UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANTAGE MEDICAL ELECTRONICS, LLC & LIFESYNC CORPORATION Petitioners

v.

KPR U.S., LLC Patent Owner

Patent 8,038,484

PETITION FOR INTER PARTES REVIEW

UNDER 35 U.S.C. § 311 *ET SEQ*. AND 37 C.F.R. § 42.100 *ET SEQ*. (CLAIMS 3-11 of U.S. PATENT NO. 8,038,484)

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	MANDATORY NOTICES UNDER 37 C.F.R. § 42.8	2
	A. Real Parties-In-Interest (37 C.F.R. § 428(b)(1))	2
	B. Related Matters (37 C.F.R. § 428(b)(2))	2
	C. Lead and Back-Up Counsel and Service Information (37 C.F.R.	
	§ 42.8(b)(3-4))	3
	D. Service Information Under 37 C.F.R § 42.8(b)(4)	3
III.	GROUNDS FOR STANDING (42.104(a))	3
IV.	OVERVIEW OF CHALLENGE (§ 42.104(b))	4
V.	OVERVIEW OF THE '484 PATENT	4
VI.	PERSON OF ORDINARY SKILL IN THE RELEVANT FIELD	
	AND THE RELEVANT TIMEFRAME	5
VII.	PROSECUTION HISTORY	6
VIII.	STATE OF THE ART RELATIVE TO THE '484 PATENT	7
	A. Technical Background	8
	B. Summary of the Prior Art	12
	1. Japanese Patent Publication No. JPH09276239A, (together with	
	the English translation and Verification of Translation, "Fukuda")	
	(Ex. 1007)	12
	2. U.S. Patent No. 3,740,703 ("Sessions") (Ex. 1006)	13
	3. U.S. Patent No. 5,944,562 ("Christensson") (Ex. 1008)	13
	4. U.S. Patent No. 7,214,107 ("Powell") (Ex. 1009)	14
IX.	CLAIM CONSTRUCTION PURSUANT TO 37 C.F.R. § 42.104(B)(3)	
	A. First Opening	14
	B. Electrical Contact Member	15
	C. Contact Plane	16

	D. Second Opening	16
	E. Disposed Substantially Concentrically	17
	F. Pivotable About an Axis Orthogonal to the Contact Place	17
	G. Pivotably Coupled to the Housing About an Axis Orthogonal to the Contact Plane	
	H. Disposed Within the Housing	18
	I. Engaged Position	19
	J. Disengaged Position	20
	K. Actuating End	20
	L. Engaging Region	21
	M. Operably Engage	21
	N. Cam	21
X.	UNPATENTABILITY GROUNDS	22
	A. Ground 1: Claims 3-7 & 9-11 Are Rendered Obvious by Fukuda i View of Christensson and Sessions	
	B. Ground 2: Claim 8 Is Rendered Obvious by Fukuda in View of Christensson, Sessions and Powell	65
XI.	CONCLUSION	67
XII.	CERTIFICATE OF WORD COUNT	67
XIII.	APPENDIX OF EXHIBITS	68

I. INTRODUCTION

Advantage Medical Electronics, LLC known more commonly as "Advantage Medical Cables" ("AMC") and LifeSync Corporation ("LifeSync") petition for *inter partes* review, seeking cancellation of claims 3-11 of U.S. Patent No. 8,038,484 to Selvitelli et al. ("'484 patent," Ex. 1001), purportedly owned by KPR U.S., LLC ("purported Patent Owner").

The challenged claims are directed to ECG electrode connectors that allow a user to move a lever about an axis orthogonal to a contact plane extending through a contact member, where the lever is either disposed within a housing or includes a cam. Once released, part of the lever will engage the press stud to cause the press stud to contact the electrical contact member. The '484 patent purports to be predicated on the discovery of utilizing a lever that extends parallel to the contact plane defined by the contact member and thus pivots about an axis that is orthogonal to the contact plane. As evidenced by the prior art references cited in this Petition and the Declaration of Terry Layton, Ph.D., the use of levers that pivot about an axis orthogonal to the contact plane defined by the contact member and thus the contact member and are either disposed within a housing or include a cam was well known in the art at the time of the invention.

In this Petition, Petitioners present several references that render obvious the challenged claims of the '484 patent. Section VII of this Petition summarizes the

prosecution history of the '484 patent. Section VIII sets forth the state of the art relative to the '484 patent. Section IX sets forth the claim construction for the challenged claims of the '484 patent. Section X sets forth the detailed grounds for invalidity of the challenged claims. This showing is accompanied by the Declaration of Terry Layton, Ph.D. ("Layton Decl.," Ex. 1002.)

Petitioners are reasonably likely to prevail in showing that the challenged claims are not patentable. Therefore, *inter partes* review of the '484 patent should be instituted.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))

Petitioners certify that the following are real parties-in-interest: AMC and LifeSync.

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

On March 1, 2022, the purported Patent Owner and Cardinal Health 200, LLC ("Cardinal Health") sued the Petitioners and 3M Company in the U.S. District Court for the Southern District of Florida (civil action No. 0:22-cv-60468-RAR), alleging infringement of the '484 patent and U.S. Patent No, 8,795,004 (the "'004 patent"). The earliest service date of the complaint served on the Petitioners identified above was March 9, 2022. This Petition has been filed within one year of Petitioners being served a complaint alleging infringement of the '484 patent. 35 U.S.C. § 315(b); 37 C.F.R. § 42.101(b).

A petition has been concurrently filed on this day on the '004 patent.

C. Lead and Back-Up Counsel and Service Information (37 C.F.R. § 42.8(b)(3-4))

Petitioners appoint Scott W. Smilie (Reg. No. 44,341) of Patzik, Frank & Samotny Ltd. as lead counsel, and appoints Jeffrey A. Pine (Reg. No. 36,893) and Jordan Herzog (Reg. No. 38,182) of Patzik, Frank & Samotny Ltd. as back-up counsel. A Power of Attorney for each Petitioner identified in Section I is filed concurrently.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service of any documents to lead and back-up counsel can be made via hand delivery to Patzik, Frank & Samotny Ltd., Suite 2700, 200 S. Wacker Drive, Chicago, IL 60606. Petitioners consent to service by email at jpine@pfs-law.com, ssmilie@pfs-law.com, jherzog@pfs-law.com and ipdocket@pfs-law.com.

III. GROUNDS FOR STANDING (§ 42.104(a))

Petitioners certify that the '484 patent is available for *inter partes* review and that the Petitioners are not barred or estopped from requesting *inter partes* review challenging the claims of the '484 patent on the grounds identified in this Petition.

IV. OVERVIEW OF CHALLENGE (§ 42.104(b))

Inter partes review of the '484 patent's challenged claims is requested on the grounds for unpatentability listed in the index below.

Ground	Basis	Index of References	Claims Challenged
1	§ 103(a)	Fukuda, Christensson and Sessions	3-7, 9-11
2	§ 103(a)	Fukuda, Christensson, Sessions and Powell	8

Fukuda, Sessions and Powell were not cited or relied upon by the examiner during prosecution of the '484 patent. At no time were these references submitted to the Patent and Trademark Office in association with the application for the '484 patent. Christensson was relied on by the examiner but not in combination with Fukuda, Sessions and/or Powell. To support the proposed grounds of unpatentability, this Petition is accompanied by the declaration of technical expert Terry Layton, Ph.D. (Layton Decl., Ex. Ex. 1002.)

V. OVERVIEW OF THE '484 PATENT

The '484 patent was filed on December 9, 2008, and issued on October 18, 2011 and claims priority to U.S. provisional patent application No. 61/012,825, filed on December 11, 2007 ("Selvitelli '825 App."). The '484 patent's challenged claims are directed to an ECG connector assembly that allows a user to move a lever about an axis orthogonal to a contact plane extending through a contact

member to allow for a press stud of an electrode to be inserted therein, where the lever is either disposed within a housing or includes a cam. Once released, part of the lever will engage the narrow waist portion of a press stud and couple it with the electrical contact member.

VI. PERSON OF ORDINARY SKILL IN THE RELEVANT FIELD AND THE RELEVANT TIMEFRAME

The field of the '484 patent is biomedical connectors and, more particularly, biomedical electrode connectors for attaching a lead wire to an ECG electrode placed on a patient's body. ('484 patent, Ex. 1001, Col. 1:14-17.) Within a field, the level of ordinary skill in the art is evidenced by the prior art references of record. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). A person of ordinary skill in the art ("POSITA") is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007); *see also* Layton Decl., Ex. 1002 ¶¶ 6, 13-22.

A POSITA of the '484 patent would have had education and/or experience in the biological sciences, engineering, or medical device manufacturing and/or design along with knowledge of the scientific literature in the field. (*Id.* at ¶ 31.) Although education and experience levels may vary, a POSITA would have had at least a bachelor's degree in bioengineering, biomedical engineering, or equivalent. (*Id.*)

5

As of the earliest effective filing date of the '484 patent claims, a POSITA also would have had work experience in the field of medical devices or medical test instruments, including several years of experience designing connectors or attachment mechanisms for medical devices or medical test instruments. (*Id.* at ¶ 34.) A person holding only a bachelor's degree would be required to have had three (3) years of relevant work experience to qualify as a POSITA, but a person with a more advanced degree, such as a master's of science or doctorate, could qualify as a POSITA with fewer years of experience. (*Id.*)

VII. PROSECUTION HISTORY

Application Serial No. 12/330,550 (the "'550 patent application"), which issued as the '484 patent, included 14 claims when originally filed. ('484 patent file history, Ex. 1003, at 177-181.) In an Office Action dated November 12, 2010, the examiner requested that the claims be restricted to either electrical connectors, classified in class 439, subclass 729 or electrical connectors, classified in class 439, subclass 729 or electrical connectors, classified in class 439, subclass 159. (*Id.* at 95-100.) In response, on November 30, 2010, the Applicant of the '550 patent application ("Applicant") elected to proceed with claim 1-2 and 4-14 directed to the electrical connectors classified in class 439, subclass 729. (*Id.* at 84-91.) Claim 3 was withdrawn from further prosecution. (*Id.* at 86.)

Thereafter, the examiner rejected Claims 1-2 and 4-14 in the first Office Action dated January 13, 2011 over Christensson U.S. Patent No. 5,944,562. (*Id.*

at 71-79.) In a response dated June 13, 2011 and titled Amendment "B", the Applicant amended the independent claims to try and traverse the rejection. (*Id.* at 56-65.) The Applicant amended original claim 4 (which issued as claim 3) to include the limitations of: "an electrical contact member defining a contact plane;" "a lever pivotable about an axis orthogonal to the contact plane;" and "the engaging region configured to operably engage a narrow waist portion of the press stud and further configured to couple the narrow waist portion of the press stud with the electrical contact member when the lever is in the engaged position." (*Id.* at 58-59.)

The Applicant also amended claim 5 (which issued as claim 4) to include the limitations of: "an electrical contact member defining a contact plane;" "a lever pivotable about an axis orthogonal to the contact plane;" and "wherein the lever includes a cam configured to operably engage a narrow waist portion of the press stud and further configured to couple the narrow waist portion of the press stud with the electrical contact member when the lever is in the engaged position." (*Id.* at 59.) The examiner thereafter allowed claims 1-2 and 4-14 with the amendments on July 8, 2011. (*Id.* at 38-45.)

VIII. STATE OF THE ART RELATIVE TO THE '484 PATENT

The '484 patent is broadly directed to an ECG electrode connector having a housing, an electrical contact member defining a contact plane and a lever coupled

to the housing about an axis orthogonal to the contact plane. The '484 patent purports to overcome disadvantages well-known in the art of ECG electrode connectors, such as having to snap or press the connector onto the press stud of the electrode in a direction towards the patient, which can, among other things, cause pain and discomfort to the patient ('484 patent, Ex. 1001, Col. 1:32 to Col. 2:15.)

A. Technical Background

The electrocardiogram ("ECG" or "EKG") system is a common diagnostic tool that measures and records the electrical activity of the heart. (Layton Decl., Ex. 1002, ¶ 33.) An ECG system produces a graphic representation of electrical activity called an electrocardiograph, which records the electrical voltage in the heart in the form of a continuous strip graph or on a monitor screen. (Id.) An ECG is constructed by measuring electrical potential between various points of the body using a galvanometer or voltmeter. (Id.) A typical ECG system relies on electrodes placed on a patient in specific locations to detect electrical impulses generated by the heart during each beat. (Id.) Electrical impulses detected by the electrodes are communicated to an ECG monitor via a plurality of leadwires, each of which terminates with an electrically conductive electrode connector that is physically connected to one of the electrodes so as to be in electrical communication therewith. (*Id.*)

The electrodes include pads that that are placed on and temporarily adhered to various locations of the skin of a patient using a conductive gel or adhesive. (*Id.* at \P 34.) A metal press stud can extend upwardly from the pad to allow the lead wire to be connected thereto. (*Id.*)

There are two primary ways in which electrode connectors attach to the studs of biomedical patient electrodes, namely by pinch connection or snap/press connection. (*Id.* at \P 35.) The pinch connection can be further broken down into open end or alligator pinch connections and closed end or plate pinch connections. (*Id.*)

"Snap" or "press" connectors snap onto the stud of the electrode by the application of a downward pressure. (*Id.* at \P 36.) An example of such an electrode connector is found in U.S. patent No. 4,671,591 issued to Archer. (Ex. 1005; Layton Decl., \P 36.)

An example of an open end pinch connector is found in U.S. patent No. 4,178,052 issued to Ekbom (Ex. 1004), which discloses an open ended electrode connector adapted to pinch the stud of a patient electrode between a pair of opposing jaws. (Layton Decl., Ex. 1002, ¶ 37.) Another example of an open end electrode connector is found in Japanese patent publication no. JPH09276239 (*Id.*; Fukuda, Ex. 1007.)

An example of a closed end pinch or plate connector is found in U.S. patent No. 3,740,703 to Sessions (Ex. 1006; Layton Decl., Ex. 1002, ¶ 38.) In these connectors, the stud of the electrode is passed through an aperture in a conductive plate, and a biasing member moves a lever to retain the stud in electrical contact with the conductive plate. (*Id.*)

The prior art demonstrates that those of ordinary skill in the art were aware of the problems with snap-on electrode connectors identified in the '484 patent since at least the early 1970s. (Id. at ¶ 39.) For example, Robert W. Sessions, in his application for a Terminal Clamp filed in 1971, noted that the use of snap-on or button connectors "will result in a considerable pressure on the terminal of the electrode tending to compress the adjacent flesh of the patent until the firmness thereof is greater than the pressure forces required to effect engagement of the two terminals." (Sessions, Ex. 1006, Col. 1: 41-45; Layton Decl., Ex. 1002, ¶ 39.) When a conductive gel is used to facilitate the electrical connection between the terminal and the skin surface, the downward force applied to attach the connector to the press stud will spread the conductive gel used outwardly from the central terminus which can "effect a separation of the adhesively connected portions from the skin surface, thereby considerably reducing the effective attaching area and which, in some cases, could even result in a sufficient weakening of the adhesive bond between the electrode and the skin surface to a point where electrical

conduction is impaired by the poor connection of the electrode structure to the skin surface." (Sessions, Ex. 1006, Col. 1: 16-21; 34-64; Layton Decl., Ex. 1002, ¶ 39.) The spreading of the gel can also remove the conductive gel from in "between the inner face of the electrode terminal structure and the opposing skin surface, thus further reducing the efficiency of the conductive connection following release of the applied pressure." (Sessions, Ex. 1006, at Col. 1: 64 to Col. 2:5; Layton Decl., Ex. 1002, ¶ 39.)

Sessions solved this known problem by "the production of a terminal clip by means of which a conductor may be operatively connected to an electrode of the type described without the application of undesired pressure on the terminal in a direction towards the skin surface, i.e. by providing a structure in which the applying forces are laterally directed to portions of the terminal clip with substantially no force whatsoever being applied in a direction toward the electrode structure or the terminal thereof." (Sessions, Ex. 1006, Col. 2: 13-22; Layton Decl., Ex. 1002, \P 40.)

It was also known in the prior art that open end or alligator pinch connectors were disfavored because they could come into contact with a ground or outlet terminal that could allow an unwanted current to pass through the connector and they "cannot provide desired electrical contact and stability with a snap style contact stud.". (Layton Decl., Ex. 1002, ¶ 41; Christensson, Ex. 1008, Col.1:50-

11

52).) In order to avoid the problem of coming into contact with a ground or outlet terminal, it was known to include the electrical contact member within an insulated or non-conductive housing. (Layton Decl., Ex. 1002, \P 42.) In view of the known issues, Fukuda teaches placing an electrical contact member of an ECG connector within an insulated housing that encloses the electrical contact member and includes an opening to allow for an electrode stud to be inserted therein to engage the electrical contact member. (*Id.* at \P 42.)

B. Summary of the Prior Art

The prior art references relied upon disclose an ECG electrode connector that meets all of the limitations recited in the challenged claims. The references comprise Exhibits 1006-1009.

1. Japanese Patent Publication No. JPH09276239A, (together with the English translation and Verification of Translation, "Fukuda") (Ex. 1007)

Fukuda was filed April 9, 1996 and published October 28, 1997, and is prior art under 35 U.S.C. § 102(b). Fukuda discloses an open end pinch type biomedical electrode connector having an insulated housing (Fukuda, Ex. 1007, ¶¶ [0011] – [0012]), an electrical contact member (*Id.* at ¶ [0014]) and a lever disposed within the housing that pivots about an axis orthogonal to a contact plane between a disengaged position and an engaged position where the engaging region of the lever operably engages the press stud to cause a portion of the press stud to contact the electrical contact member. (*Id.* at \P [0024].)

2. U.S. Patent No. 3,740,703 ("Sessions") ") (Ex. 1006)

Sessions was filed November 24, 1971 and issued June 19, 1973, and is prior art under 35 U.S.C. § 102(b). Sessions discloses a closed end pinch type biomedical electrode connector having an electrical contact member having a contact opening and a lever that pivots about an axis orthogonal to a contact plane between a disengaged position and an engaged position where the engaging region of the lever operably engages the press stud to cause a portion of the press stud to contact the electrical contact member and retain it therein. (Sessions, Ex. 1006, Col. 4: 5-39; Col. 5:11-47.)

3. U.S. Patent No. 5,944,562 ("Christensson") (Ex. 1008)

Christensson was filed April 28, 1997 and issued August 31, 1999, and is prior art under 35 U.S.C. § 102(b). Christensson discloses a closed end pinch type biomedical connector having an insulated housing, an electrical contact member and a lever that pivots between a disengaged position and an engaged position. (Christensson, Ex. 1008, Col. 4: 36-40; Col. 5: 25-28; Col 6: 39-43.) Christensson further discloses that the contact opening is smaller than and substantially concentric with the opening in the housing. (*Id.* at Col 6: 34-39; Fig. 7.)

4. U.S. Patent No. 7,214,107 ("Powell") (Ex. 1009)

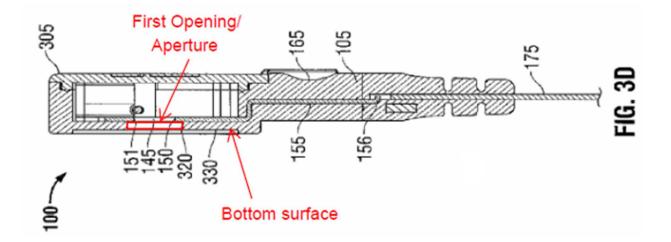
Powell was filed November 22, 2004 and published May 25, 2006 as U.S. patent publication no. 2006/0110962, and is prior art under 35 U.S.C. § 102(b). Powell discloses a biomedical electrode connector having housing and actuating members made from insulated materials such as polyethylene or acrylonitrile butadiene styrene. (Powell, Ex. 1009, Col. 1: 6-10; Col. 9: 14-25.)

IX. CLAIM CONSTRUCTION PURSUANT TO 37 C.F.R. § 42.104(B)(3)

In *inter partes* reviews filed after November 13, 2018, claims are construed according to the *Phillips* standard consistent with Article III federal courts. 83 Fed. Reg. 51340, 51340-41 (Oct. 11, 2018) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)). Claims are to be construed under the same standard as in federal court, in view of the specification and intrinsic record. *Id.* Petitioners propose that all claims should be entitled to their plain and ordinary meaning, except for the limitations addressed below.

A. First Opening

The term "first opening" is used in independent claims 3 and 4, which states "a housing having a first opening disposed therein dimensioned to operably receive the press stud of an ECG electrode pad." ('484 patent, Ex. 1001, Col. 10: 42-44, 60-62.) The specification identifies the "first opening" in the housing as the aperture 320, 620, 920 that starts at the bottom surface 330, 630 and 930 of the housing 105, 405, 705 extending upwardly through the width of the bottom portion of the housing as shown in Fig. 3D. (*Id.* at Col. 6: 60-64, Col. 7: 55-59; Col. 8: 51-54.)



For example, "the bottom surface 330 of housing 105 provides an aperture 320 disposed therein" (*Id.* at Col. 6: 60-64.) The term "first opening" is construed to mean the same as the aperture, or a hole extending through the bottom wall of the housing from the bottom surface of the housing to the inner surface of the bottom wall that is sized to allow a press stud to extend therethrough. (Layton Decl. Ex. 1002, ¶ 49.)

B. Electrical Contact Member

The term "electrical contact member" is in independent claims 3 and 4. The specification states that "the spring member biases the press stud against a mating electrical contact member provided within the connector housing to electrically couple the press stud and the contact member, and to achieve positive mechanical

coupling of the press stud and the connector housing." ('484 patent, Ex. 1001, Col. 2: 48-53.) The term "electrical contact member" is construed to mean a conductive member that makes an electrical connection upon connection with another conductive article.

C. Contact Plane

The term "contact plane" is in independent claims 3 and 4, which states that the "electrical contact member defining a contact plane" ('484 patent, Ex. 1001, Col. 10: 45, 63.) The term "contact plane" is not otherwise used in the specification of the '484 patent. The term "contact plane" was first introduced during the prosecution in Amendment "B" dated June 13, 2011 in the '484 patent application. ('484 patent file history, Ex. 1003, at 57-58, 62.) A plane is a twodimensional flat surface that extends infinitely in those two dimensions. (Layton Decl, Ex. 1002, ¶ 51.) The term contact plane is construed to mean a twodimensional flat surface that extends through at least part of the electrical contact member. (Layton Decl. Ex. 1002, ¶ 51-52.)

D. Second Opening

The term "second opening" is in claims 3 and 4. The specification identifies the opening in the electrical contact member as being the contact opening. ('484 patent, Ex. 1001, Col. 6: 53-55; Col. 7: 51-55; Col. 8: 46-51.) The term "second

opening" is construed to mean the same as the contact opening, or a hole extending through the electrical contact member.

E. Disposed Substantially Concentrically

The term "disposed substantially concentrically" is in independent claims 3 and 4, which states that the "second opening disposed substantially concentrically to the first opening." ('484 patent, Ex. 1001, Col. 10: 46-48, 64-66.) The term "concentric" or "concentrically" is not otherwise used in the specification. The term "concentric" is defined as "having a common center" or "having a common axis." (Merriam-Webster concentric definition, Ex. 1012.) The term "disposed substantially concentrically" is construed to mean that the second opening is positioned such that the axis extending through its center is the same or close to the axis extending through the first opening. (Layton Decl. Ex. 1002, ¶ 54.)

F. Pivotable About an Axis Orthogonal to the Contact Place

The term "pivotable about an axis orthogonal to the contact plane" is in independent claim 3. The term "orthogonal" means intersecting at right angles and the term "pivotable" means capable of being rotated about a pivot point. (Layton Decl. Ex. 1002, ¶ 55.) The term "pivotable about an axis orthogonal to the contact plane" is construed to mean the lever is pivotable about a pivot point defining an axis that extends perpendicularly to a contact plane defined by the electrical contact member. (*Id.*)

G. Pivotably Coupled to the Housing About an Axis Orthogonal to the Contact Plane

The term "pivotably coupled to the housing about an axis orthogonal to the contact plane" is in independent claim 4. The term "orthogonal" means intersecting at right angles and the term "pivotably coupled" means connected in a manner permitting rotation about a pivot point. (Layton Decl. Ex. 1002, ¶ 56.) The term "pivotably coupled to the housing about an axis orthogonal to the contact plane" is construed to mean the lever is connected to the housing in a manner permitting rotation about a pivot point defining an axis that extends perpendicularly to the contact plane defined by the electrical contact member. (*Id.*)

H. Disposed Within the Housing

The term "disposed within the housing" is used in claim 3, which states "a lever pivotable about an axis orthogonal to the contact plane and disposed within the housing" ('484 patent, Ex. 1001, Col. 10: 50-51.) The term "disposed within housing" is only used in the specification to refer to the pushbutton 410 and not the lever. (*Id.* at Col. 7: 34-38.) It is not otherwise used in the specification. Figs. 4 and 5 of the '484 patent show the pushbutton 410 being substantially inside of the housing 405.

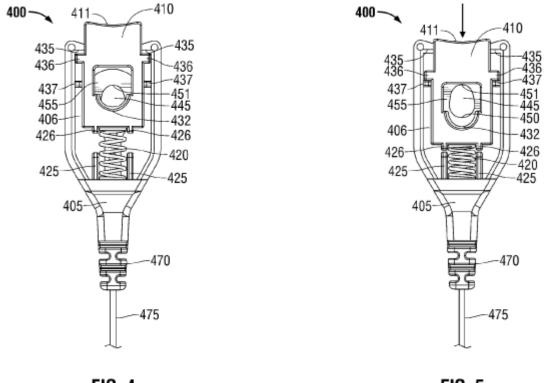


FIG. 4

FIG. 5

The term "disposed within the housing" is construed to mean located substantially inside of the housing. (Layton Decl. Ex. 1002, \P 57.)

I. Engaged Position

The term "engaged position" is used in claim 3 and is not otherwise used in the specification of the '484 patent other than the claims. The term "engaged" means to come together. (Layton Decl., Ex. 1002, ¶ 58.) The term "engaged position" is construed to mean the overall position of the lever where its engaged region contacts a press stud. (*Id.*)

J. Disengaged Position

The term "disengaged position" is used in claim 3 and is not otherwise used in the specification of the '484 patent other than the claims. The term "disengaged" means to be released from something. (Layton Decl., Ex. 1002, ¶ 59.) The term "disengaged position" is construed to mean the overall position of the lever when sufficient force is applied to its actuating portion of the lever to move its engaging portion away from a press stud to allow the electrode connector to be removed from the press stud. (*Id*.)

K. Actuating End

The term "actuating end" is in independent claim 3. The '484 patent used the term "actuating end" 1336 as the portion of a lever where "a clinician may apply finger pressure . . . that is sufficient to overcome the biasing force of biasing member 1338, thereby causing engaging region 1336 to move to a second position as herein described." ('484 patent, Ex. 1001, Col. 9: 45-49.) The term "actuate" means to put into mechanical action or motion. (Merriam-Webster actuate definition, Ex. 1010.) The "term "actuating end" is construed as being the area of the lever that may be pressed or moved in order to move the lever between an engaged and a disengaged position. (Layton Decl. Ex. 1002, ¶ 60.)

L. Engaging Region

The term "engaging region" is in independent claim 3. The '484 patent discloses, among other things, that "[e]ngaging region 716 of lever 710 includes an engaging surface 732 for coupling the connector 700 to a press stud" ('484 patent, Ex. 1001, Col. 8: 37-40.) The '484 patent further discloses that "lever 1340, may be released so that biasing member 1338 moves engaging region 1336*a* of lever 1340 against the head of the male press stud (not explicitly shown) to push or force the lower portion of the press stud into a second contact opening portion 1334b of contact opening 1334." (*Id.* at Col. 9: 62-67.) "The term "engaging region" is construed to mean the portion of the lever that includes a surface that engages the press stud when the lever is in the engaged position. (Layton Decl. Ex. 1002, ¶ 61.)

M. Operably Engage

The term "operably engage" is in claims 3 and 4. The term "engage" means to come together. (Layton Decl., Ex. 1002, \P 62.) The term "operably engage" is construed to mean to make contact with.

N. Cam

The term "cam" is in independent claim 4, which states "the lever includes a cam configured to operatively engage a narrow waist portion of the press stud and further configured to couple the narrow waist portion of the press stud with the

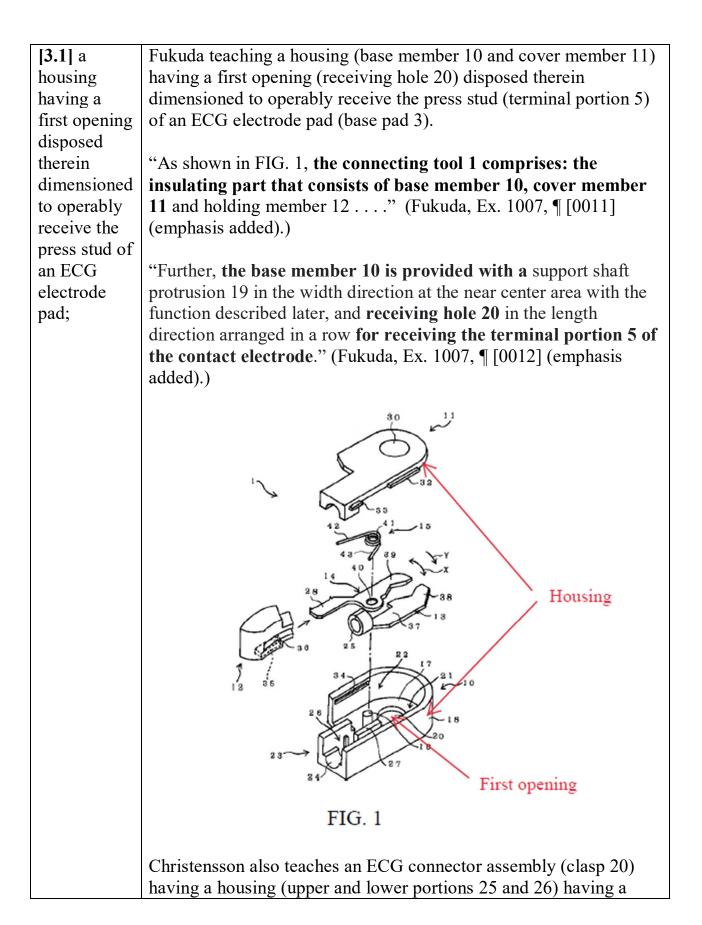
electrical contact member when the lever is in the closed position." A cam is defined as "a rotating or sliding piece (such as an eccentric wheel or a cylinder with an irregular shape) in a mechanical linkage used especially in transforming rotary motion into linear motion or vice versa." (Merriam-Webster cam definition, Ex. 1012; Layton Decl., ¶ 63.) The term "cam" is construed to mean a rotating or sliding piece in a mechanical linkage or device used especially in transforming rotary motion into relative linear motion or vice versa.

X. **UNPATENTABILITY GROUNDS**

The references reviewed below render the claimed subject unpatentable under 35 U.S.C. § 103. As detailed below, the Petitioners have a reasonable likelihood of prevailing as to each of the following grounds of unpatentability. Throughout the grounds, the figures have been annotated to identify elements of the claim in the prior art and emphasis added to the evidence to support the challenge.

А.	Ground 1: Claims 3-7 & 9-11 Are Rendered Obvious by
	Fukuda in View of Christensson and Sessions

U.S.	Fukuda in view of Christensson and Sessions
Patent No.	
8,038,484	
[3.0] An	"This invention is in regard to the bio contact electrode device used
ECG	to transmit the cardiac action potential to a monitoring device such
connector	as an electrocardiograph." (Fukuda, Ex. 1007, ¶ [0001].)
assembly,	
comprising:	(Layton Decl., Ex. 1002, ¶¶ 75-78.)

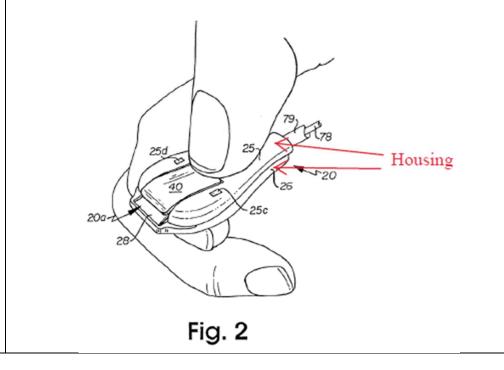


first opening (opening 26h) disposed therein dimensioned to operatively receive the press stud 17a of an ECG electrode pad.

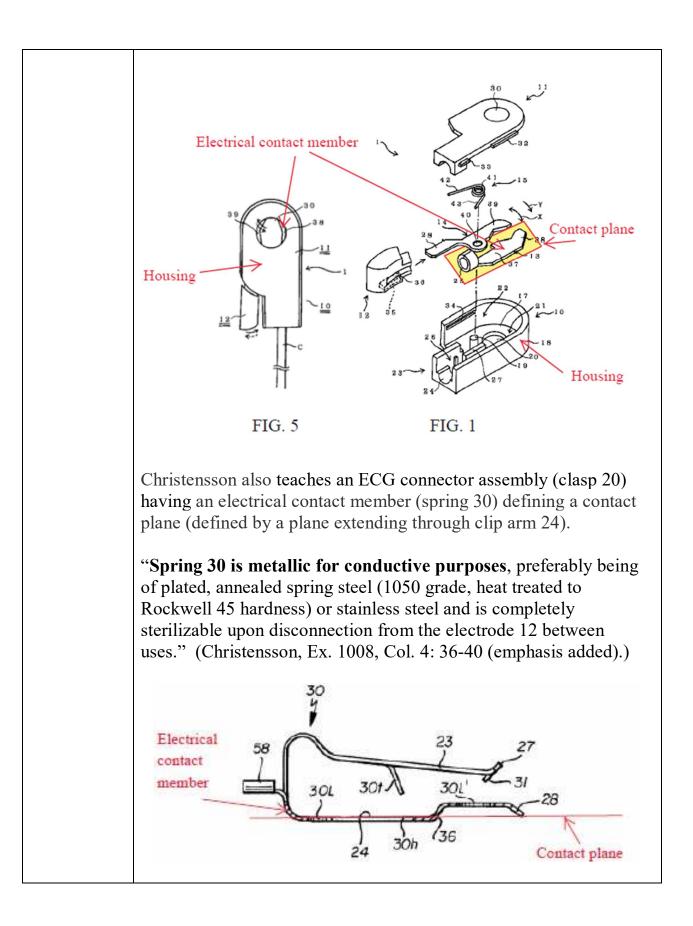
Christensson teaches that "**[t]he upper and lower portions 25 and 26 of the clasp 20 are of a molded material**, preferably plastic resin which has electrical insulating properties, typically of nylon or poly carbonate plastic which is completely sterilizable." (Christensson, Ex. 1008, Col. 5: 25-28 (emphasis added).)

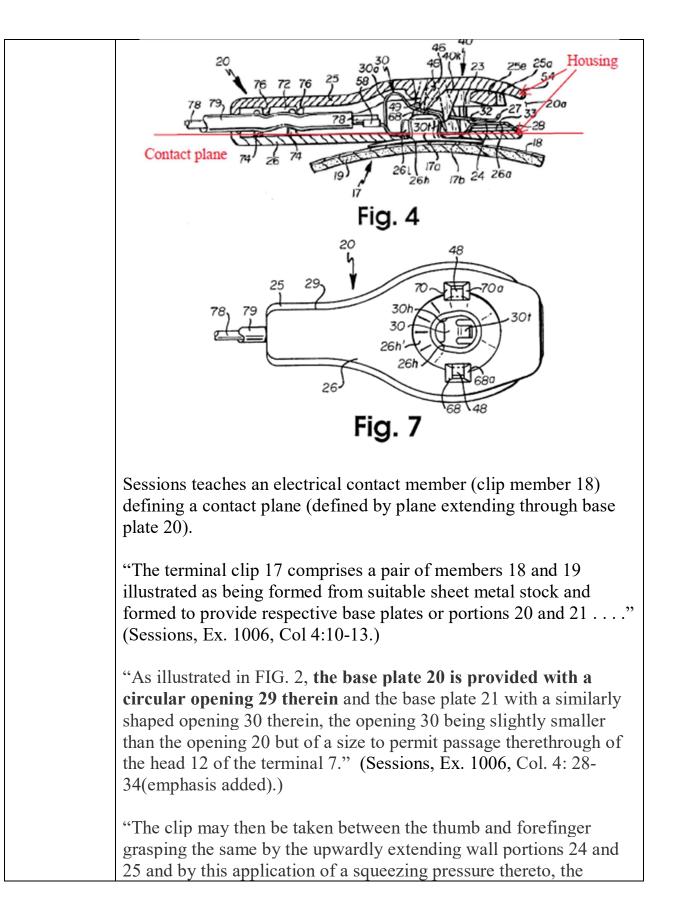
"Near the center of the bottom portion 26 of the clasp 20 is an oblong opening 26h which is slightly larger at its forward end as shown in FIG. 7." (Christensson, Ex. 1008, Col. 6: 34-36 (emphasis added).)

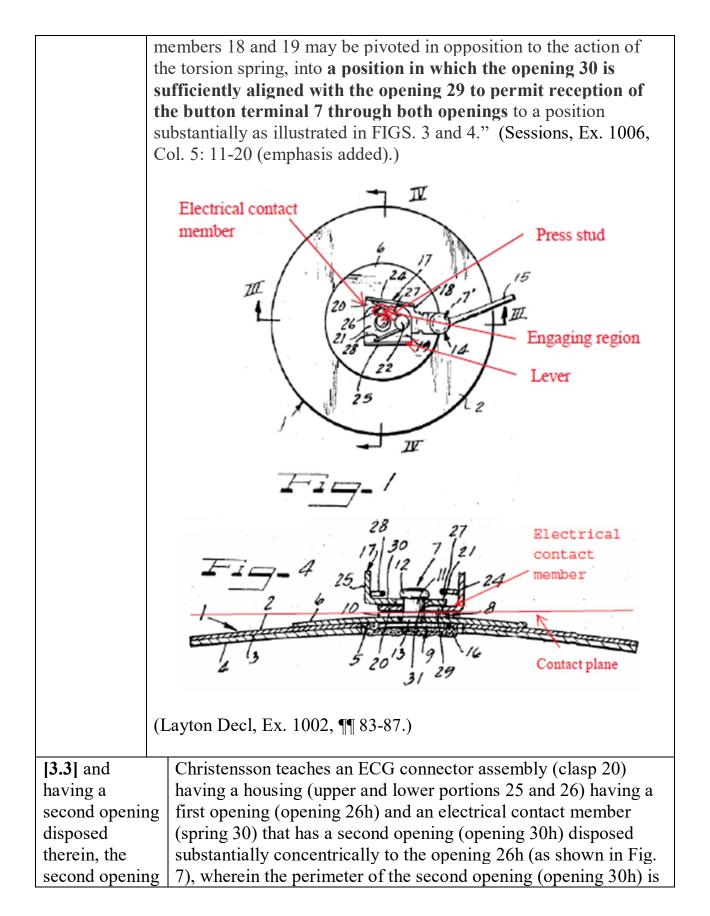
"When the stud 17a is introduced into the forward enlarged end of the opening 30h in the spring 30 through opening 26h, it can do so because the opening is large enough at its forward end to accommodate the stud 17a." (Christensson, Ex. 1008, Col. 6: 48-52 (emphasis added).)



	20 76 72 76 72 76 72 76 76 72 76 76 76 76 76 77 78 78 78 78 78 78 78 78 78
	Reg. 7
	(Layton Decl, Ex. 1002, ¶¶ 79-82.)
[3.2] an electrical contact member defining a contact	As noted above, "contact plane" is construed to mean "a two- dimensional flat surface that extends through at least a part of the electrical contact member." The contact plane may extend through the contact member at any point along its height or thickness. (Layton Decl., Ex. 1002, ¶ 84.)
plane	Fukuda teaches an electrical contact member 13 defining a contact plane (a plane extending through contact member 13).
	"In addition, in the first assembly portion 21 a holding plate 27 is projected from the bottom surface 17 in order to clamp and immobilize the first contact member 13 incorporated therein with the side wall 18." (Fukuda, Ex. 1007, ¶ [0014] (emphasis added))

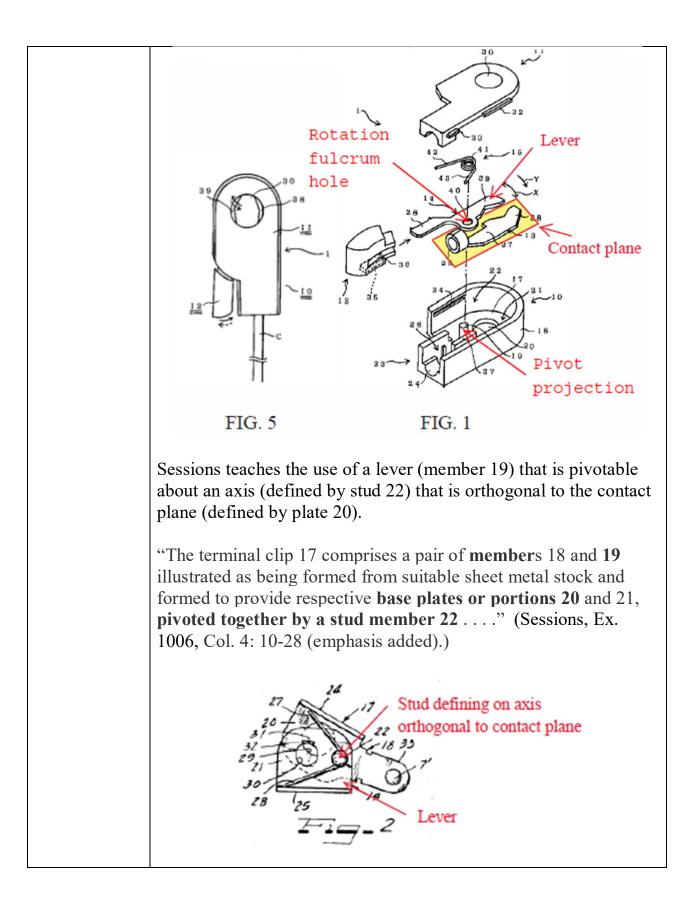






disposed	less than the perimeter of the first opening (opening 26h).
substantially	
concentrically	"Near the center of the bottom portion 26 of the clasp 20 is an
to the first	oblong opening 26h which is slightly larger at its forward end as
opening,	shown in FIG. 7. Around the opening 26h is an upwardly and
wherein the	centrally tapered surface 26h'. Aligned above it is a similarly
perimeter of	shaped opening 30h in the lower arm 24 of the spring 30 "
the second	(Christensson, Ex. 1008, Col. 6: 34-39 (emphasis added).)
opening is less	
than the	As shown in the annotated FIG. 7 below, the perimeter of the
perimeter of	second opening shown in light blue is less than the perimeter of
the first	the first opening shown in yellow. (Layton Decl., Ex. 1002, ¶
	89.)
opening; and	89.)
	20 48
	First Opening
	78, 79 30h 30
	26h'- Opening
	26h Line
	26
	Cia 7
	Fig. /
	(Layton Decl, Ex. 1002, ¶¶ 88-89.)
[3.4] a lever	Fukuda teaches a lever (contact member 14) pivotable about an
pivotable	axis (defined by pivot projection 19) orthogonal to the contact
about an axis	plane (defined by plane extending through contact member 13).
orthogonal to	
the contact	Fukuda teaches a lever or contact member 14 wherein "[t]he
plane	second contact member 14 is the side that holds the terminal
1	portion 5 of the contact electrode 2 as a pair with the first contact
	member 13 and operates to release the holding member, wherein
	an operating part 28 for conducting the movement is provided on
	the proximal end; and a rotation fulcrum hole 40 is further
	provided at a middle position The second contact member 14
	is incorporated into the second assembly portion 21 of the base
	member 10 so that the support shaft protrusion 19 of the base
	memoer to so that the support shart profitusion 17 of the base

member 10 is inserted into the rotation fulcrum hole 40 thereof. By incorporating in this way, and in a state described later when the actuating force of the spring 15 is applied, a rotational movement , i.e. a motion of clamping or releasing the terminal
portion 5 of the contact electrode 2 can be performed by moving
the operating part 28 with fingers as shown by arrow X in
FIG. 1." (Fukuda, Ex. 1007, ¶ [0020]-[0021] (emphasis added).)
FIG. 1. (Fukuda, Ex. 1007, $\ \ [0020]-[0021]$ (emphasis added).)
"An external view of the connecting tool thus obtained is shown in FIG.5. The holding member 12 is usually in a position as shown in
FIG.5. In this state, as shown in FIG. 5, a part of the <i><</i> shaped
holding members 38 and 39 is exposed in the internal space of the opening 30. Then, at the time of use, when the holding member
12 is pressed in as shown by the solid arrow, a part of the $<$
shaped holding members 38 and 39 opens in conjunction with each other. In this state, the terminal portion 5 of FIG. 3 is inserted into the opening portion 30. At this time, the tip of the terminal portion 5 fits into the space of the opening 30 and does not protrude out of the opening. This status is shown by the dotted line 5 A in FIG 7. With this incerted state, the holding member
line 5A in FIG.7. With this inserted state, the holding member 12 is released from the hand. Consequently, the holding
member 12 returns as shown by the dotted arrow in FIG. 5,
and the \leq shaped holding portions 38 and 39 also return as
shown by the dotted arrow in conjunction with the holding
member 12, and sandwich the terminal portion 5. The
terminal portion 5 is clamped in the way that the neck portion
5A (FIG. 3) of the terminal portion 5 is sandwiched between
the holding members 38 and 39 of the opening portion 30."
(Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)



	(Layton Decl, Ex. 1002, ¶ 91-92.)
[3.5] and disposed	Fukuda teaches a lever (contact member 14) disposed with the housing (base member 10 and cover member 11.)
within the	
housing	Fukuda discloses that "[t]he connecting tool 1 is formed by a first
	and second contact members 13,14; a base member 10; an
	insulating member composed of a cover member 11 and a holding
	member 12; and a spring 15 that actuates the second contact member 14 in the direction shown by the arrow. And then by
	inserting both contact members 13, 14 and spring to the base
	member 10 to make it fit in the cover member 11, both contact
	members 13, 14 and the spring are fully encircled by
	insulation." (Fukuda, Ex. 1007, Abstract.)

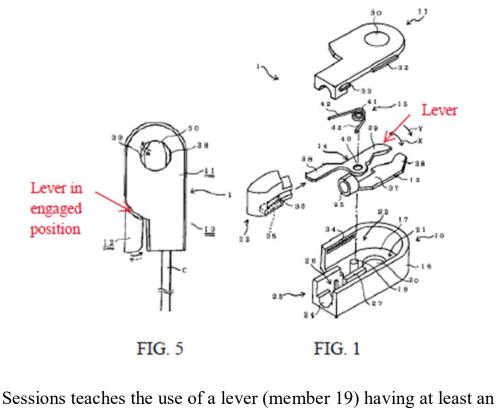
	Lever in engaged position FIG. 5 FIG. 5 FIG. 1 (Layton Decl., Ex. 1002, ¶¶ 93-95.)
[3.6] and having at least an engaged position and a disengaged position,Fukuda teaches a lever (contact member 14) having at least an engaged position (as shown in Fig. 5 without a press stud) and a disengaged position (when one moves the actuating portion of t lever inward). (Layton Decl., Ex. 1002, ¶ 96.)Fukuda teaches a lever or contact member 14 wherein "[t]he second contact member 14 is the side that holds the terminal portion 5 of the contact electrode 2 as a pair with the first conta member 13 and operates to release the holding member By incorporating in this way, and in a state described later when th actuating force of the spring 15 is applied, a rotational movement, i.e. a motion of clamping or releasing the terminal portion 5 of the contact electrode 2 can be performed by movi the operating part 28 with fingers as shown by arrow X in FIG. 1." (Fukuda, Ex. 1007, ¶ [0020]-[0021] (emphasis added	
	"An external view of the connecting tool thus obtained is shown in FIG.5. The holding member 12 is usually in a position as shown in FIG.5. In this state, as shown in FIG. 5, a part of the \leq shaped

holding members 38 and 39 is exposed in the internal space of the opening 30. Then, at the time of use, when the holding member

12 is pressed in as shown by the solid arrow, a part of the <

shaped holding members 38 and 39 opens in conjunction with each other. In this state, the terminal portion 5 of FIG. 3 is inserted into the opening portion 30. At this time, the tip of the terminal portion 5 fits into the space of the opening 30 and does not protrude out of the opening. This status is shown by the dotted line 5A in FIG.7. With this inserted state, the holding member 12 is released from the hand. Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5,

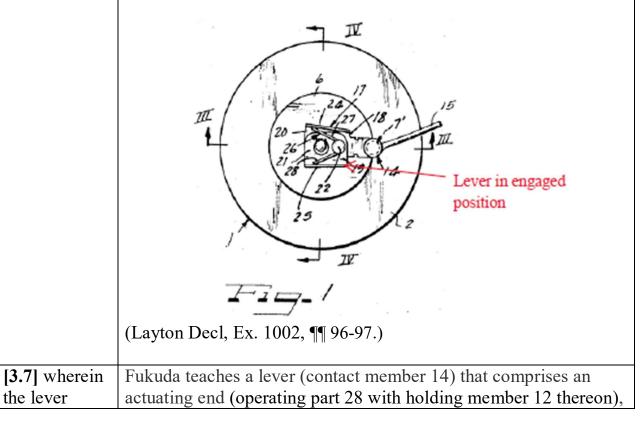
and the \leq shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30." (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)



Sessions teaches the use of a lever (member 19) having at least an engaged position (see Fig. 1) and a disengaged position (when one

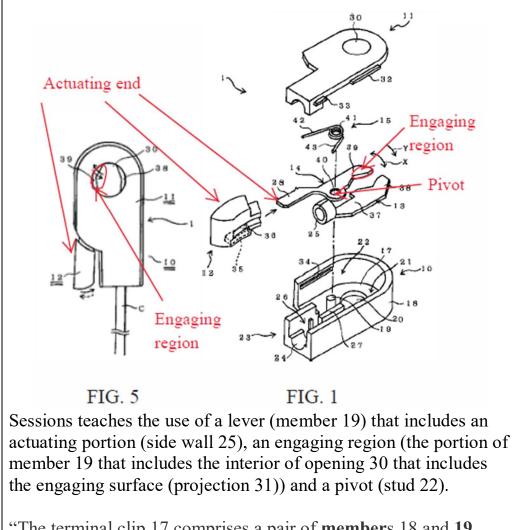
squeezes the two members together). (Layton Decl., Ex. 1002, \P 97.)

"The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and 25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening is engaged with the neck portion of the button terminal disposed below the head 12 while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7 substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal." (Sessions, Ex. 1006, Col. 5: 11-28 (emphasis added).)



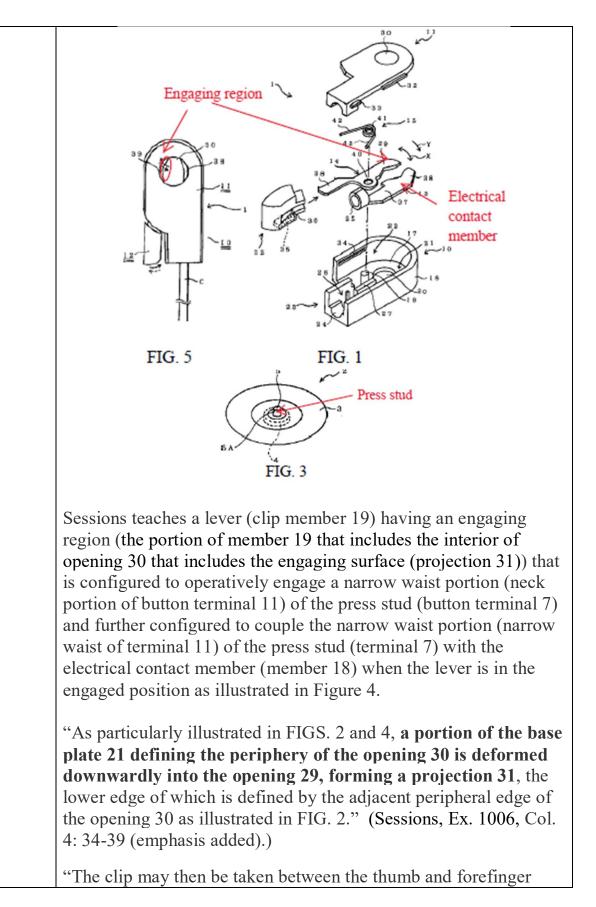
further includes an	an engaging region (the '>' shaped end of sandwiching portion 39), and a pivot (pivot projection 19).
actuating end, an engaging region, and a pivot,	Fukuda teaches a lever or contact member 14 wherein "[t]he second contact member 14 is the side that holds the terminal portion 5 of the contact electrode 2 as a pair with the first contact member 13 and operates to release the holding member, wherein an operating part 28 for conducting the movement is provided on the proximal end; while on the tip end a holding member 39
	shaped as a < that is paired with the holding member 38 of the
	first contact member 13 is provided, and a rotation fulcrum hole 40 is further provided at a middle position The second contact member 14 is incorporated into the second assembly portion 21 of the base member 10 so that the support shaft protrusion 19 of the base member 10 is inserted into the rotation fulcrum hole 40 thereof. By incorporating in this way, and in a state described later when the actuating force of the spring 15 is applied, a rotational movement , i.e. a motion of clamping or releasing the terminal portion 5 of the contact electrode 2 can be performed by moving the operating part 28 with fingers as shown by arrow X in FIG. 1 ." (Fukuda, Ex. 1007, ¶¶ [0020]-[0021] (emphasis added).)
	"An external view of the connecting tool thus obtained is shown in FIG.5. The holding member 12 is usually in a position as shown in
	FIG.5. In this state, as shown in FIG. 5, a part of the \leq shaped
	holding members 38 and 39 is exposed in the internal space of the opening 30. Then, at the time of use, when the holding member
	12 is pressed in as shown by the solid arrow, a part of the $<$
	shaped holding members 38 and 39 opens in conjunction with each other. In this state, the terminal portion 5 of FIG. 3 is inserted into the opening portion 30. At this time, the tip of the terminal portion 5 fits into the space of the opening 30 and does not protrude out of the opening. This status is shown by the dotted line 5A in FIG.7. With this inserted state, the holding member 12 is released from the hand. Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the < shaped holding portions 38 and 39 also return as
	shown by the dotted arrow in conjunction with the holding

member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30." (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)

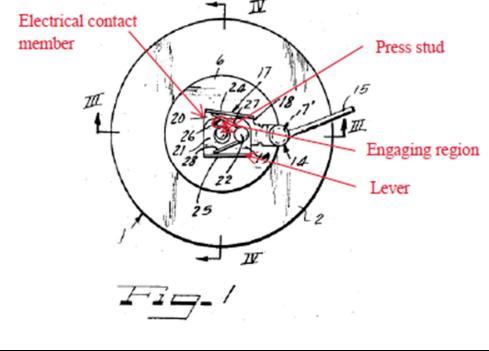


"The terminal clip 17 comprises a pair of **members** 18 and **19** illustrated as being formed from suitable sheet metal stock and formed to provide respective base plates or portions 20 and 21, **pivoted together by a stud member 22**, illustrated as having a shank 23 extending outwardly from the two base plates. Extending along an outer edge of the plate 20 is an outwardly or upwardly extending sidewall or flange 24, and in like manner **extending along an edge of the plate 21 is a similarly extending flange or sidewall 25**. Extending around the shank 23 of the stud 22 is the central portion 26' of **a torsion spring indicated generally by the** numeral 26 having like oppositely disposed portions 27 and 28 adapted to bear respectively on the flanges 24 and 25 of the respective plates thereby tending to urge the plate 18 in a clockwise direction and the plate 19 in counter clockwise direction with respect to the axis of the stud 22, producing corresponding separating movement of the walls 24 and 25." (Sessions, Ex. 1006, Col. 4: 10-28 (emphasis added).) "As particularly illustrated in FIGS. 2 and 4, a portion of the base plate 21 defining the periphery of the opening 30 is deformed downwardly into the opening 29, forming a projection 31, the lower edge of which is defined by the adjacent peripheral edge of the opening 30 as illustrated in FIG. 2." (Sessions, Ex. 1006, Col. 4: 34-39 (emphasis added).) "The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and 25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening is engaged with the neck portion of the button terminal disposed below the head 12 while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7 substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal." (Sessions, Ex. 1006 Col. 5: 11-28 (emphasis added).)

	(Layton Decl, Ex. 1002, ¶ 98-99.)
[3.8] the engaging region configured to operably engage a narrow waist portion of the press stud and further configured to couple the narrow waist portion of the press stud with the electrical contact member when the lever is in the engaged position.	Fukuda teaches a lever (member 14) having an engaging region (the > shaped end of holding member 39) configured to operably engage a narrow waist portion 5A of the press stud (terminal portion 5) to cause a portion (the narrow waist portion 5A) of the press stud (terminal portion 5) and further configured to couple the narrow waist portion 5A of the press stud (terminal portion 5) with the electrical contact member (member 13) when the lever (member 14) is in the engaged position. "Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the < shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30." (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)

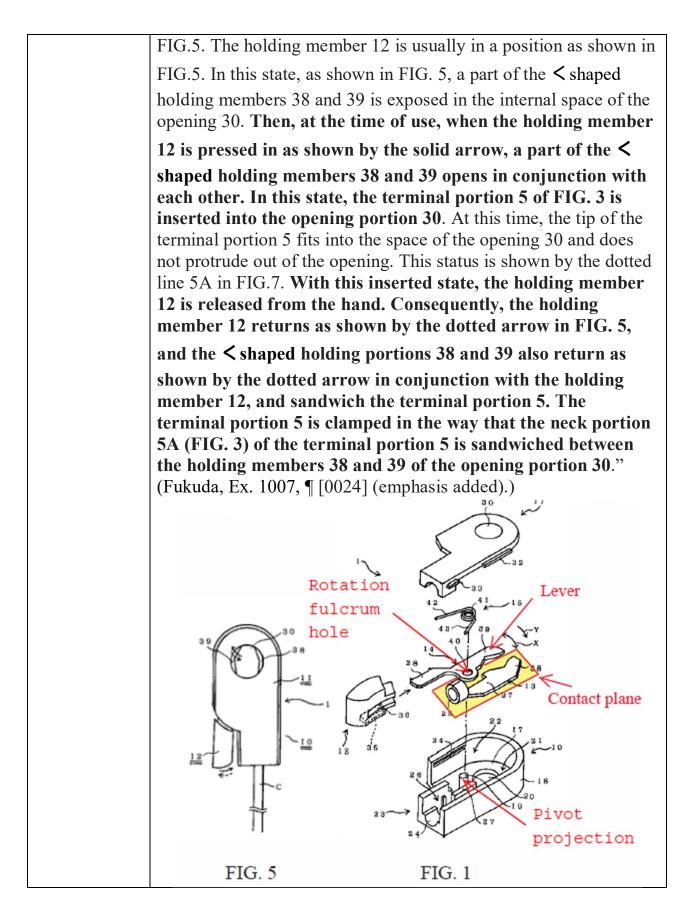


grasping the same by the upwardly extending wall portions 24 and 25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening 20 [sic, 30] is engaged with the neck portion of the button terminal disposed below the head 12 while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7 substantially diametrically opposite to the engagement of the peripheral edge of the opening with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal." (Sessions, Ex. 1006, Col. 5: 11-28 (emphasis added).) I

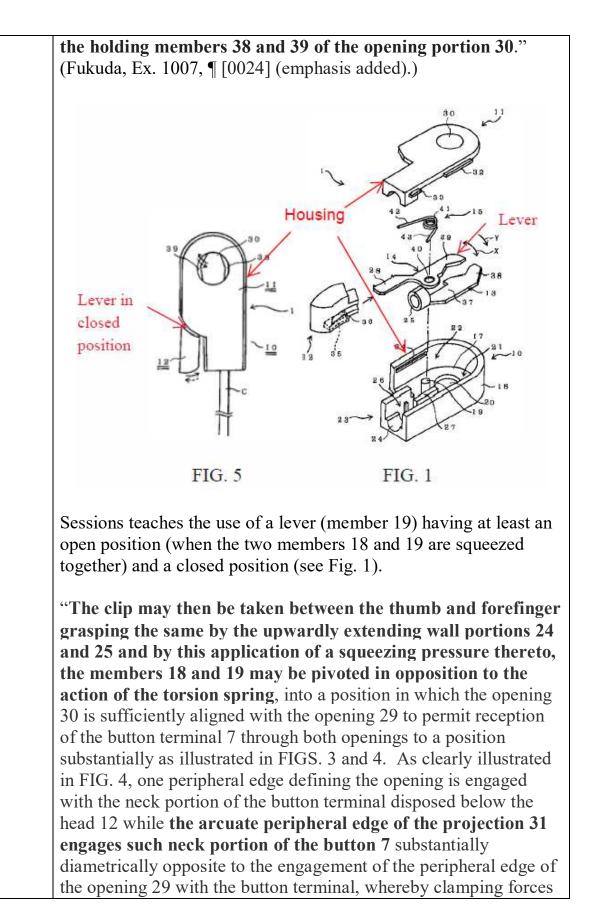


	Press stud Lever 28 7 7 7 7 7 7 7 7 7 7 7 7 7
[4.0] An ECG connector assembly, comprising:	See claim element 3.0. (Layton Decl, Ex. 1002, ¶¶ 106.)
[4.1] a housing having a first opening disposed therein dimensioned to operably receive the press stud of an ECG electrode pad;	See claim element 3.1. (Layton Decl, Ex. 1002, ¶¶ 107.)
[4.2] an electrical contact member defining a contact plane	See claim element 3.2. (Layton Decl, Ex. 1002, ¶¶ 108.)
[4.3] and having a second opening	See claim element 3.3. (Layton Decl, Ex. 1002, ¶¶ 109.)

disposed	
therein, the	
second	
opening	
disposed	
substantially	
concentrically	
to the first	
opening,	
wherein the	
perimeter of	
the second	
opening is	
less than the	
perimeter of	
the first	
opening; and	
[4.4] a lever	Fukuda teaches a lever (contact member 14) pivotably coupled to
pivotably	the housing (base member 10 and cover member 11) about an axis
coupled to the	(defined by pivot projection 19) orthogonal to the contact plane
housing about	(defined by plane extending through contact member 13).
an axis	(defined by plane extending through conduct memoer 15).
orthogonal to	Fukuda teaches a lever or contact member 14 wherein "[t]he
the contact	second contact member 14 is the side that holds the terminal
plane	portion 5 of the contact electrode 2 as a pair with the first contact
plane	member 13 and operates to release the holding member, wherein
	an operating part 28 for conducting the movement is provided on
	the proximal end; and a rotation fulcrum hole 40 is further
	provided at a middle position The second contact member 14
	is incorporated into the second assembly portion 21 of the base
	member 10 so that the support shaft protrusion 19 of the base
	member 10 so that the support shart protrusion 19 of the base member 10 is inserted into the rotation fulcrum hole 40
	thereof . By incorporating in this way, and in a state described later when the actuating force of the spring 15 is applied a rotational
	when the actuating force of the spring 15 is applied, a rotational
	movement , i.e. a motion of clamping or releasing the terminal
	portion 5 of the contact electrode 2 can be performed by moving
	the operating part 28 with fingers as shown by arrow X in
	FIG. 1 ." (Fukuda, Ex. 1007, ¶¶ [0020]-[0021] (emphasis added).)
	"An automolycical of the compactive to althree althree list in the
	"An external view of the connecting tool thus obtained is shown in

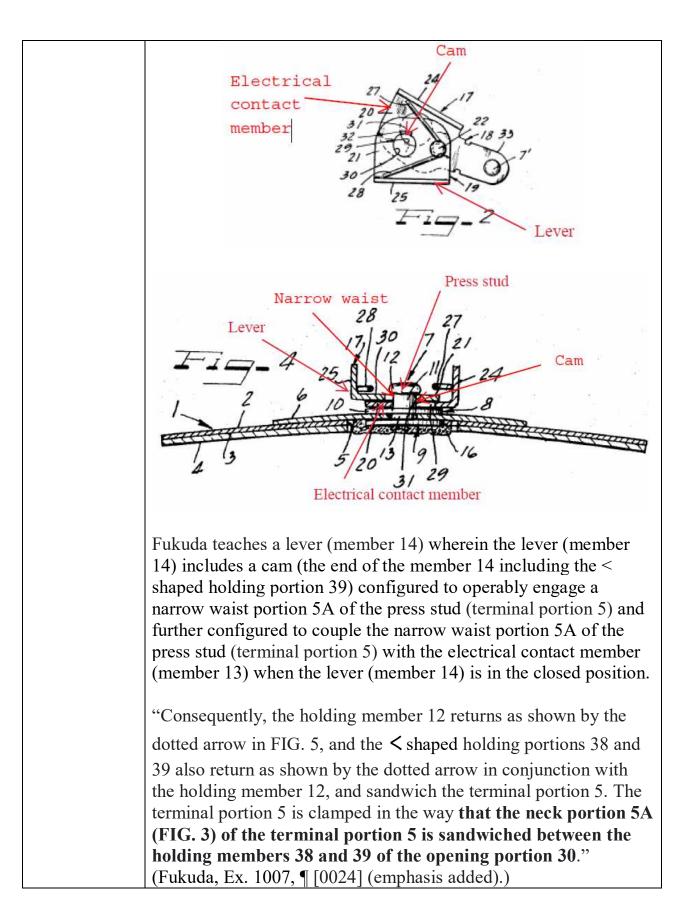


	(Layton Decl, Ex. 1002, ¶¶ 110-111.)
[4.5] and having at least an open position and a closed	Fukuda teaches a lever (contact member 14) having at least an open position (when one moves the actuating portion of the lever inward) and a closed position (Fig. 5). (Layton Decl., Ex. 1002, ¶ 99.)
position,	Fukuda teaches a lever or contact member 14 wherein "[t]he second contact member 14 is the side that holds the terminal portion 5 of the contact electrode 2 as a pair with the first contact member 13 and operates to release the holding member By incorporating in this way, and in a state described later when the actuating force of the spring 15 is applied, a rotational movement , i.e. a motion of clamping or releasing the terminal portion 5 of the contact electrode 2 can be performed by moving the operating part 28 with fingers as shown by arrow X in FIG. 1 ." (Fukuda, Ex. 1007, ¶¶ [0020]-[0021] (emphasis added).) "An external view of the connecting tool thus obtained is shown in
	FIG.5. The holding member 12 is usually in a position as shown in
	FIG.5. In this state, as shown in FIG. 5, a part of the \leq shaped holding members 38 and 39 is exposed in the internal space of the opening 30. Then, at the time of use, when the holding member
	12 is pressed in as shown by the solid arrow, a part of the $<$
	shaped holding members 38 and 39 opens in conjunction with each other. In this state, the terminal portion 5 of FIG. 3 is inserted into the opening portion 30. At this time, the tip of the terminal portion 5 fits into the space of the opening 30 and does not protrude out of the opening. This status is shown by the dotted line 5A in FIG.7. With this inserted state, the holding member 12 is released from the hand. Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the < shaped holding portions 38 and 39 also return as
	shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between

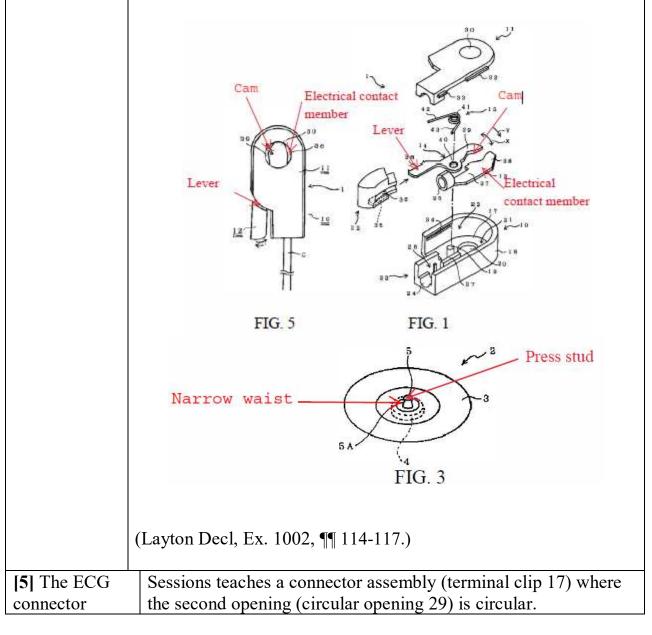


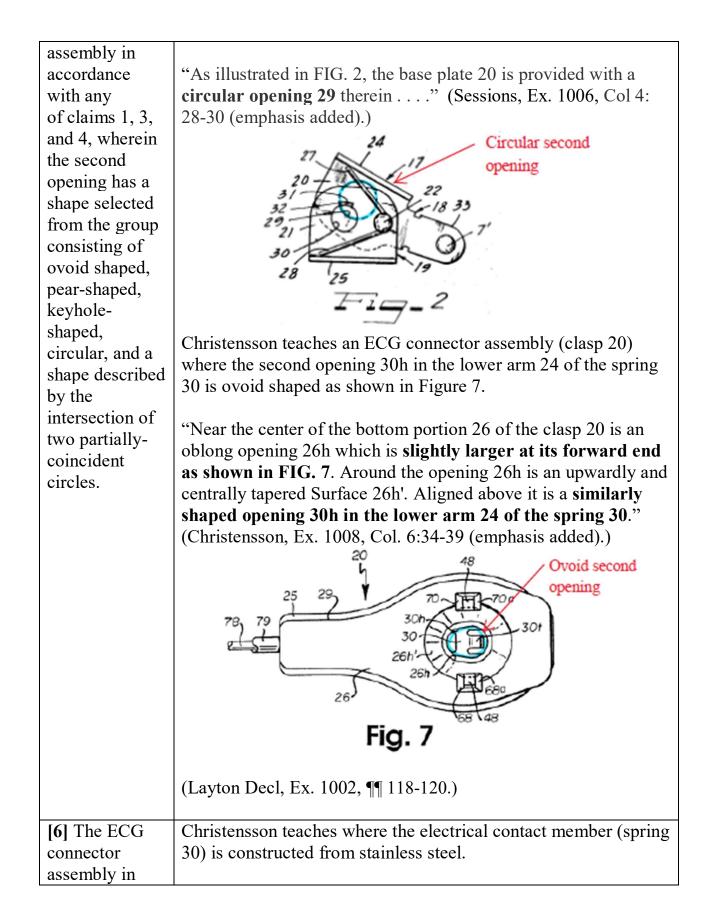
	are exerted by the respective members of the clip upon such button
	terminal." (Sessions, Ex. 1006, Col. 5: 11-28 (emphasis added).)
	(Layton Decl, Ex. 1002, $[112-113.]$
	(Layton Deci, Ex. 1002, $ = 112-113.$)
[1 (] when in	As noted above the tame "earry" is construct to mean "a notating
[4.6] wherein	As noted above, the term "cam" is construed to mean "a rotating
the lever	or sliding piece in a mechanical linkage or device used especially
includes a	in transforming rotary motion into relative linear motion or vice
cam	versa."
configured to	Services to show a lower (aline member 10) having a same (anote
operably	Sessions teaches a lever (clip member 19) having a cam (arcuate
engage a	projection 31 having an arcuate peripheral edge) that engages a
narrow waist	narrow waist portion of the press stud (terminal 7) and couples the
portion of the	narrow waist portion of the press stud 7 with the electrical contact
press stud and further	member (base plate 20) as illustrated in Figure 4.
	"As newticularly illustrated in FIGS 2 and 4 a newtion of the base
configured to	"As particularly illustrated in FIGS. 2 and 4, a portion of the base
couple the	plate 21 defining the periphery of the opening 30 is deformed
narrow waist	downwardly into the opening 29, forming a projection 31, the
portion of the	lower edge of which is defined by the adjacent peripheral edge of the energy 20 as illustrated in EIC 2" (Sessions Ex. 1006 Col
press stud	the opening 30 as illustrated in FIG. 2." (Sessions, Ex. 1006, Col.
	4: 54-59 (emphasis added).)
	"The clip may then be taken between the thumb and forefinger
with the electrical contact member when	4: 34-39 (emphasis added).)"The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and

the lever is in	25 and by this application of a squeezing pressure thereto, the
the closed	members 18 and 19 may be pivoted in opposition to the action of
position.	the torsion spring, into a position in which the opening 30 is
	sufficiently aligned with the opening 29 to permit reception of the
	button terminal 7 through both openings to a position substantially
	as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one
	peripheral edge defining the opening is engaged with the neck
	portion of the button terminal disposed below the head 12 while
	the arcuate peripheral edge of the projection 31 engages such
	neck portion of the button 7 substantially diametrically opposite
	to the engagement of the peripheral edge of the opening 29 with
	the button terminal, whereby clamping forces are exerted by the
	respective members of the clip upon such button
	terminal." (Sessions, Ex. 1006, Col. 5: 11-28 (emphasis added).)
	(Sessions, Ex. 1000, Col. 5. 11-26 (chiphasis added).)
	When attaching the Sessions connector to a press stud, the lever
	(member 19) and an engaged press stud (terminal 7) collectively
	form a mechanical linkage. The rotation of the lever (member 19)
	to its closed position causes parallel rotation of the lever's cam
	(arcuate projection 31). When the lever (member 19) rotates into
	contact with a press stud (terminal 7), its cam (arcuate projection
	31) engages the neck portion 11 of the press stud (terminal 7), and
	the rotary motion of the lever (member 19) is transformed into
	relative linear motion of the press stud (terminal 7) coupling the
	neck portion 11 of the press stud with the electrical contact
	member (plate 18) of Sessions. (Layton Decl., Ex. 1002, ¶115.)
	T
	Electrical
	contact
	member III. 122 × 18 7 6
	and the second s
	Press stud
	25

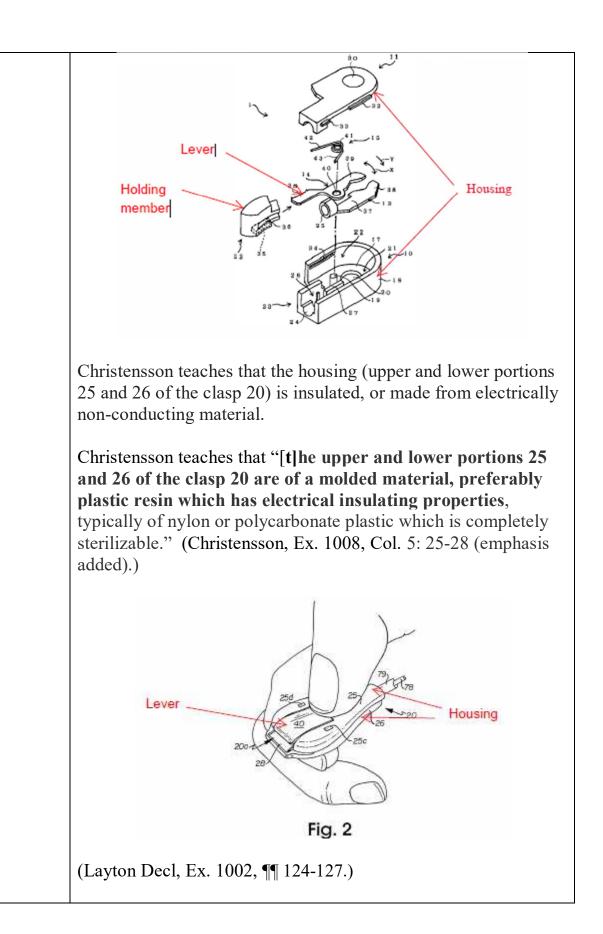


When attaching the Fukuda connector to a press stud, the lever (member 14) and an engaged press stud (terminal portion 5) collectively form a mechanical linkage. When the lever (member 14) rotates into contact with a press stud (terminal portion 5), its cam (< shaped holding member 39) engages the neck portion 5A of the press stud (terminal portion 5), and the rotary motion of the lever (member 14) is transformed into relative linear motion of the press stud (terminal portion 5), coupling the narrow waist portion of the press stud (terminal portion 5) with the electrical contact member (13) of Fukuda. (Layton Decl., Ex. 1002, ¶ 117.)

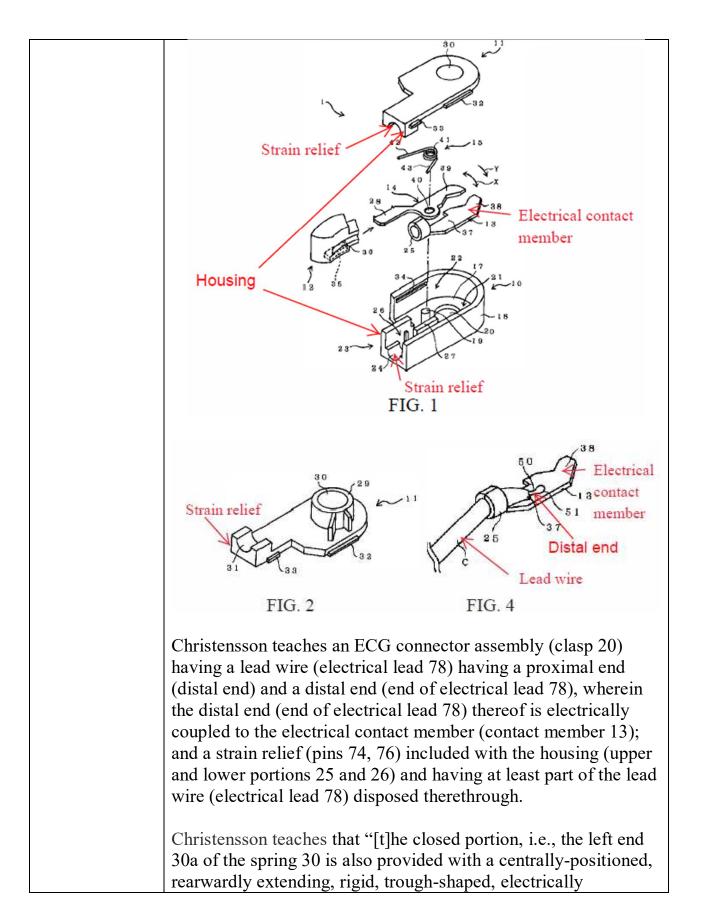


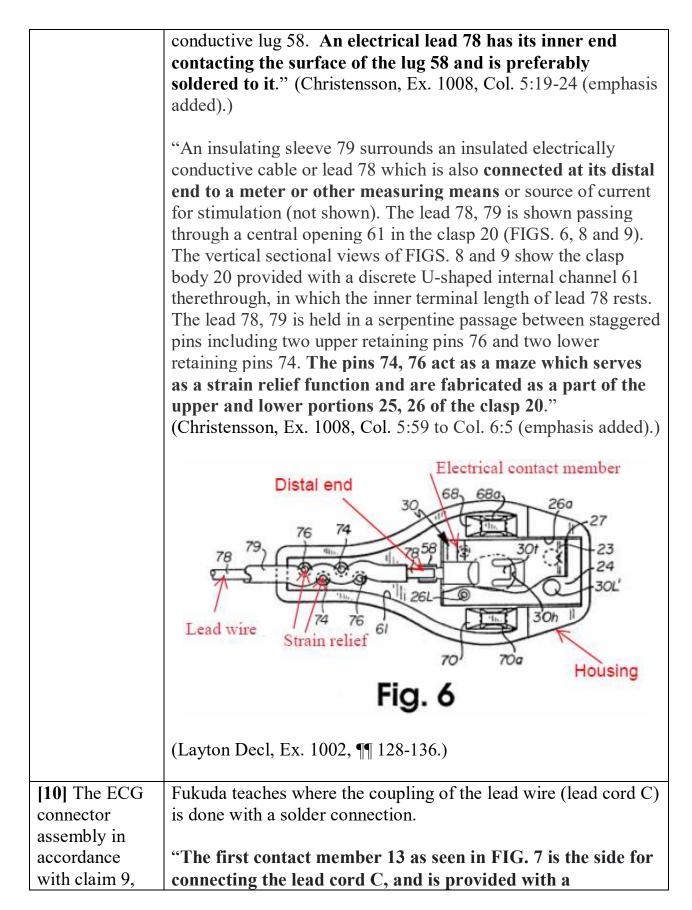


accordance	Christensson teaches that "[s]pring 30 is metallic for conductive
with any	purposes, preferably being of plated, annealed spring steel
of claims 1, 3,	$(1050^{\circ} \text{ grade, heat treated to Rockwell 45 hardness})$ or stainless
and 4, wherein	steel and is completely sterilizable upon disconnection from the
the electrical	electrode 12 between uses." (Christensson, Ex. 1008, Col. 4:37-
contact member	41 (emphasis added).)
is constructed	
from material	(Layton Decl, Ex. 1002, ¶¶ 121-123.)
selected from	
the group	
consisting of	
stainless steel	
and low-carbon	
steel.	
[7] The ECG	Fukuda teaches that the housing (base member 10 and cover
connector	member 11) is insulated, or made from electrically non-
assembly in	conducting material.
accordance	
with any	"The insulating part features: base member that is formed to
of claims 1, 3,	allow the parts of the said contact members and the spring fitted
and 4, wherein	in, a cover member constructed to cover the base assembly
the housing is	into which each part of the contactor member and the spring
constructed	been incorporated, and a holding member that covers the
from	operating part by fitting the operating part of the second contact
electrically	member." (Fukuda, Ex. 1007, ¶ [0008] (emphasis added).)
non-conducting	
material.	"Each member of the insulating part is formed by plastic
	molding." (Fukuda, Ex. 1007, ¶ [0012] (emphasis added).)



[9] The ECG	Fukuda teaches an ECG connector assembly (connecting tool 1)
connector	that comprises a lead wire (lead cord C) having a proximal end
assembly in	and a distal end (the tip of the lead cord C), wherein the distal
accordance	end (end of wire shown at 51) thereof is electrically coupled to
with any	the electrical contact member (contact member 13); and a strain
of claims 1, 3,	relief (semi-circular groove 31 along with semi-circular groove
and 4, further	24) included with the housing (base member 10 and cover
comprising:	member 11) and having at least part of the lead wire (lead cord
a lead wire	C) disposed therethrough.
having a	
proximal end	Fukuda teaches "as seen from FIG. 2 showing the back side of
and a distal	the cover member 11, a pressing portion 29 is protruded, and in
end, wherein	the part corresponds to the cord introducing portion 23 of the
the distal end	base member 10, a semi-circular groove 31 is provided in pair
thereof is	with the semicircular groove 24 in the cord introducing
electrically	portion to press down the lead cord." (Fukuda, Ex. 1007, ¶
coupled to the	[0015] (emphasis added).)
electrical	
contact	"FIG. 4 shows a state in which the lead cord C is attached to
member; and	the first contact member 13. The tip of the lead cord C is
a strain relief	passed through the compression ring 25 and guided to the
included with	connecting member 37, the insulating part at the tip of the cord C
the housing and	is peeled off, core wire 50 is pulled out and soldered to the
having at least	connecting member 37. The soldered state is shown as 51.
part of the lead	After that, the compression ring 25 is crimped and the lead cord
wire disposed	C is tightened and fixed." (Fukuda, Ex. 1007, ¶ [0018]
therethrough.	(emphasis added).)
	(emphasis added).)
L	

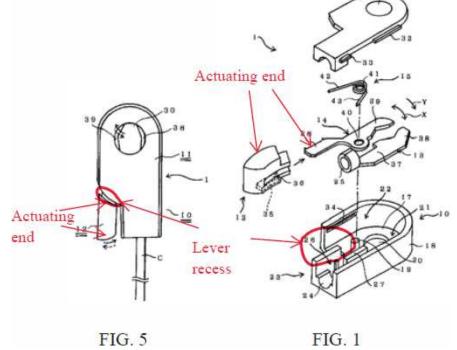




wherein the coupling of the	connecting portion 37 on the proximal end for connecting to the lead cord, and as shown in FIG.3 the tip end is structured
lead wire to the	with a \leq shaped holding member 38 for holding the terminal
electrical contact member	portion 5 of the contact electrode 2. At the proximal end of the
is selected from	holding member 37, a compression ring 25 is provided for
the group	stabilizing the lead cord to avoid applying tension to the
consisting of a	soldering part of the lead cord where it connects to
solder	connecting portion 37.
connection, a	FIG. 4 shows a state in which the lead cord C is attached to the
crimp	first contact member 13. The tip of the lead cord C is passed
connection, a	through the compression ring 25 and guided to the connecting
welded	member 37, the insulating part at the tip of the cord C is peeled
connection, and a wire bond	off, core wire 50 is pulled out and soldered to the connecting
connection.	member 37 . The soldered state is shown as 51. After that, the
•••••••••	compression ring 25 is crimped and the lead cord C is tightened and fixed." (Fukuda, Ex. 1007, ¶¶ [0017]-[0018] (emphasis
	added).)
	38
	Electrical
	1 3 contact
	51 member
	25 37
	Distal end
	Lead wire
	FIG. 4
	Christensson teaches where the coupling of the lead wire
	(electrical lead 58) is done with a solder connection.
	Christensson teaches that "[t]he closed portion, i.e., the left end
	30a of the spring 30 is also provided with a centrally-positioned,
	rearwardly extending, rigid, trough-shaped, electrically
	conductive lug 58. An electrical lead 78 has its inner end contacting the surface of the lug 58 and is preferably
	soldered to it." (Christensson, Ex. 1008, Col. 5:19-24 (emphasis
	added).)

	Image: Distal end for the sector of the s
[11] The ECG connector assembly in accordance with any of claims 1 and 4, further comprising:	Fukuda teaches a lever recess (as shown in Figs. 1 and 5) provided within the housing (base member 10 and cover member 11) dimensioned to receive at least part of the lever (contact member 14) while the lever is positioned in a closed position (see Fig. 5). "The second assembly portion 22 is formed in the way that the integrated second contact member 14 causes the
a lever recess provided within the housing dimensioned to receive at least part of the lever while the lever is positioned in a closed position.	operating part 28 to project out of the base member 10." (Fukuda, Ex. 1007, ¶ [0014] (emphasis added).) "The holding member 12 is formed in a block shape with a fitting hole 35 and a spring receiving groove 36. This holding member 12 is fitted to the operating part 28 (described later) of the second contact member 14 through the fitting hole 35, and functions to cover the operating part 28 with insulation. Also the holding member 12 functions to provide an actuating force in order to sandwich the terminal portion 5 of the contact electrode 2 with the second contact member 14 by receiving the elastic contact of the spring 15 through the spring receiving groove 36 as described later." (Fukuda, Ex. 1007, ¶ [0016].)
	"An external view of the connecting tool thus obtained is shown in FIG.5. The holding member 12 is usually in a position as

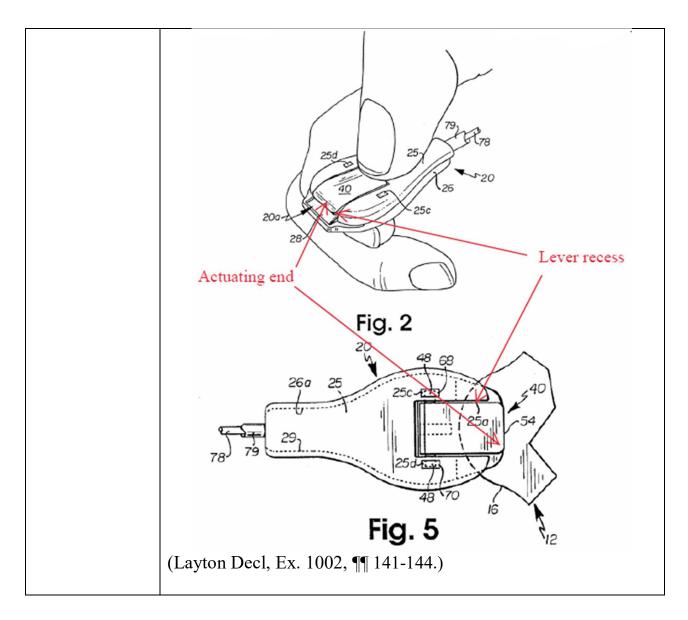
shown in FIG.5. . . . Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the < shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30." (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)



Christensson teaches a lever recess (central cavity 25a) provided within the housing (upper and lower member 25, 26) dimensioned to receive at least part of the lever 40 while the lever 40 is positioned in a closed position, as shown in Figures 2 and 5.

"Affixed above the intermediate portion of upper clip arm 23 is a thumb-length jaw operating lever 40 which rotates forwardly on laterally extending aligned pivots 48 between a lever-up inoperative position (FIG. 3) and a lever-down operating position (FIG. 4) in line with the clasp body.... It should be

noted that during the jaw closing operation, the free end 54 of lever 40 swings forwardly toward the jaw opening 20a. This permits it to be easily operated with the finger or thumb, tending to move the open clasp 20 toward engagement with the electrode 12 rather than away from it." (Christensson, Ex. 1008, Col. 4:46-50; 52-57 (emphasis added).)
"The upper and lower portions 25 and 26 of the clasp 20 are of a molded material, preferably plastic resin which has electrical insulating properties, typically of nylon or poly carbonate plastic which is completely sterilizable. The upper portion 25 has a forwardly facing, upwardly opening, central cavity 25a to receive the lever 40 (FIG. 5)." (Christensson, Ex. 1008, Col. 5: 25-30 (emphasis added).)
"In FIG. 5 is shown a top plan view of the clasp 20 with the lever 40 in the operating mode. In this mode the lever 40 is thrown forwardly into the upwardly opening cavity 25a which receives the free end 54 of the lever 40, providing a clasp that is free of projections and has a smoothly contoured surface ." (Christensson, Ex. 1008, Col. 6:24-29 (emphasis added).)



Rationale to Combine: A POSITA would have been motivated to combine Fukuda with Christensson and Sessions, and such combination would have had a reasonable expectation of success. The references themselves provide a motivation to combine. In particular, Christensson discloses that the use of open end pinch clips, as taught by Fukuda, "has certain disadvantages and, in particular, cannot provide desired electrical contact and stability with a snap style contact stud."

(Christensson, Ex. 1008, Col. 1: 50-52.) In order to address that problem, Christensson teaches a closed end pinch type ECG connector having an electrical contact member with an oblong opening within the opening of the bottom wall of the housing that includes a larger first portion that allows the bulbous head of the stud through and a smaller second portion that locks the stud in place relative to the connector and prevent it from being withdrawn. (*Id.* at Col 6: 34-65.)

Christensson thus teaches that closed end pinch type ECG connectors provide a more secure physical connection to ECG electrodes than open end pinch type connectors (referred to as "alligator clip" connectors by Christensson), and thus Christensson provides a motivation to combine certain features of closed end pinch type connectors such those disclosed in Sessions and Christensson, into open end pinch type connectors such as Fukuda, in order to achieve a more secure connection between the connector and the press stud. (Christensson, Ex. 1008, Col. 1:50-59; see also, Layton Decl., Ex. 1002, ¶175-177.)

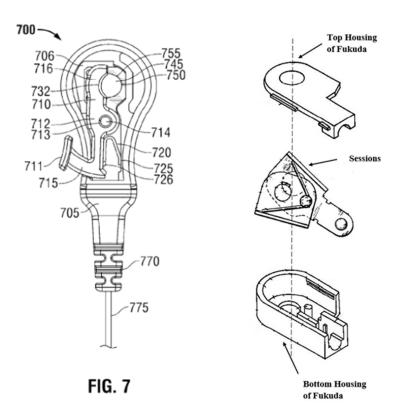
Fukuda teaches an open end pinch type ECG connector having all of the limitations of claim 1 except for the second opening of the electrical contact member, and its positioning and size relative to the first opening of the housing. (Layton, Decl., Ex. 1002, ¶¶ 146-147.) Christensson teaches a closed end pinch type ECG connector having an electrical contact member having a second opening substantially concentric with and having a smaller perimeter than the first opening.

(Christensson, Ex. 1008, Col. 6: 34-43.) While Fukuda teaches a lever pivotable about an axis orthogonal to a contact plane, this structure is also taught by Sessions, but in the context of a closed end pinch type ECG connector, rather than an open end pinch type connector. (Sessions, Ex. 1006, Col. 4: 10-28.) It would have been obvious for a POSITA to use the electrical contact member of Christensson or Sessions and the lever of Fukuda in order to achieve the more secure physical connection afforded by closed end pinch type ECG connectors. (Layton Decl., Ex. 1002, ¶¶ 149-152.)

The combination of Fukuda, Sessions and Christensson as applied to claim 3 also renders obvious claims 4-11 patent, and the motivation of achieving the more secure physical connection afforded by closed end pinch ECG connectors also applies to the combination of Fukuda, Sessions and Christensson relative to these claims. (Layton Decl., Ex. 1002, ¶¶ 153-155.)

A POSITA would have had a reasonable expectation of success in combining Fukuda, Sessions and Christensson as applied to claims 3-11 of the '484 patent because the electrical contact members of Fukuda (contact member 13), Sessions (plate 20) and Christensson (spring 30), and the levers of Fukuda (contact member 14) and Sessions (member 19), are highly analogous components. (Layton Decl., Ex. 1002, ¶ 156.) The electrical contact members of closed end pinch type ECG connectors of Christensson and Session are readily adaptable for

placement within the housing (base member 10 and cover member 11) of Fukuda, in place of the open end pinch type electrical contact member of Fukuda. (*Id.* at ¶¶ 157-158.) For example, as shown in Fig. 7 of the '484 patent and the annotated Fig. below, the connector of Sessions may be readily placed within the housing of Fukuda to obtain a closed end pinch type connector within a housing as disclosed in the '484 patent. (*Id.* at ¶¶ 159-160.)

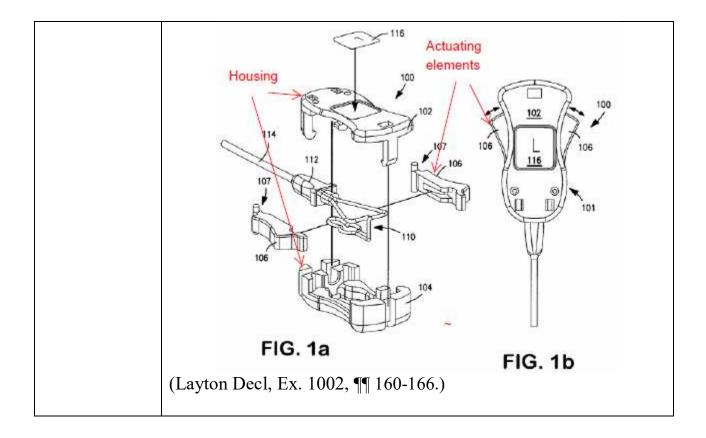


It would have been a routine matter for manufacturer to modify the open end pinch connector taught in Fukuda to a closed end pinch connector taught by Sessions or Christensson. (*Id.* at \P 156.) It is well established that the combination of familiar elements according to known methods is likely to be obvious when it does no more than lead to a predictable result. KSR Intern. Co. v. Teleflex Inc., 550

U.S. 398, 416 (2007.)

U.S.	Fukuda in view of Christensson, Sessions and Powell
Patent No.	
8,038,484	
[8] The ECG	Powell teaches that the housing (housing elements 102, 104) is
connector	constructed from acrylonitrile butadine styrene or polyethylene.
assembly in	
accordance	"The connector body comprises top and bottom connector
with claim 7,	housing elements 102, 104, as well as two opposed actuator
wherein the	elements 106 which are pivoted at their one end 107 so as to
housing	allow the opposing or distal end to move with respect to the
material is	housing elements 102, 104. Each of these components comprise
selected from	a molded polymer such as ABS (acrylonitrile butadine
the group	styrene), although other materials such as polyethylene,
consisting of	fluoropolymers (e.g., ETFE), and the like may be used. ABS is
polybutylene	selected in the illustrated embodiment for its comparatively high
terephthalate,	strength and other excellent mechanical properties, as well as
polyethylene	comparatively low cost and ease of handling." (Powell, Ex. 1009,
terephthalate,	Col. 9: 18-25 (emphasis added).)
polyvinyl	
chloride,	
acrylonitrile	
butadiene	
styrene,	
polyethylene,	
polypropylene,	
thermoplastic	
urethanes,	
thermoplastic elastomers,	
and fiber-	
reinforced	
polymers.	
porymers.	

B. Ground 2: Claim 8 Is Rendered Obvious by Fukuda in View of Christensson, Sessions and Powell



Rationale to Combine: Regarding claim 8, Fukuda, Sessions and Christensson do not expressly disclose that the housing is made from a particular type of non-conductive material. Powell teaches that the housing may be made from ABS or polyethylene. Such types of non-conductive materials were well known to a POSITA to use for a housing for an electrode connector and would be merely a matter of design choice. (Layton Decl., Ex. 1002, ¶ 165.) Moreover, a POSITA would have had a reasonable expectation of success in combining Fukuda, Sessions, Christensson and Powell as applied to claim 8, as the types of non-conductive materials are readily interchangeable. (*Id.* at ¶¶ 165-166.)

XI. CONCLUSION

There is a reasonable likelihood that Petitioners will prevail on claims 3-11 of the 8,038,484 patent. *Inter partes* review should be instituted for each challenged claim.

XII. CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for the Petitioner, Petitioners declare that the argument section of this Petition (Sections I and III-XI) has a total of 13,458 words, according to the word count tool in Microsoft Word[™].

Respectfully submitted,

PATZIK, FRANK & SAMOTNY LTD.

Dated: August 2, 2022

/Jeffrey A. Pine/ Jeffrey A. Pine Reg. No. 36,893 Scott W. Smilie Reg. No. 44,341 Jordan Herzog Reg. No. 38,182 200 South Wacker Drive Suite 2700 Chicago, IL 60606

XII. APPENDIX OF EXHIBITS

Exhibit No.	Description	Identifier
Ex. 1001	U.S. Patent No. 8,038,484	'484 patent
Ex. 1002	Declaration of Terry Layton, Ph.D.	Layton Decl.
Ex. 1003	File History of U.S. Patent No.	'484 patent file
	8,038,484	history
Ex. 1004	U.S. Patent No. 4,178,052	Ekborn
Ex. 1005	U.S. Patent No. 4,671,591	Archer
Ex. 1006	U.S. Patent No. 3,740,703	Sessions
Ex. 1007	Japanese Patent Publication No.	Fukuda
	JPH09276239A	
Ex. 1008	U.S. Patent No. 5,944,562	Christensson
Ex. 1009	U.S. Patent No. 7,214,107	Powell
Ex. 1010	Merriam-Webster online	Meriam-Webster
	dictionary, https://www.merriam-	actuate definition
	webster.com/dictionary/actuate	
Ex. 1011	Merriam-Webster online	Merriam-Webster
	dictionary, https://www.merriam-	concentric
	webster.com/dictionary/concentric	definition
Ex. 1012	Merriam-Webster online	Merriam-Webster
	dictionary, https://www.merriam-	cam definition
	webster.com/dictionary/cam	

CERTIFICATE OF SERVICE

Under 37 C.F.R.§§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on August 2, 2022, a complete and entire copy of the PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,038,484 UNDER 35. U.S.C. § 311 ET SEQ. AND 37 CFR § 42.100 ET SEQ. encompassing all exhibits and Power of Attorney, were served on a flashdrive via FedEx Priority Overnight at the correspondence address of record for the patent owner of the subject patent and patent owner's litigation counsel as follows:

- 1) KPR U.S., LLC c/o CARDINAL HEALTH 777 WEST STREET MANSFIELD, MASSACHUSETTS 02048
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Dated: August 2, 2022

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