



26 May 2022

## **PATENTS ACT 1977**

BETWEEN		
	ProSys International Limited	Proprietor
	and	
	Cath Dry Inc	Opponent
PROCEEDINGS  Application	under section 74B for review of Opinion 14/21	
, topinoa ii oi	in respect of EP(UK) 2667922	
HEARING OFFICER	Phil Thorpe	
Hearing date: 04 March 2022		

### **DECISION**

- In Opinion 14/21 ("the opinion"), issued 29<sup>th</sup> October 2021, the examiner was asked to consider whether a product ("the Cath Dry HD") infringed EP 2667922 ("the patent"). It was the examiner's opinion that it did not.
- The proprietor of the patent ("the proprietor") has requested a review of the opinion under section 74B of the Patents Act (the "Act"). The application for review was received within the three-month period from the date of issue of the opinion, with the application being accompanied by a statement setting out the proprietor's grounds for review. Cath Dry Inc ("the opponent") have contested the application and filed a counter statement on 30<sup>th</sup> December 2021.
- The matter came before me for a hearing on 4<sup>th</sup> March 2022. The proprietor was represented Gareth Ashton of Baron Warren Redfern and Cath Dry Inc was represented by Dr Stoyan Radkov of Priority IP Ltd.

### **Grounds for review**

- The grounds for a review of an opinion are set out in rule 98(5) of the Patents Rules 2007 which reads:
  - 98(5). The application may be made on the following grounds only -

- a) that the opinion wrongly concluded that the patent in suit was invalid, or was invalid to a limited extent: or
- b) that, by reason of its interpretation of the specification of the patent in suit, the opinion wrongly concluded that a particular act did not or would not constitute an infringement of the patent.
- The nature of a review under section 74B was considered by the Patents Court in *DLP Limited*<sup>1</sup> in which Kitchen J said (my emphasis):
  - 22. In the case of an appeal under rule 77K, the decision the subject of the appeal is itself a review of the opinion of the examiner. More specifically, it is a decision by the hearing officer as to whether or not the opinion of the examiner was wrong. I believe that a hearing officer, on review, and this court, on appeal, should be sensitive to the nature of this starting point. It was only an expression of an opinion, and one almost certainly reached on incomplete information. Upon considering any particular request, two different examiners may quite reasonably have different opinions. So also, there well may be opinions with which a hearing officer or a court would not agree but which cannot be characterised as wrong. Such opinions merely represent different views within a range within which reasonable people can differ. For these reasons I believe a hearing officer should only decide an opinion was wrong if the examiner has made an error of principle or reached a conclusion that is clearly wrong. Likewise, on appeal, this court should only reverse a decision of a hearing officer if he failed to recognise such an error or wrong conclusion in the opinion and so declined to set it aside. Of course this court must give a reasoned decision in relation to the grounds of appeal but I think it is undesirable to go further. It is not the function of this court (nor is it that of the hearing officer) to express an opinion on the question the subject of the original request.
- Hence a review is not intended to be a second opinion on the matters presented in the opinion. Whether I necessarily agree or disagree with the examiner's opinion is also not the matter at hand in this review. Furthermore, the matter is not whether any of the parties agrees or disagrees with the opinion. What matters is whether the examiner made an error of principle or reached a conclusion in their opinion which was clearly wrong.
- The proprietor submits that the examiner has wrongly concluded that the Cath Dry HD does not fall within claim 1 of the patent. In particular, the examiner is said to have incorrectly interpreted claim 1.

### The Patent

As explained in the opinion, the patent relates to apparatus for shielding a catheter from contact with water. It has particular utility in protecting the catheter and the aperture where the catheter exits the patient's body from getting wet when for example the patient is taking a shower. The apparatus is relatively simple comprising essentially a plastic bag for containing the catheter with a first seal surrounding the

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<sup>&</sup>lt;sup>1</sup> DLP Limited [2007] EWHC 2669

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 an enclosure defining an internal volume for receipt of the catheter. The guard device also seals to the patient's skin around the first seal to protect the first seal from ingress of water.

9 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.

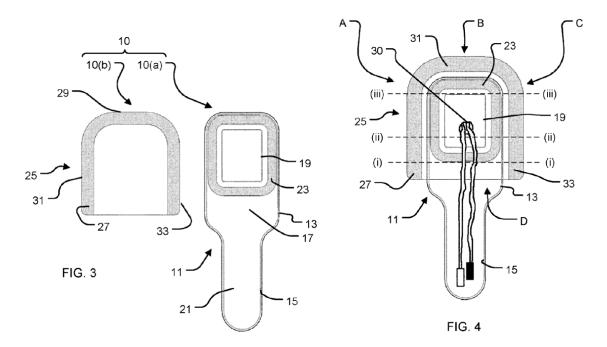
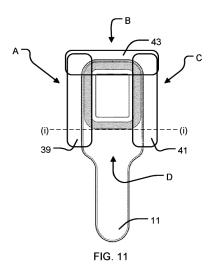


Figure 11 illustrates a slightly different embodiment in which the guard device is formed of three separate cover components (39,41,43) which adhere to both the bag and the patient's skin.



- 11 Claim 1 of the patent reads:
  - 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 (10) 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 (10a).

# The Cath Dry HD

For the purposes of the opinion the Cath Dry HD was identified 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.





## **Argument and analysis**

- Much of the material provided by the proprietor and the opponent regarding this review concerns the examiner's understanding of the Cath Dry HD. However, the ground in rule 98(5)(b) is that the opinion wrongly concluded the situation regarding infringement "by reason of its interpretation of the specification of the patent in suit". Hence my focus needs to be on how the opinion interpreted the patent.
- 14 My review must also focus on the material before the examiner when they came to their opinion. The opponent provided additional evidence including a witness statement, photographs and videos that was not available to the examiner. Unless it demonstrates that the examiner reached a conclusion that was clearly wrong on the basis of the material before the examiner at the time then this additional evidence is of no real value.
- 15 The examiner set out their construction of the claim essentially in paragraphs 18-23 of the opinion. They noted firstly in paragraph 18 that:

"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."

16 The opinion goes on to define this result to be achieved as that:

"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."

The examiner then recognises that there is no explicit statement that the first seal must in isolation provide a "watertight seal" although they note 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. The examiner refers to the description where it notes:

"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)."

18 The examiner concludes in relation to the two seals in paragraph 23 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."

19 Mr Ashton drew my attention to the term "watertight" used by the examiner, arguing that this is not a requirement of the patent. He goes further in a letter dated 18<sup>th</sup> November 2021 to argue that "The whole point of having two seals in the patent is because each individual seal is <u>not</u> "watertight". To support this contention, he points to paragraph 5 in the patent. That paragraph seems to be discussing an arrangement shown in a prior art patent document rather than the invention and more specifically a situation in which a seal has not been properly applied by a patient. Mr Ashton also refers to paragraph 32 of the patent in which the two shields are said to cooperate "in a manner ... to reduce the likelihood of water from a shower coming into contact with the exit site of a catheter.". This he argues supports a

construction of claim 1 "as requiring the first and second seals to both resist passage of water". I cannot however find any basis in the patent for the invention to be aimed at "resisting passage of water". There is reference to a "leak-resistant medical barrier" in one of the prior art solutions referred to though the referenced prior art also includes a "waterproof bandage.". Rather the teaching of the patent is about sealing against water contact with the catheter exit which suggests more than just resisting passage of water.

I agree that the word "watertight" itself is not found in the patent. However, it seems to me that the examiner was simply paraphrasing the patent for example where it refers to "seal against water ingress" in paragraphs 37, 38 and 53 and the requirement in claim 1 to "seal against water contact". I do not believe that the term as used in the opinion is intended to mean anything more. I find support for this in the examiner's assessment of the Cath Dry HD where for example they note that "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." This assessment equates "watertight" with the wording in the claim namely sealing the exit aperture from contact with water. The opinion then goes on to consider the inner ring of the Cath Dry HD and concludes that

"the purpose of the desiccant [the inner ring] 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."

- Again, I do not believe that the examiner has applied an overly restrictive construction on the requirement of the seal but has considered whether it would allow water to pass. I can find no fault with this.
- Mr Ashton also argued that the examiner erred in their construction of claim 1 in that they excluded the possibility that the two shields need not be separate but could overlap or be integrated into a single component, as described in paragraph 48 of the patent. This argument does not arise from any explicit interpretation of the patent in the opinion. Rather according to their letter dated 18<sup>th</sup> November 2021 it seems to be something that the proprietor has surmised based on how the opinion considered the Cath Dry HD and that on that basis "no other rational explanation can be discerned".
- The relevant parts of the opinion are paragraphs 34-41. In these the examiner sets out why they consider the product does not infringe the patent. Central to the examiner's opinion is their belief that the product does not have a second shield providing a second seal against water contact with the catheter exit aperture. This opinion is however based on their assessment of the design of Cath Dry HD in particular whether the adhesive ring 12 and the adhesive covered ring 18 of desiccant material are one or two shield components as required by the claim. In concluding that they comprise just the one shield there is nothing to suggest that the examiner has wrongly construed claim 1 to exclude from its scope the possibility that the two shields need not be separate but could overlap or be integrated into a single component. Rather the assessment that the two rings essentially comprise one seal was a determination based on the construction of the Cath Dry HD.

Hence, I do not believe that either of the attacks on the examiner's construction succeed. Indeed the attacks fall some way short of showing that the examiner's construction was clearly wrong.

### Conclusion

- I find that the opinion did not wrongly conclude that a particular act did not or would not constitute an infringement of the patent by reason of its interpretation of the specification of the patent in suit.
- 26 I therefore make no order to set the opinion aside.

### Costs

- 27 Given the low-cost nature of the opinion service and the fact that reviews can usually be decided on the basis of the papers it is usual for there to be no cost order.
- In this case, the opponent sought a hearing in person prior to EPO opposition proceedings. The proprietor would have been content with a decision on the papers after the opposition proceedings. Nevertheless, it was the request for a review from the proprietor that led to the hearing. On balance it would seem appropriate for each side to bear its own costs.

## Appeal

29 Any appeal must be lodged within 28 days after the date of this decision.

Phil Thorpe
Deputy Director acting for the Comptroller