NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**KONINKLIJKE PHILIPS N.V., PHILIPS ELECTRONICS NORTH AMERICA CORPORATION,**
*Plaintiffs-Appellants*

**v.**

**ZOLL MEDICAL CORPORATION,**
*Defendant-Cross-Appellant*

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2014-1764, 2014-1791

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Appeals from the United States District Court for the District of Massachusetts in No. 1:10-cv-11041-NMG, Judge Nathaniel M. Gorton.

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Decided: July 28, 2016

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J. MICHAEL JAKES, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by KATHLEEN DALEY, LUKE MCCAMMON, DAVID MROZ, JASON LEE ROMRELL, ROBERT SHAFFER, SUSAN TULL.

DAVID ISAAC GINDLER, Irell & Manella LLP, Los Angeles, CA, argued for defendant-cross-appellant. Also repre-

sented by ALAN J. HEINRICH; DAVID C. MCPHIE, Newport Beach, CA.

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Before LOURIE, DYK, and HUGHES, *Circuit Judges*.

HUGHES, *Circuit Judge*.

Philips sued Zoll for infringement of numerous patents related to external defibrillators. Zoll counterclaimed for infringement of its own patents covering related technology. The parties presented their cases to a jury, which found, among other things, that both parties' patents are not invalid, both parties directly infringe the asserted patents, but Zoll does not contributorily infringe the asserted Philips patents. The district court denied all motions for judgment as a matter of law, and both parties appeal these denials. For the reasons set forth below, we affirm-in-part, reverse-in-part, and vacate-in-part the district court's judgment. We remand the case for further proceedings.

## I. BACKGROUND

Philips and Zoll both manufacture and sell external defibrillators. Defibrillators are electronic devices that apply an electrical shock to a person's heart for therapeutic purposes. Defibrillators are commonly used to treat ventricular fibrillation, which occurs when the muscle fibers of a person's heart contract without coordination. Application of an electrical shock interrupts the irregular contractions, allowing the heart to return to its normal rhythm of contraction.

"External" defibrillators are defibrillators that are not implanted in a person's body. Because they are provided outside of the person's body, external defibrillators must deliver the electrical shock indirectly, as applied to the surface of the person's skin. In addition, because the electrical shock must pass through the person's skin and

thorax before reaching the person's heart, external defibrillators generally need to operate at higher voltages and/or currents than implanted defibrillators.

This application of high levels of electricity to the surface of a person's skin to treat a time-sensitive medical condition introduces numerous challenges, which the patents-in-suit address.

### A. Waveform Patents

Philips asserted a first group of patents that we will refer to as the "waveform" patents. These are: U.S. Patent 5,607,454; U.S. Patent 5,749,905; and U.S. Patent 6,047,212.

In the most general sense, the waveform patents are directed to controlling the waveform of the electrical shock that is delivered to a subject person's body. The waveform patents explain that one challenge with external defibrillators is that of subject variability. With implanted defibrillators, only a single person is ever the subject of the device, so the device can be precisely tuned to deliver the ideal electrical shock to that subject. But an external defibrillator may be used on multiple subjects, each with a distinct body composition. The differences between different subjects' hearts, the differences between the electrical impedance created by different subjects' thoraxes, and other body composition differences mean that an ideal external defibrillator would be capable of providing different electrical shocks. But configuring the various parameters of the electrical shock, e.g., the initial voltage and duration of the initial voltage phase, can be a complicated technique that typically can only be executed by a trained professional.

The waveform patents aim to address this challenge by providing an external defibrillator that can automatically vary the electrical shock based on the body composition of the subject, eliminating the need for a trained

operator. *See* '454 patent, col. 3 ll. 37–40. The waveform patents disclose that an external defibrillator can be configured to detect an "electrical parameter" of the subject, such as the electrical impedance of the subject's thorax, and then adjust the electrical shock based on this monitored electrical parameter. *See id.* at col. 3 ll. 44–53.

Philips asserted the following claims of the waveform patents against Zoll: '454 patent claim 51; '905 patent claims 4 and 8; and '212 patent claims 1 and 5. *See* J.A. 108–11.

B. Self-Test Patents

Philips asserted a second group of patents that we will refer to as the "self-test" patents. These are: U.S. Patent 5,800,460 and U.S. Patent 5,879,374.

The self-test patents are directed to an external defibrillator's capability to test its own functional status without human intervention. External defibrillators prior to the self-test patents tended to be deployed in high-usage environments, such as a hospital emergency room, where they could be tested regularly to ensure their operability. But in low-usage environments, such as an emergency medical vehicle or in a stationary deployment in an office building, regular testing was inconvenient.

The self-test patents aim to address this challenge by providing a self-testing capability within an external defibrillator. *See* '460 patent, col. 1 ll. 44–48. The self-testing capability allows the external defibrillator to periodically, e.g., once per day, test the functionality of its components, e.g., that its battery is sufficiently charged. *See id.* at col. 1 ll. 38–48. The external defibrillator provides a visual and/or audible indicator of the self-test results. *See id.* at Abstract.

Philips asserted the following claims of the self-test patents against Zoll: '460 patent claim 7; and '374 patent claims 42–43 and 67–68. *See* J.A. 105–06.

### C. Electrode Patent

Zoll asserted U.S. Patent 5,330,526, which is directed to an electrode for use with an external defibrillator.

Prior to the '526 patent, it was common practice to provide an electrolytic gel on the surface of the electrodes of an external defibrillator. After soaking into the subject's skin, the electrolytes in the gel would provide a conducting path from the electrodes through the outer surface of the subject's skin. This allowed the electrical shock to easily pass into the subject's body instead of dissipating on the surface of the subject's skin. It was common to provide the electrodes and electrolytic gel to have an electrical resistance of less than 1 ohm, thereby heightening this conductivity factor.

The '526 patent discloses that this very low resistance characteristic of the electrode and electrolytic gel can actually be disadvantageous. In particular, use of very low resistance electrodes and electrolytic gel demonstrated that some burning occurs on the subject's skin at the outer edge of the electrolytic gel. *See* '526 patent, col. 1 l. 57–col. 2 l. 7. As a result, the '526 patent discloses various configurations of the electrode and electrolytic gel, each configuration having an electrical resistance of at least 1 ohm. *See id.* at col. 2 ll. 16–49.

Zoll asserted claims 1, 8–9, 11–12, 19, and 24–25 of the '526 patent against Philips. *See* J.A. 115.

### D. District Court Proceedings

The district court submitted various issues of infringement and validity to a jury, but bifurcated all dam-

ages issues for a later trial. The jury made the following determinations.[1]

First, the jury found each of the following claims of the waveform and self-test patents not invalid: '454 patent claim 51; '905 patent claims 4 and 8; '460 patent claim 7; and '374 patent claims 42–43 and 67–68. *See* J.A. 112–13.

Second, the jury found that Zoll directly infringed each of the following claims of the waveform and self-test patents with at least one of its products: '454 patent claim 51; '905 patent claims 4 and 8; '212 patent claims 1 and 5; '460 patent claim 7; and '374 patent claims 42–43 and 67–68. *See* J.A. 105–11.

Third, the jury found that Zoll had neither contributorily nor inducedly infringed any of the following claims of the waveform and self-test patents with any of its products: '454 patent claim 51; '905 patent claims 4 and 8; '460 patent claim 7; and '374 patent claims 42–43 and 67–68. *See* J.A. 105–11.

Fourth, the jury found that Philips directly infringed each of the following claims of the '526 patent with at least one of its products: claims 1, 8–9, 11–12, 19, and 24–25. *See* J.A. 115. The jury further found that each of these claims was not invalid. *See* J.A. 116.

Philips and Zoll moved for judgment as a matter of law on each of the foregoing grounds on which it did not prevail. The district court summarily denied JMOL without discussion.

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[1] The jury made findings on several other issues presented by Philips and Zoll. *See* J.A. 104–16. Because the parties do not appeal those additional issues, we do not address them further in this opinion.

Philips and Zoll appeal those denials. We have jurisdiction under 28 U.S.C. § 1292(c)(2). *See Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1317 (Fed. Cir. 2013) (en banc).

## II. STANDARD OF REVIEW

This court reviews denial of a JMOL motion according to the law of the regional circuit. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1341 (Fed. Cir. 2011). The First Circuit reviews the grant or denial of JMOL de novo. *See Soto-Lebron v. Fed. Express Corp.*, 538 F.3d 45, 56 (1st Cir. 2008). "Courts may only grant a judgment contravening a jury's determination when the evidence points so strongly and overwhelmingly in favor of the moving party that no reasonable jury could have returned a verdict adverse to that party." *Marcano Rivera v. Turabo Med. Ctr. P'ship*, 415 F.3d 162, 167 (1st Cir. 2005) (internal quotation marks omitted).

We address Philips's and Zoll's arguments in the following order. First, we address Zoll's cross-appeal as to invalidity and direct infringement of the waveform and self-test patents in parts III. and IV., respectively. Second, we address Philips's appeal as to indirect infringement of the waveform and self-test patents in part V. Third, we address Philips's appeal as to indefiniteness of the electrode patent in part VI. Finally, we address Philips's appeal as to the admission of evidence in part VII.

## III. INVALIDITY OF WAVEFORM AND SELF-TEST CLAIMS

The jury found claims of Philips's waveform and self-test patents not invalid over various prior art references. Zoll contests these verdicts as discussed below.

### A. Waveform Claims

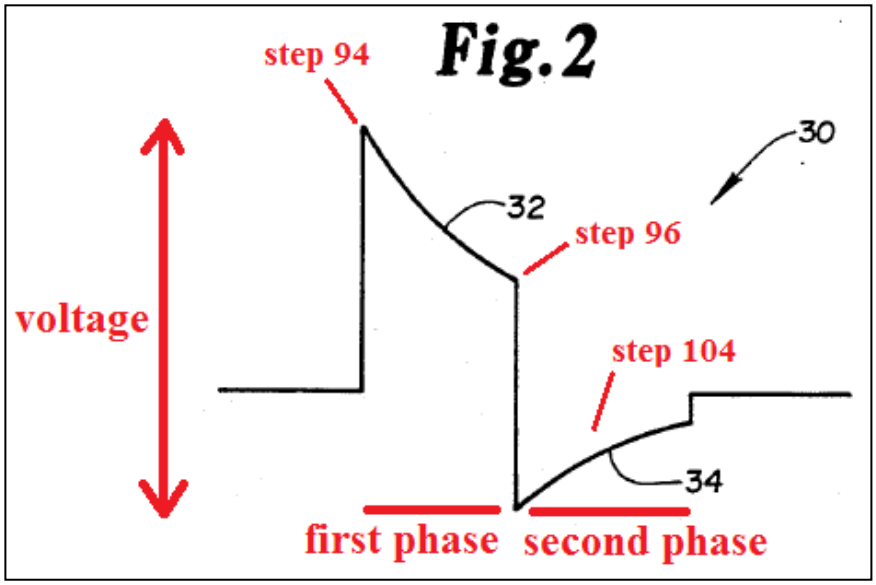
The jury found that claims 4 and 8 of the waveform '905 patent were not anticipated by U.S. Patent 5,432,686 (Kroll). Claim 4 recites the following:

> A method for delivering 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 parameter during the discharging step;
>
> shaping the waveform so that an initial parameter of a waveform phase depends on a value of the electrical parameter.

Claim 8 is dependent on claim 4. Anticipation is a question of fact, *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1322 (Fed. Cir. 2012), and we will overturn the jury's verdict only if "the evidence points so strongly and overwhelmingly in favor" of anticipation that "no reasonable jury could have returned" the jury's verdict of no anticipation, *Marcano Rivera*, 415 F.3d at 167. Zoll argues that no reasonable jury could conclude that Kroll fails to disclose each of the features of claim 4. We disagree.

Kroll discloses a method for delivering electrotherapy to a subject. The method illustrated in Figure 7 of Kroll includes a step 94 of beginning delivery of energy from a capacitor into the subject's body, a step 96 of waiting for the capacitor discharge voltage to decay a "given percentage," and a step 104 of continuing to discharge energy from the capacitor but with a reversed polarity. *See* Kroll,

Fig. 7, col. 9 ll. 46–68. This is further illustrated in the marked up Figure 2 of Kroll shown below:[2]




As shown, discharging of the energy across the subject's body begins at some starting voltage (step 94), discharging continues until some predefined "given percentage" of the starting voltage has been dissipated (step 96), and then the polarity of the voltage is reversed and the discharging of the energy continues (step 104). The initial discharging of the energy constitutes a first phase of discharge 32, while the reverse-polarity discharge of the energy constitutes a second phase of discharge 34.

Kroll suggests that the "given percentage" that triggers the end of the first phase of discharge is optimally 44% of the starting voltage level. *See* Kroll, col. 9 ll. 55–

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[2] Our markup includes the Y axis label for "voltage," the labeling of the "first phase" and "second phase," and the labeling of the steps 94, 96, and 104.

58. Importantly, the "given percentage" is a value calculated from mathematical equations of physiology, which are not specific to the subject being treated during execution of the method. *See* Kroll, Abstract, col. 6 ll. 16–40.

It is indisputable that Kroll discloses the "discharging" step of claim 4. The question is whether Kroll monitors a "patient-dependent parameter" and then "shap[es] the waveform so that an initial parameter of a waveform phase" is based on that "patient-dependent parameter."

In some sense, the voltage being dissipated into the subject's body in Kroll is a "patient-dependent parameter." When the method of Kroll is performed, the subject's body forms part of a closed circuit that is arranged in the following series: the defibrillator (which sets the current and has an inherent electrical resistance); the first electrode; the patient's body (which has a subject-specific electrical resistance as discussed previously); the second electrode; and back to the defibrillator. Because voltage and resistance are directly related to one another by Ohm's law—voltage = current × resistance—and because the current is fixed by the defibrillator, the voltage dissipating into the subject's body is at least in part dependent on the patient's own particular electrical resistance. Thus, the dissipating voltage in Kroll might be considered a "patient-dependent parameter." And because the method of Kroll requires observing the dissipating voltage level so as to stop dissipation when it reaches the "given percentage," Kroll arguably discloses the "monitoring" step of claim 4.

It is less clear that Kroll discloses the "shaping" step of claim 4. The Kroll method stops dissipation in the first phase at 44% of the starting voltage, and the method then begins dissipation in the second phase at that same voltage level (with the current flowing in the opposite direction). Therefore, Zoll argues, voltage is a "patient-dependent parameter," and because the initial voltage

level of the second phase of dissipation is based on a percentage value of that parameter, Kroll discloses the "shaping" step of claim 4.

But that incorrectly describes what occurs in the Kroll method. In Kroll, the first phase of dissipation always ends at 44% (or some other predetermined "given percentage") of the starting voltage of the first phase. Neither the 44% value nor the starting voltage is dependent on the subject being treated. *See* Kroll, col. 4–6. Rather, these characteristics are computed absent a patient-specific resistance value. *See id.* at col. 6 ll. 41–46. Therefore, the starting voltage and the ending voltage of the first phase are not dependent on the subject being treated. Because the starting voltage of the second phase is the same as the ending voltage of the first phase, it too does not depend on the subject being treated. So, the subject-specific electrical resistance does not change the starting or ending amplitudes of the waveform. Instead, it will affect how quickly the voltage dissipates, essentially shortening or lengthening the time of the first phase and the second phase (the x-axis in Figure 2 of Kroll).

Thus Kroll discloses fixed, non-subject-specific starting and ending voltages for the waveform, and incidentally the waveform may be compressed or stretched in time in a patient-dependent way. The parties did not dispute the meaning of "shaping the waveform," and the district court did not expressly construe this language. J.A. 101–03. Whether Kroll's method discloses the "shaping" step of claim 4 is a factual question left to the jury for resolution based on the ordinary meaning of the claims. Both Philips and Zoll presented expert evidence to explain why this incidental compressing/stretching of the waveform is or is not sufficient disclosure of the "shaping" step of claim 4. The jury found that it is not, and Philips's evidence in support thereof is sufficient for a reasonable jury to reach the same conclusion. *See* J.A. 5046–50. Because

claim 8 depends on claim 4, the evidence is also sufficient to support the verdict of no anticipation for claim 8.

Therefore, we affirm the district court's denial of JMOL of invalidity as to claims 4 and 8 of the waveform '905 patent.

B. Claim 7 of the '460 Self-Test Patent

The jury found that claim 7 of the self-test '460 patent was not anticipated by U.S. Patent 5,579,234 (Wiley). Claim 7, including its dependencies on claims 1, 5, and 6, recites the following:

> A method of performing a self-test in an external defibrillator, the method comprising the following steps:
>
> generating a test signal automatically;
>
> turning on a power system within the external defibrillator in response to the test signal; and
>
> performing a plurality of automatic self-tests within the external defibrillator for determining the status of the defibrillator;
>
> wherein the performing step comprises performing said plurality of automatic self-tests within the external defibrillator on a schedule;
>
> wherein the performing step comprises performing a first automatic self-test on a first periodic schedule;
>
> wherein the performing step comprises performing a second automatic self-test on a second periodic schedule.

Zoll argues that no reasonable jury could conclude that Wiley fails to disclose each of these features. We agree.

Wiley discloses various methods for automatically testing an electronic device during periods of non-use. *See*

Wiley, Abstract. As relevant here, Wiley discloses with respect to Figure 4A a method of testing an electronic device that includes both an hourly power-on at step 210 and a daily "autotest" at step 236. *See* Wiley, Fig. 4A, col. 6 ll. 21–30, col. 7 ll. 25–43. The device powers itself on every hour to perform a "CPU Test" at step 210. *See id.* at Fig. 4A, col. 6, ll. 21–31, col. 7 ll. 14–24. During this hourly "CPU Test," "the CPU performs its standard power-up self-tests internal to the particular type of CPU" at step 210. *Id.* at col. 6 ll. 21–23. The device then checks if it is the proper time of day to perform the daily "autotest." *See id.* at col. 7 ll. 14–17. If so, then the device (once daily) "begins a series of primary autotest functions 236," which can include testing whether various memory resources and specialized microprocessors are working properly. *Id.* at col. 7 l. 32–col. 8 l. 11.

Therefore, Wiley on its face discloses both the "first automatic self-test on a first periodic schedule"—the hourly CPU test—and the "second automatic self-test on a second periodic schedule"—the more extensive daily "autotest"—of claim 7. Philips counters that the hourly "CPU test" is not an automatic self-test at all, but rather a sort of precursor for determining whether the daily "autotest" can be performed. *See* Philips Reply Br. 48–49. But it is undeniable that both the hourly test and the daily test are automatic, periodic, self-tests by the device. The only evidence that Philips presented to the contrary was the following exchange between Philips's attorney and its expert witness:

> Q: . . . But can we also discuss [Wiley] with respect to what it doesn't show?
>
> A: It does not show at all the second periodic self-test on the second periodic schedule.
>
> Q: Is that because it only has a single periodic schedule?

> A: That's right. There's only one schedule 24 hours and multiple tests conducted on this one schedule.

J.A. 5095. This amounts to nothing more than Philips's expert plainly claiming that the hourly "CPU Test" does not exist, even though it unmistakably does. Philips points to nowhere in the trial record where it presented to the jury its presently proffered theory that the "CPU Test" is somehow not a test but rather a precursor to a test. In contrast, Zoll did present the jury with an explanation of both the hourly and daily self-tests in the Wiley disclosure. *See* J.A. 2858–59.

Therefore, the evidence overwhelmingly favors the conclusion that Wiley discloses both of the self-tests recited in claim 7. Wiley describes two periodic, automatic self-tests, and Zoll's expert explained this to the jury in clear terms. Philips's only rebuttal was a factually incorrect, conclusory statement by its expert witness. *See, e.g.*, *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1172 (Fed. Cir. 2015) ("Conclusory statements by an expert, however, are insufficient to sustain a jury's verdict."); *Intellectual Sci. & Tech., Inc. v. Sony Elecs., Inc.*, 589 F.3d 1179, 1185–86 (Fed. Cir. 2009) (conclusory statement by expert, standing alone, insufficient to support jury finding of fact). Zoll's expert explained how Wiley disclosed the other elements of claim 7, and Philips does not contend that Wiley fails to disclose any of those other features.

Philips also argues that even if Wiley discloses all of the steps of claim 7, Wiley does not anticipate because it does not disclose performing each step in the order specified in the claim. But we generally do not construe method claims to require a specific ordering of the steps unless the claims explicitly recite or implicitly require such an ordering. *See Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342–43 (Fed. Cir. 2001). Philips made no request at the district court for a narrowing

construction of claim 7 that would require the steps of the method to be performed in any particular order, and we see nothing in the language of that claim to warrant such a construction on appeal.

Therefore, even drawing all inferences from the trial evidence in Philips's favor, no reasonable jury could have found that Wiley fails to anticipate claim 7. As such, we reverse the district court's denial of JMOL of invalidity as to claim 7 of the self-test '460 patent.

C. Claim 43 of the '374 Self-Test Patent

The jury found that claim 43 of the self-test '374 patent was not anticipated by the VIVAlink product brochure. Claim 43 recites the following:

> An external defibrillator comprising:
>
> a high-voltage delivery system; and
>
> a self-test system, the self-test system comprising a test signal generator and a fail-safe visual display.

Zoll argues that no reasonable jury could conclude that VIVAlink fails to disclose each of these features. We agree.

The VIVAlink brochure is a product brochure describing the VIVAlink AED defibrillator device. Among other features, the VIVAlink brochure notes the "Ease of Maintenance" of the VIVAlink AED. J.A. 14942. Under that heading, the VIVAlink brochure explains:

> While the VivaLink AED is dormant, the microprocessor will automatically check the conditions of the battery, the electrodes/electrode cables and the internal electronics every 24 hours. On a weekly basis, it will automatically check the capacitor, the charging circuit and the high voltage circuit. If any system is not within preset specifi-

> cations, an audible and visual warning (Maintenance Alert) is triggered. Audible warnings will last until the batteries are exhausted but the visual warning signal will remain indefinitely. The visual warning signal can be clearly seen simply by looking at the VivaLink AED.

J.A. 14942. According to Zoll, this self-testing procedure discloses the "test signal generator" of claim 43, and the visual warning discloses the "fail-safe visual display."

Whether the visual warning of the VIVAlink brochure discloses the "fail-safe visual display" of claim 43 depends on the meaning of that claim feature. The district court did not provide any explicit construction for that claim term. J.A. 101–03. The specification of the '374 patent suggests that the "fail-safe" feature requires the visual display to continue displaying some visual indicator even if the electrical power to the device is lost. *See* '374 patent, col. 5 ll. 34–39 ("The status indicator should be fail-safe so that the indicator will indicate an inoperable status if the system monitor should fail."), col. 5 l. 66–col 6 l. 5 ("The primary advantages of the visual display of the preferred embodiment are its low power requirements and the fact that it is powered by an AC signal rather than a DC signal. This latter point assures the display's fail-safe nature, since the shutter of the middle plate 66 cannot be maintained opaque without the active involvement of the system monitor generating the AC signal.").

Philips urges a narrower construction of "fail-safe visual display." According to Philips, a display is fail-safe not just by maintaining a visual indicator when electrical power is lost, but by affirmatively displaying a negative indicator (like "NOT OK") when the electrical power is lost. *See* Philips Reply Br. 42–46. According to Philips, the visual warning of the VIVAlink brochure may continue displaying a positive indicator (like "OK") when the electrical power is lost if that was the status indicator at

the time of power loss. Therefore, according to Philips, the visual indicator of the VIVAlink brochure is not a "fail-safe visual display."

But neither the broad language of claim 43 nor the general description of the fail-safe visual display in the specification of the '374 patent requires such a narrow meaning of "fail-safe." It is certainly possible that a "fail-safe" display may actively change from a positive to a negative indicator if electrical power is lost, but this is not required by the claims. "Fail-safe" simply requires that a visual indicator persists even if the device loses electrical power. The VIVAlink brochure clearly discloses this.

Philips's alleged evidence supporting its narrower claim construction is unpersuasive. Philips cites primarily to its own expert's testimony discussing the visual display *of Zoll's defibrillator device* as part of the infringement case. *See* Philips Reply Br. 42–44. Evidence regarding the characteristics of the accused products is not pertinent to define the scope of the asserted claims. The only actual evidence that Philips presented to the jury regarding the visual warning of VIVAlink was the following statement by Philips's expert witness about the VIVAlink brochure:

> Yes. This is very, very short, you know, a few pages brochure. And the relevant part for this consideration is right here. This is the only information available. So this does not really disclose the entire self-test because it does not teach how to make or use self-test. <u>It does not disclose fail-safe visual display</u>. More importantly, it does not disclose turning on of the power systems in response to a test signal, which is a critical part of a self-test.

J.A. 5095–96 (underlining added). This conclusory statement does nothing more than state Philips's preferred conclusion that the claim feature is not disclosed by the

prior art. It provides no evidence on which the reasonable jury could rely. *See MobileMedia*, 780 F.3d at 1172. And Zoll did explain the visual warning of VIVAlink to the jury and why it is "fail-safe." *See* J.A. 2864–65. Therefore, the evidence overwhelmingly shows that the VIVAlink visual warning that "will remain indefinitely" despite exhaustion of the batteries is a "fail-safe visual display."

Philips seeks to buttress its position by arguing that the VIVAlink brochure does not enable a fail-safe visual display. *See* Philips Reply Br. 46–47. But Philips's expert said nothing whatsoever about enablement of the "fail-safe visual display" feature; his statement that VIVAlink "does not teach how to make or use" was directed strictly at the "self-test" feature, not the "fail-safe visual display." *See* J.A. 5095–96. In any event, such a conclusory statement is insufficient to prove lack of enablement of a prior art reference. *See MobileMedia*, 780 F.3d at 1172.

Therefore, we conclude, based on the evidence presented at trial, that no reasonable jury could have found that the VIVAlink brochure fails to anticipate claim 43. As such, we reverse the district court's denial of JMOL of invalidity as to claim 43 of the self-test '374 patent.

D. Claims 42 and 67–68 of the '374 Self-Test Patent

The jury found that claims 42 and 67–68 of the '374 self-test patent were not obvious over the Zoll PD1400 defibrillator. Claim 42 recites the following:

> A method for automatically determining and indicating an operational status of an external defibrillator, the method comprising the following steps:
>
> generating a test signal within the external defibrillator automatically and periodically;

> performing a self-test in response to the test signal; and
>
> indicating the operational status of the defibrillator based on a result of the self-test;
>
> the generating, performing, and indicating steps being performed prior to any attempted use of the defibrillator.

Claim 67 is an independent claim that recites a similar method as claim 42. Claim 68 is dependent on claim 67. Obviousness is a question of law based on underlying questions of fact, *see Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1327 (Fed. Cir. 2009), and we review the ultimate conclusion of obviousness de novo and the underlying factual findings, implicitly in favor of the verdict, under the regional circuit's reasonable jury standard, *see Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1294 (Fed. Cir. 2009). Zoll argues that the PD1400 defibrillator renders each of claims 42 and 67–68 obvious. We disagree.

Zoll alleges that the only feature of claims 42 and 67–68 differentiating them from the prior art is that the claims require the self-testing to be done "automatically," i.e., not in response to a human pushing a button. *See* Zoll's Principal Br. 36–39. Philips does not refute this characterization. *See* Philips's Reply Br. 50–54. Instead, Philips argues that the automation of the self-tests was a non-obvious improvement. And Philips points to numerous indicia of non-obviousness supporting this conclusion.

The evidence supporting the jury's verdict of no invalidity is considerable. Philips's expert witness explained that the Patent Office considered and rejected the position that user-initiated self-testing renders the claims obvious. J.A. 5097. Philips's expert testified that designing an automatic self-test prior to user intervention presented challenges in managing battery power consumption that

were not obvious to overcome. J.A. 1827, 1839–40. Philips's witnesses testified that the automatic self-test feature was critical in allowing the defibrillators to be stowed unsupervised in public spaces. J.A. 1817, 1828–29, 1407–10, 2026–27. Philips's expert witness testified that the self-test feature, allowing for public and unsupervised stowage of the defibrillators, met a long-felt but unmet need. J.A. 5101–02. Philips demonstrated market success of its defibrillators incorporating the automatic self-test feature, that success stemming in part from the ability to sell the defibrillators over-the-counter and for home use. J.A. 1355, 2030–31.

All of this evidence taken together provides ample basis from which a reasonable jury could conclude that claims 42 and 67–68 would not have been obvious over user-instigated self-testing defibrillators. Zoll's counter-argument and accompanying evidence put forward the position that automating user-instigated self-tests to run automatically would have been obvious. But this does not render the sum of the evidence supporting the opposite conclusion somehow lacking. We will therefore not disturb the ultimate legal conclusion that the claims would not have been obvious over the PD1400 defibrillator and other user-instigated self-testing devices.

Therefore, we affirm the district court's denial of JMOL of invalidity as to claims 42 and 67–68 of the self-test '374 patent.

## IV. DIRECT INFRINGEMENT OF THE WAVEFORM AND SELF-TEST CLAIMS

The jury found that Zoll directly infringes numerous claims of the waveform and self-test patents. Zoll contests the jury's verdict on two general grounds: first, that Zoll's devices do not perform the features of some of the claims; second, that even if Zoll's devices perform the features of the claims, Zoll is not the party using the devices in a directly infringing way. Infringement is a

question of fact that we review under the regional circuit's reasonable jury standard. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1056 (Fed. Cir. 2010); *Marcano Rivera*, 415 F.3d at 167.

A. Waveform Claims – Claim Construction

The jury found that Zoll directly infringes claim 51 of the '454 waveform patent and claims 4 and 8 of the '905 waveform patent. Zoll argues that this verdict was in error because the district court presented an incorrect construction of those claims to the jury. We disagree.

The waveform claims recite "A method for applying electrotherapy to a patient" in the preamble, a step of "discharging the energy source," and a step of "monitoring [a patient-dependent / an] electrical parameter during the discharging step." The district court construed the "discharging" and "monitoring" steps to mean, respectively, "the step of discharging the energy source" and "measuring one or more times." J.A. 101.

Zoll argues that this construction was in error. Zoll argues that recitation of "applying electrotherapy" in the preamble means that the "discharging" step includes discharging only a therapeutic level (i.e., a high voltage or current) of electrical shock, and does not include discharging any non-therapeutic level (i.e., a low voltage or current) of electrical shock. According to Zoll, devices such as its own that first deliver a non-therapeutic level of electrical shock as a "test pulse" and then a therapeutic level of electrical shock do not infringe, at least if the "monitoring" step is performed only during the test pulse.

But Zoll's claim construction is not correct. The ordinary meaning of the claim language does not suggest the narrow construction of the "discharging" step that Zoll argues. The phrase "applying electrotherapy" in the preamble simply provides a setting for the method as a whole, not any sort of clear narrowing of the "discharging"

step as Zoll proffers. Zoll notes that the '454 patent identifies a prior art reference, Kerber, that uses test pulses. *See* '454 patent, col. 3 ll. 9–19. But there is nothing in this discussion to suggest that the '454 patent disclaims any use of separate test pulses in its disclosed techniques, which, according to the patent, are distinguished by automatic monitoring and shaping (or other fine-tuning) of the waveform of the electrical energy delivered to the patient during discharge itself. *See, e.g.*, '454 patent, col. 3 ll. 45–54. This passage identifies that the use of test pulses was known, but it does not state that the use of test pulses was incompatible with the invention of the '454 patent. *See Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) ("[G]eneral statements by the inventors indicating that the invention is intended to improve upon prior art" techniques, without more, "will not be interpreted to disclaim every feature of every prior art device discussed in the 'BACKGROUND ART' section of the patent.").

Similarly, the discussion of the prior art Bell reference in the prosecution history of the '905 patent simply indicates that the Bell reference did not perform any "monitoring" step during an electrical discharge, because the waveform was determined based on a patient weight value input into the defibrillator prior to discharge. J.A. 9186 (patentee arguing that "[s]ince it delivers a quantity of energy determined by a selection made by the operated *prior* to delivery of the shock, the Bell device does not adjust energy delivered to the patient based on a value of an electrical parameter monitored *during* discharge, as required by" the claims). That is, the patentee did not argue that Bell fails to anticipate because a separate test pulse prior to a therapeutic discharge is excluded by the claims, but instead argued that Bell fails to disclose monitoring during discharge, which is required by the claims. This makes no disclaimer of use of test pulses as part of the "discharging" step.

Neither the ordinary meaning of the claim language nor the intrinsic record show any merit in Zoll's overly-narrow construction of the "discharging" step of the waveform method claims. Therefore, Zoll's claim construction arguments provide no basis to overturn the district court's denial of JMOL of no infringement as to claim 51 of the '454 waveform patent and claims 4 and 8 of the '905 waveform patent.

B. Waveform Method Claims

Zoll alternatively argues that even if its defibrillator devices can be used to infringe the waveform method claims, Zoll does not use those devices in a directly infringing way. We disagree.

Claim 51 of the '454 patent and claims 4 and 8 of the '905 patent require "discharging the energy . . . to the patient." Therefore, only the party that performs the therapeutic method on a subject patient can directly infringe.

Philips presented various elements of evidence demonstrating that Zoll used its defibrillator devices on subject patients. Zoll's fact witness testified that Zoll conducted clinical trials on its defibrillator devices. J.A. 1953. That same witness explained that Zoll performed these clinical trials to establish points of comparison between the Zoll defibrillators and competing products for the purpose of generating marketing material. J.A. 1969. Other of Zoll's marketing materials stated that Zoll had performed "human clinical studies" involving testing on more than 2,800 patients. J.A. 14569. Zoll's fact witness explained that Zoll's clinical testing involved testing on actual human subjects and testing on products already on sale. J.A. 2484. Zoll's expert witness further confirmed that clinical testing of the products by Zoll would involve testing on human subjects. J.A. 1687.

While Zoll notes that the first set of clinical trials referenced by its witnesses were performed outside the statutory damages period, J.A. 1952–53, *see* 35 U.S.C. § 286 ("[N]o recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action."), Zoll demonstrates no such deficiency as to the other clinical trials that it admits to performing. And while Zoll claims that some of its clinical testing may have been protected under 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."), Zoll's witnesses admitted that the testing was performed to generate marketing materials and on products already on sale—thus not for the purpose of receiving approval from the Food and Drug Administration.

Therefore, the jury's verdict of direct infringement of the waveform method claims was supported by several independent elements of evidence showing that Zoll infringed the waveform method claims during its own product testing and trials. For this reason, and because we previously found no merit in Zoll's claim construction arguments on the same claims, we affirm the district court's denial of JMOL of no direct infringement as to claim 51 of the '454 waveform patent and claims 4 and 8 of the '905 waveform patent.

### C. Waveform Device Claims

The jury found that Zoll directly infringes claims 1 and 5 of the '212 waveform patent. Zoll argues that this verdict was in error, because Zoll does not use its defibrillator devices in a directly infringing way. We disagree.

Claim 1 recites the following:

> An external defibrillator comprising:
>
> an energy source;
>
> first and second electrodes in electrical communication with the exterior of a patient; [and]
>
> a controller . . . .

Claim 5 is dependent on claim 1.

Zoll first argues that Philips presented insufficient evidence establishing that Zoll uses its defibrillator products in an infringing way. However, the evidence presented by Philips and discussed for the waveform method claims is also sufficient for the jury to conclude that Zoll's use of its defibrillator devices, i.e., the performance of testing and trials of its defibrillator products, directly infringed the waveform device claims.

Zoll also argues that, because the claims require a defibrillator with electrodes "in electrical communication with the exterior of a patient," Zoll does not directly infringe by making or selling its defibrillator products. Philips argues that Zoll infringes the waveform device claims through making and selling its defibrillator products because the claim language of "in electrical communication with the exterior of a patient" is functional language that does not limit the scope of the claims. Under this reasoning, the accused devices would not need to be in contact with a subject to infringe the claims, so Zoll would directly infringe the claims by simply making and selling its defibrillator devices.

Philips cites various precedents of this court as to why we should read "in electrical communication with the exterior of a patient" out of the claims. Philips argues that this language is alternatively a statement of intended use, the reading of a method step into device claims, or a nonsensical incorporation of a human being into the claim scope. But none of these arguments evade the fact

that "in electrical communication with the exterior of a patient" recites a clear, coherent limitation of the "first and second electrodes." The electrodes must be attached to a subject patient in order for a defibrillator device to come within the scope of the waveform device claims. Philips would have us read the claims as if they recited "first and second electrodes" *configured to be placed in* "electrical communication with the exterior of a patient," or something to that effect. But that is not what the claims recite. The claims must be interpreted according to their clear, ordinary meaning. *See Ancora Techs., Inc. v. Apple, Inc.*, 744 F.3d 732, 734–35 (Fed. Cir. 2014). Under that meaning, the electrodes must be in electrical communication with a subject patient, and Zoll does not infringe those claims by making and selling its defibrillator devices.

Therefore, Philips presented sufficient evidence to support the jury's verdict of direct infringement as to Zoll's use of its defibrillator devices during product testing and trials, but not as to Zoll's making and selling of its defibrillator devices. We affirm the district court's denial of JMOL of no direct infringement on this basis as to claims 1 and 5 of the '212 waveform patent.

D. Self-Test Method Claims

The jury found that Zoll directly infringes claim 7 of the '460 self-test patent and claims 42 and 67–68 of the '374 self-test patent.[3] Zoll argues that this verdict was in error, because Philips presented insufficient evidence that Zoll uses its own defibrillators in a directly infringing way, and that Zoll's sale of its defibrillator devices do not

[3] Because we find that claim 7 of the '460 self-test patent is invalid, we do not reach the direct infringement issue as to that claim.

directly infringe these self-test method claims. We disagree.

These claims recite a method for performing various self-test techniques in a defibrillator device. Claim 67 of the '374 self-test patent, for instance, recites the following:

> A method for testing and indicating an operational status of an external defibrillator comprising the following steps:
>
> generating a test signal within the external defibrillator automatically and periodically;
>
> performing a plurality of self-tests in response to the test signal to determine the operational status of a plurality of components of the defibrillator, the tests being performed without human intervention prior to any attempted use of the defibrillator; and
>
> indicating the operational status of the defibrillator in response to at least one of the self-tests.

Zoll first argues that Philips presented insufficient evidence that Zoll uses its own defibrillator devices in a directly infringing way. But the record includes ample evidence on which the jury could rely in order to conclude that Zoll's product testing and trials involved use of the defibrillator devices in a way that directly infringes the self-test method claims. A Zoll employee admitted that Zoll performs testing of its products, including the self-test functionality, prior to sale to verify that they function properly. J.A. 1897–98, 2481–84. Philips presented test reports by Zoll regarding its testing of the self-test feature. J.A. 13615–19, 13774–76. Philips's expert witness explained to the jury the significance of both of these pieces of evidence. J.A. 1897–99. This was a sufficient evidentiary basis on which a reasonable jury could con-

clude that Zoll directly infringed the self-test method claims by its pre-sale product testing.

Zoll next argues that it does not directly infringe the self-test method claims by making or selling its defibrillator devices, because it is some other party, e.g., Zoll's customers, that actually perform the steps of the claims. Zoll's point is that the steps of the self-test method claims, such as "generating a test signal within the external defibrillator automatically and periodically," are steps that are performed on an ongoing basis after Zoll has already sold the defibrillator device to another party. So, Zoll must not be the party performing the directly infringing use of the self-test method claims.

It is true that a party that sells an apparatus capable of performing a patented method is generally not liable for direct infringement if that infringing act comes to pass. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir. 2003). Instead, the direct infringer would be the party who put that apparatus to use to perform the patented method. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1221 (Fed. Cir. 2014). But this case presents the complicating detail that Zoll may sell the defibrillators configured to *automatically* perform the self-test method claims without any additional intervention by Zoll's customers. *Compare* J.A. 1899, *with* J.A. 5266, 7055, 12143–49. Philips argues that such "automatic" infringement establishes direct infringement by the seller of the apparatus, relying on *SiRF Technology, Inc. v. International Trade Commission*, 601 F.3d 1319 (Fed. Cir. 2010). But Philips's argument seeks to extend the holding in *SiRF* to a place where we have previously declined to take it:

> Contrary to Ericsson's assertions, our decision in *SiRF* did not create direct infringement liability whenever an alleged infringer sells a product that is capable of executing the infringing method.

> Our decision in *SiRF* is not applicable here because all of the steps of the method in claims 1 and 2 of the '215 patent are performed on the end product, which is controlled by a third party. *See SiRF*, 601 F.3d at 1331. Unlike the method in *SiRF*, there are no steps automatically performed by equipment controlled by [the selling party]. In fact, none of our decisions have found direct infringement of a method claim by sales of an end user product which performs the entire method, and we decline to do so here.

*Ericsson*, 773 F.3d 1221–22. We again decline to extend the scope of direct infringement to the point that Philips advocates. As in *Ericsson*, all of the steps of the self-test method claims are performed by the defibrillator devices, wholly out of the control of Zoll. Furthermore, there is considerable conflict in the record as to whether Zoll's defibrillator will actually automatically perform the self-test method claims upon sale to a Zoll customer, or whether some further activation and installation steps are required by the purchaser before the defibrillator will perform those methods. As such, we do not find this to be an appropriate case in which to establish direct infringement liability for a seller of an apparatus that may perform patented methods.

Therefore, Philips presented sufficient evidence to support the jury's verdict of direct infringement as to Zoll's own use of its defibrillator devices during product testing and trials, but not as to Zoll's alleged use of the self-test method claims by sale of its defibrillator products. We affirm the district court's denial of JMOL of no direct infringement on this basis as to claims 42 and 67–68 of the '374 self-test patent.

## V. INDIRECT INFRINGEMENT OF THE WAVEFORM AND SELF-TEST CLAIMS

The jury found that Zoll does not contributorily infringe claim 51 of the '454 waveform patent, claims 4 and 8 of the '905 waveform patent, claim 7 of the '460 self-test patent, and claims 42–43 and 67–68 of the '374 self-test patent.[4] A party is liable for contributory infringement under 35 U.S.C. § 271(c) if: 1) "there is direct infringement," 2) "the accused infringer had knowledge of the patent," 3) "the component has no substantial noninfringing uses," and 4) "the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010). Philips argues that, based on the evidence presented at trial, no reasonable jury could have concluded that any of these four requirements were not met by Zoll for the waveform and self-test patents. We address each of the four requirements in turn.

### A. Direct Infringement

Philips alleges that customers of Zoll performed the requisite acts of direct infringement for the contributory infringement claim against Zoll. Zoll responds that Philips failed to prove that any of Zoll's customers actually performed this direct infringement.

In preceding portions of this opinion, we have already explained that sufficient evidence demonstrated that Zoll infringed each of the contested waveform and self-test method claims when performing testing and trials on its own defibrillator devices in the manner in which they were intended to operate. A Zoll employee testified that Zoll controls about 50% of the North American hospital

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[4] Because we find that claim 7 of the '460 self-test patent and claim 43 of the '374 self-test patent are invalid, we do not reach the contributory infringement issue as to those claims.

market and about 40% of the ambulance market. J.A. 1953. Therefore, for the jury to conclude that the direct infringement requirement of the contributory infringement claim was not met, it would have had to conclude that not a single one of Zoll's customers in this sizable share of the market used the devices for their intended purposes as Zoll itself does. Absent any evidence suggesting such a strange occurrence, this is not a conclusion that could be reached by a reasonable jury.

Therefore, lack of direct infringement cannot stand as the basis for the jury's verdict of no contributory infringement.

B. Knowledge

Philips alleges that Zoll had the requisite knowledge of the waveform and self-test patents as of 2008 based on an infringement contention letter that Philips delivered to Zoll. Zoll alleges that these infringement contentions were not sufficiently specific to establish the requisite knowledge, and that Zoll had a good faith belief in non-infringement.

Section 271(c) "require[s] a showing that the alleged contributory infringer knew that the combination for which his component was especially designed was both patented and infringing." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964); *see also Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004). Zoll undoubtedly knew about the waveform and self-test patents and Philips's allegation of infringement as of the date of Philips's infringement letter, dated 28 July 2009. J.A. 12706–13. The July 2009 letter specifically identifies the '460 self-test patent and '374 self-test patent and refutes some previously discussed theory of invalidity. J.A. 12710. The July 2009 letter further discusses two family member patents of the '454, '905, and '212 waveform patents, those family member patents having considerably similar claims as the

asserted waveform patents. J.A. 12706. The July 2009 letter also addressed the same non-infringement contention as to the waveform patents that Zoll ultimately raised at trial. J.A. 12706.

Zoll argues that its good faith belief in non-infringement negates the knowledge requirement, pointing to its arguments against the direct infringement verdicts discussed *supra* at 20–29. For the claims of the '454 waveform patent and the '905 waveform patent, we find that Zoll's belief in non-infringement, based on its reasonable claim construction argument, does negate the knowledge requirement of contributory infringement. The Supreme Court has explained that if an accused infringer "reads the patent's claims differently from the plaintiff," and if "that reading is reasonable," then the accused infringer should not be liable for indirect infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015). While we ultimately concluded that Zoll's claim construction argument against the jury's direct infringement verdict for the waveform claims was incorrect, *see supra* at 21–23, that argument was based on a reasonable interpretation of the claims in light of the specification and the prosecution history. Because this belief in non-infringement was reasonable, it is a sufficient basis on which to ground the jury's implicit finding of insufficient knowledge for contributory infringement.

But for the claims of the '374 self-test patent, Zoll's non-infringement contentions amounted to nothing more than an allegation that *Zoll's customers, not Zoll,* were using the Zoll defibrillator devices in a directly infringing way. *See supra* at 26–29. This is not a defense to the knowledge requirement for contributory infringement because it evinces that Zoll knew it was potentially contributing to direct infringement of the '374 self-test patent. Therefore, Zoll had the requisite knowledge of the '374 self-test patent and infringement as of July 28, 2009.

Philips suggests that Zoll had this knowledge even earlier. A Zoll employee admitted to being notified of Philips's allegations of infringement as early as 2008. J.A. 1958–59, 1978–80. The July 2009 letter also is clearly a continuation of some ongoing discussion between counsel for Philips and Zoll. However, Philips does not direct our attention to any proof of this earlier 2008 infringement contention, and we cannot assume that it was presented to the jury given that it does not appear in the record before us. Therefore, we are limited to saying that no reasonable jury could have concluded that Zoll lacked knowledge of the '374 self-test patent and Philips's allegations of infringement as of July 2009.

Accordingly, as of July 2009, lack of knowledge of the patents and infringement cannot stand as the basis for the jury's verdict of no contributory infringement for the claims of the '374 self-test patent. However, lack of knowledge of the patents and infringement can stand as the basis for the jury's verdict of no contributory infringement for the claims of the '454 waveform patent and the '905 waveform patent.

C. Substantial Non-Infringing Use

Philips alleges that the Zoll defibrillators do not have any substantial non-infringing use for the self-test features. In response, Zoll identifies several allegedly non-infringing uses that it claims the jury could have relied on to reach its verdict.

An accused contributory infringer will not be held liable for such infringement if the "component" or "material or apparatus" that that party sells is "suitable for substantial noninfringing use." § 271(c); *see also Ricoh Co., Ltd. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1337 (Fed. Cir. 2008). A complication arises when the asserted patent claims cover only one aspect or feature of the "component" or "material or apparatus" that the accused contributory infringer sells. *See Ricoh*, 550 F.3d at 1337–

40. That complication is present in this case, because the self-test features that are covered by the '374 self-test patent are general features of the composite defibrillator devices.

In such cases, we have sought to assure that the accused contributory infringer is not "'permitted to escape liability as a contributory infringer merely by embedding [the infringing apparatus] in a larger product with some additional, separable feature before importing and selling it.'" *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009) (quoting *Ricoh*, 550 F.3d at 1337 (modifications in *Lucent*)). To reach this end, we have sought to determine whether the infringing component is "'separate and distinct'" from other functions of the composite product. *Fujitsu*, 620 F.3d at 1330 (quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 849 (Fed. Cir. 2010), *aff'd on other grounds*, 564 U.S. 91 (2011)). In the cases where we have directly addressed this issue, we have generally been fairly liberal in finding the accused components separate. *See Fujitsu*, 620 F.3d at 1330–31 (finding message fragmentation feature of wireless access point devices separate and distinct from other features of those devices); *i4i*, 598 F.3d at 848–49 (finding XML editor separate and distinct from other features of Microsoft Word); *Lucent*, 580 F.3d at 1321 (finding date-picker tool separate and distinct from other features of Microsoft Outlook); *Ricoh*, 550 F.3d at 1336–40 (vacating district court finding that optical disk drive has substantial non-infringing uses apart from patented disk-writing technology).

For the self-test patents, Zoll argues that the jury could have found a substantial non-infringing use in the form of either automatic self-tests running on a single periodic schedule or self-tests running only when instigated by a user. Zoll's Principal Br. 63–64.

As to the user-instigated self-tests, a reasonable jury could only conclude that this is a "separate and distinct" feature from the automatic, periodic self-test feature. In *Fujitsu*, we considered a similar argument regarding the message fragmentation feature in IEEE 802.11 wireless access point devices. *See Fujitsu*, 620 F.3d at 1330. There the accused contributory infringer argued that disabling packet fragmentation was a substantial non-infringing use. *See id.* We held that disabling the patented feature altogether was a separate and distinct mode of operation. *See id.*

> In the present case, [the accused contributory infringer] argues that because a user can turn off the infringing features, then there are substantial noninfringing uses. However, it is undisputed that, when activated, the product is infringing. Whether a user activates fragmentation is relevant to the extent of direct infringement, but does not establish substantial noninfringing uses.

*Id.* at 1331. This logic applies even more so here, where the record clearly shows that creation of the patented automatic, periodic self-tests was a key aspect of the products and allowed their proliferation in the marketplace. Therefore, no reasonable jury could find disabling of this critical self-test feature to be anything but a separate and distinct mode of operation for the defibrillator devices.

Zoll's arguments regarding the use of a single periodic schedule for self-tests in its devices is inapposite, because only claim 7 of the '460 self-test patent requires more than one schedule for periodic self-tests, and we have already found that claim invalid.

Therefore, a substantial non-infringing use cannot stand as the basis for the jury's verdict of no contributory infringement for the claims of the '374 self-test patent.

### D. Material Part of the Invention

Philips argues that the self-test features are material parts of the defibrillator devices, and Zoll does not contest the point. We also think the point is incontestable, and thus lack of materiality cannot stand as the basis for the jury's contributory infringement verdict.

* * *

Based on the foregoing, we find that no reasonable jury could have reached the actual jury's verdict of no contributory infringement by Zoll, but only as to the claims of the '374 self-test patent. Therefore, we reverse the district court's denial of JMOL of contributory infringement as to claims 42 and 67–68 of the '374 self-test patent, and we affirm the district court's denial of JMOL of contributory infringement as to claim 51 of the '454 waveform patent and claims 4 and 8 of the '905 waveform patent.

## VI. INDEFINITENESS OF ELECTRODE CLAIMS

The jury found that claims 1, 8–9, 11–12, 19, and 24–25 of the '526 patent were not invalid. Philips argues that this verdict was in error, either because no reasonable jury could find the claims are not indefinite, or because the district court improperly instructed the jury on the standard for indefiniteness. We agree with Philips's latter argument.

Claim 1 of the '526 patent recites, in part:

> An electrode for transcutaneously delivering defibrillation pulses to a patient's heart, the electrode comprising:
>
> a conducting plate . . . , and
>
> a layer of electrolytic gel comprising a concentration of an electrolyte that produces a combination series resistance of two of said electrodes,

> when measured with the electrodes configured in a series circuit with a 50 Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than 1 Ω when a 200 Joule defibrillation pulse is discharged into the series circuit . . . .

Independent claim 24 recites a similar feature, and all of the other asserted claims are dependent on one of these two independent claims.

The above-quoted language of claim 1 attempts to cover the inventive discovery of the '526 patent, i.e., that low resistance of the electrode's electrolytic gel is beneficial to a point, but not below 1 ohm of resistance. In order to specify this scope of claim coverage, claim 1 essentially instructs the reader to take a defibrillator device, place the two electrodes together with the electrolytic gel between them—thus omitting the human subject from the circuit—arrange 50 ohms resistance in series with the electrodes, and then apply 200 joules of electrical energy into this circuit. With this configuration, the electrical resistance across the series of two electrodes and electrolytic gel should be more than 1 ohm.

"The Supreme Court has instructed that 'a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.'" *SimpleAir, Inc. v. Sony Ericsson Mobile Commc'ns AB*, 820 F.3d 419, 432 (Fed. Cir. 2016) (quoting *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014)). The Supreme Court laid out this standard, the need to inform with reasonable certainty, in *Nautilus*, which effected a change in the law over our previous standard for determining indefiniteness: "amenable to construction" or "insolubly ambiguous." *See Dow Chem. Co. v. Nova Chems. Corp.*, 803 F.3d 620, 630–31 (Fed. Cir.

2015). "Indefiniteness is a question of law that we review de novo, subject to a determination of underlying facts," *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1343 (Fed. Cir. 2016) (internal citations omitted), which we review under the regional circuit's reasonable jury standard, *Marcano Rivera*, 415 F.3d at 167.

Philips argues that the claim scope is insufficiently definite to satisfy 35 U.S.C. § 112 ¶ 2. In particular, because neither the claims nor the specification clarify what temperature the procedure should be performed at, how old the electrodes should be, or how many previous electrical shocks should have been applied with the electrodes, the asserted claims of the '526 patent fail to specify the scope of the claims to a sufficiently reasonable degree of clarity. Philips provided expert testimony showing a significant degree of variance in measured resistance as each of these factors changed.

But we do not find this evidence to be so clearly in favor of finding the claims indefinite that we think it appropriate to overturn the jury's verdict. The jury could have discounted Philips's experimental results and expert testimony regarding room temperature because the experiments were performed at an energy level (150 joules) different from the level specified by the claims (200 joules). The jury could have viewed the evidence on number of sequential shocks and age of the electrodes as a relatively minor source of imprecision in the claims. It is uncontested that the resistance of the electrodes only increases as the number of sequential shocks and age of the electrodes increases. Therefore, the lack of precision for having not specified these parameters would only create a lack of clarity for an ordinary artisan if the electrodes showed a resistance less than, but close to, the 1 ohm cutoff. Even then, the jury could have credited the opinion of Zoll's expert witness, who testified that an ordinary artisan would understand the age of the electrode to be bounded by its date of expiration and the

number of sequential shocks to most likely be the first such shock.

Therefore, while the lack of precise bounds on these three parameters may mean that the claims do not specify their scope with absolute precision, we cannot say that the evidence overwhelmingly proves by clear and convincing evidence that the claims fail to specify their bounds with reasonable certainty. For this reason, we do not reverse the district court's denial of JMOL of indefiniteness.

On the other hand, this elucidation of ambiguity in the scope of the claims does raise concern as to the charge the jury received prior to reaching its verdict. In instructing the jury on the indefiniteness count, the district court stated the following:

> In this case, Philips contends that the claims of Zoll's '526 patent are invalid because the language of the claims is indefinite. To prevail on that contention, Philips must show by clear and convincing evidence that a person of ordinary skill in the art would not understand what is and is not covered by the claims of Zoll's patent.
>
> The amount of detail required for a claim to be definite depends on the particular invention, the prior art, and the written description contained in the patent. Absolute clarity is not necessary. Rather, only claims that are insolubly ambiguous are indefinite. The claim language need only be as precise as the subject matter permits. Furthermore, the fact that a person of ordinary skill in the art would have to engage in some experimentation to determine the scope of the claim does not render the claim indefinite so long as the experimentation is not undue or excessive.

J.A. 5336. The district court presented these instructions to the jury prior to the Supreme Court's decision in *Nautilus*, which explains why the language of "insolubly ambiguous" was included in those instructions. Philips argues that this instruction—"only claims that are insolubly ambiguous are indefinite"—was rendered legally incorrect by *Nautilus* and resulted in a prejudice to Philips.

This court "will set aside the jury verdict, 'if the movant can establish that those instructions were legally erroneous, and that the errors had prejudicial effect.'" *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1365–66 (Fed. Cir. 2013), *rev'd on other grounds*, 135 S. Ct. 1920 (2015) (quoting *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004)) (internal quotation marks omitted).

It is without dispute that the "insolubly ambiguous" standard is legally erroneous after *Nautilus*. *See Dow*, 803 F.3d at 630–31. The only significant question in this case is whether the inclusion of the reference to the "insolubly ambiguous" standard in the broader instructions on indefiniteness thereby effected a prejudice on Philips. We conclude that it did. While we have not clarified the relationship between "insolubly ambiguous" and "reasonably certain," it must be admitted that the "insolubly ambiguous" standard is a harder threshold to meet than the post-*Nautilus* standard. Thus, if the jury actually applied the "insolubly ambiguous" standard, then it would be fair to conclude that the jury instructions prejudiced Philips, especially in light of the extensive case on indefiniteness that Philips presented—even though not sufficient to merit JMOL.

Zoll argues that, taken in the broader context of the jury instructions (as quoted above), the reference to the "insolubly ambiguous" standard was innocuous and not prejudicial. While there may be some factual scenario

where the reference to "insolubly ambiguous" is non-prejudicial, this is not that case. Here, the sentence, "Rather, only claims that are insolubly ambiguous are indefinite," is the strongest, most forceful statement in the entire instructions on indefiniteness. It seems almost certain that amidst the back-and-forth, give-and-take of the remainder of the jury instructions on indefiniteness, the jury would gravitate to the single, definitive statement in the instructions. Furthermore, this sentence is juxtaposed with, "Absolute clarity is not necessary," and connected with "rather, only," which slants the playing field against a finding of indefiniteness in a way that is no longer appropriate after *Nautilus*. On this basis, we find that the district court's reference to the insolubly ambiguous standard was prejudicial.

Therefore, while we do not find Philips's case on indefiniteness to be so overwhelming as to mandate a reversal of JMOL, we believe that the jury instructions incorporating the pre-*Nautilus* standard for indefiniteness warrant setting aside the jury verdict of no invalidity for indefiniteness. We affirm the district court's denial of JMOL of invalidity for indefiniteness, we reverse the district court's denial of a new trial on invalidity for indefiniteness, we vacate the jury verdict of no invalidity, and we remand the case for a new trial on invalidity for claims 1, 8–9, 11–12, 19, and 24–25 of the '526 patent.[5]

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[5] At trial, the only question of invalidity presented to the jury was indefiniteness. As discussed in the next section, an alleged prior art device, the Marquette electrode, might support additional theories of invalidity of the claims of the '526 patent. If so, those questions should also be presented to the jury at a new trial on invalidity.

## VII. ADMISSIBILITY OF EVIDENCE

The district court excluded evidence related to two distinct elements of prior art that Philips desired to present to the jury as grounds for prior art-based invalidity of the '526 patent claims. Philips argues that each of these exclusions was in error and warrants the relief of a new trial on invalidity.[6] This court reviews evidentiary rulings under the law of the regional circuit, *see AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1295 (Fed. Cir. 2014), which the First Circuit reviews for abuse of discretion, *see Acosa-Mestre v. Hilton Int'l of Puerto Rico, Inc.*, 156 F.3d 49, 56–57 (1st Cir. 1998).

Philips attempted to present evidence related to a prior art device, the Marquette Responder 1200 electrode. To show that the Marquette electrode was an invalidating prior art reference on sale prior to the '526 patent's priority date, Philips garnered three pieces of evidence: deposition testimony of an employee of Marquette Electronics, J.A. 5680–89; a Marquette Electronics sales report, J.A. 5676–79; and a Food and Drug Administration premarketing filing, a "510(k)" application, J.A. 5629–75. In denying the Marquette electrode as a ground of prior art invalidity, the district court stated:

> After consideration of the parties' supplemental memoranda with respect to the 510K notifications to the Food and Drug Administration, Dockets No. 522 and 523, the Court agrees with Zoll that such

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[6] Because we have already granted Philips the requested relief of a new trial on invalidity for the ground of indefiniteness in the preceding section, this section addresses only what grounds the district court may consider appropriate to be presented to the jury in that new invalidity trial.

> notifications are not prior art under the Patent Act, and Zoll's motion to exclude is therefore allowed.

J.A. 5005. The district court then excluded the Marquette electrode 510(k) application "as well as any testimony that intends to rely upon" that 510(k) application.

This court has repeatedly clarified that oral testimony can be used as the primary basis for evidencing prior art-based invalidity. *See, e.g.*, *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1301–02 (Fed. Cir. 2016); *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1374 (Fed. Cir. 2010). The question to be answered when such an invalidity defense is proffered is whether the oral testimony is sufficiently corroborated by other evidence. *See TransWeb*, 812 F.3d at 1301–02. This question is analyzed under a rule of reason approach and is a question of fact. *See Fleming v. Escort Inc.*, 774 F.3d 1371, 1377 (Fed. Cir. 2014).

Here, Philips attempted to use the Marquette electrode as a prior art device, not the 510(k) application as a prior art publication. *See* J.A. 5009–10. Philips intended to use the testimony of the Marquette employee to establish the Marquette electrode as an invalidating prior art device on public sale prior to the priority date of the '526 patent. The sales report and 510(k) application were presented as evidence to corroborate this oral testimony of the Marquette employee. Therefore, the relevant legal question was whether the Marquette employee's testimony was sufficiently corroborated, not whether the 510(k) application was publicly available. By excluding the Marquette electrode evidence without answering the relevant legal question, the district court abused its discretion. *See Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 134 S. Ct. 1744, 1748 n.2 (2014) ("'A district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law or on a clearly

erroneous assessment of the evidence.'" (quoting *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990))). However, while this necessitates that we vacate the district court's denial of Philips's motion for a new trial, we do not think that it is so clear that a new trial on validity using the Marquette electrode is appropriate. It may be that the evidence provided to corroborate the Marquette employee's oral testimony is insufficient under our case law. Because this is a question of fact, we must remand the issue for determination by the district court in the first instance. And the question of corroboration is generally a question left to the jury, unless the district court concludes that there is insufficient corroboration as a matter of law. *See Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1372 (Fed. Cir. 2007).

Philips also attempted to present a prior art invalidity defense based on a 510(k) application for the Physio-Control Fast-Patch. The district court excluded this evidence in the same passage quoted above. For this prior art defense, though, Philips attempted to use the 510(k) application as a prior art publication in its own right. "When considering whether a given reference qualifies as a prior art 'printed publication,' the key inquiry is whether the reference was made 'sufficiently accessible to the public interested in the art' before the critical date." *Voter Verified, Inc. v. Premier Election Sols., Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989)).

Philips theorizes that some member of the public could have found out about the application, requested it from the FDA, and then received it, because the confidentiality of the application had expired prior to the priority date of the '526 patent. But this relies on a considerable amount of conjecture that is not supported by the record. As to this particular 510(k) application, Philips presented no evidence of indexing or cataloguing, which, while not prerequisites, serve as hallmarks of public accessibility.

*See Voter Verified*, 698 F.3d at 1380. While the record shows that a third-party did request the 510(k) application using a Freedom of Information Act request prior to the priority date of the '526 patent, J.A. 5586, the record also shows that the FOIA requester did not receive the 510(k) application until after the '526 patent's priority date, J.A. 5585. The fact that the application was not received by a member of the public until then further supports the district court's implicit determination that the Physio-Control 510(k) application was not sufficiently available to the public prior to the priority date of the '526 patent. Therefore, the district court did not abuse its discretion in excluding this evidence from the invalidity trial.

Based on the foregoing, we affirm the district court's denial of a new trial based on exclusion of the Physio-Control 510(k) application evidence, we vacate the district court's denial of a new trial based on exclusion of the Marquette electrode device evidence, and we remand to the district court for a determination of whether the testimony as to the Marquette electrode is sufficiently corroborated to proceed in a new invalidity trial.

## VIII. CONCLUSION

For the reasons stated herein, we act on the district court's judgments as follows:

we affirm the district court's denial of JMOL of invalidity as to claims 4 and 8 of the waveform '905 patent;

we reverse the district court's denial of JMOL of invalidity as to claim 7 of the self-test '460 patent;

we reverse the district court's denial of JMOL of invalidity as to claim 43 of the self-test '374 patent;

we affirm the district court's denial of JMOL of invalidity as to claims 42 and 67–68 of the self-test '374 patent;

we affirm the district court's denial of JMOL of no direct infringement as to claim 51 of the '454 waveform patent and claims 4 and 8 of the '905 waveform patent;

we affirm the district court's denial of JMOL of no direct infringement as to claims 1 and 5 of the '212 waveform patent;

we affirm the district court's denial of JMOL of no direct infringement as to claims 42 and 67–68 of the '374 self-test patent;

we reverse the district court's denial of JMOL of contributory infringement as to claims 42 and 67–68 of the '374 self-test patent;

we affirm the district court's denial of JMOL of contributory infringement as to claim 51 of the '454 waveform patent and claims 4 and 8 of the '905 waveform patent;

we affirm the district court's denial of JMOL of invalidity for indefiniteness for claims 1, 8–9, 11–12, 19, and 24–25 of the '526 patent;

we reverse the district court's denial of a new trial on invalidity for indefiniteness for claims 1, 8–9, 11–12, 19, and 24–25 of the '526 patent;

we vacate the jury verdict of no invalidity for claims 1, 8–9, 11–12, 19, and 24–25 of the '526 patent;

we remand the case for a new trial on invalidity for claims 1, 8–9, 11–12, 19, and 24–25 of the '526 patent;

we affirm the district court's denial of a new trial based on exclusion of the Physio-Control 510(k) application evidence;

we vacate the district court's denial of a new trial based on exclusion of the Marquette electrode device evidence; and

we remand to the district court for a determination of whether the testimony as to the Marquette electrode is sufficiently corroborated to proceed in a new invalidity trial.

**AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED**

COSTS

No costs.