opinion, apply to the comptroller for a review of the opinion.

Matthew Jefferson
Examiner

NOTE

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