Patents Act 1977 **Opinion Number** **03/21**

OPINION UNDER SECTION 74A

Patent	GB 2521877 B
Proprietor(s)	Sooma Oy
Exclusive Licensee	
Requester	Temple Bright LLP, on behalf of Sooma Oy
Observer(s)	AWA SWEDEN AB, on behalf of Flow Neuroscience AB Sweden
Date Opinion issued	25 May 2021

The request

1. Temple Bright LLP, acting on behalf of Sooma Oy ("the proprietor"), has requested the comptroller to issue an opinion as to whether patent GB 2521877 B ("the patent") is infringed by the Flow Neuroscience AB 'FL-100' headset and accompanying app (together, "the product"). Specifically, an opinion is requested in relation to claim 1 of the patent as to whether the product amounts to indirect infringement under section 60(2) of the Act. Several enclosures have been filed in support of the request, including:

    - "*Transcranial direct current stimulation for the treatment of major depressive disorder: A summary of preclinical, clinical and translational findings*", Brunoni et al., in Progress in Neuro-Psychopharmacology & Biological Psychiatry 39 (2012);

    - "*Transcranial direct current stimulation: State of the art 2008*", Nitsche et al., in Brain Stimulation (2008, 1);

    - Screenshots from www.flowneuroscience.com accessed in the United Kingdom;

    - The Flow FL-100 User Manual;

    - "*The Flow Brain Stimulation Headset For The Treatment Of Depression: Overview Of Its Safety, Efficacy And Portable Design*", Brunoni et al., in Expert Review of Medical Devices, Vol 17, 2020, Issue 9;

    - Screenshots of Flow app; and

    - A video showing sequence of preliminary app screens, followed by headset

positioning and associated app screens.

Observations and observations in reply

2. Observations on the request were filed by AWA SWEDEN AB on behalf of Flow Neuroscience AB Sweden (“the observer”) disputing indirect infringement. Subsequently, observations in reply were filed by the proprietor.

The patent

3. The patent has the title “System and method for transcranial stimulation of a head region of a subject”. It was filed on 7 January 2014 with no declaration of priority. The patent was granted on 23 March 2016 and it remains in force.

4. The patent relates to a system for transcranial direct current stimulation (tDCS) of the head region of a subject, e.g. a person. Paragraph [002] of the patent explains what tDCS is:

> *Transcranial direct current simulation (tDCS) is a form of neurostimulation which includes, for example, delivering a constant and low current directly to a brain region of a person, namely a subject, through electrodes; such a low current is optionally in a range of 0.5 mA to 2 mA, but is optionally greater than 2 mA, or less than 0.5 mA in certain circumstances. tDCS is useful, for example, for treating patients with brain injuries, such as strokes, for treating depression, anxiety, tinnitus, chronic pain, and for enhancing language and mathematical abilities, addressing attention span problem, for enhancing problem solving abilities, for improving memory, and for enhancing a coordination of body movements.*

5. An example of how the system described in the patent works is shown in Figs. 1, 2A and 2B of the patent (reproduced below). Fig. 1 shows that the system 100 includes a power controller 102 and electrical contacts 104 and 106 positioned on the head region 110 of a subject (e.g. a user) and connected to the power controller 102 through wires 108. Electrical contact 104 is a positive electrode (anode) and contact

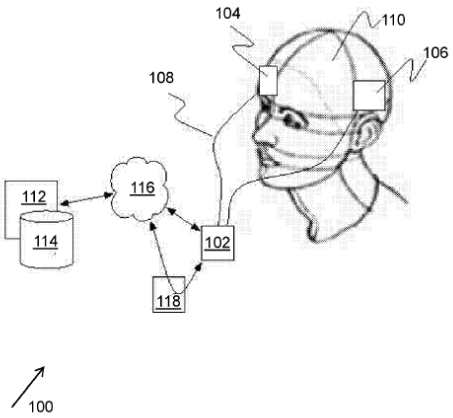


FIG.1

106 is a negative electrode (cathode). In paragraph [004], the patent explains that, conventionally, medical professionals place the anode and cathode on a person's head in accordance with an internationally recognized '10-20' system, which is a system for describing locations which are appropriate when applying scalp electrodes in the context of an EEG test or experiment. The power controller 102 includes an electric drive arrangement (e.g. a power source) for driving electrodes 104 and 106 to cause transcranial stimulation of the head region 110 of the subject. Power controller 102 may be operated locally by an operator using their mobile wireless communication device 118 (e.g. a smartphone). Power controller 102 provides the anode 104 with a constant low current which flows through the skull and brain of the subject to the cathode 106 to create an electrical circuit. The anode 104 and cathode 106 may be positioned on the head region 110 in the form of a head band or cap.

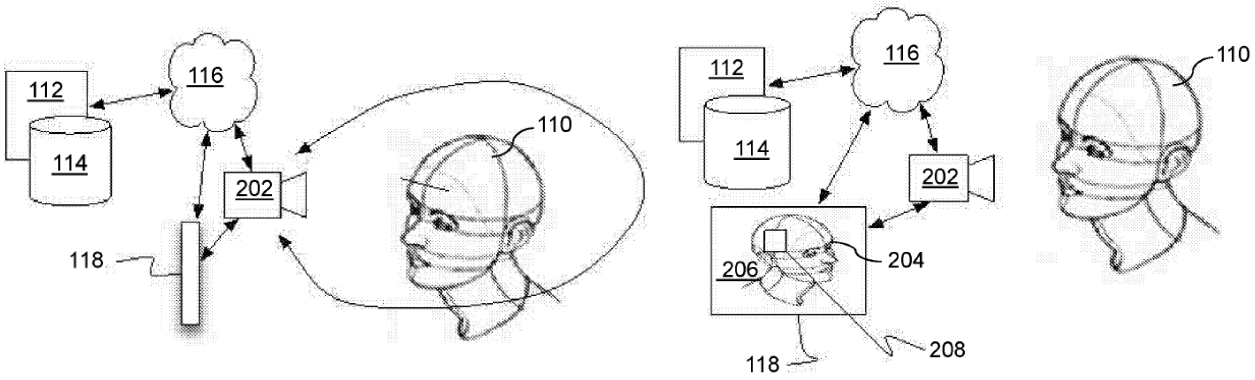


FIG.2A FIG.2B

6. As shown in Fig. 2A, the system also includes a monitoring arrangement for monitoring the spatial positions of the electrodes relative to the head region 110. The monitoring arrangement 202 includes a sensing arrangement in the form of a camera (which may be part of device 118) for capturing images of head region 110 when anode 104 and cathode 106 are positioned on head region 110. The monitoring arrangement may be a software application running on the device 118, and camera 202 may provide the captured images to the device 118 for further analysis. Optionally, the electrodes may include "features" (e.g. light sources or coloured/patterned markers) which enable measuring of the spatial positions of the electrodes using the sensing arrangement. Alternatively, the sensing arrangement may be a sensing instrument or motion sensor (e.g. gyroscope, accelerometer) attached directly to an electrode.

7. Fig. 2B illustrates how the system improves the transcranial stimulation of the head region of a subject by providing feedback to the operator. The monitoring arrangement displays a three-dimensional image 204 on a user interface 206 of the device 118. The image 204 includes an indicator 208 to indicate to the operator whether the current spatial positions of the electrodes 104 and 106 on the head region are correct. The indicator 208 may point towards one or more correct positions if the sensed positions are not correct. The operator may then reposition the electrodes 104 and 106 based on the feedback. The monitoring arrangement may optionally adjust the electrical signals generated by the power controller 202 as a function of the positional errors pertaining to the placement of the electrodes.

The claims

8. While the patent contains a set of eight claims, I have only been asked to give an opinion regarding claim 1. Adopting the lettering of the features of claim 1 used in the request, claim 1 defines the system in the following terms:

> *(a) A system for transcranial stimulation of a head region of a subject,*
>
> *(b) wherein the system includes an electrode arrangement comprising a plurality of electrodes coupled to at least one electrode drive arrangement,*
>
> *(c) wherein the plurality of electrodes are operable to contact onto a scalp of the head region of the subject,*
>
> *(d) wherein the at least one drive arrangement is operable to generate electrical signals for driving the plurality of electrodes to cause transcranial stimulation of the head region of the subject,*
>
> *(e) characterized in that the system includes a monitoring arrangement for monitoring spatial positions of the plurality of electrodes relative to the head region of the subject*
>
> *(f) and mutual relative positions of the plurality of electrodes,*
>
> *(g) and for indicating positional errors of the one or more electrodes*
>
> *(h) for enabling repositioning of the plurality of electrodes and a change in the electrical signals applied to the plurality of electrodes,*
>
> *(i) for providing improved transcranial stimulation of the head region of the subject.*

The law

9. Indirect infringement is provided for by section 60(2) of the act:

> *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.*

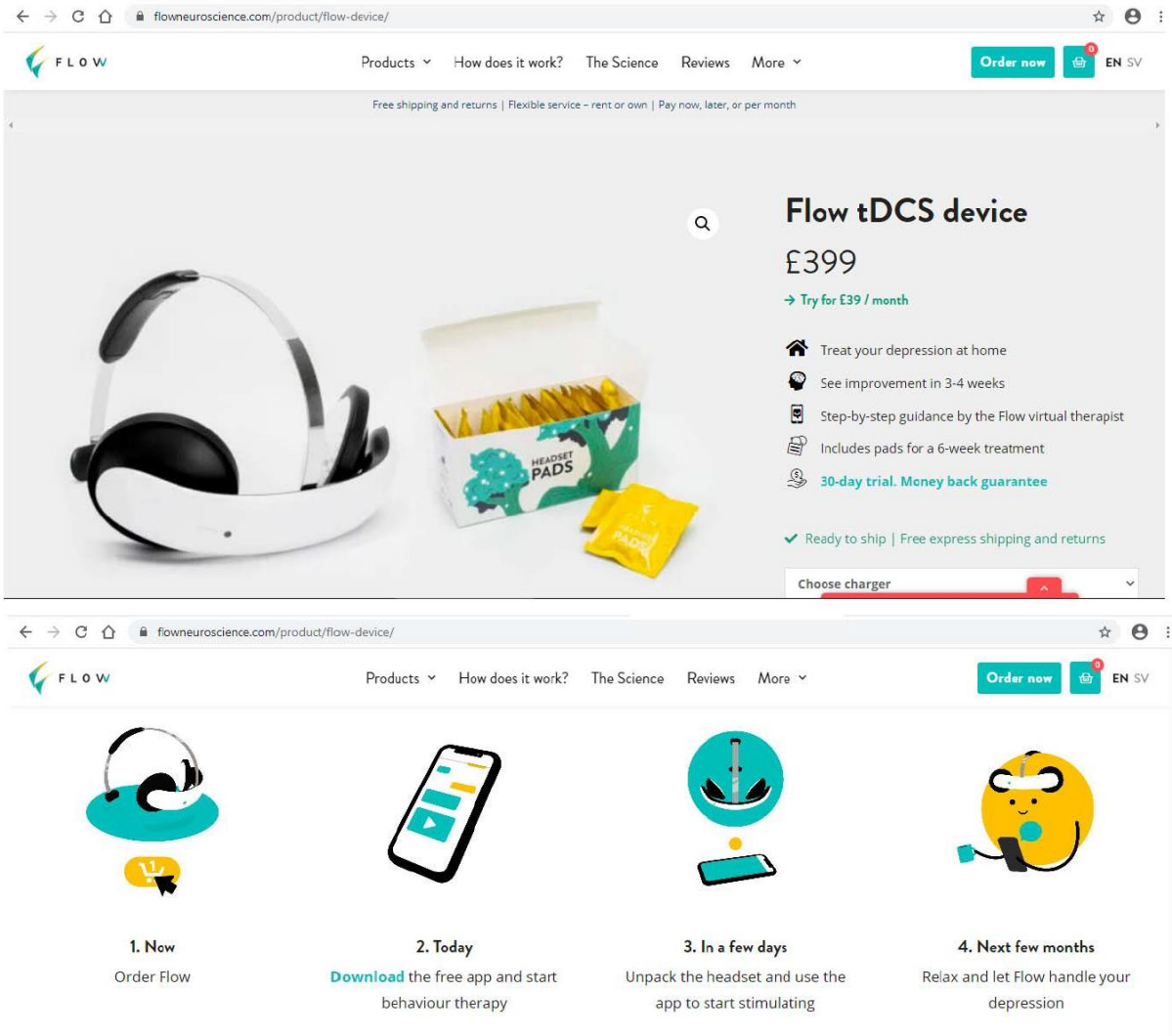
10. Thus, under section 60(2) a person may infringe a patent if, without consent, they supply or offer to supply in the UK a person not entitled to work the invention with means relating to “an essential element” of an invention for putting the invention into effect in the UK. A person does not infringe unless they know, or it is “obvious to a reasonable person in the circumstances”, that those means are suitable and

intended for putting the invention into effect in the UK. The “intention” to use the means for putting the invention into effect is on the part of the end user, not the supplier of the product, as held by the UK Court of Appeal in *Grimme v Scott* [2010] EWCA Civ 1110.

The product

11. The request sets out the details of the product. The product comes in two parts: a headset (Model: FL-100) and an accompanying smartphone app. According to the proprietor, the headset is sold directly from the Flow Neuroscience website[1] and the app is available free of charge from the App Store and Google Play. This is not contested by the observer. Two of the screenshots taken from the website (provided by the proprietor and reproduced below) helpfully indicate the two parts of the product.

12. Elsewhere, the website confirms that the headset is a “portable tDCS device” and that, “Transcranial Direct Current Stimulation (tDCS) is the technique used in the Flow tDCS device. This type of brain stimulation has been used to treat depression for decades…” Page 3 of the Flow FL-100 User Manual that accompanies the



[1] www.flowneuroscience.com

headset includes a drawing (reproduced below) that reminds the user, “Don’t forget to download the app “Flow – Depression””. The website further explains that:

The Flow depression app has two important functions:

1. *The app includes a full treatment programme for depression, based on Behaviour Therapy*

2. *and it used to control the Flow tDCS device.*

13. Page 9 of the User Manual advises the user of “Prerequisites”, and these are said to be, “A smartphone or other device running either Apple iOS11+ or Android 5.0+.” A diagram on page 6 of the User Manual (reproduced above) gives an overview of the constituent features of the headset. It includes a pair of circular electrodes 7 that sit on a curved base attached to one end of a metal arch 7. The other end of the metal arch 7 is described as a “Back piece” 11. There are also pads 6 and pad holder rings 3.

14. The website explains that, “The Flow tDCS device is Bluetooth controlled and managed through the Flow depression app. Consequently, the first thing to do is to download the app Flow – Depression. Inside the app you will meet your virtual therapist, Flow, who guides you through the treatment programme. The app will give you step-by-step instructions on how to start the headset, put it on and begin your first stimulation session.”

15. Pages 11-12 of the User Manual (reproduced below) shows the user, “11. How to Perform a Treatment Session”. They remind the user to “Make sure Bluetooth is enabled on your smartphone” and to, “Start the Flow app and log in”. The drawings included on these pages also illustrate how the headset is to be donned on the subject’s head. The length of the metal arch is adjustable so that the back piece sits comfortably on the back of the head, with the electrodes positioned in the forehead region of the head. The instructions advise the user to, “Make sure the headset does not sit too low” and that, “The app shows you how to correctly position the headset using the camera on your device.”

16. Three of the screenshots of the app provided by the proprietor (and reproduced below) give some more information on how the app (when operated on a user’s device) tells the user to position the headset correctly. For example, the first two screenshots show the user how to “Put on the headset”. In both screenshots, the app shows a model user wearing the headset on their head and it instructs the user

11. How to Perform a Treatment Session

- Ensure your forehead is free from any makeup or hair products before you start.
- If you have a fringe, it is recommended that you use a hair tie to remove it from your forehead.
- Take out the headset from the box.
- Press the button on the headset and make sure it blinks twice. If not, charge the headset.
- Make sure Bluetooth is enabled on your smartphone.
- Start the Flow app and log in with the email address & password you chose in section 9 above.
- Select the next session in the app and press "Start" to start the session. Note that how often you can use the headset is restricted per week and day.
- Follow the instructions given by the virtual therapist in the app.
- When told to, follow the instructions on how to prepare the headset, as below:

1. 

Take a new pair of Headset Pads from the pouch.

2. 

Attach them to the electrodes using the Pad Holder Rings.

3. 
Adjust the length of the metal arch by sliding the back piece.

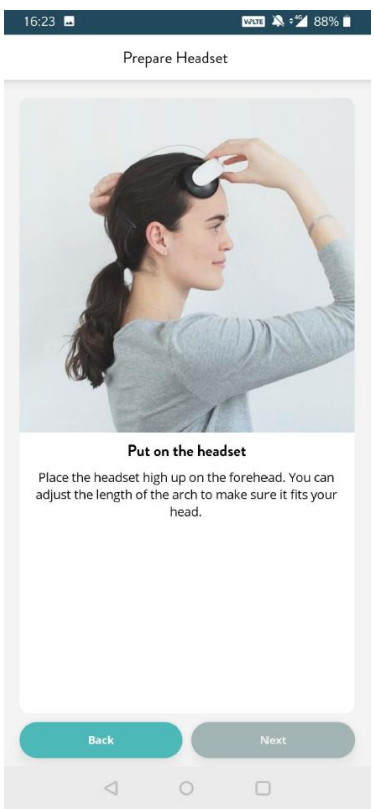
4. 
The end of the arch should sit comfortably on the back of your head.

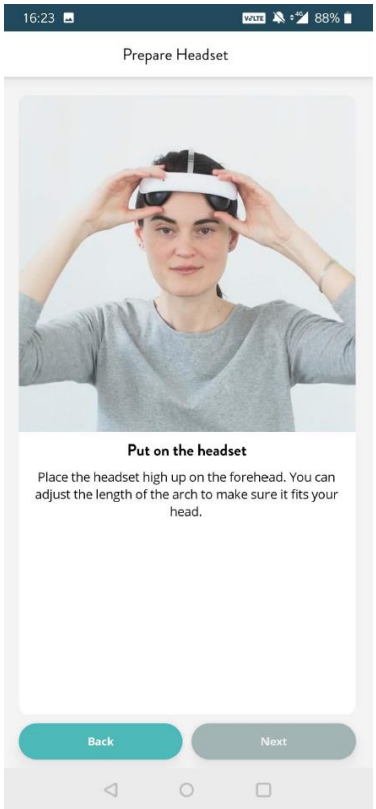
5. 
Make sure the headset does not sit too low.

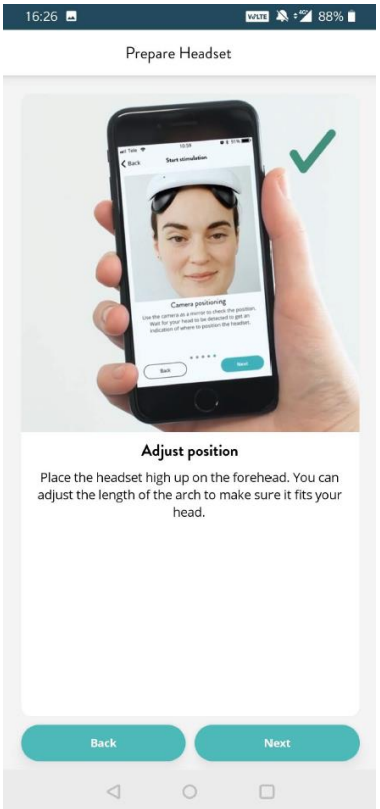
The app shows you how to correctly position the headset using the camera on your device.

6. Before starting the stimulation, you can press and hold the "Tingle" button in the app to test how the stimulation feels. Hold the "Tingle" button for at least 10 seconds.

7. Start the stimulation by pressing the "Start stimulation" button in the app.







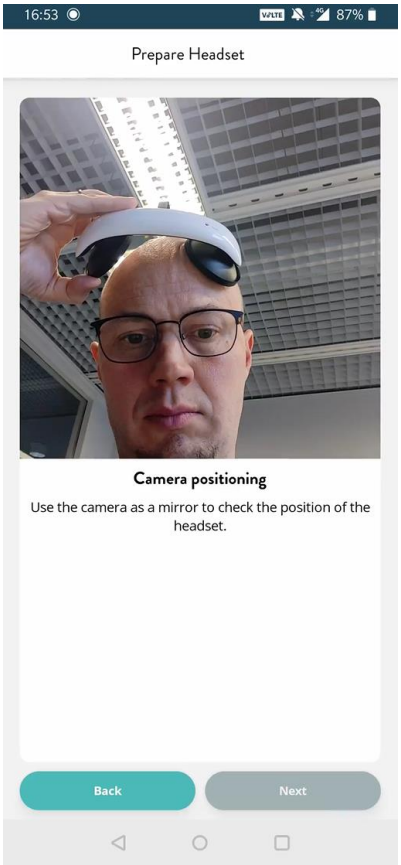
to "Place the headset high up on the forehead. You can adjust the length of the arch to make sure it fits your head." In the third screenshot, the app tells the user to "Adjust position". The third screenshot is also marked with a green tick on the upper right-hand side of an image showing the model user holding their mobile phone. The text accompanying that image says:

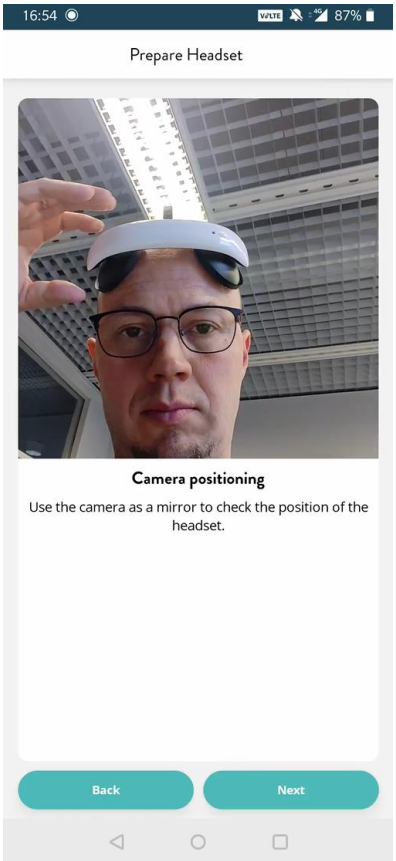
Camera Positioning

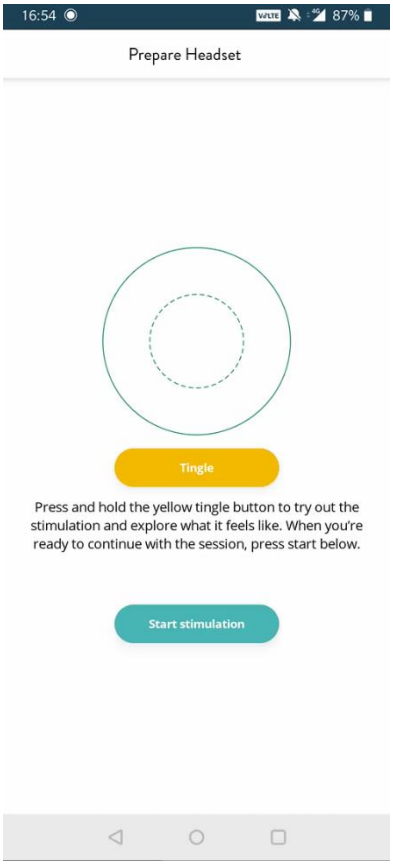
Use the camera as a mirror to check the position. Wait for your head to be detected to get an indication of where to position the headset.

17. I agree with the proprietor that the reference to the camera being used "as a mirror" apparently means that the app causes the phone camera to operate in 'selfie' mode so that the user sees their image on the screen. However, in my opinion, it is not readily apparent from the third screenshot (alone) what is meant by the instruction to wait for the head to be "detected" by the app. Nor is it clear from the third screenshot how the app may give to the user "an indication of where to position the headset".

18. An apparent example of a head being "detected" is found in the video of the app provided by the proprietor. The observer admits that the first part of the video (from 00:00 to 01:02) includes, "an instruction video in the app accompanying the headset". This instruction video shows the model user putting the headset on their head. It seems to me that the model user positions the headset on their head by following steps that include those illustrated by the three screenshots of the app that I have just described above. The observer also admits that the latter part of the video (from 01:02 to 01:26) shows, "a real example of a user checking the positioning of the headset" using the "mirroring function" of the app. To attempt to illustrate what is going on, I have selected three screenshots from this part of the video and reproduced them below. The first two screenshots concern "Camera Positioning". They show an instruction to the real user to "Use the camera as a mirror to check the position of the headset". In the first screenshot (taken at 1:12), the user is apparently holding one of the electrodes away from their forehead, and the "Next" button is greyed out. However, in the second screenshot (taken at 1:14) the user has released







the electrode so that both electrodes are apparently now contacting the user's head, and the "Next" button is now apparently activated because it has turned green. According to the proprietor, activating the "Next" button in this way allows the user to proceed to start the stimulation on the final screen of the app – see the third screenshot (taken at 1:29).

19. However, in my view, it is not readily apparent from the video what technical steps (if any) are performed by the app that lead it to change the colour of the displayed "Next" button from greyed-out to green. Helpfully, the relevant technical steps performed by the app are admitted by the observer in their submissions where they say:

> *It is true that the Product, just as many other products for neuromuscular or transcranial stimulation, performs a measurement checking whether the electrodes contact the skin of the user. This is made by providing a weak measuring current over the electrodes. Once it is confirmed that the electrodes contact the skin of the user the stimulation is made activatable. This is a simple security measure so that activation of the electrodes is not done unnecessarily…*

20. To paraphrase the observer, they admit that the app measures whether the electrodes are in electrical contact with the user's skin. When electrical contact is confirmed, it is indicated to the user by the "Next" button turning green, thereby making the stimulation functions activatable by the user in the final app screen.

21. I return now to my point about how the app provides the "indication of where to position the headset", mentioned in the final screenshot discussed at paragraphs 16 and 17 above, and what form this "indication" may take within the app. The proprietor suggests it appears the indication may be a reference to the visual feedback given to the user through the camera image (i.e. the "mirroring" function provided by the camera) and/or the confirmation that the electrodes are in electrical contact with the head (i.e. by the "Next" button changing colour to green). The observer does not dispute this, so I accept the proprietor's suggestions at face value.

Claim construction

22. Before I can consider the question whether the product indirectly infringes claim 1, I must construe claim 1 and determine the extent of protection afforded by claim 1 accordingly. The proprietor has reminded me that I must interpret claim 1 in the context of the description and drawings as required by section 125(1) and take account of the Protocol on the Interpretation of Article 69 of the European Patent Convention as required by section 125(3). In doing so, I accept, as the proprietor says, I must give the claims a "purposive" (or "normal") interpretation[2] by asking what the person skilled in the art would have understood the patentee to be using the language of the claims to mean.

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[2] In *Generics UK Ltd (t/a Mylan) v Yeda* [2017] EWHC 2629 (Pat), Arnold J (as he then was) confirmed (at [134]-[138]) the continuing requirement to interpret patent specifications purposively, having considered the earlier judgment of the UK Supreme Court in *Actavis v Eli Lilly* [2017] UKSC 48. Arnold J's conclusion was approved by Lord Kitchin in *Icescape Ltd v. Ice-World International BV* [2018] EHCA Civ 2219 (at [60]).

23. The proprietor identifies the relevant skilled person as, “an experienced biomedical engineer with some knowledge of tDCS and the 10-20 principles”. This is not disputed by the observer. I agree with the proprietor.

24. As the proprietor explains, the physical components of the system are an electrode arrangement coupled to an electrode drive arrangement (defined in feature (b)) and a monitoring arrangement (defined in feature (e)). The remaining features of the invention are defined by using what the proprietor calls “functional language”, i.e. by reference to the intended use of the system’s physical components. For example, the proprietor points out that the word “for” is used in several places in claim 1 (see features (a), (d), (e), (g), (h), and (i)). I agree with the proprietor that the word “for” appearing in claim 1 would be interpreted to mean ‘suitable for’. I believe the skilled person would also understand that claim 1 may be implemented using one or more computing devices. I agree with the proprietor that, insofar as claim 1 may be computer implemented, the word “for” effectively means ‘programmed to’, following the judgments of the UK High Court in *Philips v Nintendo*[3] and *Rovi v Virgin*[4].

25. From the submissions of both parties, it seems to me that the dispute does not concern features (a)-(d). In my opinion, these features would be interpreted straightforwardly by the skilled person, so I need not say anything more about them here. In contrast, the meaning of features (e)-(i) is at the heart of the dispute so I will give my opinion on how these features would be interpreted by the skilled person.

“monitoring”

26. I accept, as the proprietor says, that the word “monitoring” in feature (e) would be interpreted broadly to mean any form of surveillance or attentive observation. In other words, I believe the word “monitoring” would be understood to take its usual meaning in the art. I also accept the proprietor’s submission that the term “monitoring” as it is used in claim 1 does not necessarily entail additional active steps (beyond surveillance or attentive observation) by the system.

27. The proprietor also refers me to paragraph [0015] of the patent and in doing so (it seems to me) the proprietor appears to suggest that the word “monitoring” may simply refer to the provision of any form of feedback to the operator. Respectfully, I must disagree. I believe the skilled person would understand the first sentence of paragraph [0015] to be making a distinction between monitoring and feedback:

> “Embodiments of the present disclosure provide a system and method for monitoring the spatial positions of electrodes relative to the head region **and** providing a feedback to the operator accordingly.” (My emphasis.)

28. In my view, the skilled person would understand from the context of the patent that while giving feedback is provided based on “monitoring”, providing feedback is not “monitoring” as such.

(e) “a monitoring arrangement for monitoring spatial positions of the plurality of electrodes relative to the head region of the subject”

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[3] *Koninklijke Philips Electronics N.V. v Nintendo of Europe GmbH* [2014] EWHC 1959 (Pat), at [99]-[105]

[4] *Rovi v Virgin* [2014] EWHC 1559 (Pat), at [128]-[132]

29. Throughout the description, the patent consistently refers to monitoring the in-use or operative positions of the electrodes, i.e. monitoring the positions of the electrodes when they are on or are contacting the subject's head region. For example, in paragraph [004]:

> ***Spatial positions*** *of the anode and the cathode* ***on person's head*** *is crucial, as different medical disorders require modulation of different brain regions, and consequently different* ***spatial positions*** *of the anode and cathode* ***on person's head*** *…* (my emphasis).

30. This is also seen in paragraph [005] ("there exists a need for a method and system that **monitors positions** of electrodes **on a given head region**"); in paragraph [0026] ("the electrical contacts 104 and 106 are **positioned on a head region** 110 of a subject, for example a user"); in paragraph [0029] ("The sensing arrangement 202 includes at least one camera … for capturing one or more images of the head region 110 **when the anode 104 and cathode 106 are positioned on the head region** 110"); in paragraph [0035] ("In an exemplary embodiment, the anode 104 and the cathode 106 are optionally positioned **on the head region** 110 in a form of a head band or a cap"); and in paragraph [0039] ("the electrodes 104 and 106 **contact onto skin of the head region** 110 of the subject").

31. Therefore, in my view, it is clear the skilled person would understand that the "spatial positions" claimed in feature (e) are the in-use positions of the electrodes, i.e. the spatial positions of the electrodes on a subject's head. Accordingly, I believe the skilled person would understand the functionality of the monitoring arrangement defined in feature (e) to mean that it must be suitable for monitoring the in-use positions of the electrodes relative to the head region of the subject. I would add that I believe that the skilled person would understand, from the reference to paragraph [0029] that I have given above, that *a camera* (such as camera 202 in figs. 2A and 2B) is one example of a monitoring arrangement that is suitable for providing the monitoring functionality defined in feature (e).

(f) "and mutual relative positions of the plurality of electrodes"

32. Following my discussion of feature (e), I believe feature (f) would be interpreted by the skilled person to require that the monitoring arrangement is suitable for monitoring the relative in-use positions of the plurality of electrodes. In my view, the skilled person would understand from the patent that a camera (such as camera 202 in figs. 2A & 2B) is one example of a monitoring arrangement that is suitable to provide this functionality.

(g) "and for indicating positional errors of the one or more electrodes"

33. While feature (g) is worded so that it refers to "the one or more electrodes", I believe this appears to be a minor typographical error since the system of claim 1 is necessarily limited to a plurality of electrodes (see feature (b)). It appears that this part of claim 1 should read, "one or more of the plurality of electrodes"; this is how I believe the skilled person would interpret this part of feature (g).

34. Feature (g) also refers to "positional errors". The description does not give an explicit definition of what is meant by this phrase. Paragraphs [004]-[005] of the patent

provide useful context that highlights problems with the correct positioning of electrodes on the subject's head (with my emphasis in bold):

> *[004]* ***Spatial positions of the anode and the cathode on person's head is crucial****, as different medical disorders require modulation of different brain regions, and consequently different spatial positions of the anode and cathode on person's head, and a slight variation in a relative spatial distance between the anode and cathode may significantly influence an effectiveness of such treatment. Conventionally, medical professionals, i.e. doctors, manually place the anode and cathode on the person's head in accordance with an internationally recognized ' 10-20 system', which is a system for describing locations which are appropriate when applying scalp electrodes in a context of an EEG test or experiment. This system is based on a relationship between a location of a given electrode and a corresponding underlying area of cerebral cortex.* *The "10- 20 system" uses locations of cranial landmarks, such as nasion, inion, left and right tragus to determine electrode positions on the scalp. The "10" and "20" refer to the fact that actual distances between adjacent electrodes are either 10% or 20% of the total front-back, namely nasion to inion, or right-left, namely right tragus to left tragus, distance of the skull of the person*
>
> *[005] However,* ***the manual placement of electrodes*** *by doctors* ***is susceptible to positional errors, and even a small positional error may affect the overall effectiveness of the treatment. A correct placement of the electrodes is particularly important when the electrodes are used to deliver therapeutic stimulation in repeated stimulation sessions on, for example, consecutive days. In other words, an accurate reproduction of a stimulation site is therefore important. Therefore, there exists a need for a method and system that monitors positions of electrodes on a given head region****, or forces the positions based on anatomical markers,* ***that enables the positional errors of electrodes to be reduced****, and facilitates repositioning the electrodes for an improved transcranial stimulation.*

35. Amongst other things, I believe the skilled person would understand from these paragraphs that precise positioning of electrodes on a subject's head is "critical" and that accurate reproduction of the site of stimulation on the head is "important". I believe the skilled person would understand that positioning electrodes in this way ensures that the correct or intended region of the brain or underlying area of cerebral cortex is stimulated. Therefore, it follows that the "positional errors" defined in feature (f) would be interpreted as meaning errors in the in-use or operative positioning of one or more of the electrodes on the subject's head. I believe the same interpretation flows from the context of paragraph [0033]:

> *The monitoring arrangement displays a three-dimensional image 204 on a user interface 206 of the mobile wireless communication device 118, wherein the three-dimensional image 204* ***includes at least one indicator 208 to indicate to the operator whether or not one or more of the current spatial positions of the electrodes 104 and 106 on the head region are correct****.* (My emphasis.)

36. I believe the skilled person would understand that feature (g) is not limited to any particular way of "indicating" the positional errors of the electrodes. All that is necessary is that a feedback about positional errors is given to the operator in some manner (see [0015] and [0033]). For example, the skilled person would understand that the indication of positional errors may be provided visually via a user interface (i.e. screen) of a device (see [0032] & [0033]).

(h) "for enabling repositioning of the plurality of electrodes and a change in the electrical signals applied to the plurality of electrodes"

37. In my view, feature (h) would be construed straightforwardly by the skilled person. Firstly, feature (h) requires that the function for indicating positional errors in feature (g) is suitable for "enabling repositioning of the plurality of electrodes". In the context of the patent, this would be understood to mean that the functionality for indicating positional errors allows *the user* to reposition the electrodes (see [008], [0015], [0025], [0033], [0041]). Secondly, feature (h) requires that the function for indicating positional errors in feature (g) is also suitable for enabling a change in the electrical signals applied to the plurality of electrodes (see [008], [0025], [0041]).

(i) "for providing improved transcranial stimulation of the head region of the subject"

38. Although feature (i) appears to be somewhat problematic because the word "improved" appears to invite a comparison with another, seemingly undefined, feature, I think its meaning would be clear to the skilled person in the context of paragraph [0015]:

> *Based on the feedback, the operator may reposition the electrodes for an improved transcranial stimulation. Alternatively, the system and method may modify/control electrical signals to be applied to the electrodes for the improved transcranial stimulation.*

39. Thus, I believe the skilled person would understand that feature (i) means the monitoring arrangement is suitable for providing improved transcranial stimulation by virtue of having the functionality defined in feature (h).

Is checking whether the electrodes make electrical contact with the skin "monitoring" for the purposes of the patent?

40. There is one final point of construction that I must consider. In their observations in reply, the proprietor says that:

> "What Flow's attorneys describe [page 2] as *"a measurement checking whether the electrodes contact the skin of the user…by providing a weak measuring current over the electrodes"* **is monitoring for the purposes of Claim 1 of the Patent**". (My emphasis given in bold.)

41. I understand the proprietor to be arguing, amongst other things, that the functional features of features (e)-(i) of claim 1 relating to the monitoring arrangement would be understood by the skilled person in the context of the patent to mean (or to have a meaning that extends to include) that the monitoring arrangement is suitable for monitoring whether the electrodes are in *electrical* contact with the skin of a user or

subject by providing a weak measuring current over the electrodes.

42. I have considered the patent carefully, and I am unable to identify any explicit or implied statement in the description or drawings to the effect that monitoring the positions of the electrodes means (or encompasses) monitoring whether they are in *electrical* contact with a subject's skin in this way. As I explained earlier, the patent teaches the skilled person several different ways of monitoring the positions of the electrodes on a subject's head, e.g. by using a camera, lights, markers, or motion sensors. Yet, as I understand it, there is no mention in the patent of monitoring the correct positioning of the electrodes on the head by monitoring whether the electrodes are in electrical contact with the subject's skin using a measuring current. Nor is it said, for example, that a positional error arises when there is no such detected electric contact between an electrode and skin. Nor is there any suggestion that there is a need to determine whether there is electrical contact of the electrodes with the skin to enable positional errors to be reduced, to facilitate repositioning of electrodes, or to improve transcranial stimulation. While I accept the patent clearly identifies the problem of making sure that the electrodes are positioned correctly to stimulate the intended brain region or underlying area of cerebral cortex (see [004]-[005] discussed above), and that this problem can be addressed by a system that monitors *positions* of electrodes on a given head region, the patent does not seem (to me) to identify any problem with the way in which the electrodes make *electrical* contact with the subject's skin.

43. To support their argument, the proprietor refers to paragraph [0034] of the patent where it is stated that:

> *In an example, the monitoring arrangement is operable to enable the power controller 102 to provide electrical signals to the electrodes 104 and 106 only when the* ***positions*** *of the electrodes 104 and 106 have been verified.* (My emphasis.)

44. I don't think this paragraph helps the proprietor since it is, it seems to me, entirely confined to verifying the "positions" of the electrodes, as opposed to verifying whether the electrodes are in *electrical* contact with the subject's skin (e.g. using a measuring current).

45. In the request the proprietor states that:

> *The invention is pithily summarised in the flow diagram of Figure 5.* ***This emphasises (a) ensuring contact to the skin****, (b) driving tDCS current to the electrodes, and (c) a monitoring arrangement to enable repositioning of electrodes as necessary, so as to provide "improved transcranial stimulation of the head region".* (My emphasis.)

46. I agree with the proprietor that Fig. 5 summarises how the system of claim 1 would be used. I believe the skilled person would understand from the flow diagram in Fig. 5 that at step 506 the monitoring arrangement "indicates positional errors of the electrodes" (see [0041]) after ensuring (as the proprietor puts it) at step 502 that "the electrodes 104 and 106 contact onto skin of the head region 110 of the subject" (see [0039]). Therefore, I believe the skilled person would understand Fig. 5 to be making a distinction between the idea of "contact onto skin" and the idea of a "positional

error". In other words, since positional errors are said to be indicated after ensuring the electrodes "contact onto" the subject's skin, I believe the skilled person would understand this means a positional error is not related to whether the electrodes contact onto the skin.

47. For all of these reasons, I must say that I am, respectfully, unable to agree with the proprietor that features (e)-(i) would be understood to mean (or to have a meaning that includes) a function of monitoring whether the electrodes are in electrical contact with the subject's skin by using a measuring current.

Indirect infringement

48. The observer does not dispute the proprietor's allegation that the headset and app comprising the product are supplied or offered for supply (albeit separately) by the observer in the UK. Nor does the observer dispute the proprietor's allegation that it knows the product is intended to be put into effect in the UK. I agree with the proprietor that for the purposes of confirming indirect infringement it is necessary for me to determine whether the headset and the app of the product amount to 'means essential', i.e. whether they constitute means relating to an "essential element" of the invention as required by section 60(2).

49. The proprietor alleges that the product has all the features (a)-(i) of claim 1. Yet the proprietor also explains that, because the product (alone) does not include the mobile device on which the app must be run, it reserves its position on whether the product (alone) would *directly* infringe claim 1 under section 60(1). Thus, the proprietor alleges indirect infringement under section 60(2).

50. The proprietor contends there is no doubt that the product amounts to means relating to an essential element of the invention because the only technical requirements it omits to provide "are a power supply and a standard smartphone or other such mobile device." In other words, the proprietor's view is that, "the Product, once the app is installed on a mobile device, infringes Claim 1 of the Patent according to the latter's literal meaning". (By "literal" I understand the proprietor to mean 'normal' or 'purposive'.)

51. The observer (rightly, in my opinion) does not dispute that the product exhibits features (a)-(d) of claim 1, so it is not necessary for me to consider features (a)-(d) any further. However, the observer denies that features (e)-(i) are implemented by the product. Hence, before I can give my opinion on whether the product is 'means essential', I must give my opinion on whether the product, when installed or run on a user's device, has or implements features (e)-(i).

Feature (e)

52. The proprietor says the monitoring arrangement is provided by the functionality of the app installed on the mobile device, the Bluetooth communication between the headset and mobile device, and the camera and screen of the mobile device, in combination. On the other hand, the observer says that during use of the product no monitoring of the spatial positions of the plurality of electrodes relative to the head region is performed. It says the only monitoring made by the product is to check

whether there is an electric connection between the electrodes or not.

53. I agree with the proprietor. When the app is installed and run on a user's device, it uses the device's camera as a sensor that captures images of the subject wearing the headset. I believe this means the camera must also necessarily capture images of the positions of the headset's electrodes on the subject's head. In this way, the use of the device's camera in combination with the device's display (i.e. as a "mirror") means the product is suitable for monitoring the in-use positions of the electrodes relative to the head region of the subject, according to feature (e) as I have construed it above.

Feature (f)

54. I believe it follows that, by using the user device's camera/screen to capture/display images of the subject wearing the headset, the product (when the app is installed on a user's device) is also suitable for monitoring the relative in-use positions of the electrodes, according to feature (f) as I have construed it. The observer says that the product does not comprise an arrangement for monitoring mutual relative positions of the electrodes. It argues the forehead frame on to which the product's electrodes are arranged is not mechanically adjustable. Hence, the relative positions of the electrodes of the product cannot be adjusted and therefore it makes no sense monitoring the relative positions of the electrodes. Respectfully, I do not agree. In my view, feature (f) places no limitation on whether either electrode is mechanically adjustable. All that is necessary to fulfil feature (f) is that the monitoring arrangement (in this case, the camera/screen of the user's device) is suitable for monitoring (in this case, capturing images of the subject wearing the headset) the relative positions of the electrodes on the subject's head. In my opinion, it is not relevant whether the electrodes of the product are mechanically adjustable on the frame.

Feature (g)

55. The proprietor points to the observer's admission that the product makes a measurement checking whether the electrodes are in electrical contact with the skin (by using a weak measurement current), and the product's ability to indicate whether either electrode is detected to be in contact with the subject's skin (i.e. by the "Next" button changing colour from greyed-out to green), to argue that the product necessarily implements feature (g). However, in feature (g) as I have construed it above, indicating positional errors does not mean (or have a meaning that extends to include) indicating whether electrodes are in *electrical* contact with the subject's head. So, it is my view that the protection afforded by feature (g) does not extend to include the product's undoubted ability to indicate whether the electrodes are in electrical contact with the skin.

56. In my opinion, when the app installed on a user's device, the monitoring arrangements of the product do not otherwise indicate in any suitable way positional errors of the headset's electrodes to the user. I agree with the observer when they say that when using the product, it is up to the user to identify positional errors using his/her cognitive skill in combination with the selfie-function of the mobile phone. I believe evidence for this is seen, for example, on pages 11-12 of the instruction manual where it is the user that is instructed to "Make sure the headset does not sit too low". I also agree with the observer that the green tick shown in the video

(apparently similar to the green tick in the third screenshot taken from the app, discussed at paragraph 16 above), is provided purely for illustration purposes only. In my opinion, this green tick is not provided as any part of the monitoring provided by the product. In my opinion, when the app is installed on a user's device, the product is not suitable for indicating positional errors of one or more of the electrodes, as required by feature (g).

Features (h) and (i)

57. As I have construed them above, feature (h) depends upon feature (g). Similarly, feature (i) depends upon feature (h). Since it is my opinion that feature (g) would not be implemented by the product, it must logically follow that neither feature (h) nor feature (i) are implemented by the product. I agree with the observer that features (h) and (i) are not implemented by the product when the app is installed on the user's device.

Does the product constitute means relating to an "essential element" of the invention?

58. To summarise my analysis of features (a)-(i) of claim 1 in relation to the product, it is my opinion that features (a)-(f) would be implemented by the product when the app is installed on a user's device. However, it is also my opinion that features (g)-(i) would *not* be implemented by the product when the app is installed on a user's device.

59. There is no doubt in my mind that feature (g) of the invention – i.e. a system for transcranial stimulation including a monitoring arrangement that is suitable for indicating positional errors of one or more of a plurality of electrodes – is plainly an essential feature of the invention in the context of the patent when read as a whole. For example, paragraphs [004] and [005] (discussed at paragraph 34 above) clearly set out the importance of the correct placement of electrodes on the subject's head and the reproducibility of the site of stimulation. Based on this, paragraph [005] of the patent identifies a need for a system that not only monitors positions of electrodes but also enables positional errors of the electrodes to be reduced. According to the patent, this need is fulfilled by a system that necessarily provides (amongst other things) a monitoring arrangement for indicating positional errors of the electrodes – see for example paragraphs [008], [0015], [0033], [0041] and figures 2B and 5. It must also follow that features (h) and (i) must also be essential features of the invention in the context of the patent.

60. That the product does not implement features (g)-(i), when the app is downloaded or run on the user's device, shows decisively, in my opinion, that the product, as constituted by the headset and the app, cannot amount to means relating to an "essential element" of the invention as required by section 60(2). It follows that the product cannot indirectly infringe claim 1 of the patent under section 60(2).

61. I would add that neither party has suggested that in considering indirect infringement under section 60(2) I should have any regard to the *Improver* (or 'protocol') questions[5] or submitted any arguments in relation to those questions. Although it is

[5] *Actavis v Eli Lilly* [2017] UKSC 48, at [53]-[66]

not necessary for me to say so, it seems to me that the *Improver* questions relate to direct infringement under section 60(1). In any case, for the avoidance of doubt, I confirm that in reaching my opinion I have not considered the *Improver* questions.

Opinion

62. Based on the information I have been given, it is my opinion that the product does not amount to indirect infringement of claim 1 of the patent under section 60(2) of the Act.

Application for review

63. 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.

Stephen Richardson
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.