

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

**CERTAIN RADIO FREQUENCY
MICRO-NEEDLE DERMATOLOGICAL
TREATMENT DEVICES AND
COMPONENTS THEREOF**

Investigation No. 337-TA-1112

**COMPLAINANTS' PETITION FOR REVIEW OF ORDER NO. 21: INITIAL
DETERMINATION GRANTING RESPONDENTS ENDYMED MEDICAL LTD. AND
ENDYMED MEDICAL, INC.'S MOTION FOR SUMMARY DETERMINATION THAT
THE ASSERTED CLAIMS OF U.S. PATENT NO. 9,510,899 ARE INDEFINITE UNDER
35 U.S.C. § 112, ¶¶ 2 AND 6**

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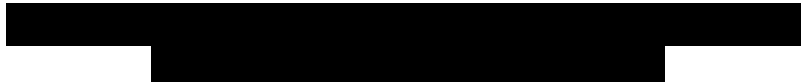
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I. INTRODUCTION

The Commission should review and reverse Order No. 21, an initial determination that improperly granted summary determination that the claims of U.S. Patent No. 9,510,899, one of the two asserted patents involved in this investigation, are invalid as indefinite.¹ The ID is erroneous for three fundamental reasons: 1) it does not apply the Federal Circuit's appropriate legal standard; 2) it repeatedly fails to resolve factual disputes in favor of the non-movant as is required in a summary determination proceeding; and 3) in at least one telling instance, it reaches a factually incorrect assumption. In the absence of factual support, it is simply inappropriate for an ID to reject the evidence that was submitted and instead assume facts to the contrary, particularly where, as here, reality is exactly the opposite of that assumption.

First, the ID incorrectly applied the relevant law governing the question of whether a claim term should be construed as a means-plus-function element pursuant to 35 U.S.C. § 112, ¶ 6. The claim term at issue here is "control module." Its purpose in the claimed invention is to govern the amount of radio frequency ("RF") energy that will be applied to a patient's skin through a group of needles. Contrary to the picture the ID attempts to paint, the control module of the claimed invention is not a complicated structure. At a time when the industry trend was to blast high amounts of energy into the skin to cause one big wound, the control module of the invention was used to cause the RF generator to apply a lower amount of energy, which led to lots of tiny wounds, leading to an unexpected result. Setting that lower level of energy simply

¹ See Order No. 21: Initial Determination Granting Respondents EndyMed Medical Ltd. and EndyMed Medical, Inc.'s Motion for Summary Determination that the Asserted Claims of U.S. Patent No. 9,510,899 Are Indefinite Under 35 U.S.C. § 112, ¶¶ 2 and 6 (hereinafter "the ID.").

required plugging in new set points into a standard control module to deliver less energy than what was known before.

The claims do not recite the term “means,” creating a presumption that § 112, ¶ 6 does not apply. That presumption can be overcome in certain circumstances, but not if “the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as *the name for structure*.” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc) (emphasis added). The ID failed to apply, or even cite, that fundamental test in reaching its decision, and ultimately came to the wrong conclusion.

Had the ID tried to answer that straightforward question—is the term “control module” a name for structure to a person of ordinary skill in the art?—it could have come to only one conclusion: persons of ordinary skill in the art use the term “control module” to refer to a known structure in the medical device field. Indeed, the un rebutted sworn testimony established that all medical devices that deliver energy to the body, like those involved in this investigation, have a control module or controller that governs the delivery of energy, and persons of skill in the art know the term, use the term, and know what structure or class of structures is meant when the term is used. Complainants² submitted literally dozens of references from the medical device field using the term “control module,” demonstrating that the term is “used in ‘common parlance or by persons of skill in the pertinent art to designate structure, such that it connotes sufficient structure to avoid the application of § 112, para. 6.’” *Diebold Nixdorf, Inc. v. Int’l Trade Comm’n*, 899 F.3d 1291, 1302 (Fed. Cir. 2018) (quoting *Advanced Ground Information Sys., Inc., Life360, Inc.*, 830 F.3d 1341 (Fed. Cir. 2016) and *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382

² The Complainants are Syneron Medical Ltd., Candela Corporation, and The Massachusetts General Hospital (collectively referred to as “Syneron”).

F.3d 1354, 1359 (Fed. Cir. 2004), *overruled on other grounds by Williamson, supra.*). Moreover, Respondents in this case freely used the term “control module” in describing the accused products, in their own patents and in an FDA submission. That evidence was supported as well by declarations from two experts and even deposition testimony from Respondents’ own expert, who described a control module for an RF generator--the technology involved here--and agreed that the term was well-known:

9 Q. Would you have to use a control?

10 Maybe I misunderstood.

11 A. You mean a control module or a
12 control --

13 Q. What is a control module?

14 A. Well, it could mean many things.
15 For an RF generator it is a controller that sets
16 the output voltage of the generator, generally
17 speaking.

18 Q. Uh-huh.

19 A. But, you can control the current.
20 You can control the power.

21 Q. Is a control module a term that you
22 regularly used, or is that something that you are
23 just making up now?

24 A. Oh, no, it is a standard
25 terminology.

1 Q. In the field?

2 A. Yes.

3 Q. In 2004, was it standard
4 terminology?

5 A. To me, it is, was, yes.

6 Q. To a person of ordinary skill in the
7 art in 2004?

8 A. Yes.

9 Q. In 1994, was it a standard
10 terminology to a person of ordinary skill in the
11 art?

12 A. Yes.

Excerpt from Pearce Deposition, Exhibit 1 to Complainants’ Motion to Supplement Opposition.

Respondent EndyMed³—who bore the burden of overcoming the presumption that § 112, ¶ 6 does not apply by a preponderance of evidence—offered no contrary testimony or evidence and relied on only attorney argument to support its position. *See, e.g., Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1007 (Fed. Cir. 2018), quoting *Advanced Ground Info. Sys., Inc. v. Life360, Inc.*, 830 F.3d 1341, 1347 (Fed. Cir. 2016). Yet the ID dismissed Syneron’s evidence and instead fixated on several non-dispositive sub-factors cobbled together from case law instead of confronting the single most salient issue—whether the term itself refers to structure recognized by a person of ordinary skill in the art. Because the ID failed to apply the proper test, the ID’s conclusion that § 112, ¶ 6 applies is legal error.

Second, the ID quoted but failed to follow the basic legal framework governing rulings on summary determination motions, which compel the Administrative Law Judge to view the evidence “in the light most favorable to the party opposing the motion . . . with doubt resolved in favor of the nonmovant,” and allows the ALJ to grant summary determination only where there is no genuine issue of material fact. *See* ID at 5, citations omitted. Instead, the ID did the exact opposite, viewing the wealth of evidence regarding the common usage of the term “control module” in the relevant field—expert declarations, contemporaneous patents and other publications, and admissions from respondents’ own expert and corporate witnesses—in the light ***least favorable*** to Syneron, the non-movant. For example, the ID characterized Syneron’s evidence as not “convincing,” ID at 17, or “conclusory and unsupported” and “insufficient,” ID at 13, and dismissed Syneron’s expert testimony as “unpersuasive.” ID at 20. Yet the ID itself quoted, apparently without intending to follow, the Federal Circuit’s instruction that “[w]hen

³ The Respondents who filed the summary determination motion are EndyMed Medical Ltd. and EndyMed Medical, Inc. (“EndyMed”).

The ID simply ignored the very case law it quoted, which states that “the purpose of summary judgment [or determination] is not to deprive a litigant of a fair hearing, but to avoid an unnecessary trial.” ID at 5 (quoting *EMI Group N. Am., Inc. v. Intel Corp.*, 157 F.3d 887, 891 (Fed. Cir. 1998)). Here, the ID did exactly what it said it should not do—it deprived Syneron the right to a fair hearing in which to present evidence on the key factual issue of how persons of ordinary skill in the art use certain terms, and improperly weighed and evaluated evidence at the summary determination stage instead of construing that evidence in Syneron’s favor.

⁴ Because EndyMed never took this position in its motion, and this implausible factual determination appeared for the first time in the ID, Syneron was afforded no opportunity to contest it with additional evidence. Sworn direct testimony already exchanged between the parties as part of the pre-hearing exchange of proposed evidence establishes this fact in even more detail than what was submitted in opposition to EndyMed's original motion, and is attached at Ex. A.

Contrary to the ID's conclusion, the claim term "control module" is understood by a person of ordinary skill in the art to refer to a well-known structure in the relevant field and, therefore, the term is not a "means-plus-function" claim element to be interpreted under 35 U.S.C. § 112, ¶ 6, and the claims are not invalid as indefinite under 35 U.S.C. § 112, ¶ 2. And at a minimum, the issue should not have been resolved at the summary determination stage. The ID should be reviewed and reversed, and Syneron should be entitled to present its compelling evidence at trial.

II. PROCEDURAL BACKGROUND

The ID sets forth the procedural background related to EndyMed's motion for summary determination of invalidity under 35 U.S.C. § 112, ¶¶ 2 and 6. (Motion Docket No. 1112-006, hereinafter referred to as "EndMed Mot."). ID at 1-2. As the ID points out, the initial motion, opposition, reply, and surreply, were filed between September 11 and November 9, 2018. It should be noted, however, that the § 112, ¶ 6 issue raised in EndyMed's motion was also addressed as a claim construction issue in the parties' Markman briefs, filed on October 5 and October 30, 2018, and addressed at length during the Markman hearing on November 13, 2018. *See, e.g.*, Markman Hearing Tr. 73:3-132:14. Indeed, the ID cites to Syneron's Markman Brief and addresses certain arguments raised in the Markman briefing even though those arguments were not raised in the summary determination briefing. *See, e.g.*, ID at 14 and 16. Accordingly, Syneron suggests that the record on which the ID rested its decision is the briefs, evidence, and arguments raised in connection with both the summary determination motion itself as well as the Markman proceedings.

III. THE '899 PATENT CLAIMS AND SPECIFICATION

U.S. Patent No. 9,510,899 is titled “Method and Apparatus for Dermatological Treatment and Tissue Reshaping.” Ex. A to EndyMed Mot. The claims of the '899 patent are all directed to devices, while the claims of the other asserted patent, which is not affected by the ID, are directed to methods. Claim 1 provides:

1. A skin treatment device comprising:
a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein, wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.

'899 Patent, Claim 1 (emphasis added). Independent claims 15, 20, and 26 are similar, but also include the concept that the fractional damage includes thermally-damaged regions in the dermal layer near or between the needles, surrounded by undamaged regions.

EndyMed's motion addressed the second paragraph of claim 1, specifically the “control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles” In the preferred embodiment shown in Figure 3, the control module 330 is shown to be a structure physically located inside housing 340 and connected to RF energy source 320 in a way to enable it to control the RF energy delivered to the needles 350, which in turn causes fractional thermal damage regions 370 in the dermis 350:

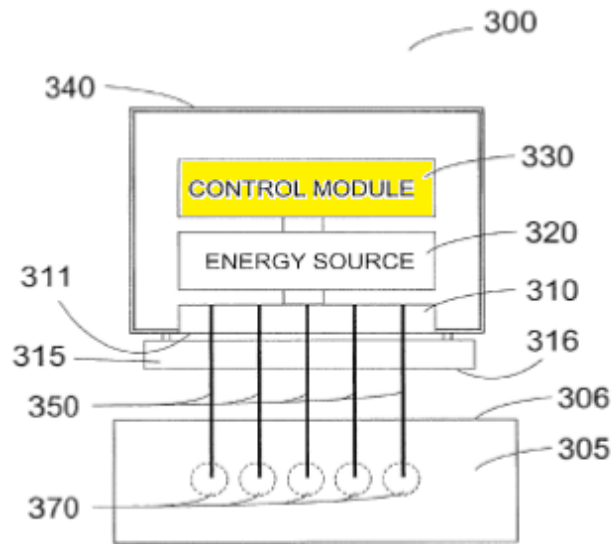


FIG. 3

The specification further indicates that the control module 330 and the energy source 320 can also be physically located outside the housing 340. *Id.* at 5:49-51. Although EndyMed’s motion contends that “control module” is a functional claim element, there is no dispute that every other feature shown in Figure 3, including housing 340, energy source 320, base 310, spacer 315, and needles 350, are physical structures.

Fundamentally, control module 330 is “configured to deliver controlled amounts of RF current to one or more needles 350.” *Id.* at 6:15-17. The control module of the preferred embodiment can also provide “application-specific settings to the energy source 320,” which then “generates a current directed to and from specified needles for selected or predetermined durations, intensities, and sequences based on these settings.” *Id.* at 5:56-61. The specification provides examples of preferred needle spacings and an example of the ranges of total energy dosage that the control module can send to each needle in the preferred spacing. *Id.* at 8:9-33.

IV. EVIDENCE REGARDING WIDESPREAD USE OF THE TERM “CONTROL MODULE” IN THE RELEVANT FIELD

As the Federal Circuit has repeatedly made clear, “[w]hen evaluating whether a claim limitation invokes § 112, ¶ 6, the essential inquiry remains ‘whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.’” *Zeroclick*, 891 F.3d at 1007, quoting *Williamson*, 792 F.3d at 1348; *see also Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996) (“What is important is ... that the term, as the name for structure, has a reasonably well understood meaning in the art.”). Accordingly, Syneron presented a range of evidence explaining the technical field encompassing the claimed invention and how people in that field use the term “control module,” including presenting many examples where the term is used in technical references. That evidence demonstrated that the term is in the “common parlance” for a known structural element in these sorts of systems and is not a coined term meant to replace a means-plus-function claim element. *See Lighting World*, 382 F.3d at 1359-60 (“In considering whether a claim term recites sufficient structure to avoid application of section 112, ¶ 6, we have not required the claim term to denote a specific structure. Instead, we have held that it is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function.”).

The device claimed in the ’899 patent is part of a class of medical devices that apply energy to human tissue. There are many such devices, from those, as here, that apply RF energy, to devices that apply optical laser energy, microwave energy, or ultrasound energy, all for

various purposes. Mehta Decl., Ex. A to Syneron Opposition to EndyMed Mot., ¶ 9.⁵ Every such medical device includes three primary components: 1) an energy source; 2) an interface for transferring energy to tissue; and 3) a control module that regulates the delivery of energy from the energy source to the tissue. Stauffer Declaration, Ex. B to Syneron Opposition to EndyMed Mot., ¶ 5;⁶ Mehta Decl. at ¶ 9. In order for a medical device that delivers energy to tissue to work, it must employ all three components. *Id.* A “control module” for controlling energy delivery to tissue is therefore a well-understood and commonly-used term in the art to refer to the structure that serves the purpose of governing power delivery to the apparatus to which it is connected. *See generally* Mehta Decl. at ¶ 14 and Attachment B; Stauffer Decl. at ¶ 14 (“Persons of ordinary skill working in the field in 2004 would certainly understand that every medical device delivering energy to tissue requires a control for controlling energy delivery, and in that context, they would understand a ‘control module’ as a specific structure for regulating the energy delivery to the tissue.”).

Syneron did not rely simply on those expert declarations, but also identified independent documentary evidence that the term “control module” was used in “common parlance” by skilled artisans in the pertinent field to designate structure. *Contra Diebold*, 899 F.3d at 1302 (criticizing the Commission and the patent owner for failing to “point to documentary evidence that the term

⁵ Declarant Bankim Mehta is an engineer and medical device entrepreneur with over 25 years of experience in the field of medical devices that deliver energy to human tissue, Mehta Decl. at ¶ 4, including specifically working on developing RF microneedling products. Mehta Decl. at ¶ 5. He testified that he has worked with engineers and scientists in the medical device field throughout his career and understands the terminology used in that field. Mehta Decl. at ¶ 6.

⁶ Paul Stauffer is a Medical Physicist currently on the faculty of Thomas Jefferson University with degrees in physics, electrical engineering, and clinical engineering, and has focused throughout his 30+ year career on medical devices that deliver energy to mammalian tissue. Stauffer Decl. at ¶¶ 2 and 4.

‘cheque standby unit’ was used either in ‘common parlance’ or by skilled artisans in the pertinent field to designate structure.”). Attachment B to Mr. Mehta’s declaration cites to and includes over 50 references using the term “control module” in the context of medical devices that apply energy to tissue, and all consistently use that term to refer to the structure that governs energy delivery. Some examples, from both before and after the 2004 filing date of the ’899 patent, are:

- Lumenis (a Respondent in this investigation) U.S. Patent Publication 2002/0165595 at ¶ 0032, Attachment B-4 to Mehta Decl., a 2002 application describing a method of ablating biological material with electromagnetic radiation delivered by optical fiber:

[0032] According to some embodiments of the present invention the illumination source **202** may be operatively connected to a control module **216**. The control module **216** may be adapted control the operation of the illumination source **202**, including but not limited to switching between an active mode and an inactive mode, controlling the intensity of the radiation, controlling the duration of each active session, controlling the wavelength of the output radiation and pulsing the output of the illumination source **202**. The control module may include known equipment used with electromagnetic radiation sources such as a power supply.

- U.S. Patent 8,287,524 at 4:22-32 and Fig. 1, Attachment B-5 to Mehta Decl., based on a 2002 patent application covering a method for performing radiation treatments on biological tissue using lasers:

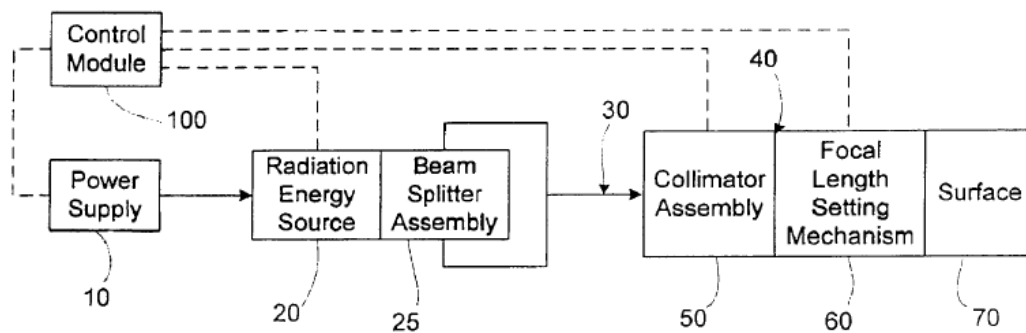


FIG. 1

A control module is further provided and is operatively associated with the radiation energy source or sources, the collector assembly, the collimator assembly, and the adjustable focal length setting mechanism. In this regard, the control module is configured to provide precise control over the total amount of radiation emitted, as well as the wavelength and energy density of the radiation that affects the biological tissue. In one embodiment of the present invention, each radiation energy source has an energy output in the range of approximately 1 mW to 25,000 milliwatts ("mW"), and utilizes a laser beam as the source of radiation energy.

- U.S. Patent 7,901,400 at 5:18-25 and Fig. 1, Attachment B-6 to Mehta Decl., based on 1999 and 2004 provisional applications covering an RF electrosurgical system:

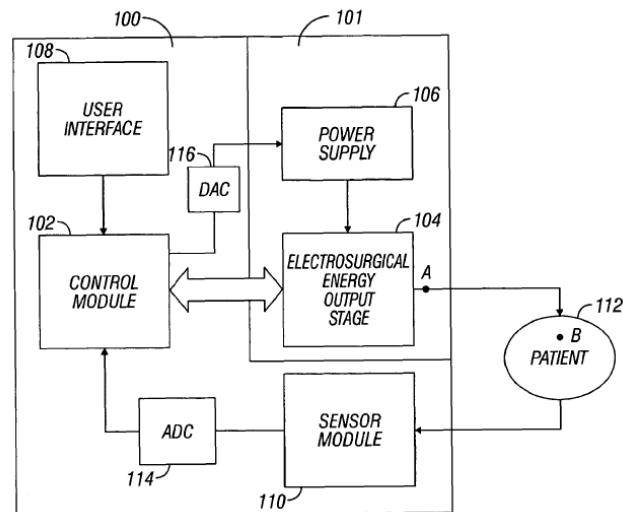


FIG. 1

various figures. Referring to FIG. 1, there is shown a schematic diagram of one embodiment of the presently-disclosed closed loop control system 100 for use with an electrosurgical generator 101. Control system 100 includes a control module 102, user interface 108 and sensor module 110. The control module 102 is operatively connected to the generator 101. The control module 102 controls energy delivery by an electrosurgical instrument to a patient. A typical electrosurgical

- U.S. Patent Publication 2009/0156958 at ¶ 93, Attachment B-10 to Mehta Decl., a patent publication based on Mr. Mehta's own 2007 provisional application covering a system for applying RF energy to dermis layer through needles:

In addition, the use of a temperature sensor 52 allows for a measurement of the adjacent dermal tissue in or near the treatment zone 160. This measurement provides a control mechanism for the power control module to adjust power delivery to the energy delivery element 36 to achieve the desired temperature/effect.

- U.S. Patent Publication 2009/0156958 at ¶ 256 and Fig. 25, Attachment B-12 to Mehta Decl., publication based on 2004 and 2006 provision applications covering system for treating skin with ultrasound energy:

lifts and deep tissue tightening are provided. For example, in accordance with an embodiment, with reference to FIG. 25, a treatment system 2100 (or otherwise referred to as a cosmetic treatment system or CTS) configured to treat a region of interest 2106 (or otherwise referred to as a treatment zone) comprises a control system 2102 (or otherwise referred to as a control module or control unit), an imaging/therapy probe with acoustic coupling 2104 (or otherwise referred to as a probe, probe system, hand wand, emitter/receiver module, removable transducer module), and a display system 2108 (or otherwise referred to as display or interactive graphical display). Control system 2102 and display system 2108 can

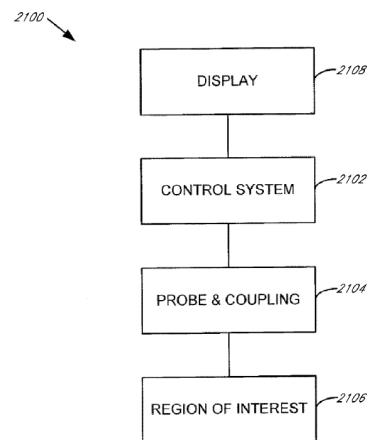


FIG. 25

- U.S. Patent Publication 2007/0173811 at ¶¶ 0035 and 0036, Attachment B-23 to Mehta Decl., a publication based on a 2006 application covering a system for tissue division:

[0035] The control module 204 processes information and/or signals input to the processor 202 by the peripheral device(s) 208 and generates control signals for modulating the electrosurgical energy in accordance with the input information and/or signals. Information input via the peripheral device 208 may include pre-surgical data entered prior to the electrosurgical procedure or information entered and/or obtained during the electrosurgical procedure through the sensor module 214. The information may include requests, instructions, ideal mapping(s) (e.g., look-up-tables, continuous mappings, etc.), sensed information and/or mode selection.

[0036] The control module 204 regulates the generator 16, e.g., the power supply 50 and/or the output stage 52, which adjust various parameters of the electrosurgical energy delivered to the patient during the electrosurgical procedure. Parameters of the delivered electrosurgical energy which may be regulated include, for example, voltage, current, resistance, intensity, power, frequency, amplitude, and/or waveform parameters, e.g., waveform shape, pulse width, duty cycle, crest factor, and/or repetition rate of the output and/or effective energy.

- U.S. Patent Publication 2008/0027509 at ¶ 0021 and Fig. 1, Attachment B-28 to Mehta Decl., publication based on a 2006 application covering a system for healing wounds and treating skin:

[0021] These and other objects of the invention are accomplished in accordance with the principles of the present invention by providing an electrode system for applying a therapy to a wound or skin that includes a feedback sensor. The electrode system may include a control module and first and second electrodes. The first electrode may be applied to the wound, while the second electrode may be applied to skin surrounding the wound. The control module is configured to apply a voltage potential across the first electrode and the second electrode. The feedback sensor is coupled to the control module, and is configured to detect at least one factor that affects wound growth or a treatment factor. The feedback sensor provides an output to the control module, and the control module may adjust the voltage potential based on the output from the feedback sensor. By adjusting the voltage potential, the control module adjusts the therapy applied to the wound.

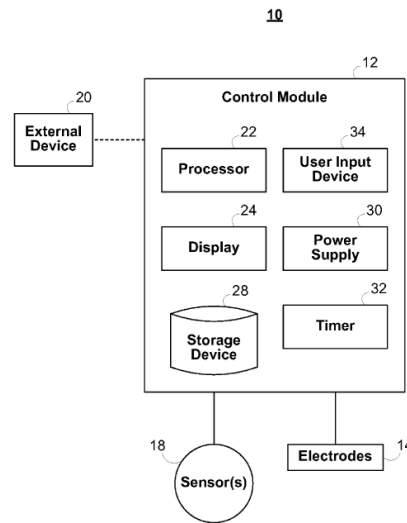
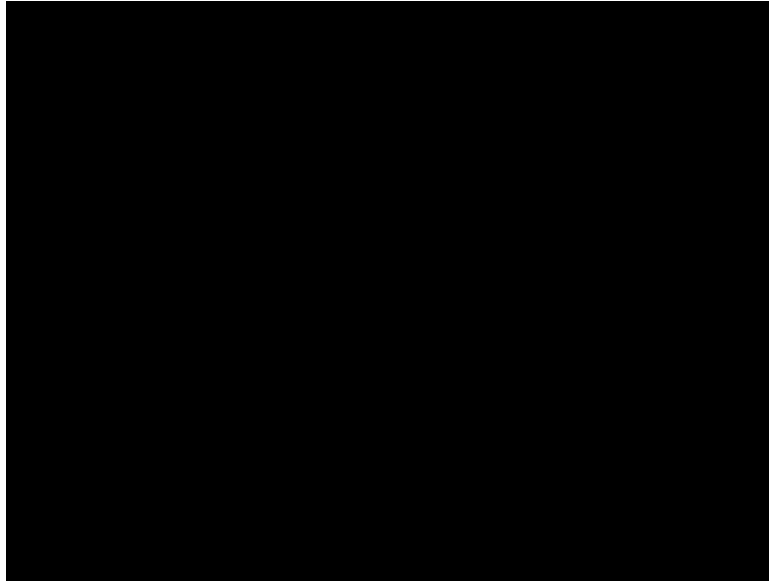


FIG. 1

Documents and testimony produced in this case also confirm that the term “control module” is widely used and understood, not a made-up or “nonce” term appearing only in the ’899 patent. For example, and as noted above, Respondents’ invalidity expert, Dr. John Pearce, used the term “control module” without being prompted, and called it “standard terminology” in the field. Ex. 1 to Motion to Supplement Opposition. Respondent Lumenis used the term,

[REDACTED]

alongside clearly structural terms like “user interface” and “RF generator,” to describe one of the components of the accused Legend product in its 510(k) application to the Food and Drug Administration:



Syneron Rebuttal Markman Brief, Ex. 8. Likewise, a Lumenis corporate representative testified at deposition about the “control module” in the Lumenis product without ever seeking clarification about what the term meant, and stated that he had never seen a medical device that delivers RF energy to the skin that doesn’t have a control module. Syneron Rebuttal Markman Brief, Ex. 9.

The evidence also made it clear that, far from being a coined term for the ’899 patent or a mere replacement for the phrase “means for controlling,” in the medical device field, “control module” is used synonymously with “controller,” “control unit,” or “control system,” all of which are interchangeable names for the structure that serves the purpose of governing power delivery to the apparatus to which it is connected. Mehta Decl. at ¶¶ 9-10, citing as an example U.S. Patent App. No. 20130345562 at ¶ 0256, disclosing “a control system 2102 (or otherwise referred to as a control module or control unit)”; Stauffer Decl. at ¶ 12 (“a person of ordinary

skill in the art working in the field in 2004 and today would interchangeably understand the term ‘control module,’ ‘controller,’ ‘control unit,’ and ‘control system’ as being one and the same in the context of controlling energy delivery to tissue.”).

The prosecution history of the related ’357 patent confirms that usage. There, the patent examiner identified a prior art patent to Utely and applied it to the pending claims in the application. The Utely patent described a system that delivered RF energy to the surface of the skin using needles, and Utely’s system identified a “controller 48” that “governs the power levels, cycles, and duration that the radio frequency energy is distributed to the applicator 30, to achieve and maintain power levels appropriate to achieve the desired treatment objectives.” The patent examiner equated the “control module” of the ’899 patent claims with the “controller” described in Utely, making no distinction between the two similar terms. In fact, the examiner even referred to Utely’s “controller 48” as “control module 48,” showing that in the context of medical devices that apply energy to tissue, “control module” is interchangeable with and has the same meaning as a “controller.” Syneron Opposition to Motion, Ex. C, at 5.⁷

In 2004, the time the ’899 application was filed, as well as today, controls for regulating energy delivery could be purchased off-the-shelf from various manufacturers or could be fashioned from off-the-shelf components. Alternatively, certain systems may also incorporate software to make up a control module or controller. But persons of ordinary skill in the art would still consider a control module or controller to be a well-recognized name for a known structural element in these sorts of systems. Mehta Decl. at ¶ 10; *see also* Stauffer Decl. at ¶ 14-15.

⁷ As a further example, U.S. Patent No. 6,126,657, issued to Edwards, described a “controller” to control the amount of RF energy being supplied to the tongue. Mehta Decl., Attachment D, at 12:22-23. Edwards’ usage of “controller” is synonymous with a control module, control unit, or control system, as those terms are used in the art. Mehta Decl. at ¶ 9.

V. ARGUMENT

The ID erred in finding that the claim term “a control module for controlling delivery of RF energy” should be treated as a means-plus-function term. Fundamentally, the ID failed to apply what the Federal Circuit has described as “the standard” and “the essential inquiry” for such determinations—whether the term would be considered a name for structure by a person of ordinary skill in the art. Instead, the ID focused on less dispositive issues, like the mere presence of the word “module” in the term, and the fact that the claim language contains a description of the function the “control module” must play. Those inquiries, while potentially relevant factors in the overall determination, are not the test, and the ID’s fixation on factors other than the “essential inquiry,” among other errors, resulted in a flawed analysis. Further, the ID abandoned any pretense of applying governing rules regarding summary determination motions and rejected evidence that should have credited and construed in Complainants’ favor.

A. The ID Failed to Justify its Conclusion that EndyMed Overcame the Presumption that §112, ¶ 6 Does Not Apply

The relevant claim language does not use the word “means.” As the Federal Circuit’s *en banc* decision in *Williamson* makes clear: if a claim does not use the language “means for” or “means,” it is presumed that §112, ¶ 6 does not apply. *Williamson*, 792 F.3d at 1348; *see also Zeroclick*, 891 F.3d at 1007. Indeed, the Federal Circuit “has long recognized the importance of the presence or absence of the word ‘means.’” *Williamson*, 792 F.3d at 1348; *Zeroclick*, 891 F.3d at 1009. “In determining whether this presumption has been rebutted, the challenger must establish by a preponderance of the evidence that the claims are to be governed by § 112, ¶ 6.” *Advanced Ground Info. Sys.*, 830 F.3d at 1347; *Zeroclick*, 891 F.3d at 1007.

There can be no serious dispute about the proper inquiry a court must undertake to determine whether a claim term should be construed as a mean-plus-function element even where the claim does not use the words “means for”:

When evaluating whether a claim limitation invokes § 112, ¶ 6, the essential inquiry remains “whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.”

Williamson, 792 F.3d at 1348; *Greenberg*, 91 F.3d at 1583 (“What is important is ... that the term, as the name for structure, has a reasonably well understood meaning in the art.”).

Zerocklick, 891 F.3d at 1007; *see also Diebold*, 899 F.3d at 1297. Nonetheless, the ID never refers to that test anywhere. And other than a single paragraph that relies on an irrelevant case, *see* ID at 14, the ID never confronts the testimonial and documentary evidence that Syneron submitted demonstrating that “control module” was understood by persons of skill in the art as a name for structure. And since the ID never even cited the proper test, the ID also never explicitly found that a person of ordinary skill in the relevant art would not have understood “control module” to be a name for structure.

The ID dismisses the patents, patent applications, and other references that use the term “control module” by citing to *Pressure Prods. Medical Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1317 (Fed. Cir. 2010) for the proposition that “simply mentioning prior art references in a patent does not suffice as a specification description to give the patentee outright claim to all of the structures disclosed in those references.” ID at 14. That case and that proposition have nothing to do with the issue at hand. In *Pressure Products*, the court was attempting to determine what corresponding structure was disclosed in the specification for an admitted means-plus-function claim element. The lower court had gone beyond the specification and identified structures appearing in cited prior art references, expanding the corresponding structure far

beyond what was expressly disclosed in the specification. The Federal Circuit reversed, finding that the corresponding structure must appear in the specification, not in other documents cited somewhere in the patent, since § 112, ¶ 6 expressly says the corresponding structure must be “described in the specification.” *Id.* at 1317. But that ruling has nothing to do with how one determines whether a claim term is used in the “common parlance” as a name for structure. In that inquiry, reference to extrinsic evidence beyond the patent itself, including for example dictionaries or prior art, is not only permitted, it may be the best way to understand the usage in the relevant field. For example, the Manual of Patent Examining Procedure § 2181, teaches examiners:

To determine whether a word, term, or phrase coupled with a function denotes structure, examiners should check whether: (1) the specification provides a description sufficient to inform one of ordinary skill in the art that the term denotes structure; (2) general and subject matter specific dictionaries provide evidence that the term has achieved recognition as a noun denoting structure; and (3) the prior art provides evidence that the term has an art-recognized structure to perform the claimed function.

See also Diebold, 899 F.3d at 1302 (criticizing the Commission and the patent owner for failing to “point to documentary evidence that the term ‘cheque standby unit’ was used either in ‘common parlance’ or by skilled artisans in the pertinent field to designate structure.”).

The ID’s complete dismissal of the testimony and documentary evidence on the common usage of “control module” in the relevant field is a significant legal error. Instead, the ID rested its decision on sub-issues that, while discussed in the *Williamson* opinion, are not dispositive of the fundamental inquiry.

First, the ID noted that the claim is written “in a format consistent with traditional means-plus-function claim limitations, merely replacing the word ‘means’ with the word ‘module’ and reciting various functions performed by the ‘control module.’” ID at 10. While that is one factor

the *Williamson* court considered, it is not at all dispositive. Many claims describe the functions that a given component in a claimed invention is supposed to perform, but that does not mean those claims are governed by § 112, ¶ 6 if they otherwise use terms that are names for structure.

As one example, in *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696 (Fed. Cir. 1999), the Federal Circuit held that the claim term “digital detector” was not governed by § 112, ¶ 6 even though the claims at issue were also written in similar fashion. Specifically, the claims recited limitations such as “a digital detector for receiving said transmission and detecting said predetermined signal in said transmission based on either a specific location or a specific time.” *Personalized Media Commc'ns*, 161 F.3d at 698. Like the ID here, the Commission in *Personalized Media Commc'ns*, having found that “digital detector” was a means-plus-function element and indefinite, argued that “this limitation is defined entirely by the functional language that follows the language ‘digital detector for’” *Personalized Media Communications*, 161 F.3d at 703. The Federal Circuit rejected that argument and found that the term “digital detector” would connote structure to a person of ordinary skill in the art notwithstanding the claim language’s format.

The claims in *Zeroclick*, *supra*, also used language similar to the “control module” limitation at issue here. For example, one patent at issue in *Zeroclick* recited “user interface code being configured to detect one or more locations touched by a movement of the user’s finger on the screen without requiring the exertion of pressure and determine therefrom a selected operation.” *Zeroclick*, 891 F.3d at 1007. The district court read that claim to be a “means” for

performing two functions—detecting locations on the screen and determining a selected operation. *Id.* The Federal Circuit reversed, despite the phrasing of the claim.⁸

Second, the ID focused on the fact that “[t]he claim merely describes ‘control module’ in functional respects and nothing else in the claim describes any structure for ‘control module.’” ID at 10. But that is also not dispositive. “[T]he mere fact that the disputed limitations incorporate functional language does not automatically convert the words into means for performing such functions.” *Zeroclick*, 891 F.3d at 1008, quoting *Greenberg*, 91 F.3d at 1583 (“Many devices take their names from the functions they perform.” The examples are innumerable, such as ‘filter,’ ‘brake,’ ‘clamp,’ ‘screwdriver,’ or ‘lock.’”). The question is not whether a control module has a function or is well-known because it performs a particular function, but whether the term would indicate a particular structure or class of structures to a person of ordinary skill in the art. *Personalized Media Commc’ns*, 161 F.3d at 705 (“Moreover, neither the fact that a ‘detector’ is defined in terms of its function, nor the fact that the term ‘detector’ does not connote a precise physical structure in the minds of those of skill in the art detracts from the definiteness of structure. . . . Even though the term ‘detector’ does not specifically evoke a particular structure, it does convey to one knowledgeable in the art a variety of structures known as ‘detectors.’”). The ID’s observations concerning the functional underpinnings for the term “control module” do not compel the conclusion that the term is not a “name for structure” to a person of ordinary skill in the art. *Lighting World*, 382 F.3d at 1359-60

⁸ Other claims in the ’899 patent present similar phrasing, for example claim 6, which covers “[t]he device of claim 1, further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.” The fact that the claim dictates how the cooler is supposed to function in the context of the claimed invention does not convert the word “cooler” from a structure into a means-plus-function element.

(“Instead, we have held that it is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function.”). Indeed, if a term is a well-known name for a structure to persons of ordinary skill in the art, it would be unlikely that the patentee would feel the need to describe that well-known structure in great detail in the specification.

Third, the ID placed an inordinate amount of weight on the fact that the word “module” appears in the term “control module.” To be sure, the Federal Circuit noted in *Williamson*, that “[m]odule” is a well-known nonce word that *can* operate as a substitute for ‘means’ in the context of § 112, para. 6,” and that nonce words “*may* invoke § 112, para. 6.” *Williamson*, 792 F.3d at 1350 (emphasis added). But saying that a word *can* operate as a substitute for “means” does not mean that it *always* does, and here the evidence is overwhelming that “control module” is a regularly-used term in the applicable field, not a “verbal construct” used only in a patent claim.

Context is everything. In *Williamson*, the “distributed learning control module,” a software module used in a system for establishing virtual classrooms, was not known in the ordinary parlance. In the medical device context however, a “control module” that governs the delivery of energy to skin is a commonly-used and well-understood term, as the evidence of record establishes. That contextual difference appears to have been missed in the ID.

In focusing myopically on the term “module” and ignoring the widespread use of “control module” in the relevant technical literature, the ID missed the point of the Federal Circuit’s warning, which is to be wary of “coined” claim terms (i.e. “verbal constructs”) that attempt to turn a functional claim limitation into an apparent structure using non-specific words

like “module,” “system,” or “unit.” Thus, for example, in *Williamson*, there was no evidence that the “distributed learning control module,” had ever been used outside of the patent or had any well-understood meaning in the computer technology field. Similarly, the phrase “symbol generator” was found to be subject to § 112, ¶ 6, since that term was not used by persons of skill in the art and instead was “a term coined for purposes of the patent-in-suit.” *Advanced Ground Info. Sys.*, 830 F.3d at 1348. The “cheque standby unit” limitation addressed in *Diebold* was also “coined by the applicant himself for purposes of claiming his invention.” *Diebold*, 899 F.3d at 1302. In distinct contrast to those cases, the evidence here demonstrated that “control module” in the medical device field is a widely-used term outside of the asserted patents for a known component in systems that deliver energy to the body, so use of the word “module” in this instance is not as a “nonce” word.

In any event, even after *Williamson*, courts have found claim phrases that use the word “module” to be structural and not means-plus-function terms where the usage in the relevant field justifies that conclusion. *See, e.g., M2M Solutions LLC v. Sierra Wireless America, Inc.*, CA No. 12-30-RGA, 2016 WL 1298961, at *6 (D. Del. Mar. 30, 2018) (finding “memory module” to be structural, and noting court’s earlier decision that “processing module” is not a means-plus-function term); *Metaswitch Networks Ltd. v. Genband USA LLC*, Case No. 2:14-CV-744-JRG-RSP, 2015 WL 11197822, at *43 (E.D. Tex. Aug. 10, 2015) (finding “system controller module” to be structural in part because it includes the word “controller,” which is a known structure). In fact, even the word “module” by itself was subsequently found to be structural. *Certain Bar Code Readers, Scan Engines, Products Containing the Same, and Components Thereof*, Inv. No. 337-TA-1061, Order No. 17 at 37 (December 28, 2017). In each case, the determination turned on the standard articulated in *Williamson*—whether the words of

the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure—not on a simplistic reaction to the presence of the word “module” in the claim phrase.

It is in this regard that the ID also erred in disregarding the testimonial and documentary evidence demonstrating that “control module” is synonymous with the term “controller,” which is often adjudicated to be a structural term not subject to § 112, ¶ 6. The ID found no legal authority supporting the notion that one can look at “the definition of one term to provide structure for another term.” ID at 13. But if the terms are indeed synonyms, it is logical to conclude that they should have the same meaning and should be treated the same for purposes of determining whether a person of ordinary skill in the art would consider them names for a structure. Even the testimony of Respondents’ expert, Dr. Pearce, demonstrates that the terms are interchangeable, as he noted that a “control module” is a “controller”:

- 13 Q. What is a control module?
14 A. Well, it could mean many things.
15 For an RF generator it is a controller that sets
16 the output voltage of the generator, generally
17 speaking.
18 Q. Uh-huh.
19 A. But, you can control the current.
20 You can control the power.
21 Q. Is a control module a term that you
22 regularly used, or is that something that you are
23 just making up now?
24 A. Oh, no, it is a standard
25 terminology.

Excerpt from Pearce Deposition, Exhibit 1 to Complainants’ Motion to Supplement Opposition.

Because “control module” and “controller” mean essentially the same thing to persons in the relevant field and are used interchangeably, it is instructive to note that most courts agree that

“controller” is recognized as a name for a structure and is not a means-plus-function element. As one ALJ put it:

The term “controller” is a common term of art with familiar structure, not a nonce word that operates as a substitute for “means” in a claim. *See* M.P.E.P. § 2181.I.A (not identifying “controller” as a substitute for “means.”). In fact, several district courts have construed “controller” outside the confines of § 112(6). And at least one district court expressly held that “controller” is not a § 112(6) term.

Certain Hybrid Electric Vehicles and Components Thereof, Inv. No. 337-TA-1042, Order No. 21 at 68 (October 6, 2017) (citations set forth in footnote below).⁹ Other courts have reached the same conclusion.¹⁰ Those decisions are relevant to the synonymous term “control module,” and

⁹ The ALJ in the *Hybrid Electric Vehicles* investigation cited the following cases, providing the parentheticals: *Braun Corp. v. Vantage Mobility Int’l, LLC.*, 608 F. Supp. 2d 1036, 1045 (N.D. Ind. 2009) (construing “controller” as a device that actuates and/or directs the operation of other components described in the specification); *Toshiba Corp. v. Lexar Media, Inc.*, No. C 03-0167-MJJ, 2005 WL 6218785, at *11 (N.D. Cal. Jan. 24, 2005) (construing “controller” as “a circuit or groups of circuits for interfacing with a memory”); *Lexar Media, Inc. v. Fuji Photo Film USA, Inc.*, No. C 03-00355-MJJ, 2007 WL 677166, at *4 (N.D. Cal. Mar. 1, 2007) (construing “controller” as “a device that interfaces between host and nonvolatile memory”); *ABB Automation Inc. v. Schlumberger Res. Mgmt. Servs., Inc.*, 254 F. Supp. 2d 475, 477 (D. Del. 2003) (applying the ordinary definition of “controller” as meaning “electronic circuitry that generates a control signal”); and *911EP v. Whelen Eng’g Co.*, 512 F. Supp. 2d 713, 726-27 (E.D. Tex. 2007) (finding that “controller” did not invoke section 112(6) because “one of ordinary skill in the art would understand ‘controller’ to refer to a specific type of circuitry”).

¹⁰ *See, e.g., Sound View Innovations LLC v. Facebook, Inc.*, No. 16-cv-116 (RGA), 2017 WL 2221177, at *4-*5 (D. Del. May 19, 2017) (“controller” is not a nonce term, and that fact that “controller” “may be a class of structures, rather than one specific structure, and may be defined with functional terms, [] does not make it means-plus-function.”); *Via Vadis LLC v. Buffalo Americas, Inc.*, Cause Nos. A-14-CV-808, -810, -813, 2016 WL 5239626, at *11-*12 (W.D. Tex. Sept. 20, 2016) (rejecting argument that “controller” is a nonce word and noting dictionary definitions of “controller” that “show that [*sic*] one of ordinary skill in the art would understand this term to have an ordinary meaning.”); No. SACV 10-1946 AG (PJWx), 2012 WL 3112005, at *16-*17 (C.D. Cal. June 14, 2012) (finding that controller, “while denoting a broad class of structures, would be understood as structural by a person of ordinary skill in the art.”); *Markem-Image Corp. v. Zipher Ltd.*, Civ. No. 10-CV-112-PB, 2011 WL 5837087, at *4 (D.N.H. Nov. 11, 2011) (“While the terms ‘controller’ and ‘monitor’ undoubtedly cover a class of structures, they

provide further reasons to conclude that “control module” is not a “verbal construct” concocted for purposes of the ’899 patent to avoid the application of § 112, ¶ 6.

Finally, the ID improperly concludes that it would not matter if a person of ordinary skill in the art would understand “control module” to refer to “sufficiently definite structure” because that “control module” would be a prior art control module, not one that can perform all the functions claimed in the ’899 patent. ID at 10; *see also* ID at 13. There is no factual or logical basis for that conclusion.

At the outset, the ID makes the unsupported assumption that the “control module” of the claimed invention is wildly different from the “control modules” that persons of ordinary skill in the art would be familiar with, although the ID cites no evidence supporting that assumption. The facts are quite to the contrary. Mr. Mehta specifically testified that:

Therefore, in this case, the invention does not lie in the complexity of the control, it lies in the recognition that limiting the amount of energy delivery through needles to cause fractional wounding provided unexpected results. In the broadest sense, the invention can be accomplished with a very simple control, analogous to a light dimmer, and no additional information is required in the specification to teach a person of ordinary skill in the art how to make the invention work.

Mehta Decl. at ¶ 15. Mr. Mehta further stated that “[i]n 2004 as today, controls for regulating energy delivery could be purchased off-the-shelf from various manufacturers or could be fashioned from off-the-shelf components.” Mehta Decl. at ¶ 17. The evidence, therefore, shows that the “control module” of the claimed invention is the same class of structures that a person of ordinary skill in the art would think of when reading the term “control module.” The ID seems to conclude that one cannot have a novel system using known structures, stating that “control

are understood by persons of skill in the art as structures, and do not amount to ‘nonce words’ or ‘verbal constructs’ that are simply substitutes for the term ‘means for.’”).

modules that could perform all of the functions claimed in the '899 patent would be an advance over the prior art control modules and would not yet have been known to a person of ordinary skill in the art.” ID at 10-11. But that is simply incorrect. It is black-letter patent law that a patentable invention can result from new uses for known components. *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 18 (1892). The patentable advance in the '899 patent is combining RF energy, needles, and a total energy level that will result in fractional wounding in the dermis, something that the class of structures known at the time as “control modules” could achieve, if configured with the inventive concept in mind.

The ID also confuses § 112, ¶ 6 indefiniteness with enablement. If the term “control module” is known as a name for structure, it does not magically transform into a means-plus-function element if the claimed invention requires the control module to accomplish something new. It is still a structural term. There may be questions as to whether the specification contains a disclosure sufficient to enable a person of ordinary skill in the art to perform the claimed invention using that class of structures, but that is a different issue. *See, e.g., Avocent Huntsville LLC v. ZPE Sys. Inc.*, 2018 WL 4677437 at *11 (N.D. Cal. Aug. 23, 2018) (court rejected argument that “web server application” is a means-plus-function element because expert was “unaware of any web server or web server application that can achieve the recited function,” and noted that since “web server application” is a “known component in the computer network field,” that challenge “is better suited for a lack of enablement challenge.”).¹¹

¹¹ The court in *Avocent Huntsville LLC* did find the term “management module” to be governed by § 112, ¶ 6, but that term was admittedly a software program, very much like the “distributed learning control module” addressed in *Williamson*, and the patentee did not demonstrate that “management module” was used in common parlance or by persons of skill in the art to designate structure. *Avocent Huntsville LLC, supra* at *10. In contrast, the “control module” of the '899 patent is not a pure software module, and Syneron showed that the term is used widely in the relevant field.

In addition, the ID overstates the “functions” that the “control module” need perform, which the ID in turn uses to assert that the invention requires something different from a “prior art” control module. In fact, in each of the claims, the fundamental job of the “control module” is the same—regulate the delivery of RF energy—which is what the structures known as “control modules” in this type of product are designed to do. The added “functions” of achieving a pattern of fractional damage in the dermis, or achieving isolated damage regions near the tips of the needles, come from the total energy level used and the use of an array of needles inserted into the dermis. But the fundamental job of the “control module” remains the same no matter how each claim describes the invention. As Dr. Pearce testified, a control module for an RF generator is a “controller that sets the output voltage of the generator” That is exactly what the control module is required to do in each of the asserted claims, and the details added in the dependent claims do not expand the overall role of the control module.¹²

¹² The ID tends to add all the supposed “functions” together, including “functions” in dependent claims that depend solely from claim 1 and not each other, and states that the “control module” must be “sufficient structure for performing all of the *claimed* functions.” ID at 11 (emphasis in original). First, that is not the analysis required by *Williamson*, which is only concerned with the question of whether the terminology used would be viewed as a name for structure to a person of ordinary skill in the art. Instead, the standard the ID identified is for a very different and inapplicable scenario where a patentee argued that a claim term that **does** use the term “means” is nonetheless **not** covered by § 112, ¶ 6. *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1304 (Fed. Cir. 1999), cited at ID at 15. In that scenario, the question is whether structural elements set forth **in the claim itself** can perform the claimed function, for if they can, then the claim is not a means-plus-function claim even though the word “means” is used. That is completely irrelevant to any of the inquiries the ID was facing here, which is whether § 112, ¶ 6 applies to a claim that **does not** use the term “means.” Second, invalidity is determined on a claim-by-claim basis, *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997), and the question of whether the claim term at issue is a name for structure must be answered on an element-by-element basis, *see e.g., Zerocklock*, 891 F.3d at 1007. One must, therefore, consider the functions required in each individual claim independently and evaluate the disputed term in the context of only those functions. It is improper to add all claimed functions together, announce that the supposed means cannot perform all of them combined, and then invalidate individual claims that do not require all of those functions to be performed.

[REDACTED]

In short, the evidence convincingly proved that the term “control module” would be understood as a name for structure by persons of ordinary skill in the art in the relevant field, and therefore EndyMed did not sustain its burden of overcoming the presumption that § 112, ¶ 6 does not apply. The ID’s ruling to the contrary is legal error and should be reviewed and reversed.

B. The ID Failed to Construe the Facts in Favor of the Non-Movants and Incorrectly Concluded that There Was No Genuine Issue of Material Fact Precluding Summary Determination

The ID utterly failed to treat Syneron’s opposition to EndyMed’s summary determination motion as the law requires. Instead of viewing the evidence that Syneron submitted “in the light most favorable to the party opposing the motion . . . with doubts resolved in favor of the nonmovant,” *see* ID at 5, quoting *Crown Operations Int’l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002), the ID repeatedly dismissed or discredited that evidence, at times substituting the ALJ’s own views. If the ID had, instead, credited Syneron’s evidence and drawn “all justifiable inferences” in Syneron’s favor, the motion should have been denied since there was, at a minimum, a genuine issue of material fact that precludes summary determination. *See* Commission Rule 210.18(b) (summary determination is appropriate only if the evidence and affidavits “show that there is no genuine issue as to any material fact and that the moving party is entitled to a summary determination as a matter of law.”).

The issue at hand—whether “control module” is governed by § 112, ¶ 6—is ultimately a claim construction issue determined as a matter of law. *Zeroclick*, 891 F.3d at 1006; *Williamson*, 792 F.3d at 1346. But claim construction determinations often involve subsidiary factual questions. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (claim construction is exclusively for the court to

determine even where the construction of a term of art may have “evidentiary underpinnings”).

As the Supreme Court has noted:

In some cases, however, the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. *See, e.g., Seymour v. Osborne*, 11 Wall. 516, 546, 20 L.Ed. 33 (1871) (a patent may be “so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning”). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the “evidentiary underpinnings” of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.

For example, if a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*.

Teva Pharm., 135 S. Ct. at 841 (emphasis in original).

The determination as to whether the term “control module” would be “understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure,” *see Williamson*, 792 F.3d at 1348, or that the term “as the name for structure, has a reasonably well understood meaning in the art,” *see Greenberg*, 91 F.3d at 1583, is undoubtedly one of those subsidiary facts and “evidentiary underpinnings” of the ultimate legal question of whether § 112, ¶ 6 applies. As a result, the ALJ should not have attempted to resolve factual disputes on that issue, but should have treated the facts as the summary determination rules require and construed them in Syneron’s favor. Further, the ALJ should have denied the motion

unless there was absolutely no factual dispute on the issue the Federal Circuit identified as “the essential inquiry.” *Zeroclick*, 891 F.3d at 1007.

Contrary to that guidance, the ID repeatedly evaluates Syneron’s evidence and, at times, disregards it. For example, the ID characterized the testimony by Syneron’s experts concerning whether “control module” is understood in the field as a name for structure to be “[c]onclusory and unsupported,” ID at 13, and found other expert testimony “unpersuasive.” ID at 20. But when evaluating a summary determination motion, “all of the nonmovant’s evidence is to be credited, and all justifiable inferences are to be drawn in the nonmovant’s favor.” *Xerox Corp.*, 267 F.3d at 1364. The ID again failed to follow that standard in rejecting the un rebutted testimony, as well as the many references that were identified by Mr. Mehta in his declaration.

The ID points to the *Diebold* decision to justify its rejection of Syneron’s evidence even where EndyMed supplied no contrary evidence concerning the use of the term “control module” in the relevant technical field. ID at 12. But that reliance is misplaced. First, the *Diebold* case does not involve a grant of summary determination. Instead, that case went to trial. *Diebold*, 899 F.3d at 1296. So, the Federal Circuit was not bound by the additional restriction of having to construe all facts in favor of the non-movant, a requirement in full force here.

Second, the evidence that the court reviewed in *Diebold* was different from the evidence facing the ALJ here. As the Federal Circuit in *Diebold* noted:

Diebold’s failure to contradict Dr. Howard’s testimony with extrinsic evidence is not fatal to its ability to overcome the presumption, as the Commission and Hyosung argue, ***unless we conclude that Dr. Howard’s testimony was sufficient to overcome conclusions drawn from the intrinsic record.*** We conclude it was not.

The Commission relied on paragraphs 185, 186, and 189 of Dr. Howard’s Witness Statement in determining that the term “cheque standby unit” is not a means-plus-function term. ***It did not cite,***

and Hyosung did not introduce, any other evidence, such as dictionary definitions, suggesting that “cheque standby unit” is a term commonly understood by persons of ordinary skill in the art to denote a device or class of devices. Cf. Greenberg, 91 F.3d at 1583 (relying on dictionary definitions that “make clear that the noun ‘detent’ denotes a type of device with a generally understood meaning in the mechanical arts, even though the definitions are expressed in functional terms,” and explaining that what matters is whether “the term, as the name for structure, has a reasonably well understood meaning in the art”).

Diebold, 899 F.3d at 1300 (emphasis added). The Federal Circuit went on to note that the expert testimony presented by the patentee in *Diebold* did not address the question of whether “‘cheque standby unit’ had a reasonably well understood meaning in the art at the time of the invention.” *Id.* But, unlike the patentee in *Diebold*, here Syneron did submit additional extrinsic evidence, in the form of patents, patent applications, and other references and testimony, demonstrating that “control module” is a term commonly understood by persons of ordinary skill in the art to denote a device or class of devices. And Syneron’s experts, Mr. Mehta and Mr. Stauffer, testified quite specifically that persons of skill in the art of medical devices would understand “control module” to be a name for structure. Mehta Decl. at ¶¶ 10 and 17; Stauffer Decl. at ¶¶ 14-15. Thus, in this case, Syneron’s evidence was more than sufficient to overcome the ID’s “conclusions drawn from the intrinsic record,” and EndyMed’s failure to present any contrary evidence means that EndyMed did not overcome the presumption that § 112, ¶ 6 does not apply.

The Federal Circuit confirmed in *Zeroclick* that the presumption against application of § 112, ¶ 6 in the absence of the word “means” is real and the party attempting to overcome the presumption must rely on actual evidence, not merely argument. In *Zeroclick*, the court reversed a district court decision bearing a striking resemblance to the ID in this investigation:

Neither of the limitations at issue uses the word “means.” Presumptively, therefore, § 112, ¶ 6 does not apply to the limitations. *Apple argued that the limitations must be construed*

under § 112, ¶ 6, but provided no evidentiary support for that position. Accordingly, Apple failed to carry its burden, and the presumption against the application of § 112, ¶ 6 to the disputed limitations remained un rebutted. The district court’s discussion is revealing: its determination that the terms must be construed as means-plus-function limitations is couched in conclusory language. ***The court relied on Apple’s arguments, contrasting them against Zeroclick’s contentions, but pointed to no record evidence that supports its ultimate conclusion regarding whether § 112, ¶ 6 applies to the asserted claims.*** Cf. J.A. 10 (“[T]he Court concludes that the term ‘program that can operate the movement of the pointer (0)’ is a means-plus-function term because the claim itself fails to recite any structure whatsoever, let alone ‘sufficiently definite structure.’ ” (quoting *Williamson*, 792 F.3d at 1349)); J.A. 12 (“[B]ecause the use of the phrase ‘user interface code’ provides the same ‘black box recitation of structure’ as the use of the word ‘module’ did in *Williamson*, and the claim language provides no additional clarification regarding the structure of the term, the Court concludes that ‘user interface code’ constitutes a means-plus-function term.” (quoting *Williamson*, 792 F.3d at 1350)). ***The court thus legally erred by not giving effect to the un rebutted presumption against the application of § 112, ¶ 6.***

Zeroclick, 891 F.3d at 1007-08 (emphasis added). The same observations can be made here—EndyMed argued that the limitation must be construed under § 112, ¶ 6, but provided no evidentiary support for that position, the ID relies on EndyMed’s arguments but pointed to no record evidence that supports its ultimate conclusion, and ultimately the ID legally erred by not giving effect to the un rebutted presumption against application of § 112, ¶ 6. The fact that the ID reached that conclusion in the context of a summary determination motion, where the evidence must be construed in Complainants’ favor, is all the more erroneous.

C. The ID Made Inaccurate Factual Assumptions in a Complete Absence of Contrary Attorney Argument, Let Alone Facts

Not only does the ID improperly weigh facts against the non-movant, it also drew its own factual conclusions in one key instance where EndyMed offered neither attorney argument or contrary facts. Specifically, Mr. Mehta’s Declaration testimony asserted that the control module

[REDACTED]

can be an off-the-shelf product. EndyMed did not contest this. Yet the ID states, “I do not find Syneron’s argument that ‘controls for regulating energy delivery could be purchased off-the-shelf’ to be convincing.” ID at 17. But that was not simply an “argument,” it was actually sworn testimony by one of Syneron’s experts. Mehta Decl. at ¶ 17 (“In 2004 as today, controls for regulating energy delivery could be purchased off-the-shelf from various manufacturers or could be fashioned from off-the-shelf components.”). And it is unquestionably a factual statement. The ALJ had no basis to simply discard that testimony in favor of her own assumptions on how medical devices are built. In fact, the ALJ’s assumptions were wrong. Mr. Mehta’s testimony itself is proof of that, and additional testimony that will be presented at trial confirms that the control module of Syneron’s commercial domestic product is built from an off-the-shelf single board computer that Syneron purchases. Dany Berube, the Syneron engineer responsible for designing the domestic industry product, has already submitted a witness statement, in which he testifies to this fact and describes the off-the-shelf board as “a standard controller.” Exhibit A, Witness Statement of Dany Berube, Q/A 13. This underscores how improper it was for the ALJ to substitute her own factual assumptions over the sworn testimony of Mr. Mehta.

In short, rather than construing the facts in Syneron’s favor, as the summary determination standards require, and allowing the full evidence to be presented and weighed at trial, the ID incorrectly characterized the sworn testimony as unconvincing, substituted the ALJ’s own views for the actual evidence, and cut off Syneron’s right to a hearing.

VI. CONCLUSION

The ID failed to correctly apply the law establishing the standard for determining whether a claim term that does not use the word “means” should, nonetheless, be governed by § 112, ¶ 6, and failed to construe the evidentiary record in Syneron’s favor as it should have done in the

context of EndyMed's summary determination motion. Accordingly, the ID granting EndyMed's summary determination motion and finding the asserted claims of the '899 patent invalid as indefinite should be reviewed and ultimately reversed.

Dated: April 3, 2019

Respectfully submitted,

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**CERTAIN RADIO FREQUENCY MICRO-
NEEDLE DERMATOLOGICAL TREATMENT
DEVICES AND COMPONENTS THEREOF**

Inv. No. 337-TA-1112

CERTIFICATE OF SERVICE

I, Jeremy Miller, hereby certify that on April 10, 2019, copies of the foregoing were filed with and served upon the following as indicated:

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