

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Gliner, et al.

U.S. Patent No.: 5,593,427

Attorney Docket No.: 38855-0007IP1

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Filing Date: February 14, 1996

Title: ELECTROTHERAPY METHOD

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 5,593,427
PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

LIFECOR427-1001	U.S. Patent No. 5,593,427 to Bradford E. Gliner, et al. (“‘427 Patent”)
LIFECOR427-1002	Prosecution History of the ‘427 Patent
LIFECOR427-1003	Notice of Allowability mailed 9/13/96
LIFECOR427-1004	McDaniel Declaration (“McDaniel Declaration”)
LIFECOR427-1005	U.S. Patent No. 3,782,389 to Bell (“Bell”)
LIFECOR427-1006	U.S. Patent No. 5,352,239 to Pless (“Pless”)
LIFECOR427-1007	U.S. Patent No. 5,431,686 to Kroll et al. (“Kroll”)
LIFECOR427-1008	<i>Koninklijke Philips Electronics NV v. Defibtech LLC</i> , Case No. C03-1322JLR, Order dated Dec. 21, 2005
LIFECOR427-1009	<i>Koninklijke Philips Electronics NV v. Cardiac Science, Inc.</i> , Civil No. 03-1064, Memorandum Opinion and Order dated Apr. 20, 2006
LIFECOR427-1010	Schuder et al., “Transthoracic Defibrillation of 100 kg Calves With Bidirectional Truncated Exponential Shocks,” <i>Trans Am Soc Artif Intern Organs</i> Vol. XXX, pp. 520-525 (1984)
LIFECOR427-1011	U.S. Patent No. 5,735,879 to Gliner et al (“Gliner”; “‘879 Patent”)
LIFECOR427-1012	U.S. Patent No. 5,607,454 to Cameron et al (“Cameron”; “‘454 Patent”)
LIFECOR427-1013	American Heritage Dictionary (3d ed. 1992), p. 1167

I. INTRODUCTION

Petitioner ZOLL Lifecor Corporation (“Lifecor” or “Petitioner”) petitions for *Inter Partes* Review (“IPR”) under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42 of claims 1-18 (“the IPR Claims”) of U.S. Patent No. 5,593,427 (“‘427 Patent”) of Bradford E. Gliner, et al. (“Patentee” or “Gliner, et al.”). As explained in this petition, there exists a reasonable likelihood that Lifecor will prevail with respect to at least one claim challenged in this petition.

The ‘427 Patent claims methods for delivering electrotherapy to a patient using a simple technique in which delivery of energy to the patient’s heart is terminated either upon determining that a measured electrical value (e.g., voltage or energy) has been reached, or determining that a predetermined time period has lapsed, whichever occurs first. But the patent was improvidently granted without full consideration to the wide body of applicable prior art, such as that relied on in this petition. For example, U.S. Patent 3,782,389 (“Bell”; LIFECOR427-1005) expressly discloses the exact limitation that served as the basis for allowance, namely, “discharg[ing] until the end of a predetermined period or until an electrical unit measured across the electrodes decays to a predetermined terminal level, whichever occurs first.” (Notice of Allowability mailed 9/13/96 at 2; LIFECOR427-1003). And the other claim limitations are taught either by Bell and/or the other references presented in this petition. Moreover, Patent Owner has obtained multiple patents in the same family without submitting terminal disclaimers, and at least one of the claims in the patent is invalid for obviousness-type double patenting over at least two of such related patents. Petitioner respectfully submits *Inter Partes* Re-

view should be instituted, and the challenged claims be canceled as unpatentable.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

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

Petitioner, ZOLL Lifecor Corporation, is the real party-in-interest.

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

Petitioner is not aware of any disclaimers or reexamination certificates for the ‘427 Patent. Petitioner has been named as a defendant in a litigation concerning the ‘427 Patent, *Koninklijke Philips N.V. and Philips Electronics North America Corp. v. ZOLL Lifecor Corp.*, Civil No. 12-1369 (W.D.PA.). Lifecor has also petitioned—on this same day—for *Inter Partes* Review of other patents at issue in that litigation, U.S. Patent No. 5,735,879 (“the ‘879 Patent”), U.S. Patent No. 5,749,905 (“the ‘905 Patent”), U.S. Patent No. 6,047,212 (“the ‘212 Patent”), U.S. Patent No. 5,607,454 (“the ‘454 Patent”), U.S. Patent No. 5,836,978 (“the ‘978 Patent”), U.S. Patent No. 5,749,904 (“the ‘904 Patent”), and U.S. Patent No. 5,803,927 (“the ‘927 Patent”) (collectively, “the Philips Waveform Patents”, all of which are owned by Koninklijke Philips N.V. and/or Philips Electronics North America Corp. (“Patent Owner” or “Philips”)).

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel:

LEAD COUNSEL	BACKUP COUNSEL
John C. Phillips, Reg. No. 35,322 3200 RBC Plaza 60 South Sixth Street Minneapolis, MN 55402 T: 858-678-4304	Dorothy P. Whelan, Reg. No. 33,814 3200 RBC Plaza 60 South Sixth Street Minneapolis, MN 55402 T: 612-337-2509

F: 877-769-7945 Email: IPR38855-0007IP1@fr.com Phillips@fr.com	F: 877-769-7945 Email: IPR38855-0007IP1@fr.com Whelan@fr.com
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D. Service Information

Please address all correspondence and service to counsel at the address provided in Section I(C). Petitioner consents to electronic service by email at IPR38855-0007IP1@fr.com.

III. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 06-1050 for the fee set in 37 C.F.R. § 42.15(a) for this Petition, and further authorizes payment for any additional fees to be charged to this Deposit Account.

IV. REQUIREMENTS FOR IPR UNDER 37 C.F.R. §§ 42.104

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

Petitioner certifies that the '427 Patent is eligible for IPR and that Petitioner is not barred or estopped from requesting IPR. The present petition is being filed within one year of service of the original complaint against Petitioner in the district court litigation.

B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

Petitioner requests *Inter Partes* review of the IPR Claims of the '427 Patent on the grounds set forth in the table below, and requests that each of the claims be found unpatentable. An explanation of how the IPR Claims are unpatentable under the statutory grounds identified below is provided in the form of detailed description and claim charts that follow, setting forth the identification of where each element can be found in the cited prior art, and the rele-

vance of that prior art. Additional explanation and support for these grounds of rejection are set forth in the McDaniel Declaration (LIFECOR427-1004).

Ground	'427 Patent Claims	Basis for Rejection of the IPR Claims
Ground 1	1-8	Obvious under 35 U.S.C. § 103 by U.S. Patent 3,782,389 (Bell , LIFECOR427-1005) in view of U.S. Patent 5,352,239 (Pless , LIFECOR427-1006)
Ground 2	9-18	Obvious under 35 U.S.C. § 103 by Bell (LIFECOR427-1005) in view of U.S. Patent 5,431,686 (Kroll , LIFECOR427-1007)
Ground 3	2, 3, 9, and 16-18	Obvious under 35 U.S.C. § 103 by Bell (LIFECOR427-1005) in view of Schuder et al., "Transthoracic Defibrillation of 100 kg Calves with Bidirectional Truncated Exponential Shocks," Trans Am Artif Intern Organs Vol. XXX, pg. 520-525 (1984) (Schuder , LIFECOR427-1010)
Ground 4	1	Obviousness-type double-patenting over claim 4 of U.S. Patent 5,735,879 (Gliner , LIFECOR427-1011)
Ground 5	9	Obviousness-type double-patenting over claim 9 of U.S. Patent 5,607,454 (Cameron , LIFECOR427-1012)

The '427 Patent issued from an application claiming priority to August 6, 1993. Accordingly, Bell is prior art under 35 U.S.C. § 102(b) because it issued on January 1, 1974, and thus was patented more than one year prior to the earliest priority date of the '427 Patent. Pless is prior art under at least 35 U.S.C. § 102(e), having priority to an application filed on December 18, 1990. Kroll is prior art under at least 35 U.S.C. § 102(e), having been filed on February 18, 1992. Schuder is prior art under at least 35 U.S.C. § 102(b) because it was published in 1984. Two of these references (Bell and Pless) were cited in an IDS, and thus made of record, but none were applied or otherwise addressed during prosecution.

C. Claim Construction under 37 C.F.R. §§ 42.104(b)(3)

The subject patent is expired, such that its claims and claim terms are properly given their “ordinary and customary meaning.” (*Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (words of a claim “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art in question at the time of the invention)). In determining the ordinary and custom meaning, the words of a claim are first given their plain meaning. (*Id.*). According to *Phillips*, the structure of the claims may breathe additional meaning into the claims, and the specification and file history also may be used to better construe a claim insofar as the plain meaning of the claims cannot be understood. Moreover, *Phillips* offers that even treatises and dictionaries may be used, albeit under limited circumstances, to determine the meaning attributed by a person of ordinary skill in the art to a claim term at the time of filing.

Other than claim terms addressed immediately below, for which information concerning constructions appropriate for this Petition is set forth, the remaining terms in the claims are not believed to require additional clarification for purposes of the present IPR.

PROPOSED CONSTRUCTIONS

(i) “monitoring”

For purposes of this Petition, the term “monitoring” is construed as “sampling on a regular or ongoing basis.” (American Heritage Dictionary (3d ed. 1992) at 1167; LIFECOR427-1013). This construction is consistent with the ‘427 Patent’s specification. For example, claim 9 recites “monitoring a patient-dependent electrical parameter.” Support for this feature ap-

appears in the specification, among other places, in FIGs. 3, 6, and 9, which illustrate three different embodiments (relevant portions shown below):

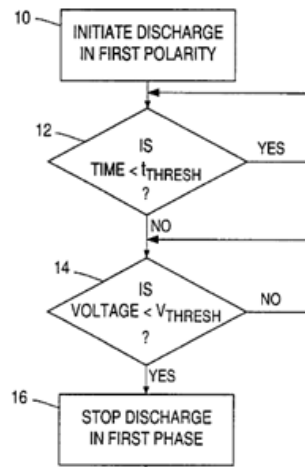


FIG. 3

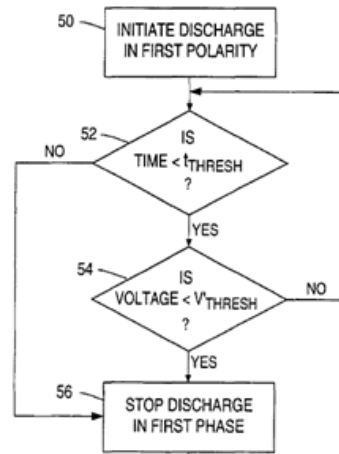


FIG. 6

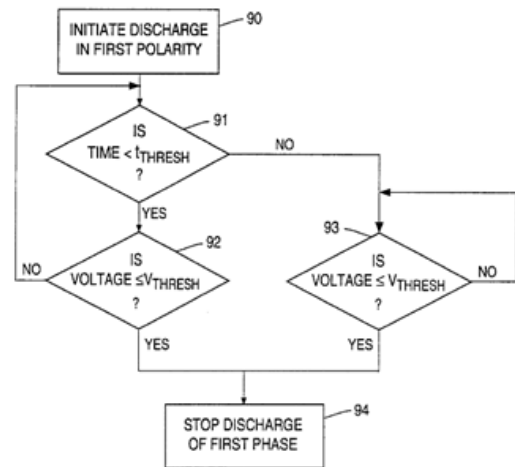


FIG. 9

As can be seen in these figures, in each of the three embodiments, voltage – a patient-dependent electrical parameter – is sampled, on an ongoing basis, in the decision loops indicated by steps 14, 54, and 92/93, respectively, until the condition “VOLTAGE < V_{THRESH}” is satisfied.

(ii) “a function of”

For purposes of this Petition, the term “a function of” is construed as “based on.” This construction is consistent with constructions set forth in Markman orders issued in litigations relating to the Philips Waveform Patents, and is harmonious with constructions offered by Patentee during those proceedings. (See *Koninklijke Philips Electronics NV v. Defibtech LLC*, Case No. C03-1322JLR, Order dated Dec. 21, 2005 at 10; LIFECOR427-1008).

(iii) “energy source”

For purposes of this Petition, the term “energy source” is construed as “a source of energy that is capable of delivering a therapeutic shock to a patient.” This construction is consistent with constructions set forth in Markman orders issued in litigations relating to the Philips Waveform Patents, and is harmonious with constructions offered by Patentee during those proceedings. (*Id. at 14*).

(iv) “truncated biphasic (multiphasic) exponential waveform”

For purposes of this Petition, the term “truncated biphasic (multiphasic) exponential waveform” is construed as “a defibrillation shock having two (at least two) truncated exponential phases of opposite polarity.” This construction is consistent with constructions set forth in Markman orders issued in litigations relating to the Philips Waveform Patents, and is harmonious with constructions offered by Patentee during those proceedings. (*See Koninklijke Philips Electronics NV v. Cardiac Science, Inc.*, Civil No. 03-1064, Memorandum Opinion and Order dated Apr. 20, 2006 at 94; LIFECOR427 -1009).

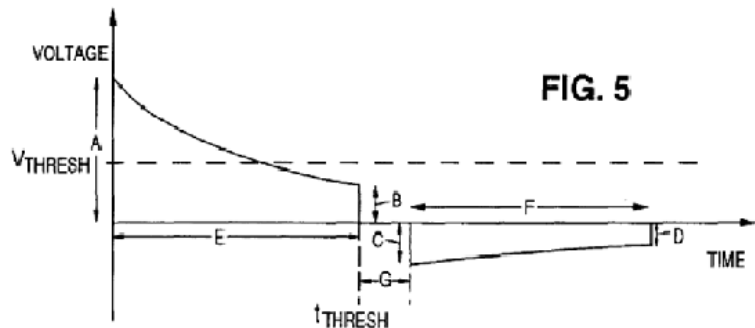
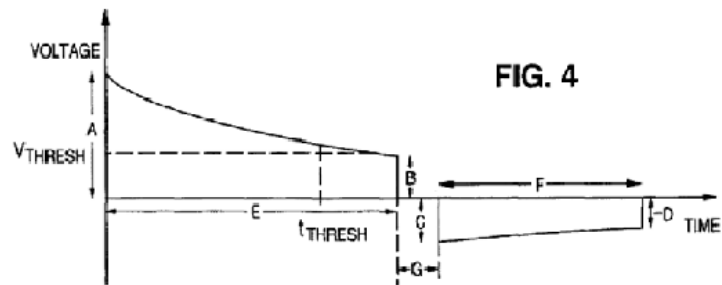
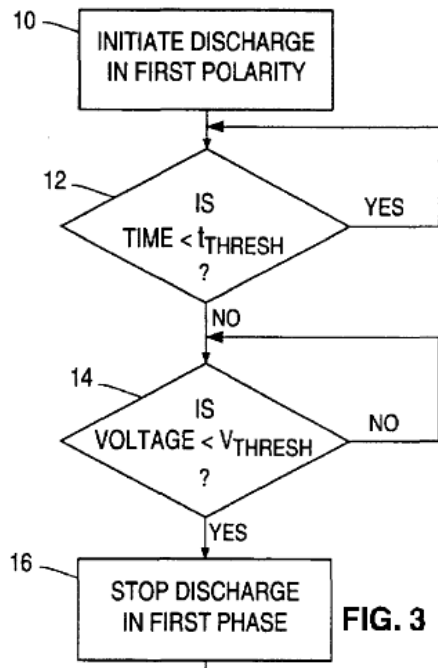
(v) “patient-dependent electrical parameter”

For purposes of this Petition, the term “patient-dependent electrical parameter” is construed as “one or more electrical values, such as voltage, current, charge, etc. that varies depending on an aspect of a patient’s particular physiology (e.g., impedance) and are sufficient to identify a value for that aspect of the physiology.” This construction is consistent with con-

structions discussed in Markman orders issued in litigations relating to the Philips Waveform Patents, and is harmonious with constructions offered by Patentee during those proceedings. (See *Koninklijke Philips Electronics NV v. Defibtech LLC*, Case No. C03-1322JLR, Order dated Dec. 21, 2005 at 11; LIFECOR427-1008).

(vi) “discharge parameter”

For purposes of this Petition, the term “discharge parameter” is construed as “a property of the delivered electrotherapeutic pulse, for example, pulse (or phase) duration.” This construction is consistent with the specification and claims of the ‘427 Patent. For example, although the exact term “discharge parameter” is not used, the specification explains what it means, among other locations, in connection with FIGs. 3-5, which according to the specification demonstrate a defibrillation method “in which information related to patient impedance is fed back to the defibrillator to change the parameters of the delivered electrotherapeutic pulse.” (‘427 patent at 5:3-7). And FIGs. 3-5 illustrate that an example of one such changed parameter is pulse (or phase) duration:



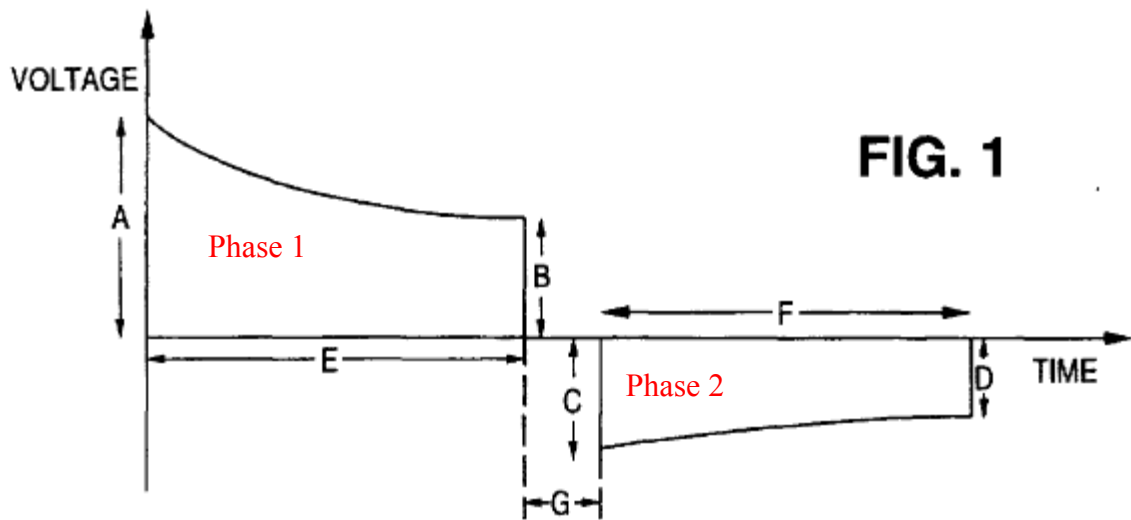
In FIG. 3 (relevant portion shown above), during discharge pulse time and voltage are monitored in steps 12 and 14, respectively, and used to determine when to “STOP DISCHARGE IN FIRST PHASE” in step 16. Depending on the values of the monitored time and voltage (the latter of which will vary from patient to patient depending on the electrical impedance of the patient), the first phase of the discharge will be stopped at different times. (*Id.* at 5:8-53). Consequently, as can be seen from FIGs. 4 and 5 above, the phase duration (“E”) will vary depending on the monitored voltage and time (that is, the value of E in FIG. 4 is greater than the value of E in FIG. 5). (*Id.*). Or in the words of the ‘427 patent, “information related to patient impedance [i.e., voltage] is fed back to the defibrillator to change the parameters of the delivered electrotherapeutic pulse [i.e., pulse duration].” (*Id.* at 5:3-7). Accordingly, “discharge

parameter” is properly construed as “a property of the delivered electrotherapeutic pulse, for example, pulse (or phase) duration.”

V. SUMMARY OF THE ‘427 PATENT

A. Brief Description

Generally, the ‘427 Patent discloses and claims a method for applying an electrical shock to a patient’s irregularly beating heart to cause the heart to resume its natural beating rhythm. (‘427 Patent at 1:7-17; LIFECOR427-1001). This technique is referred to as “defibrillation,” meaning that the goal is to stop the patient’s heart from “fibrillating” – that is, twitching irregularly rather than beating in a normal rhythmic pattern. At the time of the ‘427 Patent, it was well-known that, in applying a shock to a patient’s heart via electrodes attached to the patient’s torso, the shock could be a single positive-voltage shock (“monophasic”) or a positive voltage pulse followed by a negative voltage pulse (“biphasic”). (*Id.* at 1:46-53). When the voltage on the power source is allowed to fall naturally over time in a biphasic waveform, the result is known as a biphasic, exponentially decaying, truncated waveform such as shown in FIG. 1 of the ‘427 Patent. (*Id.*).



To illustrate this, the waveform of FIG. 1 is “biphasic”: a first phase during which voltage is applied for duration E, and a second phase during which voltage (using the opposite polarity) is applied for duration F. The gently curved shape of the waveform from the natural discharge pattern of the capacitor from which the applied voltage originates is the “exponential decay” in the waveform. And the waveform is “truncated” in that, at the end of each phase of the waveform, the voltage is cut off abruptly rather than being allowed to decay smoothly all the way down to zero. In the waveform of FIG. 1, the first phase is truncated such that the terminal voltage is B, and the second phase is truncated such that the terminal voltage is D. These three, well-known waveform characteristics (biphasic, exponential decay, truncation) were determined over many years of research and experimentation, all well-known prior to the ‘427 Patent. (*Id.*).

Also well-known before the ‘427 Patent was the fact that different patients possessed different impedance levels – that is, a measure of the resistance to electrical current passing

through the patients' skin and other tissue. (*Id.* at 2:1-30). Therefore, as a consequence of basic physical laws, upon being subjected to electricity of a given waveform, patients with higher impedance receive less electrical energy than patients with lower impedance, all other factors being equal. (*Id.*). Such differences in impedance can be compensated for, as was well-known in the art, by varying phase duration (e.g., "E" in FIG. 1) or varying the phase's initial and/or terminal voltages (e.g., "A" and "B" in FIG. 1, respectively), thereby delivering a maximized amount of electrical energy to each patient, regardless of the patient's impedance value. (*Id.*). In other words, the '427 Patent acknowledged that it was known in the art to compensate for varying impedances among patients by varying the amplitude (i.e., voltage levels) and/or duration (i.e., time period) of the pulse accordingly. (*Id.*).

Given all the admitted prior art set forth in the '427 Patent's Background section, the purported invention recited by the claims is simple and straightforward, namely, stopping discharge of the energy source when a measured electrical value reaches a predetermined level, or when a predetermined time period lapses, "**whichever occurs first.**" (*Id.* at 7:63-67; emphasis added; see also FIGs. 6-8 and 5:54-6:4). This self-evident design choice – that is, stopping discharge based on "whichever occurs first" – is the sole reason that the '427 Patent was allowed, and indeed was the stated reason for allowance. (Notice of Allowability mailed 9/13/96 at 2; LIFECOR427-1003 ("discharg[ing] until the end of a predetermined period or until an electrical unit measured across the electrodes decays to a predetermined terminal level, whichever occurs first.")). But, as established below, this exact same "whichever occurs first"

feature was disclosed in the prior art nearly 20 years before the '427 Patent was filed. (See, e.g., Bell at 4:30-42; LIFECOR427-1005).

Other aspects of the '427 Patent's claims include fixing the duration of the second phase (e.g., "F" in FIG. 1) or varying the duration of the second phase based on the first phase's terminal voltage ("B" in FIG. 1) or duration ("E" in FIG. 1). The '427 Patent admitted that it was known in the art that the total pulse duration, which includes the first phase duration and the second phase duration, affects the total amount of energy delivered to a patient. ('427 Patent at 1:59-67). In other words, given a first phase duration that terminates at a certain terminal voltage, the '427 Patent admitted that it was known in the art to set a duration for the second phase that optimizes the amount of energy delivered to the patient.

In sum, it was well-known that the various waveform characteristics could be measured and modified to fine tune the extent and manner of applying electricity to a patient's heart during defibrillation. What the '427 Patent claims to have invented is merely a trivial variant of the techniques that the '427 Patent admits are prior art. More importantly, as will be discussed in detail below, the methods claimed in the '427 Patent had already been invented by others – namely, by the patentees named in the prior art patents relied on herein.

B. Summary of the Prosecution History of the '427 Patent

The '427 Patent, filed on February 14, 1996, issued from a patent application that was a divisional application of an original application filed on August 6, 1993. Preliminary amendments were filed on the same day that the application was filed, canceling some claims and

adding new claims. Without issuing any actions, the Examiner issued a notice of allowance on September 13, 1996, stating, as the reasons for allowance:

[T]he prior art of record fails to teach the discharging step (claim 15) and the adjusting step (claim 35). In other words, there is no teaching to discharge until the end of a predetermined time period or until an electrical unit measured across the electrodes decays to a predetermined terminal level, whichever occurs first.

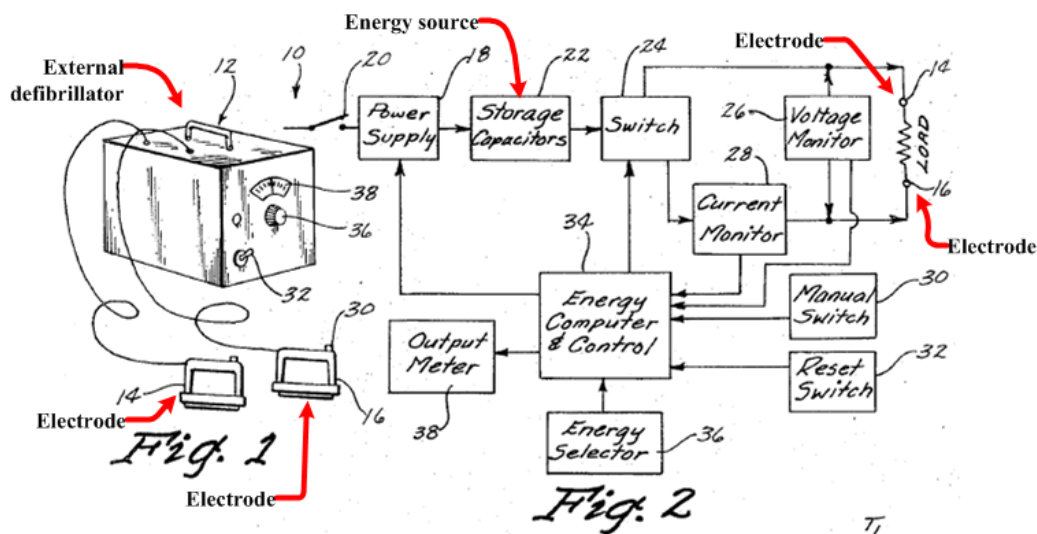
(Notice of Allowability mailed 9/13/96 at 2; LIFECOR427-1003). The '427 Patent subsequently issued on January 14, 1997.

VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE IPR CLAIM OF THE '427 PATENT IS UNPATENTABLE

As detailed below and in the following claim charts, prior art references show that independent claims 1 and 9, and their dependent claims, are unpatentable, and are merely a combination of prior art elements according to known methods to yield predictable results, and/or the use of known techniques to improve similar devices in the same way. (See *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007)). As such, "[one] of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading [the prior art]." *KSR*, 550 U.S. at 403. Consequently, there is a reasonable likelihood that at least one of the challenged claims is unpatentable.

Referring to Ground 1 (charted below), Bell discloses a defibrillator 10 having a pair of electrodes or paddles 14 and 16 engageable with the patient to deliver a predetermined energy output to the patient so that fibrillation of the heart is stopped. (Bell at 2:5-13; FIGs. 1 and

2; LIFECOR427-1005). Bell also discloses that the current monitor 28 and voltage monitor 26 feed instantaneous signals to the energy computer and control 34, which computes the energy as a continuous integration process. (*Id.* at 3:5-9). When the voltage and current indicate that the selected energy level is reached, storage capacitors 22 are disconnected from the patient. (*Id.* at 3:3-13). Bell further discloses that the output pulse width is limited to a maximum value for any given setting. (*Id.* at 4:15-18).



Bell discloses nearly all of the features recited in claims 1, 7, and 8, including “discharging the energy source across the electrodes in the predetermined polarity until the end of a predetermined time period” or until an electrical unit measured across the electrodes reaches a predetermined level, “whichever occurs first,” the very reason that the ‘427 Patent was allowed. (McDaniel Declaration at ¶ 37; LIFECOR427-1004). Specifically, as noted above, Bell discloses disconnecting capacitors 22 from the patient as soon as the voltage and current indicate that the predetermined amount of energy has been delivered to the patient. (Bell at 3:3-

13; LIFECOR427-1005). But Bell further discloses that, even if the voltage/current measurements indicate that the predetermined amount of energy has not yet been delivered, if delivery is taking “too long ... the time out input will terminate the discharge before the selected [energy] value is reached.” (*Id.* at 4:30-40). Put another way, Bell teaches that discharge will cease upon the measured voltage/current levels reaching predetermined levels corresponding to the selected energy level or upon reaching the time out period, whichever occurs first.

Bell also expressly discloses monitoring the voltage and current levels over time during discharge. (*Id.* at 3:5-9). To the extent that Bell does not explicitly use the claim language “decays to a predetermined level” (as in “an electrical unit measured across the electrodes decays to a predetermined terminal level,” as recited in claim 1, it was well-known that the voltage measured across the electrodes decays due to the natural discharge pattern of the capacitors from which the voltage originates, and that, when the delivered energy reaches a predetermined energy level, the voltage across the electrodes has decayed to a corresponding predetermined terminal voltage level. (McDaniel Declaration at ¶ 38; LIFECOR427-1004). For example, Pless discloses that a desired tilt, which is the ratio of the ending voltage value V_f to the starting voltage value V_i , can also be expressed as a desired energy since $J = 0.5 * C(V_i^2 - V_f^2)$. (Pless at 1:34-47, 3:18-23; LIFECOR427-1006). A person of ordinary skill in the art would have recognized that discharging the capacitors across the electrodes until the delivered energy reaches the predetermined energy output is the mathematical equivalent of discharging the capacitors across the electrodes until the voltage measured across the electrodes

decays to a predetermined terminal voltage level corresponding to the predetermined energy output. (McDaniel Declaration at ¶ 38; LIFECOR427-1004).

Regarding claims 2-6, to the extent that Bell does not explicitly describe the claimed features, a biphasic waveform had become known in the time between Bell and the filing of the '427 Patent as a preferred waveform for achieving defibrillation. (McDaniel Declaration at ¶ 39; LIFECOR427-1004). For example, the Background section of the '427 Patent acknowledges that biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Patent. (See, e.g., '427 Patent at 1:54-57; LIFECOR427-1001). Moreover, Pless describes generating biphasic defibrillation waveforms (Pless at 3:4-7; LIFECOR427-1006), producing a negative pulse with a timed duration (*Id.* at 7:35-41), and producing a negative pulse that is terminated when the capacitor voltage decays to less than a selected trailing voltage. (*Id.* at 5:11-22). Further, Pless describes producing a negative pulse with a duration that is a percentage of the duration of the positive pulse. (*Id.* at 3:32-25). Accordingly, a person of ordinary skill in the art would have been motivated to combine Pless' biphasic waveform with Bell's control scheme, among other reasons, because of the increased effectiveness of biphasic waveforms over monophasic waveforms, which had become widely recognized in the two decades after Bell and before the filing of the '427 patent. (Pless at 1:15-22; McDaniel Declaration at ¶ 39). As such, there is a reasonable likelihood that claims 1-8 of the '427 Patent are unpatentable based on Bell in view of Pless.

Referring to Ground 2 (charted below) applicable to claims 9-18, Bell discloses a defib-

rillator 10 having a pair of electrodes or paddles 14 and 16 engageable with a patient to deliver a predetermined energy output to the patient so that fibrillation of the heart is stopped. (Bell at 2:5-13, FIGS. 1 and 2; LIFE COR427-1005). Bell also discloses that the current monitor 28 and voltage monitor 26 feed instantaneous signals to the energy computer and control 34 which computes the energy as a continuous integration process. (*Id.* at 3:5-9). When the measured voltage and current indicate that the selected energy level is reached, storage capacitors 22 are disconnected from the patient. (*Id.* at 3:3-13). Bell further discloses that the output pulse width is limited to a maximum value for any given setting. (*Id.* at 4:15-18). Bell also discloses essentially all of the features recited in claims 9-11, including “discharging the energy source across the electrodes in a phase . . . until the end of a predetermined time period or until the monitored electrical parameter reaches a predetermined value, whichever occurs first.” Specifically, as noted above, Bell discloses disconnecting capacitors 22 from the patient as soon as the measured voltage and current indicate that the predetermined amount of energy has been delivered to the patient. (*Id.* at 3:3-13). But Bell further discloses that, even if the voltage/current measurements indicate that the predetermined amount of energy has not yet been delivered, if delivery is taking “too long . . . the time out input will terminate the discharge before the selected [energy] value is reached.” (*Id.* at 4:30-40). Put another way, Bell teaches that discharge will cease upon the measured voltage/current levels reaching predetermined levels corresponding to the selected energy level or upon reaching the time out period, whichever occurs first.

To the extent that Bell does not explicitly describe the claimed feature of “a multiphasic waveform,” such waveforms had become known in the time between Bell and the filing of the ‘427 Patent as a preferred waveform for achieving defibrillation. (McDaniel Declaration at ¶ 40; LIFECOR427-1004). For example, the Background section of the ‘427 Patent acknowledges that biphasic waveforms were well-known and in widespread use in defibrillators prior to the ‘427 Patent. (See, e.g., ‘427 Patent at 1:54-57; LIFECOR427-1001). Moreover, Kroll describes a biphasic waveform having a phase of optimum duration. (Kroll at 6:60-62; LIFECOR427-1007).

Regarding claims 12-18, to the extent that Bell does not explicitly describe the claimed features, adjusting a discharge parameter of a phase of a biphasic waveform was widely known for producing an optimum waveform. For example, Kroll describes producing a second pulse with a duration that is a fraction of the duration of the first pulse. (Kroll at 7:1-3; LIFECOR427-1007). Kroll also describes producing a second pulse that meets a fixed-duration specification. (*Id.* at 7:5-8). Accordingly, a person of ordinary skill in the art would have been motivated to combine Kroll’s biphasic waveform with Bell’s control scheme, among other reasons, because of the increased effectiveness of biphasic waveforms over monophasic waveforms. (McDaniel Declaration at ¶ 40; LIFECOR427-1004). Moreover, a person of skill would have been motivated to make such a combination despite the fact that Bell teaches an external defibrillator while Kroll teaches an implantable defibrillator. (*Id.*). As such, there is a reasonable likelihood that claims 9-18 of the ‘427 Patent are unpatentable based on Bell in

view of Kroll.

Referring to Ground 3 (charted below), Bell discloses essentially all of the features recited in claims 2, 3, 9, and 16-18. To the extent that Bell does not explicitly describe the claimed features relating to a multiphasic waveform, a biphasic waveform was widely known as a waveform for achieving defibrillation. For example, the Background section of the '427 Patent acknowledges that biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Patent. (See, e.g., '427 Patent at 1:54-57; LIFECOR427-1001). Moreover, Schuder describes bidirectional truncated exponential waveforms implemented in clinical sized apparatus for transthoracic defibrillation (Schuder at 520, ¶3; LIFECOR427-1010) and producing a negative pulse with a timed duration (Id. at 520, ¶4; Table I). Accordingly, a person of ordinary skill in the art would have been motivated to combine Schuder's biphasic waveform with Bell's control scheme, among other reasons, because of the increased effectiveness of biphasic waveforms over monophasic waveforms. (McDaniel Declaration at ¶ 41; LIFECOR427-1004). As such, there is a reasonable likelihood that claims 2, 3, 9, and 16-18 of the '427 Patent are unpatentable based on Bell in view of Schuder.

Referring to Grounds 4 and 5 (charted below), claims of the '427 Patent are obvious variants – and thus invalid under the doctrine of obviousness-type double patenting – in view of commonly owned patents to Gliner (LIFECOR427-1011) and Cameron (LIFECOR427-1012).

VII. MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH *INTER PARTES* REVIEW IS REQUESTED

In this Section, Petitioner proposes various grounds of rejection for the IPR Claims and, thus, explains the justification for *Inter Partes* Review. Petitioner presents claim charts that compare the claim language as construed under the above-ascribed claim interpretations, with the disclosure of the prior art as understood by one of ordinary skill in the art.

A. Rejections Based on Bell as Primary Reference

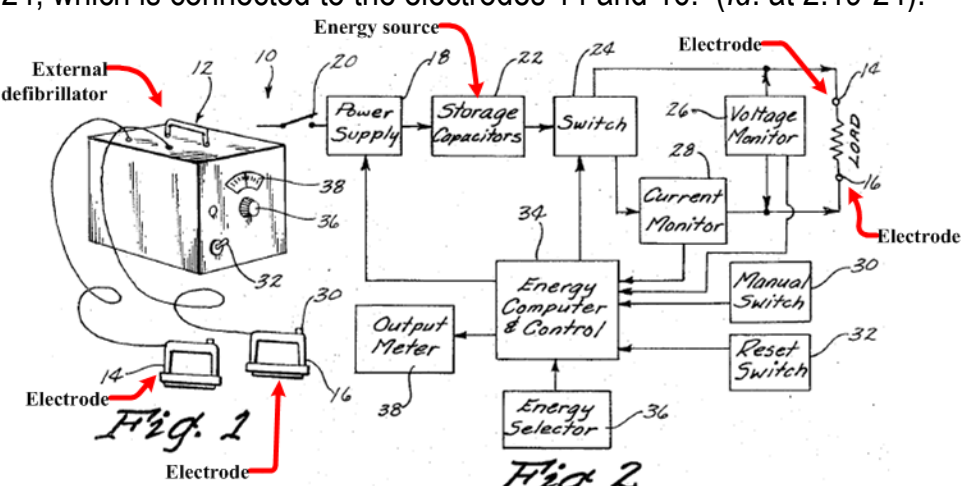
1. [GROUND 1] – Bell in view of Pless renders obvious Claims 1-8.

As noted above and shown in the following claim chart in greater detail, claims 1-8 of the '427 Patent are obvious under 35 U.S.C. § 103 based on Bell in view of Pless. A person of ordinary skill in the art would have been motivated to combine Pless' biphasic waveform with Bell's control scheme, among other reasons, because of the well-known increased effectiveness of biphasic waveforms over monophasic waveforms. (Pless at 1:15-22; LIFECOR427-1006; McDaniel Declaration at ¶ 39; LIFECOR427-1004). Moreover, a person of skill would have been motivated to make such a combination despite the fact that Bell teaches an external defibrillator while Pless teaches an implantable defibrillator. (McDaniel Declaration at ¶ 39; LIFECOR427-1004).

With regard to the discharging step of claim 1, a person of ordinary skill in the art would have recognized that discharging the capacitors across the electrodes until the delivered energy reaches the predetermined energy output is the mathematical equivalent of discharging the capacitors across the electrodes until the voltage measured across the electrodes decays to a

predetermined terminal voltage level corresponding to the predetermined energy output.

(McDaniel Declaration at ¶ 38; LIFECOR427-1004).

Claims	Bell in view of Pless
1. A method for applying electrotherapy to a patient through electrodes external to a patient, the electrodes being electrically connected in a predetermined polarity to an energy source charged to an initial level, the method comprising the following step:	Bell discloses a method for applying electrotherapy to a patient. For example, Bell discloses a defibrillator 10 having a pair of electrodes 14 and 16 engageable with a patient to deliver energy to the patient to stop fibrillation of the heart. (Bell at 2:5-13). The defibrillator 10 includes a power supply 18 electrically connected to the storage capacitors 22 to store energy from the power supply 18. (<i>Id.</i> at 2:14-20). The storage capacitors 22 are connected to a switch mechanism 24, which is connected to the electrodes 14 and 16. (<i>Id.</i> at 2:19-24).  (<i>Id.</i> at FIG. 1 and FIG. 2).
discharging the energy source across the electrodes in the predetermined polarity until the end of a predetermined time period or until an electrical unit measured across the electrodes decays to a predetermined terminal level, whichever occurs first.	Bell discloses placing the electrodes 14 and 16 in contact with the patient and connecting the stored energy source to the patient. (Bell at 2:66-3:5). A current monitor 28 and voltage monitor 26 feed instantaneous signals to the energy computer and control 34 which computes the energy as a continuous integration process. (<i>Id.</i> at 3:5-9). When the measured voltage and current indicate that the selected energy level is reached, storage capacitors 22 are disconnected from the patient. (<i>Id.</i> at 3:3-13). Bell further discloses that the output pulse width is limited to a maximum value for any given setting. (<i>Id.</i> at 4:15-18). In the case of a high patient resistance, the defibrillator will attempt to deliver the selected energy but would take too long and the time out input would terminate the discharge before the measured voltage and current indicate that the selected energy value was reached. (<i>Id.</i> at 4:30-40).

Claims	Bell in view of Pless
	Bell expressly discloses monitoring the voltage and current levels over time during discharge. (<i>Id.</i> at 3:5-9). Pless discloses that the voltage measured across the electrodes decays due to the natural discharge pattern of the capacitors, from which the voltage originates, and that, when the delivered energy reaches a predetermined energy level, the voltage measured across the electrodes has decayed to a corresponding predetermined terminal voltage level. For example, Pless discloses that a desired tilt, which is the ratio of the ending voltage value V_f to the starting voltage value V_i, can also be expressed as a desired energy since $J = 0.5 \cdot C(V_i^2 - V_f^2)$. (Pless at 1:34-47, 3:18-23).
2. The method of claim 1 further comprising the following steps after the first discharging step: reversing the polarity of connection of the energy source to the electrodes; and discharging the energy source across the electrodes in the reversed polarity.	Pless discloses reversing the polarity of the connection of the energy source to the electrodes, and discharging the energy source across the electrodes in the reversed polarity, to generate a biphasic waveform to achieve defibrillation. For example, Pless discloses that when the positive pulse ends, a negative pulse is started. (Pless at 4:63-68, 6:63-7:15). Once the negative pulse is started, the defibrillator capacitor is discharged into the patient's heart. (<i>Id.</i> at 5:11-13, 7:44-46). Moreover, the Background section of the '427 Patent admits that biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Patent. (See, e.g., '427 Patent at 1:54-57).
3. The method of claim 2 wherein the discharging step in the reversed polarity continues for a second predetermined time period.	Pless discloses discharging in the reversed polarity for a predetermined time period to generate a fixed duration second phase in a biphasic waveform. For example, Pless discloses producing a negative pulse with a timed duration. (Pless at 7:35-41). The negative pulse is applied to the heart for the timed duration. (<i>Id.</i> at 7:44-47).
4. The method of claim 2 wherein the discharging step in the reversed polarity continues until an electrical unit measured across the electrodes decays to	Pless discloses discharging in the reversed polarity until an electrical unit measured across the electrodes decays to a predetermined level to generate such a second phase. For example, Pless discloses terminating the negative pulse when the capacitor voltage decays to less than the selected trailing voltage. (Pless at 5:11-22).

Claims	Bell in view of Pless
a second predetermined terminal level.	
5. The method of claim 2 wherein the duration of the discharging step in the reversed polarity is a function of the duration of the first discharging step.	Pless discloses making the duration of the discharging in the reversed polarity a function of the duration of the first discharging. For example, Pless discloses setting the duration of the negative pulse to be a percentage of the duration of the positive pulse. (Pless at 3:32-35, 7:20-22).
6. The method of claim 2 wherein the measured electrical unit decays to a first phase end value at the end of the first discharging step, the duration of the discharging step in the reversed polarity being a function of the first phase end value.	Pless discloses making the duration of the discharging in the reversed polarity a function of the measured electrical unit first phase end value. For example, Pless discloses terminating the positive pulse when the capacitor voltage decays to less than the selected trailing voltage. (Pless at 6:28-39). Pless further discloses setting the duration of the negative pulse to be the same as the duration of the positive pulse. (<i>Id.</i> at 7:20-22).
7. The method of claim 1 wherein the energy source is a voltage source and the measured electrical unit is voltage.	Bell discloses that the defibrillator 10 includes a power supply 18 electrically connected to the storage capacitors 22 to store energy from the power supply 18. (Bell at 2:14-20).
8. The method of claim 7 wherein the voltage source comprises a capacitor.	Bell discloses that the defibrillator 10 includes a power supply 18 electrically connected to the storage capacitors 22 to store energy from the power supply 18. (Bell at 2:14-20).

2. [GROUND 2] – Bell in view of Kroll renders obvious Claims 9-

18.

As noted above and shown in the following claim chart in greater detail, claims 9-18 of the '427 Patent are obvious under 35 U.S.C. § 103 based on Bell in view of Kroll. A person of ordinary skill in the art would have been motivated to combine Kroll's biphasic waveform with Bell's control scheme, among other reasons, because of the increased effectiveness of biphasic waveforms over monophasic waveforms. (McDaniel Declaration at ¶ 40; LIFECOR427-1004). Moreover, a person of skill would have been motivated to make such a combination despite the fact that Bell teaches an external defibrillator while Kroll teaches an implantable defibrillator. (*Id.*).

Claims	Bell in view of Kroll
9. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:	Bell discloses a method for applying electrotherapy to a patient. For example, Bell discloses a defibrillator 10 having a pair of electrodes 14 and 16 engageable with a patient to deliver energy to the patient to stop fibrillation of the heart. (Bell at 2:5-13). The defibrillator 10 includes a power supply 18 electrically connected to the storage capacitors 22 to store energy from the power supply 18. (<i>Id.</i> at 2:14-20). The storage capacitors 22 are connected to a switch mechanism 24, which is connected to the electrodes 14 and 16. (<i>Id.</i> at 2:19-24).

Claims	Bell in view of Kroll
	(Id. at FIG. 1 and FIG. 2).
discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;	Bell discloses placing the electrodes 14 and 16 in contact with the patient and connecting the stored energy source to the patient. (Bell at 2:66-3:5). Kroll discloses delivering electrical energy to the patient in a biphasic waveform. (Kroll at 2:38-44). Moreover, the Background section of the '427 Patent admits that biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Patent. (See, e.g., '427 Patent at 1:54-57).
monitoring a patient-dependent electrical parameter during the discharging step;	Bell discloses a current monitor 28 and voltage monitor 26 that feed instantaneous signals to the energy computer and control 34 that computes the energy as a continuous integration process. (Id. at 3:5-9).
adjusting a discharge parameter based on a value of the monitored electrical parameter,	Bell discloses that when the energy computed from measured voltage and current values equals the selected energy, the energy source is disconnected from the patient. (Bell at 3:9-11).
the adjusting step comprising discharging the energy source across the electrodes in a phase of the multiphasic waveform	Bell discloses placing the electrodes 14 and 16 in contact with the patient and connecting the stored energy source to the patient. (Bell at 2:66-3:5). A current monitor 28 and voltage monitor 26 feed instantaneous signals to the energy computer and control 34 which computes the energy as a continuous integration process. (Id. at 3:5-9). When the measured voltage and current indicate that the selected energy level is reached, the energy source is disconnected from the pa-

Claims	Bell in view of Kroll
until the end of a predetermined time period or until the monitored electrical parameter reaches a predetermined value, whichever occurs first.	tient. (<i>Id.</i> at 3:9-11). Bell further discloses that the output pulse width is limited to a maximum value for any given setting. (<i>Id.</i> at 4:15-18). In the case of a high patient resistance, the defibrillator would attempt to deliver the selected energy but would take too long and the time out input will terminate the discharge before the measured voltage and current indicate that the selected energy value is reached. (<i>Id.</i> at 4:30-40).
10. The method of claim 9 wherein the electrical parameter is energy source voltage.	Bell discloses current monitor 28 and a voltage monitor 26 that feed instantaneous signals to the energy computer and control 34 which computes the energy as a continuous integration process. (<i>Id.</i> at 3:5-9).
11. The method of claim 9 wherein the electrical parameter is energy source current.	Bell discloses a current monitor 28 and a voltage monitor 26 that feed instantaneous signals to the energy computer and control 34 which computes the energy as a continuous integration process. (<i>Id.</i> at 3:5-9).
12. The method of claim 9 wherein the adjusting step further comprises adjusting a discharge parameter of a later phase of the multiphasic waveform as a function of a value of the electrical parameter during an earlier phase.	Kroll teaches adjusting a discharge parameter of a later phase as a function of a value of the electrical parameter during an earlier phase of a biphasic waveform. For example, Kroll discloses that the duration of the second pulse equals a fraction of the duration of the first pulse. (Kroll at 7:1-3). The duration of the first pulse is based on the capacitor discharge voltage decaying a given percentage from the preselected amount of electrical energy stored in the capacitor. (<i>Id.</i> at 9:52-55). Energy delivery continues for another fixed time period after reaching the desired voltage decay percentage. (<i>Id.</i> at 9:58-60).
13. The method of claim 12 wherein the discharge parameter of the later phase is phase duration.	Kroll teaches that phase duration was a type of discharge parameter in biphasic waveforms. For example, Kroll discloses that the duration of the second pulse equals a fraction of the duration of the first pulse. (Kroll at 7:1-3).
14. The method of	Kroll teaches adjusting the discharge parameter of the later phase

Claims	Bell in view of Kroll
claim 9 wherein the adjusting step further comprises adjusting a discharge parameter of a later phase of the multiphasic waveform as a function of duration of an earlier phase.	as a function of duration of the earlier phase in a biphasic waveform. For example, Kroll discloses that the duration of the second pulse equals a fraction of the duration of the first pulse. (Kroll at 7:1-3).
15. The method of claim 14 wherein the discharge parameter of the later phase is phase duration.	Kroll teaches that phase duration is a type of discharge parameter was well known in prior art biphasic waveforms. For example, Kroll discloses that the duration of the second pulse equals a fraction of the duration of the first pulse. (Kroll at 7:1-3).
16. The method of claim 9 wherein a phase of the multiphasic waveform has a fixed duration.	Kroll teaches a phase of the multiphasic waveform having a fixed duration. For example, Kroll discloses that the second pulse could be made to meet a fixed-duration specification. (Kroll at 7:5-8).
17. The method of claim 9 wherein the multiphasic waveform has an earlier phase and a later phase, the later phase having a fixed duration.	Kroll teaches a biphasic waveform in which the later phase has a fixed duration. For example, Kroll discloses the second pulse could be made to meet a fixed-duration specification. (Kroll at 7:5-8).
18. The method of claim 9 wherein the multiphasic waveform comprises a truncated exponential biphasic waveform.	Kroll teaches using truncated exponential biphasic waveforms for achieving defibrillation. For example, Kroll discloses a truncated capacitor-discharge pulse. (Kroll at 1:49-56). Kroll discloses that for biphasic waveforms, polarity is reversed after the initial pulse so that a second opposite-polarity pulse immediately follows the initial pulse. (<i>Id.</i> at 2:38-44). Moreover, the Background section of the '427 Patent acknowledges that truncated, exponential, biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Pa-

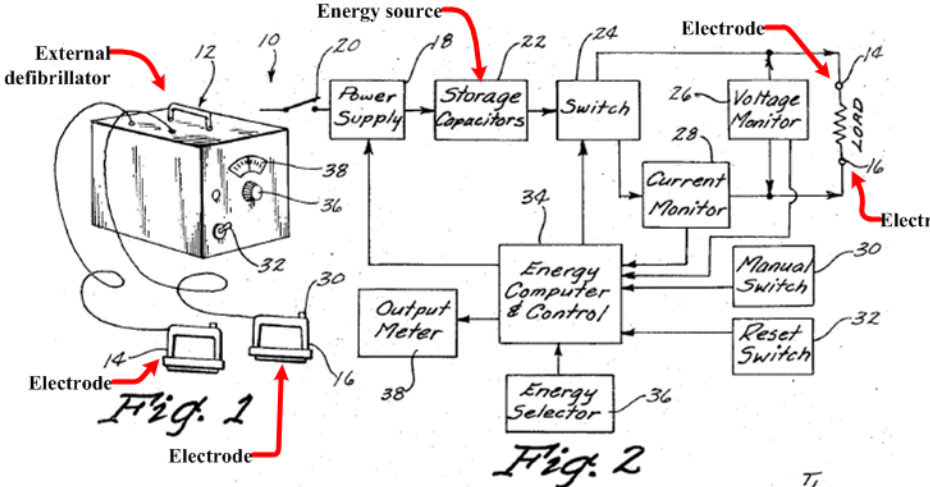
Claims	Bell in view of Kroll
	tent. (See, e.g., '427 Patent at 1:54-57).

3. [GROUND 3] – Bell in view of Schuder renders obvious

Claims 2, 3, 9, and 16-18.

As noted above and shown in the following claim chart in greater detail, claims 2, 3, 9, and 16-18 of the '427 Patent are obvious under 35 U.S.C. § 103 based on Bell in view of Schuder. A person of ordinary skill in the art would have been motivated to combine Schuder's biphasic waveform with Bell's control scheme, among other reasons, because of the increased effectiveness of biphasic waveforms over monophasic waveforms. (McDaniel Declaration at ¶ 41; LIFECOR427-1004).

Claims	Bell in view of Schuder
2. The method of claim 1 further comprising the following steps after the first discharging step: reversing the polarity of connection of the energy source to the electrodes; and discharging the energy source across the electrodes in the reversed polarity.	Schuder teaches reversing the polarity of the connection of the energy source to the electrodes, and discharging the energy source across the electrodes in the reversed polarity, to generate a biphasic waveform to achieve defibrillation. For example, Schuder discloses supplying a bidirectional truncated exponential waveform for transthoracic defibrillation. (Schuder at 520, ¶ 3; 521, ¶ 4, Table 1). Moreover, the Background section of the '427 Patent admits that biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Patent. (See, e.g., '427 Patent at 1:54-57).
3. The method of claim 2 wherein the discharging step in the reversed polarity continues for a second predetermined	Schuder teaches discharging in the reversed polarity for a predetermined time period. For example, Schuder discloses that the bidirectional waveforms have predetermined second phase durations. (Schuder at 520, ¶ 5; 521, ¶ 3; Table 1).

Claims	Bell in view of Schuder
time period. 9. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:	Bell discloses a method for applying electrotherapy to a patient. For example, Bell discloses a defibrillator 10 having a pair of electrodes 14 and 16 engageable with a patient to deliver energy to the patient to stop fibrillation of the heart. (Bell at 2:5-13). The defibrillator 10 includes a power supply 18 electrically connected to the storage capacitors 22 to store energy from the power supply 18. (<i>Id.</i> at 2:14-20). The storage capacitors 22 are connected to a switch mechanism 24, which is connected to the electrodes 14 and 16. (<i>Id.</i> at 2:19-24).  (<i>Id.</i> at FIG. 1 and FIG. 2).
discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;	Bell discloses placing the electrodes 14 and 16 in contact with the patient and connecting the stored energy source to the patient. (Bell at 2:66-3:5). Schuder discloses supplying a bidirectional truncated exponential waveform for transthoracic defibrillation. (Schuder at 520, ¶ 3; 521, ¶ 4, Table 1). Moreover, the Background section of the '427 Patent admits that biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Patent. (See, e.g., '427 Patent at 1:54-57).
monitoring a patient-dependent electrical parameter during the discharging step;	Bell discloses a current monitor 28 and a voltage monitor 26 that feed instantaneous current and voltage signals to an energy computer and control 34 which computes the energy as a continuous integration process. (Bell at 3:5-9).
adjusting a discharge parameter based on a value of the monitored elec-	Bell discloses that when the measured voltage and current indicate that the delivered energy equals the selected energy, the energy source is disconnected from the patient. (Bell at 3:9-11).

Claims	Bell in view of Schuder
trical parameter, the adjusting step comprising discharging the energy source across the electrodes in a phase of the multiphasic waveform until the end of a predetermined time period or until the monitored electrical parameter reaches a predetermined value, whichever occurs first.	Bell discloses placing the electrodes 14 and 16 in contact with the patient and connecting the stored energy source to the patient. (Bell at 2:66-3:5). A current monitor 28 and a voltage monitor 26 feed instantaneous current and voltage signals to an energy computer and control 34 which computes the energy as a continuous integration process. (Id. at 3:5-9). When the measured voltage and current indicate that the selected energy level is reached, the energy source is disconnected from the patient. (Id. at 3:9-11). Bell further discloses that the output pulse width is limited to a maximum value for any given setting. (Id. at 4:15-18). In the case of a high patient resistance, the defibrillator would attempt to deliver the selected energy but would take too long and the time out input will terminate the discharge before the measured voltage and current indicate that the selected energy value is reached. (Id. at 4:30-40).
16. The method of claim 9 wherein a phase of the multiphasic waveform has a fixed duration.	Schuder teaches a phase of the multiphasic waveform having a fixed duration. For example, Schuder discloses that the bidirectional waveforms have predetermined second phase durations. (Schuder at 520, ¶ 5; 521, ¶ 3; Table 1).
17. The method of claim 9 wherein the multiphasic waveform has an earlier phase and a later phase, the later phase having a fixed duration.	Schuder teaches a biphasic waveform in which the later phase has a fixed duration. For example, Schuder discloses that the bidirectional waveforms have predetermined second phase durations. (Schuder at 520, ¶ 5; 521, ¶ 3; Table 1).
18. The method of claim 9 wherein the multiphasic waveform comprises a truncated exponential biphasic waveform.	Schuder teaches using truncated exponential biphasic waveforms for achieving defibrillation. For example, Schuder discloses supplying a bidirectional truncated exponential waveform for transthoracic defibrillation. (Schuder at 520, ¶ 3; 521, ¶ 4, Table 1). Moreover, the Background section of the '427 Patent acknowledges that truncated, exponential, biphasic waveforms were well-known and in widespread use in defibrillators prior to the '427 Patent. (See, e.g., '427 Patent at 1:54-57).

4. [GROUND 4] – Obviousness-type double patenting of claim 1 over claim 4 of U.S. Patent 5,735,879 (Gliner)

As shown in the following claim chart in greater detail, claim 1 of the '427 Patent is invalid on the ground of nonstatutory obviousness-type double patenting over claim 4 of U.S. Patent No. 5,735,879 (Gliner; “the ‘879 Patent”; LIFECOR427-1011). Obviousness-type double patenting “requires rejection of [a] claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent.” (*In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998)). Double-patenting may occur when two applications or patents have at least one common inventor and/or are commonly assigned. (See, e.g., *In re Longi*, 759 F.2d 887, 893-94 (Fed. Cir. 1985)). The relevant analysis involves construing the claims in both patents if necessary, then determining if the subject claim is anticipated by, or obvious over, the other claim. (See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001)). The obviousness may be over the claim itself or over the claim in combination with prior art. (See, e.g., *In re Longi*, 759 F.2d at 893).

The table below shows how claim 1 of the '427 patent is obvious in view of claim 4 of the '879 patent, both of which are owned by Philips.¹ Specifically, the only substantive differ-

¹ Although a restriction requirement was imposed in a parent application, the '879 patent was filed as a continuation of that application rather than a divisional, so that any protections from

ence between the claims is that the '427 claim recites discharging until a time period or a level of decay (whichever comes first), while the '879 claim recites discharging until a time period and a level of decay. This is not a patentable distinction, however, because, as written, the '879 claim defines nothing over the '427 claim. In particular, if a device were discharged until **both** events occurred, it would necessarily be discharged until **one** of the events occurred (note that neither of the claims recites that the discharging needs to end when one or both of the events occur, and neither recites that the device needs to make an affirmative determination that an event occurred or when it occurred). But even if the '427 claim were interpreted more narrowly to require that the discharging continue until the particular point **and** stop at that point, the difference between an "and" and an "or" is simply an obvious design choice because the two are simple selections from a very finite, two-member group with no unpredictable results. (McDaniel Declaration at ¶ 42; LIFECOR427-1004).

Claim 1 of the '427 Patent	Claim 4 of the '879 Patent
1. A method for applying electrotherapy to a patient through electrodes external to a patient, the electrodes being electrically connected in a predetermined polarity to an energy source charged to an initial level, the method comprising the following step: discharging the energy source across the electrodes in the predetermined polarity un-	4. A method for applying electrotherapy to a patient through electrodes external to a patient, the electrodes being electrically connected in a first predetermined polarity to an energy source charged to an initial level, the method comprising the following step: discharging the energy source across the electrodes until the end of a predetermined

35 U.S.C. § 121 are not available here. (See *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1352 (Fed. Cir 2009)).

Claim 1 of the '427 Patent	Claim 4 of the '879 Patent
til the end of a predetermined time period or until an electrical unit measured across the electrodes decays to a predetermined terminal level, whichever occurs first.	time period and until an electrical unit measured across the electrodes decays to a predetermined terminal level.

5. [GROUND 5] – Obviousness-type double patenting of claim 9 over claim 9 of U.S. Patent 5,607,454 (Cameron)

Claim 9 of the '427 patent is invalid over claim 9 of U.S. Patent 5,607,454 (“Cameron”; the '454 patent; LIFECOR427-1012), also assigned to Philips.² In particular, as the table below shows, the claims are the same as each other for the preambles, the “discharging” limitation, and the “monitoring” limitation. The '454 claim’s limitation of “shaping the waveform ... based on a value of the monitored electrical parameter” is an example of the '427 claim’s limitation of “adjusting a discharge parameter based on a value of the monitored parameter,” so that the former fully discloses the latter also. The only substantive difference between the claims comes in the final limitation of the '427 claim, which recites discharging until a predetermined time period or until the electrical parameter reaches a predetermined level, whichever comes first. The '454 claim, however, recites both (a) controlling phase duration by a monitored electrical parameter and (b) selecting a phase duration based on monitoring elapsed time. Therefore, by the plain claim language of claim 9 of the '454 patent, both of these two

² The safe harbor of 35 U.S.C. § 121 is also not available here because the '454 patent is a continuation-in-part of the application that received the restriction requirement.

factors (which match the factors in the '427 claim) serve as limits on phase duration, and thus the discharge would occur until either factor was triggered, whichever occurs first. (McDaniel Declaration at ¶ 43; LIFECOR427-1004). Thus, claim 9 of the '454 patent recites every limitation of claim 1 of the '427 patent, and an obviousness-type double patenting rejection should issue as a result.

Claim 9 of the '427 Patent	Claim 9 of the '454 Patent
9. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps: discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform; monitoring a patient-dependent electrical parameter during the discharging step; adjusting a discharge parameter based on a value of the monitored electrical parameter, the adjusting step comprising discharging the energy source across the electrodes in a phase of the multiphasic waveform until the end of a predetermined time period <u>or</u> until the monitored electrical parameter reaches a predetermined value, whichever occurs first.	9. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps: charging the energy source to an initial level; discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform; monitoring a patient-dependent electrical parameter during the discharging step; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter, wherein: the shaping step further comprises controlling the duration of a waveform phase based on a value of the electrical parameter, the electrical parameter is charge delivered by the energy source to one of the electrodes, the discharging step begins at a discharge start time, the method further comprising the step of monitoring

Claim 9 of the '427 Patent	Claim 9 of the '454 Patent
	elapsed time from the discharge start time, the shaping step further comprising the step of determining an elapsed time value at which the charge delivered has reached a predetermined threshold, the shaping step further comprises selecting a first phase duration based on the elapsed time value.

VIII. CONCLUSION

The cited prior art references, including their combinations, that are identified in this Petition, and particular sections thereof, are exemplary in nature and are not intended to convey all manners in which the references meet all the claim limitations. The cited prior art references contain pertinent technological teachings, either explicitly or inherently disclosed, that were not previously considered in the manner presented herein, and/or relied upon on the record during original examination of the '427 Patent. At least by virtue of disclosing the limitations that served as the basis for the Office's allowance of the claims at issue, the references relied upon herein should be considered important in determining patentability. In sum, these references provide new, non-cumulative technological teachings that establish a reasonable likelihood of success as to Petitioner's claim that the IPR Claims of the '427 Patent are not patentable pursuant to the grounds presented in this Petition. Accordingly, Petitioner respectfully requests institution of *Inter Partes* Review for those claims of the '427 Patent for each of the grounds presented herein.

Respectfully submitted,

Dated: September 23, 2013

/John C. Phillips/

John C. Phillips, Reg. No. 35,322

Dorothy P. Whelan, Reg. No. 33,814

Fish & Richardson P.C.

3200 RBC Plaza

60 South Sixth Street

Minneapolis, MN 55402

T: 858-678-4304

F: 877-769-7945

(Trial No. IPR2013-_____)

Attorneys for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on September 23, 2013, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided by Express Mail, cost prepaid, to the Patent Owner by serving the correspondence address of record as follows:

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P.O. Box 3001
Briarcliff Manor, NY 10510

/Diana Bradley/

Diana Bradley
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
(858) 678-5667