### **OPINION UNDER SECTION 74A**

Patent	GB 2562978 B
Proprietor(s)	Alcolizer Pty Ltd
Exclusive Licensee	
Requester	Dragerwerk AG & Co KGaA
Observer(s)	Alcolizer Pty Ltd
Date Opinion issued	10 December 2019

## The request

- 1. The comptroller has received a request from Dragerwerk AG & Co KGaA ("the requester") to issue an opinion as to whether Patent GB 2562978 B ("the Patent") is valid in light of a breath testing device, known as the Alcofind AF-100S device ("D1"), that they assert was available to the public prior to the priority date of the Patent. In particular, the requester considers claims 1-6,8-12&14 to lack novelty over the D1 device, and claims 7&13 to lack an inventive step over the D1 device.
- 2. The Patent was granted on 4 September 2019 and is still in force. The Patent is a UK national phase application based on International (PCT) Application No. PCT/AU2017/050437 filed on 12 May 2007 and published as WO2017/193175 on 16 November 2017. The Patent claims priority from Australian Patent Application No. 2016901779 with a filing date of 13 May 2016.
- 3. The request was received on the 17 September 2019 and was accompanied by a statement explaining the request along with a user manual for the D1 device and reference to a number of URL's, including YouTube videos, documenting the availability of D1. Copies of email correspondence with the manufacturer regarding the date of sales of D1, and a computational fluid dynamics diagram (CFD) image for breath directed in the D1 device were also provided. Photographs said to be of D1 have also been submitted. Furthermore, the requester has provided a physical specimen of the D1 device. This specimen was available for inspection in Newport.
- 4. Observations were received from Dehns on behalf of the proprietor, Alcolizer Pty Ltd ("the observer"). The observations included arguments refuting the alleged lack of validity. In particular the observer considers that the requester has not proven that the features relied upon form part of the state of the art, and that the claimed invention is novel and inventive over these features in any event.
- 5. Observations in reply were subsequently received from the requester, which

included reference to further URL's respectively documenting the availability of D1, the manual and an alcohol sensor. Photographs of D1 and details of a further email correspondence with the manufacturer of D1 were also provided.

6. Further emails from the requester and observer have also been submitted regarding the observations in reply and alleged new evidence/allegations of fact.

# Alleged prior art

- 7. In order for matter to form part of the state of the art under Section 2(2) it must have been publicly available before the priority date of the Patent whether by written or oral description or by use or in any other way.
- 8. In their initial request the requester has provided PDF document of the D1 user manual, that is alleged was created on 30 June 2015 and modified on 2 July 2015. They also note that the manufacturer of D1, Da Tech Co. Ltd, states on their website that the AF-100S device was launched in March 2015. Four YouTube videos have also been referenced, which are said to demonstrate the availability of D1 before the priority date. Three of these videos are listed as "published on" 14 July 2015, 8 March 2015, and 14 November 2015 (respectively) and each refer to the D1 device. The other video ("URL 5") appears to have been incorrectly identified by the requester as being listed as published on 14 July 2015 in fact the "published on" date is 24 February 2017 (although this video does not appear to refer to D1). The requester additionally refers to URL's detailing that D1 was being offered for sale from at least 26 January 2016 (I note, however, that the URL's for the Korean sales do not appear to work). The requester also alleges that the manufacturer has confirmed via email correspondence that sales of the device started in July 2015.
- 9. In response the observer notes that the requester has not provided any witness statements regarding the manual, photographs, or sample, and there is no indication as to when the user manual was made available to the public or first published. The observer submits that even if the dates on the websites are correct, no relevant features of such a device can be determined only the product name and the external view of a breathalyzer device. Furthermore, the observer submits that no evidence has been provided regarding the provenance of the photographs and sample provided by the requester (and for this reason the observer has decided it would not be cost effective to inspect the specimen in Newport). The observer also notes that it is common for products to be changed over time (without changing the product name) and that there is no reason to assume that a contemporary product corresponds to a one made four years ago.
- 10. In reply the requester has submitted that at least one of the videos ("URL 2") clearly shows the features of D1 in particular the interior of D1. They refer to 0:21-0:24 of the video and provide a screenshot:

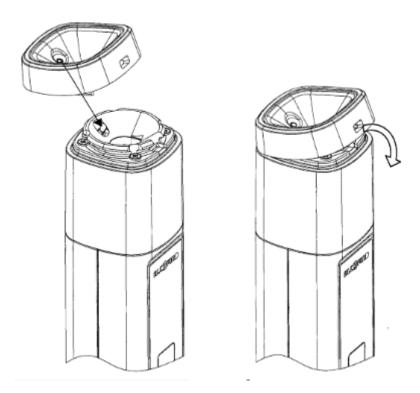


- 11. The requester states that it is clear from this screen grab (at least) that the physical specimen they have provided is identical to that shown in the video. They also note that the video "URL 4" shows the user manual provided with D1, which has the same cover as the PDF version they have submitted.
- So what was available to the public before the priority date? As a starting point, it would appear that the specimen provided to me corresponds to the device shown in the URL's provided by the requester in their initial request – the video in "URL 2" in particular shows the cap and interior of a device which clearly corresponds to the specimen. The specimen also corresponds to the photographs submitted by the requester in the initial request and observations in reply. One of the videos ("URL 4") also shows a device corresponding to the specimen along with a user manual with the same front cover as that submitted in PDF form by the requester. These videos have a publication date before the priority date. Therefore, along with the other information provided by the requester in their initial request regarding an Alcofind AF-100S device being offered for sale before the priority date. I think it is reasonable to conclude that D1 – which is shown in the videos, websites, photographs, manual and specimen – was available to the public before the priority date of the Patent and forms part of the state of the art under Section 2(2). In particular, I would note that all the information provided to me by the requester is consistent and I also see no reason to believe that the device defined by the specimen, photographs, and/or manual provided by the requester has changed or been modified since the videos were published and/or the product was available for sale.
- 13. Whilst there has been some further correspondence from the requester and observer regarding the information provided in the observations in reply, and whether it should

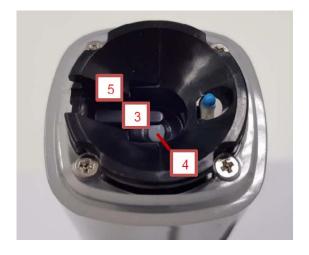
be disregarded as introducing further allegations/evidence, I believe that the information in the initial request is sufficient for me to reasonably conclude what was available before the priority date. Consequently, I have not needed to give any weight to the observations in reply.

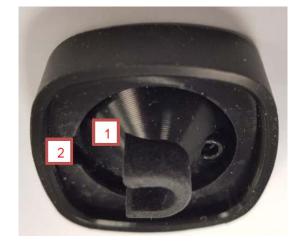
# D1 - Alcofind AF-100S device

14. D1 is a device for testing the alcohol level of a user. It comprises a main body and replaceable blow cap – see figures below taken from pages 4 and 5 of the manual.



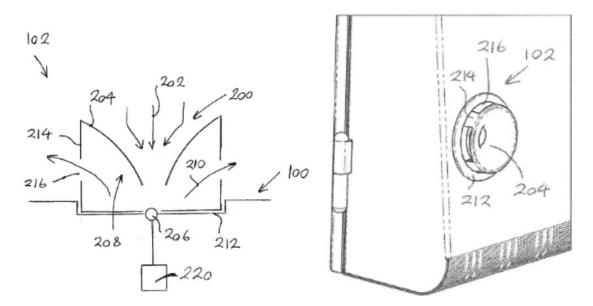
15. The blow cap has an aperture 2 and the inwardly facing surface of the blow cap has a horseshoe based fitting – see photograph on right below. The surface 5 of the main body of the device beneath blow cap is provided with a channel which is formed between a well region in the main body and the aperture 2 in blow cap - see photograph on left below. A tongue 3 is also provided in the main device which is situated in the channel. These are photographs provided by the requester.





## The Patent

16. The Patent relates to a breath tester, including a breath guide 102, for testing the presence of mind-altering substances such as alcohol. In particular, the breath guide 102 guides breath 202 through one or more apertures 216 so that it is not returned to the blower (i.e. person blowing), and thus minimises the likelihood of spread of infectious disease. Figures 2 and 3 of the Patent are reproduced below and show funnel 204, sensor 206 and diverting means 208 which also form part of the breath tester:



- 17. The Patent has fourteen claims, including independent claims to a breath tester (claim 1) and a breath guide for a breath tester (claim 10). The claims of the Patent are reproduced below.
  - 1. A breath tester including:

A sensor for sensing a mind-altering substance in breath from a blower; and A breath guide for guiding the breath;

Wherein the breath guide comprises:

A breath receptacle for receiving breath from the blower, including a funnel for funnelling the breath towards a sensor;

A wall supporting the funnel and defining one or more apertures; and

A breath diverter including the underside of the funnel arranged to divert the breath through the one or more apertures so that it is not returned to the blower.

- 2. A breath tester as claimed in claim 1, wherein the guide guides the breath so that it is not returned to the blower to thereby minimise the likelihood of spread of infectious disease.
- 3. A breath tester as claimed in any one of the preceding claims, further

including a well for receiving the guide.

- 4. A breath tester as claimed in any one of the preceding claims, further including a display for displaying the result of a test.
- 5. A breath tester as claimed in claim 4, wherein the result is a pass or fail.
- 6. A breath tester as claimed in any preceding claim, wherein the funnel is arcuate.
- 7. A breath tester as claimed in any preceding claim, wherein the wall is cylindrical.
- 8. A breath tester as claimed in any preceding claim, wherein the sensor is in register with the funnel.
- 9. A breath tester as claimed in any preceding claim, wherein the mind-altering substance is alcohol.
- 10. A breath guide for a breath tester, the guide including:

A breath receptacle for receiving breath from a blower including a funnel for funnelling breath towards a sensor in the breath tester;

A wall supporting the funnel and defining one or more apertures; and

A breath diverter including the underside of the funnel arranged to divert the received breath through the one or more apertures so that it is not returned to the blower.

- 11. A breath guide as claimed in claim 10, wherein the funnel is arcuate.
- 12. A breath guide as claimed in claims 10 to 11, received in a well.
- 13. A breath guide as claimed in any one of claims 10 to 12, wherein the wall is cylindrical.
- 14. A breath guide as claimed in any one of claimed 10-13, further including a sensor in register with the funnel.

### Claim Construction

18. Before considering the issue of validity in the request I need to construe the claims of the Patent, that is to say I must interpret it 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<sup>1</sup> and the Court of Appeal in Actavis v ICOS<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup> Generics UK Ltd (t/a Mylan) v Yeda Research and Development Co. Ltd & Anor [2017] EWHC 2629 (Pat)

<sup>&</sup>lt;sup>2</sup> Actavis Group & Ors v ICOS Corp & Eli Lilly & Co. [2017] EWCA Civ 1671

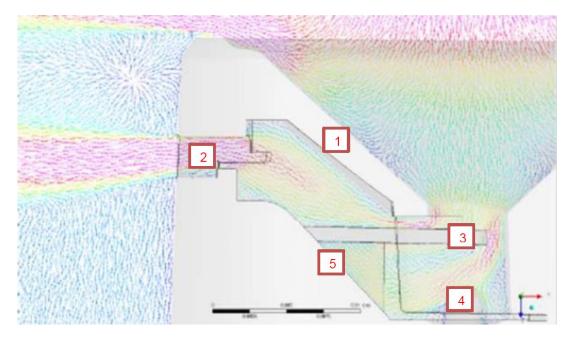
- 19. In order to interpret the claims through the eyes of the skilled person, they must first be identified. I consider the person skilled in the art to be a manufacturer or designer of breath testing devices.
- 20. I believe that consideration should be given to the construing of "the breath diverter" of independent claims 1&10. In particular claims 1&10 state that the breath guide comprises:
  - "A breath diverter including the underside of the funnel arranged to divert the received breath through the one or more apertures so that it is not returned to the blower." [my emphasis]
- 21. The requester has argued that "the underside of the funnel" can be taken to mean "a part underneath the funnel". However, I believe that the person skilled in the art would construe "the underside of the funnel" based on the description which discusses that "the breath diversion means 208 includes the underside of the funnel" and figure 2 which shows such a diversion means 208 as the underside surface of the funnel opposing the funnel surface. In particular the specification does not disclose or point towards the underside of the funnel being anything else than this.
- 22. The requester has submitted that the Patent does not discuss what would be a sufficient amount of breath diversion, so claims 1&10 should be construed broadly such that it relates to any diversion of breath through an aperture so that it is not returned to the blower. The observer construes the breath diverter to require a sufficient aperture(s) so that breath is not returned to the user and/or to sufficiently divert the breath to minimize the spread of infectious disease.
- 23. Whilst figure 3 shows apertures of a significant size, I note that claims 1&10 and the application as a whole are silent as to the size and number of the aperture(s). Thus I do not believe that the person skilled in the art would construe claims 1&10 as requiring any *particular* aperture arrangement. Looking at the description I note that paragraph 19 discusses that if the guide 102 were not present:
  - "...blown air would simply be returned from the well 212 to the blower along with mucous from previous blowers that may carry infectious disease"
- 24. Not returning breath from the area covered by the guide (e.g. the well or equivalent feature being covered by a guide) would appear to be the concept at the heart of the invention. Therefore, I consider that the person skilled in the art would construe claims 1&10 as having a breath diverter, including the underside surface of the funnel opposing the funnel surface, arranged to divert the received breath through the one or more apertures so that it is not returned to the blower from within the guide (e.g. the well or equivalent feature).
- 25. I also note that claim 10 relates to a breath guide *suitable* for a breath tester including a funnel *suitable* for funnelling breath towards a sensor (i.e. this claim does not require a sensor, only that the guide is suitable for funnelling breath towards a sensor).

## **Novelty**

26. In order for a claim to lack novelty, a prior art disclosure must clearly and unambiguously disclose all of the features of the claim. I will begin by considering the independent claims in light of D1. Claim 10 is the broadest in scope and I shall consider this claim first. Only if I find claims 1 or 10 to be not novel will I consider the respective dependent claims.

#### Claim 10

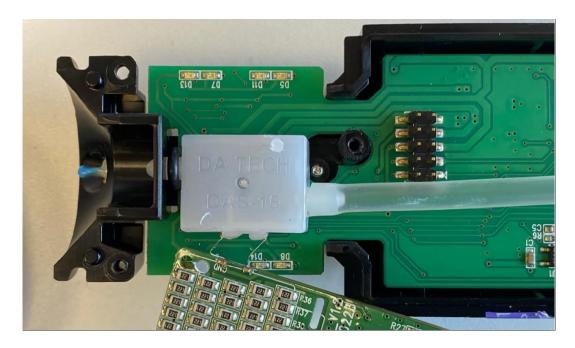
- 27. D1 discloses a breath guide for a breath tester, in the form of a blow cap. The blow cap includes a breath receptacle for receiving breath from a blower, which includes a funnel suitable for funnelling breath towards a sensor in a breath tester. A wall of the blow cap supports the funnel and this wall defines an aperture.
- 28. The observer has argued that D1 does not disclose the feature of "a breath diverter including the underside of the funnel arranged to divert the breath through the one or more apertures (in the wall supported by the funnel) so that it is not returned to the blower" as defined in claim 10. In particular, they consider the aperture to be a snap fit fastening aperture (as demonstrated by the arrow in the figure in the manual: see figure above) for use in fastening and releasing the cap. Furthermore the observer submits that the tongue feature (3) obstructs any diversion of breath through the aperture and that the aperture is not large enough to sufficiently divert breath to minimise the spread of infectious disease and would form a 'breath bottleneck'. The observer also states that the horseshoe based fitting prevents the breath from being incident on the underside of the funnel, and that the underside of the funnel does not divert the breath so that it is not returned to the blower.
- 29. The requester argues that D1 does have a breath diverter as defined in claim 10. In particular they note that the aperture is not a snap fit fastening but a vent which is open when the cap is fitted to the main body of the device. The tongue feature, according to the requester, does not block the aperture and is provided to protect a sensor. The requester states that the aperture of D1 does divert breath away from the user, which inevitably reduces the likelihood of spread of infectious diseases and does divert a proportion of the stream of breath so that it is not returned to the blower. The requester also considers the horseshoe based fitting to be part of the underside of the funnel and is arranged beneath the funnel to divert breath. The requester additionally notes that the underside surface of the funnel between the horseshoe and the aperture forms the upper surface of an air channel, and such an underside surface of the funnel does participate in diverting the breath so that it is not returned to the blower.
- 30. The requester has also provided a CFD image relating to a simulation said to be of D1 showing "computationally determined flow paths for breath directed into the D1 device". This image is shown below with the numerals corresponding to the numerals in the photographs above. The geometry of the device in the simulation is said to be identical to D1 because it was constructed from a 3D scan of the D1 device. This image, says the requester, shows that air is expelled through the aperture at 'high velocity' and provides "an informed assessment of the direction in which breath is guided by the blow cap".



- Whilst I note that there is nothing in the information provided to me regarding D1 that explicitly states the purpose of the aperture in the blow cap, it is clear from inspection of the specimen and from the videos and photographs that there is an air path from the funnel through to the aperture on the side of the cap. It is somewhat difficult to rely on the CFD image provided by the requester as, although it would appear to correspond to D1, it is not entirely clear what this image is showing or the circumstances regarding the air flow. Nevertheless, it is my opinion that the blow cap of D1 does include a breath diverter which is arranged to divert the breath through the aperture (in the wall supported by the funnel) so that it is not returned to the blower. In particular, whilst the tongue is positioned within the air channel it does not impede the flow of breath through the aperture such that breath is returned to the blower. Nor is the size of the aperture felt to prevent the expulsion of air from the side of the cap such that breath is returned to the blower. Furthermore, whilst I do not consider the 'horseshoe based fitting' to be part of the underside of the funnel, the underside surface of the funnel between the horseshoe and the aperture does in my opinion divert the breath through the aperture so that it is not returned to the blower, as it is part of the upper surface of the air channel.
- 32. Consequently, it is my opinion that claim 10 is not novel in light of D1.

#### Claim 1

- 33. Claim 1 relates to a breath tester comprising the guide of claim 10, but further includes a sensor for sensing a mind-altering substance in breath from a blower.
- 34. The requester has submitted that the 'blue sensor' that protrudes through the blow cap is a flow sensor. The requester states that the sensor for sensing a mind-altering substance is a fuel cell sensor labelled as '4' in the photographs above. They note the reference to the 'fuel cell sensor' on page 15 (specification) of the manual. The requester has also provided photographs said to be of D1 which show the internal features of the main body. One of these photographs is shown below:



- 35. The observer has submitted that as the 'blue sensor' sticks out of the blow cap, it is clear that the funnel is not funnelling the breath towards this sensor. Furthermore, there is no clear and unmistakable directions to the location of any other sensors in D1.
- 36. Based on the specimen provided (at least) I think it is reasonable to conclude that the item labelled as '4' in the photographs above is a sensor for sensing a mindaltering substance. The funnel directs breath towards this sensor.
- 37. Consequently, it is my opinion that claim 1 is not novel in light of D1.

### **Dependent claims**

- 38. The requester has submitted that dependent claims 2-6,8,9,11,12&14 are not novel in light of D1. It is my opinion that D1 discloses a well for receiving the blow cap, a display for displaying a pass/fail test result and a funnel which appears to be arcuate. Furthermore, the sensor is in register with the funnel and is for sensing alcohol.
- 39. Therefore it is my opinion that claims 2-6,8,9,11,12&14 are also not novel in light of D1.

## **Inventive Step**

- 40. The requester has also argued that claims 7&13 lack an inventive step in light of D1. To determine whether or not an invention defined in a particular claim is inventive over the prior art, I will rely on the four step test established in *Pozzoli SPA v BDMO SA [2007] EWCA Civ 588* which reformulated the well-known *Windsurfing* test. The Pozzoli steps are as follows:
  - (1)(a) Identify the notional "person skilled in the art";
  - (1)(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, determine whether those differences constitute steps which would have been obvious to the person skilled in the art.
- 41. I have identified the person skilled in the art as a manufacturer or designer of breath testing devices and his/her common general knowledge would include an understanding of the design requirements ergonomics, shape etc. for breath testing devices. The inventive contribution suggested in claims 7&13 is a breath tester with a breath guide having a cylindrical wall. D1 has a breath tester with a breath guide having a generally square shape with curved corners (see figures and photographs above). It is my opinion that the person skilled in the art, when presented with D1, would consider the shape of the wall to be a matter of design and would not exercise any inventive ingenuity in changing the shape of the breath guide to a cylinder for example to match the shape of the surface of the main body 5.
- 42. Consequently, it is my opinion that claims 7&13 lack an inventive step in light of D1.

## **Opinion**

- 43. It is my opinion that the Alcofind AF-100S device ("D1"), based on the information provided to me, forms part of the state of the art under Section 2(2).
- 44. It is my opinion that claims 1-6,8,9-11,12&14 of the Patent are not novel in light of
- 45. I am also of the opinion that claims 7&13 of the Patent are not inventive in light of what is disclosed in D1.

# **Application for review**

46. 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.

Ben Widdows		
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.