

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ENDYMED MEDICAL LTD., ENDYMED MEDICAL, INC.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case No. IPR2024-00386

U.S. Patent No. 9,480,836

**SUPPLEMENTAL DECLARATION OF DR. JEAN WOLOSZKO
IN SUPPORT OF PETITIONER'S REPLY TO PATENT OWNER'S
RESPONSE**

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I, Jean Woloszko, MD, Ph.D., declare as follows:

I. INTRODUCTION

1. I submit this Supplemental Declaration at the request of EndyMed Medical Ltd., and EndyMed Medical, Inc. (“EndyMed” or “Petitioner”) in support of Petitioner’s Reply to Patent Owner’s Response in the matter of the *Inter Partes* Review IPR2024-00386 of U.S. Patent No. 9,480,836 (“the ’836 Patent”). I have been asked, by counsel for Petitioner, to respond to certain issues raised by Patent Owner in their Patent Owner’s Response. This Declaration supplements my original Substitute Declaration (Ex.1037), in which I explained that I have reviewed paragraphs 1-271 of Dr. Bérubé’s Declaration (Ex.1003) and Exhibits cited therein, and that I agree with and adopt paragraphs 17-268 (Ex.1037, ¶22). My opinions remain the same, which I incorporate by reference herein.

2. I am being compensated for my time in this matter at an hourly rate of \$600 per hour. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this matter. My compensation is not contingent on the outcome of this matter or the specifics of my testimony. I have no personal or financial stake or interest in the outcome of the present proceeding. I am an independent consultant. All my opinions stated in this report are based on my own personal knowledge and professional judgment.

3. In the preparation of this Supplemental Declaration, I have read and considered:

- Materials referenced in paragraphs 17-268 of Dr. Bérubé's Declaration (Ex.1003);
- Materials referenced in my previous Substitute Declaration (Ex.1037);
- Patent Owner's Preliminary Response (Paper Nos. 11 (redacted version) and 13 (confidential version)) and its referenced Exhibits;
- Petitioner's Reply to Patent Owner's Preliminary Response (Paper No. 15);
- Patent Owner's Sur-Reply In Support of Patent Owner's Preliminary Response (Paper No. 16);
- Institution Decision (Paper No. 18);
- Patent Owner's Response (Paper Nos. 27 (redacted version) and 28 (confidential version)) and its referenced Exhibits; and
- Materials I cite in support of this Declaration.

II. LEGAL STANDARDS

4. In forming my opinions I have applied the legal framework set forth in the Declaration of Dany Bérubé, Ph.D. (Ex. 1003), which I incorporated by reference

in my original Substitute Declaration (Ex.1037, ¶22), and which I incorporate by reference herein.

III. OPINIONS

5. In my opinion, for the reasons discussed in my original Substitute Declaration and this Supplemental Declaration, all challenged claims 1-29 of the '836 Patent are unpatentable as being obvious over the prior art references.

A. Grounds I and II Based on Ganz

6. I have analyzed the parameter ranges of both Ganz and the '836 Patent and find neither details what level of energy needs to be discharged to have coagulation (POR, 51). The '836 Patent makes no mention of any specific energy values.

7. Additionally, none of the equations in the '836 Patent indicate what energy or power values cause only coagulation and there is no threshold that precludes ablation (Ex.1001, 10:10-39). Those energy or power values cannot be derived from the equations due to unknown “proportional constant,” N , and unknown variable values (e.g., without knowing “device resistance, needle resistance, and skin resistance values,” Ex.1001 8:43-53).

B. Na's Paper and Sylfirm Manual

8. Na's Paper (Ex.2032) operates its experiments at a maximum voltage of 36.6V, which is about a third of, or nearly three times lower than, the voltage limit

of 100V in the '836 Patent (Ex.2032, 2,8; Ex.1001, 8:30-34). Because of these wide disparities in parameter values between Na's Paper and the '836 Patent, results such as histological images without ablation formed at lower voltages in Na's Paper do not indicate ablation or carbonization will not form at nearly three times higher voltage in the '836 Patent. Accordingly, results from Na's Paper do not show the '836 Patent excludes ablation or carbonization.

9. The '836 Patent does not disclose operating at the power levels of the Sylfirm X Manual (Ex.2083).

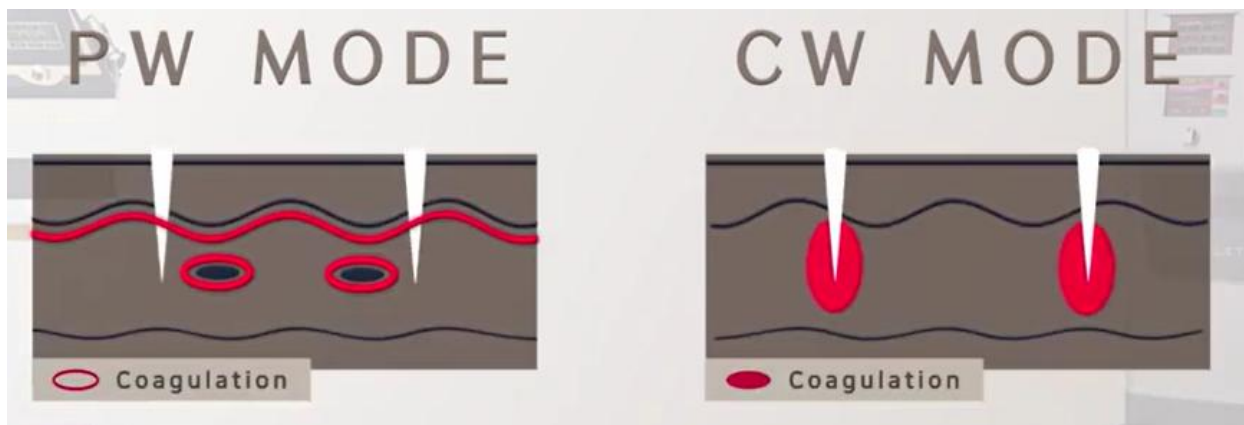
C. Commercial Success

10. I have reviewed Dr. Goldberg's arguments in paragraphs 42-56 of his declaration (Ex.2142), and do not believe Dr. Goldberg has established that the alleged commercial success of the Sylfirm X was a direct result of the claimed invention of the '836 patent. First, I understand that Mr. Crosby, Patent Owner's expert in the IPR proceedings for patents from a different patent family, such as U.S. 9,775,774, has asserted that "[t]he Sylfirm X has achieved great commercial success due to the claimed invention of the '774 Patent." (IPR2024-00383, Ex.2147 (Crosby Declaration), at ¶154). Specifically, Mr. Crosby has asserted that the "precise needle extension depth control based on the distance the user selects," is "one of the main features of the '774 Patent and one of the features that is highlighted and touted in advertising and training materials for the Sylfirm X." (IPR2024-00383, Ex.2147

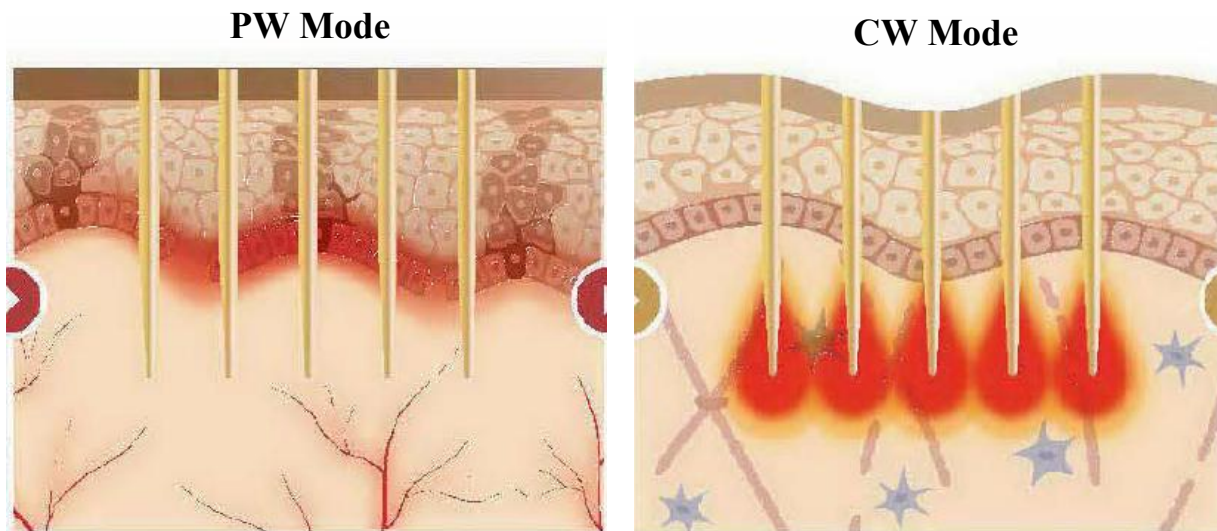
(Crosby Declaration), at ¶154). To be clear, such precise needle depth control is not a required claim limitation of the '836 patent's claims.

11. Additionally, the marketing material cited by Dr. Goldberg prominently touts another unclaimed feature of the Sylfirm X, the Sylfirm X's Pulse Wave Mode (PW Mode). The Sylfirm X is advertised as "Dual Wave" technology consisting of both "CW" ("Continuous Wave" emitting "Single Long Pulses") and "PW" ("Pulse Wave" emitting "Multiple Short Pulses") (Ex.2037, 2, 6-9; Ex.2099, 0:57). More specifically, these marketing materials repeatedly tout that the Sylfirm X is "[t]he world's first and only FDA registered Pulsed Wave (PW) and Continuous Wave (CW) Radio Frequency Micro Needling device" (Ex.2037, 2; *see also* [REDACTED]; Ex.2101, 1).

12. In contrast to the CW mode, the Sylfirm X product literature depicts the PW mode (left-image below) as causing coagulation along the red wave that is "*fully extending* from one electrode to another electrode" illustrated by white needles:



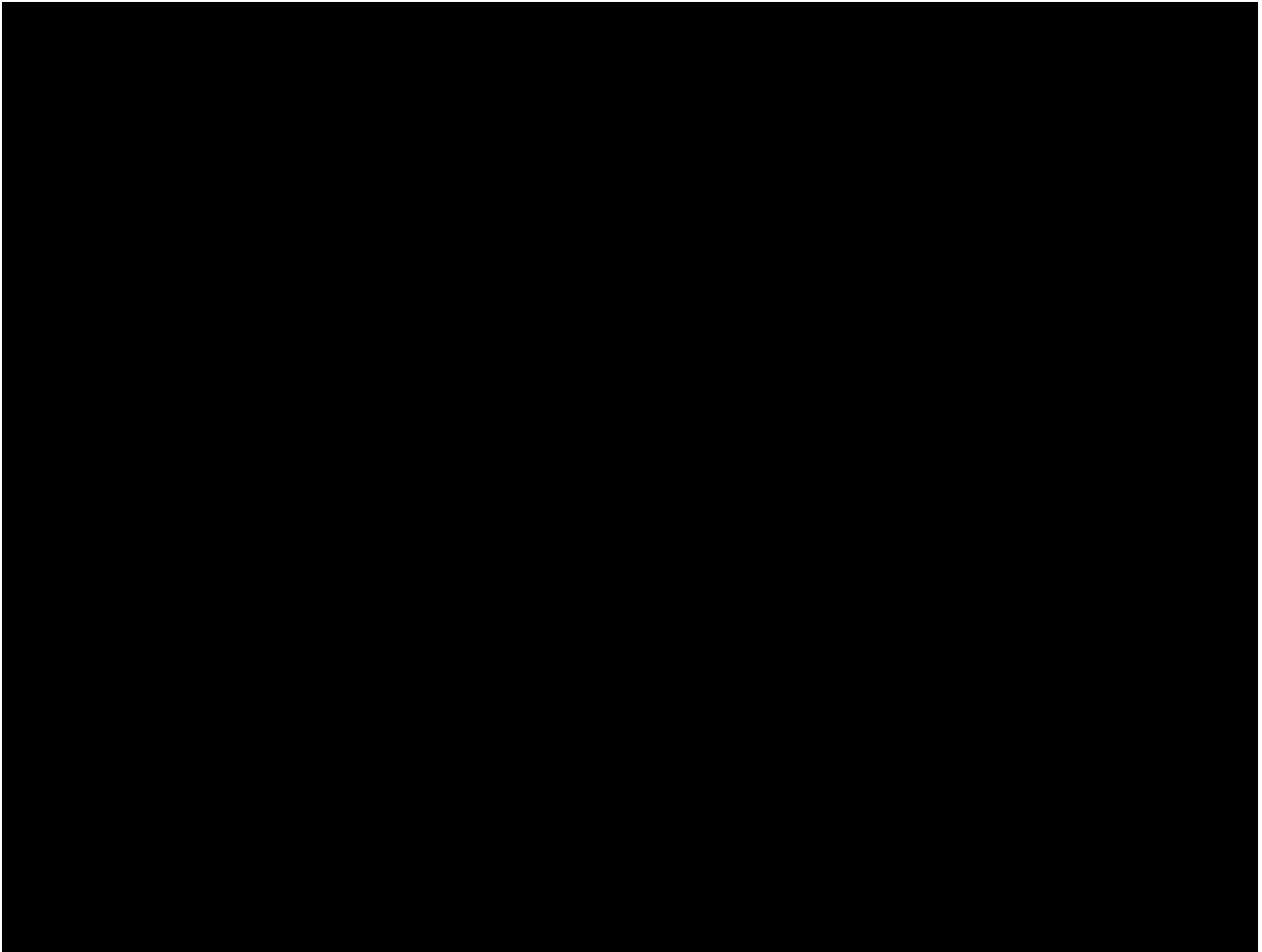
(Ex.2099, 1:00). Because the agreed construction of the '836 patent claims does not allow coagulation around the electrodes to “fully extend[]” between the electrodes, this PW mode does not practice the claim limitations. Similar depictions of coagulation fully extending between the electrodes in PW mode appear throughout Sylfirm X product literature. For example, the Sylfirm X brochure (Ex.2037) shows PW mode (left-image below) causing coagulation (*red wave*) “*fully extending*” between the electrodes along the “basement membrane,” in contrast to CW mode (labeled right-image):



(Ex.2037, 6-7). [REDACTED]

[REDACTED]

[REDACTED]



13. Dr. Goldberg attempts to attribute the Sylfirm X’s alleged commercial success to the claims based on the “[m]arketing of the Sylfirm X” in the publication, Ex.2042, “the Aesthetic Guide,” (Ex.2142, ¶¶53-54). Dr. Goldberg quotes Dr. Saluja as stating “[s]ofter, more selective coagulation’ ‘is something that I truly have seen the results for myself.’” (Ex.2142, ¶54, quoting Ex.2042). However, softer more selective coagulation is attributed to the Sylfirm X’s unclaimed PW modes. *See e.g.,*

Ex.2101, 3: “For pigmentation and vascularity, Sylfirm X’s unique PW modes provide softer, more selective coagulation in the basement membrane and vascular structures ...” (*see also* Ex.2037, 2, 6-9). Dr. Goldberg also provides quotes from Dr. Saltz and Dr. Jin (Ex.2142, ¶54, quoting Ex.2042), but there is nothing in these quotes that relates to the claimed limitations:

- *Renato Saltz, MD, director of Saltz Plastic Surgery (Park City and Salt Lake City, Utah)* —“Dr. Na is a mastermind, he didn’t just settle for good when developing an RF microneedling device, he designed the only RF microneedling device you will ever need.” *Id.*
- *Richard Jin, MD, PhD, director of RJ Clinical Institute and Cellum BioMedical (Mission Viejo and Temecula, Calif.)* — “I needed a device that could allow me to do more, and better control the outcome. I didn’t want an ordinary RF device ... Sylfirm X Ultimate Edition does more by providing me with a 300-micron depth for pain-free, no downtime treatments which encourage patient compliance. My patients are now able to come in consistently, allowing us to give them results in less time. Patients trust me with their treatment and it is my responsibility to offer them the best option available.” *Id.*

Similarly, Dr. Goldberg provides a quote from Gideon Kwok, DO (Ex.2142, ¶54), but Dr. Goldberg does not explain how the generic praise by Mr. Kwok relates to the claimed coagulation limitation:

- *Gideon Kwok, DO, co-owner and medical director of eight Skin Perfect medical clinics around southern California — clinics classified within the top 1% in the U.S. — “What really separates Sylfirm X from other technologies, besides the PW and CW modes, is being able to see immediate skin tightening while the patient experiences little or no pain. This sold me on Sylfirm X.” Id. at 16.*

14. Dr. Goldberg also cites Exs. 2044-2046 (Ex.2142, ¶53). All Exs. 2044-2046 refer to the unclaimed PW mode: Ex.2044 advertises the “pulsed-type delivery of RF signal” contrasting it with “the Na effect” (Ex.2044, 15), reporting “[m]ost of the patients showed clinical improvement” (Ex.2044, 17, 25). Ex. 2045 advertises the unclaimed “pulsed-type” technology, specifically using 30 and 40 ms pulses (Ex.2045, 1-2) for treating “the basement membrane and vascular components,”¹ which matches the Sylfirm X’s PW1 and PW2 modes (and not any of the CW modes) (Ex.2037, 6-7):

¹ The Sylfirm X’s pulsed wave mode is advertised treats “microvascular components, small blood vessels, or basement membrane with no noticeable effect on surrounding tissue” (Ex.2037, 6).

Mode	PW1	PW2
Wave Form		
Pulse Duration	30 msec	40 msec
Application	Melasma, Diffuse redness (Sensitive)	Melasma, Diffuse redness

(Ex.2037, 6).

Mode	CW1	CW2	CW3	CW4
Wave Form				
Pulse Duration	120 msec	160 msec	200 msec	300 msec
Application	Scalp	Face	Body	Scar

(Ex.2037, 7).

I understand that Dr. Goldberg admitted that he did not “know if they used a continuous wave mode for this test.” (Ex. 1044, 111:4-112:6). Paragraph 2.2 of Ex. 2045 states that “Pulsed-type, bipolar, alternating current RF using bipolar noninsulated micro-needles electrodes” was used (Ex.2045, 1). Ex.2045 also mentions that the Sylfirm X was used to generate the RF signal “at a gated on-time

pulse width of 40 milliseconds” (Ex.2045, 2). PW (pulsed wave mode) is the only mode of the Sylfirm X that allows 40 milliseconds duration (Ex.2037, 6-7).

Similarly, Ex.2046, 6 is directed to “a new invasive pulsed-type bipolar radiofrequency” (Ex.2046, title) describing PW modes that are the “short pulsed-type” (Ex.2046, 6). Ex.2046 contrasts its “pulsed-type RF,” distinguishing the “Na effect” caused by “continuous-type RF” (Ex.2046, 4).

15. Dr. Goldberg also cites Dr. Martin Braun’s testimonial in what he calls a “popular periodical, Prime” (Ex.2142, ¶55, citing Ex.2066). As discussed below, this article is paid promotional material, not an objective description. It advertises many unclaimed features including PW mode (“pulsed RF treatment at a depth of 0.3mm has the advantage or little procedural pain with virtually no prolonged redness or downtime,” Ex.2066, 3), dual wave technology (“the world’s first and only RF microneedling device equipped with dual-wave RF”; “There are four different PW and CW settings providing 8 different modes allowing the practitioner to perform delicate and customized treatment taking into consideration each patient’s skin type, skin condition and body area,” *id.*), needle depth control (“needle depth can be adjusted from 0.3-4.0 mm so we can treat thin facial skin as well as the body such as skin on the abdomen or buttocks,” *id.*) that is the subject of patent owner’s other patent (*See* IPR2024-00383, Paper 11, 61-62) and many other features unrelated to the claims.

D. Industry Praise and Peer Recognition

16. I have reviewed Dr. Goldberg’s explanations of the exhibits cited in paragraphs 58-63 of his declaration (Ex.2142). Overall, his discussion is misleading, irrelevant and often inaccurate and, as for the reasons below, does not show bona fide peer recognition or industry praise.

17. Dr. Goldberg states that “the Sylfirm X product, in 2020, the manufacturer of the Sylfirm X, ViOL, won the ‘World-Class Product of Korea’ award from the Minister of Trade, Industry & Energy of South Korea due to its contributions to and developments towards Aesthetic Medical Devices, like the Sylfirm X.” (Ex.2142, ¶58 citing Ex.2067). However, this award does not mention the Sylfirm X, let alone praise anything related to the claim limitations:



(Ex.2067).

18. Dr. Goldberg also states that “the Aesthetic Guide and Prime praised the Sylfirm X product” (Ex.2142, ¶59, citing Ex.2042 and Ex.2066). Both of these articles however are paid promotional material. Ex.2042, “the Aesthetic Guide,” is a publication entitled “Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine” (Ex.2042, 1). The first page of Ex.2042 lists a website for the Aesthetic Guide (Ex.2042, 1). I went on Aesthetic Medicine’s website, which included a search function, and I searched for “Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine.” There was only one result, which was an article also entitled “Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine,” a copy of which I include as Ex.1048. I reviewed both Ex.2042 and Ex.1048 and I can confirm that they are the same article. Ex.1048 explains that the article in Ex.2042 is sponsored content, “Sponsored By BENEV,” who I understand is the US distributor of the Sylfirm X, not genuine peer recognition or industry praise of the Sylfirm X:

4/27/25, 7:24 AM

Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine

≡ THE
AESTHETIC GUIDE

...

Sponsored By BENEV “Safe,” “effective minimally or non-invasive,” “leading-edge technology,” “research-based” and “hassle free” are all descriptors of what patients and practitioners want in aesthetic therapies. Regenerative aesthetics is where all this and more is a daily occurrence, and nowhere else is this more evident than with three key regenerative aesthetic solutions.

...

Sylfirm X's RF energy can be modulated to penetrate between 300 microns to 4 mm to treat the epidermis, basal membranes and papillary dermis, enabling treatment of superficial blemishes to deeper structures, promoting color correction and collagen remodeling while utilizing a single tip. "Dr. Na is a mastermind, he didn't just settle for good when developing an RF microneedling device, he designed the only RF microneedling device you will ever need," claimed Renato Saltz, MD, director of Saltz Plastic Surgery (Park City and Salt Lake City, Utah). "It is a smarter device that works and delivers results. Sylfirm X is simple for staff to use, and one treatment tip covers from head to toe. Ergonomic in design, it features the standard traditional adjustable depths of CW but with a patented PW mode and 300-micron depth, harnessing the 'Na Effect' which is what really sets it apart from the pack and highlights why it is a leader.

(Ex.1048, 1). The content of this sponsored article Ex.1048 matches Ex.2042:

Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine

...

Sylfirm X's RF energy can be modulated to penetrate between 300 microns to 4 mm to treat the epidermis, basal membranes and papillary dermis, enabling treatment of superficial blemishes to deeper structures, promoting color correction and collagen remodeling while utilizing a single tip. "Dr. Na is a mastermind, he didn't just settle for good when developing an RF microneedling device, he designed the only RF microneedling device you will ever need," claimed Renato Saltz, MD, director of Saltz Plastic Surgery (Park City and Salt Lake City, Utah). "It is a smarter device that works and delivers results. Sylfirm X is simple for staff to use, and one treatment tip covers from head to toe. Ergonomic in design, it features the standard traditional adjustable depths of CW but with a patented PW mode and 300-micron depth, harnessing the 'Na Effect' which is what really sets it apart from the pack and highlights why it is a leader.

(Ex.2042, 1)

Ex.2066 is also a paid promotional material. On page 3 of Ex.2066 the Prime journal's website is listed:

prime-journal.com

(Ex.2066, 4)

I went to the Prime journal's website, and under the section entitled "Advertise With U" there was a link to download the Prime-Journal Media Guide for 2025, a copy of which I have included as Ex.1046. After reviewing Ex.1046, I was able to confirm that Ex.2066 is also paid advertising: Ex.2066 is a "PRIME Promotion" (Ex.2066, 1):



"PRIME Promotion" is paid advertisement "to outline your company's unique value proposition from a physician advocate's perspective" (Ex.1046, 6). Prime Journal sells these "**PROMOTION ARTICLES**" as paid "Advertising" costing £6,000 for a 2-page article (the 2025 rate):

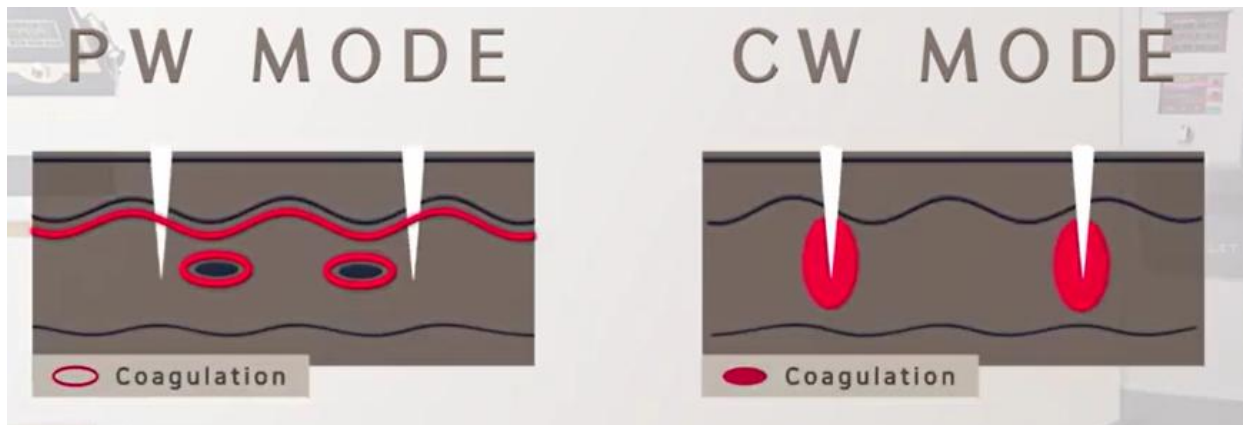




(Ex.1046, 11).

Thus, Ex.2042 and Ex.2066 do not contain true industry praise or peer recognition.

19. Dr. Goldberg also states that “respected key opinion leaders in the industry, such as Dr. Randy Miller and Dr. Seiko Kou, have also favorably reviewed the Sylfirm X device.” (Ex.2142, ¶59 citing Ex.2043). However, Ex.2043 does not mention anything related to the claims. Rather, Dr. Miller praises the fact that the Sylfirm X “has both dual wave; continuous wave and pulsed wave, so it can treat all skin types and different colors,” that “[i]t can go as superficial as 300 microns from the skin surface where pigment problems are, can also go down to 4mm for skin tightening,” none of which are required by the claims (Ex.2043). As explained above, in contrast to the CW mode, the Sylfirm X product literature depicts the PW mode (left image below) as causing coagulation (red wave) “fully extending from one electrode to another electrode” (white needles below), which is prohibited by the ‘836 Patent claims. *See e.g.*, Ex.2099, 0:59-1:08:

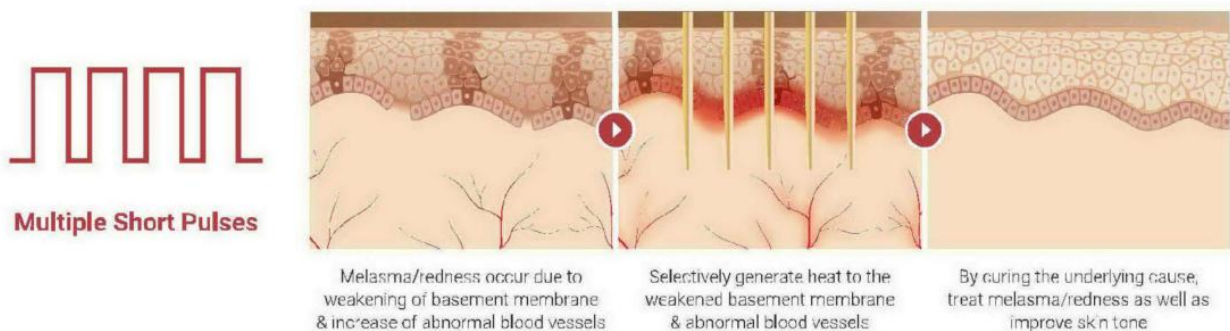


(Ex.2099, 1:00).

20. In Ex. 2043, Dr. Kou also does not mention anything related to the claims. Dr. Kou explains “The advantage of SYLFIRM X is that it enables us to improve damaged basement membrane condition of the epidermis” for treating “skin that is originally damaged by photoaging and melasma” (Ex.2043). However, that also relates to the unclaimed PW mode, which is for “[s]electively generat[ing] heat to the weakened basement membrane,” to “treat melasma” and photoaging (Ex.2037, 6, 16):

Selective Thermal Effect for Basement Membrane & Blood Vessel

- Pulsed wave irradiates RF energy in the form of multiple pulses.
- It's selectively affected highly conductive tissues such as microvascular components, small blood vessels, or basement membrane with no noticeable effect on surrounding tissue



(Ex.2037, 6).

**What does
microneedling
treatment treat?**

Microneedling treatment targets scalp skin tightening, face skin tightening and lifting, double chin, neck and body skin tightening. Recently, Short pulse Radio Frequency technology of the treatment was clinically proven to improve rosacea, acne, vulgaris, melasma, and mottled telangiectasia. It is very safe and no rebounded with lower recurrence. And needless to say, the treatment improves common issues such as skin texture, pores, photo-aging, scars, and striae.

(Ex.2037, 13). Dr. Kou’s only other praise is that the Sylfirm X is “good for combination treatment with lasers,” which is not required or mentioned by the claims (Ex.2043).

21. Dr. Goldberg also cites to the 2015 Nature Scientific reports article that the named inventor of the ‘836 Patent “Dr. Na published” (Ex.2142, ¶60, citing Ex.2032). Because the named inventor was the first named author of the 2015 Nature Scientific Reports article, this is not industry praise, but rather self-praise (*See* Ex.2032, 1).

22. Dr. Goldberg also cites to Exs.2044-2046 (Ex.2142, ¶60), without providing any explanation of the relevance of these exhibits or any page citations to these exhibits. Further, Exs.2044-2045 are both self-praise of patent owner (Ex.2044) or inventor Dr. Na (Ex.2045). Ex.2044 is a Sylfirm X marketing document published by Viol, who I understand is the original patent owner:



(Ex.2044, 1).

The Na Effect is discussed on page 4 of Ex.2044:

Continuous Wave

- Skin Reaction: Na Effect _4
- Skin Rejuvenation _5
- Acne _10

Pulsed Wave

- Skin Reaction _15
- Pigmented Lesion _17
- Vascular Lesion _25
- Skin Rejuvenation _27
- Scar _30
- Acne _31

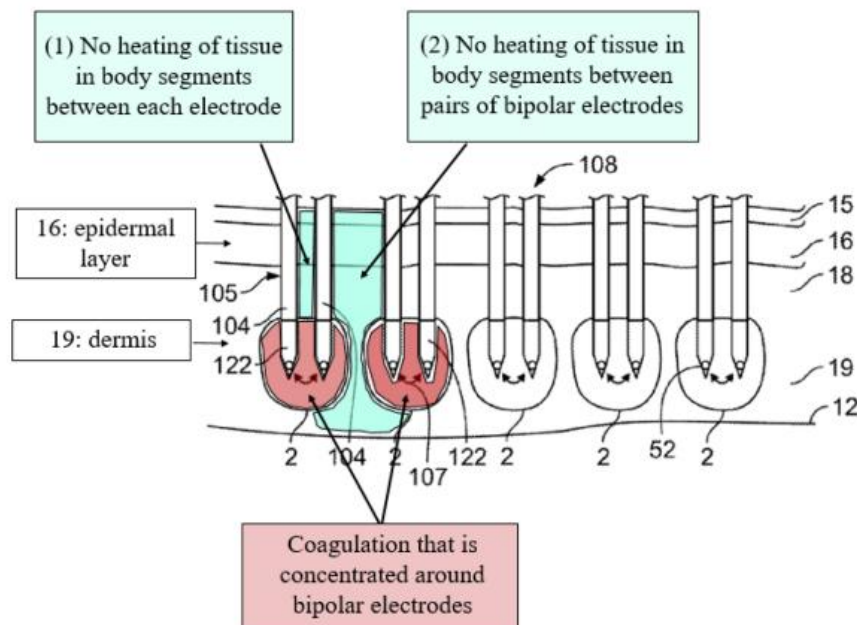
300µm

- Pigmented Lesion _32

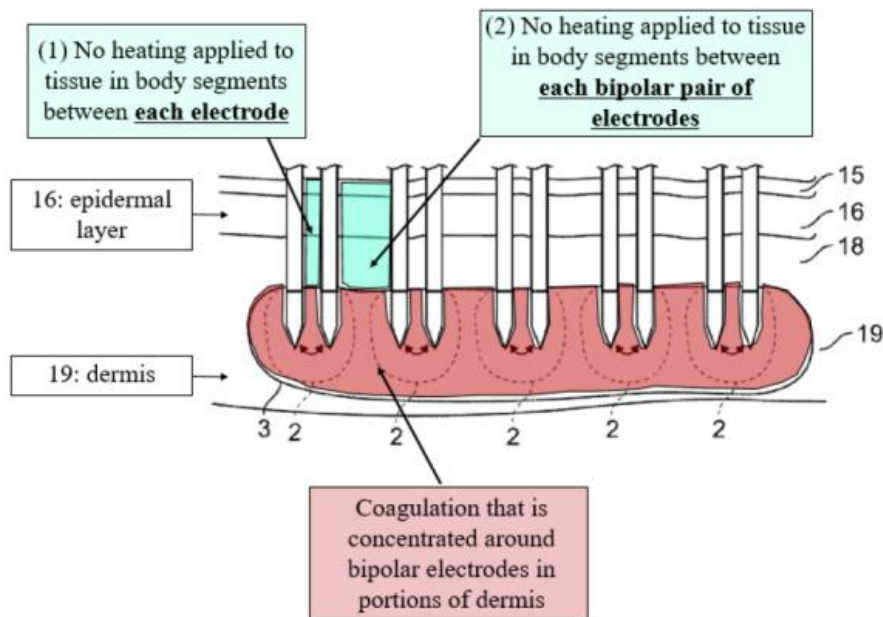
(Ex.2044, 3). However, on page 4 of Ex.2044, there is the 2015 nature article that was authored by “Jongju Na,” the named inventor of the ’836 Patent (Ex.2044, 4).

Thus, Ex. 2044 does not appear to include any industry praise, but rather self-praise by the patent owner and the named inventor. Also, as explained, both Ex.2045 and Ex. 2046 describe the unclaimed PW mode. Ex. 2045 praises the unclaimed “pulsed-type” technology, specifically using Sylfirm X’s PW1 and PW2 modes at 30 and 40 ms pulses, respectively (Ex.2045, 1-2; Ex.2037, 6-7). Ex.2046, 6 is also directed to “pulsed-type RF” (PW modes) it distinguishes from the “Na effect” caused by “continuous-type RF” (Ex.2046, 4).

23. Dr. Goldberg also cites Ex.2047 (Ex.2142, ¶61; *see also* 68). However, the praise in Ex.2047 refers to the aim “to avoid or minimize epidermal thermal damage” (Ex.2047, 2, 5). Likewise, Ex.2047 is cited for “selectively heating the dermis while sparing the epidermis” (Ex.2142, ¶68). However, absence of epidermal damage is not an advancement of the ’836 Patent. For example, as shown by the prior art, U.S. 2010/0204695, in another IPR for the ’836 Patent, IPR2022-00594, preventing epidermal coagulation can be achieved even when there is coagulation between electrodes in the dermal layer, and thus is not an advancement of the ’836 Patent (*See* IPR2022-00594, Paper 9, at 24):



(IPR2022-00594, Paper 9, 9-10).



(IPR2022-00594, Paper 9, 9-11).

Also, in another IPR for another one of patent owner's patents, patent owner and its expert stated that "thermal damage to the skin surface" (epidermis) is prevented by the unclaimed "needle extension depth control" from the other "'774 Patent." (IPR2024-00383, Paper 11, 61-62; IPR2024-00383, Ex.2147, ¶154). Additionally, Ex.2047 is funded by "Aesthetic Biomedical Inc." who employs its authors as per the "Conflict Of Interest" disclosure (Ex.2047, 1, 7) indicating its lack of objectivity in characterizing technology.

24. Dr. Goldberg also cites to Ex.2069 to assert that the "Vivace ULTRA is designed to avoid bad outcomes like 'heat-induced hyperpigmentation.'" (Ex.2142, ¶62, quoting Ex.2069). However, Ex.2069 is actually praising the fact that 'Vivace Ultra is the first RF microneedling device to also include ultrasound imaging and

mapping, which could mean the results are more precise.” (Ex.2069, 6). Specifically, “Vivace Ultra has the unique capability to visualize, through ultrasound guidance, the layers of skin one is targeting.” (*Id.*). The article attributes avoiding “heat-induced hyperpigmentation” with the “detailed view [which] allows doctors to tailor the needle depth to a patient’s skin – and if you need to adjust the needle to meet a specific goal.” (*Id.*). Ex.2069 therefore does not praise anything related to any claim limitation of the ’836 Patent.

25. Dr. Goldberg also cites Ex.2048 (Ex.2142, ¶63). The cited sections of the Harth Study only praise unclaimed features of EndyMed’s product, such as “needle quality,” “gold plated needles,” the “the unique smooth needle motorized insertion,” and not causing “epidermal coagulation.” (Ex.2048, 5-6). As discussed above regarding Ex.2047, to “avoid or minimize epidermal thermal damage” (Ex.2047, 2, 5) is not an advancement of the ’836 Patent.

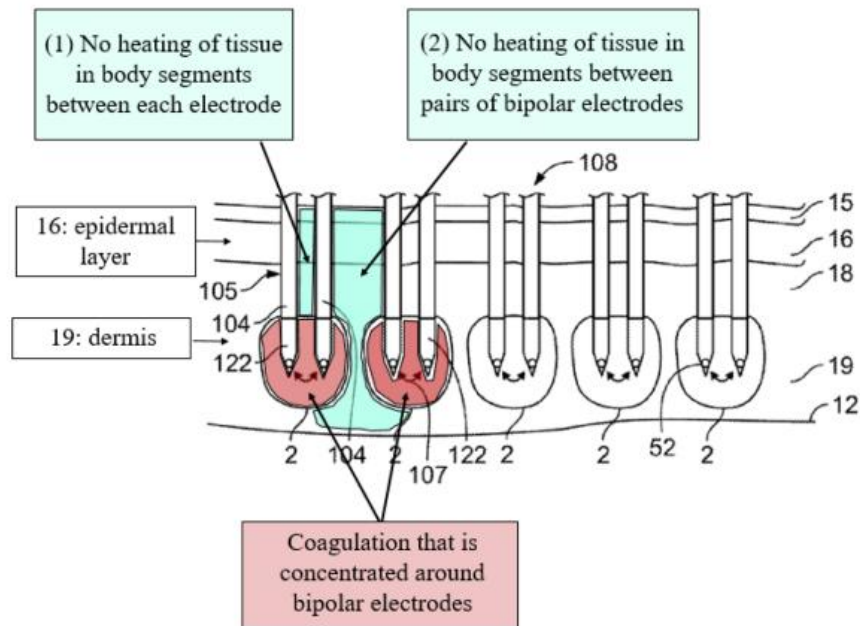
26. All of Dr. Goldberg’s evidence regarding industry praise or peer recognition (cited in Ex.2142, ¶¶58-63) appears to have been written by or paid for by patent owner, the named inventor, the Sylfirm X distributor Benev, or other interested parties (Exs. 2032, 2043-2045, 2047) and/or are irrelevant to the ’836 Patent claims (Ex.2046-2048, 2067, Ex.2069).

E. Long-Felt but Unfulfilled Need for the Inventions

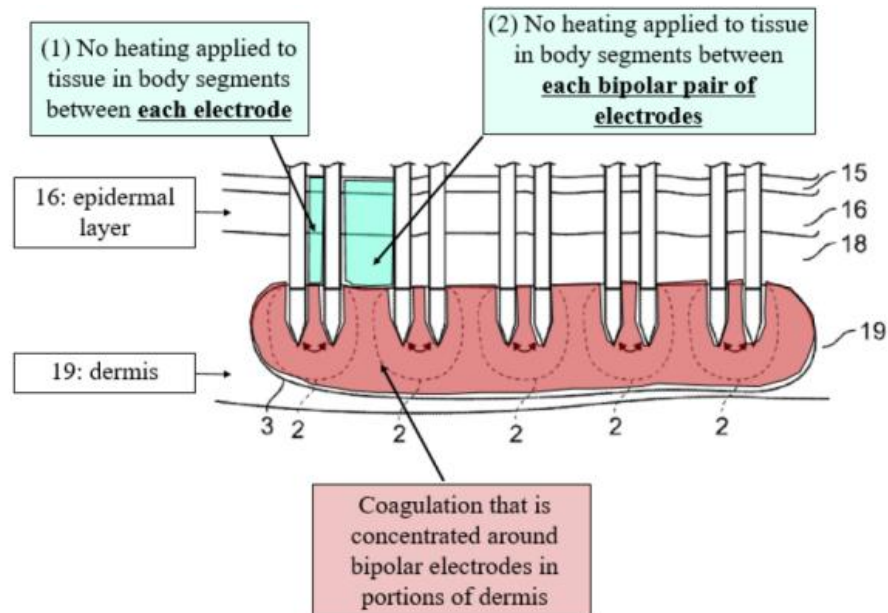
27. I have reviewed Dr. Goldberg's arguments in paragraphs 65-70 of his declaration (Ex.2142), and disagree that the '836 Patent fulfills long-felt but unfulfilled need in the industry.

28. Dr. Goldberg states the '836 Patent overcame the need to avoid epidermal damage (Ex.2142, ¶¶66-68). *See e.g.*, “prior art devices risked overheating both the epidermis and dermis, causing negative side effects like post-inflammatory hyperpigmentation and hypopigmentation,” (Ex.2142, ¶66); “the problem of overheating, burning, and harming the skin from applying too much energy to the skin” (Ex.2142, ¶67, citing Ex. 2037, 14; Ex.2044); “RF is emitted selectively heating the dermis while sparing the epidermis” (Ex.2142, ¶69, citing Ex.2048); Ex.2047 also aims “to avoid or minimize epidermal thermal damage” (Ex.2047, 2, 5) (contrary to Dr. Goldberg, Ex.2047 does not discuss the benefit to “narrow and concentrated coagulation zone[s],” Ex.2142, ¶68); and that Sylfirm X “minimizes heat damage to the epidermis” (Ex.2142, ¶68, citing Ex.2066, 3). However, prior art bipolar RF microneedling devices already avoided overheating or damaging the epidermis prior to the '836 Patent's priority date. For example, Hantash discloses “avoiding overheating of the treating zones” (Ex.1007, ¶18; *see also* Patent Owner Response, 56-57 (“Hantash is about avoiding [overheating]”)), and Hantash “reduces the incidence of scarring” (Ex.1007, ¶58). Also, the prior art

bipolar RF microneedling device that was used in the Cartessa IV IPR prevented heating in the epidermis (*see* IPR2022-00594, Paper 9, 24), and thus, would not have overheated **both** the epidermis and dermis.



(IPR2022-00594, Paper 9, 9-10).



(IPR2022-00594, Paper 9, at 9-11).

Accordingly, this prior art bipolar device already solved the problem of avoiding epidermal damage.

29. Dr. Goldberg also cites Ex.2042 for “[s]ofter, more selective coagulation” (Ex.2142, ¶68) but this is “because of the device's unique PW mode” (Ex.2042, 6), which is not claimed and not attributed to the “Na effect” (Ex.2142, ¶68).

30. Dr. Goldberg also opined that “the ’836 Patent addressed a long-felt need in the industry for a safer, effective RF microneedling treatment that avoided the drawbacks of earlier RF-based approaches, e.g., monopolar treatment and laser-based approaches” (Ex.2142, ¶71). Specifically, the drawbacks identified by Dr. Goldberg were actually just drawbacks of “monopolar configurations” (Ex.2142, ¶70), and thus already solved by the prior art bipolar microneedling devices (e.g., disclosed in Ganz, Ex.1005, ¶56).

31. Specifically, Dr. Goldberg opined “that monopolar configurations ‘result[] in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment,’” which results in pain and “short-term swelling,” and result in a “relatively large volume of tissue treated and the need to balance application of RF current with surface cooling,” which “does not permit

fine control of damage patterns and subsequent skin tightening.” (Ex.2142, ¶70 quoting Ex.2049, 3:31-56). By definition, this issue is with **non-invasive** monopolar devices, not with prior art bipolar microneedling devices. Because microneedling device insert electrode needles into the skin, and do not use surface electrodes, no active cooling of surface electrodes would be used. Dr. Goldberg agrees. (Ex.1044, 16:7-17:4; *see also id.*, 10:15-11:17).

32. Dr. Goldberg also opined that “because the system is ‘relying on a remote grounding on the patient to complete the current flow from the single electrode,’ the current ‘must flow through the patient’s body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body.” (Ex.2142, ¶70). However, again, prior art bipolar microneedling devices did not utilize what Dr. Goldberg refers to as “a remote ground”/“grounding pad” (which are actually neutral electrodes). These neutral electrodes cannot be connected to the ground for safety reasons per IEC standards. They are also used hundreds of thousands of times every day for most surgeries with an outstanding safety track record. Dr. Goldberg agrees. (Ex.1044, 20:9-19, 21:12-22).

33. Dr. Goldberg also cites to disclosure in my patent, Ex.2050, specifically column 2, lines 35-50, that “the return electrode may cause tissue desiccation or destruction at its contact point with the patient’s tissue.” (Ex.2142, ¶70). However, that section of my patent discusses how a difference between monopolar and bipolar

devices is that typically monopolar devices only generate thermal effects, such as tissue desiccation, at the active electrode (not the remote ground return electrode), but typical bipolar devices can generate thermal effects at “both the active and return electrode.” (Ex.2050, 2:35-44). Again this distinction from monopolar configuration is achieved by any typical prior art bipolar configuration. Further, my patent describes an invention for specific bipolar configurations where only one electrode (or set of electrodes) of a bipolar system causes tissue effects (*see e.g.*, Ex.2050, 5:49-53), but this improvement is irrelevant to the ’836 Patent that describes a typical bipolar configuration.

34. Dr. Goldberg states “[t]he ’836 Patent addressed and eliminated the drawbacks of monopolar configurations while maintaining the beneficial heating of tissue around the tips of the needles.” (Ex.2142, ¶70). However, Dr. Goldberg does not opine that this was a long-felt and unsolved need, let alone cite to any evidence of the industry discussing this before the ’836 Patent. The closest Dr. Goldberg gets is a citation to paragraph 40 of Manstein 090 (Ex.2142, ¶70-71). However, this paragraph only discusses monopolar embodiments of Manstein 090, and does not mention anything about bipolar devices. Rather, this paragraph simply discusses how monopolar devices can work:

The thermally damaged regions 370 can be obtained from operation of the exemplary apparatus 300 in, e.g., a monopolar configuration, in

which a remote grounding electrode (not shown in FIG. 3) can be attached to a remote part of the patient's body to complete the circuit of electricity conveyed to the needles 350 by the energy source 320. In this exemplary monopolar configuration, the RF current can generate heating around the tip regions of the needles 350, thus generating thermal damage in the tissue regions 370 adjacent to the needle tips which may be, e.g., approximately spherical or slightly elongated in shape. (Ex.2051, ¶40).

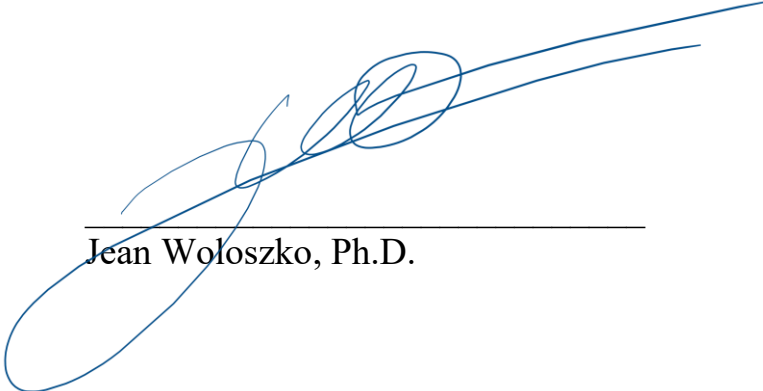
35. The Brill article (cited in the background section of Dr. Goldberg's declaration (Ex.2142, ¶17), not in the secondary considerations section) mentions issues with prior bipolar devices, but explains these issues were already solved by "smart generator technology that integrates impedance (ie, tissue resistance) feedback," and "[p]ulsing" the current," neither of which is claimed by the '836 Patent. *See* Ex.2148, 3: "With all of these new platforms, tissue carbonization, sticking, plume, and the zone of thermal damage are reduced when compared with conventional bipolar electrosurgery."

36. Additionally, all of Dr. Goldberg's evidence regarding long-felt need (cited in Ex.2142, ¶¶67-70) appears to have been written by or paid for by patent owner, the named inventor, the Sylfirm X distributor Benev, or other interested parties (*See* Exs. 2037, 2042, 2044, 2047, 2066) and/or are irrelevant to the '836 Patent claims (Ex. 2048-2051).

IV. CONCLUSION

37. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

I, Jean Woloszko, Ph.D., declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.



Jean Woloszko, Ph.D.

Executed on April 18, 2025