Patents Act 1977 **Opinion Number** **22/21**

OPINION UNDER SECTION 74A

Patent	EP 2593015 B1
Proprietor(s)	The Cleveland Clinic Foundation
Exclusive Licensee	Prevent Biometrics, Inc.
Requester	Prevent Biometrics, Inc.
Observer(s)	HitIQ Limited
Date Opinion issued	07 January 2022

The request

1. Prevent Biometrics, Inc. ("the requester"), has requested the comptroller to issue an opinion as to whether patent EP 2593015 B1 ("the Patent") is infringed by the Nexus A9 sensor and mouthguard ("the Nexus A9") which is manufactured by HitIQ Limited. In particular, an opinion is requested as to whether offering for use in the UK the method disclosed in connection with the Nexus A9 sensor and mouthguard is an infringement of the Patent under Section 60(1)(b) of the Act. Three pieces of evidence have been filed in support of the request, including:

   Vimeo Video "Hit.IQ SMART MOUTHGUARD – House of Wellness Episode 19" available at https://vimeo.com/563508030 ("the video")

   HitIQ Limited's Prospectus ("the Prospectus")

   HitIQ "transformative concussion management technology" Corporate Presentation ("the Corporate Presentation")

2. Observations were received from Albright IP on behalf of HitIQ Limited ("the observer"), and observations in reply were subsequently received from the requester.

3. HitIQ Limited have also filed a request for an opinion relating to the validity of EP 2593015 B1 (opinion 23/21).

The Patent

4. The Patent relates to a method for determining a risk of a head/neck injury due to an impact, for example whilst participated in contact sports such as rugby, mixed martial arts (MMA) etc. The method involves measuring acceleration at a lip/mouth guard worn by an athlete to determine an acceleration at a centre of gravity of the head,

which is then used to calculate impact parameters. These impact parameters are then associated with one of a number of injury classes, each injury class representing a range of probabilities that the athlete will suffer a head/neck injury given the calculated impact parameters.

5. Claim 1 of the Patent, which is the only independent claim, is reproduced below (with associated references F1-F7 which have been utilised by the observer and requester in correspondence):

F1	"A method for determining a risk of injury to a human being due to an impact comprising:
F2	measuring (144, 146, 148, 150) at least one of a linear acceleration and an angular acceleration at a first location on the human being,
F3	the first location in a one of a mouth guard and a lip guard worn by the human being;
F4	determining (156) an acceleration at a center of gravity of the head of the human being from the measured at least one of a linear acceleration and an angular acceleration at the first location, the first location being remote from the center of gravity of the head;
F5	calculating (178) a plurality of impact parameters from the determined acceleration at the center of gravity of the head;
F6	associating (180) the calculated plurality of impact parameters with an associated injury class of a plurality of injury classes, each injury class representing a range of probabilities that the human being will suffer an injury to a structure within one of the head and the neck of the human being given the calculated plurality of impact parameters; and
F7	communicating (182) the associated event class to an observer via an associated output device."

6. Claim 2 of the Patent states:

> "The method of claim 1, wherein the plurality of injury classes represent ranges of probabilities of a concussion."

Claim Construction

7. Before considering the issues 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[1] and the Court of Appeal in Actavis v ICOS[2].

8. I consider the person skilled in the art to be, prima facie, an expert in head impact technology.

9. I think there are a few features of claim 1 it is worthwhile discussing. Firstly, parts F2-F4 in claim 1 refer to a "first location in a one of a mouth guard and a lip guard" and determining an acceleration at a centre of gravity of the head "from the measured at least one of a linear acceleration and an angular acceleration at the first location, the first location being remote from the center of gravity of the head".

10. The observer has noted that in interpreting the F2-F4 part of the claim, the unique and distinct nature of the "first location" is important, They note that the Patent (see e.g. paragraphs 19-21) discloses a technique which allows for determination of acceleration at the centre of gravity of the head from an individual first location using kinematics (for example a time varying function).

11. The requester considers that claim 1 encompasses transferring accelerations from multiple locations as this includes transferring an acceleration from a first location. They note that the claim does not specify a single location, only one location or an individual location – rather it calls for a "first location" which leaves open the opportunity for the determination to include accelerations at a second, third location etc. That is, nothing in the claim precludes reliance on additional information or data to determine the acceleration at the centre of gravity. The requester further notes that the claim explicitly provides the option for more than one acceleration (i.e. linear and angular). The requester notes that the claim is not limited to any particular way of determining the acceleration at the centre of gravity.

12. Looking at the description (see for example paragraphs 10-13) I do not think the person skilled in the art would construe the "first location" as defining a single sensor only – in particular, it is clear that the mouth/lip guard can have multiple sensors in the form of a sensor array, sensor strip and/or sensor assembly, with the sensors configured to measure at least one of linear acceleration and angular acceleration (see page 3 lines 24&25). Therefore the "first location" in the mouthguard would be construed by the person skilled in the art as a location of a sensor or a location including a plurality of sensors.

13. Furthermore, as the linear/angular acceleration can be measured using sensors, I also do not think the person skilled in the art would consider the determination of acceleration to be limited to a kinematics / time varying function methodology based on a single individual sensor location. I also note that paragraph 19 discusses the position of *each* sensor assembly (relative to the head) being represented as a time varying function. The person skilled in the art would therefore construe the acceleration at the centre of gravity of the head to be determined from linear and/or angular acceleration measured using a sensor or sensors located in the mouth/lip guard.

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

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

14. Secondly, I note “a plurality of injury classes” and “range of probabilities” defined in part F6 of claim 1 are discussed in the same general terms in the description (see e.g. paragraph 24), such that the person skilled in the art would construe such terms in F6 to encompass any classifications for a head/neck injury or injuries, with each classification having a range of probabilities for that injury. For example, the person skilled in the art would construe claim 1 to encompass that the plurality of classes may be for a single type of head/neck injury - with each class defining a ranges of probabilities for that injury (see e.g. claims 2-9), or the classes may define multiple types of head/neck injuries each with respective ranges of probabilities (e.g. claim 10).

15. I also note that “the associated *event* class” has no clear antecedent in part F7 of claim 1. The person skilled in the art would construe this as “the associated *injury* class”.

The Nexus A9

16. A video, along with two documents (“the Prospectus” and “the Corporate Presentation”) have been submitted by the requester to provide information regarding the Nexus A9 sensor and mouth guard system. I shall outline the information in each of these in turn.

The video

17. This video gives an overview of a HitIQ mouthguard, which includes a discussion of a mouthguard with “sensors that measure forces” and a “system which measures a head impact”. At 45 seconds the presenter in the video comments “the impact sensor log all head knocks and highlights an athlete at risk of concussion”.

18. Furthermore the video also shows (at 2:41 – 2:50) various information presented on the screen of a device, which I have reproduced below:


Athlete Analysis
Back
2144 UNK
#50 | test
41
Impacts in Training Round 1
Impact History
THE HOUSE OF
wellness


Athlete Analysis
Back
2144 UNK
#50 | test
41
Impacts in Training Round 1
Impact History
THE HOUSE OF
wellness


Back
Athlete Analysis
2048 UNK
Total impacts
24
Impacts in Training Round 1
5650 rad/s²
53 Gs
Impact History
THE HOUSE OF
wellness


Training Round 1
1439
Training Round 1
Impact count is equal to the average for this period
Impact History
Athlete by highest rotational force
UNK, 2144
UNK, 2019
UNK, 2048
Athlete by total number of impacts
No Splits
Impacts by Splits
THE HOUSE OF
wellness

HitIQ Limited's Prospectus ("the Prospectus")

19. The prospectus has 152 pages providing an overview of HitIQ Limited. Pages 40-53 discuss the company and projects overview. In particular, Page 40 states:

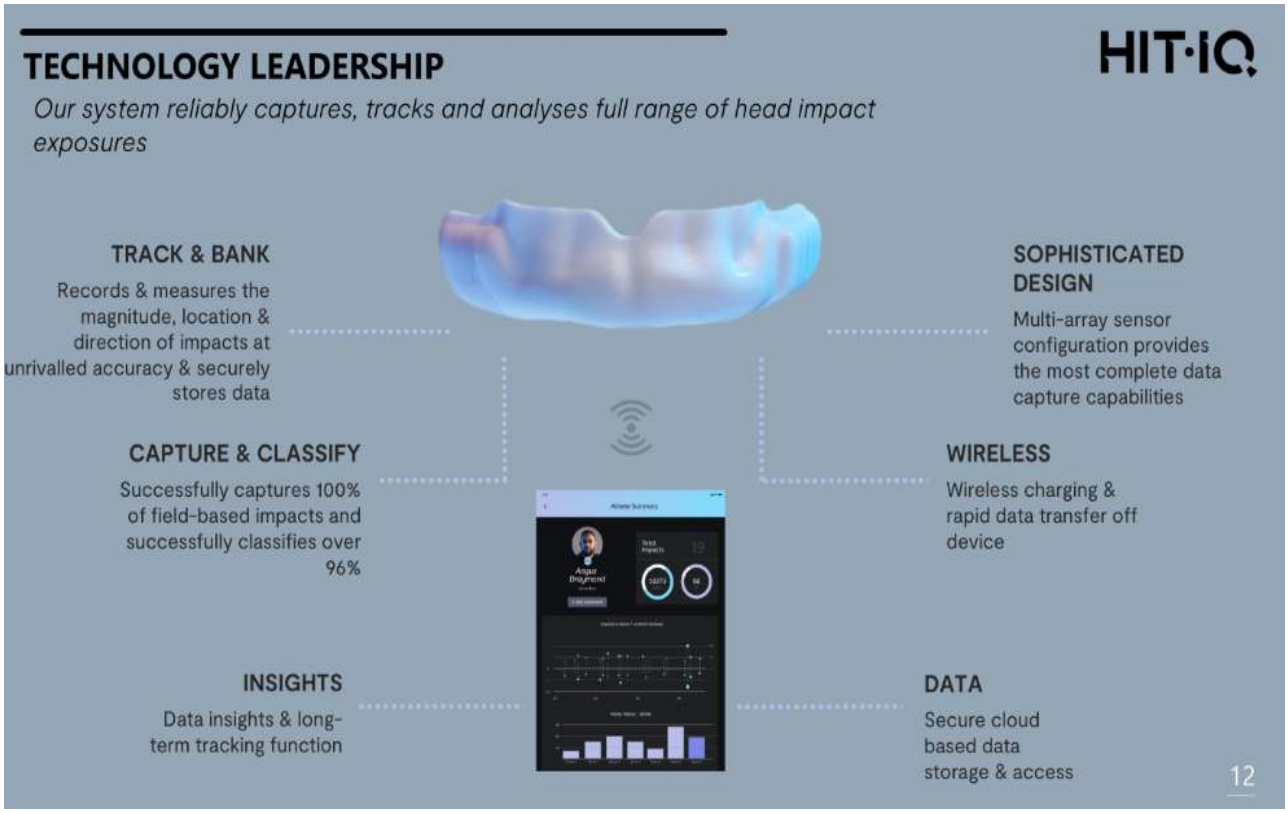
> "Through data acquisition, algorithmic transformation & analysis activities from its two core products, HitIQ is able to provide insights into:
>
> a. Linear and rotational head kinematics;
>
> b. Accumulated head impact energy;
>
> c. Assessment urgency; and
>
> d. Cognitive, vestibular and oculomotor function."

20. Pages 43-44 state:

> "HitIQ's core product is the Nexus A9 head impact mouth guard sensor…."
>
> "The primary function of the Nexus A9 Sensor is as a head impact surveillance device, built into a custom fitted mouth guard of the type usually used by the participants in the relevant sport"
>
> "HitIQ has developed a discrete mouthguard sensor to identify, collect and quantify all head impact exposures in training and game environments. The sensor has been independently validated….The validation highlights the accuracy of out impact sensor, with respect to mean absolute error margins of 3.85% across the entirety of both linear and rotational acceleration profiles"
>
> "The Nexus A9 high frequency sensor array measures parameters related to head impact injury biomechanics, specifically linear and rotational accelerations (force). HitIQ's sophisticated algorithms can accurately translate the raw accelerometry data into inferred forces experienced through the centre mass of the brain"

HitIQ “transformative concussion management technology” Corporate Presentation (“the Corporate Presentation”)

21. This document has 12 pages discussing HitIQ, in particular page 12 is reproduced below:



22. The screenshot from page 12 can also be seen more clearly below: [I have added an arrow to emphasise a dashed line in the impact history]

Infringement

23. Section 60 of the Act states that:

(*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.

(2) 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.

24. In the Supreme Court in *Actavis v Eli Lilly*[3] 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?

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

Arguments

26. I will start by asking whether the Nexus A9 infringes claim 1 as a matter of normal interpretation? The requester argues that the Nexus A9 sensor and mouthguard system performs each step of the method of claims 1&2 as a matter of normal interpretation, and thus when used or when offered for use in the UK would be an infringement under Section 60(1)(b).

27. The observer considers that the evidence provided by the requester fails to demonstrate infringement of the Patent and, in particular, parts F4 and F6 do not form part of the Nexus A9.

28. As an initial point, I think it is reasonable to conclude the video and documents provided by the requester discuss the same system – the Nexus A9 sensor and mouthguard system – and thus the information in these pages can be considered together for assessing infringement. I note that the observer does not seem to refute this point.

29. I think it is clear, from page 44 of Prospectus at least, that the Nexus A9 measures linear and rotational accelerations using some form of sensor or sensor array in a mouthguard worn by an athlete.

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

30. Whilst page 44 of the Prospectus states that “HitIQ’s sophisticated algorithms can accurately translate the raw accelerometry data into inferred forces experienced through the centre mass of the brain”, the observer does not consider the Nexus A9 to have the feature defined in part F4 of the claim as it does not determine acceleration at the centre of gravity of the head from a measured linear/angular acceleration measured at a “first location” that is “remote from the centre of gravity of the head”. The observer notes that the Nexus A9 sensor relies on a sensor array which utilises accelerometer sensors at multiple different locations on the mouthguard, and thus instead determines acceleration at the centre of gravity of the head from measured linear/angular accelerations *at a number of distinct locations*.

31. The requester considers that any single one of the Nexus A9 sensors at any one of the multiple, different, or distinct locations on the mouthguard that contributes to the determination of the acceleration at the centre of gravity is sufficient to satisfy part F4 of the claim.

32. I would note that the evidence does not give detail regarding the determination of the acceleration at the centre of gravity of the head. Nevertheless, it is my opinion that the Nexus A9 does have the features of F2-F4, as construed above in paragraphs 12&13, as it determines an acceleration at the centre of gravity based on linear/angular acceleration data measured at a first location of a sensor array in a mouthguard – as discussed in page 44 of the Prospectus.

33. The observer has commented that the video and documents provided by the requester do not provide evidence of the use of a plurality of impact parameters. However, it is my opinion that they do – see, for example, the screenshots in the video and the screenshot in the Corporate Presentation – as they show a number of impacts calculated over the various matches, the magnitude of impacts etc. and I believe that it is at least implicit that these parameters are calculated based on the “forces experienced through the centre mass of the brain”. Therefore, it is my opinion that the Nexus A9 has the features of part F5 of claim 1.

34. The observer has argued that the Nexus A9 does not have the features of part F6 of the claims. In particular the observer notes that the comment in the video (at 45 sec) that the Nexus A9 “log all head knocks and highlights an athlete at risk of concussion” and page 12 of the Corporate Presentation (Capture & Classify; Successfully captures 100% of field based impacts and successfully classifies over 96%) do not indicate that the Nexus A9 has the features of F6. In particular, there are no injury classes or discussion of classification in the video, and the Corporate Presentation does not classify impacts to injury classes.

35. The observer has also stated that, at best, the evidence regarding the Nexus A9 provides a general insinuation that it can highlight an athlete at risk of concussion (for example using some kind of threshold). This, at best, could be interpreted as a suggestion there is a binary categorisation of “at risk” (i.e. >0%) or “not at risk” (i.e. 0%). The observer further adds that when there are only two classifications, being “at risk” or “not at risk”, that fails to provide the necessary features of “each injury class representing a range of probabilities. For example, the “not at risk” indicates 0%, which is not a range of probabilities.

36. The requester considers that when the video and documents are reviewed as a

whole, they demonstrate that the Nexus A9 has the features of part F6 of claim 1. In particular, the requester highlights the comment in the video (at 45 sec) and the screenshot on page 12 of the Corporate Presentation.

37. The requester states that, in its simplest form, “a plurality of injury classes” is two injury classes (e.g. “at risk” and “not at risk”) and that the “highlighting athletes at risk of concussion” comment in the video is enough to demonstrate the use of “a plurality of injury classes” in this regard (as not highlighting an athlete classifies an athlete as not at risk). Furthermore, a “risk of concussion” reflects a probability (e.g. likelihood) that an athlete will suffer an injury.

38. With regard to page 12 of the Corporate Presentation, the requester considers the screenshot to classify single impacts as high or low risk based on magnitude (see “Impacts in Game 7 vs North Carolina”) and classifies cumulative impacts as high or low risk based on number of impacts (see “Impact History – Games”). In particular, with regard to the cumulative impacts, the requester emphasises a dashed line in the screenshot as setting a threshold set for the number of impacts – thus showing a first classification (high risk: 18-30 impacts) and a second classification (low risk: 0-18 impacts) – which establishes two separate injury classes. Furthermore, the requester notes that the threshold is set at 18 (thus allowing for some tolerable amount of cumulative impact) in the screenshot and that there is thus “a range of probabilities” of injury as it is not reasonable to suggest that a player with 17 impacts has no risk and that a player with 19 impacts magically now has risk.

39. Regarding the comment in the video – it is my opinion this generalised statement does not demonstrate the use of a “plurality of injury classes”. I note that it is not shown or discussed in the video (or the other documents) how any “highlighting” is done. For example, the “highlighting” of athletes at risk could be inferred by the user rather than explicitly presented to them.

40. With respect to the screenshot on page 12 of the Corporate Presentation, it is my opinion that it shows information regarding numbers and/or magnitude of impacts only. The “Impacts in Game 7 vs North Carolina” in particular appears to show magnitude of impacts only and is not relative to any threshold, benchmark etc. This part of the screenshot therefore does not indicate a plurality of classes, let alone a “plurality of injury classes”. The requester has referred to the dotted line in the “Impact History – Games” as a ‘threshold’ establishing two injury classes. However, it is not clearly specified anywhere in this document what this dotted line relates to. I would note that this dotted line appears to be, prima facie, *an average number of impacts* and does not relate to a threshold regarding injury. Thus it is my opinion that the screenshot on page 12 of the Corporate Presentation does not provide a “plurality of injury classes”.

41. It is also my opinion that, when considering the video, Corporate Presentation and Prospectus as a whole, there is no disclosure of the Nexus A9 providing “plurality of injury classes”. In particular there nothing to indicate that the comment in the video regarding “highlighting athletes at risk of concussion” relates to the dotted line in the screenshot of “Impact History – Games”, or has any particular correspondence to screenshots shown in the video or Corporate Presentation. Furthermore, whilst the title of the Corporate Presentation relates to “concussion management technology” there is no detail or discussion in the document itself regarding concussion that could

lead to inferring “a plurality of injury classes” in the information on page 12. Similarly, the classification referred to on page 12 (i.e. Capture & Classify) has no correspondence with the screenshot to infer “a plurality of injury classes”.

42. I would note that *even if* the dotted line in “Impact History – Games” display on page 12 of the Corporate Presentation was considered to relate to an injury threshold such that it defined two injury classifications, this screen output does not have *each* injury class representing “a range of probabilities” of head/neck injury. The video and documents regarding the Nexus A9 make no reference to probability with regard to any threshold or classes, and is silent as to the significance of any values that lie within the ‘range’ of the two classes (e.g. 0-17 impacts for the class below the dotted line threshold and 18+ for the class above the threshold). For example, it may well be the case the 18 impacts have the same probability of injury as 30 impacts (i.e. 100%).

43. Therefore, it is my opinion, based on the information provided to me, that the Nexus A9 does not have the features of part F6 of claim 1.

44. Furthermore, as a consequence of not having part F6, the Nexus A9 does not have the features of part F7 of claim 1 as it does not communicate the associated *injury class* to the user.

45. I would also note that it is my opinion that the Nexus A9 does not have part F1 of claim 1. The requester argues, similar to the argument regarding part F6 of the claims, that the comment in the video the “impact sensors log all head knocks and highlights an athlete at risk of concussion” provides evidence for part F1 of claim 1. However, it is my opinion that this comment, and/or the reference to concussion in the Corporate Presentation, is not enough to disclose *a method for determining risk of injury due to an impact* – particularly as the output of the Nexus A9 presented to the user in the screenshots only indicates number of impacts and/or magnitude.

46. Therefore, I am of the opinion that the Nexus A9 – i.e. the Nexus A9 sensor and mouth guard system – does not infringe claim 1 as a matter of normal interpretation.

47. The second issue to be addressed is asking whether the variant provided by the Nexus A9 varies in a way(s) which is immaterial? The court in Actavis UK Limited provided a reformulation of the three questions in *Improver*[4] to provide guidelines or helpful assistance in connection with this second issue. These reformulated questions are:

> (i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?
>
> (ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

[4] Improver [1990] FSR 181

(iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

48. In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was “yes” and that the answer to the third question was “no”.

49. The first question necessitates the identification of the inventive concept revealed by the Patent. In their submission, the observer does not appear to have defined an inventive concept for the Patent – but rather aims to disregard inventive character from various features of the claim based on common general knowledge (for which they refer to three documents).

50. The requester has identified the inventive concept as the combination of sensing accelerations in a mouthguard and translating those accelerations to the centre of gravity of the head. The requester considers the Nexus A9 to do this, and simply adding more sensors at more sensing locations does not change the way this is done or the result. Furthermore, the requester also notes that the use of a zero/some risk threshold with respect to part F6 of claim 1 does not change the way this is done or the result, and adds that with respect to a zero/some risk threshold in lieu of injury classes representing a range of probabilities of injury, the user has still relied on acceleration measured in a mouthguard, translated those to the centre of gravity and learning of its probability of injury risk.

51. It is my opinion that the requester’s identification of the inventive concept omits important features from claim 1. In particular I would note that the claim relates to *a method for determining risk of injury due to an impact* and thus I consider the features in F6 regarding the associating of impact parameters to an injury class, with each class representing a range of probabilities, to form part of the inventive concept. Therefore, I consider the inventive concept to reside in associating parameters, calculated based on an acceleration at the centre of gravity of the head using measured accelerations in a mouthguard, to an injury class representing a range of probabilities of a head/neck injury.

52. It is my opinion that the Nexus A9, based on the information provided to me, does not achieve substantially the same result in substantially the same way as the invention. In particular, it does not determine an injury class, nor utilise a range of probabilities. Put simply the inventive concept provides a refined way of classifying head/neck injuries which is not achieved by the Nexus A9.

53. Therefore, it is my opinion that the Nexus A9, based on the information provide to me, does not vary from the Patent in a way(s) that is immaterial.

Opinion

54. It is my opinion that the Nexus A9 as specified in the request does not fall within the scope of claim 1 as a matter of normal interpretation, nor does the Nexus A9 vary from the Patent in a way that is immaterial. Accordingly, it is my opinion that The Nexus A9 does not infringe under Section 60(1)(b) of the Act.

Application for review

55. 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.