Patents Act 1977	**Opinion Number**	**23/21**

OPINION UNDER SECTION 74A

Patent	EP 2593015 B1
Proprietor(s)	The Cleveland Clinic Foundation
Exclusive Licensee	Prevent Biometrics, Inc.
Requester	HitIQ Limited
Observer(s)	Prevent Biometrics, Inc.
Date Opinion issued	03 February 2022

The request

1. HitIQ Limited ("the requester"), has requested the comptroller to issue an opinion as to whether patent EP 2593015 B1 ("the Patent") is valid. In particular the requester has asked for an opinion relating to claims 1&2 of EP 2593015 in view of the following documents:

PA1: *In situ Measures of Head Impact Acceleration in NCAA Division I Men's Ice Hockey: Implications for ASTM F1045 and Other Ice Hockey Helmet Standards*, Journal of ASTM International, Vol. 6, No. 6, published 2009.

PA2: *Measurement of Impact Acceleration: Mouthpiece Accelerometer Versus Helmet Accelerometer*, Journal of Athletic Training 2007;42(1):5-10, published 2007

PA3: *An Algorithm for Estimating Acceleration Magnitude and Impact Location Using Multiple Nonorthogonal Single-Axis Accelerometers*, Transactions of the ASMA Vol. 126, published 2004

PA4: *Head Impact Severity Measures for Evaluating Mild Traumatic Brain Injury Risk Exposure*, Neurosurgery, 2008 April : 62(4): 789-798, published 2008

CGK1: *Measurement of 3-D Head Kinematics in Impact Conditions Employing Six-Accelerometers and Three-Angular Rate Sensors (6αω Configuration)*, Injury Biomechanics Research, Proceedings of the Thirty-Seventh International Workshop

CGK2: *Measurement of Angular Acceleration of a Rigid Body Using Linear Accelerometers*, Transactions of the ASME, Journal of Applied Mechanics, 552-556, published 1975

2. Observations were received from Barker Brettell on behalf of Prevent Biometrics, Inc ("the observer"), which included a declaration by Adam Bartsch (listed as one of the inventors of the Patent), a letter and an ESPN article with quotes from Dr. Breedlove and Good. Observations in reply were subsequently received from the requester, including a declaration by Mr David Erikson.

3. An opinion relating to infringement of EP 2593015 B1 has previously been issued (opinion 22/21).

Preliminary Matters

4. The observer has commented that the question of validity has already been sufficiently considered in examination proceedings before the EPO, and that the request for an opinion on validity should be denied under Section 74A(3)(b) and Rule (1)(b) of the Act.

5. The established practise of the Office[1] is that an opinion request must raise something new, rather than merely seeking to cover old ground. In particular the opinion request should raise a new question. As the documents submitted by the requester were not considered by the EPO during examination proceedings, I consider that the opinion request is raising a new question. It is therefore appropriate for me to consider the opinion request.

6. I would also note that in their observations in reply, the requester has provided a declaration by Mr David Erikson. As this declaration appears to provide observations on the submitted documents (i.e. CGK2 and PA3) only – rather than any *further* information or evidence per se – I deem the declaration to be 'strictly in reply' and I will therefore consider the comments in the declaration as part of this opinion.

The Patent

7. EP 2593015 B1 ("the Patent") was filed on the 15 July 2011, claiming an earliest priority date of 15 July 2010. 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.

8. 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):

[1] See decisions BL O/370/07, BL O/289/07 and BL O/298/07

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.”

9. 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

10. 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[2] and the Court of Appeal in Actavis v ICOS[3].

11. I think it is reasonable to consider the person skilled in the art to be, prima facie, an expert in head impact technology.

[2] Generics UK Ltd (t/a Mylan) v Yeda Research and Development Co. Ltd & Anor [2017] EWHC 2629 (Pat)
[3] Actavis Group & Ors v ICOS Corp & Eli Lilly & Co. [2017] EWCA Civ 1671

12. 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".

13. 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 sensor<u>s</u> 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.

14. 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.

15. 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).

16. 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".

Documents

17. The requester has referred to six documents, which are summarised below:

<u>**PA1**: *In situ Measures of Head Impact Acceleration in NCAA Division I Men's Ice Hockey: Implications for ASTM F1045 and Other Ice Hockey Helmet Standards*</u>

18. PA1 is a study that aimed to characterise head impacts sustained in situ by ice hockey players and made use of helmets with embedded sensors to measure head

accelerations of the players. The abstract states:

> "A pilot study was performed to measure head impact accelerations in collegiate men's ice hockey during the 2005–2007 seasons using helmets instrumented with Head Impact Telemetry System technology to monitor and record linear head accelerations and impact locations in situ. The objectives of this study were (1) to quantify the relationship between resultant peak linear head acceleration and impact location for in situ head impacts in collegiate men's ice hockey, (2) to quantify the frequency and severity of impacts to the facemask, and (3) to determine if in situ impacts occurred such that the peak resultant linear head acceleration was higher than the peak resultant linear headform acceleration from a 40-in. linear drop (as in ASTM F1045–99) on the same helmet at a similar impact location"

19. The 'Introduction' on Page 2 of PA1 states:

> "Recently developed technology [Head Impact Telemetry HIT System, Simbex, Lebanon, NH; Sideline Response System, Riddell, Chicago, IL], has enabled in situ monitoring of head impact accelerations during helmeted activities. Studies of in-field head acceleration in American football, reported by the authors and others, have utilized this technology to demonstrate that a wide range of impact accelerations can result in clinically diagnosed concussion, including impacts that correspond to lower impact energies than those prescribed in current hockey helmet standards"

20. On page 3, under 'Data Collection", PA1 states:

> "Instrumented helmets contained six single axis micro electric-mechanical systems MEMS accelerometers (Analog Devices, Inc., Cambridge, MA), data acquisition electronics, 128 kbyte of memory capable of storing data for up to 100 impacts, and a rf transceiver. These components were built into the liners of commercially available EPP ice hockey helmets Fig. 1 and were collectively referred to as an IHU."

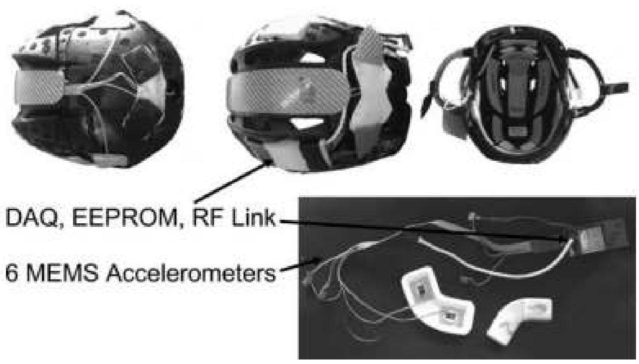


FIG. 1—*HIT System for hockey. The IHU for ice hockey consists of data acquisition and telemetry electronics as well as six MEMS accelerometers mounted within the liner of a commercially available ice hockey helmet.*

> "Each IHU transmitted data in real time to the HIT sideline controller SC, which consisted of a rf telemetry link and a laptop computer for data processing and storage. Within the SC, the data from the six nonorthogonal

accelerometers in the helmet were used to compute the head center of gravity CG, resultant linear acceleration time series, and impact location [23,24]"

(reference 23 corresponds to **PA3**, discussed below)

21. PA1 discusses at page 7:

> "Based on this work, a recommendation could be made for an appropriate pass/fail criterion that would be related to the incidence or risk of mTBI for a given set of head impact characteristics. These characteristics may include peak linear acceleration, peak rotational acceleration, impact duration, impact location, or a combination of these, and possibly other variables, such as a weighed principle component score previously proposed by the authors [17]."

<u>**PA2**: *Measurement of Impact Acceleration: Mouthpiece Accelerometer Versus Helmet Accelerometer*</u>

22. This paper is concerned with the issue that instrumented helmets may not accurately measure the actual amount of acceleration experienced by the head due to factors such as helmet-to-head fit, and looks to determine if an accelerometer attached to a mouthpiece (MP) provides a more accurate representation of headform centre of gravity (HFCOG) acceleration during impact than does an accelerometer attached to a helmet fitted on the headform. In particular, peak acceleration (*g*) and Gadd Severity Index (SI) values measured intraorally (i.e. on a mouthpiece) were tested to evaluate if they were more representative of headform centre of gravity (HFCOG) acceleration and SI than are helmet *g* and SI values.

23. A helmeted headform, corresponding to those used in the impact testing of football, hockey, baseball, and lacrosse helmets, was instrumented with respective accelerometers located at the centre of gravity, a mouthpiece and the helmet to measure the acceleration experienced by the helmeted headform upon impact – see figures 1&2 reproduced below.

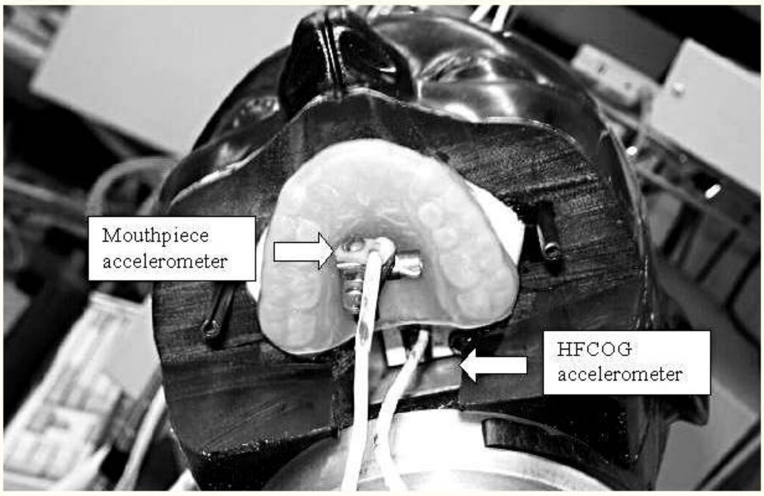


Figure 1
Modified National Operating Committee on Standards for Athletic Equipment (NOCSAE) headform with mouthpiece and headform center-of-gravity (HFCOG) accelerometers. The chin portion has been removed to show placement of accelerometer

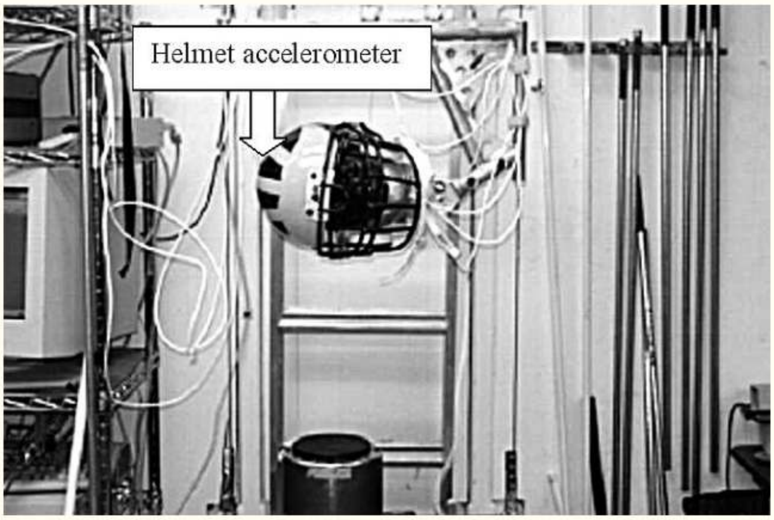
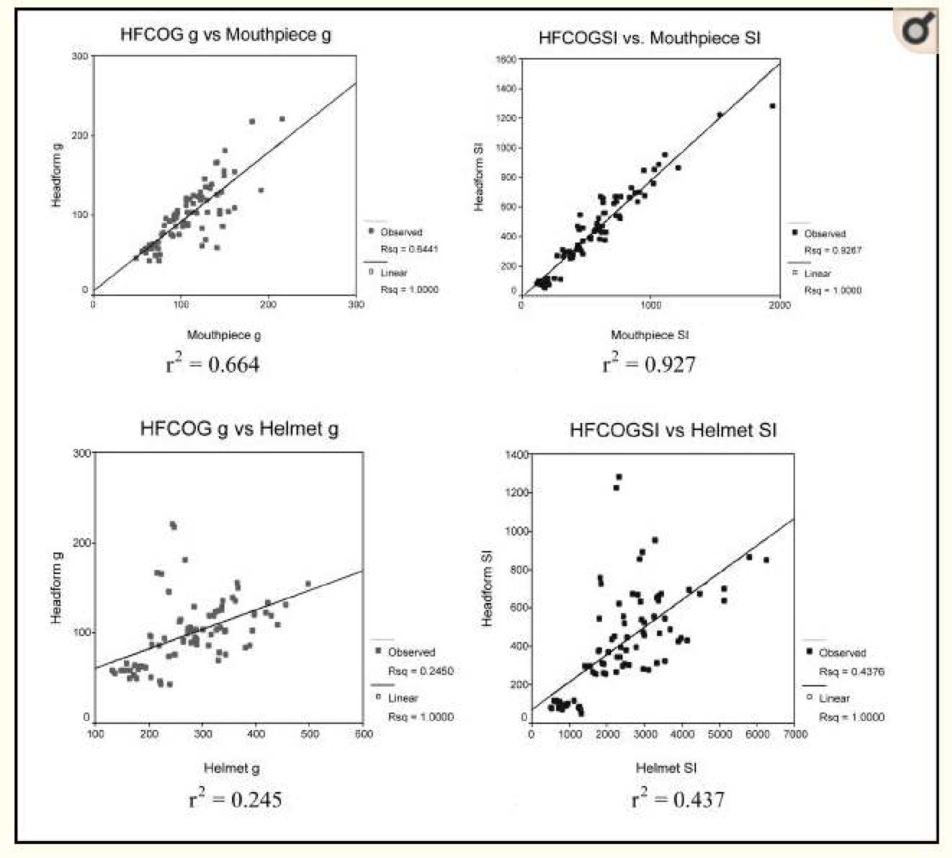


Figure 2
National Operating Committee on Standards for Athletic Equipment impact test system. The helmeted headform was dropped from various heights onto the modular elastomer programmer (black pad)

24. The study was considered to demonstrate that an accelerometer attached to an MP in a helmeted headform was a valid measurement of acceleration and SI experienced by the HFCOG. No significant differences were noted between HFCOG and MP *g* and SI measurements, and a high correlation was seen between HFCOG and MP *g* and SI measurements. Conversely, an accelerometer placed on the helmet significantly was felt to overestimate accelerations and SI in a nonuniform manner that could not be related to the acceleration and SI measured at HFCOG. The results are show below in figure 4:



25. Page 9 of PA2 states:

> "Our results validate an MP molded to the dentition as a valid method of measuring head acceleration. Future research will focus on testing the MP in live subjects in a laboratory setting to measure impact acceleration to the head in different sport activities. Also, acceleration levels to the head can be assessed and compared in many different sports to examine the potential for head injury and to determine the sports in which the greatest amount of acceleration exists. It is important to be able to measure the magnitude of head impacts in helmeted and nonhelmeted sports. The measurement of head acceleration in helmeted sports is being investigated with instrumented helmets,[8–10,26] but little success has been demonstrated in developing techniques to accurately measure head acceleration in nonhelmeted sports. This study demonstrates the potential of having a valid measuring device to accomplish this task."

26. Under "Clinical Relevance", PA2 states:

> "With the awareness of the incidence of mild traumatic brain injury increasing, the ability to measure actual head acceleration during competition will provide medical personnel, helmet manufacturers, and researchers with invaluable information to help protect athletes more effectively. Measuring head acceleration of athletes during actual competition may greatly enhance the ability of sports medicine professionals and helmet manufacturers to protect athletes. This information would help to determine the range of acceleration levels that may cause a concussion. Our findings suggest that placement of

the accelerometer on the helmet is not a valid measurement of head acceleration. The MP measurement used in this study is a more valid measure of head acceleration, because its data were comparable, highly correlated, and not significantly different from the actual acceleration the headform experienced directly. The placement of an accelerometer in an MP has the potential to allow for the direct assessment of the actual acceleration experienced by the head and not the acceleration of the helmet."

27. Under "Limitations", PA2 states:

> "We only measured linear acceleration and not rotational acceleration with impact. Rotational acceleration has been reported to be a cause of neuronal injury because of the shearing forces experienced by neuronal tissue. We used a single triaxial accelerometer at each location; the limitation of this method is that it measures the acceleration only at the location of the accelerometer, which may limit understanding of the acceleration of the whole head [32] The transfer of this method to the measurement of head acceleration in the field is being investigated in human subjects. Factors being addressed are wires exiting the mouth and MP fit. Further investigation into head acceleration measurement in nonhelmeted sports is needed"

(reference 32 corresponds to **PA3**, discussed below)

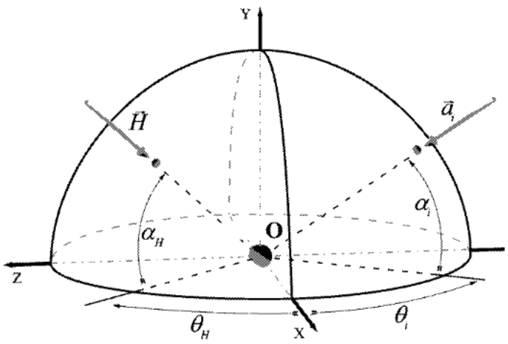
PA3: *An Algorithm for Estimating Acceleration Magnitude and Impact Location Using Multiple Nonorthogonal Single-Axis Accelerometers*

28. PA3 discusses the problems of head measurement systems which are used for correlating with brain injuries – such as the need for orthogonality in the accelerometers – and the challenge in providing such a system in a helmet. The abstract states that:

> "Accelerations of the head are the likely cause of concussion injury, but identifying the specific etiology of concussion has been difficult due to the lack of a valid animal or computer model. Contact sports, in which concussions are a rising health care concern, offer a unique research laboratory environment. However, measuring head acceleration in the field has many challenges including the need for large population sampling because of the relatively low incidence of concussions. We report a novel approach for calculating linear acceleration that can be incorporated into a head-mounted system for on-field use during contact sports."

29. PA3 presents an algorithm for calculating linear acceleration and impact location using multiple single axis accelerometers arranged normal to an object's (e.g. head's) surface, but not constrained to be orthogonal to each other. The head is modelled as a sphere in a spherical head co-ordinate system (HCS) with the origin at the sphere centre (O). The magnitude of the acceleration on the head at point O is defined by the magnitude of vector H, and the location of the impact is defined by the direction of the unit vector ($\dot{H}$). A set of n-single axis head mounted accelerometer sensors are located on the surface of the head, with the direction of the sensing axis of each accelerometer defined to be normal to the sphere surface (a_i). Figure 1 is

reproduced below:



30. Page 852 of PA3 states:

> "There are several approximations and limitations to the current algorithm and its implementation we chose to approximate the head as a hemisphere approximation for several reasons. First, it allowed the most concise presentation of the theory. Second it readily permitted the experimental study, since it was fairly straightforward to design and build a hemispherical headform with accelerometers embedded below the surface at specific elevation locations. Had we used a more realistic headform, we would have had to choose between several commercially available headforms for laboratory testing (for example, NOCSAE, Hybrid III, ASTM), all with different geometries and constructions. The algorithm can be used with non-spherical shapes simply by adding a term in Eq (1)[4] that accounts for the difference in orientation between the sensing axis and the surface normal to the location."

PA4: *Head Impact Severity Measures for Evaluating Mild Traumatic Brain Injury Risk Exposure*

31. PA4 discloses a study in which impact data was collected from football players using in-helmet systems having six single axis accelerometers. Head linear acceleration, head rotational acceleration, impact location, impact duration, Gadd Severity Index (GSI), and Head Injury Criteria (HIC) were computed for each of the impacts. Concussions were diagnosed by medical staff and later associated with the impact data. PA4 discusses the use of a weighted Principal Component Score (wPCS) - a weighted sum of linear acceleration, rotational acceleration, HIC and GSI (with objectively defined weights) multiplied by a location coefficient that was based on impact location – which was considered more predictive of concussion.

32. PA4 states under that heading 'Methods':

> "On-field head impact data were collected during the 2004, 2005, and 2006 seasons‡ from 259 players at 6 NCAA Division I schools (n=190,054) and 190 players at 7 high schools (n=99,862). All players wore Riddell football helmets (Riddell, Chicago IL) instrumented with six linear accelerometers that recorded an acceleration time history of the head center of gravity (CG) for all

4 $\|a_i\| = \|H\|\cos(\beta_i)$

impacts during practices and games [1,2]. Head linear acceleration, head rotational acceleration, impact location, impact duration, GSI, and HIC were computed for each of these impacts and stored for analysis [1,38]"

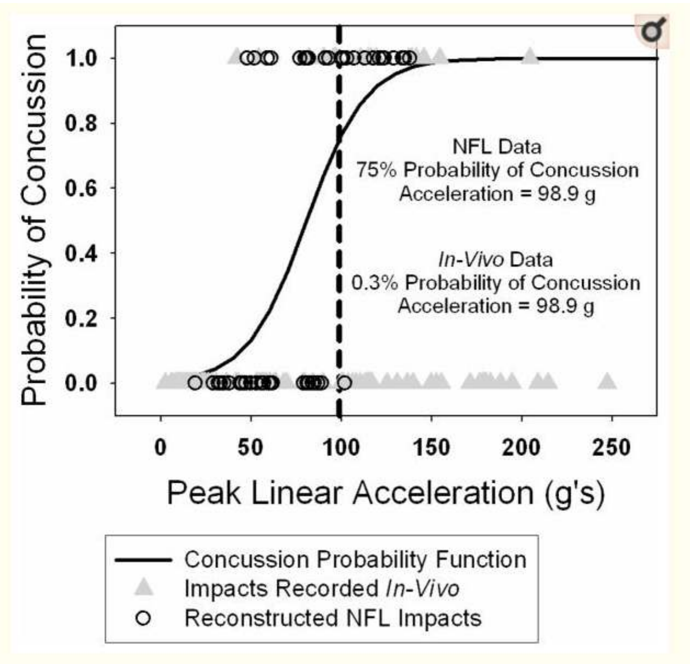
"For several classic biomechanical measures (linear acceleration, rotational acceleration, HIC), Receiver Operating Characteristic (ROC)[8,9] curves were developed from the data set. This type of curve defines the relationship between sensitivity and 1-specificity for each biomechanical measure. Sensitivity is the percentage of all concussions that were correctly identified by the measure (i.e. "correct prediction level") and 1-specificity is the percentage of all non-injurious impacts that were incorrectly identified as concussions by the measure (i.e. "false response rate"). Varying the value of the biomechanical measure that defined the tolerance level to concussion injury alters the relationship between the correct prediction level and the false response rate."

(reference 1 corresponds to **PA3**, discussed above)

33. PA4 states, under 'Discussion':

> "…the NFL study estimated that 75% of all impacts that were greater than 98.9g would result in concussion, while we collected on-field data for 3,476 impacts > 98.9g, only 11 of which (0.3%) were associated with clinical diagnosis of concussion (Figure 5)"

34. Figure 5, which relates to "Linear acceleration concussion probability function generated from NFL impacts reconstructed in the laboratory, as in Pellman, shown with 17 concussive impacts recorded in-vivo and a random sample of 100 controls (non-injurious impacts). In total there were 289,899 controls of which 3,476 were > 98.9g (the 75% concussion probability level based on NFL data)", is reproduced below:



CGK1: *Measurement of 3-D Head Kinematics in Impact Conditions Employing Six-Accelerometers and Three-Angular Rate Sensors (6αω Configuration)*

35. The requester initially stated that CGK1 was published in 2010, but did not specify when in 2010. The observer has therefore questioned whether this document is therefore prior art. The requester has subsequently commented that the Thirty-Seventh International Workshop of Injury "Biomechanics Research" was held in 2009. This 2009 date, prima facie, appears to be correct, and I will therefore treat the information in this document as being published before the priority date of the Patent.

36. In its "Introduction" section CGK1 sets out a summary of work and research in the field of measuring 3-dimensional head kinematics since the 1970's. This section highlights problems with employing six accelerometers – in particular the need to solve three non-linear ordinary differential equations – and discusses the development of new instrumentation schemes for measuring 3-dimensional kinematics of anthropomorphic test devices and post mortem test subjects, an example of which being a nine accelerometer array package (NAP). The introduction section states that:

> "An advantage of the NAP scheme is that angular acceleration with respect to the head's body-fixed coordinate system can be determined from algebraic equations using the accelerometer data without numerical differentiation (Padgaonkar et al., 1975). Accurate angular accelerations are important for calculating the linear acceleration at an inaccessible point, such as the center of gravity (CG) of the head in PMHS tests, which is commonly required to evaluate head injuries (e.g. head injury criteria, HIC)."

37. CGK1 then goes on to propose an improved head instrumentation scheme which:

> "..is capable of measuring 3-D kinematics using six accelerometers and three angular rate sensors (6aω) installed on a single tetrahedron fixture. This 6aω scheme will allow for post mortem human subjects (PMHS) to be tested in both direct impact and non-impact environments at all severities, while capturing accurate 3-D kinematics of the head in both the body-fixed coordinate system and in the lab or global coordinate system. The kinematic data obtained from the 6aω scheme should aid in the development and evaluation of injury criteria of the head."

CGK2: *Measurement of Angular Acceleration of a Rigid Body Using Linear Accelerometers*, Transactions of the ASME, Journal of Applied Mechanics, 552-556, published 1975

38. This document discusses that the acceleration of a rigid body can be determined using six accelerometers, but notes the limitations of the six accelerometer scheme, particularly due to low sensitivity and consequential accumulated stepwise integration errors. CGK2 proposes the use of a nine accelerometer configuration,

and analyses the benefits of this approach using hypothetical and experimental data. CGK2 states that:

> “To compute the angular acceleration components about the body-fixed axes, the minimum number of linear accelerometers required is five which can be arranged into three pairs, each of which has its sensitive axis pointing in one of the three orthogonal directions. A sixth accelerometer is needed to define all three linear acceleration components. One such configuration is shown in Fig 1. The six transducers are shown by the arrows in light type…” (see ‘Theoretical Developments’)
>
> “An alternate method which can circumvent the difficulties encountered during numerical integration is to use nine linear accelerometers in the configuration shown in Fig 1, by the addition of three more accelerometers in the location and direction indicated by arrows in heavy type” (see ‘A Nine-Accelerometer Scheme’)

39. Fig 1 is reproduced below:

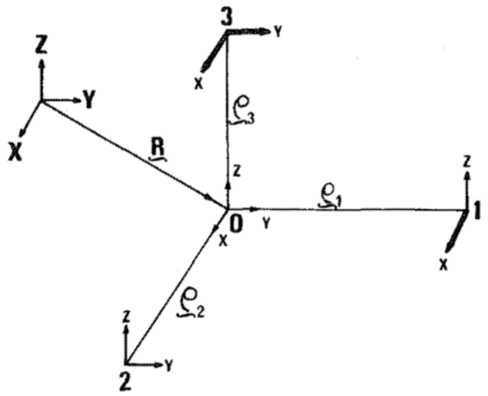


Fig. 1 Six and nine-accelerometer configurations

As shown in Fig. 1,

$\ddot{\mathbf{R}}$ = acceleration of the body-fixed frame (xyz) with respect to the inertial reference frame (XYZ)
$\mathbf{a}$ = acceleration of the point P relative to the body-fixed frame
$\vec{\omega}$ = angular velocity of the body
$\dot{\vec{\omega}}$ = angular acceleration of the body
$\mathbf{v}$ = velocity of the point P relative to the body-fixed frame
$\vec{\rho}_P$ = position vector of the point P from the origin of the body-fixed frame

Inventive Step

40. The requester has argued that claims 1&2 of the Patent are invalid due to a lack of an inventive step based on PA1 or PA4, in view of the common general knowledge.

41. 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*[5] which

[5] *Pozzoli SPA v BDMO SA [2007] EWCA Civ 588*

reformulated the well-known *Windsurfing*[6] 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.

Applying the Windsurfing/Pozzoli test

Identify the notional "person skilled in the art" and the relevant common general knowledge of that person

42. Neither the requester nor the observer have specifically identified the person skilled in the art. As discussed above, I think it is reasonable to consider the person skilled in the art to be, prima facie, an expert in head impact technology.

43. The requester has submitted that the Common General Knowledge (CGK) includes at least all published literature relating to the use of sensors, such as accelerometers, as measurement tools in the context of head injuries – this includes CGK1, CGK2, PA1, PA2, PA3 and PA4 along with "a large number of other such documents".

44. More specifically the requester has commented that the CGK includes:(a) using accelerometers to measure head impacts; (b) assessing head impacts using metrics such as GSI and HIC, which are based on center of gravity acceleration; (c) placing various accelerometer arrays on helmets/head surfaces to facilitate measurement of head impacts; (d) translating acceleration values from such accelerometer arrays on helmets/head surfaces to the center of gravity (e.g. to allow calculation of GSI and HIC, which are based on the center of gravity acceleration).

45. Whilst I note that the observer has questioned whether the documents themselves can be considered CGK, based on the disclosures of CGK1, CGK2, PA1, PA2, PA3 and PA4 as a whole it would appear reasonable to conclude that the features identified in (a)-(d) are CGK in the art of head impact technology.

46. The requester has also suggested, based on PA2, that it was part of the CGK in the art that mouth mounted sensors could be used as an alternative to helmet mounted sensors. This suggestion is problematic due to only a single document/study (PA2) being identified which discusses the use of mouth mounted sensors for measuring head accelerations. Furthermore, it is not apparent whether the study in PA2 is

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[6] *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd,* [1985] RPC 59

specific knowledge, or "at the elbow"[7] of the skilled person and thus *common* general knowledge. Nevertheless, for the purposes of assessing this opinion request, I am willing to assume that the person skilled in the art would be aware of mouth mounted sensors being used as an alternative to helmet mounted sensors, as demonstrated in PA2.

Identify the inventive concept of the claim in question or if that cannot readily be done, construe it.

47. The observer has identified the inventive concept as (1) measuring accelerations in a mouthguard; and (2) determining the acceleration at the CG based on those measurements. The requester appears to have accepted this assessment of the inventive concept.

48. However, it is my opinion that such an 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 of a plurality of classes, 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 (of a plurality) each representing a range of probabilities of a head/neck injury.

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

49. The requester has identified PA1 or PA4 as the closest prior art.

50. PA1 discloses a method in which linear acceleration was measured at a location(s) on a human being using accelerometers in a helmet. The data from the six nonorthogonal accelerometers in the helmet were used to compute the head center of gravity CG. Impact parameters, such as peak linear acceleration, can be associated with a pass/fail criterion related to risk of mild traumatic brain injuries (mTBI). It is implicit that the pass/fail criterion is communicated to an observer via "an output device" (e.g. displayed on a computer).

51. Both the requester and the observer agree that PA1 does not disclose measuring acceleration at a mouthguard or lip guard (part F3 of claim 1) and thus determining the acceleration at the head CG based on those measurements. Furthermore, whilst PA1 mentions the use of a threshold to classify a risk of brain trauma, it is my opinion that PA1 does not disclose associating the impact parameters with an injury class from a plurality of injury classes, each injury class representing a range of probabilities of a head/neck injury. Therefore, PA1 does not disclose part F6 of claim 1.

52. PA4 discloses a method in which players wearing helmets instrumented with accelerometers recorded an acceleration time history of the head center of gravity

[7] *see Raychem Corp's Patents [1998] RPC 31 Laddie J*

(CG) for impacts. Impact parameters, such as Gantt severity index (GSI) and Head Injury Criteria (HIC), were computed for the impacts. Figure 5 discusses impacts in relation to a "linear acceleration concussion probability function" generated from NFL impacts. Figure 5 shows that there were 3476 out of 289,899 (0.3%) which were greater than 98.9g (the 75% concussion probability level based on NFL data). It is implicit that the impact > 98.9g is communicated to an observer via "an output device" (e.g. displayed on a computer).

53. Both the requester and the observer agree that PA4 does not disclose measuring acceleration at a mouthguard or lip guard (part F3 of claim 1) and thus determining the acceleration at the head CG based on those measurements. Whilst the alleged injury class(es) in PA4 are not readily apparent, it would appear the impacts are not associated with an injury classification (from a plurality of classifications) each having *a range of probabilities*, rather the impacts greater than 98.9g (which is a threshold chosen based on a 75% probability from a previous NFL study) are associated with concussion (i.e. an injury class) having a probability of 0.3%. It is therefore my opinion that PA4 does not disclose part F6 of claim 1.

Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

54. The observer considers measuring accelerations in a mouthguard, and thus determining the acceleration at the head CG based on those measurements, to involve an inventive step. In particular, the observer has highlighted three reasons as to why the difference(s) requires a degree of invention:

(a) There is no reasonable expectation of success and, instead, an expectation of failure in combining the helmet related documents (PA1/PA4 and PA3) with the mouthpiece document (PA2) because sensor arrangements in a mouthpiece do not conform to the sensor arrangements in helmets (i.e. required by PA3), so the math proposed by PA3 would not work for a mouthpiece.

(b) PA2 teaches away from the proposed combination of documents because the results of PA2 suggest there is no need to do anything further with sensor results from a mouthpiece.

(c) The claimed invention is not obvious because determining accelerations at the CG based on measurements in a mouthguard yields surprising results.

55. Regarding reason (a), the observer notes that PA2 does not *calculate/determine* head CG accelerations based on measurements in the helmet or mouthpiece. Instead PA2 places an accelerometer(s) at the CG of a headform and compares those results to that of the helmet and mouthpiece.

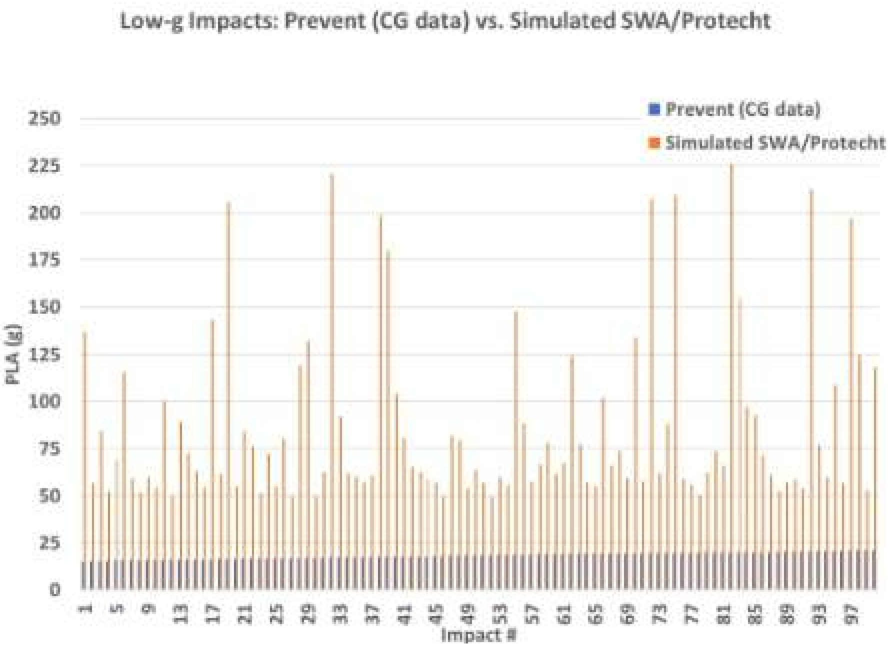
56. They further note that the disclosures of PA1 and PA4 reference PA3 with regard to calculating the CG of the head. PA3 discusses an arrangement which models the head as a sphere in a spherical head co-ordinate system and a set of n-single axis head mounted accelerometer sensors are located on the surface of the head and orientated with their sensing axis normal to the surface of the head. PA3 presents a

series of equations for calculating the magnitude of the head CG acceleration based on this arrangement.

57. The observer states that PA1 and PA3 or alternatively PA4 and PA3, cannot be properly combined with PA2 to arrive at the claimed invention because in developing a mouthguard system, the skilled person would not have any reasonable expectation of success in using helmet designs, and, instead an expectation of failure. In particular, they note that sensors on a mouthguard cannot be placed on the surface of the head nor is it practical or attainable to have sensors on a mouthguard which are orientated to have their sensitive axis pass through the head CG. They note that since the geometric/position/orientation requirements of PA3 cannot be met when placing sensors in a mouthguard, the maths proposed in PA1,PA3 and PA4 would not work to determine head CG for mouthguard sensors.

58. Regarding reason (b), the observer states that the skilled person would not have combined PA2 with PA1/PA4 and PA3 because the results in PA2 suggest that placing the sensors in the mouthguard is superior to attaching sensors to helmets and avoids the need to transfer the sensed results to the CG due to high correlation with data from the head form CG. The observer argues that experts (have and still do) believe it is not necessary to transfer mouthguard measurements to the head CG due to the proximity of the mouthguard sensors to the brain. In making this assertion the observer refers to comments by one of the inventors, Mr Adam Bartch, along with an ESPN article (dated 2021). The results in PA2 are said to teach away from transferring mouthguard sensor results to the CG because the results suggest that mouthguard sensor readings, without more, can be used as a proxy for the acceleration at the CG.

59. Lastly the observer considers determining accelerations at the CG based on measurements in a mouthguard to yield surprising results. The observer discusses an exercise undertaken (in 2021) by Mr Adam Bartch, following conversations with a competitor and an academic, in which he compared raw impact data at the (mouthguard) sensor locations with impact data at the CG, which had been determined from the sensor data. The observer considers there to be ‘drastic differences’ between the results such that those which result from the claimed method step of determining an acceleration at the CG are ‘surprising’ and make it clear that the claims of the patent are inventive. The results, which focus on 100 (out of approx. 4000) of the ‘more drastic comparisons’, is shown below:



[Prevent transfers data to CG; Protecht raw accelerometer data]

60. The requester considers measuring accelerations in a mouthguard, and thus determining the acceleration at the CG based on those measurements, to be obvious. In particular, using a mouth mounted sensor rather than a helmet mounted sensor is an obvious modification in light of PA2.

61. The requester notes the ‘limitations’ discussed in PA2 – in particular the statement that PA2 “measures the acceleration only at the location of the accelerometer, which may limit understanding of the acceleration of the whole head “. This is considered to be an acknowledgment that understanding that acceleration of the head (CG) is not possible by measuring acceleration at a point on the mouth guard. The requester also notes that this statement specifically references PA3, and that the algorithms of PA3 are particularly well suited to mouth guard applications (i.e. avoiding orthogonality requirements). In other words, the authors of PA2 were aware of (and noted) algorithms which could be used to translate acceleration at a mouthguard to acceleration at the center of gravity.

62. The requester asks the question “what would the skilled addressee think and do on the basis of the disclosure (of PA2)?”. They consider that it is clear that he/she would read the ‘Limitations’ section of PA2, and appreciate that it would be necessary to translate sensor location accelerations to the center of gravity so as to enable “understanding of the acceleration of the whole head” and look to the directly referenced algorithms in PA3 to achieve this. Furthermore, by referencing PA3, PA2 sets up an expectation of success in combining the references.

63. The requester discusses that the fundamental mathematics of head CG calculations – i.e. techniques for measuring acceleration at one point in space from accelerations at other points in space – have been known for a century. Furthermore, the requester discusses, in particular in the declaration by Mr Erikson, that the mathematics and/or algorithms used to determine acceleration at the head CG in CGK1, CGK2 and PA3 are able to be applied to a wide range of situations, such as helmets and mouth guards. There is nothing inventive, the requester states, in

suggesting mouth guard accelerations could be transformed to the center of gravity.

64. The requester considers that determining accelerations at the head CG was the accepted standard approach for measuring head acceleration and impact severity (e.g. GSI or HIC). To the extent that there might be an "unexpected result", that would come from departure from the accepted approach, in the form of an observation that measuring acceleration at a point on a mouthguard is "just as good" as measuring center of gravity acceleration. That would indeed be 'surprising', given that rotational acceleration at a point away from the center of gravity would by basic principles always seem problematic given the nature of head rotation about the neck.

65. With regard to part F6 of claim 1, the requester submits that splitting a probability calculation into partial ranges is a common and obvious statistical approach. They further note that PA4 suggests, and consideration was given to, concussions being diagnosed into Grade 1, Grade 2 or Grade 3 (although severity was not used for the purposes of the research undertaken).

66. Based on the information before me, do the differences constitute steps which would have been obvious? I note that the requester considers, based on PA2, that the skilled person would "appreciate that it would be necessary to translate sensor locations to the center of gravity so as to enable understanding of the whole head". But PA2 states that measuring only at the location of the accelerometer 'may limit' understanding. Therefore, based on the wording of PA2, and given the arguably (at least) adequate nature of the raw mouth guard acceleration data, the skilled person would therefore not consider it *necessary* to pursue the translation of mouth guard accelerations to the head CG.

67. Whilst the requester makes general comments such as the mathematics being 'applicable', 'well suited' and/or 'could work with' mouth guards. it would appear that the methodology, equations and/or algorithms used in the CGK1, CGK2 and PA3 would prima facie appear to need at least some adaption to determine the head CG using measured accelerations in a mouthguard – such adapting the six/nine accelerometer arrangement in CGK2 for a small area (i.e. a mouthguard), or adding an appropriate term to Eq (1) in PA3.

68. As the person skilled in the art, when presented with PA1 or PA4, would *firstly* have to readily consider using mouth mounted sensors as an alternative to the helmet mounted sensors, and *also* realise that the limitations of PA2 would be worth pursuing (pursuing head CG is not a *necessity,* as discussed above), and *then* provide some form of adaption, addition etc. to the methodology/algorithm of PA3 and/or apply and possibly adapt principles from other arrangements (such as CGK2) to the particular arrangement of accelerometers in a mouthguard – in order to determine the head CG using measured accelerations in the mouthguard – I think points towards a degree of invention. Put another way, modification of PA1 or PA4 based on PA2 in light of PA3/CGK1/CGK2 in my opinion does not appear routine and/or relies on hindsight, and therefore indicates an inventive step.

69. Furthermore, I cannot see how the person skilled in the art, presented with PA1 or PA4, and using the (alleged) common general knowledge of CGK1, CGK2, PA2 and PA3 would arrive at associating impact parameters with one of a plurality of injury classes – with each class representing a range of probabilities that a person will

suffer an injury – let alone a method which involved utilising *head COG acceleration determined using mouthguard measurements* and utilising *injury classifications each with a range of probabilities*.

70. Therefore it is my opinion that claim 1 of the Patent is inventive based on PA1 or PA4, in view of PA2, PA3, CGK1 and CGK2.

Opinion

71. It is my opinion that claim 1 of the Patent involves an inventive step based on PA1 or PA4, in view of PA2, PA3, CGK1 and CGK2. Therefore, the Patent is valid.

Benjamin 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.