IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CASE NO. ....TBD
U.S. PATENT NO 8,702,631
PATENT ISSUE DATE .... 22 Apr 2014
PATENT FILING DATE ....26 Nov 2008
FIRST NAMED INVENTOR.. Kevin Maher
TITLE... "Vestibular Stimulation Systems and Methods"

BEFORE THE PATENT TRIAL AND APPEAL BOARD

<u>PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,702,631</u>

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Table of Exhibits

Exhibit	Reference
1001	U.S. Patent No. 8,702,631
1002	Japanese Patent No. H07-60290B2 (**Okamoto**)
1003	U.S. Patent No. 6,800,062 (**Epley**)
1004	U.S. Patent No. 4,710,129 (**Newman**)
1005	Ashton Graybiel, *Prevention of Motion Sickness in the Slow Rotation Room by Incremental Increases in Strength of Stimulus*, Fourth Symposium on the Role of the Vestibular Organs in Space Exploration, National Academy of Sciences, p. 109-115 (1970) (8 pp.) (**Graybiel**)
1006	File History of U.S. Patent No. 8,702,631

I. INTRODUCTION

Petitioner Brain Synergy Institute, LLC requests inter partes review of claims 1-11 of U.S. Patent No. 8,702,631 (the ’631 patent) assigned to Ultrathera Technologies, Inc.

II. REQUIREMENTS FOR PETITION FOR INTER PARTES REVIEW

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the ’631 patent is available for inter partes review and Petitioner is not barred or estopped from requesting inter partes review challenging the claims on the grounds identified in this Petition.

B. Notice of Real Party in Interest (37 C.F.R. § 42.8(b)(1))

The real party in interest is Brain Synergy Institute, LLC.

C. Notice of Related Matters (37 C.F.R. § 42.8(b)(2))

Petitioner has sued the patent owner for infringing claims 2-6, 8-10, 13-16 of U.S. Patent No. 6,800,062 (the Epley reference) in Brain Synergy Institute, LLC v. Ultrathera Technologies, Inc., Case No. 13-cv-01471, pending in the United States District Court for the District of Colorado (“the Colorado litigation”).

According to Patent Office records, pending U.S. patent application 13/957,226 claims priority to the ’631 patent and thus may be affected by these proceedings.

D. Notice of Lead and Backup Counsel and Service Information (37 C.F.R. § 42.8(b)(3) and 42.8(b)(4))

Lead Counsel	Back-Up Counsel
Joshua Randall (Reg. No. 50,719) Holland & Hart, LLP 222 South Main, Suited 2200 Salt Lake City, UT 84101 Telephone: (801) 799-5841 Fax: (801) 799-5700 jnrandall@hollandhart.com	Scott Nielson (Reg. No. 50,755) Holland & Hart, LLP 222 South Main, Suited 2200 Salt Lake City, UT 84101 Telephone: (801) 660-4400 Fax: (801) 799-5700 scnielson@hollandhart.com

E. Payment of Fees (37 C.F.R. §§ 42.15(a))

The Director is authorized to charge the fees specified in 37 C.F.R. § 42.15(a) to Deposit Account No. 08-2623.

F. Proof of Service

Proof of service of this Petition on the patent owner at the correspondence address of record for the ’631 patent as well as the patent owner’s counsel of record in the Colorado litigation is attached.

G. Identification of Claims Being Challenged (37 C.F.R. § 42.104(b))

Petitioner requests claims 1-11 of the ’631 patent be found unpatentable and canceled in view of the following prior art. Each of these references is a patent or publication issued/published more than one year before the earliest claimed filing date of the ’631 patent and is therefore prior art under 35 U.S.C. § 102(b) (pre-AIA). An English translation of the Okamoto reference is included along with an affidavit attesting to the accuracy of the translation. Petitioner has annotated the Okamoto reference to include line numbers (in red font) that are not in the original.

Exhibit	**Reference**	**Pub. Date**	**Of record in ’631 Patent**
1002	Japanese Patent No. H07-60290B2 (**Okamoto**)	28 Jun 1995	No
1003	U.S. Patent No. 6,800,062 (**Epley**)	5 Oct 2004	Yes
1004	U.S. Patent No. 4,710,129 (**Newman**)	1 Dec 1987	No
1005	Ashton Graybiel, *Prevention of Motion Sickness in the Slow Rotation Room by Incremental Increases in Strength of Stimulus*, Fourth Symposium on the Role of the Vestibular Organs in Space Exploration, National Academy of Sciences, p. 109-115 (1970) (8 pp.) (**Graybiel**)	1970	No

Specifically, as discussed in detail below, Petitioner requests cancellation on the following grounds:

Ground	**Claims**	**Description**
1	1-2 and 4-11	Obvious over Okamoto in view of Epley
3	3	Obvious over Okamoto in view of Epley and Graybiel
2	1-2 and 4-11	Obvious over Epley in view of Newman
4	3	Obvious over Epley in view of Newman and Graybiel

III. BACKGROUND AND OVERVIEW OF THE ’631 PATENT

A. Content of the ’631 Patent

The ’631 patent is directed to systems and methods for vestibular stimulation in humans. The vestibular system is located in the inner ear and includes three semi-circular canals and five sense organs. ’631 patent 3:62-65; Figs. 6A-6B. The vestibular system is used to maintain balance by monitoring motion of the head and stabilizing the eyes relative to the environment. Id. 1:18-21.

The ’631 patent discloses using a computer controlled multi-axis rotational motion device to stimulate the vestibular system of a subject. Id. 3:20-26. The device can rotate a subject around one, two, or three rotational axes individually or simultaneously in a controlled manner. Id. 2:21-23. A computer system controls the movement of the device and collects and stores data. Id. 2:23-24. The computer system can independently vary the intensity of acceleration, frequency of acceleration, and duration of movement of the subject. Id. 2:34-37.

The ’631 patent discloses two embodiments of vestibular stimulation devices: a two dimensional device that rotates around the pitch and yaw axes and a three dimensional device that rotates around the pitch, yaw, and roll axes. Id. 5:2-4. The two dimensional device is described in greater detail because it is the embodiment covered by the claims. The claims do not cover the three dimensional device.

The two dimensional device rotates 360 degrees around the pitch and yaw axes. Id. 5:5-10, 16-18. The rotation around each axis can be continuous and independent of the other axis. Id. An annotated copy of Fig. 1 from the ’631 is reproduced below to show the two dimensional device and the pitch and yaw axes.

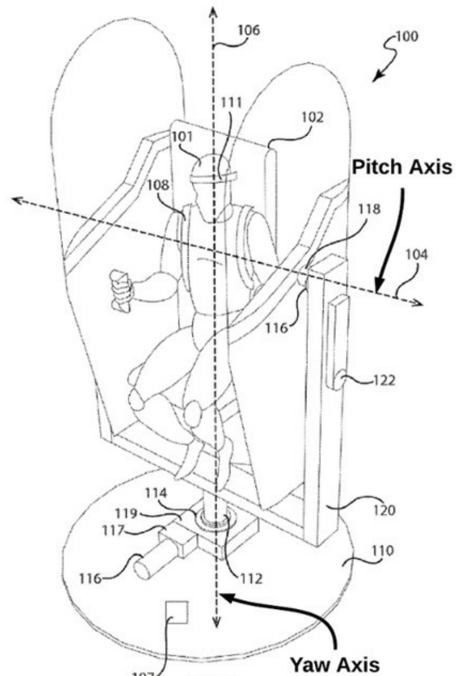


FIG. 1

The relationship of the pitch and yaw axes to each other is not explicitly described in the ’631 patent, but is shown in Fig. 1. The yaw axis 106 is the outermost axis because it is mechanically connected to the base 110 without going through the pitch axis 104. The pitch axis 104 is inside the yaw axis 106 because it is mechanically connected to the base 110 through the yaw axis 106 – i.e., the pitch shaft 118 is connected to the U-shaped frame 120 which is connected to the yaw shaft 112 which is connected to the base 110. The pitch axis 104 is directly inside the yaw axis 106 because it is mechanically connected to the yaw axis 106 without going through an intervening axis of rotation such as a roll axis.

B. Prosecution History of the ’631 Patent

The patent owner originally filed claims that broadly cover vestibular stimulation using one, two, or three axis rotation devices. Ex. 1006, pp. 278-285, Preliminary Amendment, 26 May 2010. The examiner rejected the claims as being anticipated by or obvious in view of Epley and/or U.S. Patent No. 4,710,128 (Wachsmuth).

Over the course of prosecution, the patent owner amended the claims until only two independent claims (and associated dependent claims) remained and they were limited to a two axis rotation device having a pitch axis directly inside a yaw axis and no roll axis. Id. pp. 93-97, Amendment, 24 Sep 2013; Id. p. 26, Notice of Allowance, 24 Feb 2014 (Examiner's Amendment).

The examiner noted in the Reason for Allowance section that the claims were allowed because none of the cited prior art discloses "a two axis rotational device comprising a pitch axis of rotation directly inside a yaw axis of rotation with the proviso that the device does not comprise a roll axis of rotation." Id. pp. 26-27, Notice of Allowance, 24 Feb 2014. The examiner also noted that Epley is the closest prior art and otherwise satisfies the remainder of the limitations in the allowed claims. Id.

IV. PERSON HAVING ORDINARY SKILL IN THE ART

The '631 patent describes the invention as relating to vestibular stimulation. '631 patent 1:34-36. Petitioner submits that one of skill in the art in this field would have at least a degree in a field related to human physiology plus practical experience with vestibular stimulation.

V. CLAIM CONSTRUCTION

A. Applicable Law

A claim subject to inter partes review "shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.104(b). To the extent there is any ambiguity regarding the "broadest reasonable construction" of a term, the ambiguity should be resolved in favor of the broadest construction absent amendment by the patent owner. Final Rules, 77 Fed. Reg. at 48699.

B. Broadest Reasonable Construction of Claim Terms

The terms in the claims that require construction are shown below.

1. "dose of vestibular stimulation"

Claim 1 recites administering a "dose of vestibular stimulation." This should be interpreted to mean a defined combination of one or more of the following variables: (a) the rate of acceleration around the pitch, roll, and/or yaw axes, (b) number of accelerations, (c) duration of accelerations, (d) frequency of changes in accelerations, (e) the velocity around the pitch, roll, and/or yaw axes, (f) number of starts and stops, (g) pause time, (h) rotation direction, (i) changes in rotation direction, (j) single or multi-axis rotation, (k) duration of the total profile, and the like.

The ‘631 patent describes a dose of vestibular stimulation as a “defined combination of one or more variables as discussed herein.” ’631 patent 12:11-12. It then goes on to list the variables in the previous paragraph. Id. 11:47-12:19.

2. “a pitch axis of rotation directly inside a yaw axis of rotation”

Independent claims 1 and 9 recite a two-axis rotational device having “a pitch axis of rotation directly inside a yaw axis of rotation.” This should be interpreted to mean that the rotational device is mechanically structured so that the yaw axis is between the pitch axis and the mounting base and there is no intervening axis of rotation between the pitch axis and the yaw axis.

The ’631 patent does not describe the relationship of the two axes to each other beyond what is shown in Fig. 1. Referring to Fig. 1, reproduced above, the pitch axis 104 is ***inside*** the yaw axis 106 because it is mechanically connected to the base 110 through the yaw axis 106 – e.g., the pitch shaft 118 is connected to the U-shaped frame 120 which is connected to the yaw shaft 112 which is connected to the base 110. The pitch axis 104 is ***directly inside*** the yaw axis 106 because it is mechanically connected to the yaw axis 106 without the presence of an intervening axis of rotation.

The patent owner confirmed this interpretation during prosecution as shown by the following statement included in an interview summary: “Applicant clarified that ‘a pitch axis of rotation directly inside a yaw axis of rotation’ was interpreted to define the pitch axis connected to the yaw axis without an intervening roll axis." Ex. 1006, p. 74, Applicant-Initiated Interview Summary, 24 Sep 2013.

3. "a measurable and repeatable pattern"

Independent claims 1 and 9 recite that the rotational device provides "a measurable and repeatable pattern" of acceleration intensity, acceleration frequency, and velocity (only claim 9 recites velocity). This should be interpreted to mean a pattern that is capable of being measured and repeated.

With regard to the term "measurable," the '631 patent explains that the computer system can measure various variables associated with the rotational device including the angle of the axes, direction of rotation, acceleration rate, velocity, duration, and the like. '631 patent 11:15-17; 17:4-10. Thus, the pattern is measurable if the same or similar variables are capable of being measured.

With regard to the term "repeatable," the '631 patent explains that the computer system can be used to precisely repeat a pattern of acceleration intensity, acceleration frequency, etc. Id. 14:8-17. Thus, the pattern is repeatable if it is capable of being replicated or reproduced.

4. "continuous rotation"

Independent claims 1 and 9 recite that the rotational device allows "continuous rotation" through more than 360 degrees of rotation. This should be interpreted to mean an unlimited number of rotations with or without stopping.

The ’631 patent explains that continuous rotation refers to the ability of the rotational device to rotate around an axis an unlimited number of times. ’631 patent 5:37-40, 58-60; 6:55-58; 7:13-16, 29-32; 12:1-3. For example, the ’631 patent states that the rotational device “can rotate through all 360 degrees in each axis in a controlled and continuous (i.e., unlimited rotations) amount.” Id. 12:1-3.

There is no indication that “continuous rotation” means that the rotational device must rotate continually without stopping. The ’631 patent is largely silent on this point. However, it implies that “continuous rotation” includes “starts and stops” when it describes a dose of vestibular stimulation as including “starts and stops.” Id. 11:50-54.

5. “independently and simultaneously”

Independent claim 1 recites that the pitch and yaw axes rotate “independently and simultaneously.” This should be interpreted to mean that the variables associated with pitch and yaw axes – e.g., acceleration, deceleration, velocity, etc. – are separately controlled and the axes can rotate at the same time. ’631 patent 5:5-7; 6:3-7; 13:24-27.

6. “independently and continuously”

Independent claim 9 recites that the pitch and yaw axes operate “independently and continuously.” This should be interpreted to mean that the variables associated with the pitch and yaw axes – e.g., acceleration, deceleration, velocity, etc. – can be separately controlled and the axes can rotate an unlimited number of times.

The interpretation of this phrase is a combination of the terms "independently" and "continuously" both of which were construed in the previous two sections.

7. "measuring the vestibular stimulation"

Independent claim 1 recites "measuring the vestibular stimulation" applied to the subject by the computer system. This should be interpreted to mean recording input variables to the rotational device and/or recording physiological information about the subject.

The '631 patent describes measuring vestibular stimulation in two ways. First, by quantifying and recording the input variables such as: (a) the rate of acceleration around the pitch, roll, and/or yaw axes, (b) number of accelerations, (c) duration of accelerations, (d) frequency of changes in accelerations, (e) the velocity around the pitch, roll, and/or yaw axes, (f) number of starts and stops, (g) pause time, (h) rotation direction, (i) changes in rotation direction, (j) single or multi-axis rotation, (k) duration of the total profile, and the like. '631 patent 11:47-12:19. Second, by collecting, displaying, and recording physiological information about the subject. Id. 2:25-27; 3:41-48; 11:18-19, 36-41; 14:51-57; 20:3-19.

8. "chaotic pattern or regular repeating pattern"

Dependent claim 2 recites that the pattern of acceleration is a "chaotic pattern or regular repeating pattern." The term "chaotic pattern" should be interpreted to mean a series of unpredictable and arrhythmic changes in the frequency and/or intensity of acceleration. '631 patent 13:31-33; Figs. 7 and 9. The term "regular repeating pattern" should be interpreted to mean a series of predictable and rhythmic changes in the frequency and/or intensity of acceleration. Id. 13:57-62; Figs. 8, 10-11.

VI. DETAILED EXPLANATION OF THE GROUNDS FOR UNPATENTABILITY

The claims cover use of a two-axis rotational device having a pitch axis positioned directly inside a yaw axis and no roll axis to provide vestibular stimulation to a human subject. The only reason the Patent Office allowed the claims was because it could not find a similar two-axis rotational device in the prior art. However, as shown below, such devices are known and it would be obvious to use them to provide vestibular stimulation.

A. <u>Ground 1</u>: Claims 1-2 and 4-11 Are Obvious Over Okamoto in View of Epley

Okamoto was not of record during prosecution of the '631 patent. Epley was considered but not in combination with Okamoto. All references to Okamoto are to the English translation included as Exhibit 1002.

Okamoto discloses a motion simulator including a cockpit 27 rotatably mounted to a U-shaped frame 29 that is rotatably mounted to a fixed frame 31. Okamoto 12:11-20; Figs. 3-4. Annotated copies of Figs. 3-4 are reproduced below to show the motion simulator. The X axis is the roll axis, the Y axis is the pitch axis, and the Z axis is the yaw axis. Id. 12:7-10.

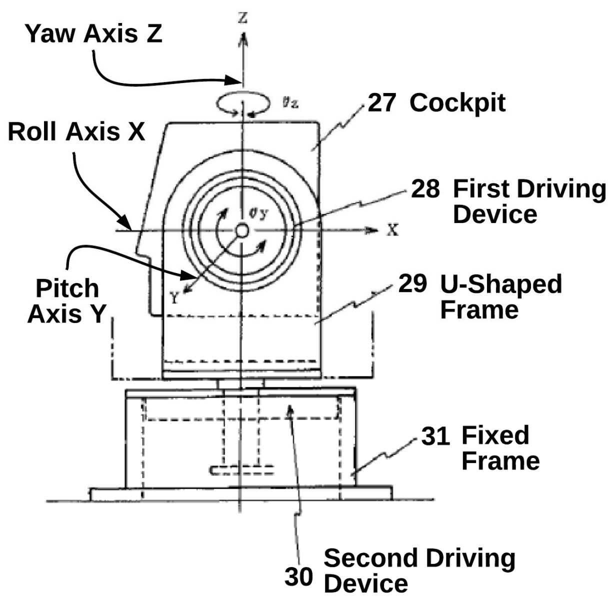


Figure 3

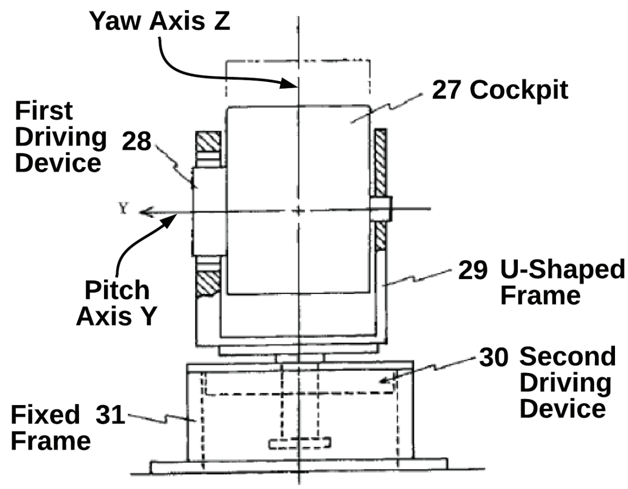


Figure 4

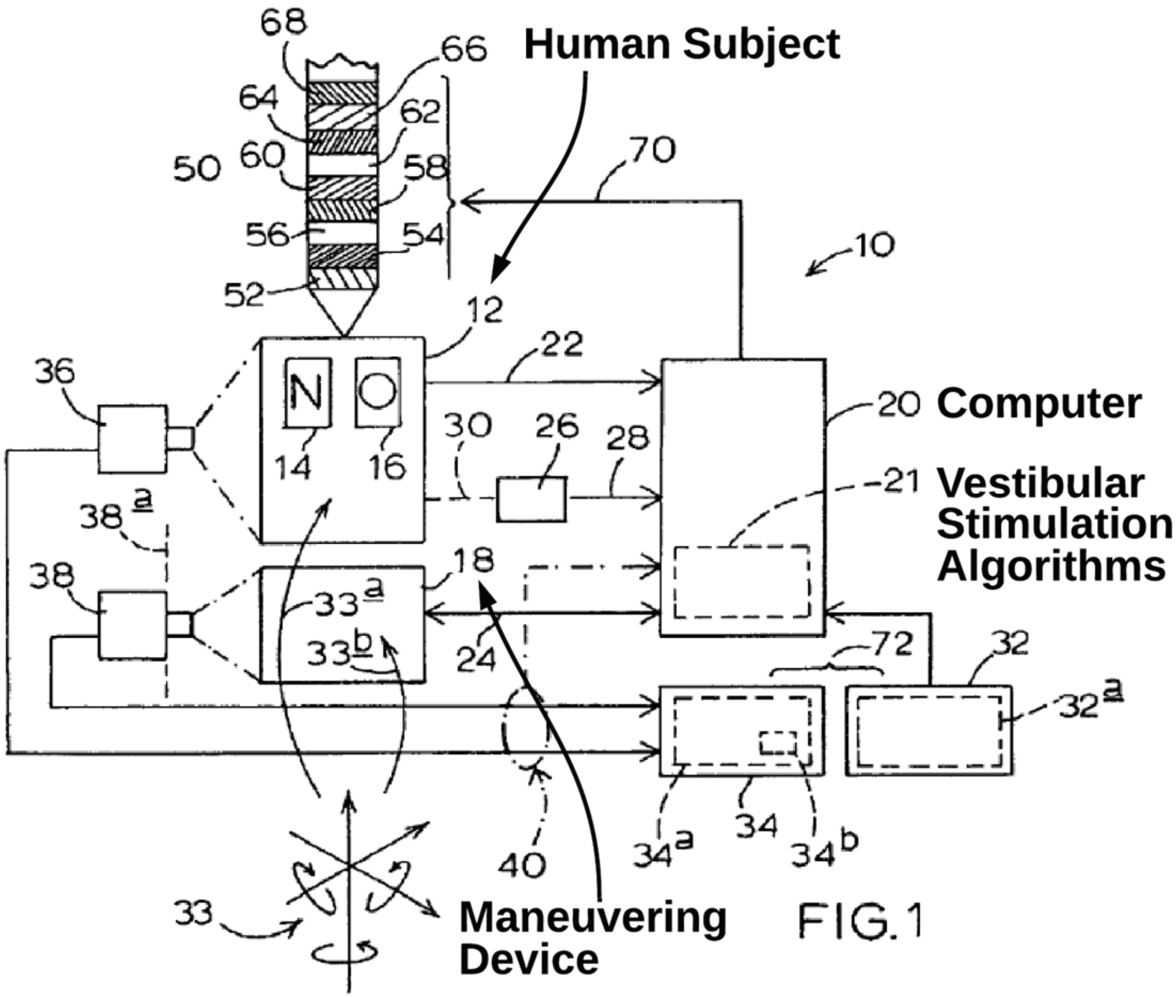
In Figs. 3-4, the first driving device 28 is an electric motor that can continuously rotate the cockpit 27 360° around the pitch axis Y. Id. 12:13-17; 13:7-8; Figs. 3-4. The second driving device 30 includes an electric motor 10_4 that can continuously rotate the cockpit 27 360° around the yaw axis Z. Id. 12:17-24; 10:10-11:14; 13:7-8; Fig. 1. The cockpit 27 does not rotate around the roll axis X.

The second driving device 30 is the device shown in Fig. 1 of Okamoto. It can move the cockpit 27 linearly along the X, Y, and Z axes as well as rotate it around the yaw axis Z. Id. 12:17-20; 10:10-11:14; Fig. 1. For example, the second driving device 30 can move the cockpit 27 side to side in the X and Y directions using the eccentric rotors 3, 4 and the motors 10_1, 10_2. Id. It can also move the cockpit 27 up and down in the Z direction using the screw rod 6 and motor 10_3. Id.

The motion simulator has the pitch axis Y directly inside the yaw axis Z. The yaw axis Z of the second driving device 30 is the output axis 9 shown in Fig. 1. Id. 12:17-20; 10:21-22; 11:2, 9-10. The output axis 9 is attached to the underside of the U-shaped frame 29. Id. The next axis connected to the yaw axis Z is the pitch axis Y. There is no intervening axis.

The motion simulator is used in medical applications to stimulate and measure bodily sensations. Id. 17:7-10. Okamoto fails to explicitly disclose using a computer system to control the motion simulator.

Epley discloses an automated, computer controlled system for vestibular stimulation. Epley, abstract. The system includes vestibular stimulation algorithms 21 stored in a computer 20 that controls a spatial maneuvering device 18. Id. 9:29-59; 10:47-57. The maneuvering device 18 can "take any one of a number of different forms" including a two-axis device capable of continuously rotating a subject through 360° around each axis. Id. 9:59-62; 6:66-7:7; 10:20-31. An annotated copy of Fig. 1 in Epley is reproduced below to show the various components of the system.



It would have been obvious to use the computer system in Epley to control the motion simulator in Okamoto because doing so constitutes nothing more than combining prior art elements according to known methods to yield predictable results. MPEP 2143(I)(A). This rationale is supported by the following findings. Id. First, Okamoto and Epley disclose all of the claimed subject matter with the only difference being the lack of an actual combination of Okamoto and Epley into a single reference (see the claim-by-claim analysis below). Second, one of skill in the art could have combined the motion simulator in Okamoto with the computer system in Epley using known methods for controlling mechanical devices with a computer system. Third, the motion simulator in Okamoto and the computer system in Epley perform the same functions when combined as they do separately. In both situations, the motion simulator in Okamoto functions as the mechanical device that holds a subject and enables the subject to move in three-dimensional space and the computer functions to control the mechanical device. Fourth, one of skill in the art would have recognized that the result of the combination is predictable – i.e., the computer system controls the motion simulator in the manner disclosed in Epley.

It also would have been obvious to use the computer system in Epley to control the motion simulator in Okamoto because doing so constitutes nothing more than using a known technique (i.e., the computer system in Epley) to improve a similar device in the same way (i.e., the motion simulator in Okamoto and the spatial maneuvering device in Epley are similar devices). MPEP 2143(I)(C). This rationale is supported by the following findings. Id. First, the motion simulator in Okamoto is a base device upon which the claimed invention can be seen as an improvement. The improvement is the use of a computer system to control movement of the motion simulator. Second, the spatial maneuvering device in Epley is comparable to the motion simulator in Okamoto and has been improved in the same way as the claimed invention (i.e., by being controlled by a computer system). Third, one of skill in the art could have applied the known improvement technique in Epley (i.e., the computer system) to the motion simulator in Okamoto with predictable results (i.e., the computer system controls the motion simulator in the manner disclosed in Epley).

It also would have been obvious to use the computer system in Epley to control the motion simulator in Okamoto because doing so constitutes nothing more than applying a known technique (i.e., the computer system in Epley) to a known device (i.e., the motion simulator in Okamoto) ready for improvement to yield predictable results. MPEP 2143(I)(D). This rationale is supported by the following findings. Id. First, the motion simulator in Okamoto is a base device upon which the claimed invention can be seen as an improvement. The improvement is the use of a computer system to control movement of the motion simulator. Second, Epley discloses a known technique that is applicable to the motion simulator in Okamoto (i.e., using a computer to control the device). Third, one of ordinary skill in the art would have recognized that applying the known technique (i.e., using a computer to control the device) to the motion simulator in Okamoto would yield the predictable result of an improved motion simulator controlled in the manner disclosed in Epley.

It also would have been obvious to use the computer system in Epley to control the motion simulator in Okamoto because doing so provides the motion simulator in Okamoto with a comprehensive, automated, programmed method of testing and treating a subject's vestibular system as taught by Epley. Epley 3:22-27; 7:40-46; MPEP 2143(I)(G). One of ordinary skill in the art would reasonably expect to be successful using the computer system in Epley to control the motion simulator in Okamoto because the computer system in Epley is already used to control a similar spatial maneuvering device.

A detailed explanation of how the combined references satisfy the claim limitations is given below.

1. Claim 1

(a) "A method of administering a dose of vestibular stimulation to a subject, comprising:"

Epley discloses methods for creating "vestibular activity which [are] directly related to spatial motion (including acceleration) and/or orientation." Epley abstract; 1:40-45. This includes administering a quantifiable measure of applied stimuli using a computer to automate the process and measure parameters such as acceleration and velocity. Id. 3:16-49; 11:19-32.

(b) "administering to a subject in a two-axis rotational device a dose of vestibular stimulation,"

(c) "wherein said two-axis rotational device comprises a pitch axis of rotation directly inside a yaw axis of rotation, with the proviso that the device does not comprise a roll axis of rotation,"

See the discussion of limitation (a) above for a description of how Epley administers a dose of vestibular stimulation. Epley discloses administering the dose using a maneuvering device having two axes. Epley 9:59-62.

Okamoto discloses using a two-axis motion simulator to stimulate and measure bodily sensations in medical related applications. Okamoto 12:7-10, 13-17; 17:7-10; Figs. 3-4. Okamoto discloses that the motion simulator has the pitch axis Y directly inside the yaw axis Z and does not include a roll axis of rotation. Id. 12:7-10, 13-17, 22-24; Figs. 3-4. The pitch axis Y is directly inside the yaw axis Z because the motion simulator is structured so that the yaw axis Z is between the pitch axis Y and the fixed frame 31 and there is no intervening rotation axis between the pitch axis Y and the yaw axis Z. The above description of Okamoto explains this in greater detail.

(d) "the rotation of each said pitch and yaw axis is independent of the other axis of rotation,"

Epley discloses that the maneuvering device can position a subject through 360° in any angle of the pitch and yaw axes thereby making it inherent that the pitch and yaw axes rotate independently of each other. Epley 7:1-3; 8:30-37.

Okamoto discloses using separate motors 28, 10_4 to rotate the pitch and yaw axes independently of each other. Okamoto 12:13-17; 11:2; Figs 1, 3-4.

(e) "the rotation velocity and acceleration around each said pitch and yaw axis controlled by a computer system,"

Epley discloses using a computer system to control the velocity and acceleration around the pitch and yaw axes. Epley 1:28-32; 8:63-67; 10:1-7, 56-67; 11:19-32; 13:5-39.

(f) "and said dose comprises a measurable and repeatable pattern of acceleration intensity and frequency around said pitch axis of rotation for a first duration and said yaw axis of rotation for a second duration,"

Epley discloses automating movement around the axes according to a preprogrammed, repeatable pattern having segments of various durations. Epley 1:28-32; 3:16-49; 7:47-64; 8:63-67; 10:1-7, 56-67; 11:19-32.

(g) "said rotational device configured to allow continuous rotation through more than 360 degrees around each said axis of rotation independently and simultaneously; and"

Epley discloses that the maneuvering device can rotate continuously through 360° for both the pitch and yaw axes. Epley 7:1-3; 8:30-37. Okamoto discloses the same for the motion simulator. Okamoto 13:7-9. See the discussion of limitation (d) above for a description of how Epley and Okamoto satisfy the requirement that the rotation is independent.

(h) "measuring the vestibular stimulation applied to said subject by said computer system."

Epley discloses measuring the vestibular stimulation applied to the subject. Epley 3:10-49; 7:40-46; 8:45-56; 14:4-8.

2. Claim 2

(a) "A method according to claim 1, wherein said pattern of acceleration is a chaotic pattern or regular repeating pattern around at least one of said axes of rotation."

Epley discloses a chaotic pattern of acceleration in the form of impulsive or ramp movements that include "rapid, unexpected, passive acceleration and/or deceleration." Epley 23:61-24:32.

Epley discloses a regular repeating pattern of acceleration as part of the canalith repositioning procedure. Id. 26:15-28:11. The subject is maneuvered through three positions using a regular pattern of acceleration. Id. At each position, the nystagmus response is measured and if a #1 nystagmus response is detected, the process is repeated. Id 27:61-63. The result is a regular repeating pattern of acceleration.

3. Claim 4

(a) "A method of improving sensory integration in a subject, comprising administering vestibular stimulation to the subject according to claim 1, wherein the subject has a disorder or condition selected from balance disorder, cerebral palsy, Down Syndrome, autism, traumatic brain injury, and stroke."

Epley discloses treating subjects who have dizziness, vertigo, and balance problems. Epley 1:6-14.

4. Claim 5

(a) "A method according to claim 1, wherein the vestibular stimulation is controlled by the subject."

Epley discloses that the vestibular stimulation can be controlled by the subject. Epley 1:28-32; 7:48-51; 10:1-5, 47-55; 12:52-62.

5. Claim 6

(a) "A method of claim 1, wherein the dose of vestibular stimulation comprises one or more inversions of the subject relative to the ground."

Epley discloses inverting the subject relative to the ground. Epley 8:10-20; 10:9-19; Fig. 3. Epley discloses inverting the subject as part of the benign paroxysmal positional vertigo procedure and the canalith repositioning procedure. Id. 25:28-28:11. Specifically, Epley describes rotating the subject backward 120° around the pitch axis as part of both procedures, which is sufficient to invert the subject. Id. 25:33-38; 26:61-65.

6. Claim 7

(a) "The method of claim 6, wherein the dose of vestibular stimulation is administered by altering one or more properties selected from the group consisting of the rate of rotation, degree of inverted position, time at said inverted position, number of inversions, length of time at non-inverted positions, and total duration of time in the rotational device."

Epley discloses administering the vestibular stimulation by altering the rate of rotation (i.e., acceleration), degree of inverted position, time at the inverted position, number of inversions, length of time at non-inverted positions, and the total duration of time in the rotational device as part of the benign paroxysmal positional vertigo procedure and the canalith repositioning procedure. Epley 25:28-

28:11. Epley alters all of these parameters as part of performing these procedures. Id.

7. Claim 8

(a) "The method of claim 1, wherein the mass of the subject is rotated about the center of rotation of the pitch axis of rotation and the yaw axis of rotation."

Epley discloses the subject seated so that the mass of the subject rotates about the center of rotation of the pitch axis and the yaw axis. Epley 10:8-17; Fig. 2. Okamoto discloses the same configuration. Okamoto 12:5-10; Figs. 3-6 (Figs. 5-6 in Okamoto show the subject relative to the X, Y, and Z axes).

8. Claim 9

(a) "A system for administering vestibular stimulation to a subject comprising:"

Epley discloses a comprehensive system including a maneuvering device used to "create vestibular activity which is directly related to spatial motion (including acceleration) and/or orientation." Epley abstract; 1:40-45.

(b) "a two-axis rotational device configured to rotate a subject around a pitch axis of rotation directly inside a yaw axis of rotation, with the proviso that the device is not configured to rotate a subject around a roll axis of rotation,"

Epley discloses a maneuvering device having two axes. Epley 9:59-62.

Okamoto discloses using a two-axis motion simulator to stimulate and measure bodily sensations in medical related applications. Okamoto 12:7-10, 13-17; 17:7-10; Figs. 3-4. Okamoto discloses that the motion simulator has the pitch axis Y directly inside the yaw axis Z and does not include a roll axis of rotation. Id. 12:7-10, 13-17, 22-24; Figs. 3-4. The pitch axis Y is directly inside the yaw axis Z because the motion simulator is structured so that the yaw axis Z is between the pitch axis Y and the fixed frame 31 and there is no intervening rotation axis between the pitch axis Y and the yaw axis Z. The above description of Okamoto explains this in greater detail.

(c) "each said axis operating independently and continuously from the other axis and configured to allow continuous rotation through more than 360 degrees of rotation around each said axis;"

Epley and Okamoto both disclose that the axes operate independently. Epley discloses that the maneuvering device can position a subject through 360° in any angle of the pitch and yaw axes thereby making it inherent that the pitch and yaw axes rotate independently of each other. Epley 7:1-3; 8:30-37. Okamoto discloses using separate motors 28, 10_4 to rotate the pitch and yaw axes independently of each other. Okamoto 12:13-17; 11:2; Figs 1, 3-4.

Epley and Okamoto both disclose that the respective maneuvering device and motion simulator can rotate continuously through 360° around both the pitch and yaw axes. Epley 7:1-3; 8:30-37; Okamoto 13:7-9.

(d) "the rotational device under the control of a computer system, the computer system including computer executable instructions to, when implemented, provide a measurable and repeatable pattern of acceleration intensity, acceleration frequency, and velocity around each said axis of rotation."

Epley discloses using a computer system to control the maneuvering device. Epley 1:28-32; 8:63-67; 10:1-7, 56-67; 11:19-32; 13:5-39. Epley discloses automating movement around the axes according to a preprogrammed, repeatable pattern having segments of various durations. Id. 1:28-32; 3:16-49; 7:47-64; 8:63-67; 10:1-7, 56-67; 11:19-32.

9. Claim 10

(a) "A system according to claim 9, wherein the computer system is further configured to provide visual stimuli to said subject."

Epley discloses providing visual stimuli to the subject using light occluding goggles, screens, and images. Epley 13:25-34; 21:46-49.

10. Claim 11

(a) "A kit comprising: a system according to claim 9; and instructions for administering a dose of vestibular stimulation."

The only difference between this claim and the system disclosed by the combination of Epley and Okamoto is the presence of the instructions. However, the instructions are not given any patentable weight because adding instructions to an otherwise known product is insufficient to distinguish it from the prior art. Astrazeneca LP v. Apotex, Inc., 633 F.3d 1042, 1064-65 (Fed. Cir. 2010) (holding that prior precedent "foreclosed the argument that simply adding new instructions to a known product creates the functional relationship necessary to distinguish the produce from the prior art.").

B. Ground 2: Claim 3 Is Obvious Over Okamoto in View of Epley and Graybiel

Okamoto and Epley are described in Ground 1. Graybiel is described below. Epley was considered during prosecution of the ’631 patent but not in combination with Okamoto and Graybiel.

Okamoto discloses a motion simulator used in medical applications to stimulate and measure bodily sensations. Okamoto 17:7-10. Epley discloses an automated, computer controlled system that can be used to control a motion simulator to produce vestibular stimulation. Epley, abstract. Okamoto and Epley do not explicitly disclose increasing the vestibular stimulation in increments in successive administrations.

Graybiel discloses that motion sickness can be prevented by incrementally increasing the strength of vestibular stimulation in successive administrations. Graybiel p. 111-113 (the section titled “Adaptation Through Control of the Subject’s Head Motions and Velocity of the SRR”). Specifically, Graybiel discloses rotating subjects at incrementally increasing velocities while the subjects moved their heads in a predetermined pattern. Id. The procedure was most effective when, at each step, the subjects were stressed to the limits of their tolerance without showing overt symptoms of motion sickness. Id. p. 115.

It would have been obvious to use the computer system in Epley to control the motion simulator in Okamoto for the reasons given in Ground 1. The following are the reasons it would be obvious to modify the combination of Okamoto and Epley to include the vestibular stimulation methods in Graybiel.

It would have been obvious to incrementally increase the vestibular stimulation in successive administrations because doing so constitutes nothing more than combining prior art elements according to known methods to yield predictable results. MPEP 2143(I)(A). This rationale is supported by the following findings. Id. First, Okamoto, Epley, and Graybiel disclose all of the claimed subject matter with the only difference being the lack of an actual combination of the references into a single reference (see the claim-by-claim analysis below). Second, one of skill in the art could have used known methods to operate the motion simulator in Okamoto and the computer system in Epley to incrementally increase the vestibular stimulation – e.g., provide instructions to the computer system that result in increasing the rotational velocity for a patient in increments as disclosed in Graybiel. Third, the motion simulator in Okamoto and the computer system in Epley perform the same functions when combined as they do separately. The only difference is that they are instructed to follow the procedure disclosed in Graybiel – i.e., incrementally increase the vestibular stimulation to treat motion sickness. Fourth, one of skill in the art would have recognized that the result of the combination is predictable – i.e., incrementally increasing the vestibular stimulation will prevent motion sickness as disclosed in Graybiel.

It also would have been obvious to incrementally increase the vestibular stimulation in successive administrations because doing so constitutes nothing more than using a known technique (i.e., the vestibular stimulation procedure in Graybiel) to improve a similar method in the same way (i.e., the vestibular stimulation techniques in Epley and Graybiel are similar methods). MPEP 2143(I)(C). This rationale is supported by the following findings. Id. First, the vestibular stimulation methods disclosed in Epley are the base methods upon which the claimed invention can be seen as an improvement. The improvement is the use of the vestibular stimulation methods disclosed in Graybiel to prevent motion sickness. Second, the vestibular stimulation methods in Graybiel are comparable to the vestibular stimulation methods disclosed in Epley and have been improved in the same way as the claimed invention (i.e., incremental increases in vestibular stimulation in successive administrations). Third, one of skill in the art could have applied the known improvement technique in Graybiel (i.e., the incrementally increasing vestibular stimulation methods) to the vestibular stimulation methods in Epley with predictable results (i.e., the computer system controls the motion simulator to provide incrementally increasing amounts of vestibular stimulation in successive administrations).

It also would have been obvious to incrementally increase the vestibular stimulation in successive administrations because doing so provides an effective method of preventing motion sickness in humans as taught by Graybiel. See discussion of Graybiel above; MPEP 2143(I)(G). One of ordinary skill in the art would reasonably expect to be successful using the vestibular stimulation methods in Graybiel to treat motion sickness because it's simply a matter of operating the computer system in Epley and the motion simulator in Okamoto in a specific way.

A detailed explanation of how the combined references satisfy the claim limitations is given below.

1. Claim 3

(a) "A method according to claim 2, wherein the vestibular stimulation is increased by increments in successive administrations of vestibular stimulation."

Graybiel discloses incrementally increasing the amount of vestibular stimulation in successive administrations. Graybiel p. 111-113 (the section titled "Adaptation Through Control of the Subject's Head Motions and Velocity of the SRR"); Table 2; Figs. 2-3. Figures 2-3 of Graybiel graphically show the incremental increase of vestibular stimulation in the form of the increased RPM of the slow rotation room. The procedure is disclosed as being most effective when, at each step, the subjects were stressed to the limits of their tolerance without showing overt symptoms of motion sickness. Id. p. 115.

C. **<u>Ground 3</u>: Claims 1-2 and 4-11 Are Obvious Over Epley in View of Newman**

Epley is described in Ground 1. Newman is described below. Epley was considered during prosecution of the ’631 patent but not in combination with Newman.

Epley discloses an automated, computer controlled system for vestibular stimulation using a two axis maneuvering device 18 capable of continuously rotating a subject through 360° around each axis. Epley 9:59-62; 6:66-7:7; 10:20-31. Epley does not explicitly disclose that the device has a pitch axis directly inside a yaw axis.

Newman discloses a simulation device that can simulate an aircraft cockpit or space capsule. Newman 1:56-60. The device includes a cabin 14 rotatably mounted to an upstanding yoke 10, which is rotatably mounted to a base 18. Id. 2:46-50; 3:6-10. The cabin 14 rotates around the pitch axis via horizontal shaft 16 and around the yaw axis via vertical shaft 12. Id. 2:28-33; 3:10-13. Fig 1 of Newman is reproduced below.

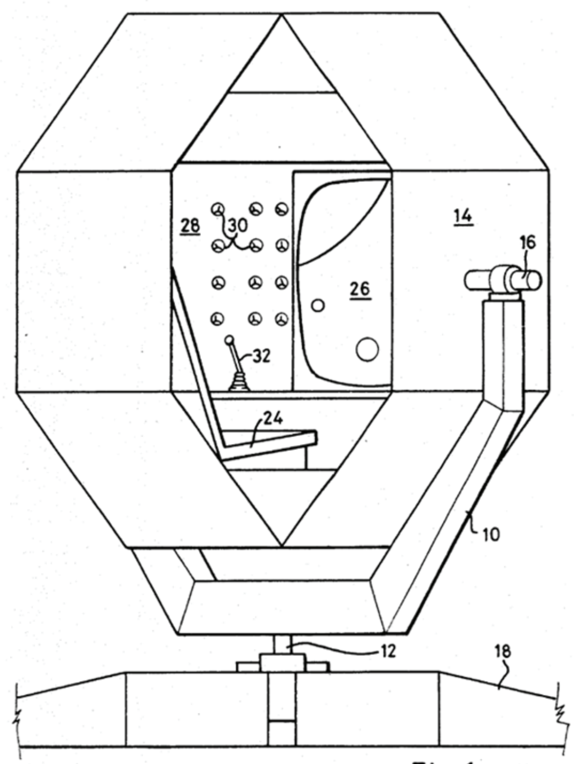


Fig.1

The pitch axis of the simulation device in Newman is directly inside the yaw axis. The vertical shaft 12 defines the yaw axis and is connected to the bottom of the yoke 10. Id. Fig. 1. The horizontal shaft 16 defines the pitch axis and is connected to the upright arms of the yoke 10 thereby making the pitch axis inside the yaw axis. There is no intervening rotational axis between the pitch axis and the yaw axis thereby making the pitch axis directly inside the yaw axis. Id.

It would have been obvious to use the simulation device in Newman with the computer system in Epley because doing so constitutes nothing more than choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. MPEP 2143(I)(E). This rationale is supported by the following findings. Id. First, at the time of the invention, Epley acknowledged that a spatial maneuvering device can have two axes that are capable of continuously rotating a subject through 360° around each axis. Epley 9:59-62; 6:66-7:7; 10:20-31. Second, there are only six axial configurations that such a maneuvering device can have – i.e., pitch inside yaw, yaw inside pitch, pitch inside roll, roll inside pitch, yaw inside roll, and roll inside yaw. Third, one of ordinary skill in the art could have pursued these six solutions with a reasonable expectation of success.

It also would have been obvious to use the simulation device in Newman with the computer system in Epley because doing so constitutes nothing more than simple substitution of one known element for another to obtain predictable results. MPEP 2143(I)(B). This rationale is supported by the following findings. Id. First, Epley discloses a computer controlled system for vestibular stimulation that differs from the claimed subject matter by the substitution of a two axis maneuvering device having the pitch axis directly inside the yaw axis for the disclosed generic two axis maneuvering device. Second, a two axis maneuvering device and its function is known in the art as shown in Newman. Third, one of ordinary skill in the art could have substituted the two axis maneuvering device in Newman for the generic two axis maneuvering device disclosed in Epley with predictable results –

i.e., the computer system controls the simulation device in the manner disclosed in Epley.

It also would have been obvious to use the simulation device in Newman with the computer system in Epley because doing so constitutes nothing more than combining prior art elements according to known methods to yield predictable results. MPEP 2143(I)(A). This rationale is supported by the following findings. Id. First, Epley and Newman disclose all of the claimed subject matter with the only difference being the lack of an actual combination of Epley and Newman into a single reference (see the claim-by-claim analysis below). Second, one of skill in the art could have combined the simulation device in Newman with the computer system in Epley using known methods for controlling mechanical devices with a computer system. Third, the simulation device in Newman and the computer system in Epley perform the same functions when combined as they do separately. In both situations, the simulation device in Newman performs the function of holding an occupant and moving under computer control and the computer system in Epley functions to control a simulation device. Fourth, one of skill in the art would have recognized that the result of the combination is predictable – i.e., the computer system controls the simulation device in the manner disclosed in Epley.

A detailed explanation of how the combination of references satisfies the claim limitations is given as follows.

1. Claim 1

(a) "A method of administering a dose of vestibular stimulation to a subject, comprising:"

Epley discloses methods for creating "vestibular activity which is directly related to spatial motion (including acceleration) and/or orientation." Epley abstract; 1:40-45. This includes administering a quantifiable measure of applied stimuli using a computer to automate the process and measure parameters such as acceleration and velocity. Id. 3:16-49; 11:19-32.

(b) "administering to a subject in a two-axis rotational device a dose of vestibular stimulation,"

(c) "wherein said two-axis rotational device comprises a pitch axis of rotation directly inside a yaw axis of rotation, with the proviso that the device does not comprise a roll axis of rotation,"

See the discussion of limitation (a) above for a description of how Epley administers a dose of vestibular stimulation. Epley discloses administering the dose using a maneuvering device having two axes. Epley 9:59-62.

Newman discloses a two-axis simulation device that can be used to simulate an aircraft cockpit or space capsule. Newman 1:56-60. The simulation device has the pitch axis directly inside the yaw axis and does not include a roll axis of rotation. The above description of Newman explains this in greater detail.

(d) "the rotation of each said pitch and yaw axis is independent of the other axis of rotation,"

Epley discloses that the maneuvering device can position a subject through 360° in any angle of the pitch and yaw axes thereby making it inherent that the pitch and yaw axes rotate independently of each other. Epley 7:1-3; 8:30-37.

Newman discloses using separate motors 20, 22 to rotate the pitch and yaw axes independently of each other. Newman 3:10-13; Figs 1-2.

(e) "the rotation velocity and acceleration around each said pitch and yaw axis controlled by a computer system,"

Epley discloses using a computer system to control the velocity and acceleration around the pitch and yaw axes. Epley 1:28-32; 8:63-67; 10:1-7, 56-67; 11:19-32; 13:5-39.

(f) "and said dose comprises a measurable and repeatable pattern of acceleration intensity and frequency around said pitch axis of rotation for a first duration and said yaw axis of rotation for a second duration,"

Epley discloses automating movement around the axes according to a preprogrammed, repeatable pattern having segments of various durations. Epley 1:28-32; 3:16-49; 7:47-64; 8:63-67; 10:1-7, 56-67; 11:19-32.

(g) "said rotational device configured to allow continuous rotation through more than 360 degrees around each said axis of rotation independently and simultaneously; and"

Epley discloses that the maneuvering device can rotate continuously through 360° for both the pitch and yaw axes. Epley 7:1-3; 8:30-37. See the discussion of limitation (d) above for a description of how Epley and Newman satisfy the requirement that the rotation is independent.

(h) "measuring the vestibular stimulation applied to said subject by said computer system."

Epley discloses measuring the vestibular stimulation applied to the subject. Epley 3:10-49; 7:40-46; 8:45-56; 14:4-8.

2. Claim 2

(a) "A method according to claim 1, wherein said pattern of acceleration is a chaotic pattern or regular repeating pattern around at least one of said axes of rotation."

Epley discloses a chaotic pattern of acceleration in the form of impulsive or ramp movements that include "rapid, unexpected, passive acceleration and/or deceleration." Epley 23:61-24:32.

Epley discloses a regular repeating pattern of acceleration as part of the canalith repositioning procedure. Id. 26:15-28:11. The subject is maneuvered through three positions using a regular pattern of acceleration. Id. At each position, the nystagmus response is measured and if a #1 nystagmus response is detected, the process is repeated. Id 27:61-63. The result is a regular repeating pattern of acceleration.

3. Claim 4

(a) "A method of improving sensory integration in a subject, comprising administering vestibular stimulation to the subject according to claim 1, wherein the subject has a disorder or condition selected from balance disorder, cerebral palsy, Down Syndrome, autism, traumatic brain injury, and stroke."

Epley discloses treating subjects who have dizziness, vertigo, and balance problems. Epley 1:6-14.

4. Claim 5

(a) "A method according to claim 1, wherein the vestibular stimulation is controlled by the subject."

Epley discloses that the vestibular stimulation can be controlled by the subject. Epley 1:28-32; 7:48-51; 10:1-5, 47-55; 12:52-62.

5. Claim 6

(a) "A method of claim 1, wherein the dose of vestibular stimulation comprises one or more inversions of the subject relative to the ground."

Epley discloses inverting the subject relative to the ground. Epley 8:10-20; 10:9-19; Fig. 3. Epley discloses inverting the subject as part of the benign paroxysmal positional vertigo procedure and the canalith repositioning procedure. Id. 25:28-28:11. Specifically, Epley describes rotating the subject backward 120° around the pitch axis as part of both procedures, which is sufficient to invert the subject. Id 25:33-38; 26:61-65.

6. Claim 7

(a) "The method of claim 6, wherein the dose of vestibular stimulation is administered by altering one or more properties selected from the group consisting of the rate of rotation, degree of inverted position, time at said inverted position, number of inversions, length of time at non-inverted positions, and total duration of time in the rotational device."

Epley discloses administering the vestibular stimulation by altering the rate of rotation (i.e., acceleration), degree of inverted position, time at the inverted position, number of inversions, length of time at non-inverted positions, and the total duration of time in the rotational device as part of the benign paroxysmal positional vertigo procedure and the canalith repositioning procedure. Epley 25:28-28:11. Epley alters all of these parameters as part of performing these procedures. Id.

7. Claim 8

(a) "The method of claim 1, wherein the mass of the subject is rotated about the center of rotation of the pitch axis of rotation and the yaw axis of rotation."

Epley discloses the subject seated so that the mass of the subject rotates about the center of rotation of the pitch axis and the yaw axis. Epley 10:8-17; Fig. 2. Newman also discloses that the subject is seated so that the mass of the subject is rotated about the center of rotation of the pitch axis and the yaw axis. Newman Fig. 1.

8. Claim 9

(a) "A system for administering vestibular stimulation to a subject comprising:"

Epley discloses a comprehensive system including a maneuvering device used to "create vestibular activity which is directly related to spatial motion (including acceleration) and/or orientation." Epley abstract; 1:40-45.

(b) "a two-axis rotational device configured to rotate a subject around a pitch axis of rotation directly inside a yaw axis of rotation, with the proviso that the device is not configured to rotate a subject around a roll axis of rotation,"

Epley discloses a maneuvering device having two axes. Epley 9:59-62.

Newman discloses a two-axis simulation device that can be used to simulate an aircraft cockpit or space capsule. Newman 1:56-60. The simulation device has the pitch axis directly inside the yaw axis and does not include a roll axis of rotation. The above description of Newman explains this in greater detail.

(c) "each said axis operating independently and continuously from the other axis and configured to allow continuous rotation through more than 360 degrees of rotation around each said axis;"

Epley and Newman both disclose that the axes operate independently. Epley discloses that the maneuvering device can position a subject through 360° in any angle of the pitch and yaw axes thereby making it inherent that the pitch and yaw axes rotate independently of each other. Epley 7:1-3; 8:30-37. Newman discloses using separate motors 20, 22 to rotate the pitch and yaw axes independently of each other. Newman 3:10-13; Figs 1-2.

Epley discloses that the maneuvering device can rotate continuously through 360° around both the pitch and yaw axes. Epley 7:1-3; 8:30-37.

(d) "the rotational device under the control of a computer system, the computer system including computer executable instructions to, when implemented, provide a measurable and repeatable pattern

of acceleration intensity, acceleration frequency, and velocity around each said axis of rotation."

Epley discloses using a computer system to control the maneuvering device. Epley 1:28-32; 8:63-67; 10:1-7, 56-67; 11:19-32; 13:5-39. Epley discloses automating movement around the axes according to a preprogrammed, repeatable pattern having segments of various durations. Id. 1:28-32; 3:16-49; 7:47-64; 8:63-67; 10:1-7, 56-67; 11:19-32.

9. Claim 10

(a) "A system according to claim 9, wherein the computer system is further configured to provide visual stimuli to said subject."

Epley discloses providing visual stimuli to the subject using light occluding goggles, screens, and images. Epley 13:25-34; 21:46-49.

10. Claim 11

(a) "A kit comprising: a system according to claim 9; and instructions for administering a dose of vestibular stimulation."

The only difference between this claim and the system disclosed by the combination of Epley and Newman is the presence of the instructions. However, the instructions are not given any patentable weight because adding instructions to an otherwise known product is insufficient to distinguish it from the prior art. Astrazeneca LP v. Apotex, Inc., 633 F.3d 1042, 1064-65 (Fed. Cir. 2010) (holding that prior precedent "foreclosed the argument that simply adding new instructions to a known product creates the functional relationship necessary to distinguish the produce from the prior art.”).

D. Ground 4: Claim 3 Is Obvious Over Epley in View of Newman and Graybiel

Epley is described in Ground 1, Newman is described in Ground 3, and Graybiel is described in Ground 2. Epley was considered during prosecution of the ’631 patent but not in combination with Newman and Graybiel.

Epley discloses an automated, computer controlled system that can be used to control a two axis maneuvering device 18 to produce vestibular stimulation. Epley, abstract; 9:59-62; 10:20-31. Newman discloses a two axis simulation device. Newman 1:56-60. Epley and Newman do not explicitly disclose increasing the vestibular stimulation in increments in successive administrations of vestibular stimulation. Graybiel discloses that motion sickness can be prevented by incrementally increasing the strength of vestibular stimulation in successive administrations. Graybiel p. 111-113 (the section titled “Adaptation Through Control of the Subject’s Head Motions and Velocity of the SRR”); see discussion in Ground 2 for greater detail about Graybiel.

It would have been obvious to use the simulation device in Newman with the computer system in Epley for the reasons given in Ground 3. The following are the reasons it would be obvious to modify the combination of Epley and Newman to include the vestibular stimulation methods in Graybiel.

It would have been obvious to incrementally increase the vestibular stimulation in successive administrations because doing so constitutes nothing more than combining prior art elements according to known methods to yield predictable results. MPEP 2143(I)(A). This rationale is supported by the following findings. Id. First, Epley, Newman, and Graybiel disclose all of the claimed subject matter with the only difference being the lack of an actual combination of the references into a single reference (see the claim-by-claim analysis below). Second, one of skill in the art could have used known methods to operate the computer system and simulation device produced by the combination of Epley and Newman to incrementally increase the vestibular stimulation – e.g., provide instructions to the computer system that result in increasing the rotational velocity for a patient in increments as disclosed in Graybiel. Third, the computer system in Epley and the simulation device in Newman perform the same functions when combined as they do separately. The only difference is that they are instructed to follow the procedure disclosed in Graybiel – i.e., incrementally increase the vestibular stimulation to treat motion sickness. Fourth, one of skill in the art would have recognized that the result of the combination is predictable – i.e., incrementally increasing the vestibular stimulation will prevent motion sickness as disclosed in Graybiel.

It also would have been obvious to incrementally increase the vestibular stimulation in successive administrations because doing so constitutes nothing more than using a known technique (i.e., the vestibular stimulation procedure in Graybiel) to improve a similar method in the same way (i.e., the vestibular stimulation techniques in Epley and Graybiel are similar methods). MPEP 2143(I)(C). This rationale is supported by the following findings. Id. First, the vestibular stimulation methods disclosed in Epley are the base methods upon which the claimed invention can be seen as an improvement. The improvement is the use of the vestibular stimulation methods disclosed in Graybiel to prevent motion sickness. Second, the vestibular stimulation methods in Graybiel are comparable to the vestibular stimulation methods disclosed in Epley and have been improved in the same way as the claimed invention (i.e., incremental increases in vestibular stimulation in successive administrations). Third, one of skill in the art could have applied the known improvement technique in Graybiel (i.e., the incrementally increasing vestibular stimulation methods) to the vestibular stimulation methods in Epley with predictable results (i.e., the computer system controls the motion simulator to provide incrementally increasing amounts of vestibular stimulation in successive administrations).

It also would have been obvious to incrementally increase the vestibular stimulation in successive administrations because doing so provides an effective method of preventing motion sickness in humans as taught by Graybiel. See discussion of Graybiel above; MPEP 2143(I)(G). One of ordinary skill in the art would reasonably expect to be successful using the vestibular stimulation methods in Graybiel to treat motion sickness because it is simply a matter of operating the computer system in Epley and the simulation device in Newman in a specific way.

A detailed explanation of how the combined references satisfy the claim limitations is given below.

1. Claim 3

(a) "A method according to claim 2, wherein the vestibular stimulation is increased by increments in successive administrations of vestibular stimulation."

Graybiel discloses incrementally increasing the amount of vestibular stimulation in successive administrations. Graybiel p. 111-113 (the section titled "Adaptation Through Control of the Subject's Head Motions and Velocity of the SRR"); Table 2; Figs. 2-3. Figures 2-3 of Graybiel graphically show the incremental increase of vestibular stimulation in the form of the increased RPM of the slow rotation room. The procedure is disclosed as being most effective when, at each step, the subjects were stressed to the limits of their tolerance without showing overt symptoms of motion sickness. Id. p. 115.

VII. CONCLUSION

For the reasons set forth above, Petitioner submits that it has established a reasonable likelihood that it will prevail on each of the claims of the '631 patent.

Accordingly, this Petition should be granted, inter partes review should be instituted, and claims 1-11 of the ’631 patent should be found unpatentable and canceled.

Respectfully submitted,

Date: 30 December 2014

/Scott Nielson/
Scott Nielson
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CERTIFICATE OF SERVICE

I certify that on 30 December 2014 a copy of this PETITION FOR INTER PARTES REVIEW, EXHIBITS 1001-1006, and PETITIONER'S POWER OF ATTORNEY were served in the manner indicated on the following attorney of record:

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